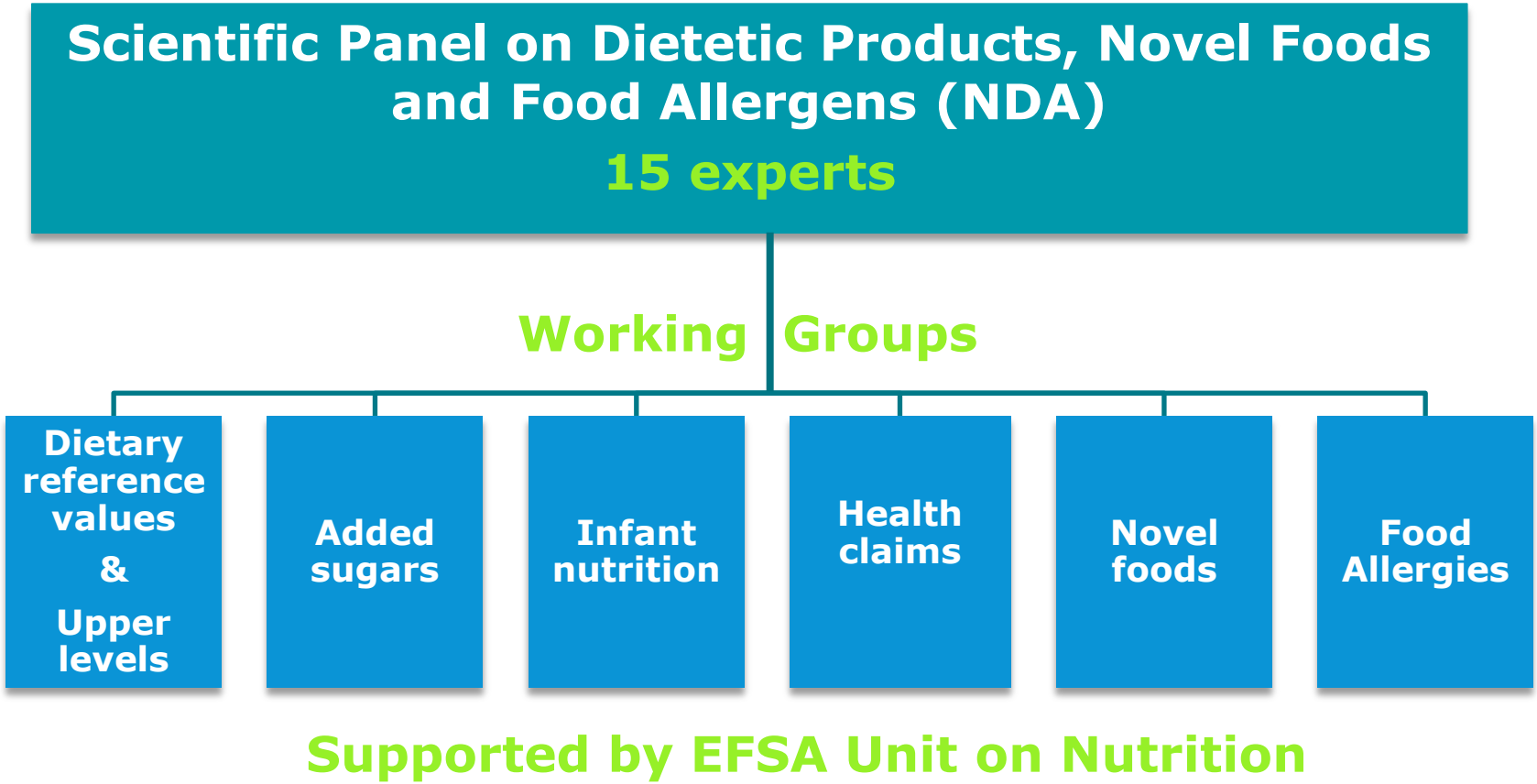
EFSA's activities in the area of nutrition

Janusz Ciok
Scientific Officer
Nutrition Unit

European College visit to EFSA
12 April 2019

efsa
European Food Safety Authority

AREAS OF NDA PANEL



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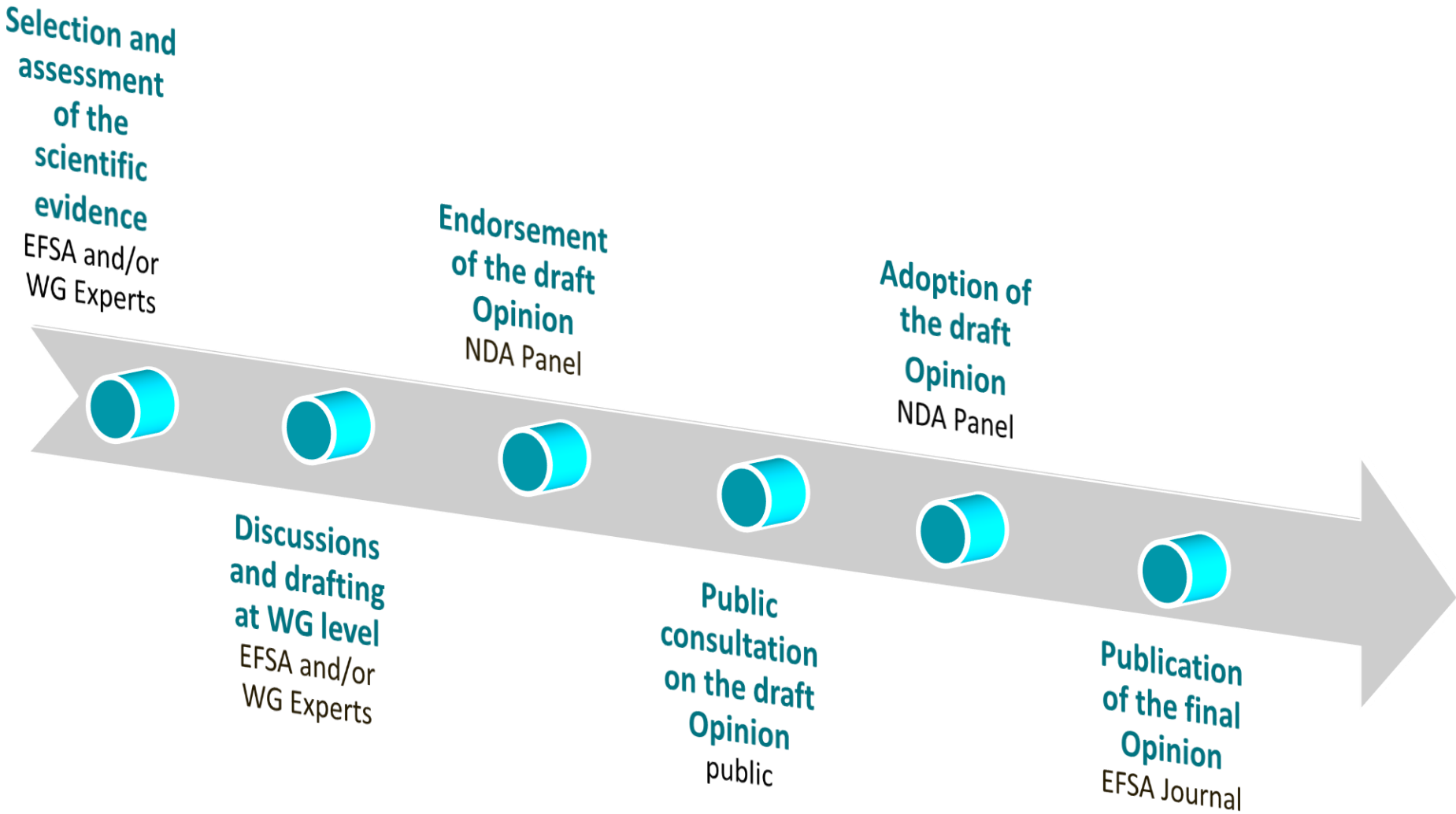
LIFECYCLE OF A GENERIC OPINION

