

28 October 2021

Welcome to the Open Session of the 118th Plenary of the NDA Panel

Trusted science for safe food



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28 October 2021

Guidelines for Observers for online open plenary meetings

Speaker: Heng Leng

NDA Panel Open plenary

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Observers may:

- Ask questions during the meeting online, when the Chair grants the opportunity
- Report on the proceedings of the meeting, while any reference to participants should respect their reputation and professional integrity

Observers may not:

- Hinder the work of the Panel
- Attempt to influence the meeting participants, in particular members of the Panel
- Distribute or request the circulation of any documents
- Make a written transcript of the meeting

No audio/video-recordings of the open plenaries are allowed

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- Chair may grant observers the opportunity to ask questions either after they have observed a discussion on a given topic, or on another topics **which fall within the remit of the Panel** in a dedicated Q&A session.
- If your questions have not been answered during the meeting, you may resubmit your questions through the **#AskEFSA** on the EFSA website.
- To allow all Observers to participate, at first interventions will be limited to 1 per Observer per session. Further contributions might be granted if time allows
- Express your interest in asking a question by **raising hand**.
- Please **state your name and affiliation** when introducing the question/comment
- **Keep it simple – short and concise**

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118th Plenary of the NDA Panel

Chair: Prof. Turck Dominique

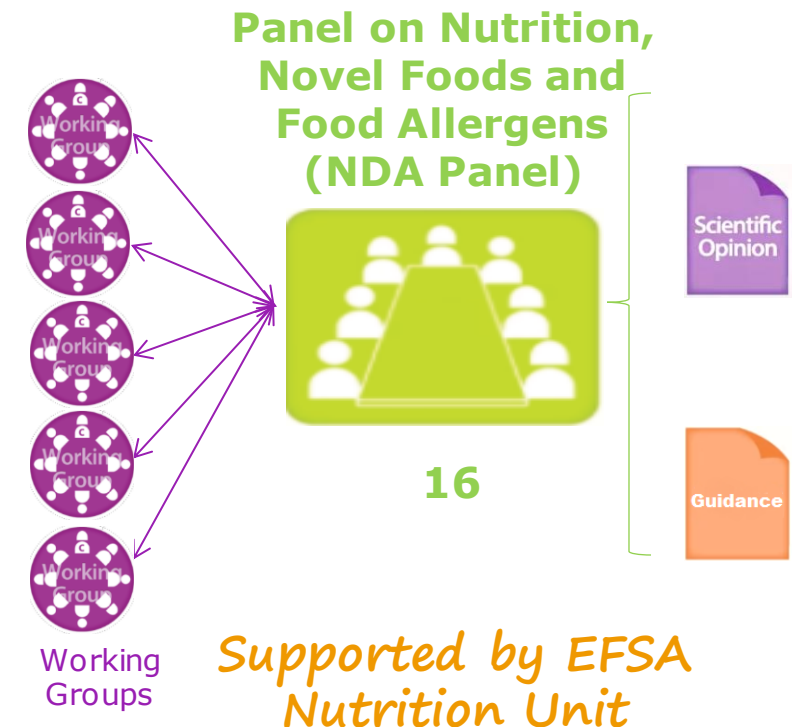
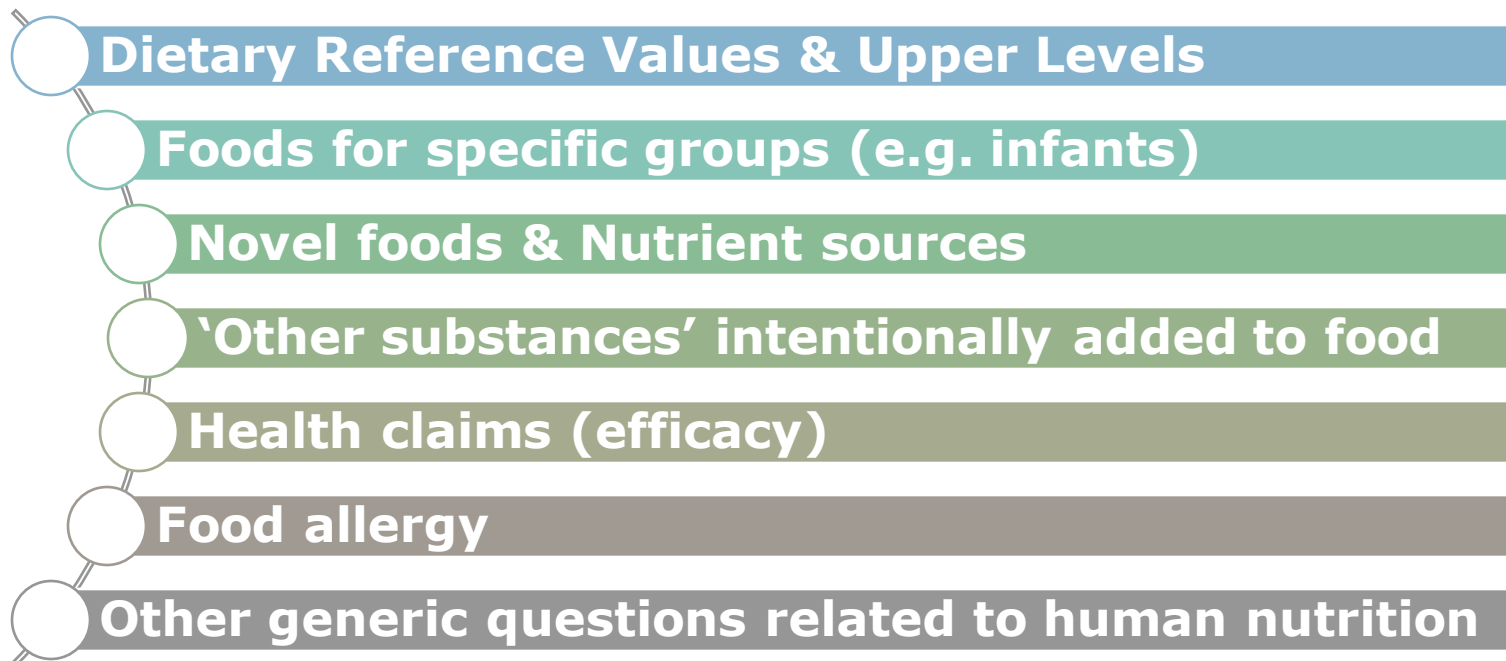
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DAY 2 – OPEN SESSION [09:00 – 14:00]

