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► B **COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011**
of 25 May 2011
implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as
regards the list of approved active substances
(Text with EEA relevance)
(OJ L 153, 11.6.2011, p. 1)

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| ► <u>M186</u> | Commission Implementing Regulation (EU) 2016/952 of 15 June 2016 | L 159 | 10 | 16.6.2016 |
| ► <u>M187</u> | Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 | L 173 | 52 | 30.6.2016 |
| ► <u>M188</u> | Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 | L 208 | 1 | 2.8.2016 |

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|----------------------|---|-------|----|------------|
| ► <u>M189</u> | Commission Implementing Regulation (EU) 2016/1414 of 24 August 2016 | L 230 | 16 | 25.8.2016 |
| ► <u>M190</u> | Commission Implementing Regulation (EU) 2016/1423 of 25 August 2016 | L 231 | 20 | 26.8.2016 |
| ► <u>M191</u> | Commission Implementing Regulation (EU) 2016/1424 of 25 August 2016 | L 231 | 25 | 26.8.2016 |
| ► <u>M192</u> | Commission Implementing Regulation (EU) 2016/1425 of 25 August 2016 | L 231 | 30 | 26.8.2016 |
| ► <u>M193</u> | Commission Implementing Regulation (EU) 2016/1426 of 25 August 2016 | L 231 | 34 | 26.8.2016 |
| ► <u>M194</u> | Commission Implementing Regulation (EU) 2016/1429 of 26 August 2016 | L 232 | 1 | 27.8.2016 |
| ► <u>M195</u> | Commission Implementing Regulation (EU) 2016/1978 of 11 November 2016 | L 305 | 23 | 12.11.2016 |
| ► <u>M196</u> | Commission Implementing Regulation (EU) 2016/2016 of 17 November 2016 | L 312 | 21 | 18.11.2016 |
| ► <u>M197</u> | Commission Implementing Regulation (EU) 2016/2035 of 21 November 2016 | L 314 | 7 | 22.11.2016 |
| ► <u>M198</u> | Commission Implementing Regulation (EU) 2017/157 of 30 January 2017 | L 25 | 5 | 31.1.2017 |
| ► <u>M199</u> | Commission Implementing Regulation (EU) 2017/195 of 3 February 2017 | L 31 | 21 | 4.2.2017 |
| ► <u>M200</u> | Commission Implementing Regulation (EU) 2017/239 of 10 February 2017 | L 36 | 39 | 11.2.2017 |
| ► <u>M201</u> | Commission Implementing Regulation (EU) 2017/244 of 10 February 2017 | L 36 | 54 | 11.2.2017 |
| ► <u>M202</u> | Commission Implementing Regulation (EU) 2017/270 of 16 February 2017 | L 40 | 48 | 17.2.2017 |
| ► <u>M203</u> | Commission Implementing Regulation (EU) 2017/359 of 28 February 2017 | L 54 | 8 | 1.3.2017 |
| ► <u>M204</u> | Commission Implementing Regulation (EU) 2017/360 of 28 February 2017 | L 54 | 11 | 1.3.2017 |
| ► <u>M205</u> | Commission Implementing Regulation (EU) 2017/375 of 2 March 2017 | L 58 | 3 | 4.3.2017 |
| ► <u>M206</u> | Commission Implementing Regulation (EU) 2017/406 of 8 March 2017 | L 63 | 83 | 9.3.2017 |
| ► <u>M207</u> | Commission Implementing Regulation (EU) 2017/407 of 8 March 2017 | L 63 | 87 | 9.3.2017 |
| ► <u>M208</u> | Commission Implementing Regulation (EU) 2017/408 of 8 March 2017 | L 63 | 91 | 9.3.2017 |
| ► <u>M209</u> | Commission Implementing Regulation (EU) 2017/409 of 8 March 2017 | L 63 | 95 | 9.3.2017 |
| ► <u>M210</u> | Commission Implementing Regulation (EU) 2017/419 of 9 March 2017 | L 64 | 4 | 10.3.2017 |
| ► <u>M211</u> | Commission Implementing Regulation (EU) 2017/428 of 10 March 2017 | L 66 | 1 | 11.3.2017 |
| ► <u>M212</u> | Commission Implementing Regulation (EU) 2017/438 of 13 March 2017 | L 67 | 67 | 14.3.2017 |
| ► <u>M213</u> | Commission Implementing Regulation (EU) 2017/555 of 24 March 2017 | L 80 | 1 | 25.3.2017 |
| ► <u>M214</u> | Commission Implementing Regulation (EU) 2017/725 of 24 April 2017 | L 107 | 24 | 25.4.2017 |
| ► <u>M215</u> | Commission Implementing Regulation (EU) 2017/753 of 28 April 2017 | L 113 | 24 | 29.4.2017 |
| ► <u>M216</u> | Commission Implementing Regulation (EU) 2017/755 of 28 April 2017 | L 113 | 35 | 29.4.2017 |
| ► <u>M217</u> | Commission Implementing Regulation (EU) 2017/781 of 5 May 2017 | L 118 | 1 | 6.5.2017 |

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|----------------------|---|-------|-----|------------|
| ► <u>M218</u> | Commission Implementing Regulation (EU) 2017/805 of 11 May 2017 | L 121 | 26 | 12.5.2017 |
| ► <u>M219</u> | Commission Implementing Regulation (EU) 2017/806 of 11 May 2017 | L 121 | 31 | 12.5.2017 |
| ► <u>M220</u> | Commission Implementing Regulation (EU) 2017/831 of 16 May 2017 | L 124 | 27 | 17.5.2017 |
| ► <u>M221</u> | Commission Implementing Regulation (EU) 2017/841 of 17 May 2017 | L 125 | 12 | 18.5.2017 |
| ► <u>M222</u> | Commission Implementing Regulation (EU) 2017/842 of 17 May 2017 | L 125 | 16 | 18.5.2017 |
| ► <u>M223</u> | Commission Implementing Regulation (EU) 2017/843 of 17 May 2017 | L 125 | 21 | 18.5.2017 |
| ► <u>M224</u> | Commission Implementing Regulation (EU) 2017/855 of 18 May 2017 | L 128 | 10 | 19.5.2017 |
| ► <u>M225</u> | Commission Implementing Regulation (EU) 2017/856 of 18 May 2017 | L 128 | 14 | 19.5.2017 |
| ► <u>M226</u> | Commission Implementing Regulation (EU) 2017/1113 of 22 June 2017 | L 162 | 27 | 23.6.2017 |
| ► <u>M227</u> | Commission Implementing Regulation (EU) 2017/1114 of 22 June 2017 | L 162 | 32 | 23.6.2017 |
| ► <u>M228</u> | Commission Implementing Regulation (EU) 2017/1115 of 22 June 2017 | L 162 | 38 | 23.6.2017 |
| ► <u>M229</u> | Commission Implementing Regulation (EU) 2017/1125 of 22 June 2017 | L 163 | 10 | 24.6.2017 |
| ► <u>M230</u> | Commission Implementing Regulation (EU) 2017/1186 of 3 July 2017 | L 171 | 131 | 4.7.2017 |
| ► <u>M231</u> | Commission Implementing Regulation (EU) 2017/1455 of 10 August 2017 | L 208 | 28 | 11.8.2017 |
| ► <u>M232</u> | Commission Implementing Regulation (EU) 2017/1491 of 21 August 2017 | L 216 | 15 | 22.8.2017 |
| ► <u>M233</u> | Commission Implementing Regulation (EU) 2017/1496 of 23 August 2017 | L 218 | 7 | 24.8.2017 |
| ► <u>M234</u> | Commission Implementing Regulation (EU) 2017/1506 of 28 August 2017 | L 222 | 21 | 29.8.2017 |
| ► <u>M235</u> | Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017 | L 224 | 115 | 31.8.2017 |
| ► <u>M236</u> | Commission Implementing Regulation (EU) 2017/1527 of 6 September 2017 | L 231 | 3 | 7.9.2017 |
| ► <u>M237</u> | Commission Implementing Regulation (EU) 2017/1529 of 7 September 2017 | L 232 | 1 | 8.9.2017 |
| ► <u>M238</u> | Commission Implementing Regulation (EU) 2017/1530 of 7 September 2017 | L 232 | 4 | 8.9.2017 |
| ► <u>M239</u> | Commission Implementing Regulation (EU) 2017/1531 of 7 September 2017 | L 232 | 6 | 8.9.2017 |
| ► <u>M240</u> | Commission Implementing Regulation (EU) 2017/2066 of 13 November 2017 | L 295 | 43 | 14.11.2017 |
| ► <u>M241</u> | Commission Implementing Regulation (EU) 2017/2069 of 13 November 2017 | L 295 | 51 | 14.11.2017 |
| ► <u>M242</u> | Commission Implementing Regulation (EU) 2017/2090 of 14 November 2017 | L 297 | 22 | 15.11.2017 |
| ► <u>M243</u> | Commission Implementing Regulation (EU) 2017/2091 of 14 November 2017 | L 297 | 25 | 15.11.2017 |
| ► <u>M244</u> | Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 | L 333 | 10 | 15.12.2017 |

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|----------------------|--|-------|-----|-----------|
| ► <u>M245</u> | Commission Implementing Regulation (EU) 2018/84 of 19 January 2018 | L 16 | 8 | 20.1.2018 |
| ► <u>M246</u> | Commission Implementing Regulation (EU) 2018/112 of 24 January 2018 | L 20 | 3 | 25.1.2018 |
| ► <u>M247</u> | Commission Implementing Regulation (EU) 2018/113 of 24 January 2018 | L 20 | 7 | 25.1.2018 |
| ► <u>M248</u> | Commission Implementing Regulation (EU) 2018/184 of 7 February 2018 | L 34 | 10 | 8.2.2018 |
| ► <u>M249</u> | Commission Implementing Regulation (EU) 2018/185 of 7 February 2018 | L 34 | 13 | 8.2.2018 |
| ► <u>M250</u> | Commission Implementing Regulation (EU) 2018/291 of 26 February 2018 | L 55 | 30 | 27.2.2018 |
| ► <u>M251</u> | Commission Implementing Regulation (EU) 2018/309 of 1 March 2018 | L 60 | 16 | 2.3.2018 |
| ► <u>M252</u> | Commission Implementing Regulation (EU) 2018/524 of 28 March 2018 | L 88 | 4 | 4.4.2018 |
| ► <u>M253</u> | Commission Implementing Regulation (EU) 2018/660 of 26 April 2018 | L 110 | 122 | 30.4.2018 |
| ► <u>M254</u> | Commission Implementing Regulation (EU) 2018/670 of 30 April 2018 | L 113 | 1 | 3.5.2018 |
| ► <u>M255</u> | Commission Implementing Regulation (EU) 2018/679 of 3 May 2018 | L 114 | 18 | 4.5.2018 |
| ► <u>M256</u> | Commission Implementing Regulation (EU) 2018/690 of 7 May 2018 | L 117 | 3 | 8.5.2018 |
| ► <u>M257</u> | Commission Implementing Regulation (EU) 2018/691 of 7 May 2018 | L 117 | 6 | 8.5.2018 |
| ► <u>M258</u> | Commission Implementing Regulation (EU) 2018/692 of 7 May 2018 | L 117 | 9 | 8.5.2018 |
| ► <u>M259</u> | Commission Implementing Regulation (EU) 2018/710 of 14 May 2018 | L 119 | 31 | 15.5.2018 |
| ► <u>M260</u> | Commission Implementing Regulation (EU) 2018/755 of 23 May 2018 | L 128 | 4 | 24.5.2018 |
| ► <u>M261</u> | Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 | L 132 | 31 | 30.5.2018 |
| ► <u>M262</u> | Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 | L 132 | 35 | 30.5.2018 |
| ► <u>M263</u> | Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 | L 132 | 40 | 30.5.2018 |
| ► <u>M264</u> | Commission Implementing Regulation (EU) 2018/917 of 27 June 2018 | L 163 | 13 | 28.6.2018 |
| ► <u>M265</u> | Commission Implementing Regulation (EU) 2018/1019 of 18 July 2018 | L 183 | 14 | 19.7.2018 |
| ► <u>M266</u> | Commission Implementing Regulation (EU) 2018/1043 of 24 July 2018 | L 188 | 9 | 25.7.2018 |
| ► <u>M267</u> | Commission Implementing Regulation (EU) 2018/1060 of 26 July 2018 | L 190 | 3 | 27.7.2018 |
| ► <u>M268</u> | Commission Implementing Regulation (EU) 2018/1061 of 26 July 2018 | L 190 | 8 | 27.7.2018 |
| ► <u>M269</u> | Commission Implementing Regulation (EU) 2018/1075 of 27 July 2018 | L 194 | 36 | 31.7.2018 |
| ► <u>M270</u> | Commission Implementing Regulation (EU) 2018/1260 of 20 September 2018 | L 238 | 30 | 21.9.2018 |
| ► <u>M271</u> | Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018 | L 238 | 62 | 21.9.2018 |
| ► <u>M272</u> | Commission Implementing Regulation (EU) 2018/1264 of 20 September 2018 | L 238 | 71 | 21.9.2018 |
| ► <u>M273</u> | Commission Implementing Regulation (EU) 2018/1265 of 20 September 2018 | L 238 | 77 | 21.9.2018 |

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|----------------------|--|-------|----|------------|
| ► <u>M274</u> | Commission Implementing Regulation (EU) 2018/1266 of 20 September 2018 | L 238 | 81 | 21.9.2018 |
| ► <u>M275</u> | Commission Implementing Regulation (EU) 2018/1278 of 21 September 2018 | L 239 | 4 | 24.9.2018 |
| ► <u>M276</u> | Commission Implementing Regulation (EU) 2018/1295 of 26 September 2018 | L 243 | 7 | 27.9.2018 |
| ► <u>M277</u> | Commission Implementing Regulation (EU) 2018/1495 of 8 October 2018 | L 253 | 1 | 9.10.2018 |
| ► <u>M278</u> | Commission Implementing Regulation (EU) 2018/1500 of 9 October 2018 | L 254 | 1 | 10.10.2018 |
| ► <u>M279</u> | Commission Implementing Regulation (EU) 2018/1501 of 9 October 2018 | L 254 | 4 | 10.10.2018 |
| ► <u>M280</u> | Commission Implementing Regulation (EU) 2018/1532 of 12 October 2018 | L 257 | 10 | 15.10.2018 |
| ► <u>M281</u> | Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 | L 294 | 15 | 21.11.2018 |
| ► <u>M282</u> | Commission Implementing Regulation (EU) 2018/1865 of 28 November 2018 | L 304 | 6 | 29.11.2018 |
| ► <u>M283</u> | Commission Implementing Regulation (EU) 2018/1913 of 6 December 2018 | L 311 | 13 | 7.12.2018 |
| ► <u>M284</u> | Commission Implementing Regulation (EU) 2018/1914 of 6 December 2018 | L 311 | 17 | 7.12.2018 |
| ► <u>M285</u> | Commission Implementing Regulation (EU) 2018/1915 of 6 December 2018 | L 311 | 20 | 7.12.2018 |
| ► <u>M286</u> | Commission Implementing Regulation (EU) 2018/1916 of 6 December 2018 | L 311 | 24 | 7.12.2018 |
| ► <u>M287</u> | Commission Implementing Regulation (EU) 2018/1917 of 6 December 2018 | L 311 | 27 | 7.12.2018 |
| ► <u>M288</u> | Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018 | L 317 | 16 | 14.12.2018 |
| ► <u>M289</u> | Commission Implementing Regulation (EU) 2019/139 of 29 January 2019 | L 26 | 4 | 30.1.2019 |
| ► <u>M290</u> | Commission Implementing Regulation (EU) 2019/147 of 30 January 2019 | L 27 | 14 | 31.1.2019 |
| ► <u>M291</u> | Commission Implementing Regulation (EU) 2019/149 of 30 January 2019 | L 27 | 20 | 31.1.2019 |
| ► <u>M292</u> | Commission Implementing Regulation (EU) 2019/151 of 30 January 2019 | L 27 | 26 | 31.1.2019 |
| ► <u>M293</u> | Commission Implementing Regulation (EU) 2019/158 of 31 January 2019 | L 31 | 21 | 1.2.2019 |
| ► <u>M294</u> | Commission Implementing Regulation (EU) 2019/168 of 31 January 2019 | L 33 | 1 | 5.2.2019 |
| ► <u>M295</u> | Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 | L 48 | 17 | 20.2.2019 |
| ► <u>M296</u> | Commission Implementing Regulation (EU) 2019/324 of 25 February 2019 | L 57 | 1 | 26.2.2019 |
| ► <u>M297</u> | Commission Implementing Regulation (EU) 2019/337 of 27 February 2019 | L 60 | 12 | 28.2.2019 |
| ► <u>M298</u> | Commission Implementing Regulation (EU) 2019/344 of 28 February 2019 | L 62 | 7 | 1.3.2019 |
| ► <u>M299</u> | Commission Implementing Regulation (EU) 2019/481 of 22 March 2019 | L 82 | 19 | 25.3.2019 |
| ► <u>M300</u> | Commission Implementing Regulation (EU) 2019/676 of 29 April 2019 | L 114 | 12 | 30.4.2019 |

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|----------------------|--|-------|-----|------------|
| ► <u>M301</u> | Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 | L 114 | 15 | 30.4.2019 |
| ► <u>M302</u> | Commission Implementing Regulation (EU) 2019/706 of 7 May 2019 | L 120 | 11 | 8.5.2019 |
| ► <u>M303</u> | Commission Implementing Regulation (EU) 2019/707 of 7 May 2019 | L 120 | 16 | 8.5.2019 |
| ► <u>M304</u> | Commission Implementing Regulation (EU) 2019/716 of 30 April 2019 | L 122 | 39 | 10.5.2019 |
| ► <u>M305</u> | Commission Implementing Regulation (EU) 2019/717 of 8 May 2019 | L 122 | 44 | 10.5.2019 |
| ► <u>M306</u> | Commission Implementing Regulation (EU) 2019/989 of 17 June 2019 | L 160 | 11 | 18.6.2019 |
| ► <u>M307</u> | Commission Implementing Regulation (EU) 2019/1085 of 25 June 2019 | L 171 | 110 | 26.6.2019 |
| ► <u>M308</u> | Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 | L 173 | 39 | 27.6.2019 |
| ► <u>M309</u> | Commission Implementing Regulation (EU) 2019/1100 of 27 June 2019 | L 175 | 17 | 28.6.2019 |
| ► <u>M310</u> | Commission Implementing Regulation (EU) 2019/1101 of 27 June 2019 | L 175 | 20 | 28.6.2019 |
| ► <u>M311</u> | Commission Implementing Regulation (EU) 2019/1137 of 3 July 2019 | L 180 | 3 | 4.7.2019 |
| ► <u>M312</u> | Commission Implementing Regulation (EU) 2019/1138 of 3 July 2019 | L 180 | 8 | 4.7.2019 |
| ► <u>M313</u> | Commission Implementing Regulation (EU) 2019/1589 of 26 September 2019 | L 248 | 24 | 27.9.2019 |
| ► <u>M314</u> | Commission Implementing Regulation (EU) 2019/1605 of 27 September 2019 | L 250 | 49 | 30.9.2019 |
| ► <u>M315</u> | Commission Implementing Regulation (EU) 2019/1606 of 27 September 2019 | L 250 | 53 | 30.9.2019 |
| ► <u>M316</u> | Commission Implementing Regulation (EU) 2019/1675 of 4 October 2019 | L 257 | 6 | 8.10.2019 |
| ► <u>M317</u> | Commission Implementing Regulation (EU) 2019/1690 of 9 October 2019 | L 259 | 2 | 10.10.2019 |

Corrected by:

- **C1** Corrigendum, OJ L 26, 28.1.2012, p. 38 (540/2011)
- **C2** Corrigendum, OJ L 235, 4.9.2013, p. 12 (200/2013)
- **C3** Corrigendum, OJ L 277, 22.10.2015, p. 60 (140/2014)
- **C4** Corrigendum, OJ L 2, 5.1.2018, p. 15 (2017/842)

▼B**COMMISSION IMPLEMENTING REGULATION (EU) No
540/2011****of 25 May 2011****implementing Regulation (EC) No 1107/2009 of the European
Parliament and of the Council as regards the list of approved
active substances****(Text with EEA relevance)****▼M1***Article 1*

The active substances, as set out in Part A of the Annex, shall be deemed to have been approved under Regulation (EC) No 1107/2009.

▼M166

The active substances approved under Regulation (EC) No 1107/2009 are as set out in Part B of the Annex to this Regulation. The basic substances approved under Regulation (EC) No 1107/2009 are as set out in Part C of the Annex to this Regulation. The low-risk active substances approved under Regulation (EC) No 1107/2009 are as set out in Part D of the Annex to this Regulation. The candidates for substitution approved under Regulation (EC) No 1107/2009 are as set out in Part E of the Annex to this Regulation.

▼B*Article 2*

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 14 June 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼ M110

ANNEX ACTIVE SUBSTANCES

▼ M1

PART A

Active substances deemed to have been approved under Regulation (EC) No 1107/2009

General provisions applying to all substances listed in this Part:

▼ B

- for the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009 in relation to each substance, the conclusions of the review report on it, and in particular the Appendices I and II thereof, shall be taken into account;
- Member States shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make it available to them on specific request.

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|------------------------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| ▼ <u>M6</u> _____ | | | | | | |
| ▼ <u>M4</u> _____ | | | | | | |
| ▼ <u>M18</u> _____ | | | | | | |
| ▼ <u>M13</u> _____ | | | | | | |
| ▼ <u>M5</u> _____ | | | | | | |
| ▼ <u>M8</u> _____ | | | | | | |
| ▼ <u>M169</u> _____ | | | | | | |
| ▼ <u>M3</u> _____ | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------------------------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| ▼ <u>M181</u> _____ | | | | | | |
| ▼ <u>M162</u> _____ | | | | | | |
| ▼ <u>M253</u> _____ | | | | | | |
| ▼ <u>M170</u> _____ | | | | | | |
| ▼ <u>M155</u> _____ | | | | | | |
| ▼ <u>M182</u> _____ | | | | | | |
| ▼ <u>M280</u> _____ | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------------------------|---|---------------|------------|------------------|------------------------|---|
| ▼ <u>M148</u> _____ | | | | | | |
| ▼ <u>M198</u> _____ | | | | | | |
| ▼ <u>M136</u> _____ | | | | | | |
| ▼ <u>M233</u> _____ | | | | | | |
| ▼ <u>M175</u> _____ | | | | | | |
| ▼ <u>M22</u> 21 | Cyclanilide CAS No 113136-77-9 CIPAC No 586 | Not available | 960 g/kg | 1 November 2001 | 31 October 2011 | Only uses as a plant growth regulator may be authorised. The maximum content of the impurity 2,4-dichloroaniline (2,4-DCA) in the active substance as manufactured should be 1 g/kg. Date of Standing Committee on Plant Health at which the review report was finalised: 29 June 2001. |
| ▼ <u>M152</u> _____ | | | | | | |
| ▼ <u>M279</u> _____ | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------------------------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| ▼ <u>M173</u> _____ | | | | | | |
| ▼ <u>M244</u> _____ | | | | | | |
| ▼ <u>M191</u> _____ | | | | | | |
| ▼ <u>M161</u> _____ | | | | | | |
| ▼ <u>M183</u> _____ | | | | | | |
| ▼ <u>M193</u> _____ | | | | | | |
| ▼ <u>M171</u> _____ | | | | | | |
| ▼ <u>M205</u> _____ | | | | | | |
| ▼ <u>M150</u> _____ | | | | | | |

▼ **B**▼ **M24**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|------------|------------------|------------------------------|--|
| 33 | Cinidon-ethyl CAS No 142891-20-1 CIPAC No 598 | (Z)-ethyl 2-chloro-3-[2-chloro-5-(cyclohex-1-ene-1,2-dicarboximido)phenyl]acrylate | 940 g/kg | 1 October 2002 | 30 September 2012 | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cinidon-ethyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — should pay particular attention to the potential for ground water contamination, when the active substance is applied in regions with vulnerable soil (e.g. soils with neutral or high pH values) and/or climatic conditions, — should pay particular attention to the protection of aquatic organisms. <p>Conditions of authorisation must include risk mitigation measures, where appropriate.</p> |
| — | | | | | | |
| 35 | Famoxadone CAS No 131807-57-3 CIPAC No 594 | 3-anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione | 960 g/kg | 1 October 2002 | ► M303 30 June 2020 ◀ | <p>Only uses as fungicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on famoxadone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> — Member States must pay particular attention to potential chronic risks of the parent substance or metabolites to earthworms; — Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures; — Member States should pay particular attention to the protection of operators. |

▼ **B**

▼ **B**▼ **M159**▼ **B**▼ **M190**▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|------------------------------|---|
| | | | | | | |
| 37 | Metalaxyl-M CAS No 70630-17-0 CIPAC No 580 | Methyl(R)-2-{{(2,6-dimethylphenyl)methoxy-acetyl} amino} propionate | 910 g/kg | 1 October 2002 | ► M303 30 June 2020 ◀ | <p>Only uses as fungicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Metalaxyl-M, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19 April 2002 shall be taken into account. In this overall assessment:</p> <p>— particular attention should be given to the potential for groundwater contamination by the active substance or its degradation products CGA 62826, and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied, where appropriate.</p> |
| | | | | | | |
| 39 | Flumioxazine CAS No 103361-09-7 CICAP No 578 | N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboximide | 960 g/kg | 1 January 2003 | ► M303 30 June 2020 ◀ | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flumioxazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 June 2002 shall be taken into account. In this overall assessment Member States:</p> <p>— must carefully consider the risk to aquatic plants and algae. Conditions of authorisation must include risk mitigation measures, where appropriate.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------------------|--|--|------------|------------------|---------------------------------|--|
| 40 | Deltamethrin CAS No 52918-63-5 CIPAC No 333 | (S)- α -cyano-3-phenoxymethyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate | 980 g/kg | 1 November 2003 | ► M313 31 October 2020 ◀ | Only uses as insecticide may be authorised For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on deltamethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 18 October 2002 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures, — should observe the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels, — must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate. |
| ▼ M239 — | | | | | | |
| ▼ M265 — | | | | | | |
| ▼ <u>B</u> | | | | | | |
| 43 | Ethoxysulfuron CAS No 126801-58-9 CIPAC No 591 | 3-(4,6-dimethoxypyrimidin-2-yl)-1-(2-ethoxyphenoxy-sulfonyl)urea | 950 g/kg | 1 July 2003 | 30 June 2013 | Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ethoxysulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|------------|------------------|------------------------|--|
| | | | | | | Member States should pay particular attention to the protection of non-target aquatic plants and algae in drainage canals. Risk mitigation measures should be applied where appropriate. |
| 44 | Foramsulfuron CAS No 173159-57-4 CIPAC No 659 | 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl)urea | 940 g/kg | 1 July 2003 | ►M303 31 July 2020 ◀ | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on foramsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account.</p> <p>In this overall assessment Member States should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied, where appropriate.</p> |
| 45 | Oxadiargyl CAS No 39807-15-3 CIPAC No 604 | 5-tert-butyl-3-(2,4-dichloro-5-propargyloxyphenyl)-1,3,4-oxadiazol-2-(3H)-one | 980 g/kg | 1 July 2003 | 30 June 2013 | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxadiargyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account.</p> <p>In this overall assessment Member States should pay particular attention to the protection of algae and aquatic plants. Risk mitigation measures should be applied where appropriate.</p> |
| 46 | Cyazofamid CAS No 120116-88-3 CIPAC No 653 | 4-chloro-2cyano-N,N-dimethyl-5-P-tolyli-midazole -1-sulfonamide | 935 g/kg | 1 July 2003 | ►M303 31 July 2020 ◀ | <p>Only uses as fungicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyazofamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|-------------------------------------|--|---|------------------|------------------------|--|
| | | | | | | <p>Animal Health on 3 December 2002 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> — Member States must pay particular attention to the protection of aquatic organisms; — Member States must pay particular attention to the degradation kinetics of the metabolite CTCA in soil, especially for Northern European regions. <p>Risk mitigation measures or use restrictions should be applied where appropriate.</p> |
| ▼ <u>M232</u> | | | | | | |
| ▼ <u>B</u> | 48 | Beta-cyfluthrin CAS No 68359-37-5 (unstated stereochemistry) CIPAC No 482 | (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid (SR)- α -cyano-(4-fluoro-3-phenoxy-phenyl)methyl ester | 965 g/kg | 1 January 2004 | <p>► <u>M313</u> 31 October 2020 ◀</p> <p>Only use as insecticide may be authorised</p> <p>Uses other than ornamental in greenhouses and seed treatment are currently not adequately supported and have not shown to be acceptable under the criteria required by the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009. To support authorisations for such uses, data and information to prove their acceptability to human consumers and the environment will have to be generated and submitted to the Member States. This will be the case in particular for data to assess in all detail the risks of outdoor foliar uses and the dietary risks of foliar treatment in edible crops.</p> <p>For the implementation of the uniform principles, the conclusions of the review report on beta-cyfluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> — Member States must pay particular attention to the protection of non-target arthropods. Conditions of authorisation should include adequate risk mitigation measures. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------------------|---|--|------------|------------------|------------------------|---|
| 49 | Cyfluthrin CAS No 68359-37-5 (unstated stereochemistry) CIPAC No 385 | (RS),-α-cyano-4-fluoro-3-phenoxybenzyl-(1RS,3RS; 1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate | 920 g/kg | 1 January 2004 | 31 December 2013 | <p>Only use as insecticide may be authorised</p> <p>Uses other than ornamental in greenhouses and seed treatment are currently not adequately supported and have not shown to be acceptable under the criteria required by the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009. To support authorisations for such uses, data and information to prove their acceptability to human consumers and the environment will have to be generated and submitted to the Member States. This will be the case in particular for data to assess in all detail the risks of outdoor foliar uses and the dietary risks of foliar treatment in edible crops.</p> <p>For the implementation of the uniform principles, the conclusions of the review report on cyfluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment:</p> <p>— Member States must pay particular attention to the protection of non-target arthropods. Conditions of authorisation should include adequate risk mitigation measures.</p> |
| ▼ M243 — | | | | | | |
| ▼ M201 — | | | | | | |
| ▼ M234 — | | | | | | |
| ▼ M227 — | | | | | | |

▼ **B**▼ **M251**▼ **M260**▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|------------|------------------|---------------------------------|--|
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| 56 | Mecoprop CAS No 7085-19-0 CIPAC No 51 | (RS)-2-(4-chloro-o-tolyloxy)-propionic acid | 930 g/kg | 1 June 2004 | 31 May 2014 | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mecoprop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> — Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States should pay particular attention to the protection of non-target arthropods. Risk mitigation measures should be applied, where appropriate. |
| 57 | Mecoprop-P CAS No 16484-77-8 CIPAC No 475 | (R)-2-(4-chloro-o-tolyloxy)-propionic acid | 860 g/kg | 1 June 2004 | ► M281 31 January 2020 ◀ | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mecoprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> — Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------------------------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| ▼ <u>M282</u> _____ | | | | | | |
| ▼ <u>M267</u> _____ | | | | | | |
| ▼ <u>M268</u> _____ | | | | | | |
| ▼ <u>M214</u> _____ | | | | | | |
| ▼ <u>M266</u> _____ | | | | | | |
| ▼ <u>M305</u> _____ | | | | | | |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|---|------------|------------------|---------------------------------|---|
| ▼ <u>M287</u> | | | | | | |
| ▼ <u>B</u> | | | | | | |
| 65 | Flufenacet CAS No 142459-58-3 CIPAC No 588 | 4'-fluoro-N-isopropyl-2-[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yloxy]acetanilide | 950 g/kg | 1 January 2004 | ► <u>M313</u> 31 October 2020 ◀ | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flufenacet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of algae and aquatic plants, — should pay particular attention to the protection of operators. <p>Risk mitigation measures should be applied where appropriate.</p> |
| ▼ <u>M207</u> | | | | | | |
| ▼ <u>M311</u> | | | | | | |
| ▼ <u>M231</u> | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|------------------------|--|---|-----------------------|------------------|---------------------------------|---|
| 69 | Fosthiazate CAS No 98886-44-3 CIPAC No 585 | (RS)-S-sec-butyl O-ethyl 2-oxo-1,3-thiazolidin-3-ylphosphothioate | 930 g/kg | 1 January 2004 | ► M313 31 October 2020 ◀ | <p>Only uses as insecticide or nematocide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fosthiazate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States</p> <ul style="list-style-type: none"> — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions; — should pay particular attention to the protection of birds and wild mammals in particular if the substance is applied during the breeding season; — should pay particular attention to the protection of non-target soil organisms. <p>Risk mitigation measures should be applied where appropriate. In order to mitigate the potential risk to small birds, product authorisations must require that a very high level of incorporation of granules into soil is achieved.</p> <p>The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.</p> |
| ▼ M259 _____ | | | | | | |
| ▼ M222 _____ | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|---|--|------------------|-------------------------------|---|
| 72 | Molinate CAS No 2212-67-1 CIPAC No 235 | S-ethyl azepane-1-carbothioate; S-ethyl perhydroazepine-1-carbothioate; S-ethyl perhydroazepine-1-thiocarboxilate | 950 g/kg | 1 August 2004 | 31 July 2014 | Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on molinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States should pay particular attention to the possibility of short-range transport of the active substance in air. |
| ▼ M278 | | | | | | |
| 74 | Ziram CAS No 137-30-4 CIPAC No 31 | Zinc bis (dimethyl-dithiocarbamate) | 950 g/kg (FAO-specification) Arsenic: maximum 250 mg/kg Water: maximum 1,5 % | 1 August 2004 | ► M294 30 April 2020 ◀ | Only uses as fungicide or as repellent may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ziram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of non-target arthropods and aquatic organisms. Risk mitigation measures should be applied, where appropriate, — Member States should observe the acute dietary exposure situation of consumers in view of future revisions of Maximum Residue Levels. |

▼ **B**

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-----------------------------------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| ▼ <u>M216</u> _____ | | | | | | |
| ▼ <u>M228</u> _____ | | | | | | |
| ▼ <u>M258</u> _____ | | | | | | |
| ▼ <u>M306</u> _____ | | | | | | |
| ▼ <u>M226</u> _____ | | | | | | |
| ▼ <u>M218</u> _____ | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|------------------------|--|---|--|------------------|---------------------------------|---|
| 81 | Pyraclostrobin CAS No 175013-18-0 CIPAC No 657 | methyl N-(2-{{1-(4-chlorophenyl)-1H-pyrazol-3-yl}oxy-methyl}phenyl) N-methoxy carbamate | 975 g/kg The manufacturing impurity dimethyl sulfate (DMS) is considered to be of toxicological concern and must not exceed a concentration of 0,0001 % in the technical product. | 1 June 2004 | ► M281 31 January 2020 ◀ | Only uses as fungicide or plant growth regulator may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyraclostrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of aquatic organisms, especially fish, — should pay particular attention to the protection of terrestrial arthropods and earthworms. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured. |
| ▼ M284 _____ | | | | | | |
| ▼ M317 _____ | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|------------|------------------|---------------------------------|--|
| 84 | Benalaxyl CAS No 71626-11-4 CIPAC No 416 | Methyl N-phenylacetate- N-2, 6-xylyl-DL- alaninate | 960 g/kg | 1 March 2005 | ► M303 31 July 2020 ◀ | Only uses as fungicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on benalaxyl, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. |
| 85 | Bromoxynil CAS No 1689-84-5 CIPAC No 87 | 3,5 dibromo – 4- hydroxybenzonitrile | 970 g/kg | 1 March 2005 | ► M303 31 July 2020 ◀ | Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bromoxynil, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of birds and wild mammals, in particular if the substance is applied in winter, and of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate. |
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▼ **M309**

▼B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|--|------------------|------------------------|---|
| 87 | Ioxynil CAS No 13684-83-4 CIPAC No 86 | 4- hydroxy- 3,5- di-iodobenzonitrile | 960 g/kg | 1 March 2005 | 28 February 2015 | Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ioxynil, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of birds and wild mammals in particular if the substance is applied in winter and to aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate. |
| 88 | Phenmedipham CAS No 13684-63-4 CIPAC No 77 | methyl 3-(3-methyl-carbaniloyloxy)carbanilate; 3-methoxycarbony-laminophenyl 3'-methylcarbanilate | Min. 970 g/kg | 1 March 2005 | ►M303 31 July 2020 ◀ | Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on phenmedipham, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate. |
| 89 | Pseudomonas chlororaphis Strain: MA 342 CIPAC No 574 | Not applicable | The amount of the secondary metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the fermentate at the point of formulation of the product must not exceed the LOQ (2 mg/l). | 1 October 2004 | ►M294 30 April 2020 ◀ | Only uses as fungicide for seed dressing in closed seed dressing machinery may be authorised. When granting authorisations, the conclusions of the review report on Pseudomonas chlororaphis, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 30 March 2004 shall be taken into account. In this overall assessment, Member States should pay particular attention to the safety of operators and workers. Risk mitigation measures should be applied where appropriate. |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|--|------------|------------------|-------------------------------|--|
| 90 | Mepanipyrim CAS No 110235-47-7 CIPAC No 611 | N-(4-methyl-6-prop-1-ynylpyrimidin-2-yl)aniline | 960 g/kg | 1 October 2004 | ► M294 30 April 2020 ◀ | <p>Only uses as fungicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mepanipyrim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 30 March 2004 shall be taken into account.</p> <p>In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.</p> |
| ▼ M247 | | | | | | |
| ▼ <u>B</u> | | | | | | |
| 92 | Thiacloprid CAS No 111988-49-9 CIPAC No 631 | (Z)-N-{3-[(6-Chloro-3-pyridinyl)methyl]-1,3-thiazolan-2-yliden}cyanamide | ≥ 975 g/kg | 1 January 2005 | ► M294 30 April 2020 ◀ | <p>Only uses as insecticide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Thiacloprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 June 2004 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <ul style="list-style-type: none"> — should pay particular attention to the protection of non-target arthropods, — should pay particular attention to the protection of aquatic organisms, — should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Risk mitigation measures should be applied where appropriate.</p> |

▼ B▼ M269▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|-----------------|------------------|------------------------------|---|
| | | | | | | |
| 94 | Imazosulfuron CAS No 122548-33-8 CIPAC No 590 | 1-(2-chloroimid-azo[1,2- α]pyridin-3-ylsul-phonyl)-3-(4,6-dimethoxypyrimidin-2-yl)urea | ≥ 980 g/kg | 1 April 2005 | ► <u>M43</u> 31. July 2017 ◀ | Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on imazosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic and terrestrial non-target plants. Risk mitigation measures should be applied where appropriate. |
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| 97 | S-metolachlor CAS No 87392-12-9 (S-isomer) 178961-20-1 (R-isomer) CIPAC No 607 | Mixture of: (aRS, 1 S)-2-chloro-N-(6-ethyl-o-tolyl)-N-(2-methoxy-1-methyl-ethyl)acetamide (80-100 %) and: (aRS, 1 R)-2-chloro-N-(6-ethyl-o-tolyl)-N-(2-methoxy-1-methyl-ethyl)acetamide (20-0 %) | ≥ 960 g/kg | 1 April 2005 | ► <u>M303</u> 31 July 2020 ◀ | Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on s-metolachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 October 2004 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the potential for groundwater contamination, particularly of the active substance and its metabolites CGA 51202 and CGA 354743, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — should pay particular attention to the protection of aquatic plants. Risk mitigation measures should be applied where appropriate. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|--|------------|------------------|------------------------------|--|
| ▼ M292 | | | | | | |
| ▼ B | | | | | | |
| 99 | Ettoxazole CAS No 153233-91-1 CIPAC No 623 | (RS)-5-tert-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro-1,3-oxazol-4-yl]phenetole | ≥ 948 g/kg | 1 June 2005 | ► M303 31 July 2020 ◀ | <p>Only uses as acaricide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on etoxazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2004 shall be taken into account.</p> <p>In this overall assessment Member States should pay particular attention to the protection of aquatic organisms.</p> <p>Risk mitigation measures should be applied where appropriate.</p> |
| 100 | Tepaloxymid CAS No 149979-41-9 CIPAC No 608 | (EZ)-(RS)-2-{1-[(2E)-3-chloroallyloxyimino]propyl}-3-hydroxy-5-perhydropyran-4-ylcyclohex-2-en-1-one | ≥ 920 g/kg | 1 June 2005 | ► M134 31 May 2015 ◀ | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tepaloxymid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2004 shall be taken into account.</p> <p>In this overall assessment, Member States should pay particular attention to the protection of terrestrial non-target arthropods.</p> <p>Risk mitigation measures should be applied where appropriate.</p> |
| ▼ M301 | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|------------|------------------|---------------------------------|---|
| 102 | Chlorotoluron (unstated stereochemistry) CAS No 15545-48-9 CIPAC No 217 | 3-(3-chloro-p-tolyl)-1,1-dimethylurea | 975 g/kg | 1 March 2006 | ► M313 31 October 2020 ◀ | PART A Only uses as herbicide may be authorised PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorotoluron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Conditions of authorisation should include risk mitigation measures, where appropriate |
| 103 | Cypermethrin CAS No 52315-07-8 CIPAC No 332 | (RS)- α -cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (4 isomer pairs: cis-1, cis-2, trans-3, trans-4) | 900 g/kg | 1 March 2006 | ► M313 31 October 2020 ◀ | PART A Only uses as insecticide may be authorised PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cypermethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment: |

▼B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|-------------------------|--|
| | | | | | | <p>— Member States must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate,</p> <p>— Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate</p> |
| 104 | Daminozide CAS No 1596-84-5 CIPAC No 330 | N-dimethylaminosuccinamic acid | 990 g/kg Impurities: — N-nitrosodimethylamine: not more than 2,0 mg/kg — 1,1-dimethylhydrazide: not more than 30 mg/kg | 1 March 2006 | ►M313 31 October 2020 ◀ | <p>PART A</p> <p>Only uses as growth regulator in non-edible crops may be authorised</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on daminozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the safety of operators and workers after re-entry. Conditions of authorisation should include protective measures, where appropriate</p> |
| 105 | Thiophanate-methyl (unstated stereochemistry) CAS No 23564-05-8 CIPAC No 262 | Dimethyl 4,4'-(o-phenylene)bis(3-thioallophanate) | 950 g/kg | 1 March 2006 | ►M313 31 October 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiophanate-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---------------------------------------|------------------------------------|------------|------------------|---------------------------------|--|
| | | | | | | Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of aquatic organisms, earthworms and other soil macro-organisms. Conditions of authorisation should include risk mitigation measures, where appropriate |
| ▼ <u>M283</u> | | | | | | |
| ▼ <u>B</u> | | | | | | |
| 107 | MCPA CAS No 94-74-6 CIPAC No 2 | 4-chloro-o-tolyloxyacetic acid | ≥ 930 g/kg | 1 May 2006 | ► <u>M313</u> 31 October 2020 ◀ | PART A Only uses as herbicide may be authorised PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on MCPA, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2005 shall be taken into account Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones |
| 108 | MCPB CAS No 94-81-5 CIPAC No 50 | 4-(4-chloro-o-toloxyl)butyric acid | ≥ 920 g/kg | 1 May 2006 | ► <u>M313</u> 31 October 2020 ◀ | PART A Only uses as herbicide may be authorised |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|-----------------------|------------------|------------------------------|---|
| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on MCPB, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2005 shall be taken into account</p> <p>Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate</p> <p>Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones</p> |
| 109 | <p>Bifenazate</p> <p>CAS No 149877-41-8</p> <p>CIPAC No 736</p> | Isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinoformate | ≥ 950 g/kg | 1 December 2005 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as acaricide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing bifenazate for uses other than on ornamental plants in greenhouses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorization is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenazate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|---------------------------------|--|
| 110 | <p>Milbemectin</p> <p>Milbemectin is a mixture of M.A3 and M.A4</p> <p>CAS No</p> <p>M.A3: 51596-10-2</p> <p>M.A4: 51596-11-3</p> <p>CIPAC No 660</p> | <p>M.A3: (10E,14E,16E,22Z)- (1R,4S,5'S,6R,6'R,8-R,13R,20R,21R,24S)- 21,24-dihydroxy- 5',6',11,13,22-penta- methyl-3,7,19-trioxa- tetra- cyclo[15.6.1.14,8.02- 0,24] pentacosa- 10,14,16,22-tetraene- 6-spiro-2'-tetrahy- dropyran-2-one</p> <p>M.A4: (10E,14E,16E,22Z)- (1R,4S,5'S,6R,6'R,8-R,13R,20R,21R,24S)- 6'-ethyl-21,24-dihy- droxy-5',11,13,22- tetramethyl-3,7,19- trioxatetra- cyclo[15.6.1. 14,8020,24] pentacosa- 10,14,16,22-tetraene- 6-spiro-2'-tetrahy- dropyran-2-one</p> | <p>≥ 950 g/kg</p> <p>The impurity O,O,O,O-tetraethyl dithiopyrophosphate (Sul-fotep) was considered of toxicological concern and a maximum level of 3 g/Kg is established.</p> | 1 December 2005 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as acaricide or insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on milbemectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.</p> <p>In this overall assessment Member States should pay particular attention to the protection of aquatic organisms.</p> <p>Risk mitigation measures should be applied where appropriate.</p> |
| 111 | <p>Chlorpyrifos</p> <p>CAS No 2921-88-2</p> <p>CIPAC No 221</p> | O,O-diethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate | <p>≥ 970 g/kg</p> <p>The impurity O,O,O,O-tetraethyl dithiopyrophosphate (Sul-fotep) was considered of toxicological concern and a maximum level of 3 g/Kg is established.</p> | 1 July 2006 | ► M281 31 January 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorpyrifos, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.</p> |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|---|------------------|---------------------------------|---|
| | | | | | | <p>Member States must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.</p> <p>Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals. They shall ensure that the notifiers at whose request chlorpyrifos has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 112 | Chlorpyrifos-methyl CAS No 5598-13-0 CIPAC No 486 | O,O-dimethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate | ≥ 960 g/kg The impurities O,O,O,O-tetra-methyl dithiopyrophosphate (Sulfotemp) and OOO-trimethyl-O-(3,5,6-trichloro-2-pyridinyl) diphosphorodithioate (Sulfotemp -ester) were considered of toxicological concern and a maximum level of 5 g/Kg is established for each impurity. | 1 July 2006 | ► M281 31 January 2020 ◀ | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorpyrifos-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account. Member States must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones. Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals in case of outdoor uses. They shall ensure that the notifiers at whose request chlorpyrifos-methyl has been included in this Annex provide such studies to the Commission within two years from the approval. |

