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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR

"Estimation of the emissions of dioxins from the use of the "CMIT-MIT SOLVENT BASED" biocidal product family (BPF) as preservative in crude oil and middle distillate fuel"

1. Background

(1) During the 34th Biocidal Products Committee meeting of March 2020, ECHA adopted its final opinion[1] on the application for authorisation of the "CMIT-MIT SOLVENT BASED" for use as preservative in aviation fuels, crude oil and middle distillate fuel (Product-type 6)[2].

(2) The presence of halogenated organic compounds, such as CMIT-MIT, in fuel may result in the formation of dioxins during fuel combustion.

(3) Dioxins and dioxin-like substances, including Polychlorinated Biphenyls (PCBs), are persistent organic pollutants (POPs) covered by the Stockholm Convention[3].

(4) Human exposure to dioxins and dioxin-like substances has been associated with a range of toxic effects, including chloracne; reproductive, developmental and neurodevelopmental effects; immunotoxicity; and effects on thyroid hormones, liver and tooth development. They are also carcinogenic. Developmental effects in males are the most sensitive toxic end-point, making children – particularly breastfed infants – the most vulnerable group.

(5) The dioxin burden on humans and the environment needs to be further reduced as large parts of the population still consume more dioxin daily than WHO recommends as a precautionary measure[4].

(6) The Stockholm Convention and the Aarhus Protocol[5] on Persistent Organic Pollutants have the objective to protect human health and the environment

[1] The opinions of ECHA are available here

[2] The use for aviation fuels was withdrawn by the applicant on 6 April 2020.

[3] http://www.pops.int/

[4] https://apps.who.int/iris/bitstream/handle/10665/329485/WHO-CED-PHE-EPE-19.4.4-eng.pdf?ua=1

[5] https://www.unece.org/env/lrtap/pops_h1.html

from persistent organic pollutants. Regulation (EU) 2019/1021[6] (the POP Regulation) was adopted to implement the Union's obligation under the previously mentioned protocol and convention. Dioxins (PCDD/PCDF) are included as substances subject to release reduction provisions in Annex III to that Regulation.

(7) In January 2019, the EU published its third implementation plan to address POPs[7]. It states that '*Releases of unintentionally produced-by-products listed in Annex C (including dioxins) are subject to continuous minimisations with the ultimate objective of total elimination, where feasible*'.

(8) In the course of the evaluation of the application for authorisation of this BPF, the German Competent Authority expressed a minority opinion and, Germany announced that it wants to request the Commission to decide in accordance with Article 44(5) of the BPR that a Union authorisation for this BPF shall not apply in the territory of Germany. Germany explained that the use of the products of this BPF in fuels for motor vehicles conflicts with its national legislation[8] that prohibits that fuels for motor vehicles contain additives with chlorine or bromine compounds as they cause formation of dioxins (PCDD) during combustion.

(9) An assessment of the risks linked to the generation of dioxins from fuel preserved with this product was not carried out by the evaluating MS (France), nor by the BPC.

(10) Therefore, the Commission considers that it should be clarified whether, the products in the family lead to the generation of dioxins to an extent that they would have unacceptable effects on human health or the environment, and whether authorising this BPF would be in line with the objectives set in Regulation (EU) 2019/1021.

2. The questions referred to ECHA

(11) In the light of the background information mentioned above, ECHA is required to:

(a) estimate the amount of formation of dioxins (in mg/year TEQ (toxic equivalents)) due to the use of "CMIT-MIT SOLVENT BASED" in fuels used for road and water transport at the maximum application rate proposed for authorisation and the highest amount of product produced per year according to the application. The Agency does not need to estimate the amount of formation of dioxins due to the use in air fuels as the applicant has requested to remove this use from the application by e-mail sent to the evaluating competent authority on 6 April 2020.

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1021&from=EN

[7] https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-848-F1-EN-MAIN-PART-1.PDF

[8] 10th Federal Emission Control Ordinance §2 (1) and (2))

(b) estimate the overall contribution to the emissions of dioxins coming from the use of "CMIT-MIT SOLVENT BASED" as preservative for fuels used in road and water transport in the worst-case scenario, and compare it, where data are available, to the emissions of dioxin coming from other sectors or sources.

(12) As regards the risks for human health, ECHA is required to :

(a) Clarify the level of the risks for human health due to the exposure via the environment, and more specifically through air pollution, by:

1. Assessing the contribution that the use of "CMIT-MIT SOLVENT BASED" will have in the exposure to dioxins.

2. Assessing the level of risks for human health, either by a quantitative assessment or a qualitative assessment.

3. Providing an opinion on whether the risks can be considered acceptable or not, with or without setting specific/conditions to the authorisation.

(13) As regards the risks for the environment, ECHA is required to:

(a) Clarify the level of the risks to the environment by:

1. Assessing the level of risks for the environment, either by a quantitative assessment or a qualitative assessment, considering the estimation of the contribution to the emission of dioxins from the use of "CMIT-MIT SOLVENT-BASED" as preservative for fuels used in road and water transport.

2. Providing its opinion on whether the risks can be considered acceptable or not, with or without setting specific/conditions to the authorisation.

(14) Based on the outcomes of the above assessment for human health and the environment, the BPC should submit an updated opinion on the application for Union authorisation to the Commission fulfilling the requirements provided in Article 44(3).

3. Elements to be considered by ECHA when addressing this question

(15) ECHA should use all relevant information to reach a conclusion on the matter, that should at least include:

(a) All the data submitted in the application, as well as the conclusions of the discussions in the BPC and its Working Groups.

(b) Any further information submitted by the applicant or other interested parties in the scope of this request within a timeline specified by the eCA or ECHA as appropriate.

(c) The minority position expressed by Germany and the comments made by Member States during the 34th meeting of the BPC.

(d) The assessment carried out by Member States in order to ban or limit the use of chlorine compounds in fuel that have legislation in place.

(e) The projections for dioxin emissions for road transport for 2005 given in the report “European Dioxin Inventory – Stage II.

(f) The data included in the summary report “Compilation of EU Dioxin Exposure and Health Data”.

4. Deadline for the ECHA opinions

(16) ECHA shall adopt its opinion by 1 July 2021 the latest.