

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

Consultation of the European Food Safety Authority on a Draft Scientific Opinion on the safety of caffeine

Issue

1. The European Food Safety Authority (EFSA) issued a Draft Scientific Opinion on the safety of caffeine for public consultation on 15 January 2015. The Food Standards Agency (FSA) is inviting the COT to submit a response to the consultation.

Background

2. The COT has considered the safety of caffeine on a number of occasions. In 2001, the Committee published a statement of the reproductive effects of caffeine. This concluded that it was *“prudent to assume that caffeine intakes above 300 mg/day show a plausible association with low birth weight and spontaneous abortion, given the available evidence from studies in experimental animals and epidemiological studies. Further studies are required to establish whether the observed association is causal. These might include the use of biomarkers of caffeine intake.”*¹

3. As a result of the COT recommendation, the Food Standards Agency (FSA) commissioned research on the effects of caffeine in pregnancy. The COT considered the results of the FSA-funded study and other published research and issued a further statement in 2008². The conclusions of the 2008 statement were:

- *“The evidence that is now available does not make it possible to identify a threshold level of caffeine intake below which there is no elevation of risk, and it seems likely that risk is increased in association with intakes in the order of 200 mg per day and perhaps even lower. However, if the relation is indeed causal, then the absolute increase in incidence of FGR from intakes less than 200 mg per day is likely to be less than 2% of infants.*
- *“The literature suggests a positive association of caffeine intake with miscarriage, but there are uncertainties relating to possible recall bias and residual confounding.*
- *“Data on maternal caffeine consumption during pregnancy and associations with adverse effects other than FGR and spontaneous*

¹ <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2001/caffeine>

² <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2008/cot200804>

miscarriage, such as pre-term birth and congenital malformations, are inconclusive.”

4. The COT conclusions underpin UK advice on caffeine consumption during pregnancy.
5. The COT has also considered the interaction of caffeine and alcohol and their combined effects on health and behaviour³. The overall conclusion was that:
 - *“the current balance of evidence does not support a harmful toxicological or behavioural interaction between caffeine and alcohol. However, because of limitations in the available data, there is substantial uncertainty, and if important new evidence emerges in the future, then this conclusion should be reviewed.”*
6. EFSA was asked to advise on a daily intake of caffeine, from all sources, that does not give rise to concerns about harmful effects to health for the general population and for specific subgroups of the population. Possible interactions between caffeine and other constituents of so-called “energy drinks”, alcohol, synephrine and physical exercise were also be addressed (see Annex A).
7. Similarly to COT, EFSA concluded that *“caffeine intakes from all sources up to 200 mg per day by pregnant women in the general population do not raise safety concerns for the fetus”*. The FSA-funded research is influential for this conclusion. Conclusions are also made for non-pregnant adults and other age groups.

Questions for the COT

8. COT members are invited to comment on any aspect of the draft opinion, and to answer the following questions:
 - i. Do Members wish to respond to the consultation?
 - ii. If so, detailed comments are requested on each section.
 - iii. Do Members agree with the EFSA conclusions, and should the identified guidance values be used by FSA in advising on safety of caffeine (subject to finalisation of the EFSA opinion)?
 - iv. Do Members wish to update their conclusions in their overarching statement on risks of chemical toxicity and allergic disease in relation to infant diet⁴ in the light of the draft EFSA opinion? Taking into

³ <http://cot.food.gov.uk/cotstatements/cotstatementsyrs/cotstatements2012/cotstatement201204>

⁴ <http://cot.food.gov.uk/sites/default/files/cot/cotstatementoverarch201203.pdf>

account that EFSA have recommended a numerical guideline for lactating women and COT did not; stating instead that “The Committee noted that the basis for the Government’s current advice to breastfeeding mothers on caffeine consumption was extrapolated from that provided to pregnant women, and the available information did not provide a basis for refining it.”

Secretariat
January 2015

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Draft Scientific Opinion on the safety of caffeine**

Draft Scientific Opinion on the safety of caffeine

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It is available at:

<http://www.efsa.europa.eu/en/consultations/call/150115.htm>