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Scientific Opinion advising on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods

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Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an Opinion advising on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. This Opinion is based on systematic reviews and meta-analyses of human studies on nutritionally adequate diets, data from the Global Burden of Disease framework, clinical practice guidelines, previous EFSA opinions and the priorities set by EU Member States in the context of their Food-Based Dietary Guidelines and associated nutrient/food intake recommendations. Relevant publications have been retrieved through comprehensive searches in PubMed. The nutrients included in the assessment have been selected based on expert knowledge. Food groups with important roles in European diets have been considered. The Panel concludes that dietary intakes of SFAs, sodium and added/free sugars are above current dietary recommendations and intakes of dietary fibre and potassium are below current dietary recommendations in a majority of European populations. As excess intakes of SFAs, sodium and added/free sugars and inadequate intakes of dietary fibre and potassium are associated with adverse health effects, they could be included in nutrient profiling models. Energy could be included in the model because a reduction in energy intake is of public health importance for European populations. In food group/category-based nutrient profiling models, total fat could replace energy owing to its high energy density in most food groups, while the energy density of food groups with low or no fat content may be well accounted for by the inclusion of (added/free) sugars in the model. Nutrients and non-nutrient components may be included in nutrient profiles for reasons other than their public health importance to allow for a better discrimination of foods within the same food category.

Keywords: diet, foods, nutrients, excess, inadequacy, diet-related chronic diseases

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1 Introduction

There is evidence from human studies about the relationship between the intake of certain nutrients and non-nutrient components of food and the development of obesity and other diet-related chronic diseases that are of importance for public health in Europe. Cardiovascular diseases (CVD), diabetes mellitus, obesity, osteoporosis, dental caries and cancer, but also iodine and iron deficiency, among others, have been considered by several European countries as public health priorities when setting food-based dietary guidelines (FBDGs) (see Appendix B, results of a questionnaire sent by EFSA to EU/EAA countries).

According to the Global Burden of Disease (GBD) database[1], in 2019, around 12% of the EU population (approx. 60 million people) were affected by CVD, with around 6 million new cases diagnosed per year. Around 10% (approx. 49 million people) suffered from type 2 diabetes mellitus (T2DM) (2 million new cases per year). Around 15% of adults were considered obese (BMI>30 kg/m^2, data from 2017)[2] and more than 23 million individuals in the EU (i.e. approx. 5% of the population) are at high risk of osteoporotic fractures (Kanis et al., 2021). Dental caries affects 20-90% of 6-year olds and almost 100% of adults.[3] Also, some types of cancers are related to diet, in particular, cancers of the gastrointestinal tract (WCRF/AICR, 2018).

A diet in line with science-based recommendations for food and nutrient intake is an important determinant of health. Because diets are composed of multiple foods, overall dietary balance may be achieved through complementation of foods with different nutrient profiles so that it is not necessary for individual foods to match the nutrient profile of a nutritionally adequate diet. Nevertheless, individual foods might influence the nutrient profile of the overall diet, depending on the nutrient profile of the particular food and its intake, in terms of frequency and amount (EFSA, 2008).

The term 'nutrient profile' refers to the nutritional composition of a food or diet, whereas 'nutrient profiling' refers to the classification of foods based on their nutritional composition for specific purposes (e.g. nutrition education, product reformulation, product labelling to help consumers make informed dietary choices, regulation of health claims, restriction of advertisement to children) (EFSA, 2008). The World Health Organization (WHO) defines nutrient profiling as 'the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health' (WHO, 2015b; Storcksdieck genannt Bonsmann et al., 2020).

Several nutrient profiling models have been developed worldwide. A systematic review that took into account publications up to 2016 identified 78 published nutrient profiling models (Labonté et al., 2018), of which 56% were newly developed models and 44% were a modification of an existing model. The models have been mainly drawn up for the purpose of establishing food standards for schools (n=27), front-of-pack labelling (n=12), restricting marketing of foods to children (n=10) and regulating health claims made on foods (n=7).

Nutrient profiling models may be established across the board, using the same criteria for all foods/food categories, or may be specific to certain food categories. The models may be based either on thresholds for individual nutrients or on an overall composite score that is the sum of scores attributed to foods according to specific criteria (EFSA, 2008; Santos et al., 2021). The majority of the nutrient profiling models identified by Labonté et al. (2018) were scoring systems, whereas three were based on thresholds of nutrients and four were hybrid systems. The majority had more than one food category to which different nutritional criteria were applied (ranging up to 99 categories). Only three models applied the same criteria across the board and 12 consisted of two categories. All models included nutrients and non-nutrient components of food that should be limited in the diet. These were mainly sodium, saturated fatty acids (SFAs) and sugars. Eighty-six percent of the models also included food groups (e.g. fruits, vegetables, nuts, legumes), nutrients (e.g. protein) and non-nutrient food

[1] http://ghdx.healthdata.org/

[2] https://ec.europa.eu/eurostat/databrowser/view/sdg_02_10/default/table?lang=en

[3] https://www.euro.who.int/en/health-topics/disease-prevention/oral-health/data-and-statistics#:~:text=In%20Europe%2C%2020%E2%80%9390%25,have%20experience%20of%20the%20disease

components (e.g. dietary fibre) whose consumption should be increased. A recent systematic review of existing nutrient profiling models, including, however, fewer models, shows similar results (Santos et al., 2021).

An important consideration when establishing nutrient profiling models is the reference quantity to which the nutrient content of a food is related, i.e. per serving size/portion, per weight/volume or per energy content. The advantages and disadvantages of the different options have been reviewed previously in detail by EFSA (2008). Finally, the validation of a nutrient profiling model is of importance in order to ensure the correct classification of foods for the purpose for which the model has been developed (Santos et al., 2021).

Front-of-pack (FOP) labelling is simplified nutrition information provided on the front of food packages aiming at helping consumers with their food choices.[4]

According to WHO (WHO, 2019), FOP refers to '*nutrition labelling systems that:*

- *are presented on the front of food packages (in the principal field of vision) and can be applied across the packaged retail food supply;*
- *comprise an underpinning nutrient profile model that considers the overall nutrition quality of the product or the nutrients of concern for [non-communicable diseases] NCDs (or both); and*
- *present simple, often graphic information on the nutrient content or nutritional quality of products, to complement the more detailed nutrient declarations usually provided on the back of food packages.*'

FOP labelling may take different forms, as reviewed by the Joint Research Centre (JRC) of the European Commission (Storcksdieck genannt Bonsmann et al., 2020).

Nutrient profiling models developed for the purpose of restricting nutrition and health claims have been reviewed by EFSA (2008), Labonté et al. (2018) and Santos et al. (2021).

1.1 Background as provided by the mandate requestor

The Commission adopted on 20 May 2020 the Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system (COM(2020) 381 final), as part of the European Green Deal. The strategy announces that to promote sustainable food consumption and facilitate the shift to healthy and sustainable diets, the Commission will adopt measures to empower consumers to make informed, healthy and sustainable food choices. In particular, the strategy announces that the Commission will propose harmonised mandatory front-of-pack nutrition labelling. The strategy further announces that to stimulate sustainable food processing and reformulation but also to facilitate the shift to healthier diets, the Commission will set nutrient profiles to restrict the promotion (via nutrition and health claims) of foods high in fat, sugars and salt.

The Farm to Fork Action Plan indicates that a proposal for harmonised mandatory front-of-pack nutrition labelling and for the setting of nutrient profiles to restrict the promotion of foods high in salt, sugars and/or fat will be submitted in Q4 2022.

On 20 May 2020, the Commission also published its Staff Working Document of the Evaluation of the Nutrition and Health Claims Regulation (SWD(2020) 95 final)[5], accompanying the Farm to Fork Strategy. The evaluation assessed the impact of the nonsetting of nutrient profiles and whether nutrient profiles are still fit for their purpose to ensure the objectives of the Claims Regulation. Overall, the evaluation findings show that the specific objective pursued by the setting of nutrient profiles is still pertinent and necessary to meet the objective of the Claims Regulation, which is a high level of consumer protection, and that therefore, the setting of nutrient profiles needs to be further considered. Article 4 of Regulation

[4] https://ec.europa.eu/food/safety/labelling-and-nutrition/food-information-consumers-legislation/nutrition-labelling_en
[5] https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-claims_swd_2020-95_part-1.pdf

1924/2006 on Nutrition and Health Claims on Foods foresees that the European Commission shall establish (by 19 January 2009) specific nutrient profiles that foods or certain groups of foods must respect in order to bear nutrition and health claims. Following the Commission's request of 19 February 2007, EFSA adopted on 31 January 2008 the Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on the setting of nutrient profiles for foods bearing nutrition and health claims. Despite the initial progress, nutrient profiles have not yet been established at EU level given the high controversy of the topic and strong opposition by some Member States in 2009, when the Commission tried to establish them.

On 20 May 2020, the Commission also adopted its report on front-of-pack nutrition labelling[6] (COM (2020) 207 final), accompanying the Farm to Fork Strategy. The Report presents the main front-of-pack nutrition labelling schemes currently implemented or being developed at EU level, as well as some of the schemes implemented at international level. The report looks into consumer understanding and impacts of the schemes, including on purchasing behaviour, food reformulation and the internal market. It also addresses the positions of Member States and stakeholders and the question of possible EU harmonisation. The report builds upon literature reviews and data gathered and analysed by the Joint Research Centre[7]. The report concludes that front-of-pack schemes have the potential to help consumers make health-conscious food choices and that evaluative schemes that use colour coding, with or without a graded indicator, appear most promising for improving the healthfulness of consumers' shopping baskets.

Nutrient profiling has various applications, including for health and nutrition claims and for front-of-pack nutrition labelling schemes. There are three main approaches for applying nutrient (profiling) criteria for front-of-pack labelling and the specific approach depends on the front-of-pack nutrition labelling system used[8].

The first typical approach to applying nutrient criteria is to enumerate the nutrient contribution that a food makes to recommended nutrient intakes (e.g. Reference Intakes); information on individual nutrients is kept separate. This approach is used in non-interpretive nutrient-specific front-of-pack schemes[9].

The second typical approach to applying nutrient profiling criteria[10] is to set threshold amounts (i.e. cut-off points) for individual nutrients, which divide nutrient contributions into categories that are either graded (e.g. high, medium and low in the case of the traffic lights label) or binary (e.g. meet the standard and do not meet the standard in the case of endorsement logos). Information on individual nutrients is kept separate. For endorsement logos, products only display the logo when all relevant cut-off points for individual nutrients are met[11].

The third typical approach is to apply algorithms to derive a consolidated score representing products' overall nutritional profile. Information on individual nutrients is combined. The approach is used for summary graded indicator schemes.

The second and third approaches differ from the first by interpreting the level of nutrient contribution that a food makes to dietary recommendations, going beyond the provision of numeric information.

Applying nutrient profiling approaches for the purpose of front-of-pack nutrition labelling and for the purpose of restricting nutrition and health claims on foods is an exercise that should take into account

[6] https://ec.europa.eu/food/sites/food/files/safety/docs/labelling-nutrition_fop-report-2020-207_en.pdf

[7] https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/front-pack-nutrition-labelling-schemes-comprehensive-review

[8] WHO guiding principles and framework manual for front-of-pack labelling for promoting healthy diet (2019)

[9] While such nutrient-specific schemes do provide some assessment of the contribution that a serving of food makes to nutrient intakes, such systems do not provide an evaluative judgement about how numerical values should be interpreted and, consequently, are referred to as a non-interpretive (WHO Health Evidence Network Synthesis Report 61)

[10] For the second and third approach, the terminology 'nutrient profiling' criteria is used; nutrient profiling is the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health (https://www.who.int/nutrition/topics/profiling/en/)

[11] Endorsement logos are therefore also considered as 'summary labels'.

dietary recommendations, public health considerations, generally acceptable scientific evidence on the relationship between diet, nutrition and health as well as other considerations of an industrial/commercial, cultural and dietary/culinary nature. Applying nutrient profiling approaches for front-of-pack labelling and for restricting claims should also stimulate product reformulation and should take into account the variability of dietary habits and traditions.

1.2 Terms of Reference as provided by the mandate requestor

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002, the European Commission requests the European Food Safety Authority to provide scientific advice for the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. In particular, the Authority is requested to provide scientific advice on the following:

- **Nutrients** of public health importance for European populations, **including non-nutrient components** of food (e.g. energy, dietary fibre)
- **Food groups** which have important roles in diets of European populations and subgroups thereof
- **Choice of nutrients and other non-nutrient components of food for nutrient profiling**

In providing scientific advice, the Authority is requested to consider the following:

Nutrients of public health importance for European populations, including non-nutrient components of food (e.g. energy, dietary fibre)

The consideration regarding nutrients as well as non-nutrient food components should be based on evidence of a dietary imbalance in European populations that might influence the development of overweight and obesity or diet-related diseases such as cardiovascular disease, or other disorders; they can include nutrients and non-nutrient food components that might be consumed to excess, as well as those for which intakes might be inadequate.

Food groups which have important roles in diets of European populations and subgroups thereof

Consideration should be given to the food groups/food categories which have important roles in diets of European populations and subgroups

- due to the quantities of energy, certain macro- and micronutrients, other substances of physiological importance as well as for other non-nutrient food components contained in the food group/food category,
- due to the role and importance of the food group/food category in the diet for the population in general or, as appropriate, of certain risk groups including children,
- due to the overall nutritional composition of the food group/food category,
- due to the presence or absence of nutritional elements that have been scientifically recognised as having an effect on health and
- due to effects on health of consuming the food group/food category.

Choice of nutrients and other non-nutrient components of food for nutrient profiling

The nutritional criteria and food components for nutrient profiling should aim to inform choice and enable interpretation of food products against risks for diet-related noncommunicable diseases (NCDs) and for promoting healthy diets.

The choice of nutrients of public health importance (e.g. sodium), including non-nutrient components of food (e.g. energy, other substances of physiological importance such as fibre) should be based on scientific evidence that underpins - directly or indirectly - the association of food components/food groups/food categories and related public health outcomes.

1.3 Context of the assessment

Upon a request from the European Commission, in 2008, the NDA Panel provided advice on nutrient profiling with the sole purpose of regulating nutrition and health claims made on foods (EFSA, 2008). The purpose was to avoid that nutrition or health claims could mislead consumers as to the overall nutritional composition of a food when trying to make 'healthy' choices in the context of a nutritionally adequate diet. Nutrient profiling models aimed at restricting nutrition and health claims on foods were not meant to communicate nutrition information to the consumer. When classifying foods as eligible to bear claims, the potential of the food to adversely affect the overall dietary balance was the main scientific consideration.

In the present mandate, the Commission requests EFSA to provide scientific advice for the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. This means that the scientific advice provided by the NDA Panel in 2008 should be extended for the purpose of helping consumers make 'healthy' choices through FOP labelling, and thus the main scientific consideration should also include the potential of foods to beneficially affect the overall dietary balance.

