Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 18,810, 23 ta' Settembru, 2011
Taqsima B

A.L. 385 ta' l-2011

ATT DWAR IL-KONTROLL TAL-PESTIĊIDI (KAP. 430)

Regolamenti ta' l-2011 li jemendaw ir-Regolamenti dwar Prodotti għall-Ħarsien tal-Pjanti (Emenda Nru. 3)

BIS-SAĦĦA tas-setgħat mogħtija bl-artikoli 4 u 5 ta' l-Att dwar il-Kontroll tal-Pestiċidi, il-Ministru għar-Riżorsi u Affarijiet Rurali, wara konsultazzjoni mal-Prim Ministru u mal-Ministru għas-Saħħa, l-Anzjani u Kura fil-Komunità, għamel dawn ir-regolamenti li ġejjin:-

Titolu u skop.
A.L. 358 ta' l- 2009.

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2011 li jemendew ir-Regolamenti dwar Prodotti għall-Ħarsien tal-Pjanti (Emenda Nru. 3), u dawn għandhom jinqraw u jiftiehmu ħaġa waħda mar-Regolamenti ta' l-2009 dwar Prodotti għall-Ħarsien tal-Pjanti, hawn iżjed 'il quddiem imsejħa "ir-regolamenti prinċipali".

(2) L-iskop ta' dawn ir-regolamenti hu li jiġu trasposti Direttiva tal-Kummissjoni 2011/2/UE tas- 7 ta' Jannar 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-miklobutanil bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/4/UE tal- 20 ta' Jannar 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż iċ-ċiklossidim bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/5/UE tal- 20 ta' Jannar 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tiġi inkluża l-imessażol bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/6/UE tal- 20 ta' Jannar 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-buprofeżin bħala sustanza attiva, Direttiva tal-Kummissjoni 2011/9/UE tal- 1 ta' Frar 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tiġi inkluża d-dodina bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/14/UE tal- 24 ta' Frar 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-profossidim bħala sustanza attiva, Direttiva tal-Kummissjoni 2011/19/UE tat- 2 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill

91/414/KEE biex jiġi inkluż it-tau-fluvalinat bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/20/UE tat- 2 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-fenossikarb bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/21/UE tat- 2 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-kletodim bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/22/UE tat- 3 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-bispiribak bħala sustanza attiva, Direttiva tal-Kummissjoni 2011/23/UE tat- 3 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE għall-inklużjoni tat-triflumuron bħala sustanza attiva, Direttiva tal-Kummissjoni 2011/25/UE tat- 3 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-bupirimat bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/26/UE tat- 3 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi d-dietofenkarb bħala sustanza attiva u li temenda d-Deċiżjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/27/UE tal- 4 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tiġi inkluża l-oriżalina bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/28/UE tal- 4 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż l-aċidu indolibutriku bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/941/KE, Direttiva tal-Kummissjoni 2011/29/UE tas- 7 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż l-etridiażol bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/30/UE tas- 7 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-ossidu tal-fenbutatin bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/31/UE tas- 7 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE fir-rigward ta' restrizzjoni fl-użu tas-sustanza attiva pirimifos-metil, Direttiva tal-Kummissjoni 2011/32/UE tat- 8 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tiġi inkluża l-isossaben bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/33/UE tat- 8 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-1-dekanol bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/941/KE, Direttiva tal-Kummissjoni 2011/34/UE tat- 8 ta' Marzu 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex ikun inkluż il-fluworokloridon bħala sustanza attiva u li temenda d-Deċiżjoni tal-

Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/39/UE tal- 11 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-fenażakwin bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/40/UE tal- 11 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi s-sintofen bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/41/UE tal- 11 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi d-ditijanon bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/42/UE tal- 11 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-flutriafol bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Deċiżjoni ta' Implimentazzjoni tal-Kummissjoni 2011/43/UE tat- 13 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-kubrit tal-ġir bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/941/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/44/UE tat- 13 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-ażadiraktin bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/941/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/45/UE tat- 13 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi d-diklofop bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/46/UE tal- 14 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-eżitijażoss bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/47/UE tal- 15 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi s-sulfat tal-aluminju bħala sustanza attiva u li temenda d-Deċiżjoni 2008/941/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/48/UE tal- 15 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-bromadiolon bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/941/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/49/UE tat- 18 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-penċikuron bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Deċiżjoni ta' Implimentazzjoni tal-Kummissjoni 2011/50/UE tad- 19 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-karbetamid bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni

2011/52/UE tal- 20 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-karbossinu bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/53/UE tal- 20 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tiġi inkluża d-dażomet bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/54/UE tal- 20 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-metaldeid bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/55/UE tas- 26 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-paklobutrażol bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/56/UE tas- 27 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi ċ-ċiprokonażol bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE, Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/57/UE tas- 27 ta' April 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż l-fluwometuron bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummisjoni 2008/934/KE, Direttiva tal-Kummissjoni 2011/58/UE tal- 10 ta' Mejju 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE għat-tiġdid tal-inklużjoni tal-karbendażim bħala sustanza attiva u Direttiva ta' Implimentazzjoni tal-Kummissjoni 2011/60/UE tat- 23 ta' Mejju 2011 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi t-tebufenożur bħala sustanza attiva u li temenda d-Deċiżjoni tal-Kummissjoni 2008/934/KE.

Jemenda Skeda I li tinsab mar-regolamenti prinċipali.

