



# Observations of FoodDrinkEurope on the Exposure Assessment in the Draft EFSA ANS Opinion on Aspartame

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# Background

Conservative estimates of exposure to aspartame made by the Panel for the general population were up to 36 mg/kg bw/day at the 95th percentile compared with an ADI of 40 mg/kg bw/day.

Estimation of exposure to dietary components requires information about

- the levels and patterns of use in foods and drinks and
- the quantities of those foods and drinks consumed and by whom.

It is then necessary to combine these two types of information to generate an estimate of total chronic exposure:

$$\text{Exposure} = \frac{[\text{concentration X occurrence}] \times [\text{amount of food consumed}]}{\text{Duration of exposure}}$$

# Actual aspartame levels of use

Following the EFSA call, data from industry and others sources were received from:

- FoodDrinkEurope
- The International Sweeteners Association
- The International chewing gum association
- The Spanish association on sweets, ProDulce,
- The Austrian Agency for Health and Food Safety
- The Dutch Food and Consumer Product Safety Authority and
- The Slovakian State Veterinary and Food Institute of Bratislava

However, the Panel decided not to take these data into account for use in the refined exposure assessment with the exception of data received from the International chewing gum association.

# Actual aspartame levels of use

- For certain potentially relevant categories there were significant differences:

**Edible ices** - industry reported up to 50 mg/kg whereas the value used in ANS exposure calculations was 800 mg/kg.

**Non-alcoholic beverages** - industry reported typical use levels of 100-350 mg/l whereas the value used in ANS exposure calculations was 600 mg/l.

- Both categories consumed in significant amounts by children

# Actual aspartame levels of use

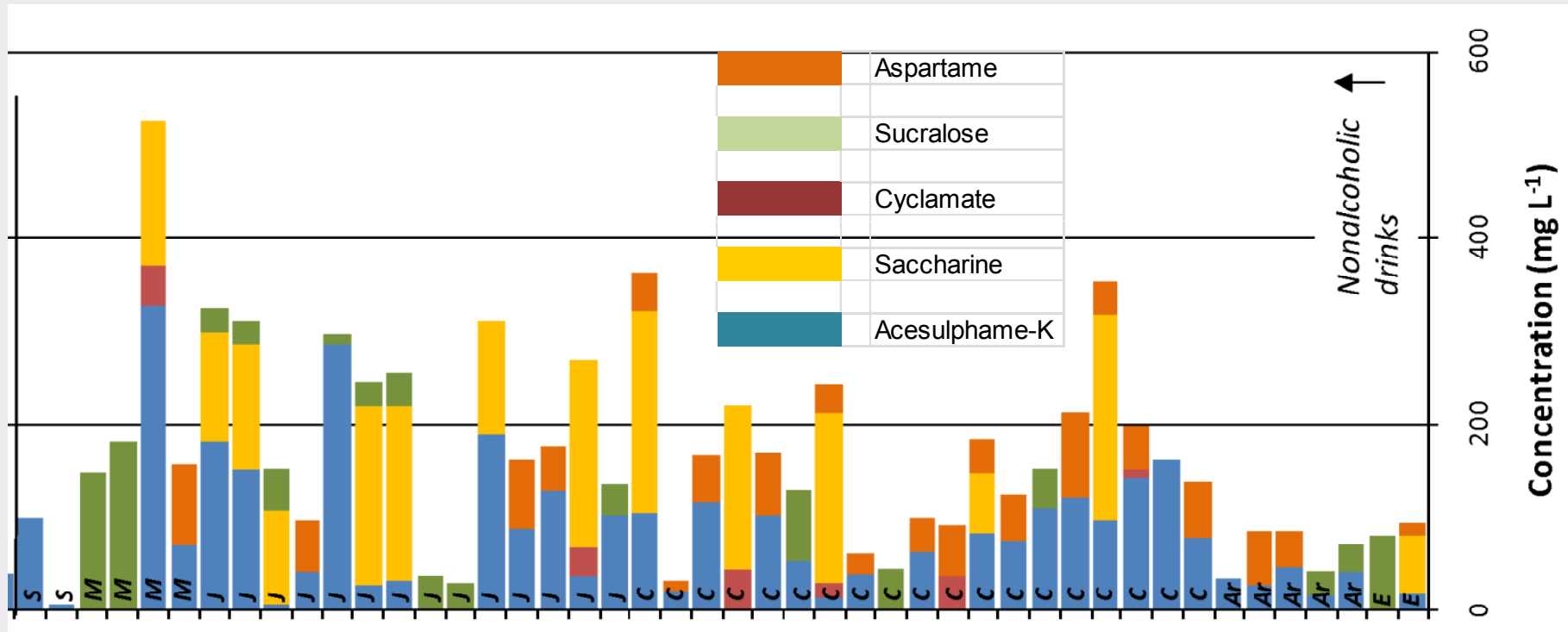
The 2009 EFSA Report on Aspartame noted that “reported exposures are not representative of levels currently (2007) used in foods and beverages” because:

- “Manufacturers will use blends of sweeteners
- Aspartame is one of the more expensive sweeteners
- New sweeteners will be placed on the market such as sucralose which will possibly replace aspartame
- There is no incentive for producers to add more sweetener than is needed”

This means that maximum use levels are unlikely to be used on a routine or regular basis.

