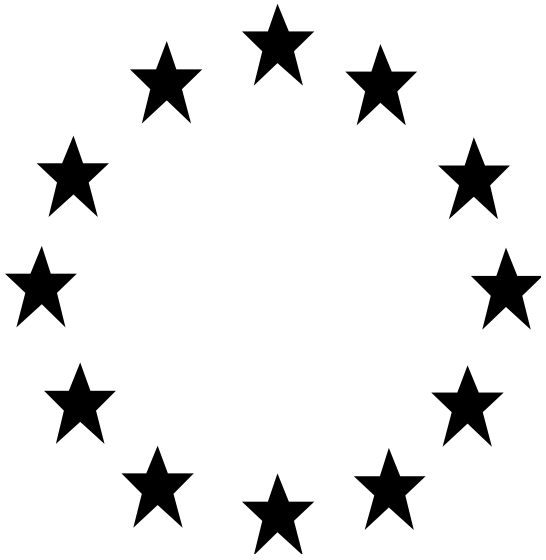

Draft Assessment Report (DAR)

- public version -

Initial risk assessment provided by the rapporteur Member State Spain for the existing active substance

RAPESEED OIL

of the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

Volume 1

September 2008

MINISTERIO DE AGRICULTURA, PESCA Y ALIMENTACIÓN

INSTITUTO NACIONAL DE INVESTIGACIÓN Y TECNOLOGÍA AGRARIA Y ALIMENTARIA (I.N.I.A.)

Ctra. De La Coruña, km. 7

28040 – Madrid

ESPAÑA

Monograph prepared in the context of the inclusion of the following active substance in Annex I of the Council Directive 91/414/EEC

RAPESEED OIL

Volume I

Report and Proposed Decision

July 2007

THE MONOGRAPH WAS PREPARED UNDER THE RESPONSIBILITY OF:

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Dr. Alonso - Prados, J. L. (Co-ordinator).
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FROM THE DOSSIERS SUBMITTED BY:

W. Neudorff GmbH KG

WITH THE ASSISTANCE OF THE FOLLOWING EXPERTS:

Identity

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Physical and chemical properties

Dra. López Goti, C.
Dpto. Protección Vegetal, I. N. I. A., Ctra. de La Coruña, km. 7, 28040 - Madrid, Spain.

Data on application and further information

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Methods of analysis

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Residue data

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Toxicology and metabolism

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Level 1: Statement of Subject Matter and Purpose of Monograph.

Level 2: Reasoned statement of the overall conclusions.

Level 3: Proposal for the decision

Level 4: Further information

LEVEL 1

RAPESEED OIL

Statement of Subject Matter and Purpose of Monograph

1 Statement of subject matter and purpose for which the monograph was prepared

1.1 Purpose for which the monograph was prepared

This monograph has been prepared for submission to the Standing Committee on the Food Chain and Animal Health to enable a decision to be made on the listing of ACTIVE SUBSTANCE in ANNEX I to Council Directive 91/414/EEC. The documentation considered during its preparation was provided by W. Neudorff GmbH KG

1.2 Summary and assessment of information relating to the collective assessment of dossiers

1.3 Identity of the active substance (IIA, 1)

1.3.1 Name and address of applicant(s) for inclusion of the active in Annex I (IIA, 1.1)

Name: W. Neudorff GmbH KG
Address: An der Mühle 3
D-31860 Emmerthal / Germany

Person to contact

Name: [redacted]
Phone: [redacted]
FAX: [redacted]

1.3.2 Common name and synonyms (IIA, 1.3)

Rapeseed oil

1.3.3 Chemical name (IIA, 1.4)

Rüböl

1.3.4 Manufacturer's development code number (IIA, 1.5)

Not relevant. No manufacturer codes number

1.3.5 CAS, EEC and CIPAC numbers (IIA, 1.6)

CAS: 8002-13-9

EINECS: 232-299-0

1.3.6 Molecular and structural formulae, molecular mass (IIA, 1.7)

It is not possible to provide this information, since rapeseed oil is a mixture of triglyceride

1.3.7 Manufacturer or manufacturers of the active substance (IIA, 1.2)

[redacted]

Person to contact

[redacted]

1.3.8 Method or methods of manufacture (IIA, 1.8)

Confidential information, See Volume IV Annex C of this monograph

1.3.9 Specification of purity of the active substance (IIA, 1.9)

Confidential information, See Volume IV Annex C of this monograph

The notifier has set the specifications according to the values stated for German Pharmaceutical Authorities Codex and to the current 5-batch analysis. The purity is not given as a single value. Notifier gives the specifications based on the composition as fatty acids and some physic-chemical parameters. Taking into account that the active substance is not a single compound but a mixture of triglycerides of fatty acids and that the mode of action is mechanical rather that chemical, RMS considers that these specifications are accepted.

1.3.10 Identity of isomers, impurities and additives (IIA, 1.10)

Confidential information, See Volume IV Annex C of this monograph

1.3.11 Analytical profile of batches (IIA, 1.11)

Confidential information, See Volume IV Annex C of this monograph

1.4 Identity of the plant protection product (IIA, 3.1; IIIA, 1) (to be included for each preparation for which an Annex III dossier was submitted)

1.4.1 Current, former and proposed trade names and development code numbers (IIIA, 1.3)

NEU 1160 I

Manufacturer's development code numbers

NEU-01160-A1-0-EC

1.4.2 Manufacturer or manufacturers of the plant protection product (IIIA, 1.2)

[redacted]

Person to contact

[redacted]

1.4.3 Type of the preparation and code (IIIA, 1.5)

Emulsifiable concentrate [Code : EC]

1.4.4 Function (IIA, 3.1; IIIA, 1.6)

Acaricide, Insecticide

1.4.5 Composition of the preparation (IIIA, 1.4)

1.4.5.1 Identity and content of the active substance

The purity is according to the values stated in German Drug Authoritiy Codex (Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994).

1.4.5.2 Identity and content of formulants

Confidential information, See Volume IV Annex C of this monograph

1.5 Uses of the plant protection product (IIA, 3.2 to 3.4; IIIA, 3.1 to 3.7, 3.9 and 12.1) (to be included for each preparation for which an Annex III dossier was submitted)

1.5.1 Field of use (IIA, 3.3; IIIA, 3.1)

Ornamental horticulture, orcharding.
NEU 1160 I is intended for the use in ornamentals in greenhouses and in woody ornamentals and fruit crops (except strawberry).

1.5.2 Effects on harmful organisms (IIA, 3.2; IIIA, 3.2)

Contact action.

1.5.3 Summary of intended uses (IIA, 3.4; IIIA, 3.3 to 3.7, 3.9)

RMS considers that the use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant. With the provided information in the dossier the evaluation has been made for the following uses:

1. **Ornamentals in glasshouse conditions: 3x 70.64 Kg ai /Ha; Interval between application: 7d**
2. **Orchards in filed (apple trees) : 1x 8.83 Kg ai/Ha m crown height (assuming 3 m height) = 26.49 kg a.s./ha**
3. **Ornamental in field:1x 21.129 Kg ai /Ha (height > 125 cm) = 21.192 kg a.s./ha**

1.5.3.1 Details of intended use

NEU 1160 I is intended for the use in ornamentals in greenhouses and in woody ornamentals and fruit crops (except strawberry).

NEU 1160 I is an acaricide/insecticide for the use against spider mites, scales, and mealy bugs. The target pests cause damage to the plants by sucking plant juices.

Spider mites are tiny arachnids of less than 0.4 mm length when mature. Most spider mites spend the winter in the egg stage. The life cycle comprises the egg stage, one larval stage, 4 nymph stages and the adult stage. Spider mites are usually found on the underside of leaves. The sucking of plant juices from individual plant cells causes a speckled appearance. When plants are heavily infested, they may be discoloured and stunted, a fine webbing may be seen on the plants, and leaves may drop prematurely.

Scale species secrete a characteristic waxy protective covering over their bodies. They can be divided into armoured scales and soft scales. In contrast to soft scales, armoured scales have a dense cover which is usually separated from the scale's body. Most armoured scales have several generations a year, whereas soft scales often have only a single generation. Eggs of both groups are often hidden under the adult female. Eggs hatch into tiny crawlers which settle down at permanent feeding sites after a few days. Adult females are immobile and have a characteristic scale cover, whereas adult males are tiny winged insects that live only a few hours. Scales may be found on either side of the leaves, on branches or stems. Damage symptoms caused by scales are reduced growth and premature leaf drop, as well as yellow spots on leaf tips. Furthermore, soft scales may produce large quantities of honeydew, which may serve as substrate for black sooty mould fungi.

Mealy bugs are soft-bodies insects covered with a white powder material. They are common pests of greenhouses. Reproduction under greenhouse conditions is year-round. Mealy bugs may form dense colonies. Some species produce "waxy wool" in which they lay their eggs. Young crawlers disperse rapidly on the plant to find suitable feeding sites. The complete life cycle takes approximately 50 days

at 20 °C. They damage the plants by sucking the juices from leaves. Leaf yellowing, leaf curling, leaf drop, and reduced plant growth are common symptoms of high infestations with mealy bugs. Furthermore, they also produce honeydew, which may serve as substrate for black sooty mould fungi.

With an early application of NEU 1160 I in orchards and woody ornamentals in the field, infestation levels with winter eggs of spider mites are suppressed, so that populations of the target species are reduced to a low level during the year.

Applications in glasshouses are intended to kill also the adult stages of spider mites, scales, and mealy bugs. Higher application amounts are necessary to achieve this effect.

1.5.3.2 Proposed application rates

In orchards, NEU 1160 I is applied at amounts of 10 L/ha and m crown height (corresponding to 8.83 kg Rapeseed oil/ha and m crown height). In woody ornamentals, the application amounts are also dependent on plants height with recommendations between 12 and 24 L/ha (10.6-21.2 g Rapeseed oil/ha).

For the application in ornamentals in greenhouses, recommended application amounts vary between 40-80 L/ha (35.3-70.6 g Rapeseed oil/ha).

1.5.3.3 Concentration of active ingredients in diluted spray

The product should be used in spray solutions of 2% product in water (v/v), corresponding to 1.77 kg Rapeseed oil/hL.

1.5.3.4 Method of application

NEU 1160 I is to be sprayed. Dependent on the size of the area to be treated, this may be done by motor sprayers, knapsack sprayers or hand sprayers. In orchards, a water amount of 500 L/ha and m crown height is recommended, whereas amounts in woody ornamentals vary between 600 and 1200 L/ha. In ornamentals in greenhouses, the product should be applied in 2000 to 4000 L/ha.

1.5.3.5 Number and timings of applications and duration of protection

In orchards and woody ornamentals, the product is used with 1 application in spring, shortly after the start of vegetation. In contrast to this, up to 3 applications with an interval of 7 days are intended in greenhouses. These applications should be timed at the beginning of infestation.

In orchards and woody ornamentals, the application should be performed in the period between the start of vegetation (bud swelling) up to mouse ear stage or bud break.

In orchards and woody ornamentals, the treatment is intended against winter eggs of spider mites. In contrast to this, all developmental stages of target species will be affected by applications in the greenhouse, however, as NEU 1160 I is a contact insecticide/acaricide, hidden stages of the target species may be less affected, so that the treatment has to be repeated after about 7 days.

1.5.3.6 Duration of protection afforded by each application

NEU 1160 I is a contact acaricide/insecticide. Thus duration of protection is dependent on the period of population recovery or re-infestations and cannot be estimated. A single application is recommended against winter stages of spider mites in orchards and woody ornamentals. In greenhouses, it is recommended to repeat the treatment after about 7 days to interfere with the recovery of pest populations from hidden stages.

1.5.3.7 Duration of protection afforded by the maximum number of applications

A single application is recommended against winter stages of spider mites in orchards and woody ornamentals. This treatment should reduce the population of mites so far that protection should last for the next months to come. Up to 3 treatments are required to achieve an optimal control of all stages of spider mites, scales and mealy bugs in ornamentals under glass. Protection then should last until a new population begins to develop. This re-infestation risk is highly dependent on conditions which are not connected with the effectiveness of NEU 1160 I.

1.5.3.8 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Succeeding crops will normally not occur in orchards or woody ornamentals. Furthermore, the active substance Rapeseed oil degrades rather rapidly in the soil or is used by the plants for energy or biosynthesis of plant compounds. Thus, no adverse effects on succeeding crops are to be expected e.g. in greenhouses.

As a general remark RMS considers that the use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant.

1.5.4 Information on authorisations in EU Member States (IIIA, 12.1)

No data submitted

List of supported uses:

Crop and/ or situation / Country	Product name	Field, glasshouse or indoor use	Pests or group of pest controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
				Type	Conc. of as (g/L)	Method kind	Growth stage & season	Number per growing season (max)	Interval between applications	kg as/hL	Water (L/ha)	kg as/ha		
Ornamentals	NEU 1160 I	Glasshouse (professional and home garden use)	Spider mites, mealy bugs, scales	EC	883	Knapsack sprayer and hand sprayer	When infestation is visible	3	7 days	1.766	2000 - 4000	35.32-70.64 (40-80 L* product/ha)	-	Effect: killing of adults
Orchards	NEU 1160 I	Field (professional and home garden use)	Eggs of spider mites	EC	883	Knapsack sprayer, motor sprayer, hand sprayer	Start of vegetation up to mouse ear stage, or bud swelling up to bud break	1	-	1.766	500 per m crown height	8.83 per m crown height (10 L product/ha and m crown height)	-	Effect: suppression of winter stages
Woody ornamentals	NEU 1160 I	Field (professional and home garden use)	Eggs of spider mites	EC	883	Knapsack sprayer, motor sprayer; hand sprayer	Start of vegetation up to bud break	1	-	1.766	600-1200	10.596-21.192 (12-24 L** product/ha)	-	Effect: suppression of winter stages

* plant height < 50 cm: 40 L product/ha (2000 L water/ha), 50-125 cm: 60 L product/ha (3000 L water/ha), > 125 cm: 80 L product /ha (4000 L water/ha)
** plant height < 50 cm: 12 L product/ha (600 L water/ha), 50-125 cm: 18 L product /ha (900 L water/ha), > 125 cm: 24 L product /ha (1200 L water/ha)

RMS considers that the use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant. With the provided information in the dossier the evaluation has been made for the following uses:

1. **Ornamentals in glasshouse conditions: 3x 70.64 Kg ai /Ha; Interval between application: 7d**
2. **Orchards in filed (apple trees) : 1x 8.83 Kg ai/Ha m crown height (assuming 3 m height) = 26.49 kg a.s./ha**
3. **Ornamental in field:1x 21.129 Kg ai /Ha (height > 125 cm) = 21.192 kg a.s./ha**

LEVEL 2

RAPESEED OIL

Reasoned statement of the overall conclusions

2 Reasoned statement of the overall conclusions drawn by the Rapporteur Member State

2.1.1 Identity

The dossier for the active substance Rape Seed Oil is submitted by W. Neudorff GmbH KG for evaluation in the context of the 4th stage of the review programme of existing active substances under Council Directive 91/414/EEC for first inclusion of an existing active substance in Annex I. The dossier was prepared in accordance with Annex IIA, points 1.8/1.11 and point 4 of the OECD guidance for industry data submissions on plant protection products and their active substances. RMS has evaluated the information provided taking into account the working document Sanco/10472/2003-rev. 5, 6.7.2004, "Concerning the data requirements for active substances of plant protection products made from plants or plant extracts".

The active substance, Rapeseed oil (Rüböl) with CAS number 8002-13-9, is not a single compound but a mixture of triglycerides of fatty acids. The active substance is not present in the formulation in the form of a salt, ester, anion or cation. The purity is not given as a single value. Notifier gives the specifications based on the composition as fatty acids and some physic-chemical parameters. All technical material has been considered as active substance. Taking into account that the mode of action is mechanical rather that chemical, RMS considers that these specifications are accepted.

The relevant formulation, NEU 1160 I (Manufacturer's code number: NEU-01160-AI-0-EC), is an emulsifiable concentrate (EC) containing 883 g /L of Rapeseed oil.

2.1.2 Physical and chemical properties

Rapeseed oil is a blend of different fatty acids. The formulation NEU 1160 I contains 4% emulgator and 96% technical rapeseed oil. Considering the composition of the two products and the small amount of emulgator in NEU 1160 I, the notifier concluded that physical and chemical properties will be determined by the major ingredient i.e. Rapeseed oil. The other ingredient might contribute negligibly to these properties. As conclusion, it was assumed that the results of studies conducted with NEU 1160 I (for the determination of physical and chemical properties) will not differ from studies conducted with rapeseed oil. Thus, values found from studies conducted on the preparation NEU 1160 I were used for the properties: relative density, auto-flammability, flash point and surface tension. **RMS considers that the study for the determination of the surface tension can not been accepted because the emulsifying co-formulant would affect this property.**

Rapeseed oil is a clear light yellow liquid with a characteristic odour. The melting/ freezing range is -12.0 – -30.6 °C and decomposes before boiling (> 350 °C). The vapour pressure and Henry's Law Constant were estimated by calculations from the chemical structure of the main molecule (oleic acid

glycerol ester). These results are considered as rouge estimation but give information about the no volatility of this compound. A correct UV-VIS report with the identification of the test substance and interpretation of the spectrum is necessary. The interpretation of the FT-IR spectrum is also necessary. The water solubility in the neutral range was estimated to be 2.551 * 10^{-20} mg/L (negligible). Rapeseed oil is very soluble in organic solvents. Its log Pow was estimated by calculations from the chemical structure of the main molecule (oleic acid glycerol ester). These results are considered as a rouge estimation but give information about its high particion to fat (log Kow = 23.2908). Its flammability is not critical, it does not present any risk for explosion and does not have oxidising properties. **A study for the determination of surface tension is required.**

The formulation NEU 1160 I is not explosive. The product is not oxidizing, and not flammable. Its pH is within the range which naturally occurs e.g. in soil. It is a surface active substance with a relative density of 0.92 at 20ºC. Its physical stability allows storage under practical and commercial conditions but the stability of the composition when it is storage for 14 days at 54°C and 2 years at ambient temperature must be determined with an accuracy method. Its technical properties indicate that no particular problems are to be expected, when it is used as recommended. The persistent foaming should be performed in CIPAC water D and the concentration used for the performance of the test should be specified.

