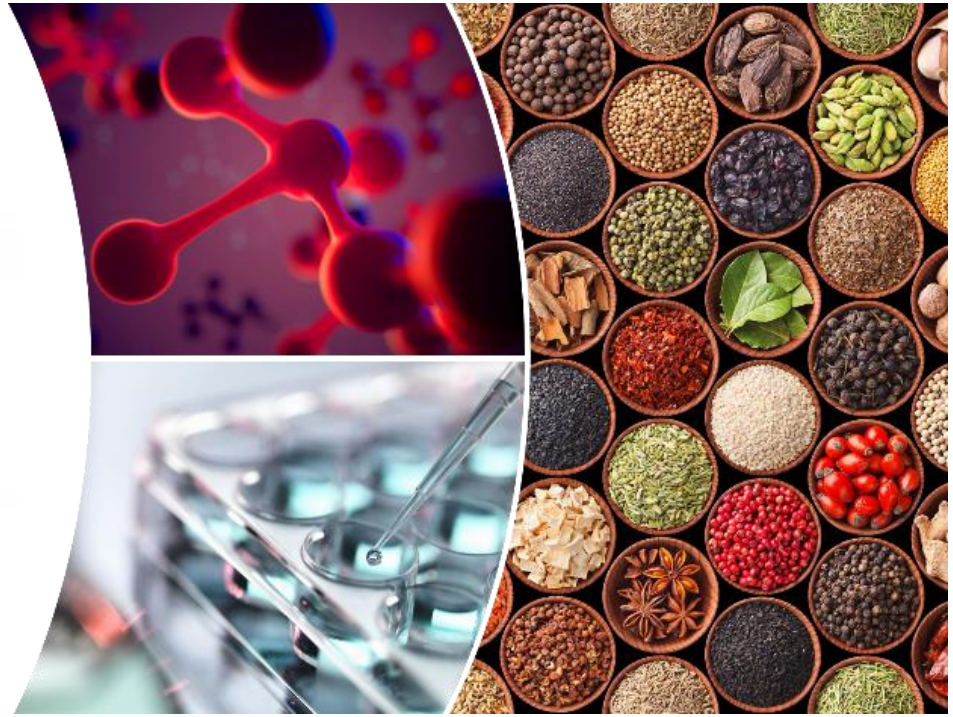



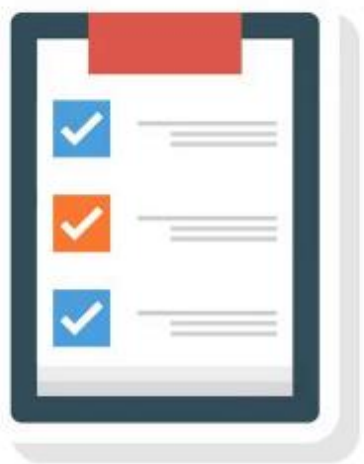
Bio 498 Entrepreneurship in Food & Nutrition Science

Regulatory requirements & Claims development

Mariana Rodrigues, Regulatory & Scientific Affairs Expert, Nestlé Research

01 April 2025

Regulatory Affairs – What is it about?



Ensure product
compliance

Support
innovations

Shape
regulatory
environment

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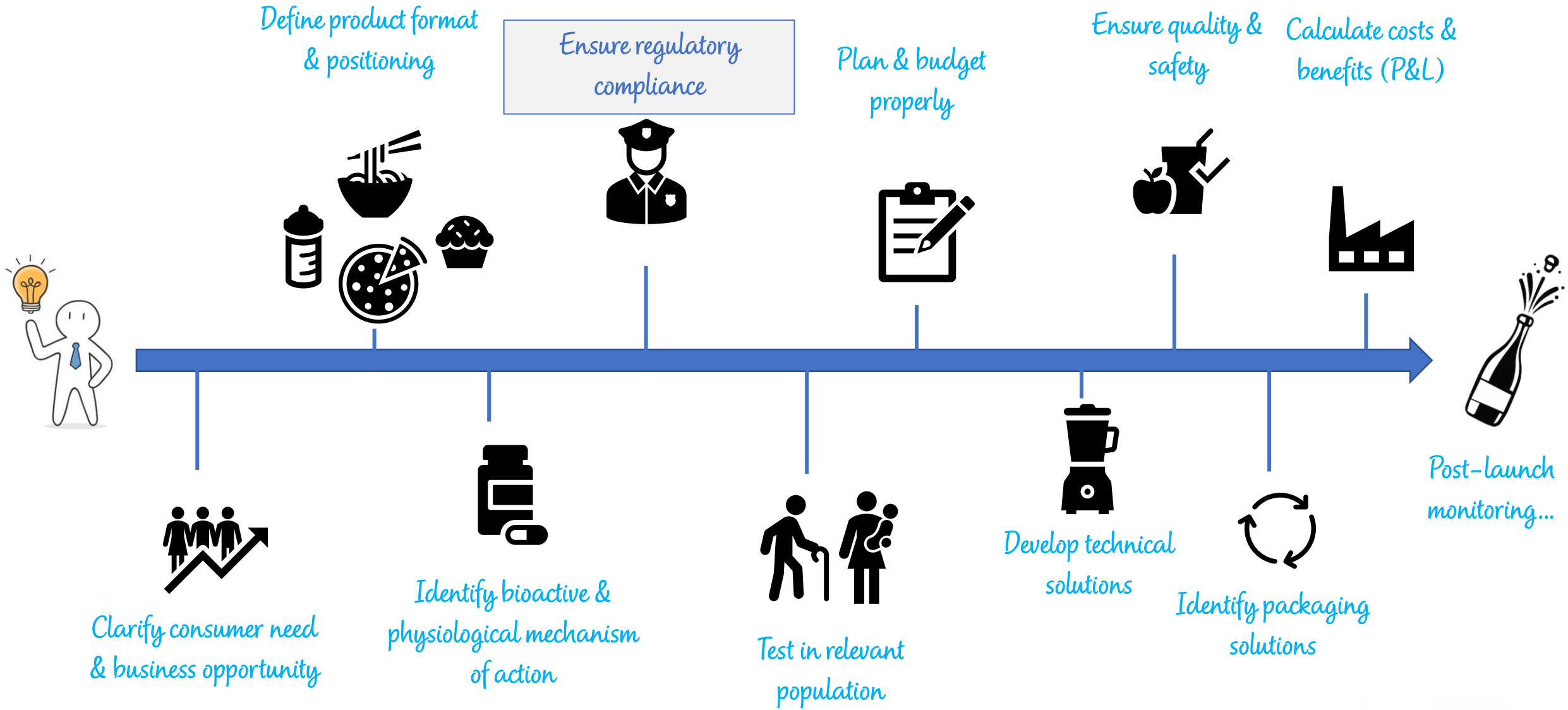
From Idea... to launch!



