CONCLUSION ON PESTICIDE PEER REVIEW

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

European Food Safety Authority[2]

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SUMMARY

Hydrolysed proteins 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].

Hydrolysed proteins was included in Annex I to Directive 91/414/EEC on 18 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[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.

Greece being the designated rapporteur Member State submitted the DAR on hydrolysed proteins in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 24 April 2008. The peer review was initiated on 31 July 2008 by dispatching the DAR for consultation of the notifiers (BIOIBERICA, S.A.; PHYTOPYL – N.G. STAVRAKIS; SICIT 2000 S.p.A.). The commenting period with Member States was launched on 16 December 2010. 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 hydrolysed proteins. The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of hydrolysed proteins as an insect attractant on deciduous fruit trees and walnut, olive, citrus, kiwi and blueberries, as proposed by the notifiers. Full details of the representative uses can be found in Appendix A to this report.

[1] On request from the European Commission, Question No EFSA-Q-2009-00283, approved 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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For the section identity, physical/chemical/technical properties and methods of analysis specifications and Annex II data packages were not available for these compounds. Several data gaps were identified for the formulated products.

Hydrolysed proteins *per se* are likely to be of low toxicological concern and no risks to human health could be expected from the use as a plant protection product. However due to the fact that a specification to include the main components in the active substance is still outstanding, a final conclusion cannot be drawn whether the technical specification is of toxicological concern and whether data waivers can be accepted and reference values are needed; therefore, a data gap and issues that cannot be finalised were identified.

According to the representative uses, it is not excluded that the edible parts of the treated crops and/or their by-products destined for animal consumption will be in contact with the hydrolysed proteins from their use as an “insect attractant”. Nevertheless, these active substances are likely to be of low toxicity and a quantitative consumer risk assessment can be waived unless the required technical specification (see section 1) raises a toxicological concern. A data gap may be required to reconsider the consumer risk assessment through dietary intake and drinking water pending the outcome of the outstanding data on the specification and on the groundwater exposure assessment.

Information to complete an adequate environmental exposure assessment is not available. The environmental exposure assessment could not be finalised.

No toxicity studies for non-target organisms were submitted in the section ecotoxicology. Studies on aquatic organisms that are necessary to fulfil the Annex II requirements are identified as a data gap. The specification of the active substances is outstanding and the environmental exposure assessments could not be finalised. Pending on the outcome of these issues, in particular, whether the exposure to the environment arising from the representative uses will be greater than the natural background level, the risk assessment for all non-target organisms, with the exception of those involved in biological methods for sewage treatment plants needs to be addressed. a data gap was identified.

KEY WORDS

Hydrolysed proteins, peer review, risk assessment, pesticide, attractant.

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BACKGROUND

Hydrolysed proteins 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].

Hydrolysed proteins was included in Annex I to Directive 91/414/EEC on 18 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[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.

Greece being the designated rapporteur Member State submitted the DAR on hydrolysed proteins in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 24 April 2008 (Greece, 2008). The peer review was initiated on 31 July 2008 by dispatching the DAR for consultation of the notifiers (BIOIBERICA, S.A.; PHYTOPYL – N.G. STAVRAKIS; SICIT 2000 S.p.A.). The commenting period with Member States was launched on 16 December 2010. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifiers were invited to respond to the comments in column 3 of the Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 5 April 2011. On the basis of the comments received and the RMS' 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 the additional information to be submitted by the notifiers, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, 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 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 an insect attractant on deciduous fruit trees and walnut, olive, citrus, kiwi and blueberries, as proposed by the notifiers. 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

[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

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 (25 March 2011)
- the Evaluation Table (14 December 2011)
- the comments received on the draft EFSA conclusion.

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

The representative formulated products for this evaluation were 'BIOCEBO', 'DACONA' and 'NUTREL' all of which are soluble concentrates (SL), they are reported to contain between 297 and 360 g/kg hydrolysed proteins.

The representative uses evaluated comprise outdoor foliar spraying on olive trees, fruit trees, walnut, citrus, fig, kiwi and blueberries. 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

A specification for these compounds should be developed and supported by batch analysis and validated methods of analysis.

No information was given on the level of microbial contamination and the mechanism for the control of such contamination and its possible increase on storage.

An Annex II data package of physchem properties was not available for these compounds.

