*Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 18,633, 17 ta' Awwissu, 2010*

*Taqsima B*

**A.L. 394 ta' l-2010**

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

### Regolamenti ta' l-2010 li jemendaw ir-Regomaneti dwar Prodott għall-Ħarsien tal-Pjanti (Emenda Nru. 3)

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 mal-Prim Ministru u mal-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-2010 li jemendew ir-Regolamenti dwar Prodotti għall-Ħarsien tal-Pjanti (Emenda Nru. 3), u dawn għandhom jinqraw u jiftiehmu bħala ħaġa waħda mar-Regolamenti ta' l-2009 dwar Prodotti għall-Ħarsien tal-Pjanti, hawn iżjed 'il quddiem imsejħin "ir-regolamenti prinċipali".

A.L. 358 ta' l-2009.

(2) L-iskop ta' dawn ir-regolamenti hu li jiġu trasposti Direttiva tal- Kummissjoni 2010/25/UE tat-18 ta' Marzu 2010 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex tinkludi l-*penoxsulam*, il-*proquinazid* u l-i*spirodiclofen* bħala sustanzi attivi, Direttiva tal- Kummissjoni 2010/27/UE tat-23 ta' April 2010 li temenda d-Direttiva tal-Kunsill 91/414/KEE għall-inklużjoni tat-*triflumizole* bħala sustanza attiva, Direttiva tal- Kummissjoni 2010/28/UE tat-23 ta' April 2010 li temenda d-Direttiva tal-Kunsill 91/414/KEE għall-inklużjoni tal-*metalaxyl* bħala sustanza attiva, Direttiva tal- Kummissjoni 2010/29/UE tas-27 ta' April 2010 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-*flonicamid* (IKI-220) bħala sustanza attiva, Direttiva tal-Kummissjoni 2010/34/UE tal-31 ta' Mejju 2010 li temenda l-Anness I tad-Direttiva tal-Kunsill 91/414/KEE fir-rigward tal-estensjoni tal-użu tas- sustanza attiva *penconazole*, Direttiva tal-Kummissjoni 2010/38/UE tat-18 ta' Ġunju 2010 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż is-*sulfuryl fluoride* bħala sustanza attiva, Direttiva tal-Kummissjoni 2010/39/UE tat-22 ta' Ġunju 2010 li temenda l-Anness I tad-Direttiva tal-

Kunsill 91/414/KEE fir-rigward tad-dispożizzjonijiet speċifiċi marbutin mas-sustanzi attivi l-*clofentezine*, id-*diflubenzuron*, il-*lenacil*, l-*oxadiazon*, il-*picloram* u l-*pyriproxyfen*, Direttiva tal- Kummissjoni 2010/42/UE tat-28 ta' Ġunju 2010 li temenda d-Direttiva tal-Kunsill 91/414/KEE biex jiġi inkluż il-FEN 560 (żerriegħa tal-fienu mitħuna) bħala sustanza attiva.

Jemenda Skeda I li tinsab mar-regolamenti prinċipali.

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

(a) il-partita 177, dwar il- clofentezine, il-kolonna "Dispożizzjonijiet speċifiċi" Part B għandha tinbidel b'dan li ġej:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on clofentezine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— 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 shall be compared and verified against this specification of the technical material;

— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate;

— the potential for long range transport via air;

— the risk to non target organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier presents to the Commission a monitoring programme to assess the potential for long-range atmospheric transport of clofentezine and the related environmental risks by 31 July 2011. The results of that

monitoring programme shall be submitted as a monitoring report to the rapporteur Member State and to the Commission by 31 July 2013.

The Member States concerned shall ensure that the notifier submits to the Commission confirmatory studies on clofentezine metabolites relating to their toxicological and environmental risk assessment by 30 June 2012.";

(b) il-partita 180, dwar il- diflubenzuron, il-kolonna "Dispożizzjonijiet speċifiċi" Part B għandha tinbidel b'dan li ġej:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on diflubenzuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— 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 shall be compared and verified against this specification of the technical material;

— the protection of aquatic organisms;

— the protection of terrestrial organisms;

— the protection of non-target arthropods including bees.