Time	No.	Topic
09:00	7	Welcome and brief introduction of Panel Members and of the Agenda for the open session
	8	Presentation of the EFSA guidelines for Observers
	9	Scientific outputs submitted for discussion and possible endorsement
	9.1	Draft Scientific Opinion on nutrient profiling approaches for the purpose of front-of-pack nutrition labelling and of restricting nutrition and health claims on foods (EFSA-Q-2021-00026)
		<i>Coffee break</i>
	10	Update on the ongoing work of the Nutrition Unit & NDA Panel
	11	New mandates
	12	Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission
	13	Questions from and answers to Observers (in application of the guidelines for Observers)
14:00		<i>End of the second day of the meeting</i>

EFSA's NDA Panel remit in Nutrition (1)

- Scientific advice and scientific and technical support on **human nutrition** in relation to Community legislation,
- At the request of the European Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme



EFSA does NOT

- develop or propose policies, legislation, norms and standards
- enforce legislation
- authorise products
- take charge of food safety/quality controls and labelling aspects
- make recommendations to consumers
- monitor or assess consumers' behaviour



Enjoy the meeting

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28 October 2021



Draft 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

Alfonso Siani, chair of the WG

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27/01/2021:
Mandate acceptance
WG Claims

Jan-Mar 2021:
Protocol Development
Endorsement
by NDA Panel

July/Sep/Oct 2021:
Draft opinion
Discussion
Endorsement
by NDA Panel Open plenary

Nov-Dec 2021:
Draft opinion
Public consultation

Mar 2022:
Opinion
Adoption

Nutrient profile: the nutrient composition of a food or diet

Nutrient profiling: the classification of foods based on their nutrient composition for specific purposes

Front-of-pack (FOP) labelling: simplified nutrition information provided on the front of food packaging aiming to help consumers with their food choices

ToR

- ❑ 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, EFSA 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**
- ❑ **The mandate excludes developing a nutrient profiling model or advising on current profiling models already in use for different purposes.**

- Nutrients and non-nutrient components of food of public health importance **identified based on expert knowledge and from a questionnaire sent by EFSA to EU/EAA countries**
- Opinion is based on
 - **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**
 - **Priorities set by EU Member States** in the context of their FBDG and associated nutrient/food intake recommendations
 - **Intake data** either derived from the EFSA Comprehensive Food Consumption Database or from national dietary surveys cited in the respective EFSA DRV Opinions
- Assessment followed the **protocol** endorsed by the Panel on 8 April 2021

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

- **Sustained positive energy balance** leads to an accumulation of body fat → development of overweight or obesity
- **Overweight and obesity increase the risk** of developing diet-related chronic diseases, such as type 2 diabetes mellitus (T2DM) or cardiovascular disease (CVD), and some cancers. Also, increased risk of all-cause mortality.
- **Weight loss** in obese adults improves cardiometabolic risk factors in a dose-response manner, significantly decreases the risk of developing T2DM and the risk of all-cause mortality
- **Prevalence of overweight and obesity** in EU Member States in
 - adult males 50-75% (obesity 10-30%)
 - adult females 35-65% (obesity 10-35%)
 - children 10-45% (obesity 8-17% boys, 5-11% girls)

- 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 (<30-35E%) favour lower energy intake, weight loss and prevent weight gain** as compared to energy dense diets containing >35 E% as fat
- Guidelines for the prevention and management of uncomplicated obesity 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.**

- Fat is an important **source of energy and facilitates the absorption of fat-soluble dietary components**, such as of fat-soluble vitamins. Fats and oils are also important sources of **essential fatty acids** (i.e. LA and ALA).
- **Reference Intake of total fat**: 20-35 E%
- **Fatty acid composition of the diet**: important determinant of blood lipid profile and CVD risk
 - Under **isocaloric conditions**, the most favourable effect 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.
 - The impact of dietary cholesterol, ARA, EPA and DHA on the blood lipid profile is expected to be low considering the low daily consumption as compared with SFAs
 - **EPA and DHA** have an effect on the primary prevention of CVD independent of their effect on the blood lipid profile.

→ SFA and TFA considered as nutrients consumed in excess, EPA and DHA as nutrients for which the intake may be inadequate

- There is a **differential effect of different SFAs** on blood lipid concentrations. While lauric, myristic and palmitic acid raise blood LDL-cholesterol when replacing carbohydrates, the effect of stearic acid is more neutral.
- 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. Therefore, mixtures of SFAs as present in mixed diets are considered in the Opinion
- Mixtures of **SFAs raise blood LDL-cholesterol** concentrations **without a threshold** below which this is not the case --> no UL could be established by the Panel in its DRV opinion on fat. However, the Panel 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** recommend **8-10 E%** as upper bound of intake.
- There is a positive and causal relationship between **blood LDL-cholesterol** concentrations and the risk of **developing ischemic CVD**. Reduction in disease risk is proportional to the reduction of LDL-cholesterol concentrations.

- 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.
 - Relationship may depend **on food matrix**
 - Under isocaloric conditions, the effect may largely depend on the **macronutrient by which SFAs are replaced** in diets → sizeable effect of replacement of SFAs with cis-PUFAs vs no benefit from replacements with refined carbohydrates (e.g. sugars)
- **Mean intakes** of SFAs are **above the recommended** upper bounds of intake of 8-10 E% in most EU countries based on national surveys considered in the Opinion on DRVs for fat. Similar findings in more recent publications
- Main **contributors to SFA** intake: dairy, fats and oils, meat and meat products

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.**

- TFAs **increase blood LDL-cholesterol** concentrations in a linear dose-dependent manner to a similar extent than SFAs. TFAs **reduce blood HDL-cholesterol concentrations** and **increase the total cholesterol to HDL-cholesterol ratio**. High intakes of TFAs have been associated with an **increased risk of ischemic CVD**.
- Like for SFA and for the same reasons, the Panel could not establish a UL; 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.
- TFAs are naturally present in dairy products and meat from ruminants and originate from industrial production or deep frying. A **major source of TFAs** in the diet are partially hydrogenated oils.
- Intakes have decreased considerably in recent years. The EC Joint Research Centre reports mean **TFA intakes at or below 1 E% in all countries and population groups** (basis 13 studies published between 2006 and 2013)
- **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. This is expected to further reduce the consumption of TFAs in the EU.

The Panel notes 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.

- Wide consensus that the intake of dietary sugars is causally related to the development of **dental caries** at all ages.
- 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
- No UL for total or added/free sugars could be set as there was no level of sugar intake at which the risk of disease was not increased. **Several authorities** have set recommendations for **added or free sugars below 10 E%, or below 5 E%**, based on various health endpoints and 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.
- 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**.

* The main difference between the intake of added and free sugars is accounted for by fruit juices

Dietary sugars (2)

- 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**.
- In infants, children and adolescents, **sweetened milk and dairy products** are also major contributors to mean intakes of added and free sugars.

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.