▼B

| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|--|------------------|---------------------------------|--|
| 113 | Maneb CAS No 12427-38-2 CIPAC No 61 | manganese ethylenebis (dithiocarbamate) (polymeric) | ≥ 860 g/kg The manufacturing impurity ethylene thiourea is considered to be of toxicological concern and must not exceed 0,5 % of the maneb content. | 1 July 2006 | ► M197 31 January 2017 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on maneb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account. Member States must pay particular attention to the potential for groundwater contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions. Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers. Member States must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods and ensure that the conditions of authorisation include risk mitigation measures. Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for developmental toxicity. They shall ensure that the notifiers at whose request maneb has been included in this Annex provide such studies to the Commission within two years from the approval. |
| 114 | Mancozeb CAS No 8018-01-7 (formerly 8065-67-5) CIPAC No 34 | Manganese ethylenebis (dithiocarbamate) (polymeric) complex with zinc salt | ≥ 800 g/kg The manufacturing impurity ethylene thiourea is considered to be of toxicological concern and must not exceed 0,5 % of the mancozeb content. | 1 July 2006 | ► M281 31 January 2020 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mancozeb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account. |

▼B

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|--|------------------|-------------------------------|---|
| | | | | | | <p>Member States must pay particular attention to the potential for groundwater contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions.</p> <p>Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers.</p> <p>Member States must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods and ensure that the conditions of authorisation include risk mitigation measures.</p> <p>Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for developmental toxicity.</p> <p>They shall ensure that the notifiers at whose request mancozeb has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 115 | Metiram CAS No 9006-42-2 CIPAC No 478 | Zinc ammoniate ethylenebis(dithiocarbamate) — poly[ethylenebis(thiuramdisulfide)] | <p>≥ 840 g/kg</p> <p>The manufacturing impurity ethylene thiourea is considered to be of toxicological concern and must not exceed 0,5 % of the metiram content.</p> | 1 July 2006 | ►M281 31 January 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metiram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.</p> <p>Member States must pay particular attention to the potential for ground water contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions.</p> <p>Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|---------------------------------|---|
| | | | | | | <p>Member States must pay particular attention to the protection of birds, mammals, aquatic organisms and non target arthropods and must ensure that the conditions of authorisation include risk mitigation measures.</p> <p>Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals. They shall ensure that the notifiers at whose request metiram has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 116 | <p>Oxamyl</p> <p>CAS No 23135-22-0</p> <p>CIPAC No 342</p> | N,N-dimethyl-2-methylcarbamoyloxy-imino-2-(methylthio)acetamide | 970 g/kg | 1 August 2006 | ► M281 31 January 2020 ◀ | <p>PART A</p> <p>Only uses as nematicide and insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxamyl, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2005 shall be taken into account. In this overall assessment,</p> <p>— Member States must pay particular attention to the protection of birds and mammals, earthworms, aquatic organisms, surface water, and groundwater in vulnerable situations.</p> <p>Conditions of authorisation should include risk mitigation measures, where appropriate.</p> <p>— Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate.</p> <p>The concerned Member States shall request the submission of further studies to confirm the risk assessment for ground water contamination in acidic soils, birds and mammals and earthworms. They shall ensure that the notifiers at whose request oxamyl has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|--|---|------------------|---------------------------------|---|
| ▼ <u>M307</u> | | | | | | |
| ▼ <u>M255</u> | | | | | | |
| ▼ <u>B</u> | | | | | | |
| 119 | Indoxacarb CAS No 173584-44-6 CIPAC No 612 | methyl (S)-N-[7-chloro-2,3,4a,5-tetrahydro-4a-(methoxycarbonyl)inden[1,2-e][1,3,4]oxadiazin-2-ylcarbonyl]-4'-(trifluoromethoxy)carbanilate | TC (Technical Material): ≥ 628 g/kg indoxacarb | 1 April 2006 | ► <u>M313</u> 31 October 2020 ◀ | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on indoxacarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 September 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of aquatic organisms. Conditions of use should include risk mitigation measures, where appropriate. |
| 120 | Warfarin CAS No 81-81-2 CIPAC No 70 | (RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin 3-(α-acetonyl-benzyl)-4-hydroxycoumarin | ≥ 990 g/kg | 1 October 2006 | 30 September 2013 | PART A Only uses as rodenticide in the form of pre-prepared bait, if appropriate, placed in specially constructed hoppers, are authorised. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|-------------------------|------------------|---------------------------------|--|
| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on warfarin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 September 2005, shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of operators, birds and non-target mammals.</p> <p>Risk mitigation measures should be applied where appropriate.</p> |
| 121 | Clothianidin CAS No 210880-92-5 CIPAC No 738 | (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitro-guanidine | ≥ 960 g/kg | 1 August 2006 | ► M245 31 January 2019 ◀ | <p>► M262 PART A</p> <p>Only uses as insecticide, in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses, may be authorised. The resulting crop must stay within a permanent greenhouse during its entire life cycle.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clothianidin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 and the conclusions of the revised addendum of the review report on clothianidin as finalised in the Standing Committee on Plants, Animals, Food and Feed on 27 April 2018 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to groundwater; — the risk to bees and bumble bees released for pollination in permanent greenhouses; — the exposure of bees via the consumption of contaminated water from the permanent greenhouses. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|--|--|------------------|-------------------------------|---|
| | | | | | | <p>Member States shall ensure that the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate. ◀</p> |
| ▼ M272 | | | | | | |
| ▼ B | | | | | | |
| 123 | Clodinafop CAS No 114420-56-3 CIPAC No 683 | (R)-2-[4-(5-chloro-3-fluoro- 2 pyridyloxy)-phenoxy]-propionic acid | ≥ 950 g/kg (expressed as clodinafop-propargyl) | 1 February 2007 | ► M294 30 April 2020 ◀ | PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clodinafop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. |
| 124 | Pirimicarb CAS No 23103-98-2 CIPAC No 231 | 2-dimethylamino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate | ≥ 950 g/kg | 1 February 2007 | ► M294 30 April 2020 ◀ | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pirimicarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. Member States must pay particular attention to the safety of operators and ensure that conditions of use prescribe the application of adequate personal protective equipment. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|---------------------------------------|------------------|-------------------------------|--|
| | | | | | | <p>Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.</p> <p>The concerned Member States shall request the submission of further studies to confirm the long term risk assessment for birds and for potential groundwater contamination, in particular concerning metabolite R35140. They shall ensure that the notifiers at whose request pirimicarb has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 125 | <p>Rimsulfuron</p> <p>CAS No 122931-48-0 (rimsulfuron)</p> <p>CIPAC No 716</p> | 1-(4-6 dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl) urea | ≥ 960 g/kg (expressed as rimsulfuron) | 1 February 2007 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rimsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account.</p> <p>Member States must pay particular attention to the protection of non target plants and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.</p> |
| | | | | | | |

▼ **M310**

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|------------|------------------|-------------------------------|--|
| 127 | <p>Triticonazole</p> <p>CAS No 131983-72-7</p> <p>CIPAC No 652</p> | (±)-(E)-5-(4-chloro-benzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol | ≥ 950 g/kg | 1 February 2007 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing triticonazole for uses other than seed treatment, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triticonazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate, — must pay particular attention to the potential for groundwater contamination, in particular from the highly persistent active substance and its metabolite RPA 406341, in vulnerable zones, — must pay particular attention to the protection of granivorous birds (long term risk). <p>Conditions of authorisation should include risk mitigation measures, where appropriate.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|------------|------------------|---------------------------------|--|
| | | | | | | The concerned Member States shall request the submission of further studies to confirm the risk assessment for granivorous birds. They shall ensure that the notifier at whose request triticonazole has been included in this Annex provide such studies to the Commission within two years from the approval. |
| 128 | Dimoxystrobin CAS No 149961-52-4 CIPAC No 739 | (E)-o-(2,5-dimethyl-phenoxymethyl)-2-methoxyimino-N-methylphenylacetamide | ≥ 980 g/kg | 1 October 2006 | ► M281 31 January 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing dimoxystrobin for indoor uses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dimoxystrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account.</p> <p>In this overall assessment Member States</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of groundwater, when the active substance is applied in a situation with a low crop interception factor, or in regions with vulnerable soil and/or climate conditions; — must pay particular attention to the protection of aquatic organisms. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The concerned Member States shall request the submission of</p> <ul style="list-style-type: none"> — a refined risk assessment for birds and mammals considering the formulated active substance; |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>— a comprehensive aquatic risk assessment considering the high chronic risk to fish and the effectiveness of potential risk mitigation measures, particularly taking into account run-off and drainage.</p> <p>They shall ensure that the notifiers at whose request dimoxystrobin has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 129 | <p>Clopyralid</p> <p>CAS No 1702-17-6</p> <p>CIPAC No 455</p> | 3,6-dichloropyridine-2-carboxylic acid | ≥ 950 g/kg | 1 May 2007 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing clopyralid for uses other than spring applications, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <p>— the protection of non target plants and groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.</p> <p>The concerned Member States shall request the submission of further studies to confirm the results on animal metabolism. They shall ensure that the notifiers at whose request clopyralid has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| 130 | Cyprodinil CAS No 121522-61-2 CIPAC No 511 | (4-cyclopropyl-6-methyl-pyrimidin-2-yl)-phenyl-amine | ≥ 980 g/kg | 1 May 2007 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyprodinil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the safety of operators and ensure that conditions of use prescribe the application of adequate personal protective equipment, — must pay particular attention to the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones. <p>The concerned Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for possible presence of residues of metabolite CGA 304075 in food of animal origin. They shall ensure that the notifiers at whose request cyprodinil has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 131 | Fosetyl CAS No 15845-66-6 CIPAC No 384 | Ethyl hydrogen phosphonate | ≥ 960 g/kg (expressed as fosetyl-Al) | 1 May 2007 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fosetyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account.</p> <p>In this overall assessment Member States:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>— must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods.</p> <p>Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones.</p> <p>The concerned Member States shall request the submission of further studies to confirm the risk assessment for non-target arthropods, in particular with regard to in-field recovery, and for herbivorous mammals. They shall ensure that the notifier at whose request fosetyl has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 132 | Trinexapac CAS No 104273-73-6 CIPAC No 732 | 4-(cyclopropyl-hydroxymethylene)-3,5-dioxo- cyclohexanecarboxylic acid | ≥ 940 g/kg (expressed as trinexapac-ethyl) | 1 May 2007 | ►M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on trinexapac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <p>— must pay particular attention to the protection of birds and mammals.</p> <p>Conditions of authorisation should include risk mitigation measures, where appropriate.</p> |
| 133 | Dichlorprop-P CAS No 15165-67-0 CIPAC No 476 | (R)-2-(2,4-dichlorophenoxy) propanoic acid | ≥ 900 g/kg | 1 June 2007 | ►M294 30 April 2020 ◀ | <p>►M89 PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>As regards cereals, only application in spring may be authorised, at rates not exceeding 800 g active substance per hectare per application.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>Use on grassland shall not be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dichlorprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 May 2006 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of birds, mammals, aquatic organisms and non-target plants.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀</p> |
| 134 | <p>Metconazole</p> <p>CAS No 125116-23-6 (unstated stereo-chemistry)</p> <p>CIPAC No 706</p> | <p>(1RS,5RS:1RS,5SR)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol</p> | <p>≥ 940 g/kg</p> <p>(sum of cis-and trans-isomers)</p> | 1 June 2007 | ►M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide and plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 May 2006 shall be taken into account.</p> <p>In this overall assessment:</p> <ul style="list-style-type: none"> — Member States must pay particular attention to the protection of aquatic organisms, birds and mammals. Conditions of authorisation should include risk mitigation measures, where appropriate, — Member States must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate. |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| 135 | Pyrimethanil CAS No 53112-28-0 CIPAC No not allocated | N-(4,6-dimethylpyrimidin-2-yl) aniline | ≥ 975 g/kg (the manufacturing impurity cyanamide is considered to be of toxicological concern and must not exceed 0,5 g/kg in the technical material) | 1 June 2007 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyrimethanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 May 2006 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones, — must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment. <p>The Member States concerned shall request the submission of further studies to confirm the risk assessment to fish. They shall ensure that the notifiers at whose request pyrimethanil has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 136 | Triclopyr CAS No 055335-06-3 CIPAC No 376 | 3,5,6-trichloro-2-pyridyloxyacetic acid | ≥ 960 g/kg (as Triclopyr butoxyethyl ester) | 1 June 2007 | ► M294 30 April 2020 ◀ | <p>► M137 PART A</p> <p>Only uses as herbicide may be authorised. Only uses with a total application per year of maximum 480 g active substance per hectare shall be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triclopyr, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014 shall be taken into account.</p> <p>In this overall assessment Member States:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <ul style="list-style-type: none"> — shall pay particular attention to the protection of groundwater under vulnerable conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated in vulnerable zones, where appropriate, — shall pay particular attention to the safety of operators and ensure that conditions of use prescribe the application of adequate personal protective equipment, — shall pay particular attention to the protection of birds, mammals, aquatic organisms and non-target plants. Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀ |
| 137 | Metrafenone CAS No 220899-03-6 CIPAC No 752 | 3'-bromo-2,3,4,6'-tetramethoxy-2',6-dimethylbenzophenone | ≥ 940 g/kg | 1 February 2007 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metrafenone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account.</p> <p>The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.</p> |
| 138 | Bacillus subtilis (Cohn 1872) Strain QST 713, identical with strain AQ 713 Culture collection No: NRRL B -21661 CIPAC No not allocated | Not applicable | | 1 February 2007 | ► M294 30 April 2020 ◀ | <p>► M158 PART A</p> <p>Only uses as fungicide and bactericide may be authorised. ◀</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Bacillus subtilis, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account.</p> |

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| 139 | <p>Spinosad</p> <p>CAS No 131929-60-7 (Spinosyn A)</p> <p>131929-63-0 (Spinosyn D)</p> <p>CIPAC No 636</p> | <p>Spinosyn A:</p> <p>(2R,3aS,5aR,5bS,9S,-13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy-β-D-erythro-pyr-anosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,-11,12,13,14,15,16a,1-6b-hexadecahydro-14-methyl-1H-8-oxacyclododeca[b]as-indacene-7,15-dione</p> <p>Spinosyn D:</p> <p>(2S,3aR,5aS,5bS,9S,-13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy-β-D-erythro-pyr-anosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,-11,12,13,14,15,16a,1-6b-hexadecahydro-4,14-dimethyl-1H-8-oxacyclododeca[b]as-indacene-7,15-dione</p> <p>Spinosad is a mixture of 50-95 % spinosyn A and 5-50 % spinosyn D</p> | ≥ 850 g/kg | 1 February 2007 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spinosad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account.</p> <p>In this overall assessment Member States</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of aquatic organisms; — must pay particular attention to the risk to earthworms when the substance is used in glasshouses. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 140 | Thiamethoxam CAS No 153719-23-4 CIPAC No 637 | (E,Z)-3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]ox-adiazinan-4-ylidene-N-nitroamine | ≥ 980 g/kg | 1 February 2007 | ► M252 30 April 2019 ◀ | <p>► M263 PART A</p> <p>Only uses as insecticide, in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses, may be authorised. The resulting crop must stay within a permanent greenhouse during its entire life cycle.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiamethoxam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 and the conclusions of the revised addendum of the review report on thiamethoxam as finalised in the Standing Committee on Plants, Animals, Food and Feed on 27 April 2018 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to groundwater; — the risk to aquatic organisms; — the risk to bees and bumble bees released for pollination in permanent greenhouses; — the exposure of bees via the consumption of contaminated water from the permanent greenhouses. <p>Member States shall ensure that the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate. ◀</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| 141 | Fenamiphos CAS No 22224-92-6 CIPAC No 692 | (RS)-ethyl 4-methylthio-m-tolyl isopropyl-phosphoramidate | ≥ 940 g/kg | 1 August 2007 | ►M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as nematocide applied by drip irrigation in greenhouses with permanent structure may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenamiphos, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account.</p> <p>In this overall assessment:</p> <p>— Member States must pay particular attention to the protection of aquatic organisms, soil non-target organisms and groundwater in vulnerable situations.</p> <p>Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.</p> |
| 142 | Ethephon CAS No 16672-87-0 CIPAC No 373 | 2-chloroethyl-phosphonic acid | ≥ 910 g/kg (technical material — TC) The manufacturing impurities MEPHA (Mono 2-chloroethyl ester, 2-chloroethyl phosphonic acid) | 1 August 2007 | ►M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ethephon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | and 1,2-Dichloroethane are of toxicological concern and must not exceed respectively 20 g/kg and 0,5 g/kg in the technical material. | | | |
| 143 | Flusilazole ⁽²⁾ CAS No 85509-19-9 CIPAC No 435 | Bis(4-fluorophenyl)(methyl) (1H-1,2,4-triazol-1-ylmethyl)silane | 925 g/kg | 1 January 2007 | 30 June 2008 ⁽²⁾ | <p>PART A</p> <p>Only uses as fungicide on the following crops may be authorised:</p> <ul style="list-style-type: none"> — cereals other than rice ⁽²⁾, — maize ⁽²⁾, — rape seed ⁽²⁾, — sugar beet ⁽²⁾, <p>at rates not exceeding 200 g active substance per hectare per application.</p> <p>The following uses must not be authorised:</p> <ul style="list-style-type: none"> — air application, — knapsack and hand-held applications, neither by amateur nor by professional users, — home gardening. <p>Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of:</p> <ul style="list-style-type: none"> — aquatic organisms. An appropriate distance must be kept between treated areas and surface water bodies. This distance may depend on the application or not of drift reducing techniques or devices, |

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| | | | | | | <p>— birds and mammals. Conditions of authorisation shall include risk mitigation measures, such as a judicious timing of the application and the selection of those formulations which, as a result of their physical presentation or the presence of agents that ensure an adequate avoidance, minimise the exposure of the concerned species,</p> <p>— operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flusilazole, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of flusilazole can be obtained.</p> <p>Member States shall request the submission of further studies to address the potential endocrine disrupting properties of flusilazole within two years after the adoption of the Test Guidelines on endocrine disruption by the Organisation for Economic Cooperation and Development (OECD). They shall ensure that the notifier at whose request flusilazole has been included in this Annex provide such studies to the Commission within two years of the adoption of the above test guidelines.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 144 | Carbendazim CAS N° 10605-21-7 CIPAC N° 263 | Methyl benzimidazol-2-ylcarbamate | <p>≥ 980 g/kg</p> <p>Relevant impurities</p> <p>2-amino-3-hydroxyphenazine (AHP): not more than 0,0005 g/kg</p> <p>2,3-diaminophenazine (DAP): not more than 0,003 g/kg</p> | 1 June 2011 | 30 November 2014 | <p>PART A</p> <p>Only uses as fungicide on the following crops may be authorised:</p> <ul style="list-style-type: none"> — cereals — rape seed — sugar and fodder beet — maize <p>at rates not exceeding</p> <ul style="list-style-type: none"> — 0,25 kg active substance per hectare per application for cereals and rape seed; — 0,075 kg active substance per hectare per application for sugar and fodder beet — 0,1 kg active substance per hectare per application for maize. <p>The following uses must not be authorised:</p> <ul style="list-style-type: none"> — air application; — knapsack and handheld applications neither by amateur nor by professional users; — home gardening. <p>Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the protection of:</p> <ul style="list-style-type: none"> — aquatic organisms. Appropriate drift mitigation measures must be applied to minimise the exposure of surface water bodies. This should include keeping a distance between treated areas and surface water bodies alone or in combination with the use of drift-reducing techniques or devices; |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <ul style="list-style-type: none"> — earthworms and other soil macro-organisms. Conditions of authorisation shall include risk mitigation measures, such as the selection of the most appropriate combination of numbers and timing of application, and, if necessary, the degree of concentration of the active substance; — birds (long term risk). Depending on the results of the risk assessment for specific uses, targeted mitigation measures to minimise the exposure may become necessary; — operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment. <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on carbendazim, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>The Member States concerned shall request that the applicant provides the following to the Commission:</p> <ul style="list-style-type: none"> — by 1 December 2011 at the latest, information as regards the toxicological and ecotoxicological relevance of the impurity AEF037197; — by 1 June 2012 at the latest, the examination of the studies included in the list in the draft re-assessment report of 16 July 2009 (Volume 1, Level 4 ‘Further information’, pp. 155 – 157); |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | — by 1 June 2013 at the latest, information on the fate and behaviour (route of aerobic degradation in soil) and the long term risk to birds. |

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| 145 | Captan CAS No 133-06-02 CIPAC No 40 | N-(trichloromethylthio) cyclohex-4-ene-1,2-dicarboximide | <p>≥ 910 g/kg</p> <p>Impurities:</p> <p>Perchloromethylmercaptan (R005406): not more than 5 g/kg</p> <p>Folpet: not more than 10 g/kg</p> <p>Carbon tetrachloride not more than 0,1 g/Kg</p> | 1 October 2007 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide can be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing captan for uses other than tomatoes Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on captan, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated in vulnerable zones, where appropriate; — the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures. |
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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|-------------------------------------|---|------------------|------------------------------|---|
| | | | | | | The Member States concerned shall request the submission of further studies to confirm the long term risk assessment for birds and mammals, as well as the toxicological assessment on metabolites potentially present in groundwater under vulnerable conditions. They shall ensure that the notifiers at whose request captan has been included in this Annex provide such studies to the Commission within two years from the approval. |
| 146 | Folpet CAS No 133-07-3 CIPAC No 75 | N-(trichloromethylthio) phthalimide | <p>≥ 940 g/kg</p> <p>Impurities:</p> <p>Perchloromethylmercaptan (R005406): not more than 3,5 g/kg</p> <p>Carbon tetrachloride not more than 4 g/kg</p> | 1 October 2007 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide can be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing folpet for uses other than winter wheat Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on folpet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of birds, mammals, aquatic and soil organisms. Conditions of authorisation should include risk mitigation measures. |

▼B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|------------|------------------|------------------------|---|
| | | | | | | The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and earthworms. They shall ensure that the notifiers at whose request folpet has been included in this Annex provide such studies to the Commission within two years from the approval. |
| 147 | Formetanate CAS No 23422-53-9 CIPAC No 697 | 3-dimethylamino-methyleneaminophenyl methylcarbamate | ≥ 910 g/kg | 1 October 2007 | ►M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing formetanate for uses other than in field tomatoes and ornamental shrubs Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on formetanate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of birds, mammals, non-target arthropods and bees and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures; — must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — must pay particular attention to the dietary exposure of consumers in view of future revisions of Maximum Residue Levels. |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|--|-----------------------|------------------|------------------------------|--|
| | | | | | | The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and non-target arthropods. They shall ensure that the notifier at whose request formetanate has been included in this Annex provide such studies to the Commission within two years from the approval. |
| ▼ <u>M315</u> | | | | | | |
| ▼ <u>M308</u> | | | | | | |
| ▼ <u>B</u> | | | | | | |
| 150 | Dimethomorph CAS No 110488-70-5 CIPAC No 483 | (E,Z) 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine | ≥ 965 g/kg | 1 October 2007 | ► <u>M303</u> 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dimethomorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — to the protection of birds, mammals and aquatic organisms. <p>Conditions of authorisation should include risk mitigation measures, where appropriate.</p> |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|-----------------------|------------------|-------------------------------|--|
| 151 | Glufosinate CAS No 77182-82-2 CIPAC No 437.007 | ammonium(DL)-homoalanin-4-yl(methyl)phosphinate | 950 g/kg | 1 October 2007 | ► M139 31. July 2018 ◀ | <p>► M57 PART A</p> <p>Only uses as herbicide for band or spot application may be authorised at rates not exceeding 750 g active substance/ha (treated surface) per application and maximum two applications per year.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing glufosinate, notably as regards the operator and consumer exposure, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on glufosinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006, shall be taken into account. In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> (a) the operator, worker and bystander safety; conditions of authorisation shall include protective measures, where appropriate; (b) the potential for groundwater contamination, where the active substance is applied in regions with vulnerable soil or climatic conditions; (c) the protection of mammals, non-target arthropods and non-target plants. <p>Conditions of authorisation shall include the application of drift reducing nozzles and spray shields and shall provide for respective labelling of plant protection products. Those conditions shall include further risk mitigation measures, where appropriate. ◀</p> |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|------------------------------|---|
| 152 | Metribuzin CAS No 21087-64-9 CIPAC No 283 | 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4H)-one | ≥ 910 g/kg | 1 October 2007 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing metribuzin for uses other than in post-emergence selective herbicide in potatoes Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metribuzin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of algae, aquatic plants, non-target plants outside the treated field and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. — must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment. <p>The Member States concerned shall request the submission of further data to confirm the risk assessment for groundwater. They shall ensure that the notifiers at whose request metribuzin has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|--|------------------|------------------------|---|
| 153 | Phosmet CAS No 732-11-6 CIPAC No 318 | O,O-dimethyl S-phthalimidomethyl phosphorodithioate; N-(dimethoxyphosphinothioylthio-methyl)phthalimide | ≥ 950 g/kg Impurities: — phosmet oxon: not more than 0,8 g/kg — iso phosmet: not more than 0,4 g/kg | 1 October 2007 | ►M303 31 July 2020 ◀ | PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on phosmet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and other non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones and reduction of run-off and drainage inputs to surface water, — must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds (acute risk) and herbivorous mammals (long term risk). They shall ensure that the notifier at whose request phosmet has been included in this Annex provides such studies to the Commission within two years from the approval. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|-----------------------|------------------|------------------------------|---|
| 154 | Propamocarb CAS No 24579-73-5 CIPAC No 399 | Propyl 3-(dimethyl- amino) propylcar- bamate | ≥ 920 g/kg | 1 October 2007 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing propamocarb for uses other than foliar applications, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, as regards worker exposure and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on propamocarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operators and workers safety. Conditions of authorisation should include protective measures, where appropriate; — the transfer of soil residues for rotating or succeeding crops; — the protection of surface and groundwater in vulnerable zones; — the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate. |

▼ B▼ M298▼ B

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|-----------------------|------------------|------------------------------|---|
| 156 | Pirimiphos-methyl CAS No 29232-93-7 CIPAC No 239 | O-2-diethylamino-6-methylpyrimidin-4-yl O,O-dimethylphosphorothioate | > 880 g/kg | 1 October 2007 | ► <u>M303</u> 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide for post harvest storage can be authorised.</p> <p>Hand-held applications shall not be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing pirimiphos-methyl for uses other than applications with automated systems in empty cereals storehouses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pirimiphos-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2007 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operators safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment including respiratory protective equipment and risk mitigation measures to reduce the exposure; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|-----------------------|------------------|-----------------------------------|---|
| 157 | Fipronil CAS No 120068-37-3 CIPAC No 581 | (±)-5-amino-1-(2,6-dichloro- α,α,α -trifluoro-para-tolyl)-4-trifluoromethylsulfinylpyrazole-3-carbonitrile | ≥ 950 g/kg | 1 October 2007 | ► M197 30 September 2017 ◀ | <p>► M73 PART A</p> <p>Only uses as insecticide for use as seed treatment may be authorised. Uses shall only be authorised for seeds intended to be sown in greenhouses and seeds of leek, onions, shallots and the group of <i>Brassica</i> vegetables intended to be sown in fields and harvested before flowering.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fipronil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2007 and the conclusions of the addendum of the review report on fipronil as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> (a) the packaging of the marketed products to avoid the generation of photodegradation products of concern; (b) the potential for groundwater contamination, especially from metabolites which are more persistent than the parent compound, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (c) the protection of granivorous birds and mammals, aquatic organisms, non-target arthropods and honey bees. <p>Member States shall also ensure that:</p> <ul style="list-style-type: none"> (a) the seed coating shall only be performed in professional seed treatment facilities; those facilities shall apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised; |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>(b) adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission;</p> <p>(c) the label of the treated seeds shall include the indication that the seeds were treated with fipronil and sets out the risk mitigation measures provided for in the authorisation;</p> <p>(d) monitoring programmes shall be initiated to verify the real exposure of bees to fipronil in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) the risk to pollinators other than honey bees;</p> <p>(b) the acute and long-term risk to colony survival and development, and the risk to bee brood from plant and soil metabolites, except the soil photolysis metabolites;</p> <p>(c) the potential exposure to dust drift emitted during the drilling procedure and the acute and long-term risk to colony survival and development, and the risk to bee brood for situations where bees forage on vegetation exposed to dust drift;</p> <p>(d) the acute and long-term risk to colony survival and development, and the risk to bee brood from foraging on insect honeydew;</p> <p>(e) the potential exposure to guttation fluid and the acute and long-term risk to colony survival and development, and the risk to bee brood;</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|------------|------------------|------------------------|---|
| | | | | | | <p>(f) the potential exposure to residues in nectar and pollen, honeydew and guttation fluid of succeeding crops or weeds occurring in fields, including the persistent soil metabolites (RPA 200766, MB 46136 and MB 45950).</p> <p>The notifier shall submit that information to the Commission, the Member States and the Authority by 30 March 2015. ◀</p> |
| 158 | <p>Beflubutamid</p> <p>CAS No 113614-08-7</p> <p>CIPAC No 662</p> | (RS)-N-benzyl-2-(4-fluoro-3-trifluoromethylphenoxy) butanamide | ≥ 970 g/kg | 1 December 2007 | ►M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on beflubutamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 May 2007 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <p>— must pay particular attention to the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
| 159 | <p>Spodoptera exigua nuclear polyhedrosis virus</p> <p>CIPAC No</p> <p>Not allocated</p> | Not applicable | | 1 December 2007 | 30 November 2017 | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---------------------------------|-----------------------|------------------|---------------------------------|---|
| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Spodoptera exigua</i> NPV, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 May 2007 shall be taken into account.</p> |
| 160 | <p>Prosulfocarb</p> <p>CAS No 52888-80-9</p> <p>CIPAC No 539</p> | S-benzyl dipropyl(thiocarbamat) | 970 g/kg | 1 November 2008 | ► M313 31 October 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prosulfocarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone, |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|------------|------------------|-------------------------|---|
| | | | | | | — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no spray buffer zone. |
| 161 | Fludioxonil CAS No 131341-86-1 CIPAC No 522 | 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile | 950 g/kg | 1 November 2008 | ►M313 31 October 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing fludioxonil for uses other than seed treatment, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted and:</p> <p>— must pay particular attention to the potential for groundwater contamination, in particular from the soil photolysis metabolites CGA 339833 and CGA 192155, in vulnerable zones,</p> <p>— must pay particular attention to the protection of fish and aquatic invertebrates.</p> <p>Conditions of authorisation should include risk mitigation measures, where appropriate.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fludioxonil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|---------------------------------|---|
| 162 | Clomazone CAS No 81777-89-1 CIPAC No 509 | 2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one | 960 g/kg | 1 November 2008 | ► M313 31 October 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clomazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones. |
| 163 | Benthiavdicarb CAS No 413615-35-7 CIPAC No 744 | [(S)-1-{{(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl}carbonyl}-2-methylpropyl]carbamic acid | <p>≥ 910 g/kg</p> <p>The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material:</p> <p>6,6'-difluoro-2,2'-dibenzothiazole: < 3,5 mg/kg</p> <p>bis(2-amino-5-fluorophenyl) disulfide: < 14 mg/kg</p> | 1 August 2008 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on benthiavdicarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety, — the protection of non-target arthropods. |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|------------------------|--|
| | | | | | | <p>Conditions of use shall include adequate risk mitigation measures, where appropriate.</p> <p>In assessing applications to authorise plant protection products containing benthialdicarb for uses other than in glasshouses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.</p> |
| 164 | <p>Boscalid</p> <p>CAS No 188425-85-6</p> <p>CIPAC No 673</p> | 2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide | ≥ 960 g/kg | 1 August 2008 | ►M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on boscalid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention</p> <ul style="list-style-type: none"> — to the operator safety, — to the long term risk to birds and soil organisms, — to the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in crop rotation. <p>Conditions of use shall include adequate risk mitigation measures, where appropriate.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|------------|------------------|------------------------------|--|
| 166 | Fluoxastrobin CAS No 361377-29-9 CIPAC No 746 | (E)-{2-[6-(2-chloro-phenoxy)-5-fluor-opyrimidin-4-yloxy]phenyl}(5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime | ≥ 940 g/kg | 1 August 2008 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluoxastrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety, in particular when handling the undiluted concentrate. Conditions of use shall include adequate protective measures, such as wearing a face shield, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the levels of residues of the metabolites of fluoxastrobin, when straw from treated areas is used as animal feeding stuff. Conditions of use shall include restrictions for feeding to animals, where appropriate, — the risk of accumulation in the soil surface, if the substance is used in perennial crops or in succeeding crops in crop rotation. |

▼ **M302**▼ B

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|----------------|------------|------------------|------------------------|--|
| | | | | | | <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The concerned Member States shall request the submission of:</p> <ul style="list-style-type: none"> — data to allow a comprehensive aquatic risk assessment to be made taking into account spray drift, run-off, drainage and the effectiveness of potential risk mitigation measures, — data on toxicity of non-rat metabolites if straw from treated areas is to be used as feedstuff. <p>They shall ensure that the notifier at whose request fluoxastrobin has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 167 | <p>Paecilomyces lilacinus (Thom)</p> <p>Samson 1974 strain 251 (AGAL: No 89/030550)</p> <p>CIPAC No 753</p> | Not applicable | | 1 August 2008 | ►M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as nematocide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Paecilomyces lilacinus, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|---|------------------|------------------------------|---|
| | | | | | | <p>— the operator safety (although there was no need to set an AOEL, as a general rule, microorganisms should be considered as potential sensitisers),</p> <p>— the protection of leaf dwelling non-target arthropods.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
| 168 | Prothioconazole CAS No 178928-70-6 CIPAC No 745 | (RS)-2-[2-(1-chloro-cyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione | <p>≥ 970 g/kg</p> <p>The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material:</p> <p>— Toluene: < 5 g/kg</p> <p>— Prothioconazole-desthio (2-(1-chloro-cyclopropyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): < 0,5 g/kg (LOD)</p> | 1 August 2008 | ► M303 31 July 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <p>— the operator safety in spray applications. Conditions of use shall include adequate protective measures,</p> <p>— the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate,</p> <p>— the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The concerned Member States shall request the submission of:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <ul style="list-style-type: none"> — information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin, — a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the toxicity resulting from the combined exposure to these compounds, — information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment. <p>They shall ensure that the notifier at whose request prothioconazole has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 169 | Amidosulfuron CAS No 120923-37-7 CIPAC No 515 | 3-(4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl)urea or 1-(4,6-dimethoxypyrimidin-2-yl)-3-mesyl(methyl) sulfamoylurea | ≥ 970 g/kg | 1 January 2009 | ►M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing amidosulfuron for uses other than meadows and pasture, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on amidosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>— the protection of groundwater due to a potential for groundwater contamination by some of the degradation products when it is applied in regions with vulnerable soil and/or climatic conditions,</p> <p>— the protection of aquatic plants.</p> <p>In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate.</p> |
| 170 | Nicosulfuron CAS No 111991-09-4 CIPAC No 709 | <p>2-[(4,6-dimethoxy-pyrimidin-2-ylcarbamo- moyl)sulfamoyl]- N,N-dimethylnicoti- namide</p> <p>or</p> <p>1-(4,6-dimethoxypyri- midin-2-yl)-3-(3- dimethylcarbamo- yl-2-pyridylsulfonyl)urea</p> | ≥ 910 g/kg | 1 January 2009 | ►M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <p>— the potential exposure of the aquatic environment to metabolite DUDN when is applied in regions with vulnerable soil conditions,</p> <p>— the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones,</p> <p>— the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone,</p> <p>— the protection of groundwater and surface water under vulnerable soil and climatic conditions.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| 171 | Clofentezine CAS No 74115-24-5 CIPAC No 418 | 3,6-bis(2-chloro-phenyl)-1,2,4,5-tetrazine | ≥ 980 g/kg (dry material) | 1 January 2009 | ►M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clofentezine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers shall be compared and verified against this specification of the technical material; — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate; — the potential for long range transport via air; — the risk to non target organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. <p>The Member States concerned shall ensure that the notifier presents to the Commission a monitoring programme to assess the potential for long-range atmospheric transport of clofentezine and the related environmental risks by 31 July 2011. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State and to the Commission by 31 July 2013.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission confirmatory studies on clofentezine metabolites relating to their toxicological and environmental risk assessment by 30 June 2012.</p> |

▼ **B**▼ **M23**

| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
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| 172 | Dicamba CAS No 1918-00-9 CIPAC No 85 | 3,6-dichloro-2-methoxybenzoic acid | ≥ 850 g/kg | 1 January 2009 | ► M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of non-target plants.</p> <p>Conditions of use shall include adequate risk mitigation measures, where appropriate.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) the identification and quantification of a group of soil transformation products formed in a soil incubation study;</p> <p>(b) the potential for long range transport through the atmosphere.</p> <p>The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013.</p> |
| 173 | Difenoconazole CAS No 119446-68-3 CIPAC No 687 | 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chloro-phenyl ether | ≥ 940g/kg Toluene maximum content: 5 g/kg | 1 January 2009 | ► M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on difenoconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms.</p> <p>Conditions of use shall include adequate risk mitigation measures, where appropriate.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) further data on the specification of the technical material;</p> <p>(b) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops, processed commodities and products of animal origin;</p> <p>(c) the potential for endocrine disrupting effects on fish (fish full life cycle study) and the chronic risk to earthworms from the active substance and the metabolite CGA 205375 ⁽¹⁶⁾;</p> <p>(d) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and on the environment.</p> <p>The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by 31 May 2012, the information set out in points (b) and (c) by 30 November 2013 and the information set out in point (d) within 2 years from the adoption of specific guidance.</p> |
| 174 | Diflubenzuron CAS No 35367-38-5 CIPAC No 339 | 1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl) urea | ≥ 950 g/kg impurity: max. 0,03 g/kg 4-chloroaniline | 1 January 2009 | ► M313 31 December 2020 ◀ | PART A ► M224 Only uses as insecticide in non-edible crops may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diflubenzuron, and in particular Appendices I and II |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>thereof, as amended in the Standing Committee on Plants, Animals, Food and Feed on 23 March 2017 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers shall be compared and verified against this specification of the technical material; — the protection of aquatic organisms, terrestrial organisms and non-target arthropods including bees; — the potential unintended exposure of food and feed crops to diflubenzuron from uses on non-edible crops (e.g. through spray drift); — the protection of workers, residents and bystanders. <p>Member States shall ensure that crops treated with diflubenzuron do not enter the food and feed chain.</p> <p>Conditions of use shall include adequate risk mitigation measures, where appropriate. ◀</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diflubenzuron, and in particular Appendices I and II</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers shall be compared and verified against this specification of the technical material; — the protection of aquatic organisms; — the protection of terrestrial organisms; — the protection of non-target arthropods including bees. <p>Conditions of use shall include adequate risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further studies to address the potential toxicological relevance of the impurity and metabolite 4-chloroaniline (PCA) by 30 June 2011.</p> |
| ▼ M23 | | | | | | |
| 175 | Imazaquin CAS No 81335-37-7 CIPAC No 699 | 2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]quinoline-3-carboxylic acid | ≥ 960 g/kg (racemic mixture) | 1 January 2009 | 31 December 2018 | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on imazaquin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) further data on the specification of the technical material;</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>(b) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and on the environment.</p> <p>The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by 31 May 2012 and the information set out in point (b) within 2 years from the adoption of specific guidance.</p> |

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| 176 | <p>Lenacil</p> <p>CAS No 2164-08-1</p> <p>CIPAC No 163</p> | 3-cyclohexyl-1,5,6,7-tetrahydrocyclopentapyrimidine-2,4(3H)-dione | ≥ 975 g/kg | 1 January 2009 | ► M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lenacil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to aquatic organisms, especially algae and aquatic plants. Conditions of authorisation shall include risk mitigation measures, such as bufferzones between treated areas and surface water bodies; — the protection of the groundwater, where the active substance is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites IN-KF 313, M1, M2 and M3 in vulnerable zones, where appropriate. <p>The Member States concerned shall ensure that the notifier submits to the Commission confirmatory information on the identity and characterisation of soil metabolites Polar B and Polars and metabolites M1, M2 and M3 which</p> |
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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>occurred in lysimeter studies and confirmatory data on rotational crops, including possible phytotoxic effects. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.</p> <p>If a decision on the classification of lenacil under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾ identifies the need for further information on the relevance of the metabolites IN-KE 121, IN-KF 313, M1; M2, M3, Polar B and Polars, the Member States concerned shall request the submission of such information. They shall ensure that the notifier provides that information to the Commission within six months from the notification of such a classification decision.</p> |
| 177 | Oxadiazon CAS No 19666-30-9 CIPAC No 213 | 5-tert-butyl-3-(2,4-dichloro-5-isopropoxyphenyl)-1,3,4-oxadiazol-2(3H)-one | ≥ 940 g/kg | 1 January 2009 | 31 December 2018 | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxadiazon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers shall be compared and verified against this specification of the technical material; — the potential for ground water contamination by the metabolite AE0608022 where the active substance is applied in situations for which prolonged anaerobic conditions may be expected to occur or in regions with vulnerable soil or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate. <p>The Member States concerned shall ensure that the notifier submits to the Commission:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|--------------------------|---|
| | | | | | | <p>— further studies to address the potential toxicological relevance of an impurity in the proposed technical specification;</p> <p>— information to further clarify the occurrence of metabolite AE0608033 in primary crops and rotational crops;</p> <p>— further trials on rotational crops (namely root crops and cereals) and a metabolism study on ruminants to confirm the consumer risk assessment;</p> <p>— information to further address the risk to earthworm-eating birds and mammals, and the long-term risk to fish.</p> <p>They shall ensure that the notifier provides such information to the Commission by 30 June 2012.</p> |
| 178 | <p>Picloram</p> <p>CAS No 1918-02-1</p> <p>CIPAC No 174</p> | 4-amino-3,5,6-trichloropyridine-2-carboxylic acid | ≥ 920 g/kg | 1 January 2009 | ►M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on picloram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.</p> <p>In the overall assessment Member States must pay particular attention to:</p> <p>— the potential for ground water contamination where picloram is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate;</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission:</p> |

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| | | | | | | <p>— further information to confirm that the monitoring analytical method applied in residue trials correctly quantifies the residues of picloram and its conjugates;</p> <p>— a soil photolysis study to confirm the evaluation of picloram degradation.</p> <p>They shall ensure that the notifier provides such information to the Commission by 30 June 2012.</p> |
| 179 | <p>Pyriproxyfen</p> <p>CAS No 95737-68-1</p> <p>CIPAC No 715</p> | 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether | ≥ 970 g/kg | 1 January 2009 | ►M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyriproxyfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.</p> <p>In the overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate; — the risk to aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate. <p>The Member States concerned shall ensure that the notifier submits to the Commission further information confirming the risk assessment in respect of two points, namely the risk posed to aquatic insects by pyriproxyfen and the metabolite DPH-pyr and the risk posed by pyriproxyfen to pollinators. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|----------------------------------|---|
| 180 | Bifenox CAS No 42576-02-3 CIPAC No 413 | Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate | <p>≥ 970 g/kg impurities:</p> <p>max. 3 g/kg 2,4-dichlorophenol</p> <p>max. 6 g/kg 2,4-dichloroanisole</p> | 1 January 2009 | ► M313 31 December 2020 ◀ | <p>► M85 PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate;</p> <p>(b) the dietary exposure of consumers to bifenox residues in products of animal origin and in succeeding rotational crops;</p> <p>(c) the environmental conditions leading to the potential formation of nitrofen.</p> <p>Member States shall impose restrictions as regards the conditions of use, where appropriate in view of point (c). ◀</p> |
| 181 | Diflufenican CAS No 83164-33-4 CIPAC No 462 | 2',4'-difluoro-2-(α,α,α -trifluoro-m-tolyloxy) nicotin-anilide | ≥ 970 g/kg | 1 January 2009 | ► M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|-----------------------|------------------|--------------------------|---|
| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diflufenican, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones shall be applied, where appropriate. |
| 182 | Fenoxaprop-P CAS No 113158-40-0 CIPAC No 484 | (R)-2[4-[(6-chloro-2-benzoxazolyl)oxy]-phenoxy]-propanoic acid | ≥ 920 g/kg | 1 January 2009 | ►M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenoxaprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non target plants, — the presence of the safener mefenpyr-diethyl in formulated products as regards operator, worker and bystander exposure, |

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| | | | | | | <p>— the persistence of the substance and of some of its degradation products in colder zones and areas where anaerobic conditions may occur.</p> <p>Conditions of authorisation should include risk mitigation measures, where appropriate.</p> |
| 183 | <p>Fenpropidin</p> <p>CAS No 67306-00-7</p> <p>CIPAC No 520</p> | (R,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]-piperidine | ≥ 960 g/kg (racemate) | 1 January 2009 | ►M313 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpropidin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone. <p>The Member States concerned shall request the submission of:</p> <ul style="list-style-type: none"> — information to further address the long-term risk to herbivorous and insectivorous birds arising from the use of fenpropidin. <p>They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the approval.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|---|------------------|------------------------|--|
| 184 | Quinoclamine CAS No 2797-51-5 CIPAC No 648 | 2-amino-3-chloro-1,4-naphthoquinone | <p>≥ 965 g/kg impurity:</p> <p>dichlone (2,3-dichloro-1,4-naphthoquinone) max. 15 g/kg</p> | 1 January 2009 | 31 December 2018 | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing quinoclamine for uses other than ornamentals or nursery plants, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on quinoclamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator, worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms, — the protection of birds and small mammals. <p>Conditions of use shall include adequate risk mitigation measures, where appropriate.</p> |
| 185 | Chloridazon CAS No 1698-60-8 CIPAC No 111 | 5-amino-4-chloro-2-phenylpyridazin-3(2H)-one | <p>920 g/kg</p> <p>The manufacturing impurity 4-amino-5-chloro-isomer is considered to be of toxicological concern and a maximum level of 60 g/kg is established.</p> | 1 January 2009 | 31 December 2018 | <p>PART A</p> <p>Only uses as herbicide in application max. of 2,6 kg/ha only every third year on the same field may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chloridazon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 December 2007 shall be taken into account.</p> |

