CONCLUSION ON PESTICIDE PEER REVIEW

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

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Fish oil 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].

Fish oil 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 fish oil in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 3 April 2008. The peer review was initiated on 31 July 2008 by dispatching the DAR for consultation of the notifier (Fluegel GmbH). 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 fish oil. The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fish oil as a game repellent in deciduous and coniferous forests and orchards, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis data gaps were identified for a specification and supporting data. Data gaps were also identified for further physical-

[1] On request from the European Commission, Question No EFSA-Q-2009-00280, adopted 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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chemical properties of the active substance and the formulation and a translation of some studies. A method of analysis is also required for the formulation.

No agreed technical specification is available and a data gap is identified in the mammalian toxicology section on the presence and maximum level of impurities and/or contaminants of potential toxicological concern; this issue could not be finalised.

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

Fish oil is a natural compound produced from fresh fish. Fate and behaviour of fish oil is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil.

The risk to non-target organisms is considered as low for the representative uses.

KEY WORDS

Fish oil, peer review, risk assessment, pesticide, repellent

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BACKGROUND

Fish oil 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].

Fish oil 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 fish oil in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 3 April 2008 (Greece, 2008). The peer review was initiated on 31 July 2008 by dispatching the DAR to the notifier Fluegel GmbH and on 16 December 2010 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notofoer 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 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 additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, were reported in the final column of the Evaluation Table.

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

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a game repellent in deciduous and coniferous forests and orchards, 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, 2011)

[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

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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.

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THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Fish oil is the given name for this active substance.

The representative formulated product for the evaluation was 'Morsuvin' a paste formulation containing 43 g/kg fish oil.

The representative uses evaluated are as a game repellent in deciduous and coniferous forests and orchards. 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 is not available for this material and a data gap for a specification with supporting batch data and analytical methods has been identified. Fish oil may contain environmental contaminants and the following maximum levels are set: 6 pg/g dioxins; 0.5 mg/kg for mercury; 2 mg/kg cadmium and lead 10 mg/kg, PCBs 5mg/kg and pesticides 10 mg/kg. The batch data are also needed to verify theses levels

The notifier stated that if the material is exposed to air during the manufacturing process undesirable chemicals can be formed. A data gap has been set for the notifier to identify these compounds.

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.

For the active material a data gap was identified to address melting point, boiling point, vapour pressure, surface tension, dissociation constant, partition co-efficient, flammability, auto-flammability explosive and oxidising properties.

The main data regarding the identity of fish oil and its physical and chemical properties are given in Appendix A.

For the formulation data gaps were identified to address shelf life, oxidising properties, explosive properties, flammability and auto-flammability. The notifier is also requested to submit a translation of the studies relevant to the emergency measures in case of an accident and of the studies relevant to the suitability of the packaging and closures. A method of analysis that can identify and at least semi-quantify the active material in the formulation is also identified as a data gap.

The need for residue analytical methods is waived due to the nature of this material.

2. Mammalian toxicity

A data gap and an issue that could not be finalised have been identified for the levels of impurities and/or contaminants of toxicological concern potentially present in the technical material since no technical specification has been agreed in section 1 on the identity of the active substance. Dioxin, mercury, cadmium, lead, PCBs and pesticides were identified as relevant impurities.

Fish oil does not have a toxic mode of action and does not present a toxicological concern by itself. It is used as feedstuffs obtained from fresh fish by-products not suitable for human consumption; based on its nature, all toxicological studies are waived and reference values are not required. No quantitative exposure and risk assessment was conducted for operators and workers, considering the risk, if any, to be negligible. No exposure is anticipated for bystanders.

3. Residues

Metabolism and residue studies were not considered relevant for evaluation due to the nature of the active substance and to the representative use. Fish oil will be used only as protection coating on the

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outside of trees in forestry or orchards. Crops destined for human and animal consumption are not intended to receive direct treatment. The risk for contamination of fruits is negligible since GAP defines that applications must be done between November and March when fruits are usually not present. Consumer risk assessments were not required due to 1) the unlikelihood of significant residues and 2) the low toxicological concern for fish oil.

4. Environmental fate and behaviour

Fish oil has been notified as mammal repellent for use on trees by application with brush onto the sprouts or on the entire plant.

