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Global perspective of the regulatory landscape of food supplements and herbal medicines

and EFSA activities on food supplements

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Trusted science for safe food

efsa
European Food Safety Authority

Terminology

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Regulatory landscape of dietary supplements and herbal medicines from a global perspective

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ABSTRACT

The number of Individuals that use dietary supplements and herbal medicine products are continuous to in... in many countries. The context of usage of a dietary supplement varies widely fr... countries supplement use is just limited to general health... purposes. To date, there is little ... even the ...

... the global regulatory ... This review summarizes a significant portion of ... comparison of the status for dietary supplements and herbal medicines ... national jurisdictions and to the extent of how new tools and methodologies can improve the regulatory application.

Global Summit on Regulatory Sciences, Beijing, September 2018
organized by
Global Coalition for Regulatory Science Research

Supplements or medicines?

Jurisdiction	"Supplements"	"Medicines"	Regulatory Agency
Australia		Complementary medicines	Therapeutic Goods Administration
Canada	Supplemented food*	Natural Health Products	Health Canada
China	Health foods	Traditional Chinese medicine	China Food and Drug Administration
EU	Food supplements		National competent authorities, EFSA (only if centralized procedures apply)
		Herbal medicinal products	European Medicine Agency
Japan	Health Foods		Consumer Affairs Agency
		Kampo medicine	Ministry of Health, Labor and Welfare
New Zealand	Supplemented food		Ministry for Primary Industries
	Dietary supplements	Herbal remedies	NZ Medicine and Medical Devices Safety Authority
USA	Dietary supplement	Botanical drugs	US-FDA

*a framework for supplemented foods is under development

Comparison of requirements

Australia
Canada
China
European Union
Japan
New Zealand
USA

"Supplements"	Allowed route of admin	Oral only
	Pre-market approval	No (US, NZ, JP, EU except if novel food) Yes (CA*, CN) N/A (AU)
	Nutrition and health claims	Yes
	Therapeutic claims	No (some exceptions for CN and JP)
"Medicine"	Pre-market approval	Yes
	Clinical trial data	Yes/No
	Historical usage	Yes
	Reported adverse reactions	Yes

*is developing a framework for supplemented foods

Consequences

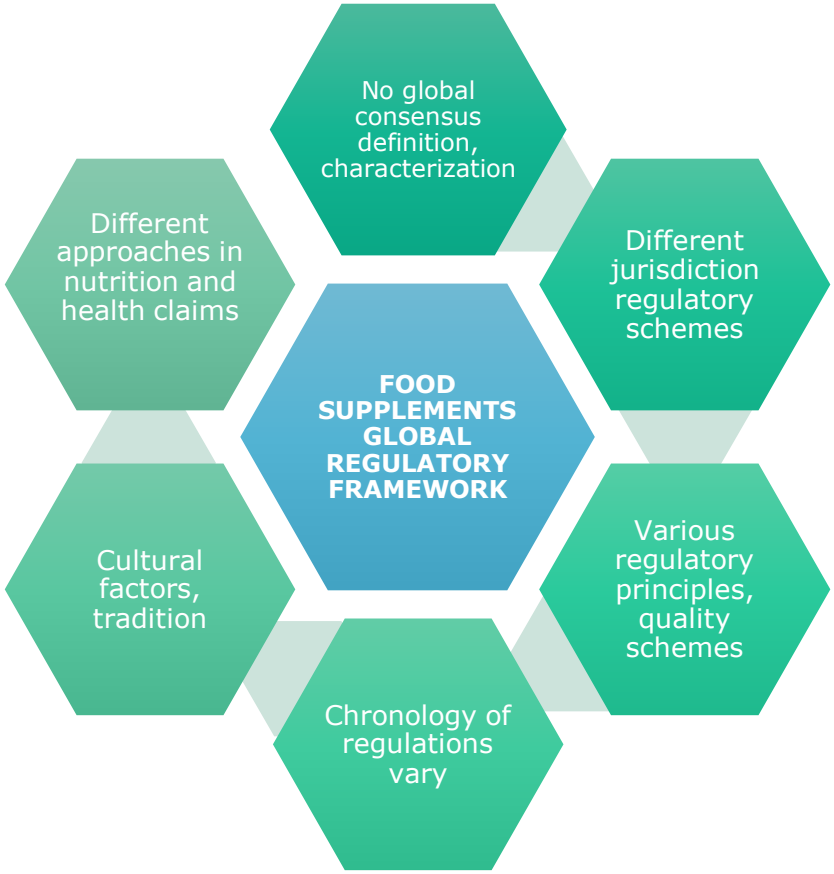
Regulatory requirements across jurisdictions and type of safety assessment vary between the categories:

- **a product** could be placed in **more than one category**
- differences in **dosage and maximum amounts** allowed
- manufacturers **must comply** with the requirements in the respective country/jurisdiction
- products **"Classified as supplements"-** significant difference across jurisdictions

  safety of consumer-main focus
- products **"Classified as medicines"-** more consistency

Green tea extract	
Supplement	*Medicine*
USA	USA
NZ	EU
CN	CA
JP	AU

Conclusions on the regulatory landscape



Role of emerging technologies

Fig. 1. Conventional and emerging safety and quality assessment methods presented at GSRS18.

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Emerging technologies may contribute to:

- harmonised approach for improved guidelines
- assess complex ingredients
- safety and quality of botanical products
- global surveillance system on origin and characteristics
- more transparent system for consumers
- collaboration between global stakeholders and experts

EFSA'S role as risk assessor

YES

- Provides independent **scientific advice** and support for EU risk managers and policy makers on food and feed safety
- Provides independent, timely risk communication
- Develops guidelines

NO

- Legislation
- Regulatory decisions
  - Classifications
  - Authorisations
  - Conditions of authorisations
  - Labelling, post-monitoring
  - Food inspections
  - Sanctions

EFSA's activities in Food Supplements

Provides independent scientific advice

Safety

Generic

Efficacy

Dietary Reference Values

Nutrient sources

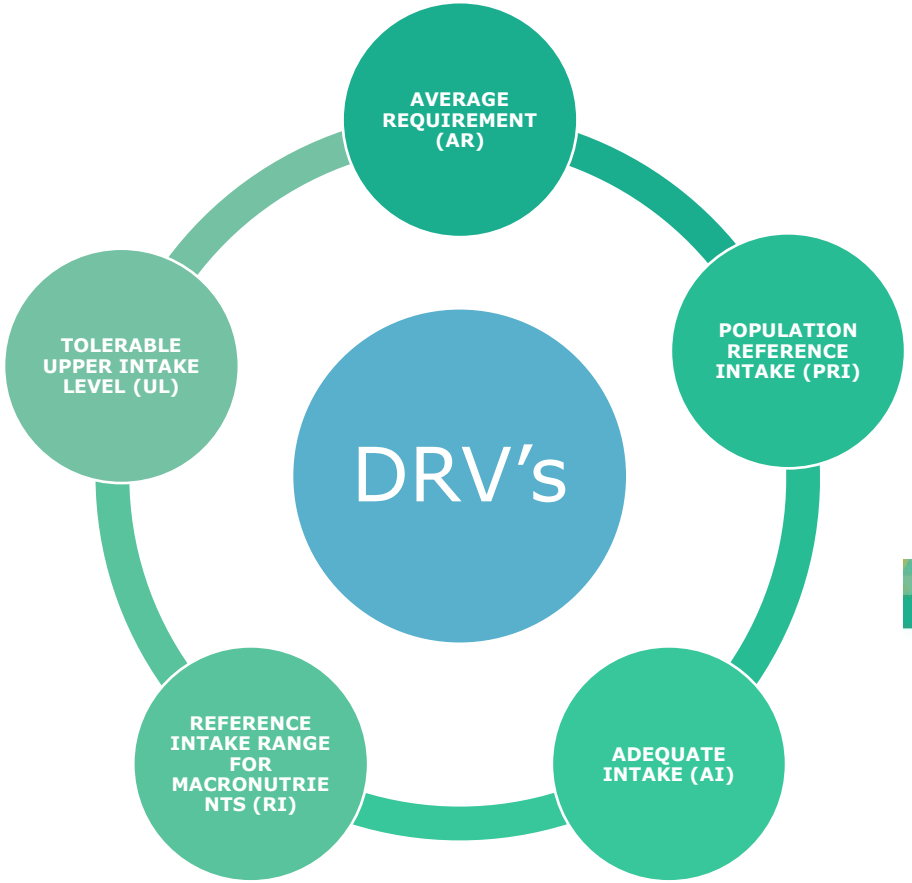
Botanicals

Novel foods

Food fortification *'Other substances'*

Health claims

Dietary Reference Values (DRVs)

