ANNEX I

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN BIOCIDAL PRODUCTS

[F1[F3No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance[b]	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies[c]	Expiry date of inclusion	Product type	Specific provisions][a]
1	sulfuryl fluoride	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 authorisations 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.
[F6			994 g/kg	1 July 2011	30 June 2013	30 June 2021	18	Member States shall ensure that authorisations 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 authorisation 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/ m^3 of tropospheric air).]
[F7 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 authorisations 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.]
[F8 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 authorisation 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 authorisations 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.]
[F9 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 November 2009	31 October 2011	31 October 2014	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 authorisations 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.]
[F10 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 authorisations 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.]

[F11]6	tebuconazole	(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 authorisations 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 compartments. 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.]
[F12 7	carbon dioxide	carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	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, 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.]
[F13			990 ml/l	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 European 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. Member States shall ensure that authorisations are subject to the following conditions: (1) Product shall only be sold to and used by professionals

								trained to use them. (2) Appropriate measures to protect operators shall be taken to ensure minimum risk, including the availability of personal protective equipment if necessary. (3) Appropriate measures shall be taken to protect bystanders, such as exclusion from the treatment area during fumigation.]
[F14 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	930 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorisations are subject to the

	CAS No: 60207-90-1						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 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.]
[F15 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 authorisations 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.]
[F16 10	K-HDO	Cyclohexylhydroxydiazene 1-oxide, potassium salt EC No: n/a CAS No: 66603-10-9 (This entry also covers the hydrated	977 g/kg	1 July 2010	30 June 2012	30 June 2020	8	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member

	forms of K-HDO)						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 authorisations 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

								(3)	protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means; 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.**]**
[F17 11	IPBC	3-iodo-2-propynyl butylcarbamate	980 g/kg	1 July 2010	30 June 2012	30 June 2020	8	Member States shall ensure	

	EC No: 259-627-5 CAS No: 55406-53-6						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.]
[F18 12	Chlorophacinone	Chlorophacinone EC No: 223-003-0 CAS No: 3691-35-8	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 authorisations 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.]
[F19 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 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, 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 authorisation 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 authorised 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.]
[F20 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 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 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.]
[F21			980 g/kg	1 February 2015	31 January 2017	31 January 2025	18	The Union level risk assessment did not address all potential uses; certain uses, such as outdoor application and use by non-professionals, were excluded. 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 application by brushing, 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. For products containing thiamethoxam 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) in accordance with 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. Products applied in such a

							way that emission via a sewage treatment plant or directly to surface water 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. Member States shall ensure that authorisations are subject to the following conditions: (1) 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. (2) Where appropriate, measures shall be taken to protect honey bees.]
[F22 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 authorisation of a

	EC No: 240-016-7 CAS No: 15879-93-3						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 authorisations 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.]
[F23 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 authorisations 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.]
[F24 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 authorisations 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.]
[F25 18	Thiacloprid	(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 authorisation 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) 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.

							(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.]
[F26 19	Indoxacarb (enantiomeric reaction mass S:R 75:25)	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-4a-carboxylate (This entry covers	796 g/kg	1 January 2010	n/a	31 December 2019	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States

	the 75:25 reaction mass of the S and R enantiomers) EC No: n/a CAS No: S-enantiomer: 173584-44-6 and R-enantiomer: 185608-75-7)						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: 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 authorised 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.]

[F27]20	aluminium phosphide releasing phosphine	aluminium phosphide EC No: 244-088-0 CAS No: 20859-73-8	830 g/kg	1 September 2011	31 August 2013	31 August 2021	14	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, 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 authorisations 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.]
[F28			830 g/kg	1 February 2012	31 January 2014	31 January 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 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

							authorisations 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 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).]
[F29 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 authorisation 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) 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.]
[F30 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 authorisation 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.]
[F31 23	boric oxide	Diboron trioxide EC No: 215-125-8 CAS No: 1303-86-2	975 g/kg	1 September 2011	31 August 2013	31 August 2021	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, 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.**]**
[[F32]24	disodium tetraborate	**[**[F33]disodium tetraborate EC No: 215-540-4 CAS No (anhydrous): 1330-43-4 CAS No (pentahydrate): 12179-04-3 CAS No (decahydrate): 1303-96-4**]**	990 g/kg	1 September 2011	31 August 2013	31 August 2021	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, 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.]
[F34 25	disodium octaborate tetrahydrate	disodium octaborate tetrahydrate EC No: 234-541-0 CAS No: 12280-03-4	975 g/kg	1 September 2011	31 August 2013	31 August 2021	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, 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.]
[F35 26	Magnesium phosphide releasing phosphine	Trimagnesium diphosphide EC 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 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 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 authorisations 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).]
[F3627	Nitrogen	Nitrogen EC No: 231-783-9 CAS No: 7727-37-9	999 g/kg	1 September 2011	31 August 2013	31 August 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, 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 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.]
[F37 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 authorisations 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.]
[F38 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 September 2021	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 authorisations 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 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)	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 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.]
[F39 30	Acrolein	Acrylaldehyde EC No: 203-453-4 CAS No: 107-02-8	0,18 g/kg	1 September 2010	Not applicable	31 August 2020	12	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, 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.]
[F40 31	Flocoumafen	4-hydroxy-3-[(1*RS*,3*RS*;1*RS*,3*RS*)-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 2013	30 September 2013	30 September 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 authorisations 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.]
[F41 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.]
[F4233	Warfarin sodium	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 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.]
[F43 34	Dazomet	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione EC No: 208-576-7 CAS No: 533-74-4	975 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.**]**
[F44 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.]
[F4536	Metofluthrin	RTZ isomer: (1R,3R)-2,2-dimethyl-3-(Z)-(prop-1-enyl)cyclopropanecarboxylic acid (2,3,5,6-tetrafluoro-4-methoxymethylbenzyl) ester (Z)-isomer EC No: n.a. CAS No: 240494-71-7 Sum of	RTZ isomer: ≥ 754 g/kg Sum of all isomers:	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,

			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	930 g/kg				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.**]**
[[F46]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-	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

	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-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-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione CAS No: 131929-63-0						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.]
[F47 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 compartments 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: — Products shall be authorised only for industrial or professional use, unless it is demonstrated 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 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.
								— 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 shall be stored after treatment under shelter or on impermeable

								hardstanding, 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 the *in situ* treatment of wood outdoors, or for treatment of wood that will be either continually exposed to

								the weather or protected from the weather but subject to frequent wetting, 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.]
[F4839	(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.]
[F49 40	Fenoxycarb	1000 g/kg	IUPAC name: Ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate EC No: 276-696-7 CAS No: 72490-01-8	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 compartments

							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 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 shall be stored after treatment under shelter or on impermeable hardstanding 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.]
[F50 41	Nonanoic acid, Pelargonic acid		IUPAC name: Nonanoic acid EC No: 203-931-2 CAS No: 112-05-0	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.**]**
[[F51]				1 October 2014	30 September 2016	30 September 2024	2	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. Member States shall ensure that authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for

								human health can be reduced to acceptable levels by other means.]
[F52 42	imidaclopr	(2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-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 environmental compartments that have not been representatively 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.]
[F53 43	Abamectin	Abamectin is a mixture of avermectin B_{1a} and avermectin B_{1b}	The active substance shall comply with all the following purities: *Abamectin:* minimum 900 g/kg *Avermectin B_{1a}:* minimum 800 g/kg *Avermectin B_{1b}:* minimum 20 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
			Abamectin: IUPAC name: 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)-sec-butyl]-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-					

			L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabinohexopyranoside EC No: 265-610-3 CAS No: 65195-55-3				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 situations 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
			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'-isopropyl-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.$1^{4,8}$.$0^{20,24}$]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabinohexopyranoside EC No: 265-611-9				

				CAS No: 65195-56-4				subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children.]
[F54 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.]
[F5 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 alternatives 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 accordance 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 following 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 concerning 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[d].
								(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.
								(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)[e].
								(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 collected for reuse or disposal.]
[F55 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.]
[F56 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.]
[F57 48	lambda-cyhalothrin	Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-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.]
[F58 49	deltamethrin	(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.**]**
[[F59]50	Copper hydroxide	Copper (II) hydroxide EC No: 243-815-9 CAS No: 20427-59-2	965 g/kg	1 February 2014	31 January 2016	31 January 2024	8	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. Member States shall ensure that authorisations are subject to the following conditions: (1) Products shall not be authorised for application by dipping, unless data have been submitted in the application for product authorisation demonstrating that that application meets the requirements of Article 5 and Annex VI, if necessary by the application of appropriate

								risk mitigation measures.
							(2)	For products authorised for industrial 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 users can be reduced to an acceptable level by other means.
							(3)	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 application of the product shall be collected for reuse or disposal.

								(4)	Products shall not be authorised for treatment of wood that will be used in outdoor constructions near or above 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 mitigation measures.
51	Copper (II) oxide	Copper (II) oxide	976 g/kg	1 February 2014	31 January 2016	31 January 2024	8	When assessing the application	

	EC No: 215-269-1 CAS No: 1317-38-0						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. Member States shall ensure that authorisations are subject to the following conditions:

								(1)	For products authorised for industrial 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 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, 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.
							(3)	Products shall not

								be authorised for treatment of wood that will be used in outdoor constructions near or above water or for the treatment of wood in contact with fresh 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 mitigation measures.
52	Basic copper carbonate	Copper(II) carbonate-copper(II) hydroxide (1:1) EC No: 235-113-6 CAS No: 12069-69-1	957 g/kg	1 February 2014	31 January 2016	31 January 2024	8	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. Member States shall

								ensure that authorisations are subject to the following conditions: (1) Products shall not be authorised for application by dipping, unless data have been submitted in the application for product authorisation demonstrating that that application meets the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. (2) For products

								authorised for industrial 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 users can be reduced to an acceptable level by other means.
							(3)	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 application of the product shall be collected for reuse or disposal.
							(4)	Products shall not be authorised

								for treatment of wood that will be used in outdoor constructions near or above water, or for the treatment of wood in direct contact with fresh 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

								mitigation measures.]
[F60 53	*bendiocarb*	2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate CAS-No: 22781-23-3 EC No: 245-216-8	970 g/kg	1 February 2014	31 January 2016	31 January 2024	18	The Union level risk assessment did not address all potential uses, but concerned, for example, application by professionals only, and excluded contact with feed or food and direct application on soil. 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. Member States shall ensure that authorisations are subject to the following conditions: Products shall not be used for the treatment of surfaces that are prone to frequent wet cleaning, other than crack

								and crevice or spot treatment, 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 industrial 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 or professional users can be reduced to an acceptable level by other means. Where relevant, measures shall be taken to prevent foraging bees from gaining access to treated nests by removing the combs or blocking the nest entrances.]
[F61 54	methyl nonyl ketone	Undecan-2-one	975 g/kg	1 May 2014	30 April 2016	30 April 2024	19	The Union level risk

	CAS No: 112-12-9 EC No: 203-937-5						assessment was based on indoor use by non-professional users. 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.]
[F62 55	*margosa extract*	IUPAC name: Not applicable CAS-No: 84696-25-3 EC No: 283-644-7 Description: margosa extract from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents	1 000 g/kg	1 May 2014	30 April 2016	30 April 2024	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. Member States shall ensure

								that authorisations are subject to appropriate risk mitigation measures for the protection of surface water, sediment and non-target arthropods.]
[F63 56	Hydrochloric acid	Hydrochloric acid CAS No: not applicable EC No: 231-595-7	929 g/kg	1 May 2014	30 April 2016	30 April 2024	2	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. Member States shall ensure that authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.]

