CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance ammonium acetate[1]

European Food Safety Authority[2]

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SUMMARY

Ammonium acetate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4].

Ammonium acetate 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 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[8], 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.

Portugal being the designated rapporteur Member State submitted the DAR on ammonium acetate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 16 April 2008. The peer review was initiated on 11 July 2008 by dispatching the DAR for consultation to the notifier Suterra LLC, and on 16 December 2010 to the Member States. 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 ammonium acetate.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of ammonium acetate as an insect attractant on fruit crops where *Ceratitis capitata* (Mediterranean fruit fly) causes damage, as proposed by the notifier at the time of submission. 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-2009-00270, issued on 16 December 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[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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Data gaps were identified in the section identity, physical and chemical properties and analytical methods.

No data gaps or areas of concern were identified in the mammalian toxicology section.

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

A data gap was identified for information on the potential for acetic acid to be formed in the dispenser and to volatilise to air. Additionally a data gap for information on vapour pressure and/or atmospheric half-life of ammonium acetate (volatilized as ammonia and acetic acid) was identified. No information or studies are available on the fate and behaviour in soil or surface water. The notifier claimed that the amounts deposited will be negligible with respect to background levels. A data gap was identified for information on background levels of ammonia and acetic acid in the different environmental compartments occurring naturally or from anthropogenic origin. These data gaps result in the environmental exposure / risk assessment being not finalised.

A data gap was identified to re-consider the risk assessment to non-target organisms once information on background levels of ammonia and acetic acid is available. Additionally a data gap was identified for the acute toxicity studies to aquatic organisms to fulfil the Annex II data requirement.

KEY WORDS

ammonium acetate, acetic acid, peer review, risk assessment, insect attractant

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BACKGROUND

Ammonium acetate is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[9], as amended by Commission Regulation (EC) No 1095/2007[10].

Ammonium acetate 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 1107/2009[11], in accordance with Commission Implementing Regulation (EU) No 540/2011[12], as amended by Commission Implementing Regulation (EU) No 541/2011[13]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[14] 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.

Portugal being the designated rapporteur Member State submitted the DAR on ammonium acetate in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 16 April 2008 (Portugal, 2008). The peer review was initiated on 11 July 2008 by dispatching the DAR for consultation and comments to the notifier Suterra LLC, and on 16 December 2010 to the Member States. 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 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 15 April 2011. On the basis of the comments received and the RMS' 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 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 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 an insect attractant on fruit crops where *Ceratitis capitata* (Mediterranean fruit fly) causes damage, as proposed by the notifier at the time of submission. A list of the relevant end points for the active substance as well as the 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,

[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

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 (18 April 2011),
- the Evaluation Table (23 November 2011),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of May 2011 containing all individually submitted addenda (Portugal, 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

Ammonium acetate (IUPAC) is considered by the International Organization for Standardization not to require a common name. The European Commission confirmed that the organic salt ammonium acetate should be considered as the active substance as it was already included in Annex I. It should be mentioned that ammonium acetate is a variant of the active substance acetic acid.

The representative formulated product for the evaluation was 'BioLure Med Fly', a vapour releasing product, (VP) consisting of three individual, retrievable, polymeric, hand-applied dispensers used in combination to make one plant protection preparation, containing 211.3 g/kg ammonium acetate, 2.7 g/kg 1,4-diaminobutane (putrescine) and 91 g/kg trimethylamine hydrochloride, registered under different trade names in several EU countries.

The representative uses evaluated comprise hand applications of the dispensers into physical traps in orchards, where *Ceratitis capitata* (Mediterranean fruit fly) causes damage, as an insect attractant. It should be emphasized however, that the product is not used alone for mass trapping, but in combination with insecticides for the control of *C. capitata.* 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 following guidance document was followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000).