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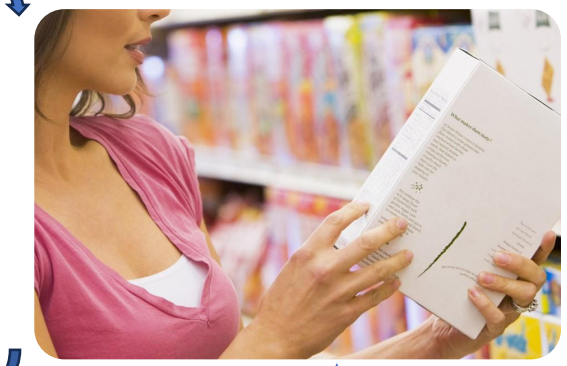
Regulatory compliance from end-to-end

Ingredients

Labelling

Communication



Objective of this lecture

To provide you with an overview on:

- ✓ Introduction to Food Regulations
- ✓ Ingredient compliance
- ✓ Labelling requirements
- ✓ Claims

Why are Food Regulations important?

01

Protect public health

02

Convey information to consumers

03

Assure fair trade practices

04

Protect the environment

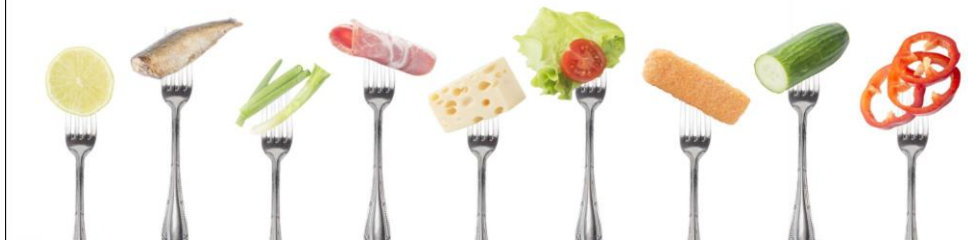
Understand and apply the applicable regulations in your target country!

This lecture will focus on EU requirements.

The General Food Law is the foundation of the EU regulatory framework

Regulation (EC) No 178/2002

- Establishes principles for food safety
  - substances that are not safe may not be placed on the market
- Establishes the European Food Safety Authority (EFSA)
- Ensures consumers are **protected from unsafe food**.
- Mandates that food businesses ensure food safety at all stages.
- Imposes responsibilities on food business operators for compliance.

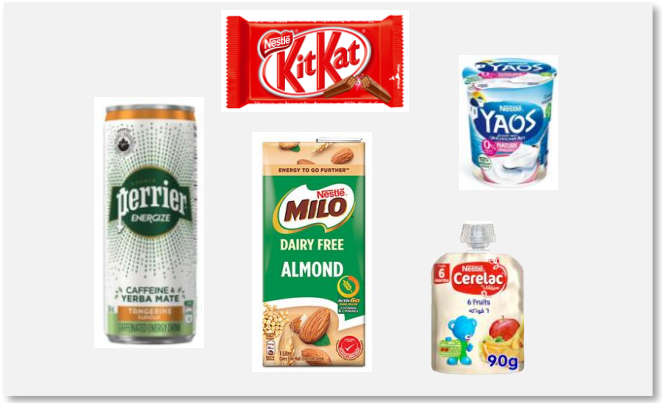


It covers the entire agri-food sector,
i.e. 'from farm to fork',

Food vs Drugs

General Foods

Regulation (EC) No 178/2002



- food means any substance or product **intended** to be or **reasonably expected** to be **ingested by humans.**
- includes **drink**, chewing gum, water.
- part of the normal diet

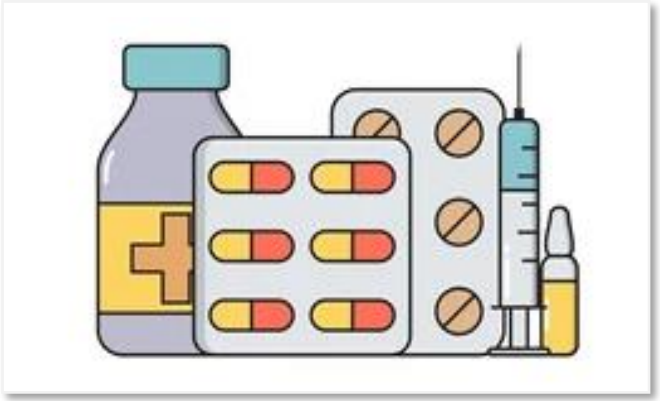
Food Supplements

Directive 2002/46/EC

- food to **supplement** the normal diet
- **concentrated sources** of nutrients or other substances with a nutritional or physiological effect, marketed in **dose form, designed to be taken in measured small unit quantities**
- It should not resemble conventional foods