[F64 57	flufenoxuron	1-[4-(2-chloro-alpha,alpha,alpha-trifluoro-para-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea EC No: 417-680-3 CAS No: 101463-69-8	960 g/kg	1 February 2014	31 January 2016	31 January 2017	8	Flufenoxuron 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. The Union level risk assessment addressed treatment of wood which will not be used in animal housing or come into contact with food or feed. Products shall not be authorised for uses or exposure scenarios that

								have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) Products shall only be used for treatment of wood intended for indoor use. (2) 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.
								(3)	Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety

								data sheets of authorised products 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 application of the product shall be collected for reuse or disposal.]

[F6558	DDACarbonate	Reaction mass of N,N-Didecyl-N,N-dimethylammonium Carbonate and N,N-Didecyl-N,N-dimethylammonium Bicarbonate EC No: 451-900-9 CAS No: 894406-76-9	Dry weight: 740 g/kg	1 February 2013	Not applicable	31 January 2023	8	The Union level risk assessment did not address all potential uses; certain uses, such as use by non-professionals, were excluded. 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. Member States shall ensure that authorisations are subject to the following conditions: (1) for industrial users 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 can be reduced to an acceptable level by other means;
								(2)	labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, 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 application of the product shall be collected for reuse or disposal;
								(3)	products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near

								or above water, or for treatment by dipping of wood that will be continually exposed to the weather or subject to frequent wetting, 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 mitigation measures.**]**

[F66]59	*cis*-tricos-9-ene (Muscalure)	*cis*-Tricos-9-ene; (Z)-Tricos-9-ene EC No: 248-505-7 CAS No: 27519-02-4	801 g/kg	1 October 2014	30 September 2016	30 September 2024	19	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use and exposure of food or feed, were excluded. 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. For products containing *cis*-tricos-9-ene 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.]
[F67 60	hydrogen cyanide	hydrogen cyanide EC No: 200-821-6 CAS No: 74-90-8	976 g/kg	1 October 2014	30 September 2016	30 September 2024	8, 14 and 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. Member States shall ensure that authorisations of products for use as a fumigant are subject to the following conditions: (1) product shall only be supplied to and used by professionals adequately trained to use them; (2) safe operational procedures during fumigation and venting shall be established for operators and bystanders; (3) products shall be used

									with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing;
								(4)	re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and bystanders by ventilation;
								(5)	exposure during and after ventilation shall be prevented from exceeding safe levels for operators and

									bystanders by the establishment of a supervised exclusion zone;
								(6)	prior to fumigation, any food and any porous material with a potential to absorb the active substance, except wood intended to be treated, shall either be removed from the space to be fumigated or protected from absorption by adequate means, and the space to

								be fumigated shall be protected against accidental ignition.]
[F6861	Didecyldimethylammonium Chloride; DDAC	N-Didecyl-N,N-dimethylammonium Chloride EC No: 230-525-2 CAS No: 7173-51-5	Dry weight: 870 g/kg	1 February 2015	31 January 2017	31 January 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. 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. Member States shall ensure that authorisations are subject to the following conditions: (1) For industrial or professional users 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 can be reduced to an acceptable level by other means.
							(2)	Products shall not be used for treatment of wood with which children may enter in direct contact, unless it can be demonstrated in

									the application for product authorisation that risks can be reduced to an acceptable level.
								(3)	Labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored

									after treatment on impermeable hard standing 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.
								(4)	Products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions

								near or above water, continually exposed to the weather or subject to frequent wetting, 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 mitigation measures.]
[F69 62	pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether EC No: 429-800-1	970 g/kg	1 February 2015	31 January 2017	31 January 2025	18	The Union level risk assessment did not address all potential uses and

	CAS No: 95737-68-1						exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals, were excluded. 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. For products containing pyriproxyfen 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) in accordance with 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. Member States shall

								ensure that authorisations are subject to the following conditions: (1) Products authorised for professionals shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means. (2) Products shall not be authorised for direct use on surface

									water, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level. (3) Products intended to be used in waste treatment facilities shall be subject to appropriate risk mitigation measures to avoid contamination of the area outside the waste treatment site.]
[F70 63	diflubenzuron	1-(4-chlorophenyl)-3-	960 g/kg	1 February 2015	31 January 2017	31 January 2025	18	The Union level	

	(2,6-difluorobenzoyl)urea EC No: 252-529-3 CAS No: 35367-38-5						risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use, use by non-professionals, and exposure of livestock were excluded. 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. For products containing diflubenzuron 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) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, with special consideration

								to the *in vivo* genotoxic metabolite PCA, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. Member States shall ensure that authorisations are subject to the following conditions unless it can be demonstrated in the application for product authorisation that the risks can be reduced to an acceptable level: (1) Professional users shall wear appropriate personal protective equipment. (2) Product information

								shall include the requirement that products shall only be used on dry manure, and that the manure must undergo complete aerobic composting by professionals prior to application on arable land. (3) Products shall not be used in water systems.]
[F71 64	Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride; C_{12-16}-ADBAC	IUPAC name: Not applicable EC No: 270-325-2 CAS No: 68424-85-1	Dry weight: 940 g/kg	1 February 2015	31 January 2017	31 January 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and

							exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. 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. Member States shall ensure that authorisations are subject to the following conditions: (1) For industrial or professional users 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 can be reduced

								to an acceptable level by other means.
							(2)	Products shall not be used for treatment of wood with which children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.
							(3)	Labels and, where provided, safety data sheets of products

								authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing 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.
							(4)	Products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, continually exposed to the weather or subject to frequentwetting, 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 mitigation measures.]

a	[F2[F3For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm]
b	[F4The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.
c	For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 4(1) within 60 days of the granting of the first authorisation, the deadline for compliance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to 30 days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(4).]
d	[F5OJ L 396, 30.12.2006, p. 1.
e	OJ L 158, 30.4.2004, p. 50.]]]

Textual Amendments

F1 Inserted by Commission Directive 2006/140/EC of 20 December 2006 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (Text with EEA relevance).

F2 Substituted by Commission Directive 2007/69/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include difethialone as an active substance in Annex I thereto (Text with EEA relevance).

F3 Substituted by Commission Directive 2012/43/EU of 26 November 2012 amending certain headings of Annex I to Directive 98/8/EC of the European Parliament and of the Council (Text with EEA relevance).

F4 Inserted by Commission Directive 2012/43/EU of 26 November 2012 amending certain headings of Annex I to Directive 98/8/EC of the European Parliament and of the Council (Text with EEA relevance).

F5 Inserted by Commission Directive 2011/71/EU of 26 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include creosote as an active substance in Annex I thereto (Text with EEA relevance).

F6 Inserted by Commission Directive 2009/84/EC of 28 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (Text with EEA relevance).

F7 Inserted by Commission Directive 2007/20/EC of 3 April 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include dichlofluanid as an active substance in Annex I thereto (Text with EEA relevance).

F8 Inserted by Commission Directive 2008/15/EC of 15 February 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include clothianidin as an active substance in Annex I thereto (Text with EEA relevance).

F9 Inserted by Commission Directive 2007/69/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include difethialone as an active substance in Annex I thereto (Text with EEA relevance).

F10 Inserted by Commission Directive 2008/16/EC of 15 February 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include etofenprox as an active substance in Annex I thereto (Text with EEA relevance).

F11 Inserted by Commission Directive 2008/86/EC of 5 September 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include tebuconazole as an active substance in Annex I thereto (Text with EEA relevance).

F12 Inserted by Commission Directive 2008/75/EC of 24 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include carbon dioxide as an active substance in Annex I thereto (Text with EEA relevance).

F13 Inserted by Commission Directive 2010/74/EU of 9 November 2010 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance carbon dioxide to product type 18 (Text with EEA relevance).

F14 Inserted by Commission Directive 2008/78/EC of 25 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include propiconazole as an active substance in Annex I thereto (Text with EEA relevance).

F15 Inserted by Commission Directive 2008/81/EC of 29 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include difenacoum as an active substance in Annex I thereto (Text with EEA relevance).

F16 Inserted by Commission Directive 2008/80/EC of 28 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include cyclohexylhydroxydiazene 1-oxide, potassium salt (K-HDO) as an active substance in Annex I thereto (Text with EEA relevance).

F17 Inserted by Commission Directive 2008/79/EC of 28 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include IPBC as an active substance in Annex I thereto (Text with EEA relevance).

F18 Inserted by Commission Directive 2009/99/EC of 4 August 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include chlorophacinone as an active substance in Annex I thereto (Text with EEA relevance).

F19 Inserted by Commission Directive 2008/85/EC of 5 September 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include thiabendazole as an active substance in Annex I thereto (Text with EEA relevance).

F20 Inserted by Commission Directive 2008/77/EC of 25 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include thiamethoxam as an active substance in Annex I thereto (Text with EEA relevance).

F21 Inserted by Commission Directive 2013/3/EU of 14 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance thiamethoxam to product-type 18 (Text with EEA relevance).

F22 Inserted by Commission Directive 2009/93/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include alphachloralose as an active substance in Annex I thereto (Text with EEA relevance).

F23 Inserted by Commission Directive 2010/10/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include brodifacoum as an active substance in Annex I thereto (Text with EEA relevance).

F24 Inserted by Commission Directive 2009/92/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include bromadiolone as an active substance in Annex I thereto (Text with EEA relevance).

F25 Inserted by Commission Directive 2009/88/EC of 30 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include thiacloprid as an active substance in Annex I thereto (Text with EEA relevance).

F26 Inserted by Commission Directive 2009/87/EC of 29 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include indoxacarb as an active substance in Annex I thereto (Text with EEA relevance).

