ANSWERING THE MANDATE

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EFSA FCM Network on 17th October 2023

EUROPEAN FOOD SAFETY AUTHORITY

BACKGROUND

Styrene is authorised without a migration limit or other restrictions for the manufacture of plastic FCM in accordance with Regulation No 10/2011.

In 2019, the International Agency for Research on Cancer (IARC) published a monograph, concluding that styrene and its primary metabolite styrene 7,8-oxide are to be classified as "**probably carcinogenic to humans**".

Therefore, the Commission requested EFSA to re-evaluate whether the evidence examined by IARC could be of consequence to the safety of styrene in FCMs.

The Panel concluded that a concern for genotoxicity associated with oral exposure to styrene could not be excluded and that additional data were required for assessing the safety of styrene in FCMs (EFSA-Q-00686).

Commission proposed limit of **40 ppb, whilst EFSA resolves question over genotoxicity.**

MANDATE

EFSA to address

- the genotoxicity associated with oral exposure to styrene.
- 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 3 of Regulation (EC) No 1935/2004.

If needed, EFSA shall

- conclude on a lower SML or alternative restrictions under which the use could be considered safe.
- in view of remaining uncertainties or knowledge gaps, or if the available data would not be suitable to support the SML of 40 ppb, request additional data or require additional studies .

EFSA INITIAL VIEW ON THE APPROACH

To address the **genotoxicity potential and safety against the 40 ppb SML**, EFSA favours:

- a fit-for-purpose process with a reasonable timeframe (15 months),
- to start with the evaluation of the new studies from the US Styrenics Industry Association's (SIRC):
  - two new available Combined Pig-a, Micronucleus, and Comet study in mice and in rats after oral administration of styrene for 28 days;
  - the expected transgenic study in mice (05.2024),
- to request additional data to answer potential uncertainties and lack of information,
- to liaise with sister Agencies (ECHA, EMA) & MSs as Observers,
- to hold a public consultation.

FCM WG VIEWS

The WG considered that a systematic review is not necessary and propose to:

1. assess the SIRC two new studies in mice & rats after oral administration of styrene,
2. assess the reliability and relevance of the oral genotoxicity studies in the IARC Monograph published in 2019,
3. assess toxicokinetic incl. metabolism studies in the IARC Monograph,
4. along with a literature search on the new *in vivo* studies (oral exposure) published since the IARC Monography in 2019 that should cover genotoxicity, toxicokinetic and metabolism.
5. the literature search should also cover human biomonitoring studies applying genotoxicity biomarkers, taking into account pharmacokinetic and metabolic differences related to the route of exposure, that can contribute to the assessment of the genotoxic potential of oral styrene in humans.
6. assess the SIRC transgenic study in mice addressing gene mutations (expected 05.2024)
7. to request additional data (clock-stop) to answer potential uncertainties and lack of info.

Within 15 months.

Thank you

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