Conditions of use shall include adequate risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission further studies to address the potential toxicological relevance of the impurity and metabolite 4-chloroaniline (PCA) by 30 June 2011.";

(ċ) il-partita 182, dwar il- lenacil, il-kolonna "Dispożizzjonijiet speċifiċi" Part B għandha tinbidel b'dan li ġej:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on lenacil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the risk to aquatic organisms, especially algae and aquatic plants. Conditions of authorisation shall include risk mitigation measures, such as bufferzones between treated areas and surface water bodies;

— the protection of the groundwater, where the active substance is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites IN-KF 313, M1, M2 and M3 in vulnerable zones, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission confirmatory information on the identity and characterisation of soil metabolites Polar B and Polars and metabolites M1, M2 and M3 which occurred in lysimeter studies and confirmatory data on rotational crops, including possible phytotoxic effects. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.

If a decision on the classification of lenacil under Directive 67/548/EEC identifies the need for further information on the relevance of the metabolites IN-KE 121, IN-KF 313, M1; M2, M3, Polar B and Polars, the Member States concerned shall request the submission of such information. They shall ensure that the notifier provides that information to the Commission within six months from the notification of such a classification decision.";

(d) il-partita 183, dwar l-*oxadiazon*, il-kolonna "Dispożizzjonijiet speċifiċi" Part B għandha tinbidel b'dan li ġej:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on oxadiazon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— 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 shall be compared and verified against this specification of the technical material;

— the potential for ground water contamination by the metabolite AE0608022 where the active substance is applied in situations for which prolonged anaerobic conditions may be expected to occur or in regions with vulnerable soil or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission:

— further studies to address the potential toxicological relevance of an impurity in the proposed technical specification;

— information to further clarify the occurrence of metabolite AE0608033 in primary crops and rotational crops;

— further trials on rotational crops (namely root crops and cereals) and a metabolism study on ruminants to confirm the consumer risk assessment;

— information to further address the risk to earthworm-eating birds and mammals, and the long-term risk to fish.

They shall ensure that the notifier provides such information to the Commission by 30 June 2012.";

(e) il-partita 184, dwar il- picloram, il-kolonna "Dispożizzjonijiet speċifiċi" Part B għandha tinbidel b'dan li ġej:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on picloram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In the overall assessment Member States must pay particular attention to:

— the potential for ground water contamination where picloram is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate;

The Member States concerned shall ensure that the notifier submits to the Commission:

— further information to confirm that the monitoring analytical method applied in residue trials correctly quantifies the residues of picloram and its conjugates;

— a soil photolysis study to confirm the evaluation of picloram degradation.

They shall ensure that the notifier provides such information to the Commission by 30 June 2012.";

(f) il-partita 185, dwar il-*pyriproxyfen*, il-kolonna "Dispożizzjonijiet speċifiċi" Part B għandha tinbidel b'dan li ġej:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pyriproxyfen, and in particular Appendices I and II thereof, as finalised in the Standing

Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In the overall assessment Member States must pay particular attention to:

— the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate;

— the risk to aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission further information confirming the risk assessment in respect of two points, namely the risk posed to aquatic insects by pyriproxfen and the metabolite DPH-pyr and the risk posed by pyriproxfen to pollinators. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.";

(g) il-partita 222, dwar il- imidacloprid, fil-kolonna "Dispożizzjonijiet speċifiċi" Part A għandu jiżdied dan li ġej wara l-aħħar sentenza:

"— the conditions of the authorisation, in particular for spray applications, include, where appropriate, risk mitigation measures to protect honey bees,

— monitoring programmes are initiated to verify the real exposure of honey bees to imidacloprid in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.";

