BPA Exposure Assessment

FoodDrinkEurope contribution

Beate Kettlitz

Director Food Policy, Science, R&D
FoodDrinkEurope

23 April 2014

Content

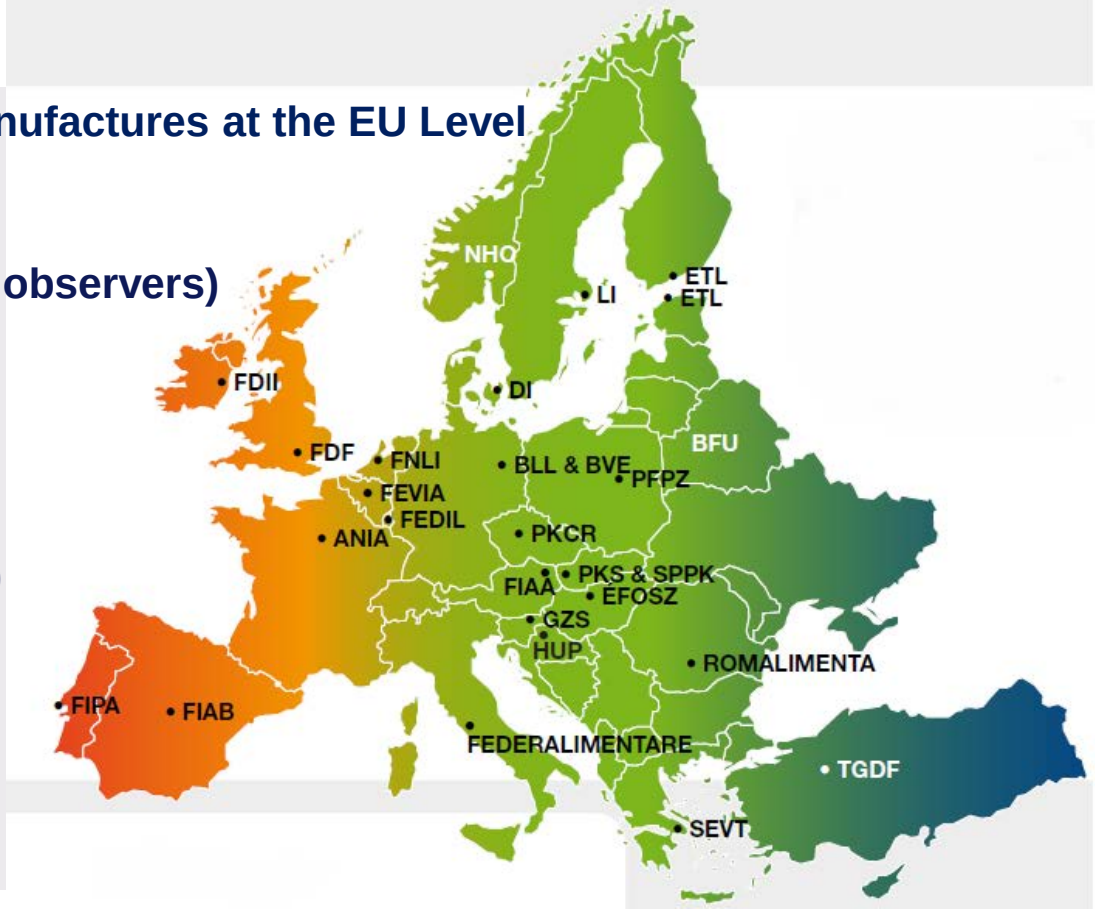
- FoodDrinkEurope – whom does the organisation represent
- Overview type of comments
- Detailed comments
- Conclusions

Who we are

Role: Represent the food and drink Manufactures at the EU Level

- **National federations (26, including 3 observers)**
- **European sector associations (25)**
- **Major food and drink companies (17)**