- Positive 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**.
- 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.
- Sodium intakes have been estimated from urinary sodium excretion data collected in 18 European countries by the Panel in its Opinion on DRVs for sodium. These data showed that mean **sodium intakes in adults and children substantially exceeded the safe and adequate level** of intake.
- **Main contributors** to sodium intake in European populations are bread, processed meat and cheese.

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.**

The Panel notes that **mean intakes of SFAs, sodium and added/free sugars exceed** the recommended upper bounds of intake in most 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 a substantial part of the European population. 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

**Nutrients and
non-nutrient
components of
food for which
intakes might be
inadequate in some
population groups
and countries in
Europe**

- The human body requires dietary protein to **support tissue growth and maintenance**.
- A Population Reference Intake (**PRI**) was set at 0.83 g of high-quality protein/kg per day (e.g. 58 g/day for a 70-kg individual). It can be applied to usual mixed diets in Europe, which is likely to contain sufficient amounts of all indispensable amino acids.
- **Protein intakes above the PRI** have **no beneficial effects** on muscle mass or function at any age.
- Dietary surveys in Europe suggest that average **protein intake** in the European populations is mostly **above the PRI**.

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.**

- **EPA** can be transformed to **eicosanoids**; involved in the regulation of blood pressure, renal function, blood coagulation, inflammatory and immunological reactions amongst other. **DHA** is a component of **structural lipids** of membranes. It is mostly found in phospholipids in the nervous tissue and the retina.
- Relationship between EPA and DHA intake and **CVD risk reduction (AI of 250 mg/day)** set based on this endpoint)
- 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.
- **Sources of EPA and DHA** are almost exclusively foods of marine origin, mainly oily fish and derived products.

- 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 Panel considers that **intakes of EPA and DHA may be below the AI in European countries with low fish consumption** (based on data from the EFSA Comprehensive Food Consumption Database)

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 and products thereof**.

- 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**.
- Dietary fibre helps to **maintain normal bowel function** and alleviates constipation by decreasing colonic transit time and increasing faecal mass. 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.
- **AI of 25 g per day** of dietary fibre from mixed foods based on normal laxation.
- 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.
- **Average intakes** of fibre across European adult populations are mostly **below the AI**.

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 the majority European 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.**

- Potassium is an essential mineral and is required for **normal cell function**. 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. There is also evidence that **inadequate potassium intakes** are associated with a **higher risk of stroke**.
- **AI 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.
- 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. Substantial potassium losses may occur during food processing and cooking.
- Mean **dietary intakes** of potassium in infants and children up to 10 years of age exceeded the AI. 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 (based on data from the EFSA Comprehensive Food Consumption Database)

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 the European adult populations, the Panel considers that an **increase in potassium intakes is of public health importance for European populations.**

- Iodine is an essential nutrient, required as a **structural and functional element of thyroid hormones**. **Iodine deficiency** can lead to **impaired thyroid function, goitre and hypothyroidism**, amongst other.
- EFSA set an **AI** for adults of **150 µg/day**, based on urinary iodine excretion levels that have been associated with the **lowest prevalence of goitre**.
- Good **sources of iodine** are marine products (such as fish, crustaceans, bivalves), eggs, milk, and their derivatives, and iodised salt with milk and dairy products contributing most to iodine intakes in European populations. **Iodine fortification of salt** has been implemented in 40 European countries, either as mandatory fortification (13 countries) or voluntary fortification (16 countries).
- **Iodine intake** can be assessed by **measuring urinary iodine excretion**. A recent analyses of 40 studies from 23 European countries reported **inadequate iodine status of the population for around half of the studies in adults** and in only **one study out of 16 in children**.

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**

- Iron is required for **oxygen transport** (as an essential component of haemoglobin), **electron transfer, oxidase activities and energy metabolism**. Iron deficiency anaemia (**IDA**) in infants and young children has been associated with impaired psychomotor development and cognitive performance.
- 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
- Foods that contain **relatively high concentrations** of iron include meat, fish, cereals, beans, nuts, egg yolks, dark green vegetables, potatoes and fortified food products.
- **Dietary iron intakes** have been estimated by EFSA using the EFSA Comprehensive Food Consumption Database. Except for 7-11 months-old infants, median iron intakes exceeded the AR in all population groups and surveys.

- However, estimates of the percentage of the population that have inadequate iron intakes vary 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.
- 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.

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.**

- 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**. Inadequate intakes of **vitamin D** lead to inefficient absorption of dietary calcium and phosphorus, and thus causes an impaired mineralisation of bone.
- 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**. Also, there is evidence that intakes of vitamin D and calcium, as compared to calcium alone, **reduces the risk of falling**.
- EFSA has proposed a **PRI (AR) for calcium** for young adults 18-24 years of age of **1,000 (860) mg/day** and for adults ≥ 25 years of **950 (750) mg/day**.
- Vitamin D3 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. **DRVs** have been derived based on the **assumption that the endogenous vitamin D synthesis is minimal**. **AI for vitamin D** for adults, including pregnant and lactating women, and children aged 1–17 years has been set by EFSA at **15 µg/day**.

- The main **contributors to calcium intake** are milk and dairy products. Dietary **sources of vitamin D** are mostly fatty fish and eggs, food supplements and fortified foods.
- Comparison of the **median calcium intake to the AR**, showed that adolescents, in particular, are at risk of inadequate intakes (based on the EFSA Comprehensive Food Consumption Database). The **prevalence on inadequate vitamin D status** based on serum 25(OH)D concentrations was estimated to be 28-67% in adults and in the vast majority of adolescents.
- 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

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 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**.

- 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.
- 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**.
- Women of childbearing age are advised to consume **folic acid supplements** in addition to food folate at a dose of **400 µg/day**.
- For healthy adults, a **PRI of 330 µg Dietary Folate Equivalents (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.
- 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.
- **Intake data** expressed as DFE are scarce and insufficient to draw conclusions.

The Panel considers that the **main public health** concern in relation to folate intakes is the **periconceptual folate intake** of women of childbearing age, that is mainly **addressed by national policies in Member States.**

intakes of **dietary fibre and potassium are inadequate** in a substantial part of the European population. **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 that intakes of **EPA and DHA may be inadequate for primary CVD risk prevention in Member States with low consumption of fish** and products thereof.

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**.

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.

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

- 28 FBDG from 27 EU Member States were reviewed
- **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. 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.
- **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. **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 jam. Recommendations in FBDG are not homogenous with respect to consumption of different 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 1 serving per day or suggest preferring fresh fruit over juice. A few countries also suggest limiting the intake of **dried fruits** or **canned fruits**.

- **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; often as substitute to meat.
- **Milk and dairy products:** important contributors to the intake of protein, calcium, riboflavin, vitamin B12 and iodine. They may, however, also contribute to SFA intake (depending on the fat content) and to added sodium or added sugar intake. Daily consumption of skimmed and semi-skimmed milk, low-fat yoghurt, sour milk products or similar and low-fat cheeses is generally recommended in FBDG.
- **Meat and meat products:** good source of high-quality protein, iron, zinc, some vitamins and MUFAs. However, they 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.

- **Fish and shellfish:** 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.
- **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.
- **Nuts and seeds:** good sources of unsaturated fatty acids (including essential fatty acids), protein, dietary fibre, vitamins and minerals. Most FBDGs contain recommendations for regular consumption of unsalted and unsweetened nuts and seeds (without extra fat).
- **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 beverage. Some Member States specifically advise moderating the intake of coffee, green and black tea, and other caffeine-containing beverages.

- Effects of some individual nutrients and non-nutrient components of food on chronic disease risk are well established.
- However, nutrients and non-nutrient components of food 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 cancers** in Western populations.

- Meta-analyses on the association **between red meat and processed meat** consumption and the development of chronic metabolic diseases 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. The association between unprocessed red meat consumption and these outcomes was generally weaker and less consistent.
- Based on colon cancer risk, processed meat and unprocessed red meat were classified by the International Agency for Research on Cancer (IARC) as group 1 and 2A carcinogens to humans.
- **Plausible mechanisms** include the intake of high amounts of sodium and other preservatives (for processed meat only), of haem iron, heat-induced carcinogens (process contaminants), and the unfavourable fatty acid profile

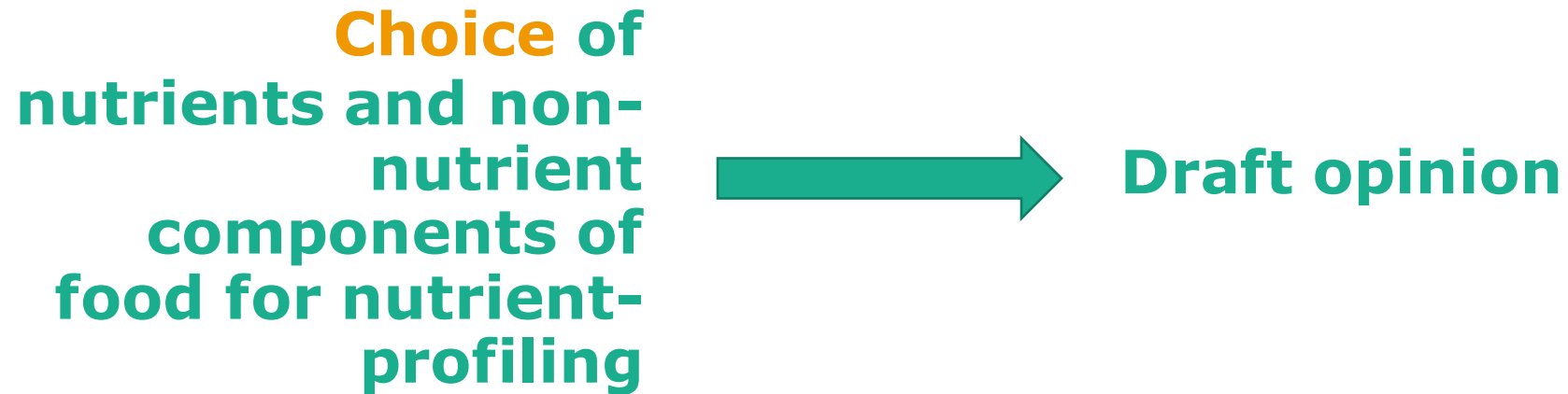
- Consumption of **dairy products** and moderate consumption of **eggs** (up to one per day) appears to be unrelated to CVD mortality, although some meta-analyses have also reported inverse (i.e. beneficial) associations between total dairy consumption and CVD endpoints other than mortality.
- **Fish intake** (1-2 servings and up to 3-4 servings per week) significantly decreases CHD mortality in a dose-response manner.
- The intake of moderate amounts of **nuts** (30-60 g/day) has been shown to beneficially affect cardiometabolic risk factors.
- Similar evidence is available for the consumption of **legumes** and CHD risk.

- Diets high in **whole grains** have been associated with lower mortality from all causes, CVD and cancer in prospective cohort studies.
- Meta-analyses from prospective cohort studies have consistently reported a lower risk of total mortality, and particularly CVD mortality, associated with the consumption of **fruits and vegetables**. The relationship with cancer risk has been less consistent.
- Recent systematic reviews and meta-analyses show positive 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 mostly modest increase in T2DM risk has been reported for high versus low consumers of boiled/baked/mashed potatoes.
 - The association between French fries and diabetes risk 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.

- 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 LDL-cholesterol concentrations and CHD risk.
- Plant-based Mediterranean-type **diets rich in olive oil** have also been traditionally associated with low CVD risk.
- 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

Food groups with important and different 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 its 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 low-fat 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.



- How can the healthy properties of oils, particularly olive oil, be reflected in nutrient profiling systems? For example in the Nutri-Score no oil gets more than a C. Is there any scientific evidence that traditional products with PDOs are healthier than a processed industrial product with a similar nutrient profile when it comes to salt and fat content?
 - Lewis Sara, European Food Law (freelance journalist)
- How will nutrient profiling (for the purpose of front-of-pack nutrition labelling and for restricting nutrition and health claims on foods), sugars reformulation targets due to be set under Farm2Fork, and the EFSA "as low as possible" opinion on sugars all fit together?
 - Prpa Emily, World Sugar Research Organisation

28 October 2021

Ongoing work of the Panel on Nutrition, Novel Foods and Food Allergens (NDA)

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Ongoing works

- Nutrient profiling (see Agenda item 9.1)
- Upper Levels for dietary sugars
- Upper Levels for vitamins & minerals
- Dietary folate equivalent (DFE)
- Novel foods & nutrient sources