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| | | | | | | <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination from metabolites B and B1 in vulnerable zones, where appropriate.</p> |
| 186 | <p>Tritosulfuron</p> <p>CAS No 142469-14-5</p> <p>CIPAC No 735</p> | 1-(4-methoxy-6-trifluoromethyl-1,3,5-triazin-2-yl)-3-(2-trifluoromethyl-benzenesulfonyl)urea | <p>≥ 960 g/kg</p> <p>The following manufacturing impurity is of toxicological concern and must not exceed a certain amount in the technical material:</p> <p>2-Amino-4-methoxy-6-(trifluoromethyl)-1,3,5-triazine: <0,2 g/kg</p> | 1 December 2008 | ►M313 30 November 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tritosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of aquatic organisms, — the protection of small mammals. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

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| 187 | Flutolanil CAS No 66332-96-5 CIPAC No 524 | α,α,α -trifluoro-3'-isopropoxy-o-toluanilide | ≥ 975 g/kg | 1 March 2009 | ► M294 29 February 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing flutolanil for uses other than potato tuber treatment, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flutolanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of authorisation should include risk mitigation measures, where appropriate.</p> |
| 188 | Benfluralin CAS No 1861-40-1 CIPAC No 285 | N-butyl-N-ethyl- α,α,α -trifluoro-2,6-dinitro-p-toluidine | ≥ 960 g/kg Impurities: — ethyl-butyl-nitrosamine: max. 0,1 mg/kg | 1 March 2009 | ► M294 29 February 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing benfluralin for uses other than lettuce and endive, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on benfluralin, and in particular Appendices I and II thereof,</p> |

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| | | | | | | <p>as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of the operators' safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in food of plant and animal origin and evaluate the dietary exposure of consumers, — the protection of birds, mammals, surface waters and aquatic organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate. <p>The Member States concerned shall request the submission of further studies on rotational crops metabolism and to confirm the risk assessment for metabolite B12 and for aquatic organisms. They shall ensure that the notifiers at whose request benfluralin has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 189 | <p>Fluazinam</p> <p>CAS No 79622-59-6</p> <p>CIPAC No 521</p> | <p>3-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2, 6-dinitro-p-toluidine</p> | <p>≥ 960 g/kg</p> <p>Impurities:</p> <p>5-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-o-toluidine</p> <p>— not more than 2 g/kg</p> | 1 March 2009 | ► M294 29 February 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing fluazinam for uses other than potatoes, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluazinam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account.</p> |

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| | | | | | | <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of the operators' and workers' safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in food of plant and animal origin and evaluate the dietary exposure of consumers, — the protection of aquatic organisms. In relation to this identified risk, risk mitigation measures, such as buffer zones, should be applied where appropriate. <p>The Member States concerned shall request the submission of further studies to confirm the risk assessment for aquatic organisms and soil macro-organisms. They shall ensure that the notifiers at whose request fluzinam has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 190 | Fuberidazole CAS No 3878-19-1 CIPAC No 525 | 2-(2'-furyl)benzimidazole | ≥ 970 g/kg | 1 March 2009 | 28 February 2019 | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing fuberidazole for uses other than seed dressing, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fuberidazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> |

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| | | | | | | <p>— the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,</p> <p>— long-term risk to mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. In such case the use of adequate equipment ensuring a high degree of incorporation in soil and a minimisation of spillage during application should apply.</p> <p>Conditions of use shall include adequate risk mitigation measures, where appropriate.</p> |
| 191 | Mepiquat CAS No 15302-91-7 CIPAC No 440 | 1,1-dimethylpiperidinium chloride (mepiquat chloride) | ≥ 990 g/kg | 1 March 2009 | ► M294 29 February 2020 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing mepiquat for uses other than in barley, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mepiquat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account.</p> <p>The Member States must pay particular attention to the residues in food of plant and animal origin and evaluate the dietary exposure of consumers.</p> |
| 192 | Diuron CAS No 330-54-1 CIPAC No 100 | 3-(3,4-dichlorophenyl)-1,1-dimethylurea | ≥ 930 g/kg | 1 October 2008 | ► M303 30 September 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide at rates not exceeding 0,5 kg/ha (areic average) may be authorised.</p> |

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| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety; conditions of use shall prescribe the use of personal protective equipment, if appropriate, — the protection of aquatic organisms and non-target plants. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> |
| 193 | <p><i>Bacillus thuringiensis</i> subsp. <i>aizawai</i></p> <p>STRAIN: ABTS-1857</p> <p>Culture collection: No SD-1372,</p> <p>STRAIN: GC-91</p> <p>Culture collection: No NCTC 11821</p> | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>Aizawai</i> ABTS-1857 (SANCO/1539/2008) and GC-91 (SANCO/1538/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |
| 194 | <p><i>Bacillus thuringiensis</i> subsp. <i>israeliensis</i> (serotype H-14)</p> <p>STRAIN: AM65-52</p> <p>Culture collection: No ATCC-1276</p> | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the</p> |

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| | | | | | | <p>review report on <i>Bacillus thuringiensis</i> subsp. <i>israeliensis</i> (serotype H-14) AM65-52(SANCO/1540/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |
| 195 | <p><i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> STRAIN: ABTS 351 Culture collection: No ATCC SD-1275 STRAIN: PB 54 Culture collection: No CECT 7209 STRAIN: SA 11 Culture collection: No NRRL B-30790 STRAIN: SA 12 Culture collection: No NRRL B-30791 STRAIN: EG 2348 Culture collection: No NRRL B-18208</p> | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | <p>PART A Only uses as insecticide may be authorised.</p> <p>PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS 351 (SANCO/1541/2008), PB 54 (SANCO/1542/2008), SA 11, SA 12 and EG 2348 (SANCO/1543/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |
| 196 | <p><i>Bacillus thuringiensis</i> subsp. <i>Tenebrionis</i> STRAIN: NB 176 (TM 141) Culture collection: No SD-5428</p> | Not applicable | No relevant impurities | 1 May 2009 | 30 April 2019 | <p>PART A Only uses as insecticide may be authorised.</p> <p>PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>tenebrionis</i> NB 176 (SANCO/1545/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |

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| 197 | Beauveria bassiana STRAIN: ATCC 74040 Culture collection: No ATCC 74040 STRAIN: GHA Culture collection: No ATCC 74250 | Not applicable | Max level of beauvericin: 5 mg/kg | 1 May 2009 | ►M294 30 April 2020 ◀ | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Beauveria bassiana ATCC 74040 (SANCO/1546/2008) and GHA (SANCO/1547/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 198 | Cydia pomonella Granulovirus (CpGV) | Not applicable | ►M122 Minimum concentration: 1×10^{13} OB/l (occlusion bodies/l) and Contaminating microorganisms (<i>Bacillus cereus</i>) in the formulated product $< 1 \times 10^7$ CFU/g ◀ | 1 May 2009 | ►M294 30 April 2020 ◀ | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Cydia pomonella Granulovirus (CpGV) (SANCO/1548/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 199 | Lecanicillium muscarium (formerly Verticillium lecanii) STRAIN: Ve 6 Culture collection: No CABI (=IMI) 268317, CBS 102071, ARSEF 5128 | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Lecanicillium muscarium (formerly Verticillium lecanii) Ve 6 (SANCO/1861/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |

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| 200 | <p>Metarhizium anisopliae var. anisopliae</p> <p>(formerly Metarhizium anisopliae)</p> <p>STRAIN: BIPESCO 5/ F52</p> <p>Culture collection: No M.a. 43; No 275-86 (acronyms V275 or KVL 275); No KVL 99-112 (Ma 275 or V 275); No DSM 3884; No ATCC 90448; No ARSEF 1095</p> | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Metarhizium anisopliae var. anisopliae (formerly Metarhizium anisopliae) BIPESCO 5 and F52 (SANCO/1862/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |
| 201 | <p>Phlebiopsis gigantea</p> <p>STRAIN: VRA 1835</p> <p>Culture collection: No ATCC 90304</p> <p>STRAIN: VRA 1984</p> <p>Culture collection: No DSM16201</p> <p>STRAIN: VRA 1985</p> <p>Culture collection: No DSM 16202</p> <p>STRAIN: VRA 1986</p> <p>Culture collection: No DSM 16203</p> <p>STRAIN: FOC PG B20/5</p> <p>Culture collection: No IMI 390096</p> | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Phlebiopsis gigantea (SANCO/1863/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |

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| | STRAIN: FOC PG SP log 6 Culture collection: No IMI 390097 STRAIN: FOC PG SP log 5 Culture collection: No IMI 390098 STRAIN: FOC PG BU 3 Culture collection: No IMI 390099 STRAIN: FOC PG BU 4 Culture collection: No IMI 390100 STRAIN: FOC PG 410.3 Culture collection: No IMI 390101 STRAIN: FOC PG97/1062/116/1.1 Culture collection: No IMI 390102 STRAIN: FOC PG B22/SP1287/3.1 Culture collection: No IMI 390103 STRAIN: FOC PG SH 1 Culture collection: No IMI 390104 STRAIN: FOC PG B22/SP1190/3.2 Culture collection: No IMI 390105 | | | | | |

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| 202 | Pythium oligandrum STRAINS: M1 Culture collection No ATCC 38472 | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | PART A Only uses as fungicide may be authorised PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Pythium oligandrum M1 (SANCO/1864/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 203 | Streptomyces K61 (formerly S. griseoviridis) STRAIN: K61 Culture collection: No DSM 7206 | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Streptomyces (formerly Streptomyces griseoviridis) K61 (SANCO/1865/2008), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 204 | Trichoderma atroviride (formerly T. harzianum) STRAIN: IMI 206040 Culture collection No IMI 206040, ATCC 20476; STRAIN: T11 Culture collection: No Spanish type culture collection CECT 20498, identical with IMI 352941 | Not applicable | No relevant impurities | 1 May 2009 | ►M294 30 April 2020 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review reports on Trichoderma atroviride (formerly T. harzianum) IMI 206040 (SANCO/1866/2008) and T-11 (SANCO/1841/2008) respectively, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |

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| 205 | Trichoderma polysporum STRAIN: Trichoderma polysporum IMI 206039 Culture collection No IMI 206039, ATCC 20475 | Not applicable | No relevant impurities | 1 May 2009 | 30 April 2019 | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Trichoderma polysporum IMI 206039 (SANCO/1867/2008), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 206 | Trichoderma harzianum Rifai STRAIN: Trichoderma harzianum T-22; Culture collection No ATCC 20847 STRAIN: Trichoderma harzianum ITEM 908; Culture collection No CBS 118749 | Not applicable | No relevant impurities | 1 May 2009 | ► M294 30 April 2020 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review reports on Trichoderma harzianum T-22 (SANCO/1839/2008) and ITEM 908 (SANCO/1840/208) respectively and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 207 | Trichoderma asperellum (formerly T. harzianum) STRAIN: ICC012 Culture collection No CABI CC IMI 392716 STRAIN: Trichoderma asperellum (formerly T. viride T25) T25 Culture collection No CECT 20178 | Not applicable | No relevant impurities | 1 May 2009 | ► M294 30 April 2020 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review reports on Trichoderma asperellum (formerly T. harzianum) ICC012 (SANCO/1842/2008) and Trichoderma asperellum (formerly T. viride T25 and TV1) T25 and TV1 (SANCO/1868/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |

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| | STRAIN: Trichoderma asperellum (formerly T. viride TV1) Culture collection No MUCL 43093 | | | | | |
| 208 | Trichoderma gamsii (formerly T. viride) STRAINS: ICC080 Culture collection No IMI CC number 392151 CABI | Not applicable | No relevant impurities | 1 May 2009 | ► M294 30 April 2020 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Trichoderma viride (SANCO/1868/2008), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|-----------------|------------------|----------------------------------|--|
| 210 | Abamectin CAS No 71751-41-2 avermectin B1a CAS No 65195-55-3 Avermectin B1b CAS No 65195-56-4 abamectin CIPAC No 495 | AvermectinB1a (10E,14E,16E,22Z)- (1R,4S,5'S,6S,6'R,8R,- 12S,13S,20R,21R, 24S)-6'-[(S)-sec-butyl]- 21,24-dihydroxy- 5',11.13,22-tetra- methyl-2-oxo-3.7,19- trioxatetra- cyclo[15.6.1.14,8 020,24]pentacosa- 10.14,16,22-tetraene-6- spiro-2'-(5',6'-dihydro- 2'H-pyran)-12-yl 2,6- dideoxy-4-O-(2,6- dideoxy-3-O-methyl- α - L-arabino-hexopyr- anosyl)-3-O-methyl- α - L-arabino-hexopyr- anoside AvermectinB1b (10E,14E,16E,22Z)- (1R,4S,5'S,6S,6'R,8R,- 12S,13S,20R,21R, 24S)-21,24-dihydroxy- 6'-isopropyl- 5',11.13,22-tetra- methyl-2-oxo-3.7,19- trioxatetra- cyclo[15.6.1.14,8 020,24]pentacosa- 10.14,16,22-tetraene-6- spiro-2'-(5',6'-dihydro- 2'H-pyran)-12-yl 2,6- dideoxy-4-O-(2,6- dideoxy-3-O-methyl- α - L-arabino-hexopyr- anosyl)-3-O-methyl- α - L-arabino-hexopyr- anoside | ≥ 850 g/kg | 1 May 2009 | ► M294 30 April 2020 ◀ | ► M212 PART A Only uses as insecticide, acaricide and nematocide may be authorised. PART B In assessing applications to authorise plant protection products containing abamectin for uses other than citrus, lettuce and tomatoes, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information are provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on abamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 and of the addendum to the review report on abamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed dated 24 January 2017 shall be taken into account. In this overall assessment Member States must pay particular attention to: <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the residues in food of plant origin and evaluate the dietary exposure of consumers, — the protection of bees, non-target arthropods, soil organisms, birds, mammals and aquatic organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones and waiting periods, should be applied where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water by two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. ◀ |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|------------|------------------|-------------------------------|---|
| 211 | Epoxiconazole CAS No 135319-73-2 (formerly 106325-08-0) CIPAC No 609 | (2RS, 3SR)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1H-1,2,4-triazole | ≥ 920 g/kg | 1 May 2009 | ► M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on epoxiconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the dietary exposure of consumers to the epoxiconazole (triazole) metabolites, — the potential for long-range transport via air, — the risk to aquatic organisms, birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate. <p>The Member States concerned shall ensure that the notifier submits to the Commission further studies addressing the potential endocrine disrupting properties of epoxiconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.</p> <p>The Member States concerned shall ensure that the notifier presents to the Commission not later than 30 June 2009 a monitoring programme to assess the long-range atmospheric transport of epoxiconazole and related environmental risks. The results of this monitoring shall be submitted as a monitoring report to the Commission by 31 December 2011 at the latest.</p> <p>The concerned Member States shall ensure that the notifier submits within two years from the approval, at the latest, information on residues of epoxiconazole metabolites in primary crops, rotational crops and products of animal origin and information to further address the long-term risk to herbivorous birds and mammals.</p> |

▼B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|------------|------------------|------------------------|--|
| 212 | Fenpropimorph CAS No 67564-91-4 CIPAC No 427 | (RS)-cis-4-[3-(4-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine | ≥ 930 g/kg | 1 May 2009 | 30 April 2019 | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpropimorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, such as restrictions of the daily work rate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones, reduction of run-off and drift reduction nozzles. <p>The Member States concerned shall request the submission of further studies to confirm the mobility in soil of the metabolite BF-421-7. They shall ensure that the notifiers at whose request fenpropimorph has been included in this Annex provide such studies to the Commission within two years from the approval.</p> |
| 213 | Fenpyroximate CAS No 134098-61-6 CIPAC No 695 | tert-butyl (E)-alpha-(1,3-dimethyl-5-phenoxypyrazol-4-ylmethyleneamino-oxy)-p-toluate | > 960 g/kg | 1 May 2009 | ►M294 30 April 2020 ◀ | <p>PART A</p> <p>Only uses as acaricide may be authorised.</p> <p>The following uses must not be authorised:</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|-----------------------|------------------|------------------------|---|
| | | | | | | <p>— applications in high crops with a high risk of spray drift, for example tractor mounted air-blast sprayer and hand-held applications.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpyroximate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <p>— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,</p> <p>— the impact on aquatic organisms and non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.</p> <p>The Member States concerned shall request the submission of information to further address:</p> <p>— the risk to aquatic organisms from metabolites containing the benzyl moiety,</p> <p>— the risk of biomagnification in aquatic food chains.</p> <p>They shall ensure that the notifiers at whose request fenpyroximate has been included in this Annex provide such information to the Commission within two years from the approval.</p> |
| 214 | Tralkoxydim CAS No 87820-88-0 CIPAC No 544 | (RS)-2-[(EZ)-1-(ethoxyimino)propyl]-3-hydroxy-5-mesityl-cyclohex-2-en-1-one | ≥ 960 g/kg | 1 May 2009 | 30 April 2019 | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> |

▼B

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|-----------------------------------|--|------------------|------------------------|---|
| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tralkoxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of the groundwater, in particular from the soil metabolite R173642 when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of herbivorous mammals. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of:</p> <ul style="list-style-type: none"> — information to further address the long-term risk to herbivorous mammals arising from the use of tralkoxydim. <p>They shall ensure that the notifiers at whose request tralkoxydim has been included in this Annex provide such information to the Commission within two years from the approval.</p> |
| 215 | <p>Aclonifen</p> <p>CAS No 74070-46-5</p> <p>CIPAC No 498</p> | 2-chloro-6-nitro-3-phenoxyaniline | <p>≥ 970 g/kg</p> <p>The impurity phenol is of toxicological concern and a maximum level of 5 g/kg is established.</p> | 1 August 2009 | ►M199 31 July 2022 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing aclonifen for uses other than sunflower, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|-----------------------|------------------|------------------------|--|
| | | | | | | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acetonifin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in rotational crops and evaluate the dietary exposure of consumers, — the protection of birds, mammals, aquatic organisms and non-target plants. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate. <p>The Member States concerned shall request the submission of further studies on rotational crops residues and relevant information to confirm the risk assessment for birds, mammals, aquatic organisms and non-target plants.</p> <p>They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the approval.</p> |
| 216 | Imidacloprid CAS No 138261-41-3 CIPAC No 582 | (E)-1-(6-Chloro-3-pyridinylmethyl)-N-nitroimidazolidin-2-ylideneamine | ≥ 970 g/kg | 1 August 2009 | ►M199 31 July 2022 ◀ | <p>►M261 PART A</p> <p>Only uses as insecticide, in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses, may be authorised. The resulting crop must stay within a permanent greenhouse during its entire life cycle.</p> |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|--|------------------|------------------------------|---|
| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on imidacloprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 and the conclusions of the revised addendum of the review report on imidacloprid as finalised in the Standing Committee on Plants, Animals, Food and Feed on 27 April 2018 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to bees and bumble bees released for pollination in permanent greenhouses, — the impact on aquatic organisms, — the exposure of bees via the consumption of contaminated water from the permanent greenhouses. <p>Member States shall ensure that the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate. ◀</p> |
| 217 | Metazachlor CAS No 67129-08-2 CIPAC No 411 | 2-chloro-N-(pyrazol-1-ylmethyl)acet-2',6'-xylidide | <p>≥ 940 g/kg</p> <p>The manufacturing impurity toluene is considered to be of toxicological concern and a maximum level of 0,05 % is established.</p> | 1 August 2009 | ► M199 31 July 2021 ◀ | <p>► M28 PART A</p> <p>Only uses as herbicide may be authorised. Applications shall be limited to a total dose of not more than 1,0 kg metazachlor/ha in a three-year period on the same field. ◀</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metazachlor, and in particular Appendices I and II</p> |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|-------------|-----------------------|------------------|--------------------------------|---|
| | | | | | | <p>thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in vulnerable zones, where appropriate.</p> <p>If metazachlor is classified under Regulation (EC) No 1272/2008 as ‘suspected of causing cancer’, the Member States concerned shall request the submission of further information on the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer.</p> <p>They shall ensure that the notifiers provide that information to the Commission within six months from the notification of such a classification decision.</p> |
| 218 | Acetic acid CAS No 64-19-7 CIPAC 838 | acetic acid | ≥ 980 g/kg | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acetic acid (SANCO/2602/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013, shall be taken into account.</p> |

▼ **M74**

▼ **M74**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to the protection of operators, the protection of groundwater and the protection of aquatic organisms.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit confirmatory information as regards:</p> <ul style="list-style-type: none"> — the acute and long-term risk to birds and mammals, — the risk to honeybees, — the risk to non-target arthropods. <p>The notifier shall submit that information to the Commission, the Member States and the Authority by 31 December 2015.</p> |

▼ **M36**

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|-----|---|-----------------------------|--|------------------|--------------------------------|---|
| 219 | <p>Aluminium ammonium sulphate</p> <p>CAS No 7784-26-1 (dodecahydrate), 7784-25-0 (anhydrous)</p> <p>CIPAC No 840</p> | Aluminium ammonium sulphate | <p>≥ 960 g/kg (expressed as dodecahydrate)</p> <p>≥ 502 g/kg (anhydrous)</p> | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as repellent may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium ammonium sulphate (SANCO/2985/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit confirmatory information as regards:</p> <ul style="list-style-type: none"> (a) the impact on the environment of the transformation/dissociation products of aluminium ammonium sulphate; (b) the risk to non-target terrestrial organisms other than vertebrates and aquatic organisms. <p>This information shall be submitted to the Member States, the Commission and the Authority by 1 January 2016.</p> |
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▼ **B**▼ **M32**

| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|---|------------------|--------------------------------|--|
| 220 | Aluminium silicate CAS No 1332-58-7 CIPAC No 841 | Not available Chemical name: Aluminium silicate | ≥ 999,8 g/kg | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as repellent may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium silicate (SANCO/2603/08) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the operator safety; conditions of use shall include the application of adequate personal and respiratory protective equipment, where appropriate.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards:</p> <p>(a) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data;</p> <p>(b) the relevance of the test material used in the toxicity dossier in view of the specification of the technical material.</p> <p>The Member States concerned shall ensure that the applicant submits such information to the Commission by 1 May 2013.</p> |
| 221 | Ammonium acetate CAS No 631-61-8 CIPAC No not allocated | Ammonium acetate | ≥ 970 g/kg Relevant impurity: Heavy metals as Pb maximum 10 ppm | 1 September 2009 | 31 August 2019 | <p>PART A</p> <p>Only uses as attractant may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ammonium acetate (SANCO/2986/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> |

▼ **B**

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------------|---|-------------------|--|------------------|--------------------------------|--|
| | | | | | | Conditions of use shall include, where appropriate, risk mitigation measures. |
| ▼ M31 | | | | | | |
| 222 | Blood meal CAS No: 90989-74-5 CIPAC No: 909 | Not available | ≥ 990 g/Kg | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as repellent may be authorised. Blood meal must be in compliance with Regulation (EC) No 1069/2009 ⁽¹⁷⁾ and Regulation (EU) No 142/2011 ⁽¹⁸⁾.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing blood meal for uses other than with direct application localised on individual plants, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorization is granted.</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on blood meal (SANCO/2604/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 March 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit to the Member States, the Commission and the Authority, confirmatory information on the specification of the technical material, by 1 March 2013.</p> |
| 223 | Calcium carbide CAS No: 75-20-7 CIPAC No: 910 | Calcium acetylide | ≥ 765 g/kg Containing 0,08 – 0,9 g/kg Calcium Phosphide | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as repellent may be authorised.</p> |

▼ **M31**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|-------------------|------------|------------------|--------------------------------|---|
| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on calcium carbide (SANCO/2605/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 March 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |
| 224 | <p>Calcium carbonate</p> <p>CAS No: 471-34-1</p> <p>CIPAC No: 843</p> | Calcium carbonate | ≥ 995 g/kg | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as repellent may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on calcium carbonate (SANCO/2606/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 March 2012 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit confirmatory information as regards:</p> <ul style="list-style-type: none"> — further data on the specification of the technical material, — analytical methods for the determination of calcium carbonate in the representative formulation and of the impurities in the technical material. <p>These information shall be submitted to the Member States, the Commission and the Authority by 1 March 2013.</p> |

▼ **B**▼ **M66**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|--|------------------|--------------------------------|--|
| 225 | Carbon dioxide CAS No: 124-38-9 CIPAC No: 844 | Carbon dioxide | <p>≥ 99,9 %</p> <p>Relevant impurities:</p> <p>phosphane max. 0,3 ppm v/v</p> <p>benzene max. 0,02 ppm v/v</p> <p>carbon monoxide max. 10 ppm v/v</p> <p>methanol max. 10 ppm v/v</p> <p>hydrogen cyanide max. 0,5 ppm v/v</p> | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as a fumigant may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on carbon dioxide (SANCO/2987/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013 shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |
| 226 | Denathonium benzoate CAS No 3734-33-6 CIPAC No 845 | Benzyldiethyl[[2,6-xylylcarbamo-yl]methyl]ammonium benzoate | ≥ 975g/kg | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as repellent may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing denathonium benzoate for uses other than brushing with automatic rolling equipment in forestry, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> |

▼ **M37**

▼ **M37**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on denathonium benzoate (SANCO/2607/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to the protection of the operators. Authorised conditions of use must prescribe the application of adequate personal protective equipment.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |

▼ **M49**

227

Ethylene

CAS No 74-85-1

CIPAC No 839

Ethylene

≥ 90 %

Relevant impurity:
ethylene oxide,
max content
1 mg/kg

1 September
2009► **M199** 31
August
2022 ◀

PART A

Only indoor uses as plant growth regulator by professional users may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ethylene (SANCO/2608/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

(a) the compliance of ethylene with the required specifications, irrespective of the form in which it is supplied to the user;

▼ **M49**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>(b) the protection of operators, workers and bystanders.</p> <p>Conditions of authorisation shall include, where appropriate, risk mitigation measures.</p> |

▼ **M106**

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| 228 | <p>Extract from tea tree</p> <p>CAS No Tea Tree Oil 68647-73-4</p> <p>Main components:</p> <p>terpinen-4-ol 562-74-3</p> <p>γ-terpinene 99-85-4</p> <p>α-terpinene 99-86-5</p> <p>1,8-cineole 470-82-6</p> <p>CIPAC No 914</p> | <p>Tea Tree Oil is a complex mixture of chemical substances.</p> | <p>Main components:</p> <p>terpinen-4-ol \geq 300 g/kg</p> <p>γ-terpinene \geq 100 g/kg</p> <p>α-terpinene \geq 50 g/kg</p> <p>1,8-cineole \geq 1 g/kg</p> <p>Relevant impurity:</p> <p>Methyl eugenol: maximum 1 g/kg of the technical material</p> | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide in greenhouse may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on extract from tea tree (SANCO/2609/2008 final) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to</p> <ul style="list-style-type: none"> — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of surface water and aquatic organisms; — the protection of honey bees, non-target arthropods, earthworms and non-target micro- and macro-organisms. |
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▼ **M106**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) the plant metabolism and consumer exposure;</p> <p>(b) the toxicity of the compounds that constitute the extract and the relevance of possible impurities other than methyl eugenol;</p> <p>(c) the groundwater exposure for the less strongly absorbed components that constitute the extract and for potential soil transformation products;</p> <p>(d) the effects on biological methods of sewage treatment.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016 at latest.</p> |

▼ **M36**

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| 229 | <p>Fat distillation residues</p> <p>CAS No: not allocated</p> <p>CIPAC No 915</p> | Not available | <p>≥ 40 % of cleaved fatty acids</p> <p>Relevant impurity: Ni maximum 200 mg/kg</p> | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as repellent may be authorised. Fat distillation residues of animal origin must be in compliance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council and Commission Regulation (EU) No 142/2011 (OJ L 54, 26.2.2011, p. 1).</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on fat distillation residues (SANCO/2610/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> |
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▼ **M36**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit confirmatory information as regards the specification of the technical material and the analysis of the maximum levels of impurities and contaminants of toxicological concern. This information shall be submitted to the Member States, the Commission and the Authority by 1 May 2013.</p> |

▼ **B**

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|-----|--|---|--|------------------|--------------------------------|--|
| 230 | <p>Fatty acids C7 to C20</p> <p>CAS No 112-05-0 (Pelargonic Acid)</p> <p>67701-09-1 (Fatty acids C7-C18 and C18 unsaturated potassium salts)</p> <p>124-07-2 (Caprylic Acid)</p> <p>334-48-5 (Capric Acid)</p> <p>143-07-7 (Lauric Acid)</p> <p>112-80-1 (Oleic Acid)</p> <p>85566-26-3 (Fatty acids C8-C10 Me esters)</p> <p>111-11-5 (Methyl octanoate)</p> <p>110-42-9 (Methyl decanoate)</p> <p>CIPAC No not allocated</p> | <p>Nonanoic acid</p> <p>Caprylic Acid, Pelargonic Acid, Capric Acid, Lauric Acid, Oleic Acid (ISO in each case)</p> <p>Octanoic Acid, Nonanoic Acid, Decanoic Acid, Dodecanoic Acid, cis-9-Octadecenoic Acid (IUPAC in each case)</p> <p>Fatty acids, C7-C10, Me esters</p> | <p>≥ 889 g/kg (Pelargonic Acid)</p> <p>≥ 838 g/kg fatty acids</p> <p>≥ 99 % fatty acid methyl esters</p> | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide, acaricide, and herbicide and plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fatty acids (SANCO/2610/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> |
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▼B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|------------|------------------|------------------------|---|
| 231 | Garlic extract CAS No 8008-99-9 CIPAC No not allocated | Food grade garlic juice concentrate | ≥ 99,9 % | 1 September 2009 | ►M199 31 August 2020 ◀ | PART A Only uses as repellent, insecticide and nematocide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on garlic extract (SANCO/2612/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 232 | Gibberellic acid CAS No 77-06-5 CIPAC No 307 | (3S,3aS,4S,4aS,7S,9-aR,9bR,12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenol(1,2-b)furan-4-carboxylic acid Alt: (3S,3aR,4S,4aS,6S,8-aR,8bR,11S)-6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4a,6-methano-3,8b-prop-lenoperhydro-indenol (1,2-b) furan-4-carboxylic acid | ≥ 850 g/kg | 1 September 2009 | ►M199 31 August 2020 ◀ | PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on gibberellic acid (SANCO/2613/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|----------------------------------|------------------|--------------------------------|---|
| 233 | Gibberellins CAS No GA4: 468-44-0 GA7: 510-75-8 GA4A7 mixture: 8030-53-3 CIPAC No not allocated | GA4: (3S,3aR,4S,4aR,7R,9-aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-3,9b-propanoazuleno[1,2-b]furan-4-carboxylic acid GA7: (3S,3aR,4S,4aR,7R,9-aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid | Review report (SANCO/2614/2008). | 1 September 2009 | ► M199 31 August 2020 ◀ | PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on gibberellins (SANCO/2614/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 234 | Hydrolysed proteins CAS No not allocated CIPAC No 901 | Not available | Review report (SANCO/2615/2008) | 1 September 2009 | ► M199 31 August 2020 ◀ | PART A Only uses as attractant may be authorised. Hydrolysed proteins of animal origin must be in compliance with Regulation (EC) No 1069/2009 ⁽¹⁷⁾ and Commission Regulation (EU) No 142/2011 ⁽¹⁸⁾ . PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on hydrolysed proteins (SANCO/2615/08) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. |

▼ M32

▼ **M32**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to the operator and worker safety; conditions of use shall include the application of adequate personal protective equipment, where appropriate.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards:</p> <p>(a) the specifications of the technical material, as commercially manufactured, supported by appropriate analytical data;</p> <p>(b) the risk to aquatic organisms.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 1 May 2013, the information set out in point (b) by 1 November 2013.</p> |

▼ **M38**

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|-----|---|---|--|------------------|--------------------------------|---|
| 235 | <p><i>Iron sulphate:</i></p> <p>Iron(II)sulfate anhydrous: CAS No 7720-78-7</p> <p>Iron(II)sulfate monohydrate: CAS No 17375-41-6</p> <p>Iron(II)sulfate heptahydrate: CAS No 7782-63-0</p> <p>CIPAC No 837</p> | <p>Iron(II)sulphate or iron(2+) sulfate</p> | <p>Iron(II)sulfate anhydrous: \geq 350 g/kg total iron.</p> <p>Relevant impurities:</p> <p>arsenic, 18 mg/kg</p> <p>cadmium, 1,8 mg/kg</p> <p>chromium, 90 mg/kg</p> <p>lead, 36 mg/kg</p> <p>mercury, 1,8 mg/kg</p> <p>expressed on the basis of the anhydrous variant</p> | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on iron sulphate (SANCO/2616/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk for operator; — the risk to children/residents playing on treated turf; — the risk to surface waters and to aquatic organisms. |
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▼ **M38**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>Conditions of use shall include, where appropriate, risk mitigation measures and the application of adequate personal protective equipment. The notifier shall submit to the Member States, the Commission and the Authority, confirmatory information as regards the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicity dossiers.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission such information by 1 May 2013.</p> |

▼ **M84**

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|-----|--|--|--|------------------|--------------------------------|---|
| 236 | <p>Kieselgur (diatomaceous earth)</p> <p>CAS No 61790-53-2</p> <p>CIPAC No 647</p> | <p>Kieselgur (no IUPAC name)</p> <p>Diatomaceous earth</p> <p>Amorphous silicon dioxide</p> <p>Silica</p> <p>Diatomite</p> | <p>The product consists of 100 % diatomaceous earth.</p> <p>Maximum 0,1 % of particles of crystalline silica with diameter below 50 µm</p> | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only indoor uses as insecticide and acaricide by professional users may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on kieselgur (diatomaceous earth) (SANCO/2617/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the safety of operators and workers. Conditions of use shall include the application of adequate personal and respiratory protective equipment. Where necessary, conditions of use shall prohibit the presence of workers after application of the product concerned for a period appropriate in view of the risks caused by that product.</p> <p>The Member States concerned shall ensure that the notifiers submit, by 25 November 2015, to the Commission, the Member States and the Authority information concerning the inhalation toxicity to confirm the occupational limits of kieselgur (diatomaceous earth).</p> |
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▼ **B**▼ **M31**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|---|---|--|------------------------|--|
| 237 | Limestone CAS No: 1317-65-3 CIPAC No: 852 | Calcium carbonate | ≥ 980 g/kg | 1 September 2009 | 31 August 2019 | PART A Only uses as repellent may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on limestone (SANCO/2618/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 March 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| ▼ M217 | | | | | | |
| ▼ M31 | 239 | Pepper dust extraction residue (PDER) CAS No: not allocated CIPAC No: not allocated | Steam distilled and solvent extracted Black pepper – <i>Piper nigrum</i> | It is a complex mixture of chemical substances, the component piperine as marker should be minimum 4 % | 1 September 2009 | ► M296 31 August 2019 ◀ PART A Only uses as repellent may be authorised. PART B In assessing applications to authorise plant protection products containing pepper dust extraction residue (PDER) for uses other than in home garden area, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorization is granted. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on pepper (SANCO/2620/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 March 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures The notifier shall submit to the Member States, the Commission and the Authority, confirmatory information on the specification of the technical material, by 1 March 2013. |

▼ **B**▼ **M115**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|--|------------------|--------------------------------|---|
| 240 | Plant oils/citronella oil CAS No 8000-29-1 CIPAC No 905 | <p>Citronella Oil is a complex mixture of chemical substances.</p> <p>The main components are:</p> <p>Citronellal (3,7-dimethyl-6-octenal).</p> <p>Geraniol ((E)-3,7-dimethyl-2,6-octadien-1-ol).</p> <p>Citronellol (3,7-dimethyl-6-octan-2-ol).</p> <p>Geranyl acetate (3,7-dimethyl-6-octen-1-yl acetate).</p> | The sum of the following impurities must not exceed 0,1 % of technical material: methyl eugenol and methyl-isoeugenol. | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on citronella oil (SANCO/2621/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; — the protection of groundwater, when the substance is applied in regions with vulnerable soil; — the risk to non-target organisms. <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) the technical specification;</p> <p>(b) data comparing natural background exposure situations of plant oils/citronella oil and methyl eugenol and methyl isoeugenol in relation to exposure from the use of plant oils/citronella oil as a plant protection product. This data shall cover human exposure as well as exposure of non-target organisms;</p> |

▼ **M115**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>(c) the groundwater exposure assessment for potential metabolites of plant oils/citronella oil, in particular for methyl eugenol and methyl isoeugenol.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016.</p> |

▼ **M100**

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|-----|--|---|--|------------------|--------------------------------|--|
| 241 | <p>Plant oils/clove oil</p> <p>CAS No 84961-50-2 (clove oil)</p> <p>97-53-0 (Eugenol — main component)</p> <p>CIPAC No 906</p> | <p>Clove Oil is a complex mixture of chemical substances.</p> <p>The main component is eugenol.</p> | <p>≥ 800 g/kg</p> <p>Relevant impurity: methyl eugenol maximum 0,1 % of the technical material</p> | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only indoor uses as post-harvest fungicide and bactericide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clove oil (SANCO/2622/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate.</p> <p>The notifier shall submit confirmatory information as regards</p> <p>(a) the technical specification;</p> <p>(b) data comparing natural background exposure situations of plant oils/ clove oil, eugenol and methyl eugenol in relation to exposure from the use of plant oils/clove oil as a plant protection product. This data shall cover human exposure.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016.</p> |
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▼ **B**▼ **M87**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---------------|--|------------------|--------------------------------|---|
| 242 | Plant oils/rape seed oil CAS No: 8002-13-9 CIPAC No: not allocated | Rape seed oil | Rape seed oil is a complex mixture of fatty acids Relevant impurity: Maximum 2 % of erucic acid | 1 September 2009 | ► M199 31 August 2020 ◀ | PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rape seed oil (SANCO/2623/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 243 | Plant oils/spear mint oil CAS No 8008-79-5 CIPAC No 908 | Spearmint oil | ≥ 550 g/kg as (R)-Carvone | 1 September 2009 | ► M199 31 August 2022 ◀ | PART A Only uses as plant growth regulator for postharvest treatment of potatoes may be authorised. Member States shall ensure that authorisations provide that hot fogging is performed exclusively in professional storage facilities and that the best available techniques are applied to exclude the release into the environment of the product (fogging mist) during storage, transport, waste disposal and application. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on plant oils/spearmint oil (SANCO/2624/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |

▼ **M37**

▼ **B**▼ **M39**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|------------------------------|--|------------------|--------------------------------|---|
| 244 | Potassium hydrogen carbonate CAS No 298-14-6 CIPAC No 853 | Potassium hydrogen carbonate | ≥ 99,5 % Impurities: Pb max. 10 mg/kg As max. 3 mg/kg | 1 September 2009 | ► M199 31 August 2020 ◀ | PART A Only uses as fungicide and insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium hydrogen carbonate (SANCO/2625/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 July 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to honeybees. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 245 | 1,4-diaminobutane (putrescine) CAS No 110-60-1 CIPAC No 854 | Butane-1,4-diamine | ≥ 990 g/kg | 1 September 2009 | 31 August 2019 | PART A Only uses as attractant may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1,4-diaminobutane (putrescine) (SANCO/2626/08) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |

▼ **M32**

▼ **B**▼ **M75**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|--------------------------------|--|
| 246 | <p>Pyrethrins: 8003-34-7 CIPAC No 32 Extract A: extractives of Chrysanthemum cinerariaefolium: 89997- 63-7 Pyrethrin 1: CAS 121-21-1 Pyrethrin 2: CAS 121-29-9 Cinerin 1: CAS 25402-06-6 Cinerin 2: CAS 121-20-0 Jasmolin 1: CAS 4466-14-2 Jasmolin 2: CAS 1172-63-0 Extract B: Pyrethrin 1: CAS 121-21-1 Pyrethrin 2: CAS 121-29-9 Cinerin 1: CAS 25402-06-6 Cinerin 2: CAS 121-20-0 Jasmolin 1: CAS 4466-14-2 Jasmolin 2: CAS 1172-63-0</p> | Pyrethrins are a complex mixture of chemical substances. | <p>Extract A: \geq 500 g/kg Pyrethrins Extract B: \geq 480 g/kg Pyrethrins</p> | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyrethrins (SANCO/2627/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to operators and workers;</p> <p>(b) the risk to non-target organisms.</p> <p>Conditions of use shall, where appropriate, include the application of adequate personal protective equipment and other risk mitigation measures.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the specification of the technical material, as commercially manufactured including information on any relevant impurities and its equivalence with the specifications of the test material used in the toxicity studies;</p> <p>(2) the risk from inhalation;</p> <p>(3) the residue definition;</p> <p>(4) the representativeness of the major component 'pyrethrin 1' as regards the fate and behaviour in soil and water.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) by 31 March 2014 and the information set out in points (2), (3) and (4) by 31 December 2015.</p> |

▼ **B**▼ **M31**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--------------------------------|---|------------------|--------------------------------|---|
| 247 | Quartz sand CAS No: 14808-60-7, 7637-86-9 CIPAC No: 855 | Quartz, dioxide Silicon | ≥ 915 g/kg Maximum 0,1 % of particles of Crystalline Silica (with diameter below 50 um.) | 1 September 2009 | ► M199 31 August 2020 ◀ | PART A Only uses as repellent may be authorised. PART B In assessing applications to authorise plant protection products containing quartz sand for uses other than on trees in forestry, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorization is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on quartz sand (SANCO/2628/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 248 | Fish oil CAS No 100085-40-3 CIPAC No 918 | Fish oil | ≥ 99 % Relevant impurity: Dioxine max. 6 pg/kg for animal feed Hg max. 0,5 mg/kg feed derived from fish and other sea food processing | 1 September 2009 | ► M199 31 August 2020 ◀ | PART A Only uses as repellent may be authorised. Fish oil must be in compliance with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fish oil (SANCO/2629/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |

▼ **M36**

▼ **M36**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|--|------------------|------------------------|---|
| | | | Cd max. 2 mg/kg feed of animal origin except in feed for domestic pets Pb max. 10 mg/kg PCBs max. 5 mg/kg | | | The notifier shall submit confirmatory information as regards the specification of the technical material and the analysis of the maximum levels of impurities and contaminants of toxicological concern. This information shall be submitted to the Member States, the Commission and the Authority by 1 May 2013. |

▼ **B**

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| 249 | Repellents by smell of animal or plant origin/ sheep fat CAS No 98999-15-6 CIPAC No not allocated | Sheep Fat | Pure sheep fat containing a maximum of 0,18 % w/w/water. | 1 September 2009 | ► M199 31 August 2020 ◀ | PART A Only uses as repellent may be authorised. Sheep fat must be in compliance with Regulation (EC) No 1069/2009 PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sheep fat (SANCO/2630/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
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▼ **M230**

▼ **M229**

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|--------------------------------|---|
| 252 | Sea-algae extract (formerly sea algae extract and sea weeds) CAS No not allocated CIPAC No not allocated | See algae extract | See algae extract is a complex mixture. Main components as markers: mannitol, fucoidans and alginates. Review report SANCO/2634/2008 | 1 September 2009 | 31 August 2019 | PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sea algae extract (SANCO/2634/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 253 | Sodium aluminium silicate CAS No 1344-00-9 CIPAC No not allocated | Sodium aluminium silicate: $\text{Na}_x[(\text{AlO}_2)_x(\text{SiO}_2)_y] \times z\text{H}_2\text{O}$ | 1 000 g/kg | 1 September 2009 | ► M296 31 August 2019 ◀ | PART A Only uses as repellent may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium aluminium silicate (SANCO/2635/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| 254 | Sodium hypochlorite CAS No: 7681-52-9 CIPAC: 848 | Sodium hypochlorite | Sodium hypochlorite: 105 g/kg-126 g/kg (122 g/L-151 g/L) technical concentrate 10-12 % (w/w) expressed as chlorine | 1 September 2009 | 31 August 2019 | PART A Only indoor uses as disinfectant may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium hypochlorite (SANCO/2988/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013 shall be taken into account. |

▼ **M51**

▼ **M51**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to operator and workers;</p> <p>(b) the exposure of soil to sodium hypochlorite and its reaction products through spreading of treated compost on organic land shall be avoided.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M127**