2. Skeda I li tinsab mar-regolamenti prinċipali għandha tiġi emendata kif ġej:-

(a) Minflok il-partita numru 149 għandu jidħol dan li ġej:

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
"149	Carbendazim CAS No 10605-21-7 CIPAC No 263	Methyl benzimidazol-2-ylcarbamate	≥ 980 g/kg Relevant impurities 2-amino-3-hydroxyphenazine (AHP): not more than 0,0005 g/kg 2,3-diaminophenazine (DAP): not more than 0,003 g/kg	1 June 2011	30 November 2014	PART A Only uses as fungicide on the following crops may be authorised: — cereals, — rape seed, — sugar and fodder beet, — maize, at rates not exceeding: — 0,25 kg active substance per hectare per application for cereals and rape seed, — 0,075 kg active substance per hectare per application for sugar and fodder beet, — 0,1 kg active substance per hectare per application for maize. The following uses must not be authorised: — air application, — knapsack and handheld applications neither by amateur nor by professional users, — home gardening. Member States shall ensure that all appropriate risk mitigation measures are applied. Particular attention must be paid to the

* Further details on identity and specification of active substances are provided in the review report.

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Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						protection of: — aquatic organisms. Appropriate drift mitigation measures must be applied to minimise the exposure of surface water bodies. This should include keeping a distance between treated areas and surface water bodies alone or in combination with the use of drift-reducing techniques or devices — earthworms and other soil macro-organisms. Conditions of authorisation shall include risk mitigation measures, such as the selection of the most appropriate combination of numbers and timing of application, and, if necessary, the degree of concentration of the active substance, — birds (long-term risk). Depending on the results of the risk assessment for specific uses, targeted mitigation measures to minimise the exposure may become necessary, — operators, who must wear suitable protective clothing, in particular gloves, coveralls, rubber boots and face protection or safety glasses during mixing, loading, application and cleaning of the equipment, unless the exposure to

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita[•]	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						the substance is adequately precluded by the design and construction of the equipment itself or by the mounting of specific protective components on such equipment. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on carbendazim, and in particular Appendices I and II thereof, shall be taken into account. The Member States concerned shall request that the applicant provides the following to the Commission: — by 1 December 2011 at the latest, information as regards the toxicological and ecotoxicological relevance of the impurity AEF037197, — by 1 June 2012 at the latest, the examination of the studies included in the list in the draft re-assessment report of 16 July 2009 (Volume 1, Level 4 "Further information", pp. 155-157), — by 1 June 2013 at the latest, information on the fate and behaviour (route of aerobic degradation in soil) and the long-term risk to birds."

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(b) Minflok il-partita numru 162 għandu jidħol dan li ġej:

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
"162	pirimiphos-methyl CAS No 29232-93-7 CIPAC No 239	O-2-diethylamino-6-methylpyrimidin-4-yl O,O-dimethylphosphorothioate	≥ 880 g/kg	1 October 2007	30 September 2017	PART A Only uses as insecticide for post harvest storage can be authorised. Hand-held applications shall not be authorised. PART B In assessing applications to authorise plant protection products containing pirimiphos-methyl for uses other than applications with automated systems in empty cereals storehouses, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pirimiphos- methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 March 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators safety. Authorised

* Further details on identity and specification of active substances are provided in the review report.

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						conditions of use must prescribe the application of adequate personal protective equipment including respiratory protective equipment and risk mitigation measures to reduce the exposure, — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels."

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(c) minnufih wara l-partita numru 323 "Bromuconazole" għandhom jiżdiedu dawn il-partiti ġodda li ġejjin:

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
"324	Myclobutanil CAS No: 88671-89-0 CIPAC No: 442	*(RS)-2-(4-chlorophenyl)-2-(1H- 1,2,4-triazol-1-ylmethyl)hexanenitrile*	≥ 925 g/kg The impurity 1-methylpyrrolidin-2-one shall not exceed 1g/kg in the technical material	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of II thereof, as finalised in the Standing Annex VI, the conclusions of the review report on myclobutanil, and in particular Appendices I and Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information on the residues of myclobutanil and its metabolites in following growing seasons and information confirming that the available residue data cover all compounds of the residue definition. The Member States concerned shall ensure that

* Further details on identity and specification of active substances are provided in the review report.

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dhul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						the applicant submits such confirmatory information to the Commission by 31 January 2013.
325	Buprofezin CAS No: 953030-84-7 CIPAC No: 681	(Z)-2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one	≥ 985 g/kg	1 February 2011	31 January 2021	PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on buprofezin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the operators' and workers' safety and ensure that conditions of use impose adequate personal protective equipment where appropriate; (b) the dietary exposure of consumers to the buprofezin (aniline) metabolites in processed food; (c) the application of an appropriate waiting period for rotational crops in greenhouses; (d) the risk to aquatic organisms and ensure that conditions of use impose adequate risk mitigation measures, where appropriate.

