94TH ADVISORY FORUM
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# 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

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EUROPEAN FOOD SAFETY AUTHORITY

# BACKGROUND

**Styrene:** authorised without a migration limit or other restrictions for the manufacture of plastic food contact materials

High priority group of substances needing re-evaluation.

**2018**, **IARC**: "**probably carcinogenic to humans**"

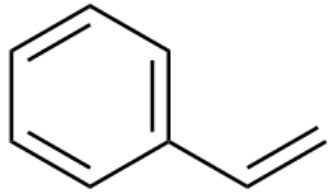
**2018, EC requested EFSA** to re-evaluate whether the evidence examined by IARC could be of consequence to the safety of styrene in FCMs.

# STYRENE RE-EVALUATION: 1ST PHASE

## 2020 EFSA opinion

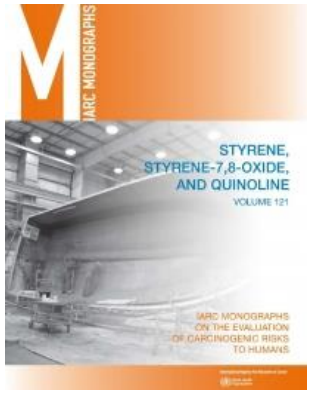
*'Assessment of the impact of the IARC Monograph Vol. 121 on the safety of the substance styrene (FCM No 193) for its use in plastic food contact materials'*

- IARC evaluation is based on high-dose occupational exposure studies and animal studies by inhalation.



Styrene

- Comprehensive analysis of the reliability and relevance of all available experimental and human findings on styrene genotoxicity, together with toxicokinetic aspects should be considered.



# CONCLUSIONS ON GENOTOXICITY OF STYRENE IN FCMS

## 2020 EFSA opinion

"The CEP Panel concluded that a concern for genotoxicity associated with oral exposure to styrene cannot be excluded.

Taking the human exposure data into account, a systematic review of genotoxicity and mechanistic data, comparative toxicokinetics and analysis of species differences is required for assessing the safety of styrene for its use in FCM".

# STYRENE RE-EVALUATION: 2ND PHASE

## 2023 EC Mandate

In accordance with Article 12(3) of Regulation (EC) No 1935/2004, the European Commission requests EFSA to provide an opinion, which addresses the following points:

- Whether styrene is genotoxic following oral exposure and the relevance to human health, and,
- 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

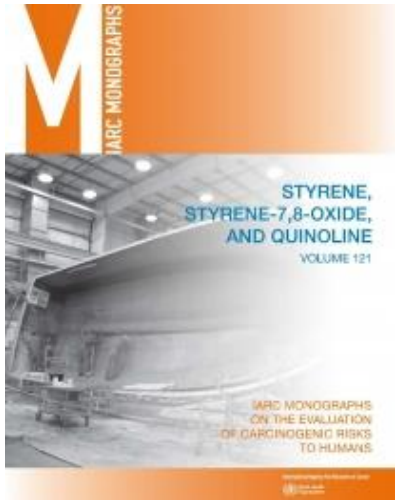
EFSA shall deliver its opinion within 15 months (max 30)

# TO ADDRESS THE MANDATE

- Data to be analysed:
  - Genotoxicity
  - Toxicokinetics (Tks)
  - Human exposure (HBM+dietary)

- Sources of data:
  - 4 studies from US SIRC: Dec. 2022, Oct. 2023, Mar. 2024
  - IARC Monograph (2019)
  - Literature search (last 7 years, 3392 papers)

SIRC Styrene Information & Research Center




# THE ASSESSMENT (2023-2024)

- ✓ **Literature search** (1 Jan. 2018 - 1 Oct. 2024)
  - updated every 4 months
  - **3392** papers > T&A and FT screenings
- ✓ FCM WG meetings on Styrene: evaluation of 4 **SIRC study reports,** studies from the **2019 IARC Monograph** and from the **literature search.**
- ✓ Presentations and regular updates at the **FCM Network** meetings.
- ✓ **2 Additional Data Request letters** (genotoxicity data).
- ✓ **Endorsement of the final draft opinion by the FCM Panel** on **04.12.2024**

# NEXT STEPS

**10 December 2024 – end of January 2025**

- Public consultation + webinar (14 Jan)

**March 2025**

- Possible adoption of the opinion by the FCM Panel

**April 2025**

- Opinion publication

# DUTCH HEALTH COUNCIL DRAFT ASSESSMENT OF STYRENE

- Proposal for reclassification of styrene as Mutagenic category 2.
- Draft under PC until 02 December 2024.


THANK YOU

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