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$ightharpoonup \underline{B}$ 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)

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| ► <u>M174</u> | Commission Implementing Regulation (EU) 2016/370 of 15 March 2016 | L 70 | 7 | 16.3.2016 |
| ► <u>M175</u> | Commission Implementing Regulation (EU) 2016/389 of 17 March 2016 | L 73 | 77 | 18.3.2016 |
| ► <u>M176</u> | Commission Implementing Regulation (EU) 2016/548 of 8 April 2016 | L 95 | 1 | 9.4.2016 |
| ► <u>M177</u> | Commission Implementing Regulation (EU) 2016/549 of 8 April 2016 | L 95 | 4 | 9.4.2016 |
| ► <u>M178</u> | Commission Implementing Regulation (EU) 2016/560 of 11 April 2016 | L 96 | 23 | 12.4.2016 |
| ► <u>M179</u> | Commission Implementing Regulation (EU) 2016/636 of 22 April 2016 | L 108 | 22 | 23.4.2016 |
| ► <u>M180</u> | Commission Implementing Regulation (EU) 2016/638 of 22 April 2016 | L 108 | 28 | 23.4.2016 |
| ► <u>M181</u> | Commission Implementing Regulation (EU) 2016/864 of 31 May 2016 | L 144 | 32 | 1.6.2016 |
| ► <u>M182</u> | Commission Implementing Regulation (EU) 2016/871 of 1 June 2016 | L 145 | 4 | 2.6.2016 |
| ► <u>M183</u> | Commission Implementing Regulation (EU) 2016/872 of 1 June 2016 | L 145 | 7 | 2.6.2016 |
| ► <u>M184</u> | Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 | L 159 | 3 | 16.6.2016 |
| ► <u>M185</u> | Commission Implementing Regulation (EU) 2016/951 of 15 June 2016 | L 159 | 6 | 16.6.2016 |
| ► <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 |

| ► <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 |

| ► <u>M218</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/805 | of 11 | May | L 121 | 26 | 12.5.2017 |
|---------------|---------------------------|------------------------|--------------|--------|-----------|-----------|--------|-------|-----|------------|
| ► <u>M219</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/806 | of 11 | May | L 121 | 31 | 12.5.2017 |
| ► <u>M220</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/831 | of 16 | 6 May | L 124 | 27 | 17.5.2017 |
| ► <u>M221</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/841 | of 17 | 7 May | L 125 | 12 | 18.5.2017 |
| ► <u>M222</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/842 | e of 17 | 7 May | L 125 | 16 | 18.5.2017 |
| ► <u>M223</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/843 | of 17 | 7 May | L 125 | 21 | 18.5.2017 |
| ► <u>M224</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/855 | of 18 | 3 May | L 128 | 10 | 19.5.2017 |
| ► <u>M225</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/856 | of 18 | 8 May | L 128 | 14 | 19.5.2017 |
| ► <u>M226</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/1113 | 3 of 22 | 2 June | L 162 | 27 | 23.6.2017 |
| ► <u>M227</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/1114 | 4 of 22 | 2 June | L 162 | 32 | 23.6.2017 |
| ► <u>M228</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/111: | 5 of 22 | 2 June | L 162 | 38 | 23.6.2017 |
| ► <u>M229</u> | Commission 2017 | Implementing | Regulation | (EU) | 2017/112: | 5 of 22 | 2 June | L 163 | 10 | 24.6.2017 |
| ►M230 | Commission | Implementing I | Regulation (| EU) 20 | 017/1186 | of 3 July | y 2017 | L 171 | 131 | 4.7.2017 |
| ► <u>M231</u> | Commission 2017 | Implementing 1 | Regulation (| (EU) 2 | 017/1455 | of 10 A | August | L 208 | 28 | 11.8.2017 |
| ► <u>M232</u> | Commission 2017 | Implementing 1 | Regulation (| (EU) 2 | 017/1491 | of 21 | August | L 216 | 15 | 22.8.2017 |
| ► <u>M233</u> | Commission 2017 | Implementing 1 | Regulation (| (EU) 2 | 017/1496 | of 23 | August | L 218 | 7 | 24.8.2017 |
| ► <u>M234</u> | Commission 2017 | Implementing 1 | Regulation (| (EU) 2 | 017/1506 | of 28 | August | L 222 | 21 | 29.8.2017 |
| ► <u>M235</u> | Commission 2017 | Implementing 1 | Regulation (| (EU) 2 | 017/1511 | of 30 A | August | L 224 | 115 | 31.8.2017 |
| ► <u>M236</u> | Commission 6 September | Implementing 2017 | g Regulat | ion | (EU) 20 |)17/152 | 7 of | L 231 | 3 | 7.9.2017 |
| ► <u>M237</u> | Commission 7 September | | g Regulat | ion | (EU) 20 |)17/152 | 9 of | L 232 | 1 | 8.9.2017 |
| ► <u>M238</u> | Commission 7 September | | g Regulat | ion | (EU) 20 |)17/153 | 0 of | L 232 | 4 | 8.9.2017 |
| ► <u>M239</u> | Commission 7 September | | g Regulat | ion | (EU) 20 |)17/153 | 1 of | L 232 | 6 | 8.9.2017 |
| ► <u>M240</u> | Commission 13 November | | g Regulat | ion | (EU) 20 | 017/206 | 6 of | L 295 | 43 | 14.11.2017 |
| ► <u>M241</u> | Commission 13 November | | g Regulat | ion | (EU) 20 | 017/206 | 9 of | L 295 | 51 | 14.11.2017 |
| ► <u>M242</u> | Commission 14 November | | g Regulat | ion | (EU) 20 |)17/209 | 0 of | L 297 | 22 | 15.11.2017 |
| ► <u>M243</u> | Commission 14 November | | g Regulat | ion | (EU) 20 |)17/209 | 1 of | L 297 | 25 | 15.11.2017 |
| ► <u>M244</u> | Commission 12 December | Implementing r 2017 | g Regulat | ion | (EU) 20 |)17/232 | 4 of | L 333 | 10 | 15.12.2017 |
| | | | | | | | | | | |

| ► <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 |
| ►M255 | Commission Implementing Regulation (EU) 2018/679 of 3 May 2018 | L 114 | 18 | 4.5.2018 |
| ► M256 | Commission Implementing Regulation (EU) 2018/690 of 7 May 2018 | L 117 | 3 | 8.5.2018 |
| ► M257 | Commission Implementing Regulation (EU) 2018/691 of 7 May 2018 | L 117 | 6 | 8.5.2018 |
| ► M258 | 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) 201 20 September 2018 | 18/1266 of | L 238 | 81 | 21.9.2018 |
| ► <u>M275</u> | Commission Implementing Regulation (EU) 201 21 September 2018 | 8/1278 of | L 239 | 4 | 24.9.2018 |
| ► <u>M276</u> | Commission Implementing Regulation (EU) 201 26 September 2018 | 8/1295 of | L 243 | 7 | 27.9.2018 |
| ► <u>M277</u> | Commission Implementing Regulation (EU) 2018/1495 of 2018 | of 8 October | L 253 | 1 | 9.10.2018 |
| ► <u>M278</u> | Commission Implementing Regulation (EU) 2018/1500 of 2018 | of 9 October | L 254 | 1 | 10.10.2018 |
| ► <u>M279</u> | Commission Implementing Regulation (EU) 2018/1501 o 2018 | of 9 October | L 254 | 4 | 10.10.2018 |
| ► <u>M280</u> | Commission Implementing Regulation (EU) 2018/1532 of 2018 | f 12 October | L 257 | 10 | 15.10.2018 |
| ► <u>M281</u> | Commission Implementing Regulation (EU) 201 20 November 2018 | 8/1796 of | L 294 | 15 | 21.11.2018 |
| ► <u>M282</u> | Commission Implementing Regulation (EU) 201 28 November 2018 | 8/1865 of | L 304 | 6 | 29.11.2018 |
| ► <u>M283</u> | Commission Implementing Regulation (EU) 201 6 December 2018 | 8/1913 of | L 311 | 13 | 7.12.2018 |
| ► <u>M284</u> | Commission Implementing Regulation (EU) 201 6 December 2018 | 8/1914 of | L 311 | 17 | 7.12.2018 |
| ► <u>M285</u> | Commission Implementing Regulation (EU) 201 6 December 2018 | 8/1915 of | L 311 | 20 | 7.12.2018 |
| ► <u>M286</u> | Commission Implementing Regulation (EU) 201 6 December 2018 | 8/1916 of | L 311 | 24 | 7.12.2018 |
| ► <u>M287</u> | Commission Implementing Regulation (EU) 201 6 December 2018 | 8/1917 of | L 311 | 27 | 7.12.2018 |
| ► <u>M288</u> | Commission Implementing Regulation (EU) 201 13 December 2018 | 8/1981 of | L 317 | 16 | 14.12.2018 |
| ► <u>M289</u> | Commission Implementing Regulation (EU) 2019/139 of 2019 | f 29 January | L 26 | 4 | 30.1.2019 |
| ► <u>M290</u> | Commission Implementing Regulation (EU) 2019/147 of 2019 | f 30 January | L 27 | 14 | 31.1.2019 |
| ► <u>M291</u> | Commission Implementing Regulation (EU) 2019/149 of 2019 | f 30 January | L 27 | 20 | 31.1.2019 |
| ► <u>M292</u> | Commission Implementing Regulation (EU) 2019/151 of 2019 | f 30 January | L 27 | 26 | 31.1.2019 |
| ► <u>M293</u> | Commission Implementing Regulation (EU) 2019/158 of 2019 | f 31 January | L 31 | 21 | 1.2.2019 |
| ► <u>M294</u> | Commission Implementing Regulation (EU) 2019/168 of 2019 | f 31 January | L 33 | 1 | 5.2.2019 |
| ► <u>M295</u> | Commission Implementing Regulation (EU) 2019/291 of 2019 | 19 February | L 48 | 17 | 20.2.2019 |
| ► <u>M296</u> | Commission Implementing Regulation (EU) 2019/324 of 2019 | 25 February | L 57 | 1 | 26.2.2019 |
| ► <u>M297</u> | Commission Implementing Regulation (EU) 2019/337 of 2019 | 27 February | L 60 | 12 | 28.2.2019 |
| ► <u>M298</u> | Commission Implementing Regulation (EU) 2019/344 of 2019 | 28 February | L 62 | 7 | 1.3.2019 |
| ► <u>M299</u> | Commission Implementing Regulation (EU) 2019/481 o 2019 | of 22 March | L 82 | 19 | 25.3.2019 |
| ► <u>M300</u> | Commission Implementing Regulation (EU) 2019/676 (2019 | of 29 April | 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 |
| ►M312 | 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 |
| ► <u>M318</u> | Commission Implementing Regulation (EU) 2019/2094 of 29 November 2019 | L 317 | 102 | 9.12.2019 |
| ► <u>M319</u> | Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 | L 7 | 11 | 13.1.2020 |
| ► <u>M320</u> | Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 | L 7 | 14 | 13.1.2020 |
| ► <u>M321</u> | Commission Implementing Regulation (EU) 2020/23 of 13 January 2020 | L 8 | 8 | 14.1.2020 |
| ► <u>M322</u> | Commission Implementing Regulation (EU) 2020/421 of 18 March 2020 | L 84 | 7 | 20.3.2020 |
| ► <u>M323</u> | Commission Implementing Regulation (EU) 2020/616 of 5 May 2020 | L 143 | 1 | 6.5.2020 |
| ► <u>M324</u> | Commission Implementing Regulation (EU) 2020/617 of 5 May 2020 | L 143 | 6 | 6.5.2020 |
| ► <u>M325</u> | Commission Implementing Regulation (EU) 2020/642 of 12 May 2020 | L 150 | 134 | 13.5.2020 |
| ► <u>M326</u> | Commission Implementing Regulation (EU) 2020/646 of 13 May 2020 | L 151 | 3 | 14.5.2020 |

| ► <u>M327</u> | Commission Implementing Ro | egulation (EU) | 2020/6 | 553 of 14 N | Лау | L 152 | 1 | 15.5.2020 |
|---------------|--|-----------------|----------|---------------|------|-------|-----|------------|
| ► <u>M328</u> | Commission Implementing Ro | egulation (EU) | 2020/8 | 369 of 24 J | une | L 201 | 7 | 25.6.2020 |
| ► <u>M329</u> | Commission Implementing Ro | egulation (EU) | 2020/8 | 392 of 29 J | une | L 206 | 5 | 30.6.2020 |
| ► <u>M330</u> | Commission Implementing Reg | gulation (EU) 2 | 2020/968 | 3 of 3 July 2 | 020 | L 213 | 7 | 6.7.2020 |
| ► <u>M331</u> | Commission Implementing Reg | gulation (EU) 2 | 020/100 | 3 of 9 July 2 | 020 | L 221 | 127 | 10.7.2020 |
| ► <u>M332</u> | Commission Implementing Reg | gulation (EU) 2 | 020/100 | 4 of 9 July 2 | 020 | L 221 | 133 | 10.7.2020 |
| ► <u>M333</u> | Commission Implementing Re 2020 | egulation (EU) | 2020/1 | 018 of 13 . | July | L 225 | 9 | 14.7.2020 |
| ► <u>M334</u> | Commission Implementing Re 2020 | gulation (EU) | 2020/11 | 60 of 5 Aug | gust | L 257 | 29 | 6.8.2020 |
| ► <u>M335</u> | Commission Implementing 2 September 2020 | Regulation | (EU) | 2020/1246 | of | L 288 | 18 | 3.9.2020 |
| ► <u>M336</u> | Commission Implementing 10 September 2020 | Regulation | (EU) | 2020/1263 | of | L 297 | 1 | 11.9.2020 |
| ► <u>M337</u> | Commission Implementing 11 September 2020 | Regulation | (EU) | 2020/1276 | of | L 300 | 32 | 14.9.2020 |
| ► <u>M338</u> | Commission Implementing 14 September 2020 | Regulation | (EU) | 2020/1280 | of | L 301 | 4 | 15.9.2020 |
| ► <u>M339</u> | Commission Implementing 15 September 2020 | Regulation | (EU) | 2020/1293 | of | L 302 | 24 | 16.9.2020 |
| ► <u>M340</u> | Commission Implementing 15 October 2020 | Regulation | (EU) | 2020/1498 | of | L 342 | 5 | 16.10.2020 |
| ► <u>M341</u> | Commission Implementing 16 October 2020 | Regulation | (EU) | 2020/1511 | of | L 344 | 18 | 19.10.2020 |
| ► <u>M342</u> | Commission Implementing 5 November 2020 | Regulation | (EU) | 2020/1643 | of | L 370 | 18 | 6.11.2020 |
| ► <u>M343</u> | Commission Implementing 8 December 2020 | Regulation | (EU) | 2020/2007 | of | L 414 | 10 | 9.12.2020 |
| ► <u>M344</u> | Commission Implementing 14 December 2020 | Regulation | (EU) | 2020/2087 | of | L 423 | 50 | 15.12.2020 |
| ► <u>M345</u> | Commission Implementing 15 December 2020 | Regulation | (EU) | 2020/2101 | of | L 425 | 79 | 16.12.2020 |
| ► <u>M346</u> | Commission Implementing 15 December 2020 | Regulation | (EU) | 2020/2104 | of | L 425 | 93 | 16.12.2020 |
| ► <u>M347</u> | Commission Implementing 15 December 2020 | Regulation | (EU) | 2020/2105 | of | L 425 | 96 | 16.12.2020 |
| ► <u>M348</u> | Commission Implementing Re 2021 | egulation (EU) | 2021/52 | 2 of 22 Janu | ıary | L 23 | 13 | 25.1.2021 |
| ► <u>M349</u> | Commission Implementing Re 2021 | egulation (EU) | 2021/81 | of 27 Janu | ıary | L 29 | 12 | 28.1.2021 |

| ► <u>M350</u> | Commission I 2021 | Implementing | Regulation (I | EU) 2021/1 | 29 of 3 Febr | uary | L 40 | 11 | 4.2.2021 |
|---------------|-----------------------------|---------------------|---------------|-------------|----------------|------|-------|----|------------|
| ► <u>M351</u> | Commission I 2021 | Implementing | Regulation (I | EU) 2021/1 | 34 of 4 Febr | uary | L 42 | 4 | 5.2.2021 |
| ► <u>M352</u> | Commission 2021 | Implementing | Regulation (| (EU) 2021/ | 413 of 8 M | arch | L 81 | 32 | 9.3.2021 |
| ► <u>M353</u> | Commission 1 2021 | Implementing | Regulation (| EU) 2021/4 | 427 of 10 M | arch | L 84 | 21 | 11.3.2021 |
| ► <u>M354</u> | Commission 1 2021 | Implementing | Regulation (| EU) 2021/4 | 459 of 16 M | arch | L 91 | 4 | 17.3.2021 |
| ► <u>M355</u> | Commission 1 2021 | Implementing | Regulation (| EU) 2021/5 | 556 of 31 M | arch | L 115 | 26 | 6.4.2021 |
| ► <u>M356</u> | Commission 1 2021 | Implementing | Regulation (| EU) 2021/5 | 566 of 30 M | arch | L 118 | 1 | 7.4.2021 |
| ►M357 | Commission I | mplementing 1 | Regulation (E | U) 2021/56 | 7 of 6 April 2 | 2021 | L 118 | 6 | 7.4.2021 |
| ► <u>M358</u> | Commission 1 2021 | Implementing | Regulation (| EU) 2021/5 | 574 of 30 M | arch | L 120 | 9 | 8.4.2021 |
| ►M359 | Commission I | mplementing | Regulation (E | EU) 2021/72 | 26 of 4 May 2 | 2021 | L 155 | 20 | 5.5.2021 |
| ►M360 | Commission I | | , | | • | | L 160 | 89 | 7.5.2021 |
| ► <u>M361</u> | Commission 2021 | 1 0 | ` | , | • | | L 174 | 2 | 18.5.2021 |
| ► <u>M362</u> | Commission 2021 | Implementing | Regulation | (EU) 2021 | /824 of 21 | May | L 183 | 35 | 25.5.2021 |
| ► <u>M363</u> | Commission 2021 | Implementing | Regulation | (EU) 2021 | /843 of 26 l | May | L 186 | 20 | 27.5.2021 |
| ► <u>M364</u> | Commission 2021 | Implementing | Regulation | (EU) 2021 | /853 of 27 | May | L 188 | 56 | 28.5.2021 |
| ► <u>M365</u> | Commission I | mplementing | Regulation (E | EU) 2021/91 | 7 of 7 June 2 | 2021 | L 201 | 19 | 8.6.2021 |
| ► <u>M366</u> | Commission 2021 | Implementing | Regulation (| (EU) 2021/ | 1191 of 19 | July | L 258 | 37 | 20.7.2021 |
| ► <u>M367</u> | Commission I 2021 | Implementing | Regulation (E | EU) 2021/13 | 379 of 19 Au | gust | L 297 | 32 | 20.8.2021 |
| ► <u>M368</u> | Commission 3 September 2 | Implementin 2021 | g Regulation | on (EU) | 2021/1446 | of | L 313 | 9 | 6.9.2021 |
| ► <u>M369</u> | Commission 3 September 2 | Implementin 2021 | g Regulation | on (EU) | 2021/1448 | of | L 313 | 15 | 6.9.2021 |
| ► <u>M370</u> | Commission 3 September 2 | Implementin 2021 | g Regulation | on (EU) | 2021/1449 | of | L 313 | 20 | 6.9.2021 |
| ► <u>M371</u> | Commission 3 September 2 | Implementin 2021 | g Regulation | on (EU) | 2021/1450 | of | L 313 | 25 | 6.9.2021 |
| ► <u>M372</u> | Commission 3 September 2 | Implementin 2021 | g Regulation | on (EU) | 2021/1452 | of | L 313 | 30 | 6.9.2021 |
| ► <u>M373</u> | Commission 6 September 2 | Implementin 2021 | g Regulation | on (EU) | 2021/1455 | of | L 315 | 1 | 7.9.2021 |
| ► <u>M374</u> | Commission 24 November | Implementin 2021 | g Regulation | on (EU) | 2021/2049 | of | L 420 | 6 | 25.11.2021 |
| ► <u>M375</u> | Commission 25 November | Implementin 2021 | g Regulation | on (EU) | 2021/2068 | of | L 421 | 25 | 26.11.2021 |
| ► <u>M376</u> | Commission 26 November | Implementin 2021 | g Regulation | on (EU) | 2021/2081 | of | L 426 | 28 | 29.11.2021 |

| ► <u>M377</u> | Commission Implementing Regulation (EU) 2022/4 of 4 January 2022 | L 1 | 5 | 5.1.2022 |
|---------------|---|-------|-----|-----------|
| ► <u>M378</u> | Commission Implementing Regulation (EU) 2022/19 of 7 January 2022 | L 5 | 9 | 10.1.2022 |
| ► <u>M379</u> | Commission Implementing Regulation (EU) 2022/43 of 13 January 2022 | L 9 | 7 | 14.1.2022 |
| ► <u>M380</u> | Commission Implementing Regulation (EU) 2022/94 of 24 January 2022 | L 16 | 33 | 25.1.2022 |
| ► <u>M381</u> | Commission Implementing Regulation (EU) 2022/159 of 4 February 2022 | L 26 | 7 | 7.2.2022 |
| ► <u>M382</u> | Commission Implementing Regulation (EU) 2022/378 of 4 March 2022 | L 72 | 2 | 7.3.2022 |
| ► <u>M383</u> | Commission Implementing Regulation (EU) 2022/383 of 4 March 2022 | L 76 | 1 | 7.3.2022 |
| ► <u>M384</u> | Commission Implementing Regulation (EU) 2022/437 of 16 March 2022 | L 89 | 3 | 17.3.2022 |
| ► <u>M385</u> | Commission Implementing Regulation (EU) 2022/456 of 21 March 2022 | L 93 | 138 | 22.3.2022 |
| ► <u>M386</u> | Commission Implementing Regulation (EU) 2022/489 of 25 March 2022 | L 100 | 7 | 28.3.2022 |
| ► <u>M387</u> | Commission Implementing Regulation (EU) 2022/496 of 28 March 2022 | L 101 | 1 | 29.3.2022 |
| ► <u>M388</u> | Commission Implementing Regulation (EU) 2022/501 of 25 March 2022 | L 102 | 1 | 30.3.2022 |
| ► <u>M389</u> | Commission Implementing Regulation (EU) 2022/686 of 28 April 2022 | L 126 | 18 | 29.4.2022 |
| ► <u>M390</u> | Commission Implementing Regulation (EU) 2022/698 of 3 May 2022 | L 130 | 3 | 4.5.2022 |
| ► <u>M391</u> | Commission Implementing Regulation (EU) 2022/708 of 5 May 2022 | L 133 | 1 | 10.5.2022 |
| ► <u>M392</u> | Commission Implementing Regulation (EU) 2022/782 of 18 May 2022 | L 140 | 3 | 19.5.2022 |
| ► <u>M393</u> | Commission Implementing Regulation (EU) 2022/800 of 20 May 2022 | L 143 | 4 | 23.5.2022 |
| ► <u>M394</u> | Commission Implementing Regulation (EU) 2022/801 of 20 May 2022 | L 143 | 7 | 23.5.2022 |
| ► <u>M395</u> | Commission Implementing Regulation (EU) 2022/808 of 23 May 2022 | L 145 | 37 | 24.5.2022 |
| ► <u>M396</u> | Commission Implementing Regulation (EU) 2022/814 of 20 May 2022 | L 146 | 6 | 25.5.2022 |
| ► <u>M397</u> | Commission Implementing Regulation (EU) 2022/1251 of 19 July 2022 | L 191 | 35 | 20.7.2022 |
| ► <u>M398</u> | Commission Implementing Regulation (EU) 2022/1468 of 5 September 2022 | L 231 | 101 | 6.9.2022 |
| ► <u>M399</u> | Commission Implementing Regulation (EU) 2022/1474 of 6 September 2022 | L 232 | 3 | 7.9.2022 |

| ► <u>M400</u> | Commission 7 September | Implementing 2022 | g Regulation | n (EU) | 2022/1480 | of | L 233 | 43 | 8.9.2022 |
|---------------|---------------------------|----------------------|----------------|-------------|---------------|------|-------|-----|------------|
| ► <u>M401</u> | Commission 24 November | Implementing | g Regulation | n (EU) | 2022/2305 | of | L 305 | 53 | 25.11.2022 |
| ► <u>M402</u> | Commission 25 November | Implementing | g Regulation | n (EU) | 2022/2314 | of | L 307 | 47 | 28.11.2022 |
| ► <u>M403</u> | Commission 25 November | Implementing 2022 | g Regulation | n (EU) | 2022/2315 | of | L 307 | 52 | 28.11.2022 |
| ► <u>M404</u> | Commission 2 December 2 | Implementing 2022 | g Regulation | n (EU) | 2022/2364 | of | L 312 | 99 | 5.12.2022 |
| ► <u>M405</u> | Commission 2023 | Implementing | Regulation (EV | U) 2023/11 | 4 of 16 Janu | uary | L 15 | 9 | 17.1.2023 |
| ► <u>M406</u> | Commission 2023 | Implementing | Regulation (EV | U) 2023/11 | 5 of 16 Janu | uary | L 15 | 13 | 17.1.2023 |
| ► <u>M407</u> | Commission 2023 | Implementing | Regulation (EV | U) 2023/11 | 6 of 16 Janu | uary | L 15 | 15 | 17.1.2023 |
| ► <u>M408</u> | Commission 2023 | Implementing | Regulation (EV | U) 2023/14 | 19 of 20 Janu | uary | L 20 | 30 | 23.1.2023 |
| ► <u>M409</u> | Commission 2023 | Implementing | Regulation (EV | U) 2023/19 | 99 of 30 Janu | uary | L 27 | 22 | 31.1.2023 |
| ► <u>M410</u> | Commission 2023 | Implementing | Regulation (EV | U) 2023/21 | 6 of 1 Febru | uary | L 30 | 7 | 2.2.2023 |
| ► <u>M411</u> | Commission 2023 | Implementing | Regulation (EV | U) 2023/22 | 23 of 27 Janu | uary | L 32 | 5 | 3.2.2023 |
| ► <u>M412</u> | Commission 2023 | Implementing | Regulation (E | EU) 2023/5 | 515 of 8 Ma | arch | L 71 | 22 | 9.3.2023 |
| ► <u>M413</u> | Commission 2023 | Implementing | Regulation (E | U) 2023/6 | 89 of 20 Ma | arch | L 91 | 1 | 29.3.2023 |
| ► <u>M414</u> | Commission 1 | Implementing I | Regulation (EU | J) 2023/741 | of 5 April 2 | 2023 | L 98 | 1 | 11.4.2023 |
| ► <u>M415</u> | Commission 1 | Implementing I | Regulation (EU | J) 2023/91 | 8 of 4 May 2 | 2023 | L 119 | 160 | 5.5.2023 |
| ► <u>M416</u> | Commission 1 | Implementing I | Regulation (EU | J) 2023/93 | 2 of 8 May 2 | 2023 | L 124 | 4 | 10.5.2023 |
| ► <u>M417</u> | Commission 2023 | Implementing | Regulation (I | EU) 2023/ | 939 of 10 I | May | L 125 | 19 | 11.5.2023 |
| ► <u>M418</u> | Commission 2023 | Implementing | Regulation (I | EU) 2023/ | 962 of 15 I | May | L 129 | 8 | 16.5.2023 |
| ► <u>M419</u> | Commission 2023 | Implementing | Regulation (I | EU) 2023/ | 998 of 23 I | May | L 136 | 4 | 24.5.2023 |
| ► <u>M420</u> | Commission 2023 | Implementing | Regulation (I | EU) 2023/ | 999 of 23 I | May | L 136 | 11 | 24.5.2023 |
| ► <u>M421</u> | Commission 2023 | Implementing | Regulation (E | EU) 2023/1 | 000 of 23 I | May | L 136 | 16 | 24.5.2023 |
| ► <u>M422</u> | Commission 2023 | Implementing | Regulation (E | EU) 2023/1 | 001 of 23 I | May | L 136 | 23 | 24.5.2023 |

| ► <u>M423</u> | Commission Implementing 2023 | Regulation (EU) | 2023/1002 of 23 | May | L 136 | 28 | 24.5.2023 |
|---------------|---|-------------------|--------------------|-------|--------|----|------------|
| ► <u>M424</u> | Commission Implementing 2023 | Regulation (EU) | 2023/1003 of 23 | May | L 136 | 35 | 24.5.2023 |
| ► <u>M425</u> | Commission Implementing 2023 | Regulation (EU) | 2023/1004 of 23 | May | L 136 | 42 | 24.5.2023 |
| ► <u>M426</u> | Commission Implementing 2023 | Regulation (EU) | 2023/1005 of 23 | May | L 136 | 49 | 24.5.2023 |
| ► <u>M427</u> | Commission Implementing 2023 | Regulation (EU) | 2023/1021 of 24 | May | L 137 | 16 | 25.5.2023 |
| ► <u>M428</u> | Commission Implementing 2023 | Regulation (EU) | 2023/1436 of 10 | July | L 176 | 10 | 11.7.2023 |
| ► <u>M429</u> | Commission Implementing 2023 | Regulation (EU) | 2023/1446 of 12 | July | L 178 | 1 | 13.7.2023 |
| ► <u>M430</u> | Commission Implementing 2023 | Regulation (EU) | 2023/1447 of 12 | July | L 178 | 7 | 13.7.2023 |
| ► <u>M431</u> | Commission Implementing | Regulation (EU) 2 | 023/1488 of 6 July | 2023 | L 183 | 1 | 20.7.2023 |
| ► <u>M432</u> | Commission Implementin | g Regulation | (EU) 2023/1755 | of | L 224 | 18 | 12.9.2023 |
| ► <u>M433</u> | Commission Implementin | g Regulation | (EU) 2023/1756 | of of | L 224 | 23 | 12.9.2023 |
| ► <u>M434</u> | Commission Implementin 11 September 2023 | g Regulation | (EU) 2023/1757 | of | L 224 | 28 | 12.9.2023 |
| ► <u>M435</u> | Commission Implementing 7 November 2023 | g Regulation | (EU) 2023/2455 | of | L 2455 | 1 | 8.11.2023 |
| ► <u>M436</u> | Commission Implementing 7 November 2023 | g Regulation | (EU) 2023/2456 | of of | L 2456 | 1 | 8.11.2023 |
| ► <u>M437</u> | Commission Implementing 16 November 2023 | g Regulation | (EU) 2023/2513 | of | L 2513 | 1 | 17.11.2023 |
| ► <u>M438</u> | Commission Implementing 21 November 2023 | g Regulation | (EU) 2023/2589 | of | L 2589 | 1 | 22.11.2023 |
| ► <u>M439</u> | Commission Implementing 21 November 2023 | g Regulation | (EU) 2023/2591 | of | L 2591 | 1 | 22.11.2023 |
| ► <u>M440</u> | Commission Implementing 21 November 2023 | g Regulation | (EU) 2023/2592 | e of | L 2592 | 1 | 22.11.2023 |
| ► <u>M441</u> | Commission Implementing 6 November 2023 | g Regulation | (EU) 2023/2657 | of of | L 2657 | 1 | 23.11.2023 |
| ► <u>M442</u> | Commission Implementing 28 November 2023 | g Regulation | (EU) 2023/2660 | of | L 2660 | 1 | 29.11.2023 |
| ► <u>M443</u> | Commission Implementing 2023 | Regulation (EU) 2 | 2024/20 of 12 Dece | ember | L 20 | 1 | 3.1.2024 |

| ► <u>M444</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/32 | 4 of 19 | January | L 324 | 1 | | 22.1.2024 |
|---------------|---------------------------|----------------|--------------|--------|----------|----------|----------|--------|---|---|------------|
| ► <u>M445</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/8 | 321 of | 8 March | L 821 | 1 | | 11.3.2024 |
| ► <u>M446</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/8 | 339 of | 8 March | L 839 | 1 | | 11.3.2024 |
| ► <u>M447</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/83 | 35 of 1 | 2 March | L 835 | 1 | | 13.3.2024 |
| ► <u>M448</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/83 | 36 of 1 | 2 March | L 836 | 1 | l | 13.3.2024 |
| ► <u>M449</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/12 | 206 of | 29 April | L 1206 | 1 | | 30.4.2024 |
| ► <u>M450</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/12 | 207 of | 29 April | L 1207 | 1 | ļ | 30.4.2024 |
| ► <u>M451</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/12 | 217 of | 29 April | L 1217 | 1 | ļ | 30.4.2024 |
| ► <u>M452</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/12 | 280 of | 30 April | L 1280 | 1 | | 3.5.2024 |
| ► <u>M453</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/1 | 696 of | 19 June | L 1696 | 1 | | 20.6.2024 |
| ► <u>M454</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/1 | 718 of | 19 June | L 1718 | 1 | | 20.6.2024 |
| ► <u>M455</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/1 | 749 of | 24 June | L 1749 | 1 | | 25.6.2024 |
| ► <u>M456</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/1 | 768 of | 26 June | L 1768 | 1 | l | 27.6.2024 |
| ► <u>M457</u> | Commission 2024 | Implementing | Regulation | (EU) | 2024/1 | 892 of | 10 July | L 1892 | 1 | ļ | 11.7.2024 |
| ► <u>M458</u> | Commission 3 September | | g Regulat | tion | (EU) | 2024/2 | 186 of | L 2186 | 1 | ļ | 4.9.2024 |
| ► <u>M459</u> | Commission 4 September | | g Regulat | tion | (EU) | 2024/2 | 198 of | L 2198 | 1 | | 5.9.2024 |
| ► <u>M460</u> | Commission 6 September | | g Regulat | tion | (EU) | 2024/2 | 221 of | L 2221 | 1 | | 9.9.2024 |
| ► <u>M461</u> | Commission 6 September | | g Regulat | tion | (EU) | 2024/2 | 390 of | L 2390 | 1 | l | 9.9.2024 |
| ► <u>M462</u> | Commission 2024 | Implementing 1 | Regulation (| (EU) 2 | 2024/277 | 77 of 31 | October | L 2777 | 1 | | 4.11.2024 |
| ► <u>M463</u> | Commission 2024 | Implementing 1 | Regulation (| (EU) 2 | 2024/278 | 31 of 31 | October | L 2781 | 1 | ļ | 4.11.2024 |
| ► <u>M464</u> | Commission 2024 | Implementing 1 | Regulation (| (EU) 2 | 2024/280 | 06 of 31 | October | L 2806 | 1 | | 4.11.2024 |
| ► <u>M465</u> | Commission 8 November | | g Regulat | tion | (EU) | 2024/2 | 878 of | L 2878 | 1 | l | 11.11.2024 |

<u>M466</u> Commission Implementing Regulation (EU) 2024/2848 of L 2848 1 12.11.2024 11 November 2024

Corrected by:

►<u>C1</u> Corrigendum, OJ L 26, 28.1.2012, p. 38 (540/2011)

►<u>C2</u> Corrigendum, OJ L 235, 4.9.2013, p. 12 (200/2013)

►C3 Corrigendum, OJ L 277, 22.10.2015, p. 60 (140/2014)

►<u>C4</u> Corrigendum, OJ L 2, 5.1.2018, p. 15 (2017/842)

►<u>C5</u> Corrigendum, OJ L 18, 27.1.2022, p. 128 (1330/2014)

▼<u>B</u>

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)

▼<u>M1</u>

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.

▼<u>B</u>

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.