Medicinal products (drug)

Directive 2001/83/EC



- products to **treat, cure, diagnose, mitigate or prevent diseases**
- Under prescription or not

General Population (Healthy)

Patients

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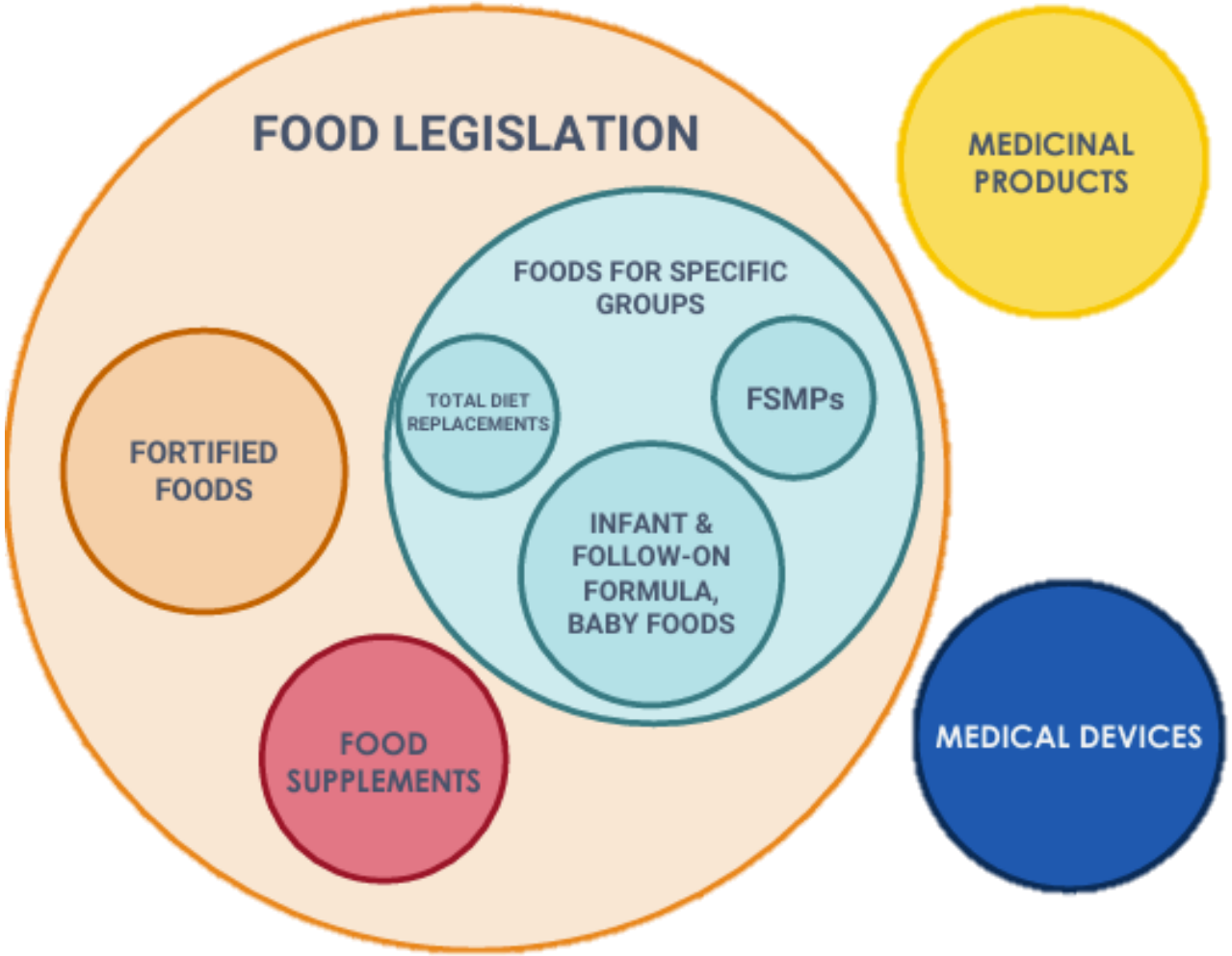
Food Regulatory Framework



Ingredients

What is an “ingredient”?

Definition - Regulation (EU) No 1169/2011 Art. 2 (f)

