

## PART B

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

General provisions applying to all substances listed in this Part:

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

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

▼ **M1**▼ **M7**

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

▼ **M5**

▼ **M5**

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

▼ **M4**

4	<p>Azoxystrobin</p> <p>CAS No 131860-33-8</p> <p>CIPAC No 571</p>	<p>methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}phenyl}-3-methoxyacrylate</p>	<p>≥ 930 g/kg</p> <p>Toluene maximum content 2 g/kg</p> <p>Z-isomer maximum content 25 g/kg</p>	1 January 2012	► <b>M295</b> 31 December 2024 ◀	<p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.</p>
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▼ **M4**

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

▼ **M6**

5	<p>Imazalil</p> <p>CAS No 35554-44-0</p> <p>73790-28-0 (replaced)</p> <p>CIPAC No 335</p>	<p>(RS)-1-(β-allyloxy-2,4-dichlorophenethyl)imidazole</p> <p>or</p> <p>allyl (RS)-1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether</p>	≥ 950 g/kg	1 January 2012	► <b>M295</b> 31 December 2024 ◀	<p>PART A</p> <p>Only uses as fungicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 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.</p>
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▼ **M6**

Number	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
						<p>In this overall assessment Member States shall:</p> <p>(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;</p> <p>(2) pay particular attention to the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels;</p> <p>(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;</p> <p>(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;</p> <p>(5) pay particular attention to risk to aquatic organisms and soil micro-organisms and long-term risk to granivorous birds and mammals.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The notifier shall submit confirmatory information as regards:</p> <p>(a) route of degradation of imazalil in soil and surface water systems;</p>

▼ **M6**

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

▼ **M3**

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

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

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

▼ **M18**

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						<p>Member States shall pay particular attention to the protection of groundwater under vulnerable conditions; the conditions of authorisation shall include, where appropriate, risk mitigation measures.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>Groundwater exposure risk assessment, and in particular:</p> <ul style="list-style-type: none"> <li>— 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,</li> <li>— 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,</li> <li>— on a groundwater exposure risk assessment for the late application in apples, pears and grapes.</li> </ul> <p>The applicant shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.</p>

▼ **M8**

9	Fluroxypyr CAS No 69377-81-7 CIPAC No 431	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	<p>► <b>M225</b> ≥ 950 g/kg (fluroxypyr-meptyl)</p> <p>The following manufacturing impurity is of toxicological concern and must not exceed the following amount in the technical material:</p> <p>N-methyl-2-pyrrolidone (NMP): &lt; 3 g/kg ◀</p>	1 January 2012	► <b>M295</b> 31 December 2024 ◀	<p>► <b>M225</b> PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluroxypyr, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 23 March 2017 shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— 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;</li> <li>— the risk to aquatic organisms.</li> </ul> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀</p>
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▼ **M1**▼ **M15**

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

▼ **M1**▼ **M14**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ( <sup>1</sup> )	Date of approval	Expiration of approval	Specific provisions
11	Oxyfluorfen CAS No 42874-03-3 CIPAC No 538	2-chloro- $\alpha,\alpha,\alpha$ -trifluoro- <i>p</i> -tolyl 3-ethoxy-4-nitrophenyl ether	$\geq 970$ g/kg  Impurities:  N,N-dimethylnitrosamine: not more than 50 $\mu$ g/kg	1 January 2012	► <b>M295</b> 31 December 2024 ◀	► <b>M203</b> 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.  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. ◀
12	1-naphthylacetamide CAS No 86-86-2 CIPAC No 282	2-(1-naphthyl)acetamide	$\geq 980$ g/kg	1 January 2012	► <b>M295</b> 31 December 2023 ◀	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

