COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Position paper on dioxins

1. The COT reviewed the scientific basis and implications for risk management of the new EFSA tolerable weekly intake (TWI) for dioxins and considered that there were substantial uncertainties over the derivation of the TWI and possible inconsistencies between the animal and human data. Given the implications for risk management, the Committee felt that the rationales for the choices of key studies were not sufficiently clear in the published opinion, which made it difficult to evaluate the strength of the evidence. These concerns meant that the COT was unable to endorse the opinion and considered it necessary to reconsider the evidence base and set its own tolerable intake.

2. EFSA established a new TWI of 2 pg/TEQ/kg bw, which is 7-fold lower than its previous tolerable intake, based on data from a Russian Children's study, identifying semen quality, following pre- and postnatal exposure, as the critical effect. The COT noted this study appeared inconsistent with the findings in a second study and considered the Russian study to provide only a weak data set. The studies on experimental animals (rodents) included in the EFSA evaluation confirmed that developmental effects occurred at body burdens similar to those used as the basis for the previous risk assessment. However, the COT considered there were inconsistencies in the animal data presented in the EFSA opinion and was unclear, in particular, regarding the rationale for the selection of the study to evaluate the critical body burdens. The COT had raised specific concerns about their reliability in 2001 and later FSA commissioned studies to address these concerns, which failed to replicate the specific findings but found other reproductive effects at similar body burdens. Overall, the data presented in EFSA's opinion implied that humans were more sensitive to dioxins than rats. However, this would be inconsistent with the existing body of data on dioxins and knowledge on the relative sensitivity of the human and rat aryl hydrocarbon receptor (AHR). Due to these uncertainties, the COT did not agree with the newly established TWI and the 7-fold reduction in the TWI appeared too conservative for the database overall. The Committee was unable to comment on the dietary exposures and whether they should be compared to the new TWI.

3. The European Commission (EC) has not yet adopted EFSA's new TWI due to ongoing work at the international level to review the basis and values of the WHO toxic equivalent factors (TEFs). The review of the TEFs and a finalised assessment by the EC are not expected until 2022, at the earliest. The COT noted that this also presupposes that the effects of concern are mediated via the AHR.

4. The Committee acknowledges that a further review of dioxins will be an extensive and lengthy undertaking. However, even if the current HBGV were immediately reduced, it would take decades to reduce body burden in the population, due to the nature of dioxins, especially their long half-life in humans. The current COT TDI was based on the most sensitive endpoint in the animal studies and is intended to protect the most sensitive population group, hence it would also be protective for all population groups and for other less sensitive effects.

5. Thus, while the re-assessment of dioxins is a necessary and important piece of work going forward, the COT does not consider it necessary in the meantime to alter its existing advice on dioxins. The COT considers that their current TDI of 2 pg/kg bw per day is protective for effects on the developing male fetus, that this was supported by later studies on this endpoint and is consistent with their consideration of the WHO-TEF concept.

COT Position Paper

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