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Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dhul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						The Member States concerned shall request the submission of confirmatory information as regards the processing and conversion factors for consumer risk assessment. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 January 2013.
326	Dodine CAS No: 2439-10-3 CIPAC No: 101	1-dodecylguanidinium acetate	≥ 950 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dodine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the potential long-term risk to birds and mammals; (b) the risk to aquatic organisms and ensure that conditions of use impose adequate risk mitigation measures; (c) the risk to non-target plants in the off-field area and ensure that conditions of use impose

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita'	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						adequate risk mitigation measures; (d) the monitoring of residue levels in pome fruit. The Member States concerned shall request the submission of confirmatory information as regards: (a) long-term risk assessment for birds and mammals; (b) risk assessment in natural surface water systems where major metabolites have potentially formed. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
327	Cycloxydim CAS No: 101205-02-1 CIPAC No: 510	*5RS)-2-[(EZ)-1-(ethoxyimino)butyl]-3- hydroxy-5-[(3RS)-thian-3-yl]cyclohex-2-en-1-one*	≥ 940 g/kg	1 June 2011	31 May 2021	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cycloxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to non-target plants. Conditions of use shall include risk

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Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						mitigation measures, where appropriate. The Member States concerned shall request the submission of further information concerning the methods for analysis of residues of cycloxydim in plant and animal products. The Member States concerned shall ensure that the applicant submits such methods of analysis to the Commission by 31 May 2013.
328	Triflumuron CAS No: 64628-44-0 CIPAC No: 548	1-(2-chlorobenzoyl)-3-[4-trifluoromethoxyphenyl]urea	≥ 955 g/kg Impurities: — N,N'-bis-[4-(trifluoromethoxy)phenyl]urea: not more than 1 g/kg, — 4-trifluoro-methoxyaniline: not more than 5 g/kg.	1 April 2011	31 March 2021	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on triflumuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account. In this overall assessment, Member States shall pay particular attention to: — the protection of the aquatic environment, — the protection of honeybees. Conditions of authorisation shall include risk mitigation measures, where appropriate. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita*	Dhul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						the applicant submits to the Commission confirmatory information as regards the long-term risk to birds, the risk to aquatic invertebrates and the risk to bee brood development. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 March 2013.
329	Bispyribac CAS No 125401-75-4 CIPAC No 748	2,6-bis(4,6-dimethoxypyrimidin-2-yloxy)benzoic acid	≥ 930 g/kg (referred to as bispyribac-sodium)	1 August 2011	31 July 2021	PART A Only uses as herbicide in rice may be authorised. PART B For the implementation of the uniform principles of Annex VI, 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 28 January 2011, shall be taken into account. In this overall assessment, Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures where appropriate. The Member States concerned shall request the submission of further information as regards the possible groundwater contamination by

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita'	Dħul fis-seħħ	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
						metabolites M03 (2-hydroxy-4,6-dimethoxypyrimidine), M04 (2,4- dihydroxy-6-methoxypyrimidine) and M10 (sodium 2-hydroxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl) oxybenzoate). They shall ensure that the applicant provides such information to the Commission by 31 July 2013.
330	Profoxydim CAS No 139001-49-3 CIPAC No 621	2 – [(1 E/Z) – [(2 R S) – 2 – (4 – chlorophenoxy) propoxyimino] butyl] – 3 – hydroxy – 5 – [(3 R S; 3 S R) – tetrahydro – 2 H – thiopyran – 3 – yl] cyclohex – 2 – enone	≥ 940 g/kg	1 August 2011	31 July 2021	PART A Only uses as herbicide in rice may be authorised. PART B For the implementation of the uniform principles of Annex VI, 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 28 January 2011 shall be taken into account. In this overall assessment, Member States must pay particular attention to: — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the long term risk to non-target organisms. Conditions of authorisation shall include risk mitigation measures where appropriate.
331	Diethofencarb CAS No: 87130-	isopropyl 3,4-diethoxycarbanila	≥ 970 g/kg Impurities:	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised.

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	20-9 CIPAC No: 513	te	Toluene: not more than 1 g/kg			PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on diethofencarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and non-target arthropods and shall ensure that conditions of use include the application of adequate risk mitigation measures. The Member States concerned shall request the submission of confirmatory information as regards: (a) the potential uptake of the metabolite 6-NO 2-DFC in succeeding crops; (b) the risk assessment for non-target arthropod species. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013.
332	Etridiazole CAS No: 2593-15-9 CIPAC No: 518	ethyl-3-trichloromethyl-1,2,4-thiadiazol-5-yl ether	≥ 970 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide in non-soil bound systems in greenhouse may be authorised. PART B

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						In assessing applications to authorise plant protection products containing etridiazole for uses other than on ornamental plants, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI the conclusions of the review report on etridiazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account. In this overall assessment Member States shall: 1. pay particular attention to the risk to operators and workers and ensure that conditions of use include the application of appropriate risk mitigation measures; 2. ensure that appropriate waste management practices are applied as regards waste water from irrigation of non-soil bound growing systems; Member States permitting the release of waste water into the sewage system or into natural water bodies, shall ensure that an appropriate risk assessment is carried out; 3. pay particular attention to the risk to aquatic organisms and ensure that conditions of use include the application of appropriate risk

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						mitigation measures. The Member States concerned shall request the submission of confirmatory information as regards: 1. the specification of the technical material, as commercially manufactured, by appropriate analytical data; 2. the relevance of the impurities; 3. the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the ecotoxicity dossiers; 4. the relevance of the plant metabolites 5-hydroxy-ethoxyetridiazole acid and 3-hydroxymethyletridiazole; 5. indirect exposure of groundwater and soil-dwelling organisms to etridiazole and to its soil metabolites dichloro-etridiazole and etridiazole acid; 6. long-range and short-range transport through the atmosphere of etridiazole acid. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points 1, 2 and 3 by 1 December 2011 and the information set out in points 4, 5 and 6 by 31 May 2013.
333	Indolylbutyric acid	4-(1H-indol-3-yl)butyric acid	≥ 994 g/kg	1 June 2011	31 May 2021	PART A Only uses as plant growth regulator in