2.1.3 Details of uses and further information

Rapeseed oil is an insecticide/acaricide e.g. for the use against spider mites, scales, and mealy bugs. The target pests cause damage to the plants by sucking plant juices. The action is by contact; Rapeseed oil suffocates insects and mites by blocking the spiracles and the body pores. It is intended to be used in ornamental horticulture and orchards. In orchards, the formulation NEU 1160 I is applied at amounts of 10 L/ha and m crown height (corresponding to 8.83 kg Rapeseed oil/ha and m crown height). In woody ornamentals, the application amounts are also dependent on plants height with recommendations between 12 and 24 L/ha (10.6-21.2 g Rapeseed oil/ha). In orchards and woody ornamentals, the product is used with 1 application in spring, shortly after the start of vegetation. For the application in ornamentals in greenhouses, recommended application amounts vary between 40-80 L/ha (35.3-70.6 g Rapeseed oil/ha) and up to 3 applications with an interval of 7 days. These applications should be timed at the beginning of infestation. NEU 1160 I is to be sprayed.

RMS considers that the use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant. With the provided information in the dossier the evaluation has been made for the following uses:

1. **Ornamentals in glasshouse conditions: 3x 70.64 Kg ai /Ha; Interval between application: 7d**
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3. **Ornamental in field:1x 21.129 Kg ai /Ha (height > 125 cm) = 21.192 kg a.s./ha**

2.1.4 Classification and labelling

No proposal for the classification and labelling of the active substance. This product is a pure edible vegetable oil which is not considered to present any hazard during normal use. Therefore no risk or safety phrases are stated.

No proposal for the classification and labelling of preparation.. This product is nearly a pure edible vegetable oil which is not considered to present any hazard during normal use. Therefore no risk or safety phrases are stated.

2.2 Methods of analysis

2.2.1 Analytical methods for analysis of the active substance as manufactured

The IUPAC methods 2.301, 2.302 and 2.311 have been reported for the determination of the fatty acids in Rapeseed oil. Only a copy of the standard IUPAC methods, without a clear reference to the manual where they were published, was provided. Similarly, DFG standard methods, Section C-Fats C-VI 10a (00) and DFG standard methods, Section C-Fats C-VI 11a (98) were reported. The notifier states that validation is not needed because they have been used for many years to determine the composition of rapeseed oil and acceptability for food uses in countries all over the world but references to collaborative studies with Rapeseed oil were not provided. RMS **considers that methods must be validated** for the Rape Seed Oil proposed for evaluation.

2.2.2 Analytical methods for formulation analysis

The notifier proposed already established IUPAC methods (2.301 and 2.302) for the determination of components of Rapeseed oil. Also, a full protocol is submitted specifically for the determination of erucic acid as attach document to the 2.302 method (IUPAC method 2.311). The dossier only includes a copy of the standard IUPAC methods without a clear reference to the manual where they were published. The notifier states that validation is not needed because they have been used for many years to determine the composition of rapeseed oil and acceptability for food uses in countries all over the world but the validation in your laboratories is not provided. **So, it is required a validation for the**

three IUPAC methods (2.301, 2.302 and 2.311 methods) according to the SANCO 825/00-rev 6 (20/06/00) guideline in the NEU 1160 I formulation..

2.2.3 Analytical methods for residue analysis

The notifier indicates that no information regarding method of analysis for **plant residues** is required when the exposure, due to the use of the plant extract as a plant protection product, is not relevant, in relation to the exposure due to consumption of the plant itself. **It would be necessary to confirm that the plant residue is not different to the natural one.** RMS agrees with the notifier but it is pending on the decision on the residue definition. If residue definition is established an analytical method for residue in plants for monitoring will be required.

There is no residue definition **in animal material**. So, it is no necessary analytical methods.

The notifier has not submitted analytical method for **soil** because considered that the natural occurrence in plants, animals and soils, together with the rapid microbial degradation eliminate the need to quantify rapeseed oil residue from applications as an insecticide or acaricide. For it, contributes with three articles of **Goring & Hamaker, 1972; Moucawi et al., 1981 and Smith, 1974**. The public literature reveals that the degradation of fatty acids in soil is biologically mediated. Fatty acids are excellent substrate for microbial growth, serving both as carbon source and as energy source. Differences lipid composition in soil are probably related to differences in the requirement for fatty acids of the different soil microflora species and the plant ground materials. The decomposition of typical lipids is influenced by soils properties to which they were added. Thus, in microbiology-active soils the rate of decomposition of C-18 lipid is expected to be high in soil wherein the microbiota is abundant and diversified. One of the conclusions of these articles is that although all the fatty acids follow the same metabolism process, differences can be quantitatively but no qualitatively. According to the SANCO/10472/2003 rev.5, a validated method for analysing the active substance in water, soil and air can be judged necessary if exposure of the concerning compartment is likely and the contribution compared to natural background levels is substantial. RMS considers that according to the data in the environmental fate and behaviour section and the ecotoxicology risk assessment the exposure of soil organism to rapeseed oil, due to an application as insecticide, is likely, furthermore the estimated the DT_{90} is 9.3 days. Therefore, analytical methods for soil is required

The notifier has not submitted analytical method for **drinking water or ground water** because considered that any contamination of this substance to drinking water or ground water is unlikely to occur. Even if the oil may be washed off treated plants by rain, it will rapidly degrade in the environment. Studies regarding degradation in water were not submitted; therefore RMS can not confirm these assumptions.

In addition the US EPA considers that, since people are exposed to this substance from food or other sources, the incremental exposure derived from non-dietary exposure such as drinking water or ground water should be minimal (US EPA 1998). Thus, a method to quantify rapeseed oil residue in waters

from applications as an insecticide or acaricide, is considered not necessary. The notifier concludes that the conclusions on the fate and behaviour in soil can be extrapolated to the water compartment. **A**ccording to the Guidance Document on Residue Analytical Methods, European Commission, Doc. No. SANCO/825/00 rev. 6 (20/06/00) if the DT_{90} is higher the three days must be submitted analytical methods. RMS considers that according to data in the environmental fate and behaviour section and the ecotoxicology risk assessment the exposure of water organism to rapeseed oil, due to an application as insecticide, is likely, furthermore the estimated DT_{90} is 9.3 days. **Therefore, analytical method for water is required**

As the Rapeseed oil does not volatize, analytical method for the determination of the metabolites **in air** is not required.

A method for **body fluids and tissues** is not required, because Rapeseed oil is not classified as toxic or highly toxic.

2.3 Impact on human and animal health

2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

2.3.1.1 Toxicokinetics and metabolism

Rapeseed oil is, like all vegetable oils, metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via ß-oxidation.

2.3.1.2 Acute toxicity, irritancy and skin sensitization

The quality of rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001). Therefore no studies on acute toxicity (acute oral, dermal or inhalation toxicity, skin or eye irritation and skin sensitisation) were undertaken with rapeseed oil. However, acute toxicity studies conducted with the formulation NEU 1161 I with the content of 90 % Rapeseed oil and 2 % Pyrethrum Extract (Refer to Annex IIIA, point 7.1.1 to 7.1.6, see assessment in chapter B.6.11) were submitted. The lack of toxicity reported in these studies is supporting the view that Rapeseed oil has a low acute oral, dermal or inhalation toxicity and has no skin and eye irritating or dermal sensitizing potential.

According to EU Commission Directive 2001/59/EC, classification for acute toxicity of Rapeseed oil is not required.

2.3.1.3 Short-term toxicity

Notifier has not submitted short-term toxicity studies performed with rapeseed oil. The quality of rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001). Therefore, short term oral toxicity studies are not necessary.

2.3.1.4 Genotoxicity

Notifier has not submitted genotoxicity studies performed with rapeseed oil. The quality of rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001). Rapeseed oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents and there is no indication for a genotoxic potential.

2.3.1.5 Long-term toxicity and carcinogenesis

Only two publications had been submitted in long-term section, however these reports were not according to OECD guidelines and GLPs. The quality of rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001). Therefore, long term toxicity and carcinogenesis studies are not necessary.

A long-term study was conducted with male rats, fed with diets with 20% rapeseed oil that contained low or high levels of erucic acid or soybean oil to investigate ultrastructural characteristics of the myocardium. Long-term feeding of high erucic acid rapeseed oil resulted in alteration of mitochondrial morphology, disorganization of myofibrils, and degeneration or necrosis of the cardiac muscle fiber. Low erucic acid rapeseed oil induced less severe cardiopathologic changes but the nature of the alterations was similar to that high levels of erucic acid.

Long term feeding experiments with ICR mice (6% Rapeseed oil in the diet) for 18 months resulted in an increased survival rate as compared to a control group with a diet containing equal amounts of palm oil.

2.3.1.6 Reproductive and developmental toxicity

Notifier has not presented conventional studies to assess reproductive and developmental effects after rapeseed oil administration. Instead, a scientific report was presented in order to evaluate reproductive success and outcomes after rapeseed oil administration.

The experimental survey administered a diet containing 25% rapeseed oil or corn oil (controls). Rapeseed oil in the diet was rich (41.4%) in erucic acid. Both males and females were provided with the diets for 90 days in pre-mating phase and during gestation. Half of the animals were continued until day

110 and the remaining were paired. At day 20 of gestation (rat) or day 14 (hamster), pregnant females were sacrificed and examined for reproductive outcomes. In addition, all animals (both pregnants or non-pregnants) were examined for the weight and histology of some organs, bile flow, acid contents, lithogenic index and hepatic organic anion excretory capacity examined with sulfobromophthalein in order to compare this aspects with control animals.

Effects on the mothers attributed to rapeseed oil diet consisted of decreased bodyweight in non-pregnant rats (8.7%) and hamsters (7.8%). However, female fertility index, the number and the weight of fetuses were not affected. In addition, fetuses were macroscopically considered as normal. When adult rats were examined for macroscopic/microscopic lesions and the weight of liver, kidney, heart and adrenal glands, the report did not show abnormalities.

Rapeseed oil administration decreased bile flow in pregnant hamsters. No differences could be observed in the concentration of bile acids, biliary lipids, lithogenic index and the hepatic organic anion excretory capacity examined with sulfobromophthalein.

Results of the fatty acid proportion were only presented for the hamster heart. Administering with rapeseed oil rich in erucic acid depleted linoleic acid and increased erucic acid moderately in the liver and kidney and noticeably in the heart.

2.3.1.7 Neurotoxicity

The quality of rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001).

The mode of action of Rapeseed oil as a plant protection product does not target the nervous system, therefore neurotoxic effects of Rapeseed oil are not expected.

2.3.1.8 Other toxicological studies

Metabolites: Notifier has not presented toxicity studies performed with metabolites. Rapeseed oil is, like all vegetable oils, metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via ß-oxidation.

Other risk assessments: EPA (1998) accepted data waivers requested for acute oral, dermal, inhalation, and eye toxicity, dermal sensitization, genotoxicity, reproductive and developmental toxicity, subchronic (90-day) oral and inhalation toxicity, and teratogenicity for NEU 1160 Vegetable Oil Insecticide based on the long history of use of canola as an edible fat and oil in food without any indication of deleterious effects; its low toxicity; its natural occurrence as an oil extracted from plants; its low erucic acid (less than 2%). In addition, EPA (2002) concluded that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to residues of the C8 to C18 fatty acids.

2.3.1.9 Medical data

Since there is no toxicity associated with Rapeseed oil there are no medical data regarding occupational and accidental, long term or acute toxic effects.

2.3.2 ADI, ARfD and AOEL

The quality of low-erucic acid refined rapeseed oil (no more thant 2% erucic acid) is accepted as food according to Codex Alimentarius (FAO-WHO, 2001). The applicant stated that the setting of references values is not applicable. In addition EPA (1998) accepted data waivers requested for acute oral, dermal, inhalation, and eye toxicity, dermal sensitization, genotoxicity, reproductive and developmental toxicity, subchronic (90-day) oral and inhalation toxicity, and teratogenicity for NEU 1160 Vegetable Oil Insecticide based on the long history of use of canola as an edible fat and oil in food without any indication of deleterious effects; its low toxicity; its natural occurrence as an oil extracted from plants; its low erucic acid (less than 2%).

According to Product Health and Safety Data (Document JIII 1.4.1/01) there is a Occupational exposure limit (OEL) for oil mist of 5mg/m^3 (TWA, 8h – workday) recommended based upon the ACGIH TLV (Analysis according to US NIOSH Method 5026, NIOSH Manual for Analytical Methods, 3rd Ed.).

RMS agree with the Applicant that rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001) and the setting of references values seems to be not applicable.

2.3.3 Operator, bystander and workers exposure

NEU 1160 I (883 g/L Rapeseed oil) is an Acaricide/insecticide against spider mites, mealy bugs and scales. According to Aplicant, rapeseed oil is assumed to be of very low toxicity and its content in NEU 1160 I does not warrant operator, bystander and worker exposure estimations.

According to Product Health and Safety Data (Document JIII 1.4.1/01) there is a Occupational exposure limit (OEL) for oil mist of 5mg/m^3 (TWA, 8h – workday) recommended based upon the ACGIH TLV (Analysis according to US NIOSH Method 5026, NIOSH Manual for Analytical Methods, 3rd Ed.).

Nevertheless, since there is an OEL and the method kind of application for NEU1160 I is spraying a exposure risk assessment could be done. Notifier is required to conduct an operator risk assessment.

2.4 Residues

Notifier did not provide any study on the metabolism of rapeseed oil in plant material but literature about the metabolism of triacylglycerols and fatty acids in plants were submitted. Plants will either degrade the components of this oil to provide energy for other metabolism processes, or they will use the fatty acids to synthesize phospholipids, other fatty acids or lipid depots. It was assumed that any residues of Rapeseed oil will be degraded or utilised by the plant by the time of harvest, so that it is indistinguishable from plant endogenous lipids and therefore residues trials were not reported. Nevertheless the metabolism takes place in plant tissues and inside the cell and it was not reported the ability of triacylglycerols to penetrate into the plant cells when they are applied on the plant. **RMS considers that the reported literature is not conclusive about the behaviour of rapeseed oil when is applied on the plant and some information is needed before a conclusion about the residue definition is set. Although fatty acids occur naturally in plants, some data is needed to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.**

The notifier did not provide any specific study on the metabolism of rapeseed oil in livestock but literature about the metabolism of fats was submitted. The fatty acids comprised in Rapeseed oil occur naturally in animal feed and their metabolism in animals is well known. Furthermore, Rapeseed oil is also used as a food commodity and therefore metabolism studies on rapeseed oil itself are not needed.

Rapeseed oil is a food commodity which is consumed at about 7.3 g/day in the European diet. The extent of the exposure due to the intended use as plant protection product in apples was compared to the exposure due to consumption of Rapeseed oil as a food commodity. A very worst case, assuming that all the active substance applied would be uptake by the fruit, was considered. The estimation of consumption according to the European diet was much lower than the normal daily consumption of this commodity. Furthermore, it is applied early in the growing season before the development of fruits in orchards and therefore this consumption will be even lower. Therefore no residue trials were reported. No residue definition and MRLs were set and studies on the effect of industrial processing and/or household preparation on the nature and level of residues were therefore considered not relevant. Nevertheless, RMS will do a definitive assessment when more information about residue in plants will be available.

Rapeseed oil is degraded rather rapidly in the soil and the fatty acids comprised in Rapeseed oil also occur naturally in soil. Furthermore, the active substance is used in permanent crops and greenhouses so that it is not expected that succeeding crops will occur. Studies on the effect on succeeding crops were therefore also considered not relevant.

No pre-harvest interval, re-entry period for livestock or withholding period for animal feeding stuffs have to be proposed. It is also not necessary to propose a waiting period between application and sowing or planting the crop to be protected. A waiting period between application and sowing or planting succeeding crops is not required due to the rapid degradation of the active substance in the soil.

2.4.1 Definition of the residues relevant to MRLs

No residue definition and MRLs were set. Nevertheless RMS will do a definitive assessment on the residue definition when more information about plant metabolism will be available.

2.4.2 Residues relevant to consumer safety

No residue definition was set. Estimations of TMDI, NEDI or NESTI are not applicable, since no MRLs are proposed for Rapeseed oil. Nevertheless RMS will do a definitive assessment when more information about plant metabolism will be available.

2.4.3 Residues relevant to worker safety

A re-entry period is considered not relevant, since Rapeseed oil is a natural oil which is also used as a food commodity. There is no toxicological concern of man getting in contact with this oil.

2.4.4 Proposed EU MRLs and compliance with existing MRLs

No residue definition and MRLs were set. Nevertheless RMS will do a definitive assessment on the residue definition and MRL when when more information about plant metabolism will be available.
Up to now, no MRLs have been established for Rapeseed oil by EU or European Member State.

2.4.5 Proposed EU import tolerances and compliance with existing MRLs

No EU Import tolerances exist for Rapeseed oil.

