

Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for sulfuryl fluoride in light of confirmatory data

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the risk assessment for an active substance in light of confirmatory data requested following approval in accordance with Article 6(1) of Directive 91/414/EEC and Article 6(f) of Regulation (EC) No 1107/2009. In this context EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States, the applicant and EFSA on the confirmatory data and their use in the risk assessment for sulfuryl fluoride are presented. The current report summarises the outcome of the consultation process organised by the rapporteur Member State the United Kingdom and presents EFSA's scientific views and conclusions on the individual comments received.

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Key words: sulfuryl fluoride, peer review, confirmatory data, risk assessment, pesticide, insecticide

Requestor: European Commission

Question number: EFSA-Q-2015-00511

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Suggested citation: EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for sulfuryl fluoride in light of confirmatory data. EFSA supporting publication 2015:EN-870. 14 pp.

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Summary

Sulfuryl fluoride was included in Annex I to Directive 91/414/EEC on 1 November 2010 by Commission Directive 2010/38/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on the mill processing conditions necessary to ensure that residues of fluoride ion in flour, bran and grain do not exceed the natural background levels; on tropospheric concentrations of sulfuryl fluoride. Measured concentrations should be updated regularly. 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); and on estimates of sulfuryl fluoride atmospheric lifetime based on worst case scenario, with respect to the global warming potential (GWP) by 31 August 2012.

In accordance with the specific provision, the applicant, Dow AgroSciences, submitted an updated dossier in August 2012, which was evaluated by the designated rapporteur Member State (RMS), the United Kingdom, in the form of an addendum to the draft assessment report. In compliance with guidance document SANCO 5634/2009-rev.6.1, the RMS distributed the addendum to Member States, the applicant and EFSA for comments on 4 June 2015. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 4 September 2015. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table.

The current report summarises the outcome of the consultation process organised by the RMS, the United Kingdom, and presents EFSA's scientific views and conclusions on the individual comments received.

In the section on residues, several comments received indicate that there are doubts whether the confirmatory data requirement can be regarded as addressed by the current submission. It was expressed, that further considerations and discussions are probably necessary. The rapporteur Member State does not share the view of EFSA and the commenting Member States.

With respect to fate and behaviour, EFSA agrees with the RMS proposal that conditions set at the time of Annex I inclusion should be maintained. No precise data on emission (based on sulfuryl fluoride sales) have been provided by the applicant. Without having this information on a regular basis, it is not possible to obtain more precise calculations of atmospheric lifetime and global warming potential. The confirmatory data requirement cannot be considered fully addressed since further monitoring of atmospheric sulfuryl fluoride must be provided by the applicant to address its potential accumulation into the atmosphere and its effects as greenhouse gas.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Sulfuryl fluoride was included in Annex I to Directive 91/414/EEC¹ on 1 November 2010 by Commission Directive 2010/38/EU,² and has been deemed to be approved under Regulation (EC) No 1107/2009,³ in accordance with Commission Implementing Regulation (EU) No 540/2011⁴, as amended by Commission Implementing Regulation (EU) No 541/2011⁵. EFSA previously finalised a Conclusion on this active substance on 17 December 2009 in the EFSA Journal 2010;8(1):1441 (EFSA, 2010).

It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on the mill processing conditions necessary to ensure that residues of fluoride ion in flour, bran and grain do not exceed the natural background levels; on tropospheric concentrations of sulfuryl fluoride. Measured concentrations should be updated regularly. 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); and on estimates of sulfuryl fluoride atmospheric lifetime based on worst case scenario, with respect to the global warming potential (GWP) by 31 August 2012.

In accordance with the specific provision, the applicant, Dow AgroSciences, submitted an updated dossier in August 2012, which was evaluated by the designated rapporteur Member State (RMS), the United Kingdom, in the form of an addendum to the draft assessment report (United Kingdom, 2015a). In compliance with guidance document SANCO 5634/2009-rev.6.1 (European Commission, 2013), the RMS distributed the addendum to Member States, the applicant and the EFSA for comments on 4 June 2015. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 4 September 2015. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table.

The current report summarises the outcome of the consultation process organised by the RMS, the United Kingdom, and presents EFSA's scientific views and conclusions on the individual comments received.

1.2. Interpretation of the Terms of Reference

On 22 December 2014 the European Commission requested EFSA to provide scientific assistance with respect to the risk assessment of confirmatory data following approval of an active substance in accordance with Article 6(1) of Directive 91/414/EEC and Article 6(f) of Regulation (EC) No 1107/2009. EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States, the applicant and EFSA on the risk assessment of confirmatory data for sulfuryl fluoride are presented.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The deadline for providing the finalised report is 3 October 2015.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focused peer review and to provide its conclusions on certain specific points.

