

Info session: (Re-)Evaluating Food Additives
DAY 1: 19 March 2024
SESSION 1 | Food additives re-evaluation: taking stock



UPDATE ON THE EXPOSURE PROTOCOL FOR SWEETENERS

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OUTLINE OF PRESENTATION

- Dietary exposure assessment
- Exposure protocol 2020 & adopted opinions
- Revised version of the protocol



TWO PROTOCOLS FOR SWEETENERS

- Protocol on hazard identification and characterisation of the sweeteners
 - Revised Protocol on Hazard Identification and Characterisation of Sweeteners | [Zenodo](#)
- Protocol for the exposure assessment of the sweeteners

Protocol on hazard identification and characterisation of sweeteners



Annex A- Draft protocol for the assessment of hazard identification and characterisation of sweeteners

EFSA Panel on Food Additives and Flavourings (FAF)



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

EFSA Panel on Food Additives and Flavourings (FAF)

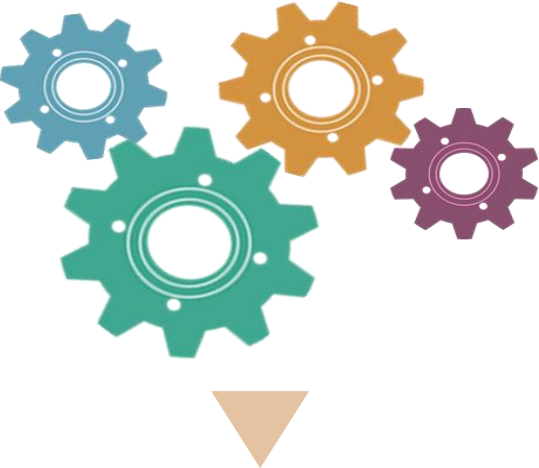


DIETARY EXPOSURE ASSESSMENT: HOW IS THE EXPOSURE ASSESSMENT PERFORMED?

Occurrence



Use levels/analytical data per substance and food



Exposure



Consumption



Individual consumption (kg body weight)



SWEETENERS EXPOSURE ASSESSMENT PROTOCOL – 2020

- Approach based on:
 - EFSA Comprehensive food consumption database

<https://www.efsa.europa.eu/en/data-report/food-consumption-data>

- Call for data for sweeteners (2018 & 2020 for aspartame)

Call for food additives **usage level** and/or **concentration data** in food and beverages intended for human consumption

Deadline: 1 October 2018

Call for Aspartame (E 951) **use level and/or **analytical data** in food and beverages intended for human consumption**

Published: 24 June 2020 **Deadline:** 1 October 2020 - 23:59 (CEST) **Expired**

Share:   



Food consumption data

Food consumption data are essential for assessing how exposed people are to potential risks in the food chain.



SWEETENERS EXPOSURE ASSESSMENT PROTOCOL – 2020 (2)

Ad-hoc methodology for sweeteners

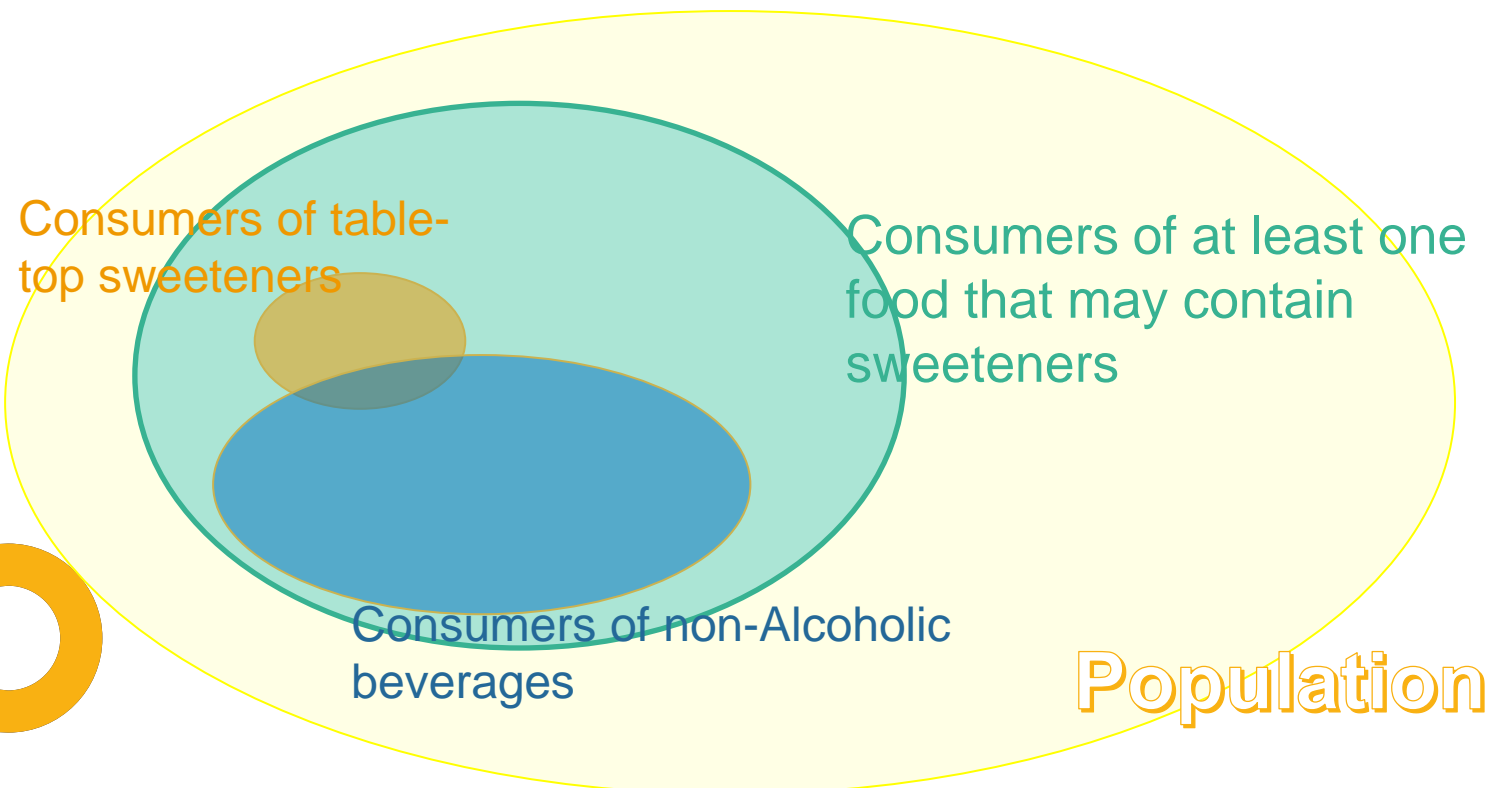
- Based on the facets available to select foods of interest

Sugar-related info

- “Without added sugar”
- “Sugar free”
- “Low / Reduced sugar”
- “Light”

Ingredients

- Artificial sweeteners
- Neotame



- Using the consumers only approach



SWEETENERS EXPOSURE ASSESSMENT PROTOCOL – 2020 (3)

Chronic exposure to sweeteners

- Scenarios:
 - i. Regulatory maximum level exposure assessment scenario:** Using MPLs
 - ii. Refined exposure assessment scenarios:** using the available data (use levels / analytical data): based on brand-loyalty principle
 - consumption of 1 food category combined with its maximum reported use level / highest reliable percentile different from the maximum level analysed (food category having, at the individual level, the highest contribution to the total individual mean exposure)
 - Using the mean of the typical reported use levels or the mean/median of analytical results for the remaining food categories.
 - iii. Scenario using the population of the refined scenario with the MPLs: Refined regulatory exposure assessment scenarios**



OPINIONS ADOPTED UNDER THIS PROTOCOL

Thaumatococcus
E 957

Neohesperidine
E 959

Erythritol
E 968

1st polyol

Intense sweeteners

Polyols

Acute effect

Acute ref dose

Acute exposure estimates

Sweeteners



REVISION OF THE PROTOCOL: ACUTE EXPOSURE ESTIMATES

- Acute dietary exposure (short-term exposure)
 - Per day or per meal
- Assessment based on same data as for the chronic exposure
- Scenario is based on the **refined exposure assessment scenarios** and brand-loyalty principle, however:
 - **2 main food categories combined with maximum reported use level / highest reliable percentile different from the maximum level analysed**: it is considered likely that the same person will consume foods from more than one food category with the highest concentration of sweetener on a single day especially consumers following dietary restrictions
- Outputs: 95th, 97.5th and 99th percentiles of exposure per day and meal



REVISION OF THE PROTOCOL: FACETS

Intense sweeteners

Regulatory scenario

Facets applied to the FCs with restriction (“energy reduced or no added sugar”)

Refined scenarios

Facets applied to all FCs (with or without restrictions)

Polyols

Regulatory and refined scenarios

Facets applied to the FCs with restriction (“energy reduced or no added sugar”)

* For the FCs considered to be the main ones contributing to the dietary exposure, the facets are never applied (gum drops, chewing gum, table-top sweeteners, energy drinks and food supplements)



REVISION OF THE PROTOCOL: WHEN

Update in the methodology for erythritol opinion from December 2022



Endorsement during the mandate of the current panel – June 2024



Revision of the protocol from September 2023



Publication 3rd quarter 2024



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