CONCLUSION ON PESTICIDE PEER REVIEW

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

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Ethylene 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].

Ethylene 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.

The United Kingdom being the designated rapporteur Member State submitted the DAR on ethylene in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 7 January 2008. The peer review was initiated on 14 July 2008 by dispatching the DAR to the notifier, the EU Ethylene Task Force, and on 24 February 2011 to the Member States, for consultation and comments. Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and that the EFSA should deliver its conclusions on ethylene.

[1] On request from the European Commission, Question No EFSA-Q-2009-00277, 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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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of ethylene as a plant growth regulator on bananas and potatoes, as proposed by the notifier. The representative use dealing with *in situ* generation of ethylene from ethanol is not falling under the provisions of Directive 91/414/EEC. Full details of the representative uses can be found in Appendix A to this report.

No data gaps were identified in the section on identity, physical chemical properties and analytical methods.

Data gaps were identified in the mammalian toxicology section to set reference values for ethylene based on adequate toxicological information if the levels of exposure of consumers, operators, workers and bystanders are shown to exceed natural background exposure levels; and for operator, worker and bystander exposure risk assessment regarding ethylene and ethylene oxide.

A consumer risk assessment could not be conducted. Experimental data are required which would substantiate that residue levels of ethylene and its probable major metabolites in treated bananas and treated potatoes are less than or similar to background levels measured in untreated crops.

In the environmental fate and behaviour section a data gap has been identified for adequate estimates or experimental measurements of environmental concentrations in air of ethylene and ethylene oxide after ventilation of the gassing room. Ethylene oxide has potential for long-range transport through the atmosphere and a critical area of concern was identified.

A data gap has been identified in the ecotoxicology section for the aquatic toxicity studies essential to fulfil the Annex II data requirements.

KEY WORDS

ethylene, peer review, risk assessment, pesticide, plant growth regulator

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BACKGROUND

Ethylene 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].

Ethylene 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.

The United Kingdom being the designated rapporteur Member State submitted the DAR on ethylene in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 7 January 2008 (United Kingdom, 2007). The peer review was initiated on 14 July 2008 by dispatching the DAR to the notifier, the EU Ethylene Task Force, and on 24 February 2011 to 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 notifier was 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 20 June 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 and that the EFSA should deliver its conclusions on ethylene.

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 notifier, 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 a plant growth regulator on bananas and potatoes, as proposed by the notifier. A list of the relevant end

[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

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, 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 (27 September 2011),
- the Evaluation Table (12 December 2011),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of September 2011 containing all individually submitted addenda (United Kingdom, 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.

Ethylene (IUPAC) is considered by the International Organization for Standardization not to require a common name.

The representative formulated product for the evaluation was 'Ethylene Gas', a gas packed in pressure bottle or pressure tank (GA) containing 60 g/kg ethylene.

The representative uses evaluated comprise applications by gassing to bananas to promote the ripening process, and to potatoes to inhibit sprouting. 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 documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev.7 (European Commission, 2004).

The minimum purity of ethylene technical material is 999 g/kg. It was included in Annex I with a minimum purity of 990 g/kg. 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, physical, chemical and technical properties of ethylene or the representative formulation. The main data regarding the identity of ethylene and its physical and chemical properties are given in Appendix A.

Analytical methods are available for the determination of ethylene in the technical material and the representative formulation.

Given the nature and representative uses of the product the need for methods of analysis for monitoring this compound in food of plant and animal origin has currently been waived. It should be noted however, that pending on the fulfilment of the data gaps in section 7, residue analytical methods might be required in the different compartments. Monitoring methods in soil and water are not required as physical properties suggest ethylene will escape from soil and water. Residues of ethylene in air can be monitored by GC-FID with a LOQ of 0.6 μg/kg, however a data gap was identified for additional validation data to show compliance with the monitoring methods guidance document. Analytical methods for the determination of residues in body fluids and tissues are not required as ethylene is not classified as toxic or highly toxic.

2. Mammalian toxicity

Toxicological information submitted to the RMS consisted of secondary sources such as reviews and summaries. No original report was available that could be individually evaluated. Additionally a review on the toxicological information available on ethylene oxide, a relevant metabolite of ethylene, was collected and summarised.