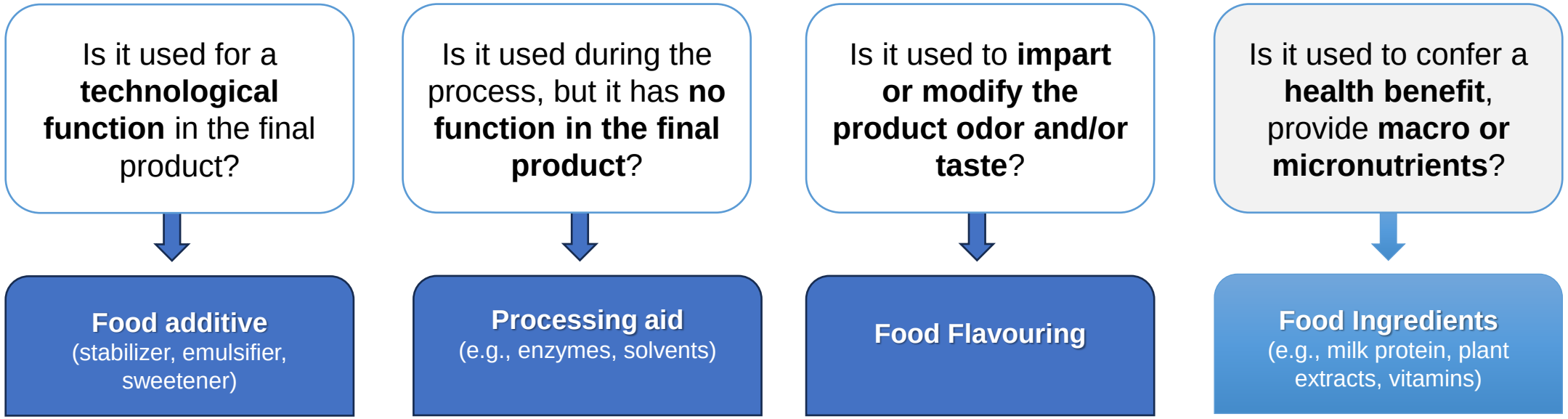
- Ingredient means **any substance or product**, including flavoring, food additives and food enzymes, and any constituent of a compound ingredient, **used** in the manufacture or preparation of a food and **still present** in the finished product, even if an altered form; residues shall not be considered as “ingredients”.

- All ingredients must be labelled* in descending order of weight, as recorded at the time of their use in the manufacture of the food.

(*with few exemptions, e.g., carriers, enzymes with no technological function in the final product, art 19 and 20)

Ingredient assessment

- Must be **safe** for human consumption
- **Allowed / authorized** in the target country
- Permitted **for the intended use**: Food vs Food supplement
- Respect minimum and maximum limits (if exist)



Food and Feed Information Portal Database | FIP

https://food.ec.europa.eu/safety/food-improvement-agents/extraction-solvents_en
https://food.ec.europa.eu/safety/food-improvement-agents/enzymes_en

https://food.ec.europa.eu/safety/food-improvement-agents/flavourings/eu-rules_en

https://food.ec.europa.eu/safety/novel-food_en
https://food.ec.europa.eu/safety/labelling-and-nutrition/addition-vitamins-and-minerals_en

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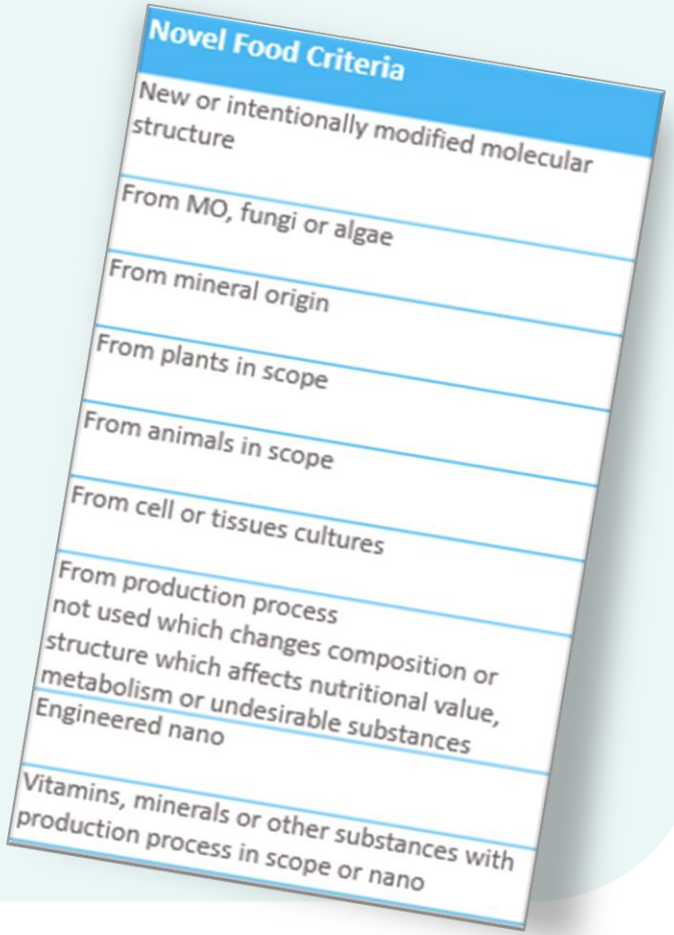
Novel Food

Definition:

- Any food that was not used for **human consumption to a significant** degree within the Union before **15 May 1997 AND**
- That falls under at least one of **10 categories**

- A novel food requires **pre-marketing authorization** including risk assessment by EFSA and risk management decision by the European Commission **before placing on the market.**



Consult the EU Novel Food Catalogue: link
And the Union list of authorized novel foods: link

Some examples

Yeast protein
Dried yeast fermentate

NOT NOVEL IN FOOD - According to the information available to the Member States' competent authorities, this product was used for human consumption to a significant degree within the Union before 15 May 1997. Thus, it is not considered to be 'novel' according to the provisions of the Novel Food Regulation (EU) 2015/2283 and its access to the market is not subject to the pre-market authorisation in accordance with Regulation (EU) 2015/2283.

Reasons why it is not novel

Fermentation by *S. cerevisiae* is a well-known process used in food production in the EU pre-1997 and involves the transformation of sugars into ethanol and carbon dioxide as the main fermentation metabolites. Sugarcane molasses (the fermentable sugar source used) is a by-product of the manufacture or refining of sucrose from sugarcane and one of the traditional substrates to produce baker's yeast (*S. cerevisiae*) with a long history of human consumption in food, mainly in bakery, confectionery, and alcoholic products.

