Brussels, 25 February 2015

FoodDrinkEurope contribution to the hearing on the draft EFSA opinion on caffeine

FoodDrinkEurope welcomes the opportunity given to all stakeholders and interested parties to comment on the draft opinion.

EFSA opinions are crucial in providing the industry with clarity based on sound science.

FoodDrinkEurope has thoroughly analysed the draft opinion and will respond to it by 15 March at the latest.

At this stage we would like to raise the following points for clarification:

1) General comments / Caffeine intake from all sources

FoodDrinkEurope supports EFSA's finding that caffeine intakes from all sources up to 400 mg per day (about 5.7 mg/kg bw) do not raise safety concerns for adults in the general population, except pregnant women. We also welcome that EFSA clarifies that the same level applies to lactating women.

2) Definition of acute intake

We would appreciate clarification on what constitutes an acute intake of caffeine. Acute intakes typically refer to consumption of a single serving/portion or consumption on an eating occasion. In the draft opinion, acute intake seems to range from a single dose to a single day.

3) Levels of no concern for children and adolescents

The opinion would benefit from a clarification by identifying the levels of no concern for children and adolescents with respect to acute consumption and daily (chronic) consumption. Section 5.4 on page 62 would particularly benefit from clarification.

a) Acute intake

Section 5.4 makes no recommendation on the level of no concern for acute intakes in children and adolescents. It does, however, recommend that the figure for acute consumption in adults (3mg/kg bw/day) can be used to derive daily caffeine intakes for children and adolescents. Clarification is needed on why the same level for acute intakes as for chronic intake is being used.

Avenue des Nerviens 9-31 - 1040 Brussels - BELGIUM - Tel. +32 2 514 11 11
info@fooddrinkeurope.eu - www.fooddrinkeurope.eu - ETI Register 75818824519-45

We have noticed that in the risk characterisation for single dose/single session a figure of 200 mg is being used for adolescents. In the risk characterisation for single dose/single session/single day for children, the figure of 3 mg/kg bw is being used. We believe that the opinion would benefit from a justification on the use of these two figures and the different approach followed.

The Panel did not include the acute exposure data in children that indicate higher doses can be considered safe, for example in lines 1631- 1635 on page 40 of the draft opinion:

"no effect of single doses of caffeine ranging from 2.5 to 10 mg/kg bw on most self-reported measures of anxiety. The Panel notes that single doses of 3 and 10 mg/kg bw had no effect on nine investigator-related items of behaviour…"

The dose level of 10mg/kg bw was not used in setting a safe dose for acute effects in children and adolescents. We kindly request EFSA to elaborate on this.

b) Daily/Chronic intakes

Clarification is needed whether the safe daily dose is the same as the safe level of intake for repeat exposure.

There seems to be an inconsistency in the risk assessment approach for adults versus children / adolescents.

Whereas the Panel notes that the information available for this population subgroup (children and adolescents) on the relationship between caffeine intakes and health outcomes is insufficient to base a safe level of caffeine intake (lines 2698 -2699, page 62) the draft opinion then goes on to recommend that the level of no concern for acute intakes of 3mg/kg for adults be used to "derive daily caffeine intake of no concern for children and adolescents" (lines 2700-2701, pages 62).

The Panel extrapolated from the acute dose level (3 mg/kg bw) to set a daily safe dose of intake for children and adolescents. The draft opinion would benefit from a justification on what basis the Panel decided this.

In the section on risk characterisation this figure is then used to assess daily caffeine intakes (repeat exposure) in these subgroups. However, the same figure of 3mg/kg bw is subsequently not used for the adult assessment. A figure of 400 mg/day (corresponding to 5.7 mg/kg bw/day) is used instead. We note an inconsistency in the risk assessment approach for adults versus children and adolescents.

We suggest that the opinion clarifies the difference between the "safe daily intake" and "intake from all sources" and which figure should be used (consistently) in the risk characterisation.

4) Caffeine consumption data – Zucconi report

In addition to the EFSA Comprehensive European Food Consumption Database a report from Zucconi et al. from 2013 (which was commissioned by EFSA) is used as the main reference for caffeine intake data. In this context we would like to highlight the following points which may lead to an overestimation of caffeine intake or an inappropriate interpretation of the data:

a) In particular the data for children are not representative for the EU and show a selection bias towards males.

b) Consumption data for all age groups have been collected through dietary recalls, including questions on what children and adolescents had consumed in the last months up to one year. The use of dietary intake protocols to measure actual food and drink consumption would have been more appropriate.

c) Regarding the consumption of energy drinks in conjunction with sporting activity, the questionnaires would have profited from drawing the attention of respondents to the distinction between sports drinks, which do not generally contain caffeine, and energy drinks.

d) Data collection on food and drink intake normally refers to the amount consumed in a certain timeframe, which is in most cases anything between one day and one month. In the Zucconi study, participants were asked if they have consumed energy drinks within the last year and, if yes, were then defined as an energy drink consumer. Could EFSA please elaborate if this different approach is considered appropriate for establishing the opinion?

5) Caffeine intake levels of no concern in pregnant women

The Panel notes in its draft scientific opinion 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. This intake level is supported by a very recent systematic review and dose-response meta-analysis (Greenwood et al., 2014)[1], which examined the relationship between caffeine intake during pregnancy and adverse birth outcomes. Based on the assessment of 60 relevant publications from 53 cohort and case-control studies, the authors conclude that there is currently insufficient scientific evidence to support further reductions in the maximum recommended intake of caffeine during pregnancy. As a consequence, the authors state that maintenance of current recommendations (i.e. 200 mg caffeine/day) is a wise precaution.

The dose response assessment in lines 2670 ff for pregnant women states that two prospective cohort studies considering risk of adverse birth weight related outcomes (i.e. FGR, SGA) were the main basis of the level of 200mg caffeine per day for pregnant women. For the purposes of clarity and future reference what did the panel define as clinically relevant for FGR (fetal growth retardation) and SGA (small for gestational age).

6) Uncertainty analysis

Finally, the opinion would benefit from the inclusion of an analysis of uncertainty within the risk assessment.

[1] Greenwood DC, Thatcher NJ, Ye J, Garrard L, Keogh G, King LG, Cade JE. Caffeine intake during pregnancy and adverse birth outcomes: a systematic review and dose-response meta-analysis. Eur J Epidemiol. 2014 Oct; 29 (10):725-34.