¹ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p.1–32.

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, 19.06.2010, p. 21–23.

³ 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. 1–50.

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.1–186.

⁵ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 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.187–188.

2. Assessment

The comments received on the pesticide risk assessment for the active substance sulfuryl fluoride in light of confirmatory data and the conclusions drawn by the EFSA are presented in the format of a reporting table.

The comments received are summarised in column 2 of the reporting table. The RMS' considerations of the comments are provided in column 3, while EFSA's scientific views and conclusions are outlined in column 4 of the table.

The finalised reporting table is provided in Appendix A of this report.

Documentation provided to EFSA

1. United Kingdom, 2015a. Addendum to the assessment report on sulfuryl fluoride, confirmatory data, June 2015. Available online: www.efsa.europa.eu.
2. United Kingdom, 2015b. Reporting table, comments on the pesticide risk assessment for sulfuryl fluoride in light of confirmatory data, September 2015.

References

- EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance sulfuryl fluoride. *EFSA Journal* 2010;8(1):1441. doi:10.2903/j.efsa.2010.1441. Available online: www.efsa.europa.eu
- European Commission, 2013. Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009. SANCO 5634/2009-rev. 6.1

Abbreviations

a.s.	active substance
DAR	draft assessment report
GAP	good agricultural practice
GWP	global warming potential
IPCC	Intergovernmental Panel on Climate Change
LOQ	limit of quantification
RMS	rapporteur Member State

Appendix A – Collation of comments from Member States, applicant and EFSA on the pesticide risk assessment for the active substance sulfuryl fluoride in light of confirmatory data and the conclusions drawn by EFSA on the specific points raised

3. Residue data

Residue trials in plants and identification of critical GAP				
No.	Column 1 Reference to addendum to assessment report	Column 2 Comments from Member States / applicant / EFSA	Column 3 Evaluation by rapporteur Member State	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data
3(1)	Confirmatory data Vol. 3, B.7	<p>DE: First it should be made clear if residue levels below 2 mg/kg or below specific natural fluoride levels in untreated food items are aimed at. In the latter case the natural background levels need to be reported more precisely (2 mg/kg is only an arbitrary level).</p> <p>Furthermore, GAP-compliant data are needed to draw conclusions from. The additionally presented non GAP-compliant data (less critical than the intended use) hardly allow the conclusion that natural background levels could be reached under the intended regime by the proposed risk management measures. However, a risk management decision is required on acceptability of the proposed measures. No robust (aggregate) risk assessment can be performed on the data available. Data requirement expressed in the peer-review cannot be regarded as addressed.</p>	<p>RMS: 2 mg/kg only refers to the limit of determination in the early trails, this has now been lowered to 1 mg/kg, presumably 'natural' levels of fluoride in untreated wheat commodities are lower than this level, with the possible exception of bran (see EFSA scientific conclusion 2010, bran may be present at up to 1 mg/kg).</p> <p>Disagree, as stated in the conclusion, sufficient residues trials data are available to make a conclusion using the proposed restrictions, however member states may wish to amend the application rate due to the shortfall in the concentrations used in the latest residue trials.</p> <p>Addressed</p>	<p>Several comments received indicate there are doubts whether the confirmatory data requirement can be regarded as addressed by the submission, and that further consideration/discussion may be necessary. This concerns in particular questions whether the submitted residue trials are sufficient</p> <ul style="list-style-type: none"> - to address residues that can be expected under cGAP conditions, as such, or in combination with proposed mitigation measures - to allow for a conclusion that natural background levels of fluoride could be reached under the intended regime, and whether the LOQ used was sufficient to facilitate such a conclusion - to consider other proposals for measures (alternative to the proposal to blend, mix, reprocess contaminated flour above background levels with flour before treatment) to ensure consumers will not be exposed to fluoride residues resulting from the use of sulfuryl fluoride <p>EFSA acknowledge that based on their response the RMS does not share the view of EFSA and the commenting MSs, and an</p>