For more details please see:
http://www.fooddrinkeurope.eu/about-us/members/



FOODDRINK EUROPE

Overview of the comments

- Summary
- Background provided by EFSA
- 4.3.1. General introduction
- 4.3.2. Summary from EFSA's call for data
- 4.3.5. Occurrence data in food
- 4.9.3. Evaluation of uncertainty in total exposure through expert judgement
- Appendix II: EFSA call for data
- Appendix III: Food categories

FOODDRINK EUROPE

Comments on the Summary

Lines 131-132 and lines 138-140

Original text:
*"**Systematic differences in BPA concentration between canned and non-canned food** were observed in a large majority of food categories, with higher BPA concentrations in the canned food"*

"Among the 19 non-canned food categories, the highest levels of BPA were found in the categories "Meat and meat products" and "Fish and other seafood" with average (MB) BPA concentrations of 9.4 and 7.4 µg/kg, respectively".

We observe that the total number of samples of canned and non-canned food is not identical (296 canned samples and 1637 non canned).
Nevertheless , direct comparisons have been made. We are therefore surprised that the conclusion was drawn in a general way, stating that the major exposure is from canned food.
The second statement regarding meat was surprising. We can see that 5% of the samples were below the limit of detection (very low amount of BPA) and the maximum detected were of 395 µg/kg, which is a large range.
The sample reported as having 395µg/kg (which in our opinion may have affected the average of BPA in this food category) is from edible offal from France, a meat product that contain internal organs and edible by-products from meat production (other than muscle and bone), which we suspect is not widely consumed in all European countries.
If the sampling is not homogenous, at least regarding the number of samples of meat and meat products , then in our opinion ,the results could be subsequently overestimated.

FOODDRINK EUROPE

Background provided by EFSA

Lines 571-576

Original text:

*"**Food production animals may be exposed to BPA which is then present in their tissues as glucuronated** (conjugated) BPA. When total BPA is measured in animal products (e.g. meat, milk, eggs) this may therefore include conjugated BPA deriving from exposure of the animal, in addition to any unconjugated BPA deriving from contamination and/or migration from food contact materials. Dietary exposure to total BPA is indeed of interest since part of the glucuronated BPA will be deconjugated to release unconjugated BPA (see Chapter 4.3.5)".*

Industry requests that scientific evidence be provided to support this finding. As of yet none has been seen.

FOODDRINK EUROPE

4.3.1. General introduction

Lines 804-807

Original text:
"In total 3 609 results were submitted to EFSA, 2 076 results for BPA occurrence in food, 988 results for BPA migration from food contact materials and 545 results for BPA occurrence in food contact materials. These data were obtained on samples collected in the European Economic Area (EEA) countries and Switzerland, the ***vast majority of the samples were collected from 2006 to 2012****".*

Question:
Are the 2,076 food samples distributed evenly over the period from 2006-2012?
More detailed information would help the reader to better understand the overall context.

FOODDRINK EUROPE

4.3.2. Summary from EFSA's call for data

Lines 815-817

Original text:
*"Data on BPA occurrence in food and beverages intended for human consumption were provided by **8 countries**, most of the information coming from **France (75.5 %),** Germany (10.1 %), Ireland (6.6 %), 816 United Kingdom (2.6 %), Norway (1.8 %), Switzerland (1.3 %), Finland (1.2 %), Spain (0.8 %)."*

8 countries delivered data, of which 75% is from France.
How have the different eating habits of European citizens been taken into consideration when assessing the overall exposure?
The vast majority of samples (75.5%) are from France. This can diminish radically the representativeness of the exposure assessment. For example, the edible offal, one of the samples provided by France, is unlikely to be consumed across Europe.

FOODDRINK EUROPE

4.3.2. Summary from EFSA's call for data

Lines 831-833

Original text:
*"Germany submitted BPA occurrence data for different kinds of food contact materials (plastic, paper and board, others, aluminium, glass). 545 results were reported from **2001 to 2012**, the large majority (98 %) originated from accredited laboratories."*

Were the 545 samples equally distributed over the period from 2001 – 2012?
This is significant since several restrictive measures on the use of BPA have entered into force in the last 3 years.

