



Healixia

**WELCOME**

# Food Supplements – Regulatory Framework and Current Developments

4 DECEMBER 2025

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# Healixia

is a Belgian non-profit organisation connecting life science professionals and aiming to further professionalize its members and concerned disciplines

## What we do



### Education

Offer an agenda full of high quality courses, webinars, conferences, workshops,...

### Networking

Create opportunities to meet new and long-known colleagues throughout the year e.g. NY event, Annual Conference, BBQ,...



### Dialogue

Debate on relevant topics and promote dialogue and cooperation with partners and other organisations within the eco-system



# Healixia

## Who we are



The professional is our member

**700+**  
members

coming from **170+**  
companies, hospitals  
& universities

### active in the following domains:

- Early Development
- Clinical Research
- Regulatory Affairs
- Medical Affairs
- Market Access
- Legal/Compliance & Ethics

## How we work

for all information about our educational and networking offer

38 active members volunteering in the executive board & education groups  
professional office management



**Professionals for professionals**

Healixia is member of:



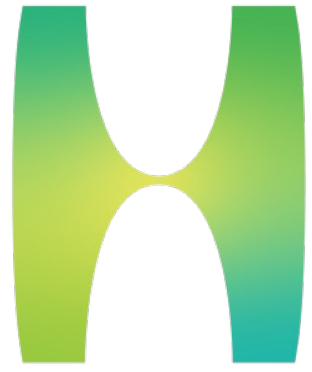
[www.healixia.be](http://www.healixia.be)  
& follow us on 



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# TODAY'S AGENDA

- 14:30 Introduction
- 14:40 Overview of the European Regulatory Framework
- 15:00 Belgian Regulatory Framework
- 15:20 Coffee break
- 15:40 Current Developments at EU Level
- 16:00 Current Developments at Belgian Level
- 16:20 Q&A and Discussion



Healixia



Valerie Vercammen



Ulrike Van den Houte

Food supplements

# Regulatory Framework and Current Developments

# Food Supplements

Regulatory Framework and Current developments

**Healixia**

**4<sup>th</sup> of December 2025**



# Table of content

Meet be-sup

Overview of the EU Regulatory Framework

Belgian Regulatory Framework

Current Developments at EU and Belgian level

# Meet be-sup!



[www.be-sup.be](http://www.be-sup.be)



[info@be-sup.be](mailto:info@be-sup.be)



<https://www.linkedin.com/company/be-sup/>

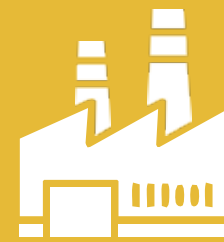


## BE-SUP: LEADING BELGIAN TRADE ASSOCIATION



### OFFICIAL BELGIAN TRADE ASSOCIATION

Be-sup, recognized by the Council of State since 1990, represents the Belgian food supplements industry, providing expertise, regulatory support, and networking.



### > 160 MEMBERS: VERTICAL INTEGRATION

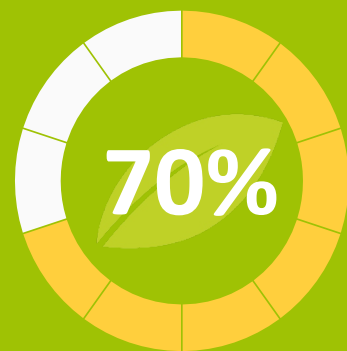
Be-sup unites >160 members, from SMEs to global players, covering the entire industry chain through strong vertical integration.



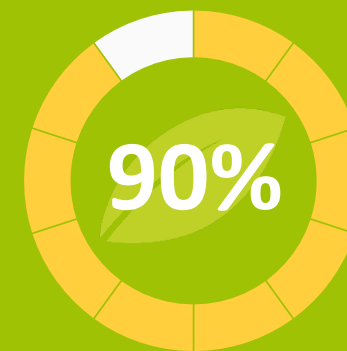
### CONNECTED TO LEADING ASSOCIATIONS

Be-sup is a member of Fevia and EHPM, ensuring industry representation and shaping of the sector at both the national and the European level.

## BE-SUP'S REPRESENTATIVITY



Be-sup members:  
70% Market Share



Be-sup members:  
90% Production Share

## BE-SUP'S MISSION



### #WATCHDOG

Defending the image & credibility of food supplements and the food supplements industry



### #FOODSUPVOCATE

Creating the best possible framework for our members to do business: advocacy, lobby



### #SUPACADEMY

Empowering our members with unique food supplement knowledge: advice, workshops, conferences, #FFS congress,...

# STRUCTURE OF BE-SUP

## 12 Board Members



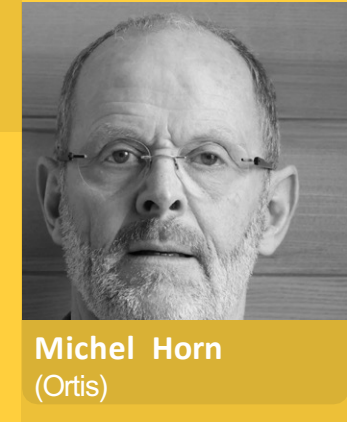
**Thomas Liénard**  
(Bio-Life ) | Vice-President



**Patrick Geysen**  
(Phytophar) | President



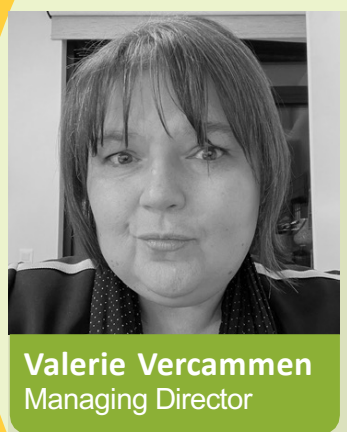
**Stefaan Vervarcke**  
(Metagenics) | Treasurer



**Michel Horn**  
(Ortis)



**Diane Beunen**  
(Equi-Nutri)



**Valerie Vercammen**  
Managing Director



**Linda Vansteenwinckel**  
Scientific Director



**Ulrike Van den Houte**  
Communications & RA  
Director



**Geert Van Gijsegem**  
(Eytelia)



**Koen Vanvuchelen**  
(Mercure Advisors)



**Gilles Gernaey**  
(Legisana)



**Pascal Debauche**  
(Pranarom)



**Neil Goffaert**  
(Lepivits)



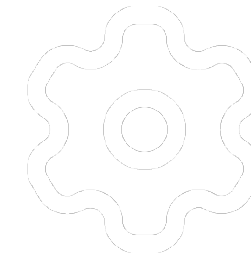
**Leen Van Beek**  
(Nestlé Health Science)

**Be-sup Team** 

## MEMBER-DRIVEN COLLABORATION

Be-sup unites industry leaders to tackle key challenges in regulation, quality, probiotics, and communication. Through dedicated working groups, we ensure innovation, compliance, and a strong sector, both in Belgium and internationally.





