Contribution ID: 94b24605-6a37-447c-a6dc-78cac1b744a3
Date: 14/11/2019 17:49:12

Public consultation on Scientific Opinion on the risks to public health related to the presence of aflatoxins in food

Fields marked with * are mandatory.

General Information

* First name

Paula

* Last name

Alvito

* E-mail

paula.alvito@insa.min-saude.pt

* Select your country

Portugal

* Category

University/public research institute

* Name of employer *(insert N/A if not applicable)*

N/A

Scientific opinion on the risk for animal and human health related to the presence of chlorinated paraffins in feed and food

* Select the chapters you want to comment

- [x] General comments
- [ ] Abstract
- [x] Summary
- [ ] 1 Introduction
- [ ] 2 Data and methodologies
- [x] 3 Assessment
- [ ] 4 Conclusions
- [ ] 5 Recommendation
- [ ] References
- [ ] Abbreviations
- [ ] Appendix A – Identification and selection of evidence relevant for the risk assessment of aflatoxins in food
- [ ] Appendix B – Summary tables hazard identification and characterisation
- [ ] Appendix C – Benchmark dose analysis of the incidence of HCC in male Fisher rats
- [ ] Appendix D – Summary tables occurrence and exposure
- [ ] Appendix E Risk characterisation
- [ ] Annex A: Dietary surveys per country and age group available in the EFSA Comprehensive Database, considered in the exposure assessment
- [ ] Annex B: Occurrence data on aflatoxins
- [ ] Annex C: Proportion of left-censored data and the mean concentrations of the quantified analytical results of AFB1 for pistachios, hazelnuts, peanuts, other nuts and dried figs
- [ ] Annex D: AFB1 and AFM1 concentrations reported for organic farming and conventional farming in selected food categories
- [ ] Annex E: Mean and high chronic dietary exposure to aflatoxins per survey and the contribution of different food groups to the dietary exposure

General comments

5000 character(s) maximum

Mycotoxins' experts on HBM4EU (https://www.hbm4eu.eu/) congratulate CONTAM Panel for the very extensive and detailed work on this opinion and highlight its importance for the assessment of European population exposure to aflatoxins through food. The reference values generated by EFSA, especially BMDL10, are considered of great interest by the scientific community since they contribute to harmonize calculations allowing a harmonized approach for the characterisation of aflatoxins.
EFSA recommendation on monitoring these toxins, "Aflatoxin occurrence should continue to be monitored in the light of potential increases due to climate change using methods with high levels of sensitivity for detection", is highly encouraged.
HBM4EU is a project integrating 30 countries that aims to assess the exposure of European citizens to food chemicals through biomonitoring. During the 2nd round of substances, deoxynivalenol (DON) and fumonisin B1 (FB1) were considered the prioritized substances within mycotoxin group. Due to the results and expertise of Portugal and the Netherlands teams on this topic, aflatoxins were considered an important candidate to also join this substance group. However, aflatoxins were not included considering the view of the stakeholders involved (EU Policy Board, EFSA and DG SANTE). Therefore, this is a limitation to the potential contribution of HBM4EU regarding the recommendation of the scientific opinion, "A well-designed study measuring dietary exposure and biomarkers of exposure is required to quantify the relationship between biomarker levels and exposure at the individual level." Nevertheless, HBM4EU chemical group leaders for mycotoxins and mycotoxin group members under this project, working closely with the different work package leaders, will try to profit from the possible opportunities during data collection to try to contribute to fill this gap when possible.

Summary

5000 character(s) maximum

-Line 92-95:
“AF-alb (AFB1-lys), urinary AF-N7-gua and urinary AFM1 are all validated biomarkers of dietary exposure to aflatoxin. However, the levels of these biomarkers cannot be converted reliably into dietary exposures in individuals. As AF-alb (AFB1-lys) better reflects longer-term exposure (i.e. several weeks), it tends to be most widely used, while urinary AFM1 and AF-N7-gua are suitable biomarkers for recent exposure”.