28 October 2021

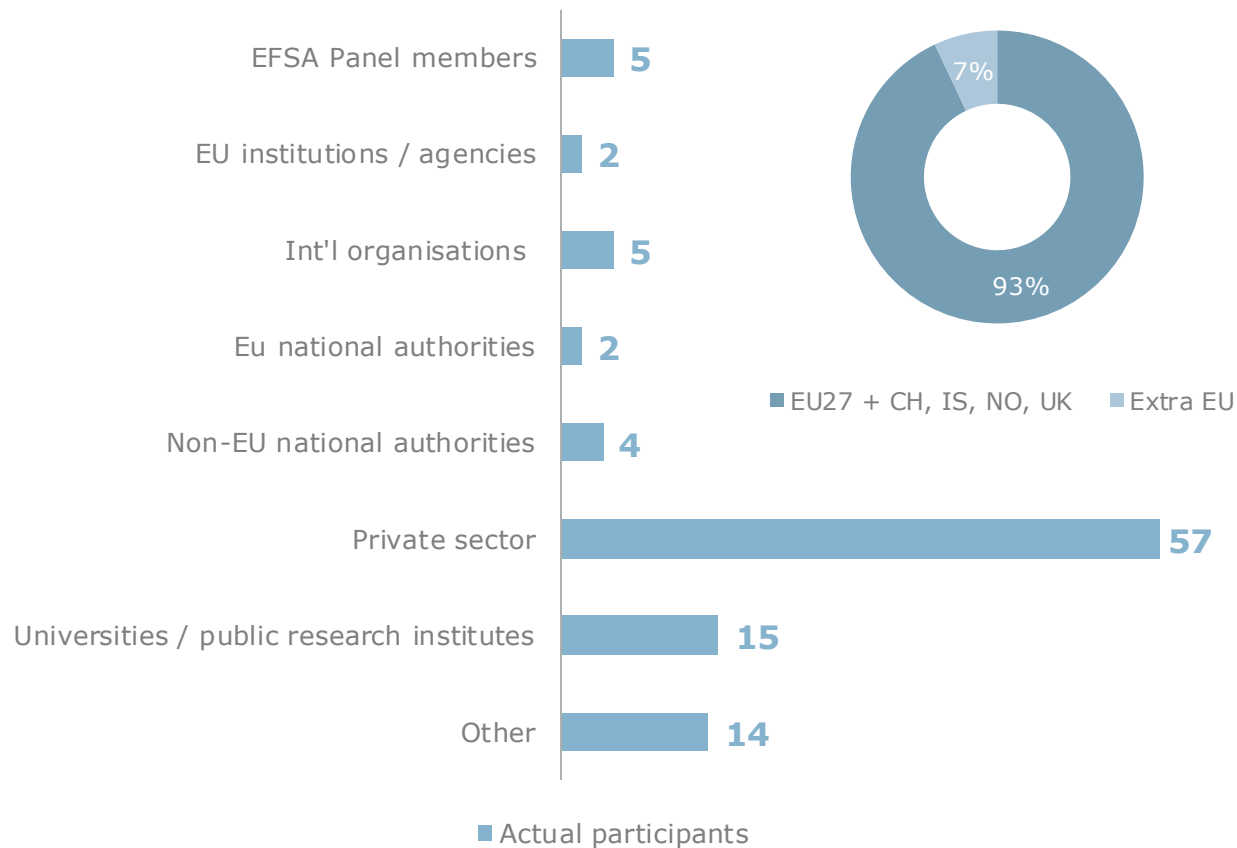
Status of Upper Levels on Sugars

Marco Vinceti, chair of the WG

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Status overview: Public consultation – closed (22 July to 30 September 2021; stakeholders meeting event – 21st September). **Adoption** end of 2021. **Publication:** beginning of 2022.

▪ **Stakeholders event:** - 141 total participants



▪ **Public consultation:**

- 723 comments received
 - 44 organisations
- Duplicate/identical comments were clustered
- Left with 491 comments to address overall
- Comments to be discussed with the WG Sugars on 3-4th and end of November and with the NDA Panel on 15-16th of December

28 October 2021

Status of Upper Levels WG activities

Androniki Naska, chair of the WG

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Support to European Commission regarding the setting of maximum amounts of vitamins and minerals added to foods⁽¹⁾ and to food supplements⁽²⁾

M-2021-0158

- **To update the guidelines of the Scientific Committee on Food (SCF)** for the development of Tolerable Upper Intake Levels for vitamins and minerals in the light of available recent scientific and methodological developments.
- **To review existing scientific evidence and provide advice on Tolerable Upper Intake Levels** for the following vitamins and minerals including their currently authorized forms for the addition to fortified foods and food supplements for the general population and, as appropriate, for vulnerable subgroups of the population: **iron, manganese, folic acid/folate, vitamin A, vitamin B6, vitamin D, vitamin E and β -carotene**
- Deadline: **March 2023**

(1) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

(2) Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplement

Objectives

- To build on the experience gained through previous SCF/NDA Panel's assessments of ULs
- To reflect conceptual and methodological developments
- To clarify principles and terminologies, where needed
- To embed EFSA's methodological guidance documents (e.g. application of systematic reviews for risk assessment, uncertainty analysis, biological relevance)

Sound and up-to-date set of principles

Approach and timeline

- Consultation of latest scientific reports on concepts and methods relevant to establishing ULs for nutrients (e.g. WHO, US NASEM, EFSA Scientific Committee)
- EFSA Workshop on 28-29 September 2021
- Draft Guidance under preparation
- Draft Guidance published and piloted in 2022
- Guidance finalised in 2023

- To **exchange views** regarding conceptual and methodological principles relevant to the revision of the guidance on establishing UL for vitamins and minerals for the European population.
- Key themes:
 - I. Applications of UL
 - II. Alternative value when data are insufficient to derive an UL
 - III. Target population
 - IV. Biological Based Model / Biomarkers of effects
 - V. Dose-response modelling
 - VI. Integration of chronic diseases risks in the framework
- **13 questions** addressed through workgroup discussions
- Focus on the **European context**, while considering the relevant developments in other parts of the world
- Focus on **vitamins and minerals**

The intention was not to reach consensus but to **collect views of experts and generate possible orientations** that will be considered by the UL WG and NDA Panel in revising the guidance on ULs.

Members of EFSA NDA Panel, Scientific Committee, and Working Groups

- Peter AGGETT
- Torsten BOHN
- Jacqueline CASTENMILLER
- Marta CROUS-BOU
- Francesco CUBADDA
- Stefaan DE HENAUW
- Helle KNUTSEN
- Inge MANGELSDORF
- Henry MCARDLE
- Androniki NASKA
- Monika NEUHÄUSER-BERTHOLD
- Kristina PENTIEVA
- Hildegard PRZYREMBEL
- Josef SCHLATTER
- Alfonso SIANI
- Frank THIES
- Dominique TURCK
- Marco VINCETI

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- Nathalie DELZENNE, University of Louvain, BE
- Susan FAIRWEATHER-TAIT, University of East Anglia, UK
- Albert FLYNN, University College Cork, IE
- Gunter Georg KUHNLE, University of Reading, UK
- Ambroise MARTIN, University of Lyon, FR
- Gunnar NORDBERG, Umea University, SE
- Caroline SPAAIJ, Health Council from the Netherlands, NL
- Aida TURRINI, Independent researcher, IT
- Sandrine WETZLER SAD, ANSES, FR

