L.N. 270 of 2012

PESTICIDES CONTROL ACT
(CAP. 430)

Biocides (Amendment) (No. 2) Regulations, 2012

IN exercise of the powers conferred by articles 4 and 5 of the Pesticides Control Act, the Minister for Resources and Rural Affairs, in consultation with the Prime Minister and with the Ministers responsible for Health and the Environment, has made the following regulations:-

Citation.

1. The title of these regulations is the Biocides (Amendment) (No. 2) Regulations, 2012, and these regulations shall be read and construed as one with the Biocides Regulations, hereinafter referred to as "the principal regulations". S.L. 430.03

Amends Schedule I to the principal regulations.

2. Part A of Schedule I to the principal regulations shall be substituted by the following:

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"PART A

List of Active Substances with Requirements Agreed At Community Level for Inclusion in Biocidal Products

No	Common Name	IUPAC Name Identifica-tion Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)

1	sulfurylfluoride	sulfuryl difluoride EC No: 220-281-5 CAS No: 2699-79-8	> 994 g/kg	1 January 2009	31 December 2010	31 December 2018	8	Member States shall ensure that authorizations are subject to the following conditions: (1) the product may only be sold to and used by professionals trained to use it; (2) appropriate risk mitigation measures are included for operators and bystanders; (3) concentrations of sulfuryl fluoride in remote tropospheric air are monitored. Member States shall also ensure that reports of the monitoring referred to in point (3) are transmitted by authorisation holders directly to the Commission every fifth year starting from 1 January 2009.
			994 g/kg	1 July 2011	30 June 2013	30 June 2021	18	Member States shall ensure that authorizations are subject to the following conditions: (1) Products shall only be sold to and used by professionals trained to use them. (2) Appropriate measures to protect fumigators and bystanders during fumigation and venting of treated buildings or other enclosures must be taken. (3) Labels and/or safety-data sheets of products shall indicate that, prior to fumigation of any enclosure, all food items must be removed. (4) Concentrations of sulfuryl fluoride in remote tropospheric air are monitored. (5) Member States shall also ensure that reports of the monitoring referred to in point (4) are transmitted by authorization holders directly to the Commission every fifth year, starting at the latest five years after the authorisation. The limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuryl fluoride/m3 of tropospheric air).

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2	dichlofluanid	N-(Dichlorofluoromethylthio)-N′,N′-dimethyl-N-phenylsulfamide EC No: 214-118-7 CAS No: 1085-98-9	> 96% w/w	1 March 2009	28 February 2011	28 February 2019	8	Member States shall ensure that authorizations are subject to the following conditions: (1) Products authorised for industrial and/or professional use must be used with appropriate personal protective equipment. (2) In view of the risks identified for the soil compartment appropriate risk mitigation measures must be taken to protect that compartment. (3) Labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for re-use or disposal.

3	clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-Nitroguanidine EC No: 433-460-1 CAS No: 210880-92-5	950 g/kg	1 February 2010	31 January 2012	31 January 2020	8	When assessing, in accordance with Article 5 and Annex VI, the application for authorization of a product, Member States shall assess those use / exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: In view of the risk identified for the soil, surface water and groundwater compartments, products cannot be authorised for the treatment of wood that will be used outdoors unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for reuse or disposal.

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4	Difethialone	3-[3-(4′-bromo[1,1′biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one EC No: n/a CAS No: 104653-34-1	976 g/kg	1 November2009	31 October 2011	31 October 2014	14	In view of the fact that the active substance characteristics render it poten-tially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 0,0025% w/w and only ready-for-use baits shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

5	etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether EC No: 407-980-2 CAS No: 80844-07-1	970 g/kg	1 February 2010	31 January 2012	31 January 2020	8	When assessing, in accordance with Article 5 and Annex VI, the application for authorisation of a product, Member States shall access those use and/or exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: In view of the risk identified for workers, products cannot be used year round unless dermal absorption data is provided to demonstrate that there are no unacceptable risks from chronic exposure. In addition, products intended for industrial use must be used with appropriate personal protective equipment.

6	tebuconazole	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl) pentan-3-ol EC No: 403-640-2 CAS No: 107534-96-3	950 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorizations are subject to the following conditions: In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those com-partments. In particular, labels and/or safety data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. In addition, products cannot be authorised for the in situ treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

7	carbondioxide	carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November2009	31 October 2011	31 October 2019	14	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.