(h) il-partita 292, dwar il- penconazole, il-kolonna "Dispożizzjonijiet speċifiċi" għandha tinbidel b'dan li ġej:

(i) Part A għandha tinbidel f'dan li ġej:

"Only uses as fungicides may be authorised.";

(ii) Fir-Raba' paragrafu ta' Part B l-ewwel sentenza "The Member States concerned shall request the submission of further information on the fate and behaviour of the soil metabolite U1.",

għandha tinbidel f'dan li ġej:

"The Member States concerned shall request the submission of further information on the fate and behaviour of the soil metabolite CGA179944 in acidic soils.";

(i) minnufih wara l-partita 306 "Malathion" għandhom jiżdiedu dawn il-partiti ġodda li ġejjin:

| Numru | Isem komuni, numri ta' identifikazzjoni | Isem IUPAC | Purita* | Dħul fis-seħħ | Skadenza ta' l-inklużjoni | Dispożizzjonijiet speċifiċi |
|---|---|---|---|---|---|---|
| "307 | Penoxsulam<br>CAS No 219714-96-2<br>CIPAC No 758 | 3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5- c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide | > 980 g/kg The impurity Bis-CHYMP 2-chloro-4-[2-(2-chloro-5-methoxy-4-pyrimidinyl)hydrazino]-5- methoxypyrimidine must not exceed 0,1 g/kg in the technical material | 1 August 2010 | 31 July 2020 | PART A<br>Only uses as herbicide may be authorised.<br><br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on penoxsulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention to:<br>— the protection of aquatic organisms,<br>— the dietary exposure of consumers to residues of the metabolite BSCTA in succeeding rotational crops,<br>— the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions.<br>Conditions of authorisation shall include risk mitigation measures, where appropriate.<br>The Member States concerned shall ensure that the notifier submits to the Commission further information to address the off-field risk to higher aquatic plants. They shall ensure that the notifier provides such information to the Commission by 31 July 2012.<br>The Rapporteur Member State shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured. |
| 308 | Proquinazid<br>CAS No 189278-12-4 | 6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one | > 950 g/kg | 1 August 2010 | 31 July 2020 | PART A<br>Only uses as fungicide may be authorised. |

* Further details on identity and specification of active substances are provided in the review report.

| Numru | Isem komuni, numri ta' identifikazzjoni | Isem IUPAC | Purita* | Dħul fis-seħħ | Skadenza ta' l-inklużjoni | Dispożizzjonijiet speċifiċi |
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| | CIPAC No 764 | | | | | PART B<br><br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on proquinazid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention:<br>— to the long-term risk to earthworm-eating birds for uses in grapevine,<br>— to the risk to aquatic organisms,<br>— the dietary exposure of consumers to proquinazid residues in products of animal origin and in succeeding rotational crops,<br>— to the operator safety.<br>Conditions of authorisation shall include risk mitigation measures, where appropriate.<br>The Rapporteur Member State shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured. |
| 309 | Spirodiclofen<br>CAS No 148477-71-8<br>CIPAC No 737 | 3-(2,4-dichlorophenyl)-2-oxo- 1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate | > 965 g/kg<br>The following impurities must not exceed a certain amount in the technical material: 3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5] dec-3-en-2-one (BAJ- 2740 enol): ≤ 6 g/kg N,N-dimethylacetamide: ≤ 4 g/kg | 1 August 2010 | 31 July 2020 | PART A<br>Only uses as acaricide or insecticide may be authorised.<br><br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on spirodiclofen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account.<br>In this overall assessment, Member States must pay particular attention:<br>— to the long-term risk to aquatic organisms, |