2.4.6 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs

Not applicable.

2.5 Fate and behaviour in the environment

Rapeseed oil is a mixture of triglycerides of fatty acids, therefore the degradation, transformation and metabolism follows the same principle as they are generally described for fatty acids and lipids. **No definition of residue was proposed by the notifier;** The residues would be present in the form of CO_2

and H_2O, all of which occur naturally in the soil and do not represent a risk to human or environmental health. **RMS considers that at least environmental risk assessment should be made to the exposure to rapeseed oil.**

Rapeseed oil is composed mostly by oleic acid (C18:1), linoleic acid (C18:2) and linolenic acid (C18:3). These fatty acids are frequently found in cellular structures (Table 2.5-1 and)

Table 2.5-1: Structure of some fatty acids found in cells[1]

Structure	Systematic name	Common name
Saturated fatty acids		
$CH_3(CH_2)_{10}COOH$	*n*-Dodecanoic acid	Lauric acid
$CH_3(CH_2)_{12}COOH$	*n*-Tetradecanoic acid	Miristic acid
$CH_3(CH_2)_{14}COOH$	*n*-hexadecanoic acid	Palmitic acid
$CH_3(CH_2)_{16}COOH$	*n*-Octadecanoic acid	Stearic acid
$CH_3(CH_2)_{18}COOH$	*n*-Eicosanoic acid	Arachidic acid
$CH_3(CH_2)_{22}COOH$	*n*-tetracosanoic acid	Lignocerid acid
Unsaturated fatty acids		
Structure		**Common name**
$CH_3(CH_2)_5CH=CH(CH_2)_7COOH$		Palmitoleic acid
$CH_3(CH_2)_7CH=CH(CH_2)_7COOH$		Oleic acid
$CH_3(CH_2)_4CH=CHCH_2CH=CH(CH_2)_7COOH$		Linoleic acid
$CH_3CH_2CH=CHCH_2CH=CHCH_2CH=CH\ (CH_2)_7COOH$		Linolenic acid
$CH_3(CH_2)_4(CH=CHCH_2)_3CH=CH(CH_2)_3COOH$		Arachidonic acid

Besides, fatty acids can be found in the soil as result of the plant and soil metabolism, and they are expected to be non-toxic and biodegradable.

The public literature reveals that the degradation of fatty acids in soil is biologically mediated. Fatty acids are excellent substrate for microbial growth, serving both as carbon source and as energy source. Differences lipid composition in soil are probably related to differences in the requirement for fatty acids of the different soil microflora species and the plant ground materials. The decomposition of typical lipids is influenced by soils properties to which they were added. Thus, in microbiology-active soils the rate of decomposition of C-18 lipid is expected to be high in soil where the microbiota is abundant and diversified.

Two studies of the rate of degradation were submitted. The first one was carried out with Neudosan and the second one with C9:0 and C10:0 . The two studies give a similar DT50 value, 3.0 days.

Neudosan (50% fatty acids potassium salt) is a PPP different of the one proposed for Annex I inclusion (triglyceride of fatty acids). According to the notifier, the results obtained can be extrapolated to the active substance, since the product is based on similar fatty acids. However, it should be highlight that the solubility of the salts of fatty acids is higher than the solubility in the triglycerides of fatty acids. This fact can have an influence in the bio-availability and degradation rate of the active substance.

[1] Darnell, J., Lodish H. and Baltimore, D. 1993. Molecular Cell Biology (Spanish edition). Ediciones Omega. Barcelona.

Nevertheless, in the case of lipids (glycerol esters of fatty acids) or waxes (Monoalcohol ester of fatty acids), enzymic hydrolysis can occur very readily. On the other hand, the rate of degradation of the fatty acids will depend on the soil properties and the fatty acid requirements of the microorganisms. Fresh water algae, like marine algae, are also rich in fatty acid composition.

The ready biodegradation was demonstrated in Pelargonic Acid (C10:0). The test substance (C10:0) does not correspond to the active substance (trygliceride of fatty acids).

According to the notifier, the degradation of fatty acids in water is similar in almost all respects to the degradation in soil. Water in its natural environment is a habitat for a wide variety of algae, bacteria, yeasts and fungi as well as higher organisms. Each of these organisms contains fatty acids as part of their cellular membranes and food reserves. They also metabolize the fatty acids to release energy for normal growth and development. **However, with the available information, it is not possible to extrapolate the conclusions on the fate and behaviour in soil to the water compartment.**

For active substances like Rapeseed oil, which represent a mixture of fatty acids, experimental determination of adsorption/desorption will not give reliable results. Alternatively, adsorption/desorption was calculated form the chemical structure (SAR determination) of the leading ester, i.e. oleic acid ester. This approximation sowed a Koc > 10.000 L/Kg . Taking this into account and based on the biodegradation of fatty acids in soil, no calculation of PEC (ground water) was done.

The predicted environmental concentrations were submitted for soil, surface water and sediment. The calculations are based on the following assumptions:

1.- Ornamentals in glasshouse conditions: 3x 70.64 Kg ai /Ha; Interval between application: 7d
2.- Orchards in filed (fruit crops) : 1x 8.83 Kg ai/Ha m crown height (assuming 3 m height)
3.- Ornamental in field:1x 21.129 Kg ai /Ha (height > 125 cm).

4.- DT50 in soil/sediment and water: 3 d (SFO). there is not enough information in the fate and behaviour section to confirm that the assumption of that the DT50 in soil can be extrapolated to water systems

5.- Actual PEC and TWA are based on SFO kinetics

For PEC soil an interception factor of 25% was supposed for ornamental and 50% for orchards

The results of these calculations are summarized in the tables below.

Table 2.5-2: Actual concentration and time-weighted average (TWA) PEC_{soil} of NEU 1160 I in ornamentals (glass house)

Day	Application number	Days post application	PECs[1]	
			Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	-	70.64	-
1	-	-	55.15	-
2	-	-	43.06	-
4	-	-	26.24	
7	2	-	83.13	-
8	-	-	64.90	-
9	-	-	50.67	-
14	3	0	85.34	85.34
15	-	1	66.62	75.59
16	-	2	52.01	67.30
18	-	4	31.70	54.16
21	-	7	15.09	40.54
28	-	14	2.67	23.85
35	-	21	0.47	16.32
42	-	28	0.08	12.30
64	-	50	0.00	6.89
114	-	100	0.00	3.45
365	-	351	0.00	0.96

1 Assumption: use rate: 3 applications of 70.64 kg a.s./ha; interval of 7 days between applications, 25% interception by plants; bulk density of soil: 1.5 g/cm3; soil depth: 5 cm; DT50 = 2.8 days

Table 2.5-3: Actual concentration and time-weighted average (TWA) PEC_{soil} of NEU 1160 I in orchards

Day	Application number	PECs[1]	
		Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	17.66	17.66
1	-	13.79	15.64
2	-	10.76	13.93
4	-	6.56	11.21
7	-	3.12	8.39
14	-	0.55	4.94
21	-	0.10	3.38
28	-	0.02	2.55
50	-	0.00	1.43
100	-	0.00	0.71
365	-	0.00	0.20

[1]Assumption: use rate: 1 applications of 26.49 kg a.s./ha; 50% interception by plants; bulk density of soil: 1.5 g/cm^3; soil depth: 5 cm; DT_{50} = 2.8 days

Table 2.5-4: Actual concentration and time-weighted average (TWA) PEC_{soil} of NEU 1160 I in ornamentals (field)

Day	Application number	PECs1	
		Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	21.19	21.19
1	-	16.54	18.77
2	-	12.92	16.71
4	-	7.87	13.45
7	-	3.75	10.07
14	-	0.66	5.92
21	-	0.12	4.05
28	-	0.02	3.05
50	-	0.00	1.71
100	-	0.00	0.86
365	-	0.00	0.24

[1]Assumption: use rate: 1 applications of 21.19 kg a.s./ha; 25% interception by plants; bulk density of soil: 1.5 g/cm^3; soil depth: 5 cm; DT_{50} = 2.8 days

The initial for greenhouse uses of Rapeseed oil was based on PECsw value was calculated based on a loading of 0.1 % of application rate and for a water depth of 30 cm in a lentic water body, according to the following equation:

$$PEC_{SWini} = \frac{A \cdot dr}{V_{sw} \cdot 100}$$

where

A = application rate in [µg/m²]

dr = loading to the water body [%] and

Vsw = water volume per m² [L/m²]

The loading is based on recommendations for greenhouse applications by the Dutch CTB1.

To calculate concentrations in surface water (PECSW ini, PECSW actual and TWA) for the active substance after outdoor applications, the tiered approach as recommended in the guidance document SANCO/4802/20011 was used.

1 CTB: Authorisation manual, Appendix A: Drift percentages, version 0.2, 2004.

Table 2.5-5: Actual concentration and time-weighted average (twa) PECSW of Rapeseed oil after three applications of NEU 1160 I at a rate of 70.64 kg a.s./ha

Day	Appl. No.	Days post final appl.	Rapeseed oil	
			PECSW actual (µg a.s./L)	PECSW twa (µg a.s./L)
0	1	-	23.52	-
7	2	-	27.68	-
14	3	0	**28.42**	28.42
15	-	1	22.19	25.17
16	-	2	17.32	22.41
18	-	4	10.56	18.04
21	-	7	5.02	13.50
28	-	14	0.89	7.94
35	-	21	0.16	5.44
42	-	28	0.03	4.10
56	-	42	0.00	2.73
64	-	50	0.00	2.30
114	-	100	0.00	1.15
164	-	150	0.00	0.77
214	-	200	0.00	0.57
374	-	360	0.00	0.32

To calculate concentrations in surface water for outdoor applications, the tiered approach as recommended in the guidance document SANCO/4802/20011 was used.

The key application data used in the FOCUS_SW calculations are summarised in Table 2.5-6. The key substance parameters for FOCUS evaluation steps 1, 2 and 3 are summarised in Table 2.5-7

Table 2.5-6: Key application data used in the FOCUS_SW calculations

Parameter	Orchards	Ornamentals
Application rate	26.490 kg a.s./ha* 30 L NEU 1160 I/ha	21.192 kg a.s./ha** 24 L NEU 1160 I/ha
Number of applications	1/year	1/year
Region of use	North- and South-EU	North- and South-EU
FOCUS Crop scenario	Pome/stone fruit, early	Vines, late application
Plant interception (applicability depends on the model software used)	Step 1: not relevant Step 2: minimal crop cover (20%) Step 3: interception depending on growth stage	Step 1: not relevant Step 2: minimal crop cover (40%) Step 3: interception depending on growth stage
Application method	Drainage scenarios: air blast Runoff scenarios: air blast, CAM2	Drainage scenarios: air blast Runoff scenarios: air blast, CAM2
Application timing	Step 1: not relevant Step 2: March to May Step 3***: beginning of emergence to 30 days after emergence	Step 1: not relevant Step 2: March to May Step 3***: beginning of emergence to 30 days after emergence

* application rate corresponds to 3 m crown height
** application rate corresponds to plant height > 125 cm
*** time period for first and last possible application

All FOCUS_SW site scenarios were used without any change. The concentrations presented are the maximum concentrations in the given simulation period.

Table 2.5-7: Key substance parameters used in the FOCUS_SW calculations

Parameter	FOCUS evaluation steps			Rapeseed oil	
	1	2	3	input value	range
Vapour pressure (Pa) (calculated for 25 °C)			x	1.33×10^{-18}	n.r.
Solubility in water (mg/L)	x	x	x	0.000001*	n.r.
K_{OC} (mL/g)	x	x	x	1724000**	n.r.
Freundlich sorption exponent			x	0.9***	n.r.
Plant uptake			x	0.0	n.r.
$DT_{50\ soil}$[a] (days)		x	x	2.0****	1.9 to 2.0 (n = 2)
$DT_{50\ water}$[b] (days)		x	x	2.8	n.r.
$DT_{50\ sediment}$[c] (days)		x	x	2.0	n.r.
$DT_{50\ system}$[d] (days)	x			2.8	n.r.

n.r. not relevant
* corresponds to the minimum input value for step 3 modelling software, calculated value: 2.551×10^{-20} mg/L at 25 °C and the neutral range
** corresponds to the maximum input value for step 3 modelling software, calculated value: 1 x 1010 mL/g
*** default value
**** maximum value
a following 1st order kinetics, soil moisture adjusted to field capacity
b no water/sediment study available, maximum value (not moisture corrected) from laboratory soil degradation study
c no water/sediment study available, mean value from laboratory soil degradation study
d no water/sediment study available, maximum value (not moisture corrected) from laboratory soil degradation study

In the tables below the calculated PECsw ini for Step 1-2 and Step 3 are summarised.

Table 2.5-8: Maximum predicted actual concentrations of Rapeseed oil in surface water (PECSW actual) after one application of NEU 1160 I (FOCUS evaluation steps 1 and 2)

Crop (FOCUS crop scenario)	Step	No. appl.	Appl. rate (kg a.s./ha)	Region and season of appl.	Drift (%)*	Maximum PECSW actual (µg a.s./L)
Orchards (Pome/stone fruit, early)	1**	1	26.490	n.r.	29.197	2580.000
	2**	1	26.490	N, March-May	29.197	2580.000
	2**	1	26.490	S, March-May	29.197	2580.000
Ornamentals (Vines, late)	1**	1	21.192	n.r.	8.028	570.170
	2**	1	21.192	N, March-May	8.028	567.098
	2**	1	21.192	S, March-May	8.028	567.098

n.r. not relevant
N Northern Europe
S Southern Europe
* % of application rate
** concentration in water layer exceeds water solubility of Rapeseed oil

Table 2.5-9: Maximum predicted actual concentrations of Rapeseed oil in surface water (PECSW actua) after one application of NEU 1160 I at recommended application rates in orchards and ornamentals (FOCUS evaluation step 3)

Crop (FOCUS crop scenario)	Step	Scenario	Water body	No. appl.	Drift (%)*	PECsw global max. act. conc. (µg a.s./L)	
						dissolved in water	adsorbed to suspended solids
Orchards (Pome/stone fruit, early)	3	D3**	Ditch	1	23.599	867.773 a	1188.226
		D4**	Pond	1	4.730	43.961 a	81.113
		D4**	Stream	1	25.899	842.798 a	1157.405
		D5**	Pond	1	4.730	43.949 a	81.094
		D5**	Stream	1	25.899	839.754 a	1153.642
		R1**	Pond	1	4.730	43.953 a	81.101
		R1**	Stream	1	25.899	693.076 a	970.593
		R2**	Stream	1	25.899	934.169 a	1269.745
		R3**	Stream	1	25.899	1001.670 a	1352.03
		R4**	Stream	1	25.899	693.248 a	970.809
Ornamentals (Vines, late)	3	D6**	Ditch	1	5.173	134.161 a	221.411
		R1**	Pond	1	0.612	3.861 a	9.086
		R1**	Stream	1	5.152	97.760 a	166.524
		R2**	Stream	1	5.152	132.058 a	218.285
		R3**	Stream	1	5.152	141.543 a	232.344
		R4**	Stream	1	5.152	97.728 a	166.476

a peak occurs at time of spray drift event
* % of application rate
** error message: concentration in water layer exceeds water solubility of Rapeseed oil in all segments considered

The water concentrations presented generally exceed the water solubility of Rapeseed oil. The assumed higher water solubility can partly be justified by the emulsifying agent of the formulation which increases the water solubility of Rapeseed oil. Thus, the concentrations calculated were taken as a worst case though overestimating the concentrations of Rapeseed oil in water.

The concentrations of Rapeseed oil related to suspended solids in surface waters are also summarised in Table 2.5-9. These concentrations can be attributed to the extremely high Koc value of Rapeseed oil. Assuming a considerable inhibition of the adsorption of Rapeseed oil to suspended solids by the emulsifier, it can be concluded that significantly lower concentrations are reached under more realistic circumstances than predicted by standard simulation runs. Therefore, concentrations of Rapeseed oil related to suspended solids were not further considered since they represent unrealistic worst case conditions.

In the table 2.5-10 the TWA in water at 1, 2 and 4 d after the global maximum are given

Table 2.5-10: 1, 2 and 4 time weighted average (twa) PECSW of Rapeseed oil (dissolved)

Orchards (Pone/stone fruits, early).			
scenarios	**1d TWA (µg/L)**	**2d TWA (µg/L)**	**4d TWA (µg/L)**
D3- ditch	389.937	231.764	128.739
D4-pond	35.435	30.043	23.524
D4-stream	51.476	25.829	12.958
D5-pond	34.905	29.243	22.372
D5-stream	30.514	15.283	7.654
R1-pond	34.959	29.319	22.472
R1-stream	107.382	54.174	27.289
R2-stream	73.159	36.75	18.442
R3-stream	250.125	128.812	65.893
R4-stream	108.017	54.5	27.456
Ornamentals (Vine, late)			
scenarios	**1d TWA (µg/L)**	**2d TWA (µg/L)**	**4d TWA (µg/L)**
D6-ditch	38.858	20.232	10.5
R1-pond	3.137	2.654	2.046
R1-stream	14.631	7.363	3.704
R2-stream	10.246	5.141	2.578
R3-stream	34.198	17.468	8.893
R4-stream	14.529	7.312	3.678

2.6 Effects on non-target species

2.6.1 Effects on Terrestrial Vertebrates

2.6.1.1 Effects on birds

Not acute, subchronic or reproduction studies of Rapeseed oil (using technical product or with the formulated NEU 1160 I) on birds have been submitted. It can be justified that continued or repeated exposure of adults, or exposure of nest sites during the breeding season is very unlikely to occur due to it is intended to be used for greenhouse ornamentals with 3 applications (glass house, indoor) per growing season, or in orchards and woody ornamentals in the field (1 application) at the start of the vegetation period. Therefore chronic exposure can be excluded and not further information is needed according to 91/414/EEC.