▼<u>M1</u>

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> | | | | | | | |
| M169 | | | | | | | |
| √ <u>M3</u> | | | | | | | |
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| <u>▼B</u> | | | | | | | |
|----------------------|--------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| | 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>11100</u> | | | | | | | |
| ▼ <u>M182</u> | | | | | | | |
| | | | | | | | |
| ▼ <u>M280</u> | | | | | | | |
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| ▼ <u>B</u> | | | | | | | |
|-------------------|--------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| | 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>M394</u> | | | | | | | |
| ▼ <u>M152</u> | | | | | | | |
| ▼ <u>M279</u> | | | | | | | |
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| ▼ <u>B</u> | | | | | | | |
|-------------------|--------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| | 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> | | | | | | | |
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| ▼ <u>B</u> | | | | | | | |
|----------------------|--------|---|---|------------|--------------------|------------------------|--|
| • | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M215</u> | | | | | | | |
| ▼ <u>M367</u> | | | | | | | |
| ▼ <u>M159</u> | | | | | | | |
| ▼ <u>M324</u> | | | | | | | |
| ▼ <u>M190</u> | | | | | | | |
| ▼ <u>M379</u> | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 40 | Deltamethrin CAS No 52918-63-5 CIPAC No 333 | (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate | 980 g/kg | 1 November 2003 | M434 15 August 2026 ◀ | 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: |

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| <u>₹</u> | | | | | | | |
|----------------------|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | 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 auth- orisation include risk mitigation measures, where appropriate. |
| ▼ <u>M239</u> | | | | | | | |
| ▼ <u>M265</u> | | | | | | | |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M323</u> | | | | | | | |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M363</u> | | | | | | | |
| ▼ <u>M232</u> | | | | | | | |
| ▼ <u>M329</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M243</u> | | | | | | | |
| ▼ <u>M201</u> | | | | | | | |
| ▼ <u>M234</u> | | | | | | | |
| ▼ <u>M227</u> | | | | | | | |
| ▼ <u>M251</u> | | | | | | | |
| ▼ <u>M260</u> | | | | | | | |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>B</u> | 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 | ► <u>M444</u> 15 May 2025 ◀ | 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 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: — 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. |

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| <u> </u> | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u>M282</u> | | | | | | | |
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| <u>M267</u> | | | | | | | |
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| <u>M268</u> | | | | | | | |
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| <u>M266</u> | | | | | | | |
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| - 7 <u>М305</u> | | | | | | | |
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| | 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-(triflu- oromethyl)-1,3,4-thia- diazol-2-yloxy]acet- anilide | 950 g/kg | 1 January 2004 | ► M434 15 June 2025 ◀ | 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 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: — 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. Risk mitigation measures should be applied where appropriate. |
| ▼ <u>M207</u> | | | | | | | |
| ▼ <u>M311</u> | | | | | | | |
| ▼ <u>M231</u> | | | | | | | |
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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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| 69 | Fosthiazate CAS No 98886-44-3 CIPAC No 585 | (RS)-S-sec-butyl O- ethyl 2-oxo-1,3-thia- zolidin-3-ylphospho- nothioate | 930 g/kg | 1 January 2004 | ► M434 31 January 2027 ◀ | Only uses as insecticide or nematicide may be authorised. For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo on fosthiazate, and in particular Appendices I and II thereof, as finalised the Standing Committee on the Food Chain and Animal Health on 4 Ju 2003 shall be taken into account. In this overall assessment Member State — should pay particular attention to the protection of groundwater, whe the active substance is applied in regions with vulnerable soil and/or climate conditions; — should pay particular attention to the protection of birds and wi mammals in particular if the substance is applied during the breedin season; — should pay particular attention to the protection of non-target so organisms. Risk mitigation measures should be applied where appropriate. In order mitigate the potential risk to small birds, product authorisations must require that a very high level of incorporation of granules into soil is achieved. 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. |
| 259 | | | | | | |
| 222 | | | | | | |

| ▼ <u>B</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M278</u> | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 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 | <u>M413</u> 15 March 2025 ◀ | 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 nontarget 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. |
| ▼ <u>M216</u> | | | | | | | |
| ▼ <u>M228</u> | | | | | | | |
| ▼ <u>M258</u> | | | | | | | |
| ▼ <u>M306</u> | | | | | | | |
| ▼ <u>M226</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M218</u> | | | | | | | |
| | 81 | Pyraclostrobin CAS No 175013-18-0 CIPAC No 657 | methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl] oxymethyl}phenyl) N-methoxy carbamate | 975 g/kg The manufacturing impurity dimethyl sulfate (DMS) is condidered to be of toxicological concern and must not exceed a concentration of 0,0001 % in the technical product. | 1 June 2004 | ► M444 15 September 2025 ◀ | 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. |
| ▼ <u>M284</u> | | | | | | | |
| ▼ <u>M317</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M338</u> | | | | | | | |
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| ▼ <u>M337</u> | | | | | | | |
| ▼ M309 | | | | | | | |
| V 14130) | | | | | | | |
| ▼ <u>M394</u> | | | | | | | |
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| ▼ <u>B</u> | | | | | | | |
| | 88 | Phenmedipham | methyl 3-(3-methyl-carbaniloyloxy)carb- | Min. 970 g/kg | 1 March 2005 | ► <u>M415</u> 15 February | Only uses as herbicide may be authorised. |
| | | CAS No 13684-63-4 CIPAC No 77 | anilate; 3-methoxycarbony-laminophenyl 3'- | | | 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 phenmedipham, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal |
| | | | methylcarbanilate | | | | 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. |
| ▼ <u>M411</u> | | | | | | | |
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| Nun | nber Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u> 1451</u> | | | | | | |
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| <u> 1247</u> | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M293</u> | | | | | | | |
| V 1 <u>112/3</u> | | | | | | | |
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| ▼ M443 | | | | | | | |
| V <u>1/11/10</u> | | | | | | | |
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| ▼ <u>M292</u> | | | | | | | |
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| ▼ M347 | | | | | | | |
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| ▼ <u>M394</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M301</u> | | | | | | | |
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| | 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 | M434 15 August 2026 ◀ | 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 |
| ▼ <u>M374</u> | | | | | | | |
| <u>▼B</u> | | | | | | | |
| | 104 | Daminozide CAS No 1596-84-5 CIPAC No 330 | N-dimethylaminosuc- cinamic acid | 990 g/kg Impurities: — N-nitrosodimethylamine: not more than 2,0 mg/kg — 1,1-dimethyl- hydrazide: not more than 30 mg/kg | 1 March 2006 | ► M434 15 September 2025 ◀ | PART A Only uses as growth regulator in non-edible crops may be authorised |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | 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 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 |
| ▼ <u>M340</u> | | | | | | | |
| ▼ <u>M283</u> | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 107 | MCPA CAS No 94-74-6 CIPAC No 2 | 4-chloro-o-tolylo- xyacetic acid | ≥ 930 g/kg | 1 May 2006 | ► M434 15 August 2026 ◀ | 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 |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | 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-tolyloxy)butyric acid | ≥ 920 g/kg | 1 May 2006 | ► M434 15 August 2026 ◀ | 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 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 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 |
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| | Milbemec Milbemec mixture M.A4 CAS No M.A3: 51 M.A4: 51 CIPAC N | tin is a and M.A3 and 5596-10-2 | | ≥ 950 g/kg | 1 December 2005 | ► M415 15 February 2025 ◀ | PART A Only uses as acaricide or 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 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. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate. |
| ▼ <u>M320</u> | | | | | | | |
| ▼ <u>M319</u> | | | | | | | |
| ▼ <u>M394</u> | | | | | | | |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M344</u> | <u>.</u> | | | | | | |
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| ▼ <u>M435</u> | | | | | | | |
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| ▼ M414 | <u>.</u> | | | | | | |
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| ▼ M307 | • | | | | | | |
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| ▼ <u>M255</u> | ; | | | | | | |
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| ▼ M376 | | | | | | | |
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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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| 1394 | | | | | | | |
| 1272 | | | | | | | |
| <u>.</u> | | | | | | | |
| | 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 | ►M413 15 December 2025 ◀ | PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article (6) of Regulation (EC) No 1107/2009, the conclusions of the review repon clodinafop, and in particular Appendices I and II thereof, as finalised the Standing Committee on the Food Chain and Animal Health 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 | ► M413 15 March 2025 ◀ | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article (6) of Regulation (EC) No 1107/2009, the conclusions of the review rep on pirimicarb, and in particular Appendices I and II thereof, as finalised the Standing Committee on the Food Chain and Animal Health 27 January 2006 shall be taken into account. |

| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | | 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. 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. 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. |
| | 125 | Rimsulfuron CAS No 122931-48-0 (rimsulfuron) CIPAC No 716 | 1-(4-6 dimethoxy-pyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyri-dylsulfonyl) urea | ≥ 960 g/kg (expressed as rimsulfuron) | 1 February 2007 | ► M413 15 August 2025 ◀ | 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 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. 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. |
| ▼ <u>M310</u> | | | | | | | |

| Triticonazole CAS No 131983-72-7 CIPAC No 652 CAS No 131983-72-7 CIPAC NO 652 CAS No 131983-72-7 CIPAC NO 652 CAS No 131983-72-7 CIPAC NO 652 CAS No 131983-72-7 CIPAC NO 652 CAS No 131983-72-7 CIPAC NO 652 CAS No 131983-72-7 CIPAC NO 652 CAS No 131983-72-7 CIPAC NO 652 CAS No 131983-72-7 CIPAC NO 652 | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---|--------|-------------------------------------|---|------------|------------------|------------------------|--|
| | 127 | CAS No 131983-72-7 | benzylidene)-2,2- dimethyl-1-(1H-1,2,4- triazol-1-ylmethyl) | ≥ 950 g/kg | | | Only uses as fungicide may be authorised. PART B 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. For the implementation 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: — 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). Conditions of authorisation should include risk mitigation measures, where |

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| | 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. |
| ▼ <u>M428</u> | | | | | | | |
| ▼ <u>M366</u> | | | | | | | |
| <u>B</u> | | | | | | | |
| | 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 | ► M413 15 March 2025 ◀ | 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 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. In this overall assessment 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, |

| | | Purity (1) | approval | Expiration of approval | Specific provisions |
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| | | | | | must pay particular attention to the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk miti- gation measures, such as buffer zones. |
| | | | | | 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. |
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| CAS No 15845-66-6 CIPAC No 384 | Ethyl hydrogen phosphonate | ≥ 960 g/kg (expressed as fosetyl-Al) | 1 May 2007 | ► M413 15 March 2025 ◀ | 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 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. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones. 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. |
| 7 | AS No 15845-66-6 | AS No 15845-66-6 phonate | AS No 15845-66-6 phonate (expressed as fosetyl-Al) | AS No 15845-66-6 phonate (expressed as fosetyl-Al) | AS No 15845-66-6 phonate (expressed as fosetyl-Al) March 2025 ◀ |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M447</u> | | | | | | | |
| <u>▼B</u> | | | | | | | |
| | 133 | Dichlorprop-P CAS No 15165-67-0 CIPAC No 476 | (R)-2-(2,4-dichlorophenoxy) propanoic acid | ≥ 900 g/kg | 1 June 2007 | ► M413 15 March 2025 ◀ | M89 PART A Only uses as herbicide may be authorised. As regards cereals, only application in spring may be authorised, at rates not exceeding 800 g active substance per hectare per application. Use on grassland shall not 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 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. In this overall assessment Member States 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. ◀ |
| ▼ <u>M455</u> | | | | | | | |

| 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 | ► M413 15 March 2025 ◀ | 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 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. In this overall assessment Member States: — 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. 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. |
| 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 | ► <u>M460</u> 31 March 2026 ◀ | ►M137 PART A 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. |

| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | | 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 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. In this overall assessment Member States: — 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, |
| ▼ <u>M461</u> | | | | | | | aquatic organisms and non-target plants. Conditions of authorisation shall include risk mitigation measures, where appropriate. |
| | | | | | | | |
| ▼ <u>M422</u> | | | | | | | |
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| Number | Common name, identification numbers | IUPAC name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|------------|------------------|---------------------------|---|
| 139 | Spinosad CAS No 131929-60-7 (Spinosyn A) 131929-63-0 (Spinosyn D) CIPAC No 636 | Spinosyn A: (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-tetradeoxy-β- D-erythropyr- anosyloxy)-9-ethyl- 2,3,3a,5a,5b,6,7,9,10- ,11,12,13,14,15,16a,- 16b-hexadecahydro- 14-methyl-1H-8- oxacyclododeca[b]as- indacene-7,15-dione Spinosyn D: (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-tetradeoxy-β- D-erythropyr- anosyloxy)-9-ethyl- 2,3,3a,5a,5b,6,7,9,10- ,11,12,13,14,15,16a,- 16b-hexadecahydro- 4,14-dimethyl-1H-8- oxacyclododeca[b]as- indacene-7,15-dione Spinosad is a mixture of 50-95 % spinosyn A and 5-50 % spinosyn D | ≥ 850 g/kg | 1 February 2007 | ► M413 15 March 2025 ◀ | 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 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. In this overall assessment Member States — 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. Conditions of use shall include risk mitigation measures, where appropriate. |

| ▼ <u>B</u> | | | | | | | |
|----------------------|--------|-------------------------------------|------------|------------|------------------|------------------------|---------------------|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
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| ▼ <u>M335</u> | | | | | | | |
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| ▼ <u>M439</u> | | | | | | | |
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| ▼ M394 | | | | | | | |
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| Num | ber Common name, ide | | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 58 | | | | | | | |
| <u></u> | | | | | | | |
| | _ | | | | | | |
| 14 | 7 Formetanate CAS No 23422- | -53-9 | 3-dimethylamino- methyleneamin- ophenyl methylcar- bamate | ≥ 910 g/kg | 1 October 2007 | ► <u>M415</u> 15 February 2025 ◀ | PART A Only uses as insecticide and acaricide may be authorised. |
| | CIPAC No 697 | | | | | | PART B |
| | | | | | | | In assessing applications to authorise plant protection products contain formetanate for uses other than in field tomatoes and ornamental shadember States shall pay particular attention to the criteria in Article 4(Regulation (EC) No 1107/2009, and shall ensure that any necessary and information is provided before such an authorisation is granted. |
| | | | | | | | For the implementation of the uniform principles as referred to in Articl (6) of Regulation (EC) No 1107/2009, the conclusions of the review ron formetanate, and in particular Appendices I and II thereof, as finalist the Standing Committee on the Food Chain and Animal Health 29 September 2006 shall be taken into account. |
| | | | | | | | In this overall assessment Member States: |
| | | | | | | | must pay particular attention to the protection of birds, mammals, target arthropods and bees and must ensure that the conditions of orisation include, where appropriate, risk mitigation measures; |
| | | | | | | | must pay particular attention to the operator safety and ensure conditions of use prescribe the application of adequate per protective equipment; |
| | | | | | | | must pay particular attention to the dietary exposure of consume 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>M450</u> | | | | | | | |
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| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M464</u> | | | | | | | |
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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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| 80 | | | | | | |
| | | | | | | |
| 154 | Propamocarb CAS No 24579-73-5 CIPAC No 399 | Propyl amino) bamate 3-(dimethyl-propylcar- | ≥ 920 g/kg | 1 October 2007 | ► M415 15 June 2025 ◀ | PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing propamocarb for uses other than foliar applications, Member States ship pay particular attention to the criteria in Article 4(3) of Regulation (EC) 1107/2009, as regards worker exposure 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 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repon propamocarb, and in particular Appendices I and II thereof, as finalis in the Standing Committee on the Food Chain and Animal Health 24 November 2006 shall be taken into account. In this overall assessment Member States must pay particular attention—the operators and workers safety. Conditions of authorisation shot 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 authorisation should include risk mitigation measures, where appropriate. |

| <u>B</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| M298 | | | | | | | |
| D. | | | | | | | |
| B | 156 | Pirimiphos-methyl CAS No 29232-93-7 CIPAC No 239 | O-2-diethylamino-6-methylpyrimidin-4-yl O,O-dimethylphos-phorothioate | > 880 g/kg | 1 October 2007 | <u>M415</u> 15 June 2025 ◀ | PART A Only uses as insecticide for post harvest storage can be authorised. Hand-held applications shall not be authorised. PART B In assessing applications to authorise plant protection products containing pirimiphos-methyl for uses other than applications with automated system in empty cereals storehouses, Member States shall pay particular attention 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 (6) of Regulation (EC) No 1107/2009, the conclusions of the review reports of pirimiphos-methyl, and in particular Appendices I and II thereof, |
| | | | | | | | finalised in the Standing Committee on the Food Chain and Anin Health on 15 March 2007 shall be taken into account. In this overall assessment Member States must pay particular attention — the operators safety. Authorised conditions of use must prescribe application of adequate personal protective equipment includi respiratory protective equipment and risk mitigation measures reduce the exposure; — the dietary exposure of consumers in view of future revisions Maximum Residue Levels. |

| ▲ <u>B</u> | | | | | | | |
|----------------------|--------|---|---|------------|------------------|---------------------------------------|---|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>B</u> | 158 | Beflubutamid CAS No 113614-08-7 CIPAC No 662 | (RS)-N-benzyl-2-(4-fluoro-3-trifluor-omethylphenoxy) butanamide | ≥ 970 g/kg | 1 December 2007 | ► <u>M415</u> 31 October 2026 ◀ | 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 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. |
| | | | | | | | In this overall assessment Member States: — must pay particular attention to the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate |
| ▼ <u>M387</u> | | | | | | | |
| ▼ <u>B</u> | 160 | Prosulfocarb CAS No 52888-80-9 CIPAC No 539 | S-benzyl dipropyl (thiocarbamat) | 970 g/kg | 1 November 2008 | ► <u>M434</u> 31 January 2027 ◀ | 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 prosulfocarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health or 9 October 2007 shall be taken into account. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|--|------------|------------------|------------------------|---|
| | | | | | | 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, |
| | | | | | | — the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone, |
| | | | | | | — 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 | 4-(2,2-difluoro-1,3-benzodioxol-4-yl)- | 950 g/kg | 1 November 2008 | ► M434 15 June 2025 ◀ | PART A |
| | CAS No 131341-86-1 | 1H-pyrrole-3-carbon- itrile | | 2000 | June 2023 | Only uses as fungicide may be authorised. |
| | CIPAC No 522 | | | | | PART B |
| | | | | | | 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: |
| | | | | | | — 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, |
| | | | | | | must pay particular attention to the protection of fish and aquatic invertebrates. |
| | | | | | | Conditions of authorisation should include risk mitigation measures, where appropriate. |

| _ | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------------|--------|--|--|------------|------------------|----------------------------------|--|
| | | | | | | | For the implementation 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. |
| | 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 | ► <u>M434</u> 15 June 2025 ◀ | 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 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. 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, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones. |
| ▼ <u>M441</u> | | | | | | | |
| ▼ <u>B</u> | 164 | Boscalid CAS No 188425-85-6 CIPAC No 673 | 2-Chloro-N-(4'-chlorobiphenyl-2-yl) nicotinamide | ≥ 960 g/kg | 1 August 2008 | ► <u>M415</u> 15 April 2026 ◀ | PART A Only uses as fungicide may be authorised. |

| ч <u>Б</u> | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | numers | | | арргочаг | арргочаг | 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 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. In this overall assessment Member States must pay particular attention — 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. Conditions of use shall include adequate risk mitigation measures, where appropriate. |
| ▼ <u>M302</u> | | | | | | | |
| ▼ <u>B</u> | 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 | ► M415 15 June 2025 ◀ | 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 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. |

| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--------|-------------------------------------|------------|------------|------------------|------------------------|---|
| | | | | | | | In this overall assessment Member States must pay particular attention to: 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. Conditions of use shall include risk mitigation measures, where appropriate. 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. 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. |
| ▼ <u>M378</u> | | | | | | | |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|--|------------------|------------------------|---|
| 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 | ≥ 970 g/kg The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material: | 1 August 2008 | M415 15 August 2025 ◀ | 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 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. In this overall assessment Member States must pay particular attention to: — the operator safety in spray applications. Conditions of use shall include adequate protective measures, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate. Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | — Toluene: < 5 g/kg — Prothiocon- azole-desthio (2-(1-chloro- cyclopropyl)1- (2-chloro- phenyl)-3- (1,2,4-triazol- 1-yl)-propan- 2-ol): < 0,5 g/kg (LOD) | | | 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. |
| 169 | Amidosulfuron CAS No 120923-37-7 CIPAC No 515 | 3-(4,6-dimethoxypyri-midin-2-yl)-1-(N-methyl-N-methylsul-fonyl-aminosulfonyl) urea or 1-(4,6-dimethoxypyri-midin-2-yl)-3-mesyl (methyl) sulfa-moylurea | ≥ 970 g/kg | 1 January 2009 | ► M440 15 August 2025 ◀ | PART A Only uses as herbicide may be authorised. PART B 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. For the implementation 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. In this overall assessment Member States must pay particular attention to: — 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, |

| Number Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--|--|------------|-------------------|---------------------------|--|
| | | | | | — the protection of aquatic plants. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate. |
| CAS No 111991-09-4 big No 111991-09-4 CIPAC No 709 or 11-11 m di | 2-[(4,6-dimethoxy-pyrimidin-2-ylcar-bamoyl)sulfamoyl]-N,N-dimethylnicotinamide or 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-dimethylcarbamoyl-2-pyridylsulfonyl)urea | ≥ 910 g/kg | 1 January 2009 | ► M440 31 March 2027 ◀ | 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 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. In this overall assessment Member States must pay particular attention to: — the potential exposure of the aquatic environment to metabolite DUDN when is applied in regions with vulnerable soil conditions, — the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones, — 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, — the protection of groundwater and surface water under vulnerable soil and climatic conditions. |

| ▼ <u>B</u> | | | | | | | |
|-------------------|--------|--|---|--|-------------------|---------------------------|--|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| M436 | | | | | | | |
| M 23 | | | | | | | |
| | 172 | Dicamba CAS No 1918-00-9 CIPAC No 85 | 3,6-dichloro-2-methoxybenzoic acid | ≥ 850 g/kg | 1 January 2009 | ► M440 31 March 2027 ◀ | 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 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. In this overall assessment Member States shall pay particular attention to the protection of non-target plants. Conditions of use shall include adequate risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the identification and quantification of a group of soil transformation products formed in a soil incubation study; |
| | | | | | | | (b) the potential for long range transport through the atmosphere. The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013. |
| | 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-ylme- thyl)-1,3-dioxolan-2- yl]phenyl 4-chloro- phenyl ether | ≥ 940g/kg Toluene maximum content: 5 g/kg | 1 January 2009 | ► M440 15 March 2026 ◀ | PART A Only uses as fungicide may be authorised. |

▼<u>M23</u>

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | PART B |
| | | | | | | For the implementation of the uniform principles, as referred to it Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on difenoconazole, and in particular Appendices I and I thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account. |
| | | | | | | In this overall assessment Member States shall pay particular attention t the protection of aquatic organisms. |
| | | | | | | Conditions of use shall include adequate risk mitigation measures, wher appropriate. |
| | | | | | | The notifier shall submit confirmatory information as regards: |
| | | | | | | (a) further data on the specification of the technical material; |
| | | | | | | (b) residues of triazole derivative metabolites (TDMs) in primary crop- rotational crops, processed commodities and products of animal origin |
| | | | | | | (c) the potential for endocrine disrupting effects on fish (fish full life cycl study) and the chronic risk to earthworms from the active substance an the metabolite CGA 205375 (¹⁶); |
| | | | | | | (d) the possible impact of the variable isomer-ratio in the technical materia 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. |
| | | | | | | The notifier shall submit to the Member States, the Commission and th Authority the information set out in point (a) by 31 May 2012, th information set out in points (b) and (c) by 30 November 2013 and th information set out in point (d) within 2 years from the adoption of specific guidance. |

| ▼ <u>M23</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
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| <u>▼B</u> | 176 | Lenacil | 3-cyclohexyl-1,5,6,7- | ≥ 975 g/kg | 1 January | ► M440 15 | PART A |
| | -, - | | tetrahydrocyclopenta- pyrimidine-2,4(3H)- | | 2009 | August 2025 ◀ | |
| | | CAS No 2164-08-1 | dione | | | 2023 | Only uses as herbicide may be authorised. |
| | | CIPAC No 163 | | | | | 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 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. |
| | | | | | | | In this overall assessment Member States must pay particular attention to: |
| | | | | | | | — 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. |
| | | | | | | | 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 |

| <u>▼ B</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | 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. 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. |
| ▼ <u>M394</u> | | | | | | | |
| ▼B | | | | | | | |
| | 178 | Picloram CAS No 1918-02-1 CIPAC No 174 | 4-amino-3,5,6-trich-loropyridine-2-carboxylic acid | ≥ 920 g/kg | 1 January 2009 | <u>M440</u> 15 February 2028 ◀ | 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 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. In the overall assessment Member States must pay particular attention to: — 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; |
| | | | | | | | The Member States concerned shall ensure that the notifier submits to the Commission: |

| ▼ <u>Б</u> | | | | | | | |
|---------------|--------|--|---|---|-------------------|----------------------------------|---|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | further information to confirm that the monitoring analytical method applied in residue trials correctly quantifies the residues of picloram and its conjugates; |
| | | | | | | | a soil photolysis study to confirm the evaluation of picloram degra- dation. |
| | | | | | | | They shall ensure that the notifier provides such information to the Commission by 30 June 2012. |
| ▼ <u>M330</u> | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 180 | Bifenox CAS No 42576-02-3 CIPAC No 413 | Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate | ≥ 970 g/kg impurities: max. 3 g/kg 2,4- dichlorophenol max. 6 g/kg 2,4- dichloroanisole | 1 January 2009 | ► <u>M440</u> 31 March 2027 ◀ | ▶ M85 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 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. In this overall assessment Member States shall pay particular attention to: (a) the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; (b) the dietary exposure of consumers to bifenox residues in products of animal origin and in succeeding rotational crops; (c) the environmental conditions leading to the potential formation of nitrofen. Member States shall impose restrictions as regards the conditions of use, where appropriate in view of point (c). |
| | 181 | Diflufenican CAS No 83164-33-4 CIPAC No 462 | $2',4'$ -difluoro- 2 - (α,α,α) -trifluoro-m-tolyloxy) nicotinanilide | ≥ 970 g/kg | 1 January 2009 | ► M440 15 January 2026 ◀ | PART A Only uses as herbicide may be authorised. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | 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 diffurencian, 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. In this overall assessment Member States must pay particular attention to: — 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 | ► M440 15 August 2025 ◀ | 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 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. 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, — the protection of non target plants, — the presence of the safener mefenpyr-diethyl in formulated products as regards operator, worker and bystander exposure, |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | — the persistence of the substance and of some of its degradation products in colder zones and areas where anaerobic conditions may occur. |
| | | | | | | Conditions of authorisation should include risk mitigation measures, where appropriate. |
| 183 | Fenpropidin CAS No 67306-00-7 CIPAC No 520 | (R,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]-piperidine | ≥ 960 g/kg (racemate) | 1 January 2009 | ► <u>M440</u> 15 May 2027 ◀ | 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 fenpropidin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health of 14 March 2008 shall be taken into account. |
| | | | | | | In this overall assessment Member States must pay particular attention to — the operator and worker safety and ensure that conditions of us prescribe the application of adequate personal protective equipment, |
| | | | | | | — the protection of aquatic organisms and must ensure that the condition of authorisation include, where appropriate, risk mitigation measure such as buffer zone. |
| | | | | | | The Member States concerned shall request the submission of: |
| | | | | | | — information to further address the long-term risk to herbivorous and insectivorous birds arising from the use of fenpropidin. |
| | | | | | | They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the approval. |

| ▼ <u>B</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
| | | | | | | | |
| ▼ <u>M462</u> | | | | | | | |
| <u>▼B</u> | | | | | | | |
| | 187 | Flutolanil CAS No 66332-96-5 CIPAC No 524 | α,α,α-trifluoro-3'- isopropoxy-o- toluanilide | ≥ 975 g/kg | 1 March 2009 | ► <u>M444</u> 15 June 2025 ◀ | PART A Only uses as fungicide may be authorised. PART B 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. |

| _ | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | | For the implementation 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. |
| | | | | | | | 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. |
| | | | | | | | Conditions of authorisation should include risk mitigation measures, where appropriate. |
| ▼ <u>M408</u> | | | | | | | |
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| ▼ <u>B</u> | | | | | | | |
| | 189 | Fluazinam CAS No 79622-59-6 | 3-chloro-N-(3-chloro- 5-trifluoromethyl-2- pyridyl)-α,α,α- | ≥ 960 g/kg Impurities: | 1 March 2009 | ► <u>M444</u> 15 April 2026 ◀ | PART A Only uses as fungicide may be authorised. |
| | | CIPAC No 521 | trifluoro-2, 6-dinitro- p-toluidine | 5-chloro-N-(3- | | | PART B |
| | | | | chloro-5-trifluor- omethyl-2- pyridyl)-α,α,α- trifluoro-4,6- dinitro-o-toluidine — not more than | | | 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. |
| | | | | 2 g/kg | | | For the implementation 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. |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | In this overall assessment Member States must pay particular attention to: — 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. 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 |
| ▼M394 | | | | | | | fluazinam has been included in this Annex provide such studies to the Commission within two years from the approval. |
| 111071 | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 191 | Mepiquat CAS No 15302-91-7 CIPAC No 440 | 1,1-dimethylpiperidinium chloride (mepiquat chloride) | ≥ 990 g/kg | 1 March 2009 | ► M444 15 October 2025 ◀ | PART A Only uses as plant growth regulator may be authorised. PART B 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. |

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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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| | | | | | | For the implementation 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. |
| | | | | | | The Member States must pay particular attention to the residues in food of plant and animal origin and evaluate the dietary exposure of consumers. |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | 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 | ► <u>M413</u> 30 September 2025 ◀ | 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. |
| ▼ <u>M433</u> | | | | | | | |
| ▼ <u>M351</u> | | | | | | | |
| ▼ <u>M383</u> | | | | | | | |

| ▼ <u>B</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M402</u> | | | | | | | |
| ▼ <u>M364</u> | | | | | | | |
| ▼ <u>M452</u> | | | | <u> </u> | | | |
| | 204 | Trichoderma atroviride (f | formerly <i>T. harzianum</i>) | | | | |
| | | STRAIN: T11 Culture collection: No Spanish type culture collection CECT 20498, identical with IMI 352941 | Not applicable | No relevant impurities | 1 May 2009 | 15 April 2025 | 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 <i>Trichoderma harzianum</i> T-22 (SANCO/1839/2008) and ITEM 908 (SANCO/1840/208) respectively and in particular Appendices I and II |
| | | STRAIN: IMI 206040 – Culture collection No IMI 206040, ATCC 20476 | Not applicable | No relevant impurities | 1 May 2009 | 31 August 2024 | 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 |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 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 | ► <u>M413</u> 15 April 2025 ◀ | 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 harzianum T-22 (SANCO/1839/2008) and ITEM 90 (SANCO/1840/208) respectively and in particular Appendices I and I 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 | ► <u>M413</u> 15 April 2025 ◀ | PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Trichoderma asperellum (formerly T. harzianum) ICC012 (SANCO 1842/2008) and Trichoderma asperellum (formerly T. viride T25 an TV1) T25 and TV1 (SANCO/1868/2008) and in particular Appendices and II thereof, as finalised in the Standing Committee on the Food Chai 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 |
| | | STRAIN: Trichoderma asperellum | | | | | |
| | | (formerly T. viride TV1) TV1 | | | | | |
| | | Culture collection No MUCL 43093 | | | | | |
| | 208 | Trichoderma gamsii (formerly T. viride) | Not applicable | No relevant impurities | 1 May 2009 | ► <u>M413</u> 15 April 2025 ◀ | PART A |
| | | STRAINS: | | | | | Only uses as fungicide may be authorised. |
| | | ICC080 | | | | | PART B |
| | | Culture collection No IMI CC number 392151 CABI | | | | | For the implementation 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. |
| ▼ <u>M316</u> | | | | | | | |
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| ▼ <u>M412</u> | | | | | | | |
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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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| <u>M394</u> | | numbers | | | аррточаг | арргочаг | |
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| 3 | 213 | Fenpyroximate CAS No 134098-61-6 | tert-butyl (E)-alpha- (1,3-dimethyl-5-phen- | > 960 g/kg | 1 May 2009 | ► <u>M413</u> 15 June 2026 ◀ | PART A Only uses as acaricide may be authorised. |
| | | CIPAC No 695 | oxypyrazol-4-ylme- thyleneamino-oxy)-p- toluate | | | | The following uses must not be authorised: |
| | | | totuate | | | | applications in high crops with a high risk of spray drift, for exam tractor mounted air-blast sprayer and hand-held applications. |
| | | | | | | | PART B |
| | | | | | | | For the implementation of the uniform principles as referred to in Article (6) of Regulation (EC) No 1107/2009, the conclusions of the review re on fenpyroximate, and in particular Appendices I and II thereof, as final in the Standing Committee on the Food Chain and Animal Health 11 July 2008 shall be taken into account. |
| | | | | | | | In this overall assessment Member States must pay particular attention |
| | | | | | | | — the operator and worker safety and ensure that conditions of prescribe the application of adequate personal protective equipment |
| | | | | | | | — the impact on aquatic organisms and non-target arthropods and rensure that the conditions of authorisation include, where appropr risk mitigation measures. |
| | | | | | | | The Member States concerned shall request the submission of informa to further address: |
| | | | | | | | — the risk to aquatic organisms from metabolites containing the be moiety, |
| | | | | | | | — the risk of biomagnification in aquatic food chains. |
| | | | | | | | They shall ensure that the notifiers at whose request fenpyroximate has lincluded in this Annex provide such information to the Commission witton years from the approval. |

| ▼ <u>B</u> | | | | | | | |
|----------------------|--------|--|-----------------------------------|---|------------------|------------------------------|---|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 215 | Aclonifen CAS No 74070-46-5 CIPAC No 498 | 2-chloro-6-nitro-3-phenoxyaniline | ≥ 970 g/kg The impurity phenol is of toxicological concern and a maximum level of 5 g/kg is established. | 1 August 2009 | M415 31 October 2026 ◀ | PART A Only uses as herbicide may be authorised. PART B 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. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aclonifen, 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. 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 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, |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | — the protection of birds, mammals, aquatic organisms and non-targe plants. In relation to these identified risks, risk mitigation measures such as buffer zones, should be applied where appropriate. |
| | | | | | | The Member States concerned shall request the submission of furthe studies on rotational crops residues and relevant information to confirm the risk assessment for birds, mammals, aquatic organisms and non-targe plants. |
| | | | | | | They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the approval. |
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| 217 | Metazachlor | 2-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- | ≥ 940 g/kg | 1 August 2009 | ► <u>M415</u> 31 October | ► <u>M28</u> PART A |
| | CAS No 67129-08-2 CIPAC No 411 | xylidide | impurity toluene is considered to be | | 2026 ◀ | 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 or the same field. ◀ |
| | | | concern and a | | | PART B |
| | | | 0,05 % is estab- lished. | | | For the implementation 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 thereof, as finalised in the Standing Committee on the Food Chain and Animal Health or 26 September 2008 shall be taken into account. |
| | | 217 Metazachlor CAS No 67129-08-2 | 217 Metazachlor CAS No 67129-08-2 CAS No 67129-08-2 CAS No 67129-08-2 IOFAC name 10FAC name 2-chloro-N-(pyrazol-1-ylmethyl)acet-2',6'-xylidide | 217 Metazachlor CAS No 67129-08-2 CIPAC No 411 2-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide 2-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide The manufacturing impurity toluene is considered to be of toxicological concern and a maximum level of 0,05 % is estab- | 217 Metazachlor CAS No 67129-08-2 CIPAC No 411 CIPAC name COPAC name Purny (*) approval 2-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide The manufacturing impurity toluene is considered to be of toxicological concern and a maximum level of 0,05 % is estab- | 217 Metazachlor CAS No 67129-08-2 CIPAC No 411 2-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide 3-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide 3-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide 4-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide 4-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide 5-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide 6-chloro-N-(pyrazol- 1-ylmethyl)acet-2',6'- xylidide |

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|---------------------|--------|--------------------------------------|-------------|------------|------------------|---------------------------------|--|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | 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, — 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. 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. If metazachlor is classified under Regularion (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. They shall ensure that the notifiers provide that information to the |
| ▼ <u>M74</u> | 218 | Acetic acid CAS No 64-19-7 CIPAC 838 | acetic acid | ≥ 980 g/kg | 1 September 2009 | ► M429 30 November 2026 ◀ | 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 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. |

▼M74

| ▼ <u>M74</u> | | | | | | | |
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| | 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, the protection of groundwater and the protection of aquatic organisms. |
| | | | | | | | Conditions of use shall include, where appropriate, risk mitigation measures. |
| | | | | | | | The notifier shall submit confirmatory information as regards: |
| | | | | | | | — the acute and long-term risk to birds and mammals, |
| | | | | | | | — the risk to honeybees, |
| | | | | | | | — the risk to non-target arthropods. |
| | | | | | | | The notifier shall submit that information to the Commission, the Member States and the Authority by 31 December 2015. |
| ▼ M438 | | | | | | | |
| | | | | | | | |
| ▼ <u>M32</u> | | | | | | | |
| | 220 | Aluminium silicate CAS No 1332-58-7 CIPAC No 841 | Not available Chemical name: Aluminium silicate | ≥ 999,8 g/kg | 1 September 2009 | <u>M460</u> 31 March 2026 ◀ | 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 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. 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. Conditions of use shall include, where appropriate, risk mitigation measures. |