| Numru | Isem komuni, numri ta' identifikazzjoni | Isem IUPAC | Purita* | Dħul fis-seħħ | Skadenza ta' l-inklużjoni | Dispożizzjonijiet speċifiċi |
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| | | | | | | — to the operator safety,<br>— to the risk to bee brood.<br>Conditions of authorisation shall include risk mitigation measures, where appropriate. |
| 310 | Flonicamid (IKI-220)<br>CAS No 158062-67-0<br>CIPAC No 763 | N-cyanomethyl-4-(trifluoromethyl)nicotinamide | ≥ 960 g/kg<br>The impurity toluene must not exceed 3 g/kg in the technical material. | 1 September 2010 | 31 August 2020 | PART A<br>Only uses as insecticide may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flonicamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010, shall be taken into account. In this overall assessment, Member States must pay particular attention to:<br>- the risk to operators and re-entry workers,<br>- the risk to bees. Conditions of authorisation shall include risk mitigation measures where appropriate.<br>The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured. |
| 311 | Sulfuryl fluoride<br>CAS No 002699-79-8<br>CIPAC No 757 | Sulfuryl fluoride | > 994 g/kg | 1 November 2010 | 31 October 2020 | PART A<br>Only uses as insecticide/nematicide (fumigant) applied by professional users in sealable structures<br>(a) which are empty; or<br>(b) where conditions of use ensure that consumer exposure is acceptable;<br>may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sulfuryl fluoride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 |

| Numru | Isem komuni, numri ta' identifikazzjoni | Isem IUPAC | Purita* | Dħul fis-seħħ | Skadenza ta' l-inklużjoni | Dispożizzjonijiet speċifiċi |
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| | | | | | | May 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention to:<br>— the risk posed by inorganic fluoride through contaminated products, such as flour and bran that remained in the mill machinery during fumigation, or grain stored in silos in the mill. Measures are required to ensure that such products do not enter the food and feed chain,<br>— the risk to operators and the risk to workers, such as when re-entering a fumigated structure after aeration. Measures are required to ensure that they wear self containing breathing apparatus or other appropriate personal protective equipment,<br>— the risk to bystanders by applying an appropriate exclusion zone around the fumigated structure.<br>Conditions of authorisation shall include risk mitigation measures, where appropriate.<br>The Member States concerned shall ensure that the notifier submits to the Commission further information and in particular, confirmatory data on:<br>— the mill processing conditions necessary to ensure that residues of fluoride ion in flour, bran and grain do not exceed the natural background levels,<br>— tropospheric concentrations of sulfuryl fluoride. Measured concentrations should be updated regularly. The limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuryl fluoride/m3 of tropospheric air),<br>— estimates of sulfuryl fluoride atmospheric lifetime based on worst case scenario, with respect to the global warming potential (GWP).<br>They shall ensure that the notifier provides such information to the Commission by 31 August 2012. |
| 312 | Metalaxyl<br>CAS No 57837-19-1 | Methyl N-(methoxyacetyl)-N-(2,6- xylyl)-DL- | 950 g/kg<br>The impurity 2,6-dimethylaniline was | 1 July 2010 | 30 June 2020 | PART A<br>Only uses as fungicide may be authorised. |

| Numru | Isem komuni, numri ta' identifikazzjoni | Isem IUPAC | Purita' | Dħul fis-seħħ | Skadenza ta' l-inklużjoni | Dispożizzjonijiet speċifiċi |
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| | CIPAC No 365 | alaninate | considered of toxicological concern and a maximum level of 1 g/kg is established. | | | PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metalaxyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account. Member States must pay particular attention to the potential contamination of groundwater by the active substance or its degradation products CGA 62826 and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate. |
| 313 | FEN 560 (also called fenugreek or fenugreek seed powder)<br>CAS No None<br>CIPAC No None<br>The active substance is prepared from the seed powder of Trigonella foenum-graecum L. (fenugreek). | Not applicable | 100 % fenugreek seed powder without any additive and no extraction; the seed being of human food grade quality. | 1 November 2010 | 31 October 2020 | PART A<br>Only uses as elicitor of the crop's self-defence mechanisms may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on FEN 560 (fenugreek seed powder), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention to the risk to operators, workers and bystanders. Conditions of authorisation shall include risk mitigation measures where appropriate. |
| 314 | Triflumizole<br>CAS No: 99387-89-0<br>CIPAC No: 730 | (E)-4-chloro-α,α,α-trifluoro-N- (1-imidazol-1-yl-2-propoxy- ethylidene)-o-toluidine | ≥ 980 g/kg<br>Impurities:<br>Toluene: not more than 1 g/kg | 1 July 2010 | 30 June 2020 | PART A<br>Only uses as fungicide in greenhouses on artificial substrates may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on triflumizole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account. |