METHODOLOGY FOR WRITING A GENERIC OPINION



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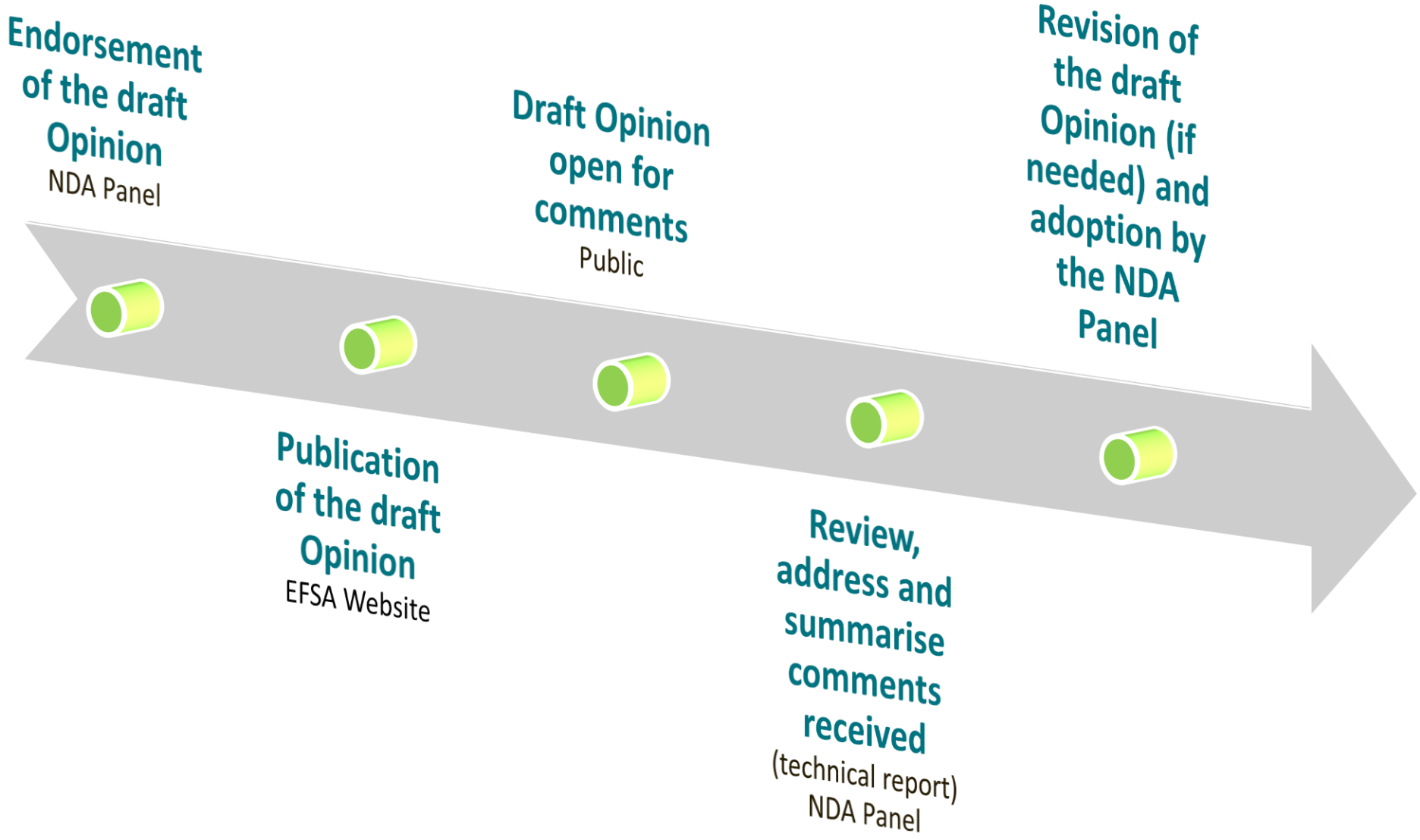
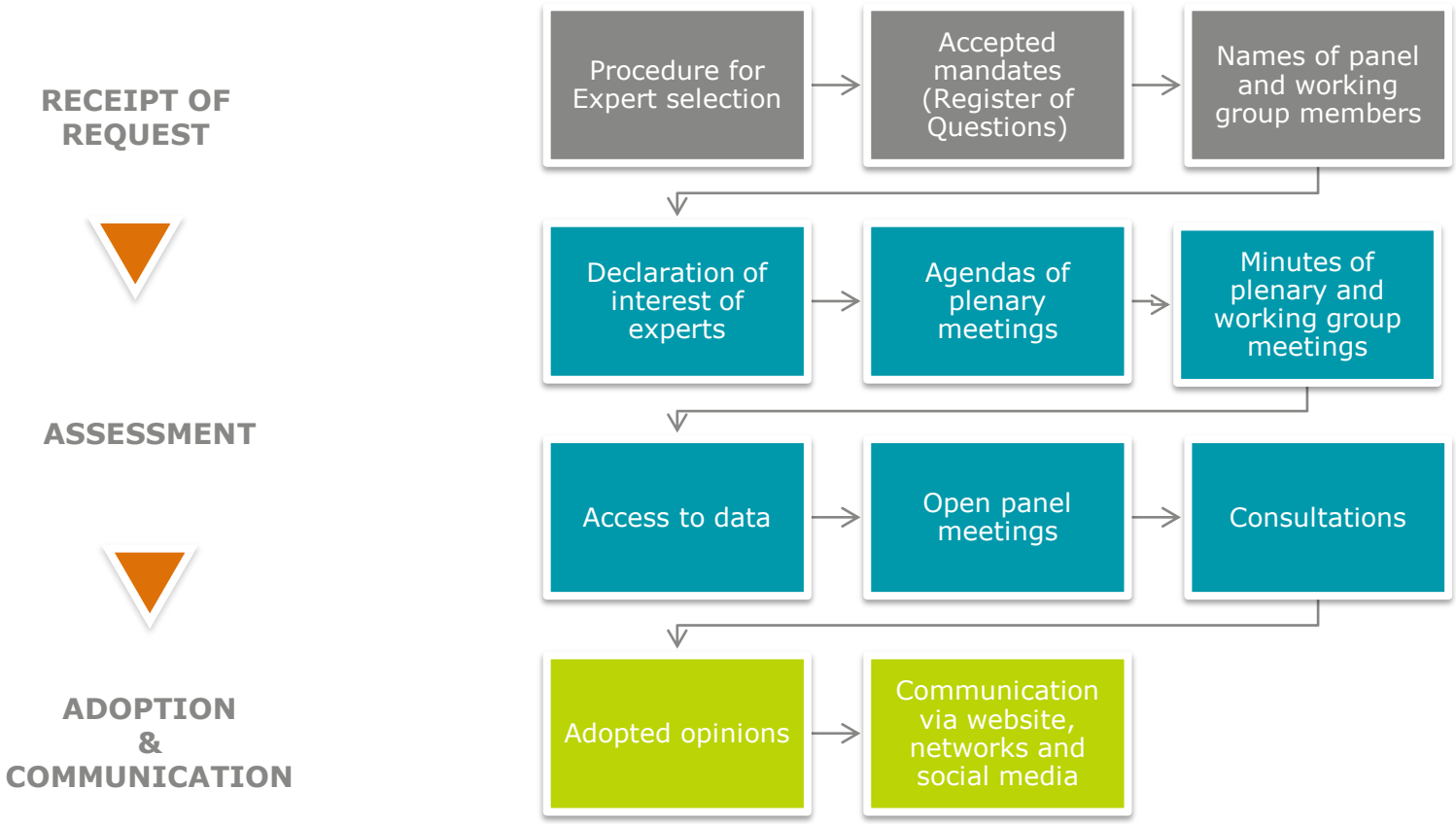
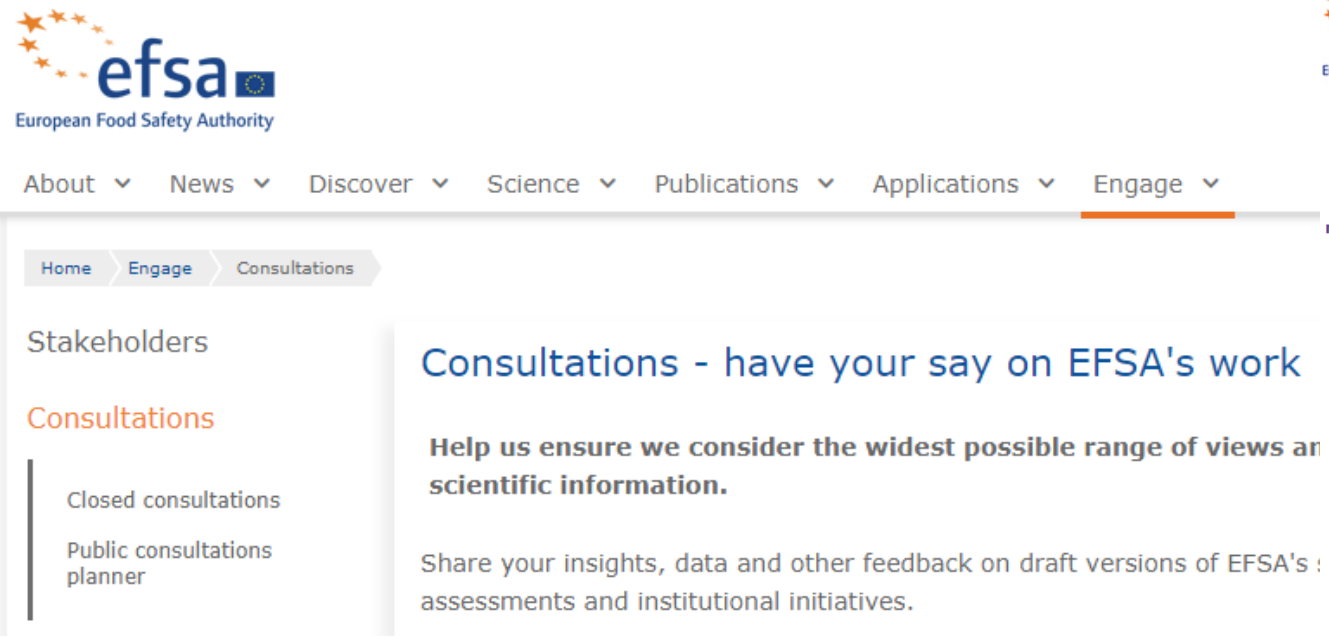
EFSA PUBLIC CONSULTATIONS ON GENERIC OPINIONS: STEPS

