FOLLOW-UP MEETING ON THE PUBLIC CONSULTATIONS ON BPA

Comments on EFSA's draft assessment of human health risks from the UK Committee on Toxicity

presented by Prof Rob Smith,
'public interest' member of COT

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Terms of reference of the COT

- To advise at the request of all Government Departments and Agencies
- To assess and advise on toxic risk to man of substances, including:
  - food additives and other chemicals with potential to be present in food
  - in workplace
  - in consumer products
  - chemicals with potential to pollute the environment
- To advise on generic principles and emerging issues

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COT membership

- 16 specialist members
  - endocrinology, epidemiology, exposure assessment, immunology, medicine, molecular biology, neurotoxicology, nutrition, pathology, pharmacokinetics, pharmacology, reproductive toxicology, risk assessment, statistics, toxicology,
- 2 non-specialist members
  - consumer and public interest
- We are all independent members

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Response by COT to draft scientific opinion on human health risks of BPA

- Impressive document overall
- COT generally agreed with conclusions
- *Not clear whether this part of opinion will be merged with exposure part*
- *If not, need diagrams of chemical structure of BPA and metabolites*
- Specific comments that follow relate to sections 2, 3, 4 and 8

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Section 2. Methodology

- Support weight of evidence approach
- *Classification system a little unusual*
- *Do not like the phrase "as likely as not" where evidence is inadequate*
- *Prefer "inadequate evidence" as descriptor*
- *Need to emphasise that classification relates to hazard identification, not risk assessment*

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Section 3. Hazard identification

- Conclusions regarding epidemiological data are appropriate
- *Some queries about weight given to different sorts of study*
- *Would be helpful to provide confidence intervals when summarising results*
- *Need to clarify argument about reliability of studies involving serum samples*

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3.1. Toxicokinetics and metabolism

- COT endorsed EFSA's use of human equivalent dose (HED)
- *No information in this part of opinion on chemistry of bisphenol A, which is pertinent to the PBPK model*

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3.2. General toxicity

- COT agreed that liver and kidney effects were “likely”
- *Noted that hypertrophy is likely to be an adaptive rather than toxic response*

3.3. Reproduction/development

- COT broadly agreed that effects on fetal growth and thyroid function were “not likely”
- *Needs to be more discussion about discrepancies between studies*

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Sections 3.4 - 3.7

COT agreed that the following effects were “not likely” overall:

- Neurological and neuroendocrine
- Immunological
- Cardiovascular
- Metabolic
- *However the description of some epidemiological studies was unclear*

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Sections 3.8 - 3.9

COT agreed that the following effects were “not likely”:

- Genotoxicity
- Carcinogenicity

COT agreed that effects on mammary gland proliferation or differentiation were “likely” but that the implications were unclear.

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Section 4. Health-based guidance value

- COT considered the proposed temporary tolerable daily intake to be appropriate
- *Some queries about the modelling*
- *Need further discussion about elements of the total uncertainty factor*

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Section 8. Recommendations

COT supported the need for

- Further good-quality research on possible non-monotonic dose-response relations for bisphenol A
- Further work on dermal absorption and metabolism of dermally absorbed BPA
- Toxicokinetics of BPA in humans *as well as* in mice

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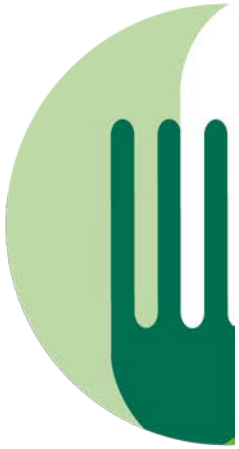
COT public documents can be found at:
http://cot.food.gov.uk/



Thank you

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