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| 255 | Straight Chain Lepidopteran Pheromones | Review report (SANCO/2633/2008) | Review report (SANCO/2633/2008) | 1 September 2009 | ► M199 31 August 2020 ◀ | <p>PART A</p> <p>Only uses as attractants may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on straight chain lepidopteran pheromones (SANCO/2633/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(1) the genotoxic profile of aldehyde group compounds;</p> <p>(2) exposure of humans and the environment resulting from the different ways of application of Straight Chain Lepidopteran Pheromones as plant protection product, in comparison with natural background levels of those pheromones.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 31 December 2015 and the information set out in point (2) by 31 December 2016.</p> |
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▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|------------------------|---|------------------------------|------------|------------------|--------------------------------|---|
| 256 | Trimethylamine hydrochloride CAS No 593-81-7 CIPAC No not allocated | Trimethylamine hydrochloride | ≥ 988 g/kg | 1 September 2009 | 31 August 2019 | PART A Only uses as attractant may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on trimethylamine hydrochloride (SANCO/2636/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |
| ▼ M36 257 | Urea CAS No 57-13-6 CIPAC No 913 | Urea | ≥ 98 % w/w | 1 September 2009 | ► M199 31 August 2020 ◀ | PART A Only uses as attractant and fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on urea (SANCO/2637/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. The notifier shall submit confirmatory information as regards: (a) the analysis method for urea and for the impurity biuret; (b) the risk for operators, workers and bystanders. The information set out in point (a) and in point (b) shall be submitted to the Member States, the Commission and the Authority respectively by 1 May 2013 and 1 January 2016. |
| ▼ M180 _____ | | | | | | |
| ▼ M179 _____ | | | | | | |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---------------------|-----------------------|------------------|--------------------------------|--|
| 260 | Aluminium phosphide CAS No 20859-73-8 CIPAC No 227 | Aluminium phosphide | ≥ 830 g/kg | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as insecticide, rodenticide, talpicide and leporicide in the form of ready-to-use aluminium phosphide containing products may be authorised.</p> <p>As rodenticide, talpicide and leporicide only outdoor uses may be authorised.</p> <p>Authorisations should be limited to professional users.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of consumers and ensure that the spent ready-to-use aluminium phosphide containing products are removed from the food commodity in uses against storage pests and subsequently an adequate additional withholding period is applied; — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment; — the protection of operators and workers during fumigation for indoor uses; — the protection of workers at re-entry (after fumigation period) for indoor uses; — the protection of bystanders against leaking of gas for indoor uses; — the protection of birds and mammals. Conditions of authorisation should include risk mitigation measures, such as the closure of the burrows and the achievement of complete incorporation of granules in the soil, where appropriate; |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---------------------|------------|------------------|--------------------------------|--|
| | | | | | | — the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones between treated areas and surface water bodies, where appropriate. |
| 261 | Calcium phosphide CAS No 1305-99-3 CIPAC No 505 | Calcium phosphide | ≥ 160 g/kg | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only outdoor uses as rodenticide and talpicide in the form of ready-to-use calcium phosphide containing products may be authorised.</p> <p>Authorisations should be limited to professional users.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on calcium phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment; — the protection of birds and mammals. Conditions of authorisation should include risk mitigation measures, such as the closure of the burrows and the achievement of complete incorporation of granules in the soil, where appropriate; — the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones between treated areas and surface water bodies, where appropriate. |
| 262 | Magnesium phosphide CAS No 12057-74-8 CIPAC No 228 | Magnesium phosphide | ≥ 880 g/kg | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as insecticide, rodenticide, talpicide and leporicide in the form of ready-to-use magnesium phosphide containing products may be authorised.</p> <p>As rodenticide, talpicide and leporicide only outdoor uses may be authorised.</p> |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>Authorisations should be limited to professional users.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on magnesium phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of consumers and ensure that the spent ready-to-use magnesium phosphide containing products are removed from the food commodity in uses against storage pests and subsequently an adequate additional withholding period is applied; — the operator safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment; — the protection of operators and workers during fumigation for indoor uses; — the protection of workers at re-entry (after fumigation period) for indoor uses; — the protection of bystanders against leaking of gas for indoor uses; — the protection of birds and mammals. Conditions of authorisation should include risk mitigation measures, such as the closure of the burrows and the achievement of complete incorporation of granules in the soil, where appropriate; — the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones between treated areas and surface water bodies, where appropriate. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|-----------------------|------------------|--------------------------------|---|
| 263 | Cymoxanil CAS No 57966-95-7 CIPAC No 419 | 1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea | ≥ 970 g/kg | 1 September 2009 | ► M199 31 August 2021 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cymoxanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. |
| 264 | Dodemorph CAS No 1593-77-7 CIPAC No 300 | cis/trans-[4-cyclo-dodecyl]-2,6-dimethylmorpholine | ≥ 950 g/kg | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as fungicide on ornamentals in glasshouse may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dodemorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|--------------------------------|--|
| | | | | | | <p>— the protection of the groundwater, when the active substance is applied in regions with vulnerable soil conditions;</p> <p>— conditions of authorisation should include risk mitigation measures, where appropriate.</p> |
| 265 | <p>2,5-Dichlorobenzoic acid methylester</p> <p>CAS No 2905-69-3</p> <p>CIPAC No 686</p> | methyl-2,5-dichlorobenzoate | ≥ 995 g/kg | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only indoor uses as plant growth regulator and fungicide for grafting of grapevines may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,5-Dichlorobenzoic acid methylester, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> |
| 266 | <p>Metamitron</p> <p>CAS No 41394-05-2</p> <p>CIPAC No 381</p> | 4-amino-4,5-dihydro-3-methyl-6-phenyl-1,2,4-triazin-5-one | ≥ 960 g/kg | 1 September 2009 | ► M199 31 August 2022 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing metamitron for uses other than on root crops, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metamitron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> |

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|--------|--|--|---|------------------|------------------------|--|
| | | | | | | <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of personal protective equipment where appropriate; — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to birds and mammals, and non-target terrestrial plants. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of further information on the impact of soil metabolite M3 on groundwater, on residues in rotational crops, on the long-term risk to insectivorous birds and the specific risk to birds and mammals that may be contaminated by the intake of water in field. They shall ensure that the notifiers at whose request metamitron has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.</p> |
| 267 | Sulcotrione CAS No 99105-77-8 CIPAC No 723 | 2-(2-chloro-4-mesylbenzoyl)cyclohexane-1,3-dione | ≥ 950 g/kg Impurities: — hydrogen cyanide: not more than 80 mg/kg — toluene: not more than 4 g/kg | 1 September 2009 | ►M199 31 August 2022 ◀ | PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulcotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; — the risk to insectivorous birds, aquatic and terrestrial non-target plants, and non-target arthropods. |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|--------------------------------|--|
| | | | | | | <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of further information on the degradation in soil and water of the cyclohexadione moiety and the long-term risk to insectivorous birds. They shall ensure that the notifier at whose request sulcotrione has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.</p> |
| 268 | <p>Tebuconazole</p> <p>CAS No 107534-96-3</p> <p>CIPAC No 494</p> | (RS)-1-p-chloro-phenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol | ≥ 905 g/kg | 1 September 2009 | ► M303 31 August 2020 ◀ | <p>► M128 PART A</p> <p>Only uses as fungicide and plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers to the tebuconazole (triazole) metabolites; — the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil or climatic conditions, in particular as regards the occurrence in groundwater of the metabolite 1,2,4-triazole; — the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures; — the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|--|------------------|------------------------|---|
| | | | | | | The Member States concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines. ◀ |
| 269 | Triadimenol CAS No 55219-65-3 CIPAC No 398 | (1RS,2RS;1RS,2SR)-1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol | ≥ 920 g/kg isomer A (1RS,2SR), isomer B (1RS,2RS) Diastereomer A, RS + SR, range: 70 to 85 % Diastereomer B, RR + SS, range: 15 to 30 % | 1 September 2009 | 31 August 2019 | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triadimenol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the presence of N-methylpyrrolidone in formulated products as regards operator, worker and bystander exposure; — the protection of birds and mammals. In relation to these identified risks risk mitigation measures, such as buffer zones, should be applied where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission: — further information on the specification; — information to further address the risk assessment for birds and mammals. — information to further address the risk of endocrine disrupting effects on fish. They shall ensure that the notifier at whose request triadimenol has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest. |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|------------------------|--|
| | | | | | | The Member States concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of triadimenol within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines. |
| 270 | Methomyl CAS No 16752-77-50 CIPAC No 264 | S-methyl (EZ)-N-(methylcarbamoyloxy)thioacetimidate | ≥ 980 g/kg | 1 September 2009 | 31 August 2019 | <p>PART A</p> <p>Only uses as insecticide on vegetables may be authorised at rates not exceeding 0,25 kg active substance per hectare per application and for a maximum of 2 applications per season.</p> <p>Authorisations shall be limited to professional users.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on methomyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 June 2009 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety: conditions of use shall prescribe the use of adequate personal protective equipment. Special attention shall be paid to the exposure of operators using knapsacks or other hand-held application equipment, — the protection of birds, — the protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as buffer zones, reduction of run-off and drift reduction nozzles, — the protection of non-target arthropods, in particular bees: risk mitigation measures to avoid all contact with bees shall be applied. |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|-----------------|--------------------|---------------------------------------|---|
| | | | | | | Member States shall ensure that methomyl-based formulations contain effective repelling and/or emetic agents. Where appropriate, conditions of authorisation shall include further risk mitigation measures. |
| 271 | Bensulfuron CAS No 83055-99-6 CIPAC No 502.201 | α -[(4,6-dimethoxy-pyrimidin-2-ylcarbamo- moyl)sulfamoyl]-o- toluic acid (bensul- furon) methyl α -[(4,6-dime- thoxypyrimidin-2- ylcarbamo-yl)sulfa- moyl]-o-toluate (ben- sulfuron-methyl) | ≥ 975 g/kg | 1 November 2009 | ► M213 31 October 2022 ◀ | PART A Only uses as a herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bensulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to the following: — the protection of aquatic organisms; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, where the active substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall ensure that the notifier submits to the Commission: — further studies on the specification, — information to further address the route and rate of degradation of bensulfuron-methyl under aerobic flooded soil conditions, — information to address the relevance of metabolites for the consumer risk assessment. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011. |
| 272 | Sodium 5-nitroguaiacolate CAS No 67233-85-6 CIPAC number not allocated | Sodium 2-methoxy-5-nitrophenolate | ≥ 980 g/kg | 1 November 2009 | ► M213 31 October 2022 ◀ | PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|-------------------------|--|
| | | | | | | <p>finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. <p>The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.</p> |
| 273 | <p>Sodium o-nitrophenolate</p> <p>CAS No 824-39-5</p> <p>CIPAC number not allocated</p> | Sodium 2-nitrophenolate; sodium o-nitrophenolate | <p>≥ 980 g/kg</p> <p>The following impurities are of toxicological concern:</p> <p>Phenol</p> <p>Max content: 0,1 g/kg</p> <p>2,4 dinitrophenol</p> <p>max content: 0,14 g/kg</p> <p>2,6 dinitrophenol</p> <p>max content: 0,32 g/kg</p> | 1 November 2009 | ►M213 31 October 2022 ◀ | <p>PART A</p> <p>Only use as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, |

▼ **B**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|--|------------------|---------------------------------|---|
| | | | | | | <p>— the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure,</p> <p>— the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.</p> |
| 274 | Sodium p-nitrophenolate CAS No 824-78-2 CIPAC number not allocated | Sodium 4-nitrophenolate; sodium p-nitrophenolate | <p>≥ 998 g/kg</p> <p>The following impurities are of toxicological concern:</p> <p>Phenol</p> <p>max content: 0,1 g/kg</p> <p>2,4 dinitrophenol</p> <p>max content: 0,07 g/kg</p> <p>2,6 dinitrophenol</p> <p>max content: 0,09 g/kg</p> | 1 November 2009 | ► M213 31 October 2022 ◀ | <p>PART A</p> <p>Only use as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <p>— the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material,</p> <p>— the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure,</p> <p>— the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|------------|------------------|---------------------------------|--|
| | | | | | | The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011. |
| 275 | Tebufenpyrad CAS No 119168-77-3 CIPAC No 725 | N-(4-tert-butylbenzyl)-4-chloro-3-ethyl-1-methylpyrazole-5-carboxamide | ≥ 980 g/kg | 1 November 2009 | ► M213 31 October 2022 ◀ | <p>PART A</p> <p>Only uses as acaricide and insecticide may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing tebufenpyrad in formulations other than water soluble bags Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebufenpyrad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, — the protection of insectivorous birds and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. <p>The Member States concerned shall ensure that the notifier submits to the Commission:</p> <ul style="list-style-type: none"> — further information confirming that no relevant impurities are present, — information to further address the risk to insectivorous birds. <p>They shall ensure that the notifier provides such information to the Commission by 31 October 2011.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|--------------------------|--|
| 276 | <p>Chlormequat</p> <p>CAS No 7003-89-6 (chlormequat)</p> <p>CAS No 999-81-5 (chlormequat chloride)</p> <p>CIPAC No 143 (chlormequat)</p> <p>CIPAC No 143.302 (chlormequat chloride)</p> | <p>2-chloroethyltrimethylammonium (chlormequat)</p> <p>2-chloroethyltrimethylammonium chloride</p> <p>(chlormequat chloride)</p> | <p>≥ 636 g/kg</p> <p>Impurities</p> <p>1,2-dichloroethane: max 0,1 g/kg (on the dry chlormequat chloride content)</p> <p>Chloroethene (vinylchloride): max 0,0005 g/kg (on the dry chlormequat chloride content)</p> | 1 December 2009 | ►M213 30 November 2021 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator on cereals and non edible crops may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing chlormequat for uses other than in rye and triticale, notably as regards the exposure of consumers, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlormequat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the protection of birds and mammals. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of further information on the fate and behaviour (adsorption studies to be performed at 20 °C, recalculation of the predicted concentrations in groundwater, surface water and sediment), the monitoring methods for determination of the substance in animal products and water, and the risk to aquatic organisms, birds and mammals. They shall ensure that the notifier at whose request chlormequat has been included in this Annex provide such information to the Commission by 30 November 2011 at the latest.</p> |

▼ B▼ M288▼ B

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|--|------------------|----------------------------------|---|
| 278 | Propaquizafop CAS No 111479-05-1 CIPAC No 173 | 2-isopropylide-namino-oxyethyl (R)-2-[4-(6-chloro-quin-oxalin-2-yloxy)phen-oxy]propionate | ≥ 920 g/kg Toluene maximum content 5 g/kg | 1 December 2009 | ► M213 30 November 2021 ◀ | PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on propaquizafop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, — the protection of non-target arthropods and ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|--|------------|------------------|----------------------------------|--|
| | | | | | | <p>The Member States concerned shall ensure that the notifier submits to the Commission:</p> <ul style="list-style-type: none"> — further information on the relevant impurity Ro 41-5259, — information to further address the risk to aquatic organisms and to non-target arthropods. <p>They shall ensure that the notifier provides such information to the Commission by 30 November 2011.</p> |
| ▼ M213 | | | | | | |
| 279 | Quizalofop-P | | | | | |
| | Quizalofop-P-tefuryl CAS No 119738-06-6 CIPAC No 641.226 | (RS)-Tetrahydro-furfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate | ≥ 795 g/kg | 1 December 2009 | ► M238 30 November 2021 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on quizalofop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information on the risk to non-target arthropods.</p> |
| | Quizalofop-P-ethyl CAS No 100646-51-3 CIPAC No 641.202 | ethyl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate | ≥ 950 g/kg | 1 December 2009 | 30 November 2021 | |

▼ **M213**

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|------------------------|--|
| | | | | | | They shall ensure that the notifier provides such information to the Commission by 30 November 2011. |
| 280 | Teflubenzuron CAS No 83121-18-0 CIPAC No 450 | 1-(3,5-dichloro-2,4-difluorophenyl)-3-(2,6-difluorobenzoyl)urea | ≥ 970 g/kg | 1 December 2009 | 30 November 2019 | <p>PART A</p> <p>Only uses as insecticide in glasshouses (on artificial substrate or closed hydroponic systems) may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing teflubenzuron for uses other than on tomatoes in greenhouses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on teflubenzuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and workers safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate, — the protection of aquatic organisms. Releases from glasshouse application must be minimised and, in any case, should not have the potential to reach in significant levels water bodies in the vicinity, — the protection of bees which should be prevented from accessing the glasshouse, — the protection of pollinator colonies purposely placed in the glasshouse, — the safe disposal of condensation water, drain water and substrate in order to preclude risks to non-target organisms and contamination of surface water and groundwater. |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | Conditions of authorisation shall include risk mitigation measures, where appropriate. |
| 281 | Zeta-cypermethrin CAS No 52315-07-8 CIPAC No 733 | Mixture of the stereoisomers (S)- α -cyano-3-phenoxy-benzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2 dimethylcyclopropanecarboxylate where the ratio of the (S);(1RS,3RS) isomeric pair to the (S);(1RS,3SR) isomeric pair lies in the ratio range 45-55 to 55-45 respectively | ≥ 850 g/kg Impurities: toluene: max 2 g/kg tars: max 12,5 g/kg | 1 December 2009 | ► M213 30 November 2021 ◀ | PART A Only uses as insecticide may be authorised. PART B In assessing applications to authorise plant protection products containing zeta-cypermethrin for uses other than in cereals, notably as regards the exposure of consumers to mPBAldehyde, a degradation product that may be formed during processing, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on zeta-cypermethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate, — the protection of birds, aquatic organisms, bees, non-target arthropods and non-target soil macro-organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information on the fate and behaviour (aerobic degradation in soil), the long-term risk to birds, aquatic organisms and non-target arthropods. They shall ensure that the notifier at whose request zeta-cypermethrin has been included in this Annex provide such information to the Commission by 30 November 2011 at the latest. |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|---|------------------|------------------------|---|
| 282 | Chlorsulfuron CAS No 64902-72-3 CIPAC No 391 | 1-(2-chlorophenylsulfonyl)-3-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)urea | <p>≥ 950 g/kg</p> <p>Impurities:</p> <p>2-Chlorobenzene-sulfonamide (IN-A4097) not more than 5 g/kg and</p> <p>4-methoxy-6-methyl-1,3,5-triazin-2-amine (IN-A4098) not more than 6 g/kg</p> | 1 January 2010 | 31 December 2019 | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms and non-target plants; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>The Member States concerned shall:</p> <ul style="list-style-type: none"> — ensure that the notifier submits to the Commission further studies on the specification by 1 January 2010. <p>If chlorsulfuron is classified as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008, the Member States concerned shall request the submission of further information on the relevance of the metabolites IN-A4097, IN-A4098, IN-JJ998, IN-B5528 and IN-V7160 with respect to cancer and ensure that the notifier provides that information to the Commission within six months from the notification of the classification decision concerning that substance.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|------------------------|---|
| 283 | Cyromazine CAS No 66215-27-8 CIPAC No 420 | N-cyclopropyl-1,3,5-triazine-2,4,6-triamine | ≥ 950 g/kg | 1 January 2010 | 31 December 2019 | <p>PART A</p> <p>Only uses as insecticide in greenhouses may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing cyromazine for uses other than in tomatoes, notably as regards the exposure of consumers, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyromazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of aquatic organisms, — the protection of pollinators. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of further information on the fate and behaviour of the soil metabolite NOA 435343 and on the risk to aquatic organisms. They shall ensure that the notifier at whose request cyromazine has been included in this Annex provide such information to the Commission by 31 December 2011 at the latest.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|---|------------------|----------------------------------|--|
| 284 | Dimethachlor CAS No 50563-36-5 CIPAC No 688 | 2-chloro-N-(2-methoxyethyl)acet-2',6'-xylidide | ≥ 950 g/kg Impurity 2,6-dimethylaniline: Not more than 0,5 g/kg | 1 January 2010 | ► M213 31 December 2021 ◀ | <p>PART A</p> <p>Only uses as herbicide in application max. of 1,0 kg/ha only every third year on the same field may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dimethachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and non-target plants; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from metabolites CGA 50266, CGA 354742, CGA 102935 and SYN 528702 in vulnerable zones, where appropriate.</p> <p>The Member States concerned shall:</p> <ul style="list-style-type: none"> — ensure that the notifier submits to the Commission further studies on the specification by 1 January 2010. |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|----------------------------------|---|
| | | | | | | If dimethachlor is classified as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008, the Member States concerned shall request the submission of further information on the relevance of the metabolites CGA 50266, CGA 354742, CGA 102935 and SYN 528702 with respect to cancer and ensure that the notifier provides that information to the Commission within six months from the notification of the classification decision concerning that substance. |
| 285 | Etofenprox CAS No 80844-07-1 CIPAC No 471 | 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether | ≥ 980 g/kg | 1 January 2010 | ► M213 31 December 2021 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on etofenprox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of bees and non-target arthropods; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate. <p>The Member States concerned shall:</p> <ul style="list-style-type: none"> — ensure that the notifier submits to the Commission further information on the risk to aquatic organisms including the risk to sediment dwellers and biomagnification, |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>— the submission of further studies on the endocrine disruption potential in aquatic organisms (fish full life cycle study).</p> <p>They shall ensure that the notifiers provide such studies to the Commission by 31 December 2011.</p> |
| 286 | Lufenuron CAS No 103055-07-8 CIPAC No 704 | (RS)-1-[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoro-propoxy)-phenyl]-3-(2,6-difluorobenzoyl)-urea | ≥ 970 g/kg | 1 January 2010 | 31 December 2019 | <p>PART A</p> <p>Only indoor uses or use in outdoor bait stations as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lufenuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the high persistency in the environment and the high risk for bioaccumulation and shall ensure that the use of lufenuron has no adverse long-term effects on non-target organisms, — the protection of birds, mammals, soil non-target organisms, bees, non-target arthropods, surface waters and aquatic organisms in vulnerable situations. <p>The Member States concerned shall:</p> <ul style="list-style-type: none"> — ensure that the notifier submits to the Commission further studies on the specification by 1 January 2010. |
| 287 | Penconazole CAS No 66246-88-6 CIPAC No 446 | (RS) 1-[2-(2,4-dichloro-phenyl)-pentyl]-1H-[1,2,4] triazole | ≥ 950 g/kg | 1 January 2010 | ►M213 31 December 2021 ◀ | <p>PART A</p> <p>Only uses as fungicides may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on penconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|--------------------------|---|
| | | | | | | <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of further information on the fate and behaviour of the soil metabolite CGA179944 in acidic soils. They shall ensure that the notifier at whose request penconazole has been included in this Annex provide such information to the Commission by 31 December 2011 at the latest.</p> |
| 288 | Tri-allate CAS No 2303-17-5 CIPAC No 97 | S-2,3,3-trichloroallyl di-isopropyl (thiocarbamate) | ≥ 940 g/kg NDIPA (Nitroso-diisopropylamine) max. 0,02 mg/kg | 1 January 2010 | ►M213 31 December 2021 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tri-allate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the dietary exposure of consumers to residues of tri-allate in treated crops as well as in succeeding rotational crops and in products of animal origin — the protection of aquatic organisms and non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, |

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| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---------------------------|------------------|----------------------------------|---|
| | | | | | | <p>— the potential for ground water contamination by the degradation products TCPSA when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission:</p> <p>— further information to assess the primary plant metabolism,</p> <p>— further information on the fate and behaviour of the soil metabolite diisopropylamine,</p> <p>— further information on the potential for biomagnification in aquatic food chains,</p> <p>— information to further address the risk to fish-eating mammals and the long-term risk to earthworms.</p> <p>They shall ensure that the notifier provides such information to the Commission by 31 December 2011.</p> |
| 289 | Triflurosulfuron CAS No 126535-15-7 CIPAC No 731 | 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoysulfamoyl]-m-toluic acid | ► M29 ≥ 960 g/kg ◀ | 1 January 2010 | ► M313 31 December 2020 ◀ | <p>► M29 PART A</p> <p>Only uses as a herbicide may be authorised. ◀</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triflurosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <p>— the dietary exposure of consumers to residues of metabolites IN-M7222 and IN-E7710 in succeeding rotational crops and in products of animal origin,</p> |

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|--------|---|--|-----------------------|------------------|------------------------|---|
| | | | | | | <p>— the protection of aquatic organisms and aquatic plants from the risk arising from triflurosulfuron and the metabolite IN-66036 and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate,</p> <p>— the potential for ground water contamination by the degradation products IN-M7222 and IN-W6725 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.</p> <p>If triflurosulfuron is classified as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008, the Member States concerned shall request the submission of further information on the relevance of the metabolites IN-M7222, IN-D8526 and IN-E7710 with respect to cancer. They shall ensure that the notifier provides that information to the Commission within six months from the notification of the classification decision concerning that substance.</p> |
| 290 | Difenacoum CAS No 56073-07-5 CIPAC No 514 | 3-[(1RS,3RS;1RS,3SR)-3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxy-coumarin | ≥ 905 g/kg | 1 January 2010 | 30 December 2019 | <p>PART A</p> <p>Only uses as rodenticide in the form of pre-prepared baits placed in specially constructed, tamper resistant and secured bait boxes are authorised.</p> <p>The nominal concentration of the active substance in the products shall not exceed 50 mg/kg.</p> <p>Authorisations shall be limited to professional users.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on difenacoum, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of birds and non-target mammals from primary and secondary poisoning. Risk mitigation measures shall be applied where appropriate.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>The Member States concerned shall ensure that the notifier submits to the Commission further information on methods for the determination of residues of difenacoum in body fluids.</p> <p>They shall ensure that the notifier provides such information to the Commission by 30 November 2011.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information on the specification of the active substance as manufactured.</p> <p>They shall ensure that the notifier provides such information to the Commission by 31 December 2009.</p> |

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| 292 | sulphur CAS No 7704-34-9 CIPAC No 18 | sulphur | ≥ 990 g/kg | 1 January 2010 | ► <u>M213</u> 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as fungicide and acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulphur, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2009 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>— the protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submit to the Commission further information to confirm the risk assessment for birds, mammals, sediment dwelling organisms and non-target arthropods. They shall ensure that the notifier at whose request sulphur has been included in this Annex provide such data to the Commission at latest by 30 June 2011.</p> |
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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|---|------------------|----------------------------------|---|
| 293 | Tetraconazole CAS No 112281-77-3 CIPAC No 726 | (RS)-2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propyl-1,1,2,2-tetrafluoroethyl ether | ≥ 950 g/kg (racemic mixture) Impurity toluene: not more than 13 g/kg | 1 January 2010 | ► M213 31 December 2021 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tetraconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms and non-target plants; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. <p>The Member States concerned shall request:</p> <ul style="list-style-type: none"> — the submission of further information on a refined consumer risk assessment, — further information on the specification regarding ecotoxicology, — further information on the fate and behaviour of potential metabolites in all relevant compartments, — the refined risk assessment of such metabolites to birds, mammals aquatic organisms and non-target arthropods, — further information on the potential for endocrine disrupting effects to birds, mammals and fish. <p>They shall ensure that the notifier provides such information to the Commission by 31 December 2011.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--------------|-----------------------------|------------------|----------------------------------|--|
| 294 | Paraffin oils CAS No 64742-46-7 CAS No 72623-86-0 CAS No 97862-82-3 CIPAC No n.a. | paraffin oil | European Pharmacopoeia 6.0 | 1 January 2010 | ► M213 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3, and in particular Appendices I and II thereto shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The Member States concerned shall request:</p> <p>— the submission of the specification of the technical material as commercially manufactured to verify the compliance with purity criteria of European Pharmacopoeia. 6.0.</p> <p>They shall ensure that the notifiers provides such information to the Commission by 30 June 2010.</p> |
| 295 | Paraffin oil CAS No 8042-47-5 CIPAC No n.a. | paraffin oil | European Pharmacopoeia. 6,0 | 1 January 2010 | ► M213 31 December 2020 ◀ | <p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on paraffin oil 8042-47-5, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The Member States concerned shall request:</p> <p>The submission of the specification of the technical material as commercially manufactured to verify the compliance with purity criteria of European Pharmacopoeia. 6,0</p> <p>They shall ensure that the notifier provides such information to the Commission by 30 June 2010.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|---|------------------|-------------------------------|---|
| 296 | Cyflufenamid CAS No 180409-60-3 CIPAC No 759 | (Z)-N-[α-(cyclopropylmethoxyimino) – 2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide | > 980 g/kg | 1 April 2010 | ► M236 31 March 2023 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyflufenamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 October 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> |
| 297 | Fluopicolide CAS No 239110-15-7 CIPAC No 787 | 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide | <p>≥ 970 g/kg</p> <p>The impurity toluene must not exceed 3 g/kg in the technical material.</p> | 1 June 2010 | ► M236 31 May 2023 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluopicolide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 November 2009 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms, — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — to the risk to operators during application, — the potential for long range transport via air. |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|---|------------------|--------------------------|--|
| | | | | | | <p>Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential accumulation and exposure in vulnerable areas, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information on the relevance of the metabolite M15 for groundwater by 30 April 2012 at the latest.</p> |
| 298 | Heptamaloxylglucan CAS No 870721-81-6 CIPAC No Not available | Full IUPAC name in footnote (1) Xyl p: xylopyranosyl Glc p: glucopyranosyl Fuc p: fucopyranosyl Gal p: galactopyranosyl Glc-ol: glucitol | ≥ 780 g/kg The impurity Patulin must not exceed 50 µg/kg in the technical material. | 1 June 2010 | ►M236 31 May 2021 ◀ | PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on heptamaloxylglucan, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 November 2009 shall be taken into account. |
| 299 | 2-phenylphenol (including its salts such as the sodium salt) CAS No 90-43-7 CIPAC No 246 | biphenyl-2-ol | ≥ 998 g/kg | 1 January 2010 | ►M213 31 December 2021 ◀ | PART A Only uses as a post-harvest fungicide for indoor use may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2-phenylphenol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 November 2009, as amended in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account. In this overall assessment Member States must pay particular attention: <ul style="list-style-type: none"> — to the protection of operators and workers and ensure that conditions of use prescribe the application of adequate personal protective equipment, |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|---|------------------|------------------------|--|
| | | | | | | <p>— to put in place appropriate waste management practices to handle the waste solution remaining after application, including the cleaning water of the drenching and other application systems. Member States permitting the release of wastewater into the sewage system, shall ensure that a local risk assessment is carried out.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission:</p> <p>— further information on the potential for skin depigmentation for workers and consumers due to possible exposure to the metabolite 2-phenylhydroquinone (PHQ) on citrus peel,</p> <p>— further information to confirm that the analytical method applied in residue trials correctly quantifies the residues of 2-phenylphenol, PHQ and their conjugates.</p> <p>They shall ensure that the notifier provides such information to the Commission by 31 December 2011.</p> <p>Furthermore, the Member States concerned shall ensure that the notifier submits to the Commission further information to confirm the residue levels occurring as a result of application techniques other than those in drench chambers.</p> <p>They shall ensure that the notifier provides such information to the Commission by 31 December 2012.</p> |
| 300 | Malathion CAS No 121-75-5 CIPAC No 12 | diethyl (dimethoxyphosphinothioylthio)succinate or S-1,2-bis(ethoxycarbonyl)ethyl O,O-dimethyl phosphorodithioate racemate | ≥ 950 g/kg Impurities: Isomalathion: not more than 2 g/kg | 1 May 2010 | ►M236 30 April 2022 ◀ | <p>►M277 PART A</p> <p>Only uses as an insecticide in greenhouses with a permanent structure may be authorised. Authorisations shall be limited to professional users.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on malathion, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|--|------------------|------------------------------|--|
| | | | | | | <p>(a) releases from greenhouses, such as condensation water, drain water, soil or artificial substrate, in order to preclude risks to aquatic organisms;</p> <p>(b) the protection of pollinator colonies purposely placed in the greenhouse;</p> <p>(c) the protection of operators and workers, so as to ensure that the conditions of use prescribe the use of adequate personal protective equipment, where appropriate;</p> <p>(d) the protection of consumers in the case of processed commodities.</p> <p>Member States shall ensure that malathion-based formulations are accompanied by the necessary instructions to avoid any risk of formation of isomalathion in excess of the permitted maximum quantities during storage and transport.</p> <p>Conditions of authorisation shall include risk mitigation measures and provide for adequate labelling of plant protection products. ◀</p> |
| 301 | Penoxsulam CAS No 219714-96-2 CIPAC No 758 | 3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide | <p>> 980 g/kg</p> <p>The impurity</p> <p>Bis-CHYMP</p> <p>2-chloro-4-[2-(2-chloro-5-methoxy-4-pyrimidinyl)hydrazino]-5-methoxypyrimidine must not exceed 0,1 g/kg in the technical material</p> | 1 August 2010 | ► M241 31 July 2023 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on penoxsulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|------------------------|---|
| | | | | | | <p>— the protection of aquatic organisms,</p> <p>— the dietary exposure of consumers to residues of the metabolite BSCTA in succeeding rotational crops,</p> <p>— the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information to address the off-field risk to higher aquatic plants. They shall ensure that the notifier provides such information to the Commission by 31 July 2012.</p> <p>The Rapporteur Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.</p> |
| 302 | Proquinazid CAS No 189278-12-4 CIPAC No 764 | 6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one | > 950 g/kg | 1 August 2010 | ►M241 31 July 2022 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on proquinazid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention:</p> <p>— to the long-term risk to earthworm-eating birds for uses in grapevine,</p> <p>— to the risk to aquatic organisms,</p> <p>— the dietary exposure of consumers to proquinazid residues in products of animal origin and in succeeding rotational crops,</p> <p>— to the operator safety.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|---|------------------|------------------------|---|
| | | | | | | <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Rapporteur Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.</p> |
| 303 | <p>Spirodiclofen</p> <p>CAS No 148477-71-8</p> <p>CIPAC No 737</p> | 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate | <p>> 965 g/kg</p> <p>The following impurities must not exceed a certain amount in the technical material:</p> <p>3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5]dec-3-en-2-one (BAJ-2740 enol): ≤ 6 g/kg</p> <p>N,N-dimethylacetamide: ≤ 4 g/kg</p> | 1 August 2010 | 31 July 2020 | <p>PART A</p> <p>Only uses as acaricide or insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spirodiclofen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention:</p> <ul style="list-style-type: none"> — to the long-term risk to aquatic organisms, — to the operator safety, — to the risk to bee brood. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> |
| 304 | <p>Metalaxyl</p> <p>CAS No 57837-19-1</p> <p>CIPAC No 365</p> | Methyl N-(methoxyacetyl)-N-(2,6-xylyl)-DL-alaninate | <p>950 g/kg</p> <p>The impurity 2,6-dimethylaniline was considered of toxicological concern and a maximum level of 1 g/kg is established.</p> | 1 July 2010 | ►M241 30 June 2023 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metalaxyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|--|------------------|--------------------------------|---|
| | | | | | | Member States must pay particular attention to the potential contamination of groundwater by the active substance or its degradation products CGA 62826 and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate. |
| 305 | Flonicamid (IKI-220) CAS No 158062-67-0 CIPAC No 763 | N-cyanomethyl-4-(trifluoromethyl)nicotinamide | ≥ 960 g/kg The impurity toluene must not exceed 3 g/kg in the technical material. | 1 September 2010 | ► M241 31 August 2023 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flonicamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010, shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to operators and re-entry workers, — the risk to bees. <p>Conditions of authorisation shall include risk mitigation measures where appropriate.</p> <p>The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.</p> |
| 306 | Triflumizole CAS No 99387-89-0 CIPAC No 730 | (E)-4-chloro- α,α,α -trifluoro-N-(1-imidazol-1-yl-2-propoxyethylidene)-o-toluidine | ≥ 980 g/kg Impurities: Toluene: not more than 1 g/kg | 1 July 2010 | 30 June 2020 | <p>PART A</p> <p>Only uses as fungicide in greenhouses on artificial substrates may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triflumizole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|-------------------|-----------------------|------------------|---------------------------------|--|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the operator and worker safety: conditions of use shall prescribe the use of adequate personal protective equipment, — the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, as appropriate, risk mitigation measures. |
| 307 | <p>Sulfuryl fluoride</p> <p>CAS No 002699-79-8</p> <p>CIPAC No 757</p> | Sulfuryl fluoride | > 994 g/kg | 1 November 2010 | ► M248 31 October 2023 ◀ | <p>► M202 PART A</p> <p>Only uses as insecticide/nematicide (fumigant) applied by professional users in sealable structures may be authorised insofar:</p> <p>(a) these structures are empty; or</p> <p>(b) where food or feed commodities are present in a fumigated facility, the users and the food business operators ensure that only the food or feed commodities compliant with the existing maximum residue levels for sulfuryl fluoride and fluoride ion set by Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽¹⁹⁾ may enter the food and feed chain; to this purpose, the users and the food business operators shall fully implement measures equivalent to the HACCP principles as laid down in Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽²⁰⁾; in particular, the users shall identify the critical control point at which control is essential to prevent maximum residue levels to be exceeded, and establish and implement effective monitoring procedures at that critical control point.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfuryl fluoride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 7 December 2016 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|----------------|---|------------------|-------------------------|---|
| | | | | | | <p>— the risk posed by inorganic fluoride through contaminated products, such as flour and bran that remained in the mill machinery during fumigation, or grain stored in silos in the mill. Measures are required to ensure that only products complying with the existing MRLs enter the food and feed chain;</p> <p>— the risk to operators and the risk to workers, such as when re-entering a fumigated structure after aeration. Measures are required to ensure that they wear self-containing breathing apparatus or other appropriate personal protective equipment;</p> <p>— the risk to bystanders by applying an appropriate exclusion zone around the fumigated structure.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The notifier shall submit to the Commission, Member States and the Authority monitoring data on tropospheric concentrations of sulfuric fluoride every fifth year, starting from 30 June 2017. The limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuric fluoride/m³ of tropospheric air). ◀</p> |
| 308 | <p>FEN 560 (also called fenugreek or fenugreek seed powder)</p> <p>CAS No</p> <p>None</p> <p>CIPAC No</p> <p>None</p> <p>The active substance is prepared from the seed powder of <i>Trigonella foenum-graecum</i> L. (fenugreek).</p> | Not applicable | 100 % fenugreek seed powder without any additive and no extraction; the seed being of human food grade quality. | 1 November 2010 | ►M296 31 October 2020 ◀ | <p>PART A</p> <p>Only uses as elicitor of the crop's self-defence mechanisms may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on FEN 560 (fenugreek seed powder), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to the risk to operators, workers and bystanders.</p> <p>Conditions of authorisation shall include risk mitigation measures where appropriate.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|--|------------------|----------------------------------|---|
| 309 | <p>Haloxyfop-P</p> <p>CAS No Acid: 95977-29-0</p> <p>Ester: 72619-32-0</p> <p>CIPAC No Acid: 526</p> <p>Ester: 526.201</p> | <p>Acid: (R)-2-[4-(3-chloro-5-trifluoromethyl-2-pyridyloxy)phenoxy]propanoic acid</p> <p>Ester: Methyl (R)-2-{}{4-[3-chloro-5-(trifluoromethyl)-2-pyridyloxy]phenoxy}{}propionate</p> | <p>≥ 940 g/kg</p> <p>(Haloxyfop-P-methyl ester)</p> | 1 January 2011 | ► M254 31 December 2023 ◀ | <p>► M168 PART A</p> <p>Only uses as herbicide may be authorised at rates not exceeding 0,052 kg active substance per hectare per application, and only one application may be authorised every 3 years.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on haloxyfop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater from the relevant soil metabolite DE-535 pyridinone when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the safety of operators and ensure that conditions of use prescribe the use of adequate personal protective equipment, — the protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones, — the consumer safety as regards the occurrence in groundwater of metabolite DE-535 pyridinol. ◀ |
| 310 | <p>Napropamide</p> <p>CAS No 15299-99-7</p> | (RS)-N,N-diethyl-2-(1-naphthyloxy)propionamide | <p>≥ 930 g/kg</p> <p>(Racemic mixture)</p> <p>Relevant impurity</p> <p>Toluene: not more than 1,4 g/kg</p> | 1 January 2011 | ► M254 31 December 2023 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on napropamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> |

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| | | | | | | <p>— operator safety: conditions of use shall prescribe the use of adequate personal protective equipment, where necessary,</p> <p>— protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones,</p> <p>— consumer safety as regards the occurrence in groundwater of the metabolite 2-(1-naphthyloxy)propionic acid, hereinafter 'NOPA'.</p> <p>The Member States concerned shall ensure that the applicant presents to the Commission, by 31 December 2012 at the latest, information confirming the surface water exposure assessment as regards the photolysis metabolites and the metabolite NOPA and information for the risk assessment of aquatic plants.</p> |
| 311 | Quinmerac CAS No 90717-03-6 CIPAC No 563 | 7-chloro-3-methylquinoline-8-carboxylic acid | ≥ 980 g/kg | 1 May 2011 | ►M270 30 April 2024 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on quinmerac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>— the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>— the dietary exposure of consumers to residues of quinmerac (and its metabolites) in succeeding rotational crops</p> <p>— the risk to aquatic organisms and the long term risk for earthworms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

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| | | | | | | <p>The Member States concerned shall request the submission of information as regards:</p> <ul style="list-style-type: none"> — the potential of plant metabolism to result in an opening of the quinoline ring; — residues in rotational crops and the long term risk for earthworms due to the metabolite BH 518-5. <p>They shall ensure that the applicant provides such confirmatory data and information to the Commission by 30 April 2013.</p> |
| 312 | <p>Metosulam</p> <p>CAS No 139528-85-1</p> <p>CIPAC No 707</p> | <p>2',6'-dichloro-5,7-dimethoxy-3'-methyl[1,2,4]triazolo</p> <p>[1,5-a]pyrimidine-2-sulfonanilide</p> | ≥ 980 g/kg | 1 May 2011 | 30 April 2021 | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metosulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms; — the risk to non-target plants in the off-field area. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission, by 30 October 2011, further information on the specification of the active substance as manufactured.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission, by 30 April 2013, confirmatory information as regards:</p> |

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| | | | | | | <ul style="list-style-type: none"> — potential pH dependence of soil adsorption, groundwater leaching and surface water exposure for metabolites M01 and M02; — potential genotoxicity of one impurity. |
| 313 | Pyridaben CAS No 96489-71-3 CIPAC No 583 | 2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyrididin-3(2H)-one | >980 g/kg | 1 May 2011 | ►M270 30 April 2023 ◀ | <p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyridaben, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the risk to aquatic organisms and mammals, — the risk to non target arthropods including honeybees. <p>Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify the real exposure of honeybees to pyridaben in areas extensively used by such bees for foraging or by beekeepers, where and as appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> — the risks for the water compartment resulting from the exposure to aqueous photolysis metabolites W-1 and B-3, — the potential long term risk for mammals, — the assessment of fat soluble residues. <p>They shall ensure that the applicant provides such confirmatory information to the Commission by 30 April 2013.</p> |

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| 314 | Zinc phosphide CAS No 1314-84-7 CIPAC No 69 | Trizinc diphosphide | ≥ 800 g/kg | 1 May 2011 | ► M270 30 April 2024 ◀ | <p>PART A</p> <p>Only uses as rodenticide in the form of ready-to-use baits placed in bait stations or target locations may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on zinc phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.</p> <p>In this overall assessment Member States should pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of non target organisms. Risk mitigation measures should be applied as appropriate in particular to avoid the spread of baits where only part of the content has been consumed. |
| 315 | Fenbuconazole CAS No 114369-43-6 CIPAC No 694 | (R,S) 4-(4-chloro-phenyl)-2-phenyl-2-(1H-1,2,4-triazol-1-ylmethyl)butyronitrile | ≥ 965 g/kg | 1 May 2011 | 30 April 2021 | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenbuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the dietary exposure of consumers to the residues of triazole derivative metabolites (TDMs), — the risk to aquatic organisms and mammals. |

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|--------|--|---|------------|------------------|-----------------------------|--|
| | | | | | | <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory data on residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin.</p> <p>They shall ensure that the applicant provides such studies to the Commission by 30 April 2013.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission further information addressing the potential endocrine disrupting properties of fenbuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.</p> |
| 316 | Cycloxydim CAS No 101205-02-1 CIPAC No 510 | (5RS)-2-[(EZ)-1-(ethoxyimino)butyl]-3-hydroxy-5-[(3RS)-thian-3-yl]cyclohex-2-en-1-one | ≥ 940 g/kg | 1 June 2011 | ► M274 31 May 2023 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cycloxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to non-target plants.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of further information concerning the methods for analysis of residues of cycloxydim in plant and animal products.</p> <p>The Member States concerned shall ensure that the applicant submits such methods of analysis to the Commission by 31 May 2013.</p> |

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| 317 | 6-Benzyladenine CAS No 1214-39-7 CIPAC No 829 | N6-benzyladenine | ≥ 973 g/kg | 1 June 2011 | ► M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 6-benzyladenine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate.</p> |
| 318 | Bromuconazole CAS No 116255-48-2 CIPAC No 680 | 1-[(2RS,4RS:2RS,4SR)-4-bromo-2-(2,4-dichlorophenyl)tetrahydrofurfuryl]-1H-1,2,4-triazole | ≥ 960 g/kg | 1 February 2011 | ► M254 31 January 2024 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bromuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account.</p> <p>In this overall assessment, Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — operator's safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; — protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones. <p>The Member States concerned shall ensure that the applicant presents to the Commission:</p> <ul style="list-style-type: none"> — further information on residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; |

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| | | | | | | <p>— information to further address the long term risk to herbivorous mammals.</p> <p>They shall ensure that the applicant at whose request bromuconazole has been included in this Annex provides such confirmatory information to the Commission by 31 January 2013 at the latest.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission further information addressing the potential endocrine disrupting properties of bromuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.</p> |
| 319 | <p>Myclobutanil</p> <p>CAS No 88671-89-0</p> <p>CIPAC No 442</p> | <p>RS)-2-(4-chloro-phenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile</p> | <p>≥ 925 g/kg</p> <p>The impurity 1-methylpyrrolidin-2-one shall not exceed 1 g/kg in the technical material</p> | 1 June 2011 | 31 May 2021 | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on myclobutanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information on the residues of myclobutanil and its metabolites in following growing seasons and information confirming that the available residue data cover all compounds of the residue definition.</p> <p>The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 January 2013.</p> |

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| 320 | Buprofezin CAS No 953030-84-7 CIPAC No 681 | (Z)-2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one | ≥ 985 g/kg | 1 February 2011 | ► M254 31 January 2023 ◀ | <p>► M204 PART A</p> <p>Only uses as insecticide and acaricide on non-edible crops may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on buprofezin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the operators' and workers' safety and ensure that conditions of use impose the use of adequate personal protective equipment where appropriate, — the application of an appropriate waiting period for rotational crops in greenhouses, — the risk to aquatic organisms and ensure that conditions of use impose adequate risk mitigation measures, where appropriate. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀</p> |
| 321 | Triflumuron CAS No 64628-44-0 CIPAC No: 548 | 1-(2-chlorobenzoyl)-3-[4-trifluoromethoxyphenyl]urea | ≥ 955 g/kg Impurities: — N,N'-bis-[4-(trifluoromethoxy)phenyl]urea: not more than 1 g/kg — 4-trifluoromethoxyaniline: not more than 5 g/kg | 1 April 2011 | 31 March 2021 | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triflumuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> <p>In this overall assessment, Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of the aquatic environment; — the protection of honey bees. Conditions of authorisation shall include risk mitigation measures, where appropriate. |

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| | | | | | | <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards the long-term risk to birds, the risk to aquatic invertebrates and the risk to bee brood development.</p> <p>The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 March 2013.</p> |
| 322 | Hymexazol CAS No 10004-44-1 CIPAC No 528 | 5-methylisoxazol-3-ol (or 5-methyl-1,2-oxazol-3-ol) | ≥985 g/kg | 1 June 2011 | ►M274 31 May 2023 ◀ | <p>PART A</p> <p>Only uses as fungicide for seed pelleting of sugar beets in professional seed treatment facilities may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on hymexazol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the operators and workers safety. Conditions of authorisation shall include protective measures, where appropriate, — the risk to granivorous birds and mammals. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards the nature of residues in root crops and the risk for granivorous birds and mammals.</p> <p>The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.</p> |

