



EFSA Principles and Tools related to Risk Assessment of Food Enzymes

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RISK ASSESSMENT FRAMEWORK ON FOOD ENZYME

2008.12.16

Reg. (EC) 1331/2008: **common authorisation procedure**

Reg. (EC) 1332/2008: **food enzyme**

Reg. (EC) 1333/2008: food additives

Reg. (EC) 1334/2008: flavourings

2009.7.23

EFSA GD on submission of food enzyme dossier

2011.3.10

Reg. (EU) 234/2011: **implementing Reg. (EC) 1331/2008 on content and procedure**

2012.6.27

Reg. (EU) 562/2012 : **specific data requirement**

2011.7.8 - **Explanatory note (v1)**

2013.1.17 – 1st EFSA Info session

2014.4.7 - Explanatory note (v2)

2014.5.14 – 1st Sci Op

2014.5.27 – 2nd EFSA Info session

2014.7.25 – three more Sci Op

2014.11.14 – Explanatory note (v3)

2015.2.18 – the 5th Sci Op


2015.3.11

deadline for receiving applications

2016.2.3 – 3rd EFSA Info session

Subsequent steps: Public consultation, revision of the statement, adoption by CEF Panel, publication

DEFINITIONS from REGULATION (EC) NO 1332/2008

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- **'Food Enzyme'** means a **product** obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms: containing one or more enzymes capable of catalyzing a specific biochemical reaction;
 - **'Food Enzyme preparation'** means a **formulation** consisting of one or more food enzymes in which substances such as food additives and/or other food ingredients are incorporated to facilitate their storage, sale, standardisation, dilution or dissolution.

CEF PANEL GUIDANCE ON FOOD ENZYMES, 2009

'Potential human exposure to the food enzyme and to any other constituent or by-product of concern should be assessed considering all proposed uses.'

- Food Enzyme is a **mixture of different substances**
 - Food enzyme
 - Other constituents (source organisms)
 - By-product of concern (manufacturing process, reaction and fate in food)
- The exposure assessment is referring to the mg of Total Organic Substances (TOS) contained in the Food Enzymes as the main sources of any potential hazard.
- Route of exposure: oral intake
 - If information from other routes of exposure is available, they should be included during problem formulation.
- All proposed uses
 - Defined by each applicant in the submitted dossier
 - Relevant food groups





DIETARY EXPOSURE ASSESSMENT

Needs of exposure estimation

- during hazard identification / characterisation
- during risk determination
- crude vs refined estimation through a tier approach

Basic formula

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

Source of concentration data

- Substrates
- Converted food ingredients / foods
- Foods as consumed

Types of the substances

- hazardous compounds
- nutrients


from dossiers



Food classification

Matching concentration source to food items surveyed


existing tools from EFSA

Source of consumption data

- Food ingredients
- Foods as consumed

Exposure scenario:

- acute or chronic exposure

Consumer:

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



EFSA COMPREHENSIVE EUROPEAN FOOD CONSUMPTION DATABASE

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

Home > Science > Data collection & analysis

Data collection and analysis

Food consumption

Comprehensive database

Biological hazards

Chemical contaminants

Chemical residues









Standardisation

Toolbox - how to submit data






Methodology

• [Survey Details](#) 

Chronic food consumption statistics

Intake	All subjects	Consumers only
grams per day* (g/day)	 	 
grams per day per kilogram of body weight* (g/kg bw per day)	 	 

Acute food consumption statistics

Intake	All days	Consuming days only
grams per day* (g/day)	 	 
grams per day per kilogram of body weight* (g/kg bw per day)	 	 

Previous work on food consumption

In 2008 EFSA published its Concise Database that gathered data on food consumption for adults in Europe. Data were elaborated at country level according to both broad categories (e.g. milk and dairy-based products) and subcategories (e.g. cheese). It served as a starting point for EFSA to develop the EFSA Comprehensive European Food Consumption Database.

EFSA COMPREHENSIVE EUROPEAN FOOD CONSUMPTION DATABASE

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

EU MENU PROJECTS



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

MAGNITUDE OF THE DATABASE

Number of	1 st release	2 nd 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

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

FOODEX SYSTEM

Four hierarchical systems of food names, structured on child-parent relation: L1 (20), L2 (140), L3 (ca. 1300), L4 (ca. 1700).

Table 1: Main food groups of the FoodEx classification according to the number of subgroups for each of the three hierarchical levels

No	Main food group	Number of subgroups at		
		Level 2	Level 3	Level 4
1	Grains and grain-based products	7	59	247
2	Vegetables and vegetable products (including fungi)	16	133	0
3	Starchy roots and tubers	2	16	0
4	Legumes, nuts and oilseeds	5	52	0
5	Fruit and fruit products	9	120	53
6	Meat and meat products (including edible offal)	12	92	39
7	Fish and other seafood (including amphibians, reptiles, snails and insects)	6	65	0
8	Milk and dairy products	9	234	59
9	Eggs and egg products	2	12	0
10	Sugar and confectionary	7	59	12
11	Animal and vegetable fats and oils	6	41	0
12	Fruit and vegetable juices	8	67	0
13	Non-alcoholic beverages (excepting milk based beverages)	5	22	36
14	Alcoholic beverages	7	31	0
15	Drinking water (water without any additives except carbon dioxide; includes water ice for consumption)	4	2	0
16	Herbs, spices and condiments	10	124	0
17	Food for infants and small children	6	26	0
18	Products for special nutritional use	5	35	0
19	Composite food (including frozen products)	11	54	22
20	Snacks, desserts, and other foods	3	16	0
Total		140	1260	468

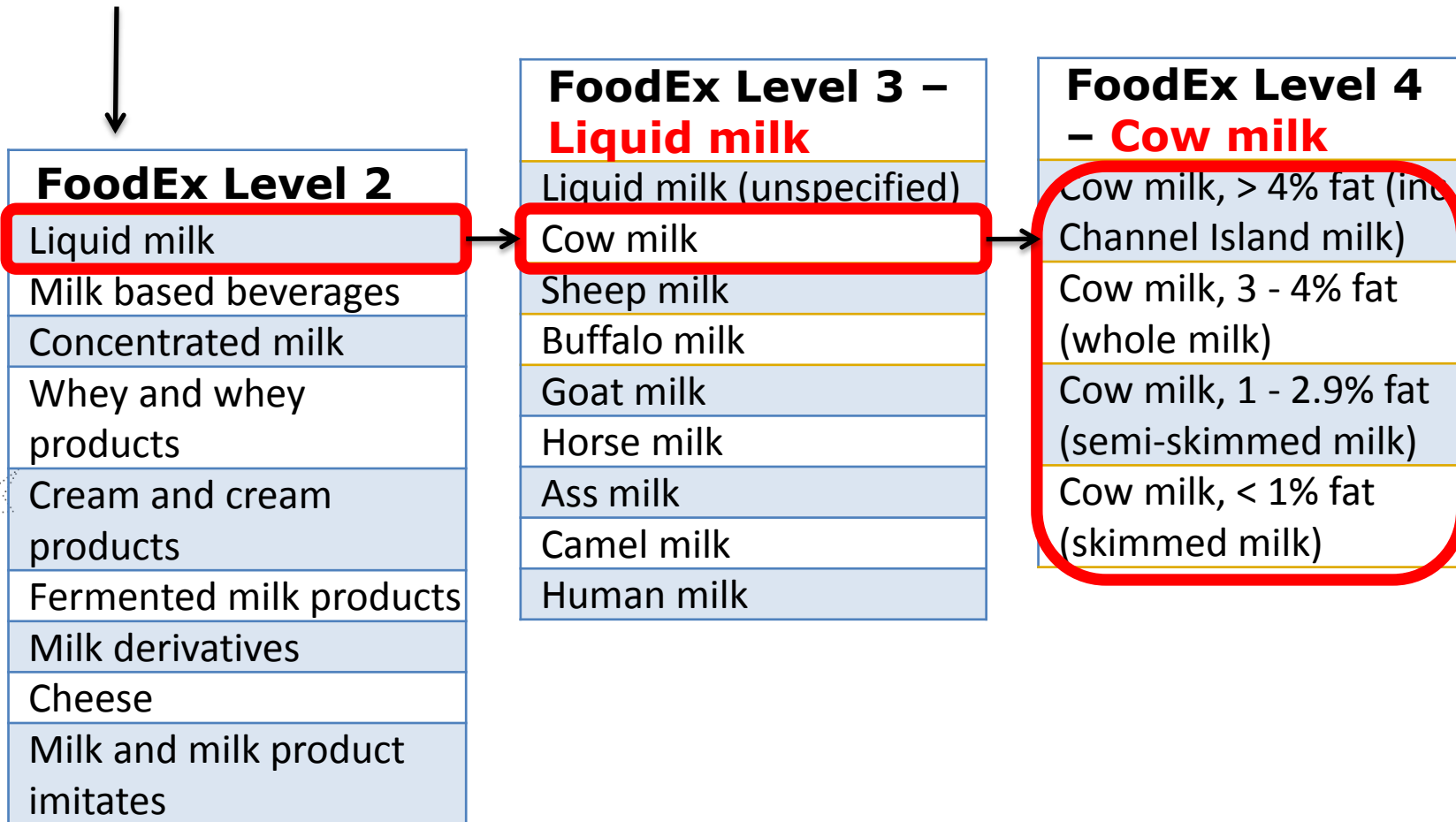
http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1970.pdf

<http://www.efsa.europa.eu/en/supporting/pub/804e>

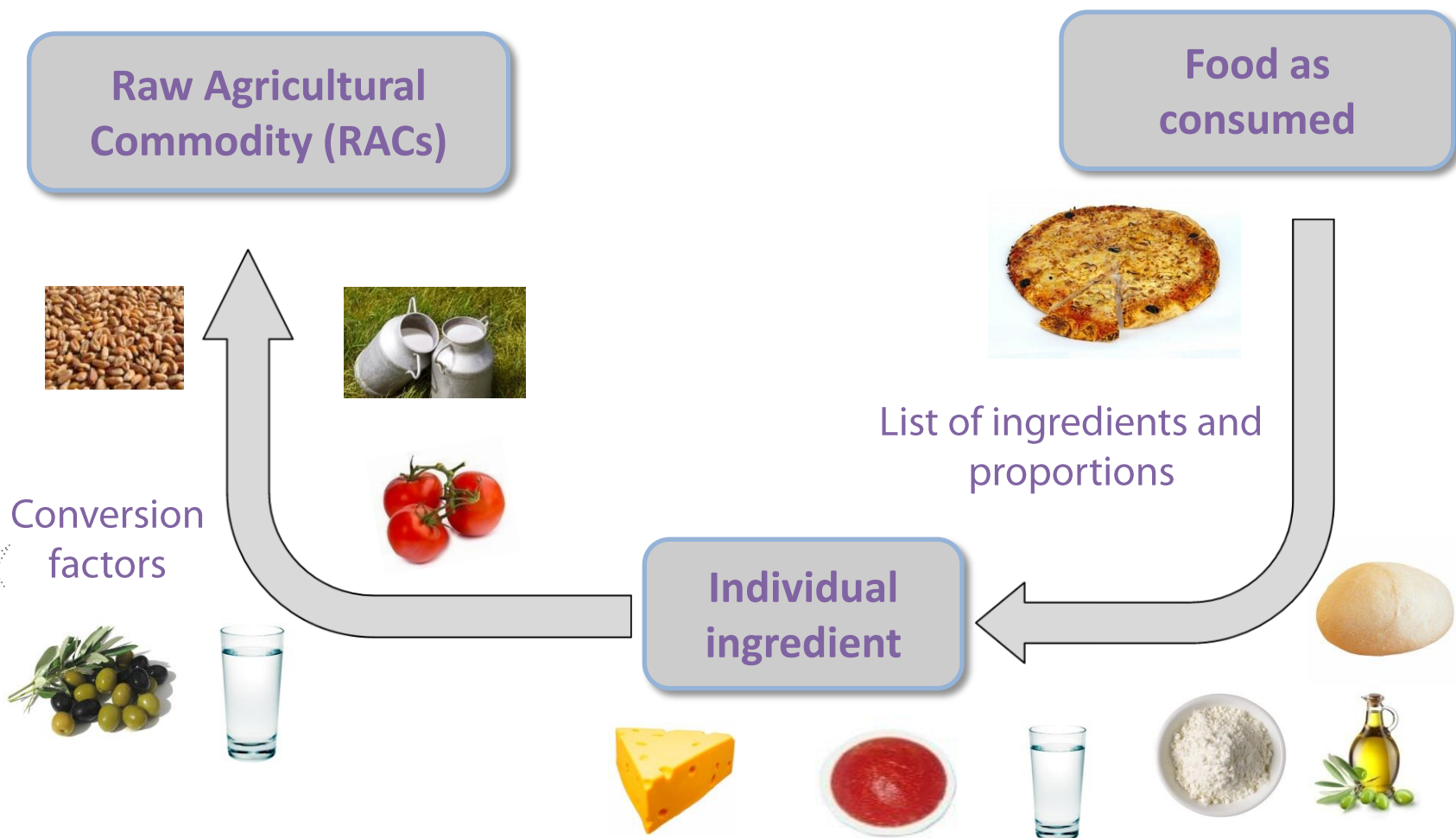
FOOD CLASSIFICATION - FOODEX

FoodEx name example:

Level 1 - Milk and dairy products



FOOD RECIPIES, AS CONSUMED AND RAC



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



NEXT TOPIC

- ✓ Food Enzyme Definition and CEF Panel remit
- ✓ The EFSA Comprehensive Consumption DB
- ✓ The EFSA FOODEX System

QPS - Qualified Presumption of Safety

QPS - QUALIFIED PRESUMPTION OF SAFETY

*EFSA is requested to assess the safety of a broad range of biological agents in the context of notifications for market authorisation as sources of food and feed additives, **enzymes** and plant protection products.*



European Food Safety Authority

EFSA Journal 2015;13(6):4138

SCIENTIFIC OPINION

**Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA.
2: Suitability of taxonomic units notified to EFSA until March 2015¹**

EFSA Panel on Biological Hazards (BIOHAZ)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

This scientific output, published on 27 October 2015, replaces the previous version published on 25 June 2015.*

ABSTRACT

EFSA is requested to assess the safety of a broad range of biological agents in the context of notifications for

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4138.pdf

QPS - QUALIFIED PRESUMPTION OF SAFETY (2)

Specific information should be submitted supporting that the MO can be considered as under QPS status



Susceptibility to antibiotics

Proof that the specific MO is not antibiotic resistant



QPS
species/genus

Certificate of public deposit

Proof that the specific MO maintains its identity



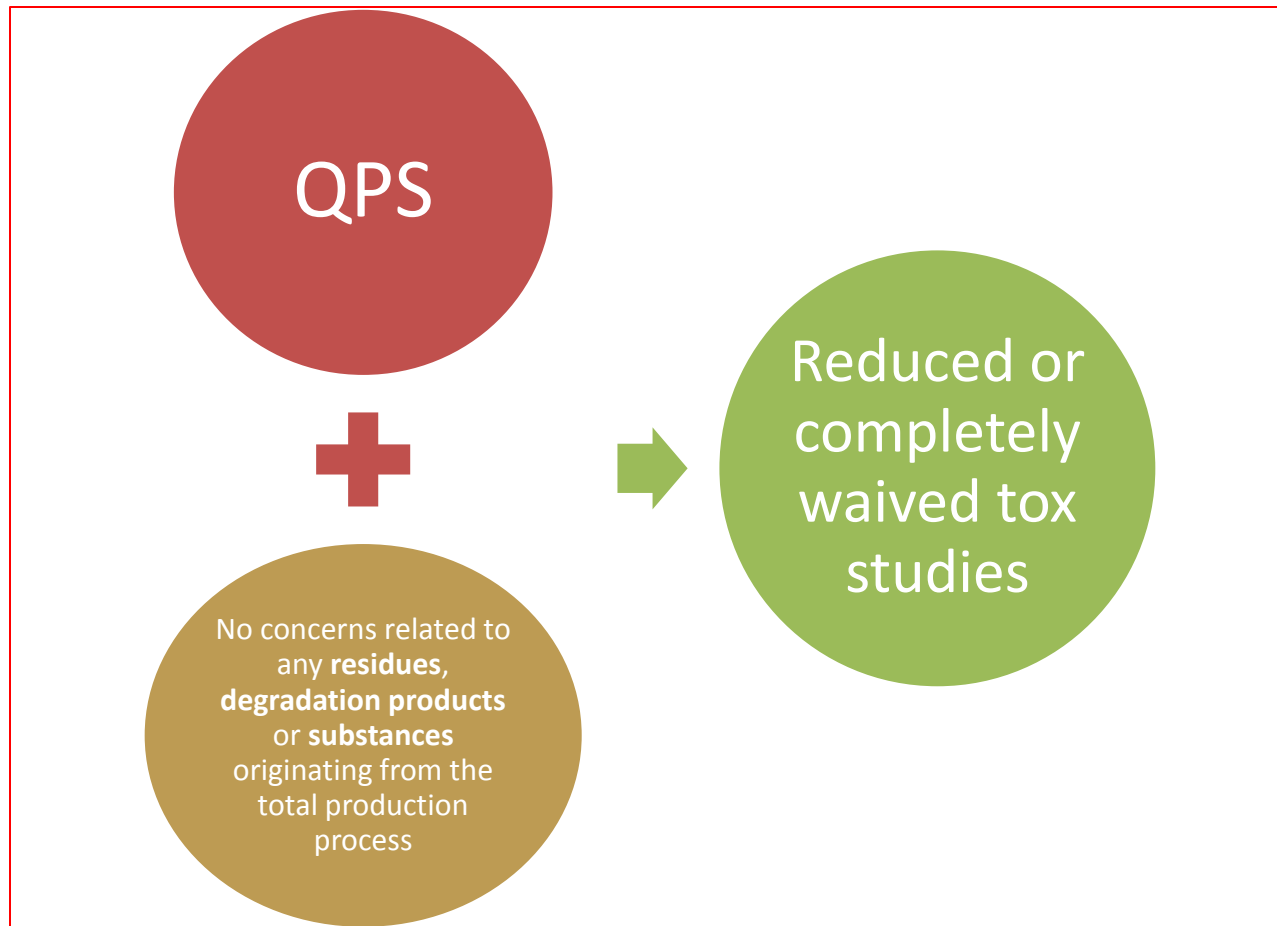
Full taxonomic identity

Proof that the specific MO can be classified under specific QPS species or genus

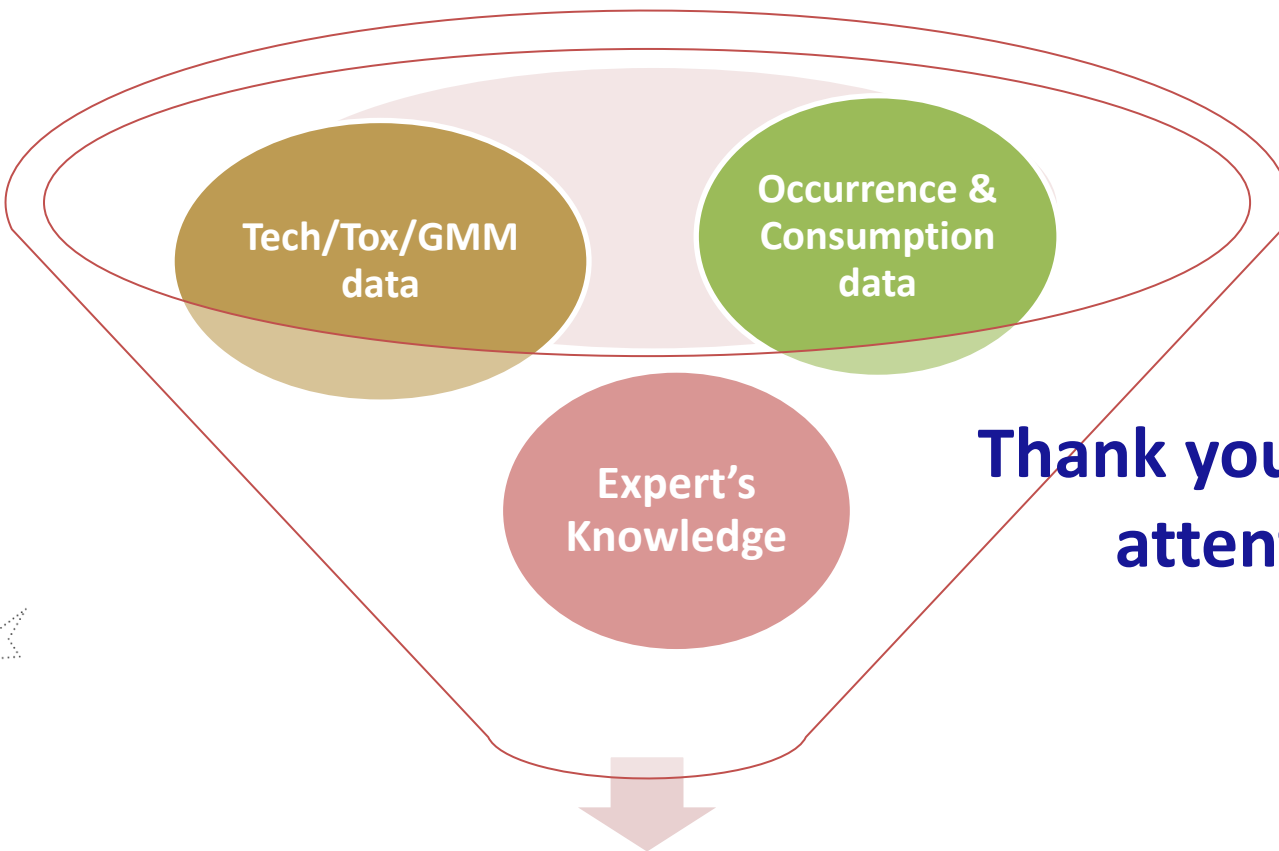


QPS - QUALIFIED PRESUMPTION OF SAFETY

QPS and Food Enzymes



DATA + EXPERTISE = RISK ASSESSMENT



**Thank you for your
attention!**

Risk Assessment

