Helsinki, 17 March 2017

[redacted]

Decision number: CCH-D-2114355634-46-01/F
Substance name: Rape oil, oxidized
EC number: 305-871-3
CAS number: 95193-59-2
Registration number: [redacted]
Submission number subject to follow-up evaluation: [redacted]
Submission date subject to follow-up evaluation: 10 November 2015

FOLLOW-UP EVALUATION DECISION TAKEN UNDER ARTICLE 42(1) OF THE REACH REGULATION

Based on Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has examined the information you submitted as a response to decision CCH-D-2114292324-49-01/F ('the compliance check decision').

> **ECHA concludes that after the expiry of the deadline set in the compliance check decision, your registration does not comply with the information requirements in Annex X, 9.4.4., Annex X, 9.4.6., and Annex IX, 9.4.2. to the REACH Regulation.**

Therefore, ECHA communicates this decision to the Member State competent authority (MSCA) and national enforcement authority (NEA) of your country for enforcement action.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

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Appendix 1: Reasons

This decision is necessary after the follow-up evaluation according to Article 42(1) of the REACH Regulation, because in your updated registration as a response to the decision CCH-D-2114292324-49-01/F ("compliance check decision") you have provided substantial new experimental data which ECHA has assessed for compliance with the information requirements of the REACH Regulation and the outcome is that your registration still does not comply with the information requirements addressed in the compliance check decision.

0. Assessment of read-across approach

In the compliance check decision you were requested to submit information derived with the registered substance. In the updated registration subject to follow-up evaluation, you have applied a read-across approach based on grouping of substances (category approach) and provided experimental studies with an analogue substance (linseed oil, oxidized, EC 272-038-8) and category and read-across documentation.

You proposed a category constisting of linseed oil, oxidized (EC 272-038-8) (BLO), castor oil, oxidized (EC 269-128-4) (BCO), and rape oil, oxidized (EC 305-871-3) (BRO). Read-across was used to fill the data gaps for rape oil, oxidized for long-term toxicity to terrestrial invertebrates, long-term toxicity on plants and effects on soil microorganism from studies conducted with linseed oil, oxidized. To support the read-across, you submitted a read-across justification document ([redacted]).

ECHA considers that the read-across cannot be accepted.

You summarise the category justification as "*it can be concluded that BLO, BRO and BCO share similar physico-chemical properties and similar structures. Due to higher level of polyunsaturated fatty acid chains in BLO, this substance may present a higher level of peroxides and may be the worst case scenario in terms of toxicology*."

You attempt to link potential toxicity to the presence of peroxides, and the formation of peroxides to the amount of double bonds. You do however not provide further information to substantiate whether the amount of double bonds and the percentage of [redacted] in the starting material indeed would correlate with any observed effect. You did consider adverse effects observed in the terrestrial studies with plants and soil microorganisms conducted with BLO being physical rather than toxic effects:

"*The test material is known for its property to form a coating/film on surface substrates. When this occurs on the roots of the plants or on the micro-organism cells, the exchange of minerals, nutrients, oxygen and CO2 will be hampered. This is a likely explanation that the observed effects are due to a physical effect rather than to a toxicological effect*".
While this explanation is not necessarily incorrect, ECHA highlights that for this argument it is assumed that exposure takes only place via the dissolved water phase, which remains speculative without further evidence. Furthermore, you did not address why peroxides would not play a role for the observed adverse effects. It is noted that you provided also a new WAF study with algae conducted with BLO, which showed adverse effects caused by the test material (based on nominal loading rates the 72h-ErL10, 72h-EbL10, 72h-ErL50 and 72h-EbL50 were found to be 61, 41, >100 and 75 mg/L respectively).

However, the observed effect has not been further discussed in relation to your read-across hypothesis. ECHA considers that you did not provide sufficient evidence to the argument that "*Due to higher level of polyunsaturated fatty acid chains in BLO, this substance may present a higher level of peroxides and may be the worst case scenario in terms of toxicology.*"

BCO has an additional hydroxyl group. You argue that the oxidative process occurring during production of BLO and BRO also would lead to the formation of hydro-fatty acids and state that alkyl hydroperoxide (ROOH) and dialkyl peroxide (ROOR) can decompose to produce hydroxyl compounds. Therefore, you say, the differences between the raw materials would be reduced as the oils are further oxidized. You did not use analytical information (e.g. as given in section 1.4 of IUCLID) to substantiate your claim regarding the formation of hydroxyl compounds during the production process. It is further noted that BCO is liquid while BRO and BLO are viscous liquids. ECHA considers that you have not provided sufficient evidence to the argument that "*the differences between the raw materials are reduced as the oils are further oxidized*", and did not sufficiently address how the remaining difference in chemical structure would effect the property to be read-across.

