

COMMISSION IMPLEMENTING REGULATION (EU) 2017/270**of 16 February 2017****amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance sulfuryl fluoride****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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 ⁽¹⁾, and in particular the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2010/38/EU ⁽²⁾ provides further confirmatory information on estimates of sulfuryl fluoride atmospheric lifetime, the tropospheric concentrations of sulfuryl fluoride and the milling conditions, necessary to ensure that residues of fluoride ion in cereals do not exceed the natural background levels.
- (2) Active substances included in Annex I to Directive 91/414/EEC ⁽³⁾ are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The notifier submitted additional information with a view to confirm the risk assessment for the fate of sulfuryl fluoride in the atmosphere and for the residues of fluoride ion in milling products present in the machinery during the fumigation.
- (4) The United Kingdom assessed the additional information submitted by the notifier. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission, and the European Food Safety Authority, hereinafter 'the Authority', on 4 June 2015.
- (5) The Commission considered that according to the additional information provided by the notifier, it could not be excluded that the residue levels in milling products present in the machinery during the fumigation will exceed the natural background concentration for fluoride ion or will not meet the relevant maximum residue levels. Therefore the conditions of approval should be amended to ensure that milling products present in the treated facilities always comply with provisions of Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁵⁾. Furthermore it considered that the information submitted has not demonstrated the steady state of sulfuryl fluoride in troposphere; consequently there is also a need for further monitoring of its tropospheric concentrations until the steady state is fully proven and to submit this information in this regard to the Commission, Member States and the European Food Safety Authority on regular basis, every fifth year.
- (6) Sulfuryl fluoride is also approved as a biocidal active substance according to Commission Directive 2009/84/EC ⁽⁶⁾. Due to the same concerns about the environmental fate of sulfuryl fluoride as for the pesticidal uses, additional information including a monitoring of the tropospheric concentrations has been required. Submission dates of information should be the same, in order to avoid redundant work and rationalize the evaluation process.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2010/38/EU of 18 June 2010 amending Council Directive 91/414/EEC to include sulfuryl fluoride as active substance (OJ L 154, 19.6.2010, p. 21).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ 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).

⁽⁵⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

⁽⁶⁾ Commission Directive 2009/84/EC of 28 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride as an active substance in Annex I thereto (OJ L 197, 29.7.2009, p. 67).

- (7) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (8) The applicant was given the possibility to submit comments on the review report.
- (9) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing sulfuryl fluoride which are not complying with the restricted conditions of approval.
- (10) For plant protection products containing sulfuryl fluoride, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest 18 months after the entry into force of this Regulation.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary amend or withdraw existing authorisations for plant protection products containing sulfuryl fluoride as active substance by 9 September 2017.

Article 3

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire 12 months after restriction or withdrawal of the respective authorisation at the latest.

Article 4

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 February 2017.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

The column 'Specific provisions' of row 307, sulfuryl fluoride, in Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

PART A

Only uses as insecticide/nematicide (fumigant) applied by professional users in sealable structures may be authorised insofar:

- (a) these structures are empty; or
- (b) where food or feed commodities are present in a fumigated facility, the users and the food business operators ensure that only the food or feed commodities compliant with the existing maximum residue levels for sulfuryl fluoride and fluoride ion set by Regulation (EC) No 396/2005 of the European Parliament and of the Council (*) may enter the food and feed chain; to this purpose, the users and the food business operators shall fully implement measures equivalent to the HACCP principles as laid down in Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council (**); in particular, the users shall identify the critical control point at which control is essential to prevent maximum residue levels to be exceeded, and establish and implement effective monitoring procedures at that critical control point.

PART B

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfuryl fluoride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 7 December 2016 shall be taken into account.

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

- 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 only products complying with the existing MRLs enter the food and feed chain;
- 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;
- the risk to bystanders by applying an appropriate exclusion zone around the fumigated structure.

Conditions of authorisation shall include risk mitigation measures, where appropriate.

The notifier shall submit to the Commission, Member States and the Authority monitoring data on tropospheric concentrations of sulfuryl fluoride every fifth year, starting from 30 June 2017. 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).

(*) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

(**) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).'