The minimum purity of ammonium acetate is open as a data gap was identified for the five batch data generated with validated methods. No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity of the active substance; however, a data gap was identified for additional information concerning the starting materials of the manufacturing process. With respect to the physical, chemical and technical properties of ammonium acetate or the representative formulation data gaps were identified for the vapour pressure of the active substance and for a shelf-life study of the preparation. Data gaps were also identified for analytical method(s) for the determination of the active substance in the technical material and for the determination of the content of the active substance in the respective dispenser for monitoring purposes.

The need for methods of analysis for monitoring this compound in food of plant and animal origin have been waived due to the specific kind of application. Data gaps need to be filled (see section 4) before a conclusion on the need for monitoring methods in the environment can be finalised. A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

None of the data requirements according to Annex II of Directive 91/414/EC have been fulfilled. Only an evaluation of bibliographical references has been provided. This was accepted by the peer review considering the low exposure to ammonium acetate arising from the representative use, the other uses of ammonium acetate (a.o. food and feed additives), and the nature of the compound (dissociating to acetic acid and ammonia).

No relevant data were provided for the acute toxicity testing of ammonium acetate. No further data were presented for short-term toxicity, genotoxicity, long-term toxicity and carcinogenicity and reproductive toxicity. With regard to neurotoxicity, rats fed with 20% ammonium acetate in the diet had three-fold increased ammonemia after 7 days, but this was still insufficient to produce encephalopathy. Spontaneous motor activity and motor coordination were inhibited after injecting 100

and 200 mg/kg bw intraperitoneally to male rats, whereas with 400 and 800 mg/kg bw the animals exhibited convulsive movements.

In humans, the oral ingestion of 15.4 g ammonium acetate induced an augmentation of the urea production by the liver, but no increased ammonemia (limited study design). During the last seven years, no toxicological effect has been registered in production, handling, transport and application of the active substance and the preparation.

Based on the available information, it is not possible to propose an acceptable daily intake (ADI), an acceptable operator exposure level (AOEL) or an acute reference dose (ARfD). However, reference values are not needed for the representative use since operator, worker, bystander exposure to ammonium acetate can be considered as negligible, and there is no consumer exposure. In addition, the exposure to the degradation product ammonia is also considered to be negligible.

3. Residues

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

According to the representative uses, ammonium acetate is contained in a vapour releasing dispenser with two other individual active substances (respectively trimethylamine hydrochloride and 1,4-diaminobutane (putrescine)) in the preparation 'BioLure Med Fly'. These active substances are placed inside hand-applied physical traps in the canopy of the trees, and, held within the dispensers, never come into direct contact with the crops. It can also be reasonably assumed that residues of ammonium acetate and its degradation products ammonia and acetic acid on fruits through volatilisation and deposition will be insignificant. Therefore a quantitative consumer dietary risk assessment can be waived due to the specific kind of application.

4. Environmental fate and behaviour

Ammonium acetate is one of the three components of an attractant for the control of *Ceratitis capitata*. It is used to attract the flies to physical traps by releasing ammonia and acetic acid to the atmosphere from vapour dispensers. An amount of 392 g a.s./ha (in 100 dispensers) is expected to be released over a period of 49 d. This corresponds to an emission rate of 8.0 g a.s./ha/day.

Considering the representative use, ammonia and acetic acid will be released into the air. A data gap was identified during the peer review for information on the potential for acetic acid to be formed in the dispenser and to volatilise to air. Additionally a data gap for information on vapour pressure and/or atmospheric half-life of ammonium acetate (volatilized as ammonia and acetic acid) was identified to conclude the assessment.

No information or studies are available on the fate and behaviour in soil or surface water. Deposition of ammonia and acetic acid to soil and surface water may occur. The notifier claimed that the amounts deposited will be negligible with respect to background levels. However, no information is available on the naturally occurring background levels of ammonia or levels that may be present in the different compartments as a consequence of other anthropogenic sources (e.g. from the use of fertilizers). This information would be required to make a comparison with levels that might be estimated to occur as a consequence of the representative use assessed. Therefore, a data gap was identified during the peer review for information of background levels of ammonia and acetic acid in the different environmental compartments occurring naturally or from anthropogenic origin. This data gap results in the environmental exposure and risk assessments being not finalised.

