

L.N. 319 of 2019

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

Sustainable Use of Pesticides (Amendment No 2) Regulations, 2019

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

1. The title of these regulations is the Sustainable Use of Pesticides (Amendment No 2) Regulations, 2019 and these regulations shall be read and construed as one with the Sustainable Use of Pesticides Regulations, hereinafter referred to as "the principal regulations".

Title.
S.L. 430.08.

2. Sub-regulation (2) of regulation 1 of the principal regulations shall be substituted by the following:

Amends regulation 1 of the principal regulations.

"(2) The scope of these regulations is to transpose Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides and Commission Directive (EU) 2019/782 of 15 May 2019 amending Directive 2009/128/EC of the European Parliament and of the Council as regards the establishment of harmonised risk indicators."

3. Sub-regulation (1) of regulation 14 of the principal regulations shall be substituted by the following:

Amends regulation 14 of the principal regulations.

"(1) Harmonised risk indicators as established in Schedule IV shall be made use of, provided that the Director may continue to use existing national indicators or adopt other appropriate indicators in addition to the harmonised ones."

4. Immediately after regulation 14 of the principal regulations there shall be added the following new regulation:

Adds new regulation 14A to the principal regulations.

"Director shall request information as deemed necessary. 14A. The Director shall request information related to quantities of substances contained in pesticides placed on the market or other information as deemed necessary to achieve the objectives of these regulations."

5. Schedule IV of the principal regulations shall be substituted by the following:

Substitutes Schedule IV of the principal regulations.

"Schedule IV**SECTION 1****Harmonised Risk Indicators**

The harmonised risk indicators are listed in Sections 2 and 3 of this Schedule

SECTION 2**Harmonised Risk Indicator 1: Hazard-based Harmonised Risk Indicator based on the quantities of active substances placed on the market in plant protection products under Regulation (EC) No 1107/2009**

1. This indicator shall be based on statistics on the quantities of active substances placed on the market in plant protection products under Regulation (EC) No 1107/2009, provided to the Commission (Eurostat) under Annex I (Statistics on the placing on the market of pesticides) of Regulation (EC) No 1185/2009. Those data are categorised into 4 Groups, which are divided into 7 Categories.
2. The following general rules shall apply for the calculation of Harmonised Risk Indicator 1:
 - (a) the Harmonised Risk Indicator 1 shall be calculated on the basis of the categorisation of active substances into the 4 Groups and 7 Categories set out in Table 1;
 - (b) the active substances in Group 1 (categories A and B) shall be those listed in Part D of the Annex to Commission Implementing Regulation (EU) No 540/2011;
 - (c) the active substances in Group 2 (categories C and D) shall be those listed in Parts A and B of the Annex to Implementing Regulation (EU) No 540/2011;
 - (d) the active substances in Group 3 (categories E and F) shall be those listed in Part E of the Annex to Implementing Regulation (EU) No 540/2011;
 - (e) the active substances in Group 4 (category G) shall be those not approved under Regulation (EC) No 1107/2009, and therefore not listed in the Annex to Implementing Regulation (EU) No 540/2011;
 - (f) the weightings in row (vi) in Table 1 shall apply.
3. Harmonised Risk Indicator 1 shall be calculated by multiplying the annual quantities of active substances placed on the market for each Group in Table 1 by the relevant hazard weighting set out in Row (vi), followed by the aggregation of the results of these calculations.

4. The quantities of active substances placed on the market for each Group and Category in Table 1 may be calculated.

Table 1

Categorisation of active substances and hazard weightings for the purpose of calculating Harmonised Risk Indicator 1

Row	Groups						
	1		2		3		4
(i)	Low-risk active substances which are approved or deemed to be approved under Article 22 of Regulation (EC) No 1107/2009, and which are listed in Part D of the Annex to Implementing Regulation (EU) No 540/2011		Active substances approved or deemed to be approved under Regulation (EC) No 1107/2009, and not falling in other categories, and which are listed in Parts A and B of the Annex to Implementing Regulation (EU) No 540/2011		Active substances approved or deemed to be approved under Article 24 of Regulation (EC) No 1107/2009, which are candidates for substitution, and which are listed in Part E of the Annex to Implementing Regulation (EU) No 540/2011		Active substances which are not approved under Regulation (EC) No 1107/2009, and therefore which are not listed in the Annex to Implementing Regulation (EU) No 540/2011
(ii)	Categories						
(iii)	A	B	C	D	E	F	G
(iv)	Micro-organisms	Chemical active substances	Micro-organisms	Chemical active substances	Which are not classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors	Which are classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors, where exposure of humans is negligible	
(v)	Hazard Weightings applicable to quantities of active substances placed on the market in products authorised under Regulation (EC) No 1107/2009						
(vi)	1		8		16		64

5. The baseline for Harmonised Risk Indicator 1 shall be set at 100 and is equal to the average result of the above calculation for the period 2011-2013.

