Dietary exposure assessment to genetically modified foods

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EFSA technical meeting with applicants on GMOs

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www.efsa.europa.eu

GMO FOOD & FEED SAFETY SSESSMENT

Genetic modification processes

Over-expressing new genes to a crop

Silencing / attenuating endogenous genes

Production of newly expressed proteins

Production of *de novo* constituents

Altered level of endogenous constituents

FF safety assessment

	Bioinformatics	*in vitro* tests	*in vivo* tests
Toxicology			
Allergenicity / adjuvanticity			
Nutrition			

FF post-market monitoring

DIETARY EXPOSURE ASSESSMENT TO GM FOODS

Objectives:

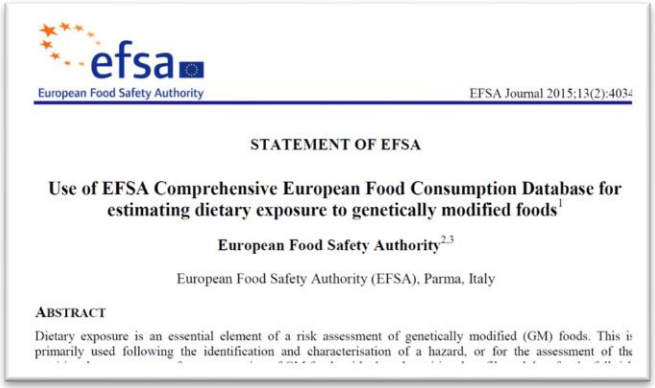
- **To assess the risk of adverse health effects to the consumers as a consequence of a specific exposure to GM foods**

→ *Dietary exposure is an essential element of the risk assessment on GM foods.*

What kind of substances in GM foods are under consideration?

- **newly expressed proteins**
- **other constituents with altered levels**
  - occurring *de novo* in GM foods (absent in its conventional counterpart)
  - higher or lower content in GM foods (than in its conventional counterpart)

http://www.efsa.europa.eu/en/efsajournal/doc/4034.pdf



European Food Safety Authority EFSA Journal 2015;13(2):4034

STATEMENT OF EFSA

Use of EFSA Comprehensive European Food Consumption Database for estimating dietary exposure to genetically modified foods[1]

European Food Safety Authority[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Dietary exposure is an essential element of a risk assessment of genetically modified (GM) foods. This is primarily used following the identification and characterisation of a hazard, or for the assessment of the

DIETARY EXPOSURE ASSESSMENT TO GM FOODS

Dietary exposure scenario:

- **Replacement of conventional foods or food ingredients with the GM substances under consideration**

→ *Conservative to ensure safety – full replacement*

→ *With reflection to reality practices – partial replacement & foods as consumed*

Consumption data sources

- **Determined by the purpose of the assessment**
  - Disappearance data
  - Consumption survey

The anticipated dietary intake is estimated on the basis of representative consumption data. Data on import and production quantities may provide additional information for the intake assessment (Regulation (EU) No 503/2013).

Concentration / occurrence data sources

- **Determined by the applicant**
  - Protein content
  - Nutrient content

Note that occurrence data are discussed only in generic terms in the EFSA statement.

http://www.efsa.europa.eu/en/efsajournal/doc/4034.pdf

DIETARY EXPOSURE ASSESSMENT TO GM FOODS

When a dietary exposure is performed?

- during hazard identification / characterisation
- during risk determination

How it is calculated?

Dietary intake estimate = [substance in foods] **x** amount of foods consumed

Types of the substances
- hazardous compounds
- Nutrients

Source of concentration data
- Raw agriculture commodity
- Processed fractions
- Foods as consumed

Food classification

Matching concentration source to food items surveyed

Exposure scenario in dietary survey:
- acute or chronic exposure

Consumer:
- general or vulnerable population
- average, high or low consumers

FOOD RECIPES, AS CONSUMED AND RAC

Raw Agricultural Commodity (RACs)

Food as consumed

List of ingredients and proportions

Conversion factors

Individual ingredient

General rule: the source of concentration data should be specified in the exposure assessment, and the choice of such source should be justified.

