CONCLUSION ON PESTICIDE PEER REVIEW

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

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State the United Kingdom, for the pesticide active substance carbon dioxide are reported. The context of the peer review was that required by Commission Regulation (EC) No 2229/2004 as amended by Commission Regulation (EC) No 1095/2007. The conclusions were reached on the basis of the evaluation of the representative uses of carbon dioxide as an insecticide on stored cereal grains, fatty seeds, medicinal plants, spices, tobacco, tea and dried fruits. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

KEY WORDS

Carbon dioxide, peer review, risk assessment, pesticide, insecticide, acaricide

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[2] Correspondence: pesticides.peerreview@efsa.europa.eu

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SUMMARY

Carbon dioxide is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004, as amended by Commission Regulation (EC) No 1095/2007.

Carbon dioxide was included in Annex I to Directive 91/414/EEC on 20 December 2008 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, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010, 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 carbon dioxide in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 15 July 2008 The peer review was initiated on 7 August 2008 by dispatching the DAR for consultation of the notifier Pesticides Con troll Service, Irleand, and subsequqently to all Member States on 9 September 2011. 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 carbon dioxide.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of carbon dioxide as an insecticide on stored cereal grains, fatty seeds, medicinal plants, spices, tobacco, tea and dried fruits as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

Data gaps were identified for the section analytical methods.

The toxicological database is not suitable either to set an AOEC or to support the occupational limits of carbon dioxide and therefore the risk assessment for non-dietary exposure cannot be concluded. Due to the high application rates applied, the amount of trace impurities in the technical material could reach significant levels, with possible concern for the exposure of operators, workers and bystanders: a data gap was therefore set to address the issue.

Due to the high application rates of carbon dioxide and in view of the application pattern, the amount of trace impurities in the technical material may reach significant levels and a potential concern for the consumer exposure cannot be excluded. Therefore a data gap was set.

Carbon dioxide is representing the end point in mineralisation of organic substances. Therefore it is not subject to biological degradation. Testing for the biodegradability of carbon dioxide and testing for route and rate of degradation in soil or water is scientifically unjustified and therefore not relevant. Because of the rapid dilution of carbon dioxide in adjacent air it is not reasonable to calculate PEC-values for environmental compartments for the use of carbon dioxide in storage protection.

A data gap was identified in the ecotoxicology section to provide the acute toxicity studies on fish, aquatic invertebrates and algae. No critical areas of concern were indentified in this section

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BACKGROUND

Carbon dioxide 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]

Carbon dioxide was included in Annex I to Directive 91/414/EEC[5] on 20 December 2008 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,[6] in accordance with Commission Implementing Regulation (EU) No 540/2011,[7] as amended by Commission Implementing Regulation (EU) No 541/2011.[8] In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[9] 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 carbon dioxide in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 15 July 2008 (United Kingdom, 2008). The peer review was initiated on 7 August 2008 by dispatching the DAR to the notifier Pesticides Control Service, Ireland for consultation and comments and subsequently to all Member States on 9 September 2011. 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 17 January 2012. 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, and additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

[3] Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC. OJ L 379, 24.12.2004, p.13-63.

[4] Commission Regulation (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC. OJ L 246, 21.9.2007, p.19-28.

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.

[6] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p.1-50.

[7] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.1-186.

[8] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187-188.

[9] Commission Regulation (EU) No 114/2010 of 9 February 2010 amending Regulation (EC) No 2229/2004 as regards the time period granted to EFSA for the delivery of its view on the draft review reports concerning the active substances for which there are clear indications that they do not have any harmful effects. OJ L 37, 10.2.2010, p.12.

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 October 2012.

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 insecticide on stored cereal grains, fatty seeds, medicinal plants, spices, tobacco, tea and dried fruits, as proposed by the notifier. 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, 2012) 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 (12 January 2012)
- the Evaluation Table (10 December 2012)
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR and the Peer Review Report, both documents were considered as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

The International Organization for Standardization does not require a common name for carbon dioxide (IUPAC).

The representative formulated products for the evaluation were 'Aligal 2' and 'Carbo Kohlensäure', both gas formulations (GA), containing 999 g/kg carbon dioxide. The plant protection products are identical with the technical material.