Observers

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- Douglas BALENTINE, US FDA
- Carolin BENDADANI, DG SANCO
- Florence BERNARDY, Belgian Health Council
- Stephanie BODENBACH, DG SANCO
- Lisette BRINK, Netherlands Nutrition Centre
- Anja BRÖNSTRUP, German Federal Ministry of Food and Agriculture
- Carolyn CHUNG, US FDA
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- Janette DE GOEDE, Health Council from the Netherlands
- Marjolein DE JONG, RIVM
- Amanda MCFARLANE, Health Canada
- Sinead O'MAHONY, Food Safety Authority of Ireland
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- Magali TAQUET, Belgium Health, Food Chain Safety and Environment
- Michele ULENS, Belgian Health Council
- Janneke, VERKAIK-KLOOSTERMAN, RIVM
- Anke WEIBENBORN, BfR
- Maria XIPSITI, FAO
- Essie YAMINI, US FDA

I. Applications of UL

- **Current definition of UL found appropriate:** consistent with UL that have been established previously and its applications in risk assessment and risk management are established
- New section on the **applications of UL** (for individuals, populations) considered useful.

II. Alternative value when data are insufficient to derive an UL

- The totality of evidence available should be used
- Lack of agreement on whether a specific term should be applied, and, if so, what the term might be
- **Communication** of the nature of the evidence and associated uncertainties critical in risk characterisation
- **Application may be more limited** than UL (e.g. to assess the proportion of the population at risk of adverse effect) but might be used as a conservative value that provides a reference point for risk management decisions

III. Target population

- General agreement to define the target population as “**general population**”, i.e. everyone besides particular groups that would be pre-specified
- General agreement that the term “**general healthy population**” **should not be used** as it is difficult to define for the purposes of UL

IV. Biological Based Model / Biomarkers of effects

- Adverse (health) effects from excessive intake of a nutrient may cover a very broad range, from **failure of homeostasis leading to overload and accumulation to overt toxicity**; expert judgement required.
- Selection of a biomarker that is both specific and sensitive may involve two steps,
 - (1) strength of evidence on the relationship of the **biomarker with the adverse health endpoint**
 - (2) strength of evidence on the dose-response relationship of the **nutrient intake with the biomarker**
- Totality of information available to be used, including mechanistic evidence for biological plausibility
- Use of a biomarker may **reduce the need for an uncertainty factor** or the magnitude of the uncertainty factor; on the other hand, additional **specific uncertainties arise (e.g. validation)**

V. Dose-response modelling

- **Useful and desirable alternative to the NOAEL (LOAEL) approach**, when data allow
- Limitations of modelling group mean (aggregated) response data to predict response at individual level (general issue)
- In principle **BMD approach** could be used for nutrients, but difficult in practice and adaptations required
- **Flexibility** required regarding the choice of the modelling method
- **Specific uncertainties** associated to modelling (e.g. due to assumptions)

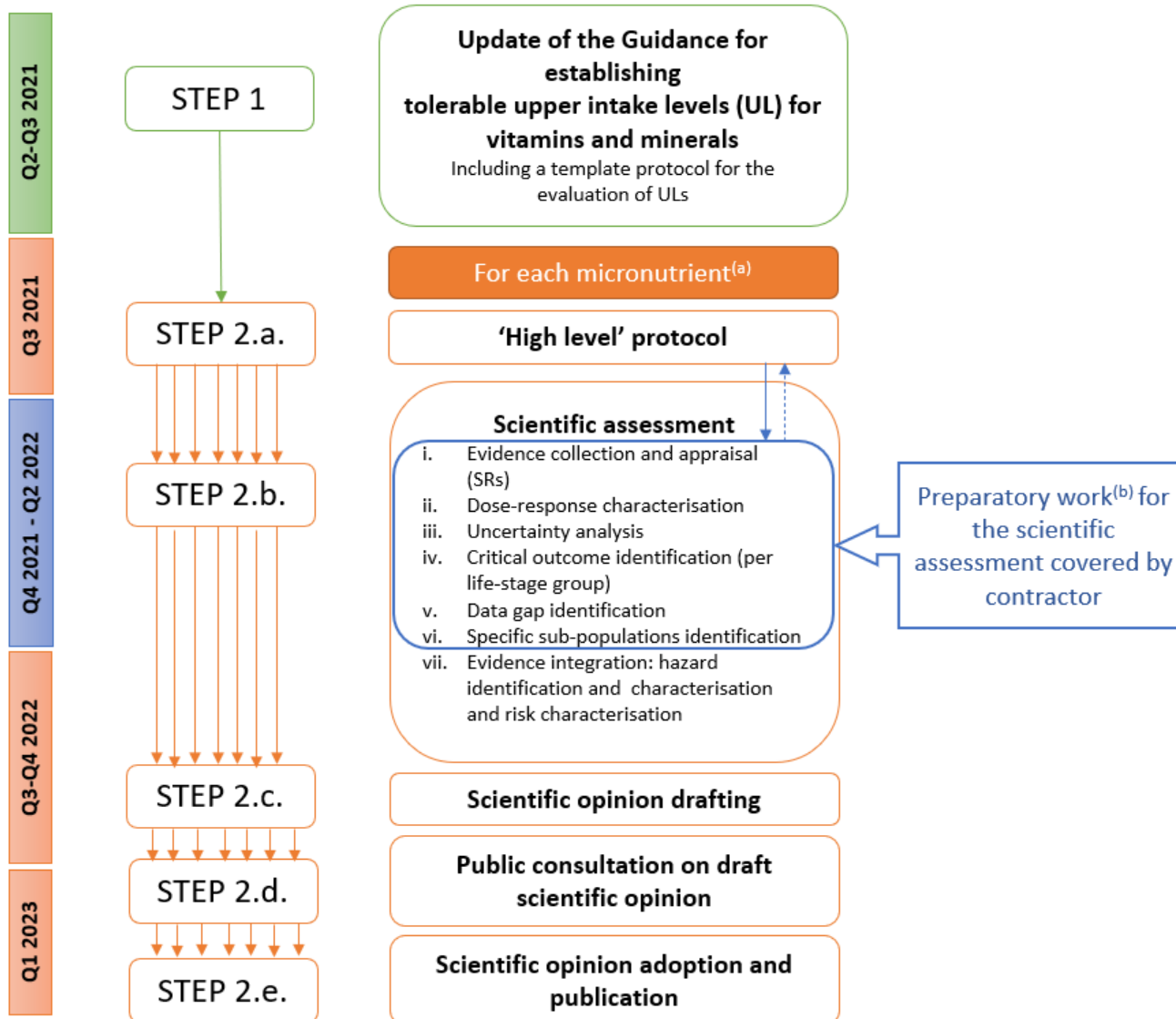
IV. Integration of chronic diseases risks in the framework