5. Ecotoxicology

The risk to non-target organisms could be considered as low for the representative use providing the exposure is below the background level of ammonia and acetic acid. However, in view of the data gap identified in section 4 for information on the background level the ecotoxicology risk assessment

could not be finalised. A data gap is identified to re-consider the risk assessment to non-target organisms once such information is available. Additionally a data gap was identified for the acute toxicity studies to aquatic organisms to fulfil the Annex II data requirement.

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
ammonium acetate variants (default)	-	Data gap pending on the information on the background level

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)[(a)]	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
ammonium acetate variants (default)	-	-	-	Yes	Data gap pending on the information on the background level

(a): EFSA's reading of Council Directive 98/83/EC[15] on the quality of drinking water intended for human consumption is, that as attractants, volatile compounds that may be formed from ammonium acetate, would not be considered as pesticides under this directive, so the parametric drinking water limit of 0.1µg/L for pesticides, usually used as a decision making criteria regarding groundwater exposure, does not apply.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
ammonium acetate variants (default)	Data gap pending on the information on the background level

[15] OJ L 330,5.12.1998, p.32

6.4. Air

Compound (name and/or code)	**Toxicology**
ammonium acetate variants (default)	Data available of limited validity
ammonia	No data available
acetic acid	No data available

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).

- Five batch data generated with validated methods (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)

- Additional information concerning the starting materials of the manufacturing process (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)

- Method for the determination of the active substance in the technical material and for the determination of the content of active substance in the respective dispenser for monitoring purposes (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)

- Shelf life study of the preparation (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 1)

- Information on the potential for acetic acid to be formed in the dispenser and volatilise to air (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 4)

- Information on vapour pressure and/or atmospheric half-life of ammonium acetate (volatilized as ammonia and acetic acid) (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see sections 1 and 4)

- Information on the naturally occurring background levels of ammonia and acetic acid or levels that may be present in the different compartments as a consequence of fertiliser applications or other anthropogenic sources (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 4)

- Ecotoxicology risk assessment should be re-considered based on the information on the background levels of ammonia and acetic acid (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 5).

- Acute toxicity studies with aquatic organisms to fulfil the Annex II data requirement (relevant for all representative uses evaluated; submission date proposed by the notifier: the notifier has indicated that they have withdrawn their support for this substance; see section 5)

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

- None

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 and risk assessment could not be finalised pending confirmation that the amounts of ammonia and acetic acid released are negligible with respect to environmental background levels, and information on the volatility and half-life of ammonia and acetic acid in the upper atmosphere, in order to assess the potential for long-range atmospheric transport.

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.

- None

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.)

Representative use		**Fruit crops**
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	X[1]
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X[1]
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X[1]
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	X[1]
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L[(a)] breached	
	Assessment not finalised	X[1]
Comments/Remarks		

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

REFERENCES

EFSA (European Food Safety Authority), 2011 Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance ammonium acetate.

European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999.

European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000.

European Commission, 2008. Review Report for the active substance ammonium acetate 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 ammonium acetate in Annex I of Directive 91/414/EEC. SANCO/2986/08 – rev.1, 24 August 2008.

Portugal, 2008. Draft Assessment Report (DAR) on the active substance ammonium acetate prepared by the rapporteur Member State Portugal in the framework of Directive 91/414/EEC, April 2008.

Portugal, 2011. Final Addendum to Draft Assessment Report on ammonium acetate, compiled by EFSA, May 2011.

