

FACET FINAL MEETING

ADDITIVES EXPOSURE ASSESSMENT

BRUSSELS – 26th OCTOBER 2012
Karine VIN and Jean Luc VOLATIER (ANSES)



ADDITIVE EXPOSURE ASSESSMENT

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- **PARTICIPANTS: WP3 & WP9**

- ANSES: Jean Luc VOLATIER, Karine VIN
- UCD: Aine HEARTY, Aileen CONNOLLY
- FCRA: David TENNANT
- FOODDRINKEUROPE: Beate KETTLITZ, Miguel PRIETO
- CRÈME: Cian O'MAHONY



ADDITIVE EXPOSURE ASSESSMENT

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- **THREE DIFFERENT MAIN PURPOSES :**

- Evaluation and re-evaluation for authorisation (DG SANCO and EFSA)
- Post market monitoring (member states, article 27 R 1333/2008)
- Research, other risk assessments



FOOD ADDITIVES: DEFINITION

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- **DEFINITION:**

- any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food
- intentionally added to food for a technological purpose



FOOD ADDITIVES: DEFINITION

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- **26 FUNCTIONAL CATEGORIES (Annex 1 of regulation R1333/2008)**

- Sweeteners
- Colours
- Preservatives
- Antioxidants
- Carriers
- Acids, acidity regulators
- Anti-caking agents
- Bulking agents
- Emulsifiers, emulsifying salts
- Firming agents
- Flavour enhancers
- Foaming agents
- Glazing agents
- Humectants
- Modified starches
- Packaging gases
- Propellants
- Raising agents
- Sequestrants
- Stabilisers
- Thickeners
- Anti-foaming agents
- Flour treatment agents
- Gelling agents



ADDITIVES REGULATION

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- **EVALUATION AND RE-EVALUATION OF APPROVED FOOD ADDITIVES (R 1331 and 1333/2008)**

- Upon receipt of an application, the commission should initiate the procedure and where necessary seek the opinion of the EFSA (§11 R 1331/2008, article 5)
- Food additives which were permitted before 20 January 2009 shall be subject to a new risk assessment carried out by the Authority (EFSA) article 32 R 1333/2008



ADDITIVES REGULATION

- **POST MARKET MONITORING (article 27 R 1333/2008)**

- 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.
- 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)



EFSA ADDITIVES EXPOSURE ASSESSMENT METHOD

- **EFSA scientific opinion « Guidance for submission for food additive evaluations » 16 August 2012**

- Proposed uses and exposure assessment (§ 3)
- Tier 1 (budget method) no longer appropriate
- Exposure assessment tool developed by EFSA : FAIM
- Summary statistics EFSA comprehensive database and applicant proposed uses and use level
- « the panel will initially consider only maximum proposed and maximum permitted levels »
- FoodEx EFSA classification system AND Annex 2 R 1333/2008



EFSA ADDITIVES EXPOSURE ASSESSMENT METHOD

• EFSA ADDITIVES EXPOSURE ASSESSMENT METHOD AND FACET

- Use of the EFSA comprehensive database : YES AND NO
→ FACET includes dietary surveys of the EFSA comprehensive database but not all surveys
- FACET uses the classification system of the R 1333/2008 regulation but doesn't need to use EFSA Foodex
- FACET uses maximum permitted levels, can use maximum or usual levels
- Other types of uses : natural occurrence YES, food supplements NO, flavouring YES, food contact material YES, pharmaceutical or cosmetic product NO



EFSA ADDITIVES EXPOSURE ASSESSMENT METHOD

- Different age classes : toddlers, children, adolescents, adults, elderly YES
- Use of the 95th percentile of intake : YES (and far more)
- “the panel will consider on a case-by-case basis on how to calculate extremes of overall exposure from all or different sources”
→ FACET uses raw individual intake data
- Dedicated FAIM exposure assessment tool will be made available by EFSA → no relative validation with FAIM because not available during the FACET project



ADDITIVES EXPOSURE ASSESSMENT

• PRIORITY ADDITIVES: criteria for selection

- Additives already identified as priority additives (intake Tier 2 > ADI - COM2001) → 19 additives

Additive code	Additive name	Criteria of selection	Additive main function
E160b	Annatto, Bixin, Norbixin	tier 3 (COM 2001)	colour
E210-213	Benzoic acid and its salts	tier 3 (COM 2001)	preservative
E220-228	Sulphites	tier 3 (COM 2001)	preservative
E249-250	Nitrites	tier 3 (COM 2001)	preservative
E321	Butylated hydroxytoluene	tier 3 (COM 2001)	antioxidant
E338-341/343/450-452	Phosphoric acid and phosphates	tier 3 (COM 2001)	leavening agent
E432-436	Polyoxyethylen sorbitan monooleate, monooleate, monopalmitate, monostearate and tristearate	tier 3 (COM 2001)	emulsifier
E473-474	Sucrose esters of fatty acids and sucroglycerides	tier 3 (COM 2001)	emulsifier
E475	Polyglycerol esters of fatty acids	tier 3 (COM 2001)	emulsifier
E481-482	Sodium and calcium stearoyl-2-lactylate	tier 3 (COM 2001)	emulsifier
E483	Stearyl tartrate	tier 3 (COM 2001)	emulsifier
E481/492/495	Sorbitan monostearate, tristearate and monopalmitate	tier 3 (COM 2001)	emulsifier
E493-494	Sorbitan monooleate and monooleate	tier 3 (COM 2001)	emulsifier
E520-523	Aluminium sulphates	tier 3 (COM 2001)	firming agent
E535-538	Ferrocyanides	tier 3 (COM 2001)	anticaking agent
E541	Sodium aluminium phosphate acid	tier 3 (COM 2001)	leavening agent
E554-556/559	Aluminium silicates	tier 3 (COM 2001)	anticaking agent
E558	Bentonite	tier 3 (COM 2001)	anticaking agent
E950	Acesulfame potassium	tier 3 (COM 2001)	sweetener



NB: bentonite has been removed since then



ADDITIVES EXPOSURE ASSESSMENT

• PRIORITY ADDITIVES: criteria for selection

- Additives of no safety concern in themselves (no ADI) but which can suffer an environmental contamination (pesticides, dioxin...) → 4 additives

Additive code	Additive name	Criteria of selection	Additive main function
E 322	Lecithins	possible environmental contamination	emulsifier
E 412	Guar gum	possible environmental contamination	thickener
E 414	Acacia gum	possible environmental contamination	thickener
E 471	Mono- and diglycerides of fatty acids	possible environmental contamination	emulsifier

- Additives used quantum satis although they have an ADI → 5 additives

Additive code	Additive name	Criteria of selection	Additive main function
E 150b, c, d	Caramel	qs with ADI	colour
E 160a	Carotene	qs with ADI	colour
E 160d	Lycopene	qs with ADI	colour
E 407	Carrageenan	qs with ADI	thickener
E 472e	Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids	qs with ADI	emulsifier



ADDITIVES EXPOSURE ASSESSMENT

• PRIORITY ADDITIVES: criteria for selection

- Additives for which the ADI has been revised recently (Azo-dye colours)
→ 3 additives

Additive code	Additive name	Criteria of selection	Additive main function
E 104	Quinoline yellow	ADI lowered	colour
E 110	Sunset yellow	ADI lowered	colour
E 124	Ponceau 4R	ADI lowered	colour

- Consumer concern (EFSA request)
→ 1 additive

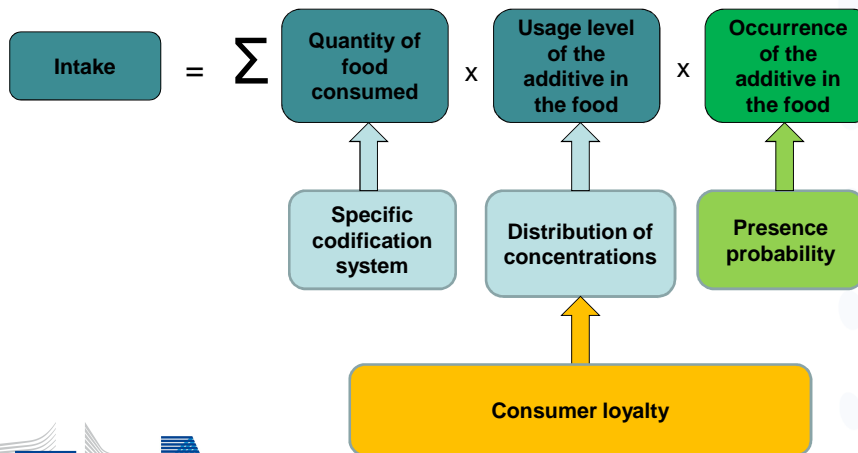
Additive code	Additive name	Criteria of selection	Additive main function
E 951	Aspartame	request of EFSA	sweetener

→ List of 32 additives (31 without bentonite)



ADDITIVES EXPOSURE ASSESSMENT

• EXPOSURE ASSESSMENT FOR ADDITIVES



ADDITIVES EXPOSURE ASSESSMENT

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- **FOOD CODIFICATION**

- Construction / validation / improvement of a list of food categories connected to the additives regulation
- Adaptation to the last update of the regulation realized
- Consumption data of the 8 selected countries (Finland, France, Hungary, Ireland, Italy, Poland, Portugal, UK) codified through the FERA web interface: Facet code + flags (nutritional information, presence of filling, coatings and toppings for bakery wares)



ADDITIVES EXPOSURE ASSESSMENT

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- **FOOD CODIFICATION**

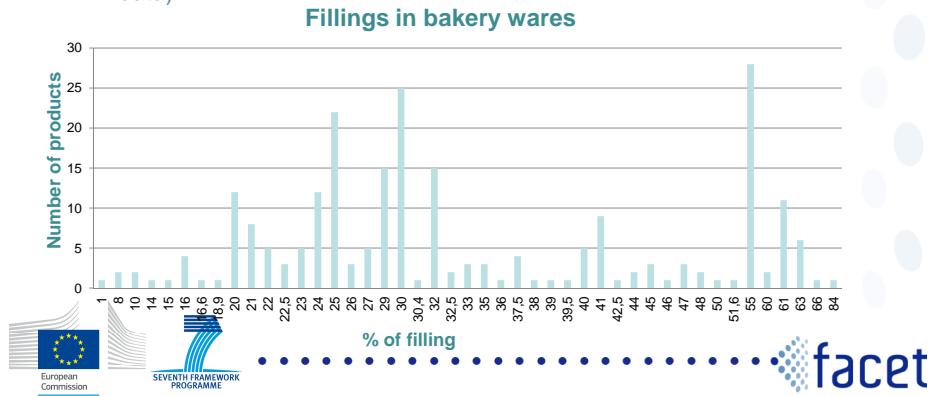
- Use of recipes for composite foods: decomposition of composite foods in ingredients then codification of the ingredients. Recipes given for each participating country
- Edible casings / edible cheese rind: taken into account with the consumption of sausages/cheeses respectively: fixed ratio (6% for casings / 10% for rinds)



ADDITIVES EXPOSURE ASSESSMENT

• FOOD CODIFICATION

- Coatings / fillings / toppings: taken into account with bakery wares: use of distributions of fillings... (distribution established on the basis of french data)



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ADDITIVES EXPOSURE ASSESSMENT

• CONCENTRATION DATA

- Data collected from the industry by FoodDrinkEurope for the 31 targeted additives
- Quality check: validation of data, verification of consistency, integration of conversion factor when necessary (phosphates expressed as P2O5, colours expressed as pigment)...
- Codification of data



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ADDITIVES EXPOSURE ASSESSMENT

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- **CONCENTRATION DATA**

- Work of the expert group to define:

- typical min and max → P25 and P75
- extreme min and max → P5 and P95
- % of products in the typical range

→ Fitted distribution of concentration reconstituted by the software



ADDITIVES EXPOSURE ASSESSMENT

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- **CONCENTRATION DATA**

- Use of maximum permitted level (MPL) for the remaining additives (Tier 2)
- Construction of a database with updated MPL



ADDITIVES EXPOSURE ASSESSMENT

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- **OCCURRENCE DATA**

- Definition: presence probability of an additive in a food category
- Calculations realized and analyzed at a high level of codification (e.g. non alcoholic beverages)
- Additives of the same “family” studied together: e.g. phosphates
- For a given food category / additive:

$$\text{occurrence} = \frac{\text{number of products containing the additive}}{\text{total number of products in the food category}}$$



ADDITIVES EXPOSURE ASSESSMENT

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- **OCCURRENCE DATA**

- Data gathered in WP6
 - Purchase of targeted food categories in the 8 participating countries (Finland, France, Hungary, Ireland, Italy, Poland, Portugal, UK)
 - Collection of data on food additives
 - Calculation of occurrences by country and at global level to avoid brand effect (1 major brand targeted by country)

→ Data available for some additives / some food categories only



ADDITIVES EXPOSURE ASSESSMENT

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- **OCCURRENCE DATA**

- Data gathered in GNPD
 - Use of Global New Product Database (marketing database)
 - Collection of data for the 8 selected countries, on a period of 3 years
 - Calculation of occurrences by country and at global level
- Data available for the 31 targeted additives / all food categories
- For the remaining additives (no data), default value = 100%, assuming that the additive is always present when permitted



ADDITIVES EXPOSURE ASSESSMENT

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- **OCCURRENCE DATA**

- Comparison of results: for the studied food groups (11 food groups) and the selected additives (31 additives)

	WP6	GNPD
Occurrence = 0%	82%	49%
0% < occurrence ≤ 5%	6%	45%
5% < occurrence	12%	6%

→ About 90% of the occurrences < 5%



ADDITIVES EXPOSURE ASSESSMENT

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- **OCCURRENCE DATA**

- Comparison of results: number of major discrepancies (difference > 10%):

	Number of comparisons	Number of discrepancies	% of discrepancies
At global level	341	20	5.9%
At country level	2635	174	6.6%

→ Difference between GNPD and WP6 due to sampling method:

Additive or food category not specifically targeted ⇒ no occurrence

Targeted additive / food category ⇒ Higher occurrence in WP6



ADDITIVES EXPOSURE ASSESSMENT

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- **OCCURRENCE DATA**

- Values retained for the final database : higher value

→ WP6 data in general

→ GNPD data

for missing combinations (additive; food category)

when WP6 occurrence is null

when WP6 occurrence < GNPD (2% of the data)



ADDITIVES EXPOSURE ASSESSMENT

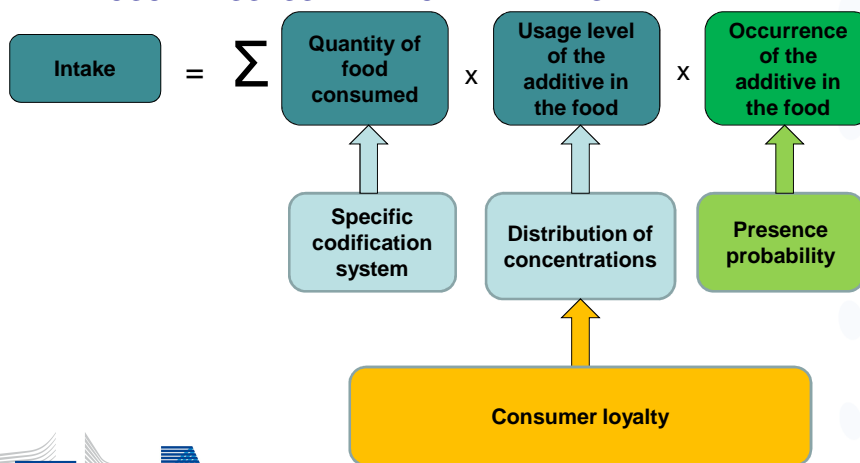
• CONSUMER LOYALTY

- Defined by food category
- Consumer loyalty = 0%: the consumer consumes indifferently all brands available for the food category
 - Random sampling of the concentration value for each eating occasion
- Consumer loyalty = 100%: the consumer consumes always the same unique brand for the food category
 - Only 1 random sampling of the concentration value by individual



