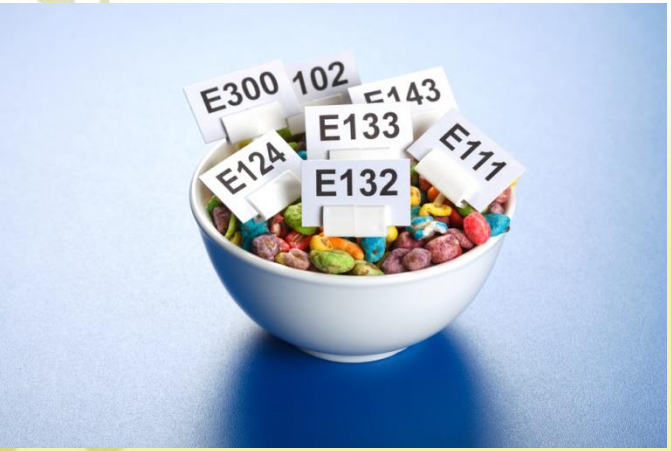

Risk assessment: food additives

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1st Croatian Food Safety Risk Assessment Conference
6-7 October 2015, Osijek, Croatia

National Food Chain Safety Office (since 2012)

a versatile **authority for:**

- ✓**food chain safety ,**
- ✓soil conservation,
- ✓plant production,
- ✓animal breeding,
- ✓forestry,
- ✓hunting,
- ✓fishery,
- ✓wine control,
- ✓agricultural administration,
- ✓pálinka (Hungarian alcoholic beverage) control .

Risk Assessment integrated

- a dedicated directorate
- planning procedure (risk based monitoring)

Government Decree No.22/2012. (II. 29.)

Happy Birthday to HAH!

It may contain:

- colorants,
- preservatives,
- antioxidants,
- stabilisers,
- emulsifiers,
- sweeteners,
- etc.

Role of risk assessment:
Is it safe (enough) to eat?

Why food additives?

- Present almost in all kind of food
- Persistent, lifelong consumption
- Consumed even by children and pregnant women
- Consumers anxiety
- Legal obligation: monitoring food additives intake

Consumers and the media

The Telegraph

Additives DO harm children - and a ban could cut child hyperactivity by a third, say scientists

CHINADAILY.COM.CN

EWG Releases First 'Dirty Dozen' List for Food Additives

Food additive scandal scares public yet again

Mail Online

3 kg food additives are consumed a year

Parents warned about artificial food additives

Food watchdog calls for EU wide ban on additives linked to hyperactivity in children

- Revulsion
- Fear
- Disapproval
- Negative feelings
- Uncertainty
- Confusion
- Anxiety
- Lack of relevant information and knowledge
- Rejection

„For a variety of reasons, some consumers might regard the use of food additives, especially artificial ones, with suspicion; food additives are considered unnatural, unhealthy or even a public health risk."

/Bearth et al., The consumer's perception of artificial food additives: Influences on acceptance, risk and benefit perceptions , 2014/

Eurobarometer, 2010

(http://ec.europa.eu/public_opinion/archives/eb_special_359_340_en.htm
http://www.efsa.europa.eu/en/riskcommunication/riskperception)

- EU legislation on food additives is based on the principle that only additives that have passed a full safety assessment are authorised for use. Despite this, an Eurobarometer survey indicated that **66% of European consumers** were **concerned** over the presence of additives in food. In addition, there is little understanding as to why the EFSA is reassessing food additives currently in use.

- Worry about "*additives like colours, preservatives or flavourings used in food or drinks*" ranks third in the 'medium levels of worry' issues.

Why aspartam?

- **Controversial from the first approval**
- **Widespread in many products**
- **Consumed by pregnants, children**
- **Hugh media coverage**
- **Significant consumer anxiety**
- **Scientific debate, concerns + new scientific knowledge**
- **MPL levels are known**
- **Proper for working out a national framework** (as required by 1333/2008/EC)

The Beginning of the **Aspartame Story**

***1965**: **discovered** by American chemist, **James M. Schlatter**.*
*(by reaction of among others **L-asparatic acid** and **L-phenylalanine**)*

1974**: initial approval by **FDA** - quickly **revoked

***1974-1981:** comprehensive **review** of the authenticity of the aspartame research data by FDA*

***1981: FDA** has **approved** uses of aspartame in food and authorized to begin **marketing** it.*

(GAO, 1987)

FDA officials describe aspartame as

"***one of the most thoroughly tested and studied food additives the agency has ever approved***"

and

its safety as "*clear cut*".

The weight of existing scientific evidence indicates that aspartame is safe as a non-nutritive sweetener.

GAO: U.S. Government Accountability Office

Scientific concerns

- **Carcinogenicity:**
  The famous Ramazzini studies

Morando Soffritti, M.D.