FOODDRINK EUROPE

4.3.5. Occurrence data in food

Lines 1099-1102

Original text:
"Systematic differences in BPA concentration between canned and non-canned food were observed in the ***large majority of food categories****, with higher BPA concentrations in the canned food. However,* ***noteworthy differences in BPA levels can also be observed within the canned and the non-canned food*** *categories as illustrated in Table 3 (see column "All – Average BPA")".*

Canned and non-canned food categories are mentioned in table 3 (page 30). The number of samples directly comparable in food categories for canned and non-canned food varies significantly within each category.
For example:

- Grains and grain-based products: Canned = 18; Non-canned = 95
- Vegetables and vegetable products: Canned = 73; Non-canned = 201
- Meat and meat products: Canned = 16; Non-canned = 191
- Composite food: Canned = 25; Non-canned = 107

We also observe the total number of samples of canned and non-canned food is not completely identical (296 canned samples and 1,637 non-canned)
Nevertheless direct comparisons have been made. We are therefore surprised that the conclusion was drawn in a general way, stating that the major expose is from canned food.

FOODDRINK EUROPE

Similar comment on the summary (Lines 131-132)

4.3.5. Occurrence data in food

Lines 1110-1112

Original text:
*"Among the 19 non-canned food categories, the **highest levels of BPA were found in the categories "Meat and meat products"** and "Fish and other seafood" with average BPA concentrations (MB) of **9.4** and 7.4 µg/kg, respectively (Table 3, column "All – average BPA")".*

This statement regarding meat was surprising.
Nevertheless from the table 3 (page 30) we can see that 5% of the samples were below the limit of detection (very low amount of BPA) and the maximum detected were of 395 µg/kg, which is a large range.
The sample reported as having 395µg/kg (which in our opinion may have affected the average of BPA in this food category) is from edible offal from France, a meat product that contain internal organs and edible by-products from meat production (other than muscle and bone), which we suspect is not widely consumed in all European countries.
If the sampling is not homogenous , at least regarding the number of samples of meat and meat products , then in our opinion ,the results could be overestimated.
We believe that would be interesting to know exactly how many samples from meat types (and which types) sausages and pates are in the batch because this has a major impact in the consumption both in the daily intake and the frequency of intake.

FOODDRINK EUROPE

4.3.5. Occurrence data in food

Lines 1113-1122

Original text:
"Any BPA to which food production animals are exposed is likely to be present in their tissues as glucuronated BPA (ANSES, 2013). When BPA is measured in food of animal origin (e.g. meat, milk, eggs), it is possible that deconjugation occurs. Another potential source of unconjugated BPA in meat products is its migration from any food contact materials or from articles used in the processing of the product. With the exception of the data submitted by France through EFSA "s call for data, none of the methods, published in the scientific literature or obtained through the EFSA "s call, described deconjugation steps and so it was assumed that the BPA concentrations reported were for unconjugated BPA only. The levels of total and unconjugated BPA in foods of animal origin were reported by ANSES to be virtually the same (ANSES, 2013). Therefore the data on total BPA reported by France were merged with the other data from EFSA "s call for data."

Industry has so far not seen any scientific evidence to support this finding by ANSES.

FOODDRINK EUROPE

4.9.3. Evaluation of uncertainty in total exposure ugh expert judgement

Lines 3320-3323

Original text:
The current exposure assessment of BPA from all sources shows that diet is the main source of exposure to BPA in all population groups (from 78 to 99%). Canned food and non-canned meat and meat products are the two main dietary contributors to BPA exposure in the large majority of countries and age classes."

"The uncertainty around the estimates of dietary exposure based on the EFSA comprehensive database was judged as relatively low".