▼ **M10**

▼ **M10**

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

▼ **M11**

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

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

▼ **M16**

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

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

▼ **M12**

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

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

▼ **M19**

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

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

▼ **M1**▼ **M17**

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

▼ **M21**



▼ **M21**

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

▼ **M20**

19	<p>Acrinathrin</p> <p>CAS No 101007-06-1</p> <p>CIPAC No 678</p>	<p>(S)-<math>\alpha</math>-cyano-3-phenoxymethyl (Z)-(1R,3S)-2,2-dimethyl-3-[2-(2,2,2-trifluoro-1-trifluoromethyl-ethoxycarbonyl)vinyl]cyclopropanecarboxylate or</p> <p>(S)-<math>\alpha</math>-cyano-3-phenoxymethyl (Z)-(1R)-cis-2,2-dimethyl-3-[2-(2,2,2-trifluoro-1-trifluoromethyl-ethoxycarbonyl)vinyl]cyclopropanecarboxylate</p>	<p><math>\geq 970</math> g/kg</p> <p>Impurities:</p> <p>1,3-dicyclohexylurea: not more than 2 g/kg</p>	1 January 2012	► <b>M295</b> 31 December 2023 ◀	<p>PART A</p> <p>Only uses as insecticide and acaricide may be authorised at rates not exceeding 22,5 g/ha per application.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acrinathrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2011 shall be taken into account.</p> <p>In this overall assessment Member States:</p> <p>(a) shall pay particular attention to the protection of operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;</p> <p>(b) shall pay particular attention to the risk to aquatic organisms, in particular fish, and shall ensure that conditions of authorisation include risk mitigation measures, where appropriate;</p>
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▼ **M20**

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

▼ **M25**

20	Prochloraz CAS No 67747-09-5 CIPAC No 407	<i>N</i> -propyl- <i>N</i> -[2-(2,4,6-trichlorophenoxy)ethyl]imidazole-1-carboxamide	<p>≥ 970 g/kg</p> <p>Impurities:</p> <p>Sum of dioxins and furans (WHO-PCDD/T TEQ) <sup>(13)</sup>: not more than 0,01 mg/kg</p>	1 January 2012	► <b>M295</b> 31 December 2023 ◀	<p>PART A</p> <p>Only uses as fungicide may be authorised. In the case of outdoor uses, rates shall not exceed 450 g/ha per application.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prochloraz, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011, shall be taken into account.</p>
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▼ **M25**

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

▼ **M1**▼ **M30**

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

▼ **M30**

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

▼ **M33**

23	<p>Bifenthrin</p> <p>CAS No 82657-04-3</p> <p>CIPAC No 415</p>	<p>2-methylbiphenyl-3-ylmethyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate</p> <p>or</p> <p>2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate</p>	<p>≥ 930 g/kg</p> <p>Impurities:</p> <p>Toluene: not more than 5 g/kg</p>	1 August 2012	<p>► <b>M296</b> 31 July 2019 ◀</p>	<p>► <b>M250</b> PART A</p> <p>Only uses as insecticide in greenhouses with a permanent structure may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account.</p> <p>In this overall assessment, Member States must pay particular attention to:</p>
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▼ **M33**

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

▼ **M34**

24	Fluxapyroxad CAS No 907204-31-3 CIPAC No 828	3-(difluoromethyl)-1-methyl- <i>N</i> -(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide	<p>≥ 950 g/kg</p> <p>The impurity toluene must not exceed 1 g/kg in the technical material</p>	1 January 2013	31 December 2022	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluxapyroxad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to groundwater, if the active substance is applied under vulnerable soil and/or climatic conditions.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The purity given in this entry is based on a pilot plant production. The examining Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.</p>
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▼ **M1**▼ **M35**▼ **M40**▼ **M41**

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

▼ **M41**

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

▼ **M42**

28	Phosphane  CAS No 7803-51-2  CIPAC No 127	Phosphane	<p>≥ 994 g/kg</p> <p>The relevant impurity arsane must not exceed 0,023 g/kg in the technical material</p>	1 April 2013	31 March 2023	<p>Authorisations shall be limited to professional users.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on phosphane, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 September 2012 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators in and around the treated premises during the treatment as well as during and after the aeration;</li> <li>— the protection of workers in and around the treated premises during the treatment as well as during and after the aeration;</li> <li>— the protection of bystanders around the treated premises during the treatment as well as during and after the aeration.</li> </ul> <p>Conditions of use shall include risk mitigation measures, like permanent monitoring of the phosphane concentration by automatic devices, the use of personal protection equipment and setting-up an area around the treated premise where bystanders are denied, where appropriate.</p>
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▼ **M1**