In the general principles for setting nutrient profiling models for the regulation of nutrition and health claims made on foods (EFSA, 2008) and for setting FBDGs[12] at national level (EFSA NDA Panel, 2010d), the NDA Panel noted that:

a) The nutrient profile of the overall (habitual) diet is an important determinant of health and the nutrient profile of a nutritionally adequate diet is defined by science-based recommendations for intakes of energy and nutrients (i.e. Dietary Reference Values (DRVs)).

b) Because diets are composed of multiple foods, overall dietary balance may be achieved through complementation of foods with different nutrient profiles, so that it is not necessary for individual foods to match the nutrient profile of a nutritionally adequate diet. Nevertheless, individual foods might influence the nutrient profile of the overall diet, depending on the nutrient profile of the particular food and its intake, in terms of amount and frequency.

c) For some foods, there is evidence of health benefits that cannot be attributed to their specific content of nutrients (e.g. fruits and vegetables). The level of consumption of foods with established relationships to health that are not nutrient specific should be considered when establishing FBDGs for individual countries.

d) For a number of nutrients and food groups, a dietary imbalance can increase the risk of obesity and diet-related diseases (e.g. CVD, some cancers, T2DM, osteoporosis and dental disease) that are of importance for public health in the EU. These include nutrients and foods that might be consumed to excess, as well as those for which intakes might be inadequate.

e) Nutrient profiling models should take into account the dietary role and importance of food groups and their contribution of nutrients to the overall diet of the population (or specific population groups), in order to ensure that some food items in food groups with an important dietary role might be eligible to bear claims.

f) The choice of nutrients to be included in nutrient profiling models should be driven by their public health importance for EU populations.

The Panel notes that these scientific considerations could underpin the setting of nutrient profiling models both for restricting claims on foods and for helping consumers to make 'healthy' food choices.

[12] FBDG constitute science-based policy recommendations in the form of guidelines for healthy eating

1.4 Interpretation of the Terms of Reference

The Panel understands that the scientific advice requested relates to the identification of:

a) **Nutrients and foods, including non-nutrient components of food** (e.g. energy, dietary fibre), that are of importance for public health in European populations. These include nutrients and foods that might be consumed in excess, as well as those for which intakes might be inadequate, in the context of current dietary recommendations on healthy diets either by European countries or independent scientific bodies.

b) **Food groups** with important dietary roles in European populations and subgroups thereof owing to their nutrient composition and their (habitual) intake, as recognised by Member States in FBDGs. FBDGs also make distinctions between different foods within these food groups based on their potential to influence, beneficially or adversely, the overall dietary balance for certain nutrients. The dietary roles of these food groups might differ across Member States owing to the variability of dietary habits and traditions.

c) **Criteria that could guide the choice** of nutrients, including non-nutrient components of food, **for the nutrient profiling of foods**, with the scope of developing harmonised mandatory FOP nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods.

The Panel also understands that this mandate is not a request to develop a nutrient profiling model or to provide advice on current profiling models already in use for different purposes.

The Panel further understands that the mandate is restricted to providing advice on the relationships between nutrients, non-nutrient components, foods and food groups and diet-related chronic diseases and does not cover any considerations related to the sustainability of the food chain. The Panel acknowledges that, in addition to scientific considerations, other issues may be taken into account by the European Commission in establishing nutrient profiling models for the above-mentioned purposes, e.g. feasibility and product innovation.

2 Data and Methodologies

2.1 Data

The data used in the present opinion are review publications, in particular systematic reviews and meta-analyses of human intervention and observational studies on nutritionally adequate diets, data from the Global Burden of Disease framework, clinical practice guidelines, previous EFSA opinions, and the priorities set by EU Member States in the context of their FBDGs and associated nutrient/food intake recommendations. Relevant publications have been retrieved through comprehensive searches in PubMed. Priority was given to previous assessments of EFSA, followed by systematic reviews and associated meta-analyses. In few cases, results of individual human studies have been considered, when this was relevant.

2.2 Methodologies

For this scientific assessment, a protocol (Appendix A) has been developed in line with existing methodology (EFSA, 2020).

The nutrients and non-nutrient components of food of public health importance for European populations that are consumed in excess or in inadequate[13] amounts have been identified based on expert knowledge and from a questionnaire sent by EFSA to EU/EAA countries through EFSA focal points (see Appendix B).

[13] In the context of this Opinion inadequate is to be interpreted as insufficient

2.3 Definitions

In the context of this Opinion, the following definitions apply:

- Nutrient profile: Nutritional composition of a food or diet.
- Nutrient profiling: Classification of foods based on their nutritional composition for specific purposes.
- Population Reference Intake (PRI): The level of (nutrient) intake that is adequate for almost all (97.5%) in a population group.
- Average Requirement (AR): The level of (nutrient) intake that is adequate for half of the people in a population group, given a normal distribution of requirements.
- Adequate Intake (AI): This value is estimated when a PRI cannot be established because an AR cannot be determined. It can, for example, be based on the average observed daily level of intake by a population group (or groups) of apparently healthy people that is assumed to be adequate.
- Reference Intake Range for macronutrients (RI): The intake range for macronutrients, expressed as % of the energy intake (E%). These apply to ranges of intakes that are adequate for maintaining health and are associated with a low risk of selected chronic diseases.
- Tolerable Upper Intake Level (UL): The maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans.
- Dietary Reference Values (DRVs): A set of nutrient reference values that include AR, PRI, AI, RI and UL. These values guide professionals on the amount of a nutrient needed to maintain health in an otherwise healthy individual or group of people.
- Cardiovascular disease (CVD): A general term referring to conditions affecting the heart and blood vessels. The most common is coronary heart disease. Stroke, transient ischemic attack, arrhythmia, peripheral vascular disease and aortic disease are other examples of CVD.[14]
- Coronary heart disease (CHD): The most common form of CVD. A pathological process characterised by atherosclerotic plaque accumulation in the coronary arteries, whether obstructive or non-obstructive (Knuuti et al., 2019).
- Cardiovascular event: Used to denote the composite of a variety of adverse events related to the cardiovascular system.
- Type 2 diabetes mellitus (T2DM): Diabetes is a group of metabolic diseases characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action, or both. T2DM encompasses individuals who have insulin resistance and usually have relative insulin deficiency (American Diabetes Association, 2014).
- Dietary fibre: In EFSA's scientific opinion on DRVs for carbohydrates and dietary fibre (EFSA NDA Panel, 2010b), dietary fibre denotes all non-digestible carbohydrates. The definition of dietary fibre for regulatory purposes in the EU is laid down in Regulation (EU) No 1169/2011.[15]
- Saturated fatty acids (SFAs): SFAs are characterised by carbon chains that contain no double bonds, i.e. only single bonds.

[14] https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cardiovascular-disease

[15] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22.11.2011, p. 18–63.

- *trans*-Fatty acids (TFAs): Unsaturated fatty acids (fatty acids with ≥1 double bond) that contain at least one double bond in the *trans* configuration (i.e. hydrogen atoms are positioned on the opposite side of the carbon chain at a double bond).
- *cis*-Fatty acids: Unsaturated fatty acids (fatty acids with ≥1 double bond) in which all double bonds are in the *cis* configuration (i.e. the hydrogen atoms are positioned at the same side of the carbon chain at a double bond).
- Monounsaturated fatty acids (MUFAs): Fatty acids characterised by one double bond in the carbon chain.
- Polyunsaturated fatty acids (PUFAs): Fatty acids characterised by more than one double bond in the carbon chain.
- Long-chain (LC)-PUFAs: PUFAs with a chain length of ≥20 carbon atoms and ≥3 double bonds.
- Omega 3 (n-3) fatty acids: PUFAs characterised by the presence of a double bond, three carbon atoms away from the terminal methyl group in their chemical structure.
- Omega 6 (n-6) fatty acids: PUFAs characterised by the presence of a double bond, six carbon atoms away from the terminal methyl group in their chemical structure.
- Linoleic acid (LA): Essential PUFA, precursor of the n-6 family, with 18 carbon atoms and two *cis* double bonds (C18:2, n-6).
- alpha-Linolenic acid (ALA): Essential PUFA, precursor of the n-3 family, with 18 carbon atoms and two *cis* double bonds (C18:3, n-3).
- Arachidonic acid (ARA): PUFA of the n-6 group with 20 carbon atoms and four *cis* double bonds (C20:4, n-6).
- Eicosapentaenoic acid (EPA): LC-PUFA of the n-3 group with 20 carbon atoms and five *cis* double bonds (C20:5, n-3).
- Docosahexaenoic acid (DHA): LC-PUFA of the n-3 group with 22 carbon atoms and six *cis* double bonds (C22:6, n-3).
- Total sugars: Main types of mono- and disaccharides found in mixed diets (i.e. glucose, fructose, galactose, sucrose, lactose, maltose and trehalose) (EFSA NDA Panel, 2021).[16]
- Added sugars: Mono- and disaccharides added to foods as ingredients during processing or preparation at home, and sugars eaten separately or added to foods at the table.
- Free sugars: Added sugars plus sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates.
- Core food groups: Food groups supplying most macro- and micronutrients in the diet as recommended in FBDGs.
- Non-core food groups: Food groups for which FBGDs generally advise to limit consumption.

[16] According to European legislation (Regulation (EU) No 1169/2011), sugar alcohols (polyols) such as sorbitol, xylitol, mannitol and lactitol, which are low-calorie sugar replacers that can be used in foods also for purposes other than sweetening, are 'carbohydrates' not included under the term 'sugars' and will not be considered in this opinion. Alongside polyols, other substances used as sugar replacers and other mono- or disaccharides present in the diet in marginal amounts are not included in the term 'sugars' for the purpose of this assessment (e.g. isomaltulose, D-tagatose)

3 Assessment

3.1 Nutrients and non-nutrient components of foods of public health importance for European populations

Harmonised data on food intakes of infants, children, adults, older people, pregnant and lactating women in 21 European Member States plus the UK are available in the EFSA Comprehensive Food Consumption Database.[17] The methods used for estimating dietary intakes varied among countries and even within countries. Nutrient intakes for these population groups have been calculated using the EFSA Nutrient Composition Database[18] (Roe et al., 2013). The database covers approximately 1,750 food entries and additional facet descriptors included in the EFSA food classification system (FoodEx2), and contains data for energy, macro- and micronutrients from national food composition databases up to 2012, provided by 14 national food database compiler organisations. These data have been used by EFSA to provide intake estimates, mostly for micronutrients, in scientific opinions on DRVs for nutrients since 2014. The nutrients for which such intake estimates from the EFSA Comprehensive Food Consumption Database are available are sugars, choline, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin E, vitamin K, vitamin D (infants only), calcium, copper, iron, magnesium, phosphorus, potassium, selenium and zinc and these have been used in the present Opinion. For nutrients for which such harmonised intake estimates are not available, the Opinion is mostly based on nutrient intakes derived from national dietary surveys cited in the respective EFSA Opinions on DRVs.

3.1.1 Nutrients and non-nutrient components of food for which intakes might exceed recommended levels in most population groups and countries in Europe

3.1.1.1 Energy

It is well-established that a sustained positive energy balance, i.e. when energy intake exceeds requirements, leads to an accumulation of body fat (Hall et al., 2011). This may ultimately result in the development of overweight or obesity. Overweight and obesity increase the risk of developing diet-related chronic diseases, such as T2DM or CVD, and some cancers (World Cancer Research Fund and American Institute for Cancer Research, 2018). Overweight and obesity have also been associated with a higher all-cause mortality (Mongraw-Chaffin et al., 2015; Aune et al., 2016b; Global BMI Mortality Collaboration et al., 2016). Evidence from randomised controlled trials (RCTs) shows that weight loss in obese adults improves cardiometabolic risk factors in a dose-response manner, namely blood pressure, blood lipid profile and blood glucose control. It has also been shown in RCTs that weight loss, and its maintenance over time, significantly decreases the risk of developing T2DM in obese individuals (Jensen et al., 2014) and reduces the risk of all-cause mortality (Ma et al., 2017).

Data on the prevalence of overweight (i.e. body mass index (BMI) $\geq$25 kg/m^2) or obesity (i.e. BMI $\geq$30 kg/m^2) in adults in Europe are available from Eurostat[19], the Global Obesity Observatory[20] and WHO.[21] Estimates from the different data providers differ to a certain extent, possibly owing to the different assessment techniques (self-reports vs. measured weights and heights) and populations studied. However, they indicate that the prevalence of overweight or obesity in EU Member States ranges between around 50 to 75% in males and between around 35 to 65% in females. The prevalence of obesity ranges between around 10 to 30% in males and 10 to 35% in females, depending on the country.

Combining data of different age groups from 2007 to 2019 and using different cut-offs for defining overweight and obesity (i.e. WHO, International Obesity Task Force (IOTF), Centers for Disease Control

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[17] https://www.efsa.europa.eu/en/food-consumption/comprehensive-database
[18] https://www.efsa.europa.eu/en/microstrategy/food-composition-data
[19] https://ec.europa.eu/eurostat/databrowser/view/HLTH_EHIS_BM1E__custom_970518/default/table?lang=en
[20] https://data.worldobesity.org/
[21] https://www.who.int/data/gho/data/themes/topics/topic-details/GHO/ncd-risk-factors

(CDC) or other), the Global Observatory for Obesity reports a prevalence of overweight or obesity in children in EU Member States of around 10 to 45%.[22] WHO data in 5 to 19-year-old children indicate a prevalence of overweight or obesity (BMI>+1 SD above the median) between 25 and 40% in boys and between 20 and 35% in girls. The prevalence of obesity (BMI>+2 SD above the median) is between 8 and 17% in boys and between 5 and 11% in girls.

ARs for energy were set by EFSA in 2013 (EFSA NDA Panel, 2013) for children and adults, by sex, assuming a normal body weight, based on the calculated resting energy expenditure and considering different physical activity levels. For infants, the AR was based on measurements of total energy expenditure in healthy, full-term and initially breast-fed infants, plus the energy requirement for growth. A PRI was not derived, as this implies an energy intake that is above the requirement for almost all individuals in a group. As the AR still exceeds the energy needs of half of the individuals in the group, it can be used to assess energy intakes in groups of healthy people but is of limited value for individuals (EFSA NDA Panel, 2013).

Lacking information on the physical activity level of the individuals included in dietary surveys in summary publications, and owing to the complex mechanisms regulating energy balance, it is difficult to establish whether energy intakes in a population exceed energy requirements solely based on intake data. However, considering the high prevalence of overweight and obesity in Europe, it can be inferred that energy intakes are higher than required to maintain a normal body weight (BMI of 18.5 to 24.9 kg/m^2) in a large proportion of the European population.

While DRVs for protein are set based on physiological requirements (see Section 3.1.2.1), those for fat and digestible carbohydrates are not, but need to reflect the difference between total energy requirement and energy provided by protein. Digestible carbohydrates are not essential and physiological requirements for essential fatty acids cover only part of the energy needs. Therefore, the RIs for digestible carbohydrates (45 to 65 E%) and total fat (20 to 35 E%) have been derived by EFSA (EFSA NDA Panel, 2010c, b) based on their effects on the blood lipid profile (i.e. the upper bound for carbohydrates and the lower bound for fat) and the observation that high fat diets may promote energy intake and weight gain (i.e. the upper bound for fat and the lower bound for carbohydrates). Also, practical considerations (e.g. observed levels of intake, achievable dietary patterns) have been taken into account. Owing to the positive impact of energy restriction and weight loss on cardiometabolic risk factors and chronic disease risk, the specific effect of individual macronutrients on these endpoints is generally assessed in isocaloric exchange with each other (Willett et al., 1997).

Energy-containing food constituents (macronutrients, dietary fibre, alcohol, polyols) have been assigned energy conversion factors for labelling purposes[23], as shown in Table 1. In some cases (e.g. glycaemic carbohydrates, dietary fibre, polyols), such energy-conversion factors are average values that reflect the energy provided by the food constituent as found in mixed diets or are average values set based on practical considerations. They do not necessarily reflect the energy provided by specific components in the group (Elia and Cummings, 2007).

Table 1 Energy conversion factors for energy-containing food constituents for labelling purposes

Food constituent	Energy conversion factor
Fat	9 kcal/g (37 kJ/g)
Alcohol	7 kcal/g (29 kJ/g)
Protein	4 kcal/g (17 kJ/g)
Glycaemic carbohydrates	4 kcal/g (17 kJ/g)
Polyols	2.4 kcal/g (10 kJ/g)
Dietary fibre	2 kcal/g (8 kJ/g)

[22] Data on the prevalence of obesity alone in children are not available from this data source

[23] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.OJ L 304, 22.11.2011, p. 18–63

Although energy intake appears more important than the macronutrient composition of diets for weight loss and the prevention of weight gain, there is some evidence that diets with a moderate fat content (<30-35 E%) favour lower energy intake, weight loss and prevent weight gain as compared to energy dense diets containing >35 E% as fat (EFSA NDA Panel, 2010c). Guidelines for the prevention and management of uncomplicated obesity[24] (NICE, 2015; Yumuk et al., 2015) recommend limiting energy intake and decreasing the consumption of energy-dense foods, among other interventions, both to prevent excessive weight gain and manage overweight and obesity.

Taking into account the high prevalence of overweight and obesity in Europe, the Panel considers that a reduction in energy intake is of public health importance for European populations.

3.1.1.2 Fat

Fat is an important source of energy and facilitates the absorption of fat-soluble dietary components such as fat-soluble vitamins. Fats and oils are also important sources of essential fatty acids (i.e. LA and ALA).

An RI has been established for total fat between 20 E% and 35 E% for adults, suggesting that wide ranges of total fat intake are compatible with nutritionally adequate diets. The lower bound corresponds to the lowest observed intakes in European countries with no overt signs of deficiencies and no adverse effects on blood lipids. The upper bound is based on evidence that moderate fat intakes may favour lower energy intake, weight loss and prevent weight gain, although it is acknowledged that total fat intakes > 35 E% may be compatible with both good health and normal body weight, depending on dietary patterns and the level of physical activity (EFSA NDA Panel, 2010c).

While the RI for total fat is partly based on practical considerations (e.g. current levels of intake, achievable dietary patterns), the fatty acid composition of the diet is an important determinant that influences blood lipid concentrations and CVD risk. Under isocaloric conditions, the most favourable blood lipoprotein profile for atherosclerosis risk prevention is achieved by replacing mixtures of SFAs and TFAs with *cis*-MUFAs (mostly oleic acid) and/or mixtures of *cis*-PUFAs (mostly the n-6 *cis*-PUFA LA, the n-3 *cis*-PUFA ALA and the n-3 LC-PUFAs EPA and DHA). These effects are dose-dependent (EFSA NDA Panel, 2010c, 2011d, b).

The main dietary determinant of blood low-density lipoprotein (LDL)-cholesterol concentrations is saturated fat. Dietary cholesterol has a similar dose-response effect on blood LDL-cholesterol, but it is consumed in considerably lower daily amounts (in the milligram range). Similarly, the impact of ARA (a n-6 *cis*-PUFA) and of EPA and DHA on the blood lipid profile is expected to be low considering the low daily consumption (in the milligram range) in European diets as compared to SFAs.

Although the replacement of mixtures of SFAs and TFAs by mixtures of *cis*-MUFAs and/or mixtures of *cis*-PUFAs results in a more favourable blood lipid profile for ischemic CVD prevention, DRVs for SFAs, TFAs, *cis*-MUFA or *cis*-PUFA could not be set by EFSA based on this endpoint for different reasons that are explained in the following.

Mixtures of SFAs and TFAs were shown to increase LDL-cholesterol concentrations in a dose-response manner as compared to carbohydrates, mixtures of *cis*-MUFAs and mixtures of *cis*-PUFAs, and to increase CVD risk compared to *cis*-PUFAs (mainly LA). Owing to the linearity of the dose-response, a UL could not be established. The Panel considered that the intake of SFAs and TFAs should be as low as possible in the context of a nutritionally adequate diet.

cis-MUFAs have no known specific role in preventing or promoting diet-related diseases (EFSA NDA Panel, 2010c; Schwingshackl et al., 2021) and hence no DRV has been set.

[24] Obesity without other morbidities

In view of the different metabolic effects of the various dietary *cis*-PUFAs, no DRVs were established by EFSA for either total *cis*-PUFAs or the n-3/n-6 ratio.

There is an inverse (i.e. beneficial) relationship between the intake of LA and blood LDL-cholesterol concentrations, while this relationship is positive (also beneficial) for HDL-cholesterol concentrations. In addition, LA lowers fasting blood triglyceride concentrations when compared to carbohydrates, and LA, when replacing mixtures of SFAs, decreases cardiovascular events in the population (EFSA NDA Panel, 2010c). All these relationships are linear and dose-dependent, with no threshold value. While ALA has similar effects on blood lipids than LA, its relationship with CVD risk when replacing SFAs is less established. In both cases, data on blood lipids and chronic disease risk reduction could not be used to establish a DRV. AIs for these essential fatty acids were derived from the lowest estimated mean intakes of various population groups from a number of European countries where overt deficiency symptoms are not present. For adults, the AI for LA is 4 E% and for ALA 0.5 E%. Their relative contribution to the blood lipid profile and CVD risk when replacing SFAs and TFAs in the diet could in part depend on the different amounts in which they are consumed.

Conversely, an AI of 250 mg/day for EPA and DHA combined was derived based on primary CVD risk prevention. At these levels of EPA and DHA intake, other mechanisms than their effect on the blood lipid profile (e.g. antiarrhythmic effects) may be more important, as explained in Section 3.1.2.2. on EPA and DHA.

In the context described above, SFAs and TFAs will be considered as nutrients that may be consumed in excess, whereas EPA and DHA will be considered as nutrients for which the intake may be inadequate, in both cases in relation to CVD disease risk.

3.1.1.3 Saturated fatty acids

It is well established that the fatty acid composition of the diet is an important determinant of blood lipid concentrations and CVD risk. Under isocaloric conditions, the most favourable lipoprotein profile for atherosclerosis risk prevention is achieved by replacing SFAs and TFAs in mixed diets with *cis*-MUFAs (mostly oleic acid) and/or mixtures of *cis*-PUFAs (mostly the n-6 LA, the n-3 ALA and the n-3 LC-PUFAs EPA and DHA). These effects are dose dependent. (EFSA NDA Panel, 2010c, 2011d, b).

There is a differential effect of different SFAs on blood lipid concentrations. While lauric, myristic and palmitic acids raise blood LDL-cholesterol when replacing carbohydrates, the effect of stearic acid is more neutral (EFSA NDA Panel, 2010c, f). However, fatty acids occur as mixtures in foods and foods rich in stearic acid often contain significant amounts of palmitic acid and other SFAs that increase blood LDL-cholesterol concentrations (EFSA NDA Panel, 2010f). Therefore, the effect of mixtures of SFAs as present in mixed diets is considered below.

It has been consistently demonstrated that there is a positive and causal relationship between blood LDL-cholesterol concentrations and the risk of developing ischemic CVD, and that the reduction in disease risk is proportional to the reduction of LDL-cholesterol concentrations (EFSA NDA Panel, 2018; Mach et al., 2020). Since there was no evidence for a threshold below which mixtures of SFAs do not raise LDL-cholesterol concentrations at the levels of intake observed in mixed diets, EFSA could not establish a UL for SFAs, but considered that intakes should be as low as possible in the context of a nutritionally adequate diet compatible with current dietary patterns and traditions in European populations. Several Member States have recommended upper bounds of intake that are mostly in the range of 8-10 E%.[25]

Despite the well-established LDL-cholesterol-raising effects of SFAs, some meta-analyses of observational studies failed to show a positive association between the intake of SFAs in mixed diets and CVD risk in isocaloric exchange with other macronutrients (Siri-Tarino et al., 2010; de Souza et al., 2015; Zhu et al., 2019; Kang et al., 2020). Several possible explanations have been advanced. On the one hand, it has been proposed that the relationship may depend on the food matrices in which SFAs

[25] https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/dietary-fats-table-4_en

are consumed, and that other nutrient and/or non-nutrient components of SFA-rich foods may modify the risk of developing CVD (Mozaffarian et al., 2010; Mozaffarian, 2016; Astrup et al., 2020). On the other hand, it is possible that, under isocaloric conditions, the health benefits of reducing SFAs in relation to ischemic CVD risk prevention largely depend on the macronutrient by which they are replaced in the diet. For example, while the CVD risk-lowering effect of *cis*-PUFAs (primarily LA and n-3 LC-PUFA) are sizeable, no benefit is obtained from replacing SFAs with refined carbohydrates (e.g. sugars) (Briggs et al., 2017; Visseren et al., 2021).

The SFA content of fats and oils is variable. The highest percentages of SFAs, expressed as % of total fatty acids, are found in coconut oil (about 90%), palm kernel oil (about 85%), cocoa butter (about 60%), butter, palm oil, lamb fat (all about 50%), beef fat (about 45%) and pork fat (about 40%). The relative proportion of individual SFAs in different food sources also differs. The major SFA in palm oil and butter is palmitic acid, while coconut oil and palm kernel oil contain lauric acid as the predominant fatty acid (EFSA NDA Panel, 2010c; Devi and Khatkar, 2018). The saturated fat component of beef, lamb and pork is characterised by high amounts of palmitic and stearic acid (Wood et al., 2007).

In a review of sources and dietary intakes of fatty acids in Europe, Eilander et al. (2015) reported that the main contributors to SFA intake were dairy (i.e. 17-41%), fats and oils (9-37%), meat and meat products (15-30%), cake and pastry/desserts and sugar/preserve confectionary (reported without percentage contribution to overall SFA intake). Only in Finland and the UK, were cereals and cereal products also significant contributors to SFA intake (16-18%). The authors noted that data on the fatty acid composition of some foods listed in national food composition databases are incomplete indicating that the actual SFA, *cis*-MUFA and *cis*-PUFA intakes calculated based on these incomplete composition data may have been underestimated.

In the food consumption surveys considered in the Scientific Opinion on DRVs for fats (EFSA NDA Panel, 2010c), mean intakes of SFAs in most EU Member States were above the recommended upper bounds of intake of 8-10 E%. This is in agreement with more recent publications (Micha et al. (2014), Eilander et al. (2015) and the European Commission[26]). Intake data on individual SFAs could not be retrieved.

As SFAs increase LDL-cholesterol concentrations, an established risk factor for ischemic CVD, and the majority of European populations exceed the upper bounds of intake recommended by some Member States, the Panel considers that a reduction in intake of SFAs as present in mixed diets is of public health importance for European populations.

3.1.1.4 *Trans* fatty acids

TFAs increase blood LDL-cholesterol concentrations in a linear dose-dependent manner to a similar extent to SFAs. In addition, and different from SFAs, TFAs reduce blood high-density lipoprotein (HDL)-cholesterol concentrations and increase the total cholesterol to HDL-cholesterol ratio (EFSA NDA Panel, 2010c; Mach et al., 2020). High intakes of TFAs have been associated with an increased risk of ischemic CVD (Bendsen et al., 2011).

Owing to the positive (i.e. unfavourable) and linear dose-response relationship between the intake of TFAs and adverse effects on the blood lipid profile, EFSA could not establish a UL for TFAs. However, several European Member States have recommended upper bounds of intake for TFAs <1-2 E% by considering what is practically achievable within the context of a nutritionally adequate diet based on known patterns of intake of foods and nutrients in specific populations (EFSA NDA Panel, 2010c).

TFAs are naturally present in dairy products and meat from ruminants, usually at concentrations between 2 and 9% of total fat (Mouratidou et al., 2014). They may also originate from deodorisation of vegetable oils and from heating oils at temperatures >220°C, such as in deep frying (EFSA NDA Panel, 2010c). A major source of TFAs in the diet are partially hydrogenated oils that are used in the

[26] https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/dietary-fats-5b_en

manufacturing of margarines and spreads, fine bakery wares, and fillings of confectionary, among others (Mach et al., 2020).

Intakes of TFAs have decreased considerably in Europe owing to reformulation of food products. Already in 2004, mean intakes of TFAs were close to 1-2 E% in most European countries (EFSA NDA Panel, 2010c). In a report of the JRC of the European Commission published in 2014 (Mouratidou et al., 2014) that considered data from 13 studies published between 2006 and 2013, mean intakes of TFAs were at 1 E% or below in all countries and population groups. TFAs intakes >1 E% were observed in 25% of the surveyed individuals between the age of 20 and 30 years, the age group with the highest intakes. However, even in this population group, maximum intakes were around 1.2 E%. In addition, as of April 2021, food products that are sold within the European Union may not contain industrially produced TFAs in amounts exceeding 2% of total fat.[27] This is expected to further reduce the consumption of TFAs in the EU.

The Panel notes that the adverse health effects of diets high in TFAs are well documented. The Panel also notes, however, that mean intakes of TFAs in most European countries and population groups are at or below upper bounds of intakes recommended by some Member States within the context of nutritionally adequate diets. The implementation of current European legislation limiting the use of industrially produced TFAs is expected to further reduce intakes.

3.1.1.5 Dietary sugars

There is wide consensus that the intake of dietary sugars is causally related to the development of dental caries at all ages (Jepsen et al., 2017). There is also evidence that high intakes of added and free sugars increase the risk of developing chronic metabolic diseases including obesity, non-alcoholic fatty liver disease, T2DM, dyslipidaemia and hypertension, possibly through an increase in energy intake and body weight, among other mechanisms (WHO, 2015a; EFSA NDA Panel, 2021).