▼M32

| ▼ <u>M32</u> | | Г | | | | | 1 |
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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 applicant submits to the Commission confirmatory information as regards: |
| | | | | | | | (a) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data; |
| | | | | | | | (b) the relevance of the test material used in the toxicity dossier in view of the specification of the technical material. |
| | | | | | | | The Member States concerned shall ensure that the applicant submits such information to the Commission by 1 May 2013. |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M352</u> | | | | | | | |
| ▼ M31 | | | | | | | |
| V <u>M31</u> | 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 | ► <u>M429</u> 30 November 2026 ◀ | 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 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. Conditions of use shall include, where appropriate, risk mitigation measures. |
| ▼ <u>M369</u> | | | | | | | |
| ▼ <u>M384</u> | | | | | | | |
| ▼ <u>M394</u> | | | | | | | |
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| <u>₹</u> В | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| 7 <u>M49</u> | 227 | Ethylene CAS No 74-85-1 CIPAC No 839 | Ethylene | ≥ 90 % Relevant impurity: ethylene oxide, max content 1 mg/kg | 1 September 2009 | ► M429 30 November 2026 ◀ | 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 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo on ethylene (SANCO/2608/2008) and in particular Appendices I and thereof, as finalised in the Standing Committee on the Food Chain an 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; (b) the protection of operators, workers and bystanders. Conditions of authorisation shall include, where appropriate, risk mitigation measures. |
| 7 <u>M106</u> | 228 | Extract from tea tree CAS No Tea Tree Oil 68647-73-4 Main components: terpinen-4-ol 562-74-3 γ-terpinene 99-85-4 α-terpinene 99-86-5 1,8-cineole 470-82-6 CIPAC No 914 | Tea Tree Oil is a complex mixture of chemical substances. | Main components: $terpinen-4-ol \geq 300 \text{ g/kg}$ $\gamma\text{-terpinene} \geq 100 \text{ g/kg}$ $\alpha\text{-terpinene} \geq 50 \text{ g/kg}$ $1,8\text{-cineole} \geq 1 \text{ g/kg}$ Relevant impurity: | 1 September 2009 | M429 31 January 2026 ◀ | PART A Only uses as fungicide in greenhouse may be authorised. PART B For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review reponent extract from tea tree (SANCO/2609/2008 final) and in particul Appendices I and II thereof, as finalised in the Standing Committee the Food Chain and Animal Health on 13 December 2013 shall be take into account. In this overall assessment Member States shall pay particular attention—the protection of operators and workers, ensuring that conditions of u include the application of adequate personal protective equipment, whe appropriate; |

▼ M106

| Numbe | r Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------|---|------------------------------|--|------------------|---|---|
| | | | Methyl eugenol: maximum 1 g/kg of the technical | | | the protection of groundwater, when the substance is applied in region with vulnerable soil and/or climatic conditions; |
| | | | material | | | — the protection of surface water and aquatic organisms; |
| | | | | | | — the protection of honey bees, non-target arthropods, earthworms an non-target micro- and macro-organisms. |
| | | | | | | Conditions of use shall include risk mitigation measures, where appropriate |
| | | | | | | The notifier shall submit confirmatory information as regards: |
| | | | | | | (a) the plant metabolism and consumer exposure; |
| | | | | | | (b) the toxicity of the compounds that constitute the extract and the relevance of possible impurities other than methyl eugenol; |
| | | | | | | (c) the groundwater exposure for the less strongly absorbed components the constitute the extract and for potential soil transformation products; |
| | | | | | | (d) the effects on biological methods of sewage treatment. |
| | | | | | | The notifier shall submit to the Commission, the Member States and th Authority that information by 30 April 2016 at latest. |
| 432 | | | | | | |
| 460 | | | | | | |
| 230 | Fatty acids C7 to C20 | | | | | |
| | CAS No 112-05-0 (Pelargonic Acid) | Nonanoic acid Caprylic Acid, | ≥ 889 g/kg (Pelargonic Acid) | 1 September 2009 | 1 December 2026 | PART A Only uses as insecticide, acaricide, and herbicide and plant growth regulator |
| | 67701-09-1 (Fatty acids C7-C18 and C18 unsaturated potassium salts) Caprylic Acid, Pelargonic Acid, Capric Acid, Capric Acid, Capric Acid, Capric Acid, Capric Acid, Capric Acid, Oleic Acid (ISO in each case) Caprylic Acid, Pelargonic Acid, Capric Ac | ≥ 838 g/kg fatty acids | | | may be authorised. PART B | |
| | | | For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo | | | |
| | 124-07-2 (Caprylic Acid) | (130 in each case) | | | on fatty acids (SANCO/2610/2008) and in particular Appendices I and thereof, as finalised in the Standing Committee on the Food Chain ar Animal Health shall be taken into account. | |
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▼ M460

| _ | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--------|---|--|---|---------------------|---------------------------------|--|
| | | | Octanoic Acid, Nonanoic Acid, Decanoic Acid, Dodecanoic Acid, cis-9-Octadecenoic Acid (IUPAC in each case) Fatty acids, C7-C10, Me esters | | | | Conditions of use shall include, where appropriate, risk mitigation measures. |
| | | 143-07-7 (Lauric Acid) 112-80-1 (Oleic Acid) 85566-26-3 (Fatty acids C8-C10 Me esters) 111-11-5 (Methyl octanoate) 110-42-9 (Methyl decanoate) CIPAC No not allocated | Nonanoic acid Caprylic Acid, Pelargonic Acid, Capric Acid, Lauric Acid, Oleic Acid (ISO in each case) Octanoic Acid, Nonanoic Acid, Decanoic Acid, Decanoic Acid, Dodecanoic Acid, cis-9-Octadecenoic Acid (IUPAC in each case) Fatty acids, C7-C10, Me esters | ≥ 889 g/kg (Pelargonic Acid) ≥ 838 g/kg fatty acids ≥ 99 % fatty acid methyl esters | 1 September 2009 | 31 August 2024 | |
| ▼ <u>M350</u> | | | | | | | |
| <u>▼B</u> | 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 | ≥ 850 g/kg | 1 September 2009 | ► <u>M429</u> 15 July 2025 ◀ | 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. |

| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | 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 | | | | Conditions of use shall include, where appropriate, risk mitigation measures. |
| | 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-oxoper-hydro-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-oxoper-hydro-4a,7-methano-9b,3-propenoazuleno [1,2-b]furan-4-carboxylic acid | Review report (SANCO/2614/2008). | 1 September 2009 | ► M429 15 July 2025 ◀ | 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. |
| ▼ <u>M445</u> | | | | | | | |
| ▼ <u>M38</u> | 235 | Iron sulphate: Iron(II)sulfate anhydrous: CAS No 7720-78-7 | Iron(II)sulphate or iron(2+) sulfate | Iron(II)sulfate anhydrous: ≥ 350 g/kg total iron. | 1 September 2009 | ► <u>M429</u> 30 November 2026 ◀ | PART A Only uses as herbicide may be authorised. |

▼<u>M38</u>

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | Iron(II)sulfate monohydrate: CAS No 17375-41-6 Iron(II)sulfate heptahydrate: CAS No 7782-63-0 CIPAC No 837 | | Relevant impurities: arsenic, 18 mg/kg cadmium, 1,8 mg/kg chromium, 90 mg/kg lead, 36 mg/kg mercury, 1,8 mg/kg expressed on the basis of the anhydrous variant | | | 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 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. In this overall assessment Member States shall pay particular attention to — the risk for operator; — the risk to children/residents playing on treated turf; — the risk to surface waters and to aquatic organisms. Conditions of use shall include, where appropriate, risk mitigation measure and the application of adequate personal protective equipment. The notifies 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. The Member States concerned shall ensure that the notifier submits to the Commission such information by 1 May 2013. |
| <u>M345</u> | | | | | | |
| M394 | | | | | | |
| <u>M217</u> | | | | | | |
| M394 | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| M115 | <u> </u> | | | | | | |
| | 240 | Plant oils/citronella oil CAS No 8000-29-1 CIPAC No 905 | Citronella Oil is a complex mixture of chemical substances. The main components are: Citronellal (3,7-dimethyl-6-octenal). Geraniol ((E)-3,7-dimethyl-2,6-octadien-1-ol). Citronellol (3,7-dimethyl-6-octan-2-ol). Geranyl acetate (3,7-dimethyl-6-octen-1yl acetate). | 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 ◀ | 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 repor on citronella oil (SANCO/2621/2008) and in particular Appendices I and I 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 In this overall assessment Member States shall pay particular attention to — 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. The notifier shall submit confirmatory information as regards: (a) the technical specification; (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 onn-target organisms; (c) the groundwater exposure assessment for potential metabolites of plan oils/citronella oil, in particular for methyl eugenol and methy isoeugenol. The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016. |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M100</u> | 241 | Plant oils/clove oil CAS No 84961-50-2 (clove oil) 97-53-0 (Eugenol — main component) CIPAC No 906 | Clove Oil is a complex mixture of chemical substances. The main component is eugenol. | ≥ 800 g/kg Relevant impurity: methyl eugenol maximum 0,1 % of the technical material | 1 September 2009 | ► M429 31 January 2026 ◀ | PART A Only indoor uses as post-harvest fungicide and bactericide 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 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. 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. The notifier shall submit confirmatory information as regards (a) the technical specification; (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. The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016. |
| ▼ <u>M87</u> | 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 | ► M460 31 March 2026 ◀ | 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. |

| ▼ <u>M87</u> | | | | | | | |
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| | 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. |
| ▼ <u>M37</u> | 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 | ► M429 31 January 2026 ◀ | 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. |
| ▼ <u>M372</u> | | | | | | | |
| ▼ <u>M394</u> | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u>M75</u> | | | | | | | |
| | 246 | 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 121-21-1 Pyrethrin 1: CAS 121-21-1 Pyrethrin 2: CAS 121-21-1 Pyrethrin 1: CAS 121-21-1 Pyrethrin 2: CAS 121-20-9 Cinerin 1: CAS 25402-06-6 Cinerin 2: CAS 121-20-0 Jasmolin 1: CAS 4466-14-2 Jasmolin 1: CAS 4466-14-2 Jasmolin 2: CAS 1172-63-0 | Pyrethrins are a complex mixture of chemical substances. | Extract A: ≥ 500 g/kg Pyrethrins Extract B: ≥ 480 g/kg Pyrethrins | 1 September 2009 | ► M429 15 June 2026 ◀ | PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyrethrins (SANCO/2627/2008) and in particular Appendices I and I thereof, as finalised in the Standing Committee on the Food Chain an Animal Health shall be taken into account. In this overall assessment Member States shall pay particular attention to (a) the risk to operators and workers; (b) the risk to non-target organisms. Conditions of use shall, where appropriate, include the application of adequate personal protective equipment and other risk mitigation measures. The applicant shall submit confirmatory information as regards: (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 toxicit studies; (2) the risk from inhalation; (3) the residue definition; (4) the representativeness of the major component 'pyrethrin 1' as regard the fate and behaviour in soil and water. 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. |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ M431 | | | | | | | |
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| ▼ <u>M401</u> | | | | | | | |
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| ▼ <u>M399</u> | | | | | | | |
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| ▼ <u>M230</u> | | | | | | | |
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| ▼ <u>M229</u> | | | | | | | |
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| ▼ M394 | | | | | | | |
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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
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| ▼ M397 | | | | | | | |
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| ▼ <u>M446</u> | | | | | | | |
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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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| 260 | Aluminium phosphide CAS No 20859-73-8 CIPAC No 227 | Aluminium phosphide | ≥ 830 g/kg | 1 September 2009 | ► M429 30 November 2026 ◀ | PART A Only uses as insecticide, rodenticide, talpicide and leporicide in the form of ready-to-use aluminium phosphide containing products may be authorised. As rodenticide, talpicide and leporicide only outdoor uses may be authorised. Authorisations should be limited to professional users. 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 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. In this overall assessment Member States must pay particular attention to: — 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 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; |

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| | 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. |
| ▼ <u>M394</u> | | | | | | | |
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| ▼ <u>B</u> | | | | | | | |
| | 262 | Magnesium phosphide CAS No 12057-74-8 CIPAC No 228 | Magnesium phosphide | ≥ 880 g/kg | 1 September 2009 | ► M429 30 November 2026 ◀ | PART A Only uses as insecticide, rodenticide, talpicide and leporicide in the form of ready-to-use magnesium phosphide containing products may be authorised. As rodenticide, talpicide and leporicide only outdoor uses may be authorised. Authorisations should be limited to professional users. 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 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. In this overall assessment Member States must pay particular attention to: — 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; |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | — 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. |
| | | | | | | |
| 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 | M429 15 August 2026 ◀ | 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 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. In this overall assessment Member States must pay particular attention to: — 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|--|------------|------------------|--|---|
| 264 | Dodemorph CAS No 1593-77-7 CIPAC No 300 | cis/trans-[4-cyclo-dodecyl]-2,6-dimethylmorpholine | ≥ 950 g/kg | 1 September 2009 | ► <u>M452</u> 31 August 2024 ◀ | PART A Only uses as fungicide on ornamentals in glasshouse 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 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. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil conditions; — conditions of authorisation should include risk mitigation measures, where appropriate. |
| 265 | 2,5-Dichlorobenzoic acid methylester CAS No 2905-69-3 CIPAC No 686 | methyl-2,5-dichloro- benzoate | ≥ 995 g/kg | 1 September 2009 | ► <u>M429</u> 30 November 2026 ◀ | PART A Only indoor uses as plant growth regulator and fungicide for grafting of grapevines 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 2,5-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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|------------|------------------|---------------------------------|---|
| 266 | Metamitron CAS No 41394-05-2 CIPAC No 381 | 4-amino-4,5-dihydro- 3-methyl-6-phenyl- 1,2,4-triazin-5-one | ≥ 960 g/kg | 1 September 2009 | ► M429 30 November 2026 ◀ | PART A Only uses as herbicide may be authorised. PART B 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. For the implementation 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. In this overall assessment Member States must pay particular attention to: — 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. Conditions of authorisation shall include risk mitigation measures, where appropriate. |

| 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 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. |
| 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 | ► M429 30 November 2026 ◀ | 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|---|------------|------------------|------------------------|---|
| | | | | | | Conditions of authorisation shall include risk mitigation measures, where appropriate. |
| | | | | | | 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. |
| 268 | Tebuconazole | (RS)-1-p-chloro- phenyl-4,4-dimethyl- | ≥ 905 g/kg | 1 September 2009 | ► M429 15 August | ►M128 PART A |
| | CAS No 107534-96-3 | 3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol | | 200) | 2026 ◄ | Only uses as fungicide and plant growth regulator may be authorised. |
| | CIPAC No 494 | yimetiiyi)-pentan-3-oi | | | | 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 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: |
| | | | | | | — 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. |

| ▲ B | | | | | | | |
|-------------------|--------|--|---|------------|------------------|------------------------|---|
| | 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. |
| ▼ M394 | | | | | | | |
| | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 271 | Bensulfuron CAS No 83055-99-6 CIPAC No 502.201 | α-[(4,6-dimethoxy-pyrimidin-2-ylcar-bamoyl)sulfamoyl]-o-toluic acid (bensulfuron) methyl α-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-o-toluate (bensulfuron-methyl) | ≥ 975 g/kg | 1 November 2009 | M434 15 August 2026 ◀ | 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---------------------------------------|------------|------------------|--------------------------|--|
| 272 | Sodium 5-nitroguaia-colate CAS No 67233-85-6 CIPAC number not allocated | Sodium 2-methoxy-5- nitrophenolate | ≥ 980 g/kg | 1 November 2009 | ► M434 31 January 2027 ◀ | 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 finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 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 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. 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|--------------------------|--|
| 273 | Sodium o-nitrophenolate CAS No 824-39-5 CIPAC number not allocated | Sodium 2-nitrophenolate; sodium onitrophenolate | ≥ 980 g/kg The following impurities are of toxicological concern: Phenol Max content: 0,1 g/kg 2,4 dinitrophenol max content: 0,14 g/kg 2,6 dinitrophenol max content: 0,32 g/kg | 1 November 2009 | ► M434 31 January 2027 ◀ | 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 finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 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 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. 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|---|---|------------------|--------------------------|--|
| 274 | Sodium p-nitrophenolate CAS No 824-78-2 CIPAC number not allocated | Sodium 4-nitrophenolate; sodium pnitrophenolate | ≥ 998 g/kg The following impurities are of toxicological concern: Phenol max content: 0,1 g/kg 2,4 dinitrophenol max content: 0,07 g/kg 2,6 dinitrophenol max content: 0,09 g/kg | 1 November 2009 | ► M434 31 January 2027 ◀ | 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 finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 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 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. 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|--|------------|------------------|--------------------------|--|
| 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 | ► M434 31 January 2027 ◀ | PART A Only uses as acaricide and insecticide may be authorised. PART B 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. For the implementation 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. In this overall assessment Member States must pay particular attention to: — 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. The Member States concerned shall ensure that the notifier submits to the Commission: — further information confirming that no relevant impurities are present, — information to further address the risk to insectivorous birds. They shall ensure that the notifier provides such information to the Commission by 31 October 2011. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 276 | Chlormequat CAS No 7003-89-6 (chlormequat) CAS No 999-81-5 (chlormequat chloride) CIPAC No 143 (chlormequat) CIPAC No 143.302 (chlormequat chloride) | 2-chloroethyltrimethylammonium (chlormequat) 2-chloroethyltrimethylammonium chloride (chlormequat chloride) | ≥ 636 g/kg Impurities 1,2-dichloroe- thane: max 0,1 g/ kg (on the dry chlormequat chloride content) Chloroethene (vinylchloride): max 0,0005 g/kg (on the dry chlor- mequat chloride content) | 1 December 2009 | ►M434 28 February 2027 ◀ | PART A Only uses as plant growth regulator on cereals and non edible crops may be authorised. PART B 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. For the implementation 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. 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; — the protection of birds and mammals. 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 (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. |

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| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| M288 | | | | | | |
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| <u>B</u> | | | | | | |
| 278 | Propaquizafop CAS No 111479-05-1 CIPAC No 173 | 2-isopropylide- namino-oxyethyl (R)- 2-[4-(6-chloro-quin- oxalin-2-yloxy) phenoxy]propionate | ≥ 920 g/kg Toluene maximum content 5 g/kg | 1 December 2009 | ►M434 28 February 2027 ◀ | 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 or 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. |

| _ | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| _ | | | | | | | The Member States concerned shall ensure that the notifier submits to the Commission: — further information on the relevant impurity Ro 41-5259, — information to further address the risk to aquatic organisms and to not target arthropods. They shall ensure that the notifier provides such information to the Commission by 30 November 2011. |
| 1213 | | | | | | | |
| | 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 | ► <u>M434</u> 28 February 2027 ◀ | PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 2 |
| | | Quizalofop-P-ethyl CAS No 100646-51-3 | ethyl (R)-2-[4-(6- chloroquinoxalin-2- yloxy)phenoxy] | ≥ 950 g/kg | 1 December 2009 | ► <u>M434</u> 28 February 2027 ◀ | (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo on quizalofop-P, and in particular Appendices I and II thereof, as finalise in the Standing Committee on the Food Chain and Animal Health 23 January 2009 shall be taken into account. |
| | | CIPAC No 641.202 | propionate | | | | In this overall assessment Member States must pay particular attention |
| | | | | | | | the specification of the technical material as commercially manufacture which must be confirmed and supported by appropriate analytical dates The test material used in the toxicity dossiers should be compared a verified against this specification of the technical material, |
| | | | | | | | — the operator and worker safety and ensure that conditions of u prescribe the application of adequate personal protective equipment, |
| | | | | | | | the protection of non-target plants and ensure that conditions of autorisation include risk mitigation measures such as buffer zones, who appropriate. |
| | | | | | | | Conditions of authorisation shall include risk mitigation measures, who appropriate. |
| | | | | | | | The Member States concerned shall ensure that the notifier submits to t Commission further information on the risk to non-target arthropods. |

| ▼ <u>M213</u> | Number | Common name, identification | IUPAC name | Purity (1) | Date of | Expiration of | Specific provisions |
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| | | numbers | TOTAL MAINE | Turity () | approval | approval | Specific provisions |
| | | | | | | | They shall ensure that the notifier provides such information to the Commission by 30 November 2011. |
| ▼ <u>M394</u> | | | | | | | |
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| | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| _ | 284 | Dimethachlor | 2-chloro-N-(2-metho- | ≥ 950 g/kg | 1 January | ► <u>M440</u> 15 | PART A |
| | | CAS No 50563-36-5 | xyethyl)acet-2',6'- xylidide | Impurity 2,6-dimethylaniline: | 2010 | October 2026 ◀ | Only uses as herbicide in application max. of 1,0 kg/ha only every third year on the same field may be authorised. |
| | | CIPAC No 688 | | Not more than 0,5 g/kg | | | 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 dimethachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health or 26 February 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, |
| | | | | | | | 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. |
| | | | | | | | Conditions of authorisation shall include risk mitigation measures and moni toring programmes shall be initiated to verify potential groundwater con tamination from metabolites CGA 50266, CGA 354742, CGA 102935 and SYN 528702 in vulnerable zones, where appropriate. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | The Member States concerned shall: — ensure that the notifier submits to the Commission further studies on the specification by 1 January 2010. 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 | ► M440 31 March 2027 ◀ | 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 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. In this overall assessment Member States must pay particular attention to: — 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. |

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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 on the risk to aquatic organisms including the risk to sediment dwellers and biomagnification, |
| | | | | | | | — the submission of further studies on the endocrine disruption potential in aquatic organisms (fish full life cycle study). |
| | | | | | | | They shall ensure that the notifiers provide such studies to the Commission by 31 December 2011. |
| ▼ <u>M394</u> | <u>.</u> | | | | | | |
| | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 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 | ► M440 15 October 2026 ◀ | PART A Only uses as fungicides 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 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. 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. 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 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 |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|---|---|--|-------------------|---------------------------|---|
| 288 | Tri-allate CAS No 2303-17-5 CIPAC No 97 | S-2,3,3-trichloroallyl di-isopropyl (thiocarbamate) | ≥ 940 g/kg NDIPA (Nitrosodiisopropylamine) max. 0,02 mg/kg | 1 January 2010 | ► M440 31 March 2027 ◀ | 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 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. 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, — 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, — 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. The Member States concerned shall ensure that the notifier submits to the Commission: — further information to assess the primary plant metabolism, |

| ▼ <u>B</u> | | | | | | | |
|----------------------|--------|--------------------------------------|------------|------------|-------------------|---------------------------|--|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | further information on the fate and behaviour of the soil metabolite diisopropylamine, further information on the potential for biomagnification in aquatic food chains, information to further address the risk to fish-eating mammals and the long-term risk to earthworms. They shall ensure that the notifier provides such information to the |
| W 3 4 4 2 7 | | | | | | | Commission by 31 December 2011. |
| ▼ <u>M437</u> | | | | | | | |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>M48</u> | | | | | | | |
| ▼ R | | | | | | | |
| <u>▼</u> B | 292 | sulphur CAS No 7704-34-9 CIPAC No 18 | sulphur | ≥ 990 g/kg | 1 January 2010 | ► M440 15 April 2025 ◀ | PART A Only uses as fungicide 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 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. In this overall assessment Member States shall pay particular attention to: — the protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate. |

| 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 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. |
| 293 | Tetraconazole CAS No 112281-77-3 CIPAC No 726 | (RS)-2-(2,4-dich-lorophenyl)-3-(1H-1.2,4-triazol-1-yl)-propyl-1.1,2,2-tetra-fluoroethyl ether | ≥ 950 g/kg (racemic mixture) Impurity toluene: not more than 13 g/kg | 1 January 2010 | ► M440 31 March 2027 ◀ | 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 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. In this overall assessment Member States must pay particular attention to: — 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. The Member States concerned shall request: — the submission of further information on a refined consumer risk assessment, — further information on the specification regarding ecotoxicology, |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 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 | ► <u>M440</u> 31 March 2027 ◀ | — 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. They shall ensure that the notifier provides such information to the Commission by 31 December 2011. ▶ M393 Part A Only uses as insecticide, acaricide 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 paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3, including its addendum, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. ◀ |
| 295 | Paraffin oil CAS No 8042-47-5 CIPAC No n.a. | paraffin oil | European Pharmacopoeia. 6,0 | 1 January 2010 | ► M440 15 August 2025 ◀ | 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 paraffin oil 8042-47-5, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | The Member States concerned shall request: The submission of the specification of the technical material as commercially manufactured to verify the compliance with purity criteria of European Pharmacopoeia. 6,0 They shall ensure that the notifier provides such information to the Commission by 30 June 2010. |
| 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 | <u>M444</u> 30 June 2027 ◀ | 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 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. 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. Conditions of authorisation shall include risk mitigation measures, where appropriate. |
| 297 | Fluopicolide CAS No 239110-15-7 CIPAC No 787 | 2,6-dichloro-N-[3-chloro-5-(trifluor-omethyl)-2-pyri-dylmethyl]benzamide | ≥ 970 g/kg The impurity toluene must not exceed 3 g/kg in the technical material. | 1 June 2010 | ► M415 31 August 2026 ◀ | 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 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. |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | In this overall assessment, Member States must pay particular attention to: |
| | | | | | | | — 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. |
| | | | | | | | 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. |
| | | | | | | | 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. |
| | | | | | | | |
| ▼ <u>M403</u> | | | | | | | |
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| - = | | | | | | | |
| | 299 | 2-phenylphenol | biphenyl-2-ol | ≥ 998 g/kg | 1 January | ► M440 15 | PART A |
| | 277 | (including its salts such | olphenyi-2-ol | ≥ 990 g/kg | 2010 | November | |
| | | as the sodium salt) | | | | 2027 ◀ | Only uses as a post-harvest fungicide for indoor use may be authorised. |
| | | CAS No 90-43-7 | | | | | PART B |
| | | CIPAC No 246 | | | | | For the implementation 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|-------------------------------------|------------|------------|------------------|------------------------|--|
| | | | | | | In this overall assessment Member States must pay particular attention: |
| | | | | | | — to the protection of operators and workers and ensure that conditions of use prescribe the application of adequate personal protective equipment, |
| | | | | | | — 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. |
| | | | | | | The Member States concerned shall ensure that the notifier submits to the Commission: |
| | | | | | | — further information on the potential for skin depigmentation for workers and consumers due to possible exposure to the metabolite 2-phenylhy-droquinone (PHQ) on citrus peel, |
| | | | | | | — further information to confirm that the analytical method applied in residue trials correctly quantifies the residues of 2-phenylphenol, PHQ and their conjugates. |
| | | | | | | They shall ensure that the notifier provides such information to the Commission by 31 December 2011. |
| | | | | | | 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. |
| | | | | | | They shall ensure that the notifier provides such information to the Commission by 31 December 2012. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 300 | Malathion CAS No 121-75-5 CIPAC No 12 | diethyl (dimethoxyphosphinothioylthio) succinate or S-1,2-bis(ethoxycarbonyl)ethyl O,Odimethyl phosphorodithioate racemate | ≥ 950 g/kg Impurities: Isomalathion: not more than 2 g/kg | 1 May 2010 | ► M413 31 July 2026 ◀ | Only uses as an insecticide in greenhouses with a permanent structure may be authorised. Authorisations shall be limited to professional users. 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 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. In this overall assessment, Member States must pay particular attention to: (a) releases from greenhouses, such as condensation water, drain water, soil or artificial substrate, in order to preclude risks to aquatic organisms; (b) the protection of pollinator colonies purposely placed in the greenhouse; (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; (d) the protection of consumers in the case of processed commodities. 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. |

| 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 and provide for adequate labelling of plant protection products. ◀ |
| 301 | Penoxsulam CAS No 219714-96-2 CIPAC No 758 | 3-(2,2-difluoro-ethoxy)-N-(5,8-dimethoxy[1,2,4] triazolo[1,5-c]pyri-midin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide | > 980 g/kg The impurity Bis-CHYMP 2-chloro-4-[2-(2-chloro-5-methoxy-4-pyrimidinyl) hydrazino]-5-methoxypyrimidine must not exceed 0,1 g/kg in the technical material | 1 August 2010 | ► M415 15 May 2026 ◀ | 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 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. In this overall assessment, Member States must pay particular attention to: — the protection of aquatic organisms, — the dietary exposure of consumers to residues of the metabolite BSCTA in succeeding rotational crops, — the protection of 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 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. |

| CA | Proquinazid CAS No 189278-12-4 CIPAC No 764 | 6-iodo-2-propoxy-3- propylquinazolin-4 (3H)-one | > 950 g/kg | 1 August 2010 | ► <u>M415</u> 15 May 2026 ◀ | 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. PART A Only uses as fungicide may be authorised. |
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| CA | CAS No 189278-12-4 | propylquinazolin-4 | > 950 g/kg | | ► <u>M415</u> 15 May 2026 ◀ | |
| 394 | | | | | | 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 repor on proquinazid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health of 22 January 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention—to the long-term risk to earthworm-eating birds for uses in grapevine—to the risk to aquatic organisms,—the dietary exposure of consumers to proquinazid residues in products of animal origin and in succeeding rotational crops,—to the operator safety. Conditions of authorisation shall include risk mitigation measures, where appropriate. 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 304 | Metalaxyl CAS No 57837-19-1 CIPAC No 365 | Methyl N-(metho- xyacetyl)-N-(2,6- xylyl)-DL-alaninate | 950 g/kg The impurity 2,6-dimethylaniline was considered of toxicological concern and a maximum level of 1 g/kg is established. | 1 July 2010 | ► M415 30 September 2026 ◀ | 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 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. 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-(tri-fluoromethyl)nicotinamide | ≥ 960 g/kg The impurity toluene must not exceed 3 g/kg in the technical material. | 1 September 2010 | ► M429 30 November 2026 ◀ | 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 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. In this overall assessment, Member States must pay particular attention to: — the risk to operators and re-entry workers, — the risk to bees. Conditions of authorisation shall include risk mitigation measures 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. |

| Number C ▼ <u>M394</u> ▼ <u>B</u> | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| , | Sulfuryl fluoride CAS No 002699-79-8 CIPAC No 757 | Sulfuryl fluoride | > 994 g/kg | 1 November 2010 | M434 31 January 2027 ◀ | Only uses as insecticide/nematicide (fumigant) applied by professional users in sealable structures may be authorised insofar: (a) these structures are empty; or (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. 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 sulfuryl fluoride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | — 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; |
| | | | | | | | — 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; |
| | | | | | | | — the risk to bystanders by applying an appropriate exclusion zone around the fumigated structure. |
| | | | | | | | Conditions of authorisation shall include risk mitigation measures, where appropriate. |
| | | | | | | | The notifier shall submit to the Commission, Member States and the Authority monitoring data on tropospheric concentrations of sulfuryl 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 sulfuryl fluoride/m³ of tropospheric air). ◀ |
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| | 310 | Napropamide CAS No 15299-99-7 | (RS)-N,N-diethyl-2- (1-naphthyloxy) propionamide | ≥ 930 g/kg (Racemic mixture) Relevant impurity Toluene: not more than 1,4 g/kg | 1 January 2011 | ► M440 31 March 2027 ◀ | 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 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 311 | Quinmerac CAS No 90717-03-6 CIPAC No 563 | 7-chloro-3-methylqui- noline-8-carboxylic acid | ≥ 980 g/kg | 1 May 2011 | ► <u>M449</u> 31 December 2026 ◀ | In this overall assessment Member States shall pay particular attention to: — operator safety: conditions of use shall prescribe the use of adequate personal protective equipment, where necessary, — protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones, — consumer safety as regards the occurrence in groundwater of the metabolite 2-(1-naphthyloxy)propionic acid, hereinafter 'NOPA'. 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. 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 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. 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; — the dietary exposure of consumers to residues of quinmerac (and its metabolites) in succeeding rotational crops — the risk to aquatic organisms and the long term risk for earthworms. Conditions of use shall include risk mitigation measures, 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 request the submission of information as regards: |
| | | | | | | | — 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. |
| | | | | | | | They shall ensure that the applicant provides such confirmatory data and information to the Commission by 30 April 2013. |
| / <u>M394</u> | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 313 | Pyridaben | 2-tert-butyl-5-(4-tert-butylbenzylthio)-4- | >980 g/kg | 1 May 2011 | ► <u>M413</u> 31 July 2026 ◀ | PART A |
| | | CAS No 96489-71-3 | chloropyrididazin-3 | | | July 2020 4 | Only uses as insecticide and acaricide may be authorised. |
| | | CIPAC No 583 | (2H)-one | | | | 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 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. |
| | | | | | | | 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, |
| | | | | | | | — the risk to aquatic organisms and mammals, |
| | | | | | | | — the risk to non target arthropods including honeybees. |
| | | | | | | | Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify the real exposure o honeybees to pyridaben in areas extensively used by such bees for foraging or by beekeepers, where and as appropriate. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | The Member States concerned shall request the submission of confirmatory information as regards: |
| | | | | | | — 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. |
| | | | | | | They shall ensure that the applicant provides such confirmatory information to the Commission by 30 April 2013. |
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| 314 | Zinc phosphide | Trizinc diphosphide | ≥ 800 g/kg | 1 May 2011 | M449 31 December | PART A |
| | CAS No 1314-84-7 | | | | 2026 ◀ | Only uses as rodenticide in the form of ready-to-use baits placed in bait stations or target locations may be authorised. |
| | CIPAC No 69 | | | | | 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 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. |
| | | | | | | In this overall assessment Member States should pay particular attention to: |
| | | | | | | 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. |
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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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| 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 | ► M415 31 August 2026 ◀ | 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 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. In this overall assessment Member States shall pay particular attention to the risk to non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. 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. The Member States concerned shall ensure that the applicant submits such methods of analysis to the Commission by 31 May 2013. |
| 317 | 6-Benzyladenine CAS No 1214-39-7 CIPAC No 829 | N6-benzyladenine | ≥ 973 g/kg | 1 June 2011 | ► M449 15 July 2026 ◀ | 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 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. 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 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 | ► M444 30 April 2027 ◀ | 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 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. In this overall assessment, Member States shall pay particular attention to: — 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. The Member States concerned shall ensure that the applicant presents to the Commission: — further information on residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; — information to further address the long term risk to herbivorous mammals. 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. 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. |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>B</u> | | | | | | | |
| | 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 | ► M444 15 December 2025 ◀ | ▶ M204 PART A Only uses as insecticide and acaricide on non-edible crops 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 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. In this overall assessment, Member States must pay particular attention to: 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. Conditions of authorisation shall include risk mitigation measures, where appropriate. |
| ▼ <u>M394</u> | | | | | | | |
| ▼ <u>B</u> | 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 | ► <u>M415</u> 31 August 2026 ◀ | PART A Only uses as fungicide for seed pelleting of sugar beets in professional seed treatment facilities may be authorised. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | 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 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. In this overall assessment Member States shall pay particular attention to: — the operators and workers safety. Conditions of authorisation shall include protective measures, where appropriate, — the risk to granivorous birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. 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. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013. |
| 323 | Dodine CAS No 2439-10-3 CIPAC No 101 | 1-dodecylguani- dinium acetate | ≥ 950 g/kg | 1 June 2011 | ► M449 15 July 2026 ◀ | 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 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. In this overall assessment Member States shall pay particular attention to: — the potential long-term risk to birds and mammals; |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | — 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. |
| | | | | | | | The Member States concerned shall request the submission of confirmatory information as regards: |
| | | | | | | | - long-term risk assessment for birds and mammals, |
| | | | | | | | risk assessment in natural surface water systems where major meta- bolites have potentially formed. |
| | | | | | | | The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013. |
| ▼ <u>M394</u> | | | | | | | |
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| ▼ B | | | | | | | |
| _ | 326 | Indolylbutyric acid | 4-(1H-indol-3-yl) | ≥ 994 g/kg | 1 June 2011 | ► <u>M415</u> 15 | PART A |
| | | CAS No 133-32-4 | butyric acid | | | March 2026 ◀ | Only uses as plant growth regulator in ornamentals may be authorised. |
| | | CIPAC No 830 | | | | | 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 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. |
| | | | | | | | 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. |
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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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| | | | | | | | The Member States concerned shall request the submission of further information to confirm: |
| | | | | | | | — 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. |
| | | | | | | | The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013. |
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| | 328 | Tau-fluvalinate | (RS)-α-cyano-3-phen- | ≥ 920 g/kg | 1 June 2011 | | PART A |
| | | CAS No 102851-06-9 | oxybenzyl N-(2- chloro- α,α α- | (1:1 ratio of R-α- | | January 2027 ◀ | Only uses as insecticide and acaricide may be authorised. |
| | | CIPAC No 786 | trifluoro-p-tolyl)-D- | cyano and S-α- cyano isomers) | | 2027 | PART B |
| | | | valinate (Isomer ratio 1:1) | Impurities: Toluene: not more than 5 g/kg | | | For the implementation 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. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | — 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 |
| | | | | | | | The Member States concerned shall request the submission of confirmatory information as regards: |
| | | | | | | | — the risk of bioaccumulation/biomagnification in the aquatic environment; |
| | | | | | | | — the risk to non-target arthropods; |
| | | | | | | | The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013. |
| | | | | | | | The Member States concerned shall ensure that the applicant submits confirmatory information, two years after the adoption of specific guidance, as regards: |
| | | | | | | | — the possible impact on the environment of the potential enantio-selective degradation in environmental matrices. |
| ▼ <u>M27</u> | | | | | | | |
| | 329 | Clethodim CAS No 99129-21-2 CIPAC No 508 | (5RS)-2-{(1EZ)-1- [(2E)-3-chloroally- loxyimino]propyl}-5- [(2RS)-2-(ethylthio) propyl]-3-hydroxy- cyclohex-2-en-1-one | ≥ 930 g/kg Impurities: toluene max. 4 g/kg | 1 June 2011 | M415 31 August 2026 ◀ | 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 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. 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. The Member States concerned shall request the submission of confirmatory information, on the basis of most recent scientific knowledge, as regards: — the residue definition for risk assessment. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| 330 | Bupirimate CAS No 41483-43-6 CIPAC No 261 | 5-butyl-2-ethylamino-6-methylpyrimidine-4-yl dimethylsul-famate | ≥ 945 g/kg Impurities: Ethirimol: max. 2 g/kg Toluene: max. 3 g/kg | 1 June 2011 | ► M449 31 January 2027 ◀ | 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 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. 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 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. The Member States concerned shall request the submission of confirmatory information as regards: (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). 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. |