Rapeseed oil is natural oil which is also used as a food commodity. It is a mixture of esters (triglycerides) of different fatty acids. It is known that dietary lipids are processed by known metabolic pathways within the body and contribute to normal physiological functions. They are utilized as a carbon and energy source.

Taking into account that: 1) fatty acids are naturally contributing to the feed of birds, 2) the mode of action of rapeseed oil is mechanical rather than chemical, 3) secondary poisoning for birds eating contaminated food is unlikely to occur and 4) low rat acute toxicity is showed (LD_{50} > 1794.1 mg a.i./kg b.w) low risk is expected for birds as result of exposure Rapeseed oil residue in food items neither in diet nor by secondary poisoning under intended uses.

We can conclude that negligible risk to birds can be expected after NEU 1160 I use if it is applied according with Good Agriculture Practices and with the recommended use pattern. Not further information is needed.

2.6.1.2 Effects on mammals

Rapeseed oil is a dietary vegetable oil derived from seeds of *Brassica napus*. Dietary lipids are processed by known metabolic pathways within the body and contribute to normal physiological functions. They are utilized as a carbon and energy source.

Rapeseed oil is used as a contact acaricide and/or insecticide in formulations for the use against spider mites, mealy bugs and scales in ornamentals and orchards and/or for the suppression of winter eggs of spider mites in orchards and woody ornamentals. It is intended to be used for greenhouse ornamentals with 3 applications (glass house, indoor) per growing season, or in orchards and woody ornamentals in the field (1 application) at the start of the vegetation period. Application rates are dependent on the height of the plants.

In order to perform a higher tier risk assessment on mammals toxicity values of Rapeseed oil in rat were selected because of its ecotoxicological relevance in accordance with the requirements of Annex III, point 10.3 of directive 91/414/EEC.

Not acute toxicity data with the formulated product NEU 1160 I are submitted by the notifier. Instead the acute toxicity with the formulation NEU 1161 I was reported. According with the notifier, NEU 1161 I contains 90% Rapeseed oil and 2% Pyrethrum. As Pyrethrum is the more toxic ingredient of NEU 1161 I it can be concluded that the toxicity of Rapeseed oil is much lower. Thus, the results of NEU 1161 I may be extrapolated to Rapeseed oil. RMS agrees with notifier comments and it is logical to assume that NEU 1161 I will be more toxic that NEU 1160 I.

The acute LD_{50} value of formulated product (NEU 1161 I) indicates moderately low toxicity for mammals, suggesting potentially low risk to mammals even if they get in contact with the substance by accident.

For chronic toxicity not studies with technical substance or formulated have been submitted. Long-term exposure of Rapeseed oil to mammals is not indicated due to the rapid microbial degradation of Rapeseed oil in soil (lab data, DT_{50} = 3-9 days) and plants. Not long-term toxicity data for Rapeseed oil is required because the low bioaccumulation potential expected and the low acute toxicity observed in rats. Also, rapeseed oil is a natural oil which is also used as a food commodity. It is a mixture of esters (triglycerides) of different fatty acids. It is known that dietary lipids are processed by known metabolic pathways within the body and contribute to normal physiological functions. They are utilized as a carbon and energy source. Taking into account that: 1) fatty acids are naturally contributing to the feed of birds, 2) the mode of action of rapeseed oil is mechanical rather than chemical, 3) secondary poisoning for mammals eating contaminated food is unlikely to occur and 4) low rat acute toxicity is showed (LD_{50} > 1794.1 mg a.i./kg b.w), it is expected low risk to wild mammals for formulated products containing rapeseed oil.

Low risk is expected for wild mammals as result of exposure Rapeseed residue in food items neither in diet nor by secondary poisoning under intended uses.

For a first tier risk assessment, the relatively low acute toxicity data of formulated product containing Rapeseed oil to rats and the proposed use of NEU 1160 I suggests that negligible risk to wild mammals can be expected after NEU 1160 I use if it is applied according with Good Agriculture Practices and with the recommended use pattern. Not further information is required.

2.6.2 Effects on Aquatic Organisms

The acute toxicity of the active substance and one formulated product, NEU 1160 I, have been established in several studies for fish, Daphnia and green algae. Taking into account the more sensitive species in the reported acute ecotoxicity data: the aquatic invertebrate *Daphnia magna* (48h-EC_{50} = 4.5 mg a.i./L, Notifier 96.72 mg a.i./L) is the most sensitive standard test species tested follow of the vertebrate fish *Oncorhynchus mykiss* (96h-LC_{50} > 7.48 mg a.i./L, Notifier > 249.4 mg ai./L) and the green algae (72h-EbC_{50} = 41.1 mg a.i./L, Notifier 287.4 mg/L). Applying an assessment factor of 10 (for algae) or 100 (to vertebrates and invertebrates) to the lowest toxicity data, the trigger value according to the EU Uniform principles results for aquatic primary producers in a first-tier acceptable concentration of 4.11 mg a.i./L, for aquatic invertebrates of 0.045 mg a.i./L and for aquatic vertebrate of 0.0748 mg a.i./L.

The short-term first-tier data mentioned above indicate that primary producers are potentially at risk at exposure concentrations higher than 4.11 mg a.i./L. Potential risks for aquatic invertebrates might occur at concentrations higher than 0.045 mg a.i./L and for aquatic vertebrates at concentrations higher than 0.0748 mg a.i/L.

A comparison of the results from studies with the active substance and the formulation product for aquatic invertebrates indicates that the toxicity of Rapseed oil is higher that the formulated product NEU 1160 I, therefore using the toxicity data based on testing with the active substance will provide a conservative estimate of the risk of Rapseed oil to aquatic organisms. However, it is clear that formulated product NEU 1160 I is less toxic that the technical product on daphnids, and this can be considered in the risk assessment. This is in agreement with the technical composition of the formulation since the formulation contains an emulgator which reduces the mechanical effect of Rapeseed oil on daphnids.

For the characterization of Rapeseed oil ecotoxicological profile on several aquatic organisms the same batch of the technical substance has been used. The complete technical specifications of the different batches used in these ecotoxicological studies are not provided by the notifier but because are identical batches the comparability is granted. As conclusion, based on the assumption above exposed all the technical substances used in the ecotoxicological profile of Rapeseed oil are comparable and the (see below) aquatic risk assessment is adequate.

Short term risk assessment:

Aquatic organisms may be exposed to NEU 1160 I by emissions from treated fields. The provided studies and data permit an assessment of acute risk following exposure to under practical conditions.

In a first tier risk assessment, the TERa values calculated in the framework of Directive 91/414/EEC (using notifier global maximum PECsw calculations, FOCUS step 1), indicates that negligible short-risk to algae species can be expected after NEU 1160 I use if it is applied according with Good Agriculture Practices. However, TERa values for to aquatic vertebrates (rainbow trout) and aquatic invertebrates (daphnids) are below the acceptability criteria according to Annex VI of the EU-directive 91/441/EEC (table 2.6.2-1).

Table 2.6.2-1: Acute TER (TERa) values for aquatic organism exposed to Rapeseed oil. FOCUS step 1 scenario.

Organism		Toxicity (mg a.i./L)	PECsw actual concentrations (mg a.i. /L)	TERa	Trigger value EU 91/414/EEC
Pome/stone (early). Field application					
Aquatic vertebrate: fish	Notifier	> 249.4	2.580	**> 96.6**	**100**
Oncorhynchus mykiss	RMS	> 7.48	2.580	**> 2.89**	**100**
Aquatic crustacean	Notifier	> 96.72	2.580	**> 37.49**	**100**
Daphnia magna	RMS	4.5	2.580	**1.74**	**100**
Algae	Notifier	287.4	2.580	111	**10**
Desmodesmus subspicatus	RMS	41.4	2.580	16	**10**
Ornamentals (leafy veg.). Field application					
Aquatic vertebrate: fish	Notifier	> 249.4	0.570	> 437	**100**
Oncorhynchus mykiss	RMS	< 7.48	0.570	**> 13**	**100**
Aquatic crustacean	Notifier	> 96.72	0.570	> 169	**100**
Daphnia magna	RMS	4.5	0.570	**8**	**100**
Algae	Notifier	287.4	0.570	504	**10**
Desmodesmus subspicatus	RMS	41.4	0.570	72.6	**10**
Ornamentals (plant height > 125 cm (glass house use)					
Aquatic vertebrate: fish	Notifier	249.4	0.02842	8775	**100**

Organism		Toxicity (mg a.i./L)	PECsw actual concentrations (mg a.i. /L)	TERa	Trigger value EU 91/414/EEC
Oncorhynchus mykiss	RMS	7.48	0.02842	263	**100**
Aquatic crustacean	Notifier	96.72	0.02842	3403	**100**
Daphnia magna	RMS	4.5	0.02842	158	**100**
Algae	Notifier	287.4	0.02842	10112	**10**
Desmodesmus subspicatus	RMS	41.4	0.02842	492	**10**

In a refined risk assessment, using FOCUS step 2 (see table 2.6.2-2) and step 3 (tables 2.6.2-3 and 2.6.2-4), the TERa values calculated for aquatic vertebrates and invertebrates taking the more conservative approach (toxicity data from technical product and using measured concentrations) proposed by RMS show that aquatic vertebrates and invertebrates can be at risk after NEU 1160 I application in field in some scenarios (see table 2.6.2-4). However, calculations performed by the notifier indicate that negligible acute risk can be expected for aquatic vertebrates and invertebrates after NEU 1160 I application (see table 2.6.2-3). These differences can be explained for the difficulty to maintain nominal concentrations through the exposure period in the toxicity tests, as consequence of the low solubility in water of Rapeseed oil, and the water phase separation. Thus, notifier calculations are based on nominal concentrations and RMS are based on measured (estimated) concentrations.

Table 2.6.2-2: Acute TER (TERa) values for aquatic organism exposed to Rapeseed oil. FOCUS step 2 scenario for North and south of Europe.

Organism		Toxicity (mg a.i./L)	PECsw actual concentrations (mg a.i. /L)	TERa	Trigger value EU 91/414/EEC
Pome/stone (early). Field application					
Aquatic vertebrate: fish	Notifier	> 249.4	2.580	**> 96.6**	**100**
Oncorhynchus mykiss	RMS	> 7.48	2.580	**> 2.89**	**100**
Aquatic crustacean	Notifier	> 96.72	2.580	**> 37.49**	**100**
Daphnia magna	RMS	4.5	2.580	**1.74**	**100**
Ornamentals (leafy veg.). Field application					
Aquatic vertebrate: fish	Notifier	> 249.4	0.567	> 437	**100**
Oncorhynchus mykiss	RMS	> 7.48	0.567	**> 13**	**100**
Aquatic crustacean	Notifier	> 96.72	0.567	> 169	**100**
Daphnia magna	RMS	4.5	0.567	**8**	**100**

Table 2.6.2-3.: Acute toxicity/exposure ratios (TER) for fish and daphnids after use of Rapeseed oil (field use) using FOCUS step 3 scenarios**.**

Crop	Step	Scenario	Water body	TER (100) RMS	Drift (%)	PEC_{sw} (µg a.i./L) global max. act. conc.	TER (100) Notifier
Aquatic vertebrates: fish							
Pome/stone (early)	3	D3	Ditch	**>8.62**	23.599	867.773	> 287.40
	3	D4	Pond	>170	4.730	43.961	> 5673.21
	3	D4	Stream	**>8.8**	25.899	842.798	> 295.92
	3	D5	Pond	>170	4.730	43.949	> 5674.76
	3	D5	Stream	**>8.9**	25.899	839.754	> 296.99
	3	R1	Pond	>170	4.730	43.953	> 5674.24
	3	R1	Stream	**>10.7**	25.899	693.076	> 359.84
	3	R2	Stream	**>8**	25.899	934.169	> 266.97
	3	R3	Stream	**>7.5**	25.899	1001.670	> 248.98
	3	R4	Stream	>289	25.899	693.248	> 359.75
Ornamentals (leafy veg.)	3	D6	Ditch	**>55.75**	5.173	134.161	>1858.9
	3	R1	Pond	>1937	0.612	3.861	>64594
	3	R1	Stream	**>76.51**	5.152	97.76	>2551
	3	R2	Stream	**>56**	5.152	132.058	>1888
	3	R3	Stream	**>52.8**	5.152	141.543	>1762
	3	R4	Stream	**>76.53**	5.152	97.728	>2551
Aquatic invertebrates: daphnids							
Pome/stone (early)	3	D3	Ditch	**>5.2**	23.599	867.773	> 111.46
	3	D4	Pond	>102	4.730	43.961	> 2200.30
	3	D4	Stream	**>5**	25.899	842.798	> 114.77
	3	D5	Pond	>102	4.730	43.949	> 2200.91
	3	D5	Stream	**>5.35**	25.899	839.754	> 115.18
	3	R1	Pond	>102	4.730	43.953	> 2200.71
	3	R1	Stream	**>6.49**	25.899	693.076	> 139.56
	3	R2	Stream	**>4.8**	25.899	934.169	> 103.54
	3	R3	Stream	**>4.5**	25.899	1001.670	**> 96.57**
	3	R4	Stream	**>6.5**	25.899	693.248	> 139.53
Ornamentals (leafy veg.)	3	D6	Ditch	**>33**	5.173	134.161	> 720.98
	3	R1	Pond	>1165	0.612	3.861	> 25052.50
	3	R1	Stream	**>46**	5.152	97.76	> 989.44
	3	R2	Stream	**>34**	5.152	132.058	> 732.46
	3	R3	Stream	**>32**	5.152	141.543	> 683.38
	3	R4	Stream	**>47**	5.152	97.728	> 989.76

Table 2.6.2-4.: Acute toxicity/exposure ratios (TER) for fish and daphnids after use of Rapeseed oil (field use) using FOCUS step 3 scenarios. The following PEC_{twa} have been used: 4d-PEC_{twa} (fish) and 2d-PEC_{twa} (daphnids).

Crop	Step	Scenario	Water body	Drift (%)	PEC_{tsw} (µg a.i./L)	TER (100)
Aquatic vertebrates: fish (LC50 >7.48 mg a.s/L)						
Pome/stone (early)	3	D3	Ditch	23.599	128.739	**> 58**
	3	D4	Pond	4.730	23.524	> 318
	3	D4	Stream	25.899	12.958	> 577
	3	D5	Pond	4.730	22.372	> 334
	3	D5	Stream	25.899	7.654	> 977
	3	R1	Pond	4.730	22.472	> 332
	3	R1	Stream	25.899	27.289	> 274
	3	R2	Stream	25.899	18.442	> 405
	3	R3	Stream	25.899	65.893	> 113
	3	R4	Stream	25.899	27.456	> 272
Ornamentals (leafy veg.)	3	D6	Ditch	5.173	10.5	> 712
	3	R1	Pond	0.612	2.046	> 3655
	3	R1	Stream	5.152	3.704	> 2019
	3	R2	Stream	5.152	2.578	> 2901
	3	R3	Stream	5.152	8.893	> 841
	3	R4	Stream	5.152	3.678	> 2131
Aquatic invertebrates: daphnids (LC50 = 4.5 mg a.s./L)						
Pome/stone (early)	3	D3	Ditch	23.599	231.764	**19**
	3	D4	Pond	4.730	30.043	149
	3	D4	Stream	25.899	25.829	174
	3	D5	Pond	4.730	29.243	154
	3	D5	Stream	25.899	15.283	294
	3	R1	Pond	4.730	29.319	153
	3	R1	Stream	25.899	54.174	**83**
	3	R2	Stream	25.899	36.75	122
	3	R3	Stream	25.899	128.812	**35**
	3	R4	Stream	25.899	54.5	**82**
Ornamentals (leafy veg.)	3	D6	Ditch	5.173	20.232	222
	3	R1	Pond	0.612	2.654	1698
	3	R1	Stream	5.152	7.363	611
	3	R2	Stream	5.152	5.141	875
	3	R3	Stream	5.152	17.468	258
	3	R4	Stream	5.152	7.312	615

RMS Notes: It is clear that Rapeseed oil has a poor solubility in water suggesting: 1) that exposure in the relevant ecotoxicity tests can be unrealistic, and 2) lower concentrations can be reached under more realistic circumstances that the predicted for standard simulations (FOCUSsw). In addition, data from toxicity test on daphnids, performed with the formulated product, suggests that low toxicity with the formulation can be expected under more realistic conditions. **Therefore risk calculated based on toxicity data with the technical product database is conservative.**

Not chronic and/or bioaccumulation database is available to calculate a long-term risk assessment, but according with the available information aquatic vertebrates and invertebrates could be not at risk after NEU 1160 I for the following reasons:

* Low solubility of Rapeseed oil in water
* Mode of action mechanical rather than chemical
* Relatively short DT_{50} in water (estimated from soil data DT_{50} = 3-9 days)
* Low potential for bioaccumulation
* In field only 1 application is proposed
* Dietary lipids are processed by known metabolic pathways within the body and contribute to normal physiological functions. They are utilized as a carbon and energy source.

Thus, it is expected that NEU 1160 I does not impose a long-term risk to aquatic organisms when applied according to good agricultural practice.

Not relevant metabolites in water have been identified and therefore not toxicity database is available.

