EFSA'S DRAFT PROTOCOL FOR THE ASSESSMENT OF FREE SUGARS FROM ALL DIETARY SOURCES

Feedback to the European Food Safety Authority Protocol Assessment

Document addressed to the European Food Safety Authority by SAFE – Safe Food Advocacy Europe ASBL

ACKNOWLEDGMENTS

Before explaining our position, SAFE wishes to underline that we very much appreciate EFSA's decision to host a meeting regarding the proposed protocol halfway through the consultation period. Indeed, the meeting held in Brussels on the 13th of February 2018 provided SAFE with a better understanding of the proposed protocol for scientific opinion on free sugar. It allowed stakeholders the opportunity to provide their feedbacks and clarified some of the point of the proposal that needed clarification. SAFE believes that thanks to this meeting, respondents will provide EFSA with better and more useful comments.

OUTLINE:

1. INTRODUCTION

The following feedback paper was drafted by SAFE – Safe Food Advocacy Europe. SAFE is a non-profit independent organisation based in Brussels whose main objective is to ensure that the consumers' health and concerns remain at the core of the EU food legislation. SAFE monitors the EU food legislation process and cooperates with EU legislators, and with various stakeholders, to draft comprehensive food regulations. The work of SAFE is supported by its members, which are consumer, food, health, obesity and overweight patients', vegan and vegetarian associations, as well as individual members such as independent research scientists, doctors (including oncologists) and nutritionists spread across Europe (9 EU Member States). To date, our membership collectively represents the voice of over 1.500.000 European consumers.

SAFE's missions are:

- To strengthen the voice of civil society in the EU debate concerning the future of EU food regulation;
- To increase public awareness and information on food health and safety issues;
- To identify priority areas for research and raise funds for independent research on food components with direct consequences on consumers' health.

2. CONTEXT

In 2010, the European Food Safety Authority (EFSA) concluded that it "could not establish a correlation between high intake of sugar from solid food and weight gain" and that the information presently available was "insufficient to set an upper limit for sugar based on its effect on weight gain"[1]. In subsequent years, however, a great number of evidence-based scientific organisations came out with opinions that contradicted EFSA's original findings, notably 2012 Nordic Nutrition Recommendation (NNR)[2], the World Health Organisation (WHO) 2015 guidance[3], the British Scientific Advisory Committee on Nutrition (SACN) recommendations also from 2015[4], the Dietary Guidelines for Americans (DGA) 2015 to 2020[5] and Action on Sugar 2016[6]. These opinions were forged on new evidence not available at the time of EFSA's original opinion in 2010. All the above listed organisations agreed on the need to set dietary recommendations for added sugars, mainly to keep it below 10% of the energy (calorie) intake. WHO, SACN and Action on Sugar went one step further in recommending to reduce added sugars to below 5% of the total energy intake[3,4&6].

Due to this new evidence and following a joint request for an opinion from Denmark, Finland, Sweden, Iceland and Norway, EFSA will be revisiting the question. The objective of the protocol will be "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"[7].

This new query will not only concentrate on the adverse effect of added sugars on obesity, but will also serve to identify the adverse health effect of free sugars on multiple health factors, as food and drinks with a high content of sugar have been linked with a multitude of adverse health effects such as: risk factors for cardiovascular disease, type 2 diabetes, oral health problems, mental disorders and so much more. In addition, as indicated in the objective, the scope of this exercise will only cover general healthy European population (children, adolescents, adults and elderly adults). Sub-populations with extreme and distinct vulnerabilities due to genetic predisposition or other conditions will be excluded from this study. This includes sections of the population who have a disease under medical care, pregnant and lactating women and members of the population with inborn errors of carbohydrate metabolism.

