COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Last data extracted on 18.10.2023

Substance name: rape oil; rape seed oil
CAS number: 8002-13-9
EC number: 232-299-0
Dossier submitter: The Netherlands

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
13.10.2023	Belgium	FEDIOL	Industry or trade association	1

Comment received

FEDIOL is the European federation representing the interests of the European vegetable oil and protein meal industry. FEDIOL covers about 150 processing sites that crush oilseeds and/or refine crude vegetable oils and fats. These plants belong to around 35 companies. It is estimated that over 80% of the EU crushing and refining activities are covered by the FEDIOL membership structure.

FEDIOL read with attention the Combined Draft Renewal Assessment Report prepared according to Regulation (EC) N° 1107/2009 and Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) N° 1272/2008 for rapeseed oil, as prepared by The Netherlands and Finland as rapporteur and co-rapporteur Member States. The CLH report proposes to classify rapeseed oil as Aquatic Chronic 4 (H413). FEDIOL strongly objects to such a classification and would like to bring up a number of comments.

• Apart from being authorised as an active substance under Regulation (EC) N° 1107/2009, refined rapeseed oil is primarily a foodstuff as defined under Regulation (EC) N° 178/2002. The product used as a foodstuff or as a pesticide is the same, as this is food grade refined rapeseed oil. Hence, the proposed classification would impact not only the use of rapeseed oil as a pesticide, but also its use and the use of its derived products as a food, feed or other non food/feed uses. This will have serious direct and indirect impacts for our sector resulting from such a classification beyond the mere implementation of the CLP Regulation.

You will find attached the FEDIOL detailed response as sent to this consultation.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 23SAF451 FEDIOL comments to the ECHA consultation on rapeseed oil classification - 13 October 2023.pdf

Date	Country	Organisation	Type of Organisation	Comment number
12.10.2023	Germany	W.Neudorff GmbH KG and Evergreen Garden Care Deutschland GmbH	Company-Downstream user	2

Comment received

Please find here the statement prepared and submitted by the two members of the Task Force Rapeseed oil, W. Neudorff GmbH KG and Evergreen Garden Care Deutschland GmbH, regarding the proposal of the zRMS for the active substance renewal The Netherland to classify Rapeseed oil with Aquatic Chronic 4. We strongly insist against the proposed classification of Rapeseed oil.

First of all Rapeseed oil is a food item and even of food quality when used in the plant protection products. Food items are derogated from CLP and also from REACH. Just because it is used in plant protection products it is handled now as a “chemical” active substance since there is no adequate category and evaluation procedure for food items.

The use of Rapeseed oil in plant protection products is negligible compared to the daily consumption as vegetable oil in food preparation. Published figures for Germany for 2018 (Report from the ministry of agriculture) show that 4.9 Mio t oil is produced, 84.4 % were rapeseed oil
Rapeseed oil is used in numerous contexts, e.g. technical, pharmaceutical and cosmetical, and 700.000 t Rapeseed oil is used for food purpose (human consumption).
In contrast to these figures, in 2018 only 134.790 t of Rapeseed oil in plant protection products was used in Germany. The amount is increasing since it is a favourable alternative to chemical insecticides, especially in amateur gardening, 215.838 t were used in Germany in 2020.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
13.10.2023	Belgium	FEDIOL	Industry or trade association	3

Comment received

Looking at the CLH report on pages 136-137, it mentions that a classification of Aquatic Chronic 4, H410 means that toxic effects at concentrations below trigger values for classification cannot be excluded. Firstly, FEDIOL would mention an error in the reported hazard number on page 137, as Aquatic Chronic 4 equates to H413 and not H410, which equals to Aquatic Chronic 1.

FEDIOL further understands that such a classification is based on assessment of studies on rapeseed oil as such, but also on NEU 1160 I, which is a formulated pesticide and contains rapeseed oil and other substances. FEDIOL understands that the proposed classification is based on various assumptions, evidence and worst-case scenarios which are insufficient and equivocal and contradict the EFSA 2022 peer-review assessment .

Firstly, rapeseed oil is an oil and as all oils, it is very hydrophobic. Rapeseed oil can also be used as part of feed products for fish, and hence there is no reason to believe that it will have adverse effects upon them or the aquatic environment. It should also be reminded that no MRL are set for rapeseed oil used as a pesticide in Regulation (EC) N° 396/2005 and that no change is proposed by EFSA in its 2022 peer-review.