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| 323 | Dodine CAS No 2439-10-3 CIPAC No 101 | 1-dodecylguanidinium acetate | ≥ 950 g/kg | 1 June 2011 | ► M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dodine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the potential long-term risk to birds and mammals; — the risk to aquatic organisms and ensure that conditions of use impose adequate risk mitigation measures; — the risk to non-target plants in the off-field area and ensure that conditions of use impose adequate risk mitigation measures; — the monitoring of residue levels in pome fruit. <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> — long-term risk assessment for birds and mammals, — risk assessment in natural surface water systems where major metabolites have potentially formed. <p>The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.</p> |
| 324 | Diethofencarb CAS No 87130-20-9 CIPAC No 513 | isopropyl 3,4-diethoxy-carbanilate | ≥ 970 g/kg Impurities: Toluene: not more than 1 g/kg | 1 June 2011 | 31 May 2021 | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diethofencarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> |

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| | | | | | | <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and non-target arthropods and shall ensure that conditions of use include the application of adequate risk mitigation measures.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> — the potential uptake of the metabolite 6-NO₂-DFC in succeeding crops; — the risk assessment for non-target arthropod species. <p>The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013.</p> |
| 325 | Etridiazole CAS No 2593-15-9 CIPAC No 518 | ethyl-3-trichloro-methyl-1,2,4-thiadiazol-5-yl ether | ≥ 970 g/kg | 1 June 2011 | 31 May 2021 | <p>PART A</p> <p>Only uses as fungicide in non-soil bound systems in greenhouse may be authorised.</p> <p>PART B</p> <p>In assessing applications to authorise plant protection products containing etridiazole for uses other than on ornamental plants, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary information is provided before such an authorization is granted.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on etridiazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall:</p> <ul style="list-style-type: none"> — pay particular attention to the risk to operators and workers and ensure that conditions of use include the application of appropriate risk mitigation measures; — ensure that appropriate waste management practices are applied as regards waste water from irrigation of non-soil bound growing systems; Member States permitting the release of waste water into the sewage system or into natural water bodies, shall ensure that an appropriate risk assessment is carried out; |

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| | | | | | | <p>— pay particular attention to the risk to aquatic organisms and ensure that conditions of use include the application of appropriate risk mitigation measures.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the specification of the technical material, as commercially manufactured, by appropriate analytical data; 2. the relevance of the impurities; 3. the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the ecotoxicity dossiers; 4. the relevance of the plant metabolites 5-hydroxy-ethoxyetridiazole acid and 3-hydroxymethyletridiazole; 5. indirect exposure of groundwater and soil-dwelling organisms to etridiazole and to its soil metabolites dichloro-etridiazole and etridiazole acid; 6. long-range and short-range transport through the atmosphere of etridiazole acid. <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1), (2) and (3) by 30 November 2011 and the information set out in points (4), (5) and (6) by 31 May 2013.</p> |
| 326 | Indolylbutyric acid CAS No 133-32-4 CIPAC No 830 | 4-(1H-indol-3-yl)butyric acid | ≥ 994 g/kg | 1 June 2011 | ►M274 31 May 2023 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator in ornamentals may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on indolylbutyric acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the operators and workers safety. Conditions of authorisation shall include the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure.</p> |

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| | | | | | | <p>The Member States concerned shall request the submission of further information to confirm:</p> <ul style="list-style-type: none"> — the absence of clastogenicity potential of indolylbutyric acid; — the vapour pressure of indolylbutyric acid and, consequently, an inhalation toxicity study; — the natural background concentration of indolylbutyric acid in the soil. <p>The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.</p> |
| 327 | Oryzalin CAS No 19044-88-3 CIPAC No 537 | 3,5-dinitro-N4,N4-dipropylsulfanilamide | <p>≥ 960 g/kg</p> <p>N-nitrosodipropylamine:</p> <p>≤ 0,1 mg/kg</p> <p>Toluene: ≤ 4 g/kg</p> | 1 June 2011 | 31 May 2021 | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oryzalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the operator safety and ensure that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms and non target plants; — the protection of groundwater, where the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to herbivorous birds and mammals; — the risk to bees, in the flowering season. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolites OR13 ⁽⁴⁾ and OR15 ⁽⁵⁾ in vulnerable zones, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>(1) the specification of the technical material, as commercially manufactured, by appropriate analytical data, including information on the relevance of the impurities which for confidentiality reasons are referred to as impurities 2, 6, 7, 9, 10, 11, 12;</p> <p>(2) the relevance of the test material used in the toxicity dossiers in view of the specification of the technical material;</p> <p>(3) the risk assessment for aquatic organisms;</p> <p>(4) the relevance of the metabolites OR13 and OR15, and the corresponding groundwater risk assessment, if oryzalin is classified under Regulation (EC) No 1272/2008 as 'suspected of causing cancer'.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 30 November 2011 and the information set out in point (3) by 31 May 2013. The information set out in point (4) shall be submitted within six month of notification of a decision classifying oryzalin.</p> |
| 328 | Tau-fluvalinate CAS No 102851-06-9 CIPAC No 786 | (RS)- α -cyano-3-phen- oxybenzyl N-(2- chloro- α,α α - trifluoro-p-tolyl)-D- valinate (Isomer ratio 1:1) | ≥ 920 g/kg (1:1 ratio of R- α - cyano and S- α - cyano isomers) Impurities: Toluene: not more than 5 g/kg | 1 June 2011 | ►M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tau-fluvalinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to aquatic organisms and ensure that conditions of use prescribe the application of adequate risk mitigation measures; — the risk to non-target arthropods and ensure that conditions of use prescribe the application of adequate risk mitigation measures; — the test material used in the toxicity dossiers shall be compared and verified against the specification of the technical material commercially manufactured. |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> — the risk of bioaccumulation/biomagnification in the aquatic environment; — the risk to non-target arthropods; <p>The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.</p> <p>The Member States concerned shall ensure that the applicant submits confirmatory information, two years after the adoption of specific guidance, as regards:</p> <ul style="list-style-type: none"> — the possible impact on the environment of the potential enantio-selective degradation in environmental matrices. |
| ▼ M27 | 329 Clethodim CAS No 99129-21-2 CIPAC No 508 | (5RS)-2-[(1EZ)-1-[(2E)-3-chloroallyloxyimino]propyl]-5-[(2RS)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one | ≥ 930 g/kg Impurities: toluene max. 4 g/kg | 1 June 2011 | ► M274 31 May 2023 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clethodim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 December 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection to aquatic organisms, birds and mammals, and shall ensure that conditions of use include the application of adequate risk mitigation measures.</p> <p>The Member States concerned shall request the submission of confirmatory information, on the basis of most recent scientific knowledge, as regards:</p> <ul style="list-style-type: none"> — the soil and groundwater exposure assessments, — the residue definition for risk assessment. <p>The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|-----------------------------|--|
| 330 | Bupirimate CAS No 41483-43-6 CIPAC No 261 | 5-butyl-2-ethylamino-6-methylpyrimidine-4-yl dimethylsulfamate | <p>≥ 945 g/kg</p> <p>Impurities:</p> <p>Ethirimol: max. 2 g/kg</p> <p>Toluene: max. 3 g/kg</p> | 1 June 2011 | ► M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bupirimate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigations, where appropriate, — the in-field risk to non-target arthropods. <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ol style="list-style-type: none"> (1) the specification of the technical material, as commercially manufactured, by appropriate analytical data; including information on the relevance of the impurities, (2) the equivalence between the specifications of the technical material; as commercially manufactured, and those of the test material used in the toxicity dossiers, (3) the kinetic parameters, the soil degradation and the adsorption and desorption parameter for the major soil metabolite DE-B ⁽⁶⁾. <p>The Member States concerned shall ensure that the applicant submits such confirmatory data and information to the Commission set out in point (1) and (2) by 30 November 2011 and the information set out in point (3) by 31 May 2013.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 332 | Fenoxycarb CAS No 79127-80-3 CIPAC No: 425 | Ethyl 2-(4-phenoxy-phenoxy)ethyl carbamate | ≥ 970 g/kg Impurities: Toluene: max. 1 g/kg | 1 June 2011 | 31 May 2021 | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenoxycarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate, — the risk to bees and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of information confirming the risk assessment for non-target arthropods and for bee brood. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013. |
| 333 | 1-decanol CAS No 112-30-1 CIPAC No 831 | Decan-1-ol | ≥ 960 g/kg | 1 June 2011 | ► <u>M274</u> 31 May 2024 ◀ | PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1-decanol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers from residues in case of use on food or feed crops; |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>— the risk for operator and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate;</p> <p>— the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>— the risk to aquatic organisms;</p> <p>— the risk to non-target arthropods and bees that may be exposed to the active substance by visiting flowering weeds present in the crop at time of application.</p> <p>Risk mitigation measures shall be applied, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information, as regards the risk to aquatic organisms and of information confirming the groundwater, surface water and sediment exposure assessments.</p> <p>The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.</p> |
| 334 | Isoxaben CAS No 82558-50-7 CIPAC No 701 | N-[3-(1-ethyl-1-methylpropyl)-1,2-oxazol-5-yl]-2,6-dimethoxybenzamide | ≥ 910 g/kg Toluene: ≤ 3 g/kg | 1 June 2011 | ►M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on isoxaben, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, the risk to non-target terrestrial plants and the potential leaching of metabolites to groundwater.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <p>(a) the specification of the technical material, as commercially manufactured,</p> <p>(b) the relevance of the impurities;</p> <p>(c) the residues in rotational crops;</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>(d) the potential risk to aquatic organisms.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a) and (b) by 30 November 2011 and the information set out in points (c) and (d) by 31 May 2013.</p> |
| 335 | <p>Fluometuron</p> <p>CAS No: 2164-17-2</p> <p>CIPAC No: 159</p> | 1,1-dimethyl-3-(α,α,α -trifluoro-m-tolyl)urea | ≥ 940 g/kg | 1 June 2011 | ►M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as herbicide on cotton may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluometuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall:</p> <ul style="list-style-type: none"> — pay particular attention to the protection of the operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; — pay particular attention to the protection of the groundwater where the active substance is applied in regions with vulnerable soil and/or climatic conditions; they shall ensure that conditions of authorisation include risk mitigation measures and the obligation to carry out monitoring programmes to verify potential leaching of fluometuron and soil metabolites desmethyl-fluometuron and trifluoromethylaniline in vulnerable areas, where appropriate; — pay particular attention to the risk to non-target soil macro-organisms others than earthworms and non-target plants, and ensure that conditions of authorisation include risk mitigation measures, where appropriate. <p>The Member States concerned shall ensure that the applicants submit to the Commission confirmatory information as regards:</p> <ul style="list-style-type: none"> (a) the toxicological properties of the plant metabolite trifluoroacetic acid; (b) the analytical methods for the monitoring of fluometuron in air; (c) the analytical methods for the monitoring of the soil metabolite trifluoromethylaniline in soil and water; |

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| | | | | | | <p>(d) the relevance for ground water of the soil metabolites desmethyl-fluometuron and trifluoromethylaniline, if fluometuron is classified under Regulation (EC) No 1272/2008 as 'suspected of causing cancer'.</p> <p>The Member States concerned shall ensure that the applicants submit to the Commission the information set out in points (a), (b) and (c) by 31 March 2013 and the information set out in point (d) within six months from the notification of the decision classifying fluometuron.</p> |
| 336 | Carbetamide CAS No 16118-49-3 CIPAC No 95 | (R)-1-(Ethylcarbamoyl)ethyl carb-anilate | ≥ 950 g/kg | 1 June 2011 | 31 May 2021 | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on carbetamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>(b) the risk to non-target plants;</p> <p>(c) the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
| 337 | Carboxin CAS No 5234-68-4 CIPAC No 273 | 5,6-dihydro-2-methyl-1,4-oxathine-3-carboxanilide | ≥ 970 g/kg | 1 June 2011 | ►M296 31 May 2021 ◀ | <p>PART A</p> <p>Only uses as fungicide for seed treatment may be authorised.</p> <p>Member States shall ensure that authorisations provide that seed coating be performed exclusively in professional seed treatment facilities and that these facilities apply the best available techniques to exclude the release of dust clouds during storage, transport and application.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on carboxin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to operators; — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to birds and mammals. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> (a) the specification of the technical material, as commercially manufactured, -including appropriate analytical data-; (b) the relevance of the impurities; (c) comparison and verification of the test material used in the mammalian toxicity and ecotoxicity dossiers against the specification of the technical material; (d) analytical methods for the monitoring of the metabolite M6 ⁽⁷⁾ in soil, groundwater and surface water and for the monitoring of metabolite M9 ⁽⁸⁾ in groundwater; (e) additional values regarding the period required for 50 percent dissipation in soil for the soil metabolites P/V-54 ⁽⁹⁾ and P/V-55 ⁽¹⁰⁾, (f) rotational crop metabolism, (g) the long-term risk to granivorous birds, granivorous mammals and herbivorous mammals; (h) the relevance for ground water of the soil metabolites P/V-54 ⁽¹¹⁾, P/V-55 ⁽¹²⁾ and M9 ⁽¹³⁾ if carboxin is classified under Regulation (EC) No 1272/2008 as ‘suspected of causing cancer’ |

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| | | | | | | The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a), (b) and (c) by 30 November 2011, the information set out in points (d), (e), (f) and (g) by 31 May 2013 and the information set out in point (h) six months after the notification of decision classifying carboxin. |
| 338 | Cyproconazole CAS No 94361-06-5 CIPAC No 600 | (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol | ≥ 940 g/kg | 1 June 2011 | 31 May 2021 | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyproconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the dietary exposure of consumers to the residues of triazole derivative metabolites (TDMs); — the risk to aquatic organisms. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> (a) the toxicological relevance of the impurities in the technical specification; (b) analytical methods for the monitoring of cyproconazole in soil, body fluids and tissues; (c) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; (d) the long term risk to herbivorous mammals; (e) the possible environmental impact of the preferential degradation and/or conversion of the mixture of isomers. <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 30 November 2011, the information set out in points (b), (c) and (d) by 31 May 2013 and the information set out in point (e) two years after the adoption of specific guidance.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 339 | Dazomet CAS No 533-74-4 CIPAC No 146 | 3,5-dimethyl-1,3,5-thiadiazinane-2-thione or tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione | ≥ 950 g/kg | 1 June 2011 | ► M274 31 May 2023 ◀ | <p>PART A</p> <p>Only uses as nematocide, fungicide, herbicide and insecticide may be authorised. Only application as soil fumigant may be authorised. Use shall be limited to one application every third year.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dazomet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to operators, workers and bystanders; — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> (a) the potential groundwater contamination by methyl isothiocyanate; (b) the assessment of the long range atmospheric transport potential of methyl isothiocyanate and related environmental risks; (c) the acute risk to insectivorous birds; (d) the long term risk to birds and mammals. <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b), (c) and (d) by 31 May 2013.</p> |

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| 340 | <p>Metaldehyde</p> <p>CAS No 108-62-3 (tetramer)</p> <p>9002-91-9 (homopolymer)</p> <p>CIPAC No 62</p> | r-2, c-4, c-6, c-8-tetramethyl-1,3,5,7-tetroxocane | <p>≥ 985 g/kg</p> <p>acetaldehyde max. 1,5 g/kg</p> | 1 June 2011 | ►M274 31 May 2023 ◀ | <p>PART A</p> <p>Only uses as molluscicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metaldehyde, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to operators and workers; — the dietary exposure situation of consumers in view of future revisions of maximum residue levels; — the acute risk and long term risk to birds and mammals. <p>Member States shall ensure that authorisations shall contain an effective dog repellent agent.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
| 341 | <p>Sintofen</p> <p>CAS No 130561-48-7</p> <p>CIPAC No 717</p> | 1-(4-chlorophenyl)-1,4-dihydro-5-(2-methoxyethoxy)-4-oxocinnoline-3-carboxylic acid | <p>≥ 980 g/kg</p> <p>Impurities:</p> <p>2-methoxyethanol, not more than 0,25 g/kg</p> <p>N,N-dimethylformamide, not more than 1,5 g/kg</p> | 1 June 2011 | ►M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as a plant growth regulator on wheat for hybrid seed production not intended for human consumption may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sintofen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include</p> |

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| | | | | | | <p>the application of adequate risk mitigation measures. They shall ensure that wheat treated with sintofen does not enter the food and feed chain.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <p>(1) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data;</p> <p>(2) the relevance of the impurities present in the technical specifications, except of the impurities 2-methoxyethanol and N,N-dimethylformamide;</p> <p>(3) the relevance of the test material used in the toxicity and ecotoxicity dossiers in view of the specification of the technical material;</p> <p>(4) the metabolic profile of sintofen in rotational crops.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission: the information set out in points (1) (2) and (3) by 30 November 2011 and the information set out in point (4) by 31 May 2013.</p> |
| 342 | Fenazaquin CAS No 120928-09-8 CIPAC No 693 | 4-tert-butylphenethyl quinazolin-4-yl ether | ≥ 975 g/kg | 1 June 2011 | ► M274 31 May 2023 ◀ | <p>► M256 PART A</p> <p>Only uses as acaricide in greenhouses may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenazaquin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, and of the addendum to the review report on fenazaquin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 22 March 2018, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the protection of aquatic organisms;</p> <p>(b) the protection of operators, also ensuring that the conditions of the use include the application of adequate personal protective equipment;</p> |

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| | | | | | | <p>(c) the protection of bees;</p> <p>(d) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses;</p> <p>(e) the risk to consumers, in particular from the residues generated during processing;</p> <p>(f) the conditions of use to avoid exposure to residues of fenazaquin with respect to crops for human and animal consumption.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate. ◀</p> |
| 343 | <p>Azadirachtin</p> <p>CAS No 11141-17-6 (azadirachtin A)</p> <p>CIPAC No 627 (azadirachtin A)</p> | <p>Azadirachtin A:</p> <p>dimethyl (2aR,3S,4S,4aR,5S,7aS,8S,10R,10aS,10bR)-10-acetoxy-3,5-dihydroxy-4-[(1aR,2S,3aS,6aS,7S,7aS)-6a-hydroxy-7a-methyl-3a,6a,7,7a-tetrahydro-2,7-methanofuro[2,3-b]oxireno[e]oxepin-1a(2H)-yl]-4-methyl-8-{{[(2E)-2-methylbut-2-enoyl]oxy}octahydro-1H-naphtho[1,8a-c:4,5-b'c']difuran-5,10a(8H)-dicarboxylate.</p> | <p>Expressed as azadirachtin A:</p> <p>≥ 111 g/kg</p> <p>Sum of the aflatoxins B1, B2, G1, G2 must not exceeding 300 µg/kg of the azadirachtin A content.</p> | 1 June 2011 | ►M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azadirachtin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of non target arthropods and aquatic organisms. Risk mitigation measures shall be applied where appropriate. <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> — the relationship between azadirachtin A and the rest of the active components in the neem seeds extract with respect to amount, biological activity and persistence, in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material, residue definition and groundwater risk assessment. <p>The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 December 2013.</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|---|------------------|-----------------------------|--|
| 344 | Diclofop CAS No 40843-25-2 (parent) CAS No 257-141-8 (diclofop-methyl) CIPAC No 358 (parent) CIPAC No 358.201 (diclofop-methyl) | Diclofop (RS)-2-[4-(2,4-dichlorophenoxy)phenoxy]propionic acid Diclofop-methyl methyl (RS)-2-[4-(2,4-dichlorophenoxy)phenoxy]propionate | ≥ 980 g/kg (expressed as diclofop-methyl) | 1 June 2011 | ► M274 31 May 2023 ◀ | PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diclofop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: — pay particular attention to the operators and workers safety and include as a condition for authorisation the application of adequate personal protective equipment; — pay particular attention to the risk to aquatic organisms and non target plants and require risk mitigation measures to be applied. The Member States concerned shall request the submission of confirmatory information as regards: (a) a metabolism study on cereals; (b) an update of the risk assessment concerning the possible environmental impact of the preferential degradation/conversion of the isomers. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 31 May 2013 and the information set out in point (b) at latest two years after the adoption of a specific guidance document on evaluation of isomers mixtures. |
| 345 | Lime sulphur CAS No 1344 - 81 - 6 CIPAC No 17 | Calcium polysulfide | ≥ 290 g/Kg. | 1 June 2011 | ► M274 31 May 2024 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lime sulphur, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|------------|------------------|-----------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — operator safety and shall ensure that the conditions of authorisation include appropriate protective measures; — to the protection of aquatic organisms and non target arthropods and shall ensure that the conditions of use include risk mitigation measures as appropriate. |
| 346 | Aluminium sulfate CAS No 10043-01-3 CIPAC not available | Aluminium sulfate | 970 g/kg | 1 June 2011 | ► M274 31 May 2024 ◀ | <p>PART A</p> <p>Only indoor uses as post-harvest bactericide for ornamental plants may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium sulfate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards the specification of the technical material, as commercially manufactured, in the form of appropriate analytical data.</p> <p>The Member States concerned shall ensure that the applicant submits such information to the Commission by 30 November 2011.</p> |
| 347 | Bromadiolone CAS No 28772-56-7 CIPAC No 371 | 3-[(1RS,3RS;1RS,-3SR)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-coumarin | ≥ 970 g/kg | 1 June 2011 | 31 May 2021 | <p>PART A</p> <p>Only uses as rodenticide in the form of pre-prepared baits placed into the rodent tunnels may be authorised.</p> <p>The nominal concentration of the active substance in the plant protection products shall not exceed 50 mg/kg.</p> <p>Authorisations shall be granted for uses by professional users only.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bromadiolone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|------------|------------------|------------------------|--|
| | | | | | | <p>— pay particular attention to the risk to professional operators and ensure that conditions of use include the application of adequate personal protective equipment where appropriate;</p> <p>— pay particular attention to the risk to birds and non-target mammals from primary and secondary poisoning.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <p>(a) the specification of the technical material, as commercially manufactured, in the form of appropriate analytical data;</p> <p>(b) the relevance of the impurities;</p> <p>(c) the determination of bromadiolone in water with a limit of quantification of 0,01 µg/l;</p> <p>(d) the effectiveness of proposed mitigation measures to reduce risk to birds and non-target mammals;</p> <p>(e) the groundwater exposure assessment in respect of metabolites.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b) and (c) by 30 November 2011 and the information set out in points (d) and (e) by 31 May 2013.</p> |
| 348 | Paclobutrazol CAS No 76738-62-0 CIPAC No 445 | (2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol | ≥ 930 g/kg | 1 June 2011 | ►M274 31 May 2023 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on paclobutrazol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic plants and ensure that conditions of use include the risk mitigation measures, where appropriate.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|------------------|-----------------------------|---|
| | | | | | | <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <p>(1) the specification of the technical material, as commercially manufactured;</p> <p>(2) the analytical methods in soil and surface water for the metabolite NOA457654;</p> <p>(3) the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin;</p> <p>(4) the potential endocrine disrupting properties of paclobutrazol;</p> <p>(5) the potential adverse effects of breakdown products of the different optical structures of paclobutrazol and its metabolite CGA 149907 on the environmental compartments soil, water and air.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 30 November 2011, the information set out in points (3) by 31 May 2013, the information set out in point (4) within two years after the adoption of the OECD test guidelines on endocrine disruption and the information set out in point (5) within two years after the adoption of specific guidance.</p> |
| 349 | Pencycuron CAS No 66063-05-6 CIPAC No 402 | 1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea | ≥ 980 g/kg | 1 June 2011 | ► M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pencycuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of large omnivorous mammals.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> |

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| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|------------------------|--|
| | | | | | | <p>(1) the fate and behaviour in soil of the chlorophenyl and cyclopentyl portions of pencycuron;</p> <p>(2) the fate and behaviour in natural surface water and sediment systems of the chlorophenyl and phenyl portions of pencycuron;</p> <p>(3) the long-term risk to large omnivorous mammals.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1), (2) and (3) by 31 May 2013.</p> |
| 350 | Tebufenozide CAS No 112410-23-8 CIPAC No 724 | N-tert-butyl-N'-(4-ethylbenzoyl)-3,5-dimethylbenzohydrazide | <p>≥ 970 g/kg</p> <p>Relevant impurity</p> <p>t-butyl hydrazine < 0,001 g/kg</p> | 1 June 2011 | ►M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as insecticide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebufenozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall:</p> <ul style="list-style-type: none"> — pay particular attention to the safety of operators and workers after re-entry and ensure that conditions of authorisation prescribe appropriate protective equipment; — pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — pay particular attention to the protection of aquatic organism and ensure that conditions of use prescribe adequate mitigation measures; — pay particular attention to the risk to Lepidoptera non-target insects. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information, as regards:</p> <p>(1) the relevance of metabolites RH-6595, RH-2651, M2;</p> |

▼B

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|-----------------------|--------------------|----------------------------|---|
| | | | | | | <p>(2) the degradation of tebufenozide in anaerobic soils and soils of alkaline pH.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 31 May 2013.</p> |
| 351 | <p>Dithianon</p> <p>CAS No 3347-22-6</p> <p>CIPAC No 153</p> | <p>5,10-dihydro-5,10-dioxonaphtho[2,3-b]-1,4-dithiine-2,3-dicarbonitrile</p> | <p>≥ 930 g/kg</p> | <p>1 June 2011</p> | <p>►M274 31 May 2024 ◀</p> | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dithianon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall:</p> <ul style="list-style-type: none"> — pay particular attention to the protection of aquatic organisms; conditions of use shall include risk mitigation measures, where appropriate, — pay particular attention to the operator safety; conditions of use shall include the application of adequate personal protective equipment, where appropriate, — pay particular attention to the long-term risks to birds; conditions of use shall include risk mitigation measures, where appropriate. <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> — the storage stability and the nature of residues in processed products, — the aquatic and groundwater exposure assessment for phthalic acid, — the risk assessment for aquatic organisms with respect to phthalic acid, phthalaldehyde and 1,2 benzenedimethanol. <p>The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|------------------------|--|
| 352 | Hexythiazox CAS No 78587-05-0 CIPAC No 439 | (4RS,5RS)-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxo-1,3-thiazolidine-3-carboxamide | ≥ 976 g/kg (1:1 mixture of (4R, 5R) and (4S, 5S)) | 1 June 2011 | ► M274 31 May 2024 ◀ | <p>PART A</p> <p>Only uses as acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on hexythiazox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate; — the operators and workers safety. Conditions of use shall include protective measures, where appropriate. <p>The Member States concerned shall request the submission of confirmatory information as regards:</p> <ul style="list-style-type: none"> (a) the toxicological relevance of the metabolite PT-1-3 ⁽¹⁴⁾; (b) the potential occurrence of the metabolite PT-1-3 in processed commodities; (c) the potential adverse effects of hexythiazox on bee brood; (d) the possible impact of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environment. <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b) and (c) by 31 May 2013 and the information set out in point (d) two years after the adoption of specific guidance.</p> |

▼ B

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|---|------------------|-----------------------------|---|
| 353 | Flutriafol CAS No 76674-21-0 CIPAC No 436 | (RS)-2,4'-difluoro- α -(1H-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol | ≥ 920 g/kg (racemate) Relevant impurities: dimethyl sulphate: max content 0,1 g/kg dimethylformamide: max content 1 g/kg methanol: max content 1 g/kg | 1 June 2011 | ► M274 31 May 2024 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flutriafol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: — pay particular attention to the protection of the workers' safety and ensure that conditions of use include the application of adequate personal protective equipment; — pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — pay particular attention to the long-term risk to insectivorous birds. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards: (a) the relevance of the impurities present in the technical specifications; (b) the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; (c) the long-term risk to insectivorous birds. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 30 November 2011, the information set out in points (b) and (c) by 31 May 2013. |

▼B

▼C1

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|------------------------|--|
| 354 | Flurochloridone CAS No 61213-25-0 CIPAC No 430 | <i>(3RS,4RS;3RS,4SR)-3-chloro-4-chloro-methyl-1-(α,α-trifluoro-<i>m</i>-tolyl)-2-pyrrolidone</i> | ≥ 940 g/kg. Relevant impurities: Toluene: max 8 g/kg | 1 June 2011 | 31 May 2021 | PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flurochloridone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 February 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: 1. the risk for non-target plants and aquatic organisms; 2. the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicant submits to the Commission further confirmatory information as regards: 1. the relevance of impurities other than toluene; 2. the compliance of ecotoxicological test material with the technical specifications; 3. the relevance of the groundwater metabolite R42819 ⁽¹⁵⁾ ; 4. the potential endocrine disrupting properties of flurochloridone. |

▼ **C1**

| Number | Common name, identification numbers | IUPAC name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 1 December 2011, the information set out in point (3) by 31 May 2013 and the information set out in point (4) within two years after the adoption of the OECD test guidelines on endocrine disruption. |

▼ **B**

⁽¹⁾ Further details on identity and specification of active substances are provided in their review reports.

⁽²⁾ Suspended by order of the General Court of 19 July 2007 in case T-31/07 R, Du Pont de Nemours (France) SAS and others v Commission, [2007] ECR II-2767.

⁽³⁾ OJ L 353, 31.12.2008, p. 1.

⁽⁴⁾ 2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide.

⁽⁵⁾ 2-ethyl-7-nitro-1H-benzimidazole-5-sulfonamide.

⁽⁶⁾ De-ethyl-bupirimate.

⁽⁷⁾ 2- {[anilino(oxo)acetyl]sulfanyl}ethyl acetate.

⁽⁸⁾ (2*RS*)-2-hydroxy-2-methyl-*N*-phenyl-1,4-oxathiane-3-carboxamide 4-oxide.

⁽⁹⁾ 2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4-oxide.

⁽¹⁰⁾ 2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4,4-dioxide.

⁽¹¹⁾ 2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4-oxide.

⁽¹²⁾ 2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4,4-dioxide.

⁽¹³⁾ (2*RS*)-2-hydroxy-2-methyl-*N*-phenyl-1,4-oxathiane-3-carboxamide 4-oxide.

⁽¹⁴⁾ (4*S*,5*S*)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one and (4*R*,5*R*)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one.

► **C1** ⁽¹⁵⁾ R42819: (4*RS*)-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one. ◀

► **M23** ⁽¹⁶⁾ 1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol. ◀

► **M31** ⁽¹⁷⁾ OJ L 300, 14.11.2009, p. 1.

⁽¹⁸⁾ OJ L 54, 26.2.2011, p. 1. ◀

► **M202** ⁽¹⁹⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

⁽²⁰⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1). ◀

PART B

Active substances approved under Regulation (EC) No 1107/2009

General provisions applying to all substances listed in this Part:

- for the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009 in relation to each substance, the conclusions of the review report on it, and in particular the Appendices I and II thereof, shall be taken into account;
- Member States shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make it available to them on specific request.

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|--|------------------|------------------------------|---|
| 1 | Bispyribac CAS No 125401-75-4 CIPAC No 748 | 2,6-bis(4,6-dimethoxypyrimidin-2-yl)benzoic acid | ≥ 930 g/kg (referred to as bispyribac-sodium) | 1 August 2011 | ► M286 31 July 2023 ◀ | <p>PART A</p> <p>Only uses as herbicide in rice may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bispyribac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> <p>In this overall assessment, Member States shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.</p> <p>Conditions of authorisation shall include risk mitigation measures where appropriate.</p> <p>The Member States concerned shall request the submission of further information as regards the possible groundwater contamination by metabolites M03 ⁽²⁾, M04 ⁽³⁾ and M10 ⁽⁴⁾.</p> <p>They shall ensure that the applicant provides such information to the Commission by 31 July 2013.</p> |

▼ **M1**▼ **M7**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|---|------------------|------------------------|--|
| 2 | Profoxydim CAS No 139001-49-3 CIPAC No 621 | 2 - [(1 <i>E/Z</i>) - [(2 <i>R S</i>) - 2 - (4 - chloro-phenoxy) propoxy-imino] butyl] - 3 - hydroxy - 5 - [(3 <i>R S</i> ; 3 <i>S R</i>) - tetrahydro - 2 H - thiopyran - 3 - yl] cyclohex - 2 - enone | ≥ 940 g/kg | 1 August 2011 | 31 July 2021 | <p>PART A</p> <p>Only uses as herbicide in rice may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on profoxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> <p>In this overall assessment, Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the long-term risk to non-target organisms. <p>Conditions of authorisation shall include risk mitigation measures where appropriate.</p> |
| 3 | Azimsulfuron CAS No 120162-55-2 CIPAC No 584 | 1-(4,6-dimethoxy-pyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea | ≥ 980 g/kg maximum level of the impurity phenol 2 g/kg | 1 January 2012 | 31 December 2021 | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>Aerial applications may not be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azimsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> |

▼ **M5**

▼ **M5**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(1) the protection of non-target plants;</p> <p>(2) the potential for groundwater contamination, when the active substance is applied in vulnerable scenarios and/or climatic conditions;</p> <p>(3) the protection of aquatic organisms.</p> <p>Member States shall ensure that the conditions of authorisation include risk mitigation measures, where appropriate (e.g. buffer zones, in rice cultivation minimum holding periods for water prior to discharge).</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) the risk assessment on aquatic organisms;</p> <p>(b) the identification of the degradation products in the aqueous photolysis of the substance.</p> <p>The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.</p> |

▼ **M4**

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|---|---|---|---|----------------|----------------------------------|--|
| 4 | <p>Azoxystrobin</p> <p>CAS No 131860-33-8</p> <p>CIPAC No 571</p> | <p>methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]phenyl}-3-methoxyacrylate</p> | <p>≥ 930 g/kg</p> <p>Toluene maximum content 2 g/kg</p> <p>Z-isomer maximum content 25 g/kg</p> | 1 January 2012 | ► M295 31 December 2024 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> |
|---|---|---|---|----------------|----------------------------------|--|

▼ **M4**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(1) the fact that the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material;</p> <p>(2) the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>(3) the protection of aquatic organisms.</p> <p>The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards the risk assessment on groundwater and aquatic organisms.</p> <p>The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.</p> |

▼ **M6**

| | | | | | | |
|---|--|--|------------|----------------|----------------------------------|--|
| 5 | Imazalil CAS No 35554-44-0 73790-28-0 (replaced) CIPAC No 335 | (RS)-1-(β-allyloxy-2,4-dichlorophenethyl)imidazole or allyl (RS)-1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether | ≥ 950 g/kg | 1 January 2012 | ► M295 31 December 2024 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on imazalil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. |
|---|--|--|------------|----------------|----------------------------------|--|

▼ **M6**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall:</p> <ol style="list-style-type: none"> (1) pay particular attention to the fact that the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material; (2) pay particular attention to the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels; (3) pay particular attention to the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure; (4) ensure that appropriate waste management practices to handle the waste solution remaining after application, such as the cleaning water of the drenching system and the discharge of the processing waste are put in place. Prevention of any accidental spillage of treatment solution. Member States permitting the release of waste water into the sewage system shall ensure that a local risk assessment is carried out; (5) pay particular attention to risk to aquatic organisms and soil micro-organisms and long-term risk to granivorous birds and mammals. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The notifier shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> (a) route of degradation of imazalil in soil and surface water systems; |

▼ **M6**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>(b) environmental data to support the managing measures that Member States have to put in place to ensure that groundwater exposure is negligible;</p> <p>(c) a hydrolysis study to investigate the nature of residues in processed commodities.</p> <p>The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.</p> |

▼ **M3**

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| 6 | <p>Prohexadione</p> <p>CAS No 127277-53-6 (<i>prohexadione-calcium</i>)</p> <p>CIPAC No 567 (<i>prohexadione</i>)</p> <p>No 567.020 (<i>prohexadione-calcium</i>)</p> | 3,5-dioxo-4-propionylcyclohexanecarboxylic acid | <p>≥ 890 g/kg</p> <p>(expressed as prohexadione-calcium)</p> | 1 January 2012 | ► M295 31 December 2022 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prohexadione and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> |
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▼ **M13**

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| 7 | <p>Spiroxamine</p> <p>CAS No 1181134-30-8</p> <p>CIPAC No 572</p> | 8- <i>tert</i> -butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine (ISO) | <p>≥ 940 g/kg</p> <p>(diastereomers A and B combined)</p> | 1 January 2012 | ► M295 31 December 2023 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiroxamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(1) the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment;</p> |
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▼ **M13**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|--|
| | | | | | | <p>(2) the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>(3) the risk to aquatic organisms.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) the possible impact on the worker, the consumer and the environmental risk assessment of the potential stereo-selective degradation of each isomer in plant, animals and the environment;</p> <p>(b) the toxicity of the plant metabolites formed in fruit crops and the potential hydrolysis of fruit crop residues in processed commodities;</p> <p>(c) the groundwater exposure assessment for metabolite M03 ⁽⁷⁾;</p> <p>(d) the risk to aquatic organisms.</p> <p>The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by two years after the adoption of specific guidance and the information set out in points (b), (c) and (d) by 31 December 2013.</p> |

▼ **M18**

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|---|---|--|--|-----------------------|---|--|
| 8 | <p>Kresoxim-methyl</p> <p>CAS No 143 390-89-0</p> <p>CIPAC No 568</p> | <p>methyl (E)-methoxy-imino[a-(o-tolyloxy)-o-tolyl]acetate</p> | <p>≥ 910 g/kg</p> <p>Methanol: max. 5 g/kg</p> <p>Methyl chloride: max. 1 g/kg</p> <p>Toluene: max. 1 g/kg</p> | <p>1 January 2012</p> | <p>► M295 31 December 2024 ◀</p> | <p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on kresoxim-methyl and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account.</p> |
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▼ **M18**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|--|------------------|----------------------------------|--|
| | | | | | | <p>Member States shall pay particular attention to the protection of groundwater under vulnerable conditions; the conditions of authorisation shall include, where appropriate, risk mitigation measures.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>Groundwater exposure risk assessment, and in particular:</p> <ul style="list-style-type: none"> — on the lysimeter study to support the statement that the two unidentified peaks observed do not correspond to metabolites individually exceeding the trigger value of 0,1 µg/L, — on the recovery of metabolite BF 490-5 in order to confirm its absence in the lysimeter leachate at levels exceeding 0,1 µg/L, — on a groundwater exposure risk assessment for the late application in apples, pears and grapes. <p>The applicant shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.</p> |
| 9 | Fluroxypyr CAS No 69377-81-7 CIPAC No 431 | 4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid | <p>► M225 ≥ 950 g/kg (fluroxypyr-meptyl)</p> <p>The following manufacturing impurity is of toxicological concern and must not exceed the following amount in the technical material:</p> <p>N-methyl-2-pyrrolidone (NMP): < 3 g/kg ◀</p> | 1 January 2012 | ► M295 31 December 2024 ◀ | <p>► M225 PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluroxypyr, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 23 March 2017 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the potential contamination of groundwater by metabolite fluroxypyr pyridinol, when the active substance is applied in regions with alkaline or vulnerable soil or with vulnerable climatic conditions; — the risk to aquatic organisms. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀</p> |

▼ **M8**

▼ **M1**▼ **M15**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|--|------------------|----------------------------------|--|
| 10 | Tefluthrin CAS No: 79538-32-2 CIPAC No: 451 | 2,3,5,6-tetrafluoro-4-methylbenzyl (1 <i>RS</i> , 3 <i>RS</i>)-3-[(<i>Z</i>)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate Tefluthrin is a 1:1 mixture of <i>Z</i> -(1 <i>R</i> , 3 <i>R</i>) and <i>Z</i> -(1 <i>S</i> , 3 <i>S</i>) enantiomers. | ≥ 920 g/kg Hexachlorobenzene: not more than 1 mg/kg | 1 January 2012 | ► M295 31 December 2024 ◀ | PART A Only uses as insecticide may be authorised. The seed coating shall only be performed in professional seed treatment facilities. These facilities shall apply the best available techniques in order to exclude the release of dust clouds during storage, transport and application. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tefluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operators and workers safety and include among the authorised conditions of use the application of adequate personal protective equipment as well as respiratory protective equipment, — the risk to birds and mammals. Risk mitigation measures should be applied to grant a high degree of incorporation in soil and avoidance of spillage, — ensure that the label of treated seed includes the indication that the seeds were treated with tefluthrin and sets out the risk mitigation measures provided for in the authorisation. The applicant shall submit confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured; (2) a validated analytical method for water; (3) the possible environmental impact of the preferential degradation/conversion of the isomers and an estimation of the relative toxicity and risk assessment for the workers. The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 30 June 2012, the information set out in point (2) by 31 December 2012, and the information set out in point (3) 2 years after the adoption of a specific guidance document on evaluation of isomers mixture. |

▼ **M1**▼ **M14**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|--|------------------|----------------------------------|---|
| 11 | Oxyfluorfen CAS No 42874-03-3 CIPAC No 538 | 2-chloro- α,α,α -trifluoro- <i>p</i> -tolyl 3-ethoxy-4-nitrophenyl ether | ≥ 970 g/kg Impurities: N,N-dimethylnitrosamine: not more than 50 μ g/kg | 1 January 2012 | ► M295 31 December 2024 ◀ | <p>► M203 PART A</p> <p>Only uses as herbicide for banded applications close to ground from autumn to early spring may be authorised, at a rate not exceeding 150 g active substance per hectare, per year.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxyfluorfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed, shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — operator safety and ensure that conditions of use impose the application of adequate personal protective equipment where appropriate, — the risks to aquatic organisms, earthworm-eating mammals, soil-living macro-organisms, non-target arthropods and non-target plants. <p>Conditions of authorisation shall include risk mitigation measures such as no-spray buffer zones and drift reducing nozzles and shall provide for respective labelling of plant protection products. Those conditions shall include further risk mitigation measures, where appropriate. ◀</p> |
| 12 | 1-naphthylacetamide CAS No 86-86-2 CIPAC No 282 | 2-(1-naphthyl)acetamide | ≥ 980 g/kg | 1 January 2012 | ► M295 31 December 2023 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the</p> |

▼ **M10**

▼ **M10**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>review report on 1-naphthylacetamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account.</p> <p>In this overall assessment Member States:</p> <p>(a) shall pay particular attention to the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;</p> <p>(b) shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>(c) shall pay particular attention to the risk to aquatic organisms;</p> <p>(d) shall pay particular attention to the risk to non-target plants;</p> <p>(e) shall pay particular attention to the risk to birds.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the risk to non-target plants;</p> <p>(2) the long-term risk to birds.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.</p> |

▼ **M11**

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|----|---|-----------------------|------------|----------------|----------------------------------|---|
| 13 | 1-naphthylacetic acid CAS No 86-87-3 CIPAC No 313 | 1-naphthylacetic acid | ≥ 980 g/kg | 1 January 2012 | ► M295 31 December 2023 ◀ | <p>PART A</p> <p>Only uses as plant growth regulator may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1-naphthylacetic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> |
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▼ **M11**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>In this overall assessment Member States:</p> <p>(a) shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;</p> <p>(b) shall pay particular attention to the dietary exposure situation of consumers in view of future revisions of maximum residue levels;</p> <p>(c) shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>(d) shall pay particular attention to the risk to aquatic organisms;</p> <p>(e) shall pay particular attention to the risk to birds.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the route and rate of degradation in soil including an assessment of the potential for photolysis;</p> <p>(2) the long-term risk to birds.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.</p> |

▼ **M16**

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|----|---|---|------------|----------------|------------------|---|
| 14 | Fluquinconazole CAS No 136426-54-5 CIPAC No 474 | 3-(2,4-dichlorophenyl)-6-fluoro-2-(1 <i>H</i> -1,2,4-triazol-1-yl)quinazolin-4(3 <i>H</i>)-one | ≥ 955 g/kg | 1 January 2012 | 31 December 2021 | <p>PART A</p> <p>Only uses as fungicide may be authorised</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluquinconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <p>(a) shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;</p> |
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▼ **M16**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>(b) shall pay particular attention to the dietary exposure of consumers to the residues of triazole derivative metabolites (TDMs);</p> <p>(c) shall pay particular attention to the risk to birds and mammals.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin;</p> <p>(2) the contribution of the potential residues of the metabolite dione in rotational crops to the overall consumer exposure;</p> <p>(3) the acute risk to insectivorous mammals;</p> <p>(4) the long-term risk to insectivorous and herbivorous birds and mammals;</p> <p>(5) the risk to earthworm-eating mammals;</p> <p>(6) the endocrine disruption potential in aquatic organisms (fish full life cycle study).</p> <p>The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.</p> |

▼ **M12**

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|----|---|--|---|----------------|----------------------------------|--|
| 15 | <p>Fluazifop P</p> <p>CAS No 83066-88-0 (fluazifop-P)</p> <p>CIPAC No 467 (fluazifop-P)</p> | <p>(R)-2-{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy}propionic acid (fluazifop-P)</p> | <p>≥ 900 g/kg in fluazifop P-butyl</p> <p>The following impurity 2-chloro-5-(trifluoromethyl)pyridine must not exceed 1,5 g/kg in the material as manufactured.</p> | 1 January 2012 | ► M295 31 December 2023 ◀ | <p>► M53 PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluazifop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall:</p> <p>— pay particular attention to consumer safety as regards the occurrence in groundwater of the metabolite compound X ⁽⁵⁾;</p> |
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▼ **M12**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|--|
| | | | | | | <p>— pay particular attention to operator safety and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;</p> <p>— pay particular attention to the protection of surface water and groundwater in vulnerable zones;</p> <p>— pay particular attention to the risk for non-target plants.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the specification of the technical material, as commercially manufactured, including information on the relevance of the impurity R154719;</p> <p>(2) the equivalence between the specifications of the technical material, as commercially manufactured, and the specifications of the test material used in the toxicity studies;</p> <p>(3) the potential long-term risk to herbivorous mammals;</p> <p>(4) the fate and behaviour in the environment of the metabolite compounds X ⁽⁵⁾ and IV ⁽⁶⁾;</p> <p>(5) the potential risk to fish and aquatic invertebrates for the metabolite compound IV ⁽⁶⁾.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) and (2) by 30 June 2012 and the information set out in points (3), (4) and (5) by 31 December 2013. ◀</p> |