F27 Inserted by Commission Directive 2009/95/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include aluminium phosphide releasing phosphine as an active substance in Annex I thereto (Text with EEA relevance).

F28 Inserted by Commission Directive 2010/9/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance aluminium phosphide releasing phosphine to product type 18 as defined in Annex V thereto (Text with EEA relevance).

F29 Inserted by Commission Directive 2009/86/EC of 29 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include fenpropimorph as an active substance in Annex I thereto (Text with EEA relevance).

F30 Inserted by Commission Directive 2009/94/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include boric acid as an active substance in Annex I thereto (Text with EEA relevance).

F31 Inserted by Commission Directive 2009/98/EC of 4 August 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include boric oxide as an active substance in Annex I thereto (Text with EEA relevance).

F32 Inserted by Commission Directive 2009/91/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium tetraborate as an active substance in Annex I thereto (Text with EEA relevance).

F33 Substituted by Commission Directive 2012/40/EU of 26 November 2012 correcting Annex I to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance).

F34 Inserted by Commission Directive 2009/96/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include disodium octaborate tetrahydrate as an active substance in Annex I thereto (Text with EEA relevance).

F35 Inserted by Commission Directive 2010/7/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include magnesium phosphide releasing phosphine as an active substance in Annex I thereto (Text with EEA relevance).

F36 Inserted by Commission Directive 2009/89/EC of 30 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include nitrogen as an active substance in Annex I thereto (Text with EEA relevance).

F37 Inserted by Commission Directive 2009/85/EC of 29 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include coumatetralyl as an active substance in Annex I thereto (Text with EEA relevance).

F38 Inserted by Commission Directive 2009/151/EC of 27 November 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include tolylfluanid as an active substance in Annex I thereto (Text with EEA relevance).

F39 Inserted by Commission Directive 2010/5/EU of 8 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include acrolein as an active substance in Annex I thereto (Text with EEA relevance).

F40 Inserted by Commission Directive 2009/150/EC of 27 November 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include flocoumafen as an active substance in Annex I thereto (Text with EEA relevance).

F41 Inserted by Commission Directive 2010/11/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include warfarin as an active substance in Annex I thereto (Text with EEA relevance).

F42 Inserted by Commission Directive 2010/8/EU of 9 February 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include warfarin sodium as an active substance in Annex I thereto (Text with EEA relevance).

F43 Inserted by Commission Directive 2010/50/EU of 10 August 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include dazomet as an active substance in Annex I thereto (Text with EEA relevance).

F44 Inserted by Commission Directive 2010/51/EU of 11 August 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include N,N-diethyl-meta-toluamide as an active substance in Annex I thereto (Text with EEA relevance).

F45 Inserted by Commission Directive 2010/71/EU of 4 November 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include metofluthrin as an active substance in Annex I thereto (Text with EEA relevance).

F46 Inserted by Commission Directive 2010/72/EU of 4 November 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include spinosad as an active substance in Annex I thereto (Text with EEA relevance).

F47 Inserted by Commission Directive 2011/10/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include bifenthrin as an active substance in Annex I thereto (Text with EEA relevance).

F48 Inserted by Commission Directive 2011/11/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include (Z,E)-tetradeca-9,12-dienyl acetate as an active substance in Annexes I and IA thereto (Text with EEA relevance).

F49 Inserted by Commission Directive 2011/12/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include fenoxycarb as an active substance in Annex I thereto (Text with EEA relevance).

F50 Inserted by Commission Directive 2011/13/EU of 8 February 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include nonanoic acid as an active substance in Annex I thereto (Text with EEA relevance).

F51 Inserted by Commission Directive 2012/41/EU of 26 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance nonanoic acid to product type 2 (Text with EEA relevance).

F52 Inserted by Commission Directive 2011/69/EU of 1 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include imidacloprid as an active substance in Annex I thereto (Text with EEA relevance).

F53 Inserted by Commission Directive 2011/67/EU of 1 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include abamectin as an active substance in Annex I thereto (Text with EEA relevance).

F54 Inserted by Commission Directive 2011/66/EU of 1 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include 4,5-Dichloro-2-octyl-2H-isothiazol-3-one as an active substance in Annex I thereto (Text with EEA relevance).

F55 Inserted by Commission Directive 2011/78/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52 as an active substance in Annex I thereto (Text with EEA relevance).

F56 Inserted by Commission Directive 2011/79/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include fipronil as an active substance in Annex I thereto (Text with EEA relevance).

F57 Inserted by Commission Directive 2011/80/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include lambda-cyhalothrin as an active substance in Annex I thereto (Text with EEA relevance).

F58 Inserted by Commission Directive 2011/81/EU of 20 September 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include deltamethrin as an active substance in Annex I thereto (Text with EEA relevance).

F59 Inserted by Commission Directive 2012/2/EU of 9 February 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include copper (II) oxide, copper (II) hydroxide and basic copper carbonate as active substances in Annex I thereto (Text with EEA relevance).

F60 Inserted by Commission Directive 2012/3/EU of 9 February 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include bendiocarb as an active substance in Annex I thereto (Text with EEA relevance).

F61 Inserted by Commission Directive 2012/14/EU of 8 May 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include methyl nonyl ketone as an active substance in Annex I thereto (Text with EEA relevance).

F62 Inserted by Commission Directive 2012/15/EU of 8 May 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include margosa extract as an active substance in Annex I thereto (Text with EEA relevance).

F63 Inserted by Commission Directive 2012/16/EU of 10 May 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include hydrochloric acid as an active substance in Annex I thereto (Text with EEA relevance).

F64 Inserted by Commission Directive 2012/20/EU of 6 July 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include flufenoxuron as an active substance for product-type 8 in Annex I thereto (Text with EEA relevance).

F65 Inserted by Commission Directive 2012/22/EU of 22 August 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include DDACarbonate as an active substance in Annex I thereto (Text with EEA relevance).

F66 Inserted by Commission Directive 2012/38/EU of 23 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include cis-Tricos-9-ene as an active substance in Annex I thereto (Text with EEA relevance).

F67 Inserted by Commission Directive 2012/42/EU of 26 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to include hydrogen cyanide as an active substance in Annex I thereto (Text with EEA relevance).

F68 Inserted by Commission Directive 2013/4/EU of 14 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include Didecyldimethylammonium Chloride as an active substance in Annex I thereto (Text with EEA relevance).

F69 Inserted by Commission Directive 2013/5/EU of 14 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include pyriproxyfen as an active substance in Annex I thereto (Text with EEA relevance).

F70 Inserted by Commission Directive 2013/6/EU of 20 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include diflubenzuron as an active substance in Annex I thereto (Text with EEA relevance).

F71 Inserted by Commission Directive 2013/7/EU of 21 February 2013 amending Directive 98/8/EC of the European Parliament and of the Council to include Alkyl (C12-16) dimethylbenzyl ammonium chloride as an active substance in Annex I thereto (Text with EEA relevance).

ANNEX IA

LIST OF ACTIVE SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL FOR INCLUSION IN LOW-RISK BIOCIDAL PRODUCTS

[F72No	Common name	IUPAC name Identification 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	Carbon dioxide	Carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	Only for use in ready-for-use gas canisters functioning together with a

*Note:*For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm**]**

								trapping device.
[F48 2	(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	Member States shall ensure that registrations are subject to the following conditions: — Only for traps containing a maximum of 2 mg of (Z,E)-Tetradeca-9,12-dienyl acetate for indoor use, — Labels for biocidal products containing (Z,E)-tetradeca-9,12-dienyl acetate shall indicate that those products shall only be used indoors, and

*Note:*For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm**]**

									shall not be used in spaces where un-packaged food or feed is kept.]

*Note:*For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm]

Textual Amendments

F72 Inserted by Commission Directive 2007/70/EC of 29 November 2007 amending Directive 98/8/EC of the European Parliament and of the Council to include carbon dioxide as an active substance in Annex IA thereto (Text with EEA relevance).

ANNEX IB

LIST OF BASIC SUBSTANCES WITH REQUIREMENTS AGREED AT COMMUNITY LEVEL

ANNEX IIA

COMMON CORE DATA SET FOR ACTIVE SUBSTANCES CHEMICAL SUBSTANCES

1. Dossiers on active substances are required to address at least all the points listed under ‘Dossier requirements’. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

Dossier requirements

I. Applicant

II. Identity of the active substance

III. Physical and chemical properties of the active substance

IV. Methods of detection and identification

V. Effectiveness against target organisms and intended uses

VI. Toxicological profile for man and animals including metabolism

VII. Ecotoxicological profile including environmental fate and behaviour

VIII. Measures necessary to protect man, animals and the environment

IX. Classification and labelling

X. Summary and evaluation of Sections II to IX

The following data will be required to support submission on the above points.

I. APPLICANT

1.1. Name and address, etc.

1.2. Active substance manufacturer (name, address, location of plant)

II. IDENTITY

2.1. Common name proposed or accepted by ISO and synonyms

2.2. Chemical name (IUPAC nomenclature)

2.3. Manufacturer's development code number(s)

2.4. CAS and EC numbers (if available)

2.5. Molecular and structural formula (including full details of any isomeric composition), molecular mass

2.6. Method of manufacture (syntheses pathway in brief terms) of active substance

2.7. Specification of purity of the active substance in g/kg or g/l, as appropriate

2.8. Identity of impurities and additives (e.g. stabilisers), together with the structural formula and the possible range expressed as g/kg or g/l, as appropriate

2.9. The origin of the natural active substance or the precursor(s) of the active substance, e.g. an extract of a flower

2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC[(1)].