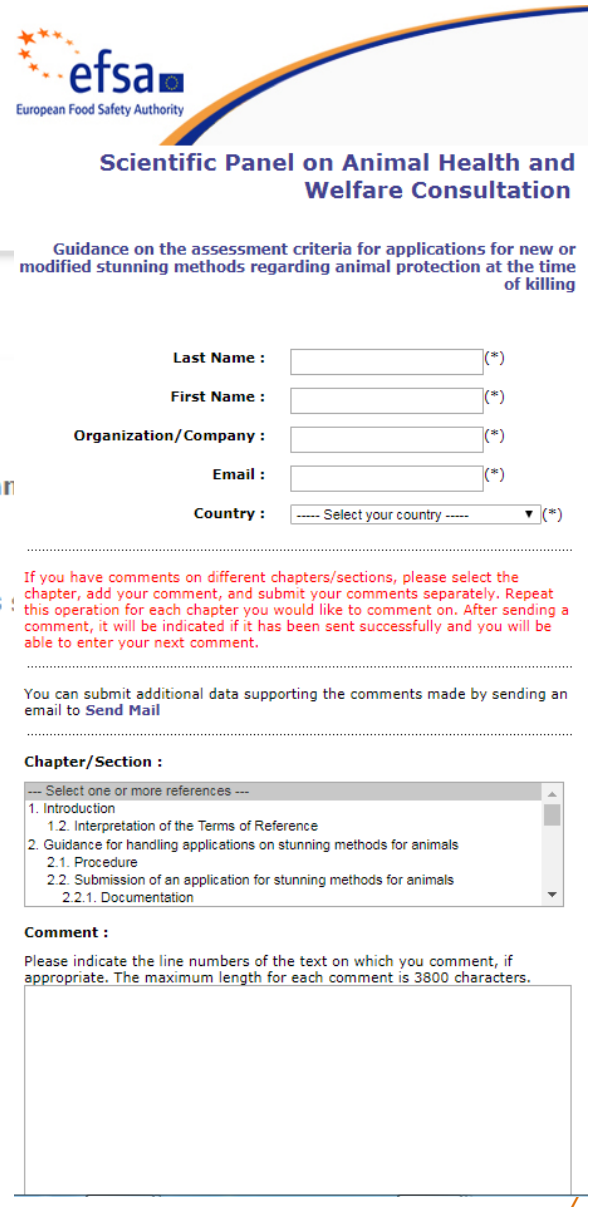


INDEPENDENT SCIENCE

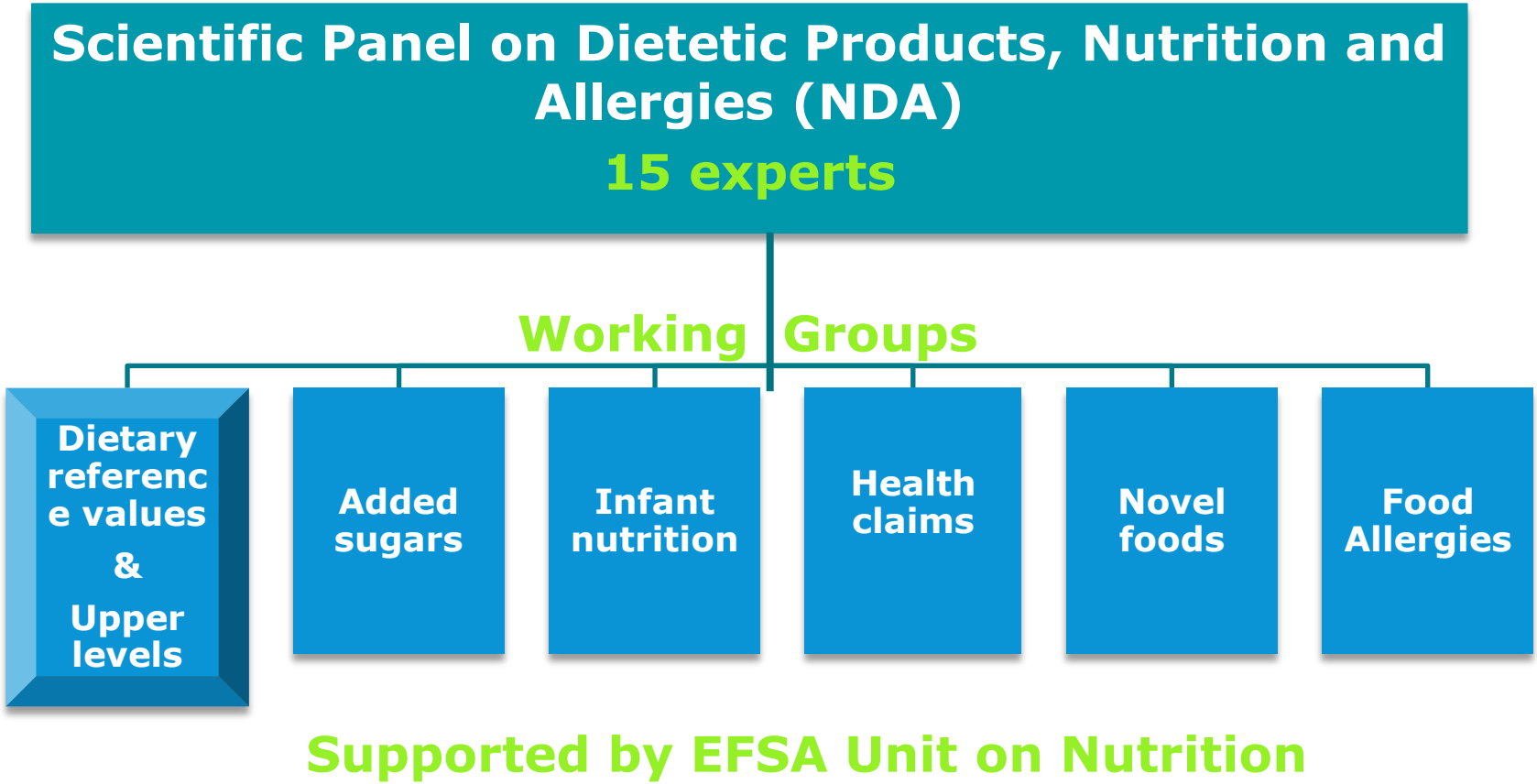


EFSA PUBLIC CONSULTATIONS_TOOLS





AREAS OF NDA PANEL



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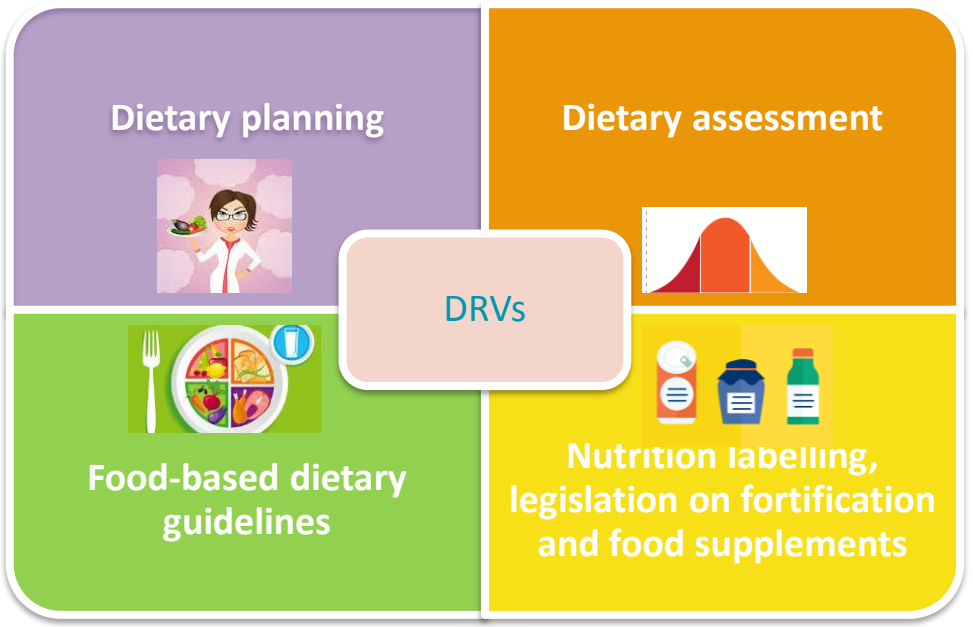
DRVs: DEFINITION AND END-USERS

Request by European Commission (2005)
to update the reference values for nutrient and energy intakes (UL excluded) established in 1993 by the Scientific Committee on Foods (SCF)

- **Requirements**
- **Excess levels**



End-users

Policy makers
Public health bodies
Health professionals (dieticians, doctors)
Nutrition research community
Food and supplement industry
…

WHAT IS DRV?

- Dietary reference values (DRVs) is an umbrella term for a set of nutrient reference values that includes:
- the average requirements (AR),
- the population reference intakes (PRI),
- the adequate intakes (AI)
- the reference intake ranges for macronutrients (RI).

These values guide professionals on the amount of a nutrient needed to maintain health in an otherwise healthy individual or group of people. DRVs also include the tolerable upper intake level (UL), which is the maximum amount of a nutrient that can be consumed safely over a long period of time.