ECHA notes that aquatic short-term tests are not sufficient to compare intrinsic ecotoxicological properties due to the limited water solubility of the constituents. There are no long-term bridging studies across the group members that would support the hypothesis.

ECHA concludes that you did not provide sufficient evidence to justify the category approach. Due to remaining uncertainties regarding the relation between the chemical structure of the UVCBs and the properties to be predicted together with the absence of any long-term bridging studies for ecotoxicity, the hypothesis for ecotoxicity, which you provided, cannot be verified.

You commented on the draft decision indicating that an *initial* literature assessment provides further information on the potential correlation of effects and the amount of double bonds and the percentage of [redacted] in the starting material. ECHA agrees that a thorough literature review could be beneficial to support your claim. Further, you commented the importance of effects seen in the dissolved water phase, because other exposure routes are unlikely. ECHA points out that this may not be the only route of exposure, especially for soil microorganisms. Further, you did not provide evidence for the claim that toxicity is caused by physical effects. In general, you would need to clarify the hypothesis for the read-across justification (toxicity only due to physical effects or toxicity related to structural features) and indicate clearly whether the observed effects support the hypothesis or not. In addition, you indicated that based on literature review, hydroxyl groups do not result in different toxicity for the endpoints considered.

However, ECHA states that you have not addressed this in your dossier. Finally, you accept that bridging studies, that would support the hypothesis, are absent. ECHA notes that such bridging studies would support the verification of the hypothesis and eventually the reliability of the read-across prediction.

1. Terrestrial Invertebrates (Annex X, 9.4.1. and Annex X, 9.4.4)

In the compliance check decision you were requested to submit information derived with the registered substance for Long-term toxicity to terrestrial invertebrates.

In the updated registration subject to follow-up evaluation, you have applied a read-across approach based on grouping of substances (category approach) and provided an experimental study according to OECD guideline 222 (Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)) with an analogue substance (linseed oil, oxidized, EC 272-038-8) and category and read-across documentation.

ECHA considers that the read-across cannot be accepted for the reasons outlined above. Therefore, the request in the compliance check decision was not met, and the following endpoint remains incompliant: information on Long-term toxicity to terrestrial invertebrates (Annex X, 9.4.4.); test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei) OECD 222 or Enchytraeid reproduction test OECD 220 or Collembolan reproduction test in soil OECD 232 with the registered substance.

2. Terrestrial Plants (Annex X, 9.4.3. and Annex X, 9.4.6.)

In the compliance check decision you were requested to submit information derived with the registered substance for Long-term toxicity to terrestrial plants.

In the updated registration subject to follow-up evaluation, you have applied a read-across approach based on grouping of substances (category approach) and provided an experimental study according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) with an analogue substance (linseed oil, oxidized, EC 272-038-8) and category and read-across documentation.

ECHA considers that the read-across cannot be accepted for the reasons outlined above. Therefore, the request in the compliance check decision was not met, and the following endpoint remains incompliant: information on Long-term toxicity testing on plants (Annex X, 9.4.6.); test method: Terrestrial plants, growth test (OECD 208) with as a minimum two monocotyledonous species and four dicotyledonous species) or test method: Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030) with the registered substance.

3. Soil microorganisms (Annex IX, 9.4.2.)

In the compliance check decision you were requested to submit information derived with the registered substance for toxicity to soil microorganisms.

In the updated registration subject to follow-up evaluation, you have applied a read-across approach based on grouping of substances (category approach) and provided an experimental study according to OECD Guideline 216 (Soil Microorganisms: Nitrogen Transformation Test) with an analogue substance (linseed oil, oxidized, EC 272-038-8) and category and read-across documentation.

ECHA considers that the read-across cannot be accepted for the reasons outlined above. Therefore, the request in the compliance check decision was not met, and the following endpoint remains incompliant: information on Effects on soil micro-organisms (Annex IX, 9.4.2.); test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216 with the registered substance.

Appendix 2: Procedural history

The compliance check decision was issued on 5 February 2015. You were required to update the registration with the requested information by 12 November 2015.

You updated your registration on 10 November 2015.

The follow-up evaluation was initiated on 27 April 2016.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments and did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposal(s) for amendment and did not modify the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You did not provide any comments on the proposed amendment(s).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-52 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date of receipt of the draft follow-up evaluation decision.

2. The Article 42(2) notification for the compliance check decision is on hold until all information requested in the compliance check decision has been received.

3. ECHA recommends that you contact your Member State's authorities to agree on when and how to bring the registration in compliance.