EFSA indicates the following: "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 of free sugars on the basis of one or more adverse effects, data gaps will be identified and reported in the Scientific Opinion"[7]. Furthermore, EFSA will try to answer the following 7 sub-questions during their investigation:

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[1] EFSA 2010: Scientific Opinion on Dietary References Values for carbohydrates and Dietary fiber, EFSA Journal 2010; 8(3):I462. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/1462

[2] Sonestedt, Emily, et al. "Does high sugar consumption exacerbate cardiometabolic risk factors and increase the risk of type 2 diabetes and cardiovascular disease?" Food & nutrition research 56.1 (2012): 19104.

[3] WHO. Guideline: sugars intake for adults and children. World Health Organization, 2015.

[4] SACN. 2015. Carbohydrates and Health Report (ISBN 9780117082847). From https://www.gov.uk/government/publications/sacn-carbohydrates-and-health-report [Google Scholar]

[5] US Department of Health and Human Services. Dietary Guidelines for Americans 2015-2020. Skyhorse Publishing Inc., 2017.

[6] Public Health England. "Young Children Still Exceeding Sugar Recommendation." Young Children Still Exceeding Sugar Recommendation - GOV.UK, 9 Sept. 2016, www.gov.uk/government/news/young-children-still-exceeding-sugar-recommendation.

[7] Vinceti, Marco. "Interpretation of the mandate and methodology applied" Technical meeting with stakeholders on the draft protocol for the assessment of free sugars. NH Hotel. Brussels, BE. 13 February 2018. Chair, EFSA WG on free sugars

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)?

3. SAFE'S COMMENT ON THE PROTOCOL

SAFE welcomes EFSA's initiative to scrutinize all types of sugar and their effects on health. Indeed, the distinction between natural sugars and free sugars has to be better explained and visible in order to inform consumers about the hazardous health effects of free sugars. We believe in the importance of the work of Action on Sugar and in the independent studies of the World Health Organization (WHO), which provide similar recommendations and suggest that the daily sugar intake should be reduced to around 5% of total energy intake.

With that said, while SAFE appreciates the fact that this proposal was published and opened to stakeholders for consultation, we would like to point out the following elements:

A. Interpretation of the Terms of Reference

A.1 Definition of sugar

SAFE strongly agrees with EFSA's determination of definition of the exposure, which amended the scope of the assessment from added sugars to free sugars. WHO definition of Free Sugars includes 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[8]. Both the presentation and the written proposal provided by EFSA clearly explained the need to amend the scope of the request from added sugars to free sugars. As pointed out by the World Health Organisation, "it should be noted that some studies are now indicating a positive association between excess intake of fruit juices and higher body weight. Essential nutrients including vitamins and minerals can be consumed through a wide variety of whole and fresh foods that are naturally low in free sugars, rather than through excess intake of fruit juices"[9].

[8] WHO. Diet, nutrition, and the prevention of chronic diseases: report of a joint WHO/FAO expert consultation. Vol. 916. World Health Organization, 2003.
[9] WHO. Guideline: sugars intake for adults and children. World Health Organization, 2015.

A.2 Target Population

Section 4.4 of the proposal outlines that: infants < 4 months of age will be excluded from the assessment on the assumption that they are exclusively fed with breastmilk or breastmilk substitutes (EFSA NDA Panel, 2009). However, SAFE finds this statement to be erroneous: in fact, only an estimated 25% of infants in the WHO European Region were exclusively breastfed for the first 6 months[10] and infant formula (breastmilk substitute) can contain added maltose, sucrose glucose, malto-dextrins and (dried) glucose syrup according to the Commission Directive 2006/141/EC of 22 December 2006[11]. In addition to that, most breastmilk substitutes currently available on the market specify only two age categories, 0-6 months and 0-12 months. This assumption will exclude a generally healthy segment of the population that does not qualify as a sub-population with extreme and distinct vulnerabilities, and which is exposed to free sugars. Finally, SAFE believes that the addition of infant < 4 months of age to the target population is even more pressing in light of the mounting scientific evidence indicating that the consumption of sugar-sweetened beverages during infancy may be a risk factor for obesity in early childhood[12].

A.3 Adverse Health Effect

Although we appreciate EFSA's need to remain within the scope of the mandate, SAFE strongly advises EFSA to consider adding mental health adverse effects, and more specifically the addictive power of sugar, to the scope of the scientific investigation (section 4.5 Adverse effects and endpoint). Currently, the health effects explored are purely adverse physical health effects. However, sugar has been found to be highly addictive due to its ability to release opioids and dopamine in the human body[13]. Long-term exposure to sugar leads to prolonged dopamine signalling, abnormal excitation of the brain's reward pathways and a need for even more sugar[14]. Studies show that when subjects are fed sugar all four steps of addition can be observed: bingeing, withdrawal, craving, and cross-sensitisation. This addiction to sugar can lead to multiple more adverse mental health issues, as there is increasing evidence suggesting that a diet high in refined sugar is linked to depression and anxiety[15]. Furthermore, high amounts of sugar in the diet increase advanced glycation end-products (AGEs, a protein bound to a glucose molecule), resulting in damage and inflammation[16]. This damage is not only related to diabetes and cardiovascular problems but can also cause and aggravate nervous inflammation.

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[10] WHO. "WHO European Region Has Lowest Global Breastfeeding Rates." WHO/Europe, World Health Organization, 5 Aug. 2015, www.euro.who.int/en/health-topics/Life-stages/maternal-and-newborn-health/news/news/2015/08/who-european-region-has-lowest-global-breastfeeding-rates.

[11] EC. "EUR-Lex Access to European Union Law." EUR-Lex - 32006L0141 - EN - EUR-Lex, 22 Dec. 2016, eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0141.

[12] Pan, Liping, et al. "A longitudinal analysis of sugar-sweetened beverage intake in infancy and obesity at 6 years." Pediatrics 134.Supplement 1 (2014): S29-S35.

[13] Avena, Nicole M., Pedro Rada, and Bartley G. Hoebel. "Evidence for sugar addiction: behavioral and neurochemical effects of intermittent, excessive sugar intake." Neuroscience & Biobehavioral Reviews 32.1 (2008): 20-39.

[14] Reichelt, Amy C. "Adolescent maturational transitions in the prefrontal cortex and dopamine signaling as a risk factor for the development of obesity and high fat/high sugar diet induced cognitive deficits." *Frontiers in behavioral neuroscience* 10 (2016): 189.

[15] Westover, Arthur N., and Lauren B. Marangell. "A cross-national relationship between sugar consumption and major depression?." Depression and anxiety 16.3 (2002): 118-120.

[16] Uribarri, Jaime, et al. "Advanced glycation end products in foods and a practical guide to their reduction in the diet." Journal of the American Dietetic Association 110.6 (2010): 911-916.

B. **Identification of the assessment sub-questions**

B.1 Exclusion of Animal Models and In-Vitro Models Experiments

While SAFE does not promote research conducted on animal models, the omission of these types of studies along with the omission of in-vitro studies will cause EFSA to render an opinion based on incomplete information. Indeed, a large number of studies on the addictive power of sugar were conducted using animal models. Although there may exist inter-species differences, these studies are indispensable when evaluating the adverse mental, hormonal and neurological health effects of free sugars on the human body[17]. EFSA could consider conducting a systematic review and meta-analysis of animal studies, and this exercise may aid in the designation of an upper limit for free sugars.

Once again, SAFE would like to thank EFSA for the opportunity to discuss this draft protocol and the need for a cut-off value for intake of “free” sugars that is not associated with adverse health effects. We hope we have brought a valuable contribution and hope that the final version of the text will respond to SAFE's concerns about the protection of citizens' health.

[17] Barré-Sinoussi, Françoise, and Xavier Montagutelli. "Animal models are essential to biological research: issues and perspectives." *Future science OA* 1.4 (2015).