▼ **M19**

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|----|--|--|--|----------------|----------------------------------|---|
| 16 | Terbuthylazine CAS No 5915-41-3 CIPAC No 234 | N2-tert-butyl-6-chloro-N4-ethyl-1,3,5-triazine-2,4-diamine | <p>≥ 950 g/kg</p> <p>Impurities:</p> <p>Propazine not more than 10 g/kg</p> <p>Atrazine not more than 1 g/kg</p> <p>Simazine not more than 30 g/kg</p> | 1 January 2012 | ► M295 31 December 2024 ◀ | <p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on terbuthylazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p> |
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▼ **M19**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>(b) the risk to mammals and earthworms.</p> <p>Conditions of use shall include risk mitigation measures and the obligation to carry out monitoring programmes to verify potential groundwater contamination in vulnerable zones, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the specification of the technical material, as commercially manufactured, by appropriate analytical data, including information on the relevance of the impurities;</p> <p>(2) the equivalence between the specifications of the technical material, as commercially manufactured, and the specifications of the test material used in the toxicity studies;</p> <p>(3) groundwater exposure assessment for the unidentified metabolites LM1, LM2, LM3, LM4, LM5 and LM6;</p> <p>(4) the relevance of the metabolites MT1 (N-tert-butyl-6-chloro-1,3,5-triazine-2,4-diamine), MT 13 (4-(tert-butylamino)-6-(ethylamino)-1,3,5-triazin-2-ol or 6-hydroxy-N2-ethyl-N4-tert-butyl-1,3,5-triazine-2,4-diamine), MT14 (4-amino-6-(tert-butylamino)-1,3,5-triazin-2-ol or N-tert-butyl-6-hydroxy-1,3,5-triazine-2,4-diamine), and of the unidentified metabolites LM1, LM2, LM3, LM4, LM5 and LM6 with respect to cancer, if terbutylazine is classified under Regulation (EC) No 1272/2008 as 'suspected of causing cancer'.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) and (2) by 30 June 2012, the information set out in point (3) by 30 June 2013 and the information set out in point (4) within six months from the notification of the classification decision concerning that substance.</p> |

▼ **M1**▼ **M17**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|------------------------|--|
| 17 | Triazoxide CAS No 72459-58-6 CIPAC No 729 | 7-chloro-3-imidazol-1-yl-1,2,4-benzotriazine 1-oxide | ≥ 970 g/kg Impurities: toluene: not more than 3 g/kg | 1 October 2011 | 30 September 2021 | PART A Only uses as fungicide for use as seed treatment may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triazoxide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account. In this overall assessment Member States: (a) shall pay particular attention to the protection of operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate; (b) shall pay particular attention to the risk to granivorous birds and shall ensure that conditions of authorisation include risk mitigation measures. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the long-term risk to granivorous mammals by 30 September 2013. |
| 18 | 8-hydroxyquinoline CAS No 148-24-3 (8-hydroxyquinoline) CIPAC No 677 (8-hydroxyquinoline) | 8-quinolinol | ≥ 990 g/kg | 1 January 2012 | 31 December 2021 | PART A Only uses as fungicide and bactericide in greenhouses may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 8-hydroxyquinoline, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2011 shall be taken into account. |

▼ **M21**

▼ **M21**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to the operator safety and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate.</p> <p>The applicant shall submit confirmatory information on 8-hydroxyquinoline and its salts as regards:</p> <p>(1) the method of analysis for air;</p> <p>(2) a new storage stability covering the storage time periods of samples from both the metabolism study and from the supervised residue trials.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.</p> |

▼ **M20**

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|----|--|---|--|----------------|----------------------------------|---|
| 19 | <p>Acrinathrin</p> <p>CAS No 101007-06-1</p> <p>CIPAC No 678</p> | <p>(S)-α-cyano-3-phenoxymethyl (Z)-(1R,3S)-2,2-dimethyl-3-[2-(2,2,2-trifluoro-1-trifluoromethyl-ethoxycarbonyl)vinyl]cyclopropanecarboxylate or</p> <p>(S)-α-cyano-3-phenoxymethyl (Z)-(1R)-cis-2,2-dimethyl-3-[2-(2,2,2-trifluoro-1-trifluoromethyl-ethoxycarbonyl)vinyl]cyclopropanecarboxylate</p> | <p>≥ 970 g/kg</p> <p>Impurities:</p> <p>1,3-dicyclohexylurea: not more than 2 g/kg</p> | 1 January 2012 | ► M295 31 December 2023 ◀ | <p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised at rates not exceeding 22,5 g/ha per application.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acrinathrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2011 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <p>(a) shall pay particular attention to the protection of operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;</p> <p>(b) shall pay particular attention to the risk to aquatic organisms, in particular fish, and shall ensure that conditions of authorisation include risk mitigation measures, where appropriate;</p> |
|----|--|---|--|----------------|----------------------------------|---|

▼ **M20**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|--|
| | | | | | | <p>(c) shall pay particular attention to the risk to non-target arthropods and bees and shall ensure that conditions of authorisation include risk mitigation measures.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the potential risk to groundwater from the metabolite 3-PBAld ⁽¹²⁾;</p> <p>(2) the chronic risk to fish;</p> <p>(3) the risk assessment for non-target arthropods;</p> <p>(4) the possible impact on the worker, the consumer and the environmental risk assessment of the potential stereo-selective degradation of each isomer in plant, animals and the environment.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information set out in points 1, 2 and 3 by 31 December 2013 and the information set out in point 4 2 years after the adoption of specific guidance.</p> |

▼ **M25**

| | | | | | | |
|----|---|--|--|----------------|----------------------------------|--|
| 20 | Prochloraz CAS No 67747-09-5 CIPAC No 407 | <i>N</i> -propyl- <i>N</i> -[2-(2,4,6-trichlorophenoxy)ethyl]imidazole-1-carboxamide | <p>≥ 970 g/kg</p> <p>Impurities:</p> <p>Sum of dioxins and furans (WHO-PCDD/T TEQ) ⁽¹³⁾: not more than 0,01 mg/kg</p> | 1 January 2012 | ► M295 31 December 2023 ◀ | <p>PART A</p> <p>Only uses as fungicide may be authorised. In the case of outdoor uses, rates shall not exceed 450 g/ha per application.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prochloraz, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011, shall be taken into account.</p> |
|----|---|--|--|----------------|----------------------------------|--|

▼ **M25**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>In this overall assessment Member States:</p> <p>(a) shall pay particular attention to the protection of operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;</p> <p>(b) shall pay particular attention to the risk to aquatic organisms, and shall ensure that conditions of authorisation include risk mitigation measures, where appropriate;</p> <p>(c) shall pay particular attention to the long-term risk to mammals and shall ensure that conditions of authorisation include risk mitigation measures, where appropriate.</p> <p>The applicants shall submit confirmatory information as regards:</p> <p>(1) comparison and verification of the test material used in the mammalian toxicity and ecotoxicity dossiers against the specification of the technical material;</p> <p>(2) the environmental risk assessment for the metal complexes of prochloraz;</p> <p>(3) the potential endocrine disrupting properties of prochloraz on birds.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority the information set out in points 1 and 2 by 31 December 2013 and the information set out in point 3 within 2 years after the adoption of the pertinent OECD test guidelines on endocrine disruption.</p> |
| ▼ M72 | | | | | | |

▼ **M1**▼ **M30**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---------------------------|---|------------------|------------------------|--|
| 22 | Metam CAS No 144-54-7 CIPAC No 20 | Methyldithiocarbamic acid | <p>≥ 965 g/kg</p> <p>Expressed as metam-sodium on a dry weight basis</p> <p>≥ 990 g/kg</p> <p>Expressed as metam-potassium on a dry weight basis</p> <p>Relevant impurities:</p> <p>methylisothiocyanate (MITC)</p> <p>— max. 12 g/kg on dry weight basis (metam-sodium),</p> <p>— max. 0,42 g/kg on dry weight basis (metam-potassium).</p> <p><i>N,N'</i>-dimethylthiourea (DMTU)</p> <p>— max. 23 g/kg on a dry weight basis (metam-sodium),</p> <p>— max. 6 g/kg on a dry weight basis (metam-potassium).</p> | 1 July 2012 | 30 June 2022 | <p>PART A</p> <p>Only uses as nematocide, fungicide, herbicide and insecticide may be authorised for application as soil fumigant prior to planting, limited to one application every third year on the same field.</p> <p>The application may be authorised in open field by soil injection or drip irrigation, and in greenhouse by drip irrigation only. The use of gas-tight plastic film for drip irrigation shall be prescribed.</p> <p>The maximum application rate shall be 153 kg/ha (corresponding to 86,3 kg/ha of MITC) in case of open field applications.</p> <p>Authorisations shall be limited to professional users.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 March 2012, shall be taken into account.</p> <p>In this overall assessment Member States:</p> <p>(a) shall pay particular attention to the protection of operators and shall ensure that the conditions of use include risk mitigation measures such as application of adequate personal protective equipment and a limitation in the daily work rate;</p> <p>(b) shall pay particular attention to the protection of workers and shall ensure that the conditions of use include risk mitigation measures, such as use of adequate personal protective equipment, re-entry period and limitation in the daily work rate;</p> |

▼ **M30**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>(c) shall pay particular attention to the protection of bystanders and residents and shall ensure that the conditions of use include risk mitigation measures, such as an appropriate buffer zone during and until 24 hours after the application from the perimeter of the application area to any occupied residences and areas used by the general public with obligation to use warning signs and ground markers;</p> <p>(d) shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions and shall ensure that the conditions of use include risk mitigation measures, such as appropriate buffer zone;</p> <p>(e) shall pay particular attention to the risk to non-target organisms and shall ensure that conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information on methyl isothiocyanate as regards:</p> <p>(1) the assessment of the long-range atmospheric transport potential and related environmental risks;</p> <p>(2) the potential groundwater contamination.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority such information by 31 May 2014.</p> |

▼ **M33**

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|----|--|---|---|---------------|-------------------------------------|--|
| 23 | <p>Bifenthrin</p> <p>CAS No 82657-04-3</p> <p>CIPAC No 415</p> | <p>2-methylbiphenyl-3-ylmethyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate</p> <p>or</p> <p>2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate</p> | <p>≥ 930 g/kg</p> <p>Impurities:</p> <p>Toluene: not more than 5 g/kg</p> | 1 August 2012 | <p>► M296 31 July 2019 ◀</p> | <p>► M250 PART A</p> <p>Only uses as insecticide in greenhouses with a permanent structure may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> |
|----|--|---|---|---------------|-------------------------------------|--|

▼ **M33**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>(a) releases from greenhouses, such as condensation water, drain water, soil or artificial substrate, in order to preclude risks to aquatic and other non-target organisms;</p> <p>(b) the protection of pollinator colonies purposely placed in the greenhouse;</p> <p>(c) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate.</p> <p>Conditions of authorisation shall include risk mitigation measures and provide for adequate labelling of plant protection products. ◀</p> |

▼ **M34**

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|----|--|--|--|----------------|------------------|--|
| 24 | Fluxapyroxad CAS No 907204-31-3 CIPAC No 828 | 3-(difluoromethyl)-1-methyl- <i>N</i> -(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide | <p>≥ 950 g/kg</p> <p>The impurity toluene must not exceed 1 g/kg in the technical material</p> | 1 January 2013 | 31 December 2022 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluxapyroxad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to groundwater, if the active substance is applied under vulnerable soil and/or climatic conditions.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The purity given in this entry is based on a pilot plant production. The examining Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.</p> |
|----|--|--|--|----------------|------------------|--|

▼ **M1**▼ **M35**▼ **M40**▼ **M41**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|------------------------|--|
| 25 | Fenpyrazamine CAS No 473798-59-3 CIPAC No 832 | S-allyl 5-amino-2,3-dihydro-2-isopropyl-3-oxo-4-(o-tolyl)pyrazole-1-carbothioate | ≥ 940 g/kg | 1 January 2013 | 31 December 2022 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpyrazamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. The purity given in this entry is based on a pilot plant production. The examining Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured. |
| 26 | <i>Adoxophyes orana granulovirus</i> Culture collection No DSM BV-0001 CIPAC No 782 | Not applicable | No relevant impurities | 1 February 2013 | 31 January 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Adoxophyes orana granulovirus</i> , and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 July 2012 shall be taken into account. |
| 27 | Isopyrazam CAS No 881685-58-1 (syn-isomer: 683777-13-1/anti-isomer: 683777-14-2) CIPAC No 963 | <i>A mixture of</i> 3-(difluoromethyl)-1-methyl-N-[(1 <i>RS</i> ,4 <i>SR</i> ,9 <i>RS</i>)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (syn-isomer – 50:50 mix of two enantiomers) <i>and</i> | ≥ 920 g/kg In a range of 78:15 % to 100:0 % syn- to anti-isomers | 1 April 2013 | 31 March 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on isopyrazam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 September 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic organisms; (b) the risk to earthworms if the substance is applied in the framework of no cultivation/minimum cultivation practices; (c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. |

▼ **M41**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|--|-------------------------|------------------|------------------------|---|
| | | 3-(difluoromethyl)-1-methyl- <i>N</i> -[(1 <i>RS</i> ,4 <i>SR</i> ,9 <i>SR</i>)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (<i>anti</i> -isomer— 50:50 mix of two enantiomers) In a range of 78:15 % to 100:0 % <i>syn</i> to <i>anti</i> . | | | | <p>Conditions of use shall include risk mitigation measures, like the exclusion of no cultivation/minimum cultivation practices, and the obligation to carry out monitoring programmes to verify potential groundwater contamination in vulnerable zones, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the relevance of the metabolites CSCD 459488 and CSCD 459489 for groundwater.</p> <p>► M145 The applicant shall submit to the Commission, the Member States and the Authority this information by 31 July 2017. ◀</p> |

▼ **M42**

| | | | | | | |
|----|---|-----------|--|--------------|---------------|---|
| 28 | Phosphane CAS No 7803-51-2 CIPAC No 127 | Phosphane | <p>≥ 994 g/kg</p> <p>The relevant impurity arsane must not exceed 0,023 g/kg in the technical material</p> | 1 April 2013 | 31 March 2023 | <p>Authorisations shall be limited to professional users.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on phosphane, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 September 2012 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators in and around the treated premises during the treatment as well as during and after the aeration; — the protection of workers in and around the treated premises during the treatment as well as during and after the aeration; — the protection of bystanders around the treated premises during the treatment as well as during and after the aeration. <p>Conditions of use shall include risk mitigation measures, like permanent monitoring of the phosphane concentration by automatic devices, the use of personal protection equipment and setting-up an area around the treated premise where bystanders are denied, where appropriate.</p> |
|----|---|-----------|--|--------------|---------------|---|

▼ **M1**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------------|--|--|---------------------------|------------------|------------------------|--|
| ▼ M45 | | | | | | |
| 29 | <i>Trichoderma asperellum</i> (strain T34) CECT number: 20417 | Not applicable | 1×10^{10} cfu/g | 1 June 2013 | 31 May 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma asperellum</i> (strain T34), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Trichoderma asperellum</i> (strain T34) is to be considered as a potential sensitiser.</p> <p>Conditions of use shall include risk mitigation measures where appropriate.</p> |
| ▼ M44 | | | | | | |
| 30 | <i>Zucchini Yellow Mosaic Virus</i> — weak strain ATCC accession number: PV-593 | Not applicable | $\geq 0,05$ mg/l | 1 June 2013 | 31 May 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Zucchini Yellow Mosaic Virus</i> — weak strain, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to non-target plants, if the crop plants are co-infected with another virus which can be transmitted by aphids.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
| ▼ M47 | | | | | | |
| 31 | Cyflumetofen CAS No 400882-07-7 CIPAC No 721 | 2-methoxyethyl (<i>RS</i>)-2-(4- <i>tert</i> -butylphenyl)-2-cyano-3-oxo-3-(α,α,α -trifluoro- <i>o</i> -tolyl)propionate | ≥ 975 g/kg (racemic) | 1 June 2013 | 31 May 2023 | ► M304 Plant protection products containing cyflumetofen shall only be authorised for uses where the level of metabolite B3 in groundwater is expected to be below 0,1 µg/L. |

▼ **M47**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyflumetofen, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account.</p> <p>In this overall assessment, Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers; — the protection of groundwater, in particular for metabolite B3, when the substance is applied in regions with vulnerable soils and/or climatic conditions; — the protection of drinking water; — the risk to aquatic organisms. <p>Conditions of use shall include risk mitigation measures, where appropriate. ◀</p> |

▼ **M46**

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|----|---|----------------|--|-------------|-------------|--|
| 32 | <i>Trichoderma atroviride</i> strain I-1237 CNCM number: I-1237 | Not applicable | 1×10^9 cfu/g $(1 \times 10^{10}$ spores/g) | 1 June 2013 | 31 May 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> strain I-1237, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Trichoderma atroviride</i> strain I-1237 is to be considered a potential sensitiser.</p> <p>Conditions of use shall include risk mitigation measures where appropriate.</p> |
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▼ **M1**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------------|---|--|---|------------------|------------------------|---|
| ▼ M52 | | | | | | |
| 33 | Ametoctradin CAS No 865318-97-4 CIPAC No 818 | 5-ethyl-6-octyl [1,2,4]triazolo[1,5-a] pyrimidin-7-amine | ≥ 980 g/kg ► C2 The impurities amitrole and o-xylene are of toxicological relevance and shall not exceed 50 mg/kg and 2 g/kg respectively in the technical material. ◀ | 1 August 2013 | 31 July 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ametoctradin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the leakage of metabolite M650F04 (¹⁴) to groundwater under vulnerable conditions. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ M50 | | | | | | |
| 34 | Mandipropamid CAS No 374726-62-2 CIPAC No 783 | (RS)-2-(4-chloro-phenyl)-N-[3-methoxy-4-(prop-2-ynyloxy)phenethyl]-2-(prop-2-ynyloxy)acetamide | ≥ 930 g/kg The impurity N-{2-[4-(2-chloro-allyloxy)-3-methoxy-phenyl]-ethyl}-2-(4-chloro-phenyl)-2-prop-2-ynyloxy-acetamide is of toxicological relevance and shall not exceed 0,1 g/kg in the technical material. | 1 August 2013 | 31 July 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mandipropamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013 shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the potential for preferential enantiomeric transformation or racemisation of mandipropamid at the soil surface as a result of soil photolysis. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 July 2015. |

▼ **M1**▼ **M56**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|---|------------------|------------------------|--|
| 35 | Halosulfuron-methyl CAS No 100785-20-1 CIPAC No 785.201 | methyl 3-chloro-5-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylate | ≥ 980 g/kg | 1 October 2013 | 30 September 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on halosulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk of leakage to groundwater of the metabolite ‘halosulfuron’ rearrangement (HSR) ⁽¹⁵⁾ under vulnerable conditions. This metabolite is considered toxicologically relevant based on the available information for halosulfuron, — the risk to non-target terrestrial plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ul style="list-style-type: none"> (a) information as regards the equivalence between the specifications of the technical material, as commercially manufactured, and the test material used in the toxicological and ecotoxicological studies; (b) information on the toxicological relevance of the impurities present in the technical specification as commercially manufactured; (c) data to clarify the potential genotoxic properties of chlorosulfonamide acid ⁽¹⁶⁾. <p>The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.</p> |
| 36 | <i>Bacillus firmus</i> I-1582 Collection number: CNCMI-1582 | Not applicable | Minimum concentration: $7,1 \times 10^{10}$ CFU/g | 1 October 2013 | 30 September 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus firmus</i> I-1582, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Bacillus firmus</i> I-1582 is to be considered as a potential sensitiser.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M58**

▼ **M1**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------------|---|----------------|--|------------------|------------------------|---|
| ▼ M62 | | | | | | |
| 37 | <i>Candida oleophila</i> strain O Collection number: MUCL40654 | Not applicable | Nominal content: 3×10^{10} CFU/g dried product Range: 6×10^9 – 1×10^{11} CFU/g dried product | 1 October 2013 | 30 September 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Candida oleophila</i> strain O, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account. |
| ▼ M60 | | | | | | |
| 38 | <i>Helicoverpa armigera nucleopolyhedrovirus</i> DSMZ number: BV-0003 | Not applicable | Minimum concentration: $1,44 \times 10^{13}$ OB/l (occlusion bodies/l) | 1 June 2013 | 31 May 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Helicoverpa armigera nucleopolyhedrovirus</i> , and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. |
| ▼ M64 | | | | | | |
| 39 | <i>Paecilomyces fumosoroseus</i> strain FE 9901 Collection number: USDA-ARS collection of Entomopathogenic Fungal Cultures U.S. Plant Soil and Nutrition laboratory, New York. Accession No ARSEF 4490 | Not applicable | Minimum $1,0 \times 10^9$ CFU/g Maximum $3,0 \times 10^9$ CFU/g | 1 October 2013 | 30 September 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Paecilomyces fumosoroseus</i> strain FE 9901, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. |

▼ **M64**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Paecilomyces fumosoroseus</i> strain FE 9901 is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate. |

▼ **M61**

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|----|---|--|--|----------------|-------------------|---|
| 40 | Potassium phosphonates (no ISO name) CAS No 13977-65-6 for potassium hydrogen phosphonate 13492-26-7 for dipotassium phosphonate Mixture: none CIPAC No 756 (for potassium phosphonates) | Potassium hydrogen phosphonate, Dipotassium phosphonate | 31,6 to 32,6 % phosphonate ions (sum of hydrogen phosphonate and phosphonate ions) 17,8 to 20,0 % potassium ≥ 990 g/kg on dry weight basis | 1 October 2013 | 30 September 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium phosphonates, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to birds and mammals, — the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the long-term risk to insectivorous birds. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015. |
|----|---|--|--|----------------|-------------------|---|

▼ **M63**

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|----|--|---|--|----------------|-------------------|--|
| 41 | Spiromesifen CAS No 283594-90-1 CIPAC No 747 | 3-mesityl-2-oxo-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutyrate | ≥ 965 g/kg (racemic) The impurity N,N-dimethylacetamide is of toxicological relevance and must not exceed 4 g/kg in the technical material. | 1 October 2013 | 30 September 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiromesifen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. |
|----|--|---|--|----------------|-------------------|--|

▼ **M63**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|---|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the long-term risk to aquatic invertebrates, — the risk to pollinating hymenoptera and non-target arthropods if exposure is not negligible, — the protection of workers and operators. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the recalculation of the predicted concentration in groundwater (PECGW) with a FOCUS GW scenario adapted to the supported uses using a Q10 value of 2,58.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.</p> |

▼ **M59**

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|----|---|----------------|---|-------------|-------------|---|
| 42 | <i>Spodoptera littoralis nucleopolyhedrovirus</i> DSMZ number: BV-0005 | Not applicable | Maximum concentration: 1×10^{12} OB/l (occlusion bodies/l) | 1 June 2013 | 31 May 2023 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Spodoptera littoralis nucleopolyhedrovirus</i> , and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account. |
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▼ **M54**

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| 43 | Bixafen CAS No 581809-46-3 CIPAC No 819 | <i>N</i> -(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide | ≥ 950 g/kg | 1 October 2013 | 30 September 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bixafen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the residues of bixafen and of its metabolites in rotational crops;</p> |
|----|---|--|------------|----------------|-------------------|---|

▼ **M54**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>(b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>(c) the risk to aquatic organisms;</p> <p>(d) the risk to soil and sediment-dwelling organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M55**

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|----|--|----------------|------------|----------------|-------------------|--|
| 44 | Maltodextrin CAS No 9050-36-6 CIPAC No 801 | None allocated | ≥ 910 g/kg | 1 October 2013 | 30 September 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on maltodextrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the potential increased growth of fungi and possible presence of mycotoxins on the surface of treated fruits;</p> <p>(b) the potential risk to honeybees and non-target arthropods.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M68**

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|----|--|-------------------------|---|-----------------|------------------|---|
| 45 | Eugenol CAS No 97-53-0 CIPAC No 967 | 4-allyl-2-methoxyphenol | ≥ 990 g/kg Relevant impurity: methyl eugenol maximum 0,1 % of the technical material | 1 December 2013 | 30 November 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on eugenol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013 shall be taken into account.</p> |
|----|--|-------------------------|---|-----------------|------------------|---|

▼ **M68**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|-----------------------|------------------|------------------------|--|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — the risk to aquatic organisms, — the risk to insectivorous birds. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ul style="list-style-type: none"> (a) the storage stability (2 years) at ambient temperature on the formulated product; (b) data comparing natural background exposure situations of eugenol and methyl eugenol in relation to exposure from the use of eugenol as a plant protection product. This data shall cover human exposure as well as exposure of birds and aquatic organisms; (c) the groundwater exposure assessment for potential metabolites of eugenol, in particular for methyl eugenol. <p>The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015.</p> |
| 46 | Geraniol CAS No 106-24-1 CIPAC No 968 | (<i>E</i>) 3,7-dimethyl-2,6-octadien-1-ol | ≥ 980 g/kg | 1 December 2013 | 30 November 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on geraniol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013 shall be taken into account.</p> |

▼ **M70**

▼ **M70**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to</p> <ul style="list-style-type: none"> — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms; — the risk to birds and mammals. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards</p> <p>(a) data comparing natural background exposure situations of geraniol in relation to exposure from the use of geraniol as a plant protection product. This data shall cover human exposure as well as exposure of birds, mammals and aquatic organisms;</p> <p>(b) the groundwater exposure.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015.</p> |

▼ **M69**

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|----|---|-------------------------------|------------|-----------------|------------------|---|
| 47 | <p>Thymol</p> <p>CAS No</p> <p>89-83-8</p> <p>CIPAC No</p> <p>969</p> | 5-methyl-2-propan-2-yl-phenol | ≥ 990 g/kg | 1 December 2013 | 30 November 2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thymol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to</p> <ul style="list-style-type: none"> — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; |
|----|---|-------------------------------|------------|-----------------|------------------|---|

▼ **M69**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>— the risk to aquatic organisms;</p> <p>— the risk to birds and mammals.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards</p> <p>(a) data comparing natural background exposure situations of thymol in relation to exposure from the use of thymol as a plant protection product. This data shall cover human exposure as well as exposure of birds, mammals and aquatic organisms;</p> <p>(b) the long-term and reproductive toxicity, in a form of a full report (in English) of the Combined Test of Repeated Oral-Administration Toxicity and Reproductive Toxicity of Thymol;</p> <p>(c) the groundwater exposure.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015.</p> |

▼ **M77**

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|----|--|---|---|-----------------|-----------------|---|
| 48 | <p>Sedaxane</p> <p>CAS No 874967-67-6</p> <p>(trans isomer: 599197-38-3/cis isomer: 599194-51-1)</p> <p>CIPAC No 833</p> | <p>mixture of 2 cis-isomers</p> <p>[(1RS,2RS)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and 2 trans-isomers</p> <p>[(1RS,2SR)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide</p> | <p>≥ 960 g/kg Sedaxane</p> <p>(range 820-890 g/kg for the 2 trans-isomers 50:50 mixture of enantiomers and range 100-150 g/kg for the 2 cis-isomers 50:50 mixture of enantiomers)</p> | 1 February 2014 | 31 January 2024 | <p>PART A</p> <p>Only uses for seed treatment may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sedaxane, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;</p> |
|----|--|---|---|-----------------|-----------------|---|

▼ **M77**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>(b) the long-term risk to birds and mammals.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite CSCD465008 in vulnerable zones, where appropriate.</p> <p>The Member States concerned shall request the submission of confirmatory information as regards the relevance of the metabolite CSCD465008, and the corresponding groundwater risk assessment, if sedaxane is classified under Regulation (EC) No 1272/2008 as 'suspected of causing cancer'.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority the relevant information within six months from the application date of the Regulation classifying sedaxane.</p> |

▼ **M79**

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|----|--|--|---|------------|---------------|--|
| 49 | <p>Emamectin</p> <p>CAS No</p> <p>emamectin: 119791-41-2</p> <p>(formerly 137335-79-6)</p> <p>and 123997-28-4</p> <p>emamectin benzoate: 155569-91-8</p> <p>(formerly 137512-74-4 and 179607-18-2)</p> | <p>Emamectin B1a:</p> <p>(10<i>E</i>,14<i>E</i>,16<i>E</i>)-(1<i>R</i>,4<i>S</i>,5'<i>S</i>,6<i>S</i>,6'<i>R</i>,8<i>R</i>,12<i>S</i>,13<i>S</i>,20<i>R</i>,21<i>R</i>,24<i>S</i>)-6'-[(<i>S</i>)-<i>sec</i>-butyl]-21,24-dihydroxy-5',11,13,22-tetra-methyl-2-oxo-(3,7,19-trioxatetracyclo-[15.6.1.1^{4,8}.0^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'<i>H</i>-pyran)-12-yl 2,6-dideoxy-3-<i>O</i>-methyl-4-<i>O</i>-(2,4,6-trideoxy-3-<i>O</i>-methyl-4-methyl-amino-α-L-<i>lyxo</i>-hexapyranosyl)-α-L-<i>arabino</i>-hexapyranoside</p> | <p>≥ 950 g/kg</p> <p>as emamectin benzoate anhydrous</p> <p>(a mixture of min. 920 g/kg emamectin B1a benzoate and max. 50 g/kg emamectin B1b benzoate)</p> | 1 May 2014 | 30 April 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on emamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to non-target invertebrates; — the protection of workers and operators. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the risk of enantio-selective metabolism or degradation.</p> <p>The applicant shall submit to the Commission, Member States and the Authority the relevant information two years after adoption of the pertinent guidance document on evaluation of isomer mixtures.</p> |
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▼ **M79**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|------------------------|---------------------|
| | emamectin B1a benzoate: 138511-97-4 emamectin B1b benzoate: 138511-98-5 CIPAC No emamectin: 791 emamectin benzoate: 791.412 | Emamectin B1b: (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i>)- (1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> , 12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24- <i>S</i>)-21,24-dihydroxy- 6'-isopropyl- 5',11,13,22-tetra- methyl-2-oxo-(3,7,19- trioxatetracyclo- [15.6.1.1 ^{4,8} .0 ^{20,24}]pen- tcosa-10,14,16,22- tetraene)-6-spiro-2'- (5',6'-dihydro-2' <i>H</i> - pyran)-12-yl 2,6- dideoxy-3- <i>O</i> -methyl- 4- <i>O</i> -(2,4,6-trideoxy- 3- <i>O</i> -methyl-4-methyl- amino- α -L-lyxo- hexapyranosyl)- α -L- <i>arabino</i> -hexapyr- anoside Emamectin B1a benzoate: (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i>)- (1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> , 12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24- <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> -butyl]- | | | | |

▼ M79

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|--|------------|------------------|------------------------|---------------------|
| | | <p>21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.-1.1^{4,8}.0^{20,24}]pentacosan-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'<i>H</i>-pyran)-12-yl 2,6-dideoxy-3-<i>O</i>-methyl-4-<i>O</i>-(2,4,6-trideoxy-3-<i>O</i>-methyl-4-methylamino-α-L-<i>lyxo</i>-hexapyranosyl)-α-L-<i>arabino</i>-hexapyranoside benzoate</p> <p>Emamectin B1b benzoate:</p> <p>(10<i>E</i>,14<i>E</i>,16<i>E</i>)-(1<i>R</i>,4<i>S</i>,5'<i>S</i>,6<i>S</i>,6'<i>R</i>,8<i>R</i>,12<i>S</i>,13<i>S</i>,20<i>R</i>,21<i>R</i>,24-<i>S</i>)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.-1.1^{4,8}.0^{20,24}]pentacosan-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'<i>H</i>-pyran)-12-yl 2,6-dideoxy-3-<i>O</i>-methyl-4-<i>O</i>-(2,4,6-trideoxy-3-<i>O</i>-methyl-4-methylamino-α-L-<i>lyxo</i>-hexapyranosyl)-α-L-<i>arabino</i>-hexapyranoside benzoate</p> | | | | |

▼ **M1**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------------|---|--|--|------------------|------------------------|--|
| ▼ M80 | | | | | | |
| 50 | <i>Pseudomonas</i> sp. strain DSMZ 13134 Collection number: DSMZ 13134 | Not applicable | Minimum concentration: 3×10^{14} cfu/kg | 1 February 2014 | 31 January 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pseudomonas</i> sp. strain DSMZ 13134, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Pseudomonas</i> sp. strain DSMZ 13134 is to be considered as a potential sensitizer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit information to confirm the absence of an acute intratracheal and intraperitoneal toxicity/infectivity/pathogenicity potential.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016.</p> |
| ▼ M76 | | | | | | |
| 51 | Fluopyram CAS No 658066-35-4 CIPAC No 807 | N-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}- α,α,α -trifluoro-o-toluamide | ≥ 960 g/kg | 1 February 2014 | 31 January 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluopyram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to birds and aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the long-term risk to insectivorous birds;</p> |

▼ **M76**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>(2) the potential for causing endocrine disrupting effects in non-target vertebrates other than mammals.</p> <p>The applicant shall submit to the Commission, Member States and the Authority the information set out in point 1 by 1 February 2016 and the information set out in point 2 within two years after adoption of the corresponding OECD test guidelines on endocrine disruption.</p> |

▼ **M78**

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| 52 | <p><i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941)</p> <p>Collection number: German Collection of Microorganisms and cell Cultures (DSMZ) with the accession numbers DSM 14940 and DSM 14941</p> | Not applicable | <p>Minimum $5,0 \times 10^9$ CFU/g for each strain;</p> <p>Maximum $5,0 \times 10^{10}$ CFU/g for each strain</p> | 1 February 2014 | 31 January 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941) is to be considered as a potential sensitizer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M82**

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|----|---|--|-----------------|-----------------|-----------------|--|
| 53 | <p>Pyriofenone:</p> <p>CAS No 688046-61-9</p> <p>CIPAC No 827</p> | (5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone | ≥ 965 g/kg | 1 February 2014 | 31 January 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyriofenone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards</p> <p>(a) the identity of two impurities to fully support the provisional specification;</p> |
|----|---|--|-----------------|-----------------|-----------------|--|

▼ **M82**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>(b) the toxicological relevance of the impurities present in the proposed technical specification except for the one impurity for which an acute oral study and an Ames test were provided.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016.</p> |

▼ **M81**

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|----|---|----------------------|--------------------------------------|-----------------|-----------------|---|
| 54 | Disodium phosphonate CAS No 13708-85-5 CIPAC No 808 | disodium phosphonate | 281-337 g/kg (TK) ≥ 917 g/kg (TC) | 1 February 2014 | 31 January 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on disodium phosphonate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to eutrophication of surface water.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards</p> <p>(a) the chronic risk to fish;</p> <p>(b) the long term risk to earthworms and soil macro-organisms.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016.</p> |
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▼ **M83**

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|----|---|---|--|-----------------|-----------------|---|
| 55 | Penflufen CAS No 494793-67-8 CIPAC No 826 | 2'-[(RS)-1,3-dimethylbutyl]-5-fluoro-1,3-dimethylpyrazole-4-carboxanilide | ≥ 950 g/kg 1:1 (R:S) ratio of enantiomers | 1 February 2014 | 31 January 2024 | <p>► M249 PART A</p> <p>Only uses to treat seeds or other propagating materials before or during sowing or planting, may be authorised, limited to one application every third year on the same field.</p> |
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▼ **M83**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on penflufen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 and of the addendum to the review report on penflufen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 13 December 2017 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> (a) the protection of operators; (b) the long-term risk to birds; (c) the protection of groundwater, when the substance is applied to regions with vulnerable soil and/or climatic conditions; (d) to the residues in surface water abductured for drinking water purposes, in or from areas where products containing penflufen are used. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the relevance of the metabolite M01 (penflufen-3-hydroxy-butyl) for groundwater if penflufen is classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁸⁾ as 'carcinogen category 2'. That information shall be submitted to the Commission, the Member States and the Authority within 6 months from the notification of the classification decision concerning that substance. ◀</p> |

▼ **M1**▼ **M88**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|------------------------|--|
| 56 | Orange oil CAS No 8028-48-6 (Orange extract) 5989-27-5 (D-limonene) CIPAC No 902 | (R)-4-isopropenyl-1-methylcyclohexene or <i>p</i> -mentha-1,8-diene | ≥ 945 g/kg (of D-limonene) The active substance shall comply with the specifications of Ph. Eur. (Pharmacopoeia Europea) 5.0 (<i>Aurantii dulcis aetheroleum</i>) and ISO 3140:2011(E) | 1 May 2014 | 30 April 2024 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on orange oil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and workers; (b) the risk to birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the metabolite fate of orange oil and the route and rate of degradation in soil and on the validation of endpoints used in the ecotoxicological risk assessment. The applicant shall submit that information to the Commission, Member States and the Authority by 30 April 2016. |
| 57 | Penthiopyrad CAS No 183675-82-3 CIPAC No 824 | (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide | ≥ 980 g/kg (50:50 racemic mixture) | 1 May 2014 | 30 April 2024 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on penthiopyrad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and workers; |

▼ **M94**

▼ M94

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>(b) the risk to aquatic and soil organisms;</p> <p>(c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>(d) the level of residues in rotational crops following consecutive application of the active substance over several years.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the non-relevance of metabolite M11 (3-methyl-1-{3-[(1-methyl-3-trifluoromethyl-1H-pyrazole-4-carbonyl)amino]thiophen-2-yl}pentanoic acid) for groundwater with the exception of evidence related to the risk of carcinogenicity, which is dependent on the classification of the parent and specified separately at (3) below;</p> <p>(2) the toxicological profile and the reference values of the metabolite PAM;</p> <p>(3) the relevance of the metabolites M11 (3-methyl-1-{3-[(1-methyl-3-trifluoromethyl-1H-pyrazole-4-carbonyl)amino]thiophen-2-yl}pentanoic acid), DM-PCA (3-trifluoromethyl-1H-pyrazole-4-carboxylic acid), PAM (1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide) and PCA (1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid) and their risk to contaminate groundwater, if penthiopyrad is classified under Regulation (EC) No 1272/2008 as carcinogenic cat. 2.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in points (1) and (2) by 30 April 2016 and the information set out in point (3) within six months from the notification of the classification decision concerning penthiopyrad.</p> |

▼ **M1**▼ **M90**▼ **M95**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|---|------------------|------------------------|--|
| 58 | Benalaxyl-M CAS No 98243-83-5 CIPAC No 766 | Methyl <i>N</i> -(phenylacetyl)- <i>N</i> -(2,6-xylyl)-D-alaninate | ≥ 950 g/kg | 1 May 2014 | 30 April 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on benalaxyl-M, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of workers at re-entry, — the risk to groundwater from the metabolites BM-M2 (N-(malonyl)-N-(2,6-xylyl)-DL-alanine) and BM-M3 (N-(malonyl)-N-(2,6-xylyl)-D-alanine), when the substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
| 59 | Tembotrione CAS No 335104-84-2 CIPAC No 790 | 2-{2-chloro-4-mesyl-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione | ≥ 945 g/kg The following relevant impurities must not exceed a certain threshold in the technical material: Toluene: ≤ 10 g/kg HCN: ≤ 1 g/kg | 1 May 2014 | 30 April 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tembotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> (a) the protection of operators and workers; (b) the risk to aquatic organisms. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M1**▼ **M92**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|-------------------------|------------------|------------------------|--|
| 60 | Spirotetramat CAS No 203313-25-1 CIPAC No 795 | <i>cis</i> -4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-2-one | ≥ 970 g/kg | 1 May 2014 | 30 April 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spirotetramat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to insectivorous birds.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the potential for endocrine disruptor effects in birds and fish to the Commission, the Member States and the Authority within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.</p> |
| 61 | Pyroxsulam CAS No 422556-08-9 CIPAC No 793 | <i>N</i> -(5,7-dimethoxy[1,2,4]triazolo[1,5- <i>a</i>]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide | ≥ 965 g/kg | 1 May 2014 | 30 April 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyroxsulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to groundwater, when the active substance is applied in regions with vulnerable soil or climatic conditions;</p> <p>(b) the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M91**

▼ **M91**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the toxicological relevance of impurity number 3 (as referred to in the review report);</p> <p>(2) the acute toxicity of the metabolite PSA;</p> <p>(3) the toxicological relevance of metabolite 6-Cl-7-OH-XDE-742.</p> <p>The applicant shall submit to the Commission, Member States and the Authority that information by 30 April 2016.</p> |

▼ **M97**

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|----|--|--|---|------------|---------------|--|
| 62 | <p>Chlorantraniliprole</p> <p>CAS No 500008-45-7</p> <p>CIPAC No 794</p> | <p>3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methyl-carbamoyl) pyrazole-5-carboxanilide</p> | <p>≥ 950 g/kg</p> <p>The following relevant impurities must not exceed a certain threshold in the technical material:</p> <p>Acetonitrile: ≤ 3 g/kg</p> <p>3-picoline: ≤ 3 g/kg</p> <p>Methanesulfonic acid: ≤ 2 g/kg</p> | 1 May 2014 | 30 April 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorantraniliprole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and to soil macroorganisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the risk to groundwater from the active substance and its metabolites IN-EQW78 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one), IN-ECD73 (2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one), IN-F6L99 (3-bromo-N-methyl-1H-pyrazole-5-carboxamide), IN-GAZ70 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-8-methylquinazolin-4(1H)-one) and IN-F9N04 (3-bromo-N-(2-carbamoyl-4-chloro-6-methylphenyl)-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide);</p> |
|----|--|--|---|------------|---------------|--|

▼ **M97**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|---|
| | | | | | | <p>(2) the risk to aquatic organisms from the photolysis metabolites IN-LBA22 (2-{{[(4Z)-2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b][1,4]oxazin-4-ylidene] amino}-5-chloro-N,3-dimethylbenzamide), IN-LBA23 (2-[3-bromo-1-(3-hydroxypyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one) and IN-LBA24 (2-(3-bromo-1H-pyrazol-5-yl)-6-chloro-3,8-dimethylquinazolin-4(3H)-one).</p> <p>The applicant shall submit to the Commission, Member States and the Authority that information by 30 April 2016.</p> |

▼ **M96**

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|----|--|----------------|---|------------|---------------|---|
| 63 | <p>Sodium silver thiosulfate</p> <p>CAS No not allocated</p> <p>CIPAC No 762</p> | Not applicable | <p>≥ 10,0 g Ag/kg</p> <p>Expressed as silver (Ag)</p> | 1 May 2014 | 30 April 2024 | <p>PART A</p> <p>Only indoor uses in non-edible crops shall be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium silver thiosulfate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to</p> <p>(a) the protection of operators and workers;</p> <p>(b) limiting the possible release of silver ions through disposal of used solutions;</p> <p>(c) the risk to terrestrial vertebrates and soil invertebrates from the use of sewage sludge in agriculture.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
|----|--|----------------|---|------------|---------------|---|

▼ **M1**▼ **M101**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|-----------------------|------------------|------------------------|--|
| 64 | Pyridalyl CAS No 179101-81-6 CIPAC No 792 | 2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether | ≥ 910 g/kg | 1 July 2014 | 30 June 2024 | <p>PART A</p> <p>Only uses in greenhouses with permanent structure may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyridalyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to re-entry workers;</p> <p>(b) the risk to groundwater when the substance is applied in regions with vulnerable soils and/or climatic conditions;</p> <p>(c) the risk to birds, mammals and aquatic organisms.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the toxicological and ecotoxicological information to address the relevance of impurities 4, 13, 16, 22 and 23;</p> <p>(2) the relevance of the metabolite HTFP and, concerning that metabolite, the groundwater risk assessment for all uses on crops in greenhouse;</p> <p>(3) the risk to aquatic invertebrates.</p> |

▼ **M101**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information as regards point (1) by 31 December 2014 and information as regards point (2) and (3) by 30 June 2016.</p> <p>The applicant shall present to the Commission, the Member States and the Authority a monitoring programme to assess the potential groundwater contamination from the metabolite HTPF in vulnerable zones by 30 June 2016. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State, the Commission and the Authority by 30 June 2018.</p> |

▼ **M105**

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|----|---|---|----------|-------------|--------------|--|
| 65 | <p>S-abscisic acid</p> <p>CAS No 21293-29-8</p> <p>CIPAC No Not allocated</p> | <p>(2Z,4E)-5-[(1S)-1-hydroxy-2,6,6-trimethyl-4-oxocyclohex-2-en-1-yl]-3-methylpenta-2,4-dienoic acid</p> <p>or</p> <p>(7E,9Z)-(6S)-6-hydroxy-3-oxo-11-apo-ε-caroten-11-oic acid</p> | 960 g/kg | 1 July 2014 | 30 June 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on S-abscisic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M104**

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|----|--|--|--|-------------|--------------|--|
| 66 | <p>L-ascorbic acid</p> <p>CAS No 50-81-7</p> <p>CIPAC No 774</p> | <p>(5R)-5-[(1S)-1,2-dihydroxyethyl]-3,4-dihydroxyfuran-2(5H)-one</p> | <p>≥ 990 g/kg</p> <p>The following relevant impurities shall not exceed:</p> <p>Methanol: ≤ 3 g/kg</p> <p>Heavy Metals: ≤ 10 mg/kg (expressed as Pb)</p> | 1 July 2014 | 30 June 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on L-ascorbic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to aquatic and soil organisms;</p> <p>(b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.</p> |
|----|--|--|--|-------------|--------------|--|

▼ **M104**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the natural background of L-ascorbic acid in the environment confirming a low chronic risk for fish and a low risk for aquatic invertebrates, algae, earthworms and soil microorganisms;</p> <p>(2) the risk to contaminate groundwater.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016.</p> |

▼ **M99**

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|----|---|---|--|-------------|--------------|---|
| 67 | <p>Spinetoram</p> <p>CAS No 935545-74-7</p> <p>CIPAC No 802</p> | <p><i>XDE-175-J (Major factor)</i></p> <p>(2<i>R</i>,3<i>aR</i>,5<i>aR</i>,5<i>bS</i>,9<i>S</i>,13<i>S</i>,14<i>R</i>,16<i>aS</i>, 16<i>bR</i>)-2-(6-deoxy-3-<i>O</i>-ethyl-2,4-di-<i>O</i>-methyl-α-L-mannopyranosyloxy)-13-[(2<i>R</i>,5<i>S</i>,6<i>R</i>)-5-(dimethylamino)tetrahydro-6-methylpyran-2-yloxy]-9-ethyl-2,3,3<i>a</i>,4,5,5<i>a</i>,5<i>b</i>,6,9,10,11,12,13,14,16<i>a</i>,16<i>b</i>-hexadecahydro-14-methyl-1<i>H</i>-as-indaceno[3,2-<i>d</i>]oxacyclododecine-7,15-dione</p> <p><i>XDE_175-L (Minor factor)</i></p> | <p>≥ 830 g/kg</p> <p>50-90 % XDE-175-J;</p> <p>and</p> <p>50-10 % XDE-175-L</p> <p>Tolerance limits (g/kg):</p> <p>XDE-175-J = 581-810</p> <p>XDE-175-L = 83-270</p> | 1 July 2014 | 30 June 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spinetoram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to aquatic and soil organisms;</p> <p>(b) the risk to non-target arthropods in-field;</p> <p>(c) the risk to bees during the application (overspray) and subsequently.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M99**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|---|------------|------------------|------------------------|---|
| | | (2S,3aR,5aS,5bS,9S,-13S,14R,16aS,16bS)-2-(6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranosyloxy)-13-[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methylpyran-2-yloxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione | | | | <p>The applicant shall submit confirmatory information as regards the equivalence between the stereochemistry of metabolites identified in the metabolism/degradation studies and in the testing material used for the toxicity and ecotoxicity studies.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information ► C3 within 6 months after the adoption of pertinent guidance on the assessment of isomers ◀.</p> |