ADDITIVES EXPOSURE ASSESSMENT

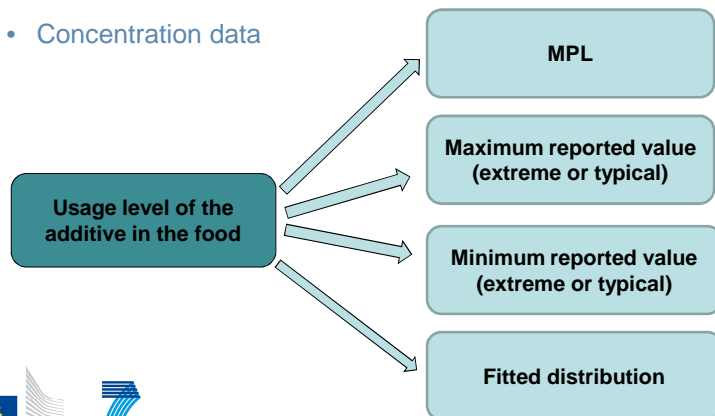
• EXPOSURE ASSESSMENT FOR ADDITIVES



ADDITIVES EXPOSURE ASSESSMENT

• EXPOSURE ASSESSMENT FOR ADDITIVES: OPTIONS GIVEN TO THE USER

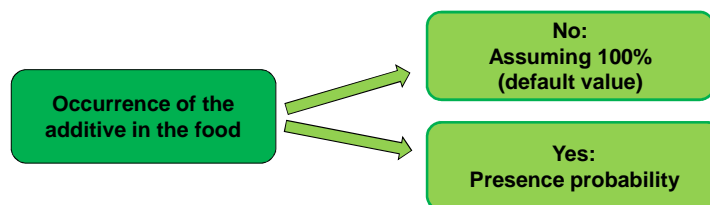
- Concentration data



ADDITIVES EXPOSURE ASSESSMENT

• EXPOSURE ASSESSMENT FOR ADDITIVES: OPTIONS GIVEN TO THE USER

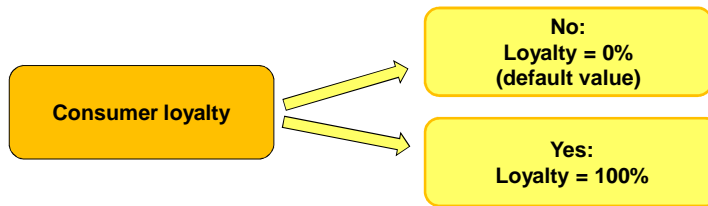
- Occurrence data: combination with all concentration options



ADDITIVES EXPOSURE ASSESSMENT

• EXPOSURE ASSESSMENT FOR ADDITIVES: OPTIONS GIVEN TO THE USER

- Consumer loyalty: possible only with the option « fitted distribution » (random sampling)



ADDITIVES EXPOSURE ASSESSMENT

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• CASE STUDY: E110 SUNSET YELLOW

- MPL for all food categories (no qs); concentration data provided by the industry; occurrence data → all options available
- ADI lowered by EFSA in 2009 & MPL revised in 2011
→ MPL updated in the database but not concentration data
- French consumption survey (INCA2)
- Population: children 3-10 years
- Comparison of results of calculation
 - ✓ using MPL vs fitted distribution
 - ✓ using occurrence data
 - ✓ using consumer loyalty

