Regulated Products in the area of Nutrition

Health Claims & Novel Foods

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efsa
European Food Safety Authority

WHY A REGULATION ON CLAIMS?

NUTRITION- HEALTH

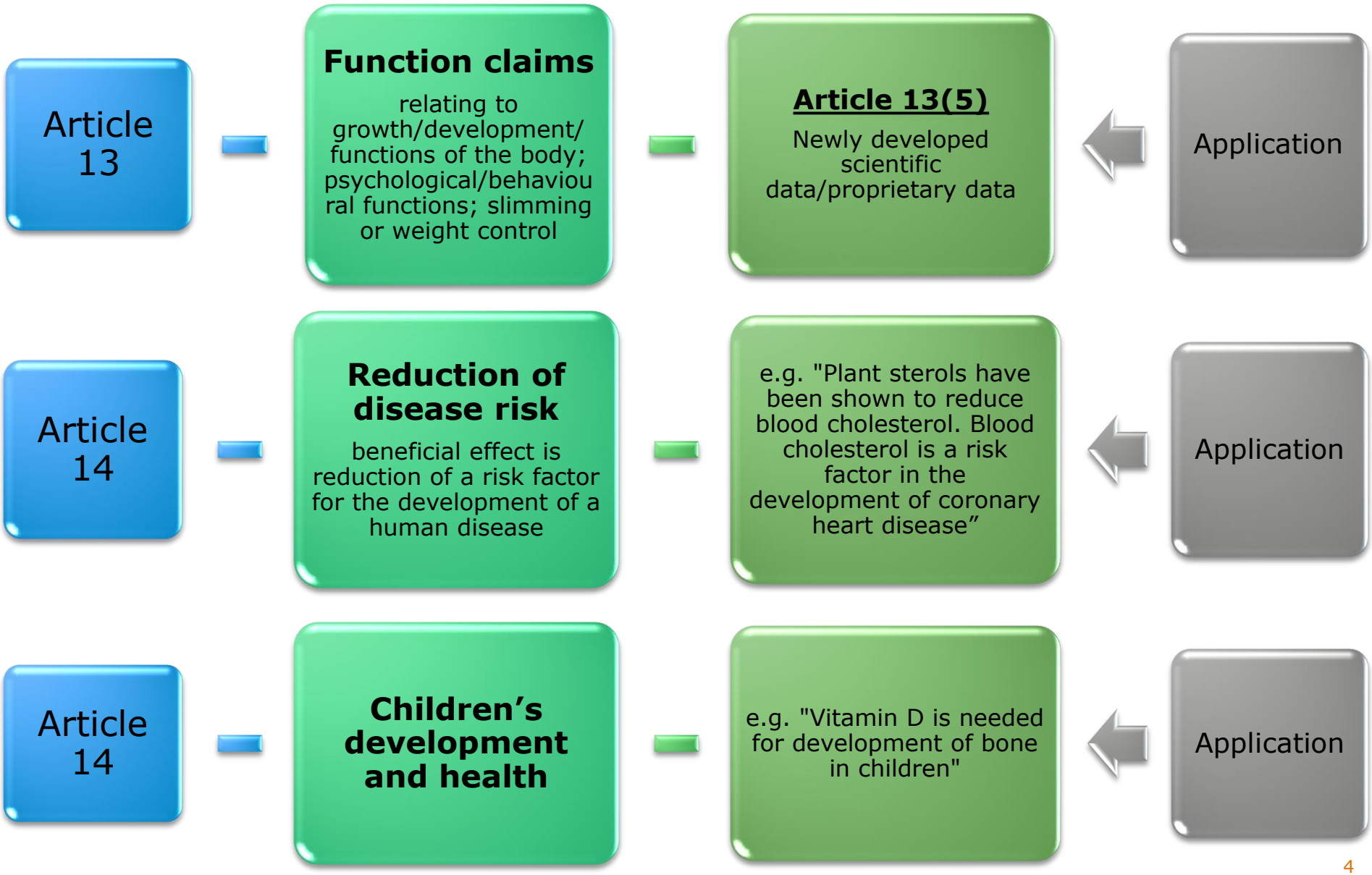
CLASSIFICATION OF NUTRITION CLAIMS

What the food contains

… suggesting that a food has particular beneficial nutritional properties due to the content of energy, nutrient or other substances

- Low energy, energy-free
- Low fat, low saturate fat
- Low sugars, sugars-free
- Low sodium/salt, sodium-free, salt-free
- High fibre, high protein
- Source of Vitamins and/or Minerals
- Contains [name of the nutrient or other substance]

CLASSIFICATION OF HEALTH CLAIMS



HEALTH CLAIMS GUIDANCE BY EFSA

Administrative guidance(-)