DIETARY EXPOSURE ASSESSMENT TO GM FOODS

EFSA Comprehensive Database

- **The only available single source of consumption data covering the majority of EU Member States in one database**

  EFSA has the right to use raw individual food consumption data for carrying out risk assessments and other scientific analyses within the activities related to EFSA's mandate. A formal authorization from the data provider must be requested for any other use of the data.

- **Only gives summary statistics for public access**
- **Kept to be country-specific**
- **Consumption data are collected continuously, resulting in periodic new release**
  - 1st release in 2010
  - 2nd release in 2015

MAGNITUDE OF THE DATABASE

Number of	1st release	2nd release
Dietary surveys	32	51
Member States	22	23
Subjects	66,492	94,532
Different foods	63,495	127,912
Different FoodEx1 codes	1,504	1,578
Different FoodEx2 codes	-	1,787
Consumption records	6,309,489	10,470,332

Courtesy from DATA unit

EFSA COMPREHENSIVE EUROPEAN FOOD CONSUMPTION DATABASE

The EFSA Comprehensive European Food Consumption Database

http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb

The Comprehensive Food Consumption Database is a source of information on food consumption across the European Union (EU). It contains detailed data for a number of EU countries. The database plays a key role in the evaluation of the risks related to possible hazards in food in the EU and allows estimates of consumers' exposure to such hazards, a fundamental step in EFSA's risk assessment work. The database will also be relevant in future for other fields of EFSA's work, such as the assessment of nutrient intakes of the EU population.

- Guidance for the use of the EFSA Comprehensive European Food Consumption Database
- Survey Details (3.3 Mb)

Chronic food consumption statistics in grams per day* (g/day)

- All subjects: PDF (8.1 Mb) | ZIP (14.48 MB)
- Consumers only: PDF (6.7 Mb) | ZIP (8.16 MB)

Chronic food consumption statistics in grams per day per kilogram of body weight* (g/kg bw per day)

- All subjects: PDF (8.3 Mb) | ZIP (15.96 MB)
- Consumers only: PDF (7.4 Mb) | ZIP (13.42 MB)

Acute food consumption statistics in grams per day* (g/day)

- All days: PDF (6.7 Mb) | ZIP (8.33 MB)
- Consuming day only: PDF (6.7 Mb) | ZIP (8.83 MB)

FOOD CLASSIFICATION - FOODEX

FoodEx

Food list: ~1,700 end-points
(food names, generic food names)

Hierarchical structure, up to 4 levels,
not equal branching
- 20 main food groups
- 2nd level composed by ~160 items

Structured on child-parent relation

LanguaL
- an international framework for food description!

Courtesy from DATA unit

FOOD CLASSIFICATION - FOODEX

FoodEx name example:

Level 1 - Milk and dairy products

FoodEx Level 2	FoodEx Level 3 – Liquid milk	FoodEx Level 4 – Cow milk
Liquid milk	Liquid milk (unspecified)	Cow milk, > 4% fat (inc Channel Island milk)
Milk based beverages	Cow milk	Cow milk, 3 - 4% fat (whole milk)
Concentrated milk	Sheep milk	Cow milk, 1 - 2.9% fat (semi-skimmed milk)
Whey and whey products	Buffalo milk	Cow milk, < 1% fat (skimmed milk)
Cream and cream products	Goat milk	
Fermented milk products	Horse milk	
Milk derivatives	Ass milk	
Cheese	Camel milk	
Milk and milk product imitates	Human milk	

FOOD CLASSIFICATION - FOODEX

FoodEx name example: maize milling products

Country	Survey	Pop Class	Foodex L3	Foodex L4	Code
Austria	Austrian Study on Nutritional Status 2010-12 - Children	Other children	Corn milling products	Corn semolina	A.01.000073
Austria	Austrian Study on Nutritional Status 2010-12 - Children	Other children	Corn milling products	Corn starch	A.01.000074
Belgium	Diet National 2004	Adolescents	Corn milling products	Corn semolina	A.01.000073
Belgium	Diet National 2004	Adolescents	Corn milling products	Corn starch	A.01.000074
United Kingdom	National Diet and Nutrition Survey	Adults	Corn milling products	Corn flour	A.01.000072
United Kingdom	National Diet and Nutrition Survey	Adults	Corn milling products	Cornmeal	A.01.000075