8	propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC No: 262-104-4 CAS No: 60207-90-1	930 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorizations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. In addition, products cannot be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

9	Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

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10	K-HDO	Cyclohexylhydroxydiazene1-oxide, potassium salt EC No: n/a CAS No: 66603-10-9 (This entry also covers thehydrated forms of K-HDO)	977 g/kg	1 July 2010	30 June 2012	30 June 2020	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. Member States shall ensure that authorizations are subject to the following conditions: (1) in view of the possible risks for the environment and workers, products shall not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in accordance with Article 5 and Annex VI; (2) in view of the assumptions made during the risk assessment, products must be used with appropriate personal protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means; (3) in view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.

11	IPBC	3-iodo-2-propynyl butylcarbamate EC No: 259-627-5 CAS No: 55406-53-6	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure that authorisations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hardstanding to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

B 2280

12	Chlorophacinone	Chlorophacinone EC No: 223-003-0	978 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the identified risks for non-target animals, the active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products other than tracking powder shall not exceed 50 mg/kg and only ready-for use products shall be authorised. 2. Products to be used as tracking powder shall only be placed on the market for use by trained professionals. 3. Products shall contain an aversive agent and, where appropriate, a dye. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

13	Thiabendazole	2-thiazol-4-yl-1H-benzoimidazole EC No: 205-725-8 CAS No: 148-79-8	985 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure that authorizations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, with respect to the double-vacuum and dipping application tasks, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorization that risks to industrial and/or professional users can be reduced to an acceptable level by others means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

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14	thiamethoxam	thiamethoxam EC No: 428-650-4 CAS No: 153719-23-4	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure that authorizations are subject to the following conditions: In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In part=-icular, labels and/or safety data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data have been submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

15	alphachloralose	(R)-1,2-O-(2.2,2-Trichloroethylidene)-α-D-glucofuranose	825 g/kg	1 July 2011	30 June 2013	30 June 2021	14	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. In particular, products cannot be authorised for outdoor use unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 40 g/kg. 2. Products shall contain an aversive agent and a dye. 3. Only products for use in tamper resistant and securely closed bait boxes shall be authorised.

16	brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-napthyl]-4-hydroxycoumarin EC No: 259-980-5 CAS No: 56073-10-0	950 g/kg	1 February 2012	31 January 2014	31 January 2017	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

17	bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one EC No: 249-205-9 CAS No: 28772-56-7	969 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

18	Thiaclopri d	(Z)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidenecyanamide EC No: n/a CAS No: 111988-49-9	975 g/kg	1 January 2010	n/a	31 December 2019	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorization that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures

								must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. 3. Products shall not be authorised for the in situ treatment of wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be in contact with surface water, unless data have been submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
19	Indoxacarb(enantiomericreactionmass S:R75:25)	Reaction mass of methyl(S)- and methyl(R)-7-chloro-2.3,4a,5-tetrahydro-2-[methoxycarbonyl-(4-trifluoromethoxyphenyl)carbamoyl]indeno[1,2-e][1.3,4]oxadiazine-4acarboxylate (This entrycovers the 75:25 reactionmass of the S and R enantiomers)EC No: n/a	796 g/kg	1 January 2010	n/a	31 December 2019	18	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate

								measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans, of non-target species and of the aquatic environment. In particular, labels and/or safety-data sheets of products authorized shall indicate that: 1. Products shall not be placed in areas accessible to infants, children and companion animals. 2. Products shall be positioned away from external drains. 3. Unused products shall be disposed of properly and not washed down the drain. For amateur uses, only ready-to-use products shall be authorised.
20	aluminium phosphide releasingphosphine	aluminium phosphide EC No: 244-088-0 CAS No: 20859-73-8	830 g/kg	1 September2011	31 August 2013	31 August 2021	14	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment.

								When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. In particular, products cannot be authorised for indoor use unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorizations are subject to the following conditions: 1. Products shall only be sold to and used by specifically trained professionals. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. These include, amongst others, the use of appropriate personal protective equipment, the use of applicators and the presentation of the product in a form designed to reduce operator exposure to an acceptable level. 3. In view of the risks identified for terrestrial non-target species, appropriate risk reduction measures must be applied. These include, amongst others, the non-treatment of areas where other burrowing mammals than the target species are present.

B 2290

			830 g/kg	1 February 2012	31 January 2014	31 January 2022	18	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorizations are subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas.

								3. For products containing aluminium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorized products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/ 2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).

B 2292

21	fenpropimorph	(+/-)-cis-4-[3-(p-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine EC No: 266-719-9 CAS No: 67564-91-4	930 g/kg	1 July 2011	30 June 2013	30 June 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means.