For the formulations the following data gaps were identified:-

'BIOCEBO': dilution stability, storage stability, low temperature stability,

'DACONA': low temperature stability, storage stability, explosive and oxidising properties and flammability.

'NUTREL', storage stability, persistent foam,

A method of analysis was identified as a data gap for all the formulations.

The requirement for methods of analysis for residues was waived as no residue definitions were proposed due to the nature of these compounds.

2. Mammalian toxicity

Hydrolysed proteins *per se* are derived by the hydrolysis of tissues from organisms that can be of plant or animal origin. Although the information provided by the applicants is very limited, hydrolysed proteins *per se* are likely to be of low toxicological concern provided hydrolysed proteins of animal origin are pathogen-free and hydrolysed proteins from plant origin do not have sensitisation potential. On this basis no risks to human health could be expected from its use as a plant protection product and data waivers for specific toxicological studies were initially supported. However, due to the fact that a specification to include the main components in the active substances is still outstanding (see section 1), a final conclusion cannot be drawn whether the technical specification is of toxicological concern and whether data waivers can be accepted and reference values are needed, as well as the operator, worker and bystander risk assessment could not be finalised.

3. Residues

According to the representative uses, it is not excluded that the edible parts of the treated crops and/or their by-products destined for animal consumption will be in contact with the hydrolysed proteins from their use as an "insect attractant". Nevertheless, these active substances are likely to be of low toxicity and a quantitative consumer risk assessment can be waived unless the required technical specification (see section 1) raises a toxicological concern. A data gap may be required to reconsider the consumer risk assessment through dietary intake and drinking water pending the outcome of the outstanding data on the specification and on the groundwater exposure assessment.

4. Environmental fate and behaviour

The section of the dossier on environmental fate and behaviour is completely empty. A specification to include the main components in the active substances is outstanding. Consequently 4 data gaps (regarding ready biodegradability; volatilisation potential and potential for long-range atmospheric transport; quantification of the amounts that are being added to the environmental compartments soil and natural surface water systems and finally potential for groundwater exposure), are identified in section 7 of this conclusion for the components in the active substances, once these have been adequately characterised. These data gaps lead to the environmental assessments being not finalised.

5. Ecotoxicology

Toxicity studies for non-target organisms were not submitted. At least toxicity studies for aquatic organisms are required according to the Annex to Commission Regulation (EU) No 544/2011 and therefore, a data gap was identified.

The specification of the active substances is outstanding and the environmental exposure assessments could not be finalised (see section 1 and 4). Furthermore, it was not possible to exclude the exposure for the other non-target organisms (i.e. birds and mammals, aquatic organisms, bees, non-target arthropods, non-target soil organisms, non-target plants) for the representative spray uses. Pending on the outcome of these issues, in particular, whether the exposure to the environment arising from the representative uses will be greater than the natural background level, the risk assessment for all non-target organisms needs to be addressed.

The exposure to sewage treatment plants was considered unlikely for the representative uses.

The risk assessment for non-target organisms cannot be finalised, with the exception of those involved in the biological processes in sewage treatment plants.

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
animal tissue hydrolysate	Data gap	Data gap for addressing the risk to soil-dwelling organisms once the specification and the environmental exposure will be finalised.
beet molasses-urea hydrolysate	Data gap	Data gap for addressing the risk to soil-dwelling organisms, once the specification and the environmental exposure will be finalised.
collagen protein hydrolysate	Data gap	Data gap for addressing the risk to soil-dwelling organisms, once the specification and the environmental exposure will be finalised.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
animal tissue hydrolysate	Data gap	Not relevant for an attractant[(a)], a groundwater exposure assessment is not available, there is a data gap	Data gap.	Data gap	Data gap to address the risk to aquatic organisms..

beet molasses-urea hydrolysate	Data gap	Not relevant for an attractant[(a)], a groundwater exposure assessment is not available, there is a data gap	Data gap	Data gap	Data gap to address the risk to aquatic organisms.
collagen protein hydrolysate	Data gap	Not relevant for an attractant[(a)], a groundwater exposure assessment is not available, there is a data gap	Data gap	Data gap	Data gap to address the risk to aquatic organisms.

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

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
animal tissue hydrolysate	Data gap to address the risk to aquatic organisms.
beet molasses-urea hydrolysate	Data gap to address the risk to aquatic organisms.
collagen protein hydrolysate	Data gap to address the risk to aquatic organisms.