The representative uses evaluated comprise applications by fumigation as insecticide/acaricide for the control of insects and mites in stored products: stored cereal grains, fatty seeds, medicinal plants, spices, tobacco, tea and dried fruits. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of carbon dioxide technical material for both notifiers is 999 g/kg. Both technical materials are meeting the specifications set by the Compressed Gases Association of America (CGA) and the European Industrial Gases Association (EIGA) including maximum contents for relevant impurities as given in Appendix A. These specifications need to be fulfilled if liquid carbon dioxide is used in foods and beverages. The technical material from both manufactures can be regarded as equivalent.

ISBT (International Society of Beverage Technologists) standardised analytical methods exist for all key characteristics of the specification, however these methods were not part of the submission and were not available to the peer review. As a consequence a data gap was identified for a validated method for the determination of the active substance and the impurities in the technical material as manufactured.

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 carbon dioxide. The available data regarding the identity of carbon dioxide and its physical and chemical properties are given in Appendix A.

The need for analytical methods for the determination of residues of carbon dioxide in plant materials, foodstuff of animal origin, in soil and water or body fluids and tissues have been waived due to the use pattern and the nature of the compound.

The occupational exposure limit for carbon dioxide is 9000 mg/m^3 (0.5 vol. %) and this limit can be monitored by standardised methods, however these were not part of the submission. As a consequence, a data gap was identified for a monitoring method for the determination of the active substance in the air.

2. Mammalian toxicity

The datapackage on carbon dioxide was very limited. It consisted mainly of published studies of limited quality and most studies were only considered supplementary.

Carbon dioxide technical materials comply with the specifications set by CGA and EIGA including maximum contents for relevant impurities (see section 1). However, as carbon dioxide is applied at high rates up to 88 kg/m3, and in view of the application pattern, the amount of trace impurities in the technical material could reach significant levels, with possible concern for the exposure of consumers operators, workers and bystanders: a data gap was therefore set to address the issue.

Carbon dioxide is a gas. Principle route of exposure is by inhalation.

Carbon dioxide is transported via blood (as carbonate) or erythrocytes. Elimination is by exhalation or by excretion in urine.

Carbon dioxide may be non-lethal at 15 % (v/v) and lethal at 20 % (v/v) after 96 h continuous inhalation exposure to rats.

The database is not suitable either to establish reliable NOAECs, to set reference values or to adequately assess the hazard. The RMS proposed to use as a reference concentration, the available occupational limits for carbon dioxide. In principle, the use of an occupational limit might be adequate because of the representative uses as a plant protection product. However, the raw data used for their derivation are not available. An acceptable operator exposure concentration (**AOEC**) could not be set. As for consumer exposure, the acceptable daily intake (**ADI**) and acute reference dose (**ARfD**) could not be set because of the lack of toxicological data; however, due to the unlikelihood of significant residues of carbon dioxide ADI and ARfD were not needed.

With regard to the different methods of application mentioned in the table of representative uses (gas-tight silo unit without circulatory fumigation; Pex-pressure chamber; Bulk storage, granary; Carvex-pressure chamber), no **exposure** estimates were presented to support the lack of leakage after treatment or the possible release in the atmosphere of carbon dioxide once the systems are open. This is of particular concern for re-entry workers and bystanders representing a data gap.

In **conclusion**, the database is not suitable to set an AOEC or to support the occupational limits of carbon dioxide leading to a critical area of concern. No exposure estimates were provided. The operator, worker and bystander risk assessment can not be concluded.

3. Residues

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

Since carbon dioxide is a major compound involved in all the biological systems and the metabolic processes of living organisms, no MRLs were proposed to support the uses of carbon dioxide as a plant protection product on stored food commodities and a consumer dietary risk assessment was considered as not necessary. However, due to the high application rates of carbon dioxide and in view of the application pattern, the amount of trace impurities in the technical material may reach significant levels and a potential concern for the consumer exposure cannot be excluded. A data gap is set to address this issue.

