European Food Safety Authority

Exposure assessment of food additives by the ANS Panel

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Exposure Assessment

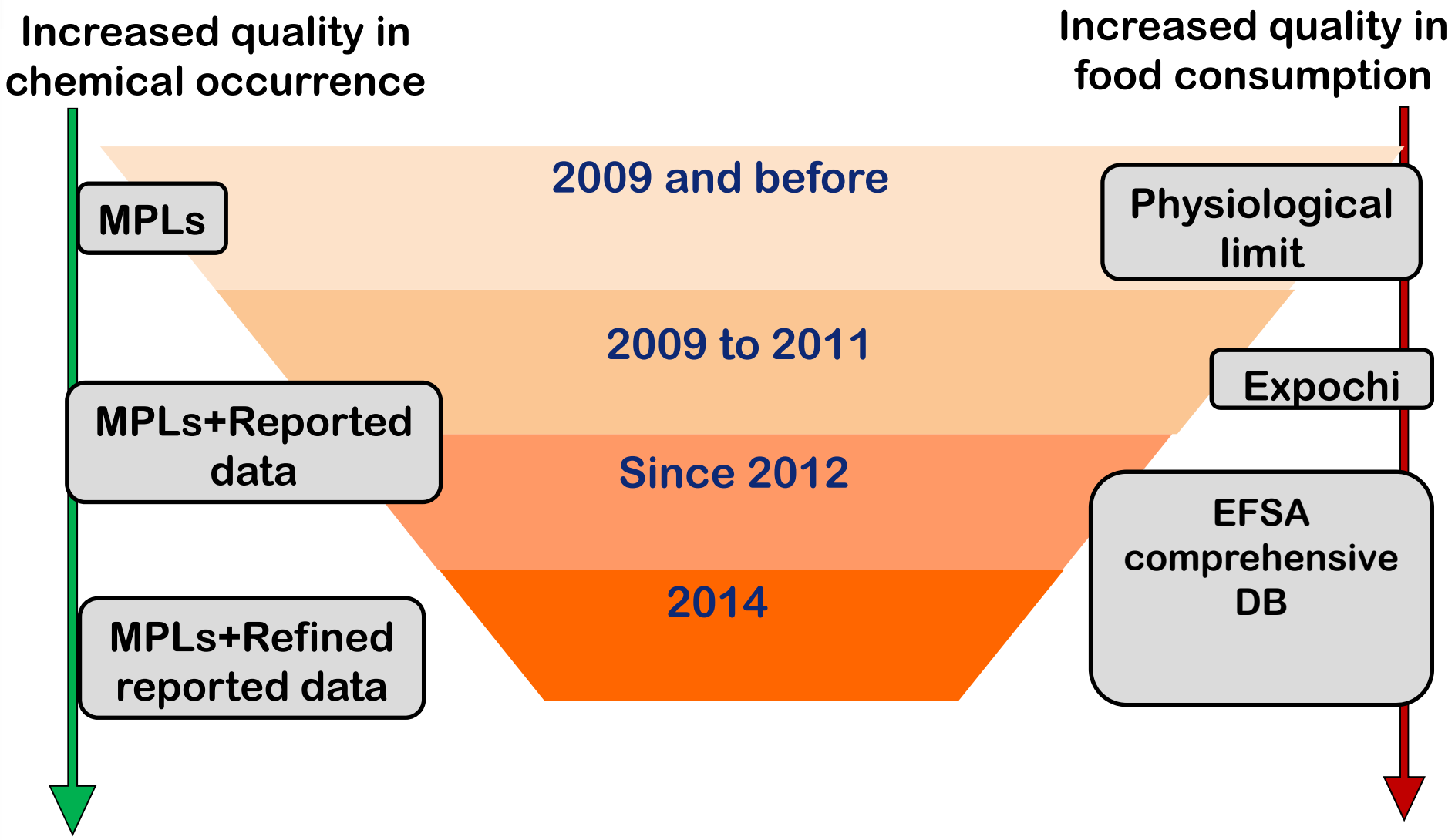
- Exposure assessment is a major component of the risk assessment process
- For the evaluation of food additives chronic exposure estimates are performed
- For food additives already authorised (re-evaluation, extension of use) and for new applications

Exposure Assessment

$$\frac{\sum(\text{chemical concentration} \times \text{food consumption})}{\text{body weight}}$$

Chemical occurrence → Dietary Exposure Assessment ← Food consumption

Current challenges in data used: Conservative to more refined



Estimating exposure to food additives

Chemical occurrence data:

- Maximum Permitted Levels (MPLs) according to Annex II of Regulation 1333/2008
- Usage levels provided by industry
- Analytical data e.g. monitoring data from Member States

Food consumption data:

- EFSA Comprehensive European Food Consumption Database (EFSA Comprehensive DB)
- 26 dietary surveys from 17 European countries
- Different age classes:
  - ✓ Toddlers (12 - 35 months): 4 surveys in 4 countries
  - ✓ Children (3 - 9 years): 15 surveys in 13 countries
  - ✓ Adolescents (10 - 17 years): 12 surveys in 10 countries
  - ✓ Adults (18 - 65 years): 15 surveys in 14 countries
  - ✓ Elderly and very elderly (> 65 years): 7 surveys in 7 countries
- Foods classified according to the FoodEx classification system

Food nomenclature

- Food classification system used in the **EU legislation (FCS)**:

  Food categories defined in Part D of Annex II to Regulation (EC) 1333/2008:

  - **4** levels
  - N = 154 food groups

- Food classification system used in the **EFSA Comprehensive DB (FoodEx)**

  - 4 levels
  - 20 main food groups (level 1)
  - > 1700 food items at the most detailed level

Correspondence table

- Decision to remain at FCS **level 2**, except for:
  - **Non-alcoholic beverages**: information on the type of beverages (fruit/vegetable juices, nectars etc.)
  - **With and without added sugar products**: distinction for confectionary, chewing-gums, flavoured drinks
  - **Cheese**: unripened, ripened, whey, processed cheese
- Some foods listed in the legislation not present in the FoodEx nomenclature:
  - Could not be represented in the FAIM template
  - Adjustments were made
- **N = 65** food groups

Correspondence table (2)

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Example of linkage between the FCS and the FoodEx classification system

FCS number	FCS name	FoodEx name	FoodEx code
8.2	Processed meat	Preserved meat	A.06.08
8.2	Processed meat	Sausages	A.06.09
8.2	Processed meat	Meat specialities	A.06.10
8.2	Processed meat	Pastes, pâtés and terrines	A.06.11
9.1	Unprocessed fish and fisheries products	Fish meat	A.07.01
9.1	Unprocessed fish and fisheries products	Crustaceans	A.07.04
9.1	Unprocessed fish and fisheries products	Water molluscs	A.07.05
9.2	Processed fish and fishery products including mollusks and crustaceans	Fish	A.07
9.2	Processed fish and fishery products including mollusks and crustaceans	Fish products	A.07.02
9.3	Fish roe	Fish roe	A.07.03.001
5.4.1	Chewing gum with added sugar	Chewing gum with added sugar	A.10.04.016
5.4.2	Chewing gum without added sugar	Chewing gum without added sugar	A.10.04.017

Correspondence table (3)

- ✓ Link to EC Food Classification System for **all food additives**
  - ➢ direct link with MPLs
- ✓ Major restriction taken into account: **energy-reduced** or **non energy-reduced products**
- ✓ Food groups linked up to FoodEx levels 4 when needed (i.e. detailed food items)

Food Additives Intake Model (FAIM1)

- Developed by the ANS Panel within the frame of the 'Guidance for submissions for food additive evaluations' (2012)
  - Around 10 exposure experts within the ANS exposure WG during 2011/2012 year
  - Prior its publication, presentation has been made and comments taken from interested parties (i.e Members states, European Commission and key industry)
- A tool to support applicants in the calculation of preliminary exposure estimates
- To serve as a first step in the dietary exposure assessment process
- Exposure model calculation with summary food consumption data from the EFSA Comprehensive DB (mean and p95)
- FoodEx food classification linked to the food classification system (FCS) defined in Annex II of Regulation 1333/2008

Outputs of the FAIM tool

- Based on MPLs and reported use levels
- Mean and high level exposure (p95) estimates
- Per age class and survey (country)
- Main contributors to the total mean exposure (food groups contributing >5%)
- Number of surveys for which the food category is a main contributing food group
- Summary results as a percentage of the ADI
- Conservative exposure estimates

Uncertainties in database used in the exposure estimates

Uncertainties still exist:

- Linkage between FCS and FoodEx not always possible or accurate:
  - ✓ large number of detailed food subcategories in the FCS (fruit and vegetables peeled, frozen etc.)
  - ✓ restrictions in the legislation that cannot be taken into account: e.g. “for vending machine”, specific national products (“sobrasada, crème de pruneaux”)
- Limited information on actual usage:
  - ✓ lack of or limited availability of data
  - ✓ no detailed information on the food items ⇨ levels applied to the entire food category
  - ✓ representativeness of the usage data provided by industry?

Refined exposure assessments:

- Are performed by the ANS Panel when necessary
- Based on individual food consumption data
- Refinements in the linkage of FoodEx - FCS food nomenclatures are considered

Food additives concentration data

- A call for food additives usage level and/or concentration data in food and beverages intended for human consumption was launched in March 2013

- Deadline for submission of data:
  - 15 September* 2013 (batch 1) - 15 food additives
  - 30 November 2013 (batch 2) - 36 food additives

- Usage data (reported use levels) were requested from the industry

- Analytical/monitoring data were requested from relevant stakeholders (industry, MS, research institutions etc.)

- In March 2014, a call for usage level and/or concentration data was launched , including 22 food additives (mostly gums) – Batch 3

* Extension of the initial deadline for submission of data (initially end of July 2013)

Data collection - structure

- In order to standardize the quality of the data transmitted to EFSA, EFSA in cooperation with the EU Member States, had developed in 2010 a harmonised data structure: 'Standard Sample Description' (SSD)

- SSD contains a list of data elements that are standardized and can be used by both data providers and data recipients to fully describe samples and analytical parameters for evaluation purposes
  - ✓ Sample descriptors: e.g. food description, sampling year, product treatment…
  - ✓ Information related to the data quality: e.g. analytical method used, accreditation…
  - ✓ Information related to the results: LOD/LOQ, expression of the result value …

- The food additives concentration data were collected in accordance to the SSD structure

Data collection - Batch 1 & 2

Batch 1*	Batch 2**
Curcumin (E 100)	Quinoline yellow (E 104)
Azorubine/Carmoisine (E 122)	Sunset Yellow (E 110)
Allura red AC (E 129)	Cochineal, Carminic acid, Carmines (E 120)
Indigotine, Indigo carmine (E 132)	Ponceau 4R (E 124)
Brown HT (E 155)	Brilliant black BN (E 151)
Chlorophylls (E 140i)	Annatto, bixin, norbixin (E160b)
Chlorophyllins (E 140ii)	Sulphur dioxide (E 220)
Copper complexes of chlorophylls (E 141i)	Sulphites (E 221 – E 228)
Copper complexes of chlorophyllins (E 141ii)	Hexamethylene tetramine (E 239)
β-Apo-8'-carotenal (E 160e)	Nitrites (E 249 – E 250)
Titanium dioxide (E 171)	Nitrates (E 251 – E 252)
Iron oxides and hydroxides E 172	Ascorbates (E 300 – E 302)
Propyl gallate E 310	Fatty acid esters of ascorbic acid (E 304i-ii)
Octyl gallate E 311	Tocopherols (E 306 – E 309)
Dodecyl gallate E 312	Glycerol (E 422)
	Sucrose acetate isobutyrate (E 444)
	Polyglycerol esters of fatty acids (E 475)
	Sorbitans (E 491 – E 495)