6.4. Air

Compound (name and/or code)	**Toxicology**
animal tissue hydrolysate	Data gap

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

beet molasses-urea hydrolysate	Data gap
collagen protein hydrolysate	Data gap

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).

- For all sources a specification should be developed and supported with batch data and validated methods of analysis and an Annex II physchem data package (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Dilution stability, storage stability and low temperature stability (relevant for all BIOCEBO representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Storage stability, low temperature stability, explosive and oxidising properties, flammability (relevant for all DACONA representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Storage stability, persistent foam (relevant for all NUTREL representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Specific methods of analysis for the technical materials and formulated products (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Due to sensitisation potential an official certificate for the non-use of genetically modified starting material should be provided for hydrolysed proteins used in DACONA (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).

- A specification to include the main components present in the active substances is outstanding (see data gap above). Once these main components are known, information to address their toxicological potential should be made available (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2).

- A specification to include the main components present in the active substances is outstanding (see data gap above). Information to address their ready biodegradability should be made available (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)

- A specification to include the main components present in the active substances is outstanding (see data gap above). Once these main components are known, information to address their volatilisation potential and potential for long range atmospheric transport should be made available (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)

- A specification to include the main components present in the active substances is outstanding (see data gap above). Once these main components are known, information (calculations) to address the levels of these components as a consequence of them being added to the environment should be made available. Consequently these levels either need to be compared to natural levels present in soil, surface water and sediment, or to effects data on organisms that inhabit these environmental compartments (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)

- A specification to include the main components present in the active substances is outstanding (see data gap above). Once these main components are known, information to address their potential to contaminate groundwater should be made available if their concentrations will be

above natural levels present in soil. If the components may contaminate groundwater, then a consumer risk assessment from the consumption of drinking water and aquatic risk assessment to cover the situations where groundwater becomes surface water will be necessary (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)

- Studies on aquatic organisms that are necessary to fulfil the Annex II requirements directly related to classification and labelling (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

- A specification to include the main components present in the active substances is outstanding (see data gap above) and the environmental exposure assessments could not be finalised (see data gap above). Pending on the outcome these issues, in particular, whether the exposure to environment arising from the representative uses will be greater than the natural background level, the risk assessment for all non-target organisms needs to be addressed, with the exception of organisms involved in the biological methods utilised in sewage treatment plants (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. As the specification to include the main components in the active substances is still outstanding a final conclusion cannot be drawn whether the technical specification is of toxicological concern and data waivers can be supported and reference values are needed, as well as the operator, worker ,bystander and consumer risk assessment could not be finalised.

2. The environmental exposure assessments to soil, surface water, aquatic sediment and groundwater could not be finalised. Consequently risk assessments to non-target organisms, with the exception of organisms involved in the biological methods utilised in sewage treatment plants, 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.

- none

9.3. Overview of the concerns for each representative use considered

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

In addition to the indications given for each use within the table, all columns are grey as technical material specifications are not available.

Representative use		Deciduous fruit trees & walnuts	Olive	Citrus	Kiwi	Blueberries
Operator risk	Risk identified					
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]
Worker risk	Risk identified					
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]
Bystander risk	Risk identified					
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]
Consumer risk	Risk identified					
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]
Risk to wild non target terrestrial vertebrates	Risk identified					
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]
Risk to aquatic organisms	Risk identified					
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]
Groundwater exposure active substance	Legal parametric value breached					
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]
Groundwater exposure metabolites	Legal parametric value breached					
	Parametric value of 10µg/L[(a)] breached					
	Assessment not finalised	X[2]	X[2]	X[2]	X[2]	X[2]

The superscript numbers in this table relate to the numbered points indicated in section 9.1 and 9.2

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

REFERENCES

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

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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.

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) ‡	**Animal tissue Hydrolysate (under the general term Hydrolysed Protein)**	**Beet molasses-Urea Hydrolysate (under the general term Hydrolysed Protein)**	**Collagen Protein Hydrolysate (under the general term Hydrolysed Protein)**
Function (*e.g.* fungicide)	Insect attractant	Insect attractant	Insect attractant
Rapporteur Member State	Greece	Greece	Greece

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Not applicable.	Not applicable.	Not applicable.
Chemical name (CA) ‡	Not applicable.	Not applicable.	Not applicable.
CIPAC No ‡	901	901	901
CAS No ‡	Not applicable.	Not applicable.	Not applicable.
EC No (EINECS or ELINCS) ‡	Not applicable.	Not applicable.	Not applicable.
FAO Specification (including year of publication) ‡	None.	None.	None.
Minimum purity of the active substance as manufactured ‡	Open	Open	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None.	None.	None.
Molecular formula ‡	Not applicable.	Not applicable.	Not applicable.
Molecular mass ‡	Not applicable.	Not applicable.	Not applicable.
Structural formula ‡	Not applicable.	Not applicable.	Not applicable.

