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Dnr 2016/02205  
Saknr 5.1

*Annica Söhlström*  
Director General

Mr Bernhard Url  
Executive Director  
European Food Safety Authority  
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Dear Mr Url

Several EU Member States and international organisations have previously found scientific basis for setting a dietary recommendation for added sugars to a maximum of 10% of total energy intake. As outlined below, new scientific data have recently been published supporting efficacy of limiting intake of added sugars. Based on recently published scientific studies and in relation to weight gain, type-2 diabetes, cardiovascular disease and related risk factors, we request scientific assistance in line with Regulation (EC) No 178/2002 in assessing if a dietary reference value for sugar with particular attention to added sugar now can be set.

EFSA's latest opinion on this matter was published 2010 and covers the scientific basis for setting reference values for carbohydrates, including dietary fibre, based on various health effects<sup>1</sup>. Reference values are given for intake of total carbohydrates and dietary fibre. A reference value for added sugars is not given in this opinion, however it does state that a high intake of sugars as sugar-sweetened beverages may contribute to weight gain. The opinion is based on an assessment of studies published until 2008-2009.

Since the publication of the 2010 EFSA Scientific Opinion several organisations and authorities have published reports that review more recent studies on health effects of dietary carbohydrates and sugars such as the Nordic Nutrition Recommendations (NNR) 2012<sup>2</sup>, the World Health Organisation (WHO) 2015<sup>3</sup>, the British Scientific Advisory

<sup>1</sup> EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal 2010; 8(3):1462, 77 pp. doi:10.2903/j.efsa.2010.1462

<sup>2</sup> Nordic Nutrition Recommendations 2012. Integrating nutrition and physical activity © Nordic Council of Ministers 2014; <http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A704251&dsid=-9109>

<sup>3</sup> WHO 2015. Guideline: Sugars intake for adults and children. Geneva: World Health Organization

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Committee on Nutrition (SACN) 2015<sup>4</sup>, and the Dietary Guidelines for Americans (DGA) 2015-2020<sup>5</sup>. These include some published research not covered in the EFSA opinion. For example, the NNR 2012 recommendations for added sugars uses new evidence on health effects, including type-2 diabetes<sup>6</sup>, body weight<sup>10</sup> as well as dietary patterns<sup>7</sup>. Further, the WHO 2015 guidance takes into consideration two systematic reviews on the associations between sugar intake and body weight<sup>8</sup> and dental health<sup>9</sup>. Based on available scientific evidence, and as outlined in the table 1 in the annex, NNR, WHO, SACN and DGA have set dietary recommendations for added sugars. It should be noted that WHO makes a conditional recommendation for reduction of the intake of free sugars to below 5% of total energy intake, while SACN recommend that the population average intake of free sugars should not exceed 5% of total dietary energy for age groups from 2 years upwards.

Recently literature searches were performed in PubMed with a focus on reviews and meta-analyses covering health effects of dietary sugars published from 2010 to April 2016. Searches were based on search terms and strategies used in a systematic review on sugars for NNR 2012<sup>10</sup>, with addition of association with body weight and dental health (see table 2 in annex for outcome). The results show that several reviews and meta-analyses on health effects of dietary sugars have been published since the publication of the EFSA opinion 2010. Some of the most relevant reviews that could be further evaluated are included in the reference list found in the annex. Articles were selected covering health effects of "sugars", "sugar-sweetened beverages" or "added sugars" among the general population. Articles focusing on weight reduction or only covering fructose are not included in the list. In addition, the SACN report on dietary

<sup>4</sup> SACN. SACN Carbohydrates and Health Report. 17 July, 2015

<https://www.gov.uk/government/publications/sacn-carbohydrates-and-health-report>

<sup>5</sup> DGA 2015-2020. <http://health.gov/dietaryguidelines/2015/guidelines/>. DGAC 2015 Report. <http://health.gov/dietaryguidelines/2015-scientific-report/>

<sup>6</sup> 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*, [S.l.], jul. 2012. <http://dx.doi.org/10.3402/fnr.v56i0.19104>

<sup>7</sup> Wirfält E, Drake I, Wallström P. What do review papers conclude about food and dietary patterns? *Food & Nutrition Research* 2013. 57: 20523  
<http://dx.doi.org/10.3402/fnr.v57i0.20523>

<sup>8</sup> Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. *BMI*. 2012 Jan 15;346:e7492. doi: 10.1136/bmj.e7492 <http://www.ncbi.nlm.nih.gov/pubmed/23321486>

<sup>9</sup> Moynihan PJ, Kelly SA. Effect on caries of restricting sugars intake: systematic review to inform WHO guidelines. *J Dent Res*. 2014;93(1):8-18  
<http://www.ncbi.nlm.nih.gov/pubmed/24323509>

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carbohydrates and US DGA 2015-2020 include a number of reviews covering sugars that also should be considered.