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| N | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M112</u> | | | | | | | |
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| ▼ <u>M394</u> | | | | | | | |
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| | 333 | 1-decanol | Decan-1-ol | ≥ 960 g/kg | 1 June 2011 | ► <u>M449</u> 15 | PART A |
| | | CAS No 112-30-1 | | | | 2026 ◀ | Only uses as plant growth regulator may be authorised. |
| | | CIPAC No 831 | | | | | 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; |
| | | | | | | | — the risk for operator and ensure that conditions of use prescribe the application of adequate 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 aquatic organisms; |
| | | | | | | | — 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. |
| | | | | | | | Risk mitigation measures shall be applied, where appropriate. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | 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. |
| | | | | | | The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013. |
| | | | | | | |
| 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 | M449 31 January 2027 ◀ | 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 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. 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. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the specification of the technical material, as commercially manufactured, (b) the relevance of the impurities; (c) the residues in rotational crops; |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | (d) the potential risk to aquatic organisms. 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. |
| 335 | Fluometuron CAS No: 2164-17-2 CIPAC No: 159 | 1,1-dimethyl-3-(α,α,α -trifluoro-m-tolyl) urea | ≥ 940 g/kg | 1 June 2011 | M449 15 July 2026 ◀ | PART A Only uses as herbicide on cotton 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 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. In this overall assessment Member States shall: — 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. The Member States concerned shall ensure that the applicants submit to the Commission confirmatory information as regards: (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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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (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'. 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. |
| ▼ M394 | | | | | | | |
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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-thia-diazine-2-thione | ≥ 950 g/kg | 1 June 2011 | M415 31 August 2026 ◀ | PART A Only uses as nematicide, 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. 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 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. In this overall assessment Member States shall pay particular attention to: — 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (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. 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. |
| 340 | Metaldehyde CAS No 108-62-3 (tetramer) 9002-91-9 (homopolymer) CIPAC No 62 | r-2, c-4, c-6, c-8-tetramethyl-1,3,5,7-tetroxocane | ≥ 985 g/kg acetaldehyde max. 1,5 g/kg | 1 June 2011 | M415 31 August 2026 ◀ | PART A Only uses as molluscicide 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 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. In this overall assessment Member States shall pay particular attention to: — 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. |

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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 authorisations shall contain an effective dog repellent agent. |
| | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| 341 | Sintofen CAS No 130561-48-7 CIPAC No 717 | 1-(4-chlorophenyl)- 1,4-dihydro-5-(2- methoxyethoxy)-4- oxocinnoline-3- carboxylic acid | ≥ 980 g/kg Impurities: 2-methoxyethanol, not more than 0,25 g/kg N,N-dimethyl-formamide, not more than 1,5 g/kg | 1 June 2011 | ► M449 15 July 2026 ◀ | PART A Only uses as a plant growth regulator on wheat for hybrid seed production not intended for human consumption 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 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. 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 the application of adequate risk mitigation measures. They shall ensure that wheat treated with sintofen does not enter the food and feed chain. The Member States concerned shall request the submission of confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data; (2) the relevance of the impurities present in the technical specifications, except of the impurities 2-methoxyethanol and N,N-dimethylformamide; (3) the relevance of the test material used in the toxicity and ecotoxicity dossiers in view of the specification of the technical material; |
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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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| | | | | | | (4) the metabolic profile of sintofen in rotational crops. 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. |
| 342 | Fenazaquin CAS No 120928-09-8 CIPAC No 693 | 4-tert-butylphenethyl quinazolin-4-yl ether | ≥ 975 g/kg | 1 June 2011 | ► M415 31 August 2026 ◀ | ▶ M256 PART A Only uses as acaricide 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 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. In this overall assessment Member States shall pay particular attention to: (a) the protection of aquatic organisms; (b) the protection of operators, also ensuring that the conditions of the use include the application of adequate personal protective equipment; (c) the protection of bees; (d) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses; (e) the risk to consumers, in particular from the residues generated during processing; |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | (f) the conditions of use to avoid exposure to residues of fenazaquin with respect to crops for human and animal consumption. Conditions of use shall include risk mitigation measures, where appropriate. ◀ |
| 343 | Azadirachtin CAS No 11141-17-6 (azadirachtin A) CIPAC No 627 (azadirachtin A) | Azadirachtin A: dimethyl (2aR,3S,4S,4aR,5S,7-aS,8S,10R,10aS,10b-R)-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. | Expressed as azadirachtin A: ≥ 111 g/kg Sum of the aflatoxins B1, B2, G1, G2 must not exceeding 300 µg/kg of the azadirachtin A content. | 1 June 2011 | ► M449 31 January 2027 ◀ | PART A ▶ M339 For the implementation 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 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 azadirachtin, and in particular Appendices I and II thereto, as finalised by the Standing Committee on Plants, Animals, Food and Feed on 17 July 2020 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; (2) the protection of non-target arthropods and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. 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 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. |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | In this overall assessment Member States shall pay particular attention to: 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. The Member States concerned shall request the submission of confirmatory information as regards: 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. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 December 2013. |
| 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 | ► <u>M415</u> 31 August 2026 ◀ | 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; |

| Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | 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 | M449 31 January 2027 ◀ | 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. In this overall assessment Member States shall pay particular attention to: — 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. |

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| Num | ber Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| 34 | Aluminium sulfate CAS No 10043-01-3 CIPAC not available | Aluminium sulfate | 970 g/kg | 1 June 2011 | ► M449 15 July 2026 ◀ | PART A Only indoor uses as post-harvest bactericide for ornamental plants 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 aluminium sulfate, and in particular Appendices I and II thereof, a finalised in the Standing Committee on the Food Chain and Anima Health on 11 March 2011 shall be taken into account. The Member States concerned shall request the submission of confirmatory information as regards the specification of the technical material, a commercially manufactured, in the form of appropriate analytical data. The Member States concerned shall ensure that the applicant submits such information to the Commission by 30 November 2011. |
| <u>//394</u> | _ | | | | | |
| <u> </u> | | | | | | |
| 34 | 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 | ► M415 31 August 2026 ◀ | 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 paclobutrazol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health of 11 March 2011 shall be taken into account. 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. The Member States concerned shall request the submission of confirmatory information as regards: |

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| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (1) the specification of the technical material, as commercially manufactured; |
| | | | | | | | (2) the analytical methods in soil and surface water for the metabolite NOA457654; |
| | | | | | | | (3) the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; |
| | | | | | | | (4) the potential endocrine disrupting properties of paclobutrazol; |
| | | | | | | | (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. |
| | | | | | | | 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. |
| ▼ <u>M394</u> | | | | | | | |
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| <u>▼</u> B | | | | | | | |
| | 350 | Tebufenozide CAS No 112410-23-8 | N-tert-butyl-N'-(4- ethylbenzoyl)-3,5- dimethylbenzohy- | ≥ 970 g/kg Relevant impurity | 1 June 2011 | ► <u>M449</u> 31 January 2027 ◀ | PART A Only uses as insecticide may be authorised. |
| | | CIPAC No 724 | drazide | t-butyl hydrazine | | 2027 | PART B |
| | | | | < 0,001 g/kg | | | For the implementation 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. |

| 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 safety of operators and workers after reentry 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. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information, as regards: (1) the relevance of metabolites RH-6595, RH-2651, M2; (2) the degradation of tebufenozide in anaerobic soils and soils of alkaline pH. 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. |
| 351 | Dithianon CAS No 3347-22-6 CIPAC No 153 | 5,10-dihydro-5,10-dioxonaphtho[2,3-b]-1,4-dithiine-2,3-dicarbonitrile | ≥ 930 g/kg | 1 June 2011 | ► M449 31 January 2027 ◀ | 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 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. |

| 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 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. The Member States concerned shall request the submission of confirmatory information as regards: — the storage stability and the nature of residues in processed products, — the aquatic and groundwater exposure assessment for phthalic acid, phthalaldehyde and 1,2 benzenedimethanol. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013. |
| 352 | Hexythiazox CAS No 78587-05-0 CIPAC No 439 | (4RS,5RS)-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxo-1,3-thia-zolidine-3-carbo-xamide | ≥ 976 g/kg (1:1 mixture of (4R, 5R) and (4S, 5S)) | 1 June 2011 | ► <u>M449</u> 31 January 2027 ◀ | PART A Only uses as 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 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. |

| | 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 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. |
| | | | | | | | The Member States concerned shall request the submission of confirmatory information as regards: |
| | | | | | | | (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. |
| | | | | | | | 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. |
| ▼ <u>M394</u> | | | | | | | |
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| ▼ <u>B</u> | | | | | | | |
|-------------------|--------|--|--|--|------------------|---------------------------|---|
| | Number | Common name, identification numbers | IUPAC name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>C1</u> | | | | | | | |
| <u>▼C1</u> | 354 | Flurochloridone CAS No 61213-25-0 CIPAC No 430 | (3RS,4RS;3RS,4SR)- 3-chloro-4-chloro- methyl-1-(α,α,α- trifluoro-m-tolyl)-2- pyrrolidone | ≥ 940 g/kg. Relevant impurities: Toluene: max 8 g/kg | 1 June 2011 | ► M415 15 March 2026 ◀ | 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: |
| | | | | | | | the relevance of impurities other than toluene; the compliance of ecotoxicological test material with the technical spec- |
| | | | | | | | 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) (2RS)-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) (2RS)-2-hydroxy-2-methyl-N-phenyl-1,4-oxathiane-3-carboxamide 4-oxide.
- (14) (4S,5S)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one and (4R,5R)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one.
- ►C1 (15) R42819: (4RS)-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one.
- $ightharpoonup \overline{M23}$ (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). ◀

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, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------------------|--------|--|--|---|------------------|--------------------------|--|
| ▼ <u>M9</u> | | | | | | | |
| | 1 | Bispyribac CAS No 125401-75-4 CIPAC No 748 | 2,6-bis(4,6-dime-thoxypyrimidin-2-yloxy)benzoic acid | ≥ 930 g/kg (referred to as bispyribac- sodium) | 1 August 2011 | ► M395 31 July 2022 ◀ | PART A Only uses as herbicide in rice may be authorised. PART B For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of treview report on bispyribac, and in particular Appendices I and thereof, as finalised in the Standing Committee on the Food Chain a Animal Health on 17 June 2011 shall be taken into account. In this overall assessment, Member States shall pay particular attention the protection of groundwater, when the active substance is applied regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures whe appropriate. |

information as regards the possible groundwater contamination by meta-

They shall ensure that the applicant provides such information to the

bolites M03 (2), M04 (3) and M10 (4).

Commission by 31 July 2013.

| ▼ <u>M1</u> | | | | | | | |
|--------------------|--------|--|---|--------------------------------|-------------------|-------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M394</u> | | | | | | | |
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| ▼ <u>M4</u> | | | | | | | |
| | 4 | Azoxystrobin | methyl (E)-2-{2[6-(2-cyanophenoxy)pyri- | ≥ 930 g/kg | 1 January 2012 | ► M463 31 May 2027 ◀ | PART A |
| | | CAS No 131860-33-8 | midin-4-yloxy] phenyl}-3-metho- | Toluene maximum content 2 g/kg | 2012 | 111ay 2027 | Only uses as fungicide may be authorised. |
| | | CIPAC No 571 | xyacrylate | Z-isomer | | | PART B |
| | | | | maximum content 25 g/kg | | | For the implementation 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. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | (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; |
| | | | | | | | (2) the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; |
| | | | | | | | (3) the protection of aquatic organisms. |
| | | | | | | | The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate. |
| | | | | | | | The Member States concerned shall request the submission of confirmatory information as regards the risk assessment on groundwater and aquatic organisms. |
| | | | | | | | The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013. |

| ▼ <u>M1</u> | | | | | | | |
|--------------------|--------|---|---|------------|-------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u>▼M6</u> | | | | | | | |
| | 5 | Imazalil CAS No 35554-44-0 73790-28-0 (replaced) CIPAC No 335 | (RS)-1-(β-allyloxy-2,4-dichlorop-henethyl)imidazole or allyl (RS)-1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether | ≥ 950 g/kg | 1 January 2012 | ► M463 31 May 2027 ◀ | 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. In this overall assessment Member States shall: (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; |

▼M6

| ▼ <u>M6</u> | | | | | | | |
|--------------|--------|---|---|--|-------------------|--------------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (5) pay particular attention to risk to aquatic organisms and soil microorganisms and long-term risk to granivorous birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) route of degradation of imazalil in soil and surface water systems; (b) environmental data to support the managing measures that Member States have to put in place to ensure that groundwater exposure is negligible; (c) a hydrolysis study to investigate the nature of residues in processed commodities. The notifier shall submit to the Member States, the Commission and the |
| <u>▼M3</u> | 6 | Prohexadione CAS No 127277-53-6 (prohexadione-calcium) CIPAC No 567 (prohexadione) No 567.020 (prohexadione-calcium) | 3,5-dioxo-4-propio- nylcyclohexanecar- boxylic acid | ≥ 890 g/kg (expressed as prohexadione- calcium) | 1 January 2012 | ► <u>M440</u> 31 May 2026 ◀ | Authority such information by 31 December 2013. 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 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. |
| ▼ <u>M13</u> | 7 | Spiroxamine CAS No 1181134-30-8 CIPAC No 572 | 8-tert-butyl-1,4-diox- aspiro[4.5]decan-2- ylmethyl(ethyl) (propyl)amine (ISO) | ≥ 940 g/kg (diastereomers A and B combined) | 1 January 2012 | ► <u>M440</u> 31 May 2026 ◀ | PART A Only uses as fungicide may be authorised. |

▼<u>M13</u>

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|------------|------------|------------------|------------------------|---|
| | | | | | | 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 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. In this overall assessment Member States shall pay particular attention to: (1) the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; (2) the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) the risk to aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (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; (b) the toxicity of the plant metabolites formed in fruit crops and the potential hydrolysis of fruit crop residues in processed commodities; (c) the groundwater exposure assessment for metabolite M03 (7); (d) the risk to aquatic organisms. 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. |

| PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in |
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| Only uses as fungicide may be authorised. PART B |
| Only uses as fungicide may be authorised. PART B |
| 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. 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. The applicant shall submit confirmatory information as regards: — 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. |
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| ▼ <u>IVII</u> | | | | | | | |
|---------------|--------|---|---|--|-------------------|---------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u>▼M8</u> | 9 | Fluroxypyr CAS No 69377-81-7 CIPAC No 431 | 4-amino-3,5-dichloro-6-fluoro-2-pyridylo-xyacetic acid | M225 ≥ 950 g/kg (fluroxypyrmeptyl) The following manufacturing impurity is of toxicological concern and must not exceed the following amount in the technical material: N-methyl-2-pyrrolidone (NMP): < 3 g/kg ◀ | 1 January 2012 | ► M463 15 February 2027 ◀ | ▶ M225 PART A Only uses as herbicide may be authorised. PART B 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. In this overall assessment, Member States must pay particular attention to: — 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. Conditions of authorisation shall include risk mitigation measures, where appropriate. ■ |
| ▼ <u>M15</u> | 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-dimethyl-cyclopropanecar-boxylate 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 | ► M463 31 May 2027 ◀ | 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. |

▼<u>M15</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------------|---------|--|---|---|-------------------|-------------------------|--|
| | Twinter | cation Numbers | | | approval | approval | 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. |
| ▼ <u>M14</u> | 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-dimethyl- nitrosamine: not more than 50 μg/ kg | 1 January 2012 | ► M463 31 May 2027 ◀ | ► M203 PART A 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. |

▼<u>M14</u>

| A 1ATT-4 | | | | | | | |
|--------------|--------|---|--------------------------|------------|-------------------|--------------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | 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 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. In this overall assessment, Member States must pay particular attention to: — 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. 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. ◀ |
| ▼ <u>M10</u> | 12 | 1-naphthylacetamide CAS No 86-86-2 CIPAC No 282 | 2-(1-naphthyl) acetamide | ≥ 980 g/kg | 1 January 2012 | ► <u>M440</u> 31 May 2026 ◀ | 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-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. In this overall assessment Member States: |

▼<u>M10</u>

| ▼ <u>IVIIU</u> | | | | | | | |
|---------------------|--------|--|-----------------------|------------|-------------------|-------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (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; |
| | | | | | | | (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; |
| | | | | | | | (c) shall pay particular attention to the risk to aquatic organisms; |
| | | | | | | | (d) shall pay particular attention to the risk to non-target plants; |
| | | | | | | | (e) shall pay particular attention to the risk to birds. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | (1) the risk to non-target plants; |
| | | | | | | | (2) the long-term risk to birds. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013. |
| ▼ <u>M11</u> | | | | | | | |
| | 13 | 1-naphthylacetic acid | 1-naphthylacetic acid | ≥ 980 g/kg | 1 January 2012 | ► M440 31 May 2026 ◀ | PART A |
| | | CAS No 86-87-3 | | | 2012 | May 2020 | Only uses as plant growth regulator may be authorised. |
| | | CIPAC No 313 | | | | | 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-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. |
| | | | | | | | In this overall assessment Member States: |

▼<u>M11</u>

| V <u>WIII</u> _ | Number | Common Name, Identifi- | IUPAC Name | Purity (1) | Date of | Expiration of | Specific provisions |
|----------------------|--------|--|--|---|-------------------|--------------------------------|--|
| ▼ <u>M394</u> | | cation Numbers | | | approval | approval | (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; (b) shall pay particular attention to the dietary exposure situation of consumers in view of future revisions of maximum residue levels; (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; (d) shall pay particular attention to the risk to aquatic organisms; (e) shall pay particular attention to the risk to birds. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the route and rate of degradation in soil including an assessment of the potential for photolysis; (2) the long-term risk to birds. The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013. |
| ▼M12 | | | | | | | |
| V <u>IV112</u> | 15 | Fluazifop P CAS No 83066-88-0 (fluazifop-P) CIPAC No 467 (fluazifop-P) | (R)-2-{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy} propionic acid (fluazifop-P) | ≥ 900 g/kg in fluazifop P-butyl The following impurity 2-chloro-5-(trifluoromethyl) pyridine must not exceed 1,5 g/kg in the material as manufactured. | 1 January 2012 | ► <u>M440</u> 31 May 2026 ◀ | ▶ <u>M53</u> 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 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. |

▼<u>M12</u>

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|------------|------------|------------------|------------------------|---|
| | | | | | | In this overall assessment Member States shall: |
| | | | | | | — pay particular attention to consumer safety as regards the occurrence in groundwater of the metabolite compound X (5); |
| | | | | | | pay particular attention to operator safety and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate; |
| | | | | | | — pay particular attention to the protection of surface water and groundwater in vulnerable zones; |
| | | | | | | — pay particular attention to the risk for non-target plants. |
| | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | (1) the specification of the technical material, as commercially manufactured, including information on the relevance of the impurity R154719; |
| | | | | | | (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; |
| | | | | | | (3) the potential long-term risk to herbivorous mammals; |
| | | | | | | (4) the fate and behaviour in the environment of the metabolite compounds X (5) and IV (6); |
| | | | | | | (5) the potential risk to fish and aquatic invertebrates for the metabolite compound IV (6). |
| | | | | | | 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. ◀ |

▼<u>M1</u>

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------------|--|--|---|-------------------|-------------------------|---|
| ▼ <u>M362</u> | | | | | | |
| 16 ▼ <u>M394</u> | Terbuthylazine CAS No 5915-41-3 CIPAC No 234 | N2-tert-butyl-6-chloro-N4-ethyl-1,3,5-triazine-2,4-diamine | ≥ 950 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material: — Propazine: maximum of 9 g/kg — Atrazine: maximum of 1 g/kg — Simazine: maximum of 9 g/kg | 1 January 2012 | ► M463 31 May 2027 ◀ | PART A Only uses as herbicide may be authorised. Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine 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 terbuthylazine, and in particular Appendices I and I thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 and updated by the Standing Committee on Plants, Animals, Food and Feed on 24 March 2021 shall be taken into account. In this overall assessment Member States shall pay particular attention to — the consumer risk assessment from exposure to metabolites of terbuthylazine, — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the risk to mammals and earthworms. 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. |

▼M1

| ▼ <u>M1</u> | | | | | | | |
|--------------------|--------------|---|--------------|------------|-------------------|---------------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M21</u> | 18 | 8-hydroxyquinoline CAS No 148-24-3 (8-hydroxyquinoline) CIPAC No 677 (8-hydroxyquinoline) | 8-quinolinol | ≥ 990 g/kg | 1 January 2012 | ► M463 31 December 2025 ◀ | 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. 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. The applicant shall submit confirmatory information on 8-hydroxyquinoline and its salts as regards: (1) the method of analysis for air; (2) a new storage stability covering the storage time periods of samples from both the metabolism study and from the supervised reidue trials. The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013. |
| ▼ <u>M39</u> 4 | <u>4</u> | | | | | | |
| | | | | | | | |
| ▼ <u>M72</u> | | | | | | | |
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▼<u>M1</u>

| <u>M1</u> | | | | | | | |
|-----------|--------|--|----------------------|--|------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| M30 | | | | | | | |
| | 22 | Metam | Methyldithiocarbamic | ≥ 965 g/kg | 1 July 2012 | | PART A |
| | | CAS No 144-54-7 CIPAC No 20 | acid | Expressed as metam-sodium on a dry weight basis | | November 2025 ◀ | Only uses as nematicide, fungicide, herbicide and insecticide may be autorised for application as soil furnigant prior to planting, limited to o application every third year on the same field. |
| | | | | ≥ 990 g/kg | | | approach every time your on the same note. |
| | | | | Expressed as metam-potassium on a dry weight basis | | | The application may be authorised in open field by soil injection or di irrigation, and in greenhouse by drip irrigation only. The use of gas-tig plastic film for drip irrigation shall be prescribed. |
| | | | | Relevant impurities: | | | The maximum application rate shall be 153 kg/ha (corresponding to 86,3 l ha of MITC) in case of open field applications. |
| | | | | methylisothio- cyanate (MITC) | | | Authorisations shall be limited to professional users. |
| | | | | — max. 12 g/kg | | | PART B |
| | | | | on dry weight basis (metamsodium), — max. 0,42 g/kg on dry weight basis | | | For the implementation of the uniform principles as referred to in Article (6) of Regulation (EC) No 1107/2009, the conclusions of the review repon metam, and in particular Appendices I and II thereof, as finalised in Standing Committee on the Food Chain and Animal Health on 9 Ma 2012, shall be taken into account. |
| | | | | (metam- potassium). | | | In this overall assessment Member States: |
| | | | | N,N'-dimethyl- thiourea (DMTU) — max. 23 g/kg on a dry weight basis | | | (a) shall pay particular attention to the protection of operators and sh ensure that the conditions of use include risk mitigation measures su as application of adequate personal protective equipment and a lintation in the daily work rate; |
| | | | | (metam-sodium), — max. 6 g/kg on a dry weight basis (metam-potassium). | | | (b) shall pay particular attention to the protection of workers and shensure that the conditions of use include risk mitigation measur such as use of adequate personal protective equipment, re-en period and limitation in the daily work rate; |

▼<u>M30</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------------|--------|--|---|---|-------------------|--------------------------------|---|
| | | | | | | | (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; |
| | | | | | | | (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; |
| | | | | | | | (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. |
| | | | | | | | The applicant shall submit confirmatory information on methyl isothio-cyanate as regards: |
| | | | | | | | (1) the assessment of the long-range atmospheric transport potential and related environmental risks; |
| | | | | | | | (2) the potential groundwater contamination. |
| _ | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority such information by 31 May 2014. |
| ▼ <u>M394</u> | | | | | | | |
| _ | | | | | | | |
| ▼ <u>M34</u> | | | | | | | |
| | 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-carbo- xamide | ≥ 950 g/kg The impurity toluene must not exceed 1 g/kg in the technical material | 1 January 2013 | ► <u>M343</u> 31 May 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 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. |

▼M34

| ▼ <u>M34</u> | | | | | | | |
|---------------------|--------|--|---|---|--------------------|--------------------------------|--|
| | Number | Common Name, Identifi- cation 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 risk to groundwater, if the active substance is applied under vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | 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. |
| ▼ <u>M35</u> | 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 | M354 ≥ 960 g/kg The following manufacturing impurity is of toxicological concern and must not exceed the following amount in the technical material: Hydrazine: maximum content: < 0,0001 % (1 mg/kg) ◀ | 1 January 2013 | ► M466 15 January 2025 ◀ | ► M354 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 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 and the Standing Committee on Plants, Animals, Food and Feed on 18 May 2020 shall be taken into account. The purity given in this entry is based on a commercial plant production. ◀ |
| ▼ <u>M40</u> | 26 | Adoxophyes orana granulovirus Culture collection No DSM BV-0001 CIPAC No 782 | Not applicable | No relevant impurities | 1 February 2013 | ► M343 31 January 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>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. |

| ▼ <u>M1</u> | | | | | | | |
|---------------------|--------|--|----------------|---|------------------|------------------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M392</u> | | | | | | | |
| ▼ <u>M42</u> | | | | | | | |
| | 28 | Phosphane CAS No 7803-51-2 CIPAC No 127 | Phosphane | ≥ 994 g/kg The relevant impurity arsane must not exceed 0,023 g/kg in the technical material | 1 April 2013 | M444 15 March 2026 ◀ | Authorisations shall be limited to professional users. For the implementation 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. In this overall assessment Member States shall pay particular attention to: — 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. 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. |
| ▼ <u>M45</u> | 29 | Trichoderma asperellum (strain T34) CECT number: 20417 | Not applicable | 1 × 10 ¹⁰ cfu/g | 1 June 2013 | ► <u>M415</u> 31 October 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 <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. |

| ▼ <u>M45</u> | | | | | | | |
|---------------------|--------|---|---|-------------------------|------------------|------------------------------------|---|
| | Number | Common Name, Identifi- cation 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>Trichoderma asperellum</i> (strain T34) is to be considered as a potential sensitiser. |
| | | | | | | | Conditions of use shall include risk mitigation measures where appropriate. |
| ▼ <u>M44</u> | 30 | Zucchini Yellow Mosaic Virus — weak strain ATCC accession number: PV-593 | Not applicable | ≥ 0,05 mg/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>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. 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. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M47</u> | 31 | Cyflumetofen CAS No 400882-07-7 CIPAC No 721 | 2-methoxyethyl (RS)- 2-(4-tert-butylp- henyl)-2-cyano-3- oxo-3-(α,α,α- trifluoro-o-tolyl) propionate | ≥ 975 g/kg (racemic) | 1 June 2013 | ► <u>M415</u> 31 October 2025 ◀ | ► 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. |

▼<u>M47</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------------|--------|--|----------------|--|------------------|------------------------------------|---|
| | | | | | | | For the implementation 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. In this overall assessment, Member States shall pay particular attention to: — 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. Conditions of use shall include risk mitigation measures, where |
| ▼ <u>M46</u> | 32 | Trichoderma atroviride strain I-1237 CNCM number: I-1237 | Not applicable | $1 \times 10^9 \text{ cfu/g}$ $(1 \times 10^{10} \text{ spores/g})$ | 1 June 2013 | ► <u>M415</u> 31 October 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 <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. 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. Conditions of use shall include risk mitigation measures where appropriate. |

| ▼ <u>M1</u> | | | | | | | |
|--------------------|--------|--|---|---|------------------|--|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M52</u> | | | | | | | |
| | 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 | ► <u>M415</u> 31 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 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. |
| ▼ <u>M50</u> | 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 | ► M415 31 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 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

| ▼ <u>M1</u> | | | | | | | |
|---------------------|--------|---|---|---|-------------------|---------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M56</u> | | | | | | | |
| | 35 | Halosulfuron-methyl CAS No 100785-20-1 CIPAC No 785.201 | methyl 3-chloro-5- (4,6-dimethoxypyri- midin-2-ylcarba- moylsulfamoyl)-1- methylpyrazole-4- | ≥ 980 g/kg | 1 October 2013 | ► M429 31 March 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 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. |
| | | | carboxylate | | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | — 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. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | (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). |
| | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015. |
| ▼ <u>M58</u> | | | | | | | |
| | 36 | Bacillus firmus I-1582 Collection number: CNCMI-1582 | Not applicable | Minimum concentration: 7,1 × 10 ¹⁰ 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>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. |
| | | | | | | | 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. Conditions of use shall include risk mitigation measures, where appropriate. |

| ▼ <u>M11</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M62</u> | 37 | Candida oleophila strain O Collection number: MUCL40654 | Not applicable | Nominal content: 3×10^{10} CFU/g dried product Range: $6 \times 10^9 - 1 \times 10^{11}$ CFU/g dried product | 1 October 2013 | ► M463 31 May 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>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. |
| ▼ <u>M60</u> | 38 | Helicoverpa armigera nucleopolyhedrovirus DSMZ number: BV- 0003 | Not applicable | Minimum concentration: 1,44 × 10 ¹³ OB/I (occlusion bodies/I) | 1 June 2013 | ► <u>M415</u> 31 October 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 <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. |
| ▼ <u>M64</u> | 39 | Paecilomyces fumoso- roseus 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 × 10 ⁹ CFU/g Maximum 3,0 × 10 ⁹ CFU/g | 1 October 2013 | ► <u>M463</u> 31 May 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>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. |

| <u>M64</u> | | | | | | | |
|------------|--------|---|--|--|-------------------|--------------------------|--|
| | Number | Common Name, Identifi- cation 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. |
| <u>M61</u> | | | | | | | |
| | 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 | ► M343 31 January 2026 ◀ | For the implementation 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. |
| <u>M63</u> | | | | | | | |
| | 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-dimethyl- butyrate | ≥ 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. |

▼<u>M63</u>

| ▼ <u>IV103</u> | | | | | | | |
|---------------------|--------|---|--|---|-------------------|------------------------------------|---|
| | Number | Common Name, Identifi- cation 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 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. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | 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. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015. |
| ▼ <u>M59</u> | 42 | Spodoptera littoralis nucleopolyhedrovirus DSMZ number: BV- 0005 | Not applicable | Maximum concentration: 1 × 10 ¹² OB/I (occlusion bodies/I) | 1 June 2013 | ► <u>M415</u> 31 October 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 <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. |
| ▼ <u>M54</u> | 43 | Bixafen CAS No 581809-46-3 CIPAC No 819 | N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide | ≥ 950 g/kg | 1 October 2013 | ► M343 31 May 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 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. In this overall assessment Member States shall pay particular attention to: (a) the residues of bixafen and of its metabolites in rotational crops; |

| ▼ <u>M154</u> | | | | | | | |
|---------------|--------|--|------------------------------|---|-------------------|--|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; |
| | | | | | | | (c) the risk to aquatic organisms; |
| | | | | | | | (d) the risk to soil and sediment-dwelling organisms. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M55</u> | | | | | | | |
| | 44 | Maltodextrin CAS No 9050-36-6 CIPAC No 801 | None allocated | ≥ 910 g/kg | 1 October 2013 | ► <u>M429</u> 28 February 2026 ◀ | For the implementation 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. In this overall assessment Member States shall pay particular attention to: (a) the potential increased growth of fungi and possible presence of mycotoxins on the surface of treated fruits; (b) the potential risk to honeybees and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M68</u> | 45 | Eugenol CAS No 97-53-0 CIPAC No 967 | 4-allyl-2-metho- xyphenol | ≥ 990 g/kg Relevant impurity: methyl eugenol maximum 0,1 % of the technical material | 1 December 2013 | ► <u>M434</u> 30 April 2026 ◀ | For the implementation 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. |

▼<u>M68</u>

| | Number | Common Name, Identifi- cation 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, 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. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (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. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015. |
| ▼ <u>M70</u> | 46 | Geraniol CAS No 106- 24-1 CIPAC No 968 | (E) 3,7-dimethyl-2,6-octadien-1-ol | ≥ 980 g/kg | 1 December 2013 | ► M434 30 April 2026 ◀ | For the implementation 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. |

▼<u>M70</u>

| | Number | Common Name, Identifi- cation 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, 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. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards (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; (b) the groundwater exposure. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015. |
| ▼ <u>M69</u> | 47 | Thymol CAS No 89-83-8 CIPAC No 969 | 5-methyl-2-propan-2- yl-phenol | ≥ 990 g/kg | 1 December 2013 | ► <u>M434</u> 30 April 2026 ◀ | For the implementation 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. In this overall assessment Member States shall pay particular attention to — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; |

▼ <u>M69</u>

| * IVIU) | | | | | | | |
|---------------------|--------|---|---|--|--------------------|-------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | — 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. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards |
| | | | | | | | (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; |
| | | | | | | | (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; |
| | | | | | | | (c) the groundwater exposure. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015. |
| ▼ <u>M77</u> | | | | | | | |
| | 48 | Sedaxane | mixture of 2 cisisomers 2'- | ≥ 960 g/kg Sedaxane | 1 February 2014 | ► M343 31 May 2025 ◀ | PART A |
| | | CAS No 874967-67-6 | [(1RS,2RS)-1,1'- bicycloprop-2-yl]-3- | (range 820-890 g/ | | | Only uses for seed treatment may be authorised. |
| | | (trans isomer: 599197- | (difluoromethyl)-1- methylpyrazole-4- | kg for the 2 trans- | | | PART B |
| | | 38-3/cis isomer: 599194- 51-1) CIPAC No 833 | carboxanilide and 2 trans-isomers 2'- [(1RS,2SR)-1,1'- bicycloprop-2-yl]-3- (difluoromethyl)-1- methylpyrazole-4- carboxanilide | isomers 50:50 mixture of enantiomers and range 100-150 g/ kg for the 2 cis- isomers 50:50 mixture of enanti- omers) | | | For the implementation 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. In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | (a) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; |

▼<u>M77</u>

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-----------------|---|--|--|------------------|---------------------------------|--|
| 9 | | | | | | (b) the long-term risk to birds and mammals. Conditions of authorisation shall include risk mitigation measures, who appropriate. The Member States concerned shall carry out monitoring programmes verify potential groundwater contamination from the metabol CSCD465008 in vulnerable zones, where appropriate. The Member States concerned shall request the submission of confirmate information as regards the relevance of the metabolite CSCD465008, a the corresponding groundwater risk assessment, if sedaxane is classifi under Regulation (EC) No 1272/2008 as 'suspected of causing cancer'. The notifier shall submit to the Commission, the Member States and the Authority the relevant information within six months from the application of the Regulation classifying sedaxane. |
| 9 49 | Emamectin CAS No emamectin: 119791-41-2 (formerly 137335-79-6) and 123997-28-4 emamectin benzoate: 155569-91-8 (formerly 137512-74-4 and 179607-18-2) | Emamectin B1a: (10E,14E,16E)- (1R,4S,5'S,6S,6' R,8R,12S,13 S,20R,21R,24S)-6'- [(S)-sec-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'H-pyran)- 12-yl 2,6-dideoxy-3- O-methyl-4-O-(2,4,6- trideoxy-3-O-methyl- 4-methylamino-α-L- lyxo-hexapyranosyl)- α-L-arabino-hexapyranoside | ≥ 950 g/kg as emamectin benzoate anhydrous (a mixture of min. 920 g/kg emamectin B1a benzoate and max. 50 g/kg emamectin B1b benzoate) | 1 May 2014 | ► M460 15 November 2026 ◀ | For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo on emamectin, and in particular Appendices I and II thereof, as finalised the Standing Committee on the Food Chain and Animal Health on 16 Ju 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to non-target invertebrates; — the protection of workers and operators. Conditions of use shall include risk mitigation measures, where appropriate The applicant shall submit confirmatory information as regards the risk enantio-selective metabolisation or degradation. 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. |