III. PHYSICAL AND CHEMICAL PROPERTIES

3.1. Melting point, boiling point, relative density ([1])

3.2. Vapour pressure (in Pa) ([1])

3.3. Appearance (physical state, colour) ([2])

3.4. Absorption spectra (UV/VIS, IR, NMR), and a mass spectrum, molar extinction at relevant wavelengths, where relevant ([1])

3.5. Solubility in water including effect of pH (5 to 9) and temperature on solubility, where relevant ([1])

3.6. Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature ([1])

3.7. Thermal stability, identity of relevant breakdown products

3.8. Flammability including auto-flammability and identity of combustion products

3.9. Flash-point

3.10. Surface tension

3.11. Explosive properties

3.12. Oxidising properties

3.13. Reactivity towards container material

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

4.1. Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of the active substance and additives (e.g. stabilisers)

4.2. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:

(a) Soil

(b) Air

(c) Water: the applicant should confirm that the substance itself and any of its degradation products which fall within the definition of pesticides given for parameter 55 in Annex I to Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption[(2)] can be estimated with adequate reliability at the MAC specified in that Directive for individual pesticides

(d) Animal and human body fluids and tissues

V. EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

5.1. Function, e.g. fungicide, rodenticide, insecticide, bactericide

5.2. Organism(s) to be controlled and products, organisms or objects to be protected

5.3. Effects on target organisms, and likely concentration at which the active substance will be used

5.4. Mode of action (including time delay)

5.5. Field of use envisaged

5.6. User: industrial, professional, general public (non-professional)

5.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

5.8. Likely tonnage to be placed on the market per year

VI. TOXICOLOGICAL AND METABOLIC STUDIES

6.1. Acute toxicity

For studies 6.1.1 to 6.1.3, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

6.1.1. Oral

6.1.2. Dermal

6.1.3. Inhalation

6.1.4. Skin and eye irritation ([3])

6.1.5. Skin sensitisation

6.2. Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study

For the following studies, 6.3 (where necessary), 6.4, 6.5, 6.7 and 6.8, the required route of administration is the oral route unless it can be justified that an alternative route is more appropriate

6.3. Short-term repeated dose toxicity (28 days)

This study is not required when a sub-chronic toxicity study is available in a rodent

6.4. Subchronic toxicity 90-day study, two species, one rodent and one non-rodent

6.5. Chronic toxicity ([4])

One rodent and one other mammalian species

6.6. Mutagenicity studies

6.6.1. *In-vitro* gene mutation study in bacteria

6.6.2. *In-vitro* cytogenicity study in mammalian cells

6.6.3. *In-vitro* gene mutation assay in mammalian cells

6.6.4. If positive in 6.6.1, 6.6.2 or 6.6.3, then an *in-vivo* mutagenicity study will be required (bone marrow assay for chromosomal damage or a micronucleus test)

6.6.5. If negative in 6.6.4 but positive *in-vitro* tests then undertake a second *in-vivo* study to examine whether mutagenicity or evidence of DNA damage can be demonstrated in tissue other than bone marrow

6.6.6. If positive in 6.6.4 then a test to assess possible germ cell effects may be required

6.7. Carcinogenicity study ([4])

One rodent and one other mammalian species. These studies may be combined with those in 6.5

6.8. Reproductive toxicity ([5])

6.8.1. Teratogenicity test — rabbit and one rodent species

6.8.2. Fertility study — at least two generations, one species, male and female

6.9. Medical data in anonymous form

6.9.1. Medical surveillance data on manufacturing plant personnel if available

6.9.2. Direct observation, e.g. clinical cases, poisoning incidents if available

6.9.3. Health records, both from industry and any other available sources

6.9.4. Epidemiological studies on the general population, if available

6.9.5. Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available

6.9.6. Sensitisation/allergenicity observations, if available

6.9.7. Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known

6.9.8. Prognosis following poisoning

6.10. Summary of mammalian toxicology and conclusions, including no observed adverse effect level (NOAEL), no observed effect level (NOEL), overall evaluation with regard to all toxicological data and any other information concerning the active substances. Where possible any suggested worker protection measures should be included in summary form

VII. ECOTOXICOLOGICAL STUDIES

7.1. Acute toxicity to fish

7.2. Acute toxicity to *Daphnia magna*

7.3. Growth inhibition test on algae

7.4. Inhibition to microbiological activity

7.5. Bioconcentration

Fate and behaviour in the environment

7.6. Degradation

7.6.1. Biotic

7.6.1.1. Ready biodegradability

7.6.1.2. Inherent biodegradability, where appropriate

7.6.2. Abiotic

7.6.2.1. Hydrolysis as a function of pH and identification of breakdown products

7.6.2.2. Phototransformation in water including identity of the products of transformation ([1])

7.7. Adsorption/desorption screening test

Where the results of this test indicate the need to do so, the test described in Annex IIIA Part XII.1 paragraph 1.2 shall be required, and/or the test described in Annex IIIA Part XII.2 paragraph 2.2

7.8. Summary of ecotoxicological effects and fate and behaviour in the environment

VIII. MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire

8.2. In case of fire, nature of reaction products, combustion gases, etc.

8.3. Emergency measures in case of an accident

8.4. Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil

8.5. Procedures for waste management of the active substance for industry or professional users

8.5.1. Possibility of reuse or recycling

8.5.2. Possibility of neutralisation of effects

8.5.3. Conditions for controlled discharge including leachate qualities on disposal

8.5.4. Conditions for controlled incineration

8.6. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms

IX. CLASSIFICATION AND LABELLING

Proposals including justification for the proposals for the classification and labelling of the active substance according to Directive 67/548/EEC

Hazard symbol(s)

Indications of danger

Risk phrases

Safety phrases
X.SUMMARY AND EVALUATION OF SECTIONS II TO IX
. . . . . .
Notes

([1]) These data must be submitted for the purified active substance of stated specification.

([2]) These data must be submitted for the active substance of stated specification.

([3]) Eye irritation test shall not be necessary where the active substance has been shown to have potential corrosive properties.

([4]) The long-term toxicity and carcinogenicity of an active substance may not be required where a full justification demonstrates that these tests are not necessary.

([5]) If, in exceptional circumstances, it is claimed that such testing is unnecessary, that claim must be fully justified.

ANNEX IIB

COMMON CORE DATA SET FOR BIOCIDAL PRODUCTS
CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

Dossier requirements

I. Applicant

II. Identity of the biocidal product

III. Physical and chemical properties of the biocidal product

IV. Methods for identification and analysis of the biocidal product

V. Intended uses of the biocidal product and efficacy for these uses

VI. Toxicology data for the biocidal product (additional to that for the active substance)

VII. Ecotoxicology data for the biocidal product (additional to that for the active substance)

VIII. Measures necessary to protect man, animals and the environment

IX. Classification, packaging and labelling

X. Summary and evaluation of Sections II to IX

The following data will be required to support submission on the above points.

I. APPLICANT

1.1. Name and address, etc.

1.2. Formulator of the biocidal product and the active substance(s) (names, addresses, including location of plant(s))

II. IDENTITY

2.1. Trade name or proposed trade name, and manufacturer's development code number of the preparation, if appropriate

2.2. Detailed quantitative and qualitative information on the composition of the biocidal product, e.g. active substance(s), impurities, adjutants, inert components

2.3. Physical state and nature of the biocidal product, e.g. emulsifiable concentrate, wettable powder, solution

III. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

3.1. Appearance (physical state, colour)

3.2. Explosive properties

3.3. Oxidising properties

3.4. Flash-point and other indications of flammability or spontaneous ignition

3.5. Acidity/alkalinity and if necessary pH value (1 % in water)

3.6. Relative density

3.7. Storage stability — stability and shelf-life. Effects of light, temperature and humidity on technical characteristics of the biocidal product; reactivity towards container material

3.8. Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability

3.9. Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised

IV. METHODS OF IDENTIFICATION AND ANALYSIS

4.1. Analytical method for determining the concentration of the active substance(s) in the biocidal product

4.2. In so far as not covered by Annex IIA, paragraph 4.2, analytical methods including recovery rates and the limits of determination for toxicologically and ecotoxicologically relevant components of the biocidal product and/or residues thereof, where relevant in or on the following:

(a) Soil

(b) Air

(c) Water (including drinking water)

(d) Animal and human body fluids and tissues

(e) Treated food or feedingstuffs

V. INTENDED USES AND EFFICACY

5.1. Product type and field of use envisaged

5.2. Method of application including description of system used

5.3. Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes

5.4. Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

5.5. Function, e.g. fungicide, rodenticide, insecticide, bactericide

5.6. Pest organism(s) to be controlled and products, organisms or objects to be protected

5.7. Effects on target organisms

5.8. Mode of action (including time delay) in so far as not covered by Annex IIA, paragraph 5.4

5.9. User: industrial, professsional, general public (non-professional)

Efficacy data

5.10. The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate

5.11. Any other known limitations on efficacy including resistance

VI. TOXICOLOGICAL STUDIES

6.1. Acute toxicity

For studies 6.1.1 to 6.1.3, biocidal products other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the product and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route

6.1.1. Oral

6.1.2. Dermal

6.1.3. Inhalation

6.1.4. For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate

6.2. Skin and eye irritation ([1])

6.3. Skin sensitisation

6.4. Information on dermal absorption

6.5. Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)

6.6. Information related to the exposure of the biocidal product to man and the operator

Where necessary, the test(s) described in Annex IIA, shall be required for the toxicologically relevant non-active substances of the preparation

VII. ECOTOXICOLOGICAL STUDIES

7.1. Foreseeable routes of entry into the environment on the basis of the use envisaged

7.2. Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself

7.3. Available ecotoxicological information relating to exotoxicological relevant non-active substances (i.e. substances of concern), such as information from safety data sheets

VIII. MEASURES TO BE ADOPTED TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1. Recommended methods and precautions concerning handling, use, storage, transport or fire

8.2. Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment; in so far as not covered by Annex IIA, paragraph 8.3

8.3. Procedures, if any, for cleaning application equipment

8.4. Identity of relevant combustion products in cases of fire

8.5. Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration

8.6. Possibility of destruction or decontamination following release in or on the following:

(a) Air

(b) Water, including drinking water

(c) Soil

8.7. Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms

8.8. Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms

IX. CLASSIFICATION, PACKAGING AND LABELLING

— Proposals for packaging and labelling

— Proposals for safety-data sheets, where appropriate

— Justification for the classification and labelling according to the principles of Article 20 of this Directive

  — Hazard symbol(s)

  — Indications of danger

  — Risk phrases

  — Safety phrases

  — Packaging (type, materials, size, etc.), compatibility of the preparation with proposed packaging materials to be included

X.SUMMARY AND EVALUATION OF SECTIONS II TO IX

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Notes

([1]) Eye-irritation test shall not be necessary where the biocidal product has been shown to have potential corrosive properties.