Yours sincerely,



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**Matti Aho**  
Director General  
Finnish Food Safety  
Authority, EVIRA,  
Finland



**For Christine Nellemann**  
Director of Institute  
National Food Institute,  
DTU, Denmark



**Lars Hanssen**  
Director of Norwegian  
Scientific Committee for  
Food Safety, Norway



**Jón Gíslason**  
Director of Icelandic Food  
and Veterinary Authority,  
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**Enclosure: Annex with two Tables and Examples of studies containing new scientific elements**

**Annex**

**Tables and examples of studies containing new scientific elements**

**Table 1. Recommendations for added sugars issued by various organizations.**

Organisation	DRV	Comment
NNR 2012	< 10 E%	
WHO 2014	< 10 E%	Conditional: < 5 E%
SACN 2015		Population mean: 5 E%
DGA 2015-2020	< 10 E%	

**Table 2. Outcome of searches in PubMed for different health impacts linked to sugar intake. Period January 2010 - April 2016. Search date 2016-04-14).**

The number of hits for article type "review" varied between 7 (mortality) and more than 400 (dental health), and for article type "meta-analysis" between 1 (mortality) and 25 (type-2 diabetes). Most articles covered associations between consumption of sugar-sweetened beverages and health outcomes. Several reviews focused on effects of fructose, these are not included in the attached reference list. Two meta-analyses are included in the WHO's guideline (Te Morenga et al. 2012; Moynihan & Kelly 2014). A new meta-analysis by Te Morenga et al. (2014) analysed results from intervention studies regarding effects of sugar intake on blood pressure and serum lipids. One review evaluated influence of funding source on conclusions on association between sugar-sweetened beverages and body weight (Massougbojji et al. 2014).

Query	Number of hits, Reviews + meta studies	Number of hits, meta studies	Comment
Glucose tolerance and insulin sensitivity	266	16	
Type-2 diabetes	329	25	
Glucose tolerance and insulin sensitivity or type-2 diabetes	434	30	
Serum lipids	51	11	
Blood pressure	44	11	
Cardiovascular disease	162	18	
All-cause mortality	7	1	No relevant meta-analyses
Body weight and obesity	297	20	
Dental caries or dental health	140	8	No relevant meta-analyses
Dental caries or dental health or oral health	417	21	No relevant meta-analyses

**Examples studies containing new scientific elements**

**Reports**

Hauner H, Bechthold A, Boeing H, Brönstrup A, Buyken A, Leschik-Bonnet E, Linseisen J, Schulze M, Strohm D, Wolfram G; German Nutrition Society. Evidence-based guideline of the German Nutrition Society: carbohydrate intake and prevention of nutrition-related diseases. *Ann Nutr Metab.* 2012;60 Suppl 1:1-58  
<http://www.ncbi.nlm.nih.gov/pubmed/22286913>

SACN. SACN Carbohydrates and Health Report. 17 July, 2015.  
<https://www.gov.uk/government/publications/sacn-carbohydrates-and-health-report>

DGA 2015-2020. <http://health.gov/dietaryguidelines/2015/guidelines/> . Published Jan 2016

DGAC 2015 Report. <http://health.gov/dietaryguidelines/2015-scientific-report>

**Type-2 Diabetes**

Imamura F, O'Connor L, Ye Z, Mursu J, Hayashino Y, Bhupathiraju SN, Forouhi NG. Consumption of sugar sweetened beverages, artificially sweetened beverages, and fruit juice and incidence of type 2 diabetes: systematic review, meta-analysis, and estimation of population attributable fraction. *BMJ.* 2015 Jul 21;351:h3576. doi: 10.1136/bmj.h3576  
<http://www.ncbi.nlm.nih.gov/pubmed/26199070>

Greenwood DC, Threapleton DE, Evans CE, Cleghorn CL, Nykjaer C, Woodhead C, Burley VJ. Association between sugar-sweetened and artificially sweetened soft drinks and type 2 diabetes: systematic review and dose-response meta-analysis of prospective studies. *Br J Nutr.* 2014;112(5):725-34 <http://www.ncbi.nlm.nih.gov/pubmed/24932880>

Sonestedt E et al. Does high sugar consumption exacerbate cardiometabolic risk factors and increase the risk of type 2 diabetes and cardiovascular disease? *Food & Nutrition Research* 2012. 56: 19104 <http://dx.doi.org/10.3402/fnr.v56i0.19104>.