▼<u>M79</u>

| Number | Common Name, Identifi- cation 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: (10E,14E,16E)- (1R,4S,5'S,6S,6' R,8R,12S,13S,20R,21- R,24S)-21,24-dihy- droxy-6'-isopropyl- 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'H-pyran)- 12-yl 2,6-dideoxy-3- O-methyl-4-O-(2,4,6- trideoxy-3-O-methyl- 4-methylamino-α-L- lyxo-hexapyranosyl)-α-L-arabino-hexapyranoside Emamectin B1a benzoate: (10E,14E,16E)- (1R,4S,5'S,6S,6' R,8R,12S,13S,20R,21- R,24S)-6'-[(S)-sec- butyl]- | | | | |

▼<u>M79</u>

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|----------|------|--|---|------------|------------------|------------------------|---------------------|
| Nun | nber | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | 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'H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino-α-L-lyxo-hexapyranosyl)-α-L-arabino-hexapyranoside benzoate | | | | |
| | | | Emamectin B1b 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>)-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}] 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-methylamino-α-L- lyxo-hexapyranosyl)- α-L-arabino-hexapyranoside benzoate | | | | |

| ▼ <u>M1</u> | | | | | | | |
|---------------------|--------|--|--|--|--------------------|-------------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M80</u> | 50 | Pseudomonas sp. strain DSMZ 13134 Collection number: DSMZ 13134 | Not applicable | Minimum concentration: 3×10 ¹⁴ cfu/kg | 1 February 2014 | ► M343 31 January 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 <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. 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. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit information to confirm the absence of an acute intratracheal and intraperitoneal toxicity/infectivity/pathogenicity potential. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016. |
| ▼ <u>M76</u> | 51 | Fluopyram CAS No 658066-35-4 CIPAC No 807 | N-{2-[3-chloro-5-(tri-fluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-o-toluamide | ≥ 960 g/kg | 1 February 2014 | <u>M444</u> 30 June 2026 ◀ | For the implementation 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. In this overall assessment Member States shall pay particular attention to the risk to birds and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the long-term risk to insectivorous birds; |

| ▼ <u>M76</u> | | | | | | | |
|---------------------|--------|---|--|--|--------------------|--------------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (2) the potential for causing endocrine disrupting effects in non-target vertebrates other than mammals. 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. |
| ▼ <u>M78</u> | | | | | | | |
| | 52 | Aureobasidium pullulans (strains DSM 14940 and DSM 14941) Collection number: German Collection of Microorganisms and cell Cultures (DSMZ) with the accession numbers DSM 14940 and DSM 14941 | Not applicable | Minimum 5,0 × 10 ⁹ CFU/g for each strain; Maximum 5,0 × 10 ¹⁰ CFU/g for each strain | 1 February 2014 | ► M343 31 January 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 <i>Aureobasidium</i> pullulans (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. 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. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M82</u> | 53 | Pyriofenone: | (5-chloro-2-methoxy- | ≥ 965 g/kg | 1 February | ►<u>M343</u> 31 | For the implementation of the uniform principles as referred to in Article 29 |
| | | CAS No 688046-61-9 CIPAC No 827 | 4-methyl-3-pyridyl) (4,5,6-trimethoxy-o- tolyl)methanone | | 2014 | January 2025 ◀ | (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. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards |
| | | | | | | | |

| ▼ <u>M182</u> | | | | | | | |
|---------------------|--------|---|---------------------------|--------------------------------------|--------------------|---------------------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (a) the identity of two impurities to fully support the provisional specification; |
| | | | | | | | (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. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016. |
| ▼ <u>M81</u> | | | | | | | |
| | 54 | Disodium phosphonate CAS No 13708-85-5 CIPAC No 808 | disodium phos- phonate | 281-337 g/kg (TK) ≥ 917 g/kg (TC) | 1 February 2014 | ► <u>M343</u> 31 January 2026 ◀ | For the implementation 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. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to the risk to eutrophication of surface water. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards |
| | | | | | | | (a) the chronic risk to fish; |
| | | | | | | | (b) the long term risk to earthworms and soil macro-organisms. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016. |

| Numbe | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------|--|--|----------------------------------|--------------------|------------------------------------|--|
| | | | | | | |
| 55 | Penflufen CAS No 494793-67-8 | 2'-[(RS)-1,3- dimethylbutyl]-5- fluoro-1,3-dimethyl- | ≥ 950 g/kg 1:1 (R:S) ratio of | 1 February 2014 | ► <u>M430</u> 31 January 2024 ◀ | <u>M398</u> PART A |
| | CIPAC No 826 | pyrazole-4-carbox- anilide | enantiomers | | | Only uses to treat cereal seeds before or during sowing may be autho limited to one application every third year on the same field. |
| | | | | | | PART B |
| | | | | | | For the implementation of the uniform principles as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of review report on penflufen, and in particular Appendices I and II the shall be taken into account. |
| | | | | | | In this overall assessment, Member States shall pay particular attentio |
| | | | | | | (a) the protection of operators; |
| | | | | | | (b) the protection of birds; |
| | | | | | | (c) the protection of groundwater, when the substance is applied to require with vulnerable soil and/or climatic conditions; |
| | | | | | | (d) to the residues in surface water abducted for drinking water purp in or from areas where products containing penflufen are used. |
| | | | | | | Conditions of use shall include risk mitigation measures, v appropriate. ◀ |

| ▼ <u>M1</u> | | | | | | | |
|---------------------|--------|--|--|---|------------------|--------------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M88</u> | 56 | Orange oil | (R)-4-isopropenyl-1- | ≥ 945 g/kg (of D- | 1 May 2014 | ►<u>M449</u> 31 | For the implementation of the uniform principles as referred to in Article 29 |
| | | CAS No 8028-48-6 (Orange extract) 5989-27-5 (D-limonene) CIPAC No 902 | methylcyclohexene or p-mentha-1,8-diene | limonene) The active substance shall comply with the specifications of Ph. Eur. (Pharmacopoeia Europea) 5.0 (Aurantii dulcis aetheroleum) and ISO 3140:2011(E) | | December 2026 ◀ | (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. |
| ▼ <u>M94</u> | 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 | ► <u>M343</u> 31 May 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 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; |

▼ <u>M94</u>

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

| ▼ <u>M1</u> | | | | | | | |
|---------------------|--------|---|---|--|------------------|--|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M90</u> | 58 | Benalaxyl-M CAS No 98243-83-5 CIPAC No 766 | Methyl N-(pheny-lacetyl)-N-(2,6-xylyl)-D-alaninate | ≥ 950 g/kg | 1 May 2014 | ► <u>M343</u> 30 April 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 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. In this overall assessment Member States shall pay particular attention to: — the protection of workers at re-entry, — the risk to groundwater from the metabolites BM-M2 (N-(malonyl)-N-(2,6-xylyl)-D-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. |
| ▼ M05 | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M95</u> | 59 | Tembotrione CAS No 335104-84-2 CIPAC No 790 | 2-{2-chloro-4-mesyl-3-[(2,2,2-trifluoro-ethoxy)methyl] benzoyl}cyclo-hexane-1,3-dione | ≥ 945 g/kg The following relevant impurities must not exceed a certain threshold in the technical material: Toluene: ≤ 10 g/kg | 1 May 2014 | ► <u>M449</u> 31 December 2026 ◀ | For the implementation 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. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and workers; |
| | | | | HCN: ≤ 1 g/kg | | | Conditions of use shall include risk mitigation measures, where appropriate. |

| ▼ <u>M11</u> | | | | | | | |
|--------------|--------|---|---|------------|------------------|----------------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M92</u> | 60 | Spirotetramat CAS No 203313-25-1 CIPAC No 795 | cis-4-(ethoxycarbony-loxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro [4.5]dec-3-en-2-one | ≥ 970 g/kg | 1 May 2014 | ► <u>M386</u> 30 April 2024 ◀ | For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spirotetramat, and in particular Appendices I and II thereof, as finalise in the Standing Committee on the Food Chain and Animal Health of 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention the risk to insectivorous birds. Conditions of use shall include risk mitigation measures, where appropriate 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, or |
| <u>M91</u> | 61 | Pyroxsulam CAS No 422556-08-9 | N-(5,7-dimethoxy [1,2,4]triazolo[1,5-a] pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide | ≥ 965 g/kg | 1 May 2014 | ► <u>M343</u> 30 April 2025 ◀ | Community agreed test guidelines. For the implementation of the uniform principles as referred to in Article (6) of Regulation (EC) No 1107/2009, the conclusions of the review repon pyroxsulam, and in particular Appendices I and II thereof, as finalised the Standing Committee on the Food Chain and Animal Health 3 October 2013 shall be taken into account. |
| | | CIPAC No 793 | | | | | In this overall assessment Member States shall pay particular attention to (a) the risk to groundwater, when the active substance is applied in region with vulnerable soil or climatic conditions; (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate |

▼ M91

| ▼ <u>M91</u> | | | | | | | |
|--------------|--------|---|---|--|------------------|--------------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | The applicant shall submit confirmatory information as regards: (1) the toxicological relevance of impurity number 3 (as referred to in the review report); (2) the acute toxicity of the metabolite PSA; (3) the toxicological relevance of metabolite 6-Cl-7-OH-XDE-742. The applicant shall submit to the Commission, Member States and the |
| ▼ <u>M97</u> | | | | | | | Authority that information by 30 April 2016. |
| | 62 | Chlorantraniliprole CAS No 500008-45-7 CIPAC No 794 | 3-bromo-4'-chloro-1- (3-chloro-2-pyridyl)- 2'-methyl-6'-(methyl- carbamoyl) pyrazole- 5-carboxanilide | ≥ 950 g/kg The following relevant impurities must not exceed a certain threshold in the technical material: Acetonitrile: ≤ 3 g/kg 3-picoline: ≤ 3 g/kg Methanesulfonic acid: ≤ 2 g/kg | 1 May 2014 | ► <u>M463</u> 31 May 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 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. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and to soil macroorganisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (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-methyl-phenyl)-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide); |

| ▼ <u>M97</u> | | · | 1 | | | | |
|---------------------|--------|--|----------------|--------------------------|------------------|------------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (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). |
| | | | | | | | The applicant shall submit to the Commission, Member States and the Authority that information by 30 April 2016. |
| ▼ <u>M96</u> | | | | | | | |
| | 63 | Sodium silver thiosulfate | Not applicable | ≥ 10,0 g Ag/kg | 1 May 2014 | ► <u>M449</u> 31 December | PART A |
| | | CAS No not allocated | | Expressed as silver (Ag) | | 2026 ◀ | Only indoor uses in non-edible crops shall be authorised. |
| | | CIPAC No 762 | | 511.01 (11g) | | | 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 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. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to |
| | | | | | | | (a) the protection of operators and workers; |
| | | | | | | | (b) limiting the possible release of silver ions through disposal of used solutions; |
| | | | | | | | (c) the risk to terrestric vertebrates and soil invertebrates from the use of sewage sludge in agriculture. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |

▼<u>M1</u>

| <u>M11</u> | | | | | | | |
|-------------|--------|--|--|------------|------------------|---------------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u>M101</u> | | | | | | | |
| | 64 | Pyridalyl | 2,6-dichloro-4-(3,3-dichloroallyloxy) | ≥ 910 g/kg | 1 July 2014 | ► <u>M416</u> 30 June 2024 ◀ | PART A |
| | | CAS No 179101-81-6 | phenyl 3-[5-(trifluor-omethyl)-2- pyridyloxy]propyl | | | | Only uses in greenhouses with permanent structure may be authorised. |
| | | CIPAC No 792 | ether | | | | PART B |
| | | | | | | | For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo on pyridalyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health of 13 December 2013, shall be taken into account. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to |
| | | | | | | | (a) the risk to re-entry workers; |
| | | | | | | | (b) the risk to groundwater when the substance is applied in regions with vulnerable soils and/or climatic conditions; |
| | | | | | | | (c) the risk to birds, mammals and aquatic organisms. |
| | | | | | | | Conditions of authorisation shall include risk mitigation measures, whe appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | (1) the toxicological and ecotoxicological information to address t relevance of impurities 4, 13, 16, 22 and 23; |
| | | | | | | | (2) the relevance of the metabolite HTFP and, concerning that metabolite the groundwater risk assessment for all uses on crops in greenhouse. |
| | | | | | | | (3) the risk to aquatic invertebrates. |

▼M101

| ▼ <u>M1101</u> | _ | | | | | | |
|----------------|--------|--|---|---|------------------|----------------------------------|---|
| | Number | Common Name, Identifi- cation 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 relevant information as regards point (1) by 31 December 2014 and information as regards point (2) and (3) by 30 June 2016. 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 HTFP 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. |
| ▼M105 | | | | | | | Talatoni, by 50 balle 2010. |
| | 65 | S-abscisic acid CAS No 21293-29-8 CIPAC No Not allocated | (2Z,4E)-5-[(1S)-1- hydroxy-2,6,6- trimethyl-4- oxocyclohex-2-en-1- yl]-3-methylpenta- 2,4-dienoic acid or (7E,9Z)-(6S)-6- hydroxy-3-oxo-11- apo-ε-caroten-11-oic acid | 960 g/kg | 1 July 2014 | ► M457 15 September 2026 ◀ | For the implementation 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. In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M104</u> | 66 | L-ascorbic acid CAS No 50-81-7 CIPAC No 774 | (5 <i>R</i>)-5-[(1 <i>S</i>)-1,2-dihy-droxyethyl]-3,4-dihy-droxyfuran-2(5 <i>H</i>)-one | ≥ 990 g/kg The following relevant impurities shall not exceed: Methanol: ≤ 3 g/kg Heavy Metals: ≤ 10 mg/kg (expressed as Pb) | 1 July 2014 | ► <u>M386</u> 30 June 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 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. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic and soil organisms; (b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. |

▼M104

| <u> 1104</u> | | 1 | | | | <u> </u> |
|--------------|--|--|---|------------------|-------------------------------|---|
| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | Conditions of use shall include risk mitigation measures, where appropria The applicant shall submit confirmatory information as regards: (1) the natural background of L-ascorbic acid in the environme confirming a low chronic risk for fish and a low risk for aquatic inve ebrates, algae, earthworms and soil microorganisms; (2) the risk to contaminate groundwater. The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016. |
| 67 | Spinetoram CAS No 935545-74-7 CIPAC No 802 | XDE-175-J (Major factor) (2R,3aR,5aR,5bS,9S,-13S,14R,16aS, 16bR)-2-(6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-L-mannopyranosyloxy)-13-[(2R,5S,6R)-5-(dimethylamino) tetrahydro-6-methyl-pyran-2-yloxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,-10,11,12,13,14,16a,1-6b-hexadecahydro-14-methyl-1 <i>H-as</i> -indaceno[3,2-d] oxacyclododecine-7,15-dione XDE_175-L (Minor factor) | ≥ 830 g/kg 50-90 % XDE- 175-J; and 50-10 % XDE- 175-L Tolerance limits (g/kg): XDE-175-J = 581- 810 XDE-175-L = 83- 270 | 1 July 2014 | <u>M386</u> 30 June 2024 ◀ | For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review reports on spinetoram, and in particular Appendices I and II thereof, as finalised the Standing Committee on the Food Chain and Animal Health of 13 December 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to (a) the risk to aquatic and soil organisms; (b) the risk to non-target arthropods in-field; (c) the risk to bees during the application (overspray) and subsequently Conditions of use shall include risk mitigation measures, where appropriate |

▼ <u>M99</u>

| ▼ <u>M99</u> | | | | | | | |
|----------------------|--------|--|---|------------|------------------|---------------------------------|---|
| _ | Number | Common Name, Identifi- cation 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-manno-pyranosyloxy)-13-[(2R,5S,6R)-5-(dimethylamino) tetrahydro-6-methyl-pyran-2-yloxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,1-1,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d] oxacyclododecine-7,15-dione | | | | 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. 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 ◄. |
| ▼ <u>M108</u> | 68 | 1,4-dimethylnaphthalene CAS No 571-58-4 CIPAC No 822 | 1,4-dimethylnaph-thalene | ≥ 980 g/kg | 1 July 2014 | ► <u>M343</u> 30 June 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 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. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and of workers at re-entry and during inspection of the warehouse; (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. Conditions of use shall include risk mitigation measures, where appropriate. |

▼<u>M108</u>

| ▼ M108 | | | | | | | |
|---------------|--------|--|---|---|------------------|---|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | The applicant shall submit confirmatory information as regards the residue definition for the active substance. The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016. |
| ▼ <u>M109</u> | | | | | | | |
| | 69 | Amisulbrom CAS No 348635-87-0 CIPAC No 789 | 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)- <i>N</i> , <i>N</i> -dimethyl-1 <i>H</i> -1,2,4-triazole-1-sulfonamide | ≥ 985 g/kg The following relevant impurity must not exceed a certain threshold in the technical material: 3-bromo-6-fluoro-2-methyl-1-(1H-1,2,4-triazol-3-ylsulfonyl)-1H-indole: ≤ 2 g/kg | 1 July 2014 | ► <u>M457</u> 15 September 2026 ◀ | For the implementation 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. In this overall assessment Member States shall pay particular attention to the risk to aquatic and soil organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (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; (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 a |

▼ M109

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | | (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; |
| | | | | | | | (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; |
| | | | | | | | (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. |
| | | | | | | | 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. |
| ▼ <u>M102</u> | | | | | | | |
| | 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 | ► <u>M457</u> 1 March 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 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. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards the potential of metabolite S5 to contaminate groundwater. |
| | | | | | | | The notifier shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016. |

▼<u>M1</u>

| ▼ <u>IVI I</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M103</u> | 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 | ► <u>M457</u> 1 March 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 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. In this overall assessment Member States shall pay particular attention to (a) the risk to groundwater if the substance is applied under vulnerable geographical or climatic conditions; (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the potential of thiencarbazone for long-range atmospheric transport and the related environmental impacts. 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. |
| ▼ <u>M114</u> | 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 | ► <u>M460</u> 15 November 2026 ◀ | For the implementation 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. In this overall assessment Member States shall pay particular attention to: |

▼M114

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | | — the protection of workers and operators; |
| | | | | | | | — the risk to birds, mammals and aquatic organisms. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | (a) an analytical method for residues in body fluids and tissues; |
| | | | | | | | (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; |
| | | | | | | | (c) the acceptability of the long-term risk to small omnivorous and small herbivorous mammals, concerning the use on outdoor ornamentals. |
| | | | | | | | The applicant shall submit that information to the Commission, the Member States and the Authority by 31 August 2016. |
| ▼ <u>M417</u> | | | | | | | |
| ▼ M119 | | | | | | | |
| - | 74 | Flubendiamide | 3-iodo- <i>N</i> '-(2-mesyl- 1,1-dimethylethyl)- <i>N</i> - | ≥ 960 g/kg | 1 September 2014 | ► <u>M386</u> 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 |
| | | CAS No 272451-65-7 | {4-[1,2,2,2-tetra-fluoro-1-(trifluor- | | | | on flubendiamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on |
| | | CIPAC No 788 | omethyl)ethyl]-o- tolyl}phthalamide | | | | 20 March 2014 shall be taken into account. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | (a) the risk to aquatic invertebrates; |
| | | | | | | | (b) the potential presence of residues in rotational crops. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |

| ▼ <u>M1</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M111</u> | 75 | Bacillus pumilus QST 2808 USDA Agricultural Research Service (NRRL) Patent culture collection in Peoria Illinois, USA under the reference number B-30087 | Not applicable | ≥ 1 × 10 ¹² CFU/ kg | 1 September 2014 | ► M430 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 <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. 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. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the identification of the aminosugar produced by <i>Bacillus pumilus</i> QST 2808; (b) analytical data for the content of that aminosugar in the production batches. The applicant shall submit that information to the Commission, the Member States and the Authority by 31 August 2016. |
| ▼ <u>M123</u> | 76 | Metobromuron CAS No 3060-89-7 CIPAC No 168 | 3-(4-bromophenyl)-1- methoxy-1- methylurea | ≥ 978 g/kg | 1 January 2015 | ► M463 31 May 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 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. In this overall assessment Member States shall pay particular attention to: (a) the protection of workers and operators; |

▼ M123

| ▼ <u>M123</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (b) the risk to birds, mammals, aquatic organisms and terrestrial non-target plants. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | (a) the toxicological assessment of the metabolites CGA 18236, CGA 18237, CGA 18238 and 4-bromoaniline; |
| | | | | | | | (b) the acceptability of the long-term risk to birds and mammals. |
| | | | | | | | The applicant shall submit that information to the Commission, the Member States and the Authority by 31 December 2016. |
| ▼ <u>M124</u> | | | | | | | |
| | 77 | Aminopyralid CAS No 150114-71-9 | 4-amino-3,6-dichloro- pyridine-2-carboxylic acid | ≥ 920 g/kg The following relevant impurity shall not exceed a | 1 January 2015 | ► <u>M463</u> 31 May 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 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. |
| | | CIPAC No 771 | | certain threshold: | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | Picloram ≤ 40 g/kg | | | (a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions; |
| | | | | | | | (b) the risk to aquatic macrophytes and terrestrial non-target plants; |
| | | | | | | | (c) chronic risk to fish. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |

▼<u>M1</u>

| ▼ <u>IVI I</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M129</u> | | | | | | | |
| | 78 | Metaflumizone | (EZ)-2'-[2-(4-cyanop- henyl)-1-(α,α,α- | ≥ 945 g/kg | 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 |
| | | CAS No 139968-49-3 | trifluoro-m-tolyl) ethylidene]-4-(triflu- oromethoxy)carbani- lohydrazide | (90-100 % E- isomer | | | on metaflumizone, and in particular Appendices I and II thereof, as finalise in the Standing Committee on Plants, Animals, Food and Feed on 11 Jul 2014 shall be taken into account. |
| | | CIPAC No 779 | | 10-0 % Z-isomer) | | | |
| | | | | The following | | | In this overall assessment Member States shall pay particular attention to |
| | | | | relevant impurities shall not exceed a certain threshold: | | | (a) the risk to fish and sediment dwelling organisms; |
| | | | | Hydrazine ≤ 1 mg/kg | | | (b) the risk to snail- or earthworm-eating birds. |
| | | | | 4-(trifluorome- thoxy)phenyl isocyanate ≤ 100 mg/kg | | | Conditions of use shall include risk mitigation measures, where appropriate |
| | | | | Toluene ≤ 2 g/kg | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | (1) the equivalence of the material used in the toxicological and ecotoxico logical studies with the proposed technical specification; |
| | | | | | | | (2) information addressing the potential of metaflumizone for bioaccumu lation in aquatic organisms and biomagnification in aquatic food chains |
| | | | | | | | 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. |

▼<u>M1</u>

| ▼ <u>M1</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M126</u> | | | | | | | |
| | 79 | Streptomyces lydicus strain WYEC 108 Collection number: American Type Culture Collection (USDA) ATCC 55445 | Not applicable | Minimum concentration: 5,0 × 10 ⁸ CFU/g | 1 January 2015 | ► M343 31 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 <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. |
| ▼ <u>M131</u> | | | | | | | |
| | 80 | Meptyldinocap CAS No 6119-92-2 CIPAC No 811 | Mixture of 75-100 % (RS)-2-(1-methyl-heptyl)-4,6-dinitrophenyl crotonate and 250 % (RS)-2-(1-methylheptyl)-4,6-dinitrophenyl isocrotonate | ≥ 900 g/kg (mixture of trans- and cis-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 | ► C5 31 March 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 meptyldinocap, and in particular Appendices I and II thereof, as finalised in the ►C5 Standing Committee on Plants, Animals, Food and Feed on 10 October 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); |

▼<u>M131</u>

| ▼ <u>M131</u> | _ | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (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. |
| | | | | | | | 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. |
| ▼ <u>M133</u> | • | | | | | | |
| | 81 | Chromafenozide | N'-tert-butyl-5- methyl-N'-(3,5- | ≥ 935 g/kg | 1 April 2015 | 31 March 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 |
| | | CAS No 143807-66-3 | xyloyl)chromane-6- carbohydrazide | The following relevant impurity must not exceed a | | | 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. |
| | | CIPAC No 775 | | certain threshold in the technical material: | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | Butyl acetate (n-buthyl acetate, | | | (a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions; |
| | | | | CAS No 123-86- 4): ≤ 8 g/kg | | | (b) the risk to non-target Lepidoptera in off-crop areas; |
| | | | | | | | (c) the risk to sediment-dwelling organisms. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | (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; |
| | | | | | | | (2) the assessment of the risk to sediment dwelling organisms from metabolite M-010; |

▼<u>M133</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|----------------------|--------|--|--|------------|------------------|------------------------|---|
| | | | | | | | (3) the leaching potential of metabolites M-006 and M-023 to groundwater. 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. |
| ▼ <u>M132</u> | | | | | | | |
| | 82 | Gamma-cyhalothrin CAS No 76703-62-3 CIPAC No 768 | (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3- [(Z)-2-chloro-3,3,3- trifluoropropenyl]- 2,2-dimethylcyclopropanecarboxylate or (S)-α-cyano-3-phenoxybenzyl (1R)-cis-3- [(Z)-2-chloro-3,3,3- trifluoropropenyl]- 2,2-dimethylcyclopropanecarboxylate | ≥ 980 g/kg | 1 April 2015 | 31 March 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 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. In this overall assessment Member States shall pay particular attention to: (a) the safety of operators and workers; (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) analytical methods for the monitoring of residues in body fluids, tissues and environmental matrices; (2) the toxicity profile of the metabolites CPCA, PBA and PBA(OH); (3) the long-term risk to wild mammals; (4) the potential for biomagnification in terrestrial and aquatic food chains. The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 31 March 2017. |

▼M1

| <u>M1</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| M130 | 83 | Bacillus amylolique- faciens subsp. plantarum strain D747 Accession number in the Agricultural Research Culture Collection (NRRL), Peoria, Illinois, USA: B-50405 Deposit number in the International Patent Organism Depositary, Tokyo, Japan: FERM | Not applicable | Minimum concentration: 2,0 × 10 ¹¹ CFU/g | 1 April 2015 | 31 March 2025 | For the implementation of the uniform principles as referred to in Article (6) of Regulation (EC) No 1107/2009, the conclusions of the review repon <i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747, and particular Appendices I and II thereof, as finalised in the Standi Committee on Plants, Animals, Food and Feed on 10 October 2014 ships taken into account. In this overall assessment Member States shall pay particular attention the protection of operators and workers, taking into account that <i>Baciliamyloliquefaciens</i> subsp. <i>plantarum</i> strain D747 is to be considered as potential sensitizer. Conditions of use shall include risk mitigation measure where appropriate. Strict maintenance of environmental conditions and quality control analysis. |
| 1154 | | BP-8234. | | | | | during the manufacturing process shall be assured by the producer. |
| | 84 | Terpenoid blend QRD 460 CIPAC No: 982 | Terpenoid blend QRD 460 is a blend of three components: — α-terpinene: 1-isopropyl-4-methylcyclohexa-1,3-diene; — p-cymene: 1-isopropyl-4-methylbenzene; — d-limonene: (R)-4-isopropenyl-1-methylcyclohexene. | The nominal concentration of each component in the active substance as manufactured should be as follows: — \alpha-terpinene: 59,7 %; — \alpha-cymene: 22,4 %; — \alpha-limonene: 17,9 %. | 10 August 2015 | 10 August 2025 | For the implementation of the uniform principles as referred to in Article (6) of Regulation (EC) No 1107/2009, the conclusions of the review reponterpenoid blend QRD-460, and in particular Appendices I and II there shall be taken into account. In this overall assessment Member States shall pay particular attention (a) the stability of formulations on storage; (b) the protection of operators and workers, ensuring that conditions of include the application of adequate personal protective equipment where appropriate; (c) the protection of groundwater, when the substance is applied in region 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. |

▼<u>M154</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| ▼M155 | | | | Each component should have a minimum purity as follows: — α-terpinene: 89 %; — p-cymene: 97 %; — d-limonene: 93 %. | | | 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 (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; (2) the equivalence of the material used in the toxicological and ecotoxicological studies with the confirmed technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 10 February 2016. |
| | 85 | Fenhexamid CAS No: 126833-17-8 CIPAC No: 603 | N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexane-1-carboxamide | ≥ 975 g/kg The following relevant impurity must not exceed a certain threshold in the technical material: — toluene: max. 1 g/kg, — 4-amino-2,3-dichlorophenol: max. 3 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 fenhexamid, 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 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. Conditions of use shall include risk mitigation measures, where appropriate. |

| ▼ <u>M1</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M151</u> | | | | | | | |
| | 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-methoxyp- henyl)pyridine-2- carboxylate | ≥ 930 g/kg | 5 August 2015 | 5 August 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 halauxifen-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 risk to aquatic and non-target terrestrial plants. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | — 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. |
| | | | | | | | The applicant shall submit that information to the Commission, the Member States and the Authority by 5 February 2016. |
| ▼ <u>M148</u> | | | | | | | |
| | 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 | For the implementation 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. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, non-target terrestrial plants, and herbivorous mammals. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |

| <u>M1</u> | | Common Name, Identifi- | <u> </u> | | Date of | Expiration of | |
|-----------|--------|---|--|--|-------------------|------------------|---|
| | Number | cation Numbers | IUPAC Name | Purity (1) | approval | approval | Specific provisions |
| 1156 | 88 | Sulfoxaflor CAS No: 946578-00-3 CIPAC No: 820 | [methyl(oxo){1-[6- (trifluoromethyl)-3- pyridyl]ethyl}- λ^6 - sulfanylidene] cyanamide | ≥ 950 g/kg | 18 August 2015 | 18 August 2025 | ▶ M389 Only uses in permanent greenhouses may be authorised. For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo on sulfoxaflor, and in particular Appendices I and II thereof, as finalised the Standing Committee on Plants, Animals, Food and Feed on 29 Ma 2015 and updated on 28 January 2022, shall be taken into account. In this overall assessment, Member States shall pay particular attention the risk to bees and bumble bees released for pollination, when produc containing the substance are applied in greenhouses. Conditions of use shall include risk mitigation measures, when appropriate. ◀ |
| M150 | 89 | Sulfosulfuron CAS No: 141776-32-1 CIPAC No: 601 | 1-(4,6-dimethoxypyri-midin-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 | For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfosulfuron, and in particular Appendices I and 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 region with vulnerable soil and/or climatic conditions; — the risk to soil non-target macro-organisms other than earthworms, not target terrestrial plants and aquatic organisms. |

| ▼ <u>M1</u> | | | | | | | |
|----------------------|--------|---|--|--|-------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M159</u> | 90 | Florasulam CAS No 145701-23-1 CIPAC No 616 | 2',6',8-trifluoro-5-methoxy[1,2,4] triazolo[1,5-c]pyrimidine-2-sulfonanilide | ≥ 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. |
| ▼ <u>M164</u> | | | | | | | |
| | 91 | Flupyradifurone CAS No: 951659-40-8 CIPAC No: 987 | 4-[(6-chloro-3-pyri- dylmethyl)(2,2-diflu- oroethyl) 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. |

| ▼ <u>M164</u> | | | | | | | |
|----------------------|--------|--|--|---|------------------|------------------------|---|
| | Number | Common Name, Identifi- cation 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. |
| ▼ <u>M167</u> | | | | | | | |
| | 92 | Rescalure CAS No: 67601-06-3 CIPAC No: Not available | (3S,6R)-(3S,6S)-6- isopropenyl-3- methyldec-9-en-1-yl acetate | \geq 750 g/kg The ratio of $(3S,6R)/(3S,6S)$ 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. |
| ▼ M165 | | | | | | | |
| | 93 | Mandestrobin CAS No: 173662-97-0 CIPAC No: Not available | (RS)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-o-tolyl] acetamide | ≥ 940 g/kg (on a dry weight basis) Xylenes (ortho, meta, para), ethyl benzene max. | 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 mandestrobin, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: |
| | | | | 5 g/kg (TK) | | | — the risk to aquatic organisms, |
| | | | | | | | — 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 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. |
| | | | | | | | The applicant shall submit that information to the Commission, the Member States and the Authority by 9 June 2016. |

| ▼ <u>M1</u> | | | | | | | |
|--------------------|--------|--|--|---|-------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M161</u> | - | | | | | | |
| | 94 | 2,4-D CAS No: 94-75-7 CIPAC No: 1 | (2,4-dichlorophenoxy) acetic acid | ≥ 960 g/kg Impurities: Free phenols (expressed as 2,4-DCP): not more than 3 g/kg. Sum of dioxins and furans (WHO-TCDD TEQ) (¹³): not more than 0,01 mg/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 2,4-D, 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, terrestrial organisms and consumers in cases of uses above 750 g/ha. Conditions of use shall include risk mitigation measures, where appropriate. The notifier shall submit to the Commission, the Member States and the Authority: (1) confirmatory information in the form of the submission of the complete study results from the existing extended one-generation study; (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. 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. |
| ▼ <u>M173</u> | 95 | Pyraflufen-ethyl CAS No 129630-19-9 CIPAC No 605.202 | ethyl [2-chloro-5-(4-chloro-5-difluorome-thoxy-1-methyl-pyrazol-3-yl)-4-fluor-ophenoxy]acetate | ≥ 956 g/kg | 1 April 2016 | 31 March 2031 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. |

| ▼ <u>M11</u> | | | | | | | |
|---------------|--------|--|--|--|------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M171</u> | 96 | Iprovalicarb CAS No 140923-17-7 CIPAC No 620 | isopropyl [(1S)-2-methyl-1-{[(1RS)-1-p-tolylethyl] carbamoyl}propyl] carbamate | ≥ 950 g/kg Impurities: Toluene: not more than 3 g/kg | 1 April 2016 | 31 March 2031 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — 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. 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 genotoxic potential of soil metabolite PMPA. This information shall be submitted by 30 September 2016. |
| ▼ <u>M174</u> | 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 | For the implementation 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. 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 Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate. |

| 1 | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------|--------|---|---|---|-------------------|------------------------|---|
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | (a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water; |
| | | | | | | | (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). |
| | | | | | | | 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. |
| <u>M453</u> | | | | | | | |
| _ M189 | | | | | | | |
| | 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 | ≥ 940 g/kg IN-Q6S09 max. 1 mg/kg IN-RYA13 max. 20 mg/kg methanesulfonic acid max. 2 g/kg acetonitrile max. 2 g/kg | 14 September 2016 | 14 September 2026 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: (a) the risk to operators; (b) the risk to aquatic organisms, bees and other non-target arthropods; (c) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses; |
| | | | | heptane max. 7 g/kg | | | (d) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. |
| | | | | 3-picoline max. 3 g/kg. | | | Conditions of use shall include risk mitigation measures, where appropriate |

| ▼ <u>M189</u> | | | | | | | |
|---------------|--------|--|--|------------|-------------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | 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. |
| ▼ <u>M192</u> | | | | | | | |
| | 100 | Isofetamid CAS No: 875915-78-9 CIPAC No: 972 | N-[1,1-dimethyl-2-(4-isopropoxy-o-tolyl)-2-oxoethyl]-3-methyl-thiophene-2-carbo-xamide | ≥ 950 g/kg | 15 September 2016 | 15 September 2026 | For the implementation 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. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to the risk to operators, workers and aquatic organisms, in particular fish. |
| | | | | | | | 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: |
| | | | | | | | (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 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. |
| | | | | | | | 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. |

| ▼ <u>IVI I</u> | | | | | | | |
|----------------|--------|--|--|---|-------------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M194</u> | | | | | | | |
| | 101 | Bacillus amylolique- faciens strain MBI 600. Accession number in the National Collection of Industrial, Marine and Food Bacteria Ltd (NCIMB), Scotland: NCIMB 12376 Deposit number in the American Type Culture Collection (ATCC): SD- 1414 | Not applicable | Minimum concentration: $5.0 \times 10^{14} \text{ CFU/kg}$ | 16 September 2016 | 16 September 2026 | For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo on <i>Bacillus amyloliquefaciens</i> strain MBI 600, and in particular Appendice I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to (a) the specification of the technical material as commercially manufactured, including full characterisation of impurities and metabolites; (b) the protection of operators and workers, taking into account the <i>Bacillus amyloliquefaciens</i> strain MBI 600 is to be considered as potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate Strict maintenance of environmental conditions and quality control analyst during the manufacturing process shall be assured by the producer. |
| M193 | | | | | | | |
| | 102 | Ethofumesate CAS No 26225-79-6 CIPAC No 233 | (RS)-2-ethoxy-2,3- dihydro-3,3-dimethyl- benzofuran-5-yl methanesulfonate | ≥ 970 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material: | 1 November 2016 | 31 October 2031 | For the implementation of the uniform principles, as referred to it Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on ethofumesate, and in particular Appendices I and I thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate in the conditions of use shall include risk mitigation measures. |

| Number | Common Name, Identifi- cation 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 | | | |
| 1190 | | | | | | |
| 103 | Picolinafen CAS No 137641-05-5 | 4'-fluoro-6-(α,α,α- trifluoro-m-tolyloxy) pyridine-2-carbox- anilide | ≥ 980 g/kg | 1 November 2016 | 30 June 2031 | For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on picolinafen, and in particular Appendices I and thereof, shall be taken into account. |
| | CIPAC No 639 | | | | | In this overall assessment Member States shall pay particular attention t |
| | | | | | | — the impurities in the technical active substance; |
| | | | | | | - the protection of mammals, especially of large herbivorous mammal |
| | | | | | | — the protection of non-target terrestrial plants; |
| | | | | | | — the protection of groundwater, when the substance is applied in region with vulnerable soil and/or climatic conditions; |
| | | | | | | — the protection of aquatic organisms, especially to algae. |
| | | | | | | Conditions of use shall include risk mitigation measures, where appropriate |