Based on inhalation data of limited validity, there are indications that ethylene exposure may result in the formation of adducts with DNA and protein, in haematological changes, liver effects, effects on the nervous system and asphyxia. However the quality of the investigations, the characterisation and magnitude of the effects, and the concentration level at which they would appear could not be

evaluated. No conclusion could be reached on the genotoxic or carcinogenic potential of ethylene, and on its reproductive or developmental toxicity. Due to the lack of data, no reference values could be set. A data gap is identified for toxicological information allowing setting reference values for ethylene if the levels of exposure of consumers, operators, workers and bystanders are shown to exceed natural background exposure levels.

Ethylene oxide appears to be more toxic than ethylene, it is classified in Annex I of Council Directive 67/5498/EEC (Council, 1967) as a category 2 carcinogen and mutagen. It is toxic by inhalation and irritant for eyes, respiratory system and skin. Ethylene oxide is of toxicological concern and therefore the risk assessment of ethylene cannot be concluded without focusing also on this metabolite. A data gap is identified to perform a risk assessment for operators, workers and bystanders exposed to ethylene oxide derived from the use of ethylene.

Exposure of operators and workers may occur when entering the application room, after ventilation and during maintenance works; bystanders may be exposed to leakages from the treatment rooms or during the venting of the gas into the atmosphere after treatment. No information is available to quantify the potential exposure derived from these scenarios (see data gap in section 4). Therefore no conclusion could be reached on the risk assessment for ethylene exposure and a data gap is set to address this issue.

3. Residues

No studies on the nature and level of residues of ethylene and potential metabolites or reaction products were available for peer review. Although not submitted in the dossier by the notifier, relevant information on ethylene residues was however reported and assessed by the RMS in the DAR.

According to data summarised by the RMS but not submitted to EFSA for the peer review, ^{14}C-labelled ethylene is metabolised very little in potatoes and ethylene oxide, the metabolite of greatest toxicological concern, is not found above the LOQ of 2 mg/kg. In research residue studies, low levels of metabolites ethylene glycole and ethylene glycole glucoside were found in potatoes, but below the LOQ of the analytical method. According to the RMS, further experimental data on both potatoes and bananas suggest that levels of ethylene in treated and untreated crops are comparable.

Nevertheless, the notifier has not submitted any experimental data on bananas and potatoes which would substantiate that the residue levels of ethylene and its probable major metabolites in treated commodities are less than or similar to levels in untreated crops. Without these relevant residue data it is not possible to conclude that the consumer exposure to ethylene is not increased over the natural background level. Consequently, a data gap was set for submission of such data.

4. Environmental fate and behaviour

No studies on the fate and behaviour of ethylene in the environment are available in the dossier. Various overviews from other governmental organisations, e.g. Environment Canada, US Environment Protection Agency, UK national assessment and OECD, have been used extensively in the assessment. Environmental partitioning using a six compartment (air, water, soil solids, sediment solids, suspended sediments and fish) model has been conducted. It was concluded that, if applied according to the representative uses, emitted ethylene is distributed to the air only and therefore exposure to the soil and water is considered to be minimal. Fugacity modelling was conducted to characterize key reaction, intercompartment and advection pathways for ethylene oxide (metabolite of ethylene) and its overall distribution in the environment. Based on the environmental fate data and the mode of use it was concluded that release to the atmosphere is unlikely to result in transfer to other environmental compartments in significant amounts. The atmospheric half-life of ethylene oxide in air

was estimated to be approximately 38 days (Atkinson calculation based on hydroxyl radical concentration of 1.5 x 10^6 molecules/cm^3), indicating a potential for long-range transport through the atmosphere. This is a critical area of concern.

No information has been provided on the concentrations of ethylene or ethylene oxide that will remain at the time of venting the gassing room and hence enter the atmosphere. In the DAR, a qualitative assessment assumed that, owing to the high vapour pressure and the low solubility in water of both ethylene and ethylene oxide, the amount of the two gases entering the atmosphere from the representative uses indoors, compared to naturally produced ethylene from plant tissues and from industrial uses, would be negligible. However, a quantitative assessment of the emissions after indoor applications is not available to confirm this supposition. Taking into account the data gap identified in the mammalian toxicity section on exposure and risk assessment for bystanders regarding ethylene and ethylene oxide (see section 2), a data gap has been identified for adequate estimates or experimental measurements of environmental concentrations after ventilation of the treated premises.