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	CAS No 133-32-4 CIPAC No 830					ornamentals may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on indolylbutyric acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the operators and workers safety. Conditions of authorisation shall include the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure. The Member States concerned shall request the submission of further information to confirm: (a) the absence of clastogenicity potential of indolylbutyric acid; (b) the vapour pressure of indolylbutyric acid and, consequently, an inhalation toxicity study; (c) the natural background concentration of indolylbutyric acid in the soil. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
334	Oryzalin	3,5-dinitro-	≥ 960 g/kg	1 June	31 May	PART A

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	CAS No: 19044-88-3 CIPAC No: 537	N4,N4-dipropylsulfanilamide	N-nitrosodipropylamine: ≤ 0,1 mg/kg Toluene: ≤ 4 g/kg	2011	2021	Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on oryzalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account. In this overall assessment Member States shall pay particular attention to: 1. the operator safety and ensure that conditions of use include the application of adequate personal protective equipment; 2. the protection of aquatic organisms and non-target plants; 3. the protection of groundwater, where the active substance is applied in regions with vulnerable soil and/or climatic conditions; 4. the risk to herbivorous birds and mammals; 5. the risk to bees, in the flowering season. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolites OR13 (2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide) and OR15 (2-

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						ethyl-7-nitro- 1H-benzimidazole-5-sulfonamide) in vulnerable zones, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: 1. the specification of the technical material, as commercially manufactured, by appropriate analytical data, including information on the relevance of the impurities which for confidentiality reasons are referred to as impurities 2, 6, 7, 9, 10, 11, 12; 2. the relevance of the test material used in the toxicity dossiers in view of the specification of the technical material; 3. the risk assessment for aquatic organisms; 4. the relevance of the metabolites OR13 and OR15, and the corresponding groundwater risk assessment, provided that oryzalin becomes classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council (OJ L 353, 31.12.2008, p. 1) as "suspected of causing cancer". The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points 1 and 2 by 1 December 2011, and the information set out in point 3 by 31 May 2013. The information set out in point 4 shall be submitted within 6 months of

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						notification of a decision classifying oryzalin.
335	Tau-fluvalinate CAS No: 102851- 06-9 CIPAC No: 786	(RS)-α-cyano-3-phenoxybenzyl N-(2-chloro- α,α α- trifluoro-p-tolyl)-D- valinate (Isomer ratio 1:1)	≥ 920 g/kg (1:1 ratio of R-α-cyano and S-α-cyano isomers) Impurities: Toluene: not more than 5 g/kg	1 June 2011	31 May 2021	PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tau-fluvalinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic organisms and ensure that conditions of use prescribe the application of adequate risk mitigation measures; (b) the risk to non-target arthropods and ensure that conditions of use prescribe the application of adequate risk mitigation measures; (c) the test material used in the toxicity dossiers shall be compared and verified against the specification of the technical material commercially manufactured. The Member States concerned shall request the submission of confirmatory information as regards:

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						— the risk of bioaccumulation/biomagnification in the aquatic environment, — the risk to non-target arthropods. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013. The Member States concerned shall ensure that the applicant submits confirmatory information, two years after the adoption of specific guidance, as regards: the possible impact on the environment of the potential enantio-selective degradation in environmental matrices.
336	Clethodim CAS No: 99129-21-2 CIPAC No: 508	(5RS)-2-{(1EZ)-1-[(2E)-3-chloroallyl-oxyimino]propyl}-5-[(2RS)-2-(ethylthio)propyl]-3-hydroxycyclohex-2- en-1-one	≥ 930 g/kg Impurities: toluene max. 4 g/kg	1 June 2011	31 May 2021	PART A Only uses as herbicide on sugar beet may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on clethodim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection to aquatic organisms, birds and

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						mammals, and shall ensure that conditions of use include the application of adequate risk mitigation measures. The Member States concerned shall request the submission of confirmatory information, on the basis of most recent scientific knowledge, as regards: — the soil and groundwater exposure assessments, — the residue definition for risk assessment. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
337	Bupirimate CAS No: 41483-43-6 CIPAC No: 261	5-butyl-2-ethylamino-6-methylpyrimidine-4-yl dimethylsulfamate	≥ 945 g/kg Impurities: Ethirimol: max. 2 g/kg Toluene: max. 3 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on bupirimate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms.

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						Conditions of au- thorisation shall include risk mitigation measures, where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigations, where appropriate, — the in-field risk to non-target arthropods. The Member States concerned shall request the submission of confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured, by appropriate analytical data; including information on the relevance of the impurities; (2) the equivalence between the specifications of the technical material; as commercially manufactured, and those of the test material used in the toxicity dossiers; (3) the kinetic parameters, the soil degradation and the adsorption and desorption parameter for the major soil metabolite DE-B (de-ethyl-bupirimate). The Member States concerned shall ensure that the applicant submits such confirmatory data and information to the Commission set out in points (1) and (2) by 30 November 2011 and the information set out in point (3) by 31 May 2013.