▼<u>M1</u>

| ▼ <u>IVI I</u> | | | | | | | |
|----------------|--------|--|---|------------|------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M191</u> | | | | | | | |
| V <u>N1191</u> | 104 | Thifensulfuron-methyl CAS No 79277-27-3 CIPAC No 452 | methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarba-moylsulfamoyl) thiophene-2-carboxylate | ≥ 960 g/kg | 1 November 2016 | 31 October 2031 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater; — the protection of non-target plants and aquatic organisms. Conditions of use shall include risk mitigation measures and the obligation to monitor the groundwater, where appropriate. The applicant shall submit to the Commission, the Member States and the |
| | | | | | | | Authority confirmatory information as regards: (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 is thifensulfuron-methyl is classified as reprotoxic category 2 under Regulation (EC) No 1272/2008 and the risk that those metabolites contaminate groundwater. |

| ▼ <u>M191</u> | | | | | | | |
|---------------|--------|--|---|------------|------------------|------------------------|---|
| | Number | Common Name, Identifi- cation 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 | | | | | | | |
| | 105 | Thiabendazole CAS No 148-79-8 CIPAC No 323 | 2-(thiazol-4-yl) benzimidazole | ≥ 985 g/kg | 1 April 2017 | 31 March 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 thiabendazole, 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 consumers, |
| | | | | | | | — the protection of groundwater, |
| | | | | | | | — the control of waste water from post-harvest uses. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | 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. |
| ▼ <u>M200</u> | | | | | | | |
| | 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-(trifluor- omethyl)-1H-pyrazol- 1-yl]ethanone | ≥ 950 g/kg | 3 March 2017 | 3 March 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 oxathiapiprolin, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. |

▼<u>M200</u>

| | Number | Common Name, Identifi- cation 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 confirmatory information as regards: |
| | | | | | | | (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. |
| | | | | | | | The applicant shall submit the information requested under points (1) and (2) by 3 September 2017. |
| ▼ <u>M207</u> | | | | | | | |
| | 107 | Iodosulfuron CAS No 185119-76-0 (parent) CAS No 144550-36-7 (iodosulfuron-methylsodium) CIPAC No 634 (parent) CIPAC No 634.501 (iodosulfuron-methylsodium) | 4-iodo-2-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl) carbamoylsulfamoyl] benzoic acid (iodosulfuron) sodium ({[5-iodo-2-(methoxycarbonyl) phenyl]sulfonyl} carbamoyl)(4-methoxy-6-methyl-1,3,5-triazin-2-yl) azanide (iodosulfuron-methyl-sodium) | ≥ 910 g/kg (expressed as iodosulfuron- methyl-sodium) | 1 April 2017 | 31 March 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 iodosulfuron, 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 consumers, — the risk to non-target terrestrial plants, — the risk to aquatic plants. 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: (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; (2) the effect of water treatment processes on the nature of residues present in drinking water. |

| ▼ M207 | | | | | | | |
|---------------|--------|--|---|---|------------------|------------------------|---|
| | Number | Common Name, Identifi- cation 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 | | | | | | | |
| | 108 | Flazasulfuron CAS No 104040-78-0 CIPAC No 595 | 1-(4,6-dimethoxypyri- midin-2-yl)-3-(3- trifluoromethyl-2- pyridylsulphonyl)urea | ≥ 960 g/kg | 1 August 2017 | 31 July 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 flazasulfuron, 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 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. |
| | | | | | | | 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 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. |
| ▼ M223 | | | | | | | |
| | 109 | Beauveria bassiana 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. |

| ▼ <u>M223</u> | | | | | | | |
|----------------------|--------|---|----------------|--|------------------|------------------------|--|
| | Number | Common Name, Identifi- cation 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 Beauveria bassiana 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. 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. |
| ▼ <u>M220</u> | | | | | | | |
| | 110 | Beauveria bassiana strain 147 Accession number in the CNCM (Collection nationale de cultures de micro-organismes) — Institut Pasteur, Paris, France: I-2960. | Not applicable | Max. level of beauvericin: 24 μg/L | 6 June 2017 | 6 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 147, 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>Beauveria bassiana</i> strain 147 is to be considered, as any microorganism, as a potential sensitizer, and paying special attention to exposure through inhalation, — the maximum level of the metabolite beauvericin in the formulated product. 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. |

▼<u>M1</u>

| ▼ <u>M1</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u>M216</u> | | | | | | | |
| | 111 | Mesosulfuron (parent) Mesosulfuron-methyl (variant) CAS No 208465-21-8 (mesosulfuron-methyl) CIPAC No 663 (mesosulfuron) CIPAC No 663.201 (mesosulfuron-methyl) | Mesosulfuron-methyl: methyl-2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-(methanesulfonamido)-p-toluate Mesosulfuron: 2-[(4,6-dimethoxy-pyrimidin-2-ylcarbamoyl)sulfamoyl]-α-methanesulfonamido-p-toluic acid | ≥ 930 g/kg (expressed as mesosulfuron- methyl) | 1 July 2017 | 30 June 2032 | For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on mesosulfuron and in particular Appendices I and thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms and non-target terrestrial plants; — the protection of groundwater. 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 perior of two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface an groundwater being made public by the Commission. |
| <u>M214</u> | | | | | | | |
| | 112 | Mesotrione CAS No 104206-82-8 CIPAC No 625 | Mesotrione 2-(4-mesyl-2-nitro-benzoyl) cyclohexane -1,3-dione | ≥ 920 g/kg R287431 max 2 mg/kg R287432 max 2 g/kg 1,2-dichloroethane max 1 g/kg | 1 June 2017 | 31 May 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 mesotrione, and in particular Appendices I and thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators, — the protection of groundwater in vulnerable regions, — the protection of mammals, aquatic and non-target plants. Conditions of use shall include risk mitigation measures, where appropriate the applicant shall submit confirmatory information as regards: 1. the genotoxic profile of the metabolite AMBA; |

▼<u>M214</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | | 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; |
| | | | | | | | 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. |
| | | | | | | | 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. |
| ▼ <u>M215</u> | | | | | | | |
| | 113 | Cyhalofop-butyl CAS No 122008-85-9 CIPAC No 596 | butyl (R)-2-[4-(4-cyano-2-fluor-ophenoxy) phenoxy] propionate | 950 g/kg | 1 July 2017 | 30 June 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 cyhalofop-butyl, 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, |
| | | | | | | | — the technical specification, |
| | | | | | | | — the protection of non-target terrestrial plants. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |

| ▼ <u>IVI I</u> | | | | | | | |
|----------------|--------|---|---|--|---------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M228</u> | 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 (expressed as Propoxyc-arbazone-sodium) | 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. |
| ▼ <u>M226</u> | 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. |
| ▼ <u>M232</u> | 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. |

| _ | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| ✓ <u>M234</u> | | | | Free phenols (expressed as 2,4-dichlorophenol (2,4-DCP)): max. 15 g/kg. Dibenzo-p-dioxins and polychlorinated dibenzofurans (TCDD toxic equivalents (TEQ)): max. 0,01 mg/kg. | | | In this overall assessment Member States shall pay particular attention to — 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. Conditions of use shall include risk mitigation measures, where appropriate |
| | 117 | Maleic hydrazide CAS No 123-33-1 CIPAC No 310 | 6-hydroxy-2H-pyridazin-3-one | ≥ 979 g/kg Until 1 November 2018, the impurity hydrazine shall not exceed 1 mg/kg in the technical material. From 1 November 2018, the impurity hydrazine shall not exceed 0,028 mg/kg in the technical material. | 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 renewal report on maleic hydrazide, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of consumers, — the operator and worker safety; the conditions of the use should include the application of adequate personal protective equipment. 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. Conditions of use shall include risk mitigation measures, where appropriate. |

▼<u>M1</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| M442 | 118 | Glyphosate CAS No: 1071-83-6 CIPAC No: 284 | N-(phosphonomethyl) glycine | ≥ 950 g/kg The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: - N-nitroso-glyphosate (NNG): & Description & D | 16 December 2023 | 15 December 2033 | Only uses as herbicide may be authorised. For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of renewal report on glyphosate, and in particular Appendices I and thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention — the co-formulants present in glyphosate-containing plant protect products, taking into account in particular the criteria for identificat of unacceptable co-formulants as set out in Commission Implement Regulation (EU) 2023/574 (29); — the consumer exposure assessment with regards to residues that may present in succeeding crops grown in rotation; — the protection of groundwater in vulnerable areas and of surface wate in particular those used for the abstraction of drinking water, consider specifically uses on sealed surfaces; — the protection of small herbivorous mammals. Member States she where considered necessary impose mitigation measures such limiting the timing of use, the number of applications or maximum dose rate. The following maximum application rates she not be exceeded unless the outcome of the risk assessment undertal for the specific uses for which authorisation is applied for demonstrated that a higher rate does not lead to any unacceptable effects on such herbivorous mammals: — For use in agriculture: 1,44 kg glyphosate per hectare, per year. |

▼ <u>M442</u>

| 1112 | | | | | | | |
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| Nu | ımber | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | For use to control invasive species in agricultural and non-agricultural areas: 1,8 kg glyphosate per hectare, per year; |
| | | | | | | | For use in non-agricultural areas: 3,6 kg glyphosate per hectare, per year; |
| | | | | | | | the protection of non-target terrestrial and aquatic plants from exposure by spray drift; |
| | | | | | | | — indirect effects on biodiversity via trophic interactions once relevant methods and guidance to identify such effects are agreed at Union level. In the absence of such methods and guidance, Member States may apply methods which they consider appropriate to determine the potential indirect effects of plant protection products containing glyphosate and which take into account their local agro-environmental conditions. When doing so, if they identify any such possible indirect effects on biodiversity, Member States shall set specific conditions or restrictions of use for plant protection products containing glyphosate, considering in particular if practical alternative control or prevention methods with lower impacts on biodiversity are available; |
| | | | | | | | — uses by non-professional users; |
| | | | | | | | compliance of pre-harvest uses with the provisions of Directive 2009/ 128/EC in conjunction with Article 55 of Regulation (EC) No 1107/ 2009. Uses for desiccation to control the time point of harvest or to optimise threshing shall not be authorised. |
| | | | | | | | Conditions of use shall include risk mitigation measures, including combinations thereof, as required. In particular, drift shall be reduced for spray applications made by professional users in agricultural fields. By default, to protect non-target terrestrial plants, an in-field non-sprayed buffer strip of at least 5 to 10 m from the field border depending on the |

▼ <u>M442</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|----------------------|--------|---|--|------------|------------------|------------------------|--|
| | | | | | | | particular use and drift reduction nozzles reducing spray drift by at least 75 %, or other risk mitigation measures with equivalent reduction of drift, shall be required, unless the outcome of the risk assessment undertaken for the specific plant protection product use indicates that such risk mitigation measures are not needed or can be lowered because there are no unacceptable risks caused by spray drift. |
| | | | | | | | In addition, Member States may set monitoring requirements when granting authorisations, in order to complement the monitoring under Directive 2000/60/EC of the European Parliament and of the Council (30) and Directive 2009/128/EC. |
| | | | | | | | Member States shall ensure that use of plant protection products containing glyphosate is minimised or prohibited in the specific areas listed in Article 12(a) of Directive 2009/128/EC. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the possible indirect effects on biodiversity via trophic interactions, within three years from the date of applicability of a relevant guidance document endorsed by the Standing Committee on Plants, Animals, Food and Feed. |
| _ | | | | | | | |
| ▼ <u>M247</u> | | | | | | | |
| | 119 | Acetamiprid CAS No 135410-20-7 CIPAC No 649 | (E)-N1-[(6-Chloro-3- pyridyl)methyl]-N2- cyano-N1-methyl- acetamidine | ≥ 990 g/kg | 1 March 2018 | 28 February 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 acetamiprid, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: |

▼ M247

| | | C N 11 C | | | D. C | F : /: C | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | — 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. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| M253 | | | | | | | |
| | 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 | For the implementation 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. |
| | | | | | | | In their overall assessment Member States shall pay particular attention to |
| | | | | | | | — 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 appli cation, soil and/or climatic conditions. |
| | | | | | | | Conditions of use shall include risk mitigation measures where appropriate |
| | | | | | | | The applicant shall submit by 1 February 2019 to the Commission, the Member States and the Authority confirmatory information as regard Level 2/3 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of bentazone. |

▼<u>M1</u>

| ▼ <u>IVI I</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ M259 | , | | | | | | |
| | 121 | Silthiofam CAS No 175217-20-6 | N-allyl-4,5-dimethyl- 2-(trimethylsilyl) thiophene-3-carbo- xamide | ≥ 980 g/kg | 1 July 2018 | 30 June 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 silthiofam and in particular Appendices I and II thereof, shall be taken into account. |
| | | | Admirac | | | | increase, shall be taken into account. |
| | | CIPAC No 635 | | | | | In their overall assessment Member States shall pay particular attention to: |
| | | | | | | | — the protection of operators, |
| | | | | | | | — the protection of groundwater in vulnerable regions, |
| | | | | | | | — the protection of birds, mammals and earthworms. |
| | | | | | | | 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: |
| | | | | | | | 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. |
| | | | | | | | 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. |

▼M1

| ▼ <u>M11</u> | | | | | | | |
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| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M255</u> | 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 | 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. In this overall assessment Member States shall pay particular attention to: — the risk to consumers as regards the potential risk from metabolites in fruit crops with edible peels. |
| ▼M258 | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| V 141230 | 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 | 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. |
| | | | | | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | — the protection of groundwater from metabolite RH-141455, |
| | | | | | | | — the protection of bees, aquatic organisms and earthworms. |
| | | | | | | | 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 |

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------|--------|--|--|-----------------------|------------------|------------------------|--|
| | | | | | | | processes on the nature of residues present in drinking water within tw years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater made public by the Commission. |
| <u>M267</u> | | | | | | | |
| | 124 | Trifloxystrobin CAS No 141517-21-7 | methyl (E)-methoxy- imino- $\{(E)$ - α - $[1$ - (α,α,α) -trifluoro-m-tolyl) ethylideneami- | ≥ 975 g/kg AE 1344136 | 1 August 2018 | 31 July 2033 | For the implementation of the uniform principles, as referred to it Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on trifloxystrobin, and in particular Appendices I and thereto, shall be taken into account. |
| | | | nooxyl]-o-tolyl} | (max. 4 g/kg) | | | |
| | | CIPAC No 617 | | | | | In this overall assessment Member States shall pay particular attention t |
| | | | | | | | the protection of groundwater when the substance is applied in region with vulnerable soil and/or climate conditions; |
| | | | | | | | — the protection of aquatic organisms, bees, and of fish-eating birds a mammals. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropria |
| | | | | | | | The applicant shall submit to the Commission, the Member States and t Authority confirmatory information as regards: |
| | | | | | | | (1) the relevance of metabolites that may occur in groundwater, taking in account any relevant classification for trifloxystrobin in accordance w Regulation (EC) No 1272/2008, in particular as toxic for reproductive category 2; |
| | | | | | | | (2) the effect of water treatment processes on the nature of residues presin surface and groundwater, when surface water or groundwater abstracted for drinking water. |

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | The applicant shall submit the information requested under point (1) with one year after the publication, on the website of the European Chemica Agency (ECHA), of the opinion adopted by the Committee for Ri Assessment of the ECHA in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to trifloxystrobin. |
| | | | | | | The applicant shall submit the information requested under point (2) with two years of a guidance document on evaluation of the effect of wat treatment processes on the nature of residues present in surface a groundwater being made public by the Commission. |
| 268 | | | | | | |
| 125 | Carfentrazone-ethyl CAS No 128639-02-1 | Ethyl (RS)-2-chloro- 3-[2-chloro-4-fluoro- 5-[4-(difluor- omethyl)-4,5- | ≥ 910 g/kg | 1 August 2018 | 31 July 2033 | For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of review report on carfentrazone-ethyl, and in particular Appendices I at II thereof, shall be taken into account. |
| | C/15 110 12003) 02 1 | dihydro-3-methyl-5- | | | | in thereof, shall be taken into decount. |
| | CIPAC No 587.202 | oxo-1 <i>H</i> - 1,2,4-triazol- 1-yl]phenyl] propionate | | | | In their overall assessment Member States shall pay particular attention |
| | | | | | | — the protection of groundwater when the substance is applied in region 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. |
| | | | | | | Conditions of use shall include risk mitigation measures, where appropria |
| | | | | | | The applicant shall submit to the Commission, the Member States and Authority confirmatory information as regards: |

▼ <u>M268</u>

| Nur | nber Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--|--|------------|--------------------|------------------------|--|
| | | | | | | (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; (2) the effect of water treatment processes on the nature of residues present in drinking water. 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. 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. |
| ▼ <u>M273</u> | | | | | | |
| 13 | Fenpicoxamid CAS No: 517875-34-2 CIPAC No: 991 | (3S,6S,7R,8R)-8-benzyl-3-{3-[(isobutyryloxy)methoxy]-4-methoxypyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl | ≥ 750 g/kg | 11 October 2018 | 11 October 2028 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — the impact of processing on the consumer risk assessment, |
| | | isobutyrate | | | | — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: |
| | | | | | | 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; |

▼<u>M273</u>

| - | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------|--------|--|--|---|------------------|------------------------|--|
| | | | | | | | 2. the effect of water treatment processes on the nature of residues presen in drinking water; |
| | | | | | | | 3. the endocrine disrupting potential of fenpicoxamid as regards the thyroic 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 approva are or are not related to a thyroid endocrine disrupting mode of action |
| | | | | | | | 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. |
| <u>M272</u> | | | | | | | |
| | 127 | Pethoxamid CAS No 106700-29-2 CIPAC No 665 | 2-chloro-N-(2-etho- xyethyl)-N-(2- methyl-1-phenylprop- 1-enyl) acetamide | ≥ 940 g/kg Impurities: Toluene: max 3 g/kg. | 1 December 2018 | 30 November 2033 | PART A Use shall be limited to one application every two years in the same field a a maximum dose of 1 200 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 renewal report on pethoxamid, and in particular Appendices I and I thereto, shall be taken into account. |
| | | | | | | | In their overall assessment Member States shall pay particular attention to |
| | | | | | | | — 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 o crop failure. |

▼<u>M272</u>

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|------------|------------|------------------|------------------------|--|
| | | | | | | 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: |
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | 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. |
| | | | | | | 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. |

| ▼ <u>M1</u> | | | | | | | |
|----------------------|--------|---|--|--|------------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M283</u> | | | | | | | |
| | 128 | Tribenuron (parent) CAS No 106040-48-6 | 2-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-methylcar-bamoyl]sulfamoyl] benzoic acid | ≥ 960 g/kg (expressed as tribenuron-methyl) | 1 February 2019 | 30 January 2034 | 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. |
| | | CIPAC No 546 | | | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | — 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. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M285</u> | | | | | | | |
| | 129 | Metschnikowia fruc- ticola strain NRRL Y- 27328 Accession number in the Agriculture Research Service Culture Collection at the National center for agri- cultural utilisation research in Peoria, Illinois USA | Not applicable | Minimum concentration: 1 × 10 ¹⁰ CFU/g | 27 December 2018 | 27 December 2028 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — 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. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be ensured by the producer. Conditions of use shall include risk mitigation measures, where appropriate. |

▼M1

| ▼ <u>M11</u> | | | | | | | |
|---------------|--------|---|----------------|--|---------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M289</u> | 130 | Beauveria bassiana 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 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — 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 microorganism, as a potential sensitiser. 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). Conditions of use shall include risk mitigation measures where appropriate. |
| ▼ <u>M290</u> | 131 | Beauveria bassiana strain PPRI 5339 Accession number in the Agricultural Research Culture Collection (NRRL) International Depositary Authority: NRRL 50757 | Not applicable | Max. level of beauvericin: 0,5 mg/kg | 20 February 2019 | 20 February 2029 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — 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; |

▼ <u>M290</u>

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|--|---|------------------|------------------------|---|
| | | | | | | 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 B. bassiana strain PPRI 5339 is to be considered, as any microorganism, as a potential sensitizer. 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). |
| ——— ▼ M297 | | | | | | Conditions of use shall include risk mitigation measures where appropriate. |
| 132 | Mefentrifluconazole CAS No: 1417782-03-6 CIPAC No: Not assigned | (2RS)-2-[4-(4-chloro-phenoxy)-2-(trifluor-omethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol | ≥ 970 g/kg The impurity N, N-dimethyl-formamide shall not exceed 0,5 g/kg in the technical material. The impurity toluene shall not exceed 1 g/kg in the technical material The impurity 1,2,4-(1H)-triazole shall not exceed 1 g/kg in the technical material | 20 March 2019 | 20 March 2029 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, such as buffer zones and/or vegetative strips, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 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. |

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|------|--------|---|--|------------|------------------|------------------------|--|
| | | | | | | | The applicant shall submit the information referred to in point 1 b 20 March 2020 and the information referred to in point 2 within tw years from the date of publication, by the Commission, of a guidanc document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. |
| M299 | | | | | | | |
| | 133 | Flutianil CAS No [958647-10-4] CIPAC No 835 | (Z)-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene](α, α,α,4-tetrafluoro-mtolylthio)acetonitrile | ≥ 985 g/kg | 14 April 2019 | 14 April 2029 | For the implementation of the uniform principles as referred to in Article 2 (6) of Regulation (EC) No 1107/2009, the conclusions of the review repo on flutianil, and in particular Appendices I and II thereof, shall be taken int account. In this overall assessment Member States shall pay particular attention to 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. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriat |
| | | | | | | | The applicant shall submit to the Commission, the Member States and t Authority confirmatory information as regards: |
| | | | | | | | the technical specification of the active substance as manufactured (bas on commercial scale production) and the compliance of the toxic batches with the confirmed technical specification; |
| | | | | | | | the effect of water treatment processes on the nature of residues prese in surface and groundwater, when surface water or ground water abstracted for drinking water; |
| | | | | | | | 3. an updated assessment of the information submitted and, where relevative further information, confirming that flutianil is not an endocrine disrupt in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (E No 1107/2009, applying also the ECHA and EFSA guidance for identication of endocrine disruptors (²²). |

▼ <u>M299</u>

| | Number | Common Name, Identifi- cation 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 14 April 2020; |
| | | | | | | | — 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 |
| | | | | | | | — referred to in point 3 by 14 April 2021. |
| ▼ <u>M305</u> | | | | | | | |
| | 134 | Isoxaflutole CAS No 141112-29-0 | (5-cyclopropyl-1,2- oxazol-4-yl)(α,α,α- trifluoro-2-mesyl-p- | ≥ 972 g/kg | 1 August 2019 | 31 July 2034 | 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 |
| | | CIPAC No 575 | tolyl)methanone | | | | thereto, 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 protection of aquatic organisms, wild mammals and 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 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. |
| | | | | | | | 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. |

▼M1

| <u>NII</u> | | | | | | | |
|-------------|--------|--|---|---|------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u>M327</u> | | | | | | | |
| | 135 | carvone 2244-16-8 (d-carvone = S-carvone = (+)-carvone) | (S)-5-isopropenyl-2- methylcyclohex-2-en- 1-one | 923 g/kg d- carvone | 1 August 2019 | 31 July 2034 | For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on carvone, and in particular Appendices I and II therefully shall be taken into account. |
| | | Carvone: 602 | (S)-p-mentha-6,8- | | | | In this overall assessment Member States shall pay particular attention to |
| | | d-carvone: not allocated | dien-2-one | | | | — the protection of operators, ensuring that conditions of use include th application of adequate personal protective equipment. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate In particular, consideration should be given to the necessary time perio before entry into storage rooms after the application of plant protectio products containing carvone. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and th Authority confirmatory information as regards: |
| | | | | | | | — the effect of water treatment processes on the nature of residues presein surface and groundwater, when surface water is abstracted for drinking water. |
| | | | | | | | The applicant shall submit that information within two years from the da 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. |
| <u>M307</u> | | | | | | | |
| | 136 | 1-methylcyclopropene CAS No 3100-04-7 CIPAC No 767 | 1-methylcyclo- propene | ≥ 980 g/kg (technical concentrate) The following impurities are of toxicological concern and must | 1 August 2019 | 31 July 2034 | Only uses as plant growth regulator for post-harvest storage in sealab warehouse may be authorised. For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on 1-methycyclopropene, and in particular Appendices and II thereto, shall be taken into account. |
| | | | | not exceed the following levels in the technical material (technical concentrate): | | | |

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--------|--|--|---|------------------|------------------------|---|
| | | | | - 1-chloro-2- methylpropene: maximum of 0,2 g/kg, - 3-chloro-2- methylpropene: maximum of 0,2 g/kg. For 1-methyl- cyclopropene generated in situ, Heptane and methylcyclo- hexane are toxico- logically relevant impurities. These impurities should remain below | | | |
| 7 <u>M311</u> | 137 | Dimethenamid-P CAS No 163515-14-8 CIPAC No 638 | (S)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy1-methylethyl) acetamide | 2 930 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: 1,1,1,2-Tetrachloroethane (TCE): ≤ 1,0 g/kg | 1 September 2019 | 31 August 2034 | For the implementation of the uniform principles, as referred to it Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on dimethenamid-P, and in particular Appendices and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, ensuring that conditions of us 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. |

| Nun | mber | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|------|--|--|--|------------------|------------------------|--|
| | | | | | | | 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 surface and groundwater, when surface water or ground water is abstracted for drinking water. |
| _ | | | | | | | 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. |
| ▼ <u>M310</u> | | | | | | | |
| 13 | 38 | Tolclofos-methyl | O-2,6-dichloro-p-tolylO, O-dimethyl | ≥ 960 g/kg | 1 September 2019 | 31 August 2034 | Only for use on ornamentals and on potatoes. |
| | | CAS No 57018-04-9 CIPAC No 479 | phosphorothioate O-2,6-dichloro-4- methylphenyl O, O- dimethyl phosphoro- | The following impurity is of toxicological concern and must not exceed the | | | 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. |
| | | | thioate | following level in the technical material: | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | Methanol max. | | | — the risk to aquatic organisms and mammals, |
| | | | | 1 g/kg | | | — the risk to consumers, in particular the potential risk from metabolite DM-TM- $\mathrm{CH_2OH}$ in potatoes, |
| | | | | | | | — the risk to operators, workers and bystanders; |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--------|--|--|--|------------------|------------------------|--|
| ▼ <u>M312</u> | 139 | Florpyrauxifen-benzyl CAS No: 1390661-72-9 CIPAC No: 990.227 | benzyl 4-amino-3- chloro-6-(4-chloro-2- fluoro-3-methoxyp- henyl)-5-fluor- opyridine-2- carboxylate | ≥ 920 g/kg The impurity toluene shall not exceed 3 g/kg in the technical material. | 24 July 2019 | 24 July 2029 | For the implementation 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. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic and terrestrial non-target plants. Conditions of use shall include risk mitigation measures such as buffer zones and/or drift reduction nozzles, where appropriate. 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. |
| ▼ <u>M454</u> | 140 | Metalaxyl-M CAS No 70630-17-0 (R) CIPAC No 580 | methyl N-(metho-xyacetyl)-N-(2,6-xylyl)-D-alaninate | ≥ 920 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material: 2,6-dimethylphenylamine: max. content: 0,5 g/kg | 1 June 2020 | 31 May 2035 | When used for seed treatment, only the treatment of seeds intended to be sown 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 metalaxyl-M, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured, — the protection of operators and workers, ensuring that the conditions of use prescribe the use 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, |

▼ M454

| _ | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| ▼ <u>M323</u> | | | | 4-methoxy-5-methyl-5H-[1,2] oxathiole 2,2-dioxide: max. content: 1 g/kg 2-[(2,6-dimethyl-phenyl)-(2-metho-xyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester: max. content < 10 g/kg | | | — the protection of non-target arthropods, birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. 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 disrupting properties 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 26 May 2022. 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 10 July 2026. |
| | 141 | Foramsulfuron CAS No 173159-57-4 CIPAC No 659 | 1-(4,6-dimethoxypyri-midin-2-yl)-3-[2-(dimethylcarbamoyl)-5-formamidophe-nylsulfonyl]urea | ≥ 973 g/kg | 1 June 2020 | 31 May 2035 | 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 foramsulfuron, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers and operators, — the risk to aquatic organisms and non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards 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, 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. |

▼<u>M1</u>

| Numb | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|------|---|---|--|---------------------|------------------------|--|
| 142 | Pyriproxyfen. 2-((1-(4-Phenoxy-phenoxy)propan-2-yl) oxy)pyridine. CIPAC No: 715. CAS No: 95737-68-1. | 4-phenoxyphenyl (RS)-2(2-pyridyloxy) propyl ether | ≥ 970 g/kg Max. impurity: Toluene 5 g/Kg | 1 August 2020 | 31 July 2035 | For the implementation of the uniform principles, as referred to Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of renewal report on pyriproxyfen and in particular Appendices I and thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention—the dietary exposure of consumers to residues of pyriproxyfen, |
| | EC No (Einecs or ELINCS): 429-800-1 | | | | | — the protection of sediment-dwelling organisms and aquatic organism— the protection of bees. |
| | | | | | | As regards the protection of sediment-dwelling organisms and aquorganisms, for outdoor use of the plant protection products containing proxyfen Member States shall include in the specific conditions approprisk mitigation measures, e.g. no-spray buffer zones and/or spray reduction, to achieve a low risk for sediment-dwelling organisms aquatic organisms. |
| | | | | | | As regards the protection of bees, for outdoor use of plant protection products containing pyriproxyfen Member States shall include in specific conditions a restriction of application to periods outside of flowering of bee attractive crops, and appropriate risk mitigate measures, e.g. no-spray buffer zones and/or spray drift reduction achieve a low risk for bees and bee larvae. |
| | | | | | | The applicant shall submit to the Commission, the Member States and Authority confirmatory information as regards the effect of water treating processes on the nature of residues present in surface and groundw when surface water is abstracted for drinking water. |

| ▼ M330 | <u></u> | | | | | | |
|---------------|----------|---|--|---|--------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | The applicant shall submit the requested confirmatory 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. |
| ▼ <u>M345</u> | <u>i</u> | | | | | | |
| | 143 | Kieselgur (Diatomaceous earth) CAS No 61790-53-2 CIPAC No 647 | No IUPAC name exists for kieselgur Other synonyms: Diatomaceous earth, Diatomite | 1 000 g/kg Minimum content of amorphous silica of 800 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: Crystalline silica with particle size below 10 μm – maximum of 1 g/kg | 1 February 2021 | 31 January 2036 | 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 kieselgur (diatomaceous earth), and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment, in particular respiratory protective equipment, and other risk mitigation measures, where appropriate. Only indoor use is permitted. Member States shall assess any extension of the use pattern beyond use in closed storage environments, in order to establish whether the proposed extensions of use fulfil the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011. Conditions of use shall include risk mitigation measures, where appropriate. |

▼M1

| ▼ <u>M11</u> | | | | | | | |
|----------------------|--------|---|--|------------------------|------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M350</u> | 144 | Garlic extract Marker components: diallylsulfide (DAS1), diallyldisulfide (DAS 2), diallyltrisulfide (DAS3), diallyltetrasulfide (DAS 4) CAS No 8000-78-0 8008-99-9 CIPAC No 916 | Garlic extract | 1 000 g/kg | 1 March 2021 | 29 February 2036 | 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 garlic extract, and in particular Appendices I and II thereto, shall be taken into account. On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate: — The risk to aquatic organisms. |
| ▼ M364 | 145 | Streptomyces strain K61 | Not applicable | No relevant impurities | 1 July 2021 | 30 June 2036 | 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>Streptomyces strain</i> K61 and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are considered as potential sensitisers, and shall ensure that adequate personal protective equipment is included as a condition of use. Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination (21). |
| ▼ <u>M363</u> | 146 | Cyazofamid CAS No: 120116-88-3 CIPAC No: 653 | 4-chloro-2-cyano-N, N-dimethyl-5-p- tolylimidazole-1- sulfonamide | ≥ 935 g/kg | 01/08/2021 | 31/07/2036 | 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 cyazofamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: |

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | | | | | (a) the specification of the technical material as commercially manufactured; |
| | | | | | | | (b) the impact of processing on the consumer risk assessment; |
| | | | | | | | (c) the protection of non-target arthropods and earthworms. |
| | | | | | | | 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 water and groundwater, when surface water or groundwater is abstracted for drinking water; |
| | | | | | | | 2. 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. |
| | | | | | | | The applicant shall submit the requested information referred to in point 1 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. |
| _ | | | | | | | As regards point 2 the applicant shall provide an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity by 16 June 2023 |
| ▼ <u>M366</u> | | | | | | | |
| | 147 | Clopyralid CAS No 1702-17-6 | 3,6-dichloropyridine- 2-carboxylic acid or 3,6dichloropicolinic acid | ≥ 950 g/kg | 1 October 2021 | 30 September 2036 | 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 clopyralid, and in particular Appendices I and II thereto, shall be taken into account. |
| | | CIPAC No 455 | | | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | — the specification of the technical material as commercially manufactured; |

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------------------------|--|----------------|------------------------|------------------|------------------------|--|
| | | | | | | the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment; possible presence of clopyralid residues in rotational crops; the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops; the protection of groundwater under vulnerable 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. The applicant shall submit this information 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. |
| ▼ <u>M378</u> 148 | Purpureocillium lilacinum strain 251 | Not applicable | No relevant impurities | 1 March 2022 | 28 February 2037 | For the implementation 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>Purpureocillium lilacinum</i> strain 251, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbi- |

