



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

urea

SANCO/2637/08 – rev. 1

04 July 2008

## FINAL

### Review report for the active substance **urea**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
28 October 2008  
in view of the inclusion of urea 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 urea, 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. Urea 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, Phytophyl N.G. Stavrakis and Forestry Commission Scotland as task force, notified to the Commission of their wish to secure the inclusion of the active substance urea in Annex I to the Directive.

In Annex I to Regulation (EC) No 2229/2004 the Commission, designated Greece as rapporteur Member State to carry out the assessment of urea on the basis of the dossiers submitted by the notifier. In Article 12 of Regulation (EC) No 2229/2004 the Commission specified furthermore that the deadline for the notifier 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.

Phytophyl N.G. Stavrakis and Forestry Commission Scotland submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses.

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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).

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, Greece submitted in April 2008 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 urea 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 Phytophyl N.G. Stavrakis and Forestry Commission Scotland on 31 July 2008 by making it available.

In accordance with the provisions of Article 24a of Regulation 2229/2004 as last amended by Regulation (EC) 1095/2007 the Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from Member States.

In accordance with the provisions of Article 24b and Article 25 (1) a of Regulation (EC) No 2229/2004 as last amended by Regulation (EC) 1095/2007, the Commission referred on 28 October 2008 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 28 October 2008.

The present review report contains the conclusions of the final examination by the Standing Committee.

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

This review report, including the background document appendices thereto, has been developed in support of the Directive **2008/127/EC**<sup>3</sup> concerning the inclusion of urea in Annex I to Directive 91/414/EEC. The Commission shall request the EFSA to deliver its view on the draft review reports by 31 December 2010 at the latest. When the Member States decide on individual plant protection products containing urea they shall take into account this review report 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. However, when the EFSA has delivered its view on the draft review report, the Commission shall revise it.

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.

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

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<sup>3</sup> Commission Directive 2008/127/EC (OJ L 344, 20.12.2008, p. 89)

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 draft assessment report, the recommendations by the rapporteur Member State and the result of the examination in accordance with the provisions of Article 24a of Regulation 2229/2004 is that there are clear indications that it may be expected that urea does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex VI of regulation (EC) 2229/2004 as last amended by Regulation (EC) 1095/2007.

These indications are however subject to compliance with the particular requirements in sections 4 and 5 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 urea containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these indications 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 review has concluded that there are acceptable exposure scenarios for consumers, operators, workers and bystanders which require however to be confirmed for each plant protection products in accordance with the relevant sections of the above-mentioned uniform principles.

It has also been 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 and biological properties**

The main properties of urea are given in Appendix I.

It has been established that for the active substance notified by the main data submitter 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 volume 1, page 57 and at section 3 of this report. The EFSA will deliver its view on this review report by 31 December 2010 at the latest.

**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 urea**

On the basis of the proposed and supported uses (as listed in Appendix II), no 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.

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

Further studies which were at this stage considered necessary were identified in the level 4 of the Draft Assessment Report.

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

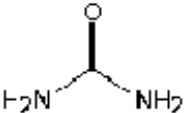
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I 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 urea in Annex I of the Directive.

**APPENDIX I****Identity; physical and chemical properties**

## UREA

<b>Common name (ISO)</b>	Urea
<b>Chemical name (IUPAC)</b>	Urea
<b>Chemical name (CA)</b>	Urea
<b>CIPAC No</b>	8352
<b>CAS No</b>	57-13-6
<b>EEC No</b>	200-315-5
<b>FAO SPECIFICATION</b>	none
<b>Minimum purity</b>	98% w/w
<b>Molecular formula</b>	NH <sub>2</sub> CONH <sub>2</sub>
<b>Molecular mass</b>	60.06
<b>Structural formula</b>	 <chem>NC(=O)N</chem>

## APPENDIX II

## List of uses supported by available data

## UREA

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		
Conifer stumps in forests, gardens, parks, etc	UK	Urea (no product name)	F	Wood-rotting pathogenic fungus <i>Heterobasidion annosum</i> (Fomes root and butt rot)	Aqueous solution	370g/L	Drench of individual stumps by hand or harvesting machine. 1 litre/sq m of stump surface	Cut stump surface. All seasons	1 per stump	Not applicable	0.375	Max 378	Max 225 Mean 5	Not applicable	Provides crucial preventative control of a major threat to UK forest reserve of timber.
Olive Trees	Greece	ENTOMELA 75 SL	F	Bactrocera oleae winged adults.	SL	250gr/kg	Spot bait sprays By Low volume sprays	Fruit, depends on the insecticide used	3-5	Depends on the insecticide used	0.675	30	0.2025	Depends on the insecticide used	
Olive Trees	Greece	ENTOMELA 50 SL	F	Bactrocera oleae winged adults.	SL	170gr/kg	Spot bait sprays By Low volume sprays	Fruit, depends on the insecticide used	3-5	Depends on the insecticide used	4.59	30	0.1377	Depends on the insecticide used	

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		
Olive Trees	Greece	ENTOMELA 55 SL	F	Bactrocera oleae winged adults.	SL	200gr/kg	Mass trapping Inside liquid traps	Fruit, until harvest	One trap per tree for all season	Not applicable	39.3-78.7	50-100	3.93-7.87	0 days	No insecticide used and there is no contact between the formulation & the fruit

- 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