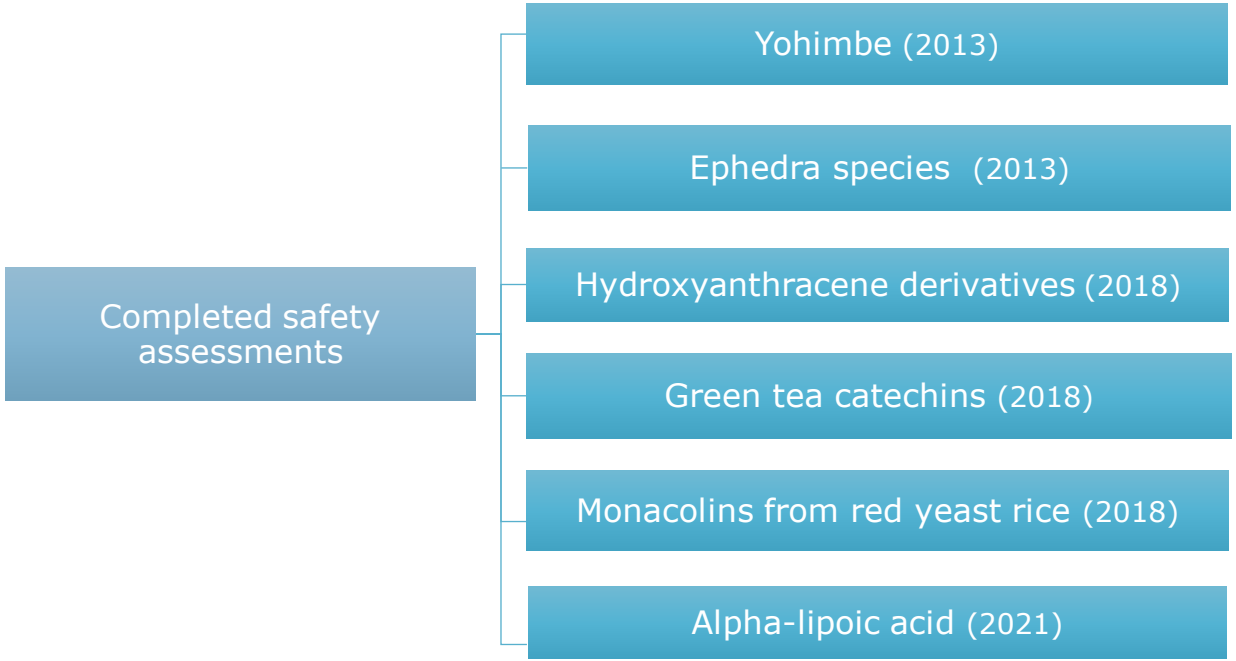


tolerable upper intake level (UL) is the maximum daily intake of a nutrient (from all sources) that can be consumed safely over a long period of time.

34 scientific opinions [published]

Safety of "Certain other substances"

- "certain other substances" = other substances than vitamins and minerals with a nutritional or physiological effect
- Article 8 of Regulation (EC) No 1925/2006 **=> safety assessment by EFSA**