▼ <u>M378</u>

| ▼ <u>M37/8</u> | | | | | | | |
|----------------------|--------|--|--|------------|------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | (b) the protection of operators and workers, taking into account that micro- organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M379</u> | • | | | | | | |
| | 149 | Flumioxazin CAS No 103361-09-7 | N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2 <i>H</i> -1,4-benzoxazin-6-yl) | ≥ 960 g/kg | 1 March 2022 | 28 February 2037 | 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 flumioxazin, and in particular Appendices I and II thereto, shall be taken into account. |
| | | CIPAC No 578 | cyclohex-1-ene-1,2- dicarboximide | | | | |
| | | | dicarboximide | | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | | | | — the specification of the technical material that is authorised for use in plant protection products; |
| | | | | | | | — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; |
| | | | | | | | — the protection of non-target plants. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | 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 disrupting properties 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 (²⁴) by 1 March 2024. |
| ▼ <u>M384</u> | | | | | | | |
| | 150 | Carbon dioxide | Carbon dioxide | 999 g/kg | 1 May 2022 | 30 April 2037 | For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the |
| | | CAS No: 124-38-9 | | | | | renewal report on carbon dioxide, and in particular Appendices I and II thereof, shall be taken into account. |
| | | CIPAC No: 844 | | | | | mercor, shall be taken into account. |

| Num | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
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| | | | The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: phosphane max. 0,3 ppm v/v benzene max. 0,02 ppm v/v carbon monoxide max. 10 ppm v/v methanol max. 10 ppm v/v hydrogen cyanide max. 0,5 ppm v/vv | | | In this overall assessment Member States shall pay particular attention to: — adequate ventilation (e.g. with a 'certificate of gas clearance') before humans can re-enter treated and/or surrounding areas (i.e. chambers, buildings and silos). — the need of buffer zones for residents (subjected to revision considering the wind-speeds in the different Member States). Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M388</u> | | | | | | |
| 15 | Beauveria bassiana strain 203 Accession number at Centraal Bureau voor Schimmelcultures (Fungal Biodiversity Centre, Institute of the Royal Netherlands Academy of Arts and Sciences, Utrecht, Netherlands): CBS 121097 | Not applicable | Max. level of beauvericin: 80 μg/kg in the formulated product. | 19 April 2022 | 18 April 2032 | Only uses on ornamental palm trees shall 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>Beauveria bassiana</i> strain 203, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the maximum level of the metabolite beauvericin in the plant protection product; |

| ▼ <u>M388</u> | | | | | | | |
|----------------------|--------|--|---------------------------------------|---|------------------|------------------------|---|
| - | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | b) the protection of operators and workers, taking into account that the species <i>Beauveria basssiana</i> , irrespective of the strain, is a potential human allergen by both skin and inhalatory exposure, and therefore 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, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (²¹). |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M390</u> | | | | | | | |
| | 152 | Bifenazate | isopropyl 2-(4- methoxybiphenyl-3- | 980 g/kg | 1 July 2022 | 30 June 2037 | Only uses on non-edible crops in permanent greenhouses shall be authorised. |
| | | 149877-41-8 736 | yl)hydrazinoformate | Toluene is of toxicological concern and must not exceed 0,7 g/kg in the technical material. | | | 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 bifenazate, 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, ensuring that conditions of use include the application of adequate personal protective equipment; |
| | | | | | | | — the risk to bees and bumble bees released for pollination in permanent greenhouses. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |

| ▼ <u>M1390</u> | • | | | | | | |
|----------------|--------|--|--|---|---------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | The applicant shall submit by 24 May 2024 to the Commission, the Member States and the Authority confirmatory information as regards points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605, in particular an updated assessment of the information submitted previously and, where relevant, further information to confirm the absence of endocrine activity. |
| ▼ <u>M397</u> | | | | | | | |
| | 153 | Straight Chain Lepi- dopteran Pheromones (aldehydes) | Details are provided in the Review Report SANTE/ 10828/2021 | Details are provided in the Review Report SANTE/10828/ 2021 | 1 September 2022 | 30 August 2037 | 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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | 154 | Straight Chain Lepi- dopteran Pheromones (alcohols) | Review Report SANTE SANTE/ 10828/2021 | Review Report SANTE SANTE/ 10828/2021 | 1 September 2022 | 30 August 2037 | 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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. |
| | | | | | | | Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |

▼<u>M1</u>

| ▼ <u>IVI I</u> | | | | | | | |
|----------------|--------|--|----------------|--|------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M402</u> | 155 | Pythium oligandrum strain M1 Culture collection No ATCC 38472 | Not applicable | No relevant impurities | 1 March 2023 | 28 February 2038 | 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>Pythium oligandrum</i> strain M1, 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 specification of the technical material as commercially manufactured, — the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitisers and that physical effects on the respiratory system due to the remnants of culture medium and co-formulants in the Microbial Pest Control Product (MPCP) cannot be excluded. Conditions of use shall include risk mitigation measures, such as: — adequate personal protective and respiratory protective equipment for |
| | | | | | | | operators using products containing Pythium oligandrum strain M1. |
| ▼ <u>M411</u> | : | | | | | | |
| | 156 | Pseudomonas chloro- raphis strain MA 342 Culture collection: NCIMB, UK: NCIMB 40616 | Not applicable | The amount of the secondary metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the in the Microbial Pest Control Agent (MPCA) must not exceed the LOQ (2.0 µg/ml). | 1 March 2023 | 28 February 2038 | Only uses as fungicide for seed dressing in closed seed dressing machinery 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 renewal report on <i>Pseudomonas chlororaphis</i> strain MA 342, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: |

▼<u>M411</u>

| <u>+11</u> | | | | | | |
|------------|--|------------|------------|------------------|------------------------|---|
| Num | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | — the level of the metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the Microbial Pest Control Agent (MPCA), which must not exceed 2 μg/ml; |
| | | | | | | — the protection of operators and workers, taking into account that <i>Pseudomonas chlororaphis</i> strain MA 342 is to be considered, as any microorganism, as a potential sensitiser, and paying special attention to exposure through inhalation. |
| | | | | | | 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 the Working Document SANCO/12116/2012. |
| | | | | | | 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: |
| | | | | | | 1. the phylogenetic taxonomic identification of the micro-organism in accordance with point 1.3 (identity, taxonomy and phylogeny) of Annex II, Part B of Commission Regulation (EU) 2022/1439 (25); |
| | | | | | | 2. the secondary metabolite DDR in accordance with SANCO/2020/12258 (²⁶), in particular on its degradation rate; |
| | | | | | | 3. the potential for gene transfer of antibiotic resistance from <i>Pseudomonas chlororaphis</i> strain MA 342 to other micro-organisms in accordance with SANTE/2020/12260 (²⁷). |
| | | | | | | The applicant shall submit the requested information referred to in points 1, 2 and 3 by 23 February 2025. |

▼<u>M1</u>

| , | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--------|--|--|---|------------------|------------------------|---------------------|
| ▼ <u>M412</u> | | | Avermectin B1a (10E,14E,16E)-(1R,4S,5'S,6S,6' R,8R,12S,13S,20R,2-1R,24S)-6'-[(S)-sec-butyl]-21,24-dihy-droxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatet-racyclo [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-hexopyranoside Avermectin B1b (10E,14E,16E)-(1R,4S,5'S,6S,6' R,8R,12S,13S,20R,2-1R,24S)-21,24-dihy-droxy-6'-isopropyl-5',11,13,22-tetra-methyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.14,8.020,24] pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'- | Purity (¹) ≥ 850 g/kg abamectin (sum of avermectin B1a and avermectin B1b), min. 800 g/kg avermectin B1b and max. 200 g/kg avermectin B1b | approval | | ^ ^ |

| ▼ <u>M412</u> | | | | | | | |
|---------------|----------|--|--|--|------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside | | | | |
| ▼ <u>M422</u> | <u>!</u> | | | | | | |
| | 158 | Bacillus amylolique- faciens strain QST 713 | n.a. | The nominal content of <i>Bacillus amyloliquefaciens</i> strain QST 713 in the technical product and formulation is Minimum: 1 × 10 ¹² CFU/kg Maximum: 3 × 10 ¹³ CFU/kg No relevant impurities | 1 July 2023 | 30 June 2038 | When authorising plant protection products containing <i>Bacillus amylolique-faciens</i> strain QST 713 for spray applications outdoors, in order to ensure the protection of non-target organisms, including bees, Member States shall: — only authorise field applications in flowering crops or in presence of flowering weed in the field outside the daily foraging period of bees; — implement risk mitigation measures which aim to reduce drift to off-field areas (e.g. considering the application of buffer zones and drift reduction nozzles). 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>Bacillus amyloliquefaciens</i> strain QST 713, and in particular Appendices I and II thereof, shall be taken into account. In addition, Member States shall pay particular attention to: — the assurance by the producer of 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 (28) — the specification of the technical material as commercially manufactured used in plant protection products; — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. |

| <u> 11</u> _ | | | 1 | | | | |
|--------------|--------|--|------------|------------------------|------------------|------------------------|--|
| 1 | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| 423 | | | | | | | |
| | 159 | Bacillus thuringiensis subsp. aizawai strain ABTS-1857 | n.a. | No relevant impurities | 1 July 2023 | 30 June 2038 | The implementation of the uniform principles, as provided for in Articl (6) of Regulation (EC) No 1107/2009, requires that the conclusions o review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-and in particular Appendices I and II thereto, are taken into account. |
| | | | | | | | In this overall assessment the Member States shall pay particular attento: |
| | | | | | | | — the protection of operators and workers, taking into account that n organisms are <i>per se</i> considered as potential sensitisers, ensuring adequate personal protective equipment is included as a condition of |
| | | | | | | | — the assurance by the producer of strict maintenance of environm conditions and quality control analysis during the manufact process, in order to ensure the fulfilment of the limits on microbiol contamination as referred to in the Working Document SANCO/12 2012 (28); |
| | | | | | | | — the protection of wild pollinators (in particular honey bee larvae bumble bees). Conditions of use shall include specific risk mitig measures, where appropriate. |
| | | | | | | | Conditions of use shall include the following risk mitigation measure |
| | | | | | | | — a minimum time period of 2 days shall be kept between the applic of plant protection products containing <i>Bacillus thuringiensis</i> s <i>aizawai</i> strain ABTS-1857 and the harvest of edible crops used fresh consumption, unless available measured or estimated rest data show levels of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain A 1857 below 10 ⁵ CFU/g at harvest. |
| | | | | | | | The applicant shall submit to the Commission, the Member States an Authority additional information as regards: |
| | | | | | | | |

| ▼ M423 | | | | | | | |
|---------------|--------|--|------------|------------------------|------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | — data in at least one representative edible crop (i.e. peppers and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10 ⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025. |
| ▼ <u>M421</u> | | | | | | | |
| | 160 | Bacillus thuringiensis subsp. aizawai GC-91 | n.a. | No relevant impurities | 1 July 2023 | 30 June 2038 | The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 and in particular Appendices I and II thereto, are taken into account. |
| | | | | | | | In this overall assessment the Member States shall pay particular attention to: |
| | | | | | | | — the protection of operators and workers, taking into account that micro- organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; |
| | | | | | | | — the assurance by the producer of 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 (28); |
| | | | | | | | — the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate. |
| | | | | | | | Conditions of use shall include the following risk mitigation measures: |
| | | | | | 1 | | |

▼ <u>M421</u>

| ▼ <u>IV1421</u> | | Common Name, Identifi- | | | Date of | Expiration of | |
|----------------------|--------|--|----------------|------------------------|-------------|---------------|---|
| | Number | cation Numbers | IUPAC Name | Purity (1) | approval | approval | Specific provisions |
| - | | | | | | | — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp <i>aizawai</i> GC-91 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 below 10 ⁵ CFU/g at harvest. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and the Authority additional information as regards: |
| _ | | | | | | | — data in at least one representative edible crop (i.e. pome fruits, grapes and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10 ⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025. |
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| ▼ <u>M420</u> | | | | | | | |
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| | 161 | Bacillus thuringiensis subsp. israelensis strain AM65-52 Culture collection No ATCC 1276 | Not applicable | No relevant impurities | 1 July 2023 | 30 June 2038 | The implementation of the uniform principles, provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the renewal report on <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52, and in particular Appendices I and II thereof, are taken into account. In this overall assessment, the Member States shall pay particular attention to: |

▼ <u>M420</u>

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--------|--|------------|------------------------|------------------|------------------------|--|
| | | | | | | | — the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitizers; |
| | | | | | | | — the assurance by the producer of 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 (28). |
| | | | | | | | — the protection of wild pollinators and of aquatic organisms (e.g. aquatic invertebrates from Diptera taxon in particular) in case of uses in open field. Conditions of use shall include specific risk mitigation measures, where appropriate. |
| | | | | | | | Conditions of use shall include risk mitigation measures, such as: |
| | | | | | | | — adequate personal protective equipment for operators using products containing <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52; |
| | | | | | | | — In case of authorisation of uses on edible crops, a minimum time period of 3 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 below 10 ⁵ CFU/g at harvest. |
| ▼ <u>M419</u> | 162 | Bacillus thuringiensis subsp. kurstaki ABTS- 351 | n.a. | No relevant impurities | 1 July 2023 | 30 June 2038 | The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 and in particular Appendices I and II thereto, are taken into account. In this overall assessment, the 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 sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; |

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|----------------------|--------|--|------------|------------------------|------------------|------------------------|--|
| | | | | | | | — the assurance by the producer of 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 (28). |
| | | | | | | | Conditions of use shall include the following risk mitigation measures: |
| | | | | | | | — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 below 10 ⁵ CFU/g as recommended by EFSA. |
| | | | | | | | The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards: |
| | | | | | | | — Data in at least one representative edible crop (i.e. on cabbage and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10 ⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025. |
| ▼ <u>M424</u> | | | | | | | |
| | 163 | Bacillus thuringiensis subsp. kurstaki EG2348 | n.a. | No relevant impurities | 1 July 2023 | 30 June 2038 | The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 and in particular Appendices I and II thereto, are taken into account. |

▼ <u>M424</u>

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|------------|------------|------------------|------------------------|---|
| | | | | | | In this overall assessment, the Member States shall pay particular attention to: |
| | | | | | | — the protection of operators and workers, taking into account that micro- organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; |
| | | | | | | — the assurance by the producer of 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 (28). |
| | | | | | | Conditions of use shall include the following risk mitigation measures: |
| | | | | | | — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp <i>kurstaki</i> EG2348 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 below 10 ⁵ CFU/g as recommended by EFSA. |
| | | | | | | The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards: |
| | | | | | | — data in at least one representative edible crop (i.e. on pome fruits and solanaceous vegetables during the fruiting period) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10 ⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025. |

▼<u>M1</u>

| IVII | | | | | | | |
|-------------|--------|---|------------|------------------------|------------------|------------------------|--|
| _ | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| <u>M427</u> | | | | | | | |
| | 164 | Bacillus thuringiensis subsp. kurstaki PB 54 | n.a. | No relevant impurities | 1 July 2023 | 30 June 2038 | The implementation of the uniform principles, as provided for in Article 2 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> PB 54 and particular Appendices I and II thereto, are taken into account. In this overall assessment, the Member States shall pay particular attentions: |
| | | | | | | | the protection of operators and workers, taking into account that microrganisms are <i>per se</i> considered as potential sensitisers, ensuring the adequate personal protective equipment is included as a condition of u the assurance by the producer of strict maintenance of environment conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiologic contamination as referred to in the Working Document SANCO/1211 2012 (28). |
| | | | | | | | Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the applicat of plant protection products containing <i>Bacillus thuringiensis</i> sub <i>kurstaki</i> PB 54 and the harvest of edible crops used for fr consumption, unless available measured or estimated residues of show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> PB 54 below CFU/g as recommended by EFSA. |
| | | | | | | | The applicant shall submit to the Commission, the Member States and Authority additional information as regards: |

| - | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------|--------|---|------------|------------------------|------------------|------------------------|--|
| _ | | | | | | | — data in at least one representative edible crop (i.e. on stone fruits an tomatoes) regarding the density decline of viable spores of <i>Bacillus thun ingiensis</i> subsp. <i>kurstaki</i> PB 54 on edible plant parts from the time of application of a plant protection product containing this active substanc until the time of harvest or until levels found are below 10 ⁵ CFU/g including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods an protocols to be employed shall be agreed between the applicant an the Rapporteur Member State by 14 December 2025. |
| <u>M425</u> | | | | | | | |
| | 165 | Bacillus thuringiensis subsp. kurstaki SA-11 | n.a. | No relevant impurities | 1 July 2023 | 30 June 2038 | The implementation of the uniform principles, provided for in Article 29(6 of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 and in particular Appendices I and II thereto, are taken into account. |
| | | | | | | | In this overall assessment, the Member States shall pay particular attention to: |
| | | | | | | | — the protection of operators and workers, taking into account that micro organisms are <i>per se</i> considered as potential sensitisers, ensuring tha adequate personal protective equipment is included as a condition of use |
| | | | | | | | — the assurance by the producer of strict maintenance of environmenta conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiologica contamination as referred to in the Working Document SANCO/12116 2012 (28). |

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|--------|---|------------|------------------------|------------------|------------------------|---|
| | | | | | | | Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp <i>kurstaki</i> SA-11 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 below 10 ⁵ CFU/g as recommended by EFSA. The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards: — data in at least one representative edible crop (i.e. on pome fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10 ⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. by 13 December 2025. |
| ▼ <u>M426</u> | | | | | | | |
| | 166 | Bacillus thuringiensis subsp. kurstaki SA-12 | n.a. | No relevant impurities | 1 July 2023 | 30 June 2038 | The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 and in particular Appendices I and II thereto, are taken into account. In this overall assessment, the 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 sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; |

▼ M426

| Numl | er Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|----------------------|--|----------------------------|--|------------------|------------------------|---|
| | | | | | | — the assurance by the producer of 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 (28). |
| | | | | | | Conditions of use shall include the following risk mitigation measures: |
| | | | | | | — A minimum time period of 1 day shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 below 10 ⁵ CFU/g as recommended by EFSA. |
| | | | | | | The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards: |
| | | | | | | — data in at least one representative edible crop (i.e. on pome fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10 ⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025. |
| ▼ <u>M438</u> | | | | | | |
| 16' | Aluminium ammonium sulfate (dodecahydrate) CAS No: 7784-26-1 CIPAC No: 840 | Aluminium ammonium sulfate | — 975 g/kg — Anhydrous - Not less than 510 g/kg — No relevant impurities | 1.2.2024 | 31.1.2039 | For the implementation 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 sulfate, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: |

| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------|--------|---|-----------------------------------|---|--------------------|------------------------|--|
| ▼M439 | | | | | | | the protection of operators and workers where relevant, ensuring that conditions of use include the application of adequate personal protective equipment; the protection of aquatic organisms when the substance is applied in regions with acidic or basic soil conditions; the protection of bees from spray applications during the flowering period of adjacent fields or when flowering weeds are present in the treated field; the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions (i.e. situations when soil pH is lower than 5,5, e.g. grassland in upland areas, areas of coniferous forestry and areas of ericaceous ornamental plant growing); the authorisation, for use on row and combinable crops, as a barrier treatment only on field edges. Conditions of use shall include risk mitigation measures where relevant. |
| | 168 | Ethephon CAS No: 16672-87-0 CIPAC No: 373 | 2-chloroethylphos- phonic acid | ≥ 692 g/kg (TK) ≥ 910 g/kg (TC, theoretical) The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: | 1 February 2024 | 31 January 2039 | For the implementation 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 thereto, shall be taken into account. 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; — the protection of bystanders and residents, ensuring that conditions of use include the use of drift reduction equipment during application. Conditions of use shall include risk mitigation measures, where appropriate. |

▼ M439

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|----------|---|--|---|------------------|------------------------|--|
| | | | TK: 1,2-dichloroethane < 0,3 g/kg 2-chloroethanol < 0,3 g/kg TC (theoretical): 1,2-dichloroethane < 0,5 g/kg 2-chloroethanol < 0,3 g/kg | | | |
| M447 169 | Trinexapac-ethyl CAS No 95266-40-3 CIPAC No 732.202 | ethyl (1RS,4EZ)-4-cyclopropyl(hydroxy) methylene-3,5-dioxo-cyclohexanecar-boxylate | ≥ 950 g/kg The following impurities shall not exceed the following levels in the technical material: — toluene: 3 g/kg — ethyl (1RS)-3-hydroxy-5-oxocyclohex-3-ene-1-carboxylate (CGA158377): 6 g/kg | 1 May 2024 | 30 April 2039 | 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 trinexapac-ethyl, and in particular Appendices I and Intereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to the specification of technical material used in plant protection products in particular when carrying out assessments of equivalence in accordance with Article 38 of Regulation (EC) No 1107/2009; — the assessment of consumer intake from the diet taking into account the residues of the metabolites of trinexapac-ethyl and the impact of processing; — the levels of residues of the metabolites of trinexapac-ethyl, when stravis used as animal feeding stuff. Conditions of use shall include restrictions for feeding of straw to animal and risk mitigation measures, where appropriate. |

| ▼ <u>M1447</u> | | | | | | | |
|----------------|----------|--|--|--|------------------|------------------------|--|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | 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 of trinexapac-ethyl and its metabolites present in surface water, when surface water is abstracted for drinking water, by 1 April 2026. |
| ▼ <u>M458</u> | <u> </u> | | | | | | |
| | 170 | Captan CAS No 133-06-2 CIPAC No 40 | N-[(trichloromethyl) thio]cyclohex-4-ene–1,2-dicarboximide | ≥ 930 g/kg perchloromethyl- mercaptan: ≤ 5 g/ kg folpet: ≤ 10 g/kg carbon tetrach- loride: ≤ 0,1 g/kg | 1 November 2024 | 31 October 2039 | For outdoor uses the following conditions shall apply: — only uses outside flowering of the crop and when no flowering weeds are present in the rows of the treated crops may be authorised, — Member States shall require that applications in orchards (e.g. apples, cherries) are only done with application equipment that increases the precision and accuracy of the application (e.g. emission shields, shielded sprayers, hooded sprayers, tunnel sprayers, sensor-controlled sprayers), and, while maintaining the application rate on the target surfaces, achieves an average reduction of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional application equipment and practice. 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 captan, and in particular Appendices I and II thereto, shall be taken into account. In addition, risk mitigations such as no-spray buffer zones from field margins, shall be required, when appropriate, by the Member States on the basis of their risk assessment to protect bees and aquatic organisms. In this overall assessment Member States shall pay particular attention to: — the compliance with the technical specification of the active substance contained in the plant protection product for which applications for authorisation are submitted, |

▼ <u>M458</u>

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|------------|------------|------------------|------------------------|---|
| | | | | | | the protection of operators and workers ensuring that conditions of use include the application of adequate personal protective equipment taking into account the high skin sensitising potential of the active substance, the protection of bystanders and residents ensuring that conditions of use include adequate risk mitigation measures taking into account the high skin sensitising potential of the active substance. In addition, Member States may set monitoring requirements when granting authorisations, in order to supplement the monitoring under Directives 2000/60/EC (31) and 2009/128/EC (32) of the European Parliament and of the Council. Within two years from 24 September 2024, the applicant shall submit to the Commission, the Member States and the Authority confirmatory |
| | | | | | | information as regards: (1) the effect of water treatment processes on the nature of residues of captan's metabolites THPI and THPAM present in ground water, when it is abstracted for drinking water; |
| | | | | | | (2) the relevance of metabolites THPI and THPAM that may occur in groundwater, taking into account the proposal of classification of captan as toxic to reproduction Category 2 and as STOT-RE Category 1 in the Opinion of the Risk Assessment Committee of the European Chemicals Agency of 14 September 2023; |
| | | | | | | (3) the storage stability of captan in high acid content matrices, in compliance with the relevant OECD Test Guideline; and |
| | | | | | | Furthermore, within 18 months from 24 September 2024, the applicant shall submit to the Commission, the Member States and the Authority: |
| | | | | | | (4) information and exposure data demonstrating that the pesticide application equipment used on orchards increases the precision and accuracy of the application and achieves a reduction of exposure of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional equipment and practices. |

▼<u>M1</u>

| ▼ <u>M1</u> | | | | | | | |
|--------------------|--------|---|---|---|--------------------|------------------------|---|
| | Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M461</u> | 171 | Metrafenone CAS No: 220899-03-6 CIPAC No: 752 | 3'-bromo-2,3,4,6'- tetramethoxy-2',6- dimethylbenzop- henone | ≥ 980 g/kg The impurity dimethyl sulphate shall not exceed 0,01 g/kg in the technical material. | 1 November 2024 | 31 October 2039 | 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 metrafenone, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers; — the consumer exposure assessment with regards to residues that may be present in food. Conditions of use shall include risk mitigation measures, where appropriate. 1) An updated assessment for point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 to confirm the absence of endocrine activity concerning the T-modality of non-target organisms other than mammals, including where relevant, further information. 2) An updated assessment of the genotoxicity of the metabolites CL 1500834 and CL 3000402. The applicant shall submit the information related to point 1 by 29 March 2026 and the information related to point 2 by 29 December 2024. |
| ▼ <u>M459</u> | 172 | Folpet CAS No: 133-07-3 CIPAC No: 75 | N-[(trichloromethyl) thio]phthalimide | ≥ 940 g/kg The following impurities shall not exceed the following levels in the technical material: | 1 November 2024 | 31 October 2039 | 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 folpet, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: |

| Number | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--------|--|------------|--|------------------|------------------------|---|
| | | | — (trichloro (chlorosulfanyl) methane) (PCMM): 2 g/kg — carbon tetrachloride: 2 g/kg — captan: 3 g/kg — carbon disulphide: 2,5 g/kg | | | the protection of aquatic organisms, ensuring a minimum of 95 % spray drift reduction next to water bodies such as that provided by a 20 m no spray buffer zone unless the outcome of the risk assessment undertaken for the specific plant protection product use indicates that such risk mitigation measures are not needed or can be lowered because there are no unacceptable risks caused by spray drift; the protection of operators (use of PPE for operators during mixing, loading and application) and workers (use of workwear and protective gloves for re-entry activities); and the protection of bystanders and residents, ensuring that conditions of use include the adequate risk mitigation measures, such as drift reduction equipment, with the aim of minimising exposure. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information to determine the levels of phthalic acid deriving from the use of folpet taking into account the background levels of phthalic acid in wheat and barley during residue field trials for the uses listed in Appendix II of the renewal report only. The applicant shall submit to the Commission, the Member States and the Authority this information by 25 March 2025. |

▼<u>M1</u>

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report. $\blacktriangleright \underline{M9}$ (2) 2-hydroxy-4,6-dimethoxypyrimidine.

M9 (-) 2-hydroxy-4,0-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.

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- (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-an a 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.onlinelibrarv.wilev.eom/doi/epdt/710.2903/i.efsa.2018.5311
- ► M379 (²⁴) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0605&from=EN ◀
- ▶ M411 (25) Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms (OJ L 227, 1.9.2022, p. 8).
- (26) Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc guide 180653 microorganism-metabolites-concern 202011.pdf.
- (27) Guidance on the approval and low-risk criteria linked to 'antimicrobial resistance' applicable to microorganisms used for plant protection (SANTE/2020/12260): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180652_microorganism-amr_202011.pdf.
- ► M419 (²⁸) pesticides ppp app-proc guide phys-chem-ana microbial-contaminant-limits.pdf (europa.eu). ◀
- ▶ M442 (29) Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable coformulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 75, 14.3.2023, p. 7).
- (30) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1). ◀
- (31) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).
- (32) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71, ELI: http://data.europa.eu/eli/dir/2009/128/oj).

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 | Equisetum arvense L. CAS No: not allocated CIPAC No: not allocated | Not applicable | European Pharmacopeia | 1 July 2014 | Equisetum arvense L. may be used in accordance with the specific conditions included in the conclusions of the review report on Equisetum arvense 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. |
| ▼ <u>M368</u> | 2 | Chitosan hydrochloride CAS No: 70694-72-3 | 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 thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014. |
| ▼ <u>M125</u> | 3 | Sucrose CAS no: 57-50-1 | α-D-glucopyranosyl- (1→2)-β-D-fructofur- anoside or β-D-fructo- furanosyl-(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. |

▼<u>M110</u>

| ▼ <u>W1110</u> | | | | | | |
|----------------|--------|--|-------------------|---|------------------|---|
| | Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Specific provisions |
| ▼ <u>M144</u> | 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. |
| ▼ <u>M147</u> | 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. ◀ |
| ▼ <u>M149</u> | 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. |
| ▼ <u>M146</u> | 7 | Salix spp. cortex CAS No: not allocated CIPAC No: not allocated | Not applicable | European Pharmacopeia | 1 July 2015 | Salix cortex shall be used in accordance with the specific conditions included in the conclusions of the review report on Salix spp. cortex (SANCO/12173/2014) and in particular Appendices I and II thereof. |

▼<u>M110</u>

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|---------------|--------|--|----------------------------------|--|------------------|---|
| | Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Specific provisions |
| ▼ <u>M157</u> | 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. |
| ▼ <u>M163</u> | 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. |
| ▼ <u>M178</u> | 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. |
| ▼ <u>M176</u> | 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. |
| ▼ <u>M195</u> | 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. |
| ▼ <u>M211</u> | . 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 Implemen- ting 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. |

▼<u>M110</u>

| V WITTU | | | | | | |
|----------------------|--------|--|-------------------|---|-------------------|---|
| | Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Specific provisions |
| ▼ <u>M210</u> | 14 | Urtica spp. CAS No 84012-40-8 (Urtica dioica extract) CAS No 90131-83-2 (Urtica urens extract) | Urtica spp. | European Pharmacopeia | 30 March 2017 | Urtica spp. shall be used in accordance with the specific conditions included in the conclusions of the review report on Urtica spp. (SANTE/11809/2016) and in particular Appendices I and II thereof. |
| ▼ <u>M209</u> | 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 specifications. | 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. |
| ▼ <u>M237</u> | 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. ► M355 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. ◄ |
| ▼ <u>M242</u> | 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. |
| ▼ <u>M240</u> | 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. |

| ▼ <u>M1110</u> | | | | | | |
|----------------|--------|--|--|--|------------------|--|
| | Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Specific provisions |
| ▼ <u>M257</u> | . 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. |
| ▼ <u>M276</u> | 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. |
| ▼ <u>M325</u> | 21 | L-cysteine (E 920) CAS No: 52-89-1 EINECS: 200-157-7 (L-cysteine hydrochloride) CAS No: 7048-04-6 EINECS: 615-117-8 (L-cysteine hydrochloride monohydrate) | L-cysteine hydro- chloride (1:1) | Min. 98,0 % L-cysteine hydrochloride (on anhydrous basis) Food grade in conformity with Commission Regu- lation (EU) No 231/2012. max. 1,5 mg/kg As max. 5 mg/kg Pb | 2.6.2020 | L-cysteine (E 920) shall be used as a mixture with matrix (flour, food grade) at a concentration of maximum 8% (of L-cysteine hydrochloride, on anhydrous basis) in accordance with the specific conditions included in the conclusions of the review report on L-cysteine (SANTE/11056/2019) and in particular Appendices I and II thereto. |
| ▼ <u>M332</u> | . 22 | Cow Milk CAS No: 8049-98-7 | Not available. | Not applicable | 30.7.2020 | Cow milk shall comply with Regulation (EC) No 1069/2009 and Commission Regulation (EU) No 142/2011. Cow milk shall be used in accordance with the specific conditions included in the conclusions of the review report on cow milk (SANTE/12816/2019), and in particular Appendices I and II thereto. |

| ▼ <u>IVI11U</u> | Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Specific provisions |
|-----------------|--------|---|---|--|------------------|---|
| ▼ <u>M349</u> | 23 | Allium cepa L. bulb extract CAS No: not allocated CIPAC No: not allocated | | The onion bulbs used to prepare the extracts shall be of food grade quality meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on Bulbus Allii Cepae | | Allium cepa L. bulb extract shall be used in accordance with the specific conditions included in the conclusions of the review report on Allium cepa L. bulb extract (SANTE/10842/2020 Rev2) and in particular Appendices I and II thereof. |
| ▼ <u>M385</u> | 24 | Chitosan CAS No: 9012-76-4 EC No: 618-480-0 | Chemical name (not IUPAC): poly[4-O-(2-acetamido-2-deoxy-β-D-glucopyranosyl)-2-amino-2-deoxy-β-D-glucopyranose] | ≥ 85 % chitosan heavy metals: max. 20 mg/kg Food grade, meeting the specifications for 'chitosan extract from fungi' as set out in Commission Implementing Regulation (EU) 2017/2470 (5) | 11 April 2022 | Chitosan shall be used in accordance with the specific conditions included in the conclusions of the review report on chitosan (SANTE/10594/2021) and in particular Appendices I and II thereto. |

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|----------------------|--------|---|-----------------------|--|------------------|---|
| | Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Specific provisions |
| ▼ <u>M448</u> | 25 | magnesium hydroxide E528 CAS No: 1309-42-8 CIPAC No: Not available | magnesium dihydroxide | 95 % Relevant impurities: Lead < 2 mg/kg Arsenic < mg/kg | 2 April 2024 | Magnesium hydroxide shall be used in accordance with the specific conditions included in the conclusions of the review report on magnesium hydroxide (PLAN/2023/2331 RR Rev2) and in particular Appendices I and II thereof. |
| ▼ <u>M456</u> | 26 | Onobrychis viciifolia (sainfoin) dried pellets CAS No: Not available CIPAC No: Not available | Not available | 1 000 g/kg Relevant impurities: Arsenic (1 g/kg), Cadmium (0,1 g/kg), Chromium-VI (0,1 g/kg), Mercury (1 g/kg), Nickel (0,1 g/kg), Lead (0,3 g/kg) | 17 July 2024 | Onobrychis viciifolia (sainfoin) dried pellets shall be used in accordance with the specific conditions included in the conclusions of the review report on Onobrychis viciifolia (sainfoin) dried pellets (PLAN/2024/790 RR rev1) and in particular Appendices I and II thereof. |
| ▼ <u>M465</u> | 27 | Allium fistulosum, processed CAS No: Not available CIPAC No: Not available | | Food grade compliant with the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council (6), Regulation (EC) No 396/2005 of the European Parliament and of the Council (7), Commission Regulation (EU) 2023/915 on maximum levels | | Allium fistulosum, processed, shall be used in accordance with the specific conditions included in the conclusions of the review report on Allium fistulosum, processed, (PLAN/2024/798) and in particular Appendices I and I thereof. |

| Number | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Specific provisions |
|--------|--|------------|--|------------------|---------------------|
| | | | for certain contami- nants in food and re- pealing Regulation (EC) No 1881/2006 (8) | | |

- (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).
- ► M385 (5) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72). ◀
- ► M465 (6) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj).
- (7) 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, ELI: http://data.europa.eu/eli/reg/2005/396/2024-05-11).
- (8) Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: http://data.europa.eu/eli/reg/2023/915/oj). ◀

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, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|---|---|---|-------------------|------------------------|--|
| _ | 1 | Isaria fumosorosea strain Apopka 97 Deposited in the American Type Culture Collection (ATCC) under the name Paecilomyces fumosoroseus Apopka ATCC 20874 | Not applicable | Minimum concentration: 1,0 × 10 ⁸ CFU/ml Maximum concentration: 2,5 × 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. |
| ▼ <u>M142</u> | 2 | COS-OGA CAS No: not allocated CIPAC No: 979 | Linear copolymer of α-1,4-D-galactopyr-anosyluronic 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. |

| ▼ <u>M1136</u> | | | | | | | |
|----------------|---|--|------------------|---|-------------------|------------------------|--|
| - | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M143</u> | 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. |
| ▼ <u>M153</u> | 4 | Pepino mosaic 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. |
| ▼ <u>M152</u> | 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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|-------------------|---|--|----------------|--|------------------|------------------------|---|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M186</u> | 6 | Saccharomyces | Not applicable | Minimum concentration: | 6 July 2016 | 6 July 2031 | For the implementation of the uniform principles as referred to in |
| | | cerevisae strain LAS02 Accession number in | | 1 × 10 ¹³ CFU/kg | | | 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. |
| | | the collection of the 'Collection Nationale de Cultures de Microorganismes' (CNCM) of the Pasteur Institute: CNCM I- | | | | | 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. |
| _ | | 3936 | | | | | Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. |
| ▼M185 | | | | | | | |
| | 7 | Trichoderma atroviride strain SC1 Accession number CBS 122089 in the | Not applicable | minimum concentration 1 × 10 ¹⁰ CFU/g | 6 July 2016 | 6 July 2031 | For the implementation 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. |
| | | collection of the Centraalbureau voor Schimmelcultures (CBS) in Utrecht, The Netherland | | | | | 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. |
| _ | | CIPAC No: 988 | | | | | Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. |
| ▼ <u>M208</u> | 8 | Mild Pepino Mosaic Virus isolate VC1 | Not applicable | Nicotine < 0,1 mg/L | 29 March 2017 | 29 March 2032 | Only the use in greenhouses may be authorised. For the implementation of the uniform principles as referred to in |
| | | Reference number DSM 26973 in the German Collection of Micro-organisms and Cell Cultures (DSMZ) | | | | | 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. |

▼ <u>M208</u>

| ▼ <u>IV12U8</u> | | | | | | | |
|----------------------|----|---|----------------|---|------------------|------------------------|---|
| _ | | Common Name, Identifi- cation 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 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. |
| | | | | | | | Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. |
| ▼ <u>M206</u> | 9 | Mild Pepino Mosaic Virus isolate VX1 | Not applicable | Nicotine < 0,1 mg/L | 29 March 2017 | 29 March 2032 | Only the use in greenhouses may be authorised. |
| | | Reference number DSM 26974 in the German Collection of Micro-organisms and | | | | | For the implementation 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. |
| | | Cell Cultures (DSMZ) | | | | | 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. |
| _ | | | | | | | Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. |
| ▼ M219 | | | | | | | |
| | 10 | Bacillus amylolique- faciens strain FZB24. Accession number in the culture collection of the 'Deutsche Sammlung von Mikro- organismen' (DSM), Germany: 10271 | Not applicable | Minimum concentration: 2 × 10 ¹⁴ CFU/kg | 1 June 2017 | 1 June 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 <i>Bacillus amyloliquefaciens</i> strain FZB24, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: |

