

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance urea¹

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SUMMARY

Urea is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004³, as amended by Commission Regulation (EC) No 1095/2007⁴.

Urea was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as ‘the Regulation’), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009⁵, in accordance with Commission Implementing Regulation (EU) No 540/2011⁶, as amended by Commission Implementing Regulation (EU) No 541/2011⁷. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010⁸, the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Greece being the designated rapporteur Member State submitted the DAR on urea in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 22 April 2008. The peer review was initiated on 31 July 2008 by dispatching the DAR for consultation of the notifiers the Forestry Commission and Phytophyl – N.G. Stavrakis. Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should deliver its conclusions on urea.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of urea as a fungicide treatment by spray and drenching to individual conifer tree stumps, as a spot spray attractant with an insecticide to olive trees, and as a mass trapping agent in liquid traps in olive groves, as proposed by the notifiers. Full details of the representative uses can be found in Appendix A to this report.

¹ On request from the European Commission, Question No EFSA-Q-2009-00302, issued on 16 December 2011.

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³ OJ L 379, 24.12.2004, p.13

⁴ OJ L 246, 21.9.2007, p.19

⁵ OJ L 309, 24.11.2009, p.1

⁶ OJ L 153, 11.6.2011, p.1

⁷ OJ L 153, 11.6.2011, p.187

⁸ OJ L 37, 10.2.2010, p.12

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In the area of identity, physical/chemical/technical properties and methods of analysis data gaps were identified for Annex II and III physchem data packages, a method of analysis for urea and the impurity biuret in the technical material. Also validated methods of analysis for urea in the formulations were identified as data gaps.

In the mammalian toxicology section the toxicological database is not suitable to set an AOEL and therefore the risk assessment for non-dietary exposure cannot be concluded.

No data gaps or critical areas of concern were identified in the residue section.

The information on the environmental fate and behaviour of urea in relation to the representative uses as a spray in olive trees and to conifer stumps was insufficient to complete the necessary environmental exposure assessment at the EU level. Data gaps were identified for satisfactory information on adsorption to soil of urea or its transformation products, for predicted environmental concentrations (PEC) in soil for urea, PEC in surface water/sediment for urea, ammonia, nitrate and nitrite, and PEC in groundwater for urea, nitrate and nitrite. No data gaps were identified for the representative uses by drench application of individual stumps by hand, or as a mass trapping agent in liquid traps. Based on the estimated atmospheric half-life performed by EFSA with US EPA AOPWIN program (v1.92), urea has a potential for long-range transport through the atmosphere.

A data gap was identified for studies on aquatic organisms to fulfil the Annex II data requirements. A data gap was also identified for the original studies summarised in the US EPA and OECD reports and the IUCLID database. Finally, a data gap was identified to address the risk to non-target organisms for the representative spray uses to conifer stumps and olive trees once the environmental exposure is finalised.

KEY WORDS

Urea, peer review, risk assessment, pesticide, fungicide, attractant

TABLE OF CONTENTS

Summary	1
Table of contents	3
Background	4
The active substance and the formulated product	6
Conclusions of the evaluation	6
1. Identity, physical/chemical/technical properties and methods of analysis	6
2. Mammalian toxicity	6
3. Residues	6
4. Environmental fate and behaviour	7
5. Ecotoxicology	7
6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments	8
6.1. Soil	8
6.2. Ground water	8
6.3. Surface water and sediment	9
6.4. Air	9
7. List of studies to be generated, still ongoing or available but not peer reviewed	10
8. Particular conditions proposed to be taken into account to manage the risk(s) identified	10
9. Concerns	11
9.1. Issues that could not be finalised	11
9.2. Critical areas of concern	11
9.3. Overview of the concerns for each representative use considered	12
References	13
Appendices	14

BACKGROUND

Urea is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004⁹, as amended by Commission Regulation (EC) No 1095/2007¹⁰.