4. Fate and behaviour

Carbon dioxide is representing the end point in mineralisation of organic substances. Therefore it is not subject to biological degradation. Since it is a gas, carbon dioxide used as a

fumigant will rapidly enter the atmosphere when vented and contribution to the naturally occurring carbon dioxide concentration will be negligible. Overall the route of dissipation is mainly by volatilisation. Testing for the biodegradability of carbon dioxide and testing for route and rate of degradation in soil or water is scientifically unjustified and therefore not relevant.

Because of the rapid dilution of carbon dioxide in adjacent air (inhomogeneous concentration on a spatial and temporal scale) it is not reasonable to calculate PEC-values for environmental compartments for the use of carbon dioxide in storage protection. It can be concluded that due to the high gradient in carbon dioxide concentration, when the fumigant is released to air finally, there will be a fast transport and dispersion of carbon dioxide in air preventing initial or time-weighted average concentrations that would be relevant with regard to ecotoxicological effects to the environment.

5. Ecotoxicology

No reliable toxicity studies on non-target organisms were available in this section. The acute toxicity studies on fish, aquatic invertebrates and algae are considered necessary to fulfil the Annex II data requirements, for formal reasons. Therefore, a data gap was identified.

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

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
Not applicable.	---	---

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
Not applicable	---	---	---	---	---

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Not applicable.	---

6.4. Air

Compound (name and/or code)	Toxicology
CO_2	Carbon dioxide may be non-lethal at 15 % (v/v) and lethal at 20 % (v/v) after 96 h continuous inhalation exposure to rats.

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).

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).

- Validated method for the determination of the active substance and the impurities in the technical material as manufactured (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Monitoring method for the determination of the active substance in the air. (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Hazard and exposure assessment (consumers and operators, workers and bystanders) of the trace impurities in the technical material that could reach significant levels due to the high and application rates of carbon dioxide and in view of the application pattern (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, see section 2-4).
- Exposure assessment for operators, workers and bystanders (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, see section 2).
- Studies to address the toxicological profile of carbon dioxide in order to set an AOEC or to support the occupational limits of carbon dioxide (relevant of all representative uses evaluated; submission date proposed by the applicant: unknown, see section 2).
- Measurements to support the lack of leakage after treatment or the possible release in the atmosphere of carbon dioxide once the systems are open (relevant of all representative uses evaluated; submission date proposed by the applicant: unknown, see section 2).
- Acute aquatic toxicity studies that are considered necessary to fulfil the Annex II requirements are needed (relevant for all representative uses evaluated; submission date proposed by the applicant: 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. The hazard and exposure assessment (consumers, operators, workers and bystanders) of the trace impurities in the technical material that could reach significant levels due to the high application rates of carbon dioxide and in view of the application pattern could not be finalised.

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.

2. The toxicological database is not suitable either to establish NOAECs, to set an AOEC, to support the occupational limit or to adequately assess the hazard. Therefore the risk assessment for operators, workers and bystanders cannot be concluded

9.3. Overview of the concerns identified 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		**Stored cereal grains**	**Storage products (except semolina, expeller, tobacco, stored cereal grains)**	**Stored cereal grains, fatty seeds**	**Medicinal plants, fatty seeds, stored cereal grains, cereal products, spices tobacco, tea, dried fruits**
Operator risk	Risk identified				
	Assessment not finalised	X[1,2]	X[1,2]	X[1,2]	X[1,2]
Worker risk	Risk identified				
	Assessment not finalised	X[1,2]	X[1,2]	X[1,2]	X[1,2]
Bystander risk	Risk identified				
	Assessment not finalised	X[1,2]	X[1,2]	X[1,2]	X[1,2]
Consumer risk	Risk identified				
	Assessment not finalised	X[1]	X[1]	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): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003.

REFERENCES

United Kingdom, 2008. Draft Assessment Report (DAR) on the active substance carbon dioxide prepared by the rapporteur Member State the United Kingdom in the framework of Directive 91/414/EEC, July 2008.

EFSA (European Food Safety Authority), 2012. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance carbon dioxide.

European Commission, 2008. Review Report for the active substance carbon dioxide 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 a.s. in Annex I of Directive 91/414/EEC. SANCO/2987/08 - rev. 1

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.