# Actual aspartame levels of use

Measured concentrations of sweeteners in non-alcoholic beverages in Belgium \*



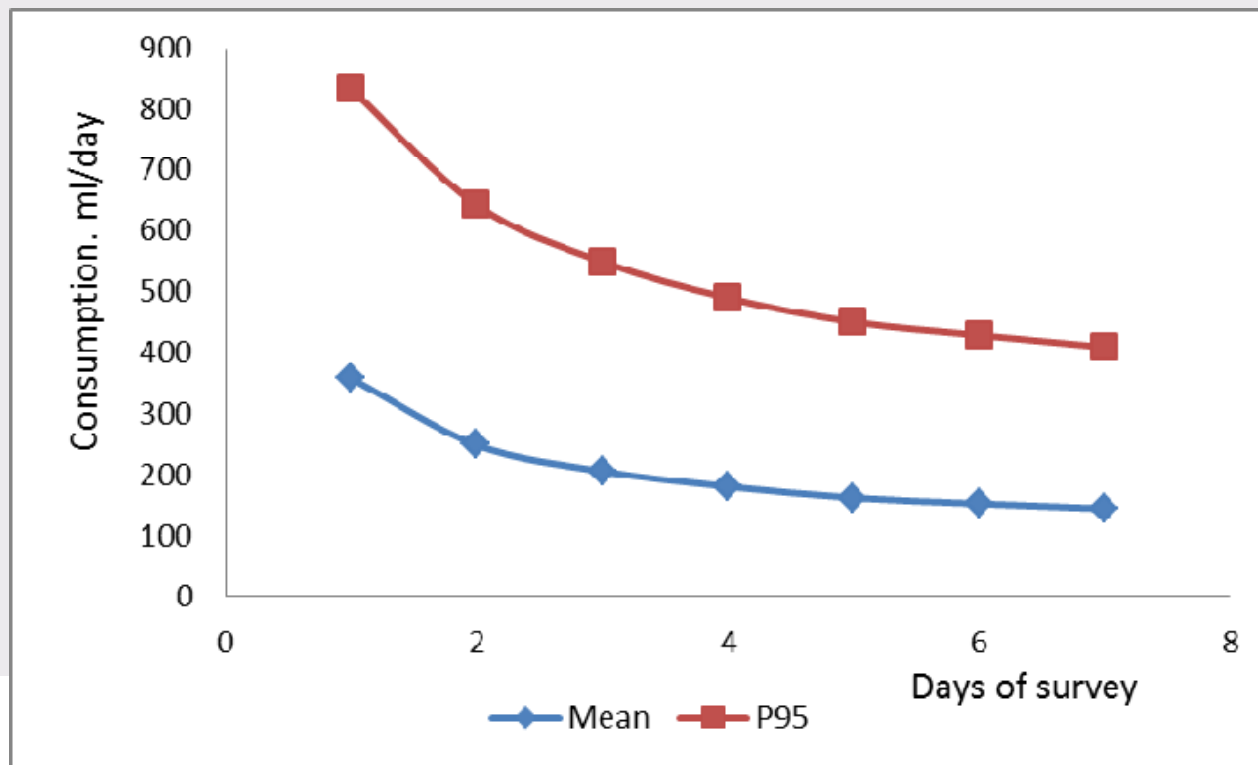
\* Huvaere K, Vandevijvere S, Hasni M, Vinkx C, Van Loco J. Dietary intake of artificial sweeteners by the Belgian population. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 2012;29(1):54-65.

# Food consumption data used for exposure assessment

- Data used for chronic exposure assessments in the EFSA system include surveys of only 2 or 3 days (not necessarily consecutive).
- For foods that are not consumed on a regular basis it is difficult to estimate 'usual' consumption.
- EFSA is aware of problem and research is being undertaken to help produce better estimates of 'usual' intake.
- Short duration surveys tend to over-estimate intakes of additives that are present intermittently in multiple foods and at variable levels.

# Food consumption data used for exposure assessment

Variation in apparent consumption of carbonated beverages by schoolchildren aged 4-18 years according to duration of survey\*



\*UK NDNS 1997



# Uncertainty analysis

- Draft Opinion identified uncertainties associated with the food consumption data, food nomenclature and reported use levels.
- In a qualitative evaluation the Panel concluded that “differences between food consumption surveys and inconsistencies in food descriptions would cause both over and under-estimation”.
- Panel also noted that “estimates should be considered as being conservative as it is assumed that all processed foods contain the sweetener aspartame (E 951) added at the MPL or the maximum reported use levels.”
- **Maximum reported use levels within each food category and extrapolation from food consumption survey of few days to estimate chronic exposure would lead to over-estimation of exposures.**

# Uncertainty analysis

Over-estimation illustrated by previously reported estimates of European national exposures for children (EFSA 2009):

Ranged up to 8 to 12 mg/kg bw/day for high level consumers (about one-third of current estimates).

Differences may be associated with:

- More refined methodology (individual survey data)
- Differences in use levels between EU countries.

**Suggests that draft Opinion may be significantly over-estimating exposures to aspartame and to its metabolic products including methanol and phenylalanine, at the upper bound.**

# Conclusion

- Exposure assessments provided in the draft Opinion are conservative.
- Degree of conservatism is not discussed but previous estimates of high level exposures to European children about one-third lower.
- Sources of this difference unclear but could include:
  - the short duration of some food consumption surveys,
  - the assumed use of maximum permitted use levels in all foods and
  - not taking account of variation in use levels between EU countries.
- In particular, usage information provided by industry on two key applications, edible ices and non-alcoholic beverages, not taken into consideration.
  
- **High level exposure estimates provided in the draft Opinion probably represent extreme theoretical worst case that would be unlikely to occur in reality.**

# Conclusion

## The Draft Opinion would benefit from:

- More refined exposure assessments taking account of known levels of use of the additive
- Better estimates of long-term, national exposure levels
- Further clarification of exposure assessment methods used
- Inclusion of more thorough uncertainty analyses and
- An evaluation of the probability of high-end exposure estimates occurring in reality.