- Chronic disease risks are adverse health effects covered by UL evaluation
- Adopting a **systematic approach for evidence appraisal and grading the strength of the evidence** considered important for consistency and gaining agreement among experts on the strength of evidence
- **Conflicting views on whether separate values from UL should be derived** on the basis of chronic disease endpoints; most participants not in favour of using a different term for the upper level derived from chronic diseases (communicated through risk characterisation without applying a specific term)
- Key differences of interpretation between UL and upper level based on chronic diseases (e.g. US NASEM CDRR) :
 - By definition, **UL is the highest allowable intake, above which risk of adverse effects increases**
 - Upper level based on chronic diseases (e.g. CDRR) may be derived from the **intake range above which intake reduction is beneficial**, i.e. expected to reduce chronic disease risk; unclear whether it can be used to identify the proportion of the population that is at (increased) risk of adverse effect (chronic disease) in a population

- Summary of the discussions
- Annexes
 - Workshop programme and list of participants
 - Workshop discussion paper
 - Presentations
- Reviewed at last UL WG meeting (19-20-22 October)

To be published as an Event report on EFSA's website (November)

Review of ULs for selected micronutrients



- **Hearings with recognised experts** on each micronutrient (November)
 - Formulation of risk assessment questions to be addressed through SRs
- **Development of 'high level' protocol** for each nutrient
- **Procurement call over summer**
 - Finalisation of the evaluation and attribution steps

Update of the opinion on UL for selenium

M-2020-0158; EFSA-Q-2020-00618

- Re-evaluate the safety in use of selenium and to provide revised tolerable upper intake levels that are unlikely to pose a risk of adverse effects from intake of this nutrient, for all population groups
- Deadline: **March 2022 (extension to be requested)**
- **On-going systematic reviews**
 - Selenium intake and **selenosis-related outcomes**; exploration of the biologically based model
 - Selenium intake and **risk of chronic diseases**
 - Prioritisation to focus efforts on the most relevant outcomes
 - Risk of bias appraisal: piloting of **Cochrane Rob-2** for RCTs and **USDA Rob-Nobs** for prospective cohort studies
- Modelling of the **dose-response relationship between selenium intake and plasma concentration**

28 October 2021

Status of Dietary Folate Equivalent (DFE)

Kristina Pentieva, chair of the WG

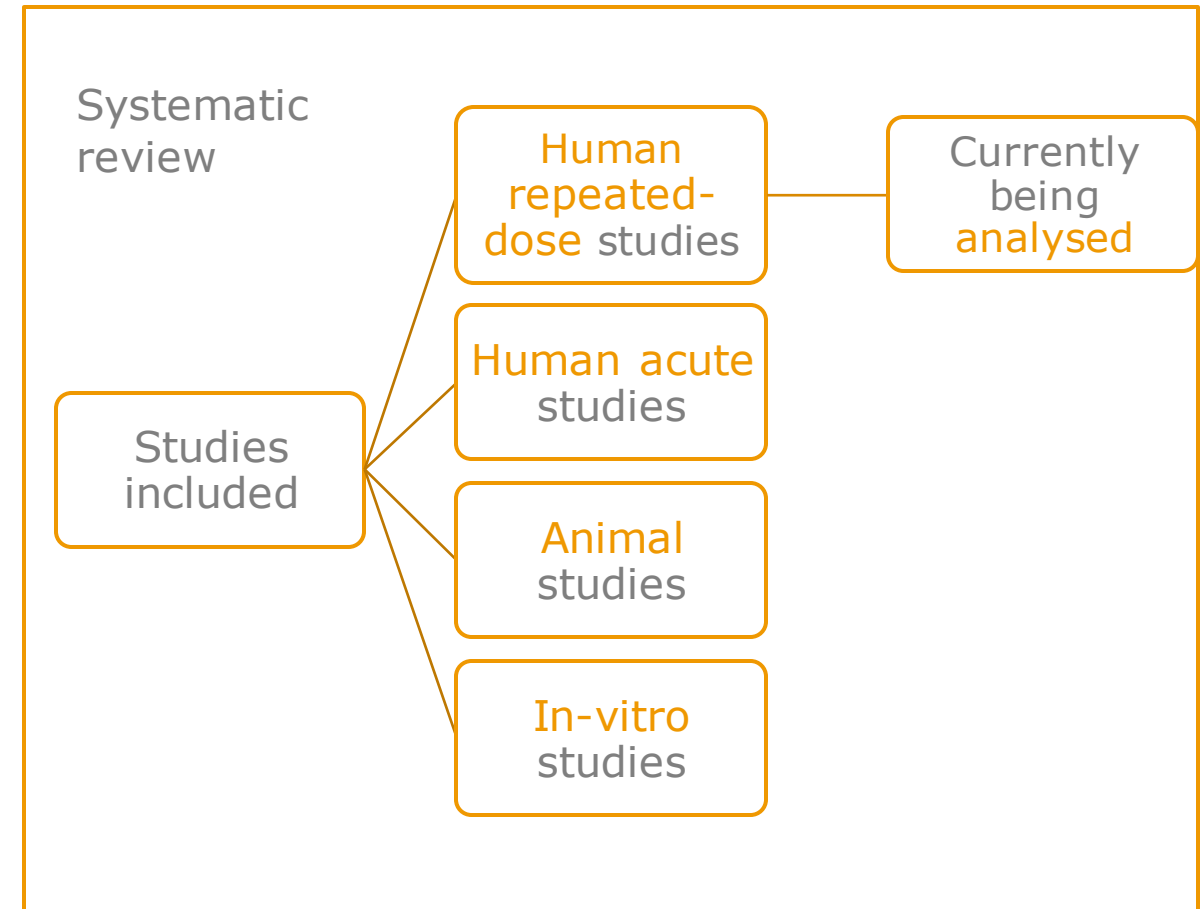
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DFE: Dietary folate equivalent

Mandate: to assess the extent to which folate is **bioavailable** from **CaLMF and 5MTHF-glucosamine** and to set a **conversion factor** of amounts of these 2 forms into **µg DFE**



