Meeting

Update on actions taken subsequent to COT advice – Paper for information

This is a paper for discussion.

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

Background

1. During 2023, COT statements have been published on:

- The bioavailability of nicotine from the use of oral nicotine pouches and assessment of the potential toxicological risk to users.
- A risk assessment of cow's milk.
- Guidance levels for the fortificants specified in the Bread and flour regulations.

2. An interim position paper has also been published on:

- Per- and Polyfluoroalkyl Substances.

3. COT opinions are frequently cited by the relevant Government Departments and Agencies in dealing with correspondence.

4. The Food Standards Agency (FSA) routinely uses the Committee's conclusions and opinions in risk assessments following food safety incidents, responding to queries from consumers and in assessing emerging risks. For instance, COT advice on lead was used to inform the response to an incident involving lead in products derived from human breast milk. Individual COT Members have also advised on incidents, for example, involving glycerol levels in slushed drinks.

5. This paper contains brief information on other actions taken subsequent to completion of recent COT discussions. This should be read in conjunction with the draft text of the Annual Report (paper TOX/2023/--), which provides the background.

COT Evaluations

Electronic Nicotine and non-nicotine delivery systems (E(N)NDS - e-cigarettes) and Oral nicotine pouches

6. The Department for Health and Social Care launched a consultation on 12th October 2023 on creating a smokefree generation and tackling youth vaping. This included quesitons on other nicotine consumer products (including nicotine pouches) and whether they should be regulated in a similar framework to vaping products. The consultation closed on 6th December 2023 and DHSC will be publishing a consultation response on next steps in legislating further.

Titanium dioxide

7. After the discussions at COT and COM, it was agreed that the toxicity and genotoxicity of titanium should be reviewed following the publication of the 2023 EFSA opinion. This is currently underway.

Maternal diet

8. Work continues on the maternal diet, with progress being made on arsenic, ergot alkaloids and ginger, along with a discussion of the phenomenon of pica.

9. Two posters were presented at the 2023 British Toxicology Society Annual Congress covering pica and providing an update on the maternal diet work respectively.

Other Committee activities

Regulated Products

10. The Committee has commented on number of AEJEG and FCM JEG opinions on various regulated products. These are being finalised prior to publication.

NLCS requests

11. The Nutrition, Labelling, Composition and Standards Group, a four country risk management group providing a framework for DHSC-led legislation, requested the Committee's advice on the levels of fortificants mandated to be added to flour, the advice has been used to inform the consultation (lead by Defra) about amending the Bread and Flour Regulations 1998. It is to ensure that by standardising the minimum levels, it would not give any cause for concern at a population level. The consultation can accessed using this link: Amending the Bread and Flour Regulations 1998 and the Bread and Flour Regulations (Northern Ireland) 1998 - Defra - Citizen Space and the response can be accessed using this link: Summary of responses and government response - GOV.UK (www.gov.uk).

12. The FSA undertook a risk assessment of the potential risk of allergic reaction (hypersensitivity to folic acid as part of the planned fortification of wheat flour to help reduce the number of neural tube defect affected pregnancies. The Committee were asked to review and comment on the assessment. The final risk assessment has been provided to DHSC, Defra and the Devolved Nations and has informed the review of the Bread and Flour Regulations 1998. New legislation is expected later in 2024.

Assurance

13. Members were asked to review and comment on the assessment carried out on the risk of allergic reactions to folic acid in UK consumers if non-wholemeal flour is fortified with folic acid without its presence being labelled on the packaging of the final food or, in the case of food sold loose, not conveyed by other means during a 3 month derogation period. The final risk assessment has been published on the COT website and has informed decisions by the Department of Health and Social Care (DHSC), Department for Environment, Food and Rural Affairs (DEFRA), FSA and Food Standards Scotland (FSS) on whether mandatory folic acid fortification of non-wholewheat flour should include a derogation period.

NAMs Road map

14. The draft version of the COT / FSA UK New Approach Methodologies Roadmap has been referenced and included in various scientific conferences and workshops. Furthermore, the roadmap is forming part of the work of the recruited computational fellow and the PhD student at the FSA working on predictive

toxicological methods using *in silico* tools.

15. After presenting at various international conferences, meetings and workshops, Members were asked to note and comment on the recent updated draft version of UK NAMs roadmap which incorporates the feedback received. This included data integrity and capability, training and the integrated transition into acceptance.

COT workshop

Evolving Our Assessment & Future Guiding Principles Workshop

16. The COT held a workshop in May 2023 to start work on updating their guidance on toxicity testing and its supporting principles. The starting point for the process was to use existing frameworks and guidance but with the aim of introducing innovative improvements where appropriate.

17. The workshop aimed to identify areas where guidance needed to evolve and included reviewing fundamental risk assessment principles, current guidance on risk assessment and what can be learned from it, integration of new approach methodologies, exploring hazard vs risk and weight of evidence. The overall objective of the workshop was to discuss how the Committee moves forward in a new era of risk assessment.

18. The finalised report will be published next year.

Opportunities and outlook for United Kingdom Food and Chemicals regulation post European Union Exit-COT Workshop Report

19. The COT, UKHSA and FSA organised a workshop in July 2022 held in Liverpool on “Opportunities and outlook for UK food and Chemicals regulation post EU exit”. The report is now available online and PDF: https://doi.org/10.46756/sci.fsa.ebr546.

20. The Secretariat is working to ensure that previous COT workshops can be finalised and published on the website.

Working Groups and Subgroups

Joint SACN-COT Working Group on plant-based drinks

21. The COT statement from 2021 is feeding into the work of the joint COT - Scientific Advisory Committee on Nutrition (SACN) Working Group (WG) on plant-based drinks. The WG has undertaken a BRAFO analysis of three plant drinks compared to cows' milk. The Committee has commented on the first draft of the report, and will have the opportunity to comment on the second draft prior to a public consultation period.

Cannabidiol (CBD)

22. A joint WG of COT and the Advisory Committee on Novel Foods and Processes (ACNFP) are reviewing the data obtained from novel food authorisation applications for cannabidiol (CBD). The evaluation of this data led to an ADI of 0.15 mg/kg bw/day (equivalent to 10 mg/day in a 70kg adult) being established)

Synthesising Epidemiological and Toxicological Evidence Working Group (SETE)

23. Following the publication of the final report and guidance of the SETE Working Group on the current practise of the Committees to integrate different evidence streams in November 2021, work continues to prepare an article on the SETE work for a scientific journal.

24. The findings of the SETE group were orally presented at a joint EFSA -BfR conference on using epidemiological studies in health risk assessments in November 2023.

Assessment of the Codex report on food allergen thresholds

25. A COT subgroup including some COT members and other external experts assessed the Codex Expert Committee report on establishing threshold levels for allergens of global importance (Part 2: review and establish threshold levels in foods for the priority allergens). No formal set methodology was employed for this assessment. The COT subgroup concluded that currently available evidence demonstrates that using reference doses based on ED05 as opposed to ED01 values would significantly impact on public health. The COT subgroup recommends that the accuracy and reliability of derived ED values should be evaluated more rigorously.

26. The COT subgroup report was published on the COT website and it will inform risk management considerations on whether it would be appropriate for

the recommended reference doses to be applied to regulated allergens in the UK.

EFSA and other public consultations

27. The COT have submitted comments to EFSA public consultations on the draft opinion on the TUL for vitamin B6, inorganic arsenic in food, polybrominated diphenyl ethers (PBDEs) in food, polychlorinated naphthalenes in food and feed, and mineral oil hydrocarbons in food.

Secretariat

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