

REASONED OPINION

Review of the existing maximum residue levels (MRLs) for sulphuric acid according to Article 12 of Regulation (EC) No 396/2005¹

European Food Safety Authority^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

A decision not to include sulphuric acid in Annex I to Directive 91/414/EEC entered into force on 24 December 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(1) of the afore mentioned regulation. Considering that the use of sulphuric acid is no longer authorised within the European Union and that no import tolerances were notified by the designated rapporteur Member State (France), EFSA based its assessment mainly on the conclusions derived by France in the framework of Directive 91/414/EEC.

On 25 October 2011 EFSA issued a draft reasoned opinion that was circulated to Member State experts for consultation. No comments were received by 06 January 2012 and the following conclusions are derived.

A risk assessment for this active substance is in principle not required considering that the use is no longer authorised in the EU and that no import tolerances have been notified. However, EFSA assessed the available data for sulphuric acid in order to assist risk managers in applying the most appropriate measures for enforcement of the potential illegal use of sulphuric acid within the EU as well as the presence of illegitimate residue levels in imported products.

Sulphuric acid is expected to dissociate into sulphate on contact with water and soil and become part of the natural sulphur cycle therefore it would not be possible to distinguish sulphate residues arising from pesticide treatment and natural sources of sulphate. Based on the information currently available, EFSA concludes that a relevant residue for enforcement of a potentially illegal use cannot be proposed.

EFSA also considers, based on the average daily intake of sulphate from drinking-water, air and food of approximately 500 mg (WHO, 2004) and the natural occurrence of sulphate in foods, considerable misuse would need to occur before consumer concern arose. In addition, applying the default MRL of 0.01 mg/kg as defined by Article 18(1) of Regulation (EC) No 396/2005 might not be appropriate since enforcement laboratories would not be able to distinguish between naturally occurring sulphate

¹ On request from EFSA, Question No EFSA-Q-2009-00079, approved on 23 January 2012.

² Correspondence: pesticides.mrl@efsa.europa.eu

³ Acknowledgement: EFSA wishes to thank the rapporteur Member State France for the preparatory work on this scientific output.

and residues resulting from the potential illegal use of sulphuric acid as a plant protection product. Inclusion of this active substance in Annex IV to the above mentioned regulation can therefore be considered by risk managers.

KEY WORDS

sulphuric acid, sulphate, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, contact herbicide.

TABLE OF CONTENTS

Summary	1
Table of contents	3
Background	4
Terms of reference	5
The active substance and its use pattern.	5
Assessment	6
Conclusions and recommendations	7
References	8
Abbreviations	9

BACKGROUND

Regulation (EC) No 396/2005⁴ establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(1) of that regulation stipulates that EFSA shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC⁵, a reasoned opinion on the review of the existing MRLs for that active substance. As a decision not to include sulphuric acid in Annex I to Directive 91/414/EEC entered into force on 24 December 2008, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2009-00079 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that the few representative uses evaluated in the framework of that directive might no longer be relevant because the use of active substances that are not included in Annex I is not allowed within the EU. Moreover, non-included substances might still be authorised in third countries requiring the establishment of import tolerances in Regulation (EC) No 396/2005.

In order to gain an overview on the pesticide residues data that have been considered for the setting of import tolerances, EFSA developed the Pesticide Residue Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

France, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for sulphuric acid and to prepare a supporting evaluation report. An evaluation report was submitted on 14 January 2011 confirming that no import tolerances for this active substance were notified to the RMS. Submission of a PROFile was therefore not considered relevant.

A draft reasoned opinion was issued by EFSA on 25 October 2011 and submitted to Member States (MS) for commenting. No comments were received by 06 January 2012.

⁴ Regulation (EC) No 396/2005 of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.

⁵ Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.

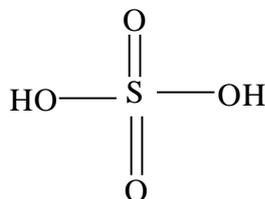
TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Sulphuric acid is both the ISO common name and the IUPAC name of the pesticide shown below.



