**Follow up to the European Parliament non-legislative 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**

**1. Resolution tabled pursuant to Rules 112(2) and (3) of the European Parliament's Rules of procedure**

**2. Reference number:** 2022/2929 (RSP)/ B9-0549/2022 / P9\_TA(2022)0434

**3. Date of adoption of the resolution:** 13 December 2022

**4. Competent Parliamentary Committee:** Committee on Environment, Public Health and Food Safety (ENVI)

**5. Brief analysis/assessment of the resolution and requests made in it:**

The resolution notes that the Commission intends to grant an authorisation to the biocidal product family CMITMIT SOLVENT BASED (‘the BPF’) (**recital A**) and recalls the Commission’s commitments to a zero-pollution ambition, the Stockholm Convention, the Aarhus Protocol and Regulation (EU) 2019/1021 on persistent organic pollutants (POPs) (**recitals B and C**). It recalls that the European Chemicals Agency (‘ECHA’) opinion of 5 March 2020[[1]](#footnote-1) included a minority opinion from Germany concluding that the use of the BPF conflicts with its national legislation (10th Federal Emission Control Ordinance § 2(1) and (2)) which prohibits fuel for on-road motor vehicles from containing additives with chlorine or bromine compounds (**recital D**). It mentions that dioxins and furans (PCDD/PCDF) belong to the category of POPs, covered by the Stockholm Convention, and are subject to release reduction provisions in Annex III to Regulation (EU) 2019/1021 because of their toxic effects on humans, and that in January 2019, the Union published its third implementation plan to address POPs[[2]](#footnote-2) stating that these are subject to continuous minimisation with the ultimate objective of total elimination, where feasible (**recitals E and F**). It refers to the Commission’s initiative to address the concerns about dioxin formation leading to the ECHA opinion of 5 July 2021[[3]](#footnote-3), which concluded that 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 in fuels (**recitals G, H and I**). It indicates that despite ECHA’s conclusion, the Commission considers that refusing the Union authorisation for ‘the BPF’ would not lead to a significant decrease of dioxin emissions and that the authorisation would be compliant with the Union’s obligations under the Stockholm Convention and Regulation (EU) 2019/1021 (**recital J**). It recalls the Commission’s reasoning that as a consequence of the ambitions of the European Green Deal[[4]](#footnote-4) and Regulation (EU) 2021/1119 of the European Parliament and of the Council[[5]](#footnote-5) to achieve climate neutrality by 2050, the overall amount of fuel that may potentially be treated with the BPF is expected to decline significantly in the coming decades, which leads to a decrease in the formation of dioxins accordingly (**recital K**). It notes that the ECHA opinion of 5 July 2021 confirms that motor vehicles powered with fuels containing chlorine are sources of dioxin and furan emission and that, although still minor compared to current dominant sources, the relative contribution of non-industrial diffuse sources, including transport, is likely to increase and that their relative importance in terms of human exposure could be higher **(recitals L and M)**. It opines that 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 BPF makes it possible to conclude whether authorising the BPF would be in line with the Stockholm Convention and Regulation (EU) 2019/1021 **(recital N)**. It finds a contradiction between the decision by the Commission to grant an authorisation for the BPF while accepting not to apply or to adjust that authorisation for Denmark, Belgium and Germany due to its potential negative effects on human health and the environment, stemming from dioxin formation **(recitals O, P, and Q)**. It points out that the requests for derogation from these Member States were also made on the grounds that alternative fuel preservatives without halogenated compounds are available, recalls that Article 5, point (c), of the Stockholm Convention obliges each party, as a minimum, where it deems it appropriate, to require the use of substitute or modified materials, products and processes to prevent the formation and release of dioxins and that Article 6(2) of Regulation (EU) 2019/1021 obliges Member States to do the same **(recitals R, S and T)**. It notes that according to the BPC opinion of 5 March 2020, one of the co-formulants of the BPF was identified as potentially having endocrine-disrupting properties, but that this was not conclusive and that for further clarification a process under REACH will be triggered by the evaluating Competent Authority (France) **(recital U)**.

