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**A.L. 539 tal-2010**

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

**Regolamenti ta' l-2010 li jemendaw ir-Regolamani dwar  
Prodotti għall-Harsien tal-Pjanti (Emenda Nru. 5)**

BIS-SAHHA 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 mal-Prim Ministru u mal-Ministru għas-Saħħa, l-Anzjani u Kura fil-Komunità, għamel dawn ir-regolamenti li ġejjin:-

**1.** (1) It-titolu ta' dawn ir-Regolamenti hu Regolamenti ta' l-2010 li jemendaw ir-Regolamenti dwar Prodotti għall-Harsien tal-Pjanti (Emenda Nru. 5), u dawn għandhom jinqraw u jiftiehmha waħda mar-Regolamenti ta' l-2009 dwar Prodotti għall-Harsien tal-Pjanti, hawn iżjed 'il quddiem imsejħin "ir-regolamenti prinċipali".

Titlu u skop.

A.L. 358 ta' l- 2009.

(2) L-iskop ta' dawn ir-regolamenti hu li jiġu trasposti Direttiva tal-Kummissjoni 2010/54/UE tal- 20 ta' Awwissu 2010 li temenda l-Anness I għad-Direttiva tal-Kunsill 91/414/KEE biex l-ażimsulfuron jerga' jiġi inkluż bħala sustanza attiva, Direttiva tal-Kummissjoni 2010/55/UE tal- 20 ta' Awwissu 2010 li temenda l-Anness I tad-Direttiva tal-Kunsill 91/414/KEE biex iġġedded l-inklużjoni tal-azoxystrobin bħala sustanza attiva, Direttiva tal-Kummissjoni 2010/56/UE tal- 20 ta' Awwissu 2010 li temenda l-Anness I tad-Direttiva tal-Kunsill 91/414/KEE biex iġġedded l-inklużjoni tal-proeżadjun bħala sustanza attiva, Direttiva tal-Kummissjoni 2010/57/UE tas- 26 ta' Awwissu 2010 li temenda l-Anness I tad-Direttiva tal-Kunsill 91/414/KEE biex iġġedded l-inklużjoni tal-imazalil bħala sustanza attiva, Direttiva tal-Kummissjoni 2010/58/UE tat- 23 ta' Awwissu 2010 li temenda d-Direttiva tal-Kunsill 91/414/KEE fir-rigward tal-estensjoni tal-użu tas-sustanza attiva iprodione.

**2.** Skeda I li tinsab mar-regolamenti prinċipali għandha tiġi emendata kif ġej:-

Jemenda Skeda I li tinsab mar-regolamenti prinċipali.

(a) il-partita 1, dwar l-imazalil, għandha tinbidel kif ġej:

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita	Dhul fis-sehh	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
“1	Imazalil CAS No 35554-44-0 73790-28-0 (replaced) CIPAC No 335	(RS)-1-(β-allyloxy-2,4-dichlorophenethyl)imidazole or allyl (RS)-1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether	≥ 950 g/kg	1 August 2011	31 July 2021	<p>PART A</p> <p>Only uses as fungicide may be authorized.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on imazalil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 July 2010 shall be taken into account. In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material,</li> <li>— the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels,</li> <li>— the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure,</li> <li>— ensure that appropriate waste management practices to handle the waste solution remaining after application, such as the cleaning water of the drenching system and the discharge of the processing waste are put in place. Prevention of any accidental spillage of treatment solution. Member States permitting the release of waste water into the sewage system shall ensure that a local risk assessment is carried out,</li> <li>— risk to aquatic organisms and soil micro-organisms and long-term risk to granivorous birds and mammals. Conditions of authorisation should include risk mitigation measures, where appropriate</li> </ul> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information and in particular confirmatory data on:</p> <ul style="list-style-type: none"> <li>— route of degradation of imazalil in soil and surface water systems,</li> <li>— environmental data to support the managing measures that Member States have to put in place to ensure that groundwater exposure is negligible,</li> <li>— a hydrolysis study to investigate the nature of residues in processed commodities.</li> </ul> <p>They shall ensure that the notifier provides such information to the Commission by 31 October 2012.”;</p>

(ii) il-partita 2, dwar *1-azoxystrobin*, għandha tinbidel kif ġej:

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita	Dhul fis-sehh	Skadenza ta' l-inkluzjoni	Dispożizzjonijiet speċifiċi
"2	Azoxystrobin CAS No 131860-33-8 CIPAC No 571	methyl (E)-2-([6-(2-cyanophenoxy) pyrimidin-4-yloxy]phenyl)-3-methoxyacrylate	≥ 930 g/kg Toluene maximum content 2 g/kg Z-isomer maximum content 25 g/kg	1 August 2011	31 July 2021	<p>PART A Only uses as fungicide may be authorised.</p> <p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 July 2010 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material,</li> <li>— the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions,</li> <li>— the protection of aquatic organisms. The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.</li> </ul> <p>The Member States concerned shall request the submission of further studies to finalise the risk assessment on groundwater and aquatic organisms. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2012.;</p>