The integrated experimental project on aspartame started in 1997 (3 studies: rats, mice)

- life-span treatment
- prenatal exposure

Results:

- **Aspartame has been shown to induce a significantly increased incidence of malignant tumors**
- **The carcinogenic effects of aspartame were shown also at dose levels to which humans could be exposed**

EFSA re-evaluation

Former evaluations:

FDA (1974, 1981) ADI = 50 mg/kg bw/day
JECFA (1980) ADI = **40 mg/kg bw/day**
SCF (1985, 1988, 1997, 2002) ADI = **40** mg/kg bw/day
EFSA (2006, 2009, 2011)

EFSA full risk assessment on aspartame: 10. December 2013.

Main conclusions:

- the results of the studies performed by *Soffritti et al.* do not provide evidence for a carcinogenic effect of aspartame
- the current ADI is considered to be safe for the general population
- the consumer exposure to aspartame is below this ADI:

	Aspartame intake (adults) *mg/kg bw/day*	Aspartame intake (children) *mg/kg bw/day*		
		12-35 months	3-9 years	10-17 years
P95 EU	2.7-27.5	11.8-36.9	7.1-32.9	2.3-13.3
average EU	0.8-8.6	3.2-16.3	2.3-12.8	0.8-4.0

Aspartame and its metabolites **pose no toxicity concern for consumers at current levels of exposure.** The ADI is not applicable to PKU (phenylketonuria) patients.

Dietary intake of aspartame in Hungary

REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives

Article 27

Monitoring of food additive intake

1. Member States **shall maintain systems to monitor the consumption and use of food additives** on a risk-based approach and report their findings with appropriate frequency to the Commission and the Authority.

2. After the Authority has been consulted, a **common methodology** for the gathering of information by the Member States on dietary intake of food additives in the Community shall be adopted in accordance with the regulatory procedure referred to in Article 28(2).

Tiered approach

finalised in 1998 by the SCOOP task of the Commission (http://ec.europa.eu/food/fs/sfp/addit_flavor/flav15_en.pdf)

***Tier 1**: **theoretical**ly estimated food **consumption** data **x** **maximum** **legally allowed level**s of the additive;*

***Tier 2**: **actual** national food **consumption** data **x** **maximum** **legally allowed levels** of the additive;*

***Tier 3**: **actual** national food **consumption** data **x** **actual** **usage level** of the additive, based on measurements or information from manufacturers.*

Food Additives Intake Model (2012-2013)

- Tier 2 approach: Consumption data coming from the **EFSA *Comprehensive Food Consumption Database*** x **maximum permitted usage levels** (of (EC) No 1333/2008), assuming that foods that can be considered contain the given additive at this maximum usage level)
- Hungary: data of the 2003 survey, containing consumption data for a total of 1360 people in the adult and elderly categories
- The expression *quantum satis* (amount which is needed) could not be interpreted by the template → table top sweeteners were not taken into consideration by the model

http://www.efsa.europa.eu/en/datexfooddb/datexfooddbspecificdata
http://www.efsa.europa.eu/en/anstopics/docs/faimtemplate.xls

FACET

Flavourings, **A**dditives and Food **C**ontact Materials **E**xposure **T**ask

http://expofacts.jrc.ec.europa.eu/facet/

- 7th FP of the EU, performed with the participation of 20 institutions from 13 countries between 2008 and 2012
- Tier 2 approach: **consumption data** x **maximum permitted additive concentrations** in different foods
- Hungarian consumption data of the 2003 survey, containing consumption data for a total of 1360 people in the adult and elderly categories.
- Detailed food classification system (additional information was also gathered, for example, if a product was *low fat content* or *reduced sugar content)*
- Products with *quantum satis* restriction (table top sweeteners in the case of aspartame) were not taken into consideration

Our own probabilistic method

- **Consumption data**: representative food consumption survey in 2009
- 3982 adults and 1010 children and teenagers, 3 days daily consumption
- 114 products out of ~ 700 were assumed to contain aspartame (in theory)
- Tier 2: maximum usable aspartame levels were looked up in the regulation
- The derived intakes were totaled for each consumer, divided by the actual body weight of the consumer. The average, median, 95 and 97,5 percentile values of the 14976 (=4992x3) daily intake values were calculated.
- Calculations were performed for the entire population, and for adults and children (by age group) as well.

Results: FAIM

	Aspartame intake mg/kg bw/day	
	Adults (18-64 years)	Elderly (≥65 years)
Average	2.3	1.9
High consumers (P95)	8.0	5.5

ADI=40 mg/kg bw/day

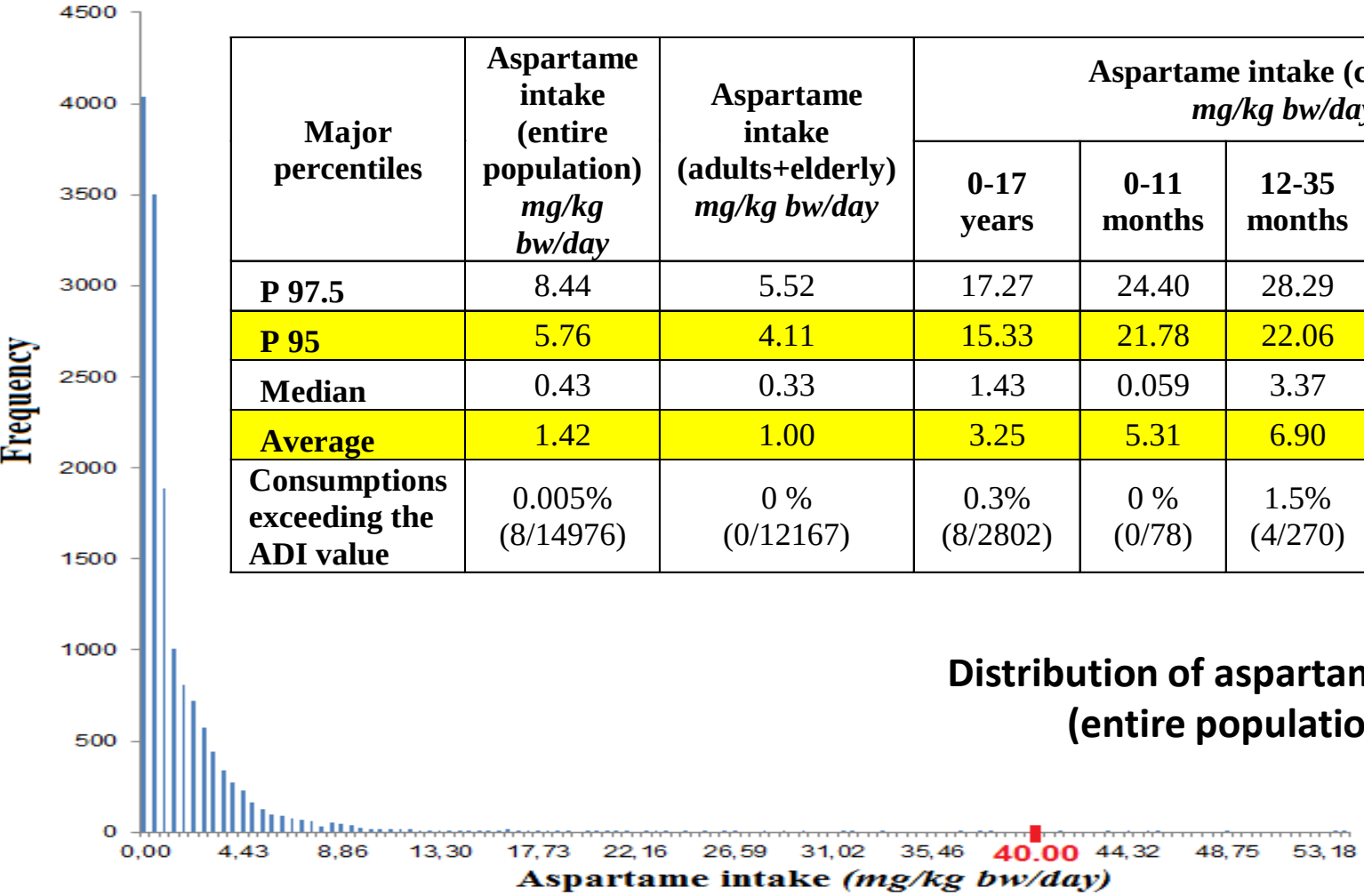
Results: FACET

Major percentiles	Aspartame intake mg/kg bw/day
P 97.5	6.7
P 95	5.6
Median	1.2
Average	1.8

ADI=40 mg/kg bw/day

Results: own (probabilistic) method

Major percentiles	Aspartame intake (entire population) *mg/kg bw/day*	Aspartame intake (adults+elderly) *mg/kg bw/day*	Aspartame intake (children) *mg/kg bw/day*				
			0-17 years	**0-11 months**	**12-35 months**	**3-9 years**	**10-17 years**
P 97.5	8.44	5.52	17.27	24.40	28.29	17.72	9.13
P 95	5.76	4.11	15.33	21.78	22.06	14.40	6.60
Median	0.43	0.33	1.43	0.059	3.37	2.16	1.06
Average	1.42	1.00	3.25	5.31	6.90	3.99	1.99
Consumptions exceeding the ADI value	0.005% (8/14976)	0 % (0/12167)	0.3% (8/2802)	0 % (0/78)	1.5% (4/270)	0.4% (4/972)	0% (0/1482)