Sediment dwelling organisms: accumulation of Rapeseed oil in the sediment is unlikely, due to the rapid degradation in nature (DT_{50} soil 3-9 days). Assuming a considerable inhibition of the adsorption of Rapeseed oil to sediment by the emulsifier under use conditions, suggests that significantly lower concentrations can be reached under more realistic circumstances than predicted by standard simulation runs (refer to Fate section). Furthermore, based on toxicity data with the formulation NEU 1160 I on daphnids (48 EC50 > 96.72 mg a.i./L) effects of Rapeseed oil on sediment dwelling organisms are not expected. No further information is required.

Conclusion: In a first tier risk assessment, the TERa values calculated in the framework of Directive 91/414/EEC (using notifier global maximum PECsw calculations, FOCUS step 1), indicates that negligible short- risk to algae species can be expected after NEU 1160 I use if it is applied according with Good Agriculture Practices.

Taking into account the more conservative approach proposed by RMS (Focus step 3, toxicity data analytical concentrations) it is clear that aquatic vertebrates and invertebrates can be at short-term risk after NEU 1160 I application in field in some scenarios. In order to be conservative RMS proposes that mitigations measures can be defined at Member state level to protect aquatic vertebrates and invertebrates after NEU 1160 I application.

It is expected that NEU 1160 I does not impose a long-term risk to aquatic organisms and sediment dwelling organisms when applied according to good agricultural practice.

2.6.3 Effects on bees and other arthropod species

Bees: Studies describing the toxicity of Rapeseed oil to bees have been not submitted by the Notifier. Rapeseed oil will be applied before sprout, when there is no bee activity therefore no more information is needed.

Therefore negligible risk to bees species can be expected after NEU 1160 I use if it is applied according with Good Agriculture Practices.

Arthropod species other than bees: Studies describing the toxicity of technical substance Rapeseed oil to terrestrial arthropods other than bees have been not submitted by the Notifier. However, two studies describing the toxicity of formulated product NEU 1160 I (containing Rapeseed oil) show that in an extended laboratory study with *Typhlodromus pyri* the 7-day LR_{50} of NEU 1160 I was > 30 L product/ha, which is equivalent to 26.49 kg Rapeseed oil/ha. In a further extended laboratory study with *Aphidius rhopalosiphi* the 48-h LR_{50} for NEU 1160 I was calculated to be 100 L product/ha, which is equivalent to 88.30 kg Rapeseed oil/ha.

To assess the risk to terrestrial arthropods following the use of NEU 1160 I, the hazard quotient (HQ), which is the ratio of the application rate (in kg a.i./ha) and acute toxicity (LR_{50} in kg a.i./ha), was determined.

Hazard quotient calculations: Ornamentals (glass house) and orchards (in field)

The resulting HQ values are presented for the worst-case use (x 3 applications) for ornamentals (glass house) and for orchards (in field, 1x application, assuming 3 m crown height, 30 L product/ha) in Table 2.6.3-1. The scenario orchards covers the in field use of woody ornamentals (maximum application rate is 24 L product/ha).

Table 2.6.3-1: Predicted risk for terrestrial arthropods arising from the use of NEU 1160 I in ornamentals (glass house, and in field use) and orchards (in field use)

Glass house: Predicted risk for terrestrial arthropods arising from the use of NEU 1160 I in ornamentals					
Test species	**Endpoint**	**LD_{50}** (kg a.i./ha)	**Exposure scenario**	**Application rate** (kg a.i./ha)	**HQ**
Typhlodromus pyri	LR_{50}, 7 d, lab.	> 26.49	In - crop	70.64	**< 2.66**
			Off – crop[1]	4.87	< 0.18
Aphidius rhopalosiphi	LR_{50}, 24 h, lab.	88.30	In - crop	70.64	0.80
			Off – crop[1]	4.87	0.05
In field: Predicted risk for terrestrial arthropods arising from the use of NEU 1160 I in orchards					
Test species	**Endpoint**	**Result** (kg a.i./ha)	**Exposure scenario**	**Application rate** (kg a.i./ha)	**HQ**
Typhlodromus pyri	LR_{50}, 7 d, lab.	> 26.49	In - crop	26.49	< 1.00
			Off – crop[2]	7.73	< 0.29
Aphidius rhopalosiphi	LR_{50}, 24 h, lab.	88.30	In - crop	26.49	0.30
			Off – crop[2]	7.73	0.09

[1] Off crop exposure was considered at 3 m distance, assuming 6.9 % drift (vines, late)

[2] Off crop exposure was considered at 3 m distance, assuming 29.20 % drift (orchards early)

As indicated by hazard quotients upper the trigger value of 2, agreed on the ESCORT 2 workshop, March 2000 effects were observed for *Typhlodromus pyri* but not effects were observed for *Aphidius rhopalosiphi* after application of NEU 1160 I at the recommended field rate in the in-crop area of ornamentals in the glass house. Therefore risk mitigation measures are needed in order to protect predatory mites after products containing Rapeseed oil for ornamentals in glass house.

As indicated by hazard quotients upper the trigger value of 2, agreed on the ESCORT 2 workshop, March 2000 not effects were observed for *Typhlodromus pyri* and for *Aphidius rhopalosiphi* in-crop after application of NEU 1160 I at the field rate in orchards (application rate of 30 L product/ha, 3m crown height, 26.49 kg a.i./ha). This scenario covers the in field use of NEU 1160 I in woody ornamentals (maximum application rate 24 L product/ha).

In order to protect predatory mite populations risk mitigation measures are required at Member state level for the intended use of NEU 1160 I for ornamentals in the glass house.

In conclusion: risk to predatory mites can be expected after NEU 1160 I, for the use proposed in glass house (3 applications). Thus in order to protect predatory mite populations risk mitigation measures are required at Member state level (for the intended use of NEU 1160 I for ornamentals in the glass house).

A negligible risk to terrestrial arthropods other than bees can be expected after in field use (1x application) of NEU 1160 I in orchards (assuming maximum application rate 30 L product/ha, 3 m crown height, 26.49 kg a.i./ha) and in woody ornamentals if it is applied according with Good Agriculture Practices.

2.6.4 Effects on earthworms and other soil macro-organisms

The short-term toxicity of technical substance has not been investigated on earthworms (*Eisenia foetida*) instead the acute toxicity of formulated product NEU 1161 I (containing Rapessed oil) have been investigated on earthworms (*Eisenia foetida*). Rapeseed oil has a moderate low acute toxicity to earthworms, thus the 14d-$LC_{50correc}$. > 500 mg NEU 1161 I/kg dry weight soil (=14d-$LC_{50corre}$ > 448.95 mg a.i./kg dry weight soil).

Not acute toxicity data with the formulated product NEU 1160 I are submitted by the notifier. Instead the acute toxicity with the formulation, NEU 1161 I was reported. According with the notifier, NEU 1161 I contains 90% Rapeseed oil and 2% Pyrethrum. As Pyrethrum is the more toxic ingredient of NEU 1161 I it can be concluded that the toxicity of Rapeseed oil is much lower. Thus, the results of NEU 1161 I may be extrapolated to Rapeseed oil. RMS agrees with notifier comments and it is logical to assume that NEU 1161 I will be more toxic that NEU 1160 I.

To assess the acute risk occurring from the application of NEU 1161 I, the acute toxicity/exposure ratio TER_A was calculated, which is the ratio of the LC_{50} (mg a.i./kg d.w.) and the initial PEC (mg a.i./kg d.w.). The resulting TERa values are presented for the worst-case use (x 3 applications) for ornamentals (glass house) and for orchards (in field, 1x application, assuming 3 m crown height, 30 L product/ha) in Table 2.6.4-1. The scenario orchards covers the in field use of woody ornamentals (maximum application rate is 24 L product/ha).

Table 2.6.4-1: Acute toxicity/exposure ratios for earthworms in ornamentals (glass house) and in field use (ornamentals and orchards).

Glass house: Acute toxicity/exposure ratios for earthworms in ornamentals					
Appl. Rate (kg a.i./ha)	**Test species**	**LC_{50} (mg a.i./kg d.w.)**	**Exposure scenario**	**Initial PEC related to soil depth (mg a.i./kg d.w.)**	**TER_A**
Ornamentals 70.64	*Eisenia foetida*	> 448.95	In-crop (25% interception)	85.34	**> 5.26**
			Off-crop1	5.89	> 76.22

In field: Acute toxicity/exposure ratios for earthworms in pome/stone and ornamentals					
Appl. Rate (kg a.i./ha)	**Test species**	**LC_{50} (mg a.i./kg d.w.)**	**Exposure scenario**	**Initial PEC related to soil depth (mg a.i./kg d.w.)**	**TER_A**
Orchards 26.49	*Eisenia foetida*	> 448.95	50% reaching soil	17.66	> 25.42
Ornamentals 21.19	*Eisenia foetida*	> 448.95	50% reaching soil	21.19	> 21.18

1 Off crop exposure was considered at 3 m distance, assuming 6.9 % drift (vines, late)

The calculated TERa values for Rapeseed oil show values above the trigger of 10 for orchards and ornamentals (in field use) and below the trigger of 10 in ornamentals (glass house). Thus, NEU 1161 I does not impose an acute risk to earthworms for the uses proposes in field and does impose an acute risk to earthworms for one of the uses proposes (ornamentals, glass-house).

Therefore, risk mitigation measures are needed for the use of earthworms in ornamentals (glass house application).

According with Fate section Rapeseed oil has a high Koc value of 1×10^{10} (obtained by calculation) and is immobile in soils, and is likely to remain on the soil.

The long-term toxicity of Rapeseed oil has not been investigated on earthworms, and not information has been submitted by the notifier. Not long term toxicity database is available to calculate a long-term risk assessment, but according with the information available earthworms could be not at risk after NEU 1160 I for the following reasons:

* Relatively short DT_{50} in soil (estimated from laboratory data DT_{50} = 3-9 days)
* Low potential for bioaccumulation
* In field only 1 application is proposed
* Dietary lipids are processed by known metabolic pathways within the body and contribute to normal physiological functions. They are utilized as a carbon and energy source.

Thus, it is expected that NEU 1160 I does not impose a long-term risk to earthworms when applied according to good agricultural practice.

In conclusion: acute risk to earthworms can be expected after NEU 1160 I, for the use proposed in glass house (3 applications). Thus in order to protect earthworm populations, risk mitigation measures are required at Member state level (for the intended use of NEU 1160 I for ornamentals in glass house).

A negligible risk to earthworms other than bees can be expected after in field use (1x application) of NEU 1160 I in orchards (assuming maximum application rate 30 L product ha, 3 m crown height, 26.49 kg a.i./ha) and in woody ornamentals if it is applied according with Good Agriculture Practices.

Chronic risk from the Rapeseed oil use can not be expected on earthworms because of rapid degradation of Rapeseed oil in soil and the low bioaccumulation potential.

With the available information a safe use of NEU 1160 I is granted for in field use of NEU 1160 I (1 application, maximum application rate 30L product/ha) to earthworms and/or other soil macro-organisms species. However, a potential acute risk is identified for use of NEU 1160 I in ornamentals (glass house, 3 applications). Therefore, risk mitigation measures are needed for the intended use on ornamentals in glass house in order to protect soil macro organism in soil.

2.6.5 Effects on soil micro-organisms

Not soil toxicity data with the formulated product NEU 1160 I on soil microorganisms are submitted by the notifier. Instead the toxicity with the formulation, NEU 1161 I was reported. According with the notifier, NEU 1161 I contains 90% Rapeseed oil and 2% Pyrethrum. As Pyrethrum is the more toxic ingredient of NEU 1161 I it can be concluded that the toxicity of Rapeseed oil is much lower. Thus, the results of NEU 1161 I may be extrapolated to Rapeseed oil. RMS agrees with notifier comments and it is logical to assume that NEU 1161 I will be more toxic that NEU 1160 I.

Negligible risk can be expected after use of NEU 1161 I on soil microflora because the effects on short term respiration rate are < 25% after 28 days for two soil types at dosage rate higher that those proposed in the GAP.

Also, negligible risk can be expected after use of NEU 1161 I on soil microflora because the effects on nitrogen turnover are < 25% after 28 days for one soil type, and for other soil the time-course show recovery at 90 days (< 25% effect after 90 days).

In conclusion, not relevant effects on soil microorganisms can be expected after NEU 1160 I use if it is applied according with Good Agriculture Practices and the recommended use pattern.

2.6.6 Effects on other non-target plants

Not toxicity data with the formulated product NEU 1160 I on non-target plants are submitted by the notifier. Instead the toxicity with the formulation, NEU 1161 I was reported. According with the notifier, NEU 1161 I contains 90% Rapeseed oil and 2% Pyrethrum. As Pyrethrum is the more toxic ingredient of NEU 1161 I it can be concluded that the toxicity of Rapeseed oil is much lower. Thus, the results of NEU 1161 I may be extrapolated to Rapeseed oil. RMS agrees with notifier comments and it is logical to assume that NEU 1161 I will be more toxic that NEU 1160 I.

The toxic effects of the NEU 1161 I on the vegetative vigour of six non-target plant species (*Raphanus sativus*, *Cucumis sativus*, *Vicia faba*, *Lycopersicon esculentum*, *Allium cepa*, *Avena sativa*) have been investigated. NEU 1161 I did not cause any statistically significant effect on fresh weight in any of the tested species. Mortality did not occur. Phytotoxicity was only observable in *Vicia faba* (< 2%) but was considered as a normal process which occurs in older leaves. Consequently, there is no evidence for an interaction between NEU 1161 I and the plant species tested.

A quantitative risk assessment for terrestrial plants is not presented here since no ER_{50} values could be determined. The application rate used in the study does not cover all the uses proposed in the GAP: covers in field use (ornamentals: 21.19 kg as/ha and orchards 26.49 kg as/ha) and excluded ornamentals in glass house (70.64 kg as./ha).

In conclusion, negligible risk to terrestrial plants after one application of NEU 1160 I (=24.76 kg Rapeseed oil/ha) can be expected, since not phytotoxic effects at this application rate are observed.

2.6.7 Effects on biological methods of sewage treatment

No information has been submitted and it is not considered relevant for the intended use of NEU 1160 I.

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

Active substance (ISO Common Name) ‡	Rapeseed oil
Function (*e.g.* fungicide)	Insecticide and acaricide
Rapporteur Member State	Spain
Co-rapporteur Member State	

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Rüböl, refined
Chemical name (CA) ‡	Rüböl, refined
CIPAC No ‡	not available
CAS No ‡	8002-13-9
EC No (EINECS or ELINCS) ‡	232-299-0
FAO Specification (including year of publication) ‡	No FAO specification
Minimum purity of the active substance as manufactured ‡	The purity complies with the Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994 Active substance is not a single compound but a mixture of triglycerides of fatty acids and the mode of action is mechanical rather that chemical: 100% of technical active substance is considered as active substance.
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	No isomers, impurities or additives are included.
Molecular formula ‡	Not possible as it is a mixture of triglycerides
Molecular mass ‡	Not possible as it is a mixture of triglycerides
Structural formula ‡	Not possible as it is a mixture of triglycerides

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	-12.0 – -30.6 °C (100%)
Boiling point (state purity) ‡	> 350°C (100%)
Temperature of decomposition (state purity)	> 350 °C (100%)
Appearance (state purity) ‡	Light yellow, liquid (100%)
Vapour pressure (state temperature, state purity) ‡	$1.33*10^{-18}$ Pa (obtained by calculation) **RMS proposal**: < 10^{-5} Pa
Henry's law constant ‡	1.49 Pa m^3/mole (obtained by calculation) **RMS proposal**: It must be considered as a rough estimation.
Solubility in water (state temperature, state purity and pH) ‡	2.551 * 10^{-20} mg/L (obtained by calculation) **RMS proposal:** negligible or < 10^{-3} mg/L
Solubility in organic solvents ‡ (state temperature, state purity)	1,2-dichloroethane > 250 g/L p-xylene > 250 g/L ethylacetate > 250 g/L n-heptane > 250 g/L acetone > 250 methanol < 10 g/L (at 20 ± 1°C, 100%)
Surface tension ‡ (state concentration and temperature, state purity)	Pending
Partition co-efficient ‡ (state temperature, pH and purity)	Log P_{ow} = 23.2908 (obtained by calculation) **RMS proposal**: log Kow (estimated) = 23.2908
Dissociation constant (state purity) ‡	Not applicable. Rape seed oil is practically not soluble in water
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Pending
Flammability ‡ (state purity)	Not relevant. Rape seed oil is a liquid
Explosive properties ‡ (state purity)	Rape seed oil does not contain explosive ingredients. In addition it is neither flammable nor autoflammable
Oxidising properties ‡ (state purity)	Rapeseed oil does not include oxidizing ingredients. In addition it is not oxidising

Summary of representative uses evaluated (*rapeseed oil*)*

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)	(m)	
Ornamentals	Europe	NEU 1160 I	Glasshouse (professional and home garden use)	Spider mites, mealy bugs, scales	EC	883 g/L	Knapsack sprayer and hand sprayer	When infestation is visible	3	7 days	1.766	2000-4000	35.32-70.64 (40-80 L[1] product/ ha)	--	Effect: killing of adults
Orchards	Europe	NEU 1160 I	Field (professional and home garden use)	Eggs of spider mites	EC	883 g/L	Knapsack sprayer, motor prayer, hand sprayer	Start of vegetation up to mouse ear stage or bud swelling up to bud break	1	--	1.766	500 per m crown height	8.83 per m crown height (10 L product/ ha and m crown height)	--	Effect: suppression of winter stages
Woody ornamentals	Europe	NEU 1160 I	Field (professional and home garden use)	Eggs of spider mites	EC	883 g/L	Knapsack sprayer, motor prayer, hand sprayer	Start of vegetation up to bud break	1	--	1.766	600-1200	10.596-21.192 (12-24 L[2] product/ ha)	--	Effect: suppression of winter stages

1 plant height < 50 cm: 40 L product/ha (2000 L water/ha), 50-125 cm: 60 L product /ha (3000 L water/ha), > 125 cm: 80 L product /ha (4000 L water/ha)
2 plant height < 50 cm: 12 L product/ha (600 L water/ha), 50-125 cm: 18 L product /ha (900 L water/ha), > 125 cm: 24 L product /ha (1200 L water/ha)

*	For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).	(i)	g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(a)	For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)	(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
(b)	Outdoor or field use (F), greenhouse application (G) or indoor application (I)	(k)	Indicate the minimum and maximum number of application possible under practical conditions of use
(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds	(l)	The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha
(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)		
(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		

(f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

RMS considers that the use *"orchards"* is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant. With the provided information in the dossier the evaluation has been made for the following uses:

1. **Ornamentals in glasshouse conditions: 3x 70.64 Kg ai /Ha; Interval between application: 7d**
2. **Orchards in filed (apple trees) : 1x 8.83 Kg ai/Ha m crown height (assuming 3 m height) = 26.49 kg a.s./ha**
3. **Ornamental in field:1x 21.129 Kg ai /Ha (height > 125 cm) = 21.192 kg a.s./ha**

Methods of Analysis

Analytical methods for the active substance (OECD data point IIA 4.2)

Technical as (analytical technique)	Fatty acids IUPAC methods 2301, 2302, 2311 and DFG standard methods: GC-FID **Validation is required**
Impurities in technical as (analytical technique)	Not relevant impurity
Plant protection product (analytical technique)	Fatty acids IUPAC methods 2301, 2302 and 2311: GC-FID Not relevant impurity **Validation is required**

Analytical methods for residues (OECD data points IIA, 4.3 to IIA 4.8)

Residue definitions for monitoring purposes

Food of plant origin		Rapeseed oil (provisional)
Food of animal origin		No residue definition
Soil		Rapeseed oil
Water	surface	Rapeseed oil
	drinking/ground	Rapeseed oil
Air		No residue definition

Monitoring/Enforcement methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Rapeseed oil is used as an edible food without any indication of deleterious effect. (provisional pending on residue definition)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required. Rapeseed oil is used as an edible food without any indication of deleterious effect.
Soil (principle of method and LOQ)	**Data required**
Water (principle of method and LOQ)	**Data required**
Air (principle of method and LOQ)	Not required. Rapeseed oil does not volatilize.
Body fluids and tissues (principle of method and LOQ)	Not required. Rapeseed oil is not regarded as toxic or very toxic.

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

	RMS/peer review proposal
Rapeseed oil	No classification is proposed.

Mammalian Toxicology

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Not applicable
Distribution ‡	Not applicable
Potential for accumulation ‡	Not applicable
Rate and extent of excretion ‡	Not applicable
Metabolism in animals ‡	Not applicable
Toxicologically relevant compounds ‡ (animals and plants)	Not applicable
Toxicologically relevant compounds ‡ (environment)	Not applicable

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2000mg/kd bw	
Rat LD_{50} dermal ‡	> 2000mg/kd bw	
Rat LC_{50} inhalation ‡	> 3.26 mg/L (The maximum attainable concentration	
Skin irritation ‡	Not irritating	
Eye irritation ‡	Not irritating	
Skin sensitisation ‡	Not sensitizing	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Not applicable	
Relevant oral NOAEL ‡	Not applicable	
Relevant dermal NOAEL ‡	Not applicable	
Relevant inhalation NOAEL ‡	Not applicable	

Genotoxicity ‡ (Annex IIA, point 5.4)

Not applicable	

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

Target/critical effect ‡	Not applicable	
Relevant NOAEL ‡	Not applicable	
Carcinogenicity ‡	Not applicable	

Mammalian Toxicology

Reproductive toxicity (Annex IIA, point 5.6)

Multigeneration study

Reproduction target / critical effect ‡	Not applicable	
Relevant parental NOAEL ‡	Not applicable	
Relevant reproductive NOAEL ‡	Not applicable	
Relevant offspring NOAEL ‡	Not applicable	

Developmental toxicity

Developmental target / critical effect ‡	Not applicable	
Relevant maternal NOAEL ‡	Not applicable	
Relevant developmental NOAEL ‡	Not applicable	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Not applicable	
Repeated neurotoxicity ‡	Not applicable	
Delayed neurotoxicity ‡	Not applicable	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Not applicable
Studies performed on metabolites or impurities ‡	Not applicable

Medical data ‡ (Annex IIA, point 5.9)

Not applicable

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	Not applicable		
AOEL ‡	Not applicable		
ARfD ‡	Not applicable		

* Correction for oral absorption.

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name)	Not applicable

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Not applicable

Mammalian Toxicology

Workers	Not applicable
Bystanders	Not applicable

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

	RMS/peer review proposal
Rapeseed Oil	No classification is proposed.

Residues

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

Plant groups covered	Not required: the metabolism of triglycerides and fatty acids is the same in all plant species and well known from open literature **Data required to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.**
Rotational crops	Not applicable. Fatty acids are rapidly degraded in soil. Furthermore, they occur naturally in soil
Metabolism in rotational crops similar to metabolism in primary crops?	Not required
Processed commodities	Not applicable
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not required
Plant residue definition for monitoring	Rapeseed oil (provisional) **Data required to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.**
Plant residue definition for risk assessment	Rapeseed oil (provisional) **Data required to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.**
Conversion factor (monitoring to risk assessment)	No required

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

Animals covered	Not applicable
Time needed to reach a plateau concentration in milk and eggs	Not applicable
Animal residue definition for monitoring	Not applicable: fatty acids of Rapeseed oil occur naturally in animals and are rapidly degraded or used for biosynthesis so that they are soon indistinguishable from the animal's endogenous fatty acids. It is proposed not to set a residue definition.
Animal residue definition for risk assessment	Not applicable (see above)
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not applicable: no metabolism studies in ruminants available.
Fat soluble residue: (yes/no)	Not applicable

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

Not required: fatty acids are rapidly degraded in soil. Furthermore, they occur naturally in soil.

Residues

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

Pending; Data required to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.

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

Livestock feeding studies are considered not relevant, since triglycerides and fatty acids contained in Rapeseed oil are taken up as normal feed by livestock. They cannot be distinguished from residues of Rapeseed oil.

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	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			

Residues

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)
Orchards	Europe Field (professional and home garden use) Knapsack sprayer, motor sprayer, hand sprayer at start of vegetation up to mouse ear stage, or bud swelling up to bud break	--	Metabolism studies and residue trials were not reported since triglycerides and fatty acids occur naturally in plants, it is not possible to distinguish between residues of Rapeseed oil and the plant's own compounds. **However additional data required to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.**			

(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

Environmental fate and behaviour

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

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

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

Not applicable

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	

Environmental fate and behaviour

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

No MRLs are proposed since residues of Rapeseed oil are indistinguishable from plant endogenous compounds.

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

Environmental fate and behaviour

Environmental fate and behaviour

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

Mineralization after 28 days ‡	7.7-57.7g C/100 g oven dried soil (n=4)
Non-extractable residues after 100 days ‡	No data
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No relevant metabolites

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.2)

Anaerobic degradation ‡ No relevant

Soil photolysis ‡ No relevant

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X[1]	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Loamy sand		5.2	20 °C / 40 %	2.8/9.4	2.02	0.99	SFO
Sandy loam		7.4	20 °C / 40 %	2.5/8.3	1.72	0.99	SFO
Geometric mean/median			-	-	1.87 (~ 2.0)	-	-

Field studies ‡ No data/ no required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡ Koc: 1 x 10^{10} L/kg (obtained by calculation)

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

Column leaching ‡	Not required due to high Koc values and rapid microbiological degradation of Rapeseed oil in soil.
Aged residues leaching ‡	Not required due to high Koc values and rapid microbiological degradation of Rapeseed oil in soil.

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

Environmental fate and behaviour

Lysimeter/ field leaching studies ‡	Not required due to high Koc values and rapid microbiological degradation of Rapeseed oil in soil.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d):2.8 days Kinetics: SFO representative worst case from lab studies.
Application data	Crop: ornamentals (glass house) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cc % plant interception: 25% Number of applications: 3 Interval (d): 7 Application rate(s): 70.64 kg as/ha

Day	Application number	Days post application	PECs	
			Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	-	70.64	-
1	-	-	55.15	-
2	-	-	43.06	-
4	-	-	26.24	
7	2	-	83.13	-
8	-	-	64.90	-
9	-	-	50.67	-
14	3	0	85.34	85.34
15	-	1	66.62	75.59
16	-	2	52.01	67.30
18	-	4	31.70	54.16
21	-	7	15.09	40.54
28	-	14	2.67	23.85
35	-	21	0.47	16.32
42	-	28	0.08	12.30
64	-	50	0.00	6.89
114	-	100	0.00	3.45
365	-	351	0.00	0.96

Parent Method of calculation	DT_{50} (d):2.8 days Kinetics: SFO representative worst case from lab studies.
Application data	Crop: orchard (field) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cc % plant interception: 50% Number of applications: 1 Application rate(s): 26.49 kg a.s./ha (corresponding to 3 m height)

Environmental fate and behaviour

Day	Application number	PECs	
		Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	17.66	17.66
1	-	13.79	15.64
2	-	10.76	13.93
4	-	6.56	11.21
7	-	3.12	8.39
14	-	0.55	4.94
21	-	0.10	3.38
28	-	0.02	2.55
50	-	0.00	1.43
100	-	0.00	0.71
365	-	0.00	0.20

Parent Method of calculation	DT_{50} (d):2.8 days Kinetics: SFO representative worst case from lab studies.
Application data	Crop: ornamentals (glass house) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cc % plant interception:25% Number of applications: 1 Application rate(s): 21.19 kg a.s./ha

Day	Application number	PECs	
		Actual concentration (mg a.s./kg)	TWA (mg a.s./kg)
0	1	21.19	21.19
1	-	16.54	18.77
2	-	12.92	16.71
4	-	7.87	13.45
7	-	3.75	10.07
14	-	0.66	5.92
21	-	0.12	4.05
28	-	0.02	3.05
50	-	0.00	1.71
100	-	0.00	0.86
365	-	0.00	0.24

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

Hydrolytic degradation of the active substance and metabolites >10 % ‡	Not applicable. Rape seed oil is practically not soluble in water.
Photolytic degradation of active substance and metabolites above 10 % ‡	Not applicable. Rape seed oil is practically not soluble in water.
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not applicable. Rape seed oil is practically not soluble in water.

Environmental fate and behaviour

Readily biodegradable ‡ (yes/no)	Yes for Pelargonic acid (C10:0) No data submitted for the a.s. According to the notifier, the study on Pelargonic acid (C10:0) may be extrapolated to Rapeseed oil but with the available information on the fate and behaviour in water this statement cannot be confirmed by RMS.

Degradation in water / sediment No data submitted

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Steps 1-2 in FOCUS 1.1; Molecular weight (g/mol): 885.4 Water solubility (mg/L): $0.1x10^{-5}$ K_{OC}/K_{OM} (L/kg): 10^6 DT_{50} soil (d):2.0 days (Lab or field. In accordance with FOCUS SFO) DT_{50} water/sediment system (d):2.8 d (worst case from soil) DT_{50} water (d):2.8 d DT_{50} sediment (d): 2.0 d
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: Macro 4.4.2; PRZM 1.5.6 Vapour pressure: 0.133 10^{-17} Pa (at 25ºC) Kom/Koc: 10^6 L/kg 1/n: 0.9 (Freundlich exponent general or for soil ,susp. solids or sediment respectively)
Application rate	Crop: orchards and ornamental Application rate(s): 26.490 kg a.s./ha in orchards (3 m heigh) ; 21.192 kg a.s./ha in ornamentals (field use) Number of applications: 1 FOCUS Scenario Pome/stone fruit, early &Vines, late Application window: beginning of emergence to 30 d after mergence

PEC_{SW}[a] Rapeseed oil	Orchards		Ornamentals (field use)	
	Max Actual concentrations (µg a.s./L)	Time weighted average (µg a.s./L)	Max Actual concentrations (µg a.s./L)	Time weighted average (µg a.s./L)
FOCUS Step 1	2580.000	not applicable	570.170	not applicable
FOCUS Step 2 (N-EU)	2580.000	not applicable	567.098	not applicable
FOCUS Step 2 (S-EU)	2580.000	not applicable	567.098	not applicable

Crop (FOCUS crop scenario)	Step	Scenario	Water body	Drift (%)*	PECsw global max. act. conc. (µg a.s./L)	Maximum PECSED actual

Environmental fate and behaviour

					dissolved in water	(µg a.s./kg dry sediment)
Orchards (Pome/stone fruit, early)	3	D3**	Ditch	23.599	867.773 a	7560.024
		D4**	Pond	4.730	43.961 a	1160.845
		D4**	Stream	25.899	842.798 a	1204.636
		D5**	Pond	4.730	43.949 a	1037.681
		D5**	Stream	25.899	839.754 a	695.807
		R1**	Pond	4.730	43.953 a	1047.716
		R1**	Stream	25.899	693.076 a	2456.252
		R2**	Stream	25.899	934.169 a	1686.545
		R3**	Stream	25.899	1001.670 a	5227.238
		R4**	Stream	25.899	693.248 a	2470.354
Ornamentals (Vines, late)	3	D6**	Ditch	5.173	134.161 a	803.355
		R1**	Pond	0.612	3.861 a	103.299
		R1**	Stream	5.152	97.760 a	340.265
		R2**	Stream	5.152	132.058 a	238.421
		R3**	Stream	5.152	141.543 a	736.448
		R4**	Stream	5.152	97.728 a	338.177

a peak occurs at time of spray drift event

** concentration in water layer exceeds water solubility of Rapeseed oil

Environmental fate and behaviour

Orchards (Pone/stone fruits, early).			
scenarios	1d TWA (µg/L)	2d TWA (µg/L)	4d TWA (µg/L)
D3- ditch	389.937	231.764	128.739
D4-pond	35.435	30.043	23.524
D4-stream	51.476	25.829	12.958
D5-pond	34.905	29.243	22.372
D5-stream	30.514	15.283	7.654
R1-pond	34.959	29.319	22.472
R1-stream	107.382	54.174	27.289
R2-stream	73.159	36.75	18.442
R3-stream	250.125	128.812	65.893
R4-stream	108.017	54.5	27.456
Ornamentals (Vine, late)			
scenarios	1d TWA (µg/L)	2d TWA (µg/L)	4d TWA (µg/L)
D6-ditch	38.858	20.232	10.5
R1-pond	3.137	2.654	2.046
R1-stream	14.631	7.363	3.704
R2-stream	10.246	5.141	2.578
R3-stream	34.198	17.468	8.893
R4-stream	14.529	7.312	3.678

PEC (ground water) **(Annex IIIA, point 9.2.1)**	No calculation of PEC (ground water) was done, because of DT50 in soil and Koc value it is unlikely that Rapeseed oil will contaminate the ground water

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 ‡	No data submitted
Volatilisation ‡	Due to the low vapour pressure of oleic acid, one of the main fatty acids in Rapeseed oil ($1.33 * 10^{-18}$ Pa), it is unlikely that the fatty acid will occur in the atmosphere.

PEC (air)

Method of calculation	Due to the low vapour pressure of oleic acid, one of the main fatty acids in Rapeseed oil ($1.33 * 10^{-18}$ Pa), it is unlikely that the fatty acid will occur in the atmosphere

$PEC_{(a)}$

Maximum concentration	negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines	Rapeseed oil

Environmental fate and behaviour

Monitoring data, if available **(Annex IIA, point 7.4)**	No data provided

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

None

Ecotoxicology

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg a.i./kg bw/day)	End point (mg/kg feed)
Birds ‡				
Mallard duck	a.s.	Acute		
Mallard duck	Preparation	Acute		
Bobwhite quail	Metabolite 1	Acute		
Bobwhite quail	a.s.	Short-term		
Mallard duck	a.s.	Long-term		
Mammals ‡				
Rat	a.s.	Acute		
Rat	NEU 1161 I 90% (w/w) Rapeseed oil 2 % (w/w) Pyrethrum	Acute	LD_{50} > 1794.1	
Mice	Metabolite 1	Acute		
Rat	a.s.	Long-term		
Additional higher tier studies ‡				

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

1) fatty acids are naturally contributing to the feed of birds,

2) the mode of action of rapeseed oil is mechanical rather than chemical,

3) secondary poisoning for birds eating contaminated food is unlikely to occur and

4) low rat acute toxicity is showed (LD50 > 1794.1 mg a.i./kg b.w)

Therefore low risk it is expected to birds for formulated products containing rapeseed oil.