(iii) il-partita 5, dwar 1-azimsulfuron, għandha tinbidel kif ġej:

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita	Dhul fis-sehh	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
“5	Azimsulfuron CAS No 120162-55-2 CIPAC No 584	1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)-pyrazol-5-ylsulfonyl]-urea	980 g/kg	1 August 2011	31 July 2021	<p>PART A</p> <p>Only uses as herbicide may be authorised. Aerial applications may not be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on azimsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 July 2010, shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of non-target plants,</li> <li>— the potential for groundwater contamination, when the active substance is applied in vulnerable scenarios and/or climatic conditions,</li> <li>— the protection of aquatic organisms.</li> </ul> <p>Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate (e.g. buffer zones, in rice cultivation minimum holding periods for water prior to discharge).</p> <p>The Member States concerned shall request the submission of further studies to finalise the risk assessment on aquatic organisms and further studies to complete the identification of the degradation products in the aqueous photolysis of the substance. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2012.”;</p>

(iv) il-partita 8 , dwar l- *Prohexadione Calcium*, għandha tinbidel kif ġej:

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita	Dhul fis-sehh	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
“8	Prohexadione CAS No: 127277-53-6 ( <i>prohexadione-calcium</i> ) CIPAC No: 567 ( <i>prohexadione</i> ) No: 567.020 ( <i>prohexadione-calcium</i> )	3,5-dioxo-4-propionylcyclohexanecarboxylic acid	≥ 890 g/kg  (expressed as prohexadione- calcium)	1 August 2011	31 July 2021	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prohexadione and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 July 2010 shall be taken into account.”; u

(iv) il-partita 50 , dwar l- *Iprodione*, għandha tinbidel kif ġej:

Numru	Isem komuni, numri ta' identifikazzjoni	Isem IUPAC	Purita	Dhul fis-sehh	Skadenza ta' l-inklużjoni	Dispożizzjonijiet speċifiċi
"50	Iprodione CAS No 36734-19-7 CIPAC No 278	3-(3,5-dichlorophenyl)- Nisopropyl-2,4- imidazolidine-1- carboximide	960 g/kg	1 January 2004	31 December 2013	<p>Only uses as fungicide and nematicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on iprodione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment, Member States:</p> <ul style="list-style-type: none"> <li>— should pay particular attention to the potential for groundwater contamination when the active substance is applied at high use rates (in particular use in turf) on acidic soils (pH below 6) under vulnerable climatic conditions,</li> <li>— must carefully consider the risk to aquatic invertebrates if the active substance is applied directly adjacent to surface waters. Risk mitigation measures should be applied, where appropriate." </li></ul>

**L.N. 539 of 2010**

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

**Plant Protection Products (Amendment) (No. 5)  
Regulations, 2010**

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 :-

**1.** (1) The title of these regulations is the Plant Protection Products (Amendment) (No. 5) Regulations, 2010 and they shall be read and construed as one with the Plant Protection Products Regulations, 2009, hereinafter referred to as “the principal regulations”.

Title and scope.

L.N. 358 of 2009.

(2) The scope of these regulations is to transpose Commission Directive 2010/54/EU of 20 August 2010 amending Annex I to Council Directive 91/414/EEC to renew the inclusion of azimsulfuron as active substance, Commission Directive 2010/55/EU of 20 August 2010 amending Annex I to Council Directive 91/414/EEC to renew the inclusion of azoxystrobin as active substance, Commission Directive 2010/56/EU of 20 August 2010 amending Annex I to Council Directive 91/414/EEC to renew the inclusion of prohexadione as active substance, Commission Directive 2010/57/EU of 26 August 2010 amending Annex I to Council Directive 91/414/EEC to renew the inclusion of imazalil as active substance, Commission Directive 2010/58/EU of 23 August 2010 amending Council Directive 91/414/EEC as regards an extension of the use of the active substance iprodione.

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

Amends Schedule I to the principal regulation.