Urea was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009¹¹, in accordance with Commission Implementing Regulation (EU) No 540/2011¹², as amended by Commission Implementing Regulation (EU) No 541/2011¹³. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010¹⁴ the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Greece being the designated rapporteur Member State submitted the DAR on urea in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 22 April 2008 (Greece, 2008). The peer review was initiated on 31 July 2008 by dispatching the DAR to the notifiers the Forestry Commission and Phytophyl – N.G. Stavrakis, and on 16 December 2010 to the Member States, for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifiers were invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 5 April 2011. On the basis of the comments received and the RMS's evaluation thereof it was concluded that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, and additional information to be submitted by the notifiers, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November – December 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide treatment by spray and drenching to individual conifer tree stumps, as a spot spray attractant with an insecticide to olive trees, and as a mass trapping agent in liquid traps in olive groves, as proposed by the notifiers. A list of the relevant end points for the active substance as well as the

⁹ OJ L 379, 24.12.2004, p.13

¹⁰ OJ L 246, 21.9.2007, p.19

¹¹ OJ L 309, 24.11.2009, p.1

¹² OJ L 153, 11.6.2011, p.1

¹³ OJ L 153, 11.6.2011, p.187

¹⁴ OJ L 37, 10.2.2010, p.12

formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (30 March 2011),
- the Evaluation Table (12 December 2011),
- the comments received on the assessment of the points of clarification,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of June 2011 containing all individually submitted addenda (Greece, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Urea is the IUPAC name for this compound there is no ISO common name.

The representative formulated products for the evaluation were a 370 g/l SL formulation (no specific product name is given), 'ENTOMELA 75 SL' containing 250 g/kg urea, 'ENTOMELA 50 SL' containing 170 g/kg urea, and 'ENTOMELA 55 SL' containing 200 g/kg urea.

The representative uses evaluated are as a fungicide treatment by spray and drenching to individual conifer tree stumps, as a spot spray attractant with an insecticide to olive trees, and as a mass trapping agent in liquid traps in olive groves. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of urea as manufactured is 98 %. Urea must comply with Regulation (EC) Number 2003/2003 relating to fertilizers. Urea contains no relevant impurities. There is no FAO specification for urea. An Annex II physchem data package was not available for urea as all the information provided was from secondary literature and no study reports were available. A method of analysis for urea and biuret in the technical material is identified as a data gap.

The main data regarding the identity of urea are given in Appendix A.

No Annex III physchem data in the form of study reports were available for the formulations and this is identified as a data gap. A data gap was also identified for a validated method of analysis for urea in the formulations.

The need for methods of analysis for residues was waived due to the nature of the compound and the fact that no residue definitions are proposed.

2. Mammalian toxicity

The information available was limited to summaries of US EPA and OECD assessments, therefore a data gap was identified for studies to address the toxicological profile of urea. With regard to consumer exposure, it is not necessary to derive an ADI or an ARfD in view of the representative uses. With regard to non-dietary exposure, it is acknowledged that urea is part of the proteins catabolism in mammals, however, due to the lack of toxicological data the risk assessment cannot be reliably concluded.

3. Residues

The conclusion is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999).

Urea can be used as a fungicide to be applied on fresh-cut stumps of conifers in forests. It can also be used as an insect attractant for the control and the suppression of the olive fruit fly and the Mediterranean fruit fly in olive trees as a spot bait spray treatment in combination with an insecticide. The spray application is recommended on the tree trunk and/or on a small area of the tree foliage. Contact with fruits must be avoided. Urea is also used as a mass trapping agent inside liquid traps. When applied under these conditions, insignificant residues of urea are expected on olive fruits. Therefore a quantitative consumer dietary risk assessment is not necessary due to the specific kinds of application.