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338	Fenbutatin oxide CAS No: 13356-08-6 CIPAC No: 359	bis[tris(2-methyl-2-phenylpropyl)-tin]oxide	≥ 970 g/kg mpurities: bis[hydroxybis(2-methyl-2-phenylpropyl)tin] oxide (SD 31723): not more than 3 g/kg	1 June 2011	31 May 2021	PART A Only uses as acaricide in greenhouses may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenbutatin oxide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the technical specification of the impurity content, — the residue levels in small tomato varieties (cherry tomatoes), — the operator safety. Conditions of use shall prescribe the application of adequate personal protective equipment, where appropriate, — the risk to aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of information confirming the results of the risk assessment, on the basis of

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						most recent scientific knowledge, as regards the impurity SD 31723. That information shall concern the following points: (a) genotoxicological potential; (b) ecotoxicological relevance; (c) spectra, storage stability and methods of analysis in the formulation. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
339	Fenoxycarb CAS No: 79127-80-3 CIPAC No: 425	Ethyl 2-(4-phenoxyphenoxy) ethyl-carbamate	≥ 970 g/kg Impurities: Toluene: max. 1 g/kg	1 June 2011	31 May 2021	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenoxycarb, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate,

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						— the risk to bees and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of information confirming the risk assessment for non- target arthropods and for bee brood. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013.
340	1-decanol CAS No: 112-30-1 CIPAC No: 831	Decan-1-ol	≥ 960 g/kg	1 June 2011	31 May 2021	PART A Only uses as plant growth regulator. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on 1-decanol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers from residues in case of use on food or feed crops, — the risk for operator and ensure that conditions of use prescribe the application of adequate personal protective equipment

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						where appropriate, — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the risk to aquatic organisms, — the risk to non-target arthropods and bees that may be exposed to the active substance by visiting flowering weeds present in the crop at time of application. Risk mitigation measures shall be applied, where appropriate. The Member States concerned shall request the submission of confirmatory information, as regards the risk to aquatic organisms and of information confirming the groundwater, surface water and sediment exposure assessments. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
341	Isoxaben CAS No: 82558-50-7 CIPAC No: 701	N-[3-(1-ethyl-1-methylpropyl)-1,2- oxazol-5-yl]-2,6-dimethoxybenzamide	≥ 910 g/kg Toluene: ≤ 3g/kg	1 June 2011	31 May 2021	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on isoxaben, and in particular Appendices I and

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						II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, the risk to non-target terrestrial plants and the potential leaching of metabolites to groundwater. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the specification of the technical material, as commercially manufactured; (b) the relevance of the impurities; (c) the residues in rotational crops; (d) the potential risk to aquatic organisms. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a) and (b) within 6 months from the entry into force of the Directive of inclusion and the information set out in points (c) and (d) by 31 May 2013.
342	Flurochloridone CAS No: 61213-25-0 CIPAC No: 430	(3RS,4RS;3RS,4SR)-3-chloro-4-chloromethyl-1-(α,α,α-trifluoro-	≥ 940 g/kg. Relevant impurities: Toluene: max 8	1 June 2011	31 May 2021	PART A Only uses as herbicide may be authorised. PART B

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		m-tolyl)-2-pyrrolidone	g/kg			For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flurochloridone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 February 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: 1. the risk for non-target plants and aquatic organisms; 2. the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicant submits to the Commission further confirmatory information as regards: 1. the relevance of impurities other than toluene; 2. the compliance of ecotoxicological test material with the technical specifications; 3. the relevance of the groundwater metabolite R42819 (R42819: (4RS)-4- (chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one); 4. the potential endocrine disrupting properties of flurochloridone. The Member States concerned shall ensure that

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						the applicant submits to the Commission the information set out in points (1) and (2) by 1 December 2011, the information set out in point (3) by 31 May 2013 and the information set out in point (4) within 2 years after the adoption of the OECD test guidelines on endocrine disruption.
343	Fluometuron CAS No: 2164-17-2 CIPAC No: 159	1,1-dimethyl-3-(α,α,α -trifluoro-m-tolyl)urea	≥ 940 g/kg	1 June 2011	31 May 2021	PART A Only uses as herbicide on cotton may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fluometuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: (a) pay particular attention to the protection of the operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; (b) pay particular attention to the protection of the groundwater where the active substance is applied in regions with vulnerable soil and/or climatic conditions; they shall ensure that

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						conditions of authorisation include risk mitigation measures and the obligation to carry out monitoring programmes to verify potential leaching of fluometuron and soil metabolites desmethyl-fluometuron and trifluoromethylaniline in vulnerable areas, where appropriate; (c) pay particular attention to the risk to non-target soil macro-organisms others than earthworms and non-target plants, and ensure that conditions of au- thorisation include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicants submit to the Commission confirmatory information as regards: (a) the toxicological properties of the plant metabolite trifluoroacetic acid; (b) the analytical methods for the monitoring of fluometuron in air; (c) the analytical methods for the monitoring of the soil metabolite trifluo- romethylaniline in soil and water; (d) the relevance for ground water of the soil metabolites desmethyl-fluometuron and trifluoromethylaniline, if fluometuron is classified under Regulation (EC) No 1272/2008 as "suspected of causing cancer". The Member States concerned shall ensure that

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						the applicants submit to the Commission the information set out in points (a), (b) and (c) by 31 March 2013 and the information set out in point (d) within 6 months from the notification of the decision classifying fluometuron.
344	Dithianon CAS No: 3347-22-6 CIPAC No: 153	5,10-dihydro-5,10-dioxonaphtho[2,3-b]-1,4- dithiine-2,3-dicarbonitrile	≥ 930 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dithianon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: (a) pay particular attention to the protection of aquatic organisms; conditions of use shall include risk mitigation measures, where appropriate; (b) pay particular attention to the operator safety; conditions of use shall include the application of adequate personal protective equipment, where appropriate; (c) pay particular attention to the long-term risks to birds; conditions of use shall include risk mitigation measures, where appropriate.