6. The result of Harmonised Risk Indicator 1 shall be expressed by reference to the baseline.
7. It shall be the duty of The Authority to calculate and publish the Harmonised Risk Indicator 1 in accordance with Article 15(2) and 15(4) of Directive 2009/128/EC for each calendar year and at the latest 20 months after the end of the year for which the Harmonised Risk Indicator 1 is being calculated.

SECTION 3

Harmonised Risk Indicator 2: Harmonised Risk Indicator based on the number of authorisations granted under Article 53 of Regulation (EC) No 1107/2009

1. This indicator shall be based on the number of authorisations granted for plant protection products under Article 53 of Regulation (EC) No 1107/2009 as communicated to the Commission in accordance with Article 53(1) of that Regulation. Those data are categorised into 4 Groups, which are divided into 7 Categories.
2. The following general rules shall apply for the calculation of the Harmonised Risk Indicator 2:
 - (a) the Harmonised Risk Indicator 2 shall be based on the number of authorisations granted under Article 53 of Regulation (EC) No 1107/2009. It shall be calculated on the basis of the categorisation of active substances into the 4 Groups and 7 Categories set out in Table 2 of this Section;
 - (b) the active substances in Group 1 (categories A and B) are listed in Part D of the Annex to Implementing Regulation (EU) No 540/2011;
 - (c) the active substances in Group 2 (categories C and D) are those listed in Parts A and B of the Annex to Implementing Regulation (EU) No 540/2011;
 - (d) the active substances in Group 3 (categories E and F) shall be those listed in Part E of the Annex to Implementing Regulation (EU) No 540/2011;
 - (e) the active substances in Group 4 (category G) shall be those not approved under Regulation (EC) No 1107/2009, and therefore not listed in the Annex to Implementing Regulation (EU) No 540/2011;

(f) the weightings in row (vi) in Table 2 of this Section shall apply.

3. The Harmonised Risk Indicator 2 shall be calculated by multiplying the number of authorisations granted for plant protection products under Article 53 of Regulation (EC) No 1107/2009 for each Group in Table 2 by the relevant hazard weighting set out in Row (vi), followed by the aggregation of the results of these calculations.

Table 2

Categorisation of active substances and hazard weightings for the purpose of calculating Harmonised Risk Indicator 2

Row	Groups						
	1		2		3		4
(i)	Low-risk active substances which are approved or deemed to be approved under Article 22 of Regulation (EC) No 1107/2009, and which are listed in Part D of the Annex to Implementing Regulation (EU) No 540/2011		Active substances approved or deemed to be approved under Regulation (EC) No 1107/2009, and not falling in other categories, and which are listed in Parts A and B of the Annex to Implementing Regulation (EU) No 540/2011		Active substances approved or deemed to be approved under Article 24 of Regulation (EC) No 1107/2009, which are candidates for substitution, and which are listed in Part E of the Annex to Implementing Regulation (EU) No 540/2011		Active substances which are not approved under Regulation (EC) No 1107/2009, and therefore which are not listed in the Annex to Implementing Regulation (EU) No 540/2011
(ii)	Categories						
(iii)	A	B	C	D	E	F	G
(iv)	Micro-organisms	Chemical active substances	Micro-organisms	Chemical active substances	Which are not classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors	Which are classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors where exposure of humans is negligible	
(v)	Hazard Weightings applicable to the number of authorisations granted under Article 53 of Regulation (EC) No 1107/2009						
(vi)	1		8		16		64

4. The baseline for Harmonised Risk Indicator 2 shall be set at 100 and is equal to the average result of the above calculation for the period 2011-2013.
5. The result of the Harmonised Risk Indicator 2 shall be expressed by reference to the baseline.
6. It shall be the duty of The Authority to calculate and publish the Harmonised Risk Indicator 2 in accordance with Article 15(2) and 15(4) of Directive 2009/128/EC for each calendar year and at the latest 20 months after the end of the year for which Harmonised Risk Indicator 2 is being calculated."