4. Environmental fate and behaviour

The information available was not sufficient to permit an appropriate assessment of the fate and behaviour of urea in the environment in relation to the representative use as a spray to olive trees and conifer stumps. Satisfactory information on the adsorption to soil of urea or its transformation products was not available. As urea is an organic fungicide, this missing information will be needed to support groundwater exposure estimates (predicted environmental concentrations, PEC_s) for urea to compare to the legal parametric drinking water limit of 0.1 µg/L. For the transformation products nitrate and nitrite, groundwater exposure assessments would also be necessary to compare against the parametric drinking water limits set¹⁵ for these inorganic compounds (50 mg/L and 0.5 mg/L, respectively). A data gap was identified for PEC in soil for urea or its transformation products consequent to the spray on olive trees and to conifer stumps. For these representative uses, PEC in surface water/sediment for urea, ammonia, nitrate and nitrite should assess/consider the potential for urea, ammonia, nitrate and nitrite to reach surface water systems, and to compare with the amounts that might occur from typical fertiliser application uses. For spray uses where aerosols may be formed during the spray operation, the potential for long-range atmospheric transport for urea was addressed by the notifier in Column B of the Evaluation Table (point of clarification 4.3 refers). An estimated half-life in air of 9.6 hr was provided by the notifier, but no specific information on the program version used for the Atkinson's calculation was given. EFSA repeated the calculation with the US EPA AOPWIN program (v1.92a, September 2010). As urea exhibits medium volatility (1.1×10^{-5} hPa at 25°C) and based on the estimated atmospheric half-life of 5.348 days (12-hr day, 1.5×10^6 OH/cm³), urea has a potential for long-range transport through the atmosphere.

With regard to the representative uses by drench of individual conifer stumps by hand and by toxicant free mass trapping, the environmental exposure of urea is expected to be negligible.

5. Ecotoxicology

No toxicity studies for non-target organisms were submitted. The information available was limited to summaries of US EPA and OECD assessments, and the IUCLID database for birds, aquatic organisms, earthworms, terrestrial non-target plants and soil micro-organisms, therefore a data gap was identified for the original studies. The available information indicated limited toxicological potential. However, acute studies on aquatic organisms are required to fulfil the Annex II data requirements, and therefore a data gap was identified. No data or information was provided regarding honeybees and non-target arthropods.

Since no reliable information on the toxicity to non-target organisms is available, and the water and soil exposure for the representative spray uses in olive trees and conifer stumps was not finalised (see data gaps in section 4), the risk assessment for aquatic organisms, soil-dwelling organisms, terrestrial plants and soil micro-organisms cannot be concluded. Additionally, it is not possible to exclude exposure for the other non-target organisms (i.e. birds and mammals, bees, non-target arthropods, sewage treatment plant organisms). Therefore a data gap was identified for the spray uses to address the ecotoxicological risk in consideration of whether the exposure will be greater than the background level.

The risk to non-target organisms can be considered as low for the drench use on conifer stumps and for mass trapping inside liquid traps in olive trees.

¹⁵ Council Directive 98/83/EC on the quality of water intended for human consumption.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
urea	No data, data not required	Data gap to address the risk to soil-dwelling organisms for the spray uses, once the environmental exposure is finalised.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
urea	No data, data required	No data, data required	Yes	No data, not required	Data gap to address the risk to aquatic organisms for the spray uses.
nitrate	No data, data required	No data, data required	No data, not required	No data, not required	Data gap to address the risk to aquatic organisms for the spray uses.

nitrite	No data, data required	No data, data required	No data, not required	No data, not required	Data gap to address the risk to aquatic organisms for the spray uses.
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6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
urea	Data gap to address the risk to aquatic organisms for the spray uses.
ammonia/ammonium	Data gap to address the risk to aquatic organisms for the spray uses.
nitrate	Data gap to address the risk to aquatic organisms for the spray uses.
nitrite	Data gap to address the risk to aquatic organisms for the spray uses.