* Deadline 15 September 2013

** Deadline 30 November 2013

Results from the call for data Batch 1 & 2

General conclusions

- Availability of food additives concentration data has improved
- Analytical data have been gathered for the first time
- Still data not available for all food categories were a given food additive is authorised (e.g. no information available or additive not in use for the specific food group ?)
- A great deal of 'data cleaning' is required following submission (e.g. errors, misclassifications in the food categories)
- Different sources of data: discrepancies may appear

Analytical data submitted - Batch 1

Data received by sampling country

Food additive	Country of sampling								
	Austria	Cyprus	Czech Rep.	Germany	Spain	Hungary	Ireland	Slovakia	Total
Curcumin (E 100)	0	0	0	281	0	10	0	0	*291*
Azorubine (E 122)	994	194	333	3296	40	480	208	1099	*6644*
Allura Red AC (E 129)	0	120	317	3490	28	144	208	673	*4980*
Indigotine (E 132)	994	0	316	2847	0	155	37	289	*4638*
Brown HT (E 155)	0	0	0	13	0	0	0	1	*14*
β-Apo-8'-carotenal (E 160e)	0	47	0	0	0	0	0	0	*47*
Titanium dioxide (E 171)	28	0	0	0	0	0	0	0	*28*
Propyl gallate (E 310)	0	0	0	149	0	0	8	75	*232*
Octyl gallate (E 311)	0	0	0	149	0	0	17	75	*241*
Dodecyl gallate (E 312)	0	0	0	189	0	0	17	140	*346*
Total	*2016*	*361*	*966*	*10414*	*68*	*789*	*495*	*2352*	*17461*

Analytical data submitted - Batch 2

Data received by sampling country

Food additive	Country of sampling						Total
	Austria	Cyprus	Czech Republic	Germany	Ireland	Slovakia	
Quinoline Yellow (E 104)	995	109	317	3558	209	102	*5290*
Sunset Yellow FCF (E 110)	998	77	328	3839	206	124	*5572*
Cochineal, Carminic acid, Carmines (E 120)	568	48	8	3062	0	170	*3856*
Ponceau 4R (E 124)	1003	119	328	4006	203	191	*5850*
Brilliant Black BN (E 151)	996	0	312	2868	0	24	*4200*
Annatto, Bixin, Norbixin (E 160b)	0	0	14	317	25	0	*356*
Sulphur dioxide (E 220)	1586	888	792	16551	460	107	*20384*
Sodium nitrite (E 250)	792	0	0	6555	240	34	*7621*
Sodium nitrate (E 251)	825	0	0	3771	240	15	*4851*
Potassium nitrate (E 252)	25	0	0	795	0	0	*820*
Ascorbic acid (E 300)	1256	0	1	0	0	7	*1264*
Alpha-tocopherol (E 307)	311	0	0	997	0	0	*1308*
Gamma-tocopherol (E 308)	0	0	0	392	0	0	*392*
Delta-tocopherol (E 309)	0	0	0	336	0	0	*336*
Glycerol	0	0	0	7745	0	0	*7745*
Total	*9355*	*1241*	*2100*	*54792*	*1583*	*774*	*69845*

Overview of the analytical data submitted

- ✓ In total, 8 countries submitted analytical data (Germany, Austria, Slovakia, Czech Republic, Cyprus, Hungary, Spain, Ireland)
- ✓ Most analytical data submitted regard food colours and sulphur dioxide
- ✓ For some food additives, no analytical data were received:
  - Chlorophylls (E 140i)
  - Chlorophyllins (E 140ii)
  - Copper complexes of chlorophylls (E 141i)
  - Copper complexes of chlorophyllins (E 141ii)
  - Iron oxides and hydroxides (E 172)

- ✓ Some Member States submitted analytical data for food additives not included in the call for data: e.g. Beetroot red (E 162), Patent blue (E 131) etc.