Question/remark
It is not clear what is meant with “validated” biomarkers. In the opinion no remark(s), criteria or definition has been given related to the classification of “validated”.
Furthermore, in section 3.1.3.1 (from lines 1329 onwards) the biomarkers AF-alb (AFB1-lys), AF-N7-gua and AFM1 are discussed and this does not shed any light on the appropriateness of these biomarkers for the determination of dietary exposure. In this section it is mentioned that AF-N7-gua adducts in urine do not show a (strong) association with the dietary intake of AFB1 (lines 1342-1344) but a good correlation (line 1359) has been shown between dietary aflatoxin intake and AF-alb levels in adults in Gambia (correlation coefficient = 0.55; $p<0.05$) and children in Tanzania (correlation coefficient = 0.43; $p<0.01$). Further on (lines 1394-1396) it is mentioned that a correlation between urinary AFM1 levels and dietary intake of AFB1 in maize ($r = 0.442$, $p<0.001$), as well as between AFM1 in urine and AF-alb in serum of the children ($r = 0.468$, $p<0.001$) was observed. In lines 1400-1404 the quote above is mentioned again without mentioning why these biomarkers cannot be converted reliably into dietary exposures in individuals.
In addition, in this respect, the term “biomarkers” should be “biomarkers of exposure”.

-Lines 143-145:
“A well-designed study is required to quantify the relationship between biomarker levels and exposure at the individual level”.

Question/remark
It is not explained what is mentioned with “a well-designed study”. Obviously, a human intervention study where aflatoxin(s) would be administered to volunteers can be ruled out with respect to the carcinogenic property of the aflatoxin(s). The combination of a duplicate diet study in Europe with (24h) urine collection can also be ruled out because of the (extremely) low number of positive samples in either diet or urine. From a statistical point of view this would require an unacceptably large population to be studied. This means that probably an epidemiological study, like a (nested) case–control study, will have to be used and this type of study has already been evaluated in the EFSA opinion.
Summarised, it would of (great) help if EFSA could explain in more detail was is meant with “a well-designed study”.

Note: the above-mentioned quotes are also summarised as bullets, respectively in the Conclusions lines 2794-2796 and Recommendations lines 2883-2884.

3. Assessment
- ☐ 3.0. Assessment (overall chapter)
- ☐ 3.1 Hazard identification and characterisation
- ☑ 3.1.1 Toxicokinetics
- ☐ 3.1.2 Toxicity in experimental animals
- ☐ 3.1.3 Observations in humans
- ☐ 3.1.4 Mode of action
- ☐ 3.1.5 Considerations of critical effects and dose–response analysis
- ☐ 3.1.6 Possibilities for derivation of a health-based guidance value (HBGV)

- [ ] 3.2 Occurrence data
- [ ] 3.2.1 Occurrence data on food as submitted to EFSA
- [ ] 3.2.2 Levels of biomarkers of exposure in the European population
- [ ] 3.2.3 Processing
- [ ] 3.3 Dietary exposure assessment for humans
- [ ] 3.3.1 Current dietary exposure assessment
- [ ] 3.3.2 Exposure of infants through breastfeeding
- [ ] 3.3.3 Previously reported dietary exposure
- [x] 3.3.4 Non-dietary sources of exposure
- [ ] 3.4 Risk characterisation
- [ ] 3.4.1 Risk characterisation based on animal data
- [ ] 3.4.2 Risk characterisation based on human data
- [ ] 3.5 Uncertainty analysis
- [ ] 3.5.1 Assessment objectives
- [ ] 3.5.2 Exposure scenario/exposure model
- [ ] 3.5.3 Model input (parameters)
- [ ] 3.5.4 Other uncertainties
- [ ] 3.5.5 Summary of uncertainties

3.1.1 Toxicokinetics

5000 character(s) maximum

-Line 799
Figure 1

Question/Remark
Suggestion to improve quality of letters of this figure

3.3.4 Non-dietary sources of exposure

5000 character(s) maximum

-Line 2569-2571:
“While occupational exposure may contribute significantly for individual workers, this is not considered further in this Scientific Opinion”.

Question/remark
Although this is not a topic for this opinion, it is proposed that a brief sentence could be added after this paragraph, since this is an important health impact topic revealing in some cases high levels of exposure to AFB1 (Appendix D, Table D1, line 3969) that is until now poorly studied and deserving particular attention. A suggestion is to added the following text: “However, due to its important consequences on health, climate change can also have an impact on workers exposure to AFB1 since in some occupational settings the handle of huge quantities of raw materials with higher AFB1 contamination (cereals, feed,..) will imply higher exposure of workers. In these cases, biomonitoring tools allow to evaluate workers exposure and to recognize what the workplace environment adds to the exposure occurring by food consumption, providing the information needed for defining the best risk management measures”.

Upload file(s) if necessary

* Do you need to upload file(s)?
  - ○ YES
  - ◉ NO

Background Documents

Aflatoxins Draft_Opinion

Annex A

Annex B

Annex C

Annex D

Annex E

privacy statement

Contact

biocontam@efsa.europa.eu