6.4. Air

Compound (name and/or code)	Toxicology
urea	No data, not required

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Annex II physchem data package for urea (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Validated method of analysis for urea and biuret in the technical material (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Annex III physchem data package for the formulations (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Validated method of analysis for urea in the formulations (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Studies to address the toxicological profile of urea (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).
- Satisfactory information on the adsorption to soil of urea and its transformation products (relevant for spray uses to conifer stumps and spot bait sprays to olive trees; submission date proposed by the notifier: unknown; see section 4).
- Predicted environmental concentrations (PEC) in soil for urea (relevant for spray uses to conifer stumps and spot bait sprays to olive trees; submission date proposed by the notifier: unknown; see section 4).
- Satisfactory information to address the potential for urea and its transformation products ammonia, nitrate and nitrite to reach surface water systems and compare the PECs to the amounts that might occur from typical fertiliser application uses (relevant for spray uses to conifer stumps and spot bait sprays to olive trees; submission date proposed by the notifier: unknown; see section 4).
- Assessments of the potential for groundwater exposure for urea and its transformation products nitrate and nitrite (relevant for spray uses to conifer stumps and spot bait sprays to olive trees; submission date proposed by the notifier: unknown; see section 4).
- The original ecotoxicological studies summarised in the US EPA and OECD assessments and the IUCLID database (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5).
- Acute studies with aquatic organisms to fulfil the Annex II data requirements (relevant for all representative uses; submission date proposed by the notifier: unknown; see section 5).
- Risk to non-target organisms to be addressed when the environmental exposure is finalised (relevant for spray uses to conifer stumps and olive trees; submission date proposed by the notifier: unknown; see section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- Trunk application to olive trees must be conducted in a manner that precludes any contamination of fruits (see section 3).

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. The environmental exposure assessment of urea and its transformation products in relation to the representative uses as a spray in olive trees and to conifer stumps could not be finalised.
2. The risk to non-target organisms could not be finalised for spray use to conifer stumps and olive trees.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

3. An AOEL could not be set and therefore the risk assessment for operators, workers and bystanders cannot be concluded.
4. Urea has the potential for long-range transport through the atmosphere¹⁶.

¹⁶ Note this is not a criterion in the Uniform Principles of Annex VI to Directive 91/414/EEC for decision making on product authorisations, but is a criterion that managers from Member States have asked to be informed about in relation to obligations Member States have under certain international treaties.

9.3. Overview of the concerns for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

In addition to the concerns indicated, the columns are also grey since urea has the potential for long-range transport through the atmosphere.

Representative use		Spray application to conifer stumps by tree harvesting machines	Spot sprays to olive trees	Mass trapping in olive groves	Drenching conifer tree stumps
Operator risk	Risk identified				
	Assessment not finalised	X ³	X ³	X ³	X ³
Worker risk	Risk identified				
	Assessment not finalised	X ³	X ³	X ³	X ³
Bystander risk	Risk identified				
	Assessment not finalised	X ³	X ³	X ³	X ³
Consumer risk	Risk identified				
	Assessment not finalised				
Risk to wild non target terrestrial vertebrates	Risk identified				
	Assessment not finalised	X ²	X ²		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified				
	Assessment not finalised	X ²	X ²		
Risk to aquatic organisms	Risk identified				
	Assessment not finalised	X ²	X ²		
Groundwater exposure active substance	Legal parametric value breached				
	Assessment not finalised	X ¹	X ¹		
Groundwater exposure metabolites	Legal parametric value breached				
	Parametric value of 10µg/L ^(a) breached				
	Assessment not finalised	X ¹	X ¹		

The superscript numbers in this table relate to the numbered points indicated as concerns

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information. A column is greyed out if there is a concern for that specific use.

(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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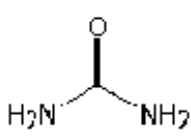
APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Urea (There is no ISO common name)
Function (e.g. fungicide)	Fungicide, attractant
Rapporteur Member State	Hellas
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Urea
Chemical name (CA) ‡	Urea
CIPAC No ‡	913
CAS No ‡	57-13-6
EC No (EINECS or ELINCS) ‡	200-315-5
FAO Specification (including year of publication) ‡	-
Minimum purity of the active substance as manufactured ‡	98%w/w Urea must comply with Regulation (EC) Number 2003/2003 relating to fertilizers
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	NH ₂ CONH ₂
Molecular mass ‡	60.06
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2) Open