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) ‡	Carbon dioxide (no ISO common name allocated)
Function (*e.g.* fungicide)	Insecticide, acaricide

Rapporteur Member State	The United Kingdom
Co-rapporteur Member State	Germany

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	carbon dioxide
Chemical name (CA) ‡	carbon dioxide
CIPAC No ‡	844
CAS No ‡	124–38-9
EC No (EINECS or ELINCS) ‡	204–696-9
FAO Specification (including year of publication) ‡	none
Minimum purity of the active substance as manufactured ‡	999 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Covered by the CGA/EIGA specification: phosphane max. 0.3 ppm v/v benzene max. 0.02 ppm v/v carbon monoxide max. 10 ppm v/v methanol max. 10 ppm v/v hydrogen cyanide max. 0.5 ppm v/v
Molecular formula ‡	CO_2
Molecular mass ‡	44.01 g/mol
Structural formula ‡	O=C=O

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	-56.6 °C at a pressure of 518500 Pa (literature)
Boiling point (state purity) ‡	-78.5 °C sublimation (literature)
Temperature of decomposition (state purity)	2000 °C (literature)
Appearance (state purity) ‡	Colourless gas (literature)
Vapour pressure (state temperature, state purity) ‡	3600 kPa at 275 K (literature) 6710 kPa at 300 K (literature)
Henry's law constant ‡	Not applicable
Solubility in water (state temperature, state purity and pH) ‡	1 L CO_2 in 1 L water (literature)
Solubility in organic solvents ‡ (state temperature, state purity)	Not applicable
Surface tension ‡ (state concentration and temperature, state purity)	Not applicable
Partition co-efficient ‡ (state temperature, pH and purity)	Not applicable
Dissociation constant (state purity) ‡	Weak acidic (literature)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Not applicable
Flammability ‡ (state purity)	Not highly flammable (material safety data sheet) No auto ignition temperature (material safety data sheet)
Explosive properties ‡ (state purity)	None (material safety data sheet)
Oxidising properties ‡ (state purity)	None (material safety data sheet)

Summary of representative uses evaluated (*carbon dioxide*)*

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	min - max (l)		
stored cereal grains	DE	Aligal 2	I	insects	GA	99.9 %	fumigation (gas-tight silo unit without circulatory fumigation)	n. a.	1	n. a.	n. a.	n. a.	10 -30 kg/t	n. a.	(20 °C, 25 d) sufficient gas concentration of 70 % CO_2 above the cereal grains inside the top of silo
storage products (except semolina, expeller, tabacco, stored cereal grains)	DE	Aligal 2	I	insects, mites	GA	99.9 %	fumigation (Pex-pressure chamber)	n. a.	max 5	n. a.	n. a.	n. a.	22 – 66 kg/m³	n. a.	22 kg/m³ (10 bar, 8 h), 44 kg/m³ (20 bar, 3 h): 66 kg/m³ (30 bar, 90 min)

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	min - max (l)		
stored cereal grains, fatty seeds	DE	Aligal 2	I	insects, mites	GA	99.9 %	fumigation (bulk storage, granary)	n. a.	1	n. a.	n. a.	n. a.	60 – 80 %	n. a.	5 – 15 °C (6 weeks), 15 – 20 °C (4 weeks), 20 – 23 °C (3 weeks), 23 –25 °C (2 weeks), 25 – 30 °C (1 week), 30 – 35 °C (4 d) For satisfactory efficacy: • Filling high: not higher than 10 m • Sufficient gas concentration of 80 % CO_2 above the bulk storage commodities
medicinal plants, fatty seeds, stored cereal grains,	DE	Carbo Kohlen-säure	I	insects, mites	GA	99.9 %	fumigation (Carvex-pressure chamber)	n. a.	max 5	n. a.	n. a.	n. a.	66 – 88 kg/m³	n. a.	66 kg/m³ (30 bar, 60 min), 44 kg/m³ (20 bar (3 h), 88 kg/m³ (37 bar, 30 min)

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
(a)			(b)	(c)	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	min - max (l)	(m)	
cereal products, spices, tobacco, tea, dried fruits															