Sulphuric acid is a contact inorganic herbicide. When first introduced it was used as a selective herbicide against broad leaved weeds, but is now principally used as a desiccant.

Sulphuric acid was evaluated in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was as a desiccant on potato, peas, linseed, onions and ornamental bulbs and corms in Northern Europe. Following the Draft Assessment Report (DAR) submission, and member state consultation, in accordance with Article 24f of Regulation (EC) No 2229/2004⁶ as last amended by Regulation (EC) No 1095/2007⁷ there were clear indications of harmful effects. Consequently, a decision on non-inclusion of the active substance was published by means of Commission Decision 2008/937/EC⁸, entering into force on 5 December 2008. According to this Commission Decision, any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC expired on 5 June 2010.

EU MRLs for sulphuric acid have not been set. Since sulphuric acid is also not included in Annex IV of Regulation (EC) No 396/2005, the default MRL of 0.01 mg/kg as defined by Article 18(1) of the Regulation applies. Ferric sulphate and ferrous sulphate however were temporarily included in Annex IV of the Regulation by means of Commission Regulation (EC) No 839/2008⁹, pending finalisation of their evaluation under Directive 91/414/EEC and pending submission of EFSA's reasoned opinion in accordance with Article 12 (1) of Regulation (EC) No 396/2005. CXLs for sulphur and sulphate are not available.

⁶ Commission Regulation (EC) No 2004/2229 of 3 December 2004, OJ L 379, 24.12.2004, p. 13-63.

⁷ Commission Regulation (EC) No 1095/2007 of 20 September 2007, OJ L 246, 21.9.2007, p. 19-28

⁸ Commission Decision 2008/937/EC of 5 December 2008, OJ L 334, 12.12.2008, p. 88-89.

⁹ Commission Regulation (EC) No 839/2008 of 31 July 2008, OJ L 234, 30.8.2008, p. 1-216.

According to the decision of non-inclusion under Annex I of Directive 91/414/EEC, plant protection products containing sulphuric acid are not authorised in EU Member States. For the purpose of this MRL review, the RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

Considering that the use of sulphuric acid is no longer authorised within the EU, that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, European consumers are not expected to be exposed to residues of this active substance and a consumer risk assessment is, in principle, not required. Risk managers might have the interest, however, to enforce the potential illegal use of sulphuric acid within the EU as well as the presence of illegitimate residue levels in imported products. In order to assist risk managers in applying the most appropriate enforcement measures, EFSA assessed the available data with particular attention for the analytical methods, the toxicological reference values and the nature of residues in plants and livestock. EFSA's assessment is mainly based on the Draft Assessment Report (DAR) prepared under Directive 91/414/EEC (France, 2007).

The toxicological assessment of sulphuric acid was not formally peer reviewed under Directive 91/414/EEC. However, France considered that an ADI is not required as residues resulting from the herbicide use are not expected in treated crops and that an ARfD is not required as systemic toxicity is not expected. The DAR also indicates that, when applied to plants sulphuric acid acts as a very rapid contact desiccant. It oxidises any organic tissue with which it is in contact and is extremely unlikely to be translocated within plants. Residues of sulphuric acid are therefore not expected to occur in treated crops. Sulphuric acid is expected to dissociate into sulphate on contact with water and soil and become part of the natural sulphur cycle therefore it would not be possible to distinguish if sulphate residues are arising from pesticide treatment or natural sources.

In particular, significant levels of sulphate are found in many common foods as shown in Table 2.2. The WHO guidelines for drinking quality (WHO, 2004) suggest that the average daily intake of sulphate from drinking-water, air and food is approximately 500 mg. The use of sulphuric acid (E513) and sulphate compounds (E514, E515 and E516) are listed in Directive 95/2/EC as food additives and no maximum concentration limits are specified for their use.

Table 1-1: Example levels of sulphate in food (Food and Nutrition Board, 2005)

Commodity	Sulphate (g/kg)
Almonds	0.9
Broccoli	0.9
Brussel sprouts	0.9
Cabbage	0.8
Dried potato	2.0
Peanuts	0.7
Sunflower seeds	0.6

Based on the information currently available, EFSA concludes that a relevant residue for enforcement of a potentially illegal use cannot be proposed. No specific analytical methods are available which

could distinguish between naturally occurring sulphate in food and residues resulting from the potential illegal use of sulphuric acid as a plant protection products.