HARMONISED FOOD CONSUMPTION DATA BY 2020

EFSA Harmonisation Collaboration Food Consumption EuropeanFoodSafetyAuthority Using EUMenu Pilot

EFSA Guidance document on a pan-European dietary survey; EFSA EU Menu proposal 2009

Four pilots 2010-2014; Update of the EFSA Guidance document 2014

Annual support for national dietary surveys 2011-2016

Harmonised food consumption data in EFSA 2015-2020

BASIC REQUIREMENTS FOR THE NEW SURVEYS

- Food consumption data from the most recent data within the country
  - collected at individual level
  - 24-hour recall or dietary record method
  - for at least two days;
- Random sample representing the target population group at national level
  - Different ages classes
  - Special population groups
- Foods coded in FoodEx2

Courtesy from DATA unit

AN EXAMPLE OF DIETARY SURVEY

Country	Survey	Subjects	Age range	Method	Days	Period
Slovakia	SK MON 2008	2761	19 - 59	24-hours dietary recall	1	2008 - 2008
Slovenia	CRP 2008	410	18 - 65	24-hours dietary recall	1	2007 - 2008
Spain	enKid	382	1 - 14	24-hours dietary recall	2	1998 - 2000
	NUT INK05	1050	4 - 18	24-hours dietary recall	2	2004 - 2005
	AESAN_FIAB	1068	17 - 60	24-hours dietary recall	2	2009 - 2009
	AESAN	418	18 - 60	Food record	3	1999 - 2001
Sweden	NFA	2495	3 - 18	24-hours dietary recall	4	2003 - 2003
	Riksmaten 1997-98	1210	18 - 74	Food record	7	1997 - 1998
	Riksmaten 2010	1797	18 - 80	Web-based dietary record	4	2010 - 2011
United Kingdom	DNSIYC_2011	2683	0.33 - 1.5	Food record	4	2011 - 2011
	NDNS	1724	19 - 64	Food record	7	2000 - 2001
	NDNS Rolling Programme Years 1-3	3073	1.5 -	Food record	4	2008 - 2011

Courtesy from DATA unit

EU MENU PROJECTS

Project started in	Dietary survey on	
	Children	Adults
2011	France	France
	Estonia	
2012	Latvia	Latvia
	Netherlands	Netherlands
	Portugal	Portugal
	Spain	Estonia
2013	Belgium	Belgium
	Cyprus	Cyprus
	Romania	Greece
		Spain
2014	Hungary	Hungary
	Italy	Italy
	Slovenia	Slovenia
	Greece	Austria
		Romania
2015	?	?
Number of dietary surveys	13	14

Courtesy from DATA unit

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 parehthesis only surveys with more than one day per subject

Courtesy from DATA unit

DIETARY EXPOSURE ASSESSMENT TO GM FOODS

Implementing Regulation (EU) No 503/2013 requests that the anticipated dietary intake is estimated on the basis of representative consumption data. Data on import and production quantities may provide additional information for the intake assessment.

Can only EFSA comprehensive database be used to estimate dietary exposure for assessing the safety of GM foods?