## Provisional Calendar 2026

- 🍃 **27/01:** Probiotics Symposium
- 🍃 **05/02:** *WS Quality - Autocontrol Advanced Course*, with Normec (at Normec Gent)
- 🍃 **February** (date TBC): *Workshop Legislation and notification of food supplements*
- 🍃 **17/03:** General Assembly in Dolce La hulpe
- 🍃 **31/03 (TBC):** *Generating evidence for food supplements: mission impossible?* (with Artialis)
- 🍃 **21/04:** *Labelling* (with AM Norman)
- 🍃 **May** (date TBC): *Webinar*
- 🍃 **25/05 (TBC):** *Workshop R&D in Food Supplements* (with Biophysium)
- 🍃 **June:** *Workshop Claims*
- 🍃 **17/09:** After Summer Meeting in the Museum for Natural Sciences in Brussels
- 🍃 **October:** *Webinar e-commerce* (with Amazon and others)
- 🍃 **November:** *Workshop Communication and #FOODSUPvocate*
- 🍃 **December:** *Webinar Regulatory Update*

→ [Check our online agenda](#)



# EU Regulatory Framework



# EU Regulatory Framework

Key EU legislation on food supplements

Health claims: regulation EC N° 1924/2006

Novel Foods Regulation



# Key EU legislation on food supplements



# The hierarchy of norms



## EU Law

Treaties

Regulations

Directives

## BE Law

Constitution

Laws/Decrees/Ordonnances

Regulatory Decrees





# EU Regulation



ADDITION VITAMINS,  
MINERALS AND OTHER  
SUBSTANCES

[R EU 1925/2006](#)

GFL: General Food  
Law

[R EU 178/2002](#)

Food supplements  
directive

[R EU 2002/46](#)

NHCR

[R EU 1924/2006](#)

FIC: Food  
Information  
Consumers

[R EU 1169/2011](#)

Mutual recognition:

[R EU 2019/515](#)

Additives

R EU  
[1333/2008](#)

NOVEL FOOD

R EU

[2015/2283](#)