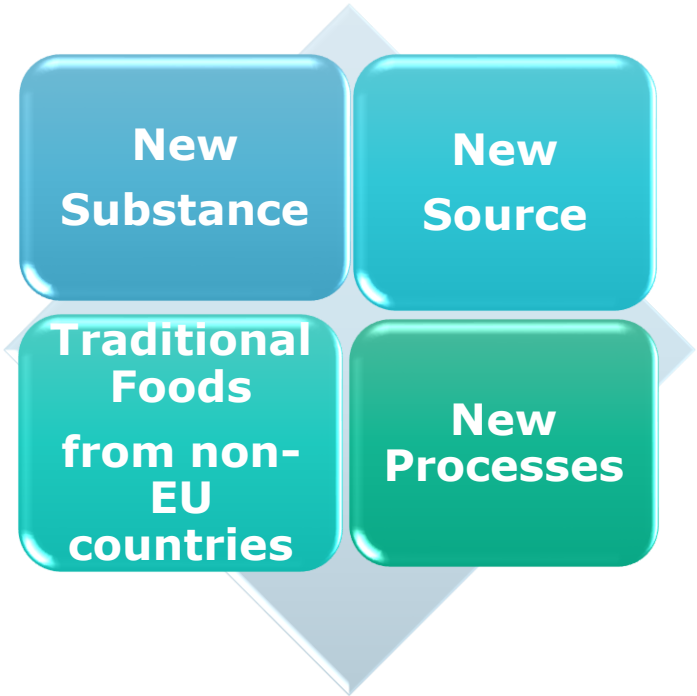
Safety & bioavailability of nutrient sources

- Safety and bioavailability of nutrient sources proposed for addition to the list of permitted substances in food supplements (Annex II of the FS directive)
- 2005 to 2009: comprehensive assessment by EFSA of substances used as sources of vitamins and minerals in food supplements, present on the EU market

Safety of novel foods

NOVEL FOODS

Regulation (EU) 2015/2283: a food that was *not consumed to a significant degree by humans in the EU prior to* ***15 May 1997***.

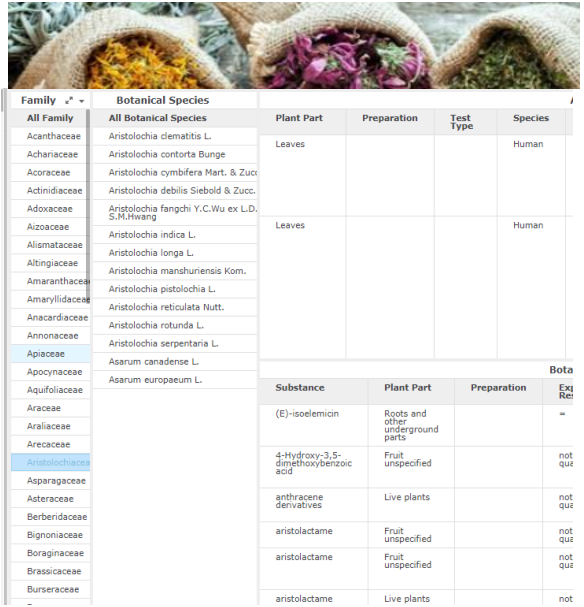


Applicable to food supplements

- Food supplements = Foods
- vitamins, minerals and other substances already used in food supplements where:
  - a new production process has been applied; or
  - they contain or consist of engineered nanomaterials;

Safety of botanicals

- Guidance for assessing botanicals (2009)
- Qualified Presumption of Safety approach for the safety assessment of botanicals (2014)
- Compendium of Botanicals - has no legal or regulatory force
  - A database of botanicals reported to contain naturally occurring substances of possible concern for human health when present in food
  - Web-based version of the Compendium
    https://www.efsa.europa.eu/en/data/compendium-botanicals



Efficacy assessment

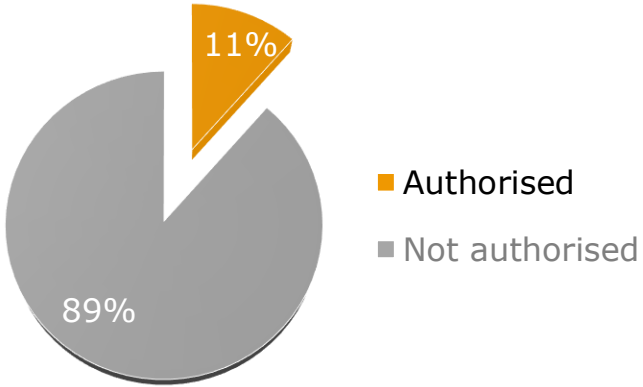
NUTRITION AND HEALTH CLAIMS

Application to a Member State → **Assessment by EFSA** → EC and Member States decide on authorisation

nutrition claim	health claim	reduction of disease risk factor claim	children's development and health
• beneficial **nutritional** properties	• relationship between a food/constituent and **health**	• food/constituent significantly reduces a **risk factor** in the development of a human disease	• relationship between food/constituent and children's development and health

Health Claims EU - Quantitative outcome

Authorisation process completed for 2,338 claims*



* 15/04/2021, source: EU Register of nutrition and health claims made on foods

- 2,163 claims on botanicals are on-hold as decided by the European Commission:
  - 615 already assessed by EFSA, all with unfavourable conclusion
  - 1,548 not yet assessed by EFSA

Traditional Herbal Medicinal Products (THMP)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Directive 2004/24/EC

EMA Committee for Herbal Medicinal Products (HMPC):

- monographs for THMP
- develop list of entries for herbal substances

National competent authorities

- national procedures

Main requirements on safety and efficacy

Traditional use registration

sufficient safety data and plausible efficacy demonstrated ⇨ **No** clinical tests and trials on safety and efficacy
Assessment of mostly bibliographic safety and efficacy data
Usage of at least *30* years *(at least 15 years within the EU)*
Used without the supervision of a medical practitioner and are not administered by injection

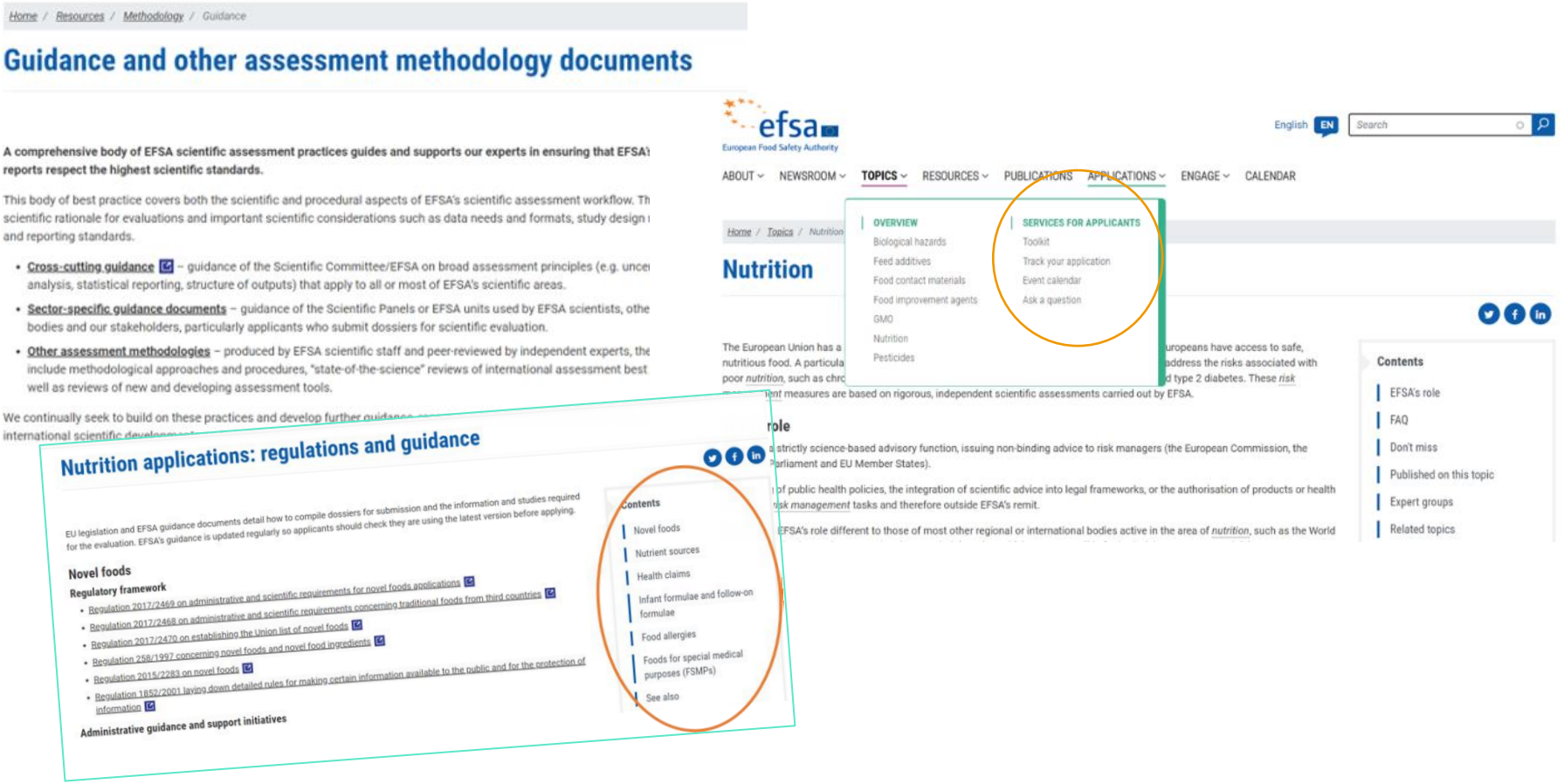
Well-established use marketing authorisation