In its draft Scientific Opinion on the UL for dietary sugars (released for public consultation), the NDA Panel concluded that the available scientific evidence did not allow to derive a UL or a safe level of intake for dietary sugars because, whenever dose-response relationships between the intake of dietary sugars and disease risk could be explored, these were positive and linear, and a level of sugar intake at which the risk of disease is not increased could not be established (EFSA NDA Panel, 2021). The Panel considered, however, that based on dental caries risk, the intake of total sugars should be as low as possible within the context of a nutritionally adequate diet. The Panel also considered that, based on the risk of developing chronic metabolic diseases and on dental caries risk, the intake of added and free sugars should be as low as possible. The Panel noted that, at levels of added or free sugars intake below 10 E%, the uncertainty is high regarding the shape and direction of the relationships between the intake of added and free sugars and chronic metabolic disease risk.

Several authorities have set recommendations for added or free sugars below 10 E%, or below 5 E%, based on various health endpoints, including chronic metabolic diseases and dental caries. Typically, such recommendations also reflect a judgement of what level of sugar intake is practically achievable within the context of a nutritionally adequate diet based on known patterns of intake of foods and nutrients in specific populations.

The main dietary source of added sugars in Europe is sucrose added at the table and to processed foods, while fructose-glucose syrups (isoglucose)[28] are increasingly used as a substitute for sucrose in processed foods and beverages due to their higher sweetness, technological characteristics, and lower price.

[27] Commission Regulation (EU) 2019/649 of 24 April 2019 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in fat of animal origin. OJ L 110, 25.4.2019, p. 17–20

[28] Council Directive 2001/111/EC of 20 December 2001 relating to certain sugars intended for human consumption. OJ L 10, 12.1.2002, p. 53–57

Food groups mostly contributing to the intake of added and free sugars in European countries are 'sugar and confectionery' (i.e. table sugar, honey, syrups, confectionery and water-based sweet desserts), followed by beverages (sugar-sweetened soft and fruit drinks, fruit juices) and fine bakery wares. The main difference between the intake of added and free sugars is accounted for by fruit juices. In infants, children and adolescents, sweetened milk and dairy products are also major contributors to mean intakes of added and free sugars. Different from total sugars, added and free sugars mainly originate from non-core food groups, except for milk and dairy products in young consumers.

There is high variability in the intake of added and free sugars across population groups and countries in Europe. In consumers of certain food groups, intakes of added and free sugars exceed the recommended intakes in most European countries.

Taking into account the well-established positive relationships between a) the intake of dietary sugars (total/added/free) and dental caries risk and b) the intake of added and free sugars and the risk of developing chronic metabolic diseases, and that intakes of added and free sugars in consumers of certain food groups exceed the recommended intakes in most European countries, the Panel considers that a reduction in the intake of added and free sugars is of public health importance for European populations. The Panel notes that decreasing the intake of added and free sugars would decrease the intake of total sugars to a similar extent.

3.1.1.6 Sodium

The positive (i.e. unfavourable) and causal relationship between the intake of dietary sodium and blood pressure is well established. High sodium intakes increase blood pressure and the risk of hypertension, which is a risk factor for CVD and chronic kidney disease (Williams et al., 2018; Arnett et al., 2019; EFSA NDA Panel, 2019b; Visseren et al., 2021).

In 2019, EFSA established a safe and adequate intake for sodium of 2.0 g/day for adults and children from 11 years of age based on the relationship between sodium intake, blood pressure values, and risk of CVDs (composite endpoint) including coronary heart disease and stroke in adults (EFSA NDA Panel, 2019b). The same year, the National Academy of Sciences in the US (NASEM, 2019) established a Chronic Disease Risk Reduction Intake (CDRR) for sodium based on the beneficial effect of reducing sodium intake on CVD risk, risk of hypertension, systolic blood pressure, and diastolic blood pressure. For individuals 14 years of age and older, sodium intakes should be reduced if above 2.3 g/day. Neither body could establish a UL for sodium.

Unprocessed foods and drinking water contain sodium, albeit in low amounts. The sodium content of processed foods can vary substantially across countries, reflecting dietary habits and taste preferences. It may also be influenced by technological considerations and by reformulation of processed foods in response to public health policies. Also, large variations exist in the sodium content of foods belonging to the same group. Sauces (particularly Asian ones), processed meat, cheese, savoury snacks and canned fish are the food groups with the highest sodium content (Webster et al., 2010; Ni Mhurchu et al., 2011; Capuano et al., 2013; Eyles et al., 2013; EFSA NDA Panel, 2019b), while the main contributors to sodium intake in European populations are bread, processed meat and cheese (European Commission, 2012; Kloss et al., 2015; EFSA NDA Panel, 2019b).

Sodium intakes have been estimated from urinary sodium excretion data collected in 18 European countries (EFSA NDA Panel, 2019b). These data showed that mean sodium intakes in adults and children exceeded the safe and adequate level of intake.

Taking into account the well-established relationships between sodium intake, blood pressure and CHD risk, and that the majority of European populations exceed the safe and adequate level of intake, the Panel considers that a reduction in the intake of dietary sodium is of public health importance for European populations.

3.1.1.7 Conclusions

The Panel notes that mean intakes of SFAs, sodium and added/free sugars exceed the recommended upper bounds of intake in the majority of European populations and subgroups thereof. The Panel considers that excessive consumption of these nutrients is associated with adverse health effects, and that a reduction in the intake of SFAs, sodium and added/free sugars is of public health importance for European populations.

The Panel also notes that, owing to the high prevalence of overweight and obesity in Europe at all ages, energy intake exceeds requirements for the maintenance of a normal body weight in the majority of European populations. The Panel considers that excess energy intake leading to overweight and obesity is associated with adverse health effects, and that a reduction of energy intake is of public health importance for European populations. Although adverse health effects of diets high in TFAs are well documented, mean intakes of TFAs in most European countries and population groups are at or below recommended limits within the context of a nutritionally adequate diet. Moreover, the public health importance of TFAs has been already addressed through the implementation of current European legislation limiting the use of industrially produced TFAs in foods, which is expected to further reduce intakes.

3.1.2 Nutrients and non-nutrient components of food for which intakes might be inadequate in relation to recommended levels in some population groups and countries in Europe

3.1.2.1 Protein

The human body requires dietary protein to support tissue growth and maintenance. The concept of protein requirement includes both total nitrogen and indispensable amino acids. In this context, protein is defined as total nitrogen x 6.25 and protein requirement is based on nitrogen content. In adults, protein requirement can be measured individually using nitrogen balance, which is the difference between nitrogen intake and the amount lost in urine, faeces, via the skin and other routes. In healthy adults who are in energy balance, the protein requirement (maintenance requirement) is defined as the amount of dietary protein sufficient to achieve zero nitrogen balance (EFSA NDA Panel, 2012a).

Animals and plants are the main dietary sources of protein. Most animal sources (meat, fish, egg, milk and dairy products) provide high-quality protein, i.e. with high digestibility and optimal indispensable amino acid composition (i.e. high biological value) for human needs. The indispensable amino acid content of plant proteins (grains and grain-based products, legumes, and nuts) and/or their digestibility is usually lower. However, the combination of different plant sources of protein (e.g. grains and legumes) may result in an adequate indispensable amino acid intake for humans (EFSA NDA Panel, 2012a).

A meta-analysis of available data on nitrogen balance as a function of nitrogen intake (Rand et al., 2003) was used to estimate the average requirement for protein in adults and children as 105 mg N (or 0.66 g high quality protein) per kg body weight per day, with the 97.5^{th} percentile being at 133 mg N (or 0.83 g high quality protein) per kg body weight per day. Thus, an intake of 0.83 g of high-quality protein/kg per day (e.g. 58 g/day for a 70-kg individual) was considered sufficient to cover the protein requirements of 97.5% of the general adult population. This PRI derived by EFSA can be applied to usual mixed diets in Europe, which are likely to contain sufficient amounts of all indispensable amino acids (EFSA NDA Panel, 2012a).

Protein intakes above the level required to achieve nitrogen balance (i.e. the PRI) have no beneficial effects on muscle mass or function at any age. The scientific evidence for the adverse health effects of high protein intakes reported in the literature (i.e. in relation to body weight control, glucose homeostasis, bone health or kidney function) did not allow to derive a UL for dietary protein (EFSA NDA Panel, 2012a).

Dietary surveys in Europe suggest that average protein intakes in the European adult population (i.e. ranging between 67 and 114 g/day in men and between 59 and 102 g/day in women) are mostly above the PRI. Dietary surveys also indicate that protein intakes are at, or more often above, the PRI in infants >6 months of age (EFSA NDA Panel, 2017), in children, and during pregnancy and lactation (EFSA NDA Panel, 2012a).

The Panel notes that average protein intakes in Europe are above the PRI in most population groups and countries, and that no beneficial effects on muscle mass or function can be expected from increasing protein intakes further.

3.1.2.2 EPA and DHA

EPA and DHA are n-3 LC-PUFAs, i.e. n-3 PUFAs with ≥20 carbon atoms. EPA can be transformed to eicosanoids. These include prostaglandins, prostacyclins and leukotrienes, which are involved in the regulation of blood pressure, renal function, blood coagulation, inflammatory and immunological reactions and other processes. DHA is a component of structural lipids of membranes. It is mostly found in phospholipids in the nervous tissue and the retina. Large amounts are accumulated in the developing brain, particularly during the first two years of life (EFSA NDA Panel, 2010c).

A meta-analysis of RCTs in adults without existing CVD comparing high with low n-3 LC PUFA consumption, showed a small but statistically significant reduction in the risk of CVD including CHD mortality and in the risk of CHD events with moderate to low certainty in the evidence (Abdelhamid et al., 2020). Prospective cohort studies also indicate that fish consumption decreases the risk of CVD, and particularly the risk of CHD mortality and sudden cardiac death, in healthy individuals (EFSA NDA Panel, 2010c, 2014c). These associations have also been observed when n-3 LC-PUFAs are used as the exposure variable instead of fish and appear to be dose dependent up to about 250 mg of EPA and DHA per day, i.e. 1-2 servings of oily fish per week (EFSA NDA Panel, 2010e, 2014c).

There are several mechanisms by which the intake of EPA and DHA from fish and fish oil could reduce CVD risk. EPA and DHA have a well-established antiarrhythmic effect and decrease blood triglycerides, blood pressure, heart rate, and platelet aggregation in a dose-response manner. The shape of these doses-response curves and their time course, however, are highly variable, as well as the relative contribution of each of these factors to CVD risk prevention. At the levels of intake observed in European diets (in the milligram/day range), the physiological effects that are most likely to account for clinical cardiovascular benefits, particularly regarding fatal CHD and sudden cardiac death prevention, are a) the modulation of myocardial sodium and calcium ion channels, reducing susceptibility to ischemia-induced arrhythmia, and b) improved myocardial efficiency as a result of reduced heart rate, lower systemic vascular resistance, and improved diastolic filling (Mozaffarian and Rimm, 2006; Mozaffarian and Wu, 2011; Rimm et al., 2018).

The AI for adults for the combination of EPA and DHA of 250 mg/day was set by the NDA Panel based on studies on fish consumption and primary prevention of CVD. The same AI was set for children aged 2 years and above. For infants >6 months and young children up to 2 years, an AI for DHA of 100 mg/day was derived based on the effect of this fatty acid on visual function in the complementary feeding period (EFSA NDA Panel, 2010c).

Sources of EPA and DHA are almost exclusively foods of marine origin, mainly oily fish and derived products.

Representative dietary intake estimates of EPA and DHA in Europe are sparse. In 2012 (EFSA NDA Panel, 2012b), the intake data available (from 4 or 5 European countries depending on the fatty acid) came from various publications using different dietary assessment methods, food composition databases and age cut-offs. Mean daily intakes in adults from food only (i.e. excluding food supplements) were between 50 mg/day and 150 mg/day for EPA and between 131 mg/day and 273 mg/day for DHA. In 2014 (EFSA NDA Panel, 2014c), harmonised nutrient intake data from seafood (including EPA and DHA combined) were calculated for the five European countries with the highest percentage of seafood consumed specified at species level in dietary surveys, using the EFSA food composition and consumption databases. Mean daily intakes of EPA and DHA in adults ranged from 122 to 585 mg/day, with high variability across countries depending on the percentage of fish consumers. Mozaffarian et al. (2017) reported median intakes of EPA and DHA from fish between 89 mg/day and 563 mg/day in prospective cohort studies conducted in five European countries, with the highest intakes being found mostly in northern European countries.

The Panel notes that harmonised EPA and DHA intake data across European countries and population groups are scarce and that intakes may vary widely across countries depending on the intake of fish/seafood and products thereof.

The average consumption of fish flesh and processed fish and seafood per day in adults and adolescents (consumers and non-consumers) in 21 EU Member States as reported in the EFSA Comprehensive Food Consumption Database ranges from around 7 to 58 g/day, the wide range also reflecting the varying percentages of individuals who consumed fish on the days of the surveys. As the data are mostly based on 24-h recalls and dietary records with 2-3 replicates[29], the percentage of individuals never consuming fish in EU Member States cannot be reliably estimated. The recommendations for fish consumption in FBDGs of EU Member States differ and range from 100 to 500 g/week. Even though in the majority of surveys the mean weekly consumption of fish flesh and processed fish and seafood reaches 100 g, comparisons to national recommendations indicate that mean intakes are below those recommendations in all or some subpopulations of adults and adolescents in Austria (pregnant women and adolescents only), the Czech Republic, Denmark, Germany, Greece, Hungary, Ireland (adults, but not in the elderly or very elderly), Italy (very elderly only), Latvia (pregnant women only), Romania and Sweden (adolescents only). The Panel notes that the available data suggest that fish consumption in some EU Member States is below national recommendations.

The Panel considers that intakes of EPA and DHA may be below the AI in European countries with low fish consumption.

The Panel considers that intakes of EPA and DHA may be inadequate for primary CVD risk reduction in Member States with low consumption of fish/seafood and products thereof.

3.1.2.3 Dietary fibre

Dietary fibre has been defined in several ways for risk assessment and management purposes. In EFSA's Scientific Opinion on DRVs for carbohydrates and dietary fibre (EFSA NDA Panel, 2010b), dietary fibre denotes all non-digestible carbohydrates. This includes non-starch polysaccharides, resistant starches, resistant oligosaccharides with three or more monomeric units and other non-digestible, but quantitatively minor components that are associated with the dietary fibre polysaccharides, especially lignin. The most recent definitions of dietary fibre proposed at national and international level are quite consistent, but differences exist regarding whether: a) associated substances (e.g. lignin) are explicitly mentioned, b) the minimum number of monosaccharide units that are required to be included in the definition, and c) the requirement, mainly for extracted, isolated, modified or synthetic carbohydrate polymers, that they have a proven health benefit (Stephen et al., 2017). Most authorities provide non-exhaustive lists of health benefits related to dietary fibre, the most common being in the areas of bowel function, and of lipid and glucose metabolism. The definition of dietary fibre for regulatory purposes in the EU is laid down in Regulation (EU) No 1169/2011.[30]

The main characteristics that may mediate the health effects of dietary fibre include viscosity and the capacity to form gels in the intestinal tract, fermentability in the colon, and water-holding capacity.