5. Ecotoxicology

Various overviews of toxicity studies to bird, mammals, aquatic organisms and non-target plants from other governmental organisation including the U.S. EPA and the OECD were provided. The notifier was requested to provide the reports of these studies during the peer review process. However further information on these studies was not submitted and therefore these data cannot be used in the risk assessment. Nevertheless, due to the representative uses of ethylene (indoor uses), no further ecotoxicity studies are needed, except for the aquatic toxicity studies that are considered necessary to fulfil the Annex II data requirements. Therefore, a data gap was identified for the acute toxicity studies of ethylene to aquatic organisms.

Due to the negligible levels of exposure, the risk to birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro and micro-organisms, terrestrial non-target plants, biological methods for sewage treatment sewage treatment plants, is considered to be low.

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
ethylene	No data, data not required	No data, data not required
ethylene oxide	No data, data not required	No data, data not required

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
ethylene	No data, data not required	No data, data not required	Yes, as a plant growth regulator[(a)]	Yes	No data, data not required
ethylene oxide	No data, data not required	No data, data not required	No data	Yes	No data, data not required

(a) according to the definition of a pesticide in Council Directive 98/83/EC[15] on the quality of water intended for human consumption

[15] OJ L330, 5.12.1998, p.32

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
ethylene	No data, data not required.
ethylene oxide	No data, data not required

6.4. Air

Compound (name and/or code)	Toxicology
ethylene	Data of limited validity
ethylene oxide	Toxic by inhalation

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).

- Additional validation data for the air method to show complience with the monitoring methods guidence document (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Adequate toxicological information allowing to set reference values for ethylene if the levels of exposure of consumers, operators, workers and bystanders is shown to exceed the natural background exposure levels (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).
- Operator, worker and bystander exposure risk assessment regarding ethylene and ethylene oxide (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).
- Experimental data on ethylene treated potatoes and banana that demonstrate consumer exposure to ethylene and its probable major metabolites is not increased over background levels (relevant for the all representative uses evaluated; submission date proposed by the notifier: unknown; see section 3).
- Adequate estimates or experimental measurements of environmental concentrations in air of ethylene and ethylene oxide after ventilation of the gassing room (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- The notifier to provide the aquatic organism toxicity studies that are considered essential to fulfil the Annex II data requirements (relevant for all representative uses evaluated; 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

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. Operator, worker, bystander and consumer exposure risk assessment to ethylene and ethylene oxide could not be finalised.
2. Predicted environmental concentration of ethylene and ethylene oxide in air after ventilation of the treated premises.

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. Ethylene oxide has potential for long-range transport.

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		Bananas Degreening/ ripening on banana 1000 ppm	Potatoes Sprout suppressant 10 ppm
Operator risk	Risk identified		
	Assessment not finalised	X[1,2]	X[1,2]
Worker risk	Risk identified		
	Assessment not finalised	X[1,2]	X[1,2]
Bystander risk	Risk identified		
	Assessment not finalised	X[1,2]	X[1,2]
Consumer risk	Risk identified		
	Assessment not finalised	X[1]	X[1]
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		
Risk to aquatic organisms	Risk identified		
	Assessment not finalised		
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L[(a)] breached		
	Assessment not finalised		
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

Council, 1967. Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 1–98.

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 ethylene.

European Commission, 1991. Commission Directive 91/325/EEC of 1 March 1991 adapting to technical progress for the twelfth time Council Directive 67/548/EEC on the approximation of the laws, Regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Official Journal L 180 , 08/07/1991 P. 0001 – 0078.

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, 2003. Guidance document on assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. SANCO/221/2000-rev 10-final, 25 February 2003.

European Commission, 2004. Guidance document on residue analytical methods. SANCO/825/00 rev. 7, 17 March 2004.

European Commission, 2008. Review report for the active substance ethylene. 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 ethylene in Annex I of Directive 91/414/EEC. SANCO/2608/08 – rev. 1, 1 August 2008.

United Kingdom, 2007. Draft Assessment Report (DAR) on the active substance ethylene prepared by the rapporteur Member State United Kingdom in the framework of Directive 91/414/EEC, December 2007.