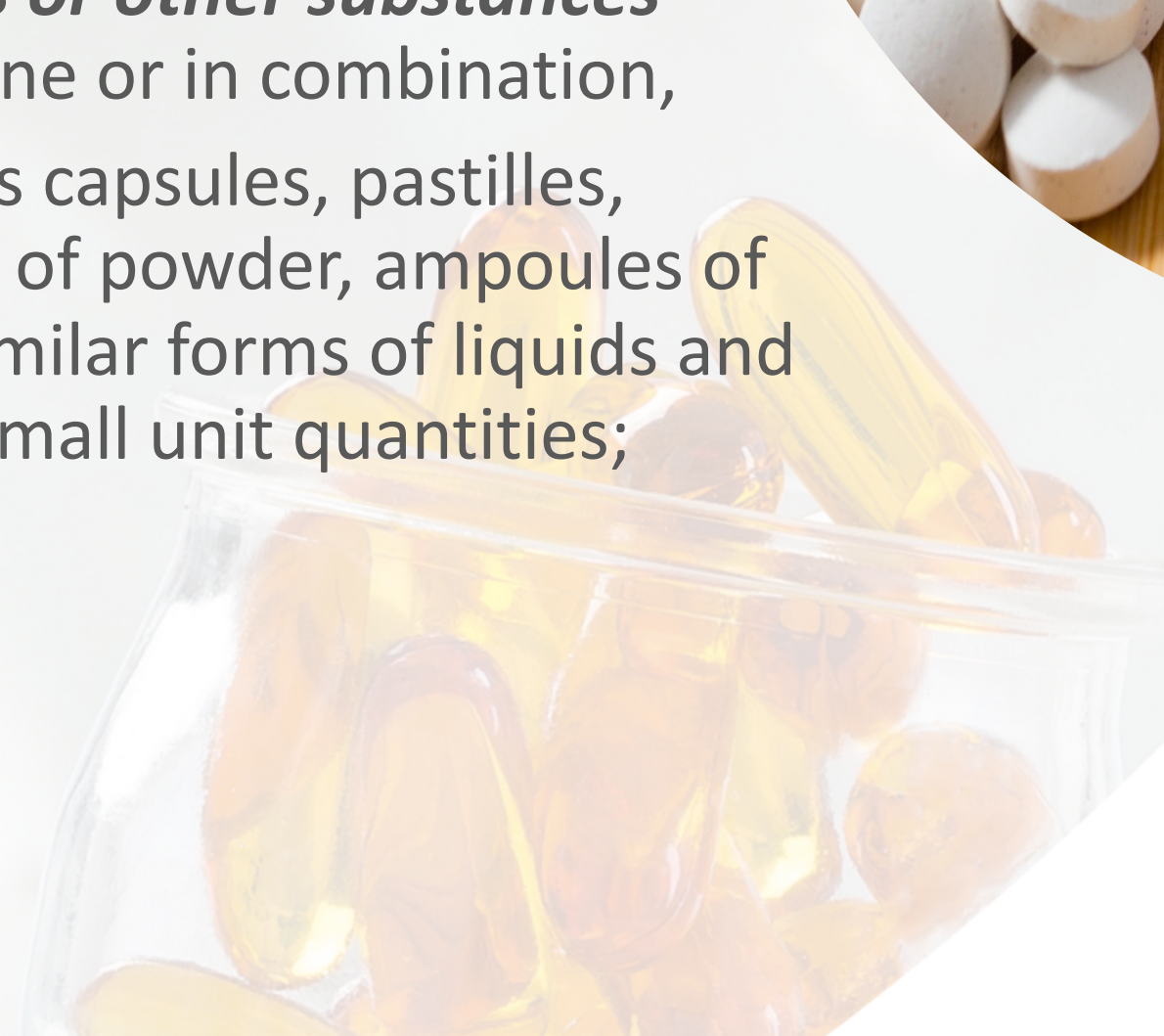
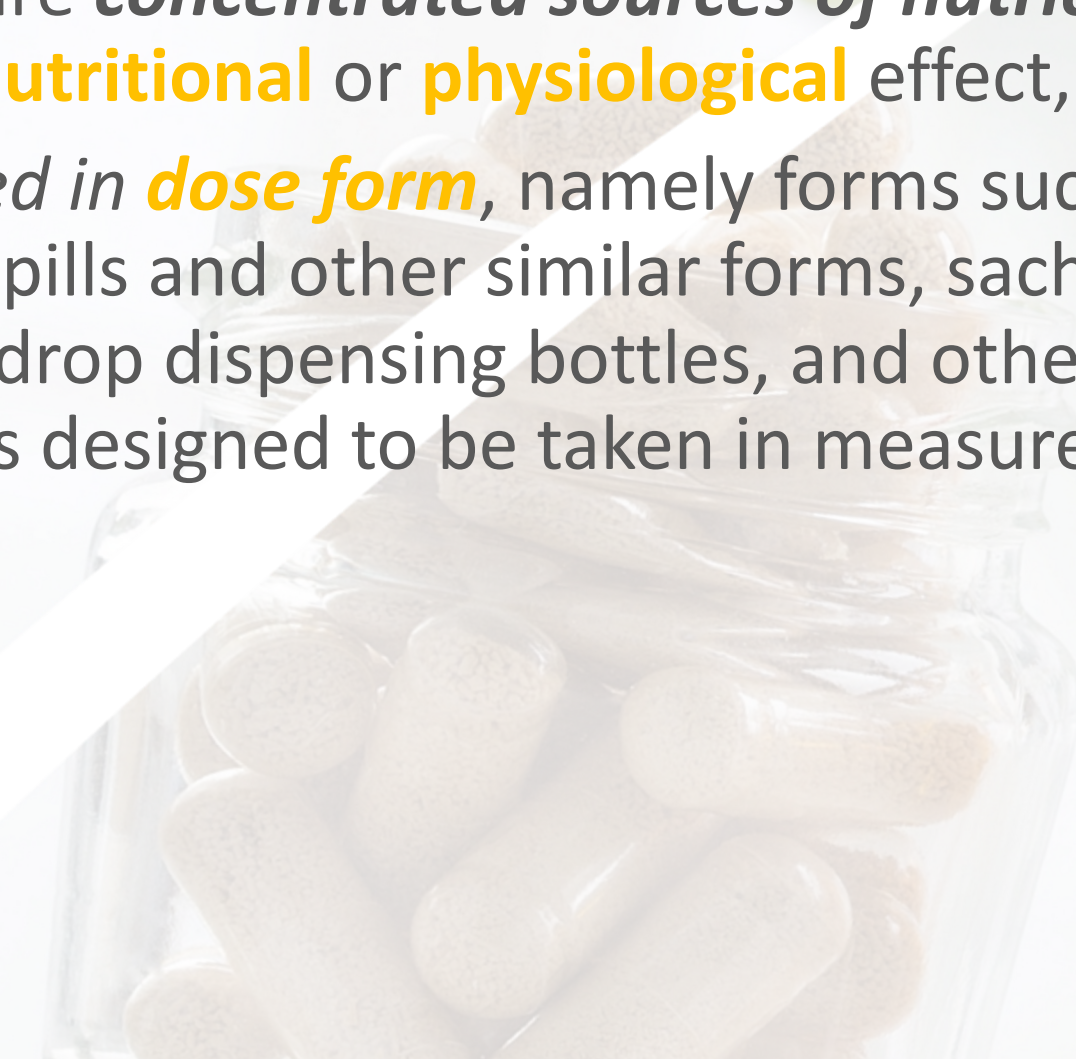
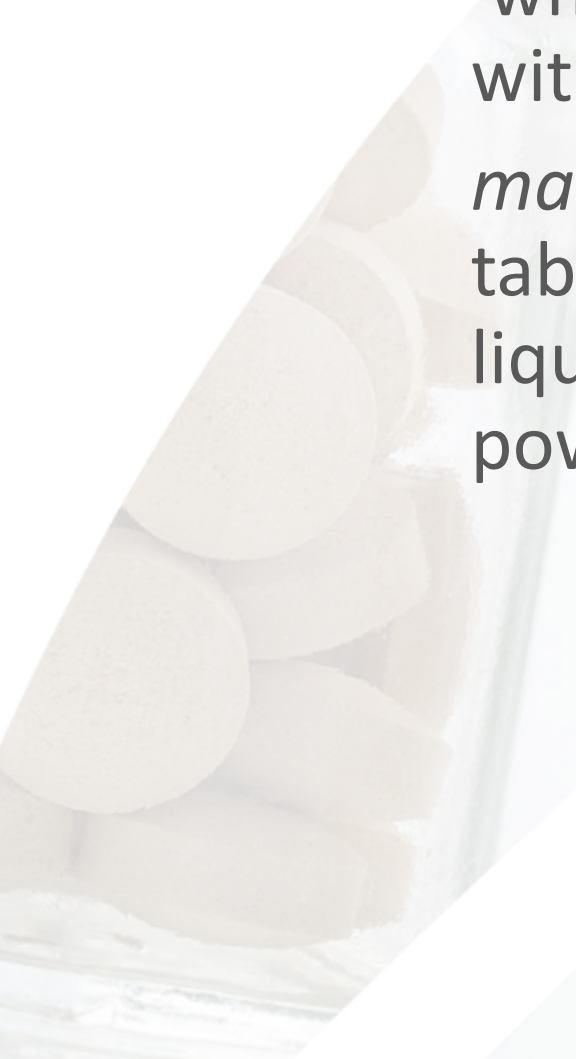


# What is a food supplement?

🌿 Food supplements directive **2002/46**

🌿 Article 2:

(a) "food supplements" means foodstuffs the purpose of which is to **supplement the normal diet** and which are **concentrated sources of nutrients or other substances** with a **nutritional** or **physiological** effect, alone or in combination, **marketed in dose form**, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;





# Which nutrients and chemical forms can be used?

🌿 The **nutrients** that may be used:

→ **Annex I** Directive 2002/46/CE

🌿 The **chemical forms** that may be used:

Compounds of vitamins and minerals which may be used  
in the manufacture of food supplements

→ **Annex II** to Directive 2002/46/CE





# Labelling requirements

## Compulsory statements:

- the designation "food supplement"
- the reference intakes (RI)
- a warning against exceeding the recommended daily allowance
- a warning that the products should be stored out of the reach of children
- a statement to the effect that food supplements should not be used as a substitute for a diversified diet
- the content of nutrients present per recommended daily dose (this may also be shown graphically)
- the name of the plant or plants in the language of the region, if it exists, as well as the scientific name (for food supplements containing plants).