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

▼ **M47**

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

▼ **M46**

32	<i>Trichoderma atroviride</i> strain I-1237  CNCM number: I-1237	Not applicable	$1 \times 10^9$ cfu/g $(1 \times 10^{10}$ spores/g)	1 June 2013	31 May 2023	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> strain I-1237, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Trichoderma atroviride</i> strain I-1237 is to be considered a potential sensitiser.</p> <p>Conditions of use shall include risk mitigation measures where appropriate.</p>
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▼ **M1**▼ **M52**▼ **M50**

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

▼ **M1**▼ **M56**

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

▼ **M58**

▼ **M1**

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

▼ **M64**

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

▼ **M61**

40	Potassium phosphonates (no ISO name)  CAS No 13977-65-6 for potassium hydrogen phosphonate  13492-26-7 for dipotassium phosphonate  Mixture: none  CIPAC No 756 (for potassium phosphonates)	Potassium hydrogen phosphonate,  Dipotassium phosphonate	31,6 to 32,6 % phosphonate ions (sum of hydrogen phosphonate and phosphonate ions)  17,8 to 20,0 % potassium  ≥ 990 g/kg on dry weight basis	1 October 2013	30 September 2023	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium phosphonates, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account.  In this overall assessment Member States shall pay particular attention to:  — the risk to birds and mammals,  — the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water.  Conditions of use shall include risk mitigation measures, where appropriate.  The applicant shall submit confirmatory information as regards the long-term risk to insectivorous birds.  The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.
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▼ **M63**

41	Spiromesifen  CAS No 283594-90-1  CIPAC No 747	3-mesityl-2-oxo-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutyrate	≥ 965 g/kg (racemic)  The impurity N,N-dimethylacetamide is of toxicological relevance and must not exceed 4 g/kg in the technical material.	1 October 2013	30 September 2023	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiromesifen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account.
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▼ **M63**

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

▼ **M59**

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

43	Bixafen  CAS No 581809-46-3  CIPAC No 819	<i>N</i> -(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide	≥ 950 g/kg	1 October 2013	30 September 2023	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bixafen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the residues of bixafen and of its metabolites in rotational crops;</p>
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▼ **M54**

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

▼ **M55**

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

45	Eugenol CAS No 97-53-0 CIPAC No 967	4-allyl-2-methoxyphenol	≥ 990 g/kg Relevant impurity: methyl eugenol maximum 0,1 % of the technical material	1 December 2013	30 November 2023	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on eugenol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013 shall be taken into account.</p>
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▼ **M68**

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

▼ **M70**

▼ **M70**

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

▼ **M69**

47	<p>Thymol</p> <p>CAS No</p> <p>89-83-8</p> <p>CIPAC No</p> <p>969</p>	5-methyl-2-propan-2-yl-phenol	≥ 990 g/kg	1 December 2013	30 November 2023	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thymol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to</p> <ul style="list-style-type: none"> <li>— the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;</li> </ul>
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▼ **M69**

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

▼ **M77**

48	<p>Sedaxane</p> <p>CAS No 874967-67-6</p> <p>(trans isomer: 599197-38-3/cis isomer: 599194-51-1)</p> <p>CIPAC No 833</p>	<p>mixture of 2 cis-isomers</p> <p>[(1RS,2RS)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and 2 trans-isomers</p> <p>[(1RS,2SR)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide</p>	<p>≥ 960 g/kg Sedaxane</p> <p>(range 820-890 g/kg for the 2 trans-isomers 50:50 mixture of enantiomers and range 100-150 g/kg for the 2 cis-isomers 50:50 mixture of enantiomers)</p>	1 February 2014	31 January 2024	<p>PART A</p> <p>Only uses for seed treatment may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sedaxane, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;</p>
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▼ **M77**

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

▼ **M79**

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

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

## ▼ M79

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

▼ **M1**

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

▼ **M76**

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

▼ **M78**

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

53	<p>Pyriofenone:</p> <p>CAS No 688046-61-9</p> <p>CIPAC No 827</p>	(5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone	$\geq 965$ g/kg	1 February 2014	31 January 2024	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyriofenone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards</p> <p>(a) the identity of two impurities to fully support the provisional specification;</p>
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▼ **M82**