WHAT IS DRV? (2)

- The average requirement (AR) - the intake of a nutrient that meets the daily needs of 50% people.
- The population reference intakes (PRI) - the intake of a nutrient that meets the daily needs of 97.5% people.
- The adequate intakes (AI) - the level of intake that is assumed to be sufficient based on observations from groups of apparently healthy people
- The reference intake ranges for macronutrients (RI) - set for total fat and total carbohydrates based on their relative contribution to total energy intake. They indicate the range of intakes of an energy source that is adequate for maintaining health.

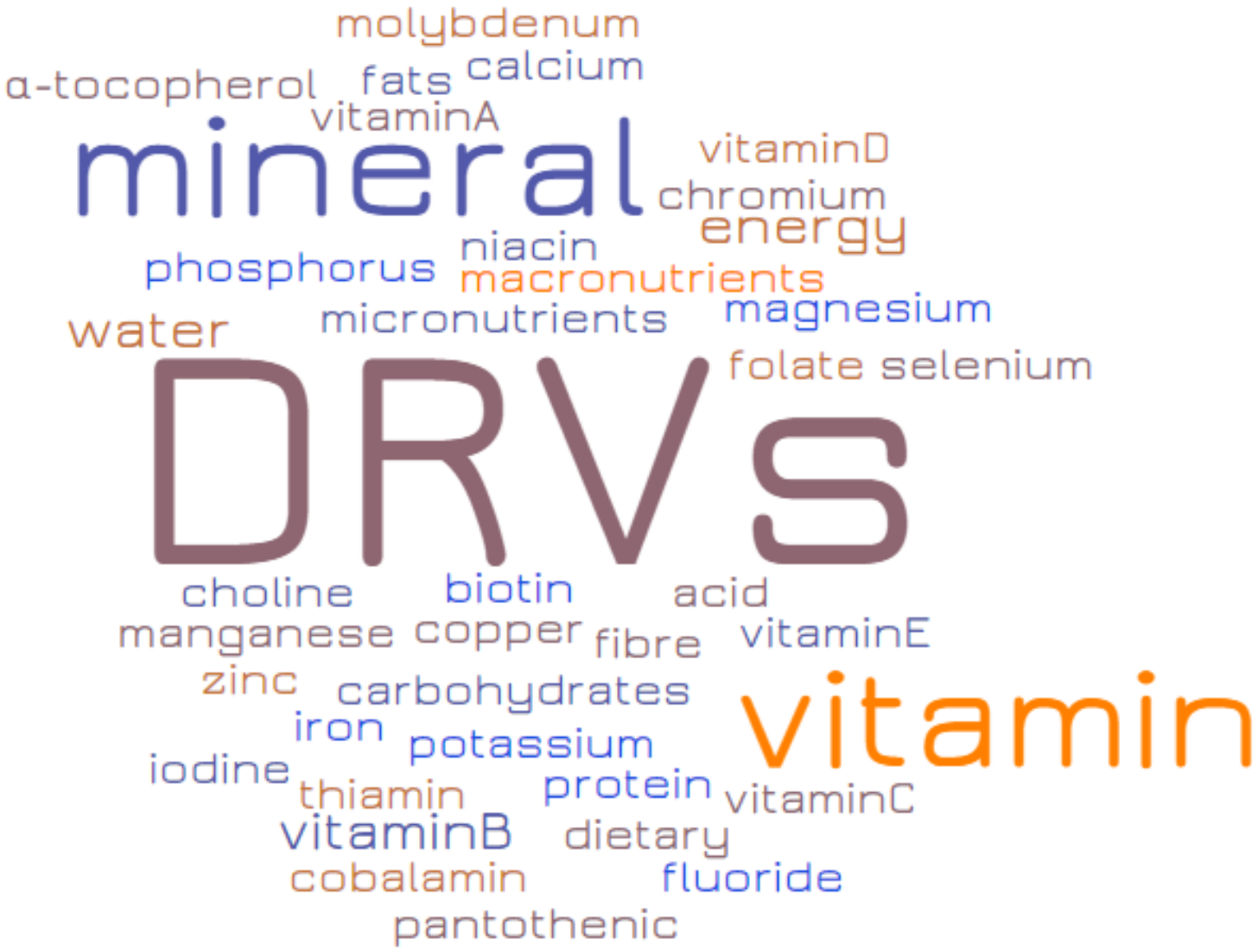
DIFFERENCE BETWEEN DRVS AND NUTRIENT RECOMMENDATIONS

- DRVs should not be viewed as recommendations for individuals.
- Rather, DRVs are scientific references for professionals, who use them when setting nutrient goals for populations or recommendations for individuals.
- Nutrient goals and recommendations are tailored to national contexts (e.g. public health priorities, nutritional status, dietary patterns, composition of available foods) and may therefore differ from country to country.
- The setting of nutrition goals and recommendations is outside EFSA's remit.