# Health claims: regulation EC N° 1924/2006



# Claims legislation: the framework

**Regulation (EC) 1924/2006** governs all nutrition & health claims used in **commercial communication** for foods and food supplements.

## Key principles:

- 🌿 Only **authorised** claims may be used (or **on-hold botanical** claims under strict conditions).
- 🌿 Claims must **not be misleading** (Art. 3).
- 🌿 Claims must be linked to a **nutrient or substance**, not the product as such.
- 🌿 **General (non-specific) claims** such as “good for your health” must be accompanied by a **specific authorised claim in immediate proximity** (C-524/18).
- 🌿 Product names, brand names and images that imply a health effect are also considered claims.





# Art 13 (1) and 13 (5)

## Article 13(1): “General function” claims

- Based on **generally accepted scientific evidence**.
- Refer to normal physiological functions, e.g.:
  - “Vitamin C contributes to the reduction of tiredness and fatigue.”
  - “Magnesium contributes to normal muscle function.”
    - Found in the **EU Positive List** (Reg. 432/2012).

## Article 13(5): “New science / proprietary data” claims

- Based on **new scientific evidence** or **proprietary data**.
- Require a **full EFSA assessment + Commission authorisation**.
- Authorised per dossier, sometimes with data protection.

E.g.: green kiwi fruit





# Art 14(1) (a): Disease risk reduction claims

## 🌿 Article 14(1)(a): Disease Risk Reduction Claims

→ Claims that reduce a **risk factor** for a disease – *not* prevention or treatment.

→ Examples (authorised):

“**Plant sterols** have been shown to reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.”

→ Must follow **exact authorised wording** and **conditions of use**.

→ Any formulation implying prevention of a disease becomes a **medical claim** (prohibited).





# Article 14(1)(b): Claims on Children's Development & Health

## Article 14(1)(b): Claims on Children's Development & Health

→ Claims specifically concerning:

- Growth and development
- Immune function in children
- Brain and visual development

→ Only **Art. 14(b)** claims are allowed when the product is **exclusively intended for children**.

→ Art. 13 claims may not be used in that case.





# Guidelines FPS Health

<https://www.health.belgium.be/nl/professionals/ondernemingen/voeding/beweringen-reclame>

🏠 > [Organisatie & beleid](#) > [Regelgeving en beleidsdocumenten](#) > [Status en gebruik van voedings- en gezondheidsclaims](#)

## Status en gebruik van voedings- en gezondheidsclaims

**Download het document**

Meer informatie over voedings- en gezondheidsclaims en hun gebruik (inclusief de lijst van toegelaten en afgewezen claims en de richtsnoeren over de flexibiliteit van de formulering).

📄 [Status en gebruik van voedings- en gezondheidsclaims](#) DOCX 953.75 KB

Download

🏠 > [Organisation & politique](#) > [Réglementation et documents de politique](#) > [Statut et utilisation des allégations nutritionnelles...](#)

## Statut et utilisation des allégations nutritionnelles et de santé

**Téléchargez le document**

Plus de détails sur les allégations nutritionnelles et de santé et leur utilisation (y compris la liste des allégations autorisées/refusées et les lignes directrices sur la flexibilité)

📄 [Statut et utilisation des allégations nutritionnelles et de santé](#) DOC 925 KB

Download





# Novel Foods Regulation



# Novel Foods

 R EU 2015/2283

 **Definition:**

Novel Food refers to foods and food ingredients **not consumed to a significant degree in the EU before 15 May 1997** and that fall under one of the recognised categories.

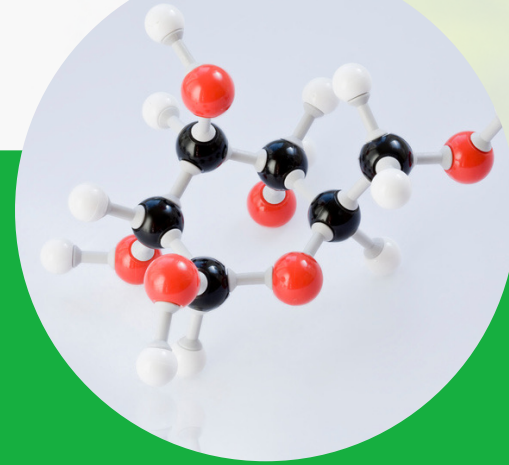




# Novel Food categories



**New production process**



**New or modified molecular structure**



**Micro-organism, fungi, algae**



**Plant-based ingredients without established safe use in the EU**



**Of mineral origin**



**From animals not used before 1997**



**Cell or tissue culture derived from plants/animals/fungi/algae**

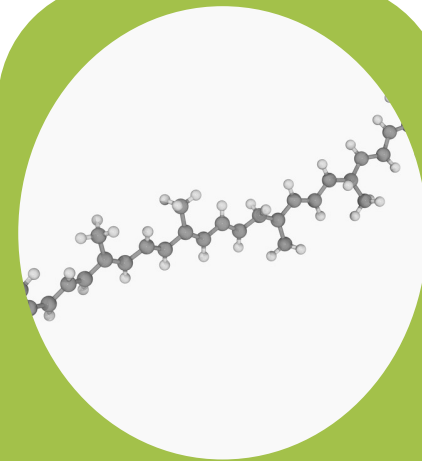


**Engineered nanomaterials**



# Examples of Novel Foods

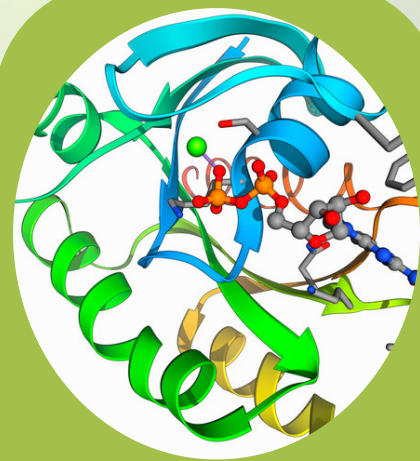
Newly synthesized /  
isolated compounds