United Kingdom, 2011. Final Addendum to Draft Assessment Report on ethylene, compiled by EFSA, September 2011.

APPENDICES

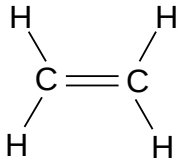
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Ethylene (no ISO common name)
Function (*e.g.* fungicide)	Plant growth regulator

Rapporteur Member State	UK
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	ethylene
Chemical name (CA) ‡	ethene
CIPAC No ‡	839
CAS No ‡	74-85-1
EC No (EINECS or ELINCS) ‡	200-815-3
FAO Specification (including year of publication) ‡	none
Minimum purity of the active substance as manufactured ‡	99.9% for the ethylene formulated and supplied in cylinders. Ethylene formed from catalytic action on ethanol is not considered a technical material.
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	C_2H_4
Molecular mass ‡	28.05 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	-169 °C (Pure)
Boiling point (state purity) ‡	103.71°C (Pure)
Temperature of decomposition (state purity)	No data
Appearance (state purity) ‡	Colourless gas with faint sweet odour
Vapour pressure (state temperature, state purity) ‡	6.95 x 10^5 Pa at 25 °C (Pure)
Henry's law constant ‡	23102.1 Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	0.131g/L at 25°C (no pH effect)
Solubility in organic solvents ‡ (state temperature, state purity)	One volume of ethylene gas dissolves in 0.5 volume of alcohol at 25°C, in about 0.05 volume of ether at 15.5°C. Slightly soluble in ethanol (200 ml/ 100 ml at 25°C); soluble in acetone and benzene; very soluble in diethyl ether
Surface tension ‡ (state concentration and temperature, state purity)	ethylene is a gas at STP
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 1.13
Dissociation constant (state purity) ‡	No dissociation (in the environment)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	solution: λ_{max} 162 nm
Flammability ‡ (state purity)	Extremely flammable
Explosive properties ‡ (state purity)	Explosive limits in air 2.7% to 36% at 25°C
Oxidising properties ‡ (state purity)	Not oxidising

Summary of representative uses evaluated (Ethylene)

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 main text)			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)		
Bananas	Northern and Southern EU	Ethylene Gas	I	Degreening / Ripening on bananas (Plant Growth Regulator)	Gas (GA)	6%	Gassing	Post harvest	One per stored batch of bananas	N/A	N/A	N/A	0.6 –1.0 L/m^3	N/A	Equivalent to an application rate of 600 – 1000 ppm
Potatoes	Northern and Southern EU	Ethylene Gas	I	Sprout suppressant (Plant growth regulator)	Gas (GA)	6%	Gassing	Post harvest	One per stored batch of potatoes	N/A	N/A	N/A	0.01 L/m3	N/A	Equivalent to an application rate of 10 ppm

(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)	GC-FID with LOQ of 0.6 µg/kg for ethylene
Impurities in technical as (analytical technique)	No relevant or significant impurities are recorded in the technical ethylene supplied in cylinders.
Plant protection product (analytical technique)	GC-FID with LOQ of 0.6 µg/kg for ethylene

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Not proposed
Food of animal origin		Not proposed
Soil		Not proposed
Water	surface	Not proposed
	drinking/ground	Not proposed
Air		ethylene

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	None as MRLs are not proposed for treated crops as ethylene is produced also by the crop itself.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	None as MRLs are not proposed for animal tissues.
Soil (analytical technique and LOQ)	None proposed as physical properties suggest ethylene will escape from soil (same justification proposed for the potential metabolite ethylene oxide.
Water (analytical technique and LOQ)	None proposed as physical properties suggest ethylene will escape from water (same justification proposed for the potential metabolite ethylene oxide.
Air (analytical technique and LOQ)	GC-FID with LOQ of 0.6 µg/kg Data gap for additional validation data
Body fluids and tissues (analytical technique and LOQ)	Not required as ethylene is not classified as toxic or highly toxic.