[29] Only in Ireland and Sweden four replicates were done and in Denmark seven.

[30] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22.11.2011, p. 18–63.

Whole grain cereals, legumes, fruits and vegetables, and potatoes when eaten with the skin, are the main sources of dietary fibre, but mushrooms, nuts and seeds also contain high amounts. In whole-grain products, the lignified outer layers are the predominant dietary fibre source. Oats and barley contain high concentrations of β-glucan, a water-soluble, viscous type of polysaccharide. Pectins are the main type of dietary fibre in fruits and vegetables and have properties similar to β-glucan (EFSA NDA Panel, 2010b).

Dietary fibre helps to maintain normal bowel function and alleviates constipation by decreasing colonic transit time and increasing faecal mass (EFSA NDA Panel, 2010b; Portalatin and Winstead, 2012). Dietary fibre increases stool bulk by enhancing the water-holding capacity of stools (Portalatin and Winstead, 2012). Fermentable components of dietary fibre are metabolised by the microbiota, which stimulates microbial growth and increases faecal bulk (Cummings, 2001).

The intake of dietary fibre as found in mixed diets has been inversely associated to the risk of developing CVD and T2DM in prospective cohort studies (EFSA NDA Panel, 2010b). This is supported by the results of recent meta-analyses investigating the relationship between dietary fibre intake and CHD (Threapleton et al., 2013; McRae, 2017), stroke (Zhang et al., 2013; McRae, 2017), cardiovascular mortality (McRae, 2017), and T2DM (Yao et al., 2014). The mechanisms by which dietary fibre could affect CVD and T2DM risk are not fully elucidated but may depend on the characteristics of the different fibre types. The viscosity and gel-forming capacity in the intestinal tract appear to influence glucose and lipid metabolism. Viscous fibres have shown to delay carbohydrate absorption and decrease the postprandial glycaemic responses to carbohydrate-rich meals. They could also lower blood total and LDL-cholesterol concentrations (Bazzano, 2008) by increasing the viscosity of the gut content, enhancing bile acid synthesis and excretion of bile acids and cholesterol in faeces (Ellegård and Andersson, 2007; Wolever et al., 2010; Wang et al., 2017). Epidemiological evidence suggests a beneficial effect of total dietary fibre on weight management (Koh-Banerjee et al., 2003; Du et al., 2010).

In 2010, EFSA derived an AI of 25 g per day of dietary fibre from mixed diets (as AOAC fibre or equivalent) that is compatible with an intestinal transit time of about two to three days and a defaecation frequency of one per day and a faecal moisture of >70%, and may be considered adequate for normal laxation in adults (EFSA NDA Panel, 2010b). Dietary fibre intake of 2 g per MJ was considered adequate for normal laxation in children based on the dietary fibre intake that is adequate for normal laxation in adults (25 g, equivalent to 2 to 3 g per MJ for daily energy intakes of 8 to 12 MJ) and taking into account that energy intake relative to body size in children is higher than in adults. The effect of dietary fibre on cardiometabolic risk is generally expected to occur at dietary fibre intakes above the AI (EFSA NDA Panel, 2010b).

Average intakes of dietary fibre across European adult populations are in all surveys, except one, below the AI of 25 g/day (data from national dietary surveys) (EFSA NDA Panel, 2010b). A more recent compilation of national intake data compiled by the European Commission[31] is mostly in line with this observation. In children, the AI of 2 g/MJ was exceeded in around half of the surveys; in the other half, mean intakes ranged from 1.7 to 1.9 g/MJ.

The Panel considers that adequate intake of dietary fibre contributes to maintaining normal bowel function and normal laxation and contributes to reducing the risk of CVD and T2DM. Taking into account that intakes of a majority of European adult populations are below recommendations, and that chronic disease risk reduction could take place at intakes above those recommended for the maintenance of normal bowel function, the Panel considers that an increase in dietary fibre intake is of public health importance for European populations.

[31] https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/dietary-fibre-overview-3_en

3.1.2.4 Potassium

Potassium is an essential mineral and is required for normal cell function. It is the predominant osmotically active intracellular element. It plays a major role in the transfer of water inside and outside cells, assists in the regulation of the acid-base balance, and contributes to establishing a membrane potential that supports electrical activity in nerve fibres and muscle cells (EFSA NDA Panel, 2016a).

Potassium intake has been reported to be associated with several health outcomes, particularly cardiovascular endpoints. Adequate dietary potassium intake protects against developing hypertension and improves blood pressure control in patients with hypertension, while inadequate potassium intake may increase blood pressure (Aburto et al., 2013). Furthermore, there is consistent evidence from observational cohort studies that potassium intakes below 3,500 mg (90 mmol)/day are associated with a higher risk of stroke (Vinceti et al., 2016).

In 2016, EFSA established an AI for potassium of 3,500 mg (90 mmol)/day for adult men and women based on the relationship between potassium intake, blood pressure and risk of stroke. For infants and children, the AIs were extrapolated from the AI for adults by isometric scaling and including a growth factor and range between 750 and 3,500 mg/day, depending on the age (EFSA NDA Panel, 2016a). This was in line with WHO recommendations given in 2012 (WHO, 2012).

Potassium is present in all foods, with the highest contents in starchy roots or tubers, vegetables, fruits, whole grains, dairy products, and coffee. In Europe, the main food groups contributing to potassium intakes were starchy roots or tubers and products thereof, grains and grain-based products, milk and dairy products, and vegetables and vegetable products and fruit and fruit products, including fruit and vegetable juices (EFSA NDA Panel, 2016a). Substantial potassium losses may occur during food processing and cooking (Barciela-Alonso and Bermejo-Barrera, 2015).

Mean dietary intakes of potassium in infants and children up to 10 years of age exceeded the AI, as reviewed in EFSA NDA Panel (2016a) based on data derived from the EFSA Comprehensive Food Consumption Database. In adults, average intakes of females were generally below the AI. Average intakes of adult males were below the AI in around half of the surveys and age categories (EFSA NDA Panel, 2016a).

Since adequate dietary intakes of potassium contribute to maintain blood pressure levels in the normal range and to reduce the risk of stroke, and dietary intakes of potassium appear to be inadequate in the majority of European adult populations, the Panel considers that an increase in potassium intakes is of public health importance for European populations.

3.1.2.5 Iodine

Iodine is an essential nutrient, required as a structural and functional element of thyroid hormones. Through the effects of these hormones, iodine has an important role in energy-yielding metabolism and the expression of genes that control several physiological functions, including embryogenesis and growth, and the development of neurological and cognitive functions (EFSA NDA Panel, 2014b).

The clinical effects of iodine deficiency are referred to as iodine deficiency disorders. Iodine deficiency can lead to impaired thyroid function, goitre and hypothyroidism, and is associated with a decreased fertility rate and increased infant mortality. Iodine deficiency is also linked to mental development disorders in children, causing poor school performance and reduced work capacity (EFSA NDA Panel, 2014b).

In 2014, EFSA set an AI for iodine for adult men and women of 150 µg/day based on urinary iodine excretion levels that have been associated with the lowest prevalence of goitre. For pregnant women, an AI of 200 µg/day was derived. For infants aged 7–11 months and for children, AIs ranged between 70 µg/day and 130 µg/day (EFSA NDA Panel, 2014b).

Foods are very variable in their content of iodine. Good sources of iodine are marine products (such as fish, crustaceans and bivalves), eggs, milk, and their derivatives, and iodised salt. It has to be, however, noted that iodine content of milk and eggs is influenced by feeding practices (EFSA NDA Panel, 2014b). Milk and dairy products are the main sources contributing to 25 - 70% of total daily iodine intake in many European populations, depending on the amount of milk and dairy products consumed and their iodine content (van der Reijden et al., 2017). Iodine intake is also related to the content of iodine salts in soils, which is low in mountainous areas and river valleys prone to flooding (WHO, 2004).

Iodine fortification of salt has been implemented in 40 European countries, either as mandatory fortification (13 countries) or voluntary fortification (16 countries), and is not regulated in the other countries. The amount of iodine that is added varies from 10–75 mg/kg salt, but is mostly in the range of 15–30 mg/kg (EFSA NDA Panel, 2014b). It is assumed that mandatory salt iodisation at 25 mg/kg salt ensures adequate iodine intake in all population groups, including pregnant and lactating women (Dold et al., 2018).

Iodine intake can be assessed by measuring urinary iodine concentration (UIC), as 90% of iodine consumed is excreted in urine. The following criteria based on urinary iodine concentration in populations have been suggested: median UIC <20 µg/L, severe iodine deficiency in the population; median UIC 20-49 µg/L, moderate iodine deficiency; median UIC 50-99 µg/L, mild iodine deficiency; median UIC 100-199 µg/L, adequate iodine intake. For pregnant women, a median UIC of <150 µg/L reflects inadequate intakes in the population, owing to the higher iodine requirements during pregnancy (WHO, 2004).

A UIC of 100 µg/L corresponds to an approximate iodine intake of 150 µg/day in adults.

In a recent study assessing iodine status in Europe based on data from 40 studies from 23 European countries, median standardised[32] UIC was <100 µg/L in 6.3% (i.e. 1 out of 16) studies in schoolchildren. In adults, 53.8% (i.e. 7 out of 13) studies indicated iodine deficiency in the population with a median standardised UIC <100 µg/L. Seven out of 11 (63.6%) studies in pregnant women had a median UIC <150 µg/L (Ittermann et al., 2020).

The Panel considers that adequate dietary intakes of iodine are important for normal thyroid function and prevent the incidence of iodine deficiency disorders. Inadequate iodine intakes that are observed in some European countries and some sub-populations are mainly addressed by national policies in Member States (see also Appendix B).

3.1.2.6 Iron

Iron is required for oxygen transport (as an essential component of haemoglobin), electron transfer, oxidase activities and energy metabolism (EFSA NDA Panel, 2015b).

Often, iron deficiency anaemia (IDA) is used as a surrogate indicator of nutritional iron deficiency. However, IDA may also have non-dietary causes, including conditions that cause blood loss or malabsorption. IDA in infants and young children has been associated with impaired psychomotor development and cognitive performance. However, much of the research performed on this outcome is confounded by socio-economic factors and by the difficulties in standardising the outcome measurements. In adults, impaired physical performance and an inefficient energy metabolism has been observed (EFSA NDA Panel, 2015b).

In the Panel's Scientific Opinion on DRVs for iron (EFSA NDA Panel, 2015b), the PRI (AR) for iron has been set at 11 (6) mg/day for adult men and post-menopausal women and at 16 (7) mg/day for pre-menopausal, pregnant and lactating women, by using a factorial approach. For children, age-specific values have been set and are stratified by age and sex subgroups, i.e. 11 (6) mg/day for infants 7-11 months, 7 (5) mg/day for 1-6-year-olds. 11 (8) mg/day for 7-11-year-old children and 12-17-year-old boys and 13 (7) mg/day for 12-17-year-old females.

Foods that contain relatively high concentrations of iron include meat, fish, cereals, beans, nuts, egg yolks, dark green vegetables, potatoes and fortified food products. The iron content of dairy products

[32] Data of the individual studies were harmonised *a posteriori* using conversion formulas established by linear regression models

and many fruits and vegetables is much lower. Bioavailability of iron from plant foods (non-haem iron) is generally much lower than that from animal (haem-iron) foods (due to a different absorption mechanism for non-haem iron versus haem-iron). The iron status in vegetarians and vegans has been reported to be markedly lower than the omnivorous counterparts in the population. However, absorption of elemental iron from plant sources can be enhanced by reducing agents present in food, most notably by the joint intake of vitamin C - this has also been acknowledged in previous EFSA Opinions (EFSA NDA Panel, 2009, 2015b).

Dietary iron intakes have been estimated by EFSA using the EFSA Comprehensive Food Consumption Database, by selecting data from 13 dietary surveys from nine countries, i.e. Finland, France, Germany, Ireland, Italy, Latvia, the Netherlands, Sweden and the UK (EFSA NDA Panel, 2015b). Except for 7-11 months-old infants, median iron intakes exceeded the AR in all population groups and surveys. In 7-11-months-old infants, median intakes were below the AR all four surveys available.

Infants that are at particular risk of iron deficiency are exclusively breastfed infants >4 months of age born to mothers with a low iron status, with early umbilical cord clamping (< 1 min after birth), born preterm, born small-for-gestational age, or with a high growth velocity. These infants may benefit from the early introduction of complementary foods that are good sources of iron (EFSA NDA Panel, 2019a). The European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) emphasises the importance of all infants receiving iron-rich complementary foods, owing to the high iron requirements during that life stage (Fewtrell et al., 2017).

The Panel is aware that estimates of the percentage of the population that have inadequate iron intakes vary (Milman, 2019, 2020a; Milman, 2020b) and depend on the reference values that are chosen as comparator. Population groups that are commonly considered to have a higher risk of inadequate iron status are women of childbearing age, pregnant women and children, including certain exclusively breast-fed infants >4 months of age (see above). Generally, routine iron supplementation (of any population group) is not encouraged in Europe owing to the risk of overconsumption of iron in individuals with sufficient iron stores. Therefore, advice for supplementary intake is limited to individuals with clinically determined impaired iron stores (Brannon and Taylor, 2017).

The Panel considers that low iron intakes are a risk factor for the development of IDA that is associated with adverse health effects. Inadequate iron intakes in infants at risk of iron deficiency are usually addressed by national nutrition policies in Member States by recommending feeding foods that are good sources of iron in the weaning period in line with the recommendations given by ESPGHAN. Inadequate iron intakes in other population subgroups are usually addressed through individual advice.

3.1.2.7 Calcium and vitamin D

Insufficient dietary supply of calcium leads to resorption of calcium from bone, causing a loss of bone mass that can result in osteopenia (i.e. lower than normal bone mineral density (BMD) and osteoporosis (EFSA NDA Panel, 2015a). Inadequate intakes of vitamin D lead to inefficient absorption of dietary calcium and phosphorus, and thus causes an impaired mineralisation of bone (EFSA NDA Panel, 2016b). However, also genotype and environmental and lifestyle factors other than calcium and vitamin D intake play key roles in the maintenance of BMD (EFSA NDA Panel, 2015a).

Combined intakes of calcium and vitamin D at levels of or above 1,200 mg and 800 IU per day, respectively, have been associated with a reduction of the risk of osteoporotic fractures (EFSA, 2009; EFSA NDA Panel, 2010a). Also, there is evidence that intakes of vitamin D and calcium, as compared to calcium alone, reduce the risk of falling (EFSA NDA Panel, 2011a). More recent meta-analyses are in line with these findings (Yao et al., 2019; Thanapluetiwong et al., 2020).