Synthetic  
Lycopene



Non-sticky  
chewing gum  
base



Ice-  
structuring  
protein

New processes



UV-treated  
milk



Milk products  
fermented  
with *B.*  
*xylanisolvens*



UV-treated  
yeast

Traditional foods from  
non-EU countries



Chia seeds



Baobab fruit



Noni juice

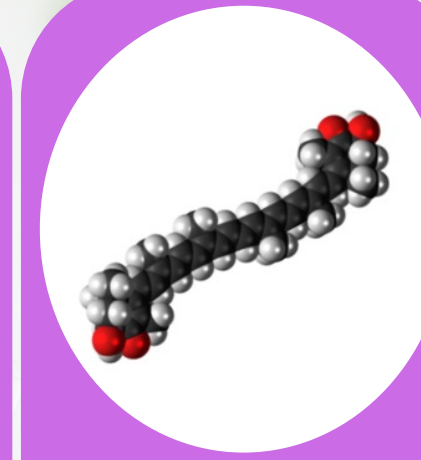
New sources



Krill oil



Lycopene  
from *B.*  
*trispota*



Astaxanthin  
from *H.*  
*pluvialis*



# How to check if an ingredient is novel!



## NF Catalogue

[https://webgate.ec.europa.eu/fip/novel\\_food\\_catalogue/](https://webgate.ec.europa.eu/fip/novel_food_catalogue/)

## Union List

What is it?

The Implementing Regulation establishing the list of novel foods compiles all the authorised novel foods in the European Union to date. It includes their conditions of use, labelling requirements, and their specifications. All authorisations are generic and the Union list serves as a reference for economic operators who wish to place in the market an authorised novel food unless data protection is requested by the applicant. The Union list is updated by the Commission to add newly authorised novel foods.

[https://eur-lex.europa.eu/eli/reg\\_impl/2017/2470/oj](https://eur-lex.europa.eu/eli/reg_impl/2017/2470/oj)

## Art 4.2 consultations

[https://food.ec.europa.eu/safety/novel-food/consultation-process-novel-food-status\\_en](https://food.ec.europa.eu/safety/novel-food/consultation-process-novel-food-status_en)





# Belgian Regulatory Framework



# BE Regulatory Framework

Legal Framework

Challenges with notification



# Legal Framework



# The hierarchy of norms

## EU Law

Treaties

Regulations

Directives

## BE Law

Constitution

Laws/Decrees/Ordonnances

Regulatory Decrees





# Legal framework Belgium

## 3 Royal Decrees:



### Nutrients:

→ Royal Decree 30/05/2021

### Botanicals:

→ Royal Decree 31/08/2021

### Other Substances:

→ Royal Decree 29/08/2021 + Ministerial Decree 22/12/2021

New  
website  
FOD/SFP  
New links!





# Challenges with notification



# Notification: what the directive says...

## Article 10 directive 2002/46:

« In order to facilitate effective control of food supplements, Member States may require the manufacturer or the person responsible for placing the product on the market in their territory to inform the competent authority of such marketing by *providing it with a model of the labelling* used for that product. »





# Notification: what Belgian law says...

- 🍃 Art. 5. Royal Decree on Nutrients (Royal Decree of 30 May 2021).
- 🍃 It is **prohibited to place on the market** foodstuffs consisting of or containing one or more nutrients **if prior notification has not been made** to the Service in accordance with the following provisions:
- 🍃 One copy of the notification file shall be submitted, or via the FOODSUP application on the website of the FPS Public Health, Food Chain Safety and Environment ([www.sante.belgique.be](http://www.sante.belgique.be)).





# Notification: what Belgian law says...

The notification file must include at least the following information:

- 1. The nature of the foodstuff;
- 2. The list of ingredients in the product (qualitative and quantitative)  
For food supplements: a complete list of ingredients, both quantitative and qualitative;  
For fortified foods: a qualitative and quantitative list of added nutrients (and, if present, data on unauthorised plants from list 1 of the AR plants);
- 3. If applicable, the nutritional analysis;
- 4. **NEW** The final version of the labelling as marketed;
- 5. The data necessary to assess the nutritional value;
- 6. **NEW** The commitment to carry out frequent analyses of the product at varying times and to make the results available to the Service;
- 7. **Proof of payment** of a fee per notified product in pre-measured form to the account of the Raw Materials and Products Budget Fund in accordance with Article 10, § 1, of the Royal Decree of 13 November 2011 setting the fees and contributions due to the Raw Materials and Products Budget Fund. (€295)





# Notification: what Belgian law says...

~~Within 30 days, the Service sends an acknowledgement of receipt to the applicant.~~

~~The acknowledgement of receipt includes a notification number.~~

**NEW** => Within 90 days, the Service may make comments and recommendations, including adapting the labelling, in particular by requiring warnings to be included.





# Notification: what Belgian law says...

**NEW: NO NUMBER IS ASSIGNED IN CASE OF (!):**

ILLEGAL!  
BE-SUP asks  
annulment  
RVS/CE

- 🍃 **Doubt about the status of the product**
- 🍃 **Claims attributing to the product properties of prevention, treatment or cure of a disease or evoking similar properties**  
→ **Opinion requested from the Borderline Commission (FAMHP - Federal Medicines Agency)**
- 🍃 **Food supplements for children < 3 years old**
- 🍃 **Doubt about product safety**  
→ **Opinion requested from advisory bodies such as the Plant Advisory Commission or the Superior Council of Health**





# What the law says <> what the Belgian authorities require (FOODSUP notification)

## Major divergences between:

- 🍃 What the European legislator is asking for: cf. EU Framework Directive 2002/46
- 🍃 What the Belgian legislator is asking for: cf. Royal Decrees (nutrients, plants, other substances)
- 🍃 What the FPS Health is asking for (notification unit, FOODSUP notification)  
=> "Inventions" of the Belgian administration: examples:
  - Temporary numbers a, b and d (NEW: the number "c" no longer exists)
  - The Five-Year Voluntary Update





# The Belgian notification procedure

🍃 **A little reminder: the administrative rules since the end of 2019: is considered a "new product" (and therefore requires a new notification):**

- Product Name Change
- Change in the quantity of one or more ingredients

🍃 **For the following changes, a new notification is NOT required:**

- Additive
- Aroma
- Chemical form of the nutrient



Merci  
be-sup!