The resolution considers that the draft Commission implementing regulation exceeds the implementing powers provided for in Regulation (EU) No 528/2012 **(paragraph 1)** and 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 **(paragraph 2**). It considers that the draft regulation 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, andthe 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 **(paragraph 3)**. Itconsiders 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 **(paragraph 4)**.

It calls on the Commission to withdraw its draft implementing regulation granting a Union authorisation for the biocidal product family ‘CMIT/MIT SOLVENT BASED’ and submit a new one to the Standing Committee on Biocidal Products (**paragraph 5**).

**6. Response to requests and overview of action taken, or intended to be taken, by the Commission:**

In response to **paragraphs 1 and 2**, the Commission would like to emphasise that the draft Commission implementing regulation granting a Union authorisation for the biocidal product family ‘CMIT/MIT SOLVENT BASED’ is fully in line with the implementing powers provided for in Article 44(5) of Regulation (EU) No 528/2012 on the placing on the market of biocidal products (the BPR). All procedural and substantial requirements set in the BPR on the assessment of the application and the granting of a Union authorisation have been correctly followed. It is also in line with the objectives of that regulation and not in conflict with the requirements of Regulation (EU) 2019/1021 as set out below.

With respect to the other provisions of the resolution, the Commission considers that they fall outside the remit of the right of scrutiny, which is limited to the question of whether an implementing act exceeds the implementing powers provided for in the basic act. The Commission is not required to justify the implementing act as regards these points. Nevertheless, the Commission has carefully considered the positions expressed by the Parliament and would like to make the following comments:

As regards **paragraph 3**, the Commission would like to note that in preparation for the draft implementing regulation, the Commission thoroughly examined the possible formation of dioxins in the light of the minority position in relation to the BPC opinion (ECHA/BPC/246/2020) submitted by the member of the BPC appointed by Germany by requesting a further opinion by the BPC in accordance with Article 75(1)(g) of the BPR. This opinion (ECHA/BPC/283/2021) concluded that, although the potential formation of dioxin from the use of C(M)IT/MIT as preservative in oil and fuel is likely to occur, it is not possible to draw any conclusions either on the potential contribution of the use of C(M)IT/MIT in fuels with respect to dioxin exposure, nor on the potential risks of chlorine additive such as C(M)IT/MIT in fuels on human health and on the environment.

As clearly explained in recital 9 of the draft implementing regulation, 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. Indeed, the same or similar chlorine-containing additives are currently allowed to be placed on the market under national legislation in the Member States as indicated in the transitional measures in Article 89 of the BPR. They can also be authorised via national authorisations by the Member States in accordance with the BPR, for which several procedures for authorisation and mutual recognition are ongoing. Furthermore, as a consequence of the ambitions of the European Green Deal and Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality the overall amount of fuel that may potentially be treated with the BPF and combusted in motors or heating systems is expected to decline significantly in the coming decades. Consequently, the possible formation of dioxins associated with the use of the ‘CMIT/MIT SOLVENT BASED’ BPF will decrease accordingly and granting of the authorisation is thus not in conflict with the requirements of the Stockholm Convention or Regulation (EU) 2019/1021.

The Commission consulted the Member States on the existence of national rules banning or regulating the addition of products containing halogenated organic compounds such as C(M)IT/MIT to fuels, the biocidal products that are allowed on their territories for their preservation, and the available alternatives for their preservation without halogenated compounds. The outcome of the consultation showed that only one Member State (Germany) and Switzerland have rules banning addition of halogenated organic compounds to certain types of fuels - but not to all. Estonia and the Netherlands have rules setting a maximum allowed content of halogenated organic compounds and the use of the ‘CMIT/MIT SOLVENT BASED’ BPF, subject to the conditions set in the summary of biocidal product characteristics, is in line with those national rules. Three Member States (Germany, Luxembourg and the Netherlands) indicated that they have similar products authorised under national regimes. Only two Member States (Germany and the Netherlands) and Switzerland provided information on other active substances without halogenated compounds that are used in preservatives for fuels. The alternatives indicated are not yet approved under the BPR and most of them have hazardous properties of concern and/or meet the exclusion criteria in Article 5(1) of the BPR, which means that they should normally not be approved.