| Numru | Isem komuni, numri ta' identifikazzjoni | Isem IUPAC | Purita' | Dħul fis-seħħ | Skadenza ta' l-inklużjoni | Dispożizzjonijiet speċifiċi |
|---|---|---|---|---|---|---|
| | | | | | | In this overall assessment Member States shall pay particular attention to:<br>- the operator and worker safety: conditions of use shall prescribe the use of adequate personal protective equipment,<br>- the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, as appropriate, risk mitigation measures." |

**L.N. 394 of 2010**

# PESTICIDES CONTROL ACT
# (CAP. 430)

## Plant Protection Products (Amendment) (No. 3) 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:-

Title and scope.

**1.** (1) The title of these regulations is the Plant Protection Products (Amendment) (No. 3) Regulations, 2010 and they shall be read and construed as one with Plant Protection Products Regulations, 2009, hereinafter referred to as "the principal regulations".

L.N. 358 of 2009.

(2) The scope of these regulations is to transpose Commission Directive 2010/25/EU of 18 March 2010 amending Council Directive 91/414/EEC to include penoxsulam, proquinazid and spirodiclofen as active substances, Commission Directive 2010/27/EU of 23 April 2010 amending Council Directive 91/414/EEC to include triflumizole as active substance, Commission Directive 2010/28/EU of 23 April 2010 amending Council Directive 91/414/EEC to include metalaxyl as active substance, Commission Directive 2010/29/EU of 27 April 2010 amending Council Directive 91/414/EEC to include flonicamid (IKI-220) as active substance, Commission Directive 2010/34/EU of 31 May 2010 amending Annex I to Council Directive 91/414/EEC as regards an extension of the use of the active substance penconazole, Commission Directive 2010/38/EU of 18 June 2010 amending Council Directive 91/414/EEC to include sulfuryl fluoride as active substance, Commission Directive 2010/39/EU of 22 June 2010 amending Annex I to Council Directive 91/414/EEC as regards the specific provisions relating to the active substances clofentezine, diflubenzuron, lenacil, oxadiazon, picloram and pyriproxyfen, Commission Directive 2010/42/EU of 28 June 2010 amending Council Directive 91/414/EEC to include FEN 560 (fenugreek seed powder) as active substance.

Amends Schedule I to the principal regulation.

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

(a) in row 177, relating to clofentezine, in the column "Specific provisions", Part B is being substituted as follows:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on clofentezine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— 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 shall be compared and verified against this specification of the technical material;

— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate;

— the potential for long range transport via air;

— the risk to non target organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier presents to the Commission a monitoring programme to assess the potential for long-range atmospheric transport of clofentezine and the related environmental risks by 31 July 2011. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State and to the Commission by 31 July 2013.

The Member States concerned shall ensure that the notifier submits to the Commission confirmatory studies on clofentezine metabolites relating to their toxicological and environmental risk assessment by 30 June 2012.";

(b) in row 180, relating to diflubenzuron, in the column "Specific provisions", Part B is being substituted as follows:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on diflubenzuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— 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 shall be compared and verified against this specification of the technical material;

— the protection of aquatic organisms;

— the protection of terrestrial organisms;

— the protection of non-target arthropods including bees.