								2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

22	boric acid	boric acid EC No: 233-139-2 CAS No: 10043-35-3	990 g/kg	1 September 2011	31 August 2013	31 August 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, he populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonst-rated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will

								be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
23	boric oxide	Diboron trioxide EC No: 215-125-8 CAS No: 1303-86-2	975 g/kg	1 September2011	31 August 2013	31 August 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.

								Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

24	disodiumtetraborate	disodium tetraborate EC No: 215-540-4 CAS No (anhydrous): 1330-43-4 CAS No (pentahydrate):12267-73-1 CAS No (decahydrate):1303-96-4	990 g/kg	1 September2011	31 August 2013	31 August 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorisations are subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will

								be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
25	disodiumoctaboratetetrahydrate	disodium octaborate tetrahydrateEC No: 234-541-0 CAS No: 12280-03-4	975 g/kg	1 September2011	31 August 2013	31 August 2021	8	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.

								Member States shall ensure that authorizations are subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. In particular, labels and/or safety-data sheets of products authorized for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

B 2300

26	Magnesiumphosphidereleasing phosphine	Trimagnesium diphosphideEC No: 235-023-7 CAS No: 12057-74-8	880 g/kg	1 February 2012	31 January 2014	31 January 2022	18	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use. When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Member States shall ensure that authorizations are subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also

								the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas. 3. For products containing magnesium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).
27	Nitrogen	Nitrogen EC No: 231-783-9 CAS No: 7727-37-9	999 g/kg	1 Septemb er2011	31 August 2013	31 August 2021	18	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Member States shall ensure that authorizations are subject to the following conditions: 1. Products may only be sold to and used by professionals trained to use them. 2. Safe working practices and safe systems of work must be in place to ensure minimum risk, including the availability of personal protective equipment if necessary.

B 2302

28	Coumatetralyl	Coumatetralyl EC No: 227-424-0 CAS No: 5836-29-3	980 g/kg	1 July 2011	30 June 2013	30 June 2016	14	In view of the identified risks for non-target animals, the active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5) (i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products other than tracking powder shall not exceed 375 mg/kg and only ready-for use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

29	tolylfluanid	Dichloro-N-[(dimethylamino)sulphonyl]fluoro-N-(p-tolyl)methanesulphenamide EC No: 211-986-9 CAS No: 731-27-1	960 g/kg	1 October 2011	30 September 2013	30 September2021	8	Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering. Member States shall ensure that authorizations are subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonst-rated in the application for product authorization that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compart-ments. In particular, labels and/or safety-data sheets of products authorised for industrial or professional use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

B 2304

30	Acrolein	Acrylaldehyde EC No: 203-453-4 CAS No: 107-02-8	913 g/kg	1 September 2010	Not applicable	31 August 2020	12	When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: 1. Waste waters containing acrolein shall be monitored prior to discharge, unless it can be demonstrated that risks for the environment can be reduced by other means. Where necessary in view of the risks to marine environment, waste waters shall be held in suitable tanks or reservoirs or appropriately treated before discharge. 2. Products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, and safe operational procedures shall be established, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means.

31	Flocoumafen	4-hydroxy-3-[(1RS,3RS;1RS,3RS)-1,2,3,4-tetrahydro-3-[4-(4-trifluoromethylbenzyloxy)phenyl]-1-naphthyl] coumarin EC No 421-960-0 CAS No 90035-08-8	955 g/kg	1 October 2011	30 September 2013	30 September2016	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. The nominal concentration of the active substance in products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. Those include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

B 2306

32	Warfarin	(RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin EC No: 201-377-6 CAS No: 81-81-2	990 g/kg	1 February 2012	31 January 2014	31 January 2017	14	The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

33	Warfarinsodium	Sodium 2-oxo-3-(3-oxo-1-phenylbutyl)chromen-4-olate EC No: 204-929-4 CAS No: 129-06-6	910 g/kg	1 February 2012	31 January 2014	31 January 2017	14	The active substance shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorizations are subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

B 2308

34	Dazomet	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione EC No: 208-576-7 CAS No: 533-74-4	960 g/kg	1 August 2012	31 July 2014	31 July 2022	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. In particular, where relevant, Member States shall assess any other use than professional use outdoors for the remedial treatment of wooden poles by insertion of granules. Member States shall ensure that authorisations are subject to the following condition: Products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means.