WHAT ARE DRVS USED FOR?

- DRVs are key concepts in the field of nutrition. They provide the scientific basis on which nutrition recommendations are built.
- They are used by nutrition and health professionals in dietary assessment and diet planning, at population and individual level.
- They can serve as the basis for risk managers or policy makers to set reference values in food labelling and establish food-based dietary guidelines.
- They are also helpful to food manufacturers for product formulation and to scientists involved in nutrition research.

DRVs: MICRO AND MACRONUTRIENTS



34 opinions published + public consultations

MORE INFO ON DRVs

EFSA JOURNAL

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Dietary Reference Values (DRVs)

Virtual Issues | First published: Dec 345, 2017 | Last updated: 19 March 2018

Dietary reference values (DRVs) is an umbrella term for the complete set of nutrient reference values which include population reference intakes (PRIs), the average requirements (ARs), adequate intakes (AIs) and reference intake (RIs) ranges for macronutrients. These values indicate the amount of a nutrient which must be consumed on a regular basis to maintain health in an otherwise healthy individual (or population). This virtual issue brings together all 32 of EFSA's scientific opinions that have been published over 7 years, covering water, fats, carbohydrates and dietary fibre, protein, energy, as well as 14 vitamins and 13 minerals.

https://efsa.onlinelibrary.wiley.com/doi/toc/10.1002/(ISSN)1831-4732.021217

DRVs – WHAT IS IN THE REMIT OF EFSA AND WHAT IS NOT

Reviewing scientific evidence → Identify suitable indicator(s) to set requirement for nutrients → Establish dietary reference values → Establish nutrient goals and recommendations → Establish food-based dietary guidelines

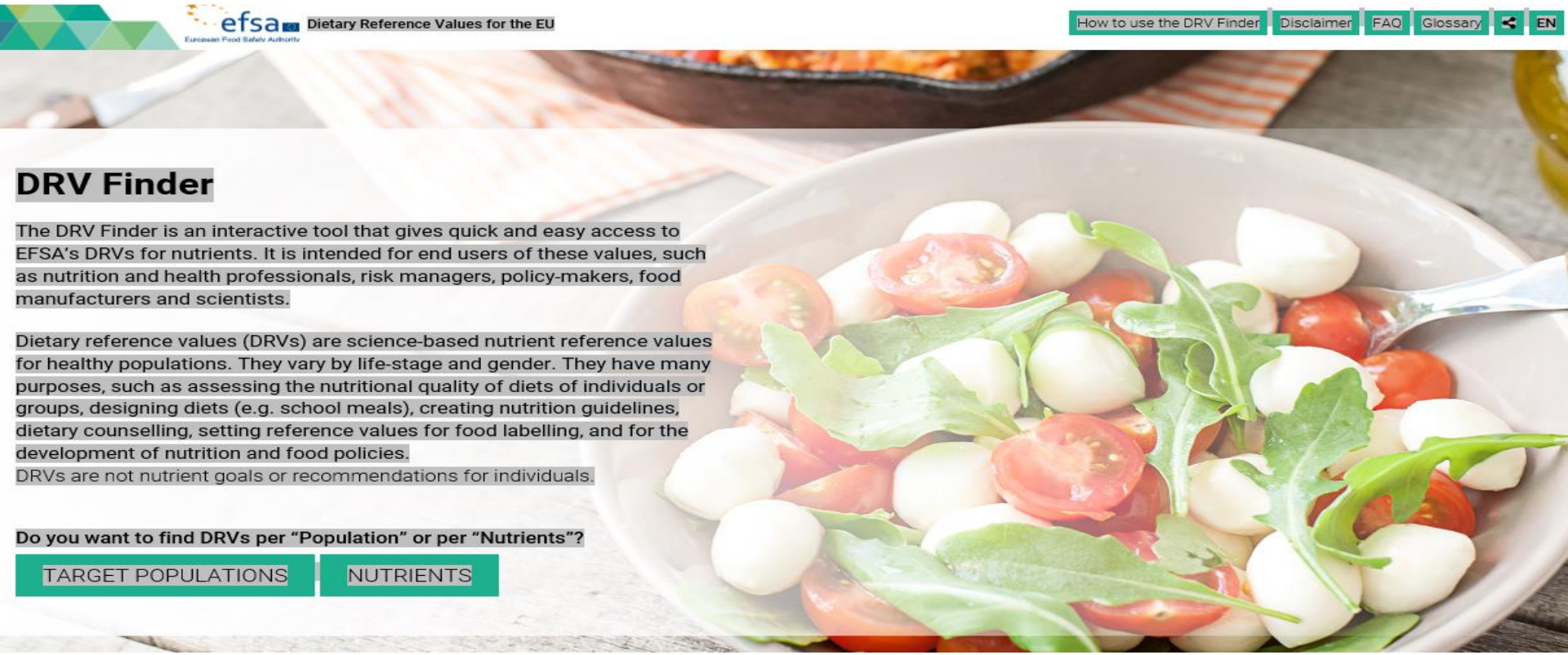
Adaptation to a specific context

SCIENTIFIC ASSESSMENT: INNOVATION & SCIENTIFIC EXCELLENCE

EFSA started recently to follow an innovative methodology (PROmoting METHods for Evidence Use in Scientific assessments – **Prometheus** project) to improve the way scientists select and use the evidence in their scientific assessments

DRV FINDER (I VALORI DI RIFERIMENTO PER LA DIETA - LARN)

- https://www.efsa.europa.eu/en/interactive-pages/drvs?lang=en



DRVs FOR SODIUM AND CHLORIDE

- last two DRV opinions were just published
- case study for the Prometheus project
- very sensitive discussion around the sodium opinion