Secondly, the formulation endpoints, which contained high levels of rapeseed oil, but also emulsifiers, solvent, surfactants and/or wetting agents, was used for the classification and labelling assessment. The CLH report itself highlights on page 137 that “using studies with the formulated product NEU 1160 I adds to the uncertainty as there are other substances present in the formulated product that could exert aquatic toxicity, i.e.: one substance has a harmonised classification as Aquatic Chronic 3 (H412), another substance has self-classifications as Aquatic Acute 1 (H400) (66% of the notifiers) and Aquatic Chronic 1 (H410) (66% of the notifiers) with half of the notifiers assigning a M-factor of 100 for both acute and chronic aquatic toxicity, while the third substance is self-classified as Aquatic Chronic 3 (H412) (70% of the notifiers) (for details see confidential annex)”. It is therefore clear from the above that it is not possible to derive which effects could be attributed to rapeseed oil per se or to the other compounds contained in NEU 1160 I. The CLH report further identifies effects in aquatic invertebrates and algae, and on that basis, derives dose response effect. FEDIOL considers that the report fully diverges from the conclusions reached in the EFSA 2022 opinion , which indicated that “Low acute and chronic risk was indicated for all representative uses of rape seed oil” (…) with the application of buffer zones in some cases. Also, table 5 on surface water and sediment of the EFSA report further highlights a “Low risk to aquatic organisms”.

In light of the above, FEDIOL considers that the proposed classification of rapeseed oil as Aquatic Chronic 4 (H413) should be reassessed and revised as it is not based on sufficiently solid evidence.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 23SAF451 FEDIOL comments to the ECHA consultation on rapeseed oil classification - 13 October 2023.pdf

Date	Country	Organisation	Type of Organisation	Comment number
11.10.2023	United Kingdom	Health and Safety Executive	National Authority	4

Comment received

Rape seed oil (EC: 232-299-0; CAS: 8002-13-9)

The CLH report proposes the ‘safety net’ classification of aquatic chronic 4 for rape oil based on the water solubility of rape oil used as the NOEC value, and the uncertainty of the effects observed being due to rape oil or other substances in the formulations used in the studies.

ECHA (2017) s. 4.1.3.3.2 states that the criteria for chronic category 4 is ‘Cases when data do not allow classification under the above criteria but there are nevertheless some grounds for concern. This includes, for example, poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, and which are not rapidly degradable…and have a log kow >= 4, indicating a potential to bioaccumulate, which will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs > water solubility or > 1 mg/l, or other evidence of rapid degradation in the environment than the ones provided by any of the methods listed in Section 4.1.2.9.5.’.

On this basis, it appears that Aquatic Chronic 4 criteria are not met given:
i) no aquatic acute toxicity L(E)C50 endpoints are below 1 mg/L;
ii) rape oil is rapidly degradable and data on fish metabolism supports a low potential for

bioaccumulation;
iii) in a chronic toxicity to fish study, no effects were observed;
iv) the only chronic toxicity to invertebrates study employed a formulation – while co-formulants (which appear to meet hazard classification criteria) were present, the reported NOEC of 1.34 a.i. mg/L (mm) is above the quoted water solubility for rape oil; and
v) in an algal growth inhibition study with rape oil, effects were only observed in treatments with nominal concentrations significantly in excess of the water solubility – due to the lack of analytical verification, the NOErC of 34 mg/L (nominal) does infer a degree of uncertainty regarding any water-soluble fraction of rape oil, although based on the presented information it does not appear justified to consider the NOEC below the water solubility. A further algal study using a formulation, reports an ErC10 of 10.7 mg a.i. /L well in excess of the quoted rape oil water solubility. This ErC10 endpoint is likely more robust than the NOErC and while there is uncertainty regarding the water-soluble fraction and any co-formulant effect, analysis of the oleic acid component at start and end were included and the CLH report states 'Actual concentrations ranged 88-110% of nominal'.

ECHA (2017) Guidance on the Application of the CLP Criteria Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures Version 5.0 July 2017

Date	Country	Organisation	Type of Organisation	Comment number
12.10.2023	Germany	COMPO GmbH	Company-Downstream user	5

Comment received

For detailed commentation please see attached document.

Summary conclusion:

COMPO GmbH is of the opinion that the active substance renewal data set shows sufficient scientific evidence according to table 4.1.0 of EU regulation (EC) N° 1272/2008 to support the non-applicability of classification as Aquatic Chronic Cat. 4 for active substance Rape oil.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment COMPO GmbH_Commenting on the proposal for Classification and Labelling (CLH report) - Rape oil.pdf

Date	Country	Organisation	Type of Organisation	Comment number
12.10.2023	Germany	W.Neudorff GmbH KG and Evergreen Garden Care Deutschland GmbH	Company-Downstream user	6

Comment received

Rapeseed oil is also a naturally-occurring oil. It is a mixture of esters (triglycerides) of different fatty acids. The main fatty acids in Rapeseed oil are Oleic acid (C18:1), Linoleic acid (C18:2) and Linolenic acid (C18:3). Fatty acids are an integral part of the cell membranes of every living organism. They also occur as food substrate in the form of their triglycerides, i.e. fats and oils. Linoleic and Linolenic acid are essential fatty acids in humans. Consequently, the background levels are high.

