Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 18,718, 11 ta' Marzu, 2011
Taqsima B

A.L. 92 tal-2011

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

Regolamenti ta' l-2011 li jemendaw ir-Regolamenti dwar il-Bijoċidi

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

Titolu u skop.

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2011 li jemendaw ir-Regolamenti dwar il-Bijoċidi, u għandhom jinqraw u jiftiehmu ħaġa waħda mar-Regolamenti ta' l-2010 dwar il-Bijoċidi, hawn iżjed 'il quddiem imsejħin "ir-regolamenti prinċipali". A.L. 525 ta' l-2010.

(2) L-iskop ta' dawn ir-regolamenti hu li jitrassponu d-Direttiva tal-Kummissjoni 2010/71/UE tal-4 ta' Novembru 2010 li temenda d-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill biex il-metoflutrin ikun inkluż bħala sustanza attiva fl-Anness I għaliha, Direttiva tal-Kummissjoni 2010/72/UE tal-4 ta' Novembru 2010 li temenda d-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill biex tinkludi l-i*spinosad* bħala sustanza attiva fl-Anness I għaliha, Direttiva tal-Kummissjoni 2010/74/UE tad-9 ta' Novembru 2010 li temenda d-Direttiva 98/8/KE tal-Parlament Ewropew u tal-Kunsill biex testendi l-inklużjoni fl-Anness I għaliha tas-sustanza attiva tad-dijossidu tal-karbonju għall-prodotti tat-tip 18.

Jemenda Skeda I li tinsab mar-regolamenti prinċipali.

2. It-Taqsima A tas-Skeda I li tinsab mar-regolamenti prinċipali, għandha tiġi amendata kif ġej:

(a) minflok il-partita Nru. 7 tagħha, għandu jidħol dan li ġej:-

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 (*)
"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 authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.

								Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.
			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.” ; u

(b) minnufih wara l-partita Nru. 35 tagħha, għandhom jidħlu dawn il-partiti ġodda li ġejjin:-

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

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

						shall verify the need to set new and/or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 and/or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.”.

L.N. 92 of 2011

PESTICIDES CONTROL ACT
(CAP. 430)

Biocides (Amendment) Regulations, 2011

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 Minister for Health, the Elderly and Community Care, has made the following regulations :-

Title and scope.

1. (1) The title of these regulations is the Biocides (Amendment) Regulations, 2011 and they shall be read and construed as one with Biocides Regulations, 2010, hereinafter referred to as "the principal regulations".

L.N. 525 of 2010.

(2) The scope of these regulations is to transpose 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, 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 and 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.

Amends Schedule I to the principal regulations.

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

(a) for item No. 7 thereof, there shall be substituted the following:

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 (*)
"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 authorization of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application

								demonstrates that risks can be reduced to acceptable levels.
			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.” ; and

(b) immediately after item No. 35 thereof, there shall be added the following new items:

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 (*)
"36	Metofluthrin	RTZ isomer: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl-(1R,3R)-2,2-dimethyl-3- (Z)-(prop-1-enyl)cyclopropanecarboxylate EC No: n.a. CAS No: 240494-71-7 Sum of all isomers: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (EZ)-(1RS,3RS;1SR,3SR)- 2,2-dimethyl-3-prop-1-enylcyclopropanecarboxylate EC No: n.a. CAS No: 240494-70-6	The active substance shall comply with both the following minimum purities: RTZ isomer: 754 g/kg Sum of all isomers: 930 g/kg	1 May 2011	Not applicable	30 April 2021	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the European level risk assessment.
37	Spinosad	EC No: 434-300-1 CAS No: 168316-95-8	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

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

Regulation (EC) No 470/2009 and/or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.” .

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — ***Printed at the Government Printing Press on recycled paper***

Prezz/*Price*
€0.56