▼ **M108**

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|----|--|-------------------------|------------|-------------|--------------|---|
| 68 | 1,4-dimethylnaphthalene CAS No 571-58-4 CIPAC No 822 | 1,4-dimethylnaphthalene | ≥ 980 g/kg | 1 July 2014 | 30 June 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1,4-dimethylnaphthalene, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the protection of operators and of workers at re-entry and during inspection of the warehouse;</p> <p>(b) the risk to aquatic organisms and fish-eating mammals the active substance is discharged from warehouses into air and surface water without further treatment.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
|----|--|-------------------------|------------|-------------|--------------|---|

▼ **M108**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>The applicant shall submit confirmatory information as regards the residue definition for the active substance.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016.</p> |

▼ **M109**

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|----|---|---|--|-------------|--------------|---|
| 69 | <p>Amisulbrom</p> <p>CAS No 348635-87-0</p> <p>CIPAC No 789</p> | <p>3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-<i>N,N</i>-dimethyl-1<i>H</i>-1,2,4-triazole-1-sulfonamide</p> | <p>≥ 985 g/kg</p> <p>The following relevant impurity must not exceed a certain threshold in the technical material:</p> <p>3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole: ≤ 2 g/kg</p> | 1 July 2014 | 30 June 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on amisulbrom, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic and soil organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the non-significance of photodegradation in the soil metabolism of amisulbrom concerning the metabolites 3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole and 1-(dimethylsulfamoyl)-1<i>H</i>-1,2,4-triazole-3-sulfonic acid to contaminate groundwater;</p> <p>(2) the low potential of amisulbrom (FOCUS drainage scenarios only) and metabolites 1-(dimethylsulfamoyl)-1<i>H</i>-1,2,4-triazole-3-sulfonic acid, 1<i>H</i>-1,2,4-triazole-3-sulfonic acid, 1<i>H</i>-1,2,4-triazole, <i>N,N</i>-dimethyl-1<i>H</i>-1,2,4-triazole-3-sulfonamide, 2-acetamido-4-fluorobenzoic acid, 2-acetamido-4-fluoro-hydroxybenzoic acid and 2,2'-oxybis(6-fluoro-2-methyl-1,2-dihydro-3<i>H</i>-indol-3-one) to contaminate surface water or to expose aquatic organisms by runoff;</p> |
|----|---|---|--|-------------|--------------|---|

▼ **M109**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>(3) depending on the outcome of the assessment under (1) and (2), where there is considerable photodegradation in soil or where there is high potential for contamination or exposure, additional analytical methods to determine all compounds of the residue definition for monitoring in surface water;</p> <p>(4) the risk from secondary poisoning for birds and mammals by 3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole;</p> <p>(5) the potential for causing endocrine disrupting effects in birds and fish by amisulbrom and its metabolite 3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in points (1) to (4) by 30 June 2016 and under point (5) within two years after the adoption of pertinent OECD test guidelines on endocrine disruption.</p> |

▼ **M102**

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|----|--|---|------------|-------------|--------------|---|
| 70 | Valifenalate CAS No 283159-90-0 CIPAC No 857 | Methyl <i>N</i> -(isopropoxycarbonyl)-L-valyl-(3 <i>RS</i>)-3-(4-chlorophenyl)-β-alaninate | ≥ 980 g/kg | 1 July 2014 | 30 June 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on valifenalate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the potential of metabolite S5 to contaminate groundwater.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016.</p> |
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▼ **M1**▼ **M103**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|------------------------|--|
| 71 | Thiencarbazone CAS No 317815-83-1 CIPAC No 797 | Methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1 <i>H</i> -1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate | ≥ 950 g/kg | 1 July 2014 | 30 June 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiencarbazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to</p> <p>(a) the risk to groundwater if the substance is applied under vulnerable geographical or climatic conditions;</p> <p>(b) the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the potential of thiencarbazone for long-range atmospheric transport and the related environmental impacts.</p> <p>That confirmatory information shall consist of the results of a monitoring programme to assess the potential of thiencarbazone for long-range atmospheric transport and the related environmental impacts. The applicant shall submit to the Commission, the Member States and the Authority this monitoring programme by 30 June 2016 and the results in form of a monitoring report by 30 June 2018.</p> |
| 72 | Acequinocyl CAS No 57960-19-7 CIPAC No 760 | 3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate | ≥ 960 g/kg | 1 September 2014 | 31 August 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acequinocyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> |

▼ **M114**

▼ **M114**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>— the protection of workers and operators;</p> <p>— the risk to birds, mammals and aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(a) an analytical method for residues in body fluids and tissues;</p> <p>(b) the acceptability of the long-term risk to small granivorous birds and small herbivorous and frugivorous mammals, concerning the use on apple and pear orchards;</p> <p>(c) the acceptability of the long-term risk to small omnivorous and small herbivorous mammals, concerning the use on outdoor ornamentals.</p> <p>The applicant shall submit that information to the Commission, the Member States and the Authority by 31 August 2016.</p> |

▼ **M117**

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|----|--|---|---|------------------|----------------|--|
| 73 | <p>Ipconazole</p> <p>CAS No</p> <p>125225-28-7 (mixture of diastereoisomers)</p> <p>115850-69-6 (ipconazole cc, cis isomer)</p> <p>115937-89-8 (ipconazole ct, trans isomer)</p> <p>CIPAC No 798</p> | <p>(1<i>RS</i>,2<i>SR</i>,5<i>RS</i>;1<i>RS</i>,2-<i>SR</i>,5<i>SR</i>)-2-(4-chlorobenzyl)-5-isopropyl-1-(1<i>H</i>-1,2,4-triazol-1-ylmethyl) cyclopentanol</p> | <p>≥ 955 g/kg</p> <p>Ipconazole cc: 875 – 930 g/kg</p> <p>Ipconazole ct: 65 – 95 g/kg</p> | 1 September 2014 | 31 August 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ipconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ol style="list-style-type: none"> 1. the risk to granivorous birds; 2. the protection of workers and operators; 3. the risk to fish. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
|----|--|---|---|------------------|----------------|--|

▼ **M117**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>The applicant shall submit confirmatory information as regards:</p> <p>(a) the acceptability of the long-term risk to granivorous birds;</p> <p>(b) the acceptability of the risk to soil macro-organisms;</p> <p>(c) the risk of enantio-selective metabolism or degradation;</p> <p>(d) the potential endocrine disrupting properties of ipconazole for birds and fish.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information under (a) and (b) by 31 August 2016, the information under (c) within two years after adoption of the pertinent guidance document on evaluation of isomer mixtures and the information under (d) within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of test guidelines agreed at EU level.</p> |

▼ **M119**

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|----|--|---|------------|------------------|----------------|---|
| 74 | <p>Flubendiamide</p> <p>CAS No 272451-65-7</p> <p>CIPAC No 788</p> | 3-iodo- <i>N</i> -(2-mesyl-1,1-dimethylethyl)- <i>N</i> -{4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]- <i>o</i> -tolyl}phthalamide | ≥ 960 g/kg | 1 September 2014 | 31 August 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flubendiamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to aquatic invertebrates;</p> <p>(b) the potential presence of residues in rotational crops.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M1**▼ **M111**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--------------------------------|------------------|------------------------|---|
| 75 | <p><i>Bacillus pumilus</i> QST 2808</p> <p>USDA Agricultural Research Service (NRRL) Patent culture collection in Peoria Illinois, USA under the reference number B-30087</p> | Not applicable | $\geq 1 \times 10^{12}$ CFU/kg | 1 September 2014 | 31 August 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus pumilus</i> QST 2808, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Bacillus pumilus</i> QST 2808 is to be considered as a potential sensitizer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(a) the identification of the aminosugar produced by <i>Bacillus pumilus</i> QST 2808;</p> <p>(b) analytical data for the content of that aminosugar in the production batches.</p> <p>The applicant shall submit that information to the Commission, the Member States and the Authority by 31 August 2016.</p> |
| 76 | <p>Metobromuron</p> <p>CAS No 3060-89-7</p> <p>CIPAC No 168</p> | 3-(4-bromophenyl)-1-methoxy-1-methylurea | ≥ 978 g/kg | 1 January 2015 | 31 December 2024 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metobromuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the protection of workers and operators;</p> |

▼ **M123**

▼ **M123**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>(b) the risk to birds, mammals, aquatic organisms and terrestrial non-target plants.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(a) the toxicological assessment of the metabolites CGA 18236, CGA 18237, CGA 18238 and 4-bromoaniline;</p> <p>(b) the acceptability of the long-term risk to birds and mammals.</p> <p>The applicant shall submit that information to the Commission, the Member States and the Authority by 31 December 2016.</p> |

▼ **M124**

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|----|---|---|--|----------------|------------------|---|
| 77 | <p>Aminopyralid</p> <p>CAS No 150114-71-9</p> <p>CIPAC No 771</p> | 4-amino-3,6-dichloro-pyridine-2-carboxylic acid | <p>≥ 920 g/kg</p> <p>The following relevant impurity shall not exceed a certain threshold:</p> <p>Picloram ≤ 40 g/kg</p> | 1 January 2015 | 31 December 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aminopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions;</p> <p>(b) the risk to aquatic macrophytes and terrestrial non-target plants;</p> <p>(c) chronic risk to fish.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M1**▼ **M129**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|---|------------------|------------------------|---|
| 78 | Metaflumizone CAS No 139968-49-3 CIPAC No 779 | (EZ)-2'-[2-(4-cyanophenyl)-1-(α,α,α -trifluoro-m-tolyl)ethylidene]-4-(trifluoromethoxy)carbanilohydrazide | ≥ 945 g/kg (90-100 % E-isomer 10-0 % Z-isomer) The following relevant impurities shall not exceed a certain threshold: Hydrazine \leq 1 mg/kg 4-(trifluoromethoxy)phenyl isocyanate \leq 100 mg/kg Toluene \leq 2 g/kg | 1 January 2015 | 31 December 2024 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metaflumizone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to fish and sediment dwelling organisms;</p> <p>(b) the risk to snail- or earthworm-eating birds.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the equivalence of the material used in the toxicological and ecotoxicological studies with the proposed technical specification;</p> <p>(2) information addressing the potential of metaflumizone for bioaccumulation in aquatic organisms and biomagnification in aquatic food chains.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under (1) by 30 June 2015 and under (2) by 31 December 2016.</p> |

▼ **M1**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|--|--|------------------|------------------------|---|
| ▼ M126 | | | | | | |
| 79 | <i>Streptomyces lydicus</i> strain WYEC 108 Collection number: American Type Culture Collection (USDA) ATCC 55445 | Not applicable | Minimum concentration: $5,0 \times 10^8$ CFU/g | 1 January 2015 | 31 December 2024 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Streptomyces lydicus</i> strain WYEC 108, and in particular Appendices I and II thereto, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic organisms; (b) the risk to soil dwelling organisms. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ M131 | | | | | | |
| 80 | Meptyldinocap CAS No 6119-92-2 CIPAC No 811 | Mixture of 75-100 % (RS)-2-(1-methylheptyl)-4,6-dinitrophenyl crotonate and 25— 0 % (RS)-2-(1-methylheptyl)-4,6-dinitrophenyl isocrotonate | ≥ 900 g/kg (mixture of <i>trans</i> - and <i>cis</i> -isomers with a defined ratio range of 25:1 to 20:1) Relevant impurity: 2,6-dinitro-4-[(4RS)-octan-4-yl]phenyl (2E/Z)-but-2-enoate max content 0,4 g/kg | 1 April 2015 | 31 March 2015 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on meptyldinocap, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 May 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to operators; (b) the risk to aquatic invertebrates. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the groundwater exposure assessment for metabolites (3RS)-3-(2-hydroxy-3,5-dinitro-phenyl)-butanoic acid (X103317) and (2RS)-2-(2-hydroxy-3,5-dinitro-phenyl)-propionic acid (X12335709); |

▼ **M131**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>(b) the possible impact of any preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environment.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (a) by 31 March 2017 and the information set out in point (b) two years after the adoption of specific guidance by the Commission.</p> |

▼ **M133**

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|----|---|---|--|--------------|---------------|---|
| 81 | <p>Chromafenozide</p> <p>CAS No 143807-66-3</p> <p>CIPAC No 775</p> | <p><i>N'</i>-<i>tert</i>-butyl-5-methyl-<i>N'</i>-(3,5-xyloyl)chromane-6-carbohydrazide</p> | <p>≥ 935 g/kg</p> <p>The following relevant impurity must not exceed a certain threshold in the technical material:</p> <p>Butyl acetate (n-buthyl acetate, CAS No 123-86-4): ≤ 8 g/kg</p> | 1 April 2015 | 31 March 2025 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chromafenozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions;</p> <p>(b) the risk to non-target Lepidoptera in off-crop areas;</p> <p>(c) the risk to sediment-dwelling organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the non-significance of the difference between the material used for ecotoxicological testing and the agreed specification of the technical material for the risk assessment;</p> <p>(2) the assessment of the risk to sediment dwelling organisms from metabolite M-010;</p> |
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▼ **M133**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>(3) the leaching potential of metabolites M-006 and M-023 to groundwater.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under (1) by 30 September 2015 and under (2) and (3) by 31 March 2017.</p> |

▼ **M132**

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|----|---|---|-----------------|--------------|---------------|---|
| 82 | <p>Gamma-cyhalothrin</p> <p>CAS No 76703-62-3</p> <p>CIPAC No 768</p> | <p>(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or</p> <p>(S)-α-cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate</p> | ≥ 980 g/kg | 1 April 2015 | 31 March 2025 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on gamma-cyhalothrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the safety of operators and workers;</p> <p>(b) the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) analytical methods for the monitoring of residues in body fluids, tissues and environmental matrices;</p> <p>(2) the toxicity profile of the metabolites CPCA, PBA and PBA(OH);</p> <p>(3) the long-term risk to wild mammals;</p> <p>(4) the potential for biomagnification in terrestrial and aquatic food chains.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 31 March 2017.</p> |
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▼ **M1**▼ **M130**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|------------------------|---|
| 83 | <p><i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747</p> <p>Accession number in the Agricultural Research Culture Collection (NRRL), Peoria, Illinois, USA: B-50405</p> <p>Deposit number in the International Patent Organism Depositary, Tokyo, Japan: FERM BP-8234.</p> | Not applicable | Minimum concentration: $2,0 \times 10^{11}$ CFU/g | 1 April 2015 | 31 March 2025 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> |
| 84 | <p>Terpenoid blend QRD 460</p> <p>CIPAC No: 982</p> | <p>Terpenoid blend QRD 460 is a blend of three components:</p> <ul style="list-style-type: none"> — α-terpinene: 1-isopropyl-4-methylcyclohexa-1,3-diene; — <i>p</i>-cymene: 1-isopropyl-4-methylbenzene; — <i>d</i>-limonene: (<i>R</i>)-4-isopropenyl-1-methylcyclohexene. | <p>The nominal concentration of each component in the active substance as manufactured should be as follows:</p> <ul style="list-style-type: none"> — α-terpinene: 59,7 %; — <i>p</i>-cymene: 22,4 %; — <i>d</i>-limonene: 17,9 %. | 10 August 2015 | 10 August 2025 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on terpenoid blend QRD-460, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> (a) the stability of formulations on storage; (b) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (d) the protection of surface water and aquatic organisms; (e) the protection of bees and non-target arthropods. |

▼ **M154**

▼ **M154**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|---|------------------|------------------------|--|
| | | | <p>Each component should have a minimum purity as follows:</p> <ul style="list-style-type: none"> — α-terpinene: 89 %; — <i>p</i>-cymene: 97 %; — <i>d</i>-limonene: 93 %. | | | <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the technical specification of the active substance as manufactured (5 batch analysis for the blend should be provided), supported by acceptable and validated methods of analysis. It should be confirmed that there are no relevant impurities present in the technical material;</p> <p>(2) the equivalence of the material used in the toxicological and ecotoxicological studies with the confirmed technical specification.</p> <p>The applicant shall submit that information to the Commission, the Member States and the Authority by 10 February 2016.</p> |

▼ **M155**

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|----|---|--|---|----------------|------------------|---|
| 85 | <p>Fenhexamid</p> <p>CAS No: 126833-17-8</p> <p>CIPAC No: 603</p> | N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexane-1-carboxamide | <p>≥ 975 g/kg</p> <p>The following relevant impurity must not exceed a certain threshold in the technical material:</p> <ul style="list-style-type: none"> — toluene: max. 1 g/kg, — 4-amino-2,3-dichlorophenol: max. 3 g/kg. | 1 January 2016 | 31 December 2030 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenhexamid, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators during field crop handheld operations, — the protection of workers re-entering indoor-treated crops, — the risk to aquatic organisms, — the long-term risk to mammals for field uses. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M1**▼ **M151**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|------------------------|---|
| 86 | Halauxifen-methyl CAS No: 943831-98-9 CIPAC No: 970.201 (halauxifen-methyl) 970 (halauxifen) | methyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)pyridine-2-carboxylate | ≥ 930 g/kg | 5 August 2015 | 5 August 2025 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on halauxifen-methyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — The risk to aquatic and non-target terrestrial plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ul style="list-style-type: none"> — The technical specification of the active substance as manufactured (based on commercial scale production). The relevance of impurities present in the technical material should be confirmed, — The compliance of the toxicity batches with the technical specification. <p>The applicant shall submit that information to the Commission, the Member States and the Authority by 5 February 2016.</p> |
| 87 | Pyridate CAS No: 55512-33-9 CIPAC No: 447 | O-6-chloro-3-phenylpyridazin-4-yl S-octyl thiocarbonate | ≥ 900 g/kg | 1 January 2016 | 31 December 2030 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyridate, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, non-target terrestrial plants, and herbivorous mammals.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M148**

▼ **M1**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|------------------------|---|
| 88 | Sulfoxaflor CAS No: 946578-00-3 CIPAC No: 820 | [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ ⁶ -sulfonylidene]cyanamide | ≥ 950 g/kg | 18 August 2015 | 18 August 2025 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfoxaflor, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to bees and other non-target arthropods;</p> <p>(b) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(a) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust;</p> <p>(b) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds;</p> <p>(c) the risk to pollinators other than honey bees;</p> <p>(d) the risk to bee brood.</p> <p>The applicant shall submit that information to the Commission, the Member States and the Authority by 18 August 2017.</p> |
| 89 | Sulfosulfuron CAS No: 141776-32-1 CIPAC No: 601 | 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-ethylsulfonylimidazo[1,2-a]pyridine-3-ylsulfonyl)urea | ≥ 980 g/kg The following relevant impurity must not exceed a certain threshold in the technical material: Phenol: < 2 g/kg | 1 January 2016 | 31 December 2030 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfosulfuron, and in particular Appendices I and II thereof shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>— the risk to soil non-target macro-organisms other than earthworms, non-target terrestrial plants and aquatic organisms.</p> |

▼ **M1**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|---|---|------------------|------------------------|--|
| ▼ M159 | | | | | | |
| 90 | Florasulam CAS No 145701-23-1 CIPAC No 616 | 2',6',8-trifluoro-5-methoxy[1,2,4]triazolo[1,5- <i>c</i>]pyrimidine-2-sulfon-anilide | ≥ 970 g/kg Impurity: 2,6-DFA, not more than 2 g/kg | 1 January 2016 | 31 December 2030 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on florasulam, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ M164 | | | | | | |
| 91 | Flupyradifurone CAS No: 951659-40-8 CIPAC No: 987 | 4-[(6-chloro-3-pyridylmethyl)(2,2-difluoroethyl)amino]furan-2(5H)-one | ≥ 960 g/kg | 9 December 2015 | 9 December 2025 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flupyradifurone, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of workers and operators, — the risk to non-target arthropods, aquatic invertebrates and small herbivorous mammals, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — residues in animal matrices and rotational crops. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities, (2) the compliance of the toxicity batches with the confirmed technical specification, (3) the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. |

▼ **M164**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | The applicant shall submit to the Commission, the Member States and the Authority the information requested under point (1) and (2) by 9 June 2016, the information requested under point (3) within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. |

▼ **M167**

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| 92 | Rescalure CAS No: 67601-06-3 CIPAC No: Not available | (3 <i>S</i> ,6 <i>R</i>)-(3 <i>S</i> ,6 <i>S</i>)-6-isopropenyl-3-methyldec-9-en-1-yl acetate | ≥ 750 g/kg The ratio of (3 <i>S</i> ,6 <i>R</i>)/(3 <i>S</i> ,6 <i>S</i>) shall be in a range of 55/45 to 45/55. The purity range for each isomer shall be 337,5 g/kg to 412,5 g/kg. | 18 December 2015 | 18 December 2025 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rescalure, and in particular Appendices I and II thereof, shall be taken into account. |
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▼ **M165**

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|----|--|---|---|-----------------|-----------------|---|
| 93 | Mandestrobin CAS No: 173662-97-0 CIPAC No: Not available | (<i>RS</i>)-2-methoxy- <i>N</i> -methyl-2-[α -(2,5-xylyloxy)- <i>o</i> -tolyl]acetamide | ≥ 940 g/kg (on a dry weight basis) Xylenes (ortho, meta, para), ethyl benzene max. 5 g/kg (TK) | 9 December 2015 | 9 December 2025 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mandestrobin, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to aquatic organisms, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities; (2) the compliance of the toxicity batches with the confirmed technical specification. <p>The applicant shall submit that information to the Commission, the Member States and the Authority by 9 June 2016.</p> |
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▼ **M1**▼ **M161**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|------------------------|--|
| 94 | 2,4-D CAS No: 94-75-7 CIPAC No: 1 | (2,4-dichlorophenoxy) acetic acid | <p>≥ 960 g/kg</p> <p>Impurities:</p> <p>Free phenols (expressed as 2,4-DCP): not more than 3 g/kg.</p> <p>Sum of dioxins and furans (WHO-TCDD TEQ) ⁽¹³⁾: not more than 0,01 mg/kg.</p> | 1 January 2016 | 31 December 2030 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,4-D, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority:</p> <p>(1) confirmatory information in the form of the submission of the complete study results from the existing extended one-generation study;</p> <p>(2) confirmatory information in the form of the submission of the Amphibian Metamorphosis Assay (AMA) (OECD (2009) Test No 231) as to verify the potential endocrine properties of the substance.</p> <p>The information set out in point (1) shall be submitted by 4 June 2016 and the information set out in point (2) by 4 December 2017.</p> |
| 95 | Pyraflufen-ethyl CAS No 129630-19-9 CIPAC No 605.202 | ethyl [2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxy]acetate | ≥ 956 g/kg | 1 April 2016 | 31 March 2031 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyraflufen-ethyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms, — the protection of non-target terrestrial plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M173**

▼ **M1**▼ **M171**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|--|------------------|------------------------|---|
| 96 | Iprovalicarb CAS No 140923-17-7 CIPAC No 620 | isopropyl [(1S)-2-methyl-1-{{[(1RS)-1-p-tolylolethyl]carbamoyl}propyl]carbamate | ≥ 950 g/kg Impurities: Toluene: not more than 3 g/kg | 1 April 2016 | 31 March 2031 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on iprovalicarb, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater from the relevant soil metabolite PMPA (¹⁷) when the active substance is applied in regions with low clay containing soil types, — the safety of operators and workers, — the protection of aquatic organisms in the case of formulated products containing other active substances. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority, confirmatory information as regards the genotoxic potential of soil metabolite PMPA. This information shall be submitted by 30 September 2016.</p> |
| 97 | Pinoxaden CAS No 243973-20-8 CIPAC No 776 | 8-(2,6-diethyl-p-tolyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropionate | ≥ 970 g/kg Toluene max. content 1 g/kg | 1 July 2016 | 30 June 2026 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pinoxaden, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 29 January 2016 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.</p> <p>The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate.</p> |

▼ **M174**

▼ **M174**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>The applicant shall submit confirmatory information as regards:</p> <p>(a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water;</p> <p>(b) the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child).</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in point (a) by 30 June 2018 and the information set out in point (b) within six months from the notification of the classification decision under Regulation (EC) No 1272/2008 concerning pinoxaden.</p> |

▼ **M175**

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|----|---|---|---|--------------|---------------|---|
| 98 | <p>Acibenzolar-S-methyl</p> <p>CAS No 135158-54-2</p> <p>CIPAC No 597</p> | S-methyl benzo[1,2,3]thiadiazole-7-carbothioate | <p>970 g/kg</p> <p>Toluene: max. 5 g/kg</p> | 1 April 2016 | 31 March 2031 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acibenzolar-S-methyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk for consumers via food intake;</p> <p>(b) the protection of operators and workers;</p> <p>(c) the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
|----|---|---|---|--------------|---------------|---|

▼ **M175**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | The applicant shall by 1 June 2017 submit to the Commission, the Member States and the Authority, confirmatory information as regards the relevance and reproducibility of the morphometric changes observed in the cerebellum of fetuses linked to exposure to acibenzolar-S-methyl and whether these changes may be produced via an endocrine mode of action. The information to be submitted shall include a systematic review of the available evidence assessed on the basis of available guidance (e.g. EFSA GD on Systematic Review methodology, 2010). |

▼ **M189**

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|----|--|---|--|-------------------|-------------------|--|
| 99 | Cyantraniliprole CAS No: 736994-63-1 CIPAC No: Not allocated. | 3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methyl-carbamoyl)pyrazole-5-carboxanilide | <p>≥ 940 g/kg</p> <p>IN-Q6S09 max. 1 mg/kg</p> <p>IN-RYA13 max. 20 mg/kg</p> <p>methanesulfonic acid max. 2 g/kg</p> <p>acetonitrile max. 2 g/kg</p> <p>heptane max. 7 g/kg</p> <p>3-picoline max. 3 g/kg.</p> | 14 September 2016 | 14 September 2026 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyantraniliprole, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to operators;</p> <p>(b) the risk to aquatic organisms, bees and other non-target arthropods;</p> <p>(c) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses;</p> <p>(d) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> |
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▼ **M1**▼ **M192**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|-----------------------|-------------------|------------------------|--|
| 100 | <p>Isofetamid</p> <p>CAS No: 875915-78-9</p> <p>CIPAC No: 972</p> | <i>N</i> -[1,1-dimethyl-2-(4-isopropoxy- <i>o</i> -tolyl)-2-oxoethyl]-3-methylthiophene-2-carboxamide | ≥ 950 g/kg | 15 September 2016 | 15 September 2026 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on isofetamid, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to operators, workers and aquatic organisms, in particular fish.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <p>(1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities;</p> <p>(2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification;</p> <p>(3) the effect of water treatment process chlorination on the nature of residues, including the potential for the formation of chlorinated residues that may be formed from residues present in surface water, when surface water is abstracted for drinking water.</p> <p>The applicant shall submit the information requested under points (1) and (2) by 15 March 2017 and the information requested under point (3) within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> |

▼ **M1**▼ **M194**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|--|-------------------|------------------------|--|
| 101 | <p><i>Bacillus amyloliquefaciens</i> strain MBI 600.</p> <p>Accession number in the National Collection of Industrial, Marine and Food Bacteria Ltd (NCIMB), Scotland: NCIMB 12376</p> <p>Deposit number in the American Type Culture Collection (ATCC): SD-1414</p> | Not applicable | <p>Minimum concentration:</p> <p>$5,0 \times 10^{14}$ CFU/kg</p> | 16 September 2016 | 16 September 2026 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> strain MBI 600, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the specification of the technical material as commercially manufactured, including full characterisation of impurities and metabolites;</p> <p>(b) the protection of operators and workers, taking into account that <i>Bacillus amyloliquefaciens</i> strain MBI 600 is to be considered as a potential sensitiser.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> |
| 102 | <p>Ethofumesate</p> <p>CAS No 26225-79-6</p> <p>CIPAC No 233</p> | (RS)-2-ethoxy-2,3-dihydro-3,3-dimethyl-benzofuran-5-yl methanesulfonate | <p>≥ 970 g/kg</p> <p>The following impurities are of toxicological concern and must not exceed the following levels in the technical material:</p> | 1 November 2016 | 31 October 2031 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on ethofumesate, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>— the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M193**

▼ **M193**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|---|------------------|------------------------|---------------------|
| | | | — EMS; ethyl methane sulfonate: maximum of 0,1 mg/kg — iBMS; iso-butyl methane sulfonate: maximum of 0,1 mg/kg | | | |

▼ **M190**

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|-----|---|--|-----------------|-----------------|--------------|---|
| 103 | Picolinafen CAS No 137641-05-5 CIPAC No 639 | 4'-fluoro-6-(α,α,α -trifluoro-m-toloxypyridine-2-carboxanilide | ≥ 980 g/kg | 1 November 2016 | 30 June 2031 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on picolinafen, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the impurities in the technical active substance; — the protection of mammals, especially of large herbivorous mammals; — the protection of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of aquatic organisms, especially to algae. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
|-----|---|--|-----------------|-----------------|--------------|---|

▼ **M1**▼ **M191**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|-----------------------|------------------|------------------------|---|
| 104 | Thifensulfuron-methyl CAS No 79277-27-3 CIPAC No 452 | methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfonyl)thiophene-2-carboxylate | ≥ 960 g/kg | 1 November 2016 | 31 October 2031 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thifensulfuron-methyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater; — the protection of non-target plants and aquatic organisms. <p>Conditions of use shall include risk mitigation measures and the obligation to monitor the groundwater, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ul style="list-style-type: none"> (1) the absence of genotoxicity of metabolites IN-A4098 and its derivative IN-B5528, IN-A5546 and IN-W8268; (2) mechanistic data to rule out an endocrine mediated mode of action for mammary gland tumours; (3) the risk to aquatic organisms from thifensulfuron-methyl and metabolite IN-D8858 and the risk to soil organisms from metabolites IN-JZ789 and 2 acid 3 triuret; (4) the relevance of the metabolites IN-A4098, IN-L9223 and IN-JZ789 if thifensulfuron-methyl is classified as reprotoxic category 2 under Regulation (EC) No 1272/2008 and the risk that those metabolites contaminate groundwater. |

▼ **M191**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|---|
| | | | | | | The applicant shall submit the information requested under point (1) by 31 March 2017, under points (2) and (3) by 30 June 2017 and under point (4) within six months after the notification of the classification decision concerning thifensulfuron-methyl. |

▼ **M198**

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|-----|--|-----------------------------------|------------|--------------|---------------|--|
| 105 | Thiabendazole CAS No 148-79-8 CIPAC No 323 | 2-(thiazol-4-yl) benzimidazole | ≥ 985 g/kg | 1 April 2017 | 31 March 2032 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiabendazole, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and consumers, — the protection of groundwater, — the control of waste water from post-harvest uses. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit by 31 March 2019 to the Commission, the Member States and the Authority confirmatory information regarding Level 2 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of thiabendazole.</p> |
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▼ **M200**

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| 106 | Oxathiapiprolin CAS No: 1003318-67-9 CIPAC No: 985 | 1-(4-{4-[(5RS)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}-1-piperidyl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]ethanone | ≥ 950 g/kg | 3 March 2017 | 3 March 2027 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxathiapiprolin, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M200**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <p>(1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities;</p> <p>(2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification.</p> <p>The applicant shall submit the information requested under points (1) and (2) by 3 September 2017.</p> |

▼ **M207**

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|-----|---|---|---|--------------|---------------|--|
| 107 | <p>Iodosulfuron</p> <p>CAS No 185119-76-0 (parent)</p> <p>CAS No 144550-36-7 (iodosulfuron-methyl-sodium)</p> <p>CIPAC No 634 (parent)</p> <p>CIPAC No 634.501 (iodosulfuron-methyl-sodium)</p> | <p>4-iodo-2-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoylsulfa-moyl]benzoic acid</p> <p>(iodosulfuron)</p> <p>sodium ({[5-iodo-2-(methoxycarbonyl)phenyl]sulfonyl} carbamoyl)(4-methoxy-6-methyl-1,3,5-triazin-2-yl)azanide</p> <p>(iodosulfuron-methyl-sodium)</p> | <p>≥ 910 g/kg (expressed as iodosulfuron-methyl-sodium)</p> | 1 April 2017 | 31 March 2032 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on iodosulfuron, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to consumers, — the risk to non-target terrestrial plants, — the risk to aquatic plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <p>(1) the genotoxic potential of the metabolite triazine-amine (IN-A4098), in order to confirm that this metabolite is not genotoxic and not relevant for the risk assessment;</p> <p>(2) the effect of water treatment processes on the nature of residues present in drinking water.</p> |
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▼ **M207**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | The applicant shall submit the information requested under point (1) 1 October 2017 and the information requested under point (2) by two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. |

▼ **M218**

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|-----|---|--|------------|---------------|--------------|---|
| 108 | Flazasulfuron CAS No 104040-78-0 CIPAC No 595 | 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulphonyl)urea | ≥ 960 g/kg | 1 August 2017 | 31 July 2032 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on flazasulfuron, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic plants, — the protection of non-target terrestrial plants, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of two years a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.</p> |
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▼ **M223**

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| 109 | <i>Beauveria bassiana</i> strain NPP111B005 Accession number in the CNCM (Collection Nationale de Culture de Microorganismes) — Institut Pasteur, Paris, France: I-2961. | Not applicable | Max. level of beauvericin 24 µg/L | 7 June 2017 | 7 June 2027 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain NPP111B005, and in particular Appendices I and II thereof, shall be taken into account. |
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▼ **M223**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers, taking into account that <i>Beauveria bassiana</i> strain NPP111B005 is to be considered, as any micro-organism, as a potential sensitizer, and paying special attention to exposure through inhalation, — the maximum level of the metabolite beauvericin in the formulated product. <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M220**

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|-----|---|----------------|------------------------------------|-------------|-------------|--|
| 110 | <p><i>Beauveria bassiana</i> strain 147</p> <p>Accession number in the CNCM (Collection nationale de cultures de micro-organismes) — Institut Pasteur, Paris, France: I-2960.</p> | Not applicable | Max. level of beauvericin: 24 µg/L | 6 June 2017 | 6 June 2027 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain 147, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers, taking into account that <i>Beauveria bassiana</i> strain 147 is to be considered, as any micro-organism, as a potential sensitizer, and paying special attention to exposure through inhalation, — the maximum level of the metabolite beauvericin in the formulated product. <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M1**▼ **M216**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|------------------------|---|
| 111 | <p>Mesosulfuron (parent)</p> <p>Mesosulfuron-methyl (variant)</p> <p>CAS No 208465-21-8 (mesosulfuron-methyl)</p> <p>CIPAC No 663 (mesosulfuron)</p> <p>CIPAC No 663.201 (mesosulfuron-methyl)</p> | <p>Mesosulfuron-methyl: methyl-2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-(methanesulfonamido)-<i>p</i>-toluate</p> <p>Mesosulfuron: 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-methanesulfonamido-<i>p</i>-toluic acid</p> | <p>≥ 930 g/kg</p> <p>(expressed as mesosulfuron-methyl)</p> | 1 July 2017 | 30 June 2032 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on mesosulfuron and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of aquatic organisms and non-target terrestrial plants; — the protection of groundwater. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.</p> |
| 112 | <p>Mesotrione</p> <p>CAS No 104206-82-8</p> <p>CIPAC No 625</p> | <p>Mesotrione</p> <p>2-(4-mesyl-2-nitrobenzoyl) cyclohexane-1,3-dione</p> | <p>≥ 920 g/kg</p> <p>R287431 max 2 mg/kg</p> <p>R287432 max 2 g/kg</p> <p>1,2-dichloroethane max 1 g/kg</p> | 1 June 2017 | 31 May 2032 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on mesotrione, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, — the protection of groundwater in vulnerable regions, — the protection of mammals, aquatic and non-target plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the genotoxic profile of the metabolite AMBA; |

▼ **M214**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|------------|------------------|------------------------|--|
| | | | | | | <p>2. the potential endocrine disrupting mode of action of the active substance in particular level 2 and 3 tests, currently indicated in the OECD Conceptual framework (OECD 2012) and analysed in the EFSA Scientific opinion on the hazard assessment of endocrine disruptors;</p> <p>3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under point 1 by 1 July 2017 and the relevant information requested under point 2 by 31 December 2017. The applicant shall submit to the Commission, the Member States and the Authority the confirmatory information requested under point 3 within a period of two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.</p> |
| 113 | Cyhalofop-butyl CAS No 122008-85-9 CIPAC No 596 | butyl (R)-2-[4-(4-cyano-2-fluorophenoxy)phenoxy]propionate | 950 g/kg | 1 July 2017 | 30 June 2032 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyhalofop-butyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, — the technical specification, — the protection of non-target terrestrial plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M215**

▼ **M1**▼ **M228**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|--|------------------|------------------------|---|
| 114 | Propoxycarbazone (parent) Propoxycarbazone-sodium (variant) CAS No 145026-81-9 (propoxycarbazone) CAS No 181274-15-7 (propoxycarbazone-sodium) CIPAC No 655 (propoxycarbazone) CIPAC No 655.011 (propoxycarbazone-sodium) | Propoxycarbazone: methyl 2-[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazole-1-carboxamido)sulfonyl]benzoate Propoxycarbazone-sodium: sodium {[2-(methoxycarbonyl)phenyl]sulfonyl}[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]azanide | ≥ 950g/kg <i>(expressed as Propoxycarbazone-sodium)</i> | 1 September 2017 | 31 August 2032 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on propoxycarbazone, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms, in particular aquatic plants and of and non-target terrestrial plants, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of 2 years of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission. |
| 115 | Benzoic acid CAS No 65-85-0 CIPAC No 622 | Benzoic acid | ≥ 990 g/kg | 1 September 2017 | 31 August 2032 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on benzoic acid and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators, ensuring that conditions of use impose the use of adequate personal protective equipment. Conditions of use shall include risk mitigation measures, where appropriate. |
| 116 | 2,4-DB CAS No 94-82-6 CIPAC No 83 | 4-(2,4-dichlorophenoxy) butyric acid | ≥ 940 g/kg Impurities: | 1 November 2017 | 31 October 2032 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,4-DB, and in particular Appendices I and II thereof, shall be taken into account. |

▼ **M232**

▼ **M232**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|---|------------------|------------------------|---|
| | | | <p>Free phenols (expressed as 2,4-dichlorophenol (2,4-DCP)): max. 15 g/kg.</p> <p>Dibenzo-<i>p</i>-dioxins and polychlorinated dibenzofurans (TCDD toxic equivalents (TEQ)): max. 0,01 mg/kg.</p> | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers, — the protection of consumers from products of animal origin, — the protection of wild mammals, — the protection of soil non-target organisms, — the protection of aquatic organisms, — the protection of non-target terrestrial plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M234**

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|-----|---|------------------------------|--|-----------------|-----------------|--|
| 117 | Maleic hydrazide CAS No 123-33-1 CIPAC No 310 | 6-hydroxy-2H-pyridazin-3-one | <p>≥ 979 g/kg</p> <p>Until 1 November 2018, the impurity hydrazine shall not exceed 1 mg/kg in the technical material.</p> <p>From 1 November 2018, the impurity hydrazine shall not exceed 0,028 mg/kg in the technical material.</p> | 1 November 2017 | 31 October 2032 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on maleic hydrazide, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of consumers, — the operator and worker safety; the conditions of the use should include the application of adequate personal protective equipment. <p>Member States shall ensure, where appropriate, that the label of the treated crops includes the indication that the crops were treated with maleic hydrazide, and the accompanying instructions to avoid exposure of the livestock.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M244**

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|-----|--|----------------------------|--|------------------|------------------|--|
| 118 | Glyphosate CAS No 1071-83-6 CIPAC No 284 | N-(phosphonomethyl)glycine | <p>≥ 950 g/kg</p> <p>Impurities:</p> <p>Formaldehyde, less than 1 g/kg</p> | 16 December 2017 | 15 December 2022 | <p>Only uses as herbicide may be authorised.</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, shall be taken into account.</p> |
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▼ **M244**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|---|------------------|------------------------|---|
| | | | <i>N</i> -Nitroso-glyphosate, less than 1 mg/kg | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses, — the protection of operators and amateur users, — the risk to terrestrial vertebrates and non-target terrestrial plants, — the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions, — compliance of pre-harvest uses with good agricultural practices. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>Member States shall ensure that use of plant protection products containing glyphosate is minimised in the specific areas listed in Article 12(a) of Directive 2009/128/EC.</p> <p>Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies.</p> <p>Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).</p> |

▼ **M247**

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|-----|---|---|------------|--------------|------------------|---|
| 119 | Acetamiprid CAS No 135410-20-7 CIPAC No 649 | (E)-N1-[(6-Chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine | ≥ 990 g/kg | 1 March 2018 | 28 February 2033 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on acetamiprid, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> |
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▼ **M247**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | <ul style="list-style-type: none"> — the risk to aquatic organisms, bees and other non-target arthropods, — the risk to birds and mammals, — the risk to consumers, — the risk to operators. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M253**

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|-----|--|--|---|-------------|-------------|---|
| 120 | Bentazone CAS No 25057-89-0 CIPAC No 366 | 3-isopropyl-1 <i>H</i> -2,1,3-benzothiadiazin-4(3 <i>H</i>)-one 2,2-dioxide | ≥ 960 g/kg 1,2-dichloroethane < 3 mg/kg | 1 June 2018 | 31 May 2025 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bentazone, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the technical specification, — the protection of operators and workers, — the risk to birds and mammals, — the protection of groundwater, particularly but not only in drinking water protected areas, and shall carefully consider the timing of application, soil and/or climatic conditions. <p>Conditions of use shall include risk mitigation measures where appropriate.</p> <p>The applicant shall submit by 1 February 2019 to the Commission, the Member States and the Authority confirmatory information as regards Level 2/3 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of bentazone.</p> |
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▼ **M1**▼ **M259**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|-----------------------|------------------|------------------------|---|
| 121 | Silthiofam CAS No 175217-20-6 CIPAC No 635 | N-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide | ≥ 980 g/kg | 1 July 2018 | 30 June 2033 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on silthiofam and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, — the protection of groundwater in vulnerable regions, — the protection of birds, mammals and earthworms. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water; 2. the relevance of the metabolites M2 and M6 taking into account any relevant classification for silthiofam in accordance with Regulation (EC) No 1272/2008, in particular as reprotoxic category 2. <p>The applicant shall submit the information mentioned in point (1) within two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater is made public by the Commission and the information requested under point (2) within one year after the publication in the European Chemicals Agency (ECHA) webpage of the opinion adopted by the Committee for risk assessment of the ECHA in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to silthiofam.</p> |

▼ **M1**▼ **M255**▼ **M258**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|------------------------|---|
| 122 | Forchlorfenuron CAS No 68157-60-8 CIPAC No 633 | 1-(2-chloro-4-pyridyl)-3-phenylurea | ≥ 978 g/kg | 1.6.2018 | 31.5.2033 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on forchlorfenuron, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>— the risk to consumers as regards the potential risk from metabolites in fruit crops with edible peels.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
| 123 | Zoxamide CAS No 156052-68-5 CIPAC No 640 | (RS)-3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-p-toluamide | ≥ 953 g/kg | 1 July 2018 | 30 June 2033 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on zoxamide, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>— the protection of groundwater from metabolite RH-141455,</p> <p>— the protection of bees, aquatic organisms and earthworms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment</p> |

▼ **M258**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | processes on the nature of residues present in drinking water within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater is made public by the Commission. |

▼ **M267**

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|-----|---|--|---|---------------|--------------|---|
| 124 | Trifloxystrobin CAS No 141517-21-7 CIPAC No 617 | methyl (E)-methoxyimino- {(E)- α -[1-(α,α,α -trifluoro-m-tolyl)ethylideneaminoxy]-o-tolyl}acetate | ≥ 975 g/kg AE 1344136 (max. 4 g/kg) | 1 August 2018 | 31 July 2033 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on trifloxystrobin, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions; — the protection of aquatic organisms, bees, and of fish-eating birds and mammals. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> (1) the relevance of metabolites that may occur in groundwater, taking into account any relevant classification for trifloxystrobin in accordance with Regulation (EC) No 1272/2008, in particular as toxic for reproduction category 2; (2) the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. |
|-----|---|--|---|---------------|--------------|---|

▼ **M267**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>The applicant shall submit the information requested under point (1) within one year after the publication, on the website of the European Chemicals Agency (ECHA), of the opinion adopted by the Committee for Risk Assessment of the ECHA in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to trifloxystrobin.</p> <p>The applicant shall submit the information requested under point (2) within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.</p> |

▼ **M268**

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|-----|--|---|------------|---------------|--------------|--|
| 125 | <p>Carfentrazone-ethyl</p> <p>CAS No 128639-02-1</p> <p>CIPAC No 587.202</p> | <p>Ethyl (RS)-2-chloro-3-[2-chloro-4-fluoro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1<i>H</i>-1,2,4-triazol-1-yl]phenyl]propionate</p> | ≥ 910 g/kg | 1 August 2018 | 31 July 2033 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on carfentrazone-ethyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions; — the protection of soil non-target organisms; — the protection of aquatic organisms; — the protection of non-target terrestrial higher plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> |
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▼ **M268**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>(1) the relevance of metabolites that may occur in groundwater, taking into account any relevant classification for carfentrazone-ethyl in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (¹⁹), in particular as carcinogen category 2;</p> <p>(2) the effect of water treatment processes on the nature of residues present in drinking water.</p> <p>The applicant shall submit the information mentioned in point (1) within one year after the publication on the website of the European Chemicals Agency of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to carfentrazone-ethyl.</p> <p>The applicant shall submit the information requested under point (2) within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.</p> |