Fish oil is a natural compound produced from fresh fish. The fate and behaviour of fish oil is expected to follow the normal pathways of dissipation and degradation common to naturally occurring residues of biological origin. The preparation Morsuvin contains 43.0 g/kg fish oil and it is a game repellent which will be used only as a protection coat on the outside of the plants. No soil contamination is expected to occur during a proper application. The preparation dries within two hours and forms a protective coating on leaves and needles. The dried preparation is not water soluble. Based on the nature of the ingredients and the formulation it is unlikely that residues of the preparation would be detected in air.

5. Ecotoxicology

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

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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 assessed Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil.	Not assessed	-

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 assessed Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil.	Not assessed	Not relevant (a)	-	No	-

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(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 a repellent, denatonium benzoate is 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. A toxicological based groundwater limit may however be appropriate.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Not assessed Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil.	-

6.4. Air

Compound (name and/or code)	**Toxicology**
Not assessed Considering the nature of the substance and the limited usage a definition of residue in the environment for risk assessment is deemed to be unnecessary for fish oil.	Study waived based on the low toxicological concern of the active substance

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

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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).

- A specification for fish oil should be developed and this should be supported by appropriate 5 batch analysis with validated methods of analysis (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Notifier to identify which undesirable chemicals can be formed when fish oil is exposed to the air (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Information or data to address the following melting point, boiling point, vapour pressure, surface tension, dissociation constant, partition coefficient, flammability, auto-flammability explosive and oxidising properties of the active (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Shelf life study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Information or data to address the following oxidising and explosive properties, flammability and auto-flammability of the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Notifier to submit a translation of the studies relevant to the emergency measures in case of an accident and of the studies relevant to the suitability of the packaging and closures (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Method of analysis for the formulation that can identify and at least semi-quantify the “active substance” (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)
- Analysis and maximum levels of impurities and/or contaminants of toxicological concern have not been specified for the technical specification (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 2)

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).

- There is no technical specification and no analysis of the maximum levels of impurities and/or contaminants of toxicological concern.

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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.

9.3. Overview of the assessments 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.)

All columns are grey as there is no technical material specification and no analysis of the maximum levels of impurities and/or contaminants of toxicological concern.

Representative use		Game repellent			
		Deciduous & Coniferous in forestry 430 g/1000 plants	Deciduous & coniferous in forestry 130 g/1000 plants	Orchard 430 g /1000 plants	Orchard 130 g /1000 plants
Operator risk	Risk identified				
	Assessment not finalised				
Worker risk	Risk identified				
	Assessment not finalised				
Bystander risk	Risk identified				
	Assessment not finalised				
Consumer risk	Risk identified				
	Assessment not finalised				
Risk to wild non target terrestrial vertebrates	Risk identified				
	Assessment not finalised				
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified				
	Assessment not finalised				
Risk to aquatic organisms	Risk identified				
	Assessment not finalised				

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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 as concerns

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

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APPENDICES

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

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

Active substance (ISO Common Name) ‡	Fish Oil
Function (*e.g.* fungicide)	Repellent

Rapporteur Member State	Hellas
Co-rapporteur Member State	-

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	-
Chemical name (CA) ‡	-
CIPAC No ‡	918
CAS No ‡	100085-40-3
EC No (EINECS or ELINCS) ‡	309-181-3
FAO Specification (including year of publication) ‡	-
Minimum purity of the active substance as manufactured ‡	Specification open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	The following maximum permissible values have been derived from the German Animal Feed Law and are proposed as follows: In the case of dioxin, 6 pg/g as the maximum permissible value for animal feed. For mercury, 0.5 mg/kg feed derived from fish and other sea food processing; for cadmium, 2 mg/kg feed of animal origin, except in feed for domestic pets; and for lead, 10 mg/kg feed. For PCBs, 5 mg/kg, and for pesticides 10 mg/kg.Data gap for supporting batch data
Molecular formula ‡	-
Molecular mass ‡	> 850 g/mol (calculated)

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Structural formula ‡	-

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Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Data gap.
Boiling point (state purity) ‡	Data gap.
Temperature of decomposition (state purity)	-
Appearance (state purity) ‡	Yellow up to red, transparent liquid with fishy odour
Vapour pressure (state temperature, state purity) ‡	Data gap.
Henry's law constant ‡	Not applicable.
Solubility in water (state temperature, state purity and pH) ‡	Not water-soluble.
Solubility in organic solvents ‡ (state temperature, state purity)	Soluble in organic solvents like ether, benzine, benzene, chloroform, carbon disulfide, tetrachloromethane, tetraline, trichloroethylene but not in cold alcohol.
Surface tension ‡ (state concentration and temperature, state purity)	Data gap.
Partition co-efficient ‡ (state temperature, pH and purity)	Data gap.
Dissociation constant (state purity) ‡	Data gap
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Not applicable.
Flammability ‡ (state purity)	Data gap.
Explosive properties ‡ (state purity)	Data gap.
Oxidising properties ‡ (state purity)	Data gap.