Melting point (state purity) ‡	
Boiling point (state purity) ‡	
Temperature of decomposition (state purity)	
Appearance (state purity) ‡	
Vapour pressure (state temperature, state purity) ‡	
Henry's law constant ‡	
Solubility in water (state temperature, state purity and pH) ‡	
Solubility in organic solvents ‡ (state temperature, state purity)	
Surface tension ‡ (state concentration and temperature, state purity)	
Partition co-efficient ‡ (state temperature, pH and purity)	
Dissociation constant (state purity) ‡	
UV/VIS absorption (max.) incl. ϵ ‡ (state purity, pH)	
Flammability ‡ (state purity)	
Explosive properties ‡ (state purity)	
Oxidising properties ‡ (state purity)	

Summary of representative uses evaluated (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	370 g/L	Drench of individual stumps by hand	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, which is of valuable strategic importance
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	370 g/L	Spray application with 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, which is of valuable strategic importance
Olive Trees	Greece	ENTOM ELA 75 SL	F	Bactrocera oleae winged adults.	SL	250 gr/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	ENTOM ELA 50 SL	F	Bactrocera oleae winged adults.	SL	170 gr/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	

Olive Trees	Greece	ENTOM ELA 55 SL	F	Bactrocera oleae winged adults.	SL	200 gr/k g	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
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Remarks:

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the 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 sucking 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 plant- 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 the time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use / economic importance / restrictions

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Open
Impurities in technical as (analytical technique)	Open
Plant protection product (analytical technique)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Not relevant
Food of animal origin	Not relevant
Soil	Not relevant
Water surface	Not relevant
drinking/ground	Not relevant
Air	Not relevant
Blood	No required

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Because of the use and the nature of the active substance (a) as a fungicide against pathogenic fungus, and (b) as an attractant in spot bait sprays or in mass trapping, no residues will occur on plants, food or feed. Therefore no analytical methods for the determination of residues in products of plant and animal origin are required.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required. See explanation above.
Soil (principle of method and LOQ)	Because of the use and the nature of the active substance no residues or contamination will occur in soil. Therefore no analytical method for the determination of residues in soil is required
Water (principle of method and LOQ)	Because of the use and the nature of the active substance no residues or contamination will occur in water. Therefore no analytical method for the determination of residues in water is required
Air (principle of method and LOQ)	Because of the use and the nature of the active substance no residues or contamination will occur in air. Therefore no analytical method for the determination of residues in air is required
Body fluids and tissues (principle of method and LOQ)	As Urea is not classified as toxic or highly toxic, no analytical method is required for its determination in body fluids and tissues.

**Classification and proposed labelling with regard to physical and chemical data
(Annex IIA, point 10)**

	RMS/peer review proposal
Active substance	RMS proposal: None

Impact on Human and Animal Health

⁽¹⁾ Limited information or no data are available. A general data gap has been established in the section on mammalian toxicology to provide studies on the toxicological profile of urea.

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate/extent of absorption ‡	No data available ⁽¹⁾
Distribution ‡	No data available ⁽¹⁾
Potential for accumulation ‡	No data available ⁽¹⁾
Rate and extent of excretion ‡	No data available ⁽¹⁾
Metabolism in animals ‡	No data available ⁽¹⁾
Toxicologically relevant compounds ‡ (animals and plants)	No data available ⁽¹⁾
Toxicologically relevant compounds ‡ (environment)	

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral ‡	No data available 14300 mg/kg b.w./day (males)
Rabbit LD ₅₀ dermal ‡	No data available, not needed
Rat LC ₅₀ inhalation ‡	No data available, not needed
Skin irritation ‡	No data available Limited indication of irritancy Slight irritant
Eye irritation ‡	No data available Limited indication of irritancy Slight irritant
Skin sensitisation ‡	No data available. Not skin sensitiser

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data available ⁽¹⁾
Relevant oral NOAEL ‡	No data available ⁽¹⁾
Relevant dermal NOAEL ‡	No data available ⁽¹⁾
Relevant inhalation NOAEL ‡	No data available ⁽¹⁾

Genotoxicity ‡ (Annex IIA, point 5.4)

