

Resolution on the draft Commission implementing regulation granting a Union authorisation for the biocidal product family ‘CMIT/MIT SOLVENT BASED’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

2022/2929(RSP) - 13/12/2022 - Text adopted by Parliament, single reading

The European Parliament adopted by 333 votes to 264, with 22 abstentions, a resolution **objecting** to the draft Commission implementing regulation granting a Union authorisation for the **biocidal product family ‘CMIT/MIT SOLVENT BASED’** in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

The draft Commission implementing regulation provides that a Union authorisation with authorisation number EU-0023657-0000 is granted to Nutrition R&D; Biosciences Netherlands B.V. for the making available on the market and use of the biocidal product family ‘CMIT/MIT SOLVENT BASED’ of product-type, as described in Annex V to Regulation (EU) No 528/2012, for preservation of de-watered crude oil and refined products (middle and light distillate fuels).

The Stockholm Convention on Persistent Organic Pollutants (‘Stockholm Convention’) and the Aarhus Protocol on Persistent Organic Pollutants have the objective of protecting human health and the environment from persistent organic pollutants (‘POPs’). Regulation (EU) 2019/1021 was adopted to implement the Union’s obligation under that Convention and that Protocol.

Dioxins and furans (PCDD/PCDF) belong to the category of POPs, covered by the Stockholm Convention, and are included as substances subject to release reduction provisions in Annex III to Regulation (EU) 2019/1021. Human exposure to dioxins and dioxin-like substances has been associated with a range of toxic effects, including carcinogenicity, chloracne, reproductive, developmental and neurodevelopmental effects, immunotoxicity, and effects on thyroid hormones, liver and tooth developments.

The Commission decided to address the concerns about dioxin formation by requesting an opinion from ECHA to estimate the amount of formation of dioxins and the overall contribution to the emissions of dioxins due to the use of the biocidal product family ‘CMIT/MIT SOLVENT BASED’ in fuels used for road and water transport, and to clarify the level of the risks to human health and the environment due to the exposure to dioxins via the environment from the use of that biocidal product family, so as to determine whether the risks can be considered acceptable or not.

In its opinion of 5 July 2021, ECHA concluded that, based on the current level of knowledge on the use of C(M)IT/MIT as a preservative in oil and fuel, it is **not possible to draw any conclusions** on the magnitude of the potential contribution of the use of C(M)IT/MIT in fuels with respect to dioxin emissions and exposure, or on the risks for human health and for the environment associated with the use of chlorine additives such as C(M)IT/MIT in fuels.

Despite ECHA's conclusion, the Commission 'considers that refusing the Union authorisation for the biocidal product family 'CMIT/MIT SOLVENT BASED' **would not lead to a significant decrease of dioxin emissions compared to granting it**' and therefore that this authorisation would be compliant with the Union's obligations under the Stockholm Convention and Regulation (EU) 2019/1021.

The scientific uncertainty as to the level of the risks to human health and the environment due to the exposure to dioxins via the environment from the use of the biocidal product family 'CMIT/MIT SOLVENT BASED' does not make it possible to reach a conclusion as to whether authorising that biocidal product family would be in line with the Stockholm Convention and Regulation (EU) 2019/1021.

Parliament considered that the draft Commission implementing decision is not consistent with Union law, in that it is not compatible with the aim and content of Regulation (EU) 2019/1021 and the requirements of the Stockholm Convention. It also considered that the draft Commission implementing regulation to grant a Union authorisation for the biocidal product family 'CMIT/MIT SOLVENT BASED' is not proportionate in light of:

- the **scientific uncertainty** as to the levels of the risks to human health and the environment due to the exposure to dioxins via the environment from the use of the biocidal product family 'CMIT/MIT SOLVENT BASED';
- the availability of **alternatives** for fuel preservation without halogenated compounds;
- the unacceptable risks that exposure to dioxins poses to human health and the environment, and the insufficient data for reaching a conclusion as to whether this authorisation would be in line with the objectives and provisions of the Stockholm Convention and of Regulation (EU) 2019/1021.

Parliament considered that therefore the Commission **should not have granted an authorisation to the biocidal product family** 'CMIT/MIT SOLVENT BASED' or, at a minimum, should have required the applicant to provide more data as to the amount of formation of dioxins and the overall contribution to the emissions of dioxins due to the use of that biocidal product family in fuels used for road and water transport, and to clarify the level of the risks to human health and the environment due to the exposure to dioxins via the environment from the use of that biocidal product family, in order for the Commission to determine whether the risks can be considered acceptable or not in view of the aims of the Stockholm Convention.

Therefore, the Commission is called on to **withdraw its draft implementing regulation** and to submit a new draft to the committee.