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

	RMS/peer review proposal
Active substance	F+ Extremely Flammable (R12)

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	No oral data available.
Distribution ‡	Based on inhalation data of limited validity, distribution is widespread throughout the body.
Potential for accumulation ‡	Based on inhalation data of limited validity, ethylene exposure results in the formation of adducts with DNA and protein.
Rate and extent of excretion ‡	Data available of limited validity.
Metabolism in animals ‡	Based on inhalation data of limited validity, ethylene is oxidised to ethylene oxide in experimental animals and humans.
Toxicologically relevant compounds ‡ (animals and plants)	Ethylene and ethylene oxide
Toxicologically relevant compounds ‡ (environment)	Ethylene and ethylene oxide.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	No data available	
Rat LD_{50} dermal ‡	No data available	
Rat LC_{50} inhalation ‡	Data available of limited validity	
Skin irritation ‡	Data available of limited validity	
Eye irritation ‡	Data available of limited validity	
Skin sensitisation ‡	Data available of limited validity	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Based on inhalation data of limited validity, asphyxia, haematological changes, some poorly reported liver effects (including increased weight) and effects on the nervous system.	
Relevant oral NOAEL ‡	No data available	
Relevant dermal NOAEL ‡	No data available	
Relevant inhalation NOAEL ‡	No data available	

Genotoxicity ‡ (Annex IIA, point 5.4)

Data available of limited validity	

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

Target/critical effect ‡	Data available of limited validity (IBT inhalation study of questionable reliability).	
Relevant NOAEL ‡	No oral data submitted (or reliable inhalation data)	
Carcinogenicity ‡	No reliable data	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Based on inhalation data, no effects were demonstrated in a screening study of limited validity. Equivocal evidence of postnatal effects (delay in coat appearance, dentition and eye opening; circulation hypotension, cholinesterase inhibition and subordination disruption).	
Relevant parental NOAEL ‡	No reliable data	
Relevant reproductive NOAEL ‡	No reliable data	
Relevant offspring NOAEL ‡	No reliable data	

Developmental toxicity

Developmental target / critical effect ‡	No data available	
Relevant maternal NOAEL ‡	No data available	
Relevant developmental NOAEL ‡	No data available	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available	
Repeated neurotoxicity ‡	No data available	
Delayed neurotoxicity ‡	Ethylene is not similar or related structurally to compounds that are capable of inducing delayed neurotoxicity.	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Data of limited validity indicate formation of adducts with DNA and proteins.

Studies performed on metabolites or impurities ‡	Data of limited validity were reported. Numerous investigations have been carried out using the metabolite ethylene oxide. It is considerably more toxic than the parent. Ethylene oxide (EO) is currently classified by the ECB as Toxic by inhalation (R23) and as an irritant (R36/37/38). The literature also indicates that it can also induce sensitisation responses. EO is also classified by the ECB as a Cat: 2 for carcinogenicity (R45) and Cat: 2 for mutagenicity (R46). There is evidence of increased incidences of tumours after oral and inhalation exposure. The literature indicates that EO also induces neurotoxicity and reproductive effects in experimental animals (foetal toxicity in the presence and absence of maternal toxicity, teratogenicity in mice, sperm effects) and there is some limited evidence of spontaneous abortions in humans.

Medical data ‡ (Annex IIA, point 5.9)

A wide range of clinical symptoms related to acute and repeated exposures to ethylene have been reported in the literature. Many of the symptoms may be related to hypoxia.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Not set, no reliable data		
AOEL ‡	Not set, no reliable data		
ARfD ‡	Not set, no reliable data		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. ‘Ethylene Gas’)	100% default value

Exposure scenarios (Annex IIIA, point 7.2)

Operator	No AOEL was set. Exposure whilst handling cylinders and maintenance work could not be assessed and a data gap was identified.

Workers	Workers will be excluded during treatment. There are uncertainties concerning levels of exposure experienced post treatment. Exposure could not be assessed and a data gap was identified.
Bystanders	Exposure could occur if leakages from the treatment rooms occur, or during venting of gas to the atmosphere (ethylene scrubbers can be used). As no information was available to quantify such exposure, exposure could not be assessed and a data gap was identified.