No data available ⁽¹⁾

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	No data available ⁽¹⁾
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Relevant NOAEL ‡	No data available ⁽¹⁾	
Carcinogenicity ‡	No data available ⁽¹⁾	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data available ⁽¹⁾	
Relevant parental NOAEL ‡	No data available ⁽¹⁾	-
Relevant reproductive NOAEL ‡	No data available ⁽¹⁾	
Relevant offspring NOAEL ‡	No data available ⁽¹⁾	

Developmental toxicity

Developmental target / critical effect ‡	No data available ⁽¹⁾	
Relevant maternal NOAEL ‡	No data available ⁽¹⁾	-
Relevant developmental NOAEL ‡	No data available ⁽¹⁾	
Relevant developmental neurotoxicity NOAEL ‡	No data available ⁽¹⁾	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available ⁽¹⁾	
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Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available ⁽¹⁾	
Studies on metabolites	No data available ⁽¹⁾	
Studies on impurities	No data available ⁽¹⁾	

Medical data ‡ (Annex IIA, point 5.9)

No data available ⁽¹⁾		
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Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	No data available; not required	-	-
AOEL ‡	Not established ⁽¹⁾	-	-
ARfD ‡	No data available; not required	-	-

Dermal absorption‡ (Annex IIIA, point 7.3)

No data available ⁽¹⁾

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Inconclusive
Workers	Inconclusive
Bystanders	Inconclusive

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Urea	-

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	No data available. Not required according to the representative uses.
Rotational crops	No data available. Not required according to the representative uses.
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No data available. Not required according to the representative uses.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Not required
Plant residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not applicable

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	No data available. Not required according to the representative uses.
Time needed to reach a plateau concentration in milk and eggs	Not applicable
Animal residue definition for monitoring	Not required
Animal residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not relevant
Fat soluble residue: (yes/no)	Not relevant

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

No data available. Not required according to the representative uses.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

No data available. Not required according to the representative uses.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Conditions of requirement of feeding studies		
	No data available. Not required according to the representative uses.		

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)

Muscle
Liver
Kidney
Fat
Milk
Eggs

	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg
	No data available. Not required according to the representative uses.

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

No supervised trials were conducted since urea is exempted from the requirement of residues data.

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
No data available. Not required according to the representative uses.						

(a) Numbers of trials in which particular residue levels were reported e.g. 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

A quantitative consumer risk assessment is not required due to the specific application pattern of urea. Contact with fruits must be avoided.

ADI	Not established.
TMDI (% ADI) according to WHO European diet	Not applicable.
TMDI (% ADI) according to national (to be specified) diets	
IEDI (WHO European Diet) (% ADI)	
NEDI (specify diet) (% ADI)	
Factors included in IEDI and NEDI	
ARfD	Not established.
IESTI (% ARfD)	Not applicable.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	
Factors included in IESTI and NESTI	

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
No data available. Not required according to the representative uses.				

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Not required.

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡

No data submitted.

Non-extractable residues after 100 days ‡

No data submitted.

Metabolites requiring further consideration ‡
- name and/or code, % of applied (range and maximum)

The main mode of degradation is enzymatic mineralization. In soil and water urea is expected to biodegrade fairly rapidly to ammonia and bicarbonate if temperature is not too low.

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days

No data submitted.

Non-extractable residues after 100 days

No data submitted.

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)

No data submitted.

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)

No data submitted.

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Urea	Aerobic conditions: No satisfactory information in dossier, information may be needed to support the data gap for groundwater exposure assessment.
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Field studies ‡

Urea	Aerobic conditions: No data submitted
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pH dependence ‡
(yes / no) (if yes type of dependence)

No data submitted.

Soil accumulation and plateau concentration ‡

There are no data on background levels of urea in forest soils, since the compound does not survive free in soil. The contribution to soil N from collateral spraying of stumps with urea can be expected to range from about 2 kg urea/ha (thinning) to a maximum of 35 kg urea/ha at clear-felling.

Laboratory studies ‡

Urea	Anaerobic conditions: No data submitted
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Soil adsorption/desorption (Annex IIA, point 7.1.2)

Urea ‡**Data gap**: Satisfactory information on adsorption to soil of urea or its transformation products

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡

No study submitted.