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						The Member States concerned shall request the submission of confirmatory information as regards: (a) the storage stability and the nature of residues in processed products; (b) the aquatic and groundwater exposure assessment for phthalic acid; (c) the risk assessment for aquatic organisms with respect to phthalic acid, phthalaldehyde and 1,2 benzenedimethanol. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013.
345	Fenazaquin CAS No: 120928-09-8 CIPAC No: 693	4-tert-butylphenethyl quinazolin-4-yl ether	≥ 975 g/kg	1 June 2011	31 May 2021	PART A Only uses as acaricide on ornamentals in greenhouses may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenazaquin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: (1) pay particular attention to the protection of aquatic organisms;

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						(2) pay particular attention to the risk to operators and ensure that conditions of use include the application of adequate personal protective equipment; (3) pay particular attention to the protection of bees and ensure that conditions of use include risk mitigation measures, where appropriate; (4) provide for conditions of use which ensure that there are no residues of fenazaquin in crops for human and animal consumption.
346	Flutriafol CAS No: 76674-21-0 CIPAC No: 436	(RS)-2,4′-difluoro-α-(1H-1,2,4- triazol-1-ylmethyl)benzhydryl alcohol	≥ 920 g/kg (racemate) Relevant impurities: dimethyl sulphate: max content 0,1 g/kg dimethylformamide: max content 1 g/kg methanol: max content 1 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on flutriafol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, shall be taken into account. In this overall assessment Member States shall: (1) pay particular attention to the protection of the workers' safety and ensure that conditions of use include the application of adequate personal protective equipment; (2) pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or

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						climatic conditions; (3) pay particular attention to the long-term risk to insectivorous birds. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards: (a) the relevance of the impurities present in the technical specifications; (b) the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; (c) the long-term risk to insectivorous birds. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 1 December 2011, the information set out in points (b) and (c) by 31 May 2013.
347	Sintofen CAS No 130561-48-7 CIPAC No 717	1-(4-chlorophenyl)-1,4-dihydro- 5-(2-methoxyethoxy)-4- oxocinnoline-3-carboxylic acid	≥ 980 g/kg Impurities: 2-methoxyethanol, not more than 0,25 g/kg N,N-dimethylformamide, not more than	1 June 2011	31 May 2021	PART A Only uses as a plant growth regulator on wheat for hybrid seed production not intended for human consumption may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sintofen, and in particular Appendices I

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			1,5 g/kg			and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate risk mitigation measures. They shall ensure that wheat treated with sintofen does not enter the food and feed chain. The Member States concerned shall request the submission of confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data; (2) the relevance of the impurities present in the technical specifications, except of the impurities 2-methoxyethanol and N,N-dimethylformamide; (3) the relevance of the test material used in the toxicity and ecotoxicity dossiers in view of the specification of the technical material; (4) the metabolic profile of sintofen in rotational crops. The Member States concerned shall ensure that the applicant submits to the Commission: the information set out in points (1) (2) and (3) by 1

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						December 2011 and the information set out in point (4) by 31 May 2013.
348	Diclofop CAS No 40843-25-2 (parent) CAS No 257-141-8 (diclofop-methyl) CIPAC No 358 (parent) CIPAC No 358.201 (diclofop-methyl)	Diclofop (RS)-2-[4-(2,4-dichlorophenoxy) phenoxy]propionic acid Diclofop-methyl methyl (RS)-2-[4-(2,4-dichlorophenoxy) phenoxy]propionate	≥ 980 g/kg (expressed as diclofop-methyl)	1 June 2011	31 May 2021	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on diclofop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: — pay particular attention to the operators and workers safety and include as a condition for authorisation the application of adequate personal protective equipment, — pay particular attention to the risk to aquatic organisms and non-target plants and require risk mitigation measures to be applied. The Member States concerned shall request the submission of confirmatory information as regards: (a) a metabolism study on cereals; (b) an update of the risk assessment concerning the possible environmental impact of the preferential degradation/conversion of the

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						isomers. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 31 May 2013 and the information set out in point (b) at latest 2 years after the adoption of a specific guidance document on evaluation of isomers mixtures.
349	Lime sulphur CAS No: 1344 – 81 – 6 CIPAC No: 17	Calcium polysulfide	≥ 290 g/Kg.	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on lime sulphur, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — operator safety and shall ensure that the conditions of authorisation include appropriate protective measures, — to the protection of aquatic organisms and non-target arthropods and shall ensure that the conditions of use include risk mitigation measures as appropriate.
350	Azadirachtin CAS No: 11141-	Azadirachtin A:	Expressed as azadirachtin A:	1 June 2011	31 May 2021	PART A Only uses as insecticide may be authorised.