# The Belgian notification procedure: the d code

**FAQ (website FPS Health = Belgian Ministry of Health) Version 11 04 2025**

***39. My file has been given a number with a code (d) and appears with a hazard symbol on the public list of notified products, what does this mean?***

*If a file has been given a number with a code (d), this means that at least one serious violation of food law has been detected on the basis of the administrative file.*

*This is the case when the product contains a prohibited ingredient, or substances or additives in quantities higher than the maximum permitted value.*

*The product cannot be made available to the consumer until it has been brought into compliance.*

*Compliance must be notified to the FPS via a file amendment.*





# The Belgian notification procedure: code b

***FAQ (website FPS Health = Belgian Ministry of Health) Version 11 04 2025***

***40. My file has been assigned a code (b), what does that mean?***

*If a file has been given a code (b), it means that the file is incomplete, either because the mandatory information to be provided has not been sent, or because the file requires a study by an advisory body, for example  
Advisory body: Plant Advisory Commission or Superior Health Council*





# The Belgian notification procedure: the code

a

**FAQ (website FPS Health = Belgian Ministry of Health) Version 11 04 2025**

***41. My file has been given a code (a), what does that mean?***

*If a dossier has been given a code (a), it means that the product does not comply with the legislation on food supplements or fortified foodstuffs and therefore cannot be placed on the market under one of these two statuses*

*= Classification as a medicine*





# Voluntary update for products > 5 years

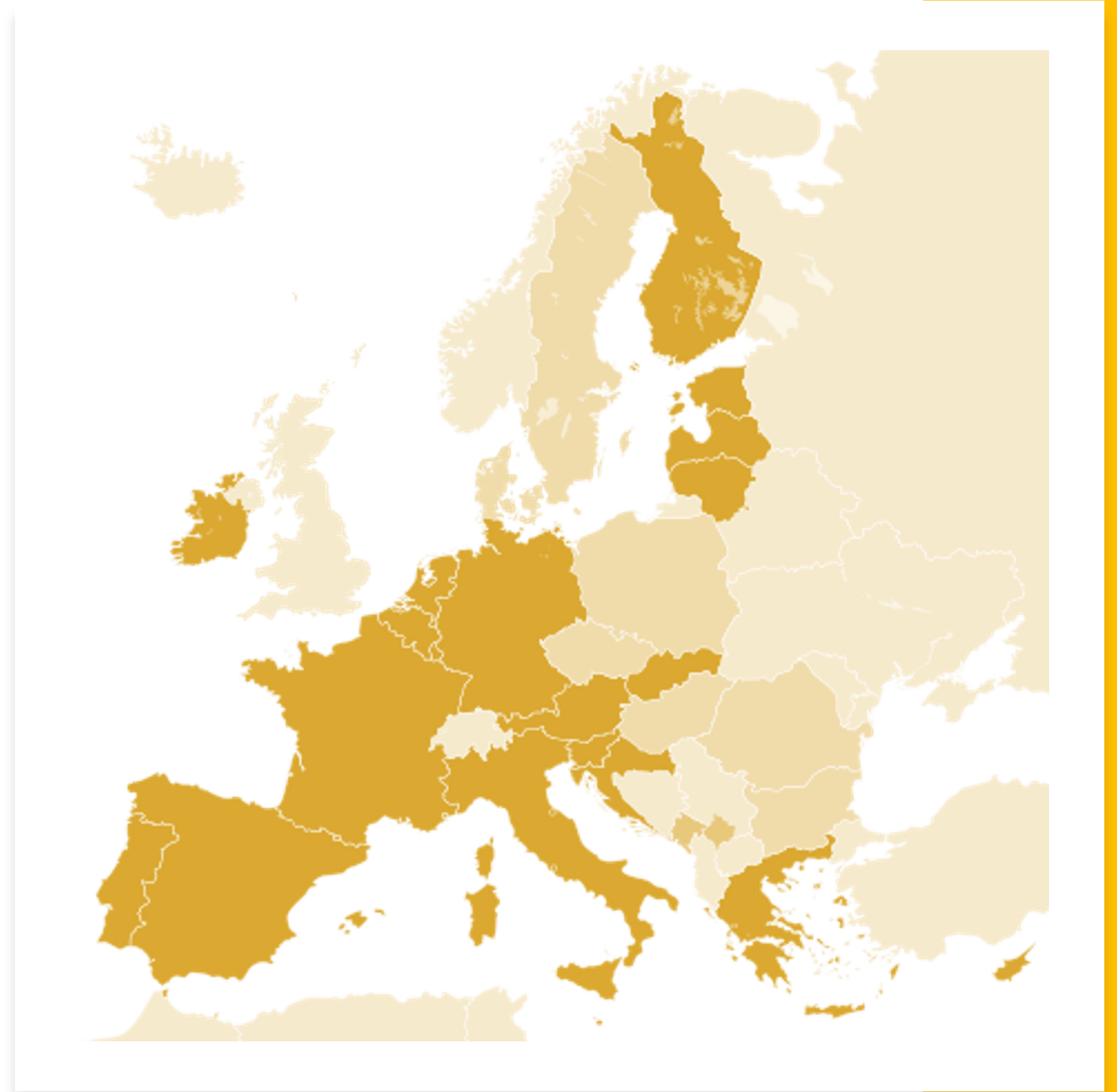
## Possibility to extend the visibility of products in the public FOODSUP database

- 🌿 Voluntary/non-compulsory (!)
- 🌿 Automatic reminder: 6 months before the end of the 5-year period
- 🌿 Choice between:
  - Extension without amendments
  - Amendments (if changes are required)
  - Products < 10/2012: only "modification" is possible.
- 🌿 Attention: new assessment by the notification service of the FPS Health!!
- 🌿 Sanction





# Current developments at EU level





# Harmonisation maximum levels vitamins & minerals



# Harmonisation maximum levels vitamins & minerals

- 🌿 Required by the 'Food Supplements Directive' (2002/46/EC), Article 5
- 🌿 Task Force of certain MSs (incl. BE)
- 🌿 EFSA was mandated to reassess the tolerable upper intake levels (UL) for vitamins & minerals
- 🌿 Several meetings in 2024
- 🌿 2025: draft regulatory proposal on the table
- 🌿 No transparency: EU COM asked MS not to communicate with stakeholders