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(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)	ISBT standard methods Data gap
Impurities in technical as (analytical technique)	ISBT standard methods Data gap
Plant protection product (analytical technique)	ISBT standard methods Data gap

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Not necessary
Food of animal origin		Not necessary
Soil		Not necessary
Water	surface	Not necessary
	drinking/ground	Not necessary
Air		Carbon dioxide

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not necessary
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not necessary
Soil (analytical technique and LOQ)	Not necessary
Water (analytical technique and LOQ)	Not necessary
Air (analytical technique and LOQ)	Data gap
Body fluids and tissues (analytical technique and LOQ)	Not necessary

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

	RMS/peer review proposal
Active substance	none

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

Rate and extent of oral absorption ‡ Distribution ‡ Potential for accumulation ‡ Rate and extent of excretion ‡	Carbon dioxide is transported via blood (as carbonate) or erythrocytes. Elimination by exhalation or by excretion in urine.
Metabolism in animals ‡	None (carbon dioxide is the end product of mammalian catabolism)
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound

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 ‡	(1) Limited information available.	
Skin irritation ‡	(1) No data available	
Eye irritation ‡	(1) No data available	
Skin sensitisation ‡	(1) No data available	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	(1) Limited information available.	
Relevant oral NOAEL ‡	No data available; not needed.	
Relevant dermal NOAEL ‡	No data available; not needed.	
Relevant inhalation NOAEL ‡	(1) Limited information available.	

Genotoxicity ‡ (Annex IIA, point 5.4)

(1) No data available	

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

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

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	(1) Limited information available.	
Relevant parental NOAEL ‡	-	

Relevant reproductive NOAEL ‡	-	
Relevant offspring NOAEL ‡	-	

Developmental toxicity

Developmental target / critical effect ‡	(1) Limited information available.	
Relevant maternal NOAEL ‡	-	
Relevant developmental NOAEL ‡	-	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	(1) No data available	
Repeated neurotoxicity ‡	(1) No data available	
Delayed neurotoxicity ‡	(1) No data available	

Other toxicological studies (Annex IIA, point 5.8)

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

Medical data ‡ (Annex IIA, point 5.9)

(1) Limited information available.

Summary (Annex IIA, point 5.10)

	Value	Study	Uncertainty factor
ADI ‡	Not necessary, not allocated		
AOEC ‡	(1) Limited information available.		
ARfD ‡	Not necessary, not allocated		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Default value of 100 % in the absence of data.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	(1) Risk assessment cannot be concluded.
Workers	
Bystanders	

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

	peer review proposal
Carbon dioxide	(1) Limited information available to conclude.

(1) Limited information or no data are available. A general data gap has been established in the section on mammalian toxicology to provide studies to address the toxicological profile of carbon dioxide in order to set an AOEC or to support the occupational limits of carbon dioxide .

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

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

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

Animals covered	No data 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)

No data required

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

Not applicable

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):	N/A	N/A	N/A
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	N/A	N/A	N/A
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Muscle	N/A	N/A	N/A
Liver	N/A	N/A	N/A
Kidney	N/A	N/A	N/A
Fat	N/A	N/A	N/A
Milk	N/A		
Eggs		N/A	

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)
Residue trials to determine the residue levels of carbon dioxide not required.						

(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 data gap was set to address the consumer exposure assessment with regard to the trace impurities in the technical material that may reach significant levels due to the high application rates of carbon dioxide and in view of the application pattern. This issue could not be finalised.

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	
Not applicable				

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

Not applicable	Not required.

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

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

Mineralisation after 100 days ‡	No data. Not required (not scientifically justified).
Non-extractable residues after 100 days ‡	No data. Not required.
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Not applicable.

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

Anaerobic degradation ‡

Mineralisation after 100 days	No data. Not required (not scientifically justified).
Non-extractable residues after 100 days	No data. Not required.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable.

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not applicable

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

Laboratory studies ‡

No data. Not applicable.

Field studies ‡

No data. Not applicable.

pH dependence ‡ (yes / no) (if yes type of dependence)	Not applicable
Soil accumulation and plateau concentration ‡	Not applicable

Laboratory studies ‡

Parent	Anaerobic conditions
	No data. Not required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

No study is available for carbon dioxide. Due to structural reasons the adsorption to soils will be very low. Using PCKOWIN 1.66, Koc = 1.5 was calculated by RMS.