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

	Animal tissue Hydrolysate (under the general term Hydrolysed Protein)	Beet molasses-Urea Hydrolysate (under the general term Hydrolysed Protein)	Collagen Protein Hydrolysate (under the general term Hydrolysed Protein)
Melting point (state purity) ‡			
Boiling point (state purity) ‡			
Temperature of decomposition (state purity)			
Appearance (state purity) ‡			
Vapour pressure (state temperature, state purity) ‡			
Henry's law constant ‡			
Solubility in water (state temperature, state purity and pH) ‡			
Solubility in organic solvents ‡ (state temperature, state purity)			
Surface tension ‡ (state concentration and temperature, state purity)			
Partition co-efficient ‡ (state temperature, pH and purity)			
Dissociation constant (state purity) ‡			
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)			
Flammability ‡ (state purity)			

Explosive properties ‡ (state purity)			
Oxidising properties ‡ (state purity)			

Summary of representative uses evaluated (*hydrolysed protein*)

Crop and/ or situation (a)	Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min-max	kg as/ha min max		
Deciduous Fruit trees Citrus Olive trees	SPAIN	BIOCEBO	F	Diptera **insects *Ceratitis capitata, Rhagoletis cerasi, Bactrocera oleae* and others.**	SL	300 g/l	Spraying	NR	Depends on the insecticide to be mixed with the attractant.	Depends on the insecticide to be mixed with the attractant.	0.45	no information provided.	no information provided.	Depends on the insecticide to be mixed with the attractant	
Olive trees	Spain	DACONA	F	***Bactrocera oleae***	SL	360 gr/kg	Spot bait sprays By Low volume sprays	Fruit, depends on the insecticide used	3-5	Depends on the insecticide used	0.958	30	0,287	Depends on the insecticide used	
Fruit trees	Spain	DACONA	F	***Ceratitis capitata***	SL	360 gr/kg	Spot bait sprays By Low volume sprays	Fruit, depends on the insecticide used	3-5	Depends on the insecticide used	0.958	30	0,287	Depends on the insecticide used	

Crop and/ or situation	Country	Product name	F G	Pests or Group of	Formulation	Application	Application rate per	PHI (days)	Remarks:

(a)			or I (b)	pests controlled (c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	treatment kg as/hL min max	treatment water L/ha minmax	treatment kg as/ha min max	(l)	(m)
Olive trees Pome fruits Stone fruits Walnut Citrus spp Fig Kiwi Blueberries	Italy, Spain, Greece, Portugal, France	NUTREL	F	Adult insects (Diptera) laying eggs on fruits	SL (n)	297 g/l	Normal volume spraying, / high pressure	7 (o)	2 - 4	10 - 30	0.3-0.5	100-200	0.3 – 1.0	Depends on the insecticide used	

Remarks: (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicate
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4); including where relevant, information on season at the time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use / economic importance / restrictions

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Methods of Analysis

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

	Animal tissue Hydrolysate (under the general term Hydrolysed Protein)	**Beet molasses-Urea Hydrolysate (under the general term Hydrolysed Protein)**	**Collagen Protein Hydrolysate (under the general term Hydrolysed Protein)**
Technical as (analytical technique)	Open	Open	Open
Impurities in technical as (analytical technique)	Open	Open	Open
Plant protection product (analytical technique)	Open	Open	Open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		No residue definition.
Food of animal origin		No residue definition.
Soil		No residue definition.
Water	surface	No residue definition.
	drinking/ground	No residue definition.
Air		No residue definition.

Analytical methods for residues (Annex IIA, point 4.2)

	Animal tissue Hydrolysate (under the general term Hydrolysed Protein)	**Beet molasses-Urea Hydrolysate (under the general term Hydrolysed Protein)**	**Collagen Protein Hydrolysate (under the general term Hydrolysed Protein)**
Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	It was stated that: "Not only the hydrolysed proteins, but also the metabolites (peptides, amino acids) coming from the biodegradation are compounds that can	Due to the nature of the active substance no analytical method is required.	See other justifications

	be found in animal and vegetal tissues. Therefore, if any analysis of residues is performed, the part that has been artificially incorporated could not be distinguished from the natural one, and then, this kind of analysis is not necessary and useful at all".		
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required. See justification above.	Not required. See justification above.	See other justifications
Soil (principle of method and LOQ)	Not required. See justification above.	Not required. See justification above.	. See other justifications
Water (principle of method and LOQ)	Not required. See justification above.	Not required. See justification above.	See other justifications
Air (principle of method and LOQ)	Not required. See justification above.	Not required. See justification above.	See other justifications.
Body fluids and tissues (principle of method and LOQ)	As "Hydrolysed Protein" is not classified as toxic or highly toxic, no analytical method is required for its determination in body fluids and tissues.	Not required. See justification above.	See other justifications.

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

	RMS/peer review proposal
Active substance	RMS proposal: None

Impact on Human and Animal Health

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

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

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	Data available of limited validity.*
Rabbit LD_{50} dermal ‡	Data available of limited validity.*
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 ‡ Relevant oral NOAEL ‡ Relevant dermal NOAEL ‡ Relevant inhalation NOAEL ‡	No data available*.

Genotoxicity ‡ (Annex IIA, point 5.4)

	No data available*.

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

Target/critical effect ‡ Relevant NOAEL ‡ Carcinogenicity ‡	No data available*.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡ Relevant parental NOAEL ‡ Relevant reproductive NOAEL ‡ Relevant offspring NOAEL ‡	No data available*.

Developmental toxicity

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

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available*.

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available*.
Studies on metabolites	No data available*.
Studies on impurities	No data available*.

Medical data‡ (Annex IIA, point 5.9)

No data available*.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	No data available*.	-	-

AOEL ‡	No data available*	-	-
ARfD ‡	No data available*	-	-

Dermal absorption‡ (Annex IIIA, point 7.3)

No data available*

Exposure scenarios (Annex IIIA, point 7.2)

Operator	No data available*
Workers	No data available*
Bystanders	No data available*

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

	RMS/peer review proposal
Hydrolysed protein PHY, SIC, BIO	Data available of limited validity to conclude*.

*Hydrolysed proteins *per se* are considered of low toxicological concern and no risks to human health are expected from its use as a plant protection product. However due to the fact that a specification to include the main components in the active substances is still outstanding a final conclusion cannot be drawn whether the technical specification is of toxicological concern leading to a data gap and issue that cannot be finalized.

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

Plant groups covered	No study provided. Not required according to the representative uses(1).
Rotational crops	No study provided. Not required according to the representative uses(1).
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant.
Processed commodities	No study provided. Not required according to the representative uses(1).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant.
Plant residue definition for monitoring	Not required(1).
Plant residue definition for risk assessment	Not required(1).
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 study provided. Not required according to the representative uses(1).
Time needed to reach a plateau concentration in milk and eggs	Not relevant
Animal residue definition for monitoring	Not required(1).
Animal residue definition for risk assessment	Not required(1).
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Not relevant
Fat soluble residue: (yes/no)	Not relevant

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

Not relevant(1)

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

Not relevant(1)

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

No study provided. Not required according to the representative uses(1).

	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)	Not Required	Not Required	Not Required

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not Required	Not Required	Not Required
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices: Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

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

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
No study provided. Not required according to the representative uses[(1)].						

(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	No data available[1]
TMDI (% ADI) according to WHO European diet	Not required[1]
TMDI (% ADI) according to EFSA PRIMo Model rev.2A	Not required[1]
TMDI (% ADI) according to national (to be specified) diets	Not required[1]
IEDI (WHO European Diet) (% ADI)	Not required[1]
NEDI (specify diet) (% ADI)	Not required[1]
Factors included in IEDI and NEDI	None
ARfD	No data available[1]
IESTI (% ARfD) according to EFSA PRIMo Model rev.2A	Not required[1]
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required[1]
Factors included in IESTI and NESTI	None

[1]Hydrolysed proteins as a plant protection product is likely to be of low toxicity and a quantitative consumer risk assessment is not needed unless the required technical specification raises a toxicological concern (see section 1). A data gap may be required to reconsider the consumer risk assessment through dietary intake and drinking water pending the outcome of the outstanding data on the specification and on the groundwater exposure assessment.

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
No study provided. Not required according to the representative uses[1].				

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

No MRL is required [(1)]

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

Mineralization after 100 days ‡	No data submitted.
Non-extractable residues after 100 days ‡	No data submitted.
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No data submitted.

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

Anaerobic degradation ‡

Mineralization after 100 days	No data submitted.
Non-extractable residues after 100 days	No data submitted.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted.

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted.

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

Laboratory studies ‡

Hydrolysed Protein	Aerobic conditions: No data submitted.

Field studies ‡

Hydrolysed Protein	Aerobic conditions: No data submitted

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

Laboratory studies ‡

Hydrolysed Protein	Anaerobic conditions: No data submitted

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Hydrolysed Protein ‡: No data submitted

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

Column leaching ‡	No data submitted.
Aged residues leaching ‡	No data submitted.
	No data submitted.
Lysimeter/ field leaching studies ‡	No data submitted.

PEC (soil) (Annex IIIA, point 9.1.3)

Hydrolysed Protein	No data submitted.
Method of calculation	
Application data	-

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	No data submitted.
Photolytic degradation of active substance and metabolites above 10 % ‡	No data submitted.
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data submitted.
Readily biodegradable ‡ (yes/no)	Data gap

Degradation in water / sediment

Hydrolysed Protein	No data submitted

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

Hydrolysed Protein	No data submitted.
Parameters used in FOCUSsw step 1 and 2	
Parameters used in FOCUSsw step 3 (if performed)	-
Application rate	-

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	No data submitted.
Application rate	-

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

Direct photolysis in air ‡	No data submitted.
Quantum yield of direct phototransformation	No data submitted.
Photochemical oxidative degradation in air ‡	Data gap
Volatilisation ‡	No data submitted.
Metabolites	-

PEC (air)

Method of calculation	No data submitted.

$PEC_{(a)}$

Maximum concentration	-

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: animal tissue hydrolysate, beet molasses-urea hydrolysate, collagen protein hydrolysate Groundwater: animal tissue hydrolysate, beet molasses-urea hydrolysate, collagen protein hydrolysate Surface water/sediment: animal tissue hydrolysate, beet molasses-urea hydrolysate, collagen protein hydrolysate Air: animal tissue hydrolysate, beet molasses-urea hydrolysate, collagen protein hydrolysate

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

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

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

A data gap needs to be filled before a conclusion may be drawn.

Effects on Non-target Species

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

Acute toxicity to mammals	No data available[1]
Acute toxicity to birds	No data available[1]
Dietary toxicity to birds	No data available[1]
Reproductive toxicity to birds	No data available[1]
Reproductive/long term toxicity to mammals	No data available[1]

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

Exposure period	Crop, use pattern	Category (*e.g.*, insectivorous bird)	Toxicity endpoint	ETE [mg ai/kg bw/day]	TER	TER risk trigger (from Annex VI)
Acute						
Short-term						
Long-term						

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

Treatment	Species	Study Type	LC_{50} /EC_{50} [mg ai/L]	LC_0 /NOEC [mg ai/L]
Data gap.				

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

Organism	Test substance	Toxicity Endpoint	PEC (µg/L)	TER [a]	TER risk trigger value (from 91/414/EEC)

[1] Once components are known, and the environmental exposure can be finalised a risk assessment, should be provided to address the risk of hydrolysed proteins to non-target organisms, whenever the exposure to environment will be greater than the natural background level.

Bioconcentration

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

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

Acute oral toxicity	No data available[1]
Acute contact toxicity	No data available[1]

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

Test substance	Exposure route	Endpoint	Maximum single application rate	Hazard quotient	Annex VI trigger
Field or semi-field tests					

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

Test	Test species	Summary of design	Endpoints
No data available[1]			

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

Acute toxicity	No data available[1]
Chronic and reproductive toxicity	No data available[1]

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Test substance	Use pattern	Test type	Endpoint	PECs (µg/kg)	TER	Annex VI trigger

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

Nitrogen mineralization ‡	No data available[1]
Carbon mineralization ‡	No data available[1]

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
No data available[1]						

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

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

Test type/organism	end point
Activated sludge	No data available not required.
Pseudomonas sp	No data available not required.

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

Compartment	
soil	-
water	-
sediment	-
groundwater	-

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	

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
none		

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

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

NOEL	no observed effect level
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year