Meeting

Bisphenol A: The Dutch National Institute for Public Health and the Environment (RIVM), BPA Part 2

This is a paper for discussion.

This does not represent the views of the Committee and should not be cited.

Introduction

1. In April 2023, the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) established a new tolerable daily intake (TDI) of 0.2 ng Bisphenol A (BPA)/kg bw per day. Although this new TDI is higher than the initially proposed level of 0.04 ng/kg bw, mean and high level consumers for all age groups would exceed the new TDI by 2-3 orders of magnitude.

2. The COT discussed the draft EFSA opinion at their extraordinary meeting in February 2022 and provided comments on the public consultation. The final EFSA opinion and diverging opinions by the European Medicines Agency (EMA) and the German Federal Institute for Risk Assessment (BfR) were discussed at their May 2023 meeting.

3. A draft interim position statement was presented to the Committee in May 2023 and following discussion, again at the September 2023 meeting. The interim position statement was accompanied by additional information on the relevant UK legislation and health based guidance values (HBGVs) for BPA established by European or international authorities.

4. One of the authorities which recently (2016) published information on BPA was the Dutch National Institute for Public Health and the Environment (RIVM). The RIVM noted that, based on new insights the current EU standards required revisiting and to reduce BPA exposure in the short term wherever possible. Special attention should thereby be given to protecting small children, pregnant

women and women who breastfeed since the developing unborn child, infants and young children are more sensitive to the effects of BPA than adults. The RIVM published a report on BPA (Part 1) in 2014, providing an overview of the current state of knowledge about BPA.

5. Part 2 of the report aiming to evaluate the scientific knowledge and discuss possible health risk was not available to the Secretariat at the September meeting. Since then, RIVM has kindly provided the link to Part 2 (Recommendations to risk management) and the following paragraphs provide a very brief summary of the main points. Please note that Section 6 of the report may be of additional interest as it has focused on alternatives to BPA.

6. In 2016, the RIVM concluded that on the current human health hazard standards and information on exposure: there is not a health concern for BPA at the levels of dietary exposure estimated by EFSA (2015); there is low concern for aggregate exposure (dietary and non-dietary); there may be a risk among neonates in intensive care units; and that there is a risk to workers involved in BPA manufacture, skin sensitisation of workers in all industrial processes working with BPA, and to fetuses of pregnant workers through dermal exposure.

7. RIVM also considered immunological data published by Menard et al. (2014) which suggested that BPA can lead to the development of food allergies and have adverse effects on resistance to infections at lower doses than anticipated by current European standards. Neonates, infants and young children appear to be more susceptive. Following the same approach as EFSA in 2015 to derive a temporary tolerable daily intake (tTDI), the RIVM concluded that the effects were observed in animals at a human equivalent dose (HED) potentially a factor of 10 lower than the HED which EFSA based its tTDI on. The RIVM concluded that the new study warranted reconsideration of the current standards and recommended that the Dutch Government file a request to EFSA to revisit the TDI, to the European Commission to revisit the OEL and to ECHA to re-open the evaluation of the health hazard of BPA.

8. Risk reduction may be achieved through substitution with alternatives and the RIVM listed a number of alternatives in its report, however noted that for most of these, toxicological characterisation is lacking.

9. The full report can be found at: Bisphenol A : Part 2. Recommendations for risk management | RIVM.

Question on which the views of the Committee are sought:

i. Do Members have any comments on the RIVM report Part 2?

ii. Does the Committee have any additional comments?

Secretariat

December 2023