Parent ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
—	—						
—	—						
Arithmetic mean/median							
pH dependence, Yes or No							

Metabolite 1 ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (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)

No data available; no study required.

Column leaching ‡	No data available; no study required.
Aged residues leaching ‡	No data available; no study required.
Lysimeter/ field leaching studies ‡	No data available; no study required.

PEC (soil) (Annex IIIA, point 9.1.3)

Due to the limited spatial and temporal exposure no PEC has been quantified.

Parent Method of calculation	Not relevant
Application data	Not performed

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		—			
Short term	24 h	—			
	2 d	—			
	4 d	—			
Long term	7 d	—			
	28 d	—			
	50 d	—			
	100 d	—			
Plateau concentration		—			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Not data. Not applicable.
Photolytic degradation of active substance and metabolites above 10 % ‡	Not data. Not applicable.
Quantum yield of direct phototransformation in water at λ > 290 nm	Not data. Not applicable.

Readily biodegradable ‡ (yes/no)	No data submitted. Testing for the ready biodegradability of carbon dioxide is scientifically unjustified and therefore not applicable.

Degradation in water / sediment

No data submitted. Not required.

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

Due to the limited spatial and temporal exposure no PEC has been quantified.

Parent Parameters used in $FOCUS_{sw}$ step 1 and 2	Not relevant.
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	Not performed.
Application rate	Not relevant.

Metabolite X Parameters used in $FOCUS_{sw}$ step 1 and 2	Not applicable.
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	Not performed.
Application rate	Not relevant.
Main routes of entry	—

PEC ground water (Annex IIIA, point 9.2.1)

Due to the limited spatial and temporal exposure no PEC has been quantified.

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

PEC_{gw} - FOCUS modelling results (80^{th} percentile annual average concentration at 1 m)

Due to the limited spatial and temporal exposure no PEC has been quantified.

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not applicable.
Photochemical oxidative degradation in air ‡	Not applicable.
Volatilisation ‡	Not applicable.
	Not applicable.
Metabolites	Not applicable.

PEC_{air}

Due to the limited spatial and temporal exposure no PEC has been quantified.

Method of calculation	Not relevant.

$PEC_{(a)}$

Maximum concentration	Not relevant because of the rapid dilution of carbon dioxide in adjacent air (inhomogeneous concentration on a spatial and temporal scale)

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: not applicable Surface Water: not applicable Sediment: not applicable Ground water: not applicable Air: CO_2

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

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

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

No classification required

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/day)	Endpoint (mg/kg feed)
Birds ‡				
No data. Not required.*				
Mammals ‡				
Not required.*				
Additional higher tier studies ‡				
Not required				

*: Due to nature of carbon dioxide and the proposed use in gas-tight silos, pressure chambers and shallow storages does not cause any relevant elevation of carbon dioxide concentration in air.

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

Not required.

Crop and application rate

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
	Acute	—		10
	Short-term	—		10
	Long-term	—		5
Higher tier refinement (Birds)				
	Acute	—		10
	Short-term	—		10
	Long-term	—		5
Tier 1 (Mammals)				
	Acute	—		10
	Long-term	—		5
Higher tier refinement (Mammals)				
	Acute	—		10
	Long-term	—		5

[1] in higher tier refinement provide brief details of any refinements used (e.g. residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

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)	Endpoint	Toxicity (mg/L)

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity (mg/L)
Laboratory tests ‡				
Fish				
No reliable data available. Data gap				
Aquatic invertebrate				
No reliable data available. Data gap				
Sediment dwelling organisms				
Not required.				
Algae				
No data available. Data gap				
Higher plant				
Not required.				
Microcosm or mesocosm tests				
Not required.				

The proposed use in gas-tight silos, pressure chambers and shallow storages does not cause any relevant elevation of carbon dioxide in aquatic system. Some summaries from published studies may give complementary information but will not be used in risk assessment.

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

FOCUS Step1

Not required.

The proposed use in gas-tight silos, pressure chambers and shallow storages does not cause any relevant elevation of carbon dioxide in aquatic system.

Crop and application rate

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger[1]
as	Fish	—	Acute				100
as	Fish	—	Chronic				10
as	Aquatic invertebrates	—	Acute				100
as	Aquatic invertebrates	—	Chronic				10
as	Algae	—	Chronic				10
as	Higher plants[2]	—	Chronic				10
as	Sediment-dwelling[3] organisms	—	Chronic				10
Metabolites	Relevant organisms	—					
Product	Relevant organisms	—					

[1] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[2] only required for herbicides
[3] consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

FOCUS Step 2

Not required.

State crop, application rate and growth stage, Northern Europe or Southern Europe

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger[4]
as		Fish	—	Acute			100
as		Fish	—	Chronic			10
as		Aquatic invertebrates	—	Acute			100
as		Aquatic invertebrates	—	Chronic			10
as		Algae	—	Chronic			10
as		Higher plants[5]	—	Chronic			10
as		Sediment-dwelling organisms[6]	—	Chronic			10
Metabolites		Relevant organisms	—				
Product		Relevant organisms	—				

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used.
[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[5] only required for herbicides
[6] consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Not required.

State crop and application rate

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (mg/L)	PEC[4]	TER	Annex VI trigger[5]
as					—			
Metabolites					—			
Product					—			
					—			
					—			

[1] drainage (D1 - D6) and run-off (R1 - R4)

[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

FOCUS Step 4

Not required.

Crop and application rate

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
				—				
				—				
				—				
				—				

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 3.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Bioconcentration

No validated data. Not required (not scientifically justified)	Active substance	Metabolite1	Metabolite2	Metabolite3
log $P_{O/W}$	—	Not applicable.		
Bioconcentration factor (BCF)[1] ‡	X*			
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	—			

[1] only required if log $P_{O/W}$ > 3.
* based on total ^{14}C or on specific compounds

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)
Not required.*		
Field or semi-field tests		

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Not required.		

*: Due to nature of carbon dioxide and the proposed use in gas-tight silos, pressure chambers and shallow storages does not cause any relevant elevation of carbon dioxide concentration in air.

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

Not required.

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
as	Contact	—	50
as	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	Endpoint	Effect (LR_{50} g/ha[1])
Not required.*			

*: Due to nature of carbon dioxide and the proposed use in gas-tight silos, pressure chambers and shallow storages does not cause any relevant elevation of carbon dioxide concentration in air.

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
	Typhlodromus pyri	—			2
	Aphidius rhopalosiphi	—			2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	Endpoint	% effect	Trigger value
Not required.*						

*: Due to nature of carbon dioxide and the proposed use in gas-tight silos, pressure chambers and shallow storages does not cause any relevant elevation of carbon dioxide concentration in air.

Field or semi-field tests
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	Endpoint[1]
Earthworms			
Not required.*			
Other soil macro-organisms			
Not required.			
Soil micro-organisms No validated data. Not required* Not required (no exposure)			
Field studies[2]			
Not required.			

[1] indicate where endpoint has been corrected due to log $P_{o/w}$ > 2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above and earthworm field studies
*: Due to nature of carbon dioxide and the proposed use in gas-tight silos, pressure chambers and shallow storages does not cause any relevant elevation of carbon dioxide concentration in the soil system.

Toxicity/exposure ratios for soil organisms

Not required.

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Not required.					
Other soil macro-organisms					
Soil mite					
Not required.					
Collembola					
Not required.					

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

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

Preliminary screening data

Not required.*

Laboratory dose response tests

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

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of as or preparation

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

Not required.

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

No validated data. Not required.	

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

Compartment	
soil	None
water	None
sediment	None
groundwater	None

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

	RMS/peer review proposal
Preparation	No classification required.*

Code/Trivial name	Chemical name	Structural formula
Carbon dioxide	Carbon dioxide	CO_2

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
---		

* The metabolite name in bold is the name used in the conclusion.

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
AOEC	acceptable operator exposure concentration
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram

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

NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
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
REACH	Registration, Evaluation, Authorisation of CHemicals
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