Crop and application rate

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

Ecotoxicology

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

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

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg a.i./L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	Rapeseed oil (96 %)	96 hr (flow-through)	Mortality, LC_{50}	> 249.4nom > 7.48mm
Oncorhynchus mykiss	Preparation	28 d(flow-through)	Growth NOEC	
Oncorhynchus mykiss	Metabolite 1	96 hr (flow-through)	Mortality, EC_{50}	
Aquatic invertebrate				
Daphnia magna	Rapeseed oil (96 %)	48 h (static)	Mortality, EC_{50}	4.5nom
Daphnia magna	a.s.	21 d (static)	Reproduction, NOEC	
Daphnia magna	NEU 1160 I (90% w/w)	48 h (static)	Mortality, EC_{50}	> 96.72mm
Daphnia magna	Preparation	21 d (static)	Reproduction, NOEC	
Daphnia magna	Metabolite 1	48 h (static)	Mortality, EC_{50}	
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	NOEC	
Chironomus riparius	Metabolite 2	28 d (static)	NOEC	

Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg a.i./L)
Algae				
Desmodesmus subcap.	Rapeseed oil (96 %)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	41.1mm 143.7mm
Pseudokirch subcap.	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	
Pseudokirch subcap.	Metabolite 1	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	
Higher plant				
Lemna gibba	a.s.	14 d (static)	Fronds, EC_{50}	
Lemna gibba	Preparation	14 d (static)	Fronds, EC_{50}	
Lemna gibba	Metabolite 1	14 d (static)	Fronds, EC_{50}	
Microcosm or mesocosm tests				
Indicate if not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

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

FOCUS step 1

Test substance	**Organism**	**Toxicity end point RMS (mg a.i./L)**	**Toxicity end point Notifier (mg a.i./L)**	**Time scale**	**PEC[3] PEC_{sw} (mg a.i./L)**	**TER RMS**	**TER Notifier**	**Annex VI Trigger[1]**
Pome/stone (early). Field application: 8.83 per m crown height (10 L product/ha and m crown height)								
Rapeseed oil	Fish	> 7.48	> 249.4	Acute	2.58	**> 2.89**	> **96.6**	100
Rapeseed oil	Aquatic invertebrates	4.5	> 96.72	Acute	2.58	**1.74**	> 37.49	100
Rapeseed oil	Algae	41.1	287.4	Chronic	2.58	16	111	10
Ornamental (leafy veg.). Field application 21.192 kg a.s./ha								
Rapeseed oil	Fish	> 7.48	> 249.4	Acute	0.570	**> 13**	> 437	100
Rapeseed oil	Aquatic invertebrates	4.5	> 96.72	Acute	0.570	**8**	> 169	100
Rapeseed oil	Algae	41.1	287.4	Chronic	0.570	72.6	504	10
Ornamentals (plant height > 125 cm, glass house use), 70.64 kg a.s./ha								
Rapeseed oil	Fish	> 7.48	> 249.4	Acute	0.0284	263	8775	100
Rapeseed oil	Aquatic invertebrates	4.5	> 96.72	Acute	0.0284	158	3403	100
Rapeseed oil	Algae	41.1	287.4	Chronic	0.0284	492	10112	10

Ecotoxicology

Test substance	Organism	Toxicity end point RMS (mg a.i./L)	Toxicity end point Notifier (mg a.i./L)	Time scale	PEC[3] PEC_{sw} (mg a.i./L)	TER RMS	TER Notifier	Annex VI Trigger[1]
a.s.	Higher plants[2]			Chronic				10
a.s.	Sediment-dwelling[3] organisms			Chronic				10
Metabolites	Relevant organisms							
Product	Relevant organisms							

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

FOCUS Step 2

North/South Europe

Test substance	Organism	Toxicity end point RMS (mg a.i./L)	Toxicity end point Notifier (mg a.i./L)	Time scale	PEC[3] PEC_{sw} (mg a.i./L)	TER RMS	TER Notifier	Annex VI Trigger[1]
Pome/stone (early). Field application : (8.83 per m crown height, 10 L product/ha and m crown height) 26.49 kg a.s./ha (3 meters crown height)								
Rapeseed oil	Fish	> 7.48	> 249.4	Acute	2.58	**> 2.89**	**> 96.6**	100
Rapeseed oil	Aquatic invertebrates	4.5	> 96.72	Acute	2.58	**1.74**	**> 37.49**	100
Ornamental (leafy veg.). Field application Field application 21.192 kg a.s./ha								
Rapeseed oil	Fish	> 7.48	> 249.4	Acute	0.567	**> 13**	> 437	100
Rapeseed oil	Aquatic invertebrates	4.5	> 96.72	Acute	0.567	**8**	> 169	100

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

Ecotoxicology

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4] µg a.i./L	TER	Annex VI trigger[5]
Pome/stone (early). Field application : (8.83 per m crown height, 10 L product/ha and m crown height) 26.49 kg a.s./ha (3 meters crown height)								
Rapeseed oil	D3	Ditch	Fish	Acute	> 7.48	867.773	**> 8.62**	100
Rapeseed oil	D4	Pond	Fish	Acute	> 7.48	43.961	> 170	100
Rapeseed oil	D4	Stream	Fish	Acute	> 7.48	842.798	**> 8.8**	100
Rapeseed oil	D5	Pond	Fish	Acute	> 7.48	43.949	> 170	100
Rapeseed oil	D5	Stream	Fish	Acute	> 7.48	839.754	**> 8.9**	100
Rapeseed oil	R1	Pond	Fish	Acute	> 7.48	43.953	> 170	100
Rapeseed oil	R1	Stream	Fish	Acute	> 7.48	693.076	**> 10.7**	100
Rapeseed oil	R2	Stream	Fish	Acute	> 7.48	934.169	**> 8**	100
Rapeseed oil	R3	Stream	Fish	Acute	> 7.48	1001.670	**> 7.5**	100
Rapeseed oil	R4	Stream	Fish	Acute	> 7.48	693.248	> 289	100
Rapeseed oil	D3	Ditch	Aquatic invertebrates	Acute	4.5	867.773	**5.2**	100
Rapeseed oil	D4	Pond	Aquatic invertebrates	Acute	4.5	43.961	102	100
Rapeseed oil	D4	Stream	Aquatic invertebrates	Acute	4.5	842.798	**5**	100
Rapeseed oil	D5	Pond	Aquatic invertebrates	Acute	4.5	43.949	102	100
Rapeseed oil	D5	Stream	Aquatic invertebrates	Acute	4.5	839.754	**5.35**	100
Rapeseed oil	R1	Pond	Aquatic invertebrates	Acute	4.5	43.953	102	100
Rapeseed oil	R1	Stream	Aquatic invertebrates	Acute	4.5	693.076	**6.49**	100
Rapeseed oil	R2	Stream	Aquatic invertebrates	Acute	4.5	934.169	**4.8**	100
Rapeseed oil	R3	Stream	Aquatic invertebrates	Acute	4.5	1001.670	**4.5**	100

Ecotoxicology

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4] µg a.i./L	TER	Annex VI trigger[5]
Rapeseed oil	R4	Stream	Aquatic invertebrates	Acute	4.5	693.248	**6.5**	100
Ornamental (leafy veg.). Field application Field application 21.192 kg a.s./ha								
Rapeseed oil	D6	Ditch	Fish	Acute	> 7.48	134.161	> **55.75**	100
Rapeseed oil	R1	Pond	Fish	Acute	> 7.48	3.861	> 1937	100
Rapeseed oil	R1	Stream	Fish	Acute	> 7.48	97.76	> **76.51**	100
Rapeseed oil	R2	Stream	Fish	Acute	> 7.48	132.058	> **56**	100
Rapeseed oil	R3	Stream	Fish	Acute	> 7.48	141.543	> **52.8**	100
Rapeseed oil	R4	Stream	Fish	Acute	> 7.48	97.728	> **76.53**	100
Rapeseed oil	D6	Ditch	Aquatic invertebrates	Acute	4.5	134.161	**33**	100
Rapeseed oil	R1	Pond	Aquatic invertebrates	Acute	4.5	3.861	1165	100
Rapeseed oil	R1	Stream	Aquatic invertebrates	Acute	4.5	97.76	**46**	100
Rapeseed oil	R2	Stream	Aquatic invertebrates	Acute	4.5	132.058	**34**	100
Rapeseed oil	R3	Stream	Aquatic invertebrates	Acute	4.5	141.543	**32**	100
Rapeseed oil	R4	Stream	Aquatic invertebrates	Acute	4.5	97.728	**47**	100

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

FOCUS Step 3

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4] µg a.i./L	TER	Annex VI trigger[5]
Pome/stone (early). Field application : (8.83 per m crown height, 10 L product/ha and m crown height) 26.49 kg a.s./ha (3 meters crown height)								
Rapeseed	D3	Ditch	Fish	Acute	> 7.48	128.739	> 58	100

Ecotoxicology

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4] µg a.i./L	TER	Annex VI trigger[5]
oil								
Rapeseed oil	D4	Pond	Fish	Acute	> 7.48	23.524	> 318	100
Rapeseed oil	D4	Stream	Fish	Acute	> 7.48	12.958	> 577	100
Rapeseed oil	D5	Pond	Fish	Acute	> 7.48	22.372	> 334	100
Rapeseed oil	D5	Stream	Fish	Acute	> 7.48	7.654	> 977	100
Rapeseed oil	R1	Pond	Fish	Acute	> 7.48	22.472	> 332	100
Rapeseed oil	R1	Stream	Fish	Acute	> 7.48	27.289	> 274	100
Rapeseed oil	R2	Stream	Fish	Acute	> 7.48	18.442	> 405	100
Rapeseed oil	R3	Stream	Fish	Acute	> 7.48	65.893	> 113	100
Rapeseed oil	R4	Stream	Fish	Acute	> 7.48	27.456	> 272	100
Rapeseed oil	D3	Ditch	Aquatic invertebrates	Acute	4.5	231.764	**19**	100
Rapeseed oil	D4	Pond	Aquatic invertebrates	Acute	4.5	30.043	149	100
Rapeseed oil	D4	Stream	Aquatic invertebrates	Acute	4.5	25.829	174	100
Rapeseed oil	D5	Pond	Aquatic invertebrates	Acute	4.5	29.243	154	100
Rapeseed oil	D5	Stream	Aquatic invertebrates	Acute	4.5	15.823	294	100
Rapeseed oil	R1	Pond	Aquatic invertebrates	Acute	4.5	29.319	153	100
Rapeseed oil	R1	Stream	Aquatic invertebrates	Acute	4.5	54.174	**83**	100
Rapeseed oil	R2	Stream	Aquatic invertebrates	Acute	4.5	36.75	122	100
Rapeseed oil	R3	Stream	Aquatic invertebrates	Acute	4.5	128.812	**35**	100
Rapeseed oil	R4	Stream	Aquatic invertebrates	Acute	4.5	54.5	**82**	100
Ornamental (leafy veg.). Field application 21.192 kg a.s./ha								
Rapeseed oil	D6	Ditch	Fish	Acute	> 7.48	10.5	> 712	100

Ecotoxicology

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4] µg a.i./L	TER	Annex VI trigger[5]
Rapeseed oil	R1	Pond	Fish	Acute	> 7.48	2.046	> 3655	100
Rapeseed oil	R1	Stream	Fish	Acute	> 7.48	3.704	> 2019	100
Rapeseed oil	R2	Stream	Fish	Acute	> 7.48	2.578	> 2901	100
Rapeseed oil	R3	Stream	Fish	Acute	> 7.48	8.893	> 841	100
Rapeseed oil	R4	Stream	Fish	Acute	> 7.48	3.678	> 2131	100
Rapeseed oil	D6	Ditch	Aquatic invertebrates	Acute	4.5	20.232	222	100
Rapeseed oil	R1	Pond	Aquatic invertebrates	Acute	4.5	2.654	1698	100
Rapeseed oil	R1	Stream	Aquatic invertebrates	Acute	4.5	7.363	611	100
Rapeseed oil	R2	Stream	Aquatic invertebrates	Acute	4.5	5.141	875	100
Rapeseed oil	R3	Stream	Aquatic invertebrates	Acute	4.5	17.468	258	100
Rapeseed oil	R4	Stream	Aquatic invertebrates	Acute	4.5	7.132	615	100

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

FOCUS Step 4

Crop and application rate

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

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 3.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used

Ecotoxicology

[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Bioconcentration				
	Rapeseed oil	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	23.29			
Bioconcentration factor (BCF)[1] ‡				
Annex VI Trigger for the bioconcentration factor	1000			
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

[1] only required if log $P_{O/W}$ >3.

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

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

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

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

It is not relevant to calculate the risk of Rapessed oil to bees because preparations containing Rapeseed oil will be applied before sprout.

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact		50
a.s.	oral		50
Preparation	Contact		50
Preparation	oral		50

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

Laboratory tests with standard sensitive species

Ecotoxicology

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Rapeseed oil	Mortality	> 26.49
Aphidius rhopalosiphi ‡	Rapeseed oil	Mortality	88.30

[1] whether end point is expressed in units of a.s.

Ornamentals (glass house): 70.64 kg a.s./ha

Test substance	Species	Effect (LR_{50} Kg/ha)	HQ in-field	HQ off-field[1]	Trigger
Rapeseed oil	*Typhlodromus pyri*	> 26.49	< **2.66**	< 0.18	2
Rapeseed oil	*Aphidius rhopalosiphi*	88.30	0.80	0.5	2

[1] Off crop exposure was considered at 3 m distance, assuming 6.9% drift

Orchards (in field): 21.192 kg a.s./ha

Test substance	Species	Effect (LR_{50} Kg/ha)	HQ in-field	HQ off-field[1]	Trigger
Rapeseed oil	*Typhlodromus pyri*	> 26.49	< 1.00	< 0.29	2
Rapeseed oil	*Aphidius rhopalosiphi*	88.30	0.30	0.09	2

[1] Off crop exposure was considered at 3 m distance, assuming 29.2 % drift

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
						50 %
						50 %
						50 %
						50 %

[1] indicate whether initial or aged residues

[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

[3] indicate if positive percentages relate to adverse effects or not

Field or semi-field tests
Indicate if not required

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

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	a.s.	Acute 14 days	

Ecotoxicology

Test organism	Test substance	Time scale	End point[1]
	a.s. ‡	Chronic 8 weeks	NOEC mg a.s./kg d.w.soil (mg a.s/ha)
	NEU 1161 I (90% rapeseed oil)	Acute 14 days	$LC_{50corre}$ 448.95 mg a.s./kg d.w.soil (mg a.s/ha)
	Preparation	Chronic	
	Metabolite 1	Acute	
	Metabolite 1	Chronic	
Other soil macro-organisms			
Soil mite	a.s. ‡		
	Preparation		
	Metabolite 1		
Collembola			
	a.s. ‡	Chronic	NOEC mg a.s./kg d.w.soil (mg a.s/ha)
	Preparation		
	Metabolite 1		
Soil micro-organisms			
Nitrogen mineralisation	NEU 1161 I (90% Rapeseed oil) ‡		< 25% effect at day 90 at 99.36 mg a.s./kg d.w.soil (99.36 Kg a.s/ha)
	Metabolite 1		
Carbon mineralisation	NEU 1161 I (90% Rapeseed oil) ‡		< 25% effect at day 28 at 99.36 mg a.s./kg d.w.soil (99.36 Kg a.s/ha)
	Metabolite 1		
Field studies[2]			
Indicate if not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Ornamentals (glass house): 70.64 kg a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	a.s. ‡	Acute			10
	a.s. ‡	Chronic			5
	NEU 1161 I	Acute	85.34	> **5.26**	10
	Preparation	Chronic			5
	Metabolite 1	Acute			10

Ecotoxicology

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
	Metabolite 1	Chronic			5
Other soil macro-organisms					
Soil mite	a.s. ‡				
	Preparation				
	Metabolite 1				
Collembola	a.s. ‡				
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached

[2] Initial PEC soil (mg a.i./kg dw)

Orchards (in field): 26.49kg a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	a.s. ‡	Acute			10
	a.s. ‡	Chronic			5
	NEU 1161 I	Acute	17.66	> 25.42	10
	Preparation	Chronic			5
	Metabolite 1	Acute			10
	Metabolite 1	Chronic			5
Other soil macro-organisms					
Soil mite	a.s. ‡				
	Preparation				
	Metabolite 1				
Collembola	a.s. ‡				
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached

[2] Initial PEC soil (mg a.i./kg dw)

Ornamentals (in field): 21.19 kg a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	a.s. ‡	Acute			10
	a.s. ‡	Chronic			5
	NEU 1161 I	Acute	21.19	> 21.18	10
	Preparation	Chronic			5
	Metabolite 1	Acute			10

Ecotoxicology

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
	Metabolite 1	Chronic			5
Other soil macro-organisms					
Soil mite	a.s. ‡				
	Preparation				
	Metabolite 1				
Collembola	a.s. ‡				
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached
[2] Initial PEC soil (mg a.i./kg dw)

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (kg a.s/ha)[2]	TER	Trigger
Raphanus sativus	NEU 1161 I	Not determined		24.76		
Cucumis sativus	NEU 1161 I	Not determined		24.76		
Vicia faba	NEU 1161 I	Not determined		24.76		
Lycopersicon esculentum	NEU 1161 I	Not determined		24.76		
Allium cepa	NEU 1161 I	Not determined		24.76		
Avena sativa	NEU 1161 I	Not determined		24.76		

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] units of a.s.

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	
Pseudomonas sp	

Ecotoxicology

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

Compartment	
soil	Parent: Rapeseed oil
water	Parent: Rapeseed oil
sediment	Parent: Rapeseed oil
groundwater	Parent: Rapeseed oil

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	R52, S61, N

	RMS/peer review proposal
Preparation	R52, S61, N

LEVEL 3

RAPESEED OIL

Proposal for the decision

3 Proposed decision with respect to the application for inclusion of the active substance in Annex I

3.1 Background to the proposed decision

Refined Rapeseed oil is a dietary vegetable oil derived from seeds of *Brassica napus*. Rapeseed oil is a natural contact insecticide/acaricide used against spider mites, scales and mealy bugs in ornamentals (field and greenhouse) and orchards.