- Systematic review
- Drafting opinion



28 October 2021

Novel Foods & Nutrient Sources

Helle Knutsen, chair of the WG on Novel Foods

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NDA Panel supported by

- 14 Novel foods WG experts
- 18 Nutri staff

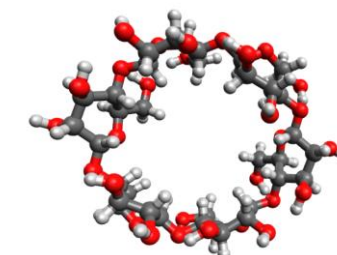
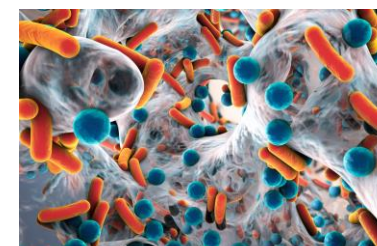
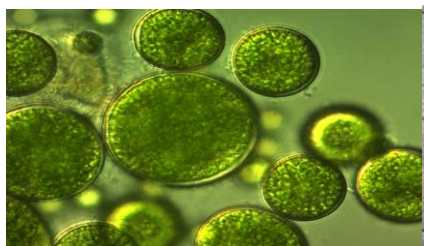
Currently almost **100 NF dossiers** actively under risk assessment

Contributions from:

- Cc WG on **Genotoxicity**
- Cc WG on **Nanotechnologies**
- SC WG on **Botanicals**
- BIOHAZ WG on **QPS**

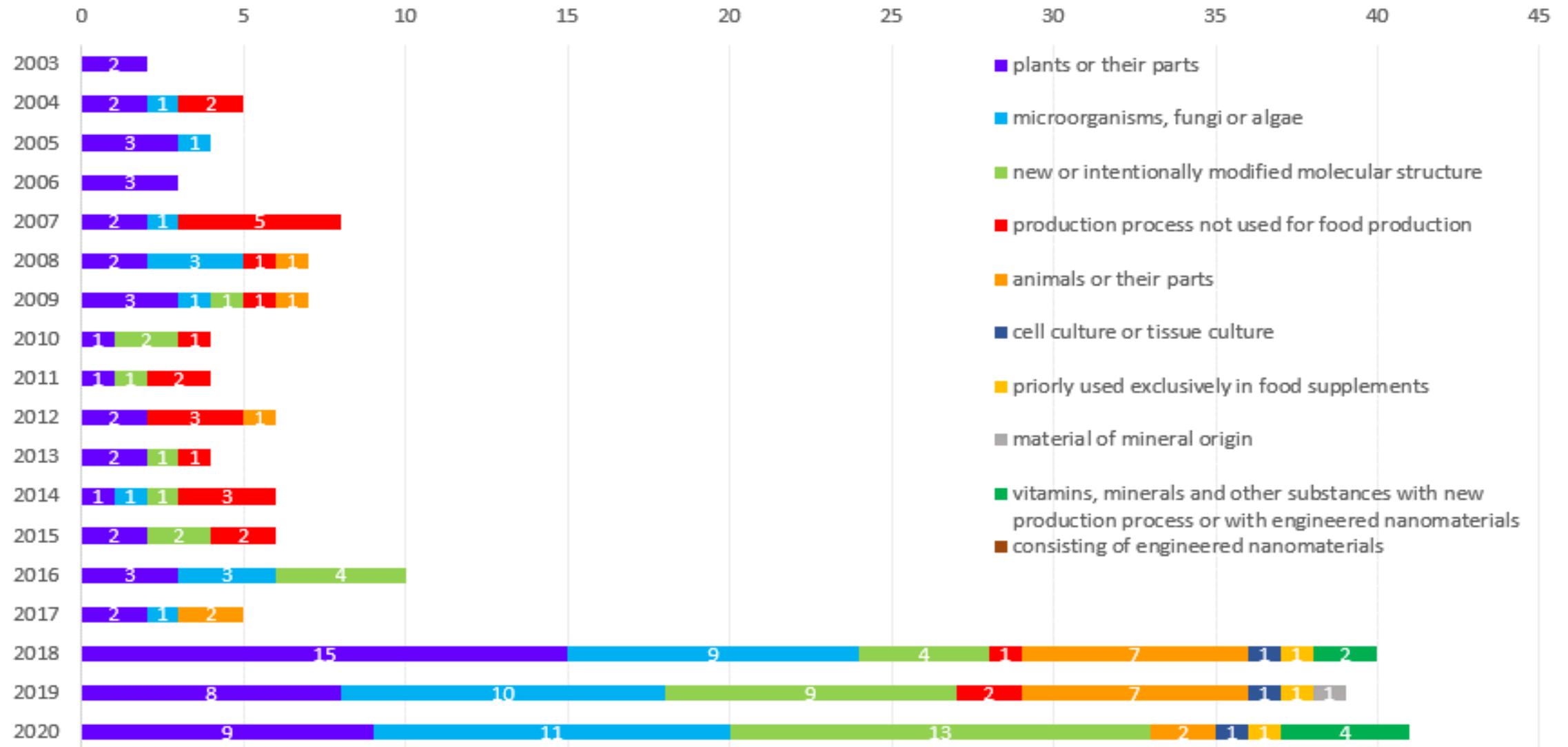
Trending topics

- Alternative proteins and their sources
 - from plants, insects, microbial biomass, fungi
- Extracts of vegetable origin
- Cannabidiol (CBD)
- Food supplements
- Human milk identical oligosaccharides
- Nanomaterials/nanoparticles
- Novel carbohydrates
- Nutritionally enhanced products



Novel foods applications 2003-2020

Novel Food Applications entered EFSA's Risk Assessment
Categories according to Regulation (EU) 2015/2283



28 October 2021



NDA Open Plenary

Questions pre-submitted by observers

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- **Q1:** How can the healthy properties of oils, particularly olive oil, be reflected in nutrient profiling systems? For example, in the Nutri-Score no oil gets more than a C. Is there any scientific evidence that traditional products with PDOs are healthier than a processed industrial product with a similar nutrient profile when it comes to salt and fat content? *By Lewis Sara, European Food Law*
- **Q2:** How will nutrient profiling (for the purpose of front-of-pack nutrition labelling and for restricting nutrition and health claims on foods), sugars reformulation targets due to be set under Farm2Fork, and the EFSA "as low as possible" opinion on sugars all fit together? *By Prpa Emily, World Sugar Research Organisation*

- **Q3:** Regarding Eurycoma longifolia (Tongkat Ali) root extract as a novel food (EFSA-Q-2018-00106, NF 2018/0169), does EFSA Scientific Committee look into EXCESS Dose consumed by heavy users (eg. 3x or 4x daily dose), in addition to intended daily dose, when comparing to toxicity data, when evaluating the safety-risk? *By TSI Daniel, Suntory Beverage & Food Asia*
- **Q4:** Is the panel developing guidance for the safety assessment of cell-based meat? *By Gartlon Joanne, Pen + Tec Consulting*

- **Q5:** Is it possible to introduce a consultation procedure with EFSA (Preliminary Assessment of Scientific Substantiation) for health claim applications before submitting the application? *By Tańska Izabela, IGI Food Consulting*

**Thank you
for your participation!**



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