# minerals: EFSA has completed work on ULs

<b>COPPER</b>	<a href="#">EFSA opinion</a> published 17 Jan 2023
<b>SELENIUM</b>	<a href="#">EFSA opinion</a> published 20 Jan 2023
<b>VITAMIN B6</b>	<a href="#">EFSA opinion</a> published 17 May 2023
<b>VITAMIN D</b>	<a href="#">EFSA opinion</a> published 8 Aug 2023
<b>FOLIC ACID/FOLATE</b>	<a href="#">EFSA opinion</a> published 9 Nov 2023
<b>MANGANESE</b>	<a href="https://www.efsa.europa.eu/sites/default/files/2024-05/ul-summary-report.pdf">https://www.efsa.europa.eu/sites/default/files/2024-05/ul-summary-report.pdf</a> <a href="#">EFSA opinion</a> published 8 Dec 2023





# Harmonisation maximum levels vitamins & minerals

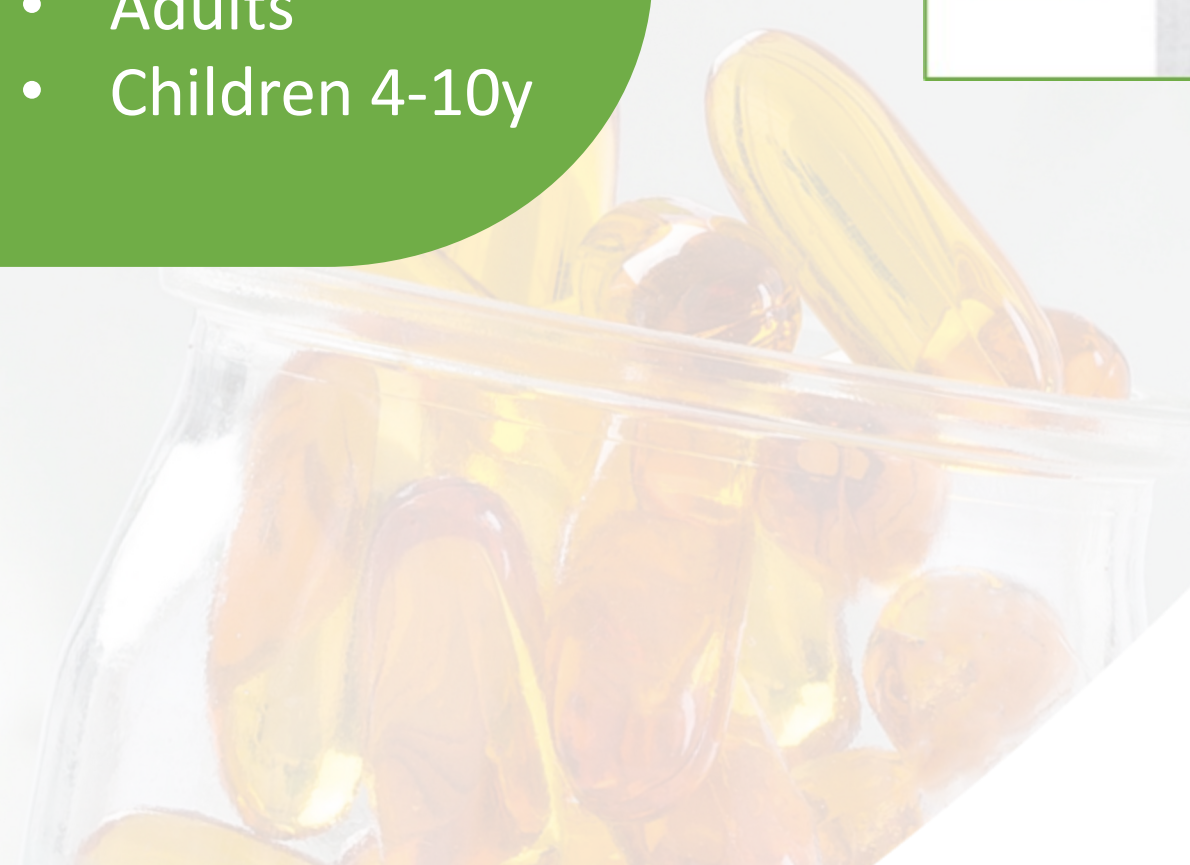
## EHPM model

-  Presented to DG SANTE and 6 National Authorities in BE, EL, IE, IT, NL, PT
-  Alignment between EHPM and FSE models: 1 voice of the EU industry

Group 1	Group 2	Group 3
<b>No risk identified:</b> No MPL proposed	<b>Low risk:</b> MPL proposed	<b>Higher risk for particular groups:</b> MPL proposed
Vitamin B1	Nicotinamide	Preformed retinol
Vitamin B2	Vitamin B6	Calcium
Biotin	Folic acid	Copper
Vitamin B12	Vitamin C	Fluoride
Pantothenic acid	Vitamin D	Iodine
Vitamin K	Vitamin E	Iron
Chromium	Magnesium	Manganese
	Molybdenum	Zinc
	Phosphorus	β-Carotene
	Selenium	Boron
	Potassium	

2 levels:

- Adults
- Children 4-10y





# Harmonisation maximum levels vitamins & minerals

- 🌿 First proposal: very restrictive: lower than [BfR model](#) (D)
- 🌿 Advocacy action EHPM, be-sup and sister associations in the EU
- 🌿 Letter to MEPs with our concerns and requests:
  - **No safety concerns** that justify a rushed decision
  - **Lack of transparency** of the process
  - **Well-functioning national approaches** should be taken into account
  - An **impact assessment** should be conducted
  - **Consumers will be impacted** negatively by a restrictive approach
- 🌿 Second proposal: leaked draft : some better...





# Information about the proposed methodology

🌿 At the Euroforum Conference on Food Supplements (November 2024), the German BfLM outlined the methodology:

- Formula:  $R = UL - P95$ 
  - UL (Upper Level): Basis set by EFSA.
  - P-95: Accounts for nutrient intake from food by 95th percentile of population.
  - R (Remaining value): Distributed between food supplements and fortified foods 1:1.

🌿 Very low values for: **Zinc, Iron, Magnesium, Calcium, Vitamin D, beta-carotene**





# Main concerns draft proposal

- Unrealistic 50/50 Distribution of the Remaining Value (R) between food supplements and fortified foods!
- Assumes maximum intake from all sources (food, fortified foods, and supplements) over an entire lifespan.
- The impact on vulnerable populations has not been considered.
- EFSA's Upper Levels (ULs) are treated as **absolute** limits.
  - This ignores built-in safety factors and real-world dietary intake variations.
- Children's intake levels assumed sufficient for adults, ignoring age-specific needs.**
- Maximum levels for children (3-10 years) applied to adolescents (up to 18 years)**
- Ignores increased nutrient needs during adolescence & adulthood.
- EFSA recognizes adolescents (10-17 years) as a distinct group, but this is overlooked.
- Fails to assess data quality, robustness, and representativeness across all Member States.