APPENDICES

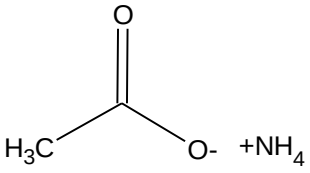
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	ammonium acetate (No ISO common name)
Function (*e.g.* fungicide)	Attractant

Rapporteur Member State	Portugal
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	ammonium acetate
Chemical name (CA) ‡	ammonium acetate
CIPAC No ‡	Not available
CAS No ‡	631-61-8
EC No (EINECS or ELINCS) ‡	211-162-9
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No relevant impurities are present
Molecular formula ‡	$C_2H_7NO_2$
Molecular mass ‡	77.08 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	114ºC (purified a.s. - unknown purity) 111.1°C (Batch 538203 - unknown purity)
Boiling point (state purity) ‡	No data submitted
Temperature of decomposition (state purity)	No data submitted
Appearance (state purity) ‡	Clumpy wet powder, white. Odour of ammonia and vinegar. (Batch 538203 - unknown purity)
Vapour pressure (state temperature, state purity) ‡	Data gap
Henry's law constant ‡	Not available
Solubility in water (state temperature, state purity and pH) ‡	827.29 g/L at 23°C (99.4% w/w, unstated pH)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 23°C: chloroform: 0.342 ± 0.008 g/L ethanol: 104.59 ± 0.23 g/L (99.4% w/w) Slightly soluble in acetone and solubility in methanol: 78.9 g/L @ 15º C (97.6% w/w)
Surface tension ‡ (state concentration and temperature, state purity)	Not available
Partition co-efficient ‡ (state temperature, pH and purity)	Not available
Dissociation constant (state purity) ‡	pKa (ammonium ion) = 9.25 (from literature) pKa (acetic acid) = 4.76 (from literature) pKb (acetate ion) = 9.24 (calculation)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Not available
Flammability ‡ (state purity)	Not highly flammable (statement from M-IIA)
Explosive properties ‡ (state purity)	Not explosive (statement from M-IIA)
Oxidising properties ‡ (state purity)	Not oxidising (statement from M-IIA)

Summary of representative uses evaluated (*ammonium acetate*)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
Orchards (Fruit crops)	Southern Europe	BioLure Med Fly	F	Mediterranean Fruit Fly *Ceratitis capitata*	VP	21.13 %(w/w) of ammonium acetate 3,92g ammonium acetate/ trap (see remarks)	Ground application by hand of 3 individual dispensers into physical traps	Mass trapping: Begin of flight of *C. capitata* or specifically when fruits become vulnerable to damage monitoring: (not PPP use) Begin of flight of *C. capitata*	Mass trapping: max 1 monitoring: (not PPP use) max 3	Approx: 6 – 8 weeks Depends upon environ-mental factors such as climate and topography	n.a.	n.a.	Mass trapping: **294-392** (75-100 traps/ ha) monitoring: (not PPP use) **1,96** (0,5 traps/ ha)	0	
Citrus									Mass trapping: max 2 monitoring: (not PPP use) max 5				Mass trapping: **196-392** (50-100 traps/ ha) monitoring: (not PPP use) **1,96** (0,5 traps/ ha)		
Other crops where *C. capitata* causes damage									Mass trapping: max 1 monitoring: (not PPP use) max 2				Mass trapping: **196-392** (50-100 traps/ ha) monitoring: (not PPP use) **1,96** (0,5 traps/ ha)		

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse 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 plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(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) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

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

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

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		The setting of an MRL is not necessary and a residue relevant to MRL is not defined.
Food of animal origin		The setting of an MRL is not necessary and a residue relevant to MRL is not defined.
Soil		Data gaps need to be fulfilled before the definition can be finalised
Water	surface	Data gaps need to be fulfilled before the definition can be finalised
	drinking/ground	Data gaps need to be fulfilled before the definition can be finalised
Air		ammonium acetate variants, ammonia and acetic acid

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Analytical methods for residues analysis for food of plant origin are not required.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Analytical methods for residues analysis for food of animal origin are not required.
Soil (analytical technique and LOQ)	Open
Water (analytical technique and LOQ)	Open
Air (analytical technique and LOQ)	Open
Body fluids and tissues (analytical technique and LOQ)	Methods for the determination of residues in body fluids and tissues are not required since ammonium acetate is not classified as toxic or very toxic.

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

	RMS/peer review proposal
Active substance	Not classified

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	No data available, not needed
Distribution ‡	No data available, not needed
Potential for accumulation ‡	No data available, not needed
Rate and extent of excretion ‡	Data available of limited validity, no further data needed
Metabolism in animals ‡	Ammonium ions, after intestinal absorption, are transformed into urea in the liver and excreted in urine
Toxicologically relevant compounds ‡ (animals and plants)	Ammonium acetate
Toxicologically relevant compounds ‡ (environment)	Ammonium acetate

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	No data available, not needed	
Rat LD_{50} dermal ‡	No data available, not needed	
Rat LC_{50} inhalation ‡	No data available, not needed	
Skin irritation ‡	Data available of limited validity, no further data needed	
Eye irritation ‡		
Skin sensitisation ‡	No data available, not needed	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Not identified based on the available data	
Relevant oral NOAEL ‡	Data available of limited validity, no further data needed	
Relevant dermal NOAEL ‡	No data available, not needed	
Relevant inhalation NOAEL ‡	No data available, not needed	

Genotoxicity ‡ (Annex IIA, point 5.4)

No data available, not needed	

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

Target/critical effect ‡	No data available, not needed	
Relevant NOAEL ‡	No data available, not needed	
Carcinogenicity ‡	No data available, not needed	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data available, not needed	
Relevant parental NOAEL ‡	No data available, not needed	
Relevant reproductive NOAEL ‡	No data available, not needed	
Relevant offspring NOAEL ‡	No data available, not needed	

Developmental toxicity

Developmental target / critical effect ‡	No data available, not needed	
Relevant maternal NOAEL ‡	No data available, not needed	
Relevant developmental NOAEL ‡	No data available, not needed	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Data available of limited validity, no further data needed	
Repeated neurotoxicity ‡	Data available of limited validity, no further data needed	
Delayed neurotoxicity ‡	No data available, not needed	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Data available of limited validity, no further data needed
Studies performed on metabolites or impurities ‡	No data available, not needed
Human data	Oral ingestion of 15.4g of ammonium acetate by humans lead to increased urea production by the liver (limited study design)

Medical data ‡ (Annex IIA, point 5.9)

During the last seven years, no case of toxicological problem has been registered in production, handling, transport and application of a.s. and preparation.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Not allocated, not needed		
AOEL ‡	Not allocated, not needed		
ARfD ‡	Not allocated, not needed		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation BioLure® Med Fly	No data available, not needed

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Negligible
Workers	Negligible
Bystanders	Negligible

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

	Proposals from the Peer review
Ammonium acetate	None

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

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

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

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

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 relevant.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level) Potential for accumulation (yes/no): Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No data available. Not required according to the representative uses.		
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant)		

	Residue levels in matrices : Mean (max) mg/kg
Muscle	Not relevant.
Liver	
Kidney	
Fat	
Milk	
Eggs	

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)

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)

ADI TMDI (% ADI) according to WHO European diet 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 IESTI (% ARfD) NESTI (% ARfD) according to national (to be specified) large portion consumption data Factors included in IESTI and NESTI	A quantitative consumer dietary risk assessment can be waived due to the specific kind of application.

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 study available. Probably not required, but data gaps need to be filled before this can be concluded.
Non-extractable residues after 100 days ‡	No study available. Probably not required, but data gaps need to be filled before this can be concluded.
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No study available. Probably not required, but data gaps need to be filled before this can be concluded.

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

Anaerobic degradation ‡

Mineralization after 100 days	No study available. Probably not required, but data gaps need to be filled before this can be concluded.
Non-extractable residues after 100 days	No study available. Probably not required, but data gaps need to be filled before this can be concluded.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No study available. Probably not required, but data gaps need to be filled before this can be concluded.

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No study available. Probably not required, but data gaps need to be filled before this can be concluded.

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median	No study available. Probably not required, but data gaps need to be filled before this can be concluded.						

Met 1	Aerobic conditions							
Soil type	X^1	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median	No study available. Probably not required, but data gaps need to be filled before this can be concluded.							

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Geometric mean/median					No study available. Probably not required, but data gaps need to be filled before this can be concluded.				

Met 1	Aerobic conditions								
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r2)	DT_{50} (d) Norm.	Method of calculation
Geometric mean/median					No study available. Probably not required, but data gaps need to be filled before this can be concluded.				

pH dependence ‡ (yes / no) (if yes type of dependence)	No data available
Soil accumulation and plateau concentration ‡	No data available

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[16]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median			No study available. Not required.				

Met 1	Anaerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Geometric mean/median			No study available. Not required.					

[16] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡No study available. Probably not required, but data gaps need to be filled before this can be concluded.							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Arithmetic mean/median							
pH dependence, Yes or No							

Metabolite 1 ‡ Probably not required, but data gaps need to be filled before this can be concluded.							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Arithmetic mean/median							
pH dependence (yes or no)							

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

Column leaching ‡	No study available. Probably not required, but data gaps need to be filled before this can be concluded..
Aged residues leaching ‡	No study available
	No study available
	No study available
	No study available
Lysimeter/ field leaching studies ‡	No study available

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	Not calculated
Application data	
Metabolite I Method of calculation	Not calculated
Application data	

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: No study available. Not required
	pH 7: No study available. Not required
	pH 9: No study available. Not required

Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : No study available. Probably not required, but data gaps need to be filled before this can be concluded.
Quantum yield of direct phototransformation in water at Σ > 290 nm	No study available. Not required.
Readily biodegradable ‡ (yes/no)	‘‘needs to be considered ‘not readily biodegradable’ in the absence of any test results on ready biodegradability’.’

Degradation in water / sediment

Parent	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Geometric mean/median				No study available. Probably not required, but data gaps need to be filled before this can be concluded.						

Metabolite 1	Distribution (eg max in water *x* after *n* d. Max. sed x % after *n* d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Geometric mean/median				No study available. Probably not required, but data gaps need to be filled before this can be concluded.						
Mineralization and non extractable residues										
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).		Non-extractable residues in sed. max x % after n d		Non-extractable residues in sed. max x % after n d (end of the study)			
No study available. Probably not required, but data gaps need to be filled before this can be concluded.										

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

Parent Parameters used in FOCUSsw step 1 and 2	Not calculated.
Parameters used in FOCUSsw step 3 (if performed)	Not applicable
Application rate	Not applicable

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Not calculated
Application rate	Not applicable

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

Direct photolysis in air ‡	No study available. No data requested.

Quantum yield of direct phototransformation	No study available. No data requested.
Photochemical oxidative degradation in air ‡	No study available. Data gap
Volatilisation ‡	No study available. Data gap
Metabolites	No study available. No data requested.

PEC (air)

Method of calculation	Emission: = 0.32 mg a.s/m^3/day (assuming an emission of 8 g a.s. / ha/day on an air volume of 25000 m^3 /ha)

$PEC_{(a)}$

Maximum concentration	Not calculated

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which groundwater exposure consideration is triggered.	Soil: ammonium acetate variants (default) Surface Water: ammonium acetate variants (default) Sediment: ammonium acetate variants (default) Ground water: ammonium acetate variants (default) Air: ammonium acetate variants (default); ammonia and acetic acid.

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

Soil (indicate location and type of study)	No study available
Surface water (indicate location and type of study)	No study available
Ground water (indicate location and type of study)	No study available
Air (indicate location and type of study)	No study available

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

Candidate for R53

Effects on Non-target Species

[1] Pending on the outstanding data in the fate and behaviour section, the risk assessment of ammonium acetate to non-target organisms for the representative uses should be re-considered.

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Indicate species.	a.s.	Acute		Not required[1]
	Preparation	Acute		
	Metabolite 1	Acute		
	a.s.	Short-term		
	a.s.	Long-term		
Mammals ‡				
Indicate species.	a.s.	Acute		Not required[1]
	Preparation	Acute		
	Metabolite 1	Acute		
	a.s.	Long-term		
Additional higher tier studies ‡				
Not required[1]				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Not required[1]

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Indicate species.	a.s.	96 hr (flow-through)	Mortality, EC_{50}	No studies submitted[2]
	a.s.	28 d (static)	Growth NOEC	
	Preparation	96 hr (flow-through)	Mortality, EC_{50}	
	Preparation	28 d(flow-through)	Growth NOEC	
	Metabolite 1	96 hr (flow-through)	Mortality, EC_{50}	

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Aquatic invertebrate				
Indicate species.	a.s.	48 h (static)	Mortality, EC_{50}	No studies submitted[2]
	a.s.	21 d (static)	Reproduction, NOEC	
	Preparation	48 h (static)	Mortality, EC_{50}	
	Preparation	21 d (static)	Reproduction, NOEC	
	Metabolite 1	48 h (static)	Mortality, EC_{50}	
Sediment dwelling organisms				
Indicate species.	a.s.	28 d (static)	NOEC	No studies submitted[2]
	Metabolite 2	28 d (static)	NOEC	
Algae				
Indicate species.	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No studies submitted[2]
	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	
	Metabolite 1	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	
Higher plant				
Indicate species.	a.s.	14 d (static)	Fronds, EC_{50}	No studies submitted[2]
	Preparation	14 d (static)	Fronds, EC_{50}	
	Metabolite 1	14 d (static)	Fronds, EC_{50}	
Microcosm or mesocosm tests				
Indicate if not required				

[2] Data gap identified for acute toxicity studies with aquatic organisms to fulfil the Annex II data requirement

Bioconcentration

	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	No studies submitted, not required			
Bioconcentration factor (BCF)‡				
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	Not required[1]	
Preparation		
Metabolite 1		
Field or semi-field tests		
Indicate if not required		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	Not required[1]	50
a.s.	oral		50
Preparation	Contact		50
Preparation	oral		50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri ‡		Mortality	Not required[1]
Aphidius rhopalosiphi ‡		Mortality	

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point
Earthworms			
	a.s. ‡	Acute 14 days	Not required[1]
	a.s. ‡	Chronic 8 weeks	
	Preparation	Acute	
	Preparation	Chronic	
	Metabolite 1	Acute	
	Metabolite 1	Chronic	
Other soil macro-organisms			
Soil mite	a.s. ‡		Not required[1]

Test organism	Test substance	Time scale	End point
	Preparation		
	Metabolite 1		
Collembola			
	a.s. ‡	Chronic	Not required[1]
	Preparation		
	Metabolite 1		
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		Not required[1]
	Metabolite 1		
Carbon mineralisation	a.s. ‡		
	Metabolite 1		

Toxicity/exposure ratios for soil organisms

Not required[1]

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure (g/ha)[2]	TER	Trigger
Not required[1]						

Additional studies (e.g. semi-field or field studies)

Not required[1]

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	Not required[1]
Pseudomonas sp	

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Data gaps need to be filled before this can be finalised
water	Data gaps need to be filled before this can be finalised
sediment	Data gaps need to be filled before this can be finalised
groundwater	Data gaps need to be filled before this can be finalised

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	R51/R53 (based on ammonium)

	RMS/peer review proposal
Preparation	No classification

ABBREVIATIONS

1/n	slope of Freundlich isotherm
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
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
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_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
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
MRL	maximum residue limit or level
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 *n*-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