The applicant for the active substance Rape Seed Oil is W. Neudorff GmbH KG. It is manufactured by [redacted]

The active substance, Rapeseed oil (Rüböl) with CAS number 8002-13-9, is not a single compound but a mixture of triglycerides of fatty acids. The active substance is not present in the formulation in the form of a salt, ester, anion or cation. The purity is not given as a single value. Notifier gives the specifications based on the composition as fatty acids and some physic-chemical parameters. All technical material has been considered as active substance. Taking into account that the mode of action is mechanical rather that chemical, RMS considers that these specifications are accepted.

Rapeseed oil is a clear light yellow liquid with a characteristic odour. The melting/ freezing range is -12.0 – -30.6 °C and decomposes before boiling (> 350 °C). The estimated vapour pressure and Henry's Law Constant give information about the no volatility of this compound. Its log Pow is high (log Kow of the main molecule (1,2,4-Trioctadec-9-en-oyl-glycerol) in water was calculated to be 23.2908). Rape seed oil is soluble in organic solvents (solubility > 250 g/L) and, as expected, insoluble in water (solubility of the main molecule (1,2,4-Trioctadec-9-en-oyl-glycerol) in water was calculated to be $2.51 \cdot 10^{-20}$ mg/L). A study for the determination of surface tension is required. No physical-chemical properties were found which indicate any risk of the user.

The formulation, NEU 1160 I (Manufacturer's code number: NEU-01160-AI-0-EC), is an emulsifiable concentrate (EC) containing 883 g /L of Rapeseed oil [redacted]emulgator and [redacted]echnical rapeseed oil).

NEU 1160 I is not explosive. The product is not oxidizing, and not flammable. Its pH is within the range which naturally occurs e.g. in soil. It is a surface active substance with a relative density of 0.92 at 20°C. Its physical stability allows storage under practical and commercial conditions but the stability of the composition when it is storage for 14 days at 54°C and 2 years at ambient temperature must be determined with an accuracy method. Its technical properties indicate that no particular problems are to be expected, when it is used as recommended.

The action is by contact; Rapeseed oil suffocates insects and mites by blocking the spiracles and the body pores. The formulation NEU 1160 I it is intended to be used for greenhouse ornamentals with 3 applications per growing season, or in orchards and woody ornamentals in the field at the start of the

vegetation period. Application rates are dependent on the height of the plants. NEU 1160 I is to be sprayed.

RMS considers that the use "*orchards*" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant. Risk assessment was made considering the m crown height proposed by the notifier and considering the dose rate as kg as/ha.

The notifier has proposed already established IUPAC methods (2.301, 2.302 and 2.311) for the determination of fatty acids contents in the active substance and in plant protection products. The RMS **requires a validation for the three IUPAC methods** (2.301, 2.302 and 2.311) according to the SANCO 825/00-rev 6 (20/06/00) guideline.

The notifier indicates that no information regarding method of analysis for plant residues is required when the exposure, due to the use of the plant extract as a plant protection product, is not relevant in relation to the exposure due to consumption of the plant itself. The RMS agrees with the notifier but plant residue definition should be clarified. If it was necessary analytical method for plants for monitoring would be requested.

The notifier has not submitted analytical method for soil and water. RMS considers that according to data in the environmental fate and behaviour section and the ecotoxicology risk assessment the exposure to rapeseed oil, due to an application as insecticide, is likely in soil and water, furthermore the estimated the DT_{90} is 9.3 days. Therefore, analytical methods for soil and water are required

The quality of low-erucic acid-refined rapeseed oil (no more thant 2% erucic acid) is accepted as food according to Codex Alimentarius (FAO-WHO, 2001). Therefore, no toxicological studies performed with the active substance and according to EU guidelines and GLP compliant have been submitted. However, acute toxicity studies performed with the preparation NEU 1160 I (90 % Rapeseed oil) and according to GLP and EU guidelines were submitted and has been evaluated. In addition published information related with toxicokinetics, acute toxicity, genotoxicity, long-term, and reproductive toxicity data performed with rapeseed oil has been evaluated.

Rapeseed oil is, like all vegetable oils, metabolized by hydrolysis of the glycerol ester to release glycerol and fatty acids. These are incorporated as normal body constituents or degraded via ß-oxidation.

The submitted **acute studies** were conducted with the formulation NEU1161 I containing Rapeseed oil (90%) as well as Pyrethrum Extract (2%). The lack of toxicity reported in these studies is supporting the view that Rapeseed oil has a low acute toxicity and according to EU Commission Directive 2001/59/EC, classification for acute toxicity of Rapeseed oil is not required

In relation to **short-term** toxicity no toxicological studies are available.

Rapeseed oil consists of esters of glycerol with saturated and unsaturated long chain fatty acids. These are natural body constituents and there is **no indication for a genotoxic potential**.

Two publications had been submitted in long-term section, however these reports were not according to OECD guidelines and GLPs.

In male rats, **long-term** feeding of high erucic acid rapeseed oil (30.9%) resulted in alteration of mitochondrial morphology, disorganization of myofibrils, and degeneration or necrosis of the cardiac muscle fiber. Low erucic acid rapeseed oil (0.9%) induced less severe cardiopathologic changes. In mice fed with 6% Rapeseed oil in the diet for 18 months an increased survival rate as compared to a control group with a diet containing equal amounts of palm oil was observed.

Rapeseed oil were not tested in conventional **reproductive** studies. In a experimental survey, rat and hamster were administered a diet containing 25% rapeseed oil rich in erucic acid (41.4%) or corn oil (controls) for 90-110 days, including pre-mating, and mating and gestation for the half of the animals. Effects on the mothers attributed to rapeseed oil diet consisted of decreased bodyweight in non-pregnant rats (8.7%) and hamsters (7.8%). However, female fertility index, the number and the weight of fetuses were not affected. There were no macroscopic lesions in fetuses and adult animals. The report did not show alterations in the weight of liver, kidney, heart and adrenal glands of the adults.

Rapeseed oil administration decreased bile flow in pregnant hamsters. No differences could be observed in the concentration of bile acids, biliary lipids, lithogenic index and the hepatic organic anion excretory capacity examined with sulfobromophthalein.

Results of the fatty acid proportion were only presented for the hamster heart. Administering with rapeseed oil rich in erucic acid depleted linoleic acid and increased erucic acid moderately in the liver and kidney and noticeably in the heart.

The mode of action of Rapeseed oil as a plant protection product does not target the nervous system, therefore neurotoxic effects of Rapeseed oil are not expected.

RMS agree with the notifier that rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001) and the setting of references values (AOEL, IDA and ARfD) seems to be not applicable. Nevertheless, there is an **Occupational exposure limit (OEL) for oil mist of 5mg/m^3 (TWA, 8h – workday).**

Based on **acute toxicity studies of the formulation** and in accordance with Annex I of Council Directive 67/548/EEC (Dangerous Substances Directive) and 99/45/EC (Dangerous Preparations Directive), classification for acute toxicity of NEU 1160 I is not required.

NEU 1160 I (883 g/L Rapeseed oil) is an Acaricide/insecticide against spider mites, mealy bugs and scales. According to notifier, rapeseed oil is assumed to be of very low toxicity and its content in NEU 1160 I does not warrant operator, bystander and worker exposure estimations. RMS agree with the Applicant that rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001) and the setting of references values seems to be not applicable.

Nevertheless, since there is an OEL and the method of application for NEU1160 I is spraying an exposure risk assessment could be done.

The notifier did not provide any study on the metabolism of rapeseed oil in plants but literature about the metabolism of triacylglycerols and fatty acids inside plants was submitted. It was assumed that any residues of Rapeseed oil will be degraded or utilised by the plant by the time of harvest, so that it is indistinguishable from plant endogenous lipids and therefore residues trials were not reported. Nevertheless RMS considers that the reported literature is not conclusive about the behaviour of rapeseed oil when is applied on the plant some data is needed before a conclusion about the residue definition is set. Although fatty acids occur naturally in plants, some data are needed to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.

The notifier did not provide any specific study on the metabolism of rapeseed oil in livestock but literature about the metabolism of fats was submitted. The fatty acids comprised in Rapeseed oil occur naturally in animal feed and their metabolism in animals is well known. Furthermore, Rapeseed oil is also used as a food commodity and therefore metabolism studies on rapeseed oil itself are not needed.

Rapeseed oil is a food commodity which is consumed at about 7.3 g/day in the European diet. The extent of the exposure due to the intended use as plant protection product in apples was compared to the exposure due to consumption of Rapeseed oil as a food commodity. A very worst case, assuming that all the active substance applied would be uptake by the fruit, was considered. The estimation of consumption according to the European diet was much lower than the normal daily consumption of this commodity. Furthermore, it is applied early in the growing season before the development of fruits in orchards and therefore this consumption will be even lower. Therefore no residue trials were reported. No residue definition and MRLs were set and studies on the effect of industrial processing and/or household preparation on the nature and level of residues were therefore considered not relevant. **Nevertheless RMS will do a definitive assessment on the residue definition when more information is available.**

Rapeseed oil is degraded rather rapidly in the soil and the fatty acids comprised in Rapeseed oil also occur naturally in soil. Studies on the effect on succeeding crops were therefore also considered not relevant.

No pre-harvest interval, re-entry period for livestock or withholding period for animal feeding stuffs have to be proposed. It is also not necessary to propose a waiting period between application and

sowing or planting the crop to be protected. A waiting period between application and sowing or planting succeeding crops is not required due to the rapid degradation of the active substance in the soil.

Taking into account that Rapeseed oil is a natural compound, it is also used as a food commodity and estimation of the consumer exposure due to the intended use as plant protection product in apples were much lower compared to the exposure due to consumption of Rapeseed oil as a food commodity, it is not likely any risk for consumers due to its use as plant protection product. **Nevertheless the notifier should submit data to confirm that none undesirable compounds are found in the plant as a consequence of the application of rapeseed oil and to conclude about the residue definition.**

Rapeseed oil is a mixture of triglycerides of fatty acids, therefore the degradation, transformation and metabolism follows the same principle as they are generally described for fatty acids and lipids. **No definition of residue in the environment was proposed by the notifier; RMS considers that the residue definition should be rapeseed oil.**

The public literature reveals that the degradation of fatty acids in soil is biologically mediated. The decomposition of typical lipids is influenced by the soil properties and the fatty acid requirements of the microorganisms. A DT_{50}= 3 days in soil is proposed based on a study carried on with Neudosan (50% fatty acids potassium salt). Although the proposed PPP for Annex I inclusion is a mixture of glycerol esters of fatty acids, according to the public literature, enzymic hydrolysis of glycerol esters of fatty acids can occur very readily.

According to the notifier, the degradation of fatty acids in water is similar in almost all respects to the degradation in soil. However, with the available information, it is not possible to extrapolate the conclusions on the fate and behaviour in soil to the water compartment.

The predicted environmental concentrations were submitted for soil, surface water and sediment

Adsorption/desorption was calculated form the chemical structure (SAR determination) of the leading ester, i.e. oleic acid ester. This approximation sowed a Koc > 10.000 L/Kg . Taking this into account and based on the biodegradation of fatty acids in soil, no calculation of PEC (ground water) was done.

With regard to ecotoxicology, low risk is expected for birds and mammals as result of exposure rapeseed oil residue in food items neither in diet nor by secondary poisoning under indoor intended uses.

The risk associated to aquatic species calculated in the framework of Directive 91/414/EEC indicates that negligible short-term risk to aquatic algae can be expected.

The short-term risk associated to aquatic vertebrates and invertebrates indicates that a potential risk can be expected in some scenarios. Risk mitigation measures can be defined at Member state level.

Concerning all aquatic species not-long term risk can be expected.

Negligible risk to terrestrial arthropods other than bees and bees can be expected after in field use (1x application) of NEU 1160 I in orchards (assuming maximum application rate 30 L product ha, 3 m crown height, 26.49 kg a.i./ha) and in woody ornamentals if it is applied according with Good Agriculture Practices.

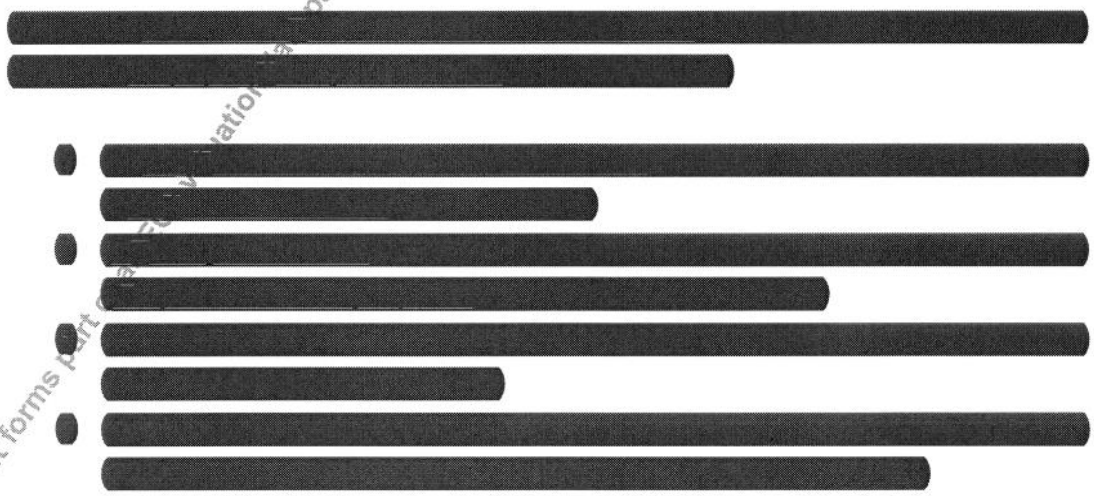
Risk to predatory mites can be expected after NEU 1160 I, for the use proposed in glass house (3 applications). Thus in order to protect predatory mite populations risk mitigation measures are required at Member state level (for the intended use of NEU 1160 I for ornamentals in the glass house).

Regarding to soil organisms considering the information available a safe use of NEU 1160 I is granted for in field use of NEU 1160 I (1 application, maximum application rate 30L product/ha) to earthworms and/or other soil macro-organisms species. However, a potential acute risk is identified for use of NEU 1160 I in ornamentals (glass house, 3 applications). Therefore, risk mitigation measures are needed for ornamentals in glass house in order to protect earthworms in soil.

Concerning all soil organisms not-long term risk can be expected.

The risk is low for soil microorganisms populations providing a sufficient margin of safety for microorganisms exposed to the residues of Rapeseed oil formulations.

3.2 Proposed decision concerning inclusion in Annex I



The information in section 3.2 has been removed upon request by the EU Commission as it relates to risk management recommendations or proposals.

LEVEL 4

RAPESEED OIL

Further information

4 Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I

4.1 Identity of the active substance

No additional information is needed concerning the identity of active substance.

4.2 Physical and chemical properties of the active substance

Data gaps for technical material:

A correct UV-VIS report with the identification of the test substance and interpretation of the spectrum is necessary.

The interpretation of the FT-IR spectrum is also necessary.

A study for the determination of surface tension is required.

Data gaps for the plant protection product NEU 1160 I:

The chemical stability of rapeseed oil when it is storage for 14 days at 54°C and 2 years at ambient temperature must be determined with an accuracy method.

The persistent foaming should be performed in CIPAC water D and the concentration used for the performance of the test should be specified.

4.3 Data on application and further information

The use "orchards" is very wide and the notifier should specify the use in the table of intended uses under GAPs. In addition, the application rate for orchards of 8.83 kg as/ha and m crown height is not accepted. A range of the application per ha must be specified, independently of the height of the plant.

The suitability of packaging must be addressed.

Procedures for the decontamination of water in the case of an accident were not provided.

4.4 Classification, packaging and labelling

No additional information is needed concerning Classification, packaging and labelling.

4.5 Methods of analysis

The RMS **requires a validation for the three IUPAC methods** (2.301, 2.302 and 2.311) for the determination of fatty acids contents in the active substance and in plant protection products.

Also they are required analytical methods to determinate rapeseed oil in **soil and water for monitoring.**

4.6 Toxicology and metabolism

Proposed ADI, AOEL and ArfD

The quality of low-erucic acid refined rapeseed oil (no more than 2% erucic acid) is accepted as food according to Codex Alimentarius (FAO-WHO, 2001). The applicant stated that the setting of references values is not applicable.

According to Product Health and Safety Data (Document JIII 1.4.1/01) there is an **Occupational exposure limit (OEL) for oil mist of 5mg/m^3 (TWA, 8h – workday)** recommended based upon the ACGIH TLV (Analysis according to US NIOSH Method 5026, NIOSH Manual for Analytical Methods, 3rd Ed.).

RMS agrees with the Applicant that rapeseed oil is accepted as food according to Codex Alimentarius (FAO-WHO, 2001) and the setting of references values seems to be not applicable.

Nevertheless, since there is an OEL and the method kind of application for NEU1160 I is spraying a exposure risk assessment could be done.

The notifier is requested to address the acceptability of this OEL for Rapeseed Oil and consider if an exposure risk assessment could be done.

4.7 Residue data

Some additional data is desirable before a conclusion about the residue definition is set. Although fatty acids occur naturally in plants, some data are needed to confirm that "not naturally occurrence fatty acids" or undesirable compounds are not found in the plant as a consequence of the application of rapeseed oil.

4.8 Environmental fate and behaviour

No additional information is needed concerning Environmental fate and behaviour.

4.9 Ecotoxicology

No additional information is needed concerning Ecotoxicology.