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

▼ **M81**

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

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

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

▼ **M1**▼ **M88**

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

▼ **M94**

## ▼ M94

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

▼ **M1**▼ **M90**▼ **M95**

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

▼ **M1**▼ **M92**

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

▼ **M91**

▼ **M91**

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

▼ **M97**

62	<p>Chlorantraniliprole</p> <p>CAS No 500008-45-7</p> <p>CIPAC No 794</p>	<p>3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methyl-carbamoyl) pyrazole-5-carboxanilide</p>	<p>≥ 950 g/kg</p> <p>The following relevant impurities must not exceed a certain threshold in the technical material:</p> <p>Acetonitrile: ≤ 3 g/kg</p> <p>3-picoline: ≤ 3 g/kg</p> <p>Methanesulfonic acid: ≤ 2 g/kg</p>	1 May 2014	30 April 2024	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorantraniliprole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and to soil macroorganisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the risk to groundwater from the active substance and its metabolites IN-EQW78 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one), IN-ECD73 (2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one), IN-F6L99 (3-bromo-N-methyl-1H-pyrazole-5-carboxamide), IN-GAZ70 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-8-methylquinazolin-4(1H)-one) and IN-F9N04 (3-bromo-N-(2-carbamoyl-4-chloro-6-methylphenyl)-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide);</p>
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▼ **M97**

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

▼ **M96**

63	<p>Sodium silver thiosulfate</p> <p>CAS No not allocated</p> <p>CIPAC No 762</p>	Not applicable	<p>≥ 10,0 g Ag/kg</p> <p>Expressed as silver (Ag)</p>	1 May 2014	30 April 2024	<p>PART A</p> <p>Only indoor uses in non-edible crops shall be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium silver thiosulfate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to</p> <p>(a) the protection of operators and workers;</p> <p>(b) limiting the possible release of silver ions through disposal of used solutions;</p> <p>(c) the risk to terrestrial vertebrates and soil invertebrates from the use of sewage sludge in agriculture.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>
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▼ **M1**▼ **M101**

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

▼ **M101**

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

▼ **M105**

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

66	<p>L-ascorbic acid</p> <p>CAS No 50-81-7</p> <p>CIPAC No 774</p>	<p>(5R)-5-[(1S)-1,2-dihydroxyethyl]-3,4-dihydroxyfuran-2(5H)-one</p>	<p>≥ 990 g/kg</p> <p>The following relevant impurities shall not exceed:</p> <p>Methanol: ≤ 3 g/kg</p> <p>Heavy Metals: ≤ 10 mg/kg (expressed as Pb)</p>	1 July 2014	30 June 2024	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on L-ascorbic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to aquatic and soil organisms;</p> <p>(b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.</p>
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▼ **M104**

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

▼ **M99**

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

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

▼ **M108**

68	1,4-dimethylnaphthalene CAS No 571-58-4 CIPAC No 822	1,4-dimethylnaphthalene	≥ 980 g/kg	1 July 2014	30 June 2024	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1,4-dimethylnaphthalene, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the protection of operators and of workers at re-entry and during inspection of the warehouse;</p> <p>(b) the risk to aquatic organisms and fish-eating mammals the active substance is discharged from warehouses into air and surface water without further treatment.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>
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▼ **M108**

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

▼ **M109**

69	<p>Amisulbrom</p> <p>CAS No 348635-87-0</p> <p>CIPAC No 789</p>	<p>3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-<i>N,N</i>-dimethyl-1<i>H</i>-1,2,4-triazole-1-sulfonamide</p>	<p>≥ 985 g/kg</p> <p>The following relevant impurity must not exceed a certain threshold in the technical material:</p> <p>3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole: ≤ 2 g/kg</p>	1 July 2014	30 June 2024	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on amisulbrom, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic and soil organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the non-significance of photodegradation in the soil metabolism of amisulbrom concerning the metabolites 3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole and 1-(dimethylsulfamoyl)-1<i>H</i>-1,2,4-triazole-3-sulfonic acid to contaminate groundwater;</p> <p>(2) the low potential of amisulbrom (FOCUS drainage scenarios only) and metabolites 1-(dimethylsulfamoyl)-1<i>H</i>-1,2,4-triazole-3-sulfonic acid, 1<i>H</i>-1,2,4-triazole-3-sulfonic acid, 1<i>H</i>-1,2,4-triazole, <i>N,N</i>-dimethyl-1<i>H</i>-1,2,4-triazole-3-sulfonamide, 2-acetamido-4-fluorobenzoic acid, 2-acetamido-4-fluoro-hydroxybenzoic acid and 2,2'-oxybis(6-fluoro-2-methyl-1,2-dihydro-3<i>H</i>-indol-3-one) to contaminate surface water or to expose aquatic organisms by runoff;</p>
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▼ **M109**

