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European Food Safety Authority

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PC-1239: Draft scientific opinion on the re-assessment of the risks to public health related to the presence of styrene in plastic materials and articles intended to come into contact with food

Dear Madam or Sir,

We kindly thank EFSA for this opportunity to provide input on its draft scientific opinion regarding the food contact chemical styrene (CAS 100-42-5).

The Food Packaging Forum (FPF) is a charitable, independent scientific organization. Our work supports protection of the public from hazardous chemicals in food contact materials and articles, by providing the scientific evidence base. In our comments on this draft opinion, we would like to highlight the following aspects.

1. Scope is insufficient to determine safety in accordance with Art. 3(1) EC 1935/2004

1.1. EFSA's interpretation of the *Terms of Reference* is too narrow, as it focuses only on the risk of styrene and ignores other chemicals that migrate from plastic materials made with styrene

As laid out in the *Terms of Reference*, the European Commission requested EFSA to provide a scientific opinion on whether the use of styrene in the manufacture of plastic and plastic layers in food contact materials can be considered safe, in accordance with Article 3(1) of Regulation (EC) No 1935/2004[1], the EU's food contact materials (FCM) Framework Regulation. Importantly, Art. 3 pertains to the materials made with styrene. Therefore, focusing only on styrene migration alone will not be sufficient for determining whether the materials made with styrene as starting substance are indeed safe.

Based on evidence from the scientific literature, there are **at least 94 chemicals that have been shown to migrate from polystyrene (PS)**, including styrene monomer, styrene oligomers, other styrene-related non-intentionally added substances, and further plastic-related chemicals including metals (FCCmigex 2025). Styrene has also been found to migrate from

[1] "Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health;"

other FCMs than PS, including from paper and board (Marc 2020; Canellas et al. 2015; Vera et al. 2014), polypropylene (PP) (Kirchkeszner et al. 2022), and recycled polyethylene terephthalate (PET) (Colombo et al. 2024; Thoden van Velzen et al. 2020). To faithfully assess the human health risk related to FCMs made by polymerization of styrene or its use in FCMs one would need to **assess the mixture toxicity of the overall migrate** from each relevant material (PS, PP, PET, etc.) and impacts on human health via genotoxic, non-genotoxic, and other mechanisms.

1.2. The interpretation of the Terms of Reference is too narrow, as it focuses only on genotoxicity and ignores other health impacts of styrene

Additionally, the interpretation of the *Terms of Reference* focuses only on genotoxicity (line 170: "*The term "toxicity" refers specifically to the genotoxic potential of styrene after oral exposure.*"). This focus is justified with previous EFSA scientific opinions (2011, 2017). However, in 2023, EFSA reduced the Tolerable Daily Intake (TDI) of the plastic monomer (and additive) bisphenol A (BPA; CAS 80-05-7) by a factor of 20,000. This robust scientific decision was based on effects on the immune system, not on genotoxicity, because "*the immune system was identified as most sensitive to BPA exposure*" (EFSA 2023). Therefore, it is unclear why in its assessment of the risks of styrene EFSA chose *a priori* to focus on genotoxicity as the only relevant mechanism related to health impacts, while Art. 3(1) refers to the endangerment of human health, which could be caused also by impacts on the immune system, brain and cardiovascular health, but also relate to metabolic disruption and reproductive disorders. All these are human health effects that are known to be affected by certain chemical exposures, and that are equally relevant to cancers caused by chemicals via genotoxicity and non-genotoxic mechanisms alike.

Genotoxicity is clearly an important endpoint, but it is not to be mistaken for the only relevant health impact that (food contact) chemicals can have (The Consortium for Children's Environmental Health 2025; Muncke et al. 2023). Adequate protection of public health requires taking all scientific evidence into consideration, including other ways that styrene and styrene-related chemicals affect human health across the entire life span, including fetal and perinatal exposure via breast milk, and via non-genotoxic mechanisms that may currently still be poorly characterised. Specifically, ECHA has determined that styrene is suspected to be toxic for reproduction (ECHA 2008) and styrene is currently being reevaluated for harmonized classification and labelling (ECHA 2023), which will include an assessment of the endocrine disrupting potential, as laid out in the EU's Chemicals Strategy for Sustainability (EU 2020).

While an assessment of the risk related to the migration of styrene alone and its genotoxic potential is important, it is not sufficient for determining the safety of materials made by polymerization of styrene. Therefore, this scientific option **cannot conclude that styrene can be safely used** in the sense of (line 137) "*Whether the use of styrene if authorised in accordance with Article 5 of Regulation (EU) No 10/2011 subject to the above mentioned SML of 40 ppb, is in accordance with Article 12(3) of Regulation (EC) No 1935/2004.*"

2. The reliance on industry-funded toxicity data is concerning and scientifically unsound

In its scientific opinion, EFSA relied strongly on 5 recent *in-vitro* studies, 4 by the US Styrenic

Information and Research Center[2] (line 191), with two studies being publicly available (Gollapudi et al. 2023, 2024) and two studies cited as "*Unpublished report*". The fifth study included in this assessment was funded by the Japanese Ministry of Health, Labour and Welfare (Murata et al. 2023). In addition, all studies were sub-chronic, focused on genotoxicity and did not include an assessment of effects on offspring (F1).

The reliance on industry-funded studies (including unpublished studies) for determining the risk of styrene for use in FCMs is concerning, due to the lack of transparency and a history of industry-paid toxicological studies unduly influencing regulatory decision making (Myers et al. 2008). Indeed, commercial interest-driven strategies have led to unnecessary exposure of the public to the hazardous plastic chemical BPA for at least two decades, with huge costs to society (Trasande et al. 2024). BPA is but one of over 12'000 intentionally used food contact chemicals and it is only now being gradually phased out of FCMs, while the public continues to be exposed to unsafe levels of BPA (Groh et al. 2021). A lesson learned from the BPA case is that regulatory agencies cannot rely on scientific data controlled by stakeholders with commercial interests (The Consortium for Children's Environmental Health 2025).

It is questionable that EFSA, in its scientific assessment of styrene, relies so heavily on such data that most likely are prone to a strong bias. If the reason for this lies in the absence of relevant independent scientific studies then the scientific opinion could state this in its conclusion, addressing the *Terms of Reference* (line 148ff: "*should there be a risk for an inconclusive opinion due to insufficiency of available data over the toxicity of styrene, the Commission invites EFSA to explore all tools at its disposal for the collection of all relevant scientific data and studies, including the potential launch of new scientific studies to support the risk assessment.*").

Again, we thank EFSA for the opportunity to provide input on this important draft scientific opinion.

Yours sincerely,

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[2] "SIRC is a nonprofit organization consisting of voting member companies involved in the manufacturing or processing of styrene, associate member companies that fabricate styrene-based products, and international members. The organization conducts research on the health effects of styrene monomer and ethylbenzene." (SIRC 2025).