ANNEX IIIA

ADDITIONAL DATA SET FOR ACTIVE SUBSTANCES CHEMICAL SUBSTANCES

1. Dossiers on active substances are required to address at least all the points listed under 'Dossier requirements'. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

III. PHYSICAL AND CHEMICAL PROPERTIES

1. Solubility in organic solvents, including effect of temperature on solubility ([1])

2. Stability in organic solvents used in biocidal products and identity of relevant breakdown products ([2])

IV. ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

1. Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant

VI. TOXICOLOGICAL AND METABOLIC STUDIES

1. Neurotoxicity study

If the active substance is an organophosphorus compound or if there are any other indications that the active substance may have neurotoxic properties then neurotoxicity studies will be required. The test species is the adult hen unless another test species is justified to be more appropriate. If appropriate, delayed neurotoxicity tests will be required. If anticholine esterase activity is detected a test for response to reactivating agents should be considered

2. Toxic effects on livestock and pets

3. Studies related to the exposure of the active substance to humans

4. Food and feedingstuffs

If the active substance is to be used in preparations for use where food for human consumption is prepared, consumed or stored, or where feedingstuff for livestock is prepared, consumed or stored the tests referred to in Section XI, part 1 shall be required

5. If any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, are considered necessary, then the test(s) referred to in Section XI, part 2 shall be required

6. If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required

7. Mechanistic study — any studies necessary to clarify effects reported in toxicity studies

VII. ECOTOXICOLOGICAL STUDIES

1. Acute toxicity test on one other, non-aquatic, non-target organism

2. If the results of the ecotoxicological studies and the intended use(s) of the active substance indicate a danger for the environment then the tests described in Sections XII and XIII shall be required

3. If the result of the test in paragraph 7.6.1.2 of Annex IIA is negative and if the likely route of disposal of the active substance is by sewage treatment then the test described in Section XIII, part 4.1 shall be required

4. Any other biodegradability tests that are relevant from the results in paragraphs 7.6.1.1 and 7.6.1.2 of Annex IIA

5. Phototransformation in air (estimation method), including identification of breakdown products ([1])

6. If the results from paragraphs 7.6.1.2 in Annex IIA or from paragraph 4, above, indicate the need to do so, or the active substance has an overall low or absent abiotic degradation, then the tests described in Section XII, part 1.1, part 2.1 and, where appropriate, part 3 shall be required

VIII. MEASURES NECESSARY TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

1. Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances[(3)]

Notes

([1]) These data must be submitted for the purified active substance of stated specification.

([2]) These data must be submitted for the active substance of stated specification.

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies

1.1. Identification of degradation and reaction products and of metabolites of the active substance in treated or contaminated foods or feedstuffs

1.2. Behaviour of the residue of the active substance, its degradation products and, where relevant, its metabolites on the treated or contaminated food or feedstuffs including the kinetics of disappearance

1.3. Overall material balance for the active substance. Sufficient residue data from supervised trials to demonstrate that residues likely to arise from the proposed use would not be of concern for human or animal health

1.4. Estimation of potential or actual exposure of the active substance to humans through diet and other means

1.5. If residues of the active substance remain on feedingstuffs for a significant period of time then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin

1.6. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the active substance

1.7. Proposed acceptable residues and the justification of their acceptability

1.8. Any other available information that is relevant

1.9. Summary and evaluation of data submitted under 1.1 to 1.8

2. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Fate and behaviour in soil

1.1. Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

1.2. Absorption and desorption in at least three soil types and, where relevant, absorption and desorption of metabolites and degradation products

1.3. Mobility in at least three soil types and where relevant mobility of metabolites and degradation products

1.4. Extent and nature of bound residues

2. Fate and behaviour in water

2.1. Rate and route of degradation in aquatic systems (as far as is not covered by Annex IIA, paragraph 7.6) including identification of metabolites and degradation products

2.2. Absorption and desorption in water (soil sediment systems) and, where relevant, absorption and desorption of metabolites and degradation products

3. Fate and behaviour in air

If the active substance is to be used in preparations for fumigants, if it is to be applied by a spray method, if it is volatile, or if any other information indicates that this is relevant, then the rate and route of degradation in air shall be determined as far as is not covered by Section VII, part 5

4. Summary and evaluation of parts 1, 2 and 3

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds

1.1. Acute oral toxicity — this need not be done if an avian species was selected for study in Section VII, part 1

1.2. Short-term toxicity — eight-day dietary study in at least one species (other than chickens)

1.3. Effects on reproduction

2. Effects on aquatic organisms

2.1. Prolonged toxicity to an appropriate species of fish

2.2. Effects on reproduction and growth rate on an appropriate species of fish

2.3. Bioaccumulation in an appropriate species of fish

2.4. *Daphnia magna* reproduction and growth rate

3. Effects on other non-target organisms

3.1. Acute toxicity to honeybees and other beneficial arthropods, e.g. predators. A different test organism shall be chosen from that used in Section VII, part 1

3.2. Toxicity to earthworms and to other soil non-target macro-organisms

3.3. Effects on soil non-target micro-organisms

3.4. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

4. Other effects

4.1. Activated sludge respiration inhibition test

5. Summary and evaluation of parts 1, 2, 3 and 4

ANNEX IIIB

ADDITIONAL DATA SET FOR BIOCIDAL PRODUCTS
CHEMICAL PRODUCTS

1. Dossiers on biocidal products are required to address at least all the points listed under ‘Dossier requirements’. Responses are required to be supported by data. The dossier requirements must be in line with technical development.

2. Information which is not necessary owing to the nature of the biocidal product or of its proposed uses need not be supplied. The same applies where it is not scientifically necessary or technically possible to supply the information. In such cases a justification, acceptable to the competent authority must be submitted. Such a justification may be the existence of a frame-formulation to which the applicant has the right of access.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 88/379/EEC should be used wherever possible to minimise animal testing.

XI. FURTHER HUMAN HEALTH-RELATED STUDIES

1. Food and feedingstuffs studies

1.1. If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin

1.2. Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

2. Other test(s) related to the exposure to humans

Suitable test(s) and a reasoned case will be required for the biocidal product

XII. FURTHER STUDIES ON FATE AND BEHAVIOUR IN THE ENVIRONMENT

1. Where relevant all the information required in Annex IIIA, Section XII

2. Testing for distribution and dissipation in the following:

(a) Soil

(b) Water

(c) Air

Test requirements 1 and 2 above are applicable only to ecotoxicologically relevant components of the biocidal product

XIII. FURTHER ECOTOXICOLOGICAL STUDIES

1. Effects on birds

1.1. Acute oral toxicity, if not already done in accordance with Annex IIB, Section VII

2. Effects on aquatic organisms

2.1. In case of application on, in, or near to surface waters

2.1.1. Particular studies with fish and other aquatic organisms

2.1.2. Residue data in fish concerning the active substance and including toxicologically relevant metabolites

2.1.3. The studies referred to in Annex IIIA, Section XIII, parts 2.1, 2.2, 2.3 and 2.4 may be required for relevant components of the biocidal product

2.2. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions

3. Effects on other non-target organisms

3.1. Toxicity to terrestrial vertebrates other than birds

3.2. Acute toxicity to honeybees

3.3. Effects on beneficial arthropods other than bees

3.4. Effects on earthworms and other soil non-target macro-organisms, believed to be at risk

3.5. Effects on soil non-target micro-organisms

3.6. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

3.7. If the biocidal product is in the form of bait or granules

3.7.1. Supervised trials to assess risks to non-target organisms under field conditions

3.7.2. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

4. Summary and evaluation of parts 1, 2, and 3

[F73ANNEX IVA

DATA SET FOR ACTIVE SUBSTANCES MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

Textual Amendments

F73 Substituted by Commission Directive 2006/50/EC of 29 May 2006 amending Annexes IVA and IVB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance).

1. For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. Dossiers on active micro-organisms shall address at least all the points listed under 'Dossier requirements' below. For all micro-organisms subject to an application for inclusion into Annex I or IA, all available relevant knowledge and information in literature must be provided. The information related to the identification and characterisation of a micro-organism including mode of action is particularly important and must be entered in sections I to IV and provides the basis for an assessment of potential impacts on human health and of environmental effects.

2. Where information is not necessary owing to the nature of the micro-organism Article 8(5) shall apply.

3. A dossier within the meaning of Article 11(1) shall be prepared on strain level of the micro-organism unless information is submitted that shows that the species is known to be sufficiently homogeneous regarding all characteristics, or the applicant provides other arguments in accordance with Article 8(5).

4. Where the micro-organism has been genetically modified within the meaning of Article 2(2) of Directive 2001/18/EC, a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in Article 4(2) of that Directive, shall also be submitted.

5. If the biocidal product action is known to be partly or entirely due to the effect of a toxin/metabolite, or if significant residues of toxins/metabolites are to be expected not related to the effect of the active micro-organism, a dossier for the toxin/metabolite shall be submitted in accordance with the requirements of Annexes IIA and, where specified, the relevant parts of Annex IIIA.

Dossier requirements

SECTIONS:

I. Identity of the micro-organism

II. Biological properties of the micro-organism

III. Further information on the micro-organism

IV. Analytical methods

V. Effects on human health

VI. Residues in or on treated materials, food and feed

VII. Fate and behaviour in the environment

VIII. Effects on non-target organisms

IX. Classification and labelling

X. Summary and evaluation of sections I to IX including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE MICRO-ORGANISM

1.1. Applicant

1.2. Manufacturer

1.3. Name and species description, strain characterisation

1.3.1. Common name of the micro-organism (including alternative and superseded names)

1.3.2. Taxonomic name and strain indicating whether it is a stock variant, a mutant strain or a genetically modified organism (GMO); for viruses, taxonomic designation of the agent, serotype, strain or mutant

1.3.3. Collection and culture reference number where the culture is deposited

1.3.4. Methods, procedures and criteria used to establish the presence and identity of the micro-organism (e.g. morphology, biochemistry, serology, etc.)