Usage data submitted – Batch 1 & 2

Food additive - Batch 1	Records (entries)	Food additive - Batch 2	Records (entries)
Curcumin (E 100)	232	Quinoline yellow (E 104)	17
Azorubine/Carmoisine (E 122)	25	Sunset Yellow (E 110)	36
Allura Red AC (E 129)	28	Cochineal, Carminic acid, Carmines (E 120)	87
Indigotine, Indigo carmine (E 132)	7	Ponceau 4R (E 124)	18
Brown HT (E 155)	1	Brilliant black BN (E 151)	7
Chlorophylls (E 140i)	19	Annatto, bixin, norbixin (E160b)	48
Chlorophyllins (E 140ii)	108	Sulphur dioxide & sulphites (E 220 - E 228)	93
Copper complexes of chlorophylls (E 141i)	22	Hexamethylene tetramine (E 239)	-
Copper complexes of chlorophyllins (E 141ii)	28	Nitrites (E 249 - E 250)	16
β-Apo-8'-carotenal (E 160e)	20	Nitrates (E 251 - E 252)	8
Titanium dioxide (E 171)	60	Ascorbates (E 300 - E 302)	336
Iron oxides and hydroxides (E 172)	28	Fatty acid esters of ascorbic acid (E 304i-ii)	78
Propyl gallate (E 310)	1	Tocopherols (E 306 - E 309)	159
Octyl gallate (E 311)	1	Glycerol (E 422)	91
Dodecyl gallate (E 312)	1	Sucrose acetate isobutyrate (E 444)	13
		Polyglycerol esters of fatty acids (E 475)	7
		Sorbitans (E 491 - E 495)	15

Data collection - Batch 3

Batch 3	
Silver (E 174)	Tragacanth (E 413)
Gold (E 175)	Acacia gum (E 414)
Erythorbic acid (E 315)	Xanthan gum (E 415)
Sodium erythorbate (E 316)	Karaya gum (E 416)
Tertiary-butyl hydroquinone (TBHQ) (E 319)	Tara gum (E 417)
Lecithins (E 322)	Gellan gum (E 418)
Agar (E 140i)	Konjac gum (E 425)
Carrageenan (E 407)	Konjac glucomannane (E 425ii)
Processed eucheuma seaweed (E 407a)	E 427 Cassia gum
Locust bean gum (E 410)	E 459 Beta-cyclodextrin
Guar gum (E 412)	E 473 Sucrose esters of fatty acids

Deadline for submission of data: **31 July 2014**

More information available on EFSA's website:
http://www.efsa.europa.eu/en/data/call/datex140310.htm

Coming up for exposure assessments: Food consumption data

- An update of the FAIM template is envisaged when new consumption data will be included in the EFSA Comprehensive DB (expected to be available in 2014)
- To reduce uncertainties due to broad food groups on high percentiles of exposure, modifications following suggestions provided by stakeholders to be taken into consideration in the current FAIM nomenclature for:
  - Fine bakery wares group
  - Milk-based beverages (incl. in non-alcoholic beverages)
  - Unprocessed meat: to separate the main food items containing FA (sausages …)
  - Alcoholic beverages: split wine and beer from other alcoholic beverages
  - Processed fruit and vegetables

Coming up for exposure assessments: occurrence data

- The ANS WGs on Food Additives, WG Exposure Assessment and EFSA (DATA and FIP unit) are currently analysing and working on the data submitted for batch 1 & 2;

- ANS WG Exposure Assessment discussing how to best use these data in the exposure assessments:

  1. Still the **MPL scenario with issue with QS**
  2. **Refined Exposure Assessment with levels to be used (max, mean…) to be defined following the data made available to EFSA**

And last but not least:
continue interaction with stakeholders

(e.g. EFSA Stakeholder Consultative Platform - Discussion Group on food chemical occurrence data)

Thank you for your attention

contact:

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