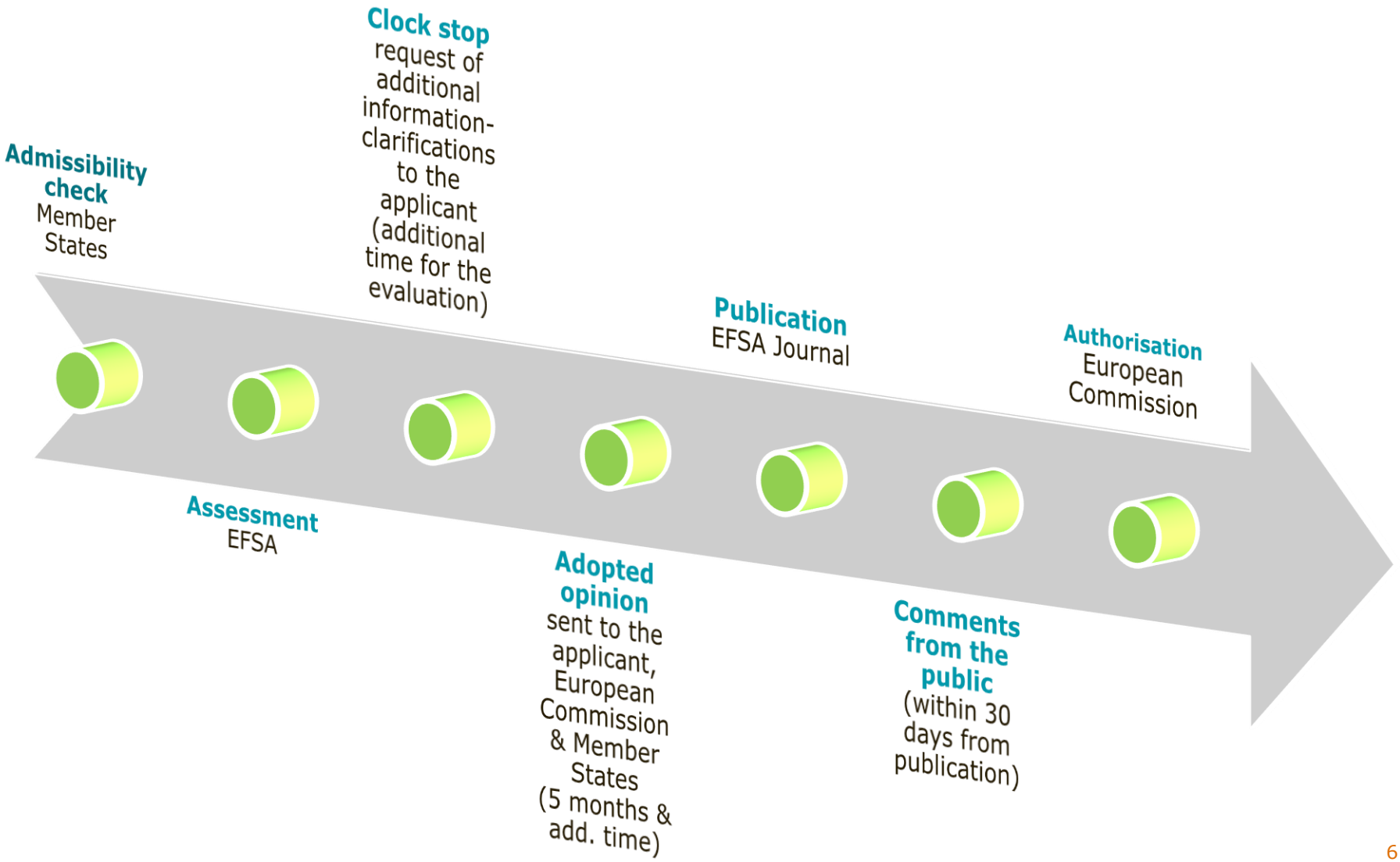
- EFSA scientific and technical guidance
  - Appendix A: Application form (mandatory)
  - Appendix B: Summary of the application (mandatory)
  - Appendix: Parts 1-6
- EC Guidance on the Regulation 1924/2006 on nutrition and health claims made on food approved by the Standing Committee on Food Chain and Animal Health

Scientific guidance(-)

- General scientific guidance for stakeholders on health claim applications
- Guidance on the scientific requirements for health claims related to functions of the nervous system, including psychological functions
- Guidance on the scientific requirements for health claims related to physical performance
- Guidance on the scientific requirements for health claims related to bone, joints, skin and oral health
- Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations
- Guidance for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms
- Guidance on health claims related to antioxidants, oxidative damage and cardiovascular health

FROM APPLICATION TO AUTHORISATION

REGULATION (EU) 1924/2006

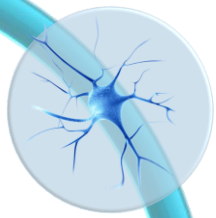


HEALTH CLAIMS

- **Any food business operator can use** authorised health claims if the conditions of use and any applicable restrictions are respected.
- **Non-authorised** health claims should **not be used**.
- **National authorities control** the use of claims.
- Health claims should only be made **for the nutrient, substance**, food or food category for which they have been authorised, and not for the food product that contains them.
- Some **flexibility of wording** of the claim is possible provided its aim is to help consumer understanding taking into account factors such as linguistic and cultural variations and the target population. Adapted wording must have the same meaning for the consumer as the authorised claim in the EU Register.

EXAMPLES OF AUTHORISED HEALTH CLAIMS

Calcium



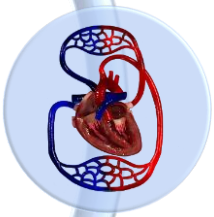
contributes to normal neurotransmission

contributes to normal muscle function

maintenance of normal bones and teeth

Folate

contributes to maternal tissue growth during pregnancy



contributes to normal blood formation

contributes to normal psychological function

NOVEL

New

Unusual

Unconventional

Innovative

16th 17th 18th 19th 20th 21st

15th May 1997

NOVEL FOODS IN EUROPEAN UNION

Regulation (EU) 1997/258 : "a food that was *not consumed to a significant degree by humans in the EU prior to 15/05/997"*