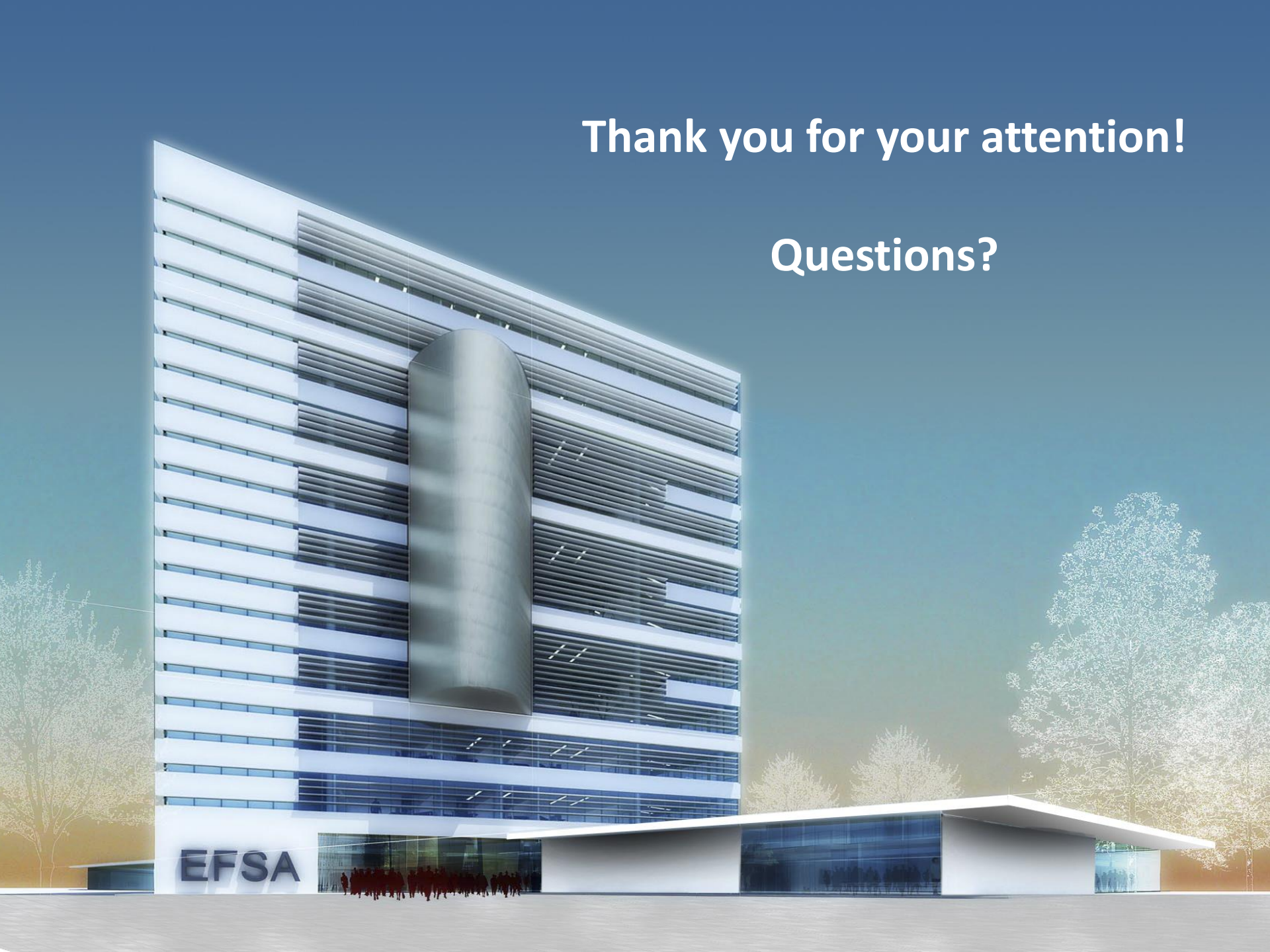
- **No, depending on the purpose of the RA question.**
  - **When crude estimate is used, EFSA database is a good starting point,** e.g. to know if a dose tested in toxicology tests covers human dietary exposure
  - **When refined estimate is needed, the estimate should be based on individual consumption (e.g., from national dietary survey). The EFSA database can be used to identify alternative datasets for countries with a comparable consumption pattern.**

DIETARY EXPOSURE ASSESSMENT TO GM FOODS

In a nutshell: exposure scenario depends on the RA question

A simplified example

Toxicological assessment	Nutritional assessment
Hazardous substances	Nutrients
Acute or chronicle dietary exposure	Chronicle or life-time dietary exposure
High consumer	Low, average and high consumers
crude estimate and refinement	Refined (accurate and realistic) estimate
Protection to EU general and vulnerable population	
When the goal is to assess the safety and adequacy of nutrient intake or to determine the possibility of harm, the concentration of the substance under consideration should be quantified from foods as consumed, as this represents more realistic exposure conditions.	



Thank you for your attention!

Questions?