Conditions of use shall include adequate risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission further studies to address the potential toxicological relevance of the impurity and metabolite 4-chloroaniline (PCA) by 30 June 2011.";

(c) in row 182 concerning lenacil, in the column "Specific provisions", Part B is being substituted as follows:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on lenacil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the risk to aquatic organisms, especially algae and aquatic plants. Conditions of authorisation shall include risk mitigation measures, such as bufferzones between treated areas and surface water bodies;

— the protection of the groundwater, where the active substance is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites IN-KF 313, M1, M2 and M3 in vulnerable zones, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission confirmatory information on the identity and characterisation of soil metabolites Polar B and Polars and metabolites M1, M2 and M3 which occurred in lysimeter studies and confirmatory data on rotational crops, including possible phytotoxic effects. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.

If a decision on the classification of lenacil under Directive 67/548/EEC identifies the need for further information on the relevance of the metabolites IN-KE 121, IN-KF 313, M1; M2, M3, Polar B and Polars, the Member States concerned shall request the submission of such information. They shall ensure that the notifier provides that information to the Commission within six months from the notification of such a classification decision.";

(d) in row 183, relating to oxadiazon, in the column "Specific provisions", Part B is being substituted as follows:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on oxadiazon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— 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 shall be compared and verified against this specification of the technical material;

— the potential for ground water contamination by the metabolite AE0608022 where the active substance is applied in situations for which prolonged anaerobic conditions may be expected to occur or in regions with vulnerable soil or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission:

— further studies to address the potential toxicological relevance of an impurity in the proposed technical specification;

— information to further clarify the occurrence of metabolite AE0608033 in primary crops and rotational crops;

— further trials on rotational crops (namely root crops and cereals) and a metabolism study on ruminants to confirm the consumer risk assessment;

— information to further address the risk to earthworm-eating birds and mammals, and the long-term risk to fish.

They shall ensure that the notifier provides such information to the Commission by 30 June 2012.";

(e) in row 184 relating to picloram, in the column "Specific provisions", Part B is being substituted as follows:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on picloram, and in

particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In the overall assessment Member States must pay particular attention to:

— the potential for ground water contamination where picloram is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate;

The Member States concerned shall ensure that the notifier submits to the Commission:

— further information to confirm that the monitoring analytical method applied in residue trials correctly quantifies the residues of picloram and its conjugates;

— a soil photolysis study to confirm the evaluation of picloram degradation.

They shall ensure that the notifier provides such information to the Commission by 30 June 2012.";

(f) in row 185, relating to pyriproxyfen, in the column "Specific provisions", Part B is being substituted as follows:

**"PART B**

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on pyriproxyfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In the overall assessment Member States must pay particular attention to:

— the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, where appropriate;

— the risk to aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate.

The Member States concerned shall ensure that the notifier submits to the Commission further information confirming the risk assessment in respect of two points, namely the risk posed to aquatic insects by pyriproxfen and the metabolite DPH-pyr and the risk posed by pyriproxfen to pollinators. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.";

(g) in row 222, relating to imidacloprid, in the column "Specific provisions", Part A the following shall be added after the last sentence:

"— the conditions of the authorisation, in particular for spray applications, include, where appropriate, risk mitigation measures to protect honey bees,

— monitoring programmes are initiated to verify the real exposure of honey bees to imidacloprid in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.";

(h) in row 292, relating to penconazole, the column "Specific provisions" is being amended as follows:

(i) for part A there shall be substituted the following:

**"PART A**

Only uses as fungicides may be authorised.";

(ii) In the fourth paragraph of Part B for the words "The Member States concerned shall request the submission of further information on the fate and behaviour of the soil metabolite U1.", there shall be substituted the words "The Member States concerned shall request the submission of further information on the fate and behaviour of the soil metabolite CGA179944 in acidic soils."; and

