

# DIRECTIVES

## 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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 <sup>(1)</sup>, and in particular the second subparagraph of Article 15(1) thereof,

Whereas:

- (1) Directive 2009/128/EC aims to reduce risks and impacts of pesticide use on human health and the environment and to promote the use of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides.
- (2) In its report of October 2017 on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides <sup>(2)</sup>, the Commission undertook to work with Member States towards reaching a consensus on the development of harmonised risk indicators.
- (3) In December 2017, in its response to the European Citizens Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides' <sup>(3)</sup>, the Commission undertook to establish harmonised risk indicators in order to monitor trends in risk reduction from pesticide use at Union level.
- (4) It is necessary to establish harmonised risk indicators in order to measure the progress achieved in meeting those objectives at Union level, which will enable Member States to manage and to report on risk at national level.
- (5) Article 15(4) of Directive 2009/128/EC requires the Commission to calculate risk indicators at Union level using statistical data collected in accordance with Union legislation concerning statistics on plant protection products and other relevant data, in order to estimate trends in risks from pesticide use.
- (6) Article 1(3) of Regulation (EC) No 1185/2009 of the European Parliament and of the Council <sup>(4)</sup> requires that the statistics produced in accordance with that Regulation, together with other relevant data, serve the purpose of Articles 4 and 15 of Directive 2009/128/EC, namely the establishment of National Action Plans and the

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 71.

<sup>(2)</sup> Report from the Commission to the European Parliament and the Council of October 2017 on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides — COM(2017) 587 final.

<sup>(3)</sup> Communication from the Commission of 12 December 2017 on the European Citizens' Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides' — C(2017) 8414 final.

<sup>(4)</sup> Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides (OJ L 324, 10.12.2009, p. 1).

calculation of indicators. To date, no harmonised approach at Union level for collecting statistics on the use of plant protection products has been achieved under Regulation (EC) No 1185/2009 and therefore no such data is available.

- (7) Article 53 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>(5)</sup> allows, in special circumstances, Member States to authorise for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be controlled by any other reasonable means. In these cases, Member States may authorise plant protection products containing either approved or non-approved active substances.
- (8) A harmonised risk indicator can only be based on statistical data collected in accordance with the Union legislation concerning statistics on plant protection products and other relevant data, and, in the absence of statistics on the use of plant protection products, the only such relevant and currently available data are statistics on the placing on the market of plant protection products, and the number of authorisations granted by Member States in special circumstances under Article 53 of Regulation (EC) No 1107/2009. Such indicators should be supplemented with other indicators so that other risk elements can be included.
- (9) It is appropriate that the categorisation of active substances used in this Directive mirror the categorisation provided for in Regulation (EC) No 1107/2009, as either low-risk active substances, candidates for substitution or other active substances, based, amongst others, on the classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(6)</sup>.
- (10) Active substances under Regulation (EC) No 1107/2009 can be either chemical active substances or micro-organisms. Directive 2009/128/EC requires Member States to give wherever possible priority to non-chemical methods of pest management. It is therefore appropriate, when establishing harmonised risk indicators, to categorise chemical active substances and micro-organisms separately.
- (11) In cases where Member States grant authorisations under Article 53 of Regulation (EC) No 1107/2009 concerning non-approved active substances, the quantities of non-approved active substances contained in the plant protection products subsequently placed on the market are communicated by Member States to the Commission in accordance with Article 3 of Regulation (EC) No 1185/2009. To date, there is no harmonised approach at Union level for collecting data on the specific quantities of approved active substances contained in plant protection products placed on the market linked to authorisations granted under Article 53 of Regulation (EC) No 1107/2009.
- (12) By combining the statistics produced in accordance with Regulation (EC) No 1185/2009 and the information on active substances in accordance with Regulation (EC) No 1107/2009, including if they are low risk active substances, candidates for substitution, or other active substances, a method of calculation can be established to produce a hazard-based harmonised risk indicator which estimates potential risks from pesticide use.
- (13) Pending the putting in place of a Union-wide harmonised data collection system on the quantities of active substances placed on the market under Article 53 of Regulation (EC) No 1107/2009, it is justified to establish a harmonised risk indicator based on the number of authorisations granted under that Article.
- (14) In order to calculate harmonised risk indicators to reflect the relative risk of using plant protection products containing different categories of approved active substances and non-approved active substances, weighting factors should be established for this purpose.
- (15) In order to measure progress in the area with a reasonable frequency, and given that Member States are required to produce data under Regulation (EC) No 1185/2009 on an annual basis and transmit it to Eurostat within 12 months of the end of the reference year, the calculation of harmonised risk indicators should be performed annually, and published at the latest 20 months after the end of the reference year in question.
- (16) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(5)</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>(6)</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

**Amendment to Annex IV to Directive 2009/128/EC**

Annex IV to Directive 2009/128/EC is replaced by the text in the Annex to this Directive.

*Article 2*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 5 September 2019 at the latest.

When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions which they adopt in the field covered by this Directive.

*Article 3*

**Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 4*

**Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 15 May 2019.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

## ANNEX

## ANNEX IV

## 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 <sup>(1)</sup>;
  - (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.

<sup>(1)</sup> 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).

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.

**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

Row	Groups						
	1	2	3	4	5	6	7
(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.'