Distribution of aspartame intake (entire population)

Summarised results of the models with Hungarian consumption data

	FAIM (adults)	FACET (adults + elderly)	Our method (2009 database)		
			Entire population	adults + elderly	children (0-17 years)
High consmers	8.0	5.6 (P95)	5.8 (P95)	4.1 (P95)	15.3 (P95)
Average	2.3	1.8	1.4	1.0	3.3

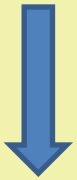
ADI=40 mg/kg bw/day

Comparison of methods

	FAIM	FACET	Our method
+	• Simple • MPL can be changed	• Detailed food categorization system (it approximates well which the major food contributors are to additive intake) • Probabilistic method	• 2009 food consumption database: including children • Foods were assigned to legally allowed limit values one by one: accurate correlation based on available data
-	• 2003 food consumption database: no children • Rough food categorization system • The most conservative (first filter), point estimation	• 2003 food consumption database: no children • MPL cannot be changed (in case of legislation change)	• Very labor intensive

Conclusions

- Aspartame exposure was estimated using three different methods
- Tier 2 approach (MPL, national food consumption data): worst-case scenario, overestimation
- Results: dietary intake is well below the ADI value for all age groups



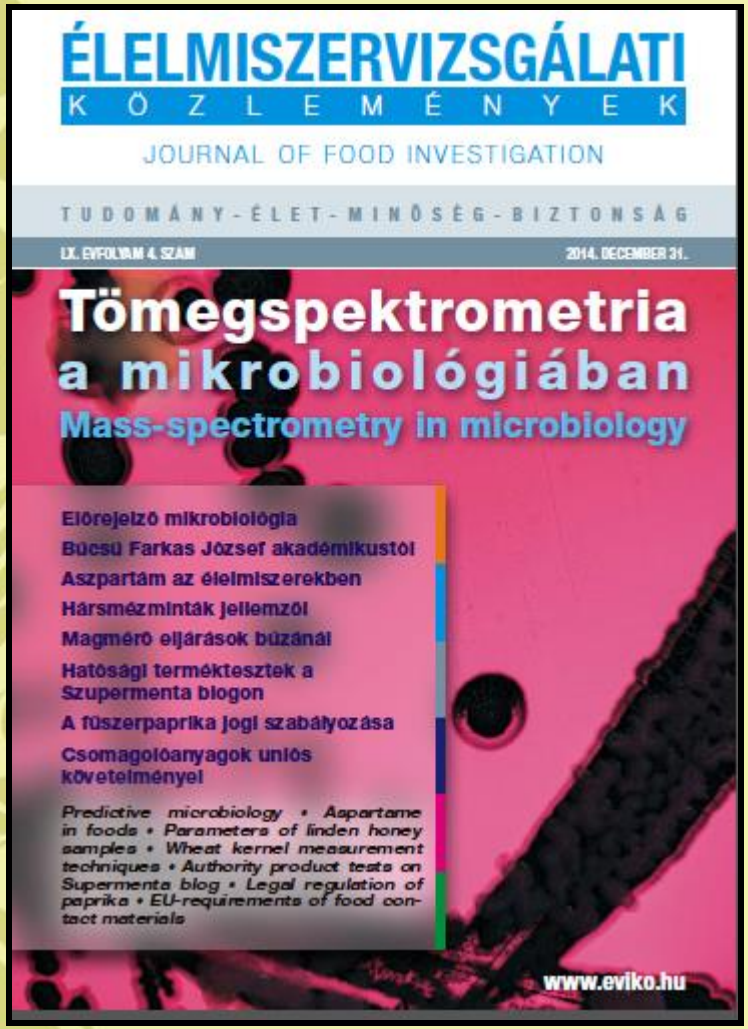
Tier 3 is not necessary

For the average Hungarian consumer, in case of the usual diet, aspartame intake is not a cause for health concern.

Lessons learnt

- Actual use level data would be needed directly from industry, in order to perform Tier 3
- Data on proportion of foods with additives would be needed (now the asumption is 100%)
- FAIM-template could be more detailed
- FAIM and FACET could be more flexible to include additional (new) data
- Possibility to insert additives of „quantum satis”
- Very detailed food consumption database needed

Journal of Food Investigation



K. F. Csáki, M. Sz. Túri, A. Zentai, L. Mészáros, R. Prisztóka, J. Sali, M. Sz. Szabó. 2014. **Estimation of the aspartame intake coming from foods and its risk assessment**. *Journal of Food Investigation*, LX, 4.

http://eviko.hu/en-us/Science/Estimation-of-the-aspartame-intake-coming-from-foods-and-its-risk-assessment

Meanwhile the consumers...

Thank you for your attention!