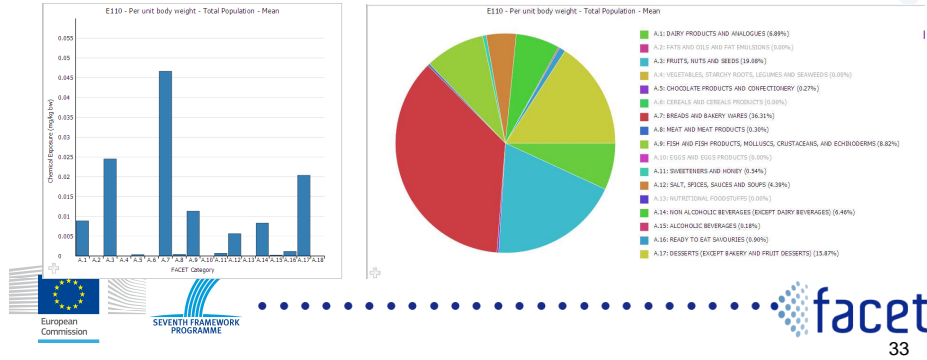
ADDITIVES EXPOSURE ASSESSMENT

• CASE STUDY: E110 SUNSET YELLOW (ADI= 1 mg/kg bw/d)

- Scenario 1 : MPL; no occurrences

	mean	P97.5
Intake (mg/kg bw/d)	0.1284 ± 0.003191	0.3997 ± 0.02547

Major contributor: bakery wares (36%)



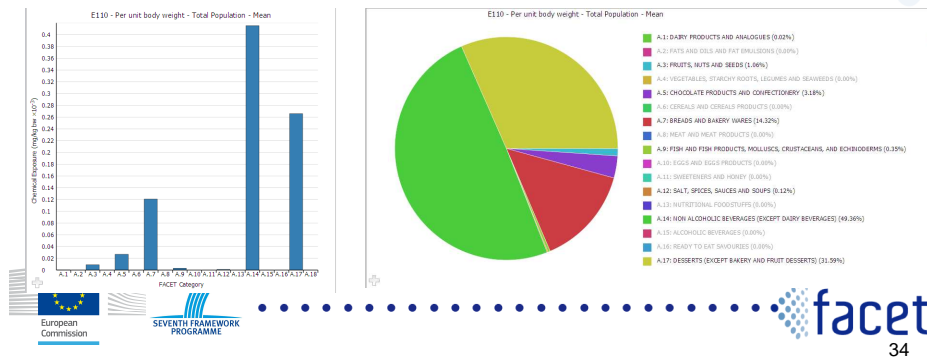
ADDITIVES EXPOSURE ASSESSMENT

• CASE STUDY: E110 SUNSET YELLOW (ADI= 1 mg/kg bw/d)

- Scenario 2 : MPL; with occurrences

	mean	P97.5
Intake (mg/kg bw/d)	0.0008413 ± 0.000116	0.008957 ± 0.001324

Major contributor: non alcoholic beverages (49%)



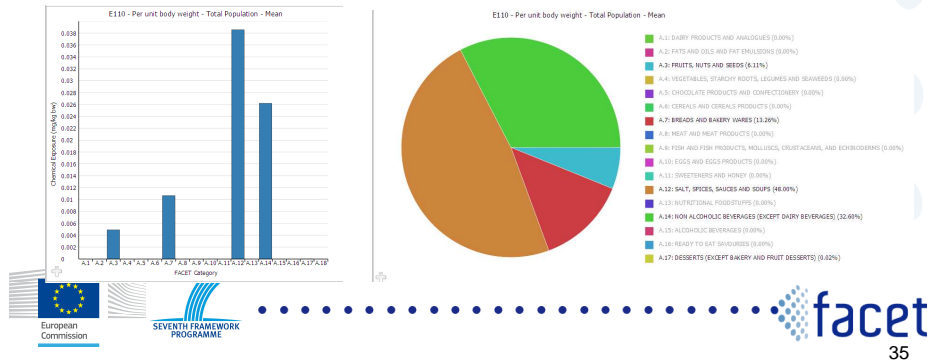
ADDITIVES EXPOSURE ASSESSMENT

• CASE STUDY: E110 SUNSET YELLOW (ADI= 1 mg/kg bw/d)

- Scenario 3 : fitted distribution; no occurrences

	mean	P97.5
Intake (mg/kg bw/d)	0.08037 ± 0.001943	0.2391 ± 0.01037

Major contributor: salt, spices, sauces and soups (48%)