(i) row 1, relating to Imazalil, should be substituted as follows:

No	Common Name, Identification Numbers	IUPAC Name	Purity	Entry into force	Expiration of inclusion	Specific provisions
“1	Imazali CAS No 35554-44-0 73790-28-0 (replaced) CIPAC No 335	(RS)-1-(β-allyloxy-2,4-dichlorophenethyl)imidazole or allyl (RS)-1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether	≥ 950 g/kg	1 August 2011	31 July 2021	<p>PART A Only uses as fungicide may be authorized.</p> <p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on imazali, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 July 2010 shall be taken into account. In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material,</li> <li>— the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels,</li> <li>— the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure,</li> <li>— ensure that appropriate waste management practices to handle the waste solution remaining after application, such as the cleaning water of the drenching system and the discharge of the processing waste are put in place. Prevention of any accidental spillage of treatment solution. Member States permitting the release of waste water into the sewage system shall ensure that a local risk assessment is carried out,</li> <li>— risk to aquatic organisms and soil micro-organisms and long-term risk to granivorous birds and mammals. Conditions of authorisation should include risk mitigation measures, where appropriate</li> </ul> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information and in particular confirmatory data on:</p> <ul style="list-style-type: none"> <li>— route of degradation of imazali in soil and surface water systems,</li> <li>— environmental data to support the managing measures that Member States have to put in place to ensure that groundwater exposure is negligible,</li> <li>— a hydrolysis study to investigate the nature of residues in processed commodities.</li> </ul> <p>They shall ensure that the notifier provides such information to the Commission by 31 October 2012.”;</p>



(ii) row 2, relating to azoxystrobin, should be substituted as follows:

No	Common Name, Identification Numbers	IUPAC Name	Purity	Entry into force	Expiration of inclusion	Specific provisions
“2	Azoxystrobin CAS No 131860-33-8 CIPAC No 571	methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-ylloxy]phenyl}-3-methoxyacrylate	≥ 930 g/kg Toluene maximum content 2 g/kg Z-isomer maximum content 25 g/kg	1 August 2011	31 July 2021	<p>PART A Only uses as fungicide may be authorised.</p> <p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 July 2010 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material,</li> <li>— the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions,</li> <li>— the protection of aquatic organisms. The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones.</li> </ul> <p>The Member States concerned shall request the submission of further studies to finalise the risk assessment on groundwater and aquatic organisms. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2012.”;</p>

(iii) row 5 relating to azimsulfuron shall be replaced by the following:

No	Common Name, Identification Numbers	IUPAC Name	Purity	Entry into force	Expiration of inclusion	Specific provisions
"5	Azimsulfuron CAS No 120162-55-2 CIPAC No 584	1-(4,6-dimethoxypyrimidin-2-yl)-3-[1-methyl-4-(2-methyl-2H-tetrazol-5-yl)pyrazol-5-ylsulfonyl]-urea	980 g/kg	1 August 2011	31 July 2021	<p>PART A</p> <p>Only uses as herbicide may be authorised. Aerial applications may not be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on azimsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 July 2010, shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the protection of non-target plants,</li> <li>— the potential for groundwater contamination, when the active substance is applied in vulnerable scenarios and/or climatic conditions,</li> <li>— the protection of aquatic organisms.</li> </ul> <p>Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate (e.g. buffer zones, in rice cultivation minimum holding periods for water prior to discharge).</p> <p>The Member States concerned shall request the submission of further studies to finalise the risk assessment on aquatic organisms and further studies to complete the identification of the degradation products in the aqueous photolysis of the substance. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2012<sup>2</sup>.</p>

(iv) row 8 relating to Prohexadione Calcium shall be replaced by the following:

No	Common Name, Identification Numbers	IUPAC Name	Purity	Entry into force	Expiration of inclusion	Specific provisions
"8	Prohexadione CAS No: 127277-53-6 ( <i>prohexadione-calcium</i> ) CIPAC No: 567 ( <i>prohexadione</i> ) No: 567.020 ( <i>prohexadione-calcium</i> )	3,5-dioxo-4-propionylcyclohexanecarboxylic acid	≥ 890 g/kg  (expressed as prohexadione- calcium)	1 August 2011	31 July 2021	PART A Only uses as plant growth regulator may be authorised.  PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prohexadione and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 July 2010 shall be taken into account.”; and

(v) row 50 relating to Iprodione shall be replaced by the following:

No	Common Name, Identification Numbers	IUPAC Name	Purity	Entry into force	Expiration of inclusion	Specific provisions
"50	Iprodione CAS No 36734-19-7 CIPAC No 278	3-(3,5-dichlorophenyl)- Nisopropyl-2,4- dioxo- imidazolidine-1- carboximide	960 g/kg	1 January 2004	31 December 2013	<p>Only uses as fungicide and nematicide may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on iprodione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002, shall be taken into account. In this overall assessment, Member States:</p> <ul style="list-style-type: none"> <li>— should pay particular attention to the potential for groundwater contamination when the active substance is applied at high use rates (in particular use in turf) on acidic soils (pH below 6) under vulnerable climatic conditions,</li> <li>— must carefully consider the risk to aquatic invertebrates if the active substance is applied directly adjacent to surface waters. Risk mitigation measures should be applied, where appropriate."</li> </ul>