The yeast fermentate that is the subject of this request does not significantly differ from existing non-novel fermented foods that also contain the yeast biomass (dead and/or alive), the derived fermentation by-products and fermentation medium.

Iron-enriched yeast

NOVEL FOOD - According to the information available to Member States' competent authorities, this product was not consumed in the EU to a significant degree as a food before 15 May 1997. Therefore, a pre-market authorisation in accordance with Regulation (EU) 2015/2283 is required before it can be placed as food on the EU market.

Reason statements:
Competent authorities of the EU Member States and the European Commission were consulted. A history of consumption to a significant degree prior May 1997 has not been demonstrated for the iron-enriched yeast. Therefore, food or food supplement consists of iron-enriched yeast are considered novel foods.

Link for the EU Novel Food status Catalogue

Link for the consultation report

Timelines for new ingredient authorization depend on the country

Same basic principle:

Ensure that food/food ingredients are safe for human consumption!

Country	New Ingredient	Timeline for approval
US	GRAS notification	1-1.5 years
EU	Novel food	~2 years
China	Novel food	~2 years
Brazil	Novel food	~1.5 years

A few recommendations on botanical substances

- Check if the botanical is **not classified as *"novel foods"***. If novel, pre-market authorization is needed.
- Check if there are **any restrictions** to use the botanical in food
  - e.g., plant lists suitable for foodstuffs published by some Member States
- Check if the botanical is **not restricted for medicine** or pharmaceutical applications

Some references:

Italy – positive list

France – positive list

Belgium – positive list

Germany – BVL - Stofflisten des Bundes und der Bundesländer

List A:	Substances that are not recommended for use in food.
List B:	Substances for which a restriction on the use in food is recommended.
List C:	Substances the use of which may be harmful to health but for which scientific uncertainty persists, or substances that have been classified as not novel in food supplements (Not NFS) only and otherwise are a novel food.

Labelling

Food Information to Consumers – General Principles

FIC Regulation (EU) N. 1169/2011

- Food Information: information concerning a food and made available to final consumers (label or other means)
- Provide a basis for final consumer to **make informed choices** and to **make safe use of food**.
- The **labeling information** must be:

accurate

easy to see and understand

not misleading

indelible

Mandatory information for prepacked foods

Art. 9 - Regulation (EU) N. 1169/2011

1. name of the food*
2. ingredient list
3. allergen information
4. quantity of certain ingredients (QUID)
5. date marking (best before / use by)
6. country of origin, if required for consumer clarity
7. name and address of the food business operator
8. net quantity*
9. special storage conditions and/or conditions of use
10. instructions for use if needed
11. alcohol level for beverages (if > 1.2%)
12. nutrition declaration

* Must be in same field of vision

Additional mandatory particulars for specific types or categories of foods laid down in Annex III (Article 10, par. 1).

Minimum font size for mandatory information:
x-height: min 1.2 mm
(or 0.9mm if surface < 80cm^2)

Example: What do you think are Mandatory labelling elements (EU)?

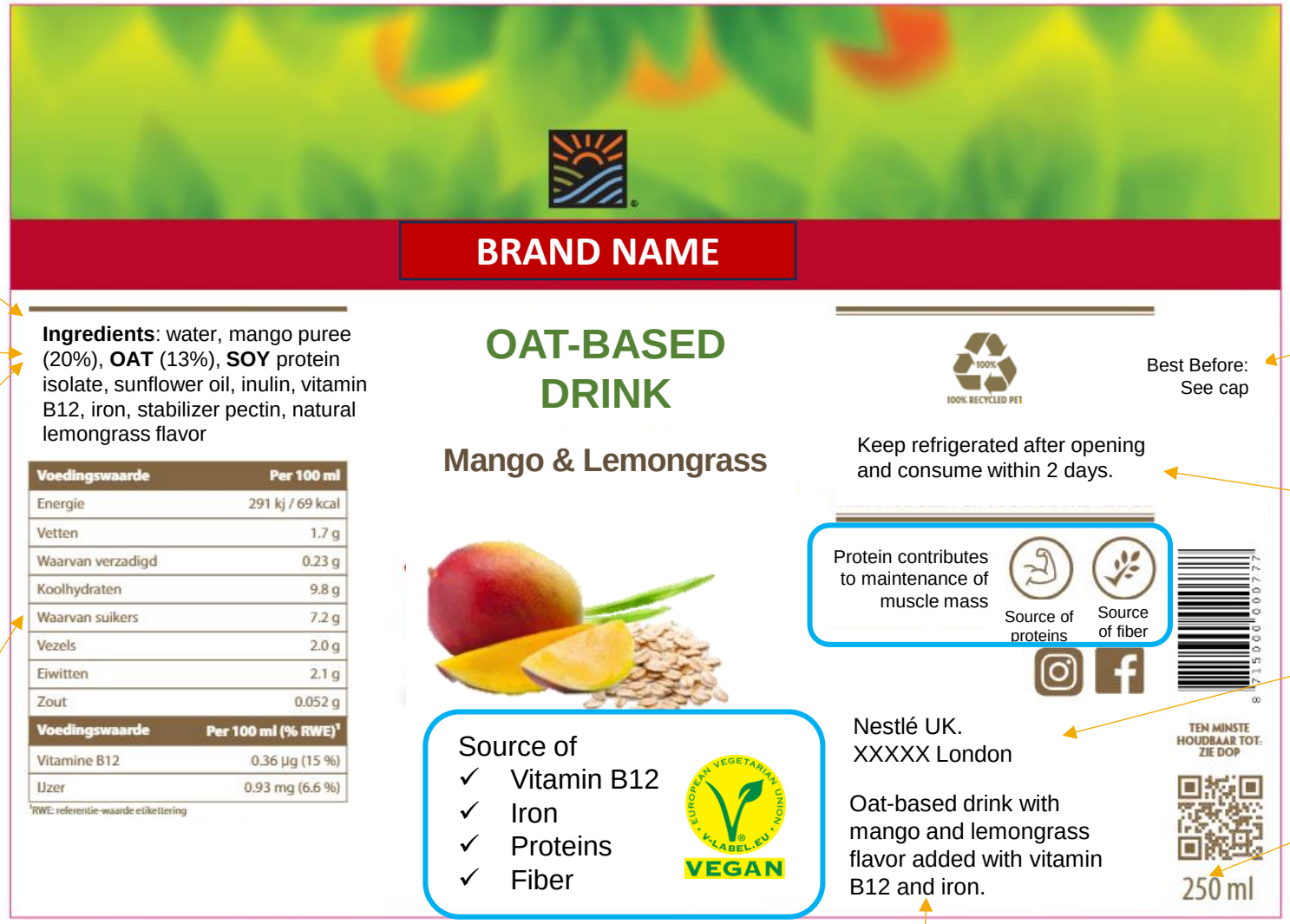
Mandatory in some cases:
- The country of origin in specific cases
- Instructions for use
- For alcoholic beverages: alcohol volume (if > 1,2%)