Aged residues leaching ‡

No study submitted.

No study submitted.

Lysimeter/ field leaching studies ‡

No study submitted.

PEC (soil) (Annex IIIA, point 9.1.3)

Urea

No study submitted. **Data Gap**

Method of calculation

Application data

-

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡

No satisfactory information provided

Photolytic degradation of active substance and metabolites above 10 % ‡

No study submitted.

Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm

No study submitted.

Readily biodegradable ‡
(yes/no)

No satisfactory information available

Degradation in water / sediment

Urea

No satisfactory information in dossier

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Urea

Data gap for surface water exposure estimates

Parameters used in FOCUS_{sw} step 1 and 2

Parameters used in FOCUS_{sw} step 3 (if performed)

-

Application rate -

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter) No study submitted. **Data gap**

Application rate -

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡ No satisfactory information provided

Quantum yield of direct phototransformation No data submitted.

Photochemical oxidative degradation in air ‡ DT₅₀ of 5.348 days derived by the Atkinson method of calculation assuming an atmospheric hydroxyl radical concentration of 1.5 x 10⁶/cm³ (calculations performed by EFSA with US EPA AOPWIN program v1.92a, September 2010))

Volatilisation ‡ Urea is essentially non-volatile in solid form. Its high water solubility, low vapour pressure (solid pure urea 80 Pa at 20 °C; calculated) and consequently low Henry's law constant (4.4E-8 atm. m³/mol) indicate that urea will not evaporate from water to atmosphere

Metabolites -

PEC (air)

Method of calculation No data submitted.

PEC_(a)

Maximum concentration -

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure. Soil: Urea
Surface Water: Urea, ammonia, nitrate, nitrite
Sediment: Urea
Ground water: Urea, nitrate, nitrite
Air: Urea

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R53, in the absence of satisfactory information having been provided on ready biodegradability

Chapter 6: Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1; Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	14300 mg/kg b.w./day (rat)
Acute toxicity to birds	No data available
Dietary toxicity to birds	No data available
Reproductive toxicity to birds	No data available
Reproductive/long term toxicity to mammals	2250 mg/kg b.w./day (rats)

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Treatment	Species	Study Type	LC ₅₀ /EC ₅₀ [mg ai/L]	LC ₀ /NOEC [mg ai/L]
No data available*				

* The notifier provided a considerable amount of information based on reviews by other organizations (US EPA, SIDS, IUCLID database). This information was not used for the aquatic risk assessment and was considered as informative only. Nevertheless, all of them are consistent of low toxicity to aquatic organisms.

Bioconcentration

Bioconcentration factor (BCF)	No data available. Not required.
Annex VI Trigger for the bioconcentration factor	Not required
Clearance time (CT ₅₀) (CT ₉₀)	Not required
Level of residues (%) in organisms after the 14 day depuration phase	Not required

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity	No data available
Acute contact toxicity	No data available

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Test	Test species	Summary of design	Endpoints
No data available ¹			

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	No data available
Chronic and reproductive toxicity	No data available

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡

No data available – exposure expected to be negligible
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Carbon mineralization ‡

No data available – exposure expected to be negligible
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ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
μg	microgram
μm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT ₅₀	period required for 50 percent disappearance (define method of estimation)
DT ₉₀	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC ₅₀	effective concentration (biomass)
EC ₅₀	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER ₅₀	emergence rate/effective rate, median
ErC ₅₀	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice

GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC ₅₀	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC _{air}	predicted environmental concentration in air
PEC _{gw}	predicted environmental concentration in ground water
PEC _{sed}	predicted environmental concentration in sediment
PEC _{soil}	predicted environmental concentration in soil
PEC _{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK _a	negative logarithm (to the base 10) of the dissociation constant
P _{ow}	partition coefficient between <i>n</i> -octanol and water
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r ²	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t _{1/2}	half-life (define method of estimation)
TER	toxicity exposure ratio
TER _A	toxicity exposure ratio for acute exposure
TER _{LT}	toxicity exposure ratio following chronic exposure
TER _{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year