Use of the EFSA Comprehensive European food consumption database in the risk assessment of GM foods

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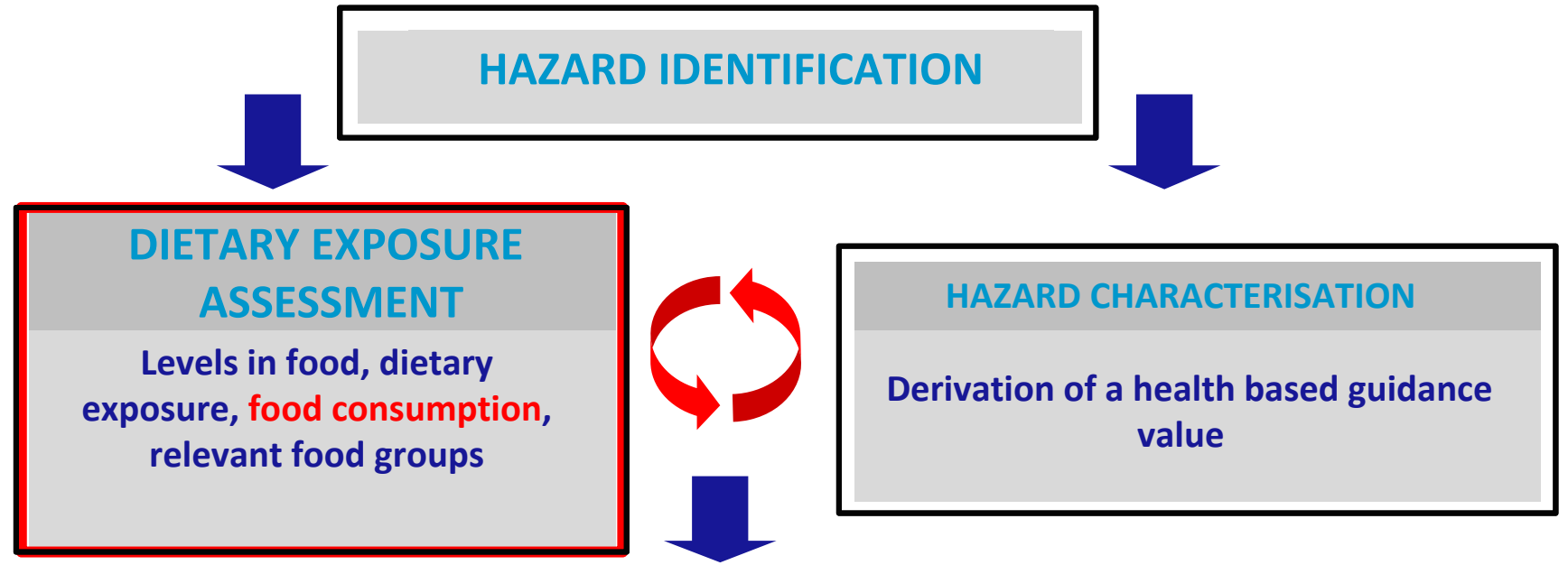
efsa
European Food Safety Authority

EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

The **EFSA** is the keystone of European Union (EU) **risk assessment** regarding food and feed safety.

RISK ASSESSMENT



GMO (COMPARATIVE) RISK ASSESSMENT

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 503/2013

of 3 April 2013

2. EXPOSURE ASSESSMENT — ANTICIPATED INTAKE/EXTENT OF USE

An estimate of the expected intake shall be an essential element in the risk assessment of genetically modified food and feed and shall also be required for the nutritional evaluation. Information shall be provided by the applicant on the intended function, the dietary role, and the expected level of use of the genetically modified food and feed in the EU. In addition, the expected range of concentrations of newly produced proteins or existing plant proteins deliberately modified in the genetically modified food(s) and feed(s) to be placed on the market shall be provided.

On the basis of representative consumption data for products obtained from the respective conventional plants, the applicant shall estimate the anticipated average and maximum intake of the genetically modified food and feed. Probabilistic methods may be used to determine ranges of plausible values rather than single values or point estimates. The applicant shall identify and consider particular groups of the EU population with an expected higher exposure and shall consider this higher exposure within the risk assessment. Any assumptions made in the exposure assessment shall be described. Recent developments in methodologies and appropriate consumption data shall be used. Data on import and production quantities may provide additional information for the intake assessment.

EFSA Comprehensive European food consumption database

GMO (COMPARATIVE) RISK ASSESSMENT

1.6. **Nutritional assessment**

1.6.1. *Objectives of the nutritional assessment*

The applicant shall provide a nutritional evaluation to demonstrate that:

(a) the introduction of the genetically modified food and feed into the market is not nutritionally disadvantageous to humans and animals, respectively. This evaluation shall include the relevance for the nutrition of newly expressed proteins, other new constituents, and changes in the levels of food and feed constituents, as well as potential alterations in the total diet of the consumer or the animal;

(b) unintended effects of the genetic modification that were identified or that may be assumed to have occurred based on the preceding molecular, compositional or phenotypic analyses, in accordance with Sections 1.2 and 1.3, have not adversely affected the nutritional value of the genetically modified food and feed.

EFSA Comprehensive European food consumption database

X

Food composition database

1.6.5. *Conclusion of the nutritional assessment*

The conclusion of the nutritional assessment of genetically modified food and feed shall indicate whether the genetically modified food and feed is nutritionally equivalent to its conventional counterpart, taking natural variations into account.

The applicant shall evaluate the result of the nutritional assessment in the light of anticipated intake of the genetically modified food and feed (see Section 2).

DIETARY EXPOSURE GM FOOD –PARTICULARITIES-

- Scenario 100% replacement
- Substances analysed in raw agricultural commodities (RACs)
- ACUTE and CHRONIC dietary exposure should be covered to properly characterise dietary exposure.
- Main focus on dietary exposure to **Newly Expressed Proteins (NEPs)**
- Endogenous constituents: **N-acetyl amino acids**
  Lectins

CONSUMPTION DATA

- Two main sources of consumption data used in GM applications:
  - **Pesticide Residues Intake MOdel (Primo) model**
  - **FAO's Food Balance Sheets (FBSs)**
- Direct link of the levels of particular constituents measured in RACs with the consumption data of RACs

CONSUMPTION DATA

- Some drawbacks associated to the use of Primo model and/or FBS:
  - FBSs are not appropriate for acute exposure
  - Primo model - developed in 2007
    - different methodology to disaggregate the consumption data
    - no possibility to exclude particular foods

EFSA statement in 2015 on the use of the EFSA Comprehensive Consumption database in GMO area

EFSA COMPREHENSIVE CONSUMPTION DATABASE

The **EFSA Comprehensive European food consumption database** contains data:

- 24-hour recall or dietary record method
- data collected at individual level
- most recent data within each country
- random sample at national level
  - different age classes, from infants to elderly
  - special population groups

EFSA COMPREHENSIVE CONSUMPTION DATABASE

Number of	
Member States	23
Dietary surveys	51
Population groups	128
Subjects	94,532
Different national food codes	127,912
Different standard food codes	1,578
Consumption records	10,470,332

EFSA COMPREHENSIVE CONSUMPTION DATABASE -AGE CLASSES-

Age class	Age range (years)	Number of surveys*	Number of countries*
Infants	0 – 1	6	6
Toddlers	1 – 3	11 (10)	10 (9)
Children	3 - 10	20 (18)	17 (15)
Adolescents	10 - 18	20 (17)	17 (14)
Adults	18 - 65	22 (17)	21 (16)
Elderly	65 - 75	16 (14)	15 (13)
Very elderly	> 75	14 (12)	14 (12)
Special population group		2 (2)	2 (2)

* In parenthesis only surveys with more than one day per subject

WHAT'S ON THE MENU IN EUROPE?

Aims to collect food consumption data at EU level:

- in different age classes (from infants to elderly)
- in all Member States (minimum 80,000 subjects)
- using methods allowing the comparison of the results from different Member States

GUIDELINE ON THE EU MENU METHODOLOGY

European Food Safety Authority

EFSA Journal 2014;12(12):3944

GUIDANCE OF EFSA

Guidance on the EU Menu methodology[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The availability of detailed, harmonised and high-quality food consumption data for use in dietary exposure assessments is a long-term objective of EFSA. In 2009, the EFSA guidance on "General principles for the collection of national food consumption data in the view of a pan-European dietary survey" was published, and a pan-European food consumption survey, also known as the "EU Menu", was launched. Based on the 2009 EFSA guidance, two EU Menu feasibility pilot studies and two methodological projects, EFSA has updated the former guidance document to cover the EU Menu methodology and therefore facilitate the collection of more harmonised food consumption data from all European Union Member States by the year 2020. This guidance has been developed by the EFSA Evidence Management Unit (DATA) and the EU Menu Working Group with Advisory Function, and has been endorsed by the EFSA Network on Food Consumption Data. It provides recommendations for the collection of more harmonised food consumption data among the EU Member States for use in dietary exposure assessments of food-borne hazards and nutrient intake estimations under the remit of EFSA's scientific panels. Food consumption information should be collected for two non-consecutive days. The 24-hour food diary method, followed by a computer-assisted personal or telephone interview (CAPI/CATI), should be used to collect data from infants and children. For all other age groups, the 24-hour dietary recall CAPI/CATI method should be used. The reported foods should be described in accordance with the EFSA FoodEx2 food classification system. A short food propensity questionnaire should be used to collect information on the consumption of some less frequently eaten foods and the consumption frequencies of food supplements. Information on the weight, height and physical activity levels of participants should also be collected in the survey.

KEY WORDS

EU Menu, pan-European dietary survey, food consumption, exposure assessment, 24-hour recall, food diary, harmonisation

European Food Safety Authority, 2014. Guidance on the EU Menu methodology. EFSA Journal 2014;12(12):3944, 77 pp. doi:10.2903/j.efsa.2014.3944

DIETARY ASSESSMENT METHOD

- **Children aged 3 months to 9 years**

The two non-consecutive one-day food diaries followed by an interview with the parent/caretaker.

- **Adolescents, adults and the elderly aged**

The 24-hour recall interview including two non-consecutive days.

- Interview administered face to face or via telephone.
- Use of different portion-size measurement aids
  - country-specific, age-appropriate and validated
- Food supplements included in the survey.
- Short food propensity questionnaire
- Questionnaire on physical activity levels

RUNNING EU MENU PROJECTS (ANNUAL SUPPORT SINCE 2011)

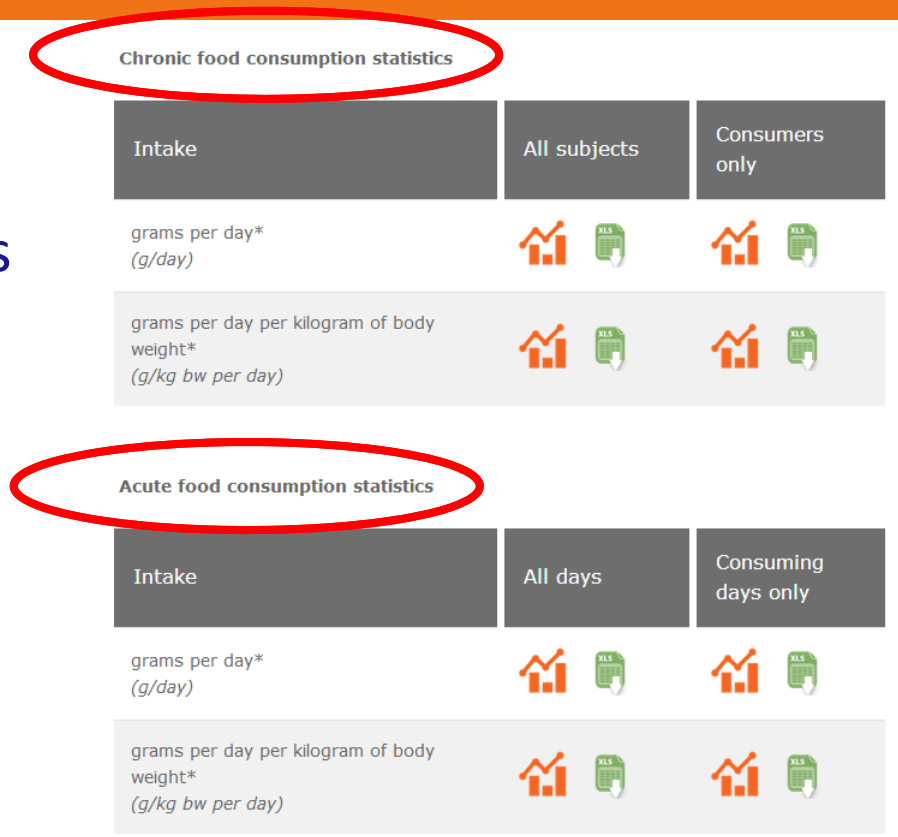
FOOD CONSUMPTION

EFSA Comprehensive European food consumption database

SUMMARY STATISTICS

Summary food consumption statistics (chronic and acute) available per:

- country,
- survey,
- age group (from infants to elderly)
- FoodEx1 food group (over 1,500)
- in g/day and g/kg bw per day.



http://www.efsa.europa.eu/en/food-consumption/comprehensive-database

NOW….

- BULGARIA, Nutrichild dietary survey

EFSA Comprehensive European food consumption database

	A	B	C	D	E	F	G	H	I	J
1									CONSUMERS ONLY	
2	Country of the dietary survey	Dietary survey	Population Class	Level 3 FoodEx Name	Level 4 FoodEx Name	Level 4 FoodEx Code	Number of consumers	Percentage of consumers	Mean consumption in grams/day	95th percentile of consumption in grams/day
3	Country	Survey	Pop Class	Foodex L3	Foodex L4	Metrics	Nr Consume	% Consumer	Mean	P95
743	Bulgaria	NUTRICHILD	Infants	Corn milling products	Corn flour	A.01.000072	1	0,1%	15,00	15,00
786	Bulgaria	NUTRICHILD	Infants	Sweet corn (Zea mays var. saccharata)	Sweet corn (Zea mays var. saccharata)	A.01.000349	2	0,2%	32,50	35,00
958	Bulgaria	NUTRICHILD	Infants	Corn chips	Corn chips	A.01.001880	35	4,1%	13,87	50,00
960	Bulgaria	NUTRICHILD	Infants	Popcorn	Popcorn	A.01.001883	2	0,2%	8,75	12,50
977	Bulgaria	NUTRICHILD	Toddlers	Corn milling products	Corn flour	A.01.000072	1	0,2%	18,00	18,00
029	Bulgaria	NUTRICHILD	Toddlers	Sweet corn (Zea mays var. saccharata)	Sweet corn (Zea mays var. saccharata)	A.01.000349	1	0,2%	5,00	5,00
240	Bulgaria	NUTRICHILD	Toddlers	Corn chips	Corn chips	A.01.001880	82	19,2%	17,23	40,00
242	Bulgaria	NUTRICHILD	Toddlers	Popcorn	Popcorn	A.01.001883	14	3,3%	18,21	37,50
258	Bulgaria	NUTRICHILD	Other children	Corn milling products	Corn flour	A.01.000072	1	0,2%	18,00	18,00
307	Bulgaria	NUTRICHILD	Other children	Sweet corn (Zea mays var. saccharata)	Sweet corn (Zea mays var. saccharata)	A.01.000349	4	0,9%	33,28	75,00
527	Bulgaria	NUTRICHILD	Other children	Corn chips	Corn chips	A.01.001880	63	14,5%	18,33	35,00
529	Bulgaria	NUTRICHILD	Other children	Popcorn	Popcorn	A.01.001883	8	1,8%	21,25	50,00
1874										

NOW….

EFSA Comprehensive European food consumption database

- **Use of EFSA Comprehensive Consumption database (summary statistics) allows…**
  - Assessment chronic and acute dietary exposure (screening tool)
  - Extensive coverage of European population
  - Selection of food commodities relevant for exposure
  - Focus on vulnerable population groups (based on age, consumption habits, life status)
  - However…

NOW….

- When linking the EFSA Comprehensive database with data from RACs **PROCESSING/RECIPES** is **NOT** considered

EFSA Comprehensive European food consumption database

DOSSIER

NEP or other constituents

NOW….

- **Use of EFSA Comprehensive Consumption database (summary statistics)**
  - It could be necessary to incorporate the use of **processing factors & recipes** when estimating dietary exposure.

  - On-going application: a **list of factors** provided to applicant to estimate dietary exposure (**HISTORY of SAFE CONSUMPTION**).

FUTURE….

Compounds measured in RAC

EFSA RAC DATABASE

EFSA Comprehensive European food consumption database

- **Development of EFSA RAC database from the Comprehensive database using standard methodology to disaggregate the consumption data.**

FOOD AS CONSUMED VS. RAC

Raw Agricultural Commodity (RACs)

Conversion factors

Food as consumed

List of ingredients and proportions

Individual ingredient

GMO – DIETARY EXPOSURE ASSESSMENT

Day 1	Day 2	Day 3	Average consumption					Chronic exposure
40 g	40 g	40 g	160/3= 53.3 g	2.6	140 g	X	3.5 µg/kg	4,9 µg
	50 g		50/3 = 16,6 g	0,4 / 1,2	24 g	X	3.5 µg/kg	0,08 µg
75 g	40 g		75/3 =25 g	1,08	27 g	X	3.5 µg/kg	0,09 µg

EFSA RAC DATABASE | Dossier | 5,07 µg

75 kg

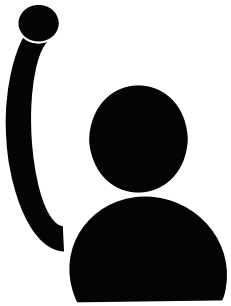
3.5 µg/kg

5,07 µg/75 kg = 0,068 µg/kg bw day

THANKS!!

https://www.efsa.europa.eu/en/panels/gmo

QUESTIONS ?



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