# Harmonisation maximum levels vitamins & minerals

- 🌿 Alignment FDE/SNE/EHPM/FSE/AESGP “Speak with 1 strong voice”  
Joined meetings 04/03/25 and 07/10/25
- 🌿 Economic impact assessment EHPM/FSE
- 🌿 EU COM confirmed: 2<sup>nd</sup> model still on the table but too premature to discuss
- 🌿 Next meeting EU COM and MS: to be confirmed
- 🌿 Consultation with stakeholders: expected in 2026? (To be confirmed)





# The so-called "Article 8" files



# Article 8 files

## What is article 8 of R EU 1925/2006?

🍃 **Safety procedure** that can be triggered if safety concerns arise with an ingredient by:

- Member State
- European Commission

🍃 3 regulatory options: the ingredient can be:

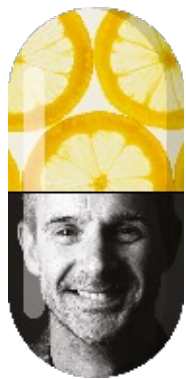
- a. **Banned.** Part **A** of Annex III of the Regulation
- b. **Restricted: e.g: maximum level:** Part **B** of Annex III
- c. **Placed under « scrutiny »:** Part **C** of Annex III

🍃 Industry has 24 months to prove security by scientific studies.

🍃 **EU COM should take a decision within 4 years :**

- authorisation, restriction or ban**



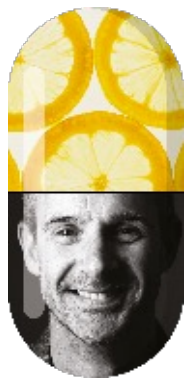


# Article 8 files

## Article 8 was activated for:

- 🌿 **Monacolines** in red yeast rice,
- 🌿 Extracts of **green tea** containing EGCG,
- 🌿 Hydroxyanthracene derivatives (**HAD**) (Aloe, Rheum, Senna, Cassia),
- 🌿 Alpha lipoic acid (**ALA**),
- 🌿 Preparations of botanicals containing **HCA** (hydroxycitric acid),
- 🌿 Botanicals containing **berberine**
- 🌿 **Fennel**: bitter and sweet





# Hydroxy Anthracene Derivatives (HAD)



## Regulation (EU) 2021/468 of 18 March 2021

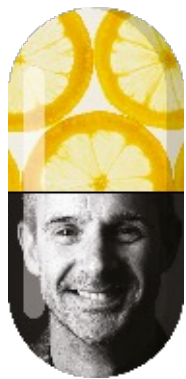
**(1) BAN:** in Part A, the following entries are added in alphabetical order:

- (1) '**aloe-emodin** and all **preparations** in which this substance is present';
- (2) '**emodin** and all preparations in which this substance is present';
- (3) 'preparations from the leaf of **Aloe species containing hydroxyanthracene derivatives**';
- (4) '**danthron** and all preparations in which this substance is present'.

**(2) SCRUTINY:** in Part C, the following entries are added in alphabetical order:

- (1) 'preparations from the root or rhizome of **Rheum palmatum L., Rheum officinale Baillon** and their hybrids containing hydroxyanthracene derivatives';
- (2) 'preparations from the leaf or fruit of **Cassia senna L.** containing hydroxyanthracene derivatives';
- (3) 'preparations from the bark of **Rhamnus frangula L., Rhamnus purshiana DC.** containing hydroxyanthracene derivatives'.





# Hydroxy Anthracene Derivatives (HADs)



🍃 **Annulment of Regulation (EU) 2021/468**

🍃 Court case European Court of Justice: **Synadiet and be-sup**

🍃 ECJ grouped all the court cases about HAD in 1 case: other cases from Ortis, Forever Living and Aboca

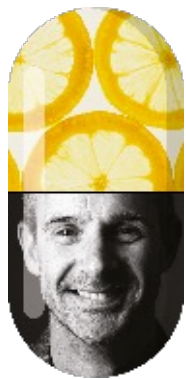
🍃 **Legal Basis for the Annulment**

= **Misapplication of Article 8** of Regulation (EC) No 1925/2006.

- 1. Lack of Evidence on Excessive Intake:** The European Commission did not prove that HADs lead to significantly high intake levels under normal conditions.
- 2. No Public Health Risk:** EFSA's 2017 opinion concluded no risk to public health under normal consumption.

**Key Arguments:** Paragraphs **78 and 79** of the judgment can be cited against national recall orders for HAD-containing products.

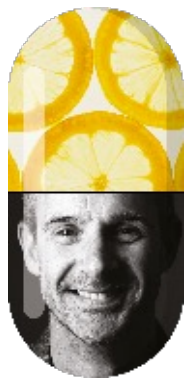




# European Commission appeals against HAD case

- 🍃 *European Commission's Appeal Against the Annulment of Regulation (EU) 2021/468 dd 13/11/2024*
- 🍃 The European Commission (EC) has lodged an appeal against the 4 rulings of the EU General Court that annulled Regulation (EU) 2021/468. (Synadiet & be-sup court case + 3 other court cases: Ortis, Forever Living and Aboca)
- 🍃 **The annulment is suspended pending the ruling of the Court of Justice.**
- 🍃 The suspension means that Regulation (EU) 2021/468 remains in force until the Court of Justice rules.
  - Part A (Banned): Aloe-emodin, emodin, danthron, and preparations containing these substances.
  - Part C (Scrutiny): Preparations from Rheum, Cassia senna, Rhamnus frangula, and Rhamnus purshiana under additional scrutiny.
  - **EU COM informed EHPM that they do not plan to launch the ban before the ending of the appeal procedure**
  - **EU COM informed EHPM that member states can forbid HADs based on the EFSA advice => de facto ban 😞**
  - **"Products ready for use after preparation in accordance with the manufacturer's instructions **containing an analysed level higher than or equal to 1 ppm aloe-emodin and/or 1 ppm emodin and/or 1 ppm aloin A + aloin B** provide clear evidence of presence of these substances in the products and are therefore of **concern for public health.**"**



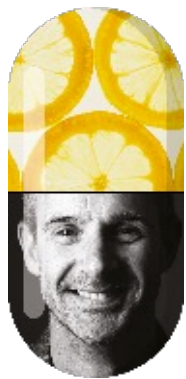


# European Commