Interpretation of the mandate and methodology applied

Marco Vinceti
Chair, EFSA WG on free sugars

Technical meeting, 13 February 2018

efsa
European Food Safety Authority

TERMS OF REFERENCE (TOR) – ORIGINAL REQUEST

Mandate requestor

National food competent authorities of Denmark, Finland, Iceland, Norway, and Sweden

Mandate

Exposure: added sugars

Science-based **cut-off value** not associated with **adverse health effects**

Target population: general *healthy* population, including children, adolescents, adults and the elderly – pregnant and lactating women NOT to be considered specifically

TERMS OF REFERENCE – *REVISED*

- **In agreement with the mandate requestor**

Exposure: **free** sugars from all dietary sources

TERMS OF REFERENCE – *INTERPRETATION*

- **By EFSA, in agreement with the mandate requestor:**
  - **Exposure**
  - **Objectives**
  - **Target population**
  - **Adverse effects and endpoints**

- **Background information to be considered**

BACKGROUND INFORMATION – EXISTING RECOMMENDATIONS

Guideline	Target population	Sugar fraction	Recommendation
EFSA, 2010	General population	Added sugars	Consider when setting FBDGs
GNS, 2012	General population	SSBs	Limit consumption
NNR, 2012	General population	Added sugars	<10E%
SACN, 2015	General population (>2 years)	Free sugars	≤ 5E%
ANSES, 2016	Adults	Total sugars	100 g/day
IoM, 2002	General population	Added sugars	<25E%
DGA, 2015	General population	Added sugars	<10E%
WHO, 2015	General population	Free sugars	<10E% <5E% conditional
AHA, 2016	Children	Added sugars	25 g/day ≥ 2 years Avoided < 2 years
ESPGHAN, 2017	Children	Free sugars	≤ 5E% ≥ 2 years (lower for < 2 years)

DEFINITION OF EXPOSURE

- ***Added sugars***: all sugars (mono- and disaccharides) used as ingredients in processed and prepared foods and sugars eaten separately or added to foods at the table.

- ***Non-milk extrinsic sugars***: sugars not located within the cellular structure of a food, e.g. in fruit juice, honey, and syrups, and those added to processed foods, excluding lactose in milk.

- ***Free sugars***: all monosaccharides (glucose, fructose, galactose) and disaccharides (sucrose, lactose, maltose, trehalose) added to foods by the manufacturer, cook, and consumer plus sugars naturally present in honey, syrups, fruit juices, and fruit juice concentrates.

OBJECTIVES OF THE ASSESSMENT

- To provide scientific advice on a **daily intake of free sugars from all dietary sources** which, if consumed for long periods of time, is **not associated with adverse health effects** in the **general healthy European population**.

- **Estimation of the intake of free sugars** from all dietary sources (foods and beverages) in the target population by age (and sex) group.

OBJECTIVES OF THE ASSESSMENT (cont.)

- **NOT a primary objective** to explore possible adverse health effects of different types (e.g. glucose vs fructose) or different sources (e.g. sugar-sweetened beverages vs solid foods) of free sugars

- **OUT OF THE SCOPE** the possible beneficial health effects of free sugars or their sources

TARGET POPULATION

- General healthy European population (children, adolescents, adults and elderly adults)

- **Excluded:** sub-populations with **extreme and distinct vulnerabilities** due to genetic predisposition or other conditions (e.g. disease under medical care, inborn errors of carbohydrate metabolism, intense physical activity)

- **Specific advice NOT to be provided** for subgroups on the basis of e.g. ethnicity, dietary habits, physical activity level (PAL), disease conditions or nutritional status

ADVERSE EFFECTS AND ENDPOINTS

Target	Disease endpoints	Surrogate endpoints
Micronutrient status	Clinical signs/symptoms of micronutrient deficiency	Biomarkers of micronutrient status Micronutrient intakes Micronutrient density of the diet (micronutrient intake/energy unit)
Teeth	Dental caries incidence/severity	None
Chronic metabolic diseases		
Adipose tissue	Obesity incidence	Body weight, BMI Body composition (body fat, lean body mass) Waist circumference Ectopic fat deposition (muscle, VAT)
Glucose homeostasis	T2DM incidence	Insulin sensitivity Beta-cell function Blood glucose control
Cardiovascular system	CVD incidence/mortality	Blood pressure Blood lipids
Liver function	Liver fibrosis/cirrhosis incidence/ mortality	Liver fat accumulation NAFLD/NASH activity score

METHODOLOGY

- Principles and process of the PROmoting METHods for Evidence Use in Scientific assessments (**PROMETHEUS**) EFSA project

- **Draft protocol** developed to **define** as much as possible **beforehand** the **strategy** to **collect** data (i.e. which data to use for the assessment and how to identify and select them), **appraise** the relevant evidence, and **weigh** and **integrate** the evidence to draw conclusions underpinning the Scientific Opinion

PRINCIPLES

- The **assessment** of the **evidence** (for both disease/surrogate endpoints) on which to base a level of intake of free sugars will rely on **human studies**

- Information from **animal and/or *in vitro* studies** will only be used, where appropriate, as background knowledge on **mode(s) of action and biological plausibility**

PRINCIPLES (cont.)

- Adverse effects will be considered first within a given target, and then across targets related to the same chronic metabolic disease

- Adverse effects related to micronutrient status, teeth and chronic metabolic diseases will, in principle, **not be combined** to derive a level of intake for free sugars

- The **suitability** of each adverse effect will be assessed **on the basis of the quality of** the available **evidence**, taking into account the related uncertainties, **and the possibility to derive quantitative estimates**

PRINCIPLES (cont.)

- If more than one adverse effect is found to be suitable and the level of intake of free sugars that can be derived from each of them differs, **scientific advice will be provided for each adverse effect separately**

- If the available evidence does not allow setting a level of intake for free sugars on the basis of one or more adverse effects, **data gaps will be identified** and reported in the Scientific Opinion

ASSESSMENT SUB-QUESTIONS

1	What are the levels of free sugars in solid foods and beverages in Europe?
2	What is the distribution of intakes of free sugars from all dietary sources (and by food source) in the target population?
3	What are the digestion, absorption and metabolism of different types of free sugars from different food matrices in humans?
4	What is the relationship between the intake of free sugars from all dietary sources and micronutrient status?
5	What is the relationship between the intake of free sugars from all dietary sources and chronic metabolic diseases (disease and/or surrogate endpoints) in the target population?
6	What is the relationship between the intake of free sugars from all dietary sources and dental caries in the target population?
7	Which could be the potential mode(s) of action for the relationships found, if any, between free sugar intake and chronic metabolic diseases (disease and/or surrogate endpoints)?

METHODS TO ASSESS EACH SUB-QUESTION

1, 2 (occurrence and intake)	EU National Food **Composition** Database Mintel's Global New Products Database EFSA Comprehensive Food **Consumption** Database
3 (ADME)	Narrative review
4 (micronutrient status)	Questionnaire to national representatives of European countries Extensive literature search
5 (chronic disease endpoints)	Systematic review
6 (dental caries)	Systematic review
7 (mode of action)	Narrative review

MANDATE AND METHODOLOGY APPLIED