1.4. Specification of the material used for manufacturing of formulated products

1.4.1. Content of the micro-organism

1.4.2. Identity and content of impurities, additives, contaminating micro-organisms

1.4.3. Analytical profile of batches

II. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

2.1. History of the micro-organism and its uses. Natural occurrence and geographical distribution

2.1.1. Historical background

2.1.2. Origin and natural occurrence

2.2. Information on target organism(s)

2.2.1. Description of the target organism(s)

2.2.2. Mode of action

2.3. Host specificity range and effects on species other than the target organism

2.4. Development stages/life cycle of the micro-organism

2.5. Infectiveness, dispersal and colonisation ability

2.6. Relationships to known plant or animal or human pathogens

2.7. Genetic stability and factors affecting it

2.8. Information on the production of metabolites (especially toxins)

2.9. Antibiotics and other anti-microbial agents

2.10. Robustness to environmental factors

2.11. Effects on materials, substances and products

III. FURTHER INFORMATION ON THE MICRO-ORGANISM

3.1. Function

3.2. Field of use envisaged

3.3. Product type(s) and category of users for which the micro-organism should be listed in Annex I, IA or IB

3.4. Method of production and quality control

3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)

3.6. Methods to prevent loss of virulence of seed stock of the micro-organism

3.7. Recommended methods and precautions concerning handling, storage, transport or fire

3.8. Procedures for destruction or decontamination

3.9. Measures in case of an accident

3.10. Procedures for waste management

3.11. Monitoring plan to be used for the active micro-organism including handling, storage, transport and use

IV. ANALYTICAL METHODS

4.1. Methods for the analysis of the micro-organism as manufactured

4.2. Methods to determine and quantify residues (viable or non-viable)

V. EFFECTS ON HUMAN HEALTH
TIER I

5.1. Basic information

5.1.1. Medical data

5.1.2. Medical surveillance on manufacturing plant personnel

5.1.3. Sensitisation/allergenicity observations

5.1.4. Direct observation, e.g. clinical cases

5.2. Basic studies

5.2.1. Sensitisation

5.2.2. Acute toxicity, pathogenicity, and infectiveness

5.2.2.1. Acute oral toxicity, pathogenicity and infectiveness

5.2.2.2. Acute inhalation toxicity, pathogenicity and infectiveness

5.2.2.3. Intraperitoneal/subcutaneous single dose

5.2.3. *In vitro* genotoxicity testing

5.2.4. Cell culture study

5.2.5. Information on short-term toxicity and pathogenicity

5.2.5.1. Health effects after repeated inhalatory exposure

5.2.6. Proposed treatment: first aid measures, medical treatment

5.2.7. Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression

END OF TIER I

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TIER II

5.3. Specific toxicity, pathogenicity and infectiveness studies

5.4. Genotoxicity — *In vivo* studies in somatic cells

5.5. Genotoxicity — *In vivo* studies in germ cells

END OF TIER II

5.6. Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation

VI. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

6.1. Persistence and likelihood of multiplication in or on treated materials, feedingstuffs or foodstuffs

6.2. Further information required

6.2.1. Non-viable residues

6.2.2. Viable residues

6.3. Summary and evaluation of residues in or on treated materials, food and feed

VII. FATE AND BEHAVIOUR IN THE ENVIRONMENT

7.1. Persistence and multiplication

7.1.1. Soil

7.1.2. Water

7.1.3. Air

7.2. Mobility

7.3. Summary and evaluation of fate and behaviour in the environment

VIII. EFFECTS ON NON-TARGET ORGANISMS

8.1. Effects on birds

8.2. Effects on aquatic organisms

8.2.1. Effects on fish

8.2.2. Effects on freshwater invertebrates

8.2.3. Effects on algae growth

8.2.4. Effects on plants other than algae

8.3. Effects on bees

8.4. Effects on arthropods other than bees

8.5. Effects on earthworms

8.6. Effects on soil micro-organisms

8.7. Further studies

8.7.1. Terrestrial plants

8.7.2. Mammals

8.7.3. Other relevant species and processes

8.8. Summary and evaluation of effects on non-target organisms

IX. CLASSIFICATION AND LABELLING

The dossier shall be accompanied by a reasoned proposals for allocating an active substance which is a micro-organism to one of the risk groups specified in Article 2 of Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work[(4)] together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.

X.SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS

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ANNEX IVB

DATA SET FOR BIOCIDAL PRODUCTS MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI

1. For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. This Annex provides data requirements for the authorisation of a biocidal product based on preparations of micro-organisms. For all

biocidal products based on preparations containing micro-organisms that are subject to application, all available relevant knowledge and information in literature should be provided. The information related to the identification and characterisation of all components in a biocidal product is particularly important and must be entered in sections I to IV and provides the basis for an assessment of possible impacts on human health and the environment.

2. Where, information is not necessary owing to the nature of the biocidal product Article 8(5) shall apply.

3. Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(5)] shall be used wherever possible to minimise animal testing.

4. Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of Section II, must be provided. Where necessary, data as established in Annexes IIB, IIIB shall be required for all the toxicologically/eco-toxicologically relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in Article 2(1)(e).

5. In cases where a new preparation is to be dealt with, extrapolation from Annex IVA, could be acceptable, provided that all the possible effects of the components, especially on pathogenicity and infectiveness, are evaluated.

Dossier requirements

SECTIONS:

I. Identity of the biocidal product

II. Physical, chemical and technical properties of the biocidal product

III. Data on application

IV. Further information on the biocidal product

V. Analytical methods

VI. Efficacy data

VII. Effects on human health

VIII. Residues in or on treated materials, food and feed

IX. Fate and behaviour in the environment

X. Effects on non-target organisms

XI. Classification, packaging and labelling of the biocidal product

XII. Summary and evaluation of sections I to XI including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

I. IDENTITY OF THE BIOCIDAL PRODUCTS

1.1. Applicant

1.2. Manufacturer of the biocidal product and the micro-organism(s)

1.3. Trade name or proposed trade name, and manufacturer's development code number of the biocidal product

1.4. Detailed quantitative and qualitative information on the composition of the biocidal product

1.5. Physical state and nature of the biocidal product

1.6. Function

II. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT

2.1. Appearance (colour and odour)

2.2. Storage stability and shelf-life

2.2.1. Effects of light, temperature and humidity on technical characteristics of the biocidal product

2.2.2. Other factors affecting stability

2.3. Explosivity and oxidising properties

2.4. Flash point and other indications of flammability or spontaneous ignition

2.5. Acidity, alkalinity and pH value

2.6. Viscosity and surface tension

2.7. Technical characteristics of the biocidal product

2.7.1. Wettability

2.7.2. Persistent foaming

2.7.3. Suspensibility and suspension stability

2.7.4. Dry sieve test and wet sieve test

2.7.5. Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)

2.7.6. Emulsifiability, re-emulsifiability, emulsion stability

2.7.7. Flowability, pourability (rinsability) and dustability

2.8. Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorised or registered

2.8.1. Physical compatibility

2.8.2. Chemical compatibility

2.8.3. Biological compatibility

2.9. Summary and evaluation of physical, chemical and technical properties of the biocidal product

III. DATA ON APPLICATION

3.1. Field of use envisaged

3.2. Mode of action

3.3. Details of intended use

3.4. Application rate

3.5. Content of micro-organism in material used (e.g. in the application device or bait)

3.6. Method of application

3.7. Number and timing of applications and duration of protection

3.8. Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment

3.9. Proposed instructions for use

3.10. Category of users

3.11. Information on the possible occurrence of the development of resistance

3.12. Effects on the materials or products treated with the biocidal product

IV. FURTHER INFORMATION ON THE BIOCIDAL PRODUCT

4.1. Packaging and compatibility of the biocidal product with proposed packaging materials

4.2. Procedures for cleaning application equipment

4.3. Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

4.4. Recommended methods and precautions concerning: handling, storage, transport or fire

4.5. Measures in the case of an accident

4.6. Procedures for destruction or decontamination of the biocidal product and its packaging

4.6.1. Controlled incineration

4.6.2. Others

4.7. Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use

V. ANALYTICAL METHODS

5.1. Methods for the analysis of the biocidal product

5.2. Methods to determine and quantify residues

VI.EFFICACY DATA

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VII. EFFECTS ON HUMAN HEALTH

7.1. Basic acute toxicity studies

7.1.1. Acute oral toxicity

7.1.2. Acute inhalation toxicity

7.1.3. Acute percutaneous toxicity

7.2. Additional acute toxicity studies

7.2.1. Skin irritation

7.2.2. Eye irritation

7.2.3. Skin sensitisation

7.3. Data on exposure

7.4. Available toxicological data relating to non-active substances

7.5. Supplementary studies for combinations of biocidal products

7.6. Summary and evaluation of effects on human health

VIII. RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

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IX. FATE AND BEHAVIOUR IN THE ENVIRONMENT

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X. EFFECTS ON NON-TARGET ORGANISMS

10.1. Effects on birds

10.2. Effects on aquatic organisms

10.3. Effects on bees

10.4. Effects on arthropods other than bees

10.5. Effects on earthworms

10.6. Effects on soil micro-organisms

10.7. Additional studies on additional species or higher tier studies such as studies on selected non-target organisms

10.7.1. Terrestrial plants

10.7.2. Mammals

10.7.3. Other relevant species and processes

10.8. Summary and evaluation of effects on non-target organisms

XI. CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT

As established in Article 20, proposals including justification for the classification and labelling of the biocidal product in accordance with the provisions set in Directive 67/548/EEC and

Directive 1999/45/EC must be submitted. The classification comprises of the description of the category/categories of danger and qualifying risk phrases for all dangerous properties. On the basis of the classification, a proposal for labelling including the hazard symbol(s) and indications of danger, risk phrases and safety phrases should be given. The classification and labelling shall be in regard to the chemical substances contained in the biocidal product. If necessary, specimens of proposed packaging shall be submitted to the competent authority of a Member State.

The dossier shall be accompanied by a reasoned proposal for allocation to one of the risk groups specified in Article 2 of Directive 2000/54/EC together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.
XII.SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS**]**
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ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)(a) OF THIS DIRECTIVE

These product-types exclude products where they are covered by the Directives mentioned in Article 1(2) of this Directive for the purposes of these Directives and their subsequent modifications.
MAIN GROUP 1: Disinfectants and general biocidal products

These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.
Product-type 1: Human hygiene biocidal products

Products in this group are biocidal products used for human hygiene purposes.
Product-type 2: Private area and public health area disinfectants and other biocidal products

Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algaecides.

Usage areas include, *inter alia*, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).
Product-type 3: Veterinary hygiene biocidal products

Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.
Product-type 4: Food and feed area disinfectants

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.
Product-type 5: Drinking water disinfectants

Products used for the disinfection of drinking water (for both humans and animals).
MAIN GROUP 2: Preservatives
Product-type 6: In-can preservatives

Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.
Product-type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.
Product-type 8: Wood preservatives

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.

This product type includes both preventive and curative products.
Product-type 9: Fibre, leather, rubber and polymerised materials preservatives

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.
Product-type 10: Masonry preservatives

Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.
Product-type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels.

Products used for the preservation of drinking water are not included in this product type.
Product-type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.
Product-type 13: Metalworking-fluid preservatives

Products used for the preservation of metalworking fluids by the control of microbial deterioration.
MAIN GROUP 3: Pest control
Product-type 14: Rodenticides

Products used for the control of mice, rats or other rodents.
Product-type 15: Avicides

Products used for the control of birds.
Product-type 16: Molluscicides

Products used for the control of molluscs.
Product-type 17: Piscicides

Products used for the control of fish; these products exclude products for the treatment of fish diseases.
Product-type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).
Product-type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

MAIN GROUP 4: Other biocidal products
Product-type 20: Preservatives for food or feedstocks

Products used for the preservation of food or feedstocks by the control of harmful organisms.
Product-type 21: Antifouling products

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.
Product-type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.
Product-type 23: Control of other vertebrates

Products used for the control of vermin.

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

CONTENTS

DEFINITIONS

(a) Hazard identification

This is the identification of the adverse effects which a biocidal product has an inherent capacity to cause.

(b) Dose (concentration) — response (effect) assessment

This is the estimate of the relationship between the dose, or level of exposure, of an active substance or substance of concern in a biocidal product and the incidence and severity of an effect.

(c) Exposure assessment

This is the determination of the emissions, pathways and rates of movement of an active substance or a substance of concern in a biocidal product and its transformation or degradation in order to estimate the concentration/doses to which human populations, animals or environmental compartments are or may be exposed.

(d) Risk characterisation

This is the estimation of the incidence and severity of the adverse effects likely to occur in a human population, animals or environmental compartments due to actual or predicted exposure to any active substance or substance of concern in a biocidal product. This may include 'risk estimation' i.e. the quantification of that likelihood.

(e) Environment

Water, including sediment, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms.

INTRODUCTION

1. This Annex lays down principles to ensure that evaluations made and decisions taken by a Member State concerning the authorisation of a biocidal product providing it is a chemical preparation results in a harmonised high level of protection for humans, animals and the environment in accordance with Article 5(1)(b) of this Directive.

2. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this a risk assessment shall be carried out to determine the acceptability or otherwise of any risks identified during the proposed normal use of the biocidal product. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product.

3. A risk assessment on the active substance or substances present in the biocidal product is always required. This will already have been carried out for the purpose of Annexes I, IA or IB. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.

4. Additional risk assessments shall be carried out, in the same manner as described above, on any other substance of concern present in the biocidal product where relevant for the use of the biocidal product.

5. In order to carry out a risk assessment data are required. These data are detailed in Annexes II, III and IV and, recognising that there are a wide variety of product types, are flexible according to the product type and associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. Member States should take due consideration of the requirements of Articles 12 and 13 of this Directive in order to avoid duplication of data submissions. The minimum set of data required for an active substance in any biocidal product type, however, shall be that detailed in Annex VIIA to Directive 67/548/EEC; these data will already have been submitted and assessed as part of the risk assessment required for entry of the active

substance into Annex I, IA or IB to this Directive. Data may also be required on a substance of concern present in a biocidal product.

6. The results of the risk assessments carried out on an active substance and on a substance of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.

7. When making evaluations and taking decisions concerning the authorisation of a biocidal product the Member State shall:

(a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;

(b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.

8. The Member State shall comply with the requirements of mutual recognition as stated in Articles 4(1), (2) and (6) of this Directive.

9. It is known that many biocidal products present only minor differences in composition and this should be taken into account when evaluating dossiers. The concept of 'frame-formulations' is relevant here.

10. It is known that certain biocidal products are considered as posing only a low risk, these biocidal products, while complying with the requirements of this Annex, are subject to a simplified procedure as detailed in Article 3 of this Directive.

11. The application of these common principles shall lead to the Member State deciding whether or not a biocidal product can be authorised, such authorisation may include restrictions on use or other conditions. In certain cases the Member State may conclude that more data are required before an authorisation decision can be made.

12. During the process of evaluation and decision-making, Member States and applicants shall cooperate in order to resolve any questions on the data requirements quickly or to identify at an early stage any additional studies required, or to amend any proposed conditions for the use of the biocidal product or to modify its nature or its composition in order to ensure full compliance with the requirements of this Annex or of this Directive. The administrative burden, especially for small and medium-sized enterprises (SMEs), shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.

13. The judgments made by the Member State during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.

EVALUATION

General principles

14. The data submitted in support of an application for authorisation of a biocidal product shall be examined for completeness and overall scientific value by the receiving Member State. After acceptance of these data the Member State shall utilise them by carrying out a risk assessment based on the proposed use of the biocidal product.

15. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product together with

a realistic worst-case scenario including any relevant production and disposal issue either of the biocidal product itself or any material treated with it.

16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail a hazard identification and the establishment of appropriate no-observed-adverse-effect levels (NOAEL), where possible. It shall also include, as appropriate, a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.

17. The results arrived at from a comparison of the exposure to the no-effect level concentrations for each of the active substances and any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.

18. The risk assessment shall determine:

(a) the risk to humans and animals,

(b) the risk to the environment,

(c) the measures necessary to protect humans, animals and the general environment during both the proposed normal use of the biocidal product and in a realistic worst-case situation.

19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

Effects on humans

20. The risk assessment shall take account of the following potential effects arising from the use of the biocidal product and the populations liable to exposure.

21. The effects previously mentioned result from the properties of the active substance and any substance of concern present. They are:

— acute and chronic toxicity,
— irritation,
— corrosivity,
— sensitisation,
— repeated dose toxicity,
— mutagenicity,
— carcinogenicity,
— reproduction toxicity,
— neurotoxicity,
— any other special properties of the active substance or substance of concern,
— other effects due to physico-chemical properties.

22. The populations previously mentioned are:

— professional users,
— non-professional users,
— humans exposed indirectly via the environment.

23. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If

this results in the biocidal product being classified according to the requirements of Article 20 of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.

24. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not lead to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern, e.g. adverse environmental effects or unacceptable residues.

25. The Member State shall apply paragraphs 26 to 29 when carrying out a dose (concentration) — response (effect) assessment on an active substance or a substance of concern present in a biocidal product.

26. For repeated dose toxicity and reproductive toxicity the dose response relationship shall be assessed for each active substance or substance of concern and, where possible, the no-observed-adverse-effect level (NOAEL) identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified.

27. For acute toxicity, corrosivity and irritation, it is not usually possible to derive a NOAEL or LOAEL on the basis of tests conducted in accordance with the requirements of this Directive. For acute toxicity, the LD50 (median lethal dose) or LC50 (median lethal concentration) value or, where the fixed dose procedure has been used, the discriminating dose shall be derived. For the other effects it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the product.

28. For mutagenicity and carcinogenicity it shall be sufficient to determine whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product. However, if it can be demonstrated that an active substance or a substance of concern identified as a carcinogen is non-genotoxic, it will be appropriate to identify a N(L)OAEL as described in paragraph 26.

29. With respect to skin sensitisation and respiratory sensitisation, in so far as there is no consensus on the possibility of identifying a dose/concentration below which adverse effects are unlikely to occur in a subject already sensitised to a given substance, it shall be sufficient to evaluate whether the active substance or substance of concern has an inherent capacity to cause such effects during use of the biocidal product.

30. Where toxicity data derived from observations of human exposure, e.g. information gained from manufacture, from poison centres or epidemiology surveys, are available special consideration shall be given to those data when carrying out the risk assessment.

31. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective of the assessment shall be to makea quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

32. The exposure assessment shall be based on the information in the technical dossier provided in conformity with Article 8 of this Directive and on any other available and relevant information. Particular account shall be taken, as appropriate, of:

— adequately measured exposure data,
— the form in which the product is marketed,
— the type of biocidal product,
— the application method and application rate,
— the physico-chemical properties of the product,
— the likely routes of exposure and potential for absorption,
— the frequency and duration of exposure,
— the type and size of specific exposed populations where such information is available.

33. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied.

These models shall:
— make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,
— be subjected to an analysis taking into account possible elements of uncertainty,
— be reliably validated with measurements carried out under circumstances relevant for the use of the model,
— be relevant to the conditions in the area of use.

Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties shall also be considered.

34. Where, for any of the effects set out in paragraph 21 a NOAEL or LOAEL had been identified, the risk characterisation shall entail comparison of the NOAEL or LOAEL with the evaluation of the dose/concentration to which the population will be exposed. Where a NOAEL or LOAEL cannot be established a qualitative comparison shall be made.

Effects on animals

35. Using the same relevant principles as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product.

Effects on the environment

36. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota following the use of the biocidal product.

37. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.

38. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not led to classification of the biocidal product then riskcharacterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:

— any indications of bioaccumulation potential,
— the persistence characteristics,
— the shape of the toxicity/time curve in ecotoxicity testing,
— indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),
— data on structurally analogous substances,
— endocrine effects.

39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.

40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 8 of this Directive. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).

41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and environment from substances notified in accordance with Council Directive 67/548/EEC[6].

42. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.

43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.

44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:
— adequately measured exposure data,
— the form in which the product is marketed,
— the type of biocidal product,
— the application method and application rate,
— the physico-chemical properties,

— breakdown/transformation products,

— likely pathways to environmental compartments and potential for adsorption/desorption and degradation,

— the frequency and duration of exposure.

45. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in paragraph 33. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.

46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.

47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

Unacceptable effects

48. Data shall be submitted to and evaluated by the Member State to assess whether the biocidal product does not cause unnecessary suffering in its effect on target vertebrates. This shall include an evaluation of the mechanism by which the effect is obtained and the observed effects on the behaviour and health of the target vertebrates; where the intended effect is to kill the target vertebrate the time necessary to obtain the death of the target vertebrate and the conditions under which death occurs shall be evaluated.

49. The Member State shall, where relevant, evaluate the possibility of the development of resistance to an active substance in the biocidal product by the target organism.

50. If there are indications that any other unacceptable effects may occur the Member State shall evaluate the possibility of such effects occurring. An example of such an unacceptable effect would be an adverse reaction to fastenings and fittings used in wood following the application of a wood preservative.

Efficacy

51. Data shall be submitted and evaluated to ascertain if the efficacy claims of the biocidal product can be substantiated. Data submitted by the applicant or held by the Member State must be able to demonstrate the efficacy of the biocidal product against the target organism when used normally in accordance with the conditions of authorisation.

52. Testing should be carried out according to Community guidelines if these are available and applicable. Where appropriate, other methods can be used as shown in the list below. If relevant acceptable field data exist, these can be used.

— ISO, CEN or other international standard method

— national standard method

— industry standard method (accepted by Member State)

— individual producer standard method (accepted by Member State)

— data from the actual development of the biocidal product (accepted by Member State).

Summary

53. In each of the areas where risk assessments have been carried out, i.e. effects on man, animals, and the environment, the Member State shall combine the results for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This should take account of any likely synergistic effects of the active substance(s) and substances of concern in the biocidal product.

54. For biocidal products containing more than one active substance any adverse effects shall also be combined to produce an overall effect for the biocidal product itself.

DECISION MAKING

General principles

55. Subject to paragraph 96, the Member State shall come to a decision regarding the authorisation for use of a biocidal product as a result of the integration of the risks arising from each active substance together with the risks from each substance of concern present in the biocidal product. The risk assessments shall cover normal use of the biocidal product together with a realistic worst-case scenario including any relevant disposal issue either of the biocidal product itself or any material treated with it.

56. In making a decision concerning authorisation, the Member State shall arrive at one of the following conclusions for each product type and for each area of use of the biocidal product for which application has been made:

1. the biocidal product cannot be authorised;

2. the biocidal product can be authorised subject to specific conditions/restrictions;

3. more data is required before a decision on authorisation can be made.