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

▼ **M102**

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

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

▼ **M114**

▼ **M114**

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

▼ **M117**

73	<p>Ipconazole</p> <p>CAS No</p> <p>125225-28-7 (mixture of diastereoisomers)</p> <p>115850-69-6 (ipconazole cc, cis isomer)</p> <p>115937-89-8 (ipconazole ct, trans isomer)</p> <p>CIPAC No 798</p>	<p>(1<i>RS</i>,2<i>SR</i>,5<i>RS</i>;1<i>RS</i>,2-<i>SR</i>,5<i>SR</i>)-2-(4-chlorobenzyl)-5-isopropyl-1-(1<i>H</i>-1,2,4-triazol-1-ylmethyl) cyclopentanol</p>	<p>≥ 955 g/kg</p> <p>Ipconazole cc: 875 – 930 g/kg</p> <p>Ipconazole ct: 65 – 95 g/kg</p>	1 September 2014	31 August 2024	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ipconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ol style="list-style-type: none"> <li>1. the risk to granivorous birds;</li> <li>2. the protection of workers and operators;</li> <li>3. the risk to fish.</li> </ol> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>
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▼ **M117**

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

▼ **M119**

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

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

▼ **M123**

▼ **M123**

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

▼ **M124**

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

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

▼ **M1**

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

▼ **M131**

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

▼ **M133**

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

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

▼ **M132**

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

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

▼ **M154**



▼ **M154**

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

▼ **M155**

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

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

▼ **M148**

▼ **M1**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <b>M156</b>						
88	Sulfoxaflor CAS No: 946578-00-3 CIPAC No: 820	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ <sup>6</sup> -sulfonylidene]cyanamide	≥ 950 g/kg	18 August 2015	18 August 2025	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfoxaflor, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>(a) the risk to bees and other non-target arthropods;</li> <li>(b) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <ul style="list-style-type: none"> <li>(a) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust;</li> <li>(b) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds;</li> <li>(c) the risk to pollinators other than honey bees;</li> <li>(d) the risk to bee brood.</li> </ul> <p>The applicant shall submit that information to the Commission, the Member States and the Authority by 18 August 2017.</p>
▼ <b>M150</b>						
89	Sulfosulfuron CAS No: 141776-32-1 CIPAC No: 601	1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-ethylsulfonylimidazo[1,2-a]pyridine-3-ylsulfonyl)urea	≥ 980 g/kg  The following relevant impurity must not exceed a certain threshold in the technical material:  Phenol: < 2 g/kg	1 January 2016	31 December 2030	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfosulfuron, and in particular Appendices I and II thereof shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;</li> <li>— the risk to soil non-target macro-organisms other than earthworms, non-target terrestrial plants and aquatic organisms.</li> </ul>

▼ **M1**

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

▼ **M164**

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

▼ **M167**

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

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

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

▼ **M173**

▼ **M1**▼ **M171**

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

▼ **M174**

▼ **M174**

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

▼ **M175**

98	<p>Acibenzolar-S-methyl</p> <p>CAS No 135158-54-2</p> <p>CIPAC No 597</p>	S-methyl benzo[1,2,3]thiadiazole-7-carbothioate	<p>970 g/kg</p> <p>Toluene: max. 5 g/kg</p>	1 April 2016	31 March 2031	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acibenzolar-S-methyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk for consumers via food intake;</p> <p>(b) the protection of operators and workers;</p> <p>(c) the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>
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▼ **M175**

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

▼ **M189**

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

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

▼ **M1**▼ **M194**

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

▼ **M193**

▼ **M193**

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

▼ **M190**

103	Picolinafen  CAS No 137641-05-5  CIPAC No 639	4'-fluoro-6-( $\alpha,\alpha,\alpha$ -trifluoro-m-toloxypyridine-2-carboxanilide	$\geq 980$ g/kg	1 November 2016	30 June 2031	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on picolinafen, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the impurities in the technical active substance;</li> <li>— the protection of mammals, especially of large herbivorous mammals;</li> <li>— the protection of non-target terrestrial plants;</li> <li>— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;</li> <li>— the protection of aquatic organisms, especially to algae.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>
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▼ **M1**▼ **M191**