35	N,N-diethyl-meta-toluamide	N,N-diethyl-m-toluamide EC No: 205-149-7 CAS No: 134-62-3	970 g/kg	1 August 2012	31 July 2014	31 July 2022	19	Member States shall ensure that authorisations are subject to the following conditions: 1. primary exposure of humans shall be minimized by considering and applying appropriate risk mitigation measures, including, where applicable, instructions for the amount and frequency of application of the product on human skin; 2. labels on products intended for application on human skin, hair or clothing shall indicate that the product is intended only for restricted use on children between two and twelve years old, and that it is not intended for use on children less than two years old, unless it can be demonstrated in the application for product authorisation that the product will meet the requirements of Article 5 and Annex VI without such measures; 3. products must contain deterrents for ingestion.

B 2310

36	Metofluthrin	RTZ isomer: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl-(1R,3R)-2,2-dimethyl-3-(Z)-(prop-1-enyl)cyclopropanecarboxylate EC No: n.a. CAS No: 240494-71-7 Sum of all isomers: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (EZ)-(1RS,3RS;1SR,3SR)-2,2-dimethyl-3-prop-1-enylcyclopropanecarboxylate EC No: n.a. CAS No: 240494-70-6	The active substance shall comply with both the following minimum purities: RTZ isomer: 754 g/kg Sum of all isomers: 930 g/kg	1 May 2011	Not applicable	30 April 2021	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the European level risk assessment.

37	Spinosad	EC No: 434-300-1 CAS No: 168316-95-8 Spinosad is a mixture of 50-95 % spinosyn A and 5-50 % spinosyn D. Spinosyn A (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-[(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)oxy]- 13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione CAS No: 131929-60-7 Spinosyn D (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-[(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyr	850 g/kg	1 November 2012	31 October 2014	31 October 2022	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: Authorisations shall be subject to appropriate risk mitigation measures. In particular, products authorised for professional use by spraying shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by others means. For products containing spinosad that may lead to residues in food or feed, Member States shall verify the need to set new and/or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 and/or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

		dimethyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione CAS No: 131929-63-0						
38	Bifenthrin	IUPAC name: 2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate EC No: n.a. CAS No: 82657-04-3	911 g/kg	1 February 2013	31 January 2015	31 January 2023	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental comp-artments and populations that have not been representatively add-ressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: Products shall be authorised only for industrial or professional use, unless it is dem-onstrated in the application for product authorisation that risks to non-professional users can be reduced to acceptable levels in accordance with Article 5 and Annex VI. Products authorised for industrial or professional use must be used with appropriate personal prot-ective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means.

								Appropriate risk mit-igation measures shall be taken to protect the soil and aquatic comp-artments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard-standing, or both, to prevent direct losses to soil or water, and that any losses from the ap-plication of the product shall be collected for reuse or disposal. Products shall not be authorised for the *in situ* treatment of wood outdoors, or for treatment of wood that will be either continually exp-osed to the weather or protected from the weather but subject to frequent wetting, unless data have been submitted dem-onstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the app-lication of appropriate risk mitigation measures.
39	(Z,E)-tetradeca-9, 12-dienyl acetate	(9Z,12E)-Tetradeca-9, 12-dien-1-yl acetate EC No: n.a. CAS No: 30507-70-1	977 g/kg	1 February 2013	31 January 2015	31 January 2023	19	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed in Union level risk assessment. Member States shall ensure that authorisations are subject to the following condition: Labels for biocidal products containing (Z,E)-tetradeca-9,12-dienyl acetate shall indicate that those products shall not be used in spaces where un-packaged food or feed is kept.

B 2314

40	Fenoxycarb	IUPAC name: Ethyl [2-(4-phenoxyphenoxy) ethyl]carbamate EC No: 276-696-7 CAS No: 72490-01-8	960 g/kg	1 February 2013	31 January 2015	31 January 2023	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental com-partments and populations that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: Appropriate risk mit-igation measures shall be taken to protect the soil and aquatic comp-artments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard-standing under roof, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. Products shall not be authorised for treatment of wood that will be used in outdoor constructions near or above water, unless data is submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.

41	Nonanoic acid, Pelargonic acid	IUPAC name: Nonanoic acid EC No: 203-931-2 CAS No: 112-05-0	896 g/kg	1 February 2013	31 January 2015	31 January 2023	19	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed in Union level risk assessment.

