Technical stakeholder event, 3 December 2019

A novel approach to dietary exposure

Protocol for the exposure assessment as part of the safety assessment of sweeteners under the food additives re-evaluation programme

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DATA Unit

Trusted science for safe food

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Sweeteners, to be re-evaluated under Regulation (EC) No 257/2010

E Number	Food additive(s)		Substance
E 420	Sorbitols	E 420 (i) E 420(ii)	Sorbitol Sorbitol syrup
E 421	Mannitols	E 421(i) E 421(ii)	Mannitol by hydrogenation Mannitol manufactured by fermentation
E 950	Acesulfame K		
E 951[(a)]	Aspartame[(a)]		
E 952	Cyclamates	E 952(i) E 952(ii) E 952(iii)	Cyclamic acid Sodium cyclamate Calcium cyclamate
E 953	Isomalt		
E 954	Saccharin and its Na, K and Ca salts	E 954(i) E 954(ii) E 954(iii) E 954(iv)	Saccharin Sodium saccharin Calcium saccharin Potassium saccharin
E 955	Sucralose		
E 957	Thaumatin		
E 959	Neohesperidine dihydrochalcone		
E 961	Neotame		
E 962	Salt of aspartame-acesulfame		
E 965	Maltitols	E 965(i) E 965(ii)	Maltitol Maltitol syrup
E 966	Lactitol		
E 967	Xylitol		
E 968	Erythritol		

Refined exposure assessment of food additives under re-evaluation

STATEMENT

EFSA Journal

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Approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Alicja Mortensen, Fernando Aguilar, Riccardo Crebelli, Alessandro Di Domenico, Birgit Dusemund, Maria Jose Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Claude Lambré, Oliver Lindtner, Peter Moldeus, Pasquale Mosesso, Dominique Parent-Massin, Agneta Oskarsson, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright, Maged Younes, Polly Boon, Christina Tlustos, Davide Arcella, Alexandra Tard and Jean-Charles Leblanc

Abstract

This statement describes the approach followed by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) for performing refined exposure assessment in the framework of the re-evaluation of already permitted food additives. Estimation of exposure is obtained through combination of different type of data originating from different sources: food additive concentration is obtained from information provided to EFSA on use levels and/or information obtained by means of analytical measurements. In recent years, the use of market research data has also been used. The statement provides also a description of the three different scenarios used for the exposure assessment of food additives under re-evaluation, from the more conservative regulatory maximum level exposure assessment scenario to more refined ones. Lastly, a description is provided on the approach used for the uncertainty analysis which accompanies the exposure assessment.

Keywords: dietary exposure, concentration data, Comprehensive European Food Consumption Database, food additives

Requestor: European Food Safety Authority

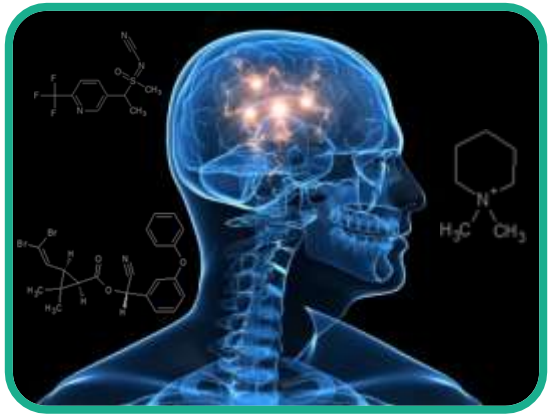
Dietary exposure assessment

efsa
European Food Safety Authority

Occurrence

Consumption

Exposure



Occurrence data

Call for data (batch 7) launched for sweeteners in 2018 (January-October)

- Use levels
- Analytical results

in food and beverages intended for human consumption.

From:

- National authorities/organisations of the Member States, and
- Interested business operators and other parties (e.g. individual food manufacturers, food manufacturer associations, research institutions, academia, food business operators and other stakeholders).

An additional call on occurrence data on aspartame (E 951) will be launched to update the assessment of exposure to aspartame (E 951), as well as to assess the total aspartame exposure from the use of the salt of aspartame-acesulfame (E 962) and aspartame (E 951).

Data submitted to EFSA (preliminary)

Sweetener	E number	Sweetener substance	Analytical results (n)	Usage levels (n)
Sorbitols	E 420	Sorbitols	8,978	386
		D-glucitol	.	
		Sorbitol syrup	.	175
Mannitol	E 421	Mannitols	248	51
		D-Mannitol	.	.
		Mannitol manufactured by fermentation, D-Manitol	.	.
Acesulfame K	E 950	Acesulfame K	32,802	530
Isomalt	E 953	Isomalt	444	98
Sucralose	E 955	Sucralose	3,910	336
Thaumatin	E 957	Thaumatin	.	1
Neohesperidine DC	E 959	Neohesperidine DC	3,801	60
Aspartame acesulfame salt	E 962	Aspartame acesulfame salt	.	8
Lactitol	E 966	Lactitol	182	3
Xylitol	E 967	Xylitol	296	113
Erythritol	E 968	Erythriol	.	43
Cyclamates	E 952	Cyclamic acid	257	9
		Sodium cyclamate	2,783	74
		Calcium cyclamate	.	6
Saccharin Na, Ca, K	E 954	Saccharin	34,913	18
		Sodium saccharin	.	.
		Calcium saccharin	.	1
		Potassium saccharin	.	1
Neotame	E 961	Neotame	3,654	2
Maltitol	E 965	Maltitols	494	96
		Maltitol syrup	.	47
Total			**92,762**	**2,058**

Comprehensive Food 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
- classified according to the FoodEx2 food classification and description system

Food consumption data

The EFSA Comprehensive European Food Consumption Database for the six following population groups: infants, toddlers, children, adolescents, adults and the elderly.

EFSA Food Consumption Survey – Harmonisation Collaboration – European Food Safety Authority – EUMenu Diet

All EU Menu projects are expected to be finalised by 2023.

Project start	Dietary survey on	
	Children	Adults
2011	France	France
	Estonia	
2012	Latvia	Latvia
	Netherlands	Netherlands
	Portugal	Portugal
	Spain	Estonia
2013	Belgium	Belgium
	Cyprus	Cyprus
		Greece
		Spain
2014	Hungary	Hungary
	Italy	Italy
	Slovenia	Slovenia
		Austria
		Romania
2015		Finland
	Poland	Poland
2016	Croatia	
	Serbia	Serbia
	FYROM	Montenegro
		Bosnia & Herzegovina
2018	Montenegro	Croatia

Dietary surveys

Age class	Age range (years)	Number of Surveys	EU MENU surveys
Infants	0 – 1	13	7
Toddlers	1 – 3	16	8
Children	3 - 10	19	8
Adolescents	10 - 18	20	11
Adults	18 - 65	22	12
Elderly and Very elderly	65 - 75	20	8
Special population groups		6	4

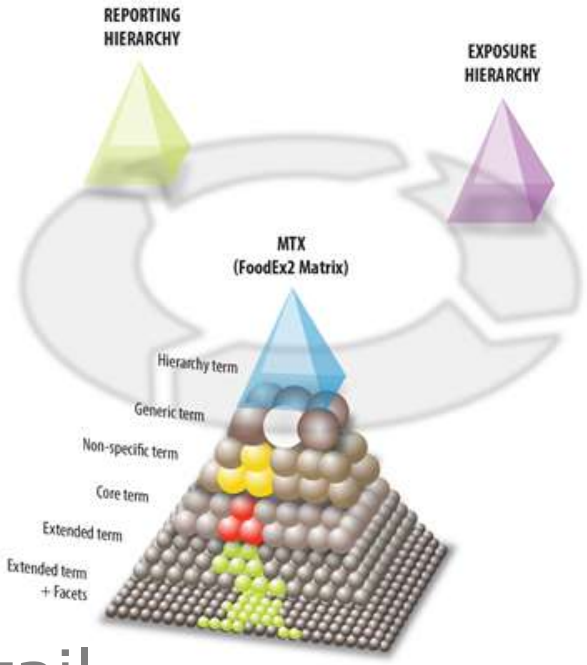
FOOD CLASSIFICATION

- Precision in estimate requires accuracy in inputs
- Less accuracy requires conservative estimates

Annex II food categories vs. FoodEx2

- Food categories as presented in Annex II, Part D, of Regulation (EC) No 1333/2008

- FoodEx2
  - food/feed classification and description system
  - common language
  - developed and maintained by EFSA
  - includes Facets, which are used to add further detail, in relation to different properties and aspects of foods



EXAMPLES of FoodEx2 facets

Process
- Concentration or drying?

Sugar-related info
- "Without added sugar"
- "Sugar free"
- "Low / Reduced sugar"
- "Light"

Physical state
- Tablets, Drops, Powder, Liquid

Ingredient
- Artificial sweeteners
- Neotame

Food categories

According to the available literature for EU countries, food categories expected to be the main contributors to the exposure for most of the sweeteners are:

- Table-top sweeteners,
- Non-alcoholic beverages,
- Food Supplements,
- Desserts,
- Confectionery
  - chewing gum,
  - candies

Food categories

Table-top sweeteners

Facets rarely reported for FoodEx2 categories: "Table-top sweeteners formulations", "Table-top sweeteners in liquid form", "Table-top sweeteners in powder form" and "Table-top sweeteners in tablets)".