Malik VS, Popkin BM, Bray GA, Després JP, Willett WC, Hu FB. Sugar-sweetened beverages and risk of metabolic syndrome and type 2 diabetes: a meta-analysis. *Diabetes Care.* 2010;33(11):2477-83 <http://www.ncbi.nlm.nih.gov/pubmed/20693348>

**Serum lipids, blood pressure, CVD**

Jayalath VH, de Souza RJ, Ha V, Mirshahi A, Blanco-Mejia S, Di Buono M, Jenkins AL, Leiter LA, Wolever TM, Beyene J, Kendall CW, Jenkins DJ, Sievenpiper JL. Sugar-sweetened beverage consumption and incident hypertension: a systematic review and

meta-analysis of prospective cohorts. *Am J Clin Nutr.* 2015;102(4):914-21  
<http://www.ncbi.nlm.nih.gov/pubmed/26269365>

Keller A, Heitmann BL, Olsen N. Sugar-sweetened beverages, vascular risk factors and events: a systematic literature review. *Public Health Nutr.* 2015;18(7):1145-54  
<http://www.ncbi.nlm.nih.gov/pubmed/25321082>

Xi B, Huang Y, Reilly KH, Li S, Zheng R, Barrio-Lopez MT, Martinez-Gonzalez MA, Zhou D. Sugar-sweetened beverages and risk of hypertension and CVD: a dose-response meta-analysis. *Br J Nutr.* 2015 14;113(5):709-17  
<http://www.ncbi.nlm.nih.gov/pubmed/25735740>

Huang C, Huang J, Tian Y, Yang X, Gu D. Sugar sweetened beverages consumption and risk of coronary heart disease: a meta-analysis of prospective studies. *Atherosclerosis.* 2014;234(1):11-6 <http://www.ncbi.nlm.nih.gov/pubmed/24583500>

Malik AH, Akram Y, Shetty S, Malik SS, Yanchou Njike V. Impact of sugar-sweetened beverages on blood pressure. *Am J Cardiol.* 2014;113(9):1574-80  
<http://www.ncbi.nlm.nih.gov/pubmed/24630785>

Te Morenga LA, Howatson AJ, Jones RM, Mann J. Dietary sugars and cardiometabolic risk: systematic review and meta-analyses of randomized controlled trials of the effects on blood pressure and lipids. *Am J Clin Nutr.* 2014;100(1):65-79  
<http://www.ncbi.nlm.nih.gov/pubmed/24808490>

Gibson S, Gunn P, Wittkind A, Cottrell R. The effects of sucrose on metabolic health: a systematic review of human intervention studies in healthy adults. *Crit Rev Food Sci Nutr.* 2013;53(6):591-614 <http://www.ncbi.nlm.nih.gov/pubmed/23627502>

Malik VS, Popkin BM, Bray GA, Després JP, Hu FB. Sugar-sweetened beverages, obesity, type 2 diabetes mellitus, and cardiovascular disease risk. *Circulation.* 2010;121(11):1356-64 <http://www.ncbi.nlm.nih.gov/pubmed/20308626>

#### ***Body weight***

Trumbo PR, Rivers CR. Systematic review of the evidence for an association between sugar-sweetened beverage consumption and risk of obesity. *Nutr Rev.* 2014;72(9):566-74  
<http://www.ncbi.nlm.nih.gov/pubmed/25091794>

Massougboji J, Le Bodo Y, Fratu R, De Wals P. Reviews examining sugar-sweetened beverages and body weight: correlates of their quality and conclusions. *Am J Clin Nutr.* 2014;99(5):1096-104 <http://www.ncbi.nlm.nih.gov/pubmed/24572563>

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Malik VS, Pan A, Willett WC, Hu FB. Sugar-sweetened beverages and weight gain in children and adults: a systematic review and meta-analysis. *Am J Clin Nutr*. 2013;98(4):1084-102 <http://www.ncbi.nlm.nih.gov/pubmed/23966427>

Pérez-Morales E, Bacardi-Gascón M, Jiménez-Cruz A. Sugar-sweetened beverage intake before 6 years of age and weight or BMI status among older children; systematic review of prospective studies. *Nutr Hosp*. 2013;28(1):47-51 <http://www.ncbi.nlm.nih.gov/pubmed/23808429>

Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. *BMJ*. 2012 Jan 15;346:e7492. doi: 10.1136/bmj.e7492 <http://www.ncbi.nlm.nih.gov/pubmed/23321486>

#### *Oral health*

Sheiham A, James WP. A new understanding of the relationship between sugars, dental caries and fluoride use: implications for limits on sugars consumption. *Public Health Nutr*. 2014;17(10):2176-84 <http://www.ncbi.nlm.nih.gov/pubmed/24892213>

Moynihan PJ, Kelly SA. Effect on caries of restricting sugars intake: systematic review to inform WHO guidelines. *J Dent Res*. 2014;93(1):8-18 <http://www.ncbi.nlm.nih.gov/pubmed/24323509>

#### *Other*

Fardet A, Boirie Y. Associations between food and beverage groups and major diet-related chronic diseases: an exhaustive review of pooled/meta-analyses and systematic reviews. *Nutr Rev*. 2014;72(12):741-62 <http://www.ncbi.nlm.nih.gov/pubmed/25406801>

Wirfält E, Drake I, Wallström P. What do review papers conclude about food and dietary patterns? *Food & Nutrition Research* 2013. 57: 20523 <http://dx.doi.org/10.3402/fnr.v57i0.20523>.

17 OCT 2016

Ref. BU/GdS/VC/jj (2016) - out- 16235976

Ms Annica Sohlström  
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Hannesplanaden, 5  
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Sweden

**Re: Request for scientific assistance in assessing a dietary reference value for sugar, with particular attention to added sugar (EFSA-Q-2016-00414)**

*Ref.: Dnr 2016/02205 - 17/06/2016*

Dear Mrs Sohlström,

I am pleased to inform you that at its plenary meeting on 21-23 September 2016, the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) discussed the mandate received by EFSA on 22 June 2016 from the National Food Agencies of Sweden, Finland, Denmark, Norway and Iceland requesting scientific assistance in line with Regulation (EC) No 178/2002 in assessing if a dietary reference value for sugar with particular attention to added sugar can be set.

The NDA Panel considered that further information is needed from the requestors in order to specifically define the task. The points for clarifications are listed in the Annex to this letter.

In addition, if considered useful to further explain EFSA's points, we would be happy to participate in a teleconference with the requestors.

Please also note that in order to ensure coherence between risk assessment, risk management and risk communication functions in the European Union, EFSA has informed the European Commission and the Advisory Forum about this mandate.

Yours sincerely,



Bernhard Url

cc: M. Aho (Finnish Food Safety Authority, EVIRA, Finland)  
C. Nellemann (National Food Institute, DTU, Denmark)  
L. Hanssen (Scientific Committee for Food Safety, Norway)  
J. Gislason (Icelandic Food and Veterinary Authority, Iceland)  
V. Curtui, G. de Seze, S. Valtueña Martínez (EFSA)  
A. Nikolakopoulou, M. Marini, F. Carlucci, S. Bodenbach, L. Terzi, J. Vergnettes (DG SANTE)



## ANNEX

### Points for clarification as requested by the NDA Panel<sup>1</sup>

The Panel considered that further information would be needed from the requestor in order to define EFSA's task (i.e. definition of the Terms of Reference) in relation to the exposure of interest (dietary component(s)), the type of value(s) to be derived and the target population for the assessment.

In relation to the **exposure of interest**, it is important to define whether the scientific assessment should address one or more of the following:

- total sugars from all sources,
- added sugars from all sources,
- total or added sugars from solid foods,
- total or added sugars from liquid foods,
- specific food source(s) containing (added) sugars,
- other.

It should also be clarified whether different types of sugars (e.g. glucose, fructose, sucrose, lactose) should be considered separately.

In relation to the **type of values to be derived**, the Panel understands that the Dietary Reference Values (DRV) of interest to the requestor is the tolerable upper intake level (UL). This could be assessed if the request relates to a nutrient (e.g. total sugars from all sources, added sugars from all sources). If the available data does not allow setting a UL, the Panel could consider providing advice on a daily intake of total or added sugars from all sources which is not associated with adverse health effects. The latter approach could also be applied to a request in relation to specific food source(s) containing (added) sugars or to sugars (total or added) in different food forms (solids vs. liquids).

In relation to the **target population**, it should be clarified whether the request applies to the general healthy population, and if so, to which specific subgroups thereof (e.g. infants, children, adolescents, adults, the elderly, pregnant and lactating women), since different health outcomes may be relevant to the assessment for each specific subgroup.

The Panel also discussed the possibility that the request refers to an update of the EFSA's Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre published in 2010 only in relation to the section on sugars. In that Opinion, the NDA Panel addressed the effects of total and added sugars on nutrient density of the diet, glucose tolerance and insulin sensitivity, serum lipids, other cardiovascular risk factors (blood pressure), body weight, type 2 diabetes, and dental caries in adults and children.

The Panel noted that the time and resources needed for the assessment will very much depend on the scope and the Terms of Reference for this task.

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<sup>1</sup> Published in the Minutes of the 74th Plenary meeting of the Scientific Panel on Dietetic Products, Nutrition and Allergies, held on 21-23 September 2016, <https://www.efsa.europa.eu/en/events/event/160921a>

24, January 2017

Dnr 2016/02205  
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Italy

**Re: Request for scientific assistance in assessing a dietary reference value for sugar, with particular attention to added sugar (EFSA-Q-2016-00414).**

Ref: BU/GdS/VC/jj (2016) -out-16235976

Dear Mr Url

We would like to thank you for considering our request for scientific assistance in line with Regulation (EC) No 178/2002 in assessing a dietary reference value for added sugar. It would benefit the risk managers and substantially support their work with dietary guidelines and nutrient recommendations if they could base their advices on an up-to-date assessment from EFSA.

The request stems from concerns from risk managers in the Nordic countries who base their decisions on scientific assessments from EFSA and scientific assessments through the Nordic Nutrition recommendation 2012 (NNR2012) [1] as well as other legitimate factors. EFSA could not set a reference value for added sugar in the Scientific Opinion in 2010 [2]. However, in their systematic literature review preceding the NNR2012 Sonestedt et al [3] concluded that "*data from prospective cohort studies published in the years 2000-2011 suggest that sugar-sweetened beverages probably [4] increase the risk of type 2 diabetes. For related metabolic risk factors, cardiovascular disease or all-cause mortality and other types of sugars, too few studies were available to draw conclusions*".

After reception of the mandate you shared with us some questions posed by the NDA panel (in the minutes of the 74<sup>th</sup> Plenary meeting) which aim to specify scientific aspects of our query. Guided by the questions posed by the NDA-panel, experts from requesting countries have deliberated in order to specify the mandate further.

Regarding exposure of interest: the scientific assessment should address added sugars from all sources, using the definition used by EFSA 2010 [4] and by NNR2012 [1] i.e. including: "sucrose, fructose, glucose, starch hydrolysates such as glucose syrup, high-fructose syrup and other isolated sugar preparations used as such or added during food preparation and manufacturing".

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Regarding type of value: the requestors are interested in a science-based cut-off value for exposure of added sugar which is not associated with adverse health effects.

Regarding target population: the target population is the general healthy population, including children, adolescents, adults and the elderly.

Finally, the Panel raised the question if the request refers to an update of the EFSA's Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre published in 2010 only in relation to the section on sugars. Indeed, the request is related to an update of the 2010 opinion i.e. addressing the effects of added sugars on nutrient density of the diet, glucose tolerance and insulin sensitivity, serum lipids, other cardiovascular risk factors (blood pressure), body weight, type-2 diabetes, and dental caries in adults and children.

Yours sincerely,



Irene Mattisson  
PhD, Senior risk-and benefit assessor, National Food Agency, Uppsala, Sweden

On behalf of Nordic nutrition experts nominated by the Nordic food authorities:  
Lene Frost Andersen, Professor, Institute of Basic Medical Sciences, Oslo University, Norway  
Bryndís Eva Birgisdóttir, Associate professor, School of Health Sciences, University of Iceland, Iceland  
Ursula Schwab, Professor, University of Eastern Finland, Kuopio, Finland

#### References:

1. *Nordic Nutrition recommendations 2012*. 5th ed. Nord. Vol. 2014:002. 2014, Nordic Council of Ministers: Copenhagen.
2. Efsa Panel on Dietetic Products Nutrition and Allergies, *Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre*. EFSA Journal, 2010. 8(3).
3. Sonestedt, E., et al., *Does high sugar consumption exacerbate cardiometabolic risk factors and increase the risk of type 2 diabetes and cardiovascular disease?* Food & Nutrition Research, 2012. 56.
4. *Criteria for assigning grade of evidence in Nordic Nutrition Recommendation 2012*. 2014 Nordic Council of Ministers: Copenhagen. p. 60-61.