(i) immediately after item 306 "Malathion" there shall be added the following new items:

| No | Common Name, Identification Numbers | IUPAC Name | Purity* | Entry into force | Expiration of inclusion | Specific provisions |
|---|---|---|---|---|---|---|
| "307 | Penoxsulam<br>CAS No 219714-96-2<br>CIPAC No 758 | *3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5- c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide* | > 980 g/kg The impurity Bis-CHYMP 2-chloro-4-[2-(2-chloro-5-methoxy-4-pyrimidinyl)hydrazino]-5- methoxypyrimidine must not exceed 0,1 g/kg in the technical material | 1 August 2010 | 31 July 2020 | PART A<br>Only uses as herbicide may be authorised.<br><br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on penoxsulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention to:<br>— the protection of aquatic organisms,<br>— the dietary exposure of consumers to residues of the metabolite BSCTA in succeeding rotational crops,<br>— the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions.<br>Conditions of authorisation shall include risk mitigation measures, where appropriate.<br>The Member States concerned shall ensure that the notifier submits to the Commission further information to address the off-field risk to higher aquatic plants. They shall ensure that the notifier provides such information to the Commission by 31 July 2012.<br>The Rapporteur Member State shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured. |
| 308 | Proquinazid<br>CAS No 189278-12-4<br><br>CIPAC No 764 | *6-iodo-2-propoxy-3-propylquinazolin-4(3*H*)-one* | > 950 g/kg | 1 August 2010 | 31 July 2020 | PART A<br>Only uses as fungicide may be authorised.<br><br>PART B |

* Further details on identity and specification of active substances are provided in the review report.

| No | Common Name, Identification Numbers | IUPAC Name | Purity* | Entry into force | Expiration of inclusion | Specific provisions |
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| | | | | | | For the implementation of the uniform principles of Annex VI, the conclusions of the review report on proquinazid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention:<br>— to the long-term risk to earthworm-eating birds for uses in grapevine,<br>— to the risk to aquatic organisms,<br>— the dietary exposure of consumers to proquinazid residues in products of animal origin and in succeeding rotational crops,<br>— to the operator safety.<br>Conditions of authorisation shall include risk mitigation measures, where appropriate.<br>The Rapporteur Member State shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured. |
| 309 | Spirodiclofen<br>CAS No 148477-71-8<br>CIPAC No 737 | *3-(2,4-dichlorophenyl)-2-oxo- 1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate* | > 965 g/kg<br>The following impurities must not exceed a certain amount in the technical material: 3-(2,4-dichlorophenyl)-4-hydroxy-1-oxaspiro[4.5] dec-3-en-2-one (BAJ- 2740 enol): ≤ 6 g/kg N,N-dimethylacetamide: ≤ 4 g/kg | 1 August 2010 | 31 July 2020 | PART A<br>Only uses as acaricide or insecticide may be authorised.<br><br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on spirodiclofen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account.<br>In this overall assessment, Member States must pay particular attention:<br>— to the long-term risk to aquatic organisms,<br>— to the operator safety,<br>— to the risk to bee brood. |

| No | Common Name, Identification Numbers | IUPAC Name | Purity* | Entry into force | Expiration of inclusion | Specific provisions |
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| | | | | | | Conditions of authorisation shall include risk mitigation measures, where appropriate. |
| 310 | Flonicamid (IKI-220)<br>CAS No 158062-67-0<br>CIPAC No 763 | N-cyanomethyl-4-(trifluoromethyl)nicotinamide | ≥ 960 g/kg<br>The impurity toluene must not exceed 3 g/kg in the technical material. | 1 September 2010 | 31 August 2020 | PART A<br>Only uses as insecticide may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on flonicamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010, shall be taken into account. In this overall assessment, Member States must pay particular attention to:<br>- the risk to operators and re-entry workers,<br>- the risk to bees. Conditions of authorisation shall include risk mitigation measures where appropriate.<br>The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured. |
| 311 | Sulfuryl fluoride<br>CAS No 002699-79-8<br>CIPAC No 757 | *Sulfuryl fluoride* | > 994 g/kg | 1 November 2010 | 31 October 2020 | PART A<br>Only uses as insecticide/nematicide (fumigant) applied by professional users in sealable structures<br>(a) which are empty; or<br>(b) where conditions of use ensure that consumer exposure is acceptable;<br>may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sulfuryl fluoride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention to: |