There is debate on the amount of calcium that is required to prevent osteoporosis. Willett et al. (2019) and WHO (2003) suggested that calcium intakes in adults of around 500 mg/day may already be sufficient to maintain bone health, based on the notion that in countries with a high fracture incidence, a minimum of 400-500 mg/day of calcium may be sufficient to prevent osteoporosis (WHO, 2003;

Willett et al., 2019) and that increasing calcium intakes above this minimum level might not have a beneficial effect on the risk of fractures (Bischoff-Ferrari et al., 2007).

However, DRVs for calcium indicate a PRI that is higher than 500 mg/day (DH, 1991; WHO/FAO, 2004; IoM, 2011; Nordic Council of Ministers, 2014; D-A-CH, 2015; EFSA NDA Panel, 2015a; ANSES, 2016; Health Council of the Netherlands, 2018).

EFSA has proposed a PRI (AR) for young adults 18-24 years of age of 1,000 (860) mg/day and for adults ≥25 years of 950 (750) mg/day. For young children aged 1-3 years, the PRI (AR) for calcium has been set at 450 (390) mg/day, for children 4-10 years at 800 (680) mg/day, for adolescents 11-17 years of age at 1,150 (960) mg/day (EFSA NDA Panel, 2015a).

Unlike other vitamins, vitamin D_3 can be synthesised in the body following exposure to sunlight or artificial UV-B irradiation. Dietary intake is, however, essential when the endogenous synthesis is insufficient to cover requirements. Factors affecting the endogenous synthesis of vitamin D_3 include latitude, season, ozone layer and clouds (absorbing UV-B irradiation), surface characteristics (reflecting UV-B irradiation), time spent outdoors, use of sunscreen, clothing, skin colour and age. As these factors may vary considerably, DRVs have been derived based on the assumption that the endogenous vitamin D synthesis is minimal (EFSA NDA Panel, 2016b).

Taking this into account, EFSA has set an AI for vitamin D for adults, including pregnant and lactating women, and children aged 1–17 years of 15 µg/day. For infants aged 7–11 months an AI of 10 µg/day was derived (EFSA NDA Panel, 2016b). These AIs can, however, mostly not, be achieved by dietary intakes alone. Intakes of around 16 µg/day from food alone (i.e. somewhat higher than the AI) were only achieved in high consumers (95^{th} percentile), according to published dietary intake data (EFSA NDA Panel, 2016b).

The main contributors to calcium intake, as reviewed in EFSA NDA Panel (2015a), are milk and dairy products that are responsible for between 38 and 85% of the intake, followed by grains and grain-based products (2-35%), water and water-based beverages (1-18%) and vegetables and vegetable products (1-11%). Composite dishes and coffee, cocoa, tea and infusions also contribute up to 12% to the intake.

Dietary sources of vitamin D are mostly fatty fish and eggs, food supplements and fortified foods. Small amounts are also provided by meat (Spiro and Buttriss, 2014).

Calcium intake was estimated in the Panel's Scientific Opinion on DRVs for calcium (EFSA NDA Panel, 2015a) by using data from the EFSA Comprehensive European Food Consumption Database. Data were available from 13 dietary surveys including nine countries (Finland, France, Germany, Ireland, Italy, Latvia (pregnant women), the Netherlands, Sweden and the UK). Comparison of the median calcium intake to the AR, showed that adolescents, in particular, are at risk of inadequate intakes. More than 50% of this population (both males and females) in four out of five surveys (i.e. those of France, Germany, Italy and the Netherlands) had calcium intakes below the AR.

The prevalence of inadequate vitamin D status, i.e. serum 25(OH)D concentrations of <45 or 50 nmol/L, in Europe was reviewed by Spiro and Buttriss (2014). Studies from Austria, France, Germany, the Netherlands, Spain and Northern Europe showed that the prevalence of serum 25(OH)D concentrations of <45 or 50 nmol/L ranged from about 28 to 67% in adults. For children, data from Austria showed that around 40% of 7-14-year-old children were below this cut-off and that 92% of 13-year old children from Denmark, Finland, Ireland and Poland did not reach serum 25(OH)D concentrations of 45-50 nmol/L. Being at a higher risk of vitamin D inadequacy, the following population groups are often advised to take vitamin D supplements: infants and young children, pregnant and breast-feeding women, older people, individuals with low or no sun exposure, people with darker skin living in Europe (e.g. NICE, 2014; Rusińska et al., 2018).

The Panel considers that adequate intakes of calcium and vitamin D are required for the maintenance of bone mass. A reduction in the risk of osteoporotic fractures and the risk of falling has only been evidenced beyond the PRI at intakes of and above 1,200 mg calcium and 800 IU vitamin D per day. The Panel notes that vitamin D status in European populations is inadequate in a large proportion of children and adults living in Europe and that population groups at particular risk of inadequate status are well known. The Panel also notes that dietary intakes of calcium may be inadequate in adolescents. Even though elderly may have sufficient calcium intakes compared with the DRVs, intakes may not be sufficient to reduce the risk of osteoporotic fractures and the risk of falling, especially if associated with a suboptimal vitamin D status.

The Panel considers that whether an increase in calcium intake is beneficial may depend on the population group and that in some cases the recommended intake cannot be achieved through dietary modifications alone. The Panel also considers that vitamin D inadequacy in at-risk populations identified in the national context is ideally addressed by national policies in Member States.

3.1.2.8 Folate

Folate is a generic term used for a family of water-soluble organic compounds that belong to the group of B-vitamins. It is an essential micronutrient, required for the synthesis of ribo- and deoxyribonucleic acids (RNA and DNA), and consequently for cell division, and tissue growth, methylation reactions and amino acid metabolism (EFSA NDA Panel, 2014a).

In folate deficiency, DNA replication and thus cell division may be impaired, leading to the production of large and immature macrocytic cells that can result in megaloblastic anaemia. It is well established that periconceptual folate supplementation is associated with a reduced risk of development of neural tube defects, a group of congenital malformations, in the developing fetus. As a consequence, women of childbearing age are advised to consume folic acid supplements in addition to food folate at a dose of 400 µg/day (IoM, 1998; EFSA NDA Panel, 2014a; D-A-CH, 2015; NHMRC, 2017; SACN, 2017).

The EFSA NDA Panel (2014a) established an AI for folate for infants aged 7-11 months of 80 µg DFE[33]/day. For children and adolescents, PRIs were derived by using allometric scaling from the adult AR, and range from 120 to 330 µg DFE/day, respectively. For healthy adults, a PRI of 330 µg DFE/day was set based on the maintenance of adequate folate status. An AI of 600 µg DFE/day was proposed for pregnancy. This value does not include the advice to consume folic acid supplements periconceptionally. For lactating women, a PRI of 500 µg DFE/day was set.

The main sources of naturally occurring food folates are dark green leafy vegetables, legumes and rice. From animal sources, beef liver and crabs are particularly high in folate. Fortified foods, such as breakfast cereals, are the main contributors to the overall dietary intake of folic acid (EFSA NDA Panel, 2014a). Dietary intake of folate was estimated by the Panel in its Opinion on DRVs for folate (EFSA NDA Panel, 2014a), based on national dietary surveys from the Netherlands, Ireland and Germany, the only surveys available at the time expressing intakes as DFEs, even though the way in which DFEs were computed was heterogeneous among them. The Panel notes that data on folate intake in Europe expressed as DFE are insufficient and do not allow conclusions to be drawn on the adequacy of intake in European populations.

The Panel considers that the main public health concern in relation to folate intakes is the periconceptional folate intake of women of childbearing age, that is mainly addressed by national policies in Member States (see also Appendix B).

3.1.2.9 Conclusions

The Panel concludes that intakes of dietary fibre and potassium are inadequate in a majority of European adult populations. An increase in the intake of these nutrients is of public health importance owing to the adverse health effects that are caused by inadequate intakes of these nutrients. An increase in intake may be achieved through modification of the habitual diet. The Panel also considers

[33] DFE: dietary folate equivalents. For combined intakes of food folate and folic acid, DFEs can be computed as follows: µg DFE = µg food folate + (1.7 x µg folic acid)

that intakes of EPA and DHA may be inadequate for primary CVD risk prevention in Member States with low consumption of fish/seafood and products thereof.

The Panel notes that intakes of calcium, vitamin D, folate, iodine and iron may also be inadequate in certain subgroups of European populations. An increase in the intake of these nutrients is important for such subgroups of the population only, and adequate intakes may not always be achieved through modification of the habitual diet. Inadequate intakes of these nutrients are usually addressed by national nutrition policies in Member States and/or individual advice.

The Panel also notes that, even if dietary protein is required to support tissue growth during childhood and adolescence and maintain muscle mass and function during adulthood and in the elderly, average protein intakes in Europe are above the PRI in most population groups and countries.

3.2 Food groups which have important roles in diets of European populations and subgroups thereof

3.2.1 Role of food groups in European diets as addressed in food-based dietary guidelines of EU Member States

Twenty-eight FBDGs from 27 EU Member States were considered in this Opinion, as compiled by Wollgast et al. (2018). Belgium had two FBDGs, one for Flanders and one for Wallonia.

Starchy foods: Starchy foods provide complex carbohydrates. When consumed in the form of whole grain products, they are also a good source of dietary fibre, B-vitamins, tocopherols and folate. This food group in FBDGs of European countries comprises mainly cereals and cereal-derived products, such as bread, pasta, rice, couscous or bulgur, and potatoes. However, it also includes products that may contain considerable amounts of sugars, fat, SFAs and/or salt, such as some breakfast cereals, fine bakery wares, fried products, snacks or some breads.

Generally, FBDGs recommend eating starchy foods several times per day with an emphasis on whole grain products, on choosing products low in SFAs, sugars and/or sodium and on reducing consumption of fried products.

The FoodEx 2 term names (level 1) in EFSA's Comprehensive Food Consumption Database associated with starchy foods are 'grains and grain-based products' and 'starchy roots and tubers and primary derivatives thereof'.

Fruits and vegetables, including juices: Fruits and vegetables are sources of vitamins, minerals and dietary fibre. FBDGs stress the importance of consuming a variety of fruits and vegetables every day. However, processing may alter the nutritional properties. For example, juicing leads to a reduction in dietary fibre content and drying to a concentration of the natural sugar content. Also, sugar could be added during processing, such as in canned fruits with syrup, compotes, marmalades or jams. FBDGs are nevertheless not homogeneous in their recommendations regarding the consumption of food products within this group. For example, fruit juices are considered equivalent to a portion of fruit in one country and as sugar-sweetened beverages in another. Most countries, however, recommend restricting the consumption of **fruit juice** to about one serving per day or suggest preferring fresh fruit over juice. A few countries also suggest limiting the intake of **dried fruits** or **canned fruits** or advise the consumption of canned fruits in natural juice rather than syrups. Some processed vegetables may also contain significant amounts of added sodium.

The FoodEx 2 term names (level 1) associated with fruits and vegetables are 'fruit and fruit products' and 'vegetable and vegetable products'. Fruit and vegetable juices and nectars are covered under 'fruit and vegetable juices and nectars (including concentrates)' also at level 1.

Legumes and pulses: Legumes and pulses provide carbohydrates, dietary fibre and protein and are also rich in micronutrients. Recommendations in FBDGs to consume legumes span from consumption of 1-2 times per week to up to 3-4 times per week. The consumption of legumes and pulses is specifically encouraged in six FBDGs and in another 10 the substitution of meat with legumes and pulses is recommended. Canned legumes and pulses may contain significant amounts of added sodium.

The associated FoodEx 2 term name is 'legumes' at level 2, nested within 'legumes, nuts, oilseeds and spices' (level 1).

Milk and dairy products: Milk and dairy products are important contributors to the intake of protein, calcium, riboflavin, vitamin B_{12} and iodine. They may, however, also contribute to SFA intake (depending on the fat content) and to added sodium or added sugar intake. FBDGs of EU Member States are consistent in recommending daily consumption of skimmed and semi-skimmed milk, low-fat yoghurt, sour milk products or similar and low-fat cheeses. In some cases, recommendations are made to choose cheeses low in salt and dairy without added sugar.

The associated FoodEx 2 term name (level 1) is 'milk and dairy products'.

Meat and meat products (including offal): Meat is a good source of high-quality protein, iron, zinc, some vitamins (e.g. vitamin A and D) and MUFAs. Meat and meat products may, however, contribute significantly to the intake of SFAs and added sodium in case of processed meat. Most FBDGs recommend limiting meat intake typically to around 300-600 g per week, mainly choosing lean meats, and not eating meat every day. Some FBDGs specifically suggest reducing consumption of red meat and processed meat. As alternatives to meat, fish, eggs, pulses and products thereof, including tofu, and mycoprotein-based foods as well as seitan are mentioned.

The associated FoodEx 2 term name (level 1) is 'meat and meat products'. Meat substitutes are not included in this category.

Fish and shellfish including products thereof: Fish, depending on the species, is a significant contributor to n-3 LC-PUFAs, iodine and vitamin D intake. Some processed fish products may be high in sodium. Regular fish consumption is recommended in all FBDGs of Member States, ranging from 1 to 4 times per week, serving sizes ranging from 30 g to 200 g, but being mostly 100-150 g. Five Member States suggest eating fatty fish, one Member State low-to-medium fat fish and four Member States indicate that it is important to vary species and fishing locations.

The associated FoodEx 2 term names at level 2 are 'fish (meat)', 'fish offal' and 'fish and seafood processed' nested under 'fish, seafood, amphibians, reptiles and invertebrates' at level 1. 'Fish processed' is found as level 3 under 'Fish and seafood processed'.

Oils and fats: Most vegetable oils are rich in MUFAs and PUFAs. Palm oil, palm kernel oil, coconut oil and animal fats are high in SFAs. Hydrogenated oils may be a source of TFAs. Generally, FBDGs recommend the consumption of vegetable oils high in unsaturated fatty acids and to limit consumption of SFAs.

The FoodEx 2 term name at level 1 is 'animal and vegetable fats and oils and primary derivatives thereof'

Nuts and seeds: Nuts and seeds are good sources of unsaturated fatty acids (including essential fatty acids), protein, dietary fibre, vitamins and minerals (e.g. calcium, magnesium, iron, zinc). Most FBDGs contain recommendations for consumption of unsalted and unsweetened nuts and seeds (without extra fat) that range from daily intake to consumption of 2-3 times per week, serving sizes ranging from 10 to 40 g, mostly being 15 to 25 g.

The associated FoodEx 2 term names at level 3 are 'treenuts' and 'oilseeds' nested under level 2 'nuts, oilseeds and oilfruits' and level 1 'legumes, nuts, oilseeds and spices'.

Non-alcoholic beverages (excluding fruit and vegetable juices): Non-alcoholic beverages are important for fluid intake. FBDGs of Member States recommend to drink between 1 and 3 L (mostly 1.5 to 2 L), preferably water, every day. Most FBDGs recommend limiting the consumption of sugar-sweetened beverages, which can contribute to the intake of added sugars to a significant extent. Some

Member States specifically advise moderating the intake of coffee, green and black tea, and other caffeine-containing beverages.