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	17-6 as azadirachtin A CIPAC No: 627 as azadirachtin A	dimethyl (2aR,3S,4S,4aR,5S,7aS,8S, 10R,10aS,10bR)-10- acetoxy-3,5-dihydroxy-4-[(1aR,2S,3aS,6aS, 7S,7aS)- 6a-hydroxy-7a-methyl-3a,6a,7,7a-tetrahydro-2,7-methanofuro[2,3-b]oxireno[e]oxepin-1a(2H)- yl]-4-methyl-8-{[(2E)-2- methylbut-2-enoyl]oxy}octahydro-1H-naphtho[1,8a-c:4,5-b′c′]difuran-5,10a(8H)-dicarboxylate.	≥ 111 g/kg Sum of the aflatoxins B 1, B 2, G 1 and G 2 must not exceed 300 µg/kg of the azadirachtin A content.			PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on azadirachtin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels, — the protection of non-target arthropods and aquatic organisms. Risk mitigation measures shall be applied where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: — the relationship between azadirachtin A and the rest of the active components in the neem seeds extract with respect to amount, biological activity and persistence, in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical

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						material, residue definition and groundwater risk assessment. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 December 2013.
351	Aluminium sulphate CAS No: 10043-01-3 CIPAC not available	*Aluminium sulphate*	970 g/kg	1 June 2011	31 May 2021	PART A Only indoor uses as post-harvest bactericide for ornamental plants may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on aluminium sulphate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. The Member States concerned shall request the submission of confirmatory information as regards the specification of the technical material, as commercially manufactured, in the form of appropriate analytical data. The Member States concerned shall ensure that the applicant submits such information to the Commission by 1 December 2011
352	bromadiolone CAS No: 28772-56-7	3-[(1RS,3RS;1RS,3SR)- 3-(4′-	≥ 970 g/kg	1 June 2011	31 May 2021	PART A Only uses as rodenticide in the form of pre-prepared baits placed into the rodent tunnels may

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	CIPAC No: 371	bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin				be authorised. The nominal concentration of the active substance in the plant protection products shall not exceed 50 mg/kg. Authorisations shall be granted for uses by professional users only. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on bromadiolone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: — pay particular attention to the risk to professional operators and ensure that conditions of use include the application of adequate personal protective equipment where appropriate, — pay particular attention to the risk to birds and non-target mammals from primary and secondary poisoning. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as

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						regards: (a) the specification of the technical material, as commercially manufactured, in the form of appropriate analytical data; (b) the relevance of the impurities; (c) the determination of bromadiolone in water with a limit of quantification of 0,01 µg/l; (d) the effectiveness of proposed mitigation measures to reduce risk to birds and non- target mammals; (e) the groundwater exposure assessment in respect of metabolites. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b) and (c) by 30 November 2011 and the information set out in points (d) and (e) by 31 May 2013.
353	Paclobutrazol CAS No: 76738-62-0 CIPAC No: 445	(2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1- yl)pentan-3-ol	≥ 930 g/kg	1 June 2011	31 May 2021	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on paclobutrazol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken

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						into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic plants and ensure that conditions of use include the risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured; (2) the analytical methods in soil and surface water for the metabolite NOA457654; (3) the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; (4) the potential endocrine disrupting properties of paclobutrazol; (5) the potential adverse effects of breakdown products of the different optical structures of paclobutrazol and its metabolite CGA 149907 on the environmental compartments soil, water and air. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 30 November 2011, the information set out in points (3) by 31 May 2013, the information set out in point (4) within two years after the adoption of

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						the OECD test guidelines on endocrine disruption and the information set out in point (5) within two years after the adoption of specific guidance.
354	Pencycuron CAS No 66063-05-6 CIPAC No 402	1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea	≥ 980 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pencycuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of large omnivorous mammals. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (1) the fate and behaviour in soil of the chlorophenyl and cyclopentyl portions of pencycuron; (2) the fate and behaviour in natural surface water and sediment systems of the chlorophenyl

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						and phenyl portions of pencycuron; (3) the long-term risk to large omnivorous mammals. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1), (2) and (3) by 31 May 2013.
355	Tebufenozide CAS No: 112410-23-8 CIPAC No: 724	N-tert-butyl-N′-(4-ethylbenzoyl)-3,5-dimethylbenzohydrazide	≥ 970 g/kg Relevant impurity t-butyl hydrazine < 0,001 g/kg	1 June 2011	31 May 2021	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on tebufenozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: (1) pay particular attention to the safety of operators and workers after re-entry and ensure that conditions of authorisation prescribe appropriate protective equipment; (2) pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) pay particular attention to the protection of

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						aquatic organisms and ensure that conditions of use prescribe adequate mitigation measures; (4) pay particular attention to the risk to Lepidoptera non- target insects. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information, as regards: (1) the relevance of metabolites RH-6595, RH-2651, M2; (2) the degradation of tebufenozide in anaerobic soils and soils of alkaline pH. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 31 May 2013.
356	Carbetamide CAS No: 16118-49-3 CIPAC No: 95	(R)-1-(Ethylcarbamoyl) ethyl carbanilate	≥ 950 g/kg	1 June 2011	31 May 2021	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI the conclusions of the review report on carbetamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, shall be taken into account.

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						In this overall assessment Member States shall pay particular attention to: (a) the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (b) the risk to non-target plants; (c) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.
357	Carboxin CAS No: 5234-68-4 CIPAC No: 273	5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide	≥ 970 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide for seed treatment may be authorised. Member States shall ensure that authorisations provide that seed coating be performed exclusively in professional seed treatment facilities and that these facilities apply the best available techniques to exclude the release of dust clouds during storage, transport and application. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on carboxin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.

