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

Review of potential risks from contaminants in the diet of infants aged 0 to 12 months and children aged 1 to 5 years

Information on TAs

1. As part of the review by the Scientific Advisory Committee on Nutrition (SACN) of Government recommendations on complementary and young child feeding, a risk assessment on tropane alkaloids (TAs) was presented to the COT in July 2018 (TOX/2018/28) and the members decided a full review on TAs was unnecessary.

2. All estimated acute exposures of infant and young children to (-)-hyoscyamine and scopolamine or the sum of (-)-hyoscyamine and scopolamine are close to or below the ARfD of 16 ng/kg bw per day. These exposures are therefore not of toxicological concern. However, although numerous TAs have been tested for and reported in the FSA unpublished report (2017), due to the lack of toxicity data this risk assessment only focused on (-)-hyoscyamine and scopolamine. Thus, the total dietary exposure of infants and young children to a combination of all TAs may be substantially underestimated.

3. The members requested additional information on the other TAs reported in the FSA's unpublished report (2017) (TOX/2018/36 Matter Arising) and inquired if information regarding pharmacological effects of other TAs and information regarding structural parts of (-)-hyoscyamine and (-) scopolamine, which are responsible for their pharmacological effects was available and could be provided (TOX/2019/22).

4. The Committee discussed the additional information and Members noted that a number of TAs were present at higher concentration than (-)-hyoscyamine and (-)-scopolamine and raised concern about the contribution of the other TAs to the overall exposure, should these TAs have equal potency to (-)-hyoscyamine and (-)-scopolamine.

5. In the absence of any inhouse expertise to give an opinion on the structure of the other TAs and their structure related potential pharmacological effects, the Secretariat proposes to include TAs in the Addendum to the Overarching Statement, including a discussion of the uncertainties surrounding the overall exposure to TAs.

6. Furthermore, the Secretariat proposes to include TAs as an in-house case study for an upcoming potency estimation paper/workshop/project which will look at utilising *in silico* methodologies to predict/simulate potencies from chemicals of little to unknown toxicity.

Questions to be asked to the Committee

i) Do the Committee, agree with their initial assessment that a full review will not be necessary, and TAs can be included in the Addendum to the Overarching Statement, including a section reflecting the uncertainties of total TA exposure?

ii) Are there any points regarding the uncertainties and total risk from TAs exposure the Committee would like to emphasise?

iii) Do members agree it would be useful to include TAs as an in-house case study for an upcoming potency estimation paper/workshop/project to gain clarity on the potential potencies of other TAs?

iv) Do the members have any other comments?

Secretariat

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