

[^{F1}ANNEX IV

Textual Amendments

- F1** Substituted by [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 \(Text with EEA relevance\)](#).

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

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(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.

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5. The result of the Harmonised Risk Indicator 2 shall be expressed by reference to the baseline.
6. The Member States and the Commission shall 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.]