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						In this overall assessment Member States shall pay particular attention to: (a) the risk to operators; (b) the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (c) the risk to birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the specification of the technical material, as commercially manufactured, including appropriate analytical data; (b) the relevance of the impurities; (c) comparison and verification of the test material used in the mammalian toxicity and ecotoxicity dossiers against the specification of the technical material; (d) analytical methods for the monitoring of the metabolite M6 [2-{[anilino(oxo)acetyl]sulfanyl}ethyl acetate.] in soil, groundwater and surface water and for the monitoring of metabolite M9 [(2RS)-2-hydroxy-2-methyl-N-phenyl-1,4-oxathiane-3-carboxamide 4-oxide.] in groundwater; (e) additional values regarding the period

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						required for 50 percent dissipation in soil for the soil metabolites P/V-54 [2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4-oxide] and P/V-55 [2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4,4-dioxide.]; (f) rotational crop metabolism; (g) the long-term risk to granivorous birds, granivorous mammals and herbivorous mammals; (h) the relevance for ground water of the soil metabolites P/V-54, P/V-55 and M9 if carboxin is classified under Regulation (EC) No 1272/2008 as "suspected of causing cancer". The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b) and (c) by 1 December 2011, the information set out in points (d), (e), (f) and (g) by 31 May 2013 and the information set out in point (h) within six months after the notification of the Decision classifying carboxin.
358	Cyproconazole CAS No: 94361-06-5 CIPAC No: 600	(2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4- triazol-1-yl)butan-2-ol	≥ 940 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cyproconazole, and in particular

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						Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the dietary exposure of consumers to the residues of triazole derivative metabolites (TDMs); (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the toxicological relevance of the impurities in the technical specification; (b) analytical methods for the monitoring of cyproconazole in soil, body fluids and tissues; (c) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; (d) the long-term risk to herbivorous mammals; (e) the possible environmental impact of the preferential degradation and/or conversion of the mixture of isomers. The Member States concerned shall ensure that the applicant submits to the Commission the

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						information set out in point (a) by 1 December 2011, the information set out in points (b), (c) and (d) by 31 May 2013 and the information set out in point (e) within two years after the adoption of specific guidance.
359	Dazomet CAS No: 533-74-4 CIPAC No: 146	3,5-dimethyl-1,3,5-thiadiazinane-2-thione or tetrahydro-3,5-dimethyl- 1,3,5-thiadiazine-2-thione	≥ 950 g/kg	1 June 2011	31 May 2021	PART A Only uses as nematicide, fungicide, herbicide and insecticide may be authorised. Only application as soil fumigant may be authorised. Use shall be limited to one application every third year. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dazomet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to operators, workers and bystanders; (b) the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (c) the risk to aquatic organisms. Conditions of use shall include risk mitigation

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						measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the potential groundwater contamination by methyl isothiocyanate; (b) the assessment of the long range atmospheric transport potential of methyl isothiocyanate and related environmental risks; (c) the acute risk to insectivorous birds; (d) the long term risk to birds and mammals. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b), (c) and (d) by 31 May 2013.
360	Metaldehyde CAS No: 108-62-3 (tetramer) 9002-91-9 (homopolymer) CIPAC No: 62	r-2, c-4, c-6, c-8-tetramethyl-1,3,5,7-tetroxocane	≥ 985 g/kg acetaldehyde max. 1,5 g/kg	1 June 2011	31 May 2021	PART A Only uses as molluscicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metaldehyde, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to:

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						(a) the risk to operators and workers; (b) the dietary exposure situation of consumers in view of future revisions of maximum residue levels; (c) the acute risk and long-term risk to birds and mammals. Member States shall ensure that authorisations shall contain an effective dog repellent agent. Conditions of use shall include risk mitigation measures, where appropriate
361	Hexythiazox CAS No 78587-05-0 CIPAC No 439	(4RS,5RS)-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxo-1,3-thiazolidine-3-carboxamide	≥ 976 g/kg (1:1 mixture of (4R, 5R) and (4S, 5S))	1 June 2011	31 May 2021	PART A Only uses as acaricide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on hexythiazox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate, — the operators and workers safety. Conditions of use shall include protective

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						measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the toxicological relevance of the metabolite PT-1-3 [*(4S,5S)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one and (4R,5R)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one*.]; (b) the potential occurrence of the metabolite PT-1-3 in processed commodities; (c) the potential adverse effects of hexythiazox on bee brood; (d) the possible impact of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environment. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b) and (c) by 31 May 2013 and the information set out in point (d) 2 years after the adoption of specific guidance.
362	Hymexazol CAS No: 10004-44-1 CIPAC No: 528	5-methylisoxazol-3-ol (or 5-methyl-1,2-oxazol-3-ol)	≥ 985 g/kg	1 June 2011	31 May 2021	PART A Only uses as fungicide for seed pelleting of sugar beets in professional seed treatment facilities may be authorised. PART B

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						For the implementation of the uniform principles of Annex VI, the conclusions of the review report on hymexazol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operators and workers safety. Conditions of authorisation shall include protective measures, where appropriate, — the risk to granivorous birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards the nature of residues in root crops and the risk for granivorous birds and mammals. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013."