Member States, as parties to the Stockholm Convention, are obliged to implement action plans to eliminate where feasible as soon as possible, the releases of substances listed in Annex III to Regulation (EU) 2019/1021 (which includes dioxins) and to require the use of substitutes where they deem it appropriate. Article 5c of the Stockholm Convention gives all Parties a margin to consider whether the obligation to require the use of substitutes is appropriate or not. As set out above, the vast majority of Member States have taken no action to require the use of substitutes to CMIT/MIT or other chlorine containing fuel additives and those who have do not require this for all uses.

As regards **paragraph 4**, the Commission would like to note that the applicant made a comprehensive attempt to assess the possible dioxin formation due to the use of the biocidal product family CMITMIT SOLVENT BASED in fuels (which when ready for use is present at a concentration of 0.0006 % (6 ppm). These calculations resulted in a total maximum emission of 0.000864 g/year toxic equivalent values (TEQ) in the whole of Europe from the use of the C(M)IT/MIT solvent as preservative in crude oil and middle distillate fuel, whilst the estimations of the total dioxin emission in Europe for road transport for 2005 indicated in the “European Dioxin Inventory-Stage II" were 41-60 g TEQ/year. However, the BPC was not in a position to confirm these estimates for the following reasons:

• There is no experimental evidence demonstrating the existence or the absence of formation of dioxins from the use of C(M)IT/MIT as preservative in oil and fuel. So while it is likely to occur, the extent cannot be estimated.

• The estimation assumes a linear relationship between chlorine content and dioxin formation, while the review of the scientific literature has shown that such relationship has not been observed as a rule for the various fuel and vehicle technology type.

• The addition of chlorine containing compounds to fuel increases dioxin formation under certain conditions (e.g. incomplete combustion as observed in vehicle engines). However, the relationship between chlorine content and dioxin formation is not yet clarified and does not seem to be broadly linear. It is hardly possible from the scientific literature to derive a reasonable worst case conversion yield representative of current EU fuels and vehicle technology types. For this, it would be necessary to establish a clear representation of the relationships between chlorine content (entering the combustion chamber) and the dioxin formation, with equations, parameters and domain of validity clearly defined. Instead, there is no consensus on the relevance of such a relationship (as general rule), very few values for chlorine content / dioxin emission are available in the literature, and numerous studies are based on outdated fuels/engines and are partly specific to non-EU countries.

• The overall situation is highly dynamic (vehicle fleet, traffic level) and all estimations are characterised by very large uncertainties. Much of the data used to estimate road traffic emissions in existing inventories date back 15-20 years. Their relevance to the current situation is questionable.

As regards **paragraph 5,** the Commission notes that there are no grounds to withdraw the draft implementing regulation and that there are no technical or legal grounds on the basis of which it could present a new draft implementing regulation refusing the authorisation of the biocidal product family CMITMIT SOLVENT BASED in fuels.

1. BPC opinion of 5 March 2020 on the Union authorisation of the biocidal Product Family: CMIT/MIT SOLVENT BASE, Product type: 6, ECHA/BPC/246/2020. [↑](#footnote-ref-1)
2. Commission report of 4 January 2019 on the review and update of the second European Union Implementation Plan in accordance with Article 8(4) of Regulation No 850/2004 on persistent organic pollutants, COM(2018)0848, <https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-848-F1-EN-MAIN-PART-1.PDF> [↑](#footnote-ref-2)
3. BPC opinion of 5 July 2021 on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on the evaluation of dioxins emissions from the use of the biocidal product family (BPF) “CMIT/MIT SOLVENT BASED” in fuels used in road and ship transport (ECHA/BPC/283/2021). [↑](#footnote-ref-3)
4. Communication of the Commission of 11 December 2019 on the European Green Deal, COM(2019)0640. [↑](#footnote-ref-4)
5. Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 (‘European Climate Law’) (OJ L 243, 9.7.2021, p. 1). [↑](#footnote-ref-5)