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

	RMS/peer review proposal
Ethylene	Open

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

Plant groups covered	Not submitted
Rotational crops	Not relevant
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	None
Residue pattern in processed commodities similar to residue pattern in raw commodities?	None
Plant residue definition for monitoring	None as MRLs are not proposed. Ethylene could be selected, but as this is produced by crops, provenance will be difficult to establish.
Plant residue definition for risk assessment	Experimental data are required to demonstrate that residue situation in treated crops is comparable to that in untreated crops
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, not required
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 applicable
Fat soluble residue: (yes/no)	Not applicable

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

Not required

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

No data, not required

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)	No data	No data	No data
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No data	No data	No data
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	No data	No data	No data
Liver	No data	No data	No data
Kidney	No data	No data	No data
Fat	No data	No data	No data
Milk	No data		
Eggs		No data	

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/ Southern Regions field or glasshouse	Trials results relevant to the representative uses (a)	Recommendation/comments	**MRL** estimated from trials according to representative use	**HR** (c)	**STMR** (b)
Potato	Post harvest	No data				
Banana	Post harvest	No data				

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.1, 2x 0.15, 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	None set, reliable data not available
TMDI (% ADI) according to WHO European diet	No information
TMDI (% ADI) according to national (to be specified) diets	Experimental data are required to demonstrate that residue situation in treated crops is comparable to that in untreated crops
IEDI (WHO European Diet) (% ADI)	Not applicable
NEDI (specify diet) (% ADI)	Not applicable
Factors included in IEDI and NEDI	Not applicable
ARfD	None set, reliable data not available
IESTI (% ARfD)	Experimental data are required to demonstrate that residue situation in treated crops is comparable to that in untreated crops
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not applicable
Factors included in IESTI and NESTI	Not applicable

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	
No information. Experimental data are required to demonstrate that residue situation in treated crops is comparable to that in untreated crops				

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

Experimental data are required to demonstrate that residue situation in treated crops is comparable to that in untreated crops. Ethylene is produced naturally by plants to a greater or lesser extent. An LOQ MRL is likely to lead to MRL exceedance.

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

Mineralization after 100 days ‡	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.
Non-extractable residues after 100 days ‡	
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	

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

Anaerobic degradation ‡

Mineralization after 100 days	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.
Non-extractable residues after 100 days	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.

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

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
No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.							

pH dependence ‡ (yes / no) (if yes type of dependence)	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.
Soil accumulation and plateau concentration ‡	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.							

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

Column leaching ‡	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.
Lysimeter/ field leaching studies ‡	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.
Application data	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	Not relevant		Not relevant	

Metabolite I	No data submitted.
Method of calculation	No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the soil is considered to be minimal.
Application data	

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	Not relevant		Not relevant	

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	No data submitted. No data are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the water is considered to be minimal.
Photolytic degradation of active substance and metabolites above 10 % ‡	
Quantum yield of direct phototransformation in water at Σ > 290 nm	
Readily biodegradable ‡ (yes/no)	

Degradation in water / sediment

Parent	No data, data not required

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

Parent	No data submitted.
Parameters used in FOCUSsw step 1 and 2	No PEC are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the water is considered to be minimal.
Ethylene oxide	No data submitted.
Parameters used in FOCUSsw step 1 and 2	No PEC are considered necessary as for all practical purposes, ethylene oxide is distributed to the air and therefore exposure of the water is considered to be minimal.

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	No data submitted. No PEC are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the water is considered to be minimal.

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

Direct photolysis in air ‡	No data submitted.
Photochemical oxidative degradation in air ‡	A theoretical calculation of the potential for photo-oxidation of ethylene in the atmosphere was submitted, using the method of Atkinson (1989). A rate constant of 8.52 x 10^{-12} cm³/molecule/sec was calculated for reaction with OH radicals. The OH radicals concentration was assumed to be 1.5 x 10^{6} molecules/cm^{3} with 12 hours irradiation. This corresponded to a first order half-life of 1.255 days (assuming 12 hour days) which was stated to be equivalent to 15.065 hours.
Metabolites	Ethylene oxide A theoretical calculation of the potential for photo-oxidation of ethylene oxide in the atmosphere was submitted, using the method of Atkinson (1989). A rate constant of 0.2803 x 10^{-12} cm³/molecule/sec was calculated for reaction with OH radicals. The OH radicals concentration was assumed to be 1.5 x 10^{6} molecules/cm^{3} with 12 hours irradiation. This corresponded to a first order half-life of 38.157 days (assuming 12 hour days).

PEC (air)

Method of calculation	No data submitted. Data gap for adequate estimates or experimental measurements of environmental concentrations in air of ethylene and ethylene oxide after ventilation of the gassing room.