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Summary of representative uses evaluated (*Fish oil*)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of Pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between appli-cations	kg as/hL min max	water L/ha min max	kg as/1000 plants min max		
Deciduous and coniferous trees in forestry	Germany	Morsuvin	F	Game repellent	PA	43.0 g/kg	coating with brush; individual plants; entire plants	September-March	1-2	6-7 months	n. a.	-	0.43	n. a.	none
Deciduous and coniferous trees in forestry	Germany	Morsuvin	F	Game repellent	PA	43.0 g/kg	coating with brush; individual plants; terminal sprouts	September-March	1-2	6-7 months	n. a.	-	0.13	n. a.	none
Orchard	Germany	Morsuvin	F	Game repellent	PA	43.0 g/kg	coating with brush; individual plants; entire plants	November-March	1-2	6-7 months	n. a.	-	0.43	n. a.	none

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Orchard	Germany	Morsuvin	F	Game repellent	PA	43.0 g/kg	coating with brush; individual plants; terminal sprouts	November-March	1-2	6-7 months	n. a.	-	0.13	n. a.	none

n. a. = not applicable

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application

(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 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 plants - type of equipment used must be indicated.

(i) g/kg or g/L

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) minimum and maximum number of application possible under practical conditions of use must be provided

(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)

Technical as (analytical technique)	Open batch data with supporting data which includes the need for a method of analysis.
Impurities in technical as (analytical technique)	Data gap.
Plant protection product (analytical technique)	Data gap.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		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.
Blood		No residue definition.

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required as no residue definition is proposed
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required as no residue definition is proposed

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Soil (principle of method and LOQ)	Not required as no residue definition is proposed
Water (principle of method and LOQ)	Not required as no residue definition is proposed
Air (principle of method and LOQ)	Not required as no residue definition is proposed
Body fluids and tissues (principle of method and LOQ)	As Fish Oil is not classified as toxic or very toxic, no analytical method is required for its determination in body fluids and tissues.

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

	RMS/peer review proposal
Active substance	RMS proposal: None

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Impact on Human and Animal Health

Fish oil does not have a toxic mode of action and does not present a toxicological concern by itself. It is used as a feedstuff obtained from fresh fish by-products not suitable for human consumption; based on its nature, the waiver for toxicological studies was deemed acceptable.

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

Rate and extent of absorption ‡	No data - not required
Distribution ‡	No data - not required
Potential for accumulation ‡	No data - not required
Rate and extent of excretion ‡	No data - not required
Metabolism in animals ‡	No data - not required
Toxicologically relevant compounds ‡ (animals and plants)	No data - not required
Toxicologically relevant compounds ‡ (environment)	No data - not required

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	No data - not required	
Rabbit LD_{50} dermal ‡	No data - not required	
Rat LC_{50} inhalation ‡	No data - not required	
Skin irritation ‡	No data - not required	
Eye irritation ‡	No data - not required	
Skin sensitisation ‡	No data - not required	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data - not required	
Relevant oral NOAEL ‡	No data - not required	
Relevant dermal NOAEL ‡	No data - not required	
Relevant inhalation NOAEL ‡	No data - not required	

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Genotoxicity ‡ (Annex IIA, point 5.4)

No data - not required	

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

Target/critical effect ‡	No data - not required
Relevant NOAEL ‡	No data - not required
Carcinogenicity ‡	No data - not required

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	No data - not required
Relevant parental NOAEL ‡	No data - not required
Relevant reproductive NOAEL ‡	No data - not required
Relevant offspring NOAEL ‡	No data - not required

Developmental toxicity

Developmental target / critical effect ‡	No data - not required
Relevant maternal NOAEL ‡	No data - not required
Relevant developmental NOAEL ‡	No data - not required

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data - not required
Repeated neurotoxicity ‡	No data - not required
Delayed neurotoxicity ‡	No data - not required

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data

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Studies performed on metabolites or impurities ‡	No data

Medical data‡ (Annex IIA, point 5.9)

