EFSA's scientific advice on Nutrition

EFSA Nutrition Unit

Collegio Europeo
Seminar on EU Nutrition Policy
7 April 2017

efsa
European Food Safety Authority

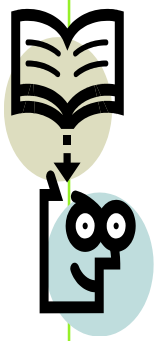
OUTLINE

- EFSA role in nutrition
- Dietary reference values (DRVs)
- Novel foods
- Health claims

MANDATE IN NUTRITION (1)

EFSA founding Regulation (EC) 178/2002

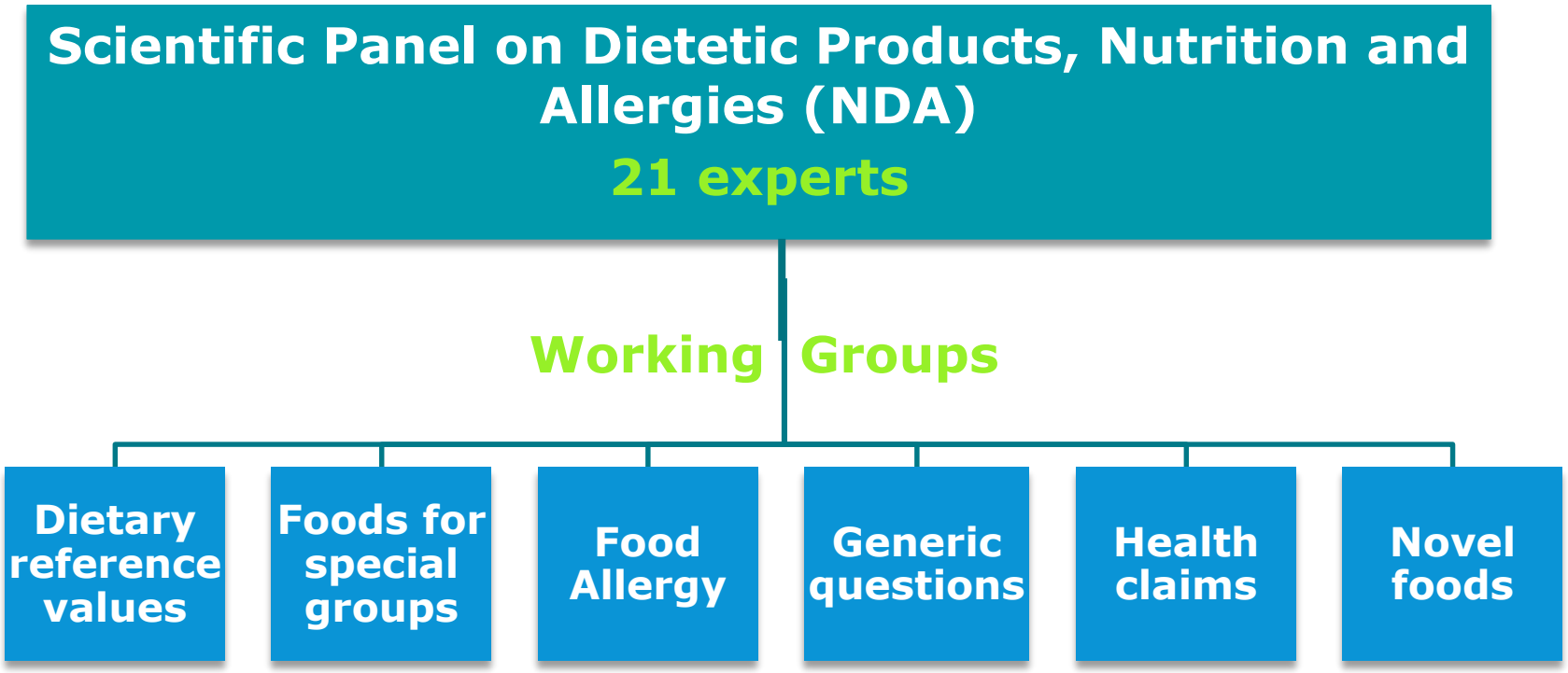
EFSA to provide



Scientific advice, *scientific or technical support on human nutrition* **in relation to EU legislation**

Assistance *concerning* **communication** *on nutritional issues* **linked to EU health programmes,** *at request of the Commission*

WHO PRODUCES EFSA'S ADVICE ON NUTRITION?