57. If the conclusion arrived at by the Member State is that additional information or data are required before an authorisation decision can be made, then the need for any such information or data shall be justified. This additional information or data shall be the minimum necessary to carry out a further appropriate risk assessment.

58. The Member State shall comply with the principles of mutual recognition as detailed in Article 4 of this Directive.

59. The Member State shall apply the rules concerning the concept of ‘frame formulations’ when making an authorisation decision on a biocidal product.

60. The Member State shall apply the rules concerning the concept of ‘low risk’ products when making an authorisation decision on such a biocidal product.

61. The Member State shall only grant authorisation to those biocidal products which, when used according to their conditions of authorisation, do not present an unacceptable risk to humans, animals or the environment, are efficacious and which contain active substances permitted at Community level to be used in such biocidal products.

62. The Member State shall impose, where appropriate, conditions or restrictions when giving authorisations. The nature and severity of these shall be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise from the use of the biocidal product.

63. In the decision-making process the Member State shall take into consideration the following:

— the results of the risk assessment, in particular the relationship between exposure and effect,

— the nature and severity of the effect,

— the risk management which can be applied,

— the field of use of the biocidal product,

— the efficacy of the biocidal product,

— the physical properties of the biocidal product,

— the benefits of using the biocidal product.

64. The Member State shall, when taking a decision concerning the authorisation of a biocidal product, take into account the uncertainty arising from the variability in the data used in the evaluation and decision-making process.

65. The Member State shall prescribe that biocidal products shall be used properly. Proper use shall include application at an efficacious dose and minimisation of use of biocidal products where possible.

66. The Member State shall take the necessary measures to ensure that the applicant proposes a label, and, where relevant, the safety-data sheet, for the biocidal product which:

— fulfils the requirements of Articles 20 and 21 of this Directive,

— contains the information on the protection of users required by Community legislation on worker protection,

— specifies in particular the conditions or restrictions under which the biocidal product may or may not be used.

Before issuing an authorisation the Member State shall confirm that these requirements must be satisfied.

67. The Member State shall take the necessary measures to ensure that the applicant proposes packaging and, where appropriate, the procedures for destruction or decontamination of the biocidal product and its packaging or any other relevant material associated with the biocidal product, which conforms to the relevant regulatory provisions.

Effects on humans

68. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in foreseeable application including a realistic worst possible scenario, the product presents an unacceptable risk to humans.

69. The Member State shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment when making a decision on the authorisation of a biocidal product.

70. The Member State shall examine the relationship between the exposure and the effect, and use this in the decision-making process. A number of factors need to be considered when examining this relationship and one of the most important is the nature of the adverse effect of the substance. These effects include acute toxicity, irritancy, corrosivity, sensitisation, repeated dose toxicity, mutagenicity, carcinogenicity, neurotoxicity, reproduction toxicity together with physico-chemical

properties, and any other adverse properties of the active substance or substance of concern.

71. The Member State shall, where possible, compare the results obtained with those obtained from previous risk assessments for an identical or similar adverse effect and decide on an appropriate margin of safety (MOS) when making an authorisation decision.

An appropriate MOS is typically 100 but an MOS higher or lower than this may be appropriate depending on, among other things, the nature of the critical toxicological effect.

72. The Member State shall, if appropriate, impose, as a condition of authorisation, the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles in order to reduce exposure for professional operators. Such equipment must be readily available to them.

73. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure, the product shall not normally be authorised.

74. If the relationship between the exposure and the effect cannot be reduced to an acceptable level then no authorisation can be given by the Member State for the biocidal product.

75. No biocidal product classified according to Article 20(1) of this Directive as toxic, very toxic or as a category 1 or 2 carcinogen, or as a category 1 or 2 mutagen, or classified as toxic for reproduction category 1 or 2, shall be authorised for use by the general public.

Effects on animals

76. The Member State shall not authorise a biocidal product if the risk assessment confirms that, in normal use, the biocidal product presents an unacceptable risk to non-target animals.

77. Using the same relevant criteria as described in the section dealing with effects on humans, the Member State shall consider the risks posed to animals from the biocidal product when making an authorisation decision.

Effects on the environment

78. The Member State shall not authorise a biocidal product if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil and air. This shall include the assessment of risks to non-target organisms in these compartments.

In considering whether there is an unacceptable risk Member States shall, when coming to a final decision in accordance with paragraph 96, take into account the criteria in paragraphs 81 to 91.

79. The basic tool used in the decision making is the PEC/PNEC ratio or, if this is not available, a qualitative estimation. Due consideration shall be given to the accuracy of this ratio due to variability in the data used both in measurements of concentration and of estimation.

In the determination of the PEC the most appropriate model should be used taking into account the environmental fate and behaviour of the biocidal product.

80. For any given environmental compartment if the PEC/PNEC ratio is equal to or less than 1 the risk characterisation shall be that no further information and/or testing are necessary.

If the PEC/PNEC ratio is greater than 1 the Member State shall judge, on the basis of the size of that ratio and on other relevant factors, if further information and/or testing are required to clarify the concern or if risk reduction measures are necessary or if the product cannot be given an authorisation at all. Relevant factors to be considered are those previously mentioned in paragraph 38.

Water

81. The Member State shall not authorise a biocidal product, if under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in water (or its sediments) has an unacceptable impact on non-target species in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

82. The Member State shall not authorise a biocidal product if, under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in groundwater exceeds the lower of the following concentrations:

(a) the maximum permissible concentration laid down by Directive 80/778/EEC, or

(b) the maximum concentration as laid down following the procedure for including the active substance in Annex I, IA or IB to this Directive, on the basis of appropriate data, in particular toxicological data

unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

83. The Member State shall not authorise a biocidal product if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:

— exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by
  - Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States[(7)],
  - Directive 80/778/EEC or
— has an impact deemed unacceptable on non-target species

unless it is scientifically demonstrated that under relevant field conditions this concentration is not exceeded.

84. The proposed instructions for use of the biocidal product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of water or its sediments is minimised.

Soil

85. Where unacceptable contamination of soil is likely to occur, the Member State shall not authorise a biocidal product if the active substance or substance of concern contained in it, after use of the biocidal product:

— during tests in the field, persists in soil for more than one year, or

— during laboratory tests, forms non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5 % in 100 days,

— has unacceptable consequences or effects on non-target organisms,

unless it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil.

Air

86. The Member State shall not authorise a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Effects on non-target organisms

87. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product if for any active substance or substance of concern:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur after use of the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) related to fat tissues in non-target vertebrates is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur, either directly or indirectly, after use of the product according to the proposed conditions of use.

88. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product if for any active substance or substance of concern in it:

— the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions the viability of aquatic organisms including marine and estuarine organisms is not threatened by the biocidal product according to the proposed conditions of use, or

— the bioconcentration factor (BCF) is greater than 1 000 for substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of exposed organisms including marine and estuarine organisms after use of the biocidal product according to the proposed conditions of use.

By way of derogation from this paragraph, Member States may, however, authorise an anti-fouling product used on commercial, public service and naval seagoing vessels for a period of up to 10 years from the date on which this Directive enters into force if similar fouling control cannot be achieved by other practicable means. When implementing this provision, Member States shall, if appropriate, take into account relevant International Maritime Organisation (IMO) resolutions and recommendations.

89. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of micro-organisms in sewage treatment plants being exposed to the biocidal product if for any active substance, substance of concern, relevant metabolite, breakdown or reaction product the PEC/PNEC ratio is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of such micro-organisms.

Unacceptable effects

90. If the development of resistance to the active substance in the biocidal product is likely the Member State shall take steps to minimise the consequences of this resistance. This may involve modification of the conditions of authorisation or even refusal of any authorisation.

91. An authorisation for a biocidal product intended to control vertebrates shall not be given unless:

— death is synchronous with the extinction of consciousness, or,

— death occurs immediately, or,

— vital functions are reduced gradually without signs of obvious suffering.

For repellent products, the intended effect shall be obtained without unnecessary suffering and pain for the target vertebrate.

Efficacy

92. Member States shall not authorise a biocidal product which does not possess acceptable efficacy when used in accordance with the conditions specified on the proposed label or with other conditions of authorisation.

93. The level, consistency and duration of protection, control or other intended effects must, as a minimum, be similar to those resulting from suitable reference products, where such products exist, or to other means of control. Where no reference products exist, the biocidal product must give a defined level of protection or control in the areas of proposed use. Conclusions as to the performance of the biocidal product must be valid for all areas of proposed use and for all areas in the Member State except where the proposed label prescribes that the biocidal product is intended for use in specific circumstances. Member States shall evaluate dose response data generated in trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.

Summary

94. In each of the areas where risk assessments have been carried out, i.e. effects on humans, animals, and the environment, the Member State shall combine the conclusions arrived at for the active substance and the substances of concern to produce an overall conclusion for the biocidal product itself. A summary should also be made of the efficacy assessment and of the unacceptable effects.

The result shall be:

— a summary of the effects of the biocidal product on humans,

— a summary of the effects of the biocidal product on animals,

— a summary of the effects of the biocidal product on the environment,

— a summary of the efficacy assessment,

— a summary of the unacceptable effects.

OVERALL INTEGRATION OF CONCLUSIONS

95. The Member State shall combine the individual conclusions arrived at with regard to effects of the biocidal product on the three sectors namely, humans, animals and the environment to arrive at an overall conclusion for the global effect of the biocidal product.

96. The Member State shall then take due consideration of any relevant unacceptable effects, the efficacy of the biocidal product and the benefits of using the biocidal product before taking an authorisation decision on the biocidal product.

97. The Member State shall ultimately decide whether or not the biocidal product can be authorised and whether this authorisation shall be subject to any restrictions or conditions in conformity with this Annex and this Directive.

(**1**) OJ L 154, 5.6.1992, p. 1.

(**2**) OJ L 229, 30.8.1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).

(**3**) OJ L 20, 26.1.1980, p. 43.

(**4**) **[**[F73]OJ L 262, 17.10.2000, p. 21.

(**5**) OJ L 200, 30.7.1999, p. 1. Directive as last amended by Commission Directive 2006/8/EC (OJ L 19, 24.1.2006, p. 12).**]**

(**6**) OJ L 227, 8.9.1993, p. 9.

(**7**) OJ L 194, 25.7.1975, p. 26. Directive as last amended by Directive 91/692/EEC (OJ L 377, 31.12.1991, p. 48).

Textual Amendments

F73 Substituted by Commission Directive 2006/50/EC of 29 May 2006 amending Annexes IVA and IVB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Text with EEA relevance).