(2) **Ingredients list**
(descending order, additives accompanied by their function, e.g., "stabilizer")

(3) **Allergen information**
(must be highlighted)

(4) **QUID** - Quantity of certain ingredients or categories of ingredients

(5) **Nutrition** declaration



(6) **Best before date**.

(7) **Storage conditions** and/or conditions of use

(8) **Food Business Operator** (name and address)

(9) **Net weight**

Nutrition and health claims, Vegan Logo: voluntary!

(1) **Name** of the food

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Food Supplements: Additional mandatory labelling elements

“ **Food Supplement**” is the legal name

- ✓ names of the **categories of nutrients/substances** that characterise the product
- ✓ portion of the product **recommended for daily consumption**
- ✓ warning **not to exceed the recommended daily dose**
- ✓ statement that it should **not be used as a substitute for a varied diet**
- ✓ statement that the product should be **stored out of the reach of young children**

(Other statements might be required, depending on the ingredients used and on the requirement in the target country)

Reminder: The labelling, presentation and advertising **must not** attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties

See: Art. 6 Directive 2002/46/EC

Communication

What is a “Claim”?

“means any message or representation, which is **not mandatory** under Community or national legislation, **including pictorial, graphic or symbolic representation**, in any form, **which states, suggests or implies that a food has particular characteristics**”

(REGULATION (EC) No 1924/2006)

It is not about words;
it is about consumer’s expectations!

Which of them is NOT considered a claim?

1

2

3

All are considered claims !!

General Principles - Claims

All claims must be…

- ✓ True
- ✓ Accurate
- ✓ Not misleading
- ✓ Substantiated
- ✓ Responsible

and guided by common sense.

Off-Pack Claims = Less strict requirements?

No ! **The requirements are the same**, regardless the communication channel
Also includes trademarks, brands, product names.

Label

Point of sales

Digital ads

Printed materials

TV

Radio

Understanding some types of claims

Ingredient claim

Content of an ingredient

- Suitable for vegetarians
- Milk & Soy
- With chia seeds
- Contains live cultures

Nutrition claim

Content of a nutrient/energy

- Source of fibre
- High in protein
- Low sodium
- No added sugar

Check conditions & permitted claims: Reg (EC) No 1924/2006

Health claim

Effect of an ingredient/food on health

Function Claims:

- Beta-glucans contribute to the maintenance of normal blood cholesterol levels

Reduction of a risk factor:

- Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease

Check permitted claims: Commission Regulation (EU) No 432/2012

Drug claim

Medical effect of an ingredient

Beta glucan **protects** from having coronary heart **diseases**

Must be true and not misleading

Must be on a **list of pre-approved claims** (EU)

Not allowed for food

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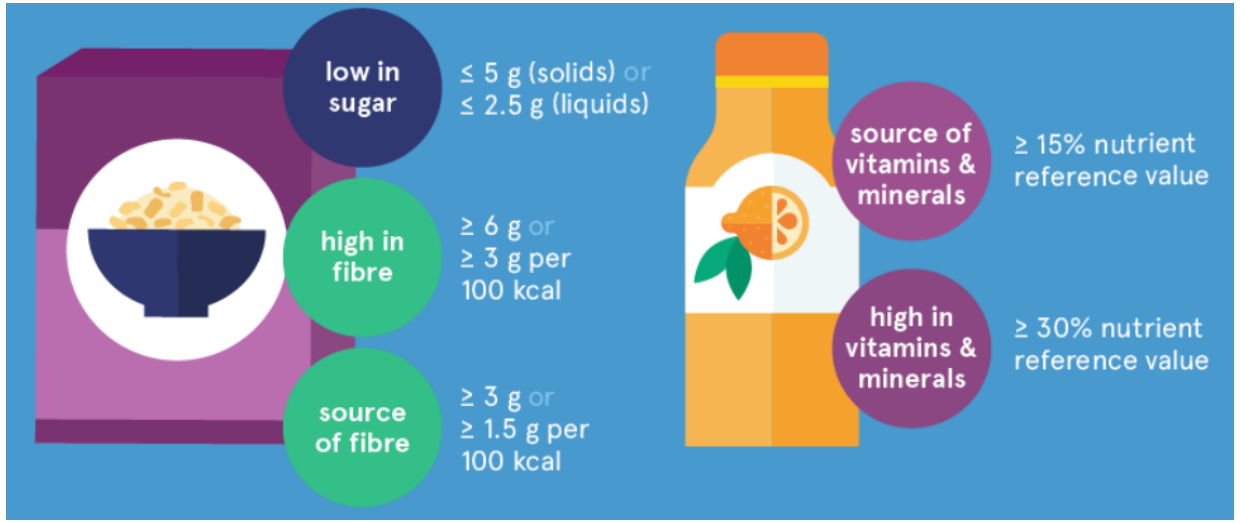
Examples of Nutrition claims

What is the minimum to claim **SOURCE OF CALCIUM**?