	An old formulation of this preparation is registered and used in Germany since 1977. No cases of poisoning or illness became known during the years of the use of this preparation.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	Not required*		
AOEL ‡	Not required*		
ARfD ‡	Not required*		

*The setting of reference values was not deemed necessary as the substance is a feedstuff and does not present a toxicological concern

Dermal absorption‡ (Annex IIIA, point 7.3)

Morsuvin (fish oil 43 g/kg PA)	No data - not required

Exposure scenarios (Annex IIIA, point 7.2)

Operator	No exposure assessment was deemed necessary as the substance does not present a toxicological concern.
Workers	No exposure assessment was deemed necessary as the substance does not present a toxicological concern.
Bystanders	No exposure is foreseen

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

	RMS/peer review proposal

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Fish oil	none

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

Plant groups covered	Not provided and not required
Rotational crops	Not provided and not required
Metabolism in rotational crops similar to metabolism in primary crops?	Not Relevant
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not Relevant
Plant residue definition for monitoring	Not Relevant
Plant residue definition for risk assessment	Not Relevant
Conversion factor (monitoring to risk assessment)	Not Relevant

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

Animals covered	Not provided and not required
Time needed to reach a plateau concentration in milk and eggs	Not Relevant
Animal residue definition for monitoring	Not Relevant
Animal residue definition for risk assessment	Not Relevant
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 provided and not required

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

Not relevant

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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 evel)	No	No	No
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		-	

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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)
Not provided and not required considering the representatives uses on deciduous and coniferous trees in forestry and in orchards						

(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

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

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

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 provided and not required				

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

Deciduous and coniferous trees in forestry	Not required
Orchards	Not required

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

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

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

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

Anaerobic degradation ‡

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

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted. Not required.

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

Laboratory studies ‡

Fish Oil	Aerobic conditions: no data submitted, not required.

Field studies ‡

Fish Oil	Aerobic conditions : no data submitted, not required.

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pH dependence (yes / no) (if yes type of dependence) ‡	No data submitted. Not required.
Soil accumulation and plateau concentration ‡	No data submitted. Not required.

Laboratory studies ‡

Fish Oil	Anaerobic conditions: no data submitted, not required.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Fish Oil: no data submitted, not required. ‡

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

Column leaching ‡	No data submitted. Not required.
Aged residues leaching ‡	No data submitted. Not required.
	No data submitted. Not required.
Lysimeter/ field leaching studies ‡	No data submitted. Not required.

PEC (soil) (Annex IIIA, point 9.1.3)

Fish Oil	No data submitted. Not required.

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

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Hydrolytic degradation of the active substance and metabolites > 10 % ‡	No data submitted. Not required.
Photolytic degradation of active substance and metabolites above 10 % ‡	No data submitted. Not required.
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data submitted. Not required.
Readily biodegradable ‡ (yes/no)	-No data submitted. Not required.

Degradation in water / sediment

Fish Oil	No data submitted. Not required

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

Fish Oil	No data submitted. Not required.

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. Not required.

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

Direct photolysis in air ‡	No data submitted. Not required.
Quantum yield of direct phototransformation	No data submitted. Not required.
Photochemical oxidative degradation in air ‡	No data submitted. Not required.
Volatilisation ‡	No data submitted. Not required.

PEC (air)

Method of calculation	No data submitted. Not required.

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$PEC_{(a)}$

Maximum concentration	-No data submitted. Not required.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Fish Oil Surface Water: Fish Oil Sediment: Fish Oil Ground water: Fish Oil Air: Fish Oil

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

Soil (indicate location and type of study)	-No data submitted. Not required.
Surface water (indicate location and type of study)	-No data submitted. Not required.
Ground water (indicate location and type of study)	-No data submitted. Not required.
Air (indicate location and type of study)	-No data submitted. Not required.

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

-

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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]

10. 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)

Species	**Test substance**	**Study Type**	**LC_{50} /EC_{50} [mg/L]***	**LC_0 /NOEC [mg/L]***
Zebrafish	Morsuvin	Static 96h	>100	100
Daphnia magna	Morsuvin	Static 48h	>100	100
Desmodesmus subspicatus	Morsuvin	Static 72h	>100	100

***** the aquatic studies are of poor quality and informative only

[1] Exposure expected to be negligible

[1] Exposure expected to be negligible

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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)

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)

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

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APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
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* The metabolite name in bold is the name used in the conclusion.

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ABBREVIATIONS

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

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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

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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

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