B 2316

42	imidaclopr id	(2E)-1-[(6-chloropyr idin- 3-yl)methyl]-N-nitroimid azolidin-2-imine EC No: 428-040-8 CAS No: 138261-41-3	970 g/kg	1 July 2013	30 June 2015	30 June 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environ-mental compart-ments that have not been representati-vely addressed in the Union level risk assessment. Products shall not be authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented, unless data is submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Authorisations shall be subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children. For products containing imidacloprid that may lead to residues in food or feed, Member States shall verify the need to set new or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/ 2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

43	Abamectin	Abamectin is a mixture of avermectin B 1a and avermectin B 1b *Abamectin:* IUPAC name: n.a. EC No: n.a. CAS No: 71751-41-2 *Avermectin B 1a :* IUPAC name: (10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R, 24S)-6'- [(S)-secbutyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.1 4,8.0 20,24]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-	The active substance shall comply with all the following purities: *Abamectin:* minimum 900 g/kg *Avermectin B 1a :* minimum 830 g/kg *Avermectin B 1b :* maximum 80 g/kg	1 July 2013	30 June 2015	30 June 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products applied in such a way that emission to a sewage treatment plant cannot be prevented shall not be authorised for those application rates for which the Union level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Authorisations shall be subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children.

		L-arabino-hexopyranosyl)- 3-O-methyl-α-L-arabinohexopyranoside EC No: 265-610-3 CAS No: 65195-55-3 *Avermectin B 1b :* IUPAC name: (10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'- 2- e EC isopropyl-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.1 4,8.0 20,24]pentacosa-10,14,16,2 tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-						

		L-arabino-hexopyranosyl)- 3-O-methyl-α-L-arabinohexopyranosid No: 265-611-9 CAS No: 65195-56-4						

B 2320

44	4,5-Dichloro-2- octyl-2H-isothiazol-3- one	4,5-Dichloro-2-octylisothiazol-3(2*H*)-one EC No: 264-843-8 CAS No: 64359-81-5	950 g/kg	1 July 2013	30 June 2015	30 June 2023	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products shall not be authorised for treatment of wood that will be continually exposed to the weather, protected from the weather but subject to frequent wetting or in contact with fresh water, unless data have been submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Member States shall ensure that authorisations are subject to the following conditions: (1) for products authorised for industrial or professional use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means;

								(2) labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing under roof, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

B 2322

45	Creosote	Creosote EC No: 232-287-5 CAS No: 8001-58-9	Grade B or Grade C creosote as specified in European Standard EN 13991:2003	1 May 2013	30 April 2015	30 April 2018	8	Biocidal products containing creosote may only be authorised for uses where the authorising Member State, based on an analysis regarding the technical and economic feasibility of substitution which it shall request from the applicant, as well as on any other information available to it, concludes that no appropriate alternatives are available. Those Member States authorising such products in their territory shall no later than 31 July 2016 submit a report to the Commission justifying their conclusion that there are no appropriate alt-ernatives and indicating how the development of alternatives is promoted. The Commission will make these reports publicly available. The active substance is to be subject to a comparative risk assessment in ac-cordance with the second subparagraph of Article 10(5)(i) before its inclusion in this Annex is renewed. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed at the Union level risk assessment.

								Member States shall ensure that authorisations are subject to the foll-owing conditions: (1) Creosote may only be used under the conditions mentioned in point 2 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 con-cerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (1). (2) Creosote shall not be used for the treatment of wood intended for those uses referred to in point 3 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006. EN L 195/50 Official Journal of the European Union 27.7.2011 (3) Appropriate risk mitigation measures shall be taken to protect workers, including down-stream users, from exposure during treatment and handling of treated wood in compliance with Regulation (EC) No 1907/2006 and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (2).

								(4) Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water and that any losses must be collect ed for reuse or disposal.
46	*Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52	Not Applicable	No relevant impurities	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means. For products containing *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

47	fipronil	(±)-5-amino-1-(2,6-dichloro-α,α,α,-trifluoro-p-tolyl)-4-trifluoromethylsulfinylpyrazole-3-carbonitrile (1:1) EC No: 424-610-5 CAS No: 120068-37-3	950 g/kg	1 October 2013	30 September 2015	30 September 2023	18	Only professional use indoors by application in locations normally inaccessible after application to man and domestic animals has been addressed in the Union level risk assessment. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.

B 2326

48	lambda-cyhalothrin	Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropro-penyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (1:1) CAS-No: 91465-08-6 EC No: 415-130-7	900 g/kg	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products applied in such a way that emission to a sewage treatment plant cannot be prevented shall not be authorised, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means. For products containing lambda-cyhalothrin that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

49	delta-methrin	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate CAS-No: 52918-63-5 EC No: 258-256-6	985 g/kg	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products shall not be authorised for indoor treatments resulting in sewage treatment plant emissions of the scale for which the Union level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.".

VERŻJONI ELETTRONIKA

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