▼ **M273**

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|-----|--|--|------------|-----------------|-----------------|---|
| 126 | Fenpicoxamid CAS No: 517875-34-2 CIPAC No: 991 | (3 <i>S</i> ,6 <i>S</i> ,7 <i>R</i> ,8 <i>R</i>)-8-benzyl-3-{3-[(isobutyryloxy)methoxy]-4-methoxypyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl isobutyrate | ≥ 750 g/kg | 11 October 2018 | 11 October 2028 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpicoxamid, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the impact of processing on the consumer risk assessment, — the risk to aquatic organisms. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; |
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▼ **M273**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|---|
| | | | | | | <p>2. the effect of water treatment processes on the nature of residues present in drinking water;</p> <p>3. the endocrine disrupting potential of fenpicoxamid as regards the thyroid modality/pathway, providing in particular mechanistic data to clarify according to Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 ⁽²⁰⁾, whether the effects observed in the studies submitted for approval are or are not related to a thyroid endocrine disrupting mode of action.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 1 by 11 October 2019, in point 2 within 2 years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission and in point 3 by 10 November 2020.</p> |

▼ **M272**

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|-----|---|--|--|-----------------|------------------|---|
| 127 | <p>Pethoxamid</p> <p>CAS No 106700-29-2</p> <p>CIPAC No 665</p> | <p>2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl) acetamide</p> | <p>≥ 940 g/kg</p> <p>Impurities:</p> <p>Toluene: max 3 g/kg.</p> | 1 December 2018 | 30 November 2033 | <p>PART A</p> <p>Use shall be limited to one application every two years in the same field at a maximum dose of 1 200 g active substance per hectare.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on pethoxamid, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk of groundwater metabolites when pethoxamid is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms and earthworms; — the risk to consumers from residues in the succeeding crops or in case of crop failure. |
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▼ M272

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|--|
| | | | | | | <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the relevance of the metabolites that may occur in groundwater, taking into account any relevant classification for pethoxamid in accordance with Regulation (EC) No 1272/2008 of the Parliament and of the Council ⁽¹⁹⁾, in particular as carcinogen category 2; 2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of pethoxamid as regards the thyroid modality/pathway as a minimum providing mechanistic data to clarify whether there is a thyroid endocrine disrupting mode of action. <p>The applicant shall submit the information requested under point 1 within one year after the publication of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) Regulation (EC) No 1272/2008 of the European Parliament and of the Council with respect to pethoxamid and the information requested.</p> <p>The applicant shall submit the information requested under point 2 within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.</p> <p>The applicant shall submit the information requested under point 3 by 10 November 2020 in accordance with Commission Regulation (EU) 2018/605 ⁽²⁰⁾ amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties and the joint guidance document to identify endocrine disrupting substances as adopted by EFSA and ECHA.</p> |

▼ **M1**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|---|--|------------------|------------------------|---|
| ▼ M283 | | | | | | |
| 128 | Tribenuron (parent) CAS No 106040-48-6 CIPAC No 546 | 2-[[[4-methoxy-6-methyl-1,3,5-triazin-2-yl)-methylcarbamoyl]sulfa-moyl]benzoic acid | ≥ 960 g/kg (expressed as tribenuron-methyl) | 1 February 2019 | 30 January 2034 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on tribenuron, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of consumers, in particular to residues on animal products, — the protection of groundwater, — the protection of aquatic organisms and of non-target terrestrial plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
| ▼ M285 | | | | | | |
| 129 | <i>Metschnikowia fructicola</i> strain NRRL Y-27328 Accession number in the Agriculture Research Service Culture Collection at the National center for agricultural utilisation research in Peoria, Illinois USA | Not applicable | Minimum concentration: 1×10^{10} CFU/g | 27 December 2018 | 27 December 2028 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Metschnikowia fructicola</i> strain NRRL Y-27328, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers, taking into account that <i>Metschnikowia fructicola</i> strain NRRL Y-27328 is to be considered as a potential sensitizer. <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be ensured by the producer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M1**▼ **M289**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|--|----------------|---------------------------------------|------------------|------------------------|--|
| 130 | <i>Beauveria bassiana</i> strain IMI389521 Accession number in the CABI Genetic Resource Collection: IMI389521 | Not applicable | Max. level of beauvericin: 0,09 mg/kg | 19 February 2019 | 19 February 2029 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain IMI389521, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the storage stability of the formulation(s) containing <i>B. bassiana</i> strain IMI389521 including the level of the metabolite beauvericin content after storage; — the content of the metabolite beauvericin produced under the application conditions; — the risk posed by beauvericin in infected insects present in the stored grain. Measures are required to ensure that such products do not enter the food and feed chain, taking into account the natural background level of beauvericin on cereal grains; — the protection of operators and workers, taking into account that <i>B. bassiana</i> strain IMI389521 is to be considered, as any micro-organism, as a potential sensitiser. <p>The compliance with strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²¹⁾.</p> <p>Conditions of use shall include risk mitigation measures where appropriate.</p> |
| 131 | <i>Beauveria bassiana</i> strain PPRI 5339 Accession number in the Agricultural Research Culture Collection (NRRL) International Depository Authority: NRRL 50757 | Not applicable | Max. level of beauvericin: 0,5 mg/kg | 20 February 2019 | 20 February 2029 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain PPRI 5339, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the level of the metabolite beauvericin content in a shelf-life study after storage of the formulation(s) containing <i>B. bassiana</i> strain PPRI 5339; |

▼ **M290**

▼ **M290**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <ul style="list-style-type: none"> — the effects on pollinators introduced in glasshouses following exposure to formulation(s) different from the representative one supporting this approval; — the protection of operators and workers, taking into account that <i>B. bassiana</i> strain PPRI 5339 is to be considered, as any micro-organism, as a potential sensitizer. <p>The compliance with strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²¹⁾.</p> <p>Conditions of use shall include risk mitigation measures where appropriate.</p> |

▼ **M297**

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|-----|--|--|---|---------------|---------------|---|
| 132 | <p>Mefentrifluconazole</p> <p>CAS No: 1417782-03-6</p> <p>CIPAC No: Not assigned</p> | (2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol | <p>≥ 970 g/kg</p> <p>The impurity N, N-dimethylformamide shall not exceed 0,5 g/kg in the technical material.</p> <p>The impurity toluene shall not exceed 1 g/kg in the technical material</p> <p>The impurity 1,2,4-(1H)-triazole shall not exceed 1 g/kg in the technical material</p> | 20 March 2019 | 20 March 2029 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mefentrifluconazole, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms. <p>Conditions of use shall include risk mitigation measures, such as buffer zones and/or vegetative strips, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water. |
|-----|--|--|---|---------------|---------------|---|

▼ **M297**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | The applicant shall submit the information referred to in point 1 by 20 March 2020 and the information referred to in point 2 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. |

▼ **M299**

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|-----|---|--|-----------------|---------------|---------------|--|
| 133 | Flutianil CAS No [958647-10-4] CIPAC No 835 | (Z)-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]($\alpha,\alpha,\alpha,4$ -tetrafluoro- <i>m</i> -tolylthio)acetonitrile | ≥ 985 g/kg | 14 April 2019 | 14 April 2029 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flutianil, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers, — the risk to aquatic organisms, — the risk to groundwater from metabolites, if the substance is applied under vulnerable soil or climatic conditions. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water; 3. an updated assessment of the information submitted and, where relevant further information, confirming that flutianil is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, applying also the ECHA and EFSA guidance for identification of endocrine disruptors ⁽²²⁾. |
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▼ **M299**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>The applicant shall submit the information:</p> <p>— referred to in point 1 by 14 April 2020;</p> <p>— referred to in point 2 within two years from the date of publication, from the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater; and</p> <p>— referred to in point 3 by 14 April 2021.</p> |

▼ **M305**

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|-----|--|--|-----------------|---------------|--------------|---|
| 134 | Isoxaflutole CAS No 141112-29-0 CIPAC No 575 | (5-cyclopropyl-1,2-oxazol-4-yl)(α,α,α -trifluoro-2-mesyl-p-tolyl)methanone | ≥ 972 g/kg | 1 August 2019 | 31 July 2034 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on isoxaflutole, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment, Member States shall pay particular attention to:</p> <p>— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions,</p> <p>— the protection of aquatic organisms, wild mammals and non-target terrestrial plants.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit this information within 2 years from the date of publication, by the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> <p>The applicant shall also provide an updated assessment to confirm that isoxaflutole is not an endocrine disruptor within the meaning of points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 and in accordance with the guidance for identification of endocrine disruptors ⁽²³⁾ by 10 May 2021.</p> |
|-----|--|--|-----------------|---------------|--------------|---|

▼ **M1**▼ **M302**▼ **M307**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|------------------------|---|
| 135 | carvone 244-16-8 (d-carvone = S-carvone = (+)-carvone) Carvone: 602 d-carvone: not allocated | (S)-5-isopropenyl-2-methylcyclohex-2-en-1-one Or (S)-p-mentha-6,8-dien-2-one | 923 g/kg d-carvone | 1 August 2019 | 31 July 2034 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on carvone, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. <p>Conditions of use shall include risk mitigation measures, where appropriate. In particular, consideration should be given to the necessary time period before entry into storage rooms after the application of plant protection products containing carvone.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ul style="list-style-type: none"> — the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water is abstracted for drinking water. <p>The applicant shall submit that information within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> |
| 136 | 1-methylcyclopropene CAS No 3100-04-7 CIPAC No 767 | 1-methylcyclopropene | <p>≥ 980 g/kg (technical concentrate)</p> <p>The following impurities are of toxicological concern and must not exceed the following levels in the technical material (technical concentrate):</p> | 1 August 2019 | 31 July 2034 | <p>Only uses as plant growth regulator for post-harvest storage in sealable warehouse may be authorised.</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on 1-methylcyclopropene, and in particular Appendices I and II thereto, shall be taken into account.</p> |

▼ **M307**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|---|------------------|------------------------|---------------------|
| | | | <p>— 1-chloro-2-methylpropene: maximum of 0,2 g/kg,</p> <p>— 3-chloro-2-methylpropene: maximum of 0,2 g/kg.</p> <p>For 1-methylcyclopropene generated <i>in situ</i>, Heptane and methylcyclohexane are toxicologically relevant impurities. These impurities should remain below 10 %.</p> | | | |

▼ **M311**

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|-----|---|--|---|------------------|----------------|--|
| 137 | <p>Dimethenamid-P</p> <p>CAS No 163515-14-8</p> <p>CIPAC No 638</p> | <p>(S)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methyl-ethyl)acetamide</p> | <p>≥ 930 g/kg</p> <p>The following impurity is of toxicological concern and must not exceed the following level in the technical material:</p> <p>1,1,1,2-Tetrachloroethane (TCE): ≤ 1,0 g/kg</p> | 1 September 2019 | 31 August 2034 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on dimethenamid-P, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of groundwater, in particular regarding the metabolites of dimethenamid-P; — the protection of aquatic organisms and small herbivorous mammals. |
|-----|---|--|---|------------------|----------------|--|

▼ **M311**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water.</p> <p>The applicant shall submit the requested information within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> |

▼ **M310**

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|-----|--|--|--|------------------|----------------|---|
| 138 | <p>Tolclofos-methyl</p> <p>CAS No 57018-04-9</p> <p>CIPAC No 479</p> | <p>O-2,6-dichloro-p-tolyl O, O-dimethyl phosphorothioate</p> <p>O-2,6-dichloro-4-methylphenyl O, O-dimethyl phosphorothioate</p> | <p>≥ 960 g/kg</p> <p>The following impurity is of toxicological concern and must not exceed the following level in the technical material:</p> <p>Methanol max. 1 g/kg</p> | 1 September 2019 | 31 August 2034 | <p>Only for use on ornamentals and on potatoes.</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on tolclofos-methyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the risk to aquatic organisms and mammals, — the risk to consumers, in particular the potential risk from metabolite DM-TM-CH₂OH in potatoes, — the risk to operators, workers and bystanders; <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
|-----|--|--|--|------------------|----------------|---|

▼ **M312**

| | | | | | | |
|-----|---|---|--|--------------|--------------|--|
| 139 | <p>Florpyrauxifen-benzyl</p> <p>CAS No: 1390661-72-9</p> <p>CIPAC No: 990.227</p> | <p>benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylate</p> | <p>≥ 920 g/kg</p> <p>The impurity toluene shall not exceed 3 g/kg in the technical material.</p> | 24 July 2019 | 24 July 2029 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 22 March 2019, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> |
|-----|---|---|--|--------------|--------------|--|

▼ **M312**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>— the protection of aquatic and terrestrial non-target plants.</p> <p>Conditions of use shall include risk mitigation measures such as buffer zones and/or drift reduction nozzles, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine activity in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 by 24 July 2021.</p> |

▼ **M1**

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

► **M9** ⁽²⁾ 2-hydroxy-4,6-dimethoxypyrimidine.

⁽³⁾ 2,4-dihydroxy-6-methoxypyrimidine.

⁽⁴⁾ sodium 2-hydroxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl)oxybenzoate. ◀

► **M53** ⁽⁵⁾ 5-(trifluoromethyl)-2(1H)-pyridinone.

⁽⁶⁾ 4-{[5-(trifluoromethyl)-2-pyridinyl]oxy}phenol. ◀

► **M13** ⁽⁷⁾ M03: [(8-tert-butyl-1,4-dioxaspiro[4.5]dec-2-yl)methyl]ethyl(propyl)amine oxide. ◀

► **M14** ⁽⁸⁾ 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-[(methoxymethyl)amino]phenol.

⁽⁹⁾ 3-chloro-4-[3-(ethenyloxy)-4-hydroxyphenoxy]benzoic acid.

⁽¹⁰⁾ 2-chloro-1-(3-methoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene.

⁽¹¹⁾ 4-(3-ethoxy-4-hydroxyphenoxy)benzoic acid. ◀

► **M20** ⁽¹²⁾ 3-phenoxybenzaldehyde. ◀

► **M25** ⁽¹³⁾ Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent (TEQ) using the WHO-toxic equivalency factors (WHO-TEFs)). ◀

► **M52** ⁽¹⁴⁾ 7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidine-6-carboxylic acid. ◀

► **M56** ⁽¹⁵⁾ 3-chloro-5-[(4,6-dimethoxy-2-pyrimidinyl)amino]-1-methyl-1*H*-pyrazole-4-carboxylic acid.

⁽¹⁶⁾ 3-chloro-1-methyl-5-sulfamoyl-1*H*-pyrazole-4-carboxylic acid. ◀

► **M171** ⁽¹⁷⁾ *p*-methyl-phenethylamine. ◀

► **M249** ⁽¹⁸⁾ OJ L 353, 31.12.2008, p. 1. ◀

► **M268** ⁽¹⁹⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1). ◀

► **M273** ⁽²⁰⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33). ◀

► **M289** ⁽²¹⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf ◀

► **M299** ⁽²²⁾ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311; ECHA-18-G-01-EN. ◀

► **M305** ⁽²³⁾ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 <https://efsa.onlinelibrary.wiley.com/doi/epdt710.2903/i.efsa.2018.5311> ◀

▼ **M110**

PART C

Basic Substances

General provisions applying to all substances listed in this Part: the Commission shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make them available to them on specific request.

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Specific provisions |
|--------|---|--|--|------------------|---|
| 1 | <i>Equisetum arvense</i> L. CAS No: not allocated CIPAC No: not allocated | Not applicable | European Pharmacopeia | 1 July 2014 | <i>Equisetum arvense</i> L. may be used in accordance with the specific conditions included in the conclusions of the review report on <i>Equisetum arvense</i> L. (SANCO/12386/2013) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014. |
| 6 | | | | | |
| 2 | Chitosan hydrochloride CAS no: 9012-76-4 | Not applicable | European Pharmacopeia Max content of heavy metals: 40 ppm | 1 July 2014 | Chitosan hydrochloride shall comply with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011. Chitosan hydrochloride may be used in accordance with specific conditions included in the conclusions of the review report on Chitosan hydrochloride (SANCO/12388/2013) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014. |
| 5 | | | | | |
| 3 | Sucrose CAS no: 57-50-1 | α -D-glucopyranosyl-(1→2)- β -D-fructofuranoside or β -D-fructofuranosyl-(2→1)- α -D-glucopyranoside | Food grade | 1 January 2015 | Only uses as basic substance being an elicitor of the crop's natural defence mechanisms are approved. Sucrose shall be used in accordance with the specific conditions included in the conclusions of the review report on sucrose (SANCO/11406/2014) and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014. |

▼ **M110**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Specific provisions |
|---------------|--|-------------------|--|------------------|---|
| ▼ M144 | | | | | |
| 4 | Calcium Hydroxide CAS No 1305-62-0 | Calcium Hydroxide | 920 g/kg Food grade The following impurities are of toxicological concern and must not exceed the levels below (expressed in mg/kg on dry matter): Barium 300 mg/kg Fluoride 50 mg/kg Arsenic 3 mg/kg Lead 2 mg/kg. | 1 July 2015 | Calcium hydroxide shall be used in accordance with the specific conditions included in the conclusions of the review report on Calcium Hydroxide (SANCO/10148/2015) and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 20 March 2015. |
| ▼ M147 | | | | | |
| 5 | Vinegar CAS No: 90132-02-8 | Not available | Food grade containing a maximum of 10 % acetic acid. | 1 July 2015 | ► M291 Vinegar shall be used in accordance with the specific conditions included in the conclusions of the review report on vinegar (SANCO/12896/2014) and in particular Appendices I and II thereof. ◀ |
| ▼ M149 | | | | | |
| 6 | Lecithins CAS No: 8002-43-5 CIPAC No: not allocated Einecs 232-307-2 | Not allocated | As described in the Annex to Regulation (EU) No 231/2012. | 1 July 2015 | Only uses as basic substance being a fungicide are approved. Lecithins shall be used in accordance with the specific conditions included in the conclusions of the review report on lecithins (SANCO/12798/2014) and in particular Appendices I and II thereof. |
| ▼ M146 | | | | | |
| 7 | <i>Salix</i> spp. cortex CAS No: not allocated CIPAC No: not allocated | Not applicable | European Pharmacopeia | 1 July 2015 | <i>Salix</i> cortex shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Salix</i> spp. cortex (SANCO/12173/2014) and in particular Appendices I and II thereof. |

▼ **M110**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Specific provisions |
|---------------|--|-------------------------------|---|------------------|---|
| ▼ M157 | | | | | |
| 8 | Fructose CAS No: 57-48-7 | β-D-fructofuranose | Food grade | 1 October 2015 | Only uses as basic substance being an elicitor of the crop's natural defence mechanisms are approved. Fructose shall be used in accordance with the specific conditions included in the conclusions of the review report on fructose (SANCO/12680/2014) and in particular Appendices I and II thereof. |
| ▼ M163 | | | | | |
| 9 | Sodium hydrogen carbonate CAS no: 144-55-8 | Sodium hydrogen carbonate | Food grade | 8 December 2015 | Sodium hydrogen carbonate shall be used in accordance with the specific conditions included in the conclusions of the review report on sodium hydrogen carbonate (SANTE/10667/2015) and in particular Appendices I and II thereof. |
| ▼ M178 | | | | | |
| 10 | Whey CAS No: 92129-90-3 | Not available | CODEX STAN 289-1995 ⁽²⁾ | 2 May 2016 | Whey shall be used in accordance with the specific conditions included in the conclusions of the review report on whey (SANTE/12354/2015) and in particular Appendices I and II thereof. |
| ▼ M176 | | | | | |
| 11 | Diammonium phosphate CAS No: 7783-28-0 | Diammonium hydrogen phosphate | Oenological grade | 29 April 2016 | Diammonium phosphate shall be used in accordance with the specific conditions included in the conclusions of the review report on diammonium phosphate (SANTE/12351/2015) and in particular Appendices I and II thereto. |
| ▼ M195 | | | | | |
| 12 | Sunflower oil CAS No: 8001-21-6 | Sunflower oil | Food grade | 2 December 2016 | Sunflower oil shall be used in accordance with the specific conditions included in the conclusions of the review report on sunflower oil (SANTE/10875/2016) and in particular Appendices I and II thereof. |
| ▼ M211 | | | | | |
| 13 | Clayed charcoal CAS No 7440-44-0 231-153-3 (Einecs) (activated charcoal) CAS No 1333-86-4 215-609-9 (Einecs) (carbon black) CAS No 1302-78-9 215-108-5 (Einecs) (bentonite) | Not available. | Charcoal: Purity required by Regulation (EU) No 231/2012 ⁽³⁾ Bentonite: Purity required by Implementing Regulation (EU) No 1060/2013 ⁽⁴⁾ | 31 March 2017 | Clayed charcoal shall be used in accordance with the specific conditions included in the conclusions of the review report on clayed charcoal (SANTE/11267/2016) and in particular Appendices I and II thereof. |

▼ **M110**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Specific provisions |
|---------------|---|--------------------|--|-------------------|---|
| ▼ M210 | | | | | |
| 14 | <i>Urtica</i> spp. CAS No 84012-40-8 (<i>Urtica dioica</i> extract) CAS No 90131-83-2 (<i>Urtica urens</i> extract) | <i>Urtica</i> spp. | European Pharmacopeia | 30 March 2017 | <i>Urtica</i> spp. shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Urtica</i> spp. (SANTE/11809/2016) and in particular Appendices I and II thereof. |
| ▼ M209 | | | | | |
| 15 | Hydrogen peroxide CAS No 7722-84-1 | Hydrogen peroxide | Solution in water ($< 5\%$) The hydrogen peroxide used to manufacture the solution shall have a purity according to the FAO JECFA specifi- cations. | 29 March 2017 | Hydrogen peroxide shall be used in accordance with the specific conditions included in the conclusions of the review report on hydrogen peroxide (SANTE/11900/2016) and in particular Appendices I and II thereof. |
| ▼ M237 | | | | | |
| 16 | Sodium chloride CAS No 7647-14-5 | Sodium chloride | 970 g/kg Food grade | 28 September 2017 | Only uses as basic substance being a fungicide and insecticide are approved. Sodium chloride shall be used in accordance with the specific conditions included in the conclusions of the review report on sodium chloride (SANTE/10383/2017) and in particular Appendices I and II thereof. |
| ▼ M242 | | | | | |
| 17 | Beer CAS No 8029-31-0 | Not applicable | Food grade | 5 December 2017 | Beer shall be used in accordance with the specific conditions included in the conclusions of the review report on beer (SANTE/11038/2017) and in particular Appendices I and II thereto. |
| ▼ M240 | | | | | |
| 18 | Mustard seeds powder | Not applicable | Food grade | 4 December 2017 | Mustard seeds powder shall be used in accordance with the specific conditions included in the conclusions of the review report on mustard seeds powder (SANTE/11309/2017) and in particular Appendices I and II thereof. |

▼ **M110**

| Number | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Specific provisions |
|---------------------|-------------------------------------|--|---|------------------|--|
| ▼ M257 19 | Talc E553B CAS No: 14807-96-6 | Magnesium hydrogen metasilicate silicate mineral | Food grade in conformity with Commission Regulation (EU) No 231/2012 ⁽³⁾ . < 0,1 % of respirable Crystalline Silica | 28 May 2018 | Talc E553B shall be used in accordance with the specific conditions included in the conclusions of the review report on Talc E553B (SANTE/11639/2017) and in particular Appendices I and II thereof. |
| ▼ M276 20 | Onion oil CAS No: 8002-72-0 | Not applicable | Food grade | 17 October 2018 | Onion oil shall be used in accordance with the specific conditions included in the conclusions of the review report on Onion oil (SANTE/10615/2018) and in particular Appendices I and II thereto. |

▼ **M110**

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.

► **M178** ⁽²⁾ Available online: <http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/> ◀

► **M211** ⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 1060/2013 of 29 October 2013 concerning the authorisation of bentonite as a feed additive for all animal species (OJ L 289, 31.10.2013, p. 33). ◀

▼ **M136**

PART D

Low-risk active substances'

General provisions applying to all substances listed in this Part: the Commission shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make them available to them on specific request.

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------------------|--|---|--|------------------|------------------------|--|
| 1 | <i>Isaria fumosorosea</i> strain Apopka 97 Deposited in the American Type Culture Collection (ATCC) under the name <i>Paecilomyces fumosoroseus</i> Apopka ATCC 20874 | Not applicable | Minimum concentration: $1,0 \times 10^8$ CFU/ml Maximum concentration: $2,5 \times 10^9$ CFU/ml | 1 January 2016 | 31 December 2030 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Isaria fumosorosea</i> strain Apopka 97, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Isaria fumosorosea</i> strain Apopka 97 is to be considered as a potential sensitiser. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. |
| ▼ M142 2 | COS-OGA CAS No: not allocated CIPAC No: 979 | Linear copolymer of α -1,4-D-galactopyranosyluronic acids and methylesterified galactopyranosyluronic acids (9 to 20 residues) with linear copolymer β -1,4-linked 2-amino-2-deoxy-D-glucopyranose and 2-acetamido-2-deoxy-D-glucopyranose (5 to 10 residues). | ≥ 915 g/kg — OGA/COS ratio comprised between 1 and 1,6 — Degree of polymerisation of COS comprised between 5 and 10 — Degree of polymerisation of OGA comprised between 9 and 20 — Degree of methylation of OGA < 10 % — Degree of acetylation of COS < 50 % | 22 April 2015 | 22 April 2030 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on COS-OGA, and in particular Appendices I and II thereof, shall be taken into account. |

▼ **M136**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|-------------------------|------------------|------------------------|---------------------|
|--|-------------------------------------|------------|-------------------------|------------------|------------------------|---------------------|

▼ **M143**

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|---|--|--------------|------------|---------------|---------------|---|
| 3 | Cerevisane (no ISO name adopted) CAS No: not allocated CIPAC No: 980 | Not relevant | ≥ 924 g/kg | 23 April 2015 | 23 April 2030 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cerevisane, and in particular Appendices I and II thereof, shall be taken into account. |
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▼ **M153**

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|---|---|----------------|---|---------------|---------------|--|
| 4 | <i>Pepino mosaic</i> virus strain CH2 isolate 1906 GenBank, accession number JN835466 CIPAC No: not allocated | Not applicable | minimum concentration 5×10^5 viral genome copies per μL | 7 August 2015 | 7 August 2030 | Only the use in greenhouses may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pepino mosaic</i> virus strain CH2 isolate 1906, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Pepino mosaic</i> virus strain CH2 isolate 1906 is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. |
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▼ **M152**

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|---|---|------------------|---|----------------|------------------|--|
| 5 | Ferric phosphate CAS No: 10045-86-0 CIPAC No: 629 | Ferric phosphate | Ferric phosphate 703 g/kg equivalent to 260 g/kg iron and 144 g/kg phosphorus | 1 January 2016 | 31 December 2030 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ferric phosphate, and in particular Appendices I and II thereof, shall be taken into account. |
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▼ **M136**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|----------------|--|------------------|------------------------|---|
| ▼ M186 | | | | | | |
| 6 | <p><i>Saccharomyces cerevisiae</i> strain LAS02</p> <p>Accession number in the collection of the 'Collection Nationale de Cultures de Micro-organismes' (CNCM) of the Pasteur Institute: CNCM I-3936</p> | Not applicable | Minimum concentration: 1×10^{13} CFU/kg | 6 July 2016 | 6 July 2031 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Saccharomyces cerevisiae</i> strain LAS02, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Saccharomyces cerevisiae</i> strain LAS02 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> |
| ▼ M185 | | | | | | |
| 7 | <p><i>Trichoderma atroviride</i> strain SC1</p> <p>Accession number CBS 122089 in the collection of the Centraalbureau voor Schimmelcultures (CBS) in Utrecht, The Netherlands</p> <p>CIPAC No: 988</p> | Not applicable | minimum concentration 1×10^{10} CFU/g | 6 July 2016 | 6 July 2031 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> strain SC1, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers. Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> |
| ▼ M208 | | | | | | |
| 8 | <p>Mild Pepino Mosaic Virus isolate VC1</p> <p>Reference number DSM 26973 in the German Collection of Micro-organisms and Cell Cultures (DSMZ)</p> | Not applicable | Nicotine < 0,1 mg/L | 29 March 2017 | 29 March 2032 | <p>Only the use in greenhouses may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Mild Pepino Mosaic Virus isolate VC1, and in particular Appendices I and II thereof, shall be taken into account.</p> |

▼ **M208**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that Mild Pepino Mosaic Virus isolate VC1 is to be considered, as any microorganism, a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> |

▼ **M206**

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| 9 | <p>Mild Pepino Mosaic Virus isolate VX1</p> <p>Reference number DSM 26974 in the German Collection of Micro-organisms and Cell Cultures (DSMZ)</p> | Not applicable | Nicotine < 0,1 mg/L | 29 March 2017 | 29 March 2032 | <p>Only the use in greenhouses may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Mild Pepino Mosaic Virus isolate VX1, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that Mild Pepino Mosaic Virus isolate VX1 is to be considered, as any microorganism, a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> |
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▼ **M219**

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| 10 | <p><i>Bacillus amyloliquefaciens</i> strain FZB24.</p> <p>Accession number in the culture collection of the 'Deutsche Sammlung von Mikroorganismen' (DSMZ), Germany: 10271</p> | Not applicable | <p>Minimum concentration:</p> 2×10^{14} CFU/kg | 1 June 2017 | 1 June 2032 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> strain FZB24, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> |
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▼ **M219**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--|---|------------|-------------------------|------------------|------------------------|--|
| | Accession number at the Agricultural Research Service Culture Collection (NRRL), USA: B-50304 | | | | | <p>— specification of the technical material as commercially manufactured, including full characterisation of impurities and metabolites;</p> <p>— the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M222**

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|----|--|----------------|---|---------------|--------------|---|
| 11 | <p><i>Coniothyrium minitans</i> strain CON/M/91-08</p> <p>Accession number in the culture collection of the 'Deutsche Sammlung von Mikroorganismen' (DSM), Germany: DSM 9660</p> <p>CIPAC No 614</p> | Not applicable | <p>► C4 Minimum content of viable spores:</p> <p>$1,17 \times 10^{12}$ CFU/kg ◀</p> | 1 August 2017 | 31 July 2032 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Coniothyrium minitans</i> strain CON/M/91-08, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>— the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M246**

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| 12 | <p>Laminarin</p> <p>CAS No 9008-22-4</p> <p>CIPAC No 671</p> | <p>(1→3)-β-D-glucan</p> <p>(according to IUPAC-IUB Joint Commission on Biochemical Nomenclature)</p> | <p>≥ 860 g/kg on dry matter (TC)</p> | 1 March 2018 | 28 February 2033 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on laminarin, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M136**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|----------------|--|------------------|------------------------|---|
| ▼ M275 | | | | | | |
| 13 | <i>Pasteuria nishizawae</i> Pn1 Culture collection: ATCC Safe Deposit (SD-5833) CIPAC No Not allocated | Not applicable | minimum concentration 1×10^{11} spores/g | 14 October 2018 | 14 October 2033 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pasteuria nishizawae</i> Pn1, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Pasteuria nishizawae</i> Pn 1 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. |
| ▼ M269 | | | | | | |
| 14 | <i>Ampelomyces quisqualis</i> strain AQ10 | Not applicable | Minimum content of viable spores: $3,0 \times 10^{12}$ CFU/kg | 1 August 2018 | 1 August 2033 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Ampelomyces quisqualis</i> strain AQ10, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitizers and ensuring that adequate personal protective equipment is included as a condition of use. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. Conditions of use shall include risk mitigation measures, where appropriate. |

▼ **M136**

| | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|-----------------------|------------------|------------------------|---------------------|
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▼ **M292**

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|----|--|----------------|---|--------------|---------------|---|
| 15 | <p><i>Clonostachys rosea</i> strain J1446</p> <p>Accession number in the culture collection of the German Collection of Micro-organisms and Cell Cultures (DSMZ): DSM 9212</p> | Not applicable | <p>Not applicable</p> <p>Gliotoxin content: max. 50 µg/kg in the technical grade of the MCPA.</p> | 1 April 2019 | 31 March 2034 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Clonostachys rosea</i> strain J1446, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of technical material as commercially manufactured in plant protection products, including full characterisation of potential metabolites of concern; — the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use; — the studies or information from the scientific literature recently made available in relation to antifungal susceptibility of <i>Clonostachys rosea</i> J1446. <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbial contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |
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▼ **M300**

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|----|---|----------------|-------------------------------|-------------|-------------|--|
| 16 | <p>ABE-IT 56 (components of lysate of <i>Saccharomyces cerevisiae</i> strain DDSF623)</p> | Not Applicable | 1 000 g/kg (active substance) | 20 May 2019 | 20 May 2034 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ABE-IT 56 (components of lysate of <i>Saccharomyces cerevisiae</i> strain DDSF623) and in particular Appendices I and II thereof, shall be taken into account.</p> |
|----|---|----------------|-------------------------------|-------------|-------------|--|

▼ **M136**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|----------------|---|------------------|------------------------|---|
| ▼ M314 | | | | | | |
| 17 | <p><i>Bacillus subtilis</i> strain IAB/BS03</p> <p>Accession number in the Spanish Type Culture Collection (CECT), Spain: CECT 7254</p> <p>Accession number in the German Type Culture Collection (DSMZ), Germany: DSM 24682</p> | Not applicable | <p>Minimum concentration:</p> <p>1×10^{13} CFU/kg</p> <p>Maximum concentration:</p> <p>5×10^{13} CFU/kg</p> | 20 October 2019 | 20 October 2034 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus subtilis</i> strain IAB/BS03, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>a) the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites;</p> <p>b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitisers, and ensuring that adequate personal protective equipment is included as a condition of use.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Working Document SANCO/12116/2012 (²).</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> |

▼ **M136**

| | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|----------------|---|------------------|------------------------|---|
| ▼ M316 | | | | | | |
| 18 | <i>Verticillium albo-atrum</i> strain WCS850 (culture collection No CBS 276.92) | Not applicable | <p>Minimum concentration:</p> <p>$0,7 \times 10^7$ CFU/ml distilled water</p> <p>Maximum concentration:</p> <p>$1,5 \times 10^7$ CFU/ml distilled water</p> <p>No relevant impurity</p> | 1 November 2019 | 31 October 2034 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Verticillium albo-atrum</i> strain WCS850, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Verticillium albo-atrum</i> strain WCS850 is to be considered as a potential sensitiser.</p> <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Commission Working Document SANCO/12116/2012 ⁽²⁾.</p> |

▼ **M136**

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

► **M292** ⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf ◀

PART E

Candidates for substitution

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|---|--|--|---|------------------|------------------------|--|
| 1 | Flumetralin CAS No 62924-70-3 CIPAC No 971 | <i>N</i> -(2-chloro-6-fluorobenzyl)- <i>N</i> -ethyl- α,α,α -trifluoro-2,6-dinitro- <i>p</i> -toluidine | 980 g/kg The impurity Nitrosamine (calculated as nitroso-dimethylamine) shall not exceed 0,001 g/kg in the technical material. | 11 December 2015 | 11 December 2022 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flumetralin, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> (a) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (c) the risk to herbivorous mammals; (d) the risk to aquatic organisms. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the technical specification of the active substance as manufactured (based on commercial scale production); 2. the compliance of the toxicity batches with the confirmed technical specification. <p>The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 11 June 2016.</p> |

▼ **M166**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|---|--|------------------|------------------------|--|
| ▼ M162 | | | | | | |
| 2 | Esfenvalerate CAS No: 66230-04-4 CIPAC No: 481 | (α S)- α -cyano-3-phenoxymethyl (2S)-2-(4-chlorophenyl)-3-methylbutyrate | 830 g/kg The impurity toluene shall not exceed 10 g/kg in the technical material. | 1 January 2016 | 31 December 2022 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on esfenvalerate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk from esfenvalerate and the 2S α R-isomer of fenvalerate to aquatic organisms including the risk for bio-accumulation through the food chain, — the risk to honeybees and non-target arthropods, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ M169 | | | | | | |
| 3 | Metsulfuron-methyl CAS No 74223-64-6 CIPAC No 441.201 | Methyl 2-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)benzoate | 967 g/kg | 1 April 2016 | 31 March 2023 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metsulfuron-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of consumers, — the protection of groundwater, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority by 30 September 2016 confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (IN-A4098) to confirm that this metabolite is not genotoxic and not relevant for risk assessment. |

▼ **M166**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|---|---------------------------|------------------|------------------------|---|
| ▼ M172 | | | | | | |
| 4 | Benzovindiflupyr CAS No: 1072957-71-1 CIPAC No: not available | <i>N</i> -[(1 <i>RS</i> ,4 <i>SR</i>)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide | 960 g/kg (50/50) racemate | 2.3.2016 | 2.3.2023 | <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on benzovindiflupyr, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification; (3) the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water. <p>The applicant shall submit to the Commission, the Member States and the Authority the information requested under points (1) and (2) by 2 September 2016 and the information requested under point (3) within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> |

▼ **M166**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|--|-------------------------|------------------|------------------------|--|
| ▼ M170 | | | | | | |
| 5 | Lambda-Cyhalothrin CAS No 91465-08-6 CIPAC No 463 | A 1:1 mixture of: (R)- α -cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropane-carboxylate and (S)- α -cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropane-carboxylate or of (R)- α -cyano-3-phenoxybenzyl (1S)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropane-carboxylate and (S)- α -cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropane-carboxylate | 900 g/kg | 1 April 2016 | 31 March 2023 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lambda-cyhalothrin, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the:</p> <p>(a) protection of operators, workers and bystanders;</p> <p>(b) metabolites potentially formed in processed commodities;</p> <p>(c) risk to aquatic organisms, mammals and non-target arthropods.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicants shall submit confirmatory information as regards:</p> <ol style="list-style-type: none"> a systematic review to assess the evidence available as regards potential sperm effects linked to exposure to lambda-cyhalothrin using guidance available (e.g. EFSA GD on Systematic Review methodology, 2010); toxicological information to assess the toxicological profile of the metabolites V (PBA) and XXIII (PBA(OH)). <p>The applicants shall submit those information to the Commission, the Member States and the Authority by 1 April 2018.</p> |

▼ **M166**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|---|---|------------------|------------------------|---|
| ▼ M205 | 6 Prosulfuron CAS No 94125-34-5 CIPAC No 579 | 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea | 950 g/kg The impurity 2-(3,3,3-trifluoro-propyl)-benzene sulphonamide shall not exceed 10 g/kg in the technical material. | 1 May 2017 | 30 April 2024 | PART A Use shall be limited to one application every three years on the same field at a maximum dose of 20 g active substance per hectare. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prosulfuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to non-target terrestrial and aquatic plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (CGA150829) to confirm that this metabolite is not genotoxic and not relevant for risk assessment. The applicant shall submit that information to the Commission, the Member States and the Authority by 31 October 2017. |
| ▼ M227 | 7 Pendimethalin CAS No 40487-42-1 CIPAC No 357 | N-(1-ethylpropyl)-2,6-dinitro-3,4-xylylene | 900 g/kg 1,2-dichloroethane ≤ 1 g/kg Total N-Nitroso compounds: max 100 ppm, of which N-Nitroso-pendimethalin: < 45 ppm. | 1 September 2017 | 31 August 2024 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pendimethalin, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers |

▼ **M227**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>shall be compared and verified against the specification of the technical material,</p> <p>— the protection of operators,</p> <p>— the protection of birds, mammals and aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>In particular, personal protective equipment such as gloves, coverall and sturdy footwear has to be worn to ensure that the AOEL is not exceeded for the operator.</p> <p>The applicant shall submit confirmatory information to the Commission, the Member States and the Authority as regards:</p> <ol style="list-style-type: none"> 1. the potential for bioaccumulation, in particular a reliable BCF value for bluegill sunfish (<i>Lepomis macrochirus</i>); 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. <p>The applicant shall submit the confirmatory information requested under point 1 by 31 December 2018. The applicant shall submit the confirmatory information requested under point 2 within a period of two years of the publication by the Commission of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> |

▼ **M239**

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|---|---|--|--|------------------------|------------------------|--|
| 8 | <p>Imazamox</p> <p>CAS No 114311-32-9</p> <p>CIPAC No 619</p> | <p>2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-methoxymethylnicotinic acid</p> | <p>≥ 950 g/kg</p> <p>The impurity cyanide ion (CN⁻) shall not exceed 5 mg/kg in the technical material.</p> | <p>1 November 2017</p> | <p>31 October 2024</p> | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on imazamox, and in particular Appendices I and II thereto, shall be taken into account.</p> |
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▼ **M239**

| | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|-----------------------|------------------|------------------------|--|
| | | | | | | <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of consumers; — the protection of aquatic plants and of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. <p>Conditions of authorisation shall include risk mitigation measures and monitoring programs shall be initiated to verify potential groundwater contamination from imazamox and metabolites CL 312622 and CL 354825 in vulnerable zones, where appropriate.</p> |

▼ **M260**

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|---|--|---|----------|-------------|--------------|--|
| 9 | Propyzamide CAS No 23950-58-5 CIPAC No 315 | 3,5-dichloro- <i>N</i> -(1,1-dimethylprop-2-ynyl) benzamide | 920 g/kg | 1 July 2018 | 30 June 2025 | <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on propyzamide and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, — the protection of groundwater in vulnerable areas, — the protection of birds, mammals, non-target plants, soil and aquatic organisms. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>In particular, personal protective equipment such as gloves, coverall and sturdy footwear has to be worn to ensure that the AOEL is not exceeded for the operator.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> |
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▼ **M260**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|-------------------------|------------------|------------------------|---|
| | | | | | | <p>1. the completion of assessment of toxicological profile of metabolites identified in significant concentration in primary and rotational crops;</p> <p>2. the soil degradation of major metabolite RH- 24580;</p> <p>3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water.</p> <p>The applicant shall submit the information mentioned under point (1) by 31 October 2018 and the information mentioned under point (2) by 30 April 2019. The applicant shall submit the confirmatory information mentioned in point (3) within two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater be made public by the Commission.</p> |

▼ **M288**

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|----|--|--|---|----------------|------------------|---|
| 10 | <p>Copper compounds:</p> <p>Copper hydroxide CAS No 20427-59-2 CIPAC No 44.305</p> <p>Copper oxychloride CAS No 1332-65-6 or 1332-40-7 CIPAC No 44.602</p> <p>Copper oxide CAS No 1317-39-1 CIPAC No 44.603</p> <p>Bordeaux mixture CAS No 8011-63-0 CIPAC No 44.604</p> <p>Tribasic copper sulphate CAS No 12527-76-3 CIPAC No 44.306</p> | <p>Copper (II) hydroxide</p> <p>Dicopper chloride trihydroxide</p> <p>Copper oxide</p> <p>Not allocated</p> <p>Not allocated</p> | <p>≥ 573 g/kg</p> <p>≥ 550 g/kg</p> <p>≥ 820 g/kg</p> <p>≥ 245 g/kg</p> <p>≥ 490 g/kg</p> | 1 January 2019 | 31 December 2025 | <p>Only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised.</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the conclusions of the review report on copper compounds and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the operator, worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment and other mitigation measures as appropriate; — the protection of water and non-target organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate; |
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▼ **M288**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|---|------------------|------------------------|--|
| | | | <p>The following impurities shall not exceed the following levels:</p> <p>Arsenic max. 0,1 mg/g Cu</p> <p>Cadmium max. 0,1 mg/g Cu</p> <p>Lead max. 0,3 mg/g Cu</p> <p>Nickel max. 1 mg/g Cu</p> <p>Cobalt max. 3 mg/kg</p> <p>Mercury max. 5 mg/kg</p> <p>Chromium max. 100 mg/kg</p> <p>Antimony max. 7 mg/kg</p> | | | <p>— the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, do not exceed the minimum necessary to achieve the desired effects and do not cause any unacceptable effect on the environment taking into account background levels of copper at the application site, and, where the information is available, copper input from other sources. Member States may in particular decide to set a maximum annual application rate not exceeding 4 kg/ha of copper.</p> |

▼ **M293**

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|----|--|--|---|--------------|---------------|---|
| 11 | <p>Methoxyfenozide</p> <p>CAS No 161050-58-4</p> <p>CIPAC No 656</p> | <p>N-tert-Butyl-N'-(3-methoxy-o-toluoyl)-3,5-xylohydrazide</p> | <p>≥ 970 g/kg</p> <p>The following impurities must not exceed the following levels in the technical material:</p> <p>Tert-butylhydrazine < 0,001 g/kg</p> <p>RH-116267 < 2 g/kg</p> | 1 April 2019 | 31 March 2026 | <p>Only uses in greenhouses shall be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on methoxyfenozide, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions; — the risk of accumulation in soil; — the protection of non-target arthropods, sediment dwelling and aquatic organisms; <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. a comparative in vitro metabolism study on methoxyfenozide, by 1 April 2020; |
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▼ **M293**

| | Common Name, Identification Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|-------------------------|------------------|------------------------|--|
| | | | | | | <p>2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water, within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> <p>The applicant shall also provide an updated assessment of the information submitted and, where relevant, further information to confirm the absence of thyroid endocrine activity in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 (²) by 1 February 2021.</p> |

▼ **M317**

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|----|---|---|--|-----------------|-----------------|---|
| 12 | alpha-cypermethrin CAS No 67375-30-8 CIPAC No 454 | <p>Racemate comprising: (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate</p> <p>or</p> <p>(R)-α-cyano-3 phenoxybenzyl-(1S)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate</p> <p>and (S)-α-cyano-3 phenoxybenzyl-(1R)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate</p> | <p>≥ 980 g/kg</p> <p>The manufacturing impurity hexane is considered to be of toxicological concern and must not exceed 1 g/kg in the technical material</p> | 1 November 2019 | 31 October 2026 | <p>For the implementation of the uniform principles, as referred to in Article 9(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on alpha-cypermethrin, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of operators, ensuring that the conditions of use prescribe the application of adequate personal protective equipment; — the consumer risk assessment; — the protection of aquatic organisms, bees and non-target arthropods. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety; 2. the potential relative toxicity of individual cypermethrin isomers, in particular the enantiomer (1S cis αR); |
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▼ **M317**

| | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|--|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water;</p> <p>4. Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605.</p> <p>The applicant shall submit the information referred to in point 1 by 30 October 2020; the information referred to in point 2 within two years from the date of publication, by the Commission, of a guidance document on evaluation of isomer mixtures; and the information referred to in point 3 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> <p>As regards Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of androgenic endocrine activity shall be submitted by 30 October 2021.</p> |

▼ **M166**

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

► **M293** ⁽²⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33). ◀