Supported by EFSA Unit on Nutrition

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

DIETARY REFERENCE VALUES (DRV)

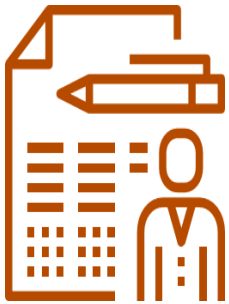
Request by Eur. Commission (2005)
to update the reference values for nutrient and energy intakes established in 1993

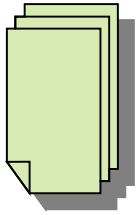
EFSA

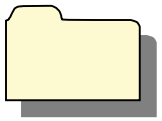
- **Preparatory work/outsourcing**
- **Working Group: Assessment /draft opinion**
- **NDA Panel: Endorsement for public consultation**
- **Working Group: Revision based on Comments received**
- **NDA Panel: Review and adoption**
- **EFSA: Publication**

- ❑ General principles for DRVs
- ❑ Comprehensive literature reviews
- ❑ Systematic literature reviews
- ❑ Meta-analysis

Re-analysis of original data when needed and possible







https://www.efsa.europa.eu/en/howwework/workingpractices

DRV - SCIENTIFIC ASSESSMENT

Science based values for daily nutrient intake derived to maintain health

for different healthy population subgroups (ages, sexes, physical activity, physiological status e.g. pregancy)

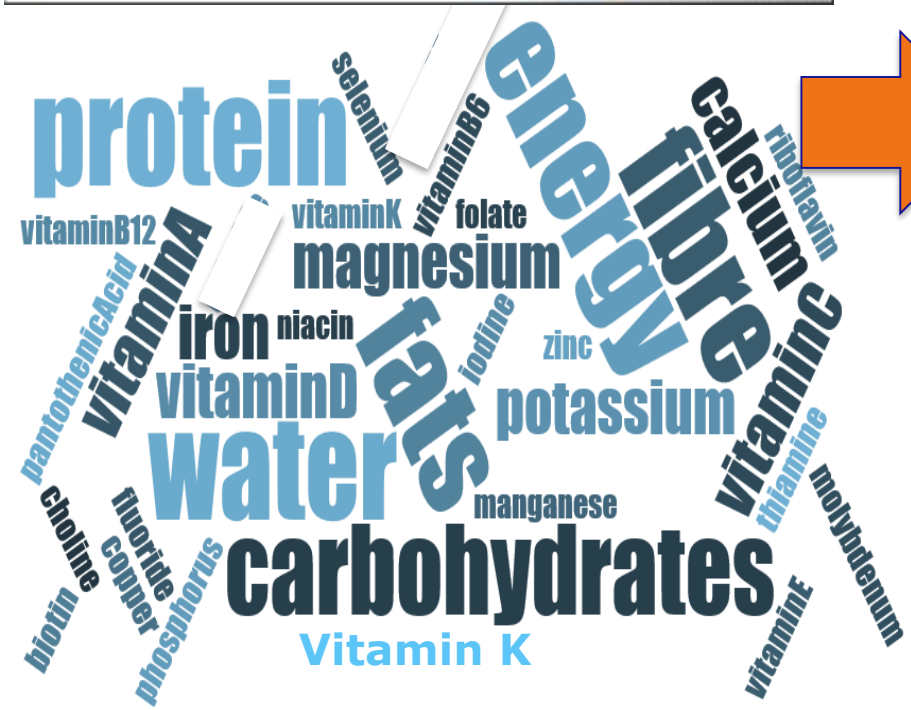
Adaptation to a specific context

Reviewing scientific evidence → **Identify suitable indicator(s) to set requirement for nutrients** → **Establish dietary reference values**

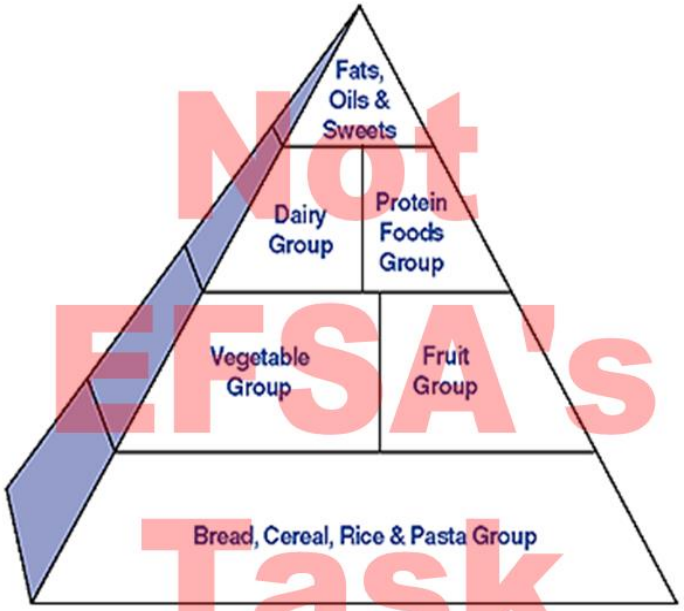
Establish nutrient goals and recommendations → **Establish food-based dietary guidelines**

DRV – 33 EFSA OPINIONS FINALISED

EFSA JOURNAL Open Access WILEY



EFSA Guidance: translation of **nutrient**-based recommendations into **food**-based recommendation



On-going:

Riboflavin (2017)

Sodium, chloride (2019)

DRV – PROMETHEUS IN SCIENTIFIC ASSESSEMENT

PROmoting METHods for Evidence Use in Scientific assessments: Sodium

PLAN

ASSESSEMENT STRATEGY

- Clarification of the scope of the assessment and definition of Conceptual framework
- Definition of the evidence needs and approach to:
  - collect or extract relevant data
  - validate or appraise evidence
  - analyse and integrate evidence

for each individual sub-question

CONDUCT

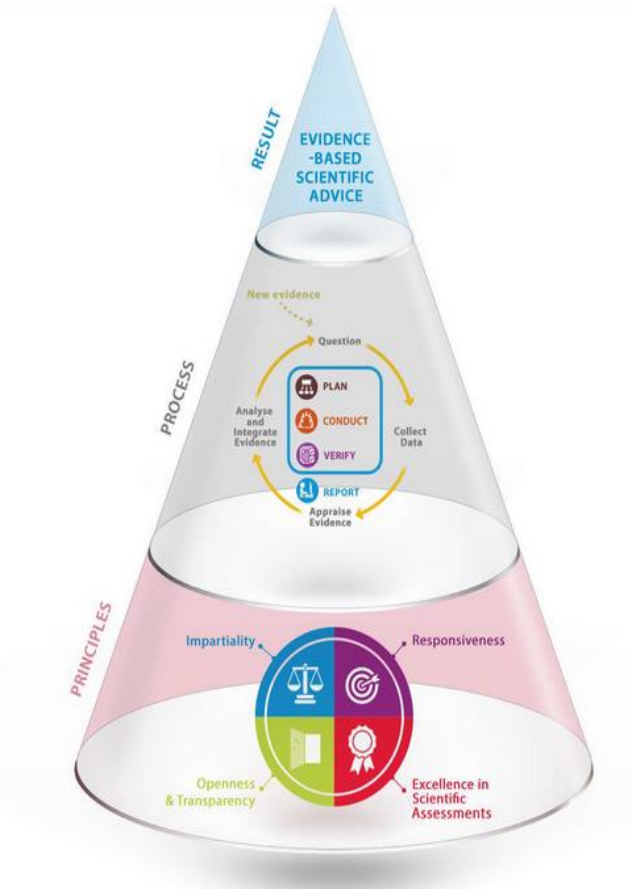
Collect or Extract relevant data

Validate or Appraise evidence

Analyse and Integrate evidence

VERIFY

DOCUMENT and REPORT



http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4121/epdf
https://www.efsa.europa.eu/interactive_pages/prometheus/prometheus

NOVEL FOOD (NF) - REGULATION (EU) 2015/2283 (1)

As of 1 January 2018

'Novel food': any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union (10 categories listed in the Regulation)

'Traditional food from a third country' is a novel food derived from primary production (plants/animals/ micro-organisms etc., processed/unprocessed) with a history of safe use in a third country.

'History of safe food use in a third country' means that the safety of the food in question has been confirmed with **compositional data** and from **experience of continued use** for at least 25 years in the customary diet of a significant number of people in at least one third country."

NF – REGULATION (EU) 2015/2283 (2)

EFSA shall consider the following:

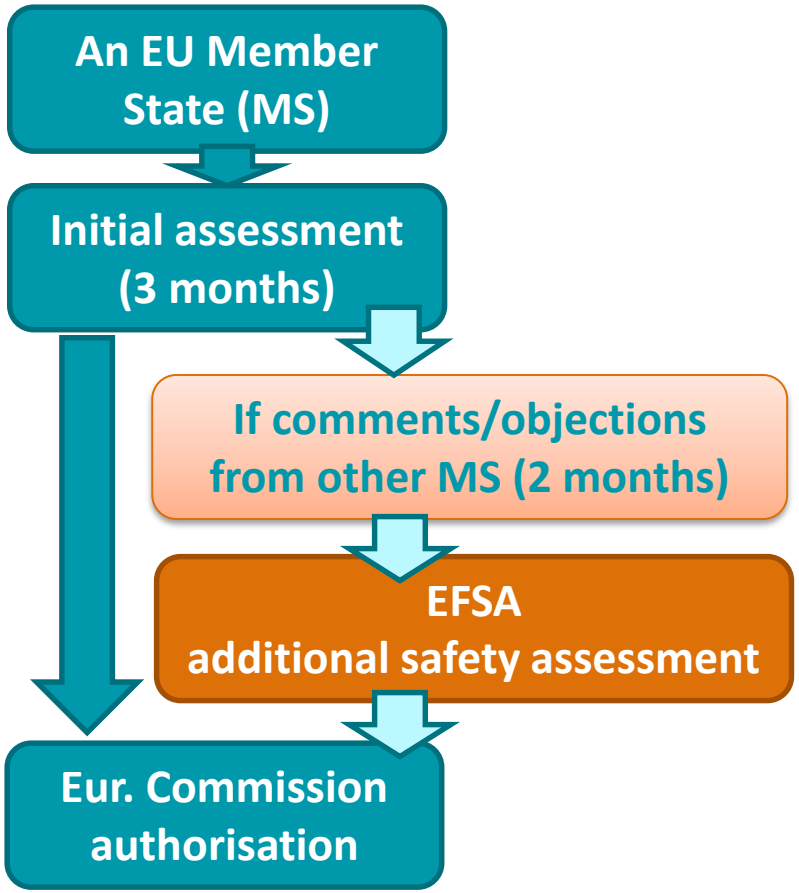
- whether the **Novel Food** is safe;
- whether the history of safe food use of a **Traditional Food** in a third country is substantiated by reliable data by the applicant;
- whether the composition of the food and the conditions of its use do **not pose a safety risk** to human health in the Union;
- whether the normal consumption of the NF/TF would be **nutritionally disadvantageous** for the consumer.