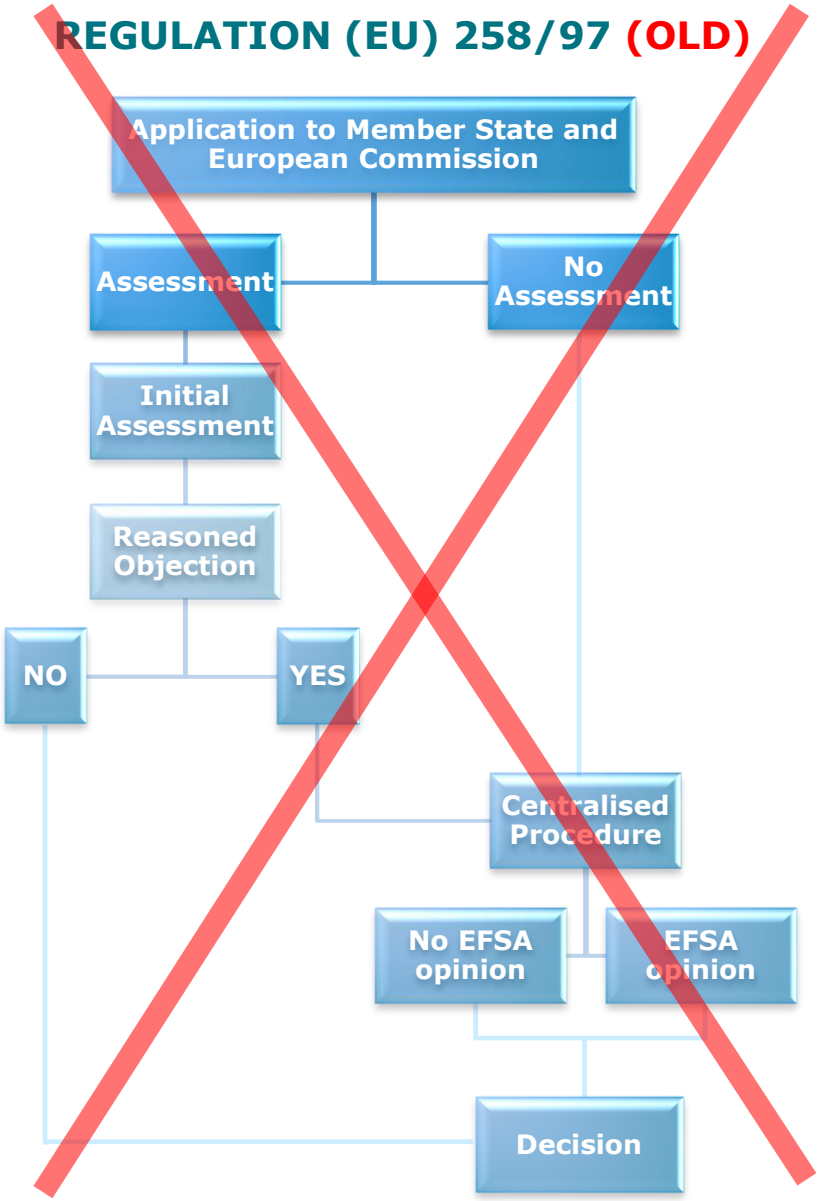
Regulation (EU) 2015/2283 : definition unchanged

TRADITIONAL FOODS FROM NON-EU COUNTRIES

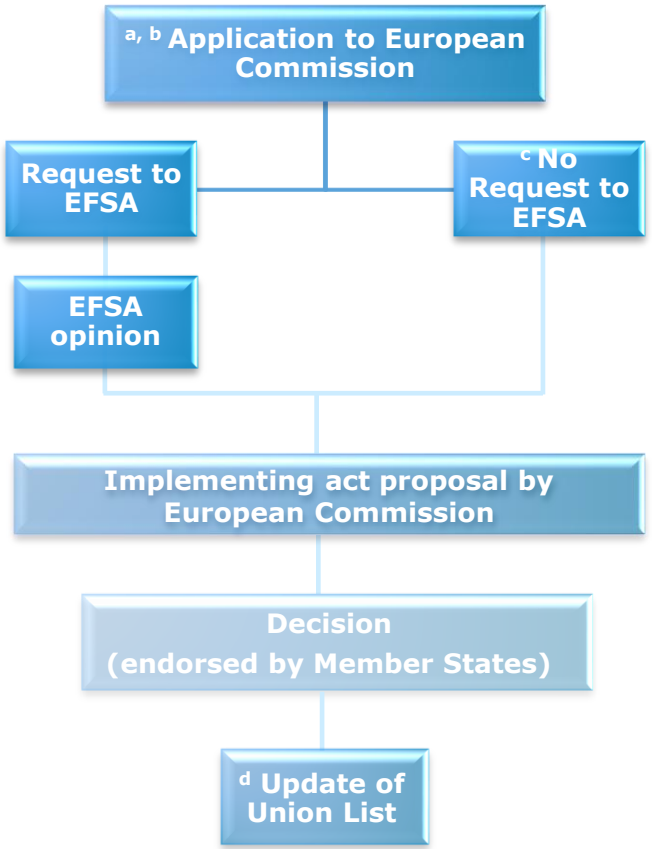
- Novel for EU (1997)
- from microorganisms, fungi or algae, plants, animals or cell/tissue cultures
- from primary production (processed or unprocessed)
- must have a "History of safe food use in a third country" confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country

AUTHORISATION PROCESS- NOVEL FOODS

REGULATION (EU) 258/97 (OLD)



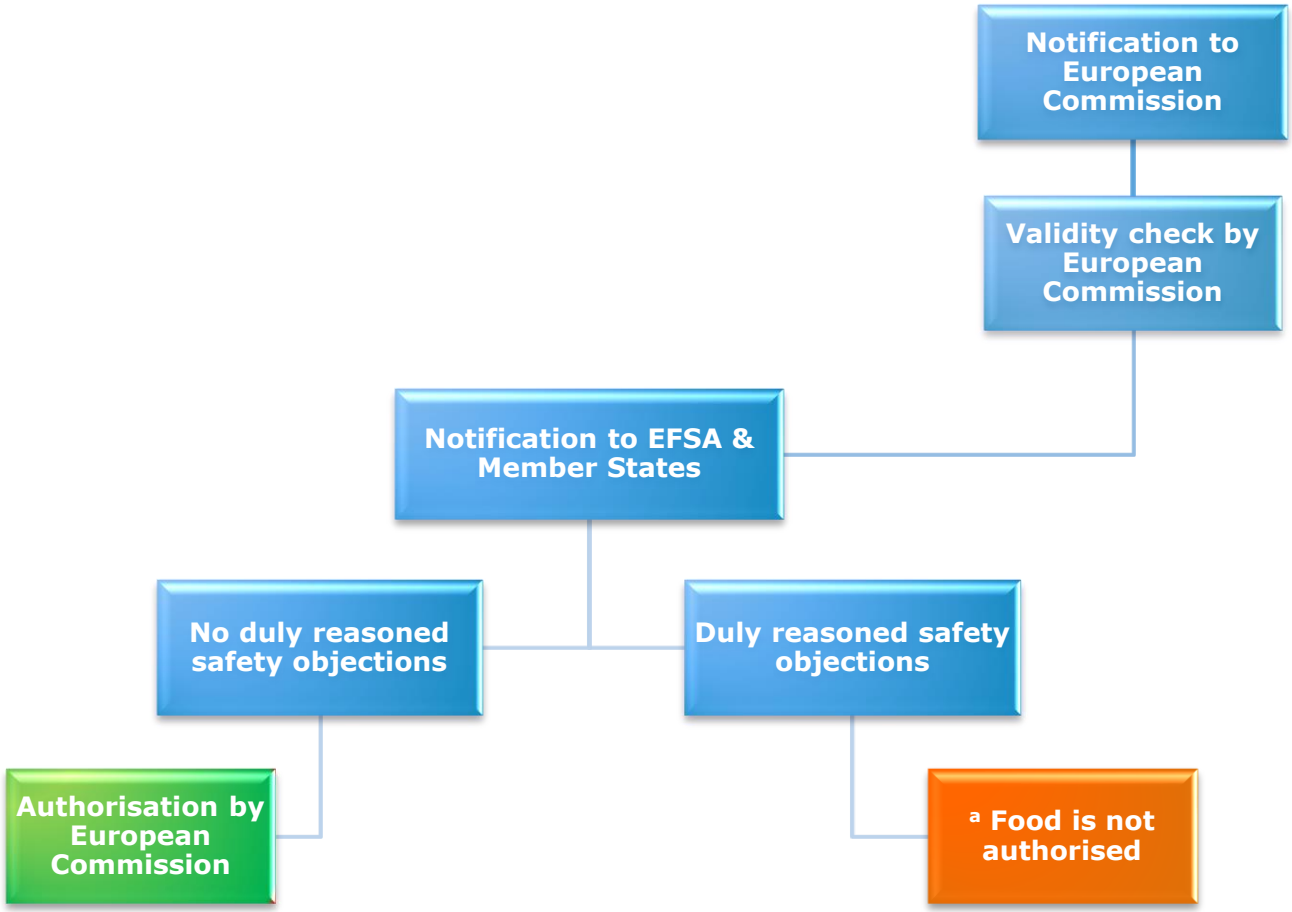
REGULATION (EU) 2015/2283 (NEW)



[a] Applicant may withdraw the application at any time.
[b] EC may terminate the update at any stage.
[c] If the update is not liable to have an effect on human health
[d] Generic authorisation, except if authorisation based on protected data

AUTHORISATION PROCESS- TRADITIONAL FOODS

REGULATION (EU) 2015/2283 (NEW)



[a] Applicant may submit an application, addressing the reasoned safety objections

NOVEL & TRADTITIONAL FOOD GUIDANCE BY EFSA

Administrative Data

Technical & scientific data

- **Introduction**
- **Identity**
- **Production process**
- **Compositional data**
- **History of use of the Novel food and its source**
- **Proposed uses and use levels**
- **Nutritional Information**
- ADME data
- Toxicological Information
- Allergenicity

Annexes to the dossier

INTRODUCTION & IDENTITY OF THE NF

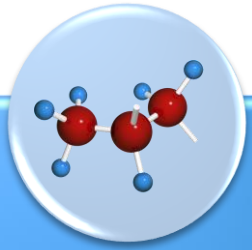
Introduction

Source, main aspects of production process, typical compositional features, purpose and intended use

Identity

Chemical substances

chemical name, CAS number, synonyms, molecular structure, molecular mass



Polymers

Structural formula of monomers, starting materials, reagents, structure of polymer, particle size, shape distribution

Microorganisms/fungi /algae

scientific (Latin) name, synonyms, species, strain identity, culture collection

From plants or their parts

scientific (Latin) name, botanical family, genus, species, subspecies, variety, part used, geographical origin

mineral origin

chemical name, CAS number, synonyms, molecular structure, molecular mass, particle characterization

From animals or their parts

scientific (Latin) name, synonyms, part used, geographical origin

cell or tissue cultures derived from animals/ plants/fungi/ algae

Engineered nanomaterials

EFSA Scientific Committee guidance

Insects and products thereof

EFSA Scientific Committee Technical report

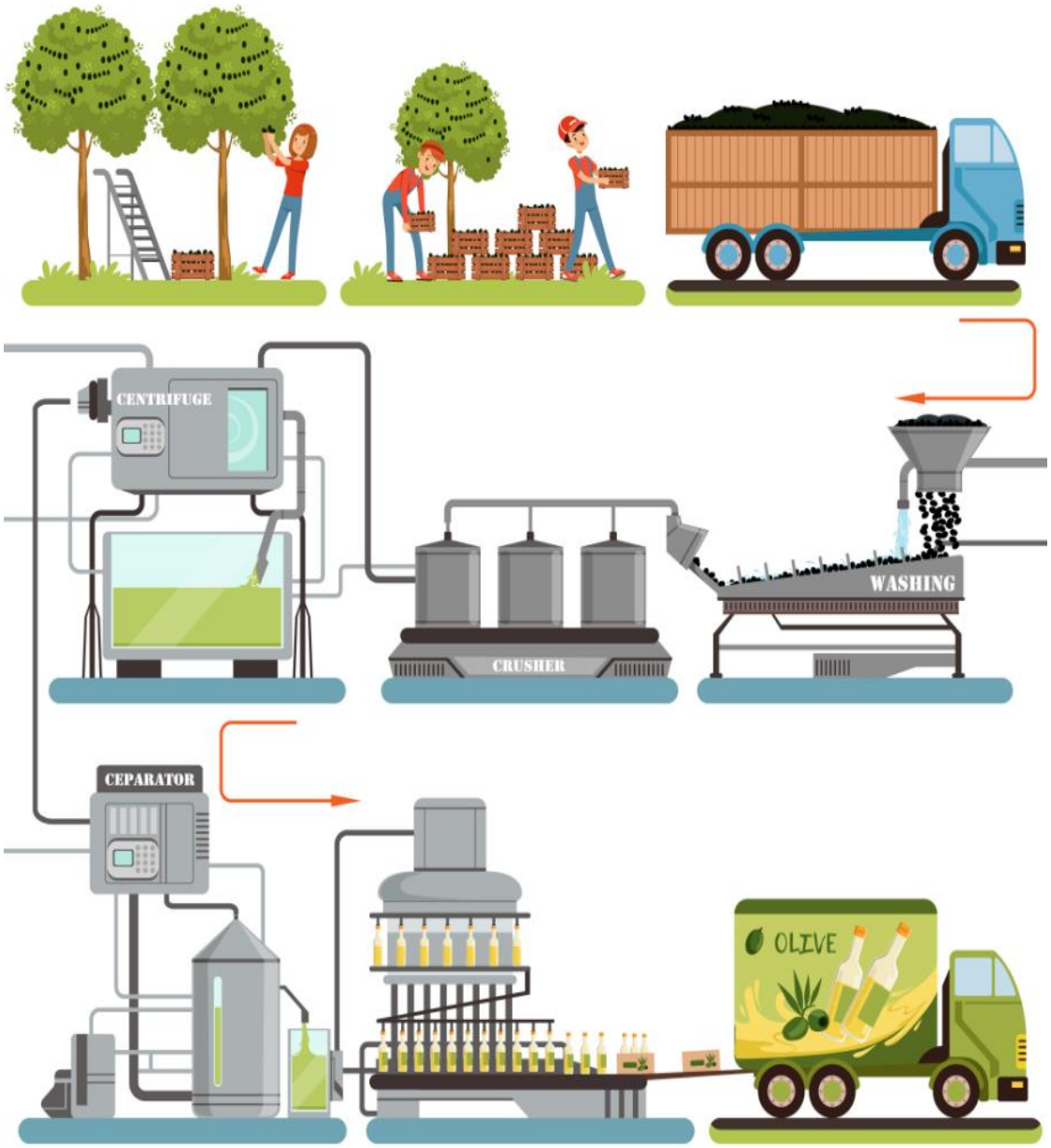
PRODUCTION PROCESS

Raw materials, starting substances, handling of sources

(e.g. plants: cultivation practice, time of harvest, animals: breeding, farming, hunting conditions, microorganisms: culture conditions)

Detailed description of the employed process

(e.g. chemical synthesis, fermentation, reagents used)



Potential by-products, impurities, contaminants

Novel aspects of the process

Flow chart

Measures implemented for production control and quality and safety assurance

(e.g. HACCP, GMP, ISO)

COMPOSITIONAL DATA

Physicochemical characterisation
Impurities, by-products, residues

Microbiological properties

Certificates of analyses
Description of methods

STANDARDS

Information on accreditation

SPECIFICATIONS

- proposed by applicant
- key parameters for characterisation and identity
- rationale for the selected parameters to be provided
- set limits regarding minimal purity
- set acceptable limits for substances of concern
- provide the methods used for analysis of all parameters

Specification parameter	Analytical method	Specification value
Appearance	USP	White or off white, crystalline solid
Solubility test	USP	soluble in water, soluble in methanol, practically insoluble in 2-propanol and dichloromethane
Identification	a) IR spectroscopy/USP <197k> b) HPLC test	a) Spectrum must comply with reference IR spectrum. b) Retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard.
Degree of coloration	EP 2.2.2., Method I	Coloration of 10 % sample solution not more intense than reference solution
Loss on drying	USP <731>	≤1.0 %
Water content	Karl Fisher method	≤0.3 %
Residue on ignition	USP <281>	≤ 0.1 %
Heavy metals	USP Method 1 <231>	≤20 ppm
Purity Assay by HPLC (on dry substance basis) anhydrous substance		≥98.5 % ≤101.5 %
Impurities Trigonelline[a)] Nicotinic Acid[b)] Nicotinamide[c)] Largest unknown impurity Sum of unknown impurities Sum of all impurities	HPLC	 < 0.05 % < 0.10 % < 0.10 % < 0.05 % < 0.20 % < 0.50 %
Residual solvents Methanol	Headspace/GC / USP<467>	≤3000 ppm
Microbiological specification Total Aerobic Microbial Count Mold and Yeasts Count *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterobacteriaceae*	Bioburden/ EP 2.6.12, 2.6.13	 ≤100 cfu/g ≤10 cfu/g Not present in 1 g Not present in 1 g Not present in 1 g

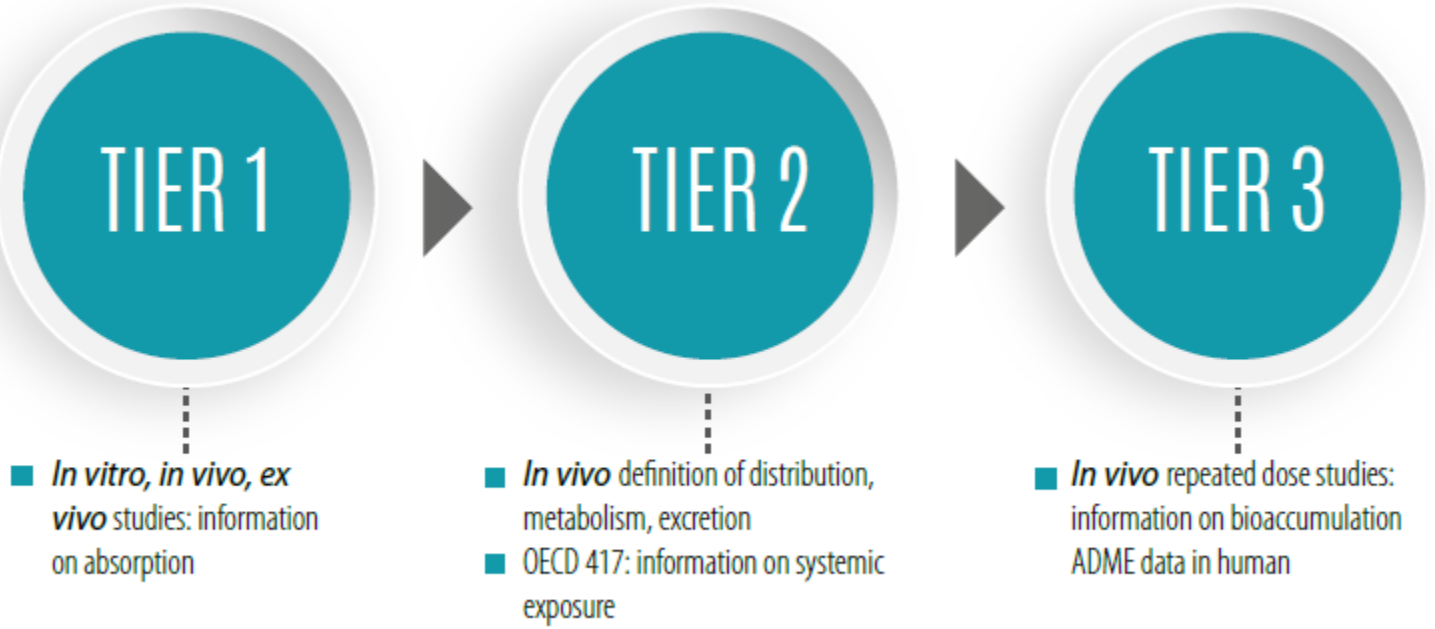
[a)] LOD=0.00015 %, LOQ=0.00044 %; [b)] LOD=0.00016 %, LOQ=0.00049 %; [c)] LOD=0.00041 %, LOQ=0.0012 %

used by legislators for the marketing authorisation serves for market control purposes

PROPOSED USES & USE LEVELS- ANTICIPATED INTAKE

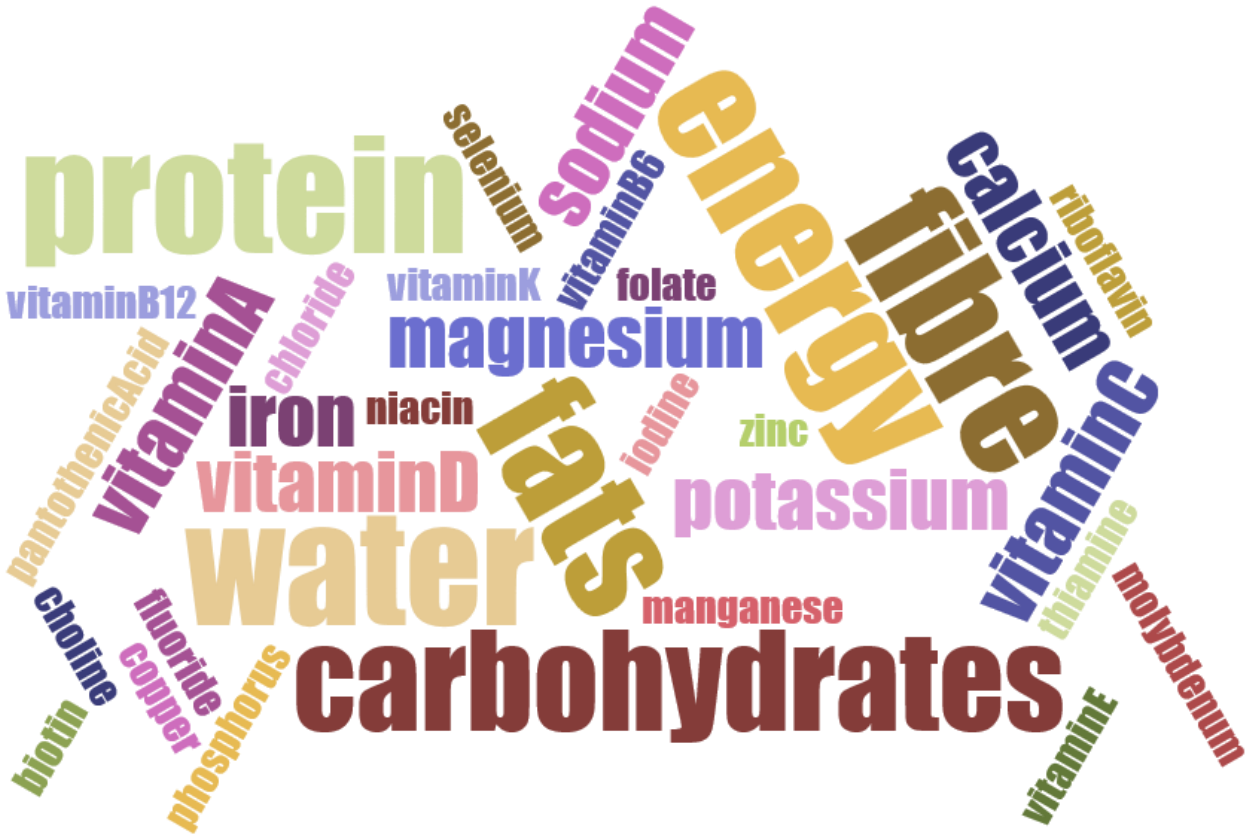
- Target population
- proposed maximum use levels for all target population groups
- Proposed uses & use levels
- food categories
- replacing another food ?
- Combined intakes from the novel food and other sources
- Estimate of exposure to undesirable substances
- Precautions and restrictions of use

ABSORPTION, DISTRIBUTION, METABOLISM & EXCRETION



- ADME data are of **major importance for deciding the appropriate toxicity testing strategy** of a novel food.
- **Absence of ADME** data would be a **barrier** to concluding on toxicological data.
- **Similarities and differences between humans and animals** have to be considered.

NUTRITIONAL INFORMATION



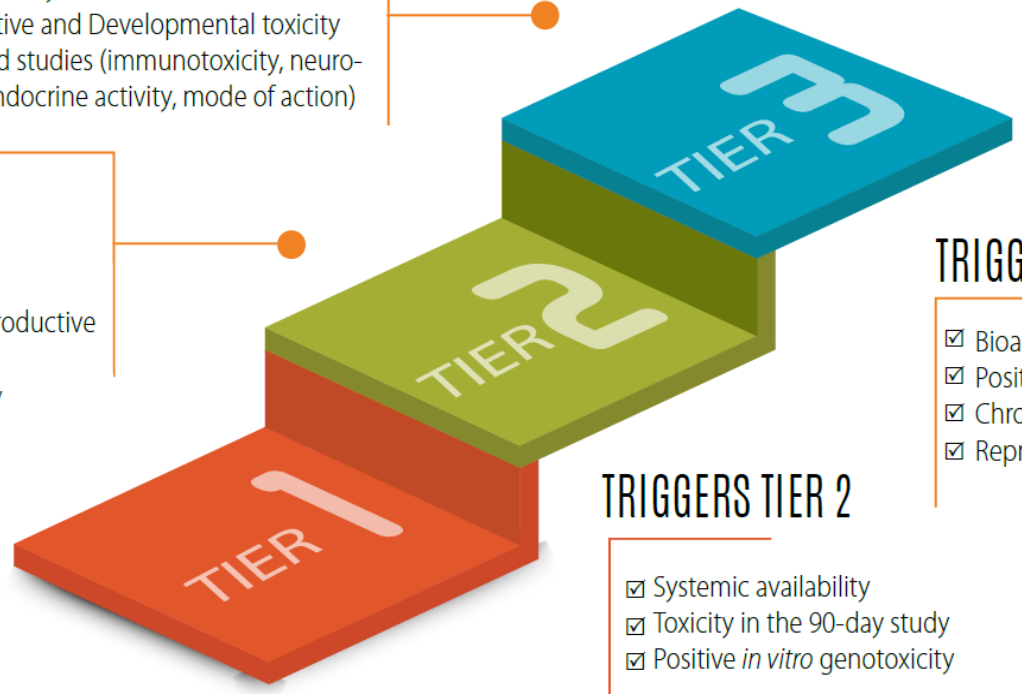
- **Should not be nutritionally disadvantageous**
  - ✓ Novel food is intended to replace another food
  - ✓ Novel production process is applied
- **Nutrients, anti-nutrients, interaction with nutrients**
- **Effects arising from production process**

TOXICOLOGICAL DATA

- ADME: repeated dose, volunteer studies
- Carcinogenicity: *Mode of Action*
- Reproductive and Developmental toxicity
- Specialised studies (immunotoxicity, neuro-toxicity, endocrine activity, mode of action)

- ADME: single dose
- Genotoxity (*in vivo*)
- Chronic toxicity
- Carcinogenicity
- Extended One-Generation Reproductive Toxicity Study (EOGRTS)
- Prenatal developmental toxicity

- Absorption
- Genotoxicity (*in vitro*)
- Extended 90-day toxity study (*in vivo*)



TRIGGERS TIER 3

- ☑ Bioaccumulation
- ☑ Positive *in vivo* genotoxicity
- ☑ Chronic carcinogenicity
- ☑ Repro and developmental toxicity

TRIGGERS TIER 2

- ☑ Systemic availability
- ☑ Toxicity in the 90-day study
- ☑ Positive *in vitro* genotoxicity

EFSA recognises the necessity to stimulate the use of safety assessment approaches that would improve the welfare of the experimental animals and reduce the number of animals used, targeting at the same time to their replacement by *in vitro* or *in silico* methods.

ALLERGENICITY

Minimum requirements: protein content, its source, production process, available experimental and human data.

No protein → very low allergenic potential

Contains proteins → has allergenic potential (default assumption

Further testing:

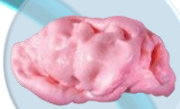
- protein analyses
- human testing

Potential or proven allergenicity is not a reason to say that a novel food is unsafe

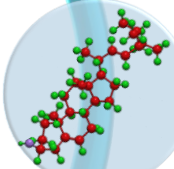
EXAMPLES OF AUTHORISED NOVEL FOODS

New Substances

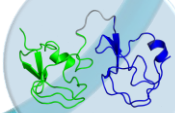
Non- sticky chewing gum base



Phytosterols



Ice-structuring protein



New Sources

Krill oil

Alfalfa

Lycopene from *B.trispora*

Traditional Foods in non EU countries

Chia seeds

Baobab fruit

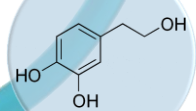
Noni Juice

New Processes

UV-treated milk

UV-treated yeast

Synthetic hydroxytyrosol



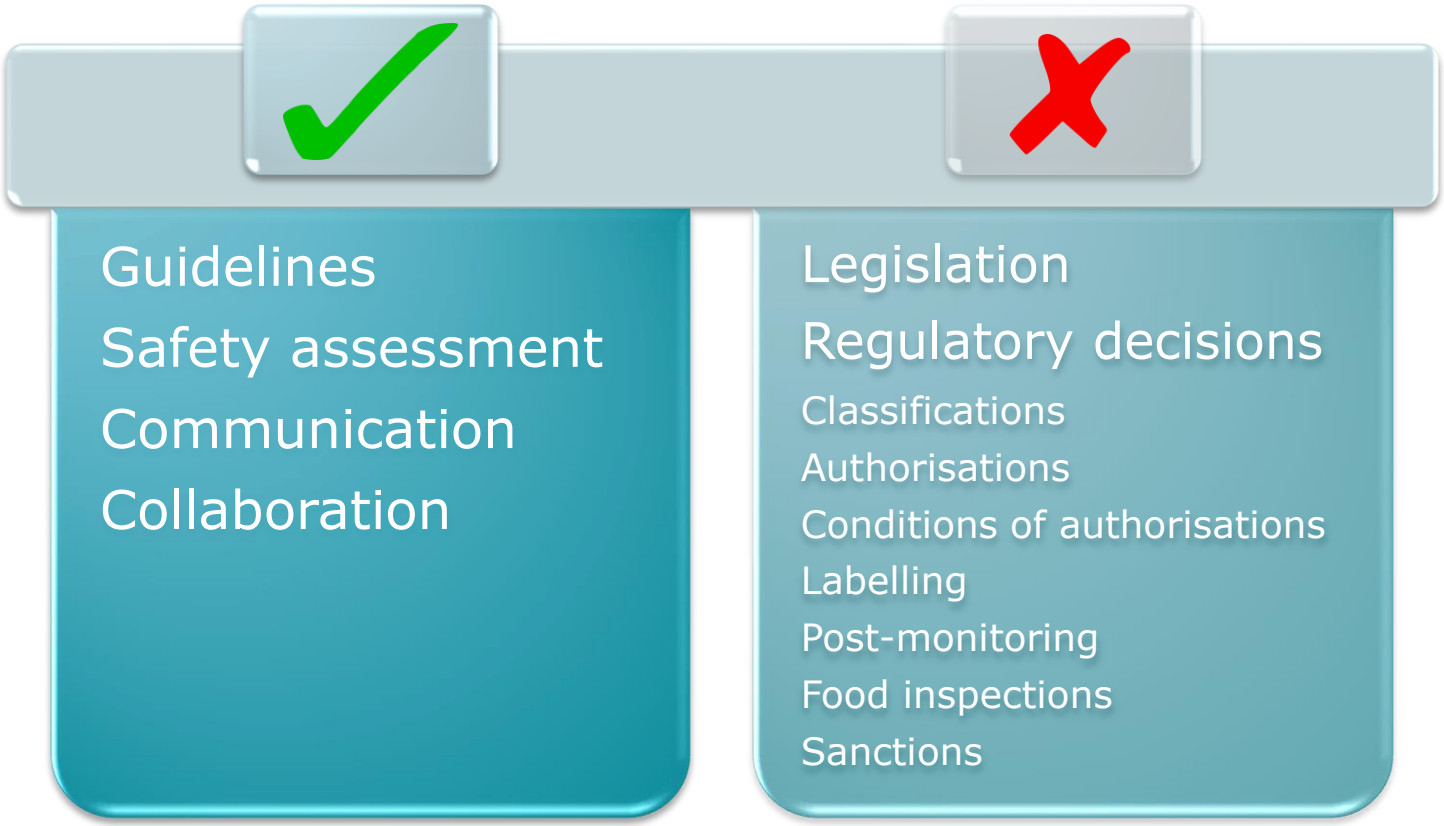
EFSA's ROLE IN HEALTH CLAIMS & NOVEL FOODS

EFSA's 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*

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THANK YOU FOR YOUR ATTENTION!

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