Scientific literature establishing that the active substances of the medicinal products in *well-established medicinal use within the EU for at least ten years*, with recognised efficacy and an acceptable level of safety
Assessment of bibliographic safety and efficacy data

Stand-alone or mixed application

Safety and efficacy data from the company's own development or a combination of own studies and bibliographic data

Guidance documents



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Guidance and other assessment methodology documents

A comprehensive body of EFSA scientific assessment practices guides and supports our experts in ensuring that EFSA's reports respect the highest scientific standards.

This body of best practice covers both the scientific and procedural aspects of EFSA's scientific assessment workflow. Th scientific rationale for evaluations and important scientific considerations such as data needs and formats, study design and reporting standards.

- **Cross-cutting guidance** – guidance of the Scientific Committee/EFSA on broad assessment principles (e.g. uncer analysis, statistical reporting, structure of outputs) that apply to all or most of EFSA's scientific areas.
- **Sector-specific guidance documents** – guidance of the Scientific Panels or EFSA units used by EFSA scientists, othe bodies and our stakeholders, particularly applicants who submit dossiers for scientific evaluation.
- **Other assessment methodologies** – produced by EFSA scientific staff and peer-reviewed by independent experts, the include methodological approaches and procedures, "state-of-the-science" reviews of international assessment best well as reviews of new and developing assessment tools.

We continually seek to build on these practices and develop further guidance international scientific

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Nutrition

The European Union has a ... Europeans have access to safe, nutritious food. A particula... address the risks associated with poor *nutrition*, such as chr... d type 2 diabetes. These *risk* ...ent measures are based on rigorous, independent scientific assessments carried out by EFSA.

Contents
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...role

...a strictly science-based advisory function, issuing non-binding advice to risk managers (the European Commission, the ...Parliament and EU Member States).

...of public health policies, the integration of scientific advice into legal frameworks, or the authorisation of products or health ...*risk management* tasks and therefore outside EFSA's remit.

...EFSA's role different to those of most other regional or international bodies active in the area of *nutrition*, such as the World

Nutrition applications: regulations and guidance

EU legislation and EFSA guidance documents detail how to compile dossiers for submission and the information and studies required for the evaluation. EFSA's guidance is updated regularly so applicants should check they are using the latest version before applying.

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- Novel foods
- Nutrient sources
- Health claims
- Infant formulae and follow-on formulae
- Food allergies
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Novel foods

Regulatory framework

- Regulation 2017/2469 on administrative and scientific requirements for novel foods applications
- Regulation 2017/2468 on administrative and scientific requirements concerning traditional foods from third countries
- Regulation 2017/2470 on establishing the Union list of novel foods
- Regulation 258/1997 concerning novel foods and novel food ingredients
- Regulation 2015/2283 on novel foods
- Regulation 1852/2001 laying down detailed rules for making certain information available to the public and for the protection of information

Administrative guidance and support initiatives

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