Non-alcoholic beverages

Relatively good identification products containing sweeteners for FoodEx2 categories.

Only in a limited number of countries facets were used to identify "Energy drinks" containing sweeteners.

Food Supplements

Only in a limited number of countries facets were used to identify products containing sweeteners.

Desserts

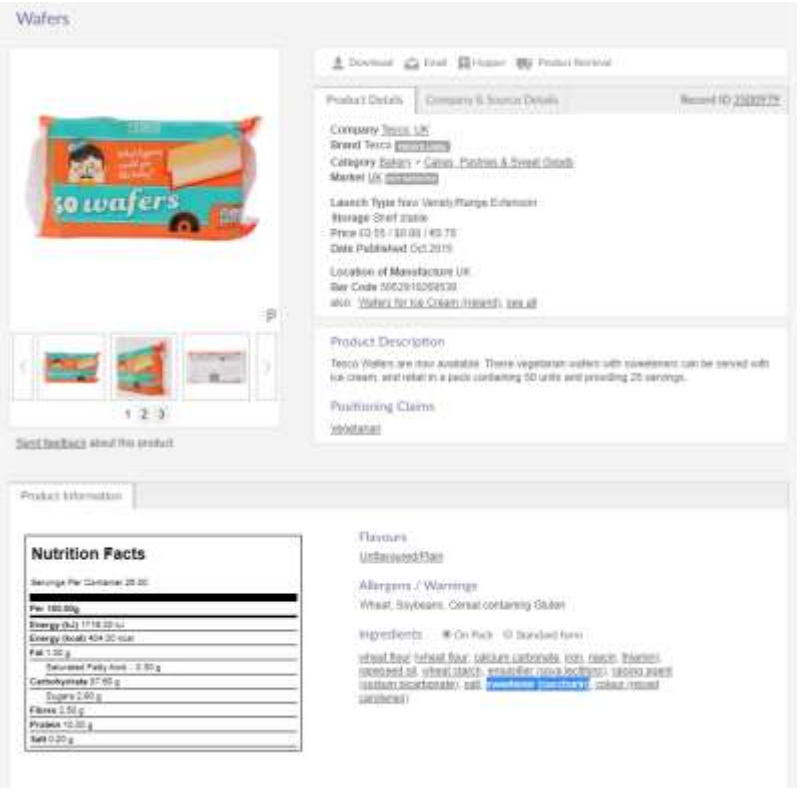
Facets used to identify products containing sweeteners were reported for some of the FoodEx2 categories related to desserts.

Confectionery

Facets were never reported for FoodEx2 categories related to confectionery, relatively low information on chewing gums.

Global New Products Database (GNPD).

- GNPD is an online database, which observes product introductions in consumer-packaged goods marketed worldwide since 1996.
- GNPD currently covers 25 EU Member States and Norway
- GNPD shows the compulsory ingredient information presented on product labels.
- GNPD has been used to support the identification of the food categories containing the sweeteners and to evaluate a possible under/overestimation of the calculated exposure.



Food categories

Food categories	GNPD categories	EU products labelled to contain sweetener(s)
Non-alcoholic beverages	Replacements & Other Drinks	58%
	Sport drinks	57%
	Carbonated Soft Drinks	31%
	Energy drinks	32%
Table-top sweeteners	Artificial Sweeteners	99%
Food Supplements	Vitamins & Dietary Supplements	21%
Desserts	Cakes, Pastries & Sweet Goods	17%
	Dessert: Frozen, Shelf-Stable, Soft Cheese Desserts, Chilled Desserts and Toppings	5-10%
Confectionery	Chewing gum	89%
	Other Sugar Confectionery	14%
	Medicated Confectionery	49%

Assumptions for the refined exposure assessment scenario (1)

- Table-top sweeteners, Chewing gum, Gum drops, Energy drinks and Vitamin and mineral supplements are always assumed to contain the sweetener under evaluation, if authorised and if adequate analytical results and/or use levels are available.

- Facets are used to identify the eating occasions assumed to contain the sweetener under evaluation for Non-alcoholic beverages and all other food categories which are not expected to be a significant source of exposure.

Assumptions for the refined exposure assessment scenario (2)

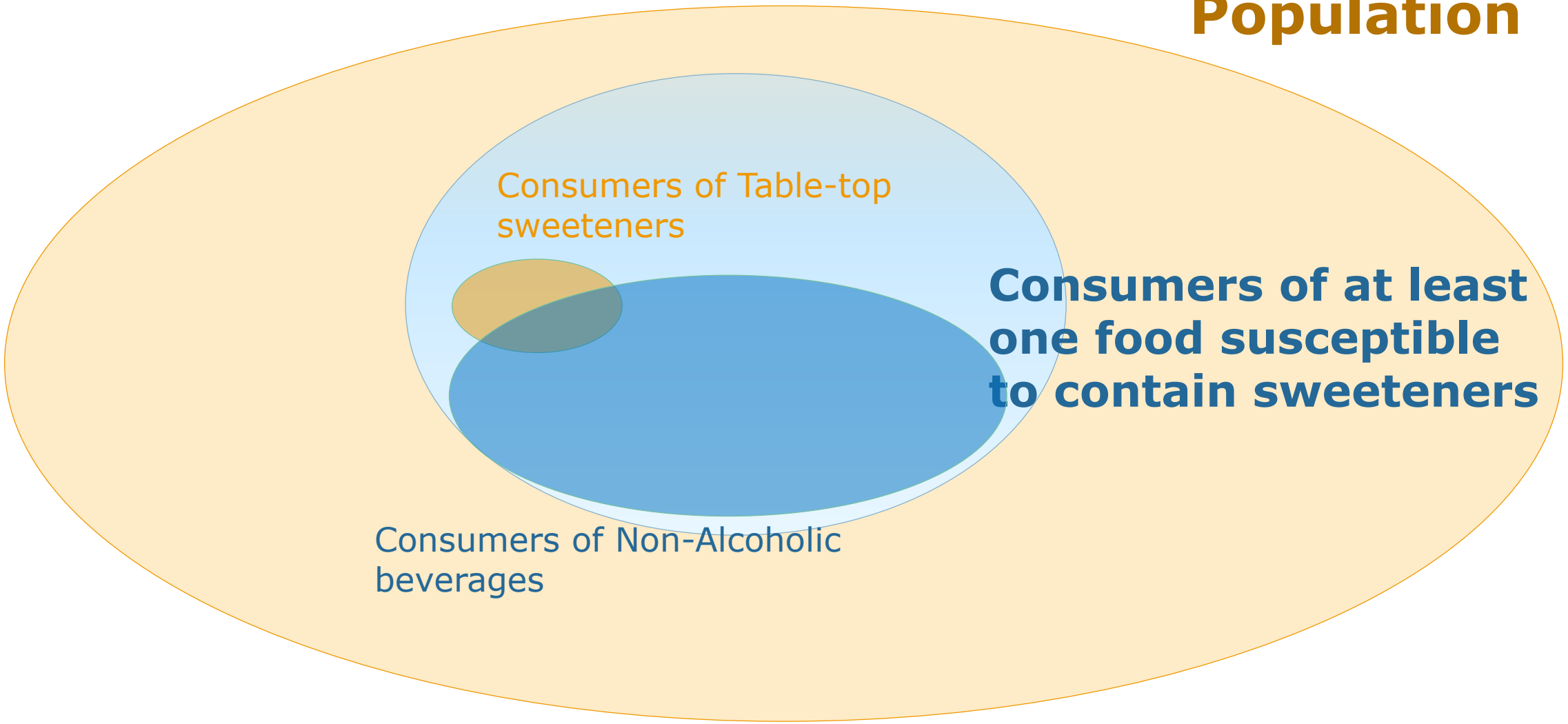
- Left-censored analytical results are excluded since it is assumed that food and beverages containing the sweetener are identified and its level is derived from the quantified analytical results only.

- Brand loyalty: individual is a long-term brand-loyal consumer of one food category containing the sweetener at the highest level reported/highest percentile different from the maximum level analysed and non-brand-loyal to the other food categories in the diet, which contain the sweetener at the mean/median of typical reported use level or analytical data.

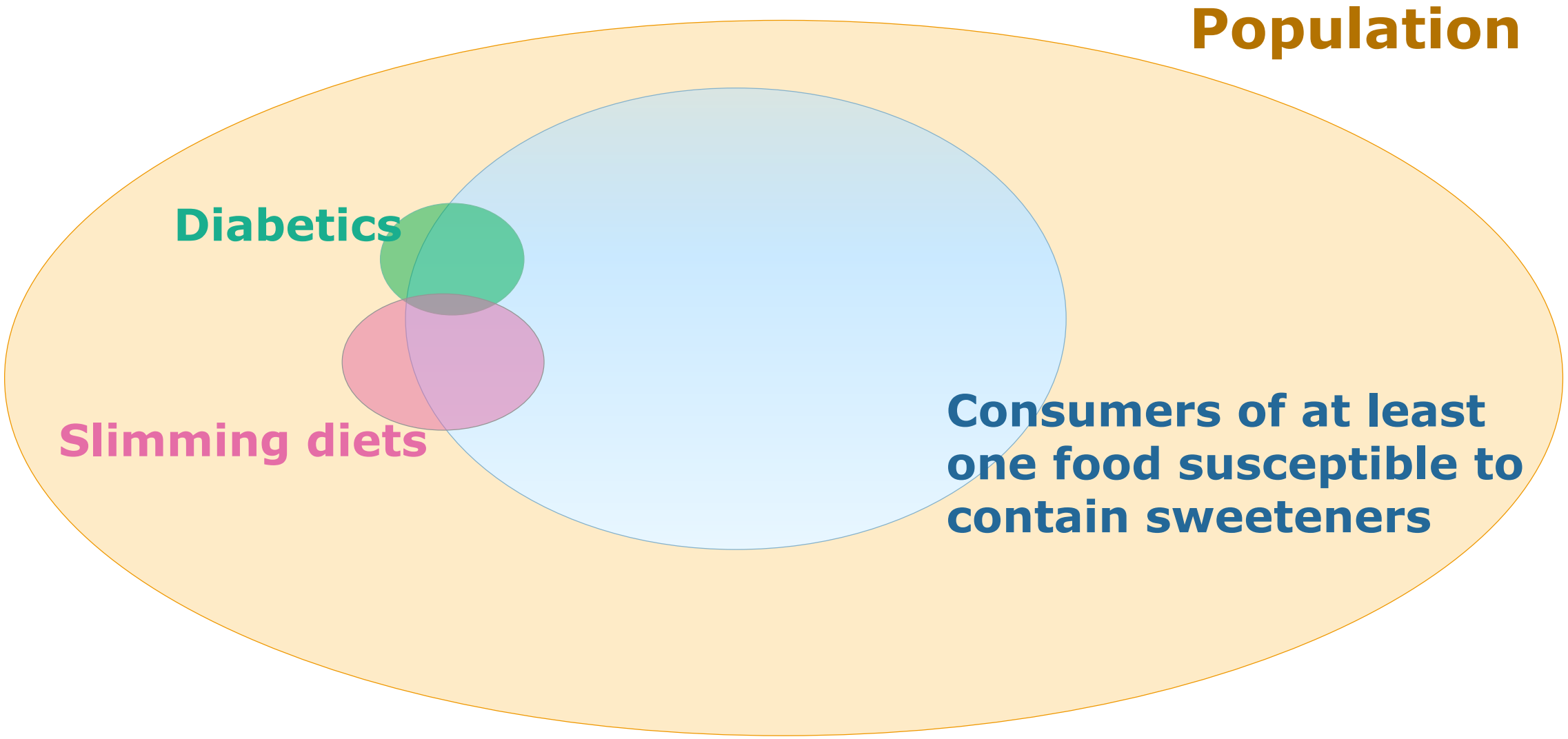
- Mean and 95th percentile of exposure calculated for consumers only of **at least** one food category containing the sweetener under evaluation

- Mean and 95th percentile of exposure calculated for consumers only of **each** food category containing the sweetener under evaluation

Target population



Target population



Regulatory maximum level scenario

Only includes food categories authorised according to x II to Regulation No 1333/2008 or any other legislation clearly defining the food or food category in which the food additive might be added with an MPL as a numerical level.

- Based on Maximum Permitted Levels (MPLs)
- Entire food categories will be assumed to contain the sweetener unless restrictions are indicated in the legislation

Uncertainty analysis

The sources of uncertainties related to the estimates of dietary exposure will be discussed and summarised in each opinion. They are related to the food consumption data and to the concentration data (use or analytical data) used, and to the scenarios presented in the opinions.

In order to evaluate the possible maximum underestimation related to the use of the FoodEx2 facets, dietary exposure will be assessed considering all foods authorised to contain a sweetener (irrespective of the facets).

The GNPD will be used as a qualitative tool to evaluate the uncertainty related to the available use/analytical data. In particular, considerations will be done on the consistency between the amount of use/analytical data for foods and beverages with label information from the GNPD.

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Panel on Food Additives and Flavourings
WG on Sweeteners

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