			<p>experts consultation may therefore appear desirable in order to further discuss the issue.</p> <p>EFSA also kindly request Commission Services to clarify if the mitigation measure underlying the assessment with regard to blending/ mixing/ reprocessing in the silos contaminated flour above background levels with flour before treatment to reduce elevated consumer exposure would be a possible/acceptable mitigation measure in the light of the general prohibition by EU food law of processing, and/or mixing for dilution purposes of not complying food or feed products.</p>	
3(2)	Vol. 3, B.7.6.1 Cereal residue trials	<p>EFSA: The submitted residue trials are not conforming to the cGAP criteria of the representative uses in flour mill and grain stores. The application rate is in all trials but one half (50%) or even less than half (20%) the requested rate, and the length of fumigation was often shorter than the notified 24 hours. It is therefore hardly possible to use this data to tell when fluoride residues will have sank below the LOQ if mills and stores are treated according to the cGAP.</p>	<p>RMS: Disagree, as stated in the conclusion, sufficient residues trials data are available to make a conclusion using the proposed restrictions, however member states may wish to amend the application rate due to the shortfall in the concentrations used in the latest residue trials.</p> <p>Addressed</p>	Refer to 3(1)
3(3)	Application rate: clarification	<p>FR: In the framework of the registration of the plant protection product PROFUME (see CIRCABC), application rates were reported as g.h.m⁻³, along with a maximum concentration per m³ (g.m⁻³). In the confirmatory data, the application is reported as g.h⁻¹.m⁻³.</p> <p>It would be highly appreciated if the application rate could be clarified in the confirmatory data, especially when a reduction of this application rate is proposed as a mitigation measure at</p>	<p>RMS: Data as requested below, from the data in the reports it is unclear if the units used were g.m⁻³ and the figures quoted are the maximum levels found through out the mill at set sampling points (i.e. 'Mill first floor')</p> <p>UK (2005) = 33-169 g.m⁻³ UK (2005) = 44-96 g.m⁻³ UK (2006) = 50-90 g.m⁻³ UK (2008) = 26-32 g.m⁻³ France (2011) = 38-72 g.m⁻³</p>	<p>Addressed.</p> <p>The requested information was reported.</p>

		Member State level.	Germany (2012) = 30-62 g.m ⁻³ Addressed Did not have access to the below reference <i>Link to the registration reports:</i> https://circabc.europa.eu/w/browse/31ecc630-cf88-4ef9-b72a-9fbc9272557a	
3(4)	Addendum	NL: It is unclear how it can be concluded that the residue trials are acceptable, since they are not performed according to the cGAP regarding the target concentration of the gas in the mill. Subsequently, it is questionable whether the confirmatory data requirement has been addressed.	RMS: Disagree, as stated in the conclusion, sufficient residues trials data are available to make a conclusion using the proposed restrictions, however member states may wish to amend the application rate due to the shortfall in the concentrations used in the latest residue trials. Addressed	Refer to 3(1)
3(5)	Addendum	NL: Is it correct that the measured residue levels in the trials are compared to the limit of detection instead of the natural background levels.	RMS: The limit of quantification is based on recovery data. Addressed	Refer to 3(1)

Estimation of the potential exposure through diet and other sources

No.	Column 1 Reference to addendum to assessment report	Column 2 Comments from Member States / applicant / EFSA	Column 3 Evaluation by rapporteur Member State	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data
3(6)	Vol. 3, B.7.16.2.1 Flour mills	EFSA: EFSA agree with the RMS conclusion that the case submitted by the applicant of disposing the first 10 minutes of full production and reprocess the next 50 minutes of production is insufficient to	RMS: The restrictions in place make it very unlikely that wheat commodities entering the food chain would contain positive residue of fluoride (i.e. greater than 0.01 mg/kg).	Refer to 3(1)

		protect consumers to elevated fluoride levels in cereal products. EFSA can however not confirm that in the light of the available data (old trials+ new significantly underdosed trials) the RMS proposal of disposing the first 20 minutes of full production and reprocess the next 60 minutes of production will be a sufficient measure to ensure fluoride residues will be below the LOQ, and consumers will not be exposed to significant fluoride levels.	Addressed	
3(7)	Vol. 3, .7.16.2.1 Flour mills	EFSA: EFSA likes to note that in terms of the proposal to blend, mix, reprocess contaminated flour above background levels with flour before treatment in the silos to mitigate elevated consumer exposure it may have to be verified by legal services if this would be a possible mitigation measure in the light of the general prohibition by EU food law of processing, and/or mixing for dilution purposes of not complying food or feed products	RMS: Noted. However, mitigation measures were reported and considered during the Annex I inclusion evaluation and peer review of sulfuryl fluoride, and the inclusion directive contains a provision for Member States to consider measures so that contaminated flour does not enter food or feed chain.	Refer to 3(1)
3(8)	Proposed mitigation measure	FR: The proposed mitigation measures are expected to allow no residue of fluoride above 1 mg/kg in flour. However, in results from Bartolome 2008, residues up to 1.7 mg/kg are reported after 60 minutes of full production. It is therefore not guaranty that the proposed mitigation measure is sufficient to lower residue levels of fluoride to below 1 mg/kg.	RMS: This is not an issue as the recommendation is to send the first 20 minutes of production to landfill and the next 60 minutes of production to be reprocessed/blended, to ensure levels of fluoride in the flour are below the LOQ. Addressed Did not have access to the below reference <i>Link to the registration reports:</i> https://circabc.europa.eu/w/browse/31ecc630-cf88-4ef9-b72a-9fbc9272557a	Refer to 3(1)

3(9)	Proposed mitigation measure	FR: In its registration report on PROFUME, Belgium proposed the following mitigation measure: "a limit to the reprocessing: max. 1 part reprocessed to 20 parts flour in production." Could the rationale for this ratio be further discussed in the confirmatory data?	RMS: The UK felt the restrictions specified are workable and acceptable, however in the conclusion recognises that specific restrictions may be required in other member states. Addressed	Refer to 3(1)
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4. Environmental fate and behaviour

Fate and behaviour in air

No.	Column 1 Reference to addendum to assessment report	Column 2 Comments from Member States / applicant / EFSA	Column 3 Evaluation by rapporteur Member State	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data
4(1)	Addendum – confirmatory data.	EFSA: RMS has thoroughly summarized and discussed new available data on atmospheric monitoring of sulfuryl fluoride. Available data seems to confirm atmospheric lifetime of sulfuryl fluoride falls in the upper limit of those already considered in sulfuryl fluoride EU evaluation as plant protection active substance (DAR, Addendum and EFSA conclusion), being expected to be <i>ca</i> 36 years. However, uncertainty associated to this estimations remains high, since the amount of emissions is not known with precision. As a matter of fact, the most relevant information is that concentration of sulfuryl fluoride in the troposphere, being still low (in the range of 2 pptv) has continued to increase since its approval for uses as pesticide in EU. The intrinsic global warming potential of sulfuryl fluoride has been also confirmed by	RMS: Agreement noted. No further action required. Addressed.	Available data seem to confirm atmospheric lifetime of sulfuryl fluoride falls in the upper limit of those already considered in the sulfuryl fluoride EU evaluation. EFSA agrees with the RMS proposal that conditions set at the time of Annex I inclusion should be maintained (eg. updated data on monitoring of sulfuryl fluoride in the atmosphere need to be provided regularly by the notifier in order to have more precise estimations of atmospheric lifetime and global warming potential). Also critical areas of concern and issues that could not be finalized at the time of publishing EFSA conclusion of sulfuryl fluoride can still be considered to be critical areas of concern and open issues. No precise data on emission (based on sulfuryl fluoride sales) has yet been provided by the applicant. Without having this information in a regular basis, it is not possible to obtain more precise calculations

		<p>recent data and assessments (including IPCC reports).</p> <p>In conclusion EFSA agrees with the RMS proposal that conditions set at the time of Annex I inclusion should be maintained (eg. updated data on monitoring of sulfuryl fluoride in the atmosphere needs to be provided regularly by the notifier in order to have more precise estimations of atmospheric lifetime and GWP). Also critical areas of concern and issues that could not be finalized at the time of publishing EFSA conclusion of sulfuryl fluoride can still be considered to be critical areas of concern and open issues. No precise data on emission (based on sulfuryl fluoride sales) has yet been provided by the applicant (not even under the confidentiality clause). Without having this information in a regular basis, it is not possible to obtain more precise calculations of atmospheric lifetime and GWP. Applicant claimed that a plateau of emissions will be reached by 2015; however, there is no data that can allow to independently confirm this. On the contrary, it may be expected that emissions will keep increasing as long as new authorizations for sulfuryl fluoride are granted (in terms of uses and geographically).</p>		<p>of atmospheric lifetime and global warming potential.</p> <p>Available data allows assuming that emissions of sulfuryl fluoride and its accumulation in the atmosphere will keep increasing as long as new authorizations for sulfuryl fluoride are granted (in terms of uses and geographically).</p>
4(2)	Addendum	<p>NL: The data provided by applicant and evaluated by the RMS answered the questions raised in the confirmatory data. Therefore NL agrees to continue the approval for sulfuryl fluoride. As indicated by the RMS future monitoring is necessary to see how atmospheric concentrations of sulfuryl fluoride evolve.</p>	<p>RMS: Agreement noted. No further action required.</p> <p>Addressed.</p>	<p>See EFSA's views above.</p>

Appendix B – Used compound code(s)

Code/trivial name	Chemical name/SMILES notation	Structural formula
Sulfonyl fluoride	Sulfonyl fluoride	