The associated FoodEx 2 term names at level 1 are 'water and water-based beverages' and 'coffee cocoa tea and infusions'.

3.2.2 Food groups and health outcomes

Even though the effects of some individual nutrients and non-nutrient components of food on chronic disease risk are well established, as described in Section 3.1, these are usually found in foods and diets as complex mixtures, where synergistic or antagonistic effects may come into play. Food processing, including the preparation and cooking methods used at home, may also influence the health effects of individual foods.

Diets high in fruits and non-starchy vegetables, whole grains, legumes, nuts and seeds, fish and shellfish, and unsaturated fat-rich vegetable oils, and low in refined starches, red meat, and processed foods and beverages with high sodium, added sugars and/or TFA content are associated with a lower risk of developing CVD, T2DM and some types of cancer in Western populations (Mozaffarian, 2016; Willett et al., 2019; USDA, 2020). The Mediterranean-style diet pattern (Davis et al., 2015) and the New Nordic diet-style pattern (Mithril et al., 2012; Mithril et al., 2013), also called Baltic Sea diet-style pattern, are good examples of such dietary patterns in Europe. The relationship between the consumption of other foods groups (e.g. dairy, butter, eggs, poultry) in mixed diets and chronic disease risk is less consistent (Mozaffarian, 2016).

Sources of protein

High quality protein is needed to ensure the growth of infants and young children, and to maintain lean body mass in the elderly. For people older than two years of age, however, a balanced plant-based diet can fulfil protein requirements (USDA, 2020). Meat, dairy, fish, eggs, legumes, and nuts are high in protein and often considered as alternatives to each other in dietary recommendations and FBDGs. However, they are also sources of other food constituents that may affect health, so that these protein sources may not be interchangeable as concerns their effect on health.

Several systematic reviews and meta-analyses have investigated the association between red meat and processed meat consumption and the development of chronic metabolic diseases (Aune et al., 2009; Micha et al., 2010; Abete et al., 2014; Wang et al., 2016; Schwingshackl et al., 2017; Tian et al., 2017; Bechthold et al., 2019; Fan et al., 2019; Neuenschwander et al., 2019; Zeraatkar et al., 2019). In some articles, red meat was defined as fresh meat from beef, veal, lamb, or pork, including hamburgers and meatballs, and processed meat as any meat preserved by the addition of chemical preservatives, smoking, curing, or salting, such as bacon, salami, sausages, hot dogs, processed deli or luncheon meat (Abete et al. (2014). These meta-analyses consistently report a positive association between the consumption of processed meat and chronic metabolic disease outcomes, such as CHD, CVD mortality, myocardial infarction, stroke and T2DM as compared to other food sources, and particularly to other protein sources. The association between unprocessed red meat consumption and these outcomes was generally weaker and less consistent.

In dose response meta-analyses conducted in the framework of these systematic reviews, the risk of disease was mostly increased at intakes of 50 and of 100-120 g/day for processed meat and unprocessed red meat, respectively.

Based on colon cancer risk, processed meat and unprocessed red meat were classified by the International Agency for Research on Cancer (IARC)[34] as group 1 and 2A carcinogens to humans, respectively.

Plausible mechanisms through which processed meat, and to a lesser extent of unprocessed red meat, could increase the risk of CVD, T2DM and certain types of cancer, include the intake of high amounts

[34] https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono114.pdf

of sodium and other preservatives (for processed meat only), haem iron and heat-induced carcinogens (process contaminants), as well as the unfavourable fatty acid profile (Al-Shaar et al., 2020; Papier et al., 2021).

Consumption of dairy products and moderate consumption of eggs (up to one per day) appears to be unrelated to CVD mortality (Rong et al., 2013; Mozaffarian, 2016; Guo et al., 2017), although some meta-analyses have also reported inverse (i.e. beneficial) associations between total dairy consumption and CVD endpoints other than mortality (Drouin-Chartier et al., 2016; Chen et al., 2021). Fish intake (1-2 servings and up to 3-4 servings per week) significantly decreases CHD mortality in a dose-response manner (Zheng et al., 2012; EFSA NDA Panel, 2014c). It has recently been estimated that the risk of CVD mortality could be decreased by 4% per 20 g/day increment in fish consumption, and an optimal intake of 60 g fish/day for CHD mortality prevention has been suggested (Willett et al., 2019; Zhang et al., 2020). The intake of moderate amounts of nuts (30-60 g/day) has been shown to beneficially affect cardiometabolic risk factors in RCTs, including blood pressure, blood lipid profile and glucose metabolism, and to decrease the risk of fatal and non-fatal CVD, T2DM and overall mortality in prospective cohort studies in substitution of other food sources (Afshin et al., 2014; Aune et al., 2016a; Mayhew et al., 2016). Similar evidence is available for the consumption of legumes and CHD risk (Afshin et al., 2014), possibly owing to the blood LDL-cholesterol and blood pressure-lowering effects reported in RCTs.

Sources of digestible carbohydrates and dietary fibre

Carbohydrates are the largest source of energy in European diets. In 2010, the EFSA NDA Panel proposed an RI for digestible carbohydrates between 45 and 60 E% applicable to both adults and children older than one year of age (EFSA NDA Panel, 2010b). Major sources of complex carbohydrates in European diets are cereals and potatoes. Whole grain cereals and potatoes, if eaten with the skin, are also good sources of dietary fibre.

Diets high in whole grains have been associated with lower mortality from all causes, CVD and cancer in prospective cohort studies. In a dose response meta-analysis, these associations were monotonic, showing a decrease in risk for total, CVD, and cancer mortality of about 7, 9 and 5%, respectively, for each serving (16 g) increase in whole grain intake per day (Zong et al., 2016).

Fruits and vegetables are also good sources of carbohydrates (naturally occurring sugars), vitamins, minerals, phytochemicals and dietary fibre. Meta-analyses from prospective cohort studies have consistently reported a lower risk of all-cause mortality, and particularly CVD mortality, associated with the consumption of fruits and vegetables (Wang et al., 2014; Aune et al., 2017; Wang et al., 2021). For each additional serving of fruits or vegetables per day (about 80 g/day), the risk appears to decrease monotonically by about 3-5% (depending on the analysis) up to five servings per day (or two servings of fruits and three of vegetables). The relationship with cancer risk has been less consistent. While Wang et al. (2014) report no association and a prospective analysis of the European Prospective Investigation into Cancer and Nutrition (EPIC) cohort only shows a very small and inconsistent risk reduction at high intakes (Boffetta et al., 2010), more recent meta-analyses including higher number of studies, participants and events, consistently show lower risk of cancer associated with the consumption of fruits and vegetables (or fruits and vegetables separately) up to about five servings per day (Aune et al., 2017; Wang et al., 2021).

Potatoes are starchy vegetables widely consumed in European diets. They contain high amounts of potassium, are a good source of dietary fibre if eaten with the skin, and provide vitamins C and B_6, among other nutrients. The relationship between the intake of potatoes and chronic disease risk, particularly T2DM, has been systematically investigated because, as is the case with other refined starches, such as white bread or white rice, they contain high amounts of readily available carbohydrates. Recent systematic reviews and meta-analyses show positive (i.e. unfavourable) dose-response relationships between the consumption of potatoes and diabetes risk in Western populations, but the strength of the association differs depending on the way potatoes are prepared. Either no or a mostly modest increase in T2DM risk has been reported for high vs. low consumers of boiled/baked/mashed potatoes (Borch et al., 2016; Zhang et al., 2018; Quan et al., 2020; Guo et al., 2021). Conversely, the association between French fries and diabetes risk is consistent across systematic reviews, and is from 2 to 6 times stronger than for boiled/baked/mashed potatoes, possibly because of the strong relationship observed also in relation to weight gain (Borch et al., 2016; Zhang et al., 2018; Quan et al., 2020; Guo et al., 2021).

Oils and fats

Fats are commonly used for cooking and dressing worldwide. Animal (such as butter and lard) and vegetable (such as oils, margarines and shortenings) fats contain mixtures of SFAs, MUFAs and PUFAs in different proportions, but also other nutrients (e.g. β-carotene and vitamin D) and non-nutrient components (e.g. polyphenols (EFSA NDA Panel, 2011c)) with potential health effects. While the relative effect of individual fat sources on blood cholesterol concentrations may be predicted by their fatty acid composition, as discussed in Sections 3.1.1.2 and 3.1.2.2, other health effects that may be related to the consumption of the fat source itself could be more difficult to anticipate.

As expected by their fatty acid profile, consumption of vegetable oils high in n-3 and n-6 PUFAs (e.g. sunflower oil, corn oil, soybean oil) in replacement of SFA-rich foods decreases blood LDL-cholesterol concentrations and CHD risk (Mozaffarian et al., 2010). Despite the more neutral effect of MUFAs (such as oleic acid in olive oil and rapeseed oil) compared with PUFAs on the blood lipid profile when replacing SFAs, replacement of dairy fat (butter) by rapeseed oil for cooking may partly explain the effect of dietary interventions in Northern Europe on the reduction of blood cholesterol concentrations and CHD mortality at national level (Puska and Ståhl, 2010). Plant-based Mediterranean-type diets rich in olive oil have also been traditionally associated with low CVD risk in observational and intervention studies (Rosato et al., 2019). Some vegetable oils that are high in SFAs, like palm oil or coconut oil, are expected to increase LDL-cholesterol, although long-term studies on chronic disease risk related to the consumption of these oils are lacking.

3.2.3 Conclusions

Food groups with important and specific dietary roles in European diets include starchy foods (cereals and potatoes), fruits and vegetables, legumes and pulses, milk and dairy products, meat and meat products, fish and shellfish and products thereof, nuts and seeds, and non-alcoholic beverages, as recognised in FBDGs in Member States. However, the dietary roles of these food groups and their relative contribution to the overall diet may vary across individual countries owing to the variability of dietary habits and traditions.

Dietary recommendations made in FBDGs by EU Member States reflect the available evidence on the consumption of certain food groups and their relationship with chronic disease risk, as reviewed in Section 3.2.2. Emphasis is put on increasing the consumption of whole grains, fruits and vegetables (in a wide variety), nuts and seeds, fish and water. Specific food products within some of these food categories that are high in SFAs, sugars and/or sodium owing to food processing are generally discouraged. Most FBDGs recommend limiting meat intake, some suggesting specifically the reduction of unprocessed red and processed meat consumption. FBDGs encourage regular consumption of fat-reduced milk and dairy products, the consumption of legumes and pulses instead of meat, and the consumption of vegetable oils rich in *cis*-MUFAs and *cis*-PUFAs instead of fats high in SFAs. The Panel notes that food groups with an important role in the diet of European populations and subgroups thereof have been identified by Member States in FBDGs. The Panel also notes that FBDGs also distinguish between different products within these food groups based on their potential to influence, beneficially or adversely, the overall dietary balance for certain nutrients.

3.3 Choice of nutrients and non-nutrient components of foods for nutrient-profiling

The choice of nutrients and non-nutrient components of food to set nutrient profiling models, for the purpose of restricting claims on foods and the purpose of FOP labelling, should be driven by their public health importance for EU populations, as discussed in Section 3.1.

Dietary intakes of SFAs, sodium and added/free sugars on one hand, and dietary fibre on the other, are respectively above and below current recommendations in a majority of European populations, and could be considered for inclusion in nutrient profiling models based on their public health importance for European populations.

Total sugars can be used as a proxy for added/free sugars in category-based nutrient profiling models because added/free sugars are the most variable fraction of total sugars between food products within a given food category. This also applies to food categories containing sugars but no added/free sugars in the unprocessed version (e.g. fruits and vegetables, milk and dairy products). Total sugars may not be equally suitable for nutrient profiling models to be applied across the board.

In self-selected diets under isocaloric conditions, a reduction in the intake of an energy-providing nutrient is accompanied by the increase in the intake of another. This substitution is of particular importance when it comes to a reduction in the intake of SFAs. As described in Section 3.1.1.3, the health effects of lowering SFA intake depend on the type of energy-providing nutrient by which SFAs are replaced in the diet. The strongest beneficial effect on blood LDL-cholesterol concentrations and CHD risk is observed when mixtures of SFAs are replaced by mixtures of *cis*-PUFAs. The effects of replacing mixtures of SFAs by mixtures of *cis*-MUFAs are less pronounced and are even lower when SFAs are replaced by carbohydrates from whole grains. A replacement of SFAs with refined carbohydrates (e.g. sugars) has not been shown to have an effect (Visseren et al., 2021). The inclusion of SFAs and (added/free) sugars in a nutrient profiling model could mostly account for the fatty acid profile of foods and for the less favourable replacement of SFAs by refined carbohydrates.

Energy could be included in nutrient profiling models because a decrease in energy intake is of public health importance for European populations owing to the high prevalence of overweight and obesity and the positive relationship between high energy dense-diets and risk of weight gain. The energy density of foods and of dairy-based beverages is mostly determined by their fat and water content, owing to their extreme energy values, while the energy density of non-alcoholic water-based beverages is mostly driven by their sugar content. In certain food groups (e.g. cereal products), dietary fibre may additionally contribute to the energy density of foods.

Differences in water content may confound energy comparisons across foods and are bigger across food groups (e.g. between solid foods and beverages) than within food groups. This confounding is a great disadvantage when energy is used in nutrient profiling models intended for application across the board. Still, energy may be a suitable criterion if applied within food groups, where the water content is relatively consistent across products in the group.

In food group/category-based nutrient profiling models, total fat could replace energy owing to its high energy density in most food groups, while the energy density of food groups with low or no fat content (e.g. water-based non-alcoholic beverages, jams and marmalades) may be well accounted for by the inclusion of (added/free) sugars in the model. However, total fat does not allow the discrimination of foods based on the nutritional quality of their fat content. Therefore, total fat cannot replace SFAs in nutrient profiling models, unless food products in a group are relatively homogeneous regarding their fat quality (e.g. milk and dairy products).

In addition to sodium, for which intakes are above recommendations, other vitamins and minerals of public health importance could be considered, mostly because their intakes in European populations or certain subgroups thereof are lower than recommended. These include potassium, iron, calcium, vitamin D, folate and iodine (see Section 3.1.2). However, for all of these nutrients, except potassium, inadequate intakes are only observed in very specific subgroups of the population, in which dietary modifications alone may not be sufficient (or appropriate) to fulfil the nutrient requirements. Inadequate intakes of these nutrients are usually addressed by national nutrition policies in Member States and/or individual advice. That is not the case for potassium, for which dietary intakes appear to be inadequate in a majority of European adult populations and thus could be considered for inclusion in nutrient profiling models.