EFSA Guidance documents
on novel food and traditional from third countries
https://www.efsa.europa.eu/en/topics/topic/novel-food

NOVEL FOOD APPLICATIONS

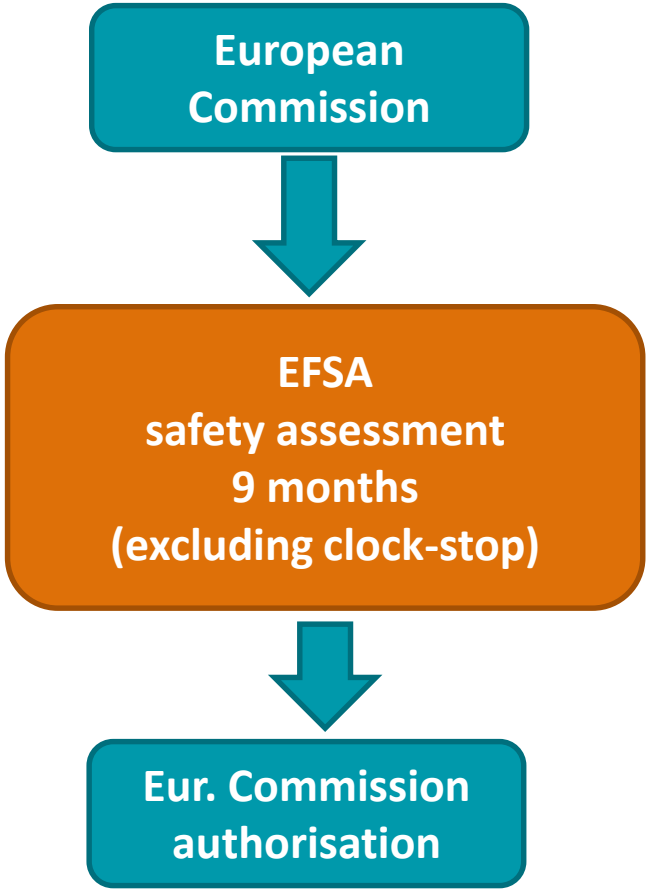
Today

Regulation (EC) No 258/1997



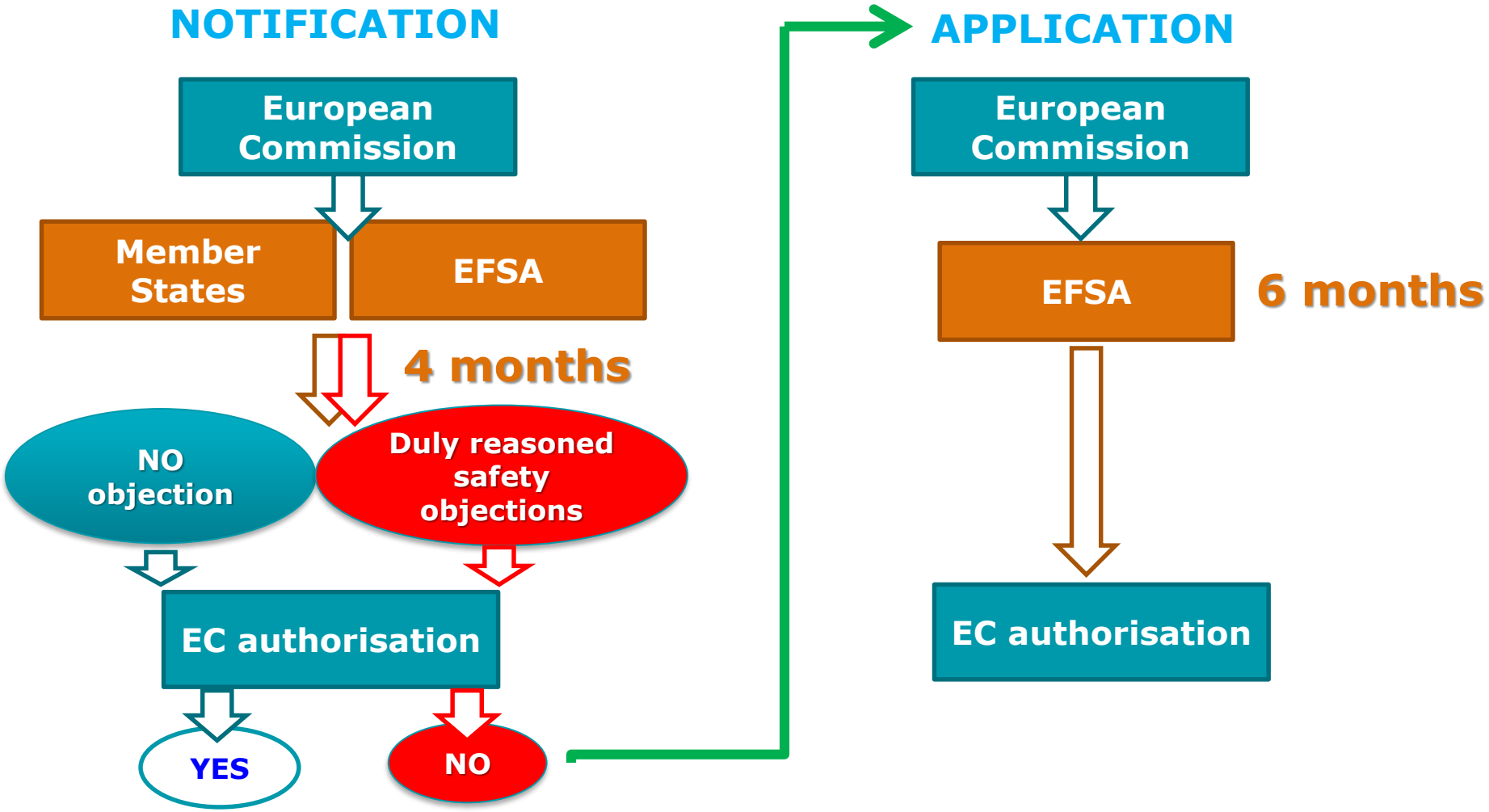
After 1 January 2018

Regulation (EU) No 2015/2283



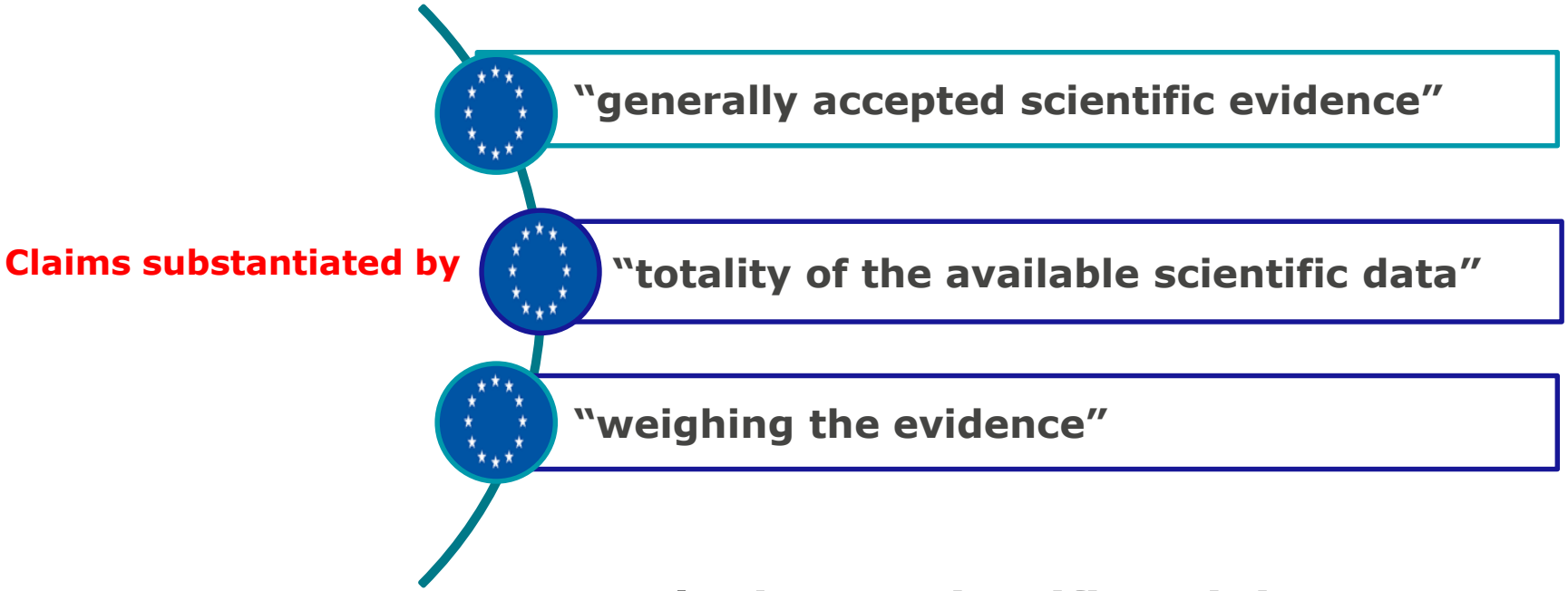
TRADITIONAL FOODS – REGULATION (EU) NO 2015/2283

Traditional foods from third countries



CLAIMS – LEGAL FRAMEWORK: REG (EC) NO 1924/2006

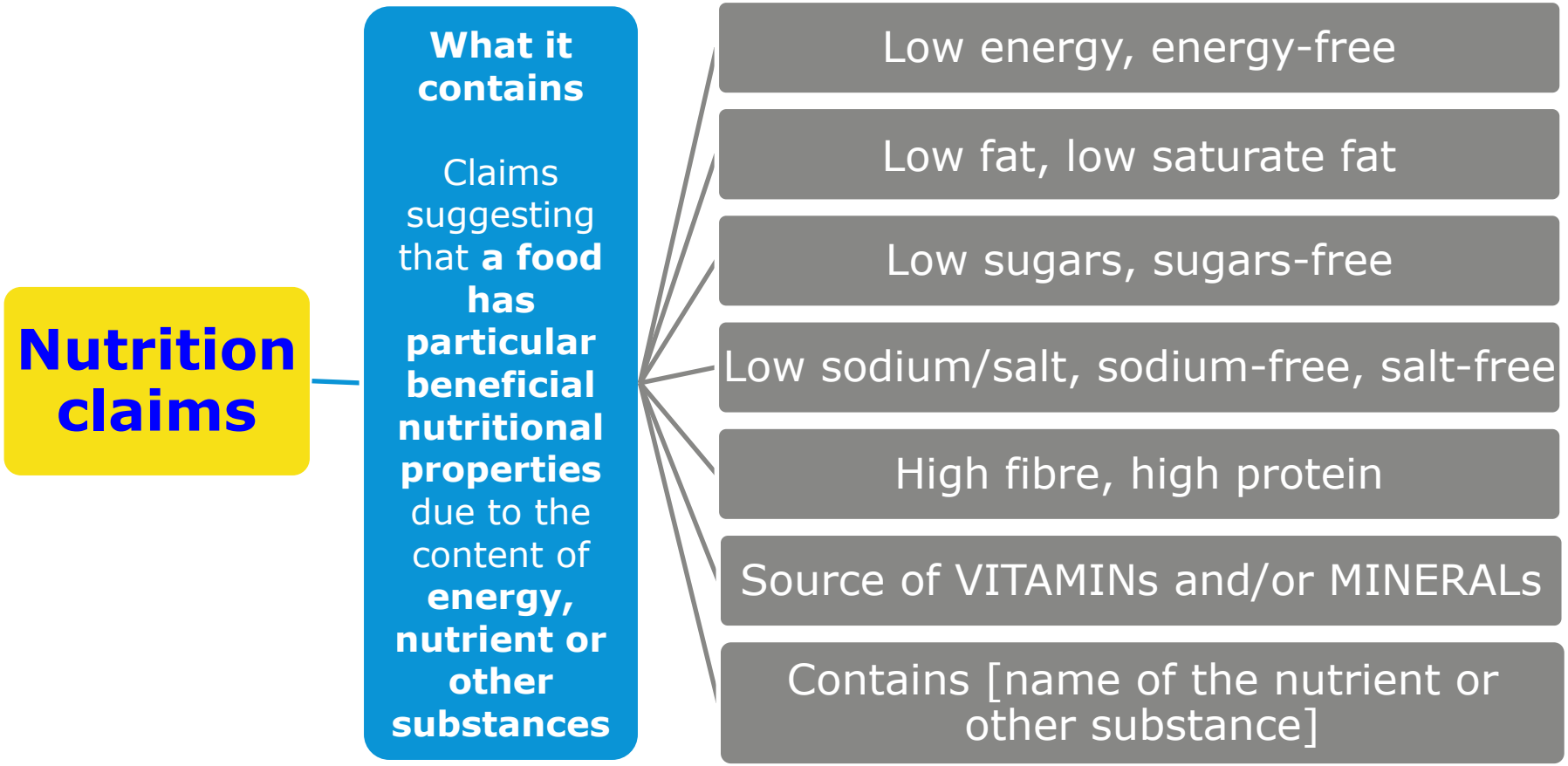
"Health claims should only be authorised for use in the Community after **a scientific assessment of the highest possible standard**"



AUTHORISATION: by Commission/Member States, European Parliament scrutiny

EU Register of Claims (http://ec.europa.eu/nuhclaims/)