Lines 3343-3343

We take note of this judgment, we are however surprised by this conclusion given the number of uncertainties highlighted in table 51, lines 5,832 ff as regards food consumption, BPA occurrence levels and body weight.

FOODDRINK EUROPE

Comments on the Appendix II

Lines
4958-4360

Original text:
"Occurrence data in food contact materials
The method for the determination of ***BPA was validated internally for 1 % of the samples analyzed. No information*** *was provided* ***on the accreditation*** *of the method for the remaining* ***99 % of the sample*** *analysed".*

This uncertainty is mentioned in table 51, BPA occurrence data, the impact on the data quality seems to be important and should be further elaborated.

FOODDRINK EUROPE

Comments on the Appendix III

Lines
5237-5240

Original text:
*"For non-canned food, concentration data from the **literature were scarce**, with only 246 samples overall, of which 159 were water samples. However, the call for data provided 1 637 samples of non-canned food, of which **France** is the main contributor with 1 433 samples (**88 % of the total non-canned food samples**)."*

Food and drink consumption habits vary widely across Europe. Some products that don't exist in some countries are extensively consumed in other and vice-versa.
Unfortunately only 8 countries delivered data, the vast majority coming from France (75%).
In our opinion this will have affected the representativeness of the data.

FOODDRINK EUROPE

Comments on the Appendix III

Lines
5318 ff

Original text:
Any BPA to which food production animals are exposed may conjugate and so may be present in their tissues as glucuronated BPA (ANSES, 2013). When BPA is measured in food of animal origin (e.g. meat, milk, eggs), it is possible that deconjugation occurs. Another potential source of unconjugated BPA in meat products is its migration from any food contact materials or from articles used in the processing of the product. ***With the exception of the data submitted by France through EFSA`s call, none of the methods, published in the scientific literature or obtained through the EFSA`s call, described deconjugation steps and so it was assumed that the BPA concentrations reported were for unconjugated BPA only.*** *The levels of total and unconjugated BPA in foods of animal origin were reported by ANSES to be virtually the same (ANSES, 2013). Therefore the data on total BPA reported by France were merged with the other data from EFSA "s call for data.*

The reasoning for the EFSA assumption does not seem to be obvious. It seems necessary to address this assumption from a toxicological point of view.

FOODDRINK EUROPE

Comments on the Appendix III

Lines 5332-5336

Original text:
"Concentration data of non-canned "Meat and meat products" were provided through the call for data by France (172 samples), Ireland (12 samples), and Norway (7 samples) for a total of 191 samples. The samples were of meat types, sausages and pates. The BPA concentration ranged from below the level of quantification (5 %) to 394.8 µg/kg (edible offal, France). The BPA concentration (middle bound) was 9.5 µg/kg"

France provided 90 % of the non-canned meat and meat products samples in the EFSA data-base. The max value (395 microgram/kg noted in table 3, page 31, and Appendix III page 167 line 5335) relates to a French sample of "edible offal", meat products made from internal organs.
This statement regarding meat was surprising.
Nevertheless from the table 3 (page 30) we can see that 5% of the samples were below the limit of detection (very low amount of BPA) and the maximum detected were of 395 µg/kg, which is a large range.
We believe that would be interesting to know exactly how many samples from the various meat types (and which types), sausages and pates were considered because this has a major impact in the consumption both in the daily intake and the frequency of intake.
If the sampling is not homogenous, at least regarding the number of samples of meat and meat products, then in our opinion the results could be overestimated. .

FOODDRINK EUROPE

Conclusions

- Collection of good quality data and exposure assessments are an essential component of a reliable risk assessment
- Food industry has raised various questions in relation to the exposure assessment, which we hope will be addressed in the final opinion
- Addressing uncertainty and variability of good quality data is essential, this should however not lead to the use of worse case scenarios being the basis for exposure assessment
- In the case of BPA exposure assessment, despite using conservative case scenarios, exposure shows to be low and is in good compliance with bio monitoring data

FOODDRINK EUROPE