Some nutrients and non-nutrient components may be included in nutrient profiling models for reasons other than their public health importance to allow for a better discrimination of foods within the same food category. In this context, n-3 LC-PUFAs**,** for which fish and shellfish including products thereof are almost the only dietary source, could be included in nutrient profiling models owing to the large differences among fish species regarding the content of these fatty acids. This is despite current uncertainties on whether intakes may be below current recommendations in some EU Member States.

Another consideration in the choice of the nutrients and non-nutrient components to be included in a nutrient profiling system is the feasibility of the nutrient profile in practice. The larger the number of components included, the more complex the nutrient profile becomes in its application.

4 Conclusions

The Panel concludes that:

- food groups with important and specific dietary roles in European diets include starchy foods (cereals and potatoes), fruits and vegetables, legumes and pulses, milk and dairy products, meat and meat products, fish and shellfish and products thereof, nuts and seeds, and non-alcoholic beverages, as recognised in FBDGs in Member States. The dietary roles of these food groups and their relative contribution to the overall diet may vary across individual countries owing to the variability of dietary habits and traditions.
- dietary recommendations made in FBDGs by EU Member States reflect the available evidence on the consumption of certain food groups and their relationship with chronic disease risk. Consumption of whole grains, fruits and vegetables, nuts and seeds, fat-reduced milk and dairy products, fish and water is encouraged, whereas food products high in SFAs, sugars and/or sodium owing to food processing are generally discouraged, even within these food categories. FBDGs also encourage regular consumption of legumes and pulses instead of meat (particularly red meat and processed meat), and the consumption of vegetable oils rich in *cis*-MUFAs and *cis*-PUFAs instead of fats high in SFAs.
- dietary intakes of SFAs, sodium and added/free sugars are above current dietary recommendations in a majority of European populations; excess intakes of these nutrients are associated with adverse health effects and therefore they could be considered for inclusion in nutrient profiling models based on their public health importance for European populations;
- energy could be included in nutrient profiling models because a decrease in energy intake is of public health importance for European populations; in food group/category-based nutrient profiling models, total fat could replace energy owing to its high energy density in most food groups, while the energy density of food groups with low or no fat content (e.g. water-based non-alcoholic beverages, jams and marmalades) may be well accounted for by the inclusion of (added/free) sugars in the model.
- intakes of dietary fibre and potassium are below current dietary recommendations in a majority of European adult populations; inadequate intakes of dietary fibre and potassium are associated with adverse health effects and therefore dietary fibre and potassium could be considered for inclusion in nutrient profiling models based on their public health importance for European populations;
- dietary intakes of iron, calcium, vitamin D, folate and iodine are below current dietary recommendations in specific sub-groups of European populations only in which dietary modifications alone may not be sufficient (or appropriate) to fulfil the nutrient requirements; inadequate intakes of these nutrients are usually addressed by national nutrition policies in Member States and/or individual advice;
- nutrients and non-nutrient components of food may be included in nutrient profiling models for reasons other than their public health importance to allow for a better discrimination of foods within the same food category.

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Appendices

Appendix A - Protocol for the provision of scientific advice on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods (endorsed by the NDA Panel on 8 April 2021)

1. Problem formulation (assessment questions and sub-questions)

The mandate can be broken down in the following questions:

1. Which nutrients and/or foods, including non-nutrient components of food (e.g. energy, dietary fibre), are of public health importance for European populations? These include:

    a) Nutrients and/or foods that might be consumed in excess, and

    b) Nutrients and/or foods for which intakes might be inadequate

in the context of dietary recommendations for healthy diets of European countries or of independent scientific bodies.

2. Which food groups (and specific food products thereof) have important dietary roles in European populations (and subgroups thereof) owing to their nutrient composition and frequency of intake?

3. Which criteria should be considered when selecting the nutrient and non-nutrient components of food for nutrient profiling?

2. Definition of evidence needs based on the sub-question formulation

To address question 1:

a) Identification of diet-related chronic diseases which were considered in the setting of FBDGs by Member States;

b) Evidence on the relationship between nutrients, non-nutrient components (e.g. energy, dietary fibre), foods and food groups, and the diet-related chronic diseases identified under point (a);

c) Selection of nutrients, non-nutrient components, foods and food groups, identified under point (b), which are considered of public health importance by one or more Member States.

To address question 2:

a) Information on main food groups and specific food products thereof with important dietary roles in European populations (and subgroups thereof) as recognised by Member States in FBDGs.

To address question 3:

a) Information on existing nutrient profiling models;

b) Evidence from questions 1 and 2 above.

3. Identification of the adequate sources of information/data

Owing to the wide scope of this mandate and the stringent deadline, the Panel will consider review publications and EFSA Scientific Opinions as the main sources of information and data. In particular, the Panel will consider:

a) Responses to a questionnaire sent to EU/EEA countries through EFSA focal points with the aim of gathering information on the diet-related chronic diseases which formed the basis of setting of FBDGs and on the nutrients, non-nutrient components, foods and food groups considered of public health importance;

b) Review publications on nutritionally adequate diets based on evidence from intervention and observational studies in humans (e.g. WHO (2003), Willett et al. (2019));

c) Data from the Global Burden of Disease framework[35];

d) Clinical practice guidelines

e) FBDGs in Europe[36];

f) EFSA Scientific Opinions on Dietary Reference Values for energy, water, macro- and micronutrients;

g) EFSA Scientific Opinions on health claims made on food;

h) Other EFSA Scientific Opinions on the relationship between nutrients and/or foods/food groups and human health, e.g. health benefits of seafood (fish and shellfish) consumption (EFSA NDA Panel, 2014c);

i) EFSA Scientific Opinions on nutrient profiles to limit health claims on foods (EFSA, 2008) and on the development of FBDGs (EFSA NDA Panel, 2010d);

j) Comprehensive review on front-of-pack labelling schemes provided by the European Commission[37].

4. Method for data extraction from included studies

No data extraction is foreseen.

5. Method for appraising evidence

Appraisal of included studies is not foreseen.

6. Preliminary identification of sources of uncertainty

- The assessment will be based on review publications and not on primary studies;
- The classification of foods into food groups may not be well defined and/or differ across sources of information and data;
- Information on the relationship between the intake of nutrients, non-nutrient components of food, foods and food groups and diet-related disease endpoints may only be available from human observational studies;

7. Methods for analysing uncertainties individually and combined

Uncertainties will be identified and documented at each step of the assessment, but no formal uncertainty assessment is foreseen.

8. Methods for synthesising evidence

The method for synthesising the evidence will be appropriate to the evidence retrieved.

[35] http://www.healthdata.org/diet; https://www.thelancet.com/gbd ; https://vizhub.healthdata.org/gbd-compare/#
[36] https://ec.europa.eu/jrc/en/health-knowledge-gateway/promotion-prevention/nutrition/food-based-dietary-guidelines#:~:text=Food%2DBased%20Dietary%20Guidelines%20(FBDGs,acceptable%20and%20practical%20to%20implement
[37] https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/front-pack-nutrition-labelling-schemes-comprehensive-review

Appendix B – Survey in EU/EEA Member States on diet-related chronic diseases considered in national Food Based Dietary Guidelines (FBDGs)

The survey had the following contents:

NAME*:

COUNTRY*:

AFFILIATION*:

EMAIL*:

DATE:

We kindly ask you to fill the survey. Please answer to the questions by ticking the relevant boxes and specify where relevant.

1. **Does your country have FBDG?**

   No □
   Yes □
   If yes, please specify the year in which your national FBDGs were last updated (or developed, if only one version exist): ________________

2. **Was the risk of diet-related chronic diseases considered when developing/updating your FBDGs?**

   No □
   Yes □

If yes, please specify the diet-related chronic diseases that were considered when developing/updating your national FBDGs: ________________

a. Cardiovascular diseases: □
b. Dyslipidemia: □
c. Hypertension: □
d. Type 2 diabetes: □
e. Overweight/obesity: □
f. Osteoporosis/bone fractures: □
g. Iron deficiency anaemia: □
h. Iodine deficiency disorders: □
i. Dental caries: □
j. Others: Please specify___________________________

3. **Have you identified at national level nutrients for which intakes may be inadequate for the whole population or subgroups thereof?**

   No □
   Yes □
   If yes, please specify the nutrients and population groups to which this applies: ________________

4. Do you have a national programme of vitamin/mineral supplementation or fortification in place in your country? (e.g. iodine in salt, vitamin D supplements for specific population groups, folate for women willing to become pregnant, etc)

No □
Yes □
If yes, please specify: ________________

Twenty-four European countries replied to the surveys with the following results:

Q		**NO**		**YES**	**Specify**	
1.	**Does your country have FBDGs?**	2x		22x	2002-2021	
2.	**Was the risk of diet-related chronic diseases considered when developing/updating your FBDGs?**			22x		
a.	Cardiovascular diseases:			21x		
b.	Dyslipidemia:			20x		
c.	Hypertension:			19x		
d.	Type 2 diabetes:			21x		
e.	Overweight/obesity:			20x		
f.	Osteoporosis/bone fractures:			18x		
g.	Iron deficiency anaemia:			15x		
h.	Iodine deficiency disorders:			16x		
i.	Dental caries:			15x		
j.	Others: Please specify					
		▪ Cancer (14x), ▪ Mental health / Neurodegenerative/ Neurocognitive disorders (e.g. Alzheimer's disease, dementia, depression and anxiety disorder) (5x) ▪ Chronic obstructive pulmonary disease (2x), ▪ Musculoskeletal diseases (the mediators of which are overweight and obesity) (1x) ▪ Arthrosis (1x) ▪ Liver cirrhosis (1x) ▪ Chronic kidney disease (1x) ▪ Digestive tract diseases (1x) ▪ Protein deficiency (1x)				

		▪ Gallbladder and biliary tract diseases (1x) ▪ Immune disorders (1x) ▪ Risk of infectious diseases (1x) ▪ Other conditions (e.g. constipation, dehydration) (1x) ▪ Prevent of birth defects (NTDs) through folic acid in women of child-bearing age (1x) ▪ Other diseases and early total mortality (1)				
3.	**Have you identified at national level nutrients for which intakes may be inadequate for the whole population or subgroups thereof?**	2x		22x		
		▪ Vitamin D (17 countries[(a)]: 13x general population[(b)], 6x children, 1x pregnant women, 4x elderly) ▪ Iodine (13 countries: 6x general population, 3x women, 2x pregnant women, 1x lactating women) ▪ Folate (12 countries: 3x general population, 2x adults, 2x children, 3x women, 3x pregnant women, 1x adolescents, 1x elderly) ▪ Calcium (8 countries: 5x general population, 1x girls, 1x elderly, 1x women, 1x adults) ▪ Iron (8 countries: 1x general population, 6x children, 1x women, 3x pregnant women, 1x elderly) ▪ Dietary fibre (7 countries: 5x general population, 1x children, 2x adults) ▪ Zinc (4 countries: 1x general population, 2x children, 1x pregnant women, 1x women, 2x elderly) ▪ Selenium (4 countries: 2x general population, 2x elderly, 1x women) ▪ Vitamin C (4 countries: 2x general population, 2x elderly) ▪ Potassium (4 countries: 2x general population, 1x elderly and older women, 1x children) ▪ Vitamin B6 (3 countries: 1x general population, 2x elderly) ▪ Magnesium (3 countries: 3x general population) ▪ Omega 3 fatty acids/ DHA / EPA (3 countries; 2x general population, 1x children, 1x adults) ▪ Vitamin B12 (3 countries: 1x general population, 1x elderly, 1x vegans) ▪ Vitamin A (2 countries: 1x general population, 1x children, 1x pregnant women, 1x elderly) ▪ Copper (2 countries: 2x general population) ▪ Protein (2 countries: 1x general population, 1x elderly) ▪ Riboflavin (2 countries: 1x general population, 1x elderly) ▪ Phosphorus (1 country: 1x general population) ▪ Thiamin (1 country: 1x general population) ▪ Chromium (1 country: 1x general population) ▪ Niacin (1 country: 1x general population) ▪ Vitamin K (1 country: 1x general population)				

		▪ Carbohydrates (1 country: pregnant women and adults, in particular elderly)				
4.	**Do you have a national programme of vitamin/mineral supplementation or fortification in place in your country? (e.g. iodine in salt, vitamin D supplements for specific population groups, folate for women willing to become pregnant, etc)**	3 x		21 x		
		▪ Iodine (16 countries: salt, supplements for pregnant women, fortification of cattle) ▪ Vitamin D (15 countries: supplements for infants and young children, pregnant women, older adults, elderly, fortification of margarines, cooking oils, dairy) ▪ Folate (13 countries: supplements for women of childbearing age, pregnant women) ▪ Vitamin B12 (3 countries: supplements for vegans and the elderly) ▪ Vitamin A (2 countries fortification of margarines and cooking oils) ▪ Selenium (1 country: addition to agricultural fertilisers) ▪ Fluoride (1 country: salt, supplements for infants) ▪ Iron (1 country: supplements for pregnant women) ▪ DHA (1 country: supplements for pregnant women) ▪ Vitamin E (1 country: fortification of margarines and cooking oils)				

(a) Multiple answers possible with respect to subpopulations at risk of inadequacy
(b) Responses in which no sub-population was specified have been considered under the category 'general population'

Glossary and/or abbreviations and/or acronyms

AICR	American Institute for Cancer research
ALA	α-linolenic acid
AI	Adequate Intake
ARA	arachidonic acid
AR	Average Requirement
BMD	bone mineral density
BMI	body mass index
CDC	Centers for Disease Control
CDRR	Chronic Disease Risk Reduction Intake
CHD	coronary heart disease
CVD	cardiovascular diseases
DHA	docosahexaenoic acid
DNA	deoxyribonucleic acid
DRV	Dietary Reference Value
E%	percentage of total energy intake
EC	European Commission
EEA	European Economic Area
EFSA	European Food safety Authority
EPA	eicosapentaenoic acid
EPIC	European Prospective Investigation into Cancer and Nutrition
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology, and Nutrition
EU	European Union
FBDG	food based dietary guideline
FOP	front-of-pack
GBD	Global Burden of Disease
HDL	high-density lipoprotein
IARC	International Agency for Research on Cancer
IDA	iron deficiency anaemia
IOTF	International Obesity Task Force
JRC	Joint Research Centre
LA	linoleic acid
LC	long-chain
LDL	low-density lipoprotein
MUFA	monounsaturated fatty acid
n-3	omega 3
n-6	omega 6
NCD	non-communicable disease

NDA	Panel on Nutrition, Novel Foods and Food Allergens
PRI	Population Reference Intake
PUFA	polyunsaturated fatty acid
RCT	randomised controlled trial
RI	Reference Intake range for macronutrients
RNA	ribonucleic acid
SFA	saturated fatty acid
T2DM	type 2 diabetes mellitus
TFA	*trans*-fatty acid
UIC	urinary iodine concentration
UL	Tolerable Upper Intake Level
WCRF	World Cancer Research Fund
WHO	World Health Organization