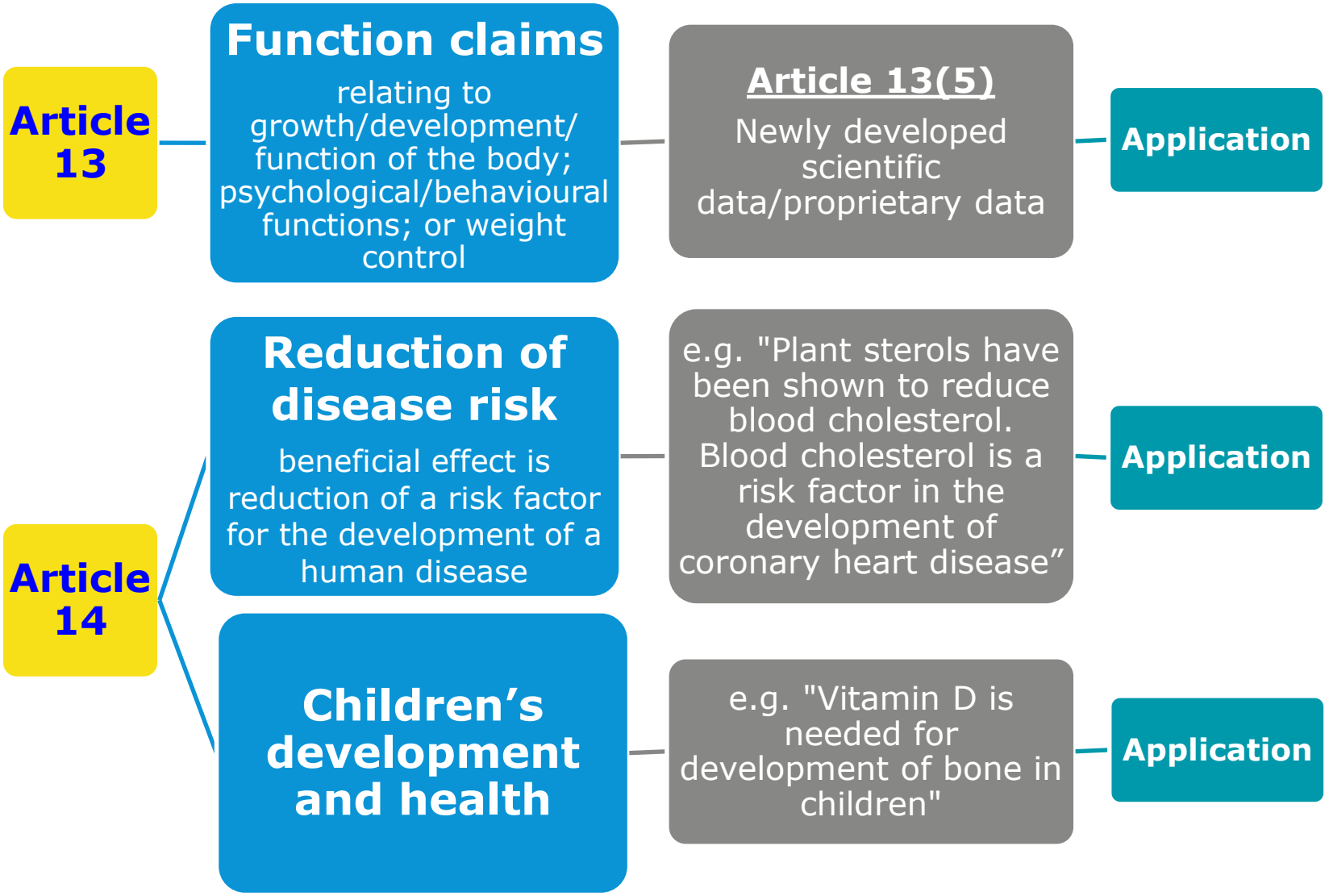
CLASSIFICATION OF CLAIMS



Use permitted as specified in Regulation (EU) No 1047/2012
no authorisation

http://ec.europa.eu/food/safety/labelling_nutrition/claims/nutrition_claims/index_en.htm

CLASSIFICATION OF HEALTH CLAIMS



HEALTH CLAIMS ON FOODS: REGULATORY REQUIREMENTS

Regulation (EU) No 1169/2011 and (EC) No 1924/2006

- Function claims **cannot** refer to a disease
- Disease risk reduction claims **cannot** refer to reduction of the risk of a disease, but to reduction of a risk factor for disease
- Subjects with a disease **cannot** be the target population for claims made on food
  - Target population for claims = **general (healthy) population or subgroups thereof**

ARTICLE 13(5) - 14 HEALTH CLAIM APPLICATIONS

An EU Member State

↓

EFSA evaluation
5 months
(excluding stop-the-clock time)

↓

Commission authorisation decision

- Authorised claim
- Final wording (consumer understanding)
- Conditions/restrictions of use

EFSA Guidance

- ❑ General scientific guidance for stakeholders on health claim applications
- ❑ Preparation and presentation of applications

Specific guidance

https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance

EFSA SCIENTIFIC ASSESSMENT: 3 MAIN QUESTIONS

A food/constituent ⟺ **A claimed effect**

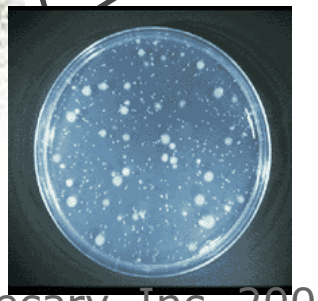
1. Is the food/constituent **characterised?**
2. Is the claimed effect based on **the essentiality of a nutrient**? OR

   Is the claimed effect **defined** and is it a **beneficial physiological effect,** and can **be measured *in vivo* in humans?**
3. Is a **cause and effect relationship** established between the consumption of the food/constituent and the claimed effect?
   - ✓for the **target group** and under the **proposed conditions of use (CoU)**

WHAT IS THE CLAIMED EFFECT?

Increasing Beneficial intestinal flora??