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

▼ **M191**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ( <sup>1</sup> )	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	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiabendazole, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and consumers,</li> <li>— the protection of groundwater,</li> <li>— the control of waste water from post-harvest uses.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit by 31 March 2019 to the Commission, the Member States and the Authority confirmatory information regarding Level 2 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of thiabendazole.</p>
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▼ **M200**

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

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

▼ **M207**

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

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

▼ **M218**

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

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

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

▼ **M220**

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

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

▼ **M214**

▼ **M214**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						<p>2. the potential endocrine disrupting mode of action of the active substance in particular level 2 and 3 tests, currently indicated in the OECD Conceptual framework (OECD 2012) and analysed in the EFSA Scientific opinion on the hazard assessment of endocrine disruptors;</p> <p>3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under point 1 by 1 July 2017 and the relevant information requested under point 2 by 31 December 2017. The applicant shall submit to the Commission, the Member States and the Authority the confirmatory information requested under point 3 within a period of two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.</p>

▼ **M215**

113	<p>Cyhalofop-butyl</p> <p>CAS No 122008-85-9</p> <p>CIPAC No 596</p>	<p>butyl (R)-2-[4-(4-cyano-2-fluorophenoxy) phenoxyl]propionate</p>	950 g/kg	1 July 2017	30 June 2032	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyhalofop-butyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators,</li> <li>— the technical specification,</li> <li>— the protection of non-target terrestrial plants.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>
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## ▼ M1

## ▼ M228

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

## ▼ M232

▼ **M232**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			Free phenols (expressed as 2,4-dichlorophenol (2,4-DCP)): max. 15 g/kg.  Dibenzo- <i>p</i> -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.

▼ **M234**

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.
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▼ **M244**

118	Glyphosate CAS No 1071-83-6 CIPAC No 284	N-(phosphonomethyl)glycine	≥ 950 g/kg  Impurities:  Formaldehyde, less than 1 g/kg	16 December 2017	15 December 2022	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 glyphosate, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M244**

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

▼ **M247**

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

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

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

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



▼ **M1**▼ **M255**

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

▼ **M258**

▼ **M258**

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

▼ **M267**

124	Trifloxystrobin  CAS No 141517-21-7  CIPAC No 617	methyl (E)-methoxyimino- {(E)- $\alpha$ -[1-( $\alpha,\alpha,\alpha$ -trifluoro-m-tolyl)ethylideneaminoxy]-o-tolyl}acetate	$\geq 975$ g/kg  AE 1344136 (max. 4 g/kg)	1 August 2018	31 July 2033	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on trifloxystrobin, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions;</li> <li>— the protection of aquatic organisms, bees, and of fish-eating birds and mammals.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> <li>(1) the relevance of metabolites that may occur in groundwater, taking into account any relevant classification for trifloxystrobin in accordance with Regulation (EC) No 1272/2008, in particular as toxic for reproduction category 2;</li> <li>(2) the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water.</li> </ol>
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▼ **M267**

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

▼ **M268**

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

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

▼ **M273**

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

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

▼ **M272**

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

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

▼ **M1**

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

▼ **M1**▼ **M289**

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

▼ **M290**



▼ **M290**

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

▼ **M297**

132	Mefentrifluconazole CAS No: 1417782-03-6 CIPAC No: Not assigned	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	<p>≥ 970 g/kg</p> <p>The impurity N, N-dimethylformamide shall not exceed 0,5 g/kg in the technical material.</p> <p>The impurity toluene shall not exceed 1 g/kg in the technical material</p> <p>The impurity 1,2,4-(1H)-triazole shall not exceed 1 g/kg in the technical material</p>	20 March 2019	20 March 2029	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mefentrifluconazole, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment;</li> <li>— the protection of aquatic organisms.</li> </ul> <p>Conditions of use shall include risk mitigation measures, such as buffer zones and/or vegetative strips, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> <li>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;</li> <li>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.</li> </ol>
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▼ **M297**