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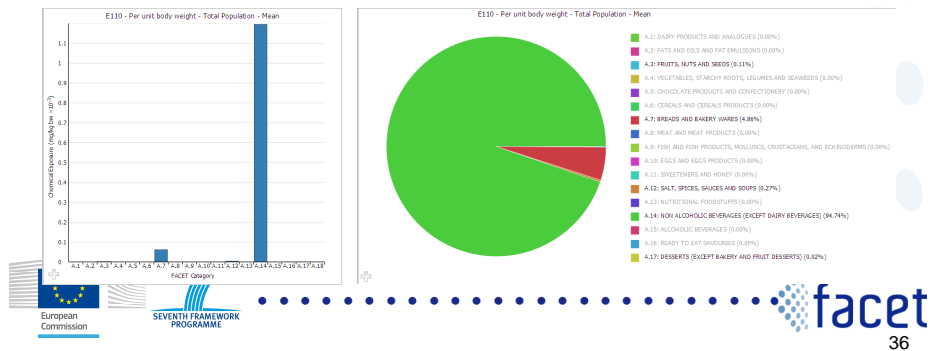
ADDITIVES EXPOSURE ASSESSMENT

• CASE STUDY: E110 SUNSET YELLOW (ADI= 1 mg/kg bw/d)

- Scenario 4 : fitted distribution; with occurrences

	mean	P97.5
Intake (mg/kg bw/d)	0.001261 ± 0.0001618	0.01289 ± 0.002058

Major contributor: non alcoholic beverages (95%)



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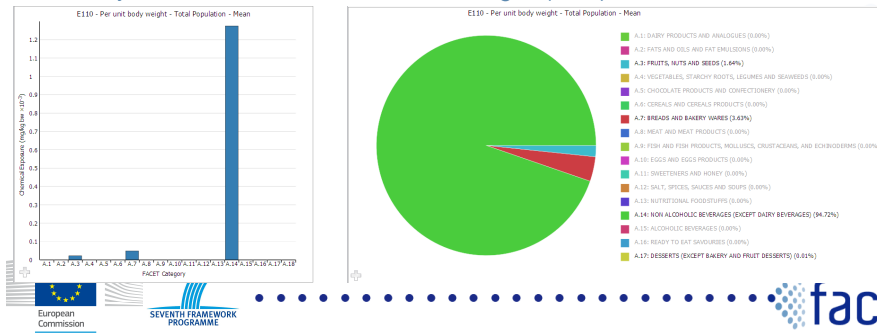
ADDITIVES EXPOSURE ASSESSMENT

• CASE STUDY: E110 SUNSET YELLOW (ADI= 1 mg/kg bw/d)

- Scenario 5 : fitted distribution; with occurrences: with brand loyalty

	mean	P97.5
Intake (mg/kg bw/d)	0.001346 ± 0.0002906	0.01289 ± 0.002058

Major contributor: non alcoholic beverages (95%)



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ADDITIVES EXPOSURE ASSESSMENT

• CASE STUDY: E110 SUNSET YELLOW (ADI= 1 mg/kg bw/d)

- Comparison of the scenarii (intake in mg/kg bw/d):

	Mean intake	P97.5	Major contributor
MPL	0.1284 ± 0.003191	0.3997 ± 0.02547	Bakery wares (36%)
MPL + occurrence	0.0008413 ± 0.000116	0.008957 ± 0.001324	Non alcoholic beverages (49%)
Fitted distribution	0.08037 ± 0.001943	0.2391 ± 0.01037	salt, spices, sauces and soups (48%)
Fitted distribution + occurrence	0.001261 ± 0.0001618	0.01289 ± 0.002058	Non alcoholic beverages (95%)
Fitted distribution + occurrence + brand loyalty	0.001346 ± 0.0002906	0.01289 ± 0.002058	Non alcoholic beverages (95%)



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ADDITIVES EXPOSURE ASSESSMENT

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- **CONCLUSION**

- User friendly tool
- Very flexible: allows an assessment at different levels of accuracy (MPL, fitted distribution, with or without occurrences...)
- Particularly adapted to a realistic exposure assessment: recommended for post market monitoring
- Potential users: DG Sanco
Members states (monitoring system for the consumption of additives: art 27 R 1333/2008)
EFSA