2017 — **Public consultation and Panel endorsement on the protocol**

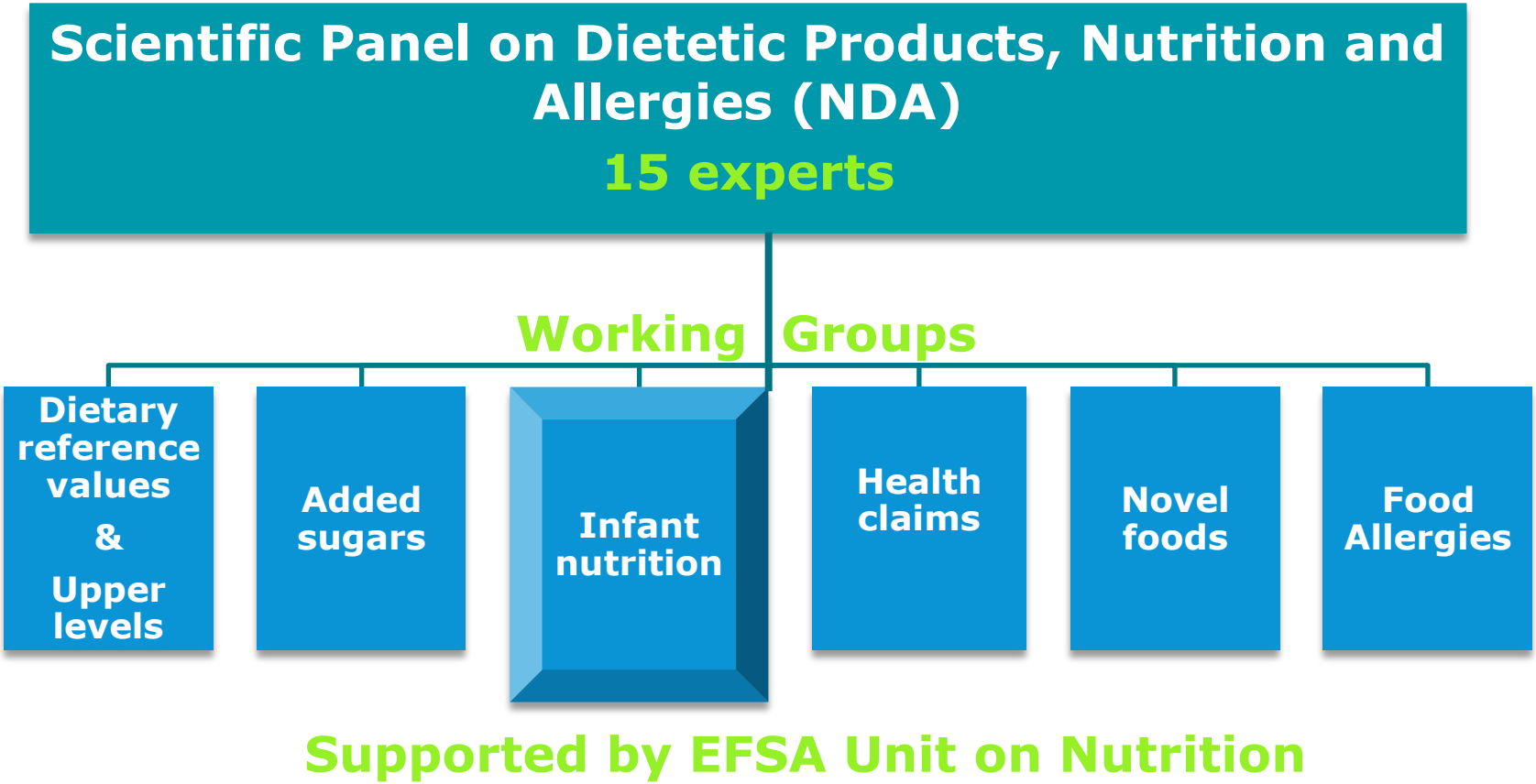
2018 — **Protocol implementation + finalisation of opinion on sodium**

June 2019 — **Deadline for publication**

DRV FOR SODIUM AND CHLORIDE

- EFSA is publicly consulting on draft dietary reference values (DRVs) for sodium and chloride, the final two nutrients in its review of scientific advice on nutrient intakes for the EU population.
- Sodium and chloride are the two elements in salt, commonly used in the diet as an ingredient, condiment or preservative.
- The Panel on Nutrition, Novel Foods and Food Allergens provisionally considers for the general adult population (including pregnant and lactating women):
- An intake of **2g sodium** per day to be safe and adequate, considering evidence on the risk of cardiovascular disease on the one hand and nutrition adequacy on the other;
- An intake of **3.1g chloride** per day to be safe and adequate, taking account that the main source of chloride in EU diets is sodium chloride.

AREAS OF NDA PANEL



See EFSA working practices at: https://www.efsa.europa.eu/en/howwework/workingpractices

AGE FOR INTRODUCTION OF COMPLEMENTARY FEEDING

Mandate (EC): to update the NDA Panel opinion (2009) (safe to introduce solid food between 4 and 6 months of age) considering new evidence

2017

Public consultation on draft protocol on systematic review

Review of data-ongoing

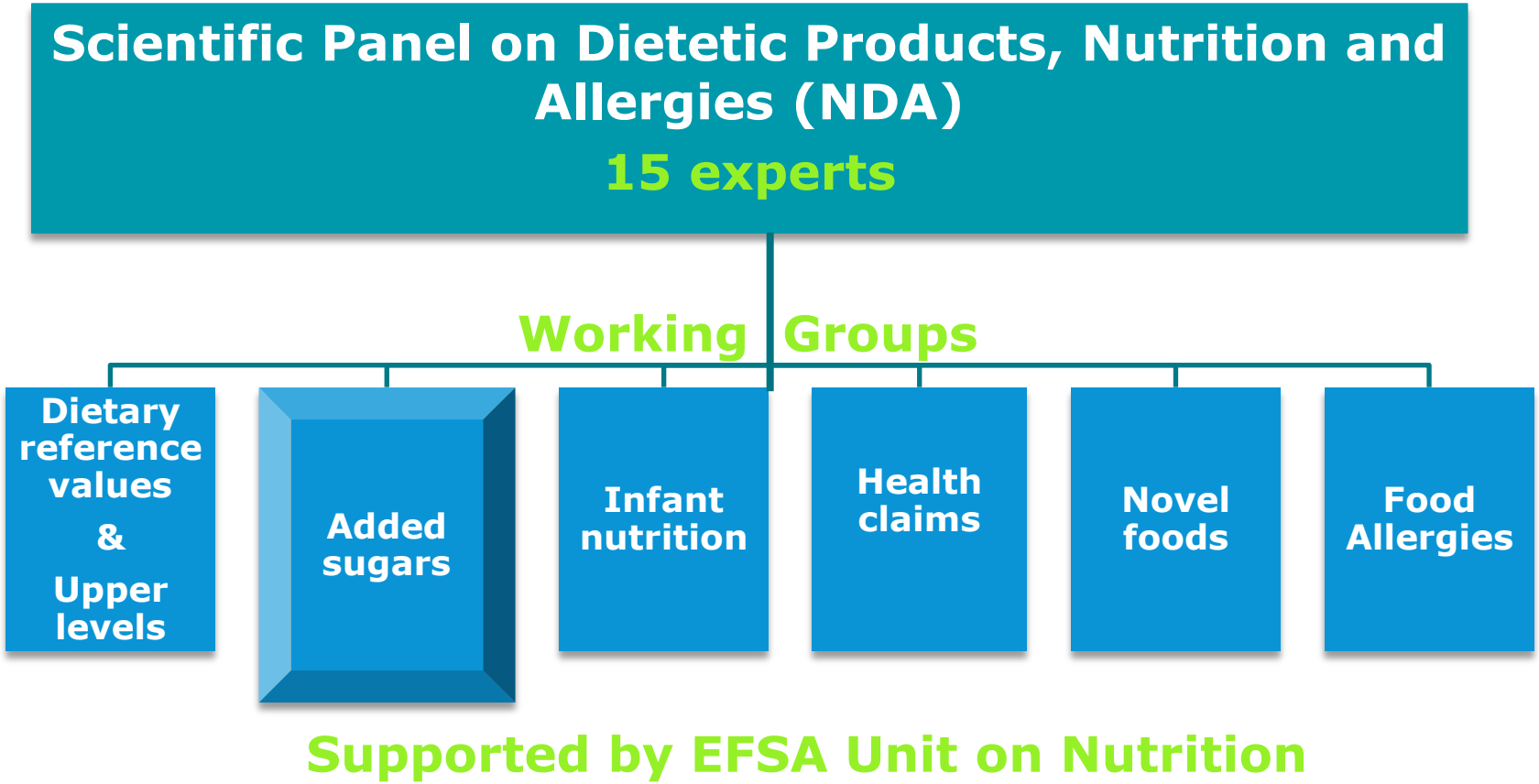
2019

Public consultation on the draft opinion and adoption

AGE FOR INTRODUCTION OF COMPLEMENTARY FEEDING –

1. Overweight and obesity
2. Diabetes mellitus types 1 and 2
3. Risk factors for cardiovascular disease (e.g. blood pressure, blood cholesterol)
4. Coeliac disease
5. Allergy
6. Dental health
7. Renal function
8. Gastrointestinal infections
9. Respiratory tract infections including otitis media
10. Neuromuscular development, cognitive development and cognitive function
11. Growth
12. Body composition
13. Food patterns, food preferences and feeding disorders
14. Indicators of nutrient status.

AREAS OF NDA PANEL



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ADDED SUGARS

ADDED SUGARS

- request by the National Food Agencies of Sweden, Finland, Denmark, Norway, and Iceland (2017)
- to derive a science-based cut-off value for a daily exposure to added sugars from all sources which is not associated with adverse health effects in the population

1Q2018
- Public consultation on the draft protocol
- Stakeholders meeting during the public consultation

Mid 2018
Endorsement by the Panel and publication of the final protocol

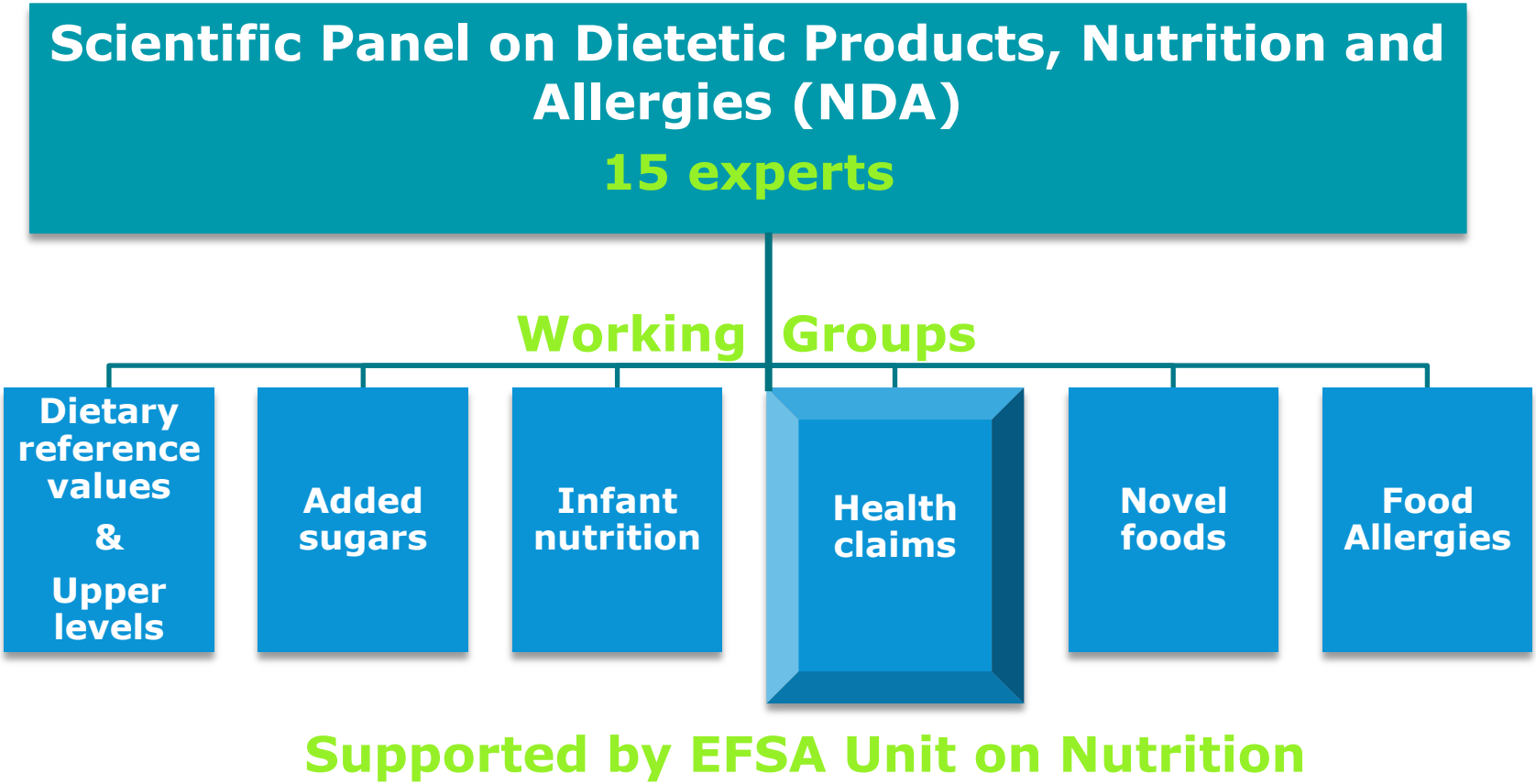
4Q/2019
Public consultation on draft opinion / technical meeting with stakeholders

Feb 2020
Deadline for adoption

ADDED SUGARS – HEALTH OUTCOMES

- Micronutrient status – clinical signs / symptoms of micronutrient deficiency
- Teeth – dental caries incidence / severity
- Adipose tissue – incidence of obesity
- Glucose homeostasis – incidence of diabetes type 2
- Cardiovascular system – incidence / mortality of cardiovascular disease
- Liver function – incidence / mortality of liver fibrosis and cirrhosis

AREAS OF NDA PANEL



See EFSA working practices at: https://www.efsa.europa.eu/en/howwework/workingpractices

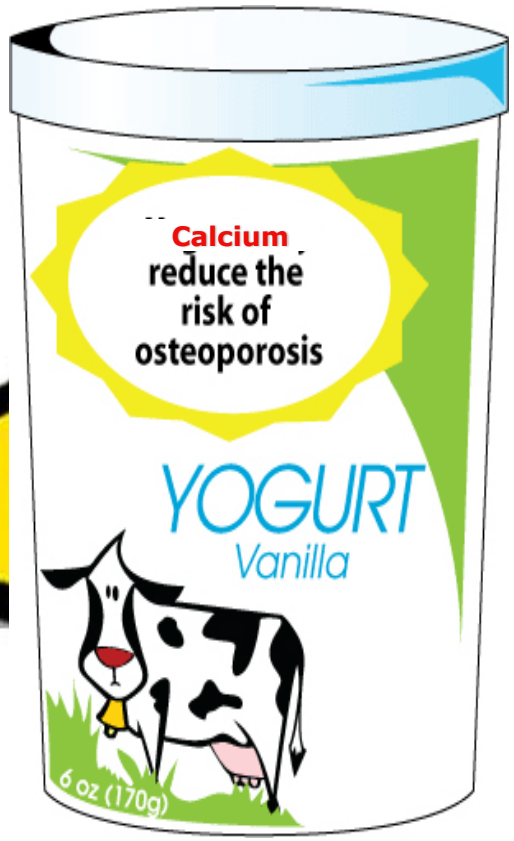
NUTRITION AND HEALTH CLAIMS

- An increasing number of foods sold in the EU bear nutrition and health claims.
- A **nutrition claim** states or suggests that a food has beneficial nutritional properties, such as “low fat”, “no added sugar” and “high in fibre”.
- A **health claim** is any statement on labels, advertising or other marketing products that health benefits can result from consuming a given food, for instance that a food can help reinforce the body’s natural defences or enhance learning ability.

Health claims

Art. 13.5. Newly developed scientific evidence

Art. 14. reduction of disease risk and children's development



Assessment of health claims

- EFSA is responsible for verifying the scientific substantiation of the submitted claims, some of which are currently in use, some of which are proposed by applicants – companies who want to submit claims for authorisation in the EU.
- This information serves as a basis for the European Commission and Member States, which will then decide whether to authorise the claims.