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

▼ **M299**

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

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

▼ **M305**

134	Isoxaflutole CAS No 141112-29-0 CIPAC No 575	(5-cyclopropyl-1,2-oxazol-4-yl)( $\alpha,\alpha,\alpha$ -trifluoro-2-mesyl-p-tolyl)methanone	$\geq 972$ g/kg	1 August 2019	31 July 2034	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on isoxaflutole, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment, Member States shall pay particular attention to:</p> <p>— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions,</p> <p>— the protection of aquatic organisms, wild mammals and non-target terrestrial plants.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit this information within 2 years from the date of publication, by the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.</p> <p>The applicant shall also provide an updated assessment to confirm that isoxaflutole is not an endocrine disruptor within the meaning of points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 and in accordance with the guidance for identification of endocrine disruptors <sup>(23)</sup> by 10 May 2021.</p>
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▼ **M1**▼ **M302**▼ **M307**

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

▼ **M307**

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

▼ **M311**

137	<p>Dimethenamid-P</p> <p>CAS No 163515-14-8</p> <p>CIPAC No 638</p>	<p>(S)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methyl-ethyl)acetamide</p>	<p>≥ 930 g/kg</p> <p>The following impurity is of toxicological concern and must not exceed the following level in the technical material:</p> <p>1,1,1,2-Tetrachloroethane (TCE): ≤ 1,0 g/kg</p>	1 September 2019	31 August 2034	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on dimethenamid-P, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment;</li> <li>— the protection of groundwater, in particular regarding the metabolites of dimethenamid-P;</li> <li>— the protection of aquatic organisms and small herbivorous mammals.</li> </ul>
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▼ **M311**

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

▼ **M310**

138	<p>Tolclofos-methyl</p> <p>CAS No 57018-04-9</p> <p>CIPAC No 479</p>	<p>O-2,6-dichloro-p-tolyl O, O-dimethyl phosphorothioate</p> <p>O-2,6-dichloro-4-methylphenyl O, O-dimethyl phosphorothioate</p>	<p>≥ 960 g/kg</p> <p>The following impurity is of toxicological concern and must not exceed the following level in the technical material:</p> <p>Methanol max. 1 g/kg</p>	1 September 2019	31 August 2034	<p>Only for use on ornamentals and on potatoes.</p> <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on tolclofos-methyl, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the risk to aquatic organisms and mammals,</li> <li>— the risk to consumers, in particular the potential risk from metabolite DM-TM-CH<sub>2</sub>OH in potatoes,</li> <li>— the risk to operators, workers and bystanders;</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>
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▼ **M312**

139	<p>Florpyrauxifen-benzyl</p> <p>CAS No: 1390661-72-9</p> <p>CIPAC No: 990.227</p>	<p>benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylate</p>	<p>≥ 920 g/kg</p> <p>The impurity toluene shall not exceed 3 g/kg in the technical material.</p>	24 July 2019	24 July 2029	<p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 22 March 2019, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p>
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▼ **M312**

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

▼ **M1**

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

► **M9** <sup>(2)</sup> 2-hydroxy-4,6-dimethoxypyrimidine.

<sup>(3)</sup> 2,4-dihydroxy-6-methoxypyrimidine.

<sup>(4)</sup> sodium 2-hydroxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl)oxybenzoate. ◀

► **M53** <sup>(5)</sup> 5-(trifluoromethyl)-2(1H)-pyridinone.

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

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

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

<sup>(9)</sup> 3-chloro-4-[3-(ethenyloxy)-4-hydroxyphenoxy]benzoic acid.

<sup>(10)</sup> 2-chloro-1-(3-methoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene.

<sup>(11)</sup> 4-(3-ethoxy-4-hydroxyphenoxy)benzoic acid. ◀

► **M20** <sup>(12)</sup> 3-phenoxybenzaldehyde. ◀

► **M25** <sup>(13)</sup> 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** <sup>(14)</sup> 7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidine-6-carboxylic acid. ◀

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

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

► **M171** <sup>(17)</sup> *p*-methyl-phenethylamine. ◀

► **M249** <sup>(18)</sup> OJ L 353, 31.12.2008, p. 1. ◀

► **M268** <sup>(19)</sup> 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** <sup>(20)</sup> 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** <sup>(21)</sup> [https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_ppp\\_app-proc\\_guide\\_phys-chem-ana\\_microbial-contaminant-limits.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf) ◀

► **M299** <sup>(22)</sup> 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** <sup>(23)</sup> Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 <https://efsa.onlinelibrary.wiley.com/doi/epdt710.2903/i.efsa.2018.5311> ◀