The classification Aquatic Chronic 4 is proposed with the comment: Considering all

uncertainties discussed above, it is proposed to apply a safety net classification as aquatic chronic category 4.

The CLP regulation states clearly on point 4.1.2.6., page 132:

Safety net classification
Category Chronic 4
Cases when data do not allow classification under the above criteria but there are nevertheless some grounds for concern. This includes, for example, poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility (note 3), and which are not rapidly degradable in accordance with Section 4.1.2.9.5 and have an experimentally determined BCF ≥ 500 (or, if absent, a log Kow ≥ 4), indicating a potential to bioaccumulate, which will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs > water solubility or > 1 mg/l, or other evidence of rapid degradation in the environment than the ones provided by any of the methods listed in Section 4.1.2.9.5.
It has been agreed that Rapeseed oil is rapidly biodegradable, has no potential to bioaccumulate, so such a safety net classification is not appropriate at all for Rapeseed oil.
In the text above this conclusion in page 137, all points raised are relativized by the RMS itself, but still “uncertainties” are seen and the safety net classification is proposed. The is contradictory in our view.
- Rapeseed oil is very hydrophobic. Therefore, the performance of correct aquatic tests is very challenging for this substance, because of the low water solubility.
That we really end up now in the discussion to classify rape seed oil is the strong evidence that the current evaluation procedure is not fitting and over-conservative and that a separate and adapted procedure for plant extracts (natural substances/low risk substances) is urgently needed.

- Chronic studies in fish and Daphnia do not show effects below the water solubility. Just the Falk (2016) study (Algal growth inhibition, static, 72 h) shows slight effects. The NOEC was expressed as equal or below the estimated water solubility. Since Rapeseed oil is readily biodegradable, these should not be enough “grounds of concern“ or “uncertainties”. There is no risk of bioaccumulation and furthermore, this slight effect could be even caused by the co-formulants (Aquatic Acute I + Chronic I) as the studies were performed with a product formulation. This is even stated by the RMS.

- Originally, the studies were evaluated as acceptable and endpoints above water solubility were derived. The RMS The Netherlands argues now that not all of the substance was dissolved (emulsion) and therefore the full measured concentration was not available. Rapeseed oil has a purely mechanical effect. Therefore, an emulsion still shows effects, as there is better surface wetting. In addition, the emulsifiers in the product provide better water solubility (that is precisely their task!). To reduce the NOEC from >1mg/L (1.34 mg a.i/L for Daphnia and <6 mg a.i./L for algae) to water solubility is more than overprotective. We are talking about orders of magnitude >106.

- We insist on taking into account the original the endpoints. The effect of Rapeseed oil is also given by the wetting of the surface, the water solubility is therefore irrelevant. The observed toxic effects are due to the co-formulants. AI tests are not possible, toxicity derived from the product (mixture) for the AI is not justified.

- Just in case if one accepts the argumentation of The Netherlands that tox. effects are visible at concentrations of the water solubility of Rapeseed oil:
Let us assume the "best case", i.e. NOEC corresponds to the highest (estimated) water solubility of 8.8E-07 mg/L: One drop of rapeseed oil (~0.04 mL, corresponds to 36.4 mg at

a density of 0.91 g/mL) would thus be sufficient to exceed the NOEC in over 41000 m^3 of water. So, if one wash down his frying pan (~50 mL of oil), he would contaminate a volume of water equivalent to ~5% of the Netherlands' annual water consumption (1.0E09 m^3, 2020). Not to mention that at such concentrations we are in the homeopathic range and outside analytical detection limits. Should there really be toxic effects for aquatic organisms from Rapeseed oil, this would already be given by natural and municipal inputs into the water cycle. Even with the existing uncertainties from the available studies, a "safety net" classification as aquatic chronic category 4 is more than inappropriate.

- Other comparable edible oils approved as active substances or basic substances are not classified and don't give any grounds of concern at all

Last, but not least we would like to draw your attention to an error in point 2.9.2.5., page 137.
There it is mentioned:
Aquatic Chronic 4, H410 (May cause long lasting harmful effects to aquatic life); as toxic effects at concentrations below trigger values for classification cannot be excluded.
Aquatic Chronic 4 is connected to the hazard statement H 413, May cause long lasting harmful effects to aquatic life, not to H410.

PUBLIC ATTACHMENTS
1. 23SAF451 FEDIOL comments to the ECHA consultation on rapeseed oil classification - 13 October 2023.pdf [Please refer to comment No. 1, 3]
2. COMPO GmbH_Commenting on the proposal for Classification and Labelling (CLH report) - Rape oil.pdf [Please refer to comment No. 5]