The Review Report (EC, 2008) highlighted the lack of information on the impurities in the active substance as a cause for concern in establishing the risk to consumers. In particular, insufficient information on the technical specification was available in the Draft Assessment Report (DAR) to exclude the possibility of the accumulation of heavy metals in treated soils and therefore the presence of heavy metal residues in treated or rotational crops. Heavy metal residues in food are not expected considering that the use of sulphuric acid is no longer authorised within the EU, that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, however such levels are controlled by Regulation (EC) No 1881/2006¹⁰, and have therefore not been considered further in this reasoned opinion.

EFSA considers, based on the average daily intake of sulphate from drinking-water, air and food of approximately 500 mg (WHO, 2004) and the natural occurrence of sulphate in foods, considerable misuse would need to occur before consumer concern arose. It is also noted that applying the default MRL of 0.01 mg/kg as defined by Article 18(1) of Regulation (EC) No 396/2005 might not be appropriate since enforcement laboratories would not be able to distinguish between naturally occurring sulphate and residues resulting from the potential illegal use of sulphuric acid as a plant protection product. Inclusion of this active substance in Annex IV to the above mentioned regulation can therefore be considered by risk managers.

CONCLUSIONS AND RECOMMENDATIONS

A risk assessment for this active substance is in principle not required considering that the use is no longer authorised in the EU and that no import tolerances have been notified. However, EFSA assessed the available data for sulphuric acid in order to assist risk managers in applying the most appropriate measures for enforcement of the potential illegal use of sulphuric acid within the EU as well as the presence of illegitimate residue levels in imported products.

Sulphuric acid is expected to dissociate into sulphate on contact with water and soil and become part of the natural sulphur cycle therefore it would not be possible to distinguish sulphate residues arising from pesticide treatment and natural sources of sulphate. Based on the information currently available, EFSA concludes that a relevant residue for enforcement of a potentially illegal use cannot be proposed.

EFSA also considers, based on the average daily intake of sulphate from drinking-water, air and food of approximately 500 mg (WHO, 2004) and the natural occurrence of sulphate in foods, considerable misuse would need to occur before consumer concern arose. In addition, applying the default MRL of 0.01 mg/kg as defined by Article 18(1) of Regulation (EC) No 396/2005 might not be appropriate since enforcement laboratories would not be able to distinguish between naturally occurring sulphate and residues resulting from the potential illegal use of sulphuric acid as a plant protection product. Inclusion of this active substance in Annex IV to the above mentioned regulation can therefore be considered by risk managers.

¹⁰ Commission Regulation (EC) No 1881/2006 of 19 December 2006. OJ L 364, 20.12.2006, p. 5-26.

REFERENCES

- EC (European Commission), 2008. Review report for the active substance Sulphuric acid. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 26 September 2008 in view of the non-inclusion of Sulphuric acid in Annex I of Council Directive 91/414/EEC. SANCO/2692/2008-Final, 25 August 2008. Available online: http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection
- France, 2007. Draft Assessment Report on the active substance sulphuric acid prepared by the rapporteur Member State France in the framework of council Directive 91/414/EEC, September 2007.
- Food and Nutrition Board, 2005. Dietary reference intakes for water, potassium, sodium, chloride and sulphate. Panel on dietary reference intakes for electrolytes and water. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. Food and Nutrition Board. The National Academies Press, Washington D.C., US, 431-432.
- WHO (World Health Organisation of the United Nations), 2004. Sulfate in drinking-water. Background document for preparation of WHO Guidelines for drinking-water quality. Geneva, World Health Organization (WHO/SDE/WSH/03.04/114).

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
CXL	codex maximum residue limit
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
MRL	maximum residue limit
MS	Member States
PROFile	(EFSA) Pesticide Residue Overview File
RMS	rapporteur Member State
WHO	World Health Organisation