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TALC (E 553b): ONGOING ASSESSMENT

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BACKGROUND

Talc (E 553b) is a food additive, permitted for use in the EU according to Regulation (EC) No 1331/2008

- Re-evaluated by EFSA in 2018
 - No safety concerns, very little absorption after dietary intake
 - Uncertainties around characterisation of the material, particle size (nano)
- EC followed up on the uncertainties identified by EFSA.
 - Call for data published in 2018
 - Mandate for an updated opinion sent to EFSA in June 2021

Talc has several applications

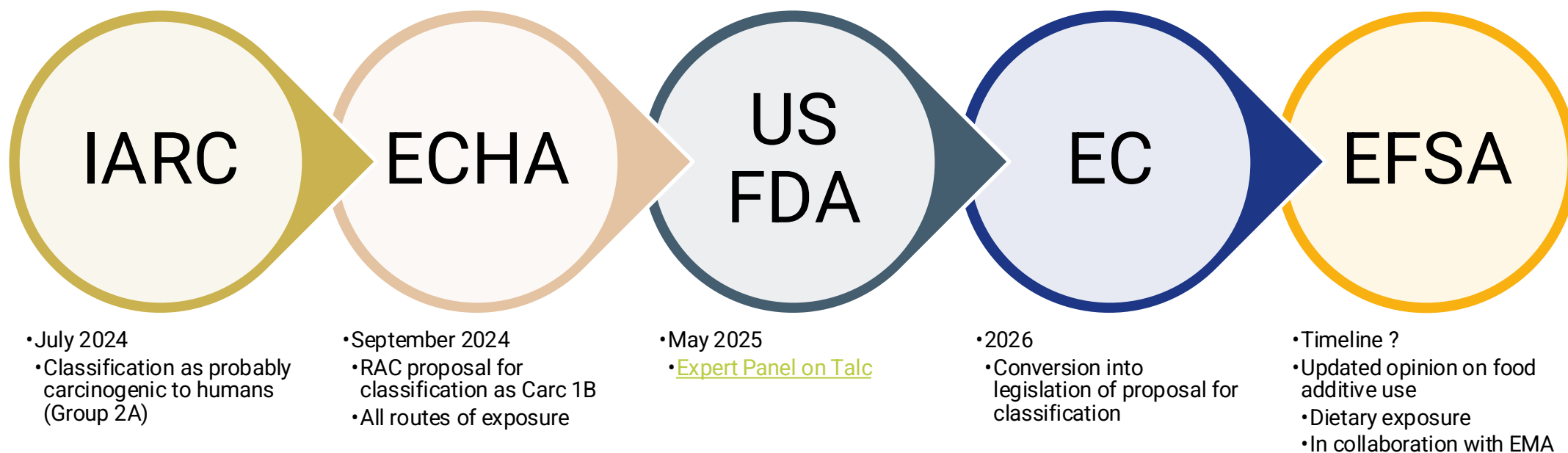
- In EFSA's remit: food contact material, pesticides, feed
- Outside EFSA: medicines, cosmetics, other industrial applications

Well known legal controversies around use of talcum powder/baby powder

- Talc used as a food additive must be free of asbestos



BROADER CONTEXT



1S1A: ONE SUBSTANCE ONE ASSESSMENT

The ECHA proposal for classification as carcinogen applies to all routes of exposure

- Overall, RAC concludes that no specific route of exposure can be designated in accordance with the CLP criteria, due to inadequacy or lack of data conclusively demonstrating the lack of carcinogenicity via other routes (such as oral or dermal).

The ongoing EFSA assessment will have to clarify what are the risks after oral exposure, the only one relevant to the use of talc as a food additive

- The EFSA opinion will be extremely relevant also to EMA given the extensive use of the substance in solid oral formulations

To perform the risk assessment, EFSA will have to take into account nano specific considerations, in line with the applicable horizontal guidance of the EFSA Scientific Committee

- Proposals for enlarging pool of experts in nano risk assessment welcome



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