Changes in microbiota should be linked to a beneficial physiological effect or clinical outcome

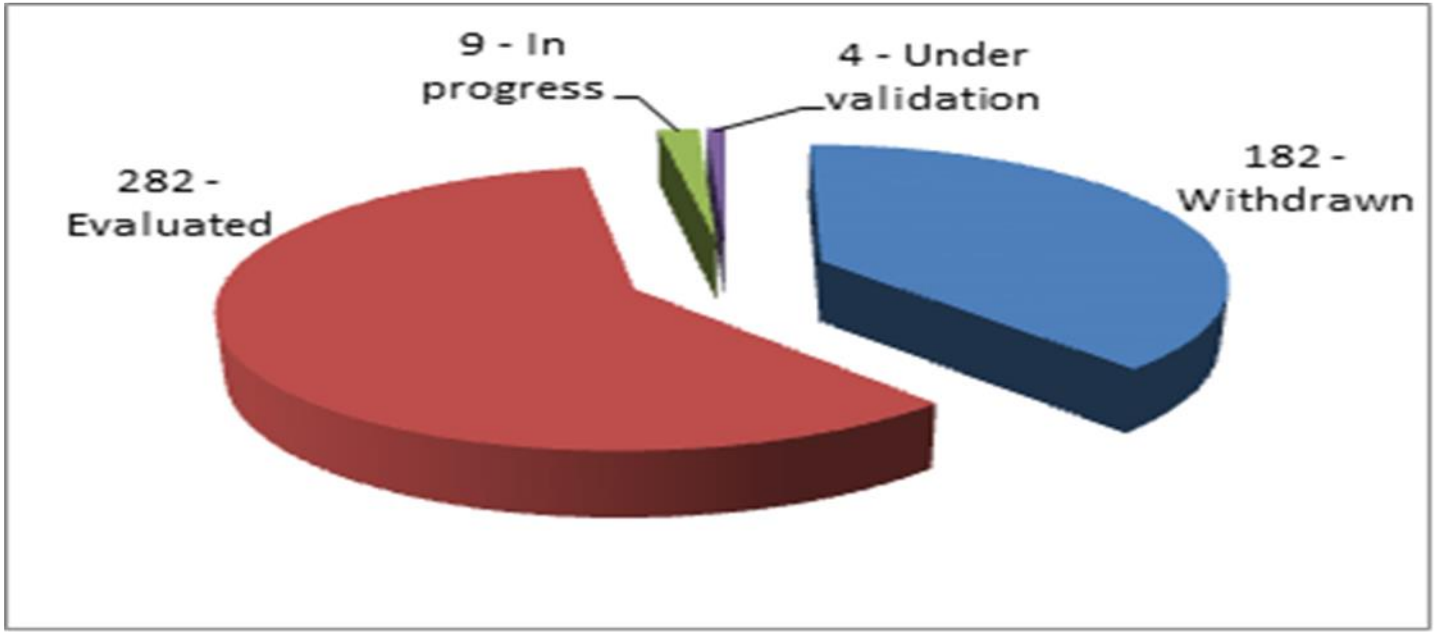


I need to maintain my normal defecation !!!!!

Adapted from NaturalMed Apothecary, Inc. 2006

HEALTH CLAIMS (STATUS MARCH 2017)

- Applications on Article 13.5 and Article 14 health claims: 477 received



- Art 13.1 list: 2849 function claims finalised except botanicals (1548 on hold)

AUTHORISED CLAIMS AND THEIR CONDITIONS OF USE

Select criteria

Claim status: Authorised

Type of claim: Art.13(5)

EFSA Opinion reference: All

Legislation: All

Search: sugar beet fibre

Match entire phrase

Reset filter

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FOOD

European Commission

European Commission > Food Safety > Food > Labelling and nutrition > Health and nutrition claims

HEALTH | FOOD | ANIMALS | PLANTS | AMR

EU Register on nutrition and health claims

The search tool only allows searches for health claims*, and not nutrition claims.

* **Health claims for which protection of proprietary data is granted** (and for which the right of use of the claim is restricted to the benefit of the applicar are **only** listed here.

You can also download the complete dataset of nutrition and health claims in the following formats: (1.14 Mb) (2.22 Mb)

EU Register | Search

Showing 1 to 1 of 1 entries (filtered from 2,310 total entries)

10 records per page

1

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 / Journal reference	Commission Regulation	Status	Entr ID
Art.13(5)	Sugar beet fibre	Sugar beet fibre contributes to an increase in faecal bulk	The claim may be used only for food which is high in that fibre as referred to in the claim HIGH FIBRE as listed in the Annex to Regulation (EC) No 1924/2006		Q-2011-00972	Commission Regulation (EU) No 40/2014 of 17/01/2014	Authorised	N/A

HIGHLIGHTS

- **NOT for EFSA**
  - Classification of Food / Novel Food
  - Labelling requirements and controls
  - Make recommendations to consumers
  - Authorise Novel Foods /Health Claims

- **For EFSA**
  - Novel Foods: safety assessment
  - Health Claims: efficacy assessment

Thank you