



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain  
Unit E.3 - Chemicals, contaminants, pesticides

**Sulphur**

SANCO/2676/08 – final

22 October 2009

Final

Review report for the active substance **sulphur**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
13 March 2009

in view of the inclusion of sulphur in Annex I of Directive 91/414/EEC

**1. Procedure followed for the re-evaluation process**

This review report has been established as a result of the re-evaluation of sulphur, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 1112/2002<sup>(1)</sup> laying down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, and Regulation (EC) No 2229/2004<sup>(2)</sup> have laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. **Sulphur** is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 in Regulation (EC) No 1112/2002, Sulfur Task Force and Sulfur Working Group notified to the Commission of their wish to secure the inclusion of the active substance sulphur in Annex I to the Directive.

In Annex I to Regulation (EC) No 2229/2004 the Commission, designated France as rapporteur Member State to carry out the assessment of sulphur on the basis of the dossiers submitted by the notifiers. In Article 12 of Regulation (EC) No 2229/2004 the Commission specified furthermore that the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required, as well as for other parties with regard to further technical and scientific information was 30 June 2005.

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<sup>1</sup> OJ No L 168, 27.06.2002, p.14.

<sup>2</sup> OJ No L 379, 24.12.2004, p.13. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

The notifiers submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore, Sulfur Task Force and Sulfur Working Group were considered to be the data submitters.

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, France submitted on 18 October 2007 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of sulphur in Annex I to the Directive.

In accordance with the provisions of Article 24 of Regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Sulfur Task Force and Sulfur Working Group being the data submitters, on 18 February 2008 by making it available.

In accordance with the provisions of Article 24 of Regulation (EC) No 2229/2004 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance sulphur (finalised 19 December 2008)<sup>3</sup>]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 25 of Regulation (EC) No 2229/2004, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 13 March 2009.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

## **2. Purposes of this review report**

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive **2009/70/EC** concerning the inclusion of sulphur in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing sulphur they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

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<sup>3</sup> EFSA Scientific Report (2008) n, 1-34.

In accordance with the provisions of Article 26 of Regulation (EC) No 2229/2004, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

### **3. Overall conclusion in the context of Directive 91/414/EEC**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing sulphur will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each plant protection product containing sulphur for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

The following reference values have been finalised as part of this re-evaluation:

ADI Not applicable  
ARfD Not applicable  
AOEL Not applicable

As stated in the EFSA conclusions, for an essential element as sulphur, exposure is evaluated against background levels and sulphur is considered to be low risk.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

### **4. Identity**

The identity of sulphur is given in Appendix I.

At the time of the evaluation no FAO specification was allocated.

The review has established that for the active substance notified by the main data submitters none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

## **5. Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA.

## **6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing sulphur.**

On the basis of the proposed and supported uses (as listed in Appendix II), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

Member States should pay particular attention to:

- the risk to birds, mammals, non target arthropods and sediment-dwelling organisms.

Risk mitigation measures should be applied where appropriate.

## **7. List of studies to be generated**

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Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Scientific report (page 26-27).

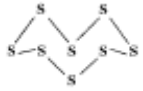
## **8. Information on studies with claimed data protection**

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

## **9. Updating of this review report**

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for sulphur in Annex I of the Directive.

**APPENDIX I****Identity****sulphur**

<b>Common name (ISO)</b>	Sulphur (E-ISO, JMAF, ESA)
<b>Chemical name (IUPAC)</b>	Sulphur
<b>Chemical name (CA)</b>	Sulphur
<b>CIPAC No</b>	18
<b>CAS No</b>	7704-34-9
<b>EEC No</b>	231-722-6
<b>FAO SPECIFICATION</b>	Not available
<b>Minimum purity</b>	990 g/kg
<b>Molecular formula</b>	S <sub>8</sub>
<b>Molecular mass</b>	32.064 (S)
<b>Structural formula</b>	

## APPENDIX II

## List of uses supported by available data

## SULPHUR

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
Cereals-Barley, rye & wheat	Germany	KUMULUS WG	F	Erysiphe graminis	WG	Sulphur 80% (w/w)	foliar spray	BBCH 25-77	1-2	14	1.2-3.2	200-400	4.8-6.4	35	
Cereals-barley, rye & wheat	Germany	NETZSCH-WEFEL STULLN	F	Erysiphe graminis	WG	Sulphur 80% (w/w)	foliar spray	BBCH 25-77	1-2	14	1.2-3.2	200-400	4.8-6.4	35	
Cereal Group	Germany	THIOVIT JET 80 WG	F	Erysiphe graminis	WG	Sulphur 80% (w/w)	foliar spray	BBCH 25-77	1-2	14	1.2-3.2	200-400	4.8-6.4	35	
Cereal Group	France	MICROTHI O-L DISPERS	F	Oidium	WG	Sulphur 80% (w/w)	foliar spray	BBCH 25-77	1-2	14	1.2-3.2	200-600	4.8-6.4	35	
Grapes	Germany	KUMULUS WG NETZSCH-WEFEL STULLN	F	Uncinula necator	WG	Sulphur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.16 - 0.64	400-1600	2.56	28	
Grapes	Germany	KUMULUS WG	F	Uncinula necator	WG	Sulphur	foliar spray	To beginning	1-8	7	0.5-2	400-	8	28	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
		NETZSCH-WEFEL STULLN				80% (w/w)		of ripening				1600			
Grape Group	France	THIOVIT JET 80 WG	F	Uncinula necator	WG	Sulphur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	1.28 - 2.56	200-1000	2.56	28	
Grape Group	France	THIOVIT JET 80 WG	F	Uncinula necator	WG	Sulphur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.8-4	200-1000	8	28	
Grape Group	France	MICROTHI O-L DISPERS	F	Acaros and Erinose	WG	Sulphur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.25-6-1.28	200-1000	2.56	28	
Grape Group	France	MICROTHI O-L DISPERS	F	Acaros and Erinose	WG	Sulphur 80% (w/w)	foliar spray	To beginning of ripening	1-8	7	0.8-4	200-1000	8	28	
Grapes	North & South EU	Sulphur 80 WG	F	Powdery mildew	WG	Sulphur 80% (w/w)	spray	To beginning of ripening	5	7-10 days	2.7-4.0	200-300	2.56	28	
Grapes	North & South EU	Sulphur Dust	F	Powdery mildew	DP	Sulphur 98.5% (w/w)	dust	To beginning of ripening	5	7-10 days	Not applicable	Not applicable	19.7-29.55	5	
Grapes	North & South EU	Sulphur 80 WG	F	Powdery mildew	WG	Sulphur 80% (w/w)	spray	To beginning of ripening	5	7-10 days	2.7-4.0	200-300	8	28	

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions

