Minutes to the COT meeting held on Tuesday, 23rd October 2018 – item 9 discussed as reserved business

RESERVED BUSINESS

Item 9: Discussion paper on the EFSA opinion on "Risk for animal and human health related to the presence of dioxins and dioxin-like PCBs in feed and food" - TOX/2018/42

1. No interests were declared.

2. The European Food Safety Authority's Panel on Contaminants in the Food Chain (CONTAM) were asked for a scientific opinion on the risks for animal and human health from to the presence of dioxins and dioxin-like PCBs (DL-PCBs) in feed and food, respectively.

3. Following a review of available animal and epidemiological data it was decided that the human risk assessment should be based on effects observed in humans, using the animal data as supportive evidence. The CONTAM Panel selected the Russian Children's Study as the most appropriate for dose-response modelling and established a Tolerable Weekly Intake (TWI) of 2 pg TEQ/kg bw/week. Members were provided with the draft EFSA Opinion and a summary of the approach used by the CONTAM Panel to establish the TWI and of their risk characterisation, for discussion, to enable the views of the COT to be submitted to EFSA.

4. As a general comment the Committee highlighted that, given the volume of information, the merging of food and feed risk assessment made following the logic and rationale behind the risk assessments for humans and animals particularly challenging.

5. Regarding the animal studies, the Committee noted the initial reservations that existed regarding the observations made in the Faqi et al. study that had formed the basis for the establishment of the TWI in previous evaluations. This had resulted in the FSA funded studies by Bell et al., which were performed using the same strains of animals and under the same conditions as the Faqi et al. study without, however, reproducing the same effects. The Committee therefore questioned the lack of discussion regarding possible weighing of the discrepancies observed, especially since the Faqi. et al study has been used in the Opinion to argue and/or justify causality for the associations observed with sperm quality in the human studies, that formed the basis for the HBGV.

6. Furthermore, the Committee discussed the lack of discussion within the body of the Opinion regarding the evidence analysis regarding the associations between TCDD exposure during infancy/prepuberty and impaired semen quality observed in the Seveso incident studies and the Russian Children's study that were considered causal. The Committee considered that due to the lack of detailed discussion the evidence synthesis was not robust.

7. The significant associations observed between PCDD-TEQ and PCDF-TEQ but not for DL-PCB-TEQ or Total -TEQ in the Russian Children's study were also discussed. The Committee considered this surprising given the MoA of these chemicals. If correct, it might suggest a revision of the TEFs was necessary. It was also noted that a discussion on the possible explanation for the associations observed, or lack thereof, was also absent.

8. The Committee agreed with the selection of the critical endpoint for the establishment of an HBGV and accepted that if possible, human data should be used for this purpose but was unable to conclude this was robust. The Committee also agreed that the model then used for establishing the HBGV would be appropriate. Discussing the TWI established, the Committee questioned its applicability to the whole population.

9. Finally, with regards to EFSA's recommendation for re-evaluation of the current TEF values, the Committee agreed that irrespective of this activity taking place, the outcome of the Opinion would not have changed.