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**L.N. 318 of 2013****PESTICIDES CONTROL ACT  
(CAP. 430)****Biocides (Amendment No. 2) Regulations, 2013**

IN exercise of the powers conferred by articles 4 and 5 of the Pesticides Control Act, the Minister for Sustainable Development, the Environment and Climate Change, in consultation with the Minister for Health, has made the following regulations:-

Citation, scope  
and  
commencement.  
S.L. 430.03

**1.** (1) The title of these regulations is the Biocides (Amendment No. 2) Regulations, 2013, and these regulations shall be read and construed as one with the Biocides Regulations, hereinafter referred to as "the principal regulations".

(2) The scope of these regulations is to transpose the following Directives:

(a) 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;

(b) 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;

(c) 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;

(d) 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;

(e) 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 (C 12-16) dimethylbenzyl ammonium chloride as an active substance in Annex I.

(3) These regulations shall come into force as from 1st February 2015.

**2.** Part A of Schedule I to the principal regulations shall be amended as follows:

Amends  
Schedule I to  
the principal  
regulations.

(a) the following shall be added to item 14 thereof, immediately at the end of the said item :

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No	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 (*)
"			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.

							<p>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:</p> <p>(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.</p> <p>(2) Where appropriate, measures shall be taken to protect honey bees." .</p>
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(b) immediately after item 60 thereof, there shall be added the following new items:

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

							<p>addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions:</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p>
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								necessary by the application of appropriate mitigation measures
62	pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy) propyl ether EC No: 429-800-1 CAS No: 95737-68-1	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 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.

								<p>(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.</p> <p>(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.</p>
63	diflubenzuron	1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl) urea EC No: 252-529-3 CAS No: 35367-38-5	960 g/kg	1 February 2015	31 January 2017	31 January 2025	18	<p>The Union level 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.</p>



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								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.
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:

							<p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(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."</p>
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