15% NVR of calcium (800mg) = 125mg



Check - REGULATION (EC) No 1924/2006

1. Vitamins and minerals which may be declared and their nutrient reference values (NRVs)

Vitamin A (µg)	800	Chloride (mg)	800
Vitamin D (µg)	5	Calcium (mg)	800
Vitamin E (mg)	12	Phosphorus (mg)	700
Vitamin K (µg)	75	Magnesium (mg)	375
Vitamin C (mg)	80	Iron (mg)	14
Thiamin (mg)	1,1	Zinc (mg)	10
Riboflavin (mg)	1,4	Copper (mg)	1
Niacin (mg)	16	Manganese (mg)	2
Vitamin B6 (mg)	1,4	Fluoride (mg)	3,5
Folic acid (µg)	200	Selenium(µg)	55
Vitamin B12 (µg)	2,5	Chromium (µg)	40
Biotin (µg)	50	Molybdenum (µg)	50
Pantothenic acid (mg)	6	Iodine (µg)	150
Potassium (mg)	2 000		

Regulation (EU) No 1169/2011

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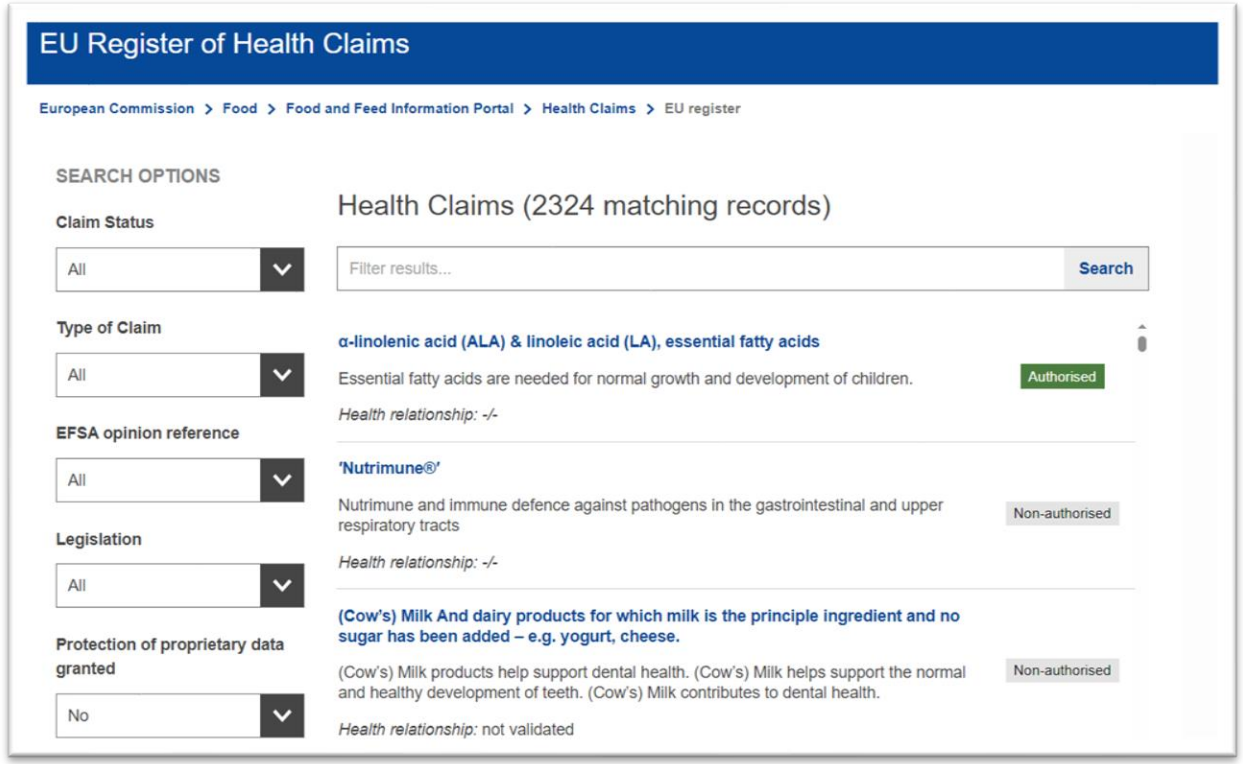
EU register of health claims

→ Check what are the authorized health claims and correspondent conditions of use
→ All health claims must be authorized prior to use.