Black tea and attention (1)

- The food proposed by the applicant as the subject of the health claim is **black tea**. The Panel considers that black tea, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is **“improve attention**”. The proposed target population is “adults in the general population”. The Panel considers that improvement of attention is a beneficial physiological effect.
- The **three** human intervention **studies** provided by the applicant **showed an effect** of black tea on attention under the conditions of use proposed by the applicant (a cumulative amount of 1040 mg of tea solids, delivering at least 90mg of caffeine and 36 mg of L-theanine consumed within a time period of up to 90 minutes).

Black tea and attention (2)

- The applicant proposed that the claimed effect depends on the concerted action of two substances, caffeine and L-theanine, both of which are present in black tea.
- The Panel notes that a claim related to caffeine and increased attention has already been evaluated with a positive outcome.
- Five human intervention studies addressed the effects of caffeine plus L-theanine vs caffeine alone on attention. The Panel considers that these studies do not show an effect of caffeine and L-theanine on attention separate to that of caffeine alone, and that the mechanism of action for L-theanine on attention proposed by the applicant is speculative. The Panel also considers that it is well established that caffeine increases attention in healthy adult individuals of both sexes at doses of at least 75 mg, and that cumulative doses of caffeine consumed over a period of 90 min are likely to exert similar effects on attention as the same dose of caffeine consumed on a single occasion.

Black tea and attention (3)

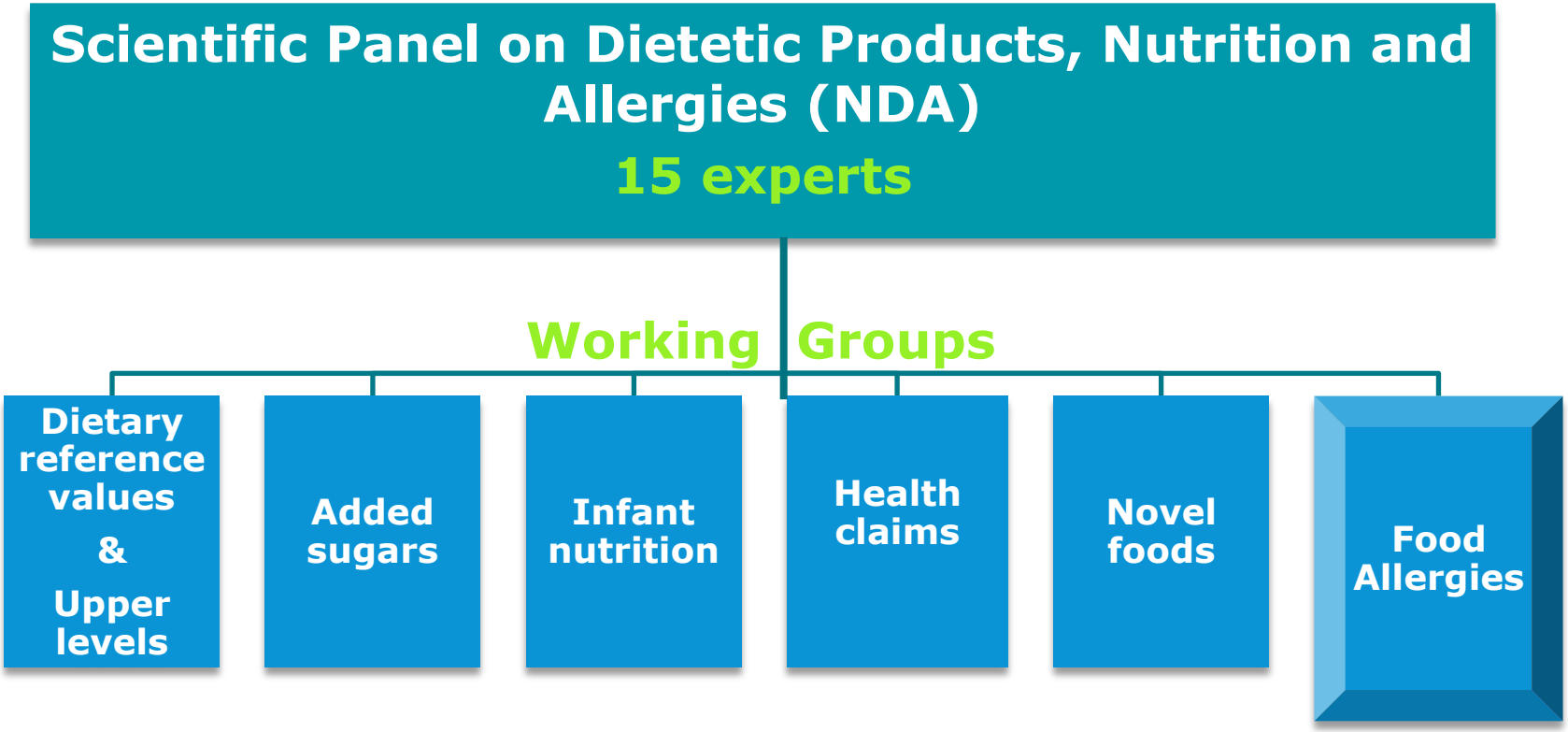
- The Panel, therefore considers that **the effect** of black tea on attention observed in the three human intervention studies provided by the applicant **can be explained by its caffeine content.**
- On the basis of the data provided the Panel concludes that a cause and effect relationship has been established between the consumption of black tea and improvement of attention.
- The Panel considers that the effect of black tea on attention can be explained by its caffeine content.
- The following wording reflects the scientific evidence: “Owing to its caffeine content, black tea improves attention”.
- In order to obtain the claimed effect, 2-3 servings of black tea providing at least 75 mg of caffeine in total should be consumed within 90 minutes. The target population is adults in the general population.

European Commission

EU Register on nutrition and health claims

Claim type	Nutrient, substance, food or food category	Claim	Conditions of use of the claim / Restrictions of use / Reasons for non-authorisation	Health relationship	EFSA opinion reference	Commission regulation	Status	Entry Id
Art.13(1)	Phosphorus	Phosphorus contributes to the maintenance of normal teeth	The claim may be used only for food which is at least a source of phosphorus as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of bone and teeth	2009;7(9):1219	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	324, 327
Art.13(1)	Plant sterols and plant stanols	Plant sterols/stanols contribute to the maintenance of normal blood cholesterol levels	In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of at least 0.8 g of plant sterols/stanols.	maintenance of normal blood cholesterol concentrations	2010;8(10):1813, 2011;9(6):2203	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	549, 550, 567, 568, 713, 1234, 1235, 1466, 1634, 1984, 2909, 3140
Art.13(1)	Potassium	Potassium contributes to normal functioning of the nervous system	The claim may be used only for food which is at least a source of potassium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	Muscular and neurological function	2010;8(2):1469	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	386

AREAS OF NDA PANEL



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FOOD ALLERGENS

- The allergenic products and substances whose presence in food must be indicated on labelling, according to EU law. These include **cereals containing gluten, milk, eggs, nuts, peanuts, soybeans, fish, crustaceans, molluscs, celery, lupin, sesame, mustard and sulphites**.
- About 75% of allergic reactions among children are caused by egg, peanut, cows' milk, fish and nuts. About 50% of allergic reactions among adults are to fruits of the latex group and of the *Rosaceae* family (which includes apples, pears, cherries, raspberries, strawberries and almonds), vegetables of the *Apiaceae* family (which includes celery, carrots and aromatic herbs) and various nuts and peanuts.

FOOD ALLERGENS

- The NDA Panel notes that the desirability of determining **thresholds for certain allergenic foods** has attracted much attention from regulatory bodies, consumer associations and industry.
- the available risk assessment approaches that could assist risk management decisions on allergen labelling. These are: the traditional risk assessment using the no observed adverse effect level (NOAEL) approach and uncertainty factors; the bench mark dose (BMD) and margin of exposure (MoE) approach; and probabilistic models.
- The Panel emphesises that the level of risk which may be acceptable, are risk management decisions, and therefore are outside EFSA's remit.
- Apllications related to **exemption from labelling**.

THANK YOU FOR YOUR ATTENTION!

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