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|----------------------|----|--|--|--|------------------|------------------------|--|
| , | | Common Name, Identifi- cation 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 | | | | | specification of the technical material as commercially manufactured, including full characterisation of impurities and metabolites; the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers. 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. |
| ▼ <u>M222</u> | | | | | | | |
| | 11 | Coniothyrium minitans strain CON/M/91-08 Accession number in the culture collection of the 'Deutsche Sammlung von Mikroorganismen' (DSM), Germany: DSM 9660 CIPAC No 614 | Not applicable | ► C4 Minimum content of viable spores: 1,17 × 10 ¹² CFU/kg ◀ | 1 August 2017 | 31 July 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 <i>Coniothyrium minitans</i> strain CON/M/91-08, 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 considered as potential sensitizers. 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. |
| ▼ <u>M246</u> | 12 | Laminarin CAS No 9008-22-4 CIPAC No 671 | (1→3)-β-D-glucan (according to IUPAC-IUB Joint Commission on Biochemical Nomenclature) | ≥ 860 g/kg on dry matter (TC) | 1 March 2018 | 28 February 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 laminarin, and in particular Appendices I and II thereto, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. |

| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|----------------------|----|---|----------------|---|------------------|------------------------|---|
| ▼ <u>M275</u> | | | | | | | |
| _ | 13 | Pasteuria nishizawae 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. |
| ▼ <u>M269</u> | 14 | Ampelomyces quisqualis strain AQ10 | Not applicable | Minimum content of viable spores: 3.0×10^{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 |
| | | | | 3,0 ^ 10 CFU/kg | | | 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. |

▼ <u>M136</u>

| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|----|---|----------------|---|------------------|------------------------|---|
| ▼ <u>M292</u> | 15 | Clonostachys rosea strain J1446 Accession number in the culture collection of the German Collection of Microorganisms and Cell Cultures (DSMZ): DSM 9212 | Not applicable | Not applicable Gliotoxin content: max. 50 μg/kg in the technical grade of the MCPA. | 1 April 2019 | 31 March 2034 | 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. In this overall assessment Member States shall pay particular attention to: — 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. 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). Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M300</u> | 16 | ABE-IT 56 (components of lysate of Saccharomyces cerevisiae strain DDSF623) | Not Applicable | 1 000 g/kg (active substance) | 20 May 2019 | 20 May 2034 | For the implementation 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. |

| ▼ <u>M1130</u> | | | | | | | |
|----------------|-----|--|----------------|--|------------------|------------------------|---|
| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M314</u> | | | | | | | |
| 1 | 117 | Bacillus subtilis strain IAB/BS03 Accession number in the Spanish Type Culture Collection (CECT), Spain: CECT 7254 Accession number in the German Type Culture Collection (DSMZ), Germany: DSM 24682 | Not applicable | Minimum concentration: 1 × 10 ¹³ CFU/kg Maximum concentration: 5 × 10 ¹³ CFU/kg | 20 October 2019 | 20 October 2034 | For the implementation 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 In this overall assessment Member States shall pay particular attention to: a) the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; b) the protection of operators and workers, taking into account the microorganisms are per seconsidered as potential sensitisers, 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, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper of Microbial Contaminant Limits for Microbial Pest Control Products contained in the Working Document SANCO/12116/2012 (²). Conditions of use shall include risk mitigation measures, wher appropriate. |

| <u>M1136</u> | | | | | | | |
|--------------|----|--|---|---|------------------|------------------------|---|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| M316 | 18 | Verticillium albo- atrum strain WCS850 (culture collection No CBS 276.92) | Not applicable | Minimum concentration: 0.7×10^7 CFU/ml distilled water Maximum concentration: 1.5×10^7 CFU/ml distilled water No relevant impurity | 1 November 2019 | 31 October 2034 | 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 it particular Appendices I and II thereto, shall be taken into account In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking int account that <i>Verticillium albo-atrum</i> strain WCS850 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, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper of Microbial Contaminant Limits for Microbial Pest Control Products contained in the Commission Working Document SANCO/12116 2012 (2). |
| M326 | 19 | Lavandulyl senecioate CAS No: 23960-07-8 CIPAC No: n.a. | (RS)-5-methyl-2-(prop- 1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate | ≥ 894 g/kg | 3 June 2020 | 3 June 2035 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Lavandulyl senecioate, and in particular Appendices I and II thereto, shall be taken into account. Member State shall assess any extension of the use pattern beyon passive dispensers, in order to establish whether the propose extensions of use fulfil the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Commission Regulation (EU) No 546/2011 (3). |
| 2 M333 | 20 | Ferric pyrophosphate CAS No: 10058-44-3 CIPAC No: — | iron(3+) diphosphate | ≥ 802 g/kg The following impurities are of toxicological and environmental concern and must not exceed the following levels in the technical material: | 3.8.2020 | 3.8.2035 | For the implementation of the uniform principles as referred to i Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ferric pyrophosphate, and in particular Appendices I and II thereto, shall be taken into account. |

▼ <u>M333</u>

| ▼ <u>M333</u> | | | | | | | |
|---------------|----|--|----------------|---|------------------|------------------------|--|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | Lead: 3 mg/kgMercury: 0,1 mg/kgCadmium: 1 mg/kg | | | |
| ▼ <u>M331</u> | | | | | | | |
| | 21 | Phlebiopsis gigantea strain VRA 1835 | Not applicable | No relevant impurities | 1 September 2020 | 31 August 2035 | 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>Phlebiopsis gigantea</i> strain VRA 1835, and in particular Appendices I and II thereto, shall be taken into account. |
| | | | | | | | Member States shall pay particular attention to the protection of operators and workers. |
| | | | | | | | Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination. |
| - | | | | | | | |
| | 22 | Phlebiopsis gigantea strain VRA 1984 | Not applicable | No relevant impurities | 1 September 2020 | 31 August 2035 | 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>Phlebiopsis gigantea</i> strain VRA 1984, and in particular Appendices I and II thereto, shall be taken into account. |
| | | | | | | | Member States shall pay particular attention to the protection of operators and workers. |
| | | | | | | | Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination. |
| | | | | | | | |

▼ <u>M331</u>

| ▼ M331 | | | | | | | |
|---------------|----|---|------------------------------|--|---------------------|------------------------|---|
| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | 23 | Phlebiopsis gigantea strain FOC PG 410.3 | Not applicable | No relevant impurities | 1 September 2020 | 31 August 2035 | 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>Phlebiopsis gigantea</i> strain FOC PG 410.3, and in particular Appendices I and II thereto, shall be taken into account. |
| | | | | | | | Member States shall pay particular attention to the protection of operators and workers. |
| | | | | | | | Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination. |
| ▼ <u>M336</u> | | | | | | | |
| | 24 | Sodium hydrogen carbonate CAS No: 144-55-8 | Sodium hydrogen carbonate | ≥ 990 g/kg Arsenic ≤ 3 mg/kg Lead ≤ 2 mg/kg Mercury ≤ 1 mg/kg | 1 October 2020 | 1 October 2035 | For the implementation 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 hydrogen carbonate, and in particular Appendices I and II thereof, shall be taken into account. |
| ▼ <u>M351</u> | 25 | Akanthomyces muscarius strain Ve6 (formerly Lecani- cillium muscarium strain Ve6) (4) | Not applicable | No relevant impurities | 1 March 2021 | 29 February 2036 | 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>Akanthomyces muscarius</i> strain Ve6 (formerly <i>Lecanicillium muscarium</i> strain Ve6) and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitisers, and shall ensure that adequate personal protective equipment is included as a condition of use. |

| ▼ M351 | | | | | | | |
|---------------|----|--|---|---|------------------|------------------------|--|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination (²). |
| ▼ <u>M352</u> | | | | | | | |
| | 26 | Blood meal 90989-74-5 909 | Not applicable | 100 % blood meal haemoglobin content: min 80 %. | 1 April 2021 | 31 March 2036 | 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 blood meal, and in particular Appendices I and II thereto, shall be taken into account. |
| | | | | | | | Member States shall pay particular attention: to the protection of fish and aquatic invertebrates when less targeted spraying techniques are used, and on the need of blood meal-containing plant protection products to be swirled before use to wet the product. |
| ▼ <u>M353</u> | 27 | 24-epibrassinolide CAS No: 78821-43-9 CIPAC No: Not applicable | (3aS,5R,6S,7aR,7bS,9-aS,10R,12aS,12bS)-10 ((2S,3R,4R,5R)-3,4-dihydroxy-5,6-dimethylheptan-2-yl) 5,6-dihydroxy-7a,9a-dimethylhex-adecahydro-3Hbenzo [c]indeno[5,4-e] oxepin-3-one | ≥ 900 g/kg | 31 March 2021 | 31 March 2036 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 4 December 2020, and in particular Appendices I and II thereto, shall be taken into account. |

| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|----|--|----------------|--|------------------|------------------------|---|
| ▼ <u>M357</u> | | | | | | | |
| | 28 | Aqueous extract from the germinated seeds of sweet Lupinus albus CAS No: Not available for the extract BLAD protein: 1219521-95-5 CIPAC No: Not allocated | Not applicable | The minimum purity is not relevant for the extract. BLAD protein content: 195 – 210 g/kg. The following relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured were identified: Total quinolizidine alkaloids (QA): (lupanine, 13α-OH-lupanine, 13α-angeloy-loxylupanine, lupinine, albine, angustofoline, 13α-tigloyloxylupanine, α-isolupanine, tetrahydro-hombifoline, multiflorine, sparteine) Maximum content: provisionally set at 0,05 g/kg | 27 April 2021 | 27 April 2036 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> , and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment, Member States shall pay particular attention to the necessary labelling instructions concerning the measures to address foaming and stability of dilutions of the formulation. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 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; and 2. in particular on the maximum content of the quinolizidine alkaloids (<i>lupanine</i> , 13α-OH-lupanine, 13α-angeloyloxylupanine, <i>lupinine</i> , albine, angustofoline, 13α-tigloyloxylupanine, α-isolupanine, tetrahydrohombifoline, multiflorine, sparteine). The applicant shall submit the information referred in points 1 and 2 by 27 October 2021. |

| - | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|----|--|----------------|---|------------------|------------------------|---|
| ▼ <u>M365</u> | | | | | | | |
| | 29 | Pepino Mosaic Virus, EU strain, mild isolate Abp1 | Not applicable | The impurity nicotine shall not exceed the following values in the technical material: | 28 June 2021 | 28 June 2036 | For the implementation 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 Virus</i> , EU strain, mild isolate Abp1 and <i>Pepino Mosaic Virus</i> , CH2 strain, mild isolate Abp2, and in particular Appendices I and II thereto, shall be taken into account. |
| | | | | max. 0,005 mg/L in Abp1 TK | | | In this overall assessment Member States shall pay particular attention to: |
| | | | | max. 3,87 x 10 ⁻⁵ mg/kg in MPCP (Nicotine has been reported to be present in tomato plants, therefore, as the microbial pest control agent (MPCA) is produced in tomato plants, nicotine is present as a consequence of the | | | a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (²). b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. |
| | | | | production method). | | | Conditions of use shall include risk mitigation measures, where appropriate |
| - | 30 | Pepino Mosaic Virus, CH2 strain, mild isolate Abp2 | Not applicable | The impurity nicotine shall not exceed the following values in the technical material: | 28 June 2021 | 28 June 2036 | For the implementation 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 Virus</i> , EU strain, mild isolate Abp1 and <i>Pepino Mosaic Virus</i> , CH2 strain, mild isolate Abp2, and in particular Appendices I and II thereto, shall be taken into account. |
| | | | | max. 0,007 mg/L in Abp2 TK | | | |

▼ <u>M365</u>

| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|----|--|--|---|--------------------|------------------------|---|
| | | | | max. 3,87 x 10 ⁻⁵ mg/kg in MPCP (Nicotine has been reported to be present in tomato plants, therefore, as the microbial pest control agent (MPCA) is produced in tomato plants, nicotine is present as a consequence of the production method). | | | In this overall assessment Member States shall pay particular attention to: a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (²). b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate |
| ▼ <u>M418</u> | 31 | Calcium carbonate CAS No 471-34-1 CIPAC No 843 Limestone CAS No 1317-65-3 CIPAC No 852 | IUPAC name: Calcium carbonate | 950 g/kg | 1 November 2021 | 31 October 2036 | 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 calcium carbonate and the review report on limestone, and in particular Appendices I and II thereto, shall be taken into account. |
| ▼ <u>M372</u> | 32 | Potassium hydrogen carbonate CAS No 298-14-6 CIPAC No 853 | IUPAC name: Potassium hydrogen carbonate | 990 g/kg | 1 November 2021 | 31 October 2036 | 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 of potassium hydrogen carbonate, and in particular Appendices I and II thereto, shall be taken into account. |

| ▼ <u>M136</u> | | | | | | | |
|----------------------|----|--|----------------|---|----------------------|------------------------|---|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M373</u> | 33 | Bacillus amylolique- faciens AH2 | n.a. | The nominal content of Bacillus amylolique-faciens AH2 in the technical product and formulation is $1,0 \times 10^{11}$ CFU/L (range $7x10^{10} - 7x10^{11}$). No relevant impurities | 27 September 2021 | 27 September 2036 | 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>Bacillus amyloliquefaciens</i> AH2 and in particular Appendices I and II thereof, shall be taken into account. |
| ▼ <u>M377</u> | 34 | Purpureocillium lilacinum strain PL11 | Not applicable | No relevant impurities | 25 January 2022 | 24 January 2037 | Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Purpureocillium lilacinum</i> strain PL11 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on |
| | | | | | | | microbiological contamination as referred to in the Working Document SANCO/12116/2012 (²); b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate. |

▼ <u>M136</u>

| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|----|--|----------------|---|---------------------|------------------------|--|
| ▼ <u>M381</u> | 35 | Bacillus amylolique- faciens IT-45 | n.a. | The nominal content of <i>Bacillus amyloliquefaciens</i> IT-45 in the technical product and formulation is: minimum: 2 x 10 ¹³ CFU/kg, maximum: 6 x 10 ¹⁴ CFU/kg. No relevant impurities | 27 February 2022 | 27 February 2037 | For the implementation 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> IT-45 shall be taken into account. |
| ▼ <u>M383</u> | 36 | Metarhizium brunneum strain Ma 43 | Not applicable | No relevant impurities | 1 May 2022 | 30 April 2037 | 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>Metarhizium brunneum</i> strain Ma 43, 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 as such considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. |
| ▼ <u>M387</u> | 37 | Spodoptera exigua multicapsid nucleo- polyhedrovirus (SeMNPV), isolate BV-0004 | Not applicable | The content of the virus in the technical grade active ingredient, produced as an isolated technical material, must be at least 2,0 × 10 ¹¹ occlusion bodies/g. | 18.4.2022 | 18.4.2037 | For the implementation 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> multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (5), |

| ▼ <u>M387</u> | | | | | | | |
|----------------------|----|---|--|---|---------------------|------------------------|---|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M397</u> | | | | | | | |
| | 38 | Straight Chain Lepidopteran Pheromones (acetates) | Details are provided in the Review Report SANTE/10828/2021 | Details are provided in the Review Report SANTE/ 10828/2021 | 1 September 2022 | 30 August 2037 | 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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M399</u> | 39 | Sheep fat CAS No: 98999-15-6 CIPAC No: 919 | Sheep fat | Minimum purity of sheep fat: 100 % No relevant impurity | 1 November 2022 | 30 October 2037 | 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 sheep fat, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. |

| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|----|---|--|--|------------------|------------------------|---|
| ▼ <u>M403</u> | 40 | Heptamaloxyloglucan CAS No: 870721-81-6 CIPAC No: 851 | α -L-fucopyranosyl- $(1\rightarrow 2)$ - β -D-galactopyranosyl- $(1\rightarrow 2)$ - α -D-xylopyranosyl- $(1\rightarrow 6)$ - $[\alpha$ -D-xylopyranosyl- $(1\rightarrow 6)$ - β -D-glucopyranosyl- $(1\rightarrow 4)$]- β -D-glucopyranosyl- $(1\rightarrow 4)$ -D-glucitol | ≥ 780 g/kg The following impurity is of toxicological and enviromental concern and must not exceed the following levels in the technical material: - Patulin, max. 50 μg/kg | 1 March 2023 | 28 February 2038 | For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on heptamaloxyloglucan, and in particular Appendices I and II thereto, shall be taken into account. |
| ▼ <u>M401</u> | 41 | Fish oil CAS No: 8016-13-5 CIPAC No: 918 | Not applicable | Minimum purity of the active substance as manufactured: Fish oil 100 % Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured: Maximum levels according to Commission Directive 2002/32/EC (6) for the following impurities, proportionate to a fish oil with a moisture content of 12 %: | 1 March 2023 | 28 February 2038 | 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 fish oil, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. |

| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|----|--|------------|--|---------------------|------------------------|--|
| | | | | 5 ng/kg of sum of polychlorinated dibenzo-paradioxins (PCDDs) and polychlorinated dibenzo-furans (PCDFs) (7) 20 ng/kg of sum of polychlorinated dibenzo-paradioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin like polychlorinated biphenyls (PCBs) (7) 0,5 mg/kg of mercury 2 mg/kg of cadmium 10 mg/kg of lead 175 μg/kg of non-dioxin- | | | |
| ▼ <u>M410</u> | 42 | Trichoderma atroviride AGR2 | n.a. | The nominal content of Trichoderma atroviride AGR2 in the technical product and formulation is Minimal: 5 x 10 ¹¹ CFU/kg Nominal: 1 x 10 ¹² CFU/kg Maximal: 1 x 10 ¹³ CFU/kg No relevant impurities | 22 February 2023 | 21 February 2038 | For the implementation 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> AGR2 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 specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; |

| ▼ M410 | | | | | | | |
|----------------------|----|--|--------------------------------|---|------------------|------------------------|---|
| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| _ | | | | | | | — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers. Use of PPE/RPE might be recommended to reduce dermal and inha- lation exposure. |
| ▼ <u>M409</u> | | | | | | | |
| | 43 | Trichoderma atroviride AT10 | n.a. | The nominal content of <i>Trichoderma atroviride</i> AT10 in the technical product and formulation is Minimal: 1 x 10 ¹¹ CFU/kg Nominal: 5 x 10 ¹¹ CFU/kg Maximal: 1 x 10 ¹² CFU/kg No relevant impurities | 20 February 2023 | 20 February 2038 | For the implementation 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> AT10 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers. Use of PPE/RPE might be considered to reduce dermal and inhalation exposure. |
| ▼ <u>M431</u> | 44 | Quartz sand (there is no ISO common name) (1) 7631-86-9 (CAS) (2) 14808-60-7 (CAS) 855 (CIPAC) | (1) Silicon dioxide (2) Quartz | 915 g/kg The impurity crystalline silica with a particle diameter ≤ 10 μm is of toxicological concern and shall not exceed a level of 0,1 % of particles in the technical material. | 1 September 2023 | 31 August 2038 | 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 quartz sand, and in particular Appendices I and II thereof, shall be taken into account. |

| ▼ M431 | | | | | | | |
|----------------------|----|--|---------------|--|------------------|------------------------|--|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| | | [So far they have been indicated as: CAS No: 14808-60-7 CIPAC No: not allocated] | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M432</u> | 45 | Fat distillation residues CAS No not available 915 (CIPAC No) | Not available | ≥ 400 g/kg of cleaved fatty acids (free/ester bonded) palmitic acid min 19 % of cleaved fatty acids stearic acid min 18 % of cleaved fatty acids oleic acid min 37 % of cleaved fatty acids acid value min 70 mg KOH/g The following impurity is of toxicological concern and shall not exceed the following levels in the technical material: | 1 November 2023 | 31 October 2038 | 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 fat distillation residues, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | nickel max 0,1 g/kg | | | |

| V <u>W1130</u> _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|----------------------|----|--|----------------|--|------------------|------------------------|---|
| ▼ <u>M433</u> | 46 | Cydia pomonella granulovirus (CpGV) | Not applicable | Bacillus cereus: < 1 × 10 ⁷ CFU/g in the formulated products. | 1 November 2023 | 31 October 2038 | For the implementation 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>Cydia pomonella</i> granulovirus (CpGV), and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (5), — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M445</u> | 47 | Hydrolysed proteins CAS No: Not applicable CIPAC No: 901 | Not available | Hydrolysed proteins. Animal tissues hydrolysate excluding ruminants hides and skins (no ISO common name): — 708 g/kg on a dry weight basis [range in TK (technical concentrate) 400-434 g/kg]. Hydrolysed proteins. Urea enriched beet molasses, hydrolysed (no ISO common name): | 1 May 2024 | 30 April 2039 | 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 hydrolysed proteins, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material for 'hydrolysed' proteins-urea enriched beet molasses, hydrolysed' as commercially manufactured on the basis of an analysis of at least five representative batches. Conditions of use shall include risk mitigation measures, where appropriate. |

▼ <u>M445</u>

| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|----------------------|----|--|------------|--|------------------|------------------------|---|
| | | | | — 110 g/kg on a dry weight basis [range in TK (technical concentrate) 90- 110 g/kg]. | | | |
| | | | | Hydrolysed Proteins. Collagen protein Hydrolysate (no ISO common name): | | | |
| | | | | — 582 g/kg on a dry weight basis [range in TK (technical concentrate) 249- 262 g/kg]. | | | |
| | | | | Lead, cadmium, arsenic, mercury and biuret in accordance with Regulation (EU) 2019/1009 on fertilising products. | | | |
| _ | | | | Formaldehyde below 1 g/kg. | | | |
| ▼ <u>M446</u> | | | | | | | |
| | 48 | Urea CAS No: 57-13-6 CIPAC No: 913 | Urea | 980 g/kg The following impurities were considered of toxicological concern and a maximum level is established of: | 1 May 2024 | 30 April 2039 | 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 urea, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: |
| | | | | Biuret: < 12 g/kg Formaldehyde: < 0,5 g/kg | | | the specification of the technical material as commercially manufactured on the basis of an analysis of at least five rep- resentative batches. |
| | | | | Cadmium: < 1 mg/kg Mercury: < 0,1 mg/kg | | | Conditions of use shall include risk mitigation measures, where appropriate. |

| Common Name, Identifi- cation Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
|--|------------|--------------------|------------------|------------------------|---------------------|
| | | Lead: < 1 mg/kg | | | |
| | | Arsenic: < 1 mg/kg | | | |

- (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-an a microbial-contaminant-limits.pdf
- ► M326 (3) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127).
- ► M351 (4) The concerned active substance was initially approved as Verticillium lecanii, but later, for scientific reasons, its name was changed to Lecanicillium muscarium strain Ve6, which was later changed again to the name under which the approval was renewed, Akanthomyces muscarius strain Ve6. ◀
- ► M387 (⁵) https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_phys-chem-ana_micro_bial-contaminant-limits.pdf
- ▶ M401 (6) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).
- (7) Expressed in World Health Organisation (WHO) toxic equivalents. ◀

Candidates for substitution

| | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---|--|--|--|------------------|-----------------------------|---|
| 1 | Flumetralin CAS No 62924-70-3 CIPAC No 971 | N-(2-chloro-6-fluor-obenzyl)-N-ethyl-α,α,α-trifluoro-2,6-dinitro-p-toluidine | 980 g/kg The impurity Nitrosamine (calculated as nitrosodimethylamine) shall not exceed 0,001 g/kg in the technical material. | 11 December 2015 | ► M466 15 January 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 flumetralin, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (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. 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); 2. the compliance of the toxicity batches with the confirmed technical specification. 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. |

| ▼ <u>IVI100</u> | | | | | | | |
|-----------------|---|---|--|---|-------------------|-----------------------------------|--|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M162</u> | 2 | Esfenvalerate CAS No: 66230-04-4 CIPAC No: 481 | (αS)-α-cyano-3-phen- oxybenzyl (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 | ► M440 31 May 2026 ◀ | For the implementation 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 2SαR-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 |
| ▼ <u>M169</u> | 3 | Metsulfuron-methyl CAS No 74223-64-6 CIPAC No 441.201 | Methyl 2-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsul-famoyl)benzoate | 967 g/kg | 1 April 2016 | ► <u>M444</u> 31 August 2026 ◀ | appropriate. For the implementation 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. |

| ▼ <u>M1166</u> | | | | | | | |
|----------------|---|--|---|---------------------------|------------------|--------------------------------|--|
| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M172</u> | | | | | | | |
| | 4 | Benzovindiflupyr CAS No: 1072957- 71-1 CIPAC No: not | N-[(1RS,4SR)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1- | 960 g/kg (50/50) racemate | 2.3.2016 | <u>M444</u> 2 August 2026 ◀ | For the implementation 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. |
| | | available | methylpyrazole-4- carboxamide | | | | In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms. |
| | | | | | | | 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 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. |
| | | | | | | | 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. |

| ▼ <u>IVI100</u> | | | | | | | |
|-----------------|---|---|--|------------|------------------|----------------------------|---|
| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M170</u> | | | | | | | |
| | 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 | ► M444 31 August 2026 ◀ | For the implementation 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. In this overall assessment Member States shall pay particular attention to the: (a) protection of operators, workers and bystanders; (b) metabolites potentially formed in processed commodities; (c) risk to aquatic organisms, mammals and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate. The applicants shall submit confirmatory information as regards: 1. 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); 2. toxicological information to assess the toxicological profile of the metabolites V (PBA) and XXIII (PBA(OH)). The applicants shall submit those information to the Commission, the Mamber States and the Authority by 1 April 2018 |
| | | | | | | | the Member States and the Authority by 1 April 2018. |

| ▼ <u>M1166</u> | | | | | | | |
|----------------------|---|--|---|--|------------------|------------------------------------|---|
| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M205</u> | 6 | Prosulfuron CAS No 94125-34-5 CIPAC No 579 | 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluor-opropyl)-phenylsul-fonyl]-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 | ► <u>M449</u> 15 June 2026 ◀ | ► M358 For the implementation 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 including its addendum, and in particular Appendices I and II thereto, shall be taken into account. In that 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 protection of consumers, taking into account exposure to metabolites of prosulfuron; the risk to non-target terrestrial and aquatic plants. Conditions of use shall include risk mitigation measures, where appropriate. |
| ▼ <u>M227</u> | 7 | Pendimethalin CAS No 40487-42-1 CIPAC No 357 | N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidene | 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 | ► <u>M460</u> 15 January 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 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 |

▼<u>M227</u>

| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|---|--|--|---|--------------------|--------------------------------|---|
| | | cation Numbers | | | approval | approval | shall be compared and verified against the specification of the technical material, — the protection of operators, — the protection of birds, mammals and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. 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. The applicant shall submit confirmatory information to the Commission, the Member States and the Authority as regards: 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. The applicant shall submit the confirmatory information requested |
| _ | | | | | | | 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. |
| ▼ <u>M239</u> | 8 | Imazamox CAS No 114311-32-9 CIPAC No 619 | 2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imid-azolin-2-yl]-5-methoxymethylnicotinic acid | ≥ 950 g/kg The impurity cyanide ion (CN ⁻) shall not exceed 5 mg/kg in the technical material. | 1 November 2017 | ► M343 31 January 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 renewal report on imazamox, and in particular Appendices I and II thereto, shall be taken into account. |

▼ <u>M239</u>

| Common Name, Identification Numbers Common Name, Identification Numbers Complete | ▼ <u>MI239</u> | | | | | | | |
|--|----------------------|---|-------------------|----------------------|------------|-------------|--------------|--|
| TM260 Propyzamide CAS No 23950-58-5 CIPAC No 315 The protection of consumers; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. The protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. 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. CAS No 23950-58-5 CIPAC No 315 The protection of groundwater in vulnerable zeros. The protection of groundwater in vulnerable areas, — the protection of operators, — the protection of operators, — the protection of operators, — the protection of groundwater in vulnerable areas, — the protection of groundwater in vulnerable areas, — the protection of groundwater in vulnerable areas, — the protection of protection of protection of groundwater in vulnerable areas, — the protection of protection of protection of groundwater in vulnerable areas, — the protection of protection of protection of protection of groundwater in vulnerable areas, — the protection of protection of protection of groundwater in vulnerable areas, — the protection of protection of protection of groundwater in vulnerable areas, — the protection of protection of groundwater in vulnerable areas, — the protection of protection of groundwater in vulnerable areas, — the protection of protection of groundwater in vulnerable areas, — the protection of protection of groundwater in vulnerable areas, — the protection of protection of groundwater in vulnerable areas, — the protection of protection of groundwater in vulnerable areas, — the protection of groundwater in vulnerable areas, — the protection of protective equipment such as gloves, coverall and sturdy footwar has to be worn to ensure that the AOEL is not exceeded for the operator. The applicant shall submit to the Commission, the | | | | IUPAC Name | Purity (1) | | | Specific provisions |
| | ▼ <u>M260</u> | 9 | CAS No 23950-58-5 | dimethylprop-2-ynyl) | 920 g/kg | 1 July 2018 | 30 June 2025 | attention to: — 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. 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. For the implementation 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. In their overall assessment Member States shall pay particular attention to: — the protection of operators, — the protection of groundwater in vulnerable areas, — the protection of birds, mammals, non-target plants, soil and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. 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. |

▼ <u>M260</u>

| _ | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-------------------------|---|---|--|-------------------|------------------------|---|
| | | | | | | the completion of assessment of toxicological profile of metabolites identified in significant concentration in primary and rotational crops; the soil degradation of major metabolite RH- 24580; 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. 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. |
| ▼ <u>M288</u> 10 | Copper compounds: Copper hydroxide CAS No 20427-59-2 CIPAC No 44.305 Copper oxychloride CAS No 1332-65-6 or 1332-40-7 CIPAC No 44.602 Copper oxide CAS No 1317-39-1 CIPAC No 44.603 Bordeaux mixture CAS No 8011-63-0 CIPAC No 44.604 Tribasic copper sulphate CAS No 12527-76-3 CIPAC No 44.306 | trihydroxide Copper oxide Not allocated | ≥ 573 g/kg ≥ 550 g/kg ≥ 820 g/kg ≥ 245 g/kg ≥ 490 g/kg | 1 January 2019 | 31 December 2025 | Only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised. 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. In their overall assessment Member States shall pay particular attention to: — 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; |

▼ <u>M288</u>

| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|------|-----|---|---|---|------------------|------------------------|--|
| | | | | The following impurities shall not exceed the following levels: Arsenic max. 0,1 mg/g Cu Cadmium max. 0,1 mg/g Cu Lead max. 0,3 mg/g Cu Nickel max. 1 mg/g Cu Cobalt max. 3 mg/kg Mercury max. 5 mg/kg Chromium max. 100 mg/kg Antimony max. 7 mg/kg | | | — the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, d not exceed the minimum necessary to achieve the desired effect and do not cause any unacceptable effect on the environmentaking 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 the set a maximum annual application rate not exceeding 4 kg/hard copper. |
| M293 | | | | | | | |
| 1 | 111 | Methoxyfenozide CAS No 161050-58-4 CIPAC No 656 | N-tert-Butyl-N'-(3-methoxy-o-toluoyl)-3,5-xylohydrazide | ≥ 970 g/kg The following impurities must not exceed the following levels in the technical material: Tert-butylhydrazine < 0,001 g/kg RH-116267 < 2 g/kg | 1 April 2019 | 31 March 2026 | Only uses in greenhouses shall be authorised. For the implementation of the uniform principles as referred to it. 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. In their 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 climate conditions; — the risk of accumulation in soil; — the protection of non-target arthropods, sediment dwelling an aquatic organisms; Conditions of use shall include risk mitigation measures, wher appropriate. The applicant shall submit to the Commission, the Member State and the Authority confirmatory information as regards: 1. a comparative in vitro metabolism study on methoxyfenozide, by 1 April 2020; |

▼ <u>M293</u>

| _ | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|---------------|----|---|--|------------|--------------------|------------------------|---|
| | | | | | | | 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. 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. |
| ▼ <u>M361</u> | | | | | | | |
| ▼ <u>M347</u> | | | | | | | |
| | 13 | etoxazole CAS No 153233-91-1 CIPAC No 623 | (RS)-5-tert-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro1,3-oxazol-4-yl]phenetole | ≥ 948 g/kg | 1 February 2021 | 31 January 2028 | Only uses on ornamental plants in permanent greenhouses shall 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 renewal report on etoxazole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: |

▼ <u>M347</u>

| ▼ <u>M347</u> | | | | | | | |
|----------------------|----|---|---|--|--------------------|------------------------|--|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
| ▼ <u>M374</u> | | | | | | | possible uptake of persistent soil metabolites in rotational crops; the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. The applicant shall submit to the Commission, the Member States and the Authority by 5 January 2023 confirmatory information as regards points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, including an updated assessment of the information already submitted and, where relevant, further information. |
| | 14 | Cypermethrin CAS No 52315-07-8 CIPAC No 332 | (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (RS)-α-cyano-3-phenoxybenzyl-(1RS)-cistrans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | 920 g/kg cis:trans: 40/60 to 60/40 The following impurities are of toxicological concern and must not exceed the following levels in the technical material: hexane: 5g/kg | 1 February 2022 | 31 January 2029 | Authorisations shall be limited to professional users. When authorising plant protection products containing cypermethrin for spray applications outdoors, in order to ensure the protection of non-target organisms, in particular aquatic organisms and non-target arthropods, including bees: risk mitigation measures achieving reduction of drift shall be required that lead to exposure ≤ 5,8 mg a.s./ha in off-crop areas and, in addition, for spring applications to concentrations in water bodies ≤ 0,0038 μg a.s./L, only uses outside flowering of the crop and when no flowering weeds are present 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 renewal report on cypermethrin, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to: the protection of aquatic organisms, non-target arthropods, including bees; |

▼ <u>M374</u>

| ▼ <u>M37/4</u> | | | | | | | |
|----------------|----|---|--|---|------------------|------------------------|---|
| | | Common Name, Identifi- cation Numbers | IUPAC Name | Purity (¹) | Date of approval | Expiration of approval | Specific provisions |
| | | | | | | | As regards Points 3.6.5 and 3.8.2 of Annex II toRegulation (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 endocrine activity shall be submitted by 15 December 2023. |
| V M455 | | | | | | | |
| ▼ <u>M455</u> | | | | | | | |
| | 15 | metconazole CAS No: 125116-23-6 (unstated stereochemistry) | (1RS,5RS:1RS,5SR)-5- (4-chlorobenzyl)-2,2- dimethyl-1-(1H-1,2,4- triazol-1-ylmethyl) cyclopentanol | ≥ 940 g/kg (sum of cisand trans-isomers), with cis-metconazole (CL 354801) level not less than 800 g/kg and not | 1 September 2024 | 31 August 2031 | Use shall be limited to professional users. 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 metconazole, and in particular Appendices I |
| | | CIPAC No: 706 | Cyclopentanol | more than 950 g/kg The following impurities | | | and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular |
| | | | | shall not exceed the | | | attention to: |
| | | | | following levels in the technical material: — toluene: 2 g/kg | | | — the consumer exposure assessment with regards to residues that may be present in the primary crops and succeeding crops grown in rotation; |
| | | | | — ethylcyclohexane: 2 g/kg | | | — the protection of operators and bystanders/residents; |
| | | | | | | | — the protection of aquatic organisms. |
| | | | | | | | Conditions of use shall include risk mitigation measures, where appropriate. |
| | | | | | | | The applicant shall submit confirmatory information as regards: |
| | | | | | | | 1. 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; |
| | | | | | | | |

| Common Name, Identifi- cation Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|--|------------|------------|------------------|------------------------|--|
| | | | | | 2. the general toxicity profile of the metabolites M11 and M21 should be further investigated in order to confirm the appropriate toxicological reference values applicable to them. Moreover, confirmation of the presence of M11 and M21 and their ratio among the monohydroxylated metconazole compounds in crops, in order to confirm the residue definition for risk assessment. The applicant shall submit the confirmatory information referred to in point 1 by 15 July 2026 and in point 2 by 15 July 2026 to the Commission, Member States and the Authority. |

▼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). ◀

►M374 (³) Directive 2000/60/ÉC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1). (⁴) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of EN 5 EN pesticides (OJ L 309, 24.11.2009, p. 71). ◀