

L.N. 90 of 2013

**PESTICIDES CONTROL ACT
(CAP. 430)**

Biocides (Amendment) Regulations, 2013

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

1. (1) The title of these regulations is the Biocides (Amendment) Regulations, 2013, and these regulations shall be read and construed as one with the Biocides Regulations, hereinafter referred to as "the principal regulations".

Citation and scope.

S.L. 430.03

(2) The scope of these regulations is to transpose 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; 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; 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; 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; 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; 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; 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; 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; 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; Commission Directive 2012/41/EU

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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; 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; and 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.

Amends
Schedule I of
the principal
regulations.

2. Schedule I to the principal regulations shall be amended as follows:-

(a) In Part A thereof, immediately after item number 49 there shall be added the following:-

"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	<p>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.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(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.</p> <p>(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 authorization that risks to industrial users can be reduced to an acceptable level by other means.</p> <p>(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.</p> <p>(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.</p>
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51	Copper (II) Oxide	Copper (II) oxide EC No: 215-269-1 CAS No: 1317-38-0	976 g/kg	1 February 2014	31 January 2016	31 January 2024	8	<p>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.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(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.</p> <p>(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.</p> <p>(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.</p>
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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	<p>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:</p> <p>(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.</p> <p>(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 authorization that risks to industrial users can be reduced to an acceptable level by other means.</p> <p>(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.</p> <p>(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</p>
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53	Bendio carb	2,2-dimethyl-1,3-benzodioxo 1-4-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	<p>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.</p> <p>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.</p>
54	Methylnonyl ketone	Undecan-2-one CAS No: 112-12-9 EC No: 203-937-5	975 g/kg	1 May 2014	30 April 2016	30 April 2024	19	<p>The Union level risk 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.</p>

55	Margosa extract	IUPAC name: Not applicable CAS-No: 84696-25-3 EC No: 283-644-7 Description : margosa extract from the kernels of <i>Azadirachta indica</i> extracted with water and further processed with organic solvents	1000 g/kg	1 May 2014	30 April 2016	30 April 2024	18	<p>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.</p> <p>Member States shall ensure that authorisations are subject to appropriate risk mitigation measures for the protection of surface water, sediment and non-target arthropods.</p>
56	Hydrochloric acid	Hydrochloric acid CAS No: not applicable EC No: 231-595-7	999 g/kg	1 May 2014	30 April 2016	30 April 2024	2	<p>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.</p> <p>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.</p>

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57	flufenoxuron	1-[4-(2-chloro-alpha, alpha-trifluoroparatoxy)-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	<p>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.</p> <p>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.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(1) Products shall only be used for treatment of wood intended for indoor use.</p> <p>(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</p> <p>(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.</p>
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58	DDA Carbon -ate	Reaction mass of N,N- Didecyl- N,N- dimethyl ammonium Carbonate and N,N- Didecyl- N,N- dimethyl ammonium 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	<p>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.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(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;</p> <p>(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;</p> <p>(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.</p>
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59	cis-tricos-9-ene (Musca lure)	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	<p>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.</p> <p>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.</p>
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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	<p>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:</p> <p>(1) product shall only be supplied to and used by professionals adequately trained to use them;</p> <p>(2) safe operational procedures during fumigation and venting shall be established for operators and bystanders;</p> <p>(3) products shall be used with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing;</p> <p>(4) re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and bystanders by ventilation;</p> <p>(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;</p> <p>(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."</p>
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(b) In Part A thereof, items 21 and 41 shall be substituted by the following, respectively:-

"21	Disodium tetraborate	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	<p>When assessing the application for authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.</p> <p>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:</p> <ol style="list-style-type: none"> 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.
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41	Nonanoic acid, Pelargonic acid	IUPAC name: Nonanoic acid EC No: 203-931-2 CAS No: 112-05-0	896 g/ kg	1 February 2013	31 January 2015	31 January 2023	19	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to environmental compartments and populations that have not been representatively addressed in Union level risk assessment.
				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."

(c) In Part A thereof, the first row of the Schedule containing the headings of the table shall be substituted by the following:

"No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
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(*) The 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.

(**) 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).

(***) 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>.

