[F1ANNEX 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 1

Harmonised Risk Indicators

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

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[(1)];

(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. The Member States and the Commission shall 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. 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.**]**

(1) **[**[F1]Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).**]**

Textual Amendments

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