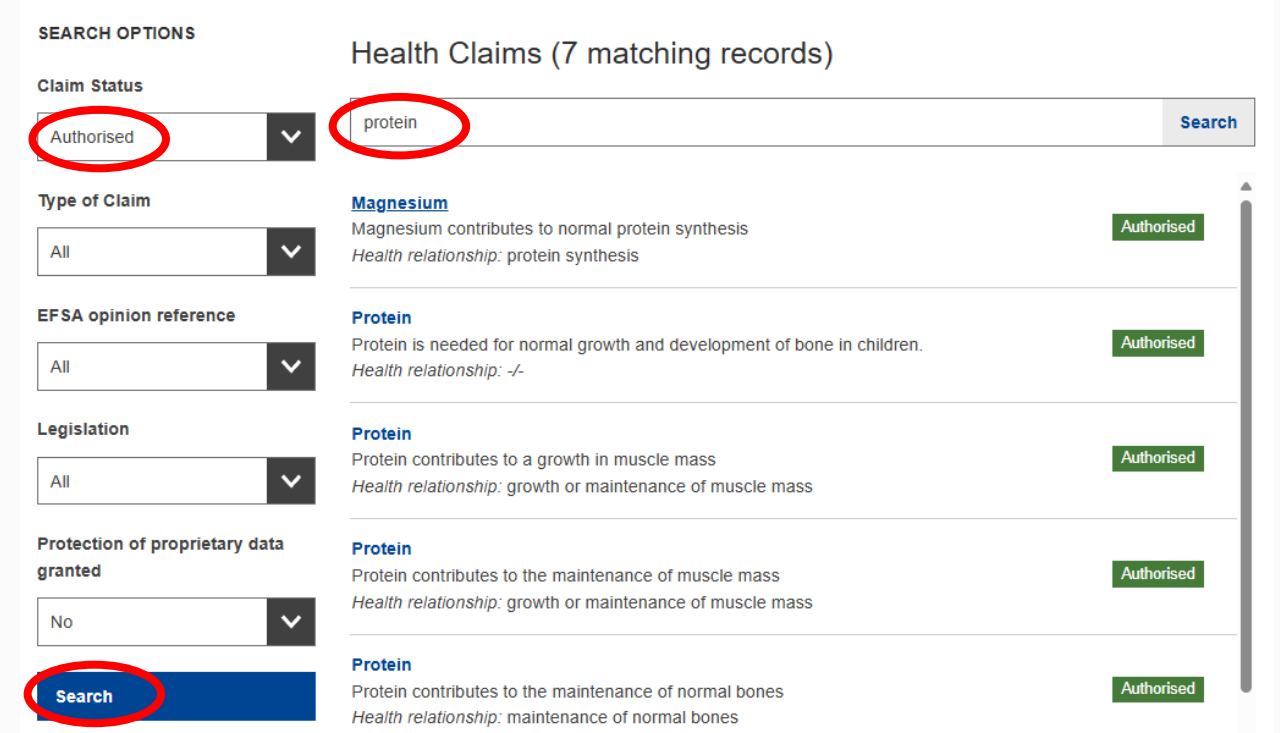
- **267 authorized health claims**
  - 229 function claims (general)
  - 6 function claims (new data)
  - 6 claims with proprietary data
  - 14 reduction of disease risk factor
  - 12 claims for children
- **>2000 non-authorized health claims**
- EFSA Opinion can be consulted



Food and Feed Information Portal Database | FIP (europa.eu)

EU register of health claims - Example

→ Authorized claims on **Protein**



Claim

Protein contributes to a growth in muscle mass

Conditions of use of the claim / Restriction of use / Reasons for non-authorisation

The claim may be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006.

SOURCE OF PROTEIN

A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12 % of the energy value of the food is provided by protein.

[Food and Feed Information Portal Database | FIP (europa.eu)]

Health Claims require additional labelling elements:

- a statement indicating the importance of a **varied and balanced diet and a healthy lifestyle**;

- the **quantity of the food and pattern of consumption** required to obtain the claimed beneficial effect:
  (E.g., '30g of walnuts consumed per day will improve the elasticity of blood vessels')

- where appropriate, a statement addressed to **persons who should avoid** using the food:
  (E.g., 'Not suitable for pregnant or breast-feeding women')

- an appropriate **warning** for products that are likely to present a health risk **if consumed to excess**

- For risk reduction claims: statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

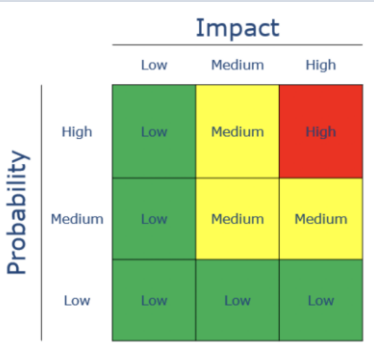
Art. 10 (2) and Art. 14 (2) of Regulation (EC) No 1924/2006

Misleading Claims are claims that cannot be substantiated

Examples of misleading claims:

- Attributing to the food properties which it does not possess
- Suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics (e.g. emphasizing the presence or absence of certain ingredients)
- Meaningless claims including incomplete comparatives and **superlatives**
- Unsubstantiated claims (“boost”- no food can boost a physiological status)

Navigating in the gray zone with Risk Assessment



Remember: **Compliance is not negotiable!**

Black	**Grey** Embraces experience & interpretation	White

- Regulations are vague or inexistent
- Multiple interpretations are possible
- Precedent is varied

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What can be the consequence of a regulatory risk?

- Damage brand / company’s reputation;
- Withdrawal product from shelves;
- Challenge from the local authority (e.g., fine);
- Loss of credibility with regulators;
- Loss of consumer's trust
- Criticism by NGOs, activists;
- Change of on- and/or off-label communication.

Useful resources

- Food Labelling Information System (europa.eu)
- Mandatory food information - European Commission (europa.eu)
- Regulation EU 1169/2011
- EU Register Health Claims: here
- Nutrition Claims in the EU: here

Thank You!

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