| No | Common Name, Identification Numbers | IUPAC Name | Purity* | Entry into force | Expiration of inclusion | Specific provisions |
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| | | | | | | — the risk posed by inorganic fluoride through contaminated products, such as flour and bran that remained in the mill machinery during fumigation, or grain stored in silos in the mill. Measures are required to ensure that such products do not enter the food and feed chain,<br>— the risk to operators and the risk to workers, such as when re-entering a fumigated structure after aeration. Measures are required to ensure that they wear self containing breathing apparatus or other appropriate personal protective equipment,<br>— the risk to bystanders by applying an appropriate exclusion zone around the fumigated structure.<br>Conditions of authorisation shall include risk mitigation measures, where appropriate.<br>The Member States concerned shall ensure that the notifier submits to the Commission further information and in particular, confirmatory data on:<br>— the mill processing conditions necessary to ensure that residues of fluoride ion in flour, bran and grain do not exceed the natural background levels,<br>— tropospheric concentrations of sulfuryl fluoride. Measured concentrations should be updated regularly. The limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuryl fluoride/m3 of tropospheric air),<br>— estimates of sulfuryl fluoride atmospheric lifetime based on worst case scenario, with respect to the global warming potential (GWP).<br>They shall ensure that the notifier provides such information to the Commission by 31 August 2012. |
| 312 | Metalaxyl<br>CAS No 57837-19-1<br>CIPAC No 365 | *Methyl N*-(methoxyacetyl)-*N*-(2,6-xylyl)-DL-alaninate | 950 g/kg<br>The impurity 2,6-dimethylaniline was considered of toxicological concern and a maximum level of | 1 July 2010 | 30 June 2020 | PART A<br>Only uses as fungicide may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metalaxyl, and in |

| No | Common Name, Identification Numbers | IUPAC Name | Purity* | Entry into force | Expiration of inclusion | Specific provisions |
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| | | | 1 g/kg is established. | | | particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account. Member States must pay particular attention to the potential contamination of groundwater by the active substance or its degradation products CGA 62826 and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate. |
| 313 | FEN 560 (also called fenugreek or fenugreek seed powder)<br>CAS No None<br>CIPAC No None<br>The active substance is prepared from the seed powder of *Trigonella foenum-graecum* L. (fenugreek). | Not applicable | 100 % fenugreek seed powder without any additive and no extraction; the seed being of human food grade quality. | 1 November 2010 | 31 October 2020 | PART A<br>Only uses as elicitor of the crop's self-defence mechanisms may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on FEN 560 (fenugreek seed powder), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention to the risk to operators, workers and bystanders. Conditions of authorisation shall include risk mitigation measures where appropriate. |
| 314 | Triflumizole<br>CAS No: 99387-89-0<br>CIPAC No: 730 | *(E)-4-chloro-α,α,α-trifluoro-N- (1-imidazol-1-yl-2-propoxy- ethylidene)-o-toluidine* | ≥ 980 g/kg<br>Impurities:<br>Toluene: not more than 1 g/kg | 1 July 2010 | 30 June 2020 | PART A<br>Only uses as fungicide in greenhouses on artificial substrates may be authorised.<br>PART B<br>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on triflumizole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account.<br>In this overall assessment Member States shall pay particular attention to:<br>- the operator and worker safety: conditions of use shall prescribe |

| No | Common Name, Identification Numbers | IUPAC Name | Purity* | Entry into force | Expiration of inclusion | Specific provisions |
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| | | | | | | the use of adequate personal protective equipment,<br>- the potential impact on aquatic organisms and must ensure that the conditions of authorisation include, as appropriate, risk mitigation measures.” |