$PEC_{(a)}$

Maximum concentration	Not calculated

Residues requiring further assessment

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

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

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	Monitoring data were presented in Section IIA 7.12 and this is summarised below: Ethylene levels in water samples were submitted. These were primarily from oceanic emissions and hence of limited relevance to the representative use.
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	Data were also referenced on the levels of ethylene recorded in air in rural and urban areas. Highest levels were recorded in urban and indoor areas contaminated with combustion products. Typical ranges were 50 mg/m^3, however in extreme cases the ranges were >1000 mg/m^3. In rural and remote sites worldwide levels were stated to be in the range of <1-5 mg/m^3. The mean atmospheric concentrations of ethylene measured at various locations throughout Germany and reported in the IUCLID data set were as follows: near a Ruhr refinery 17 $\mu l/m^3$; residential, Berlin 3.6$\mu l/m^3$; traffic road, Berlin 29.9$\mu l/m^3$; Industrial area, Berlin 3.5$\mu l/m^3$; residential near petrochemical station, Rhein/Ruhr area 69.9$\mu l/m^3$; residential near coke oven 59$\mu l/m^3$; clean area (Schwarzwald) 1.6$\mu l/m^3$.

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

Candidate for R53 (in the absence of data on ready biodegradability)

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 ‡				
Due to the representative uses of ethylene, exposure is considered to be minimal and hence data and associated risk assessment are not required.				
Mammals ‡				
Due to the representative uses of ethylene exposure is considered to be minimal and hence data and associated risk assessment are not required.				

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

No TER have been calculated and are not considered necessary for the representative uses.

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[1]
	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}	
Aquatic invertebrate				
Indicate species.	a.s.	48 h (static)	Mortality, EC_{50}	No studies submitted[1]
	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[1]
	Metabolite 2	28 d (static)	NOEC	

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Algae				
Indicate species.	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	No studies submitted[1]
	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[1]
	Preparation	14 d (static)	Fronds, EC_{50}	
	Metabolite 1	14 d (static)	Fronds, EC_{50}	
Microcosm or mesocosm tests				
Indicate if not required				

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

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step1

Due to the representative uses of ethylene as well as the physical chemical characteristics, exposure is considered to be minimal and hence PEC have not been calculated and are not considered necessary.

Bioconcentration				
	Ethylene	Ethylene oxide		
$logP_{O/W}$	1.13	-0.3		

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)
No data have been submitted – due to the representative uses of ethylene, exposure is considered to be minimal and hence data are 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 calculated	50
a.s.	oral	Not calculated	50
Preparation	Contact	Not calculated	50
Preparation	oral	Not calculated	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[1])
No data have been submitted – due to the representative uses of ethylene, exposure is considered to be minimal and hence data are not required.			

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[1]
Earthworms			
No data have been submitted – due to the representative uses of ethylene, exposure is considered to be minimal and hence data are not required.			

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)
No data have been submitted, however due to the representative uses of ethylene, exposure is considered to be minimal and hence data are not required.

Preliminary screening data

Effects	**Crop**	**Exposure**	**Concentration µg/m^3**
None or small long-term effects			

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

Test type/organism	end point
No data have been submitted – due to the representative uses of ethylene, exposure is considered to be minimal and hence data are not required.	

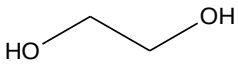
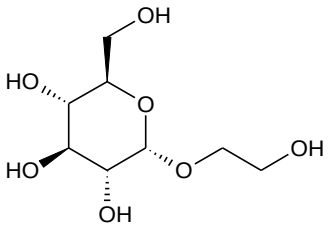
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Not applicable.
water	Not applicable.
sediment	Not applicable.
groundwater	Not applicable.

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	Data gap

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula*
Ethylene oxide	oxirane	
Ethylene glycole	ethylene glycol	
Ethylene glycole glucoside	2-hydroxyethyl α-D-glucopyranoside	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

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
CL	confidence limits
cm	centimetre
CRD	Chemical Regulation Directorate (UK)
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
ECB	European Chemicals Bureau
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
GA	gas packed in pressure bottle or pressure tank
GAP	good agricultural practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
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
IBT	Industrial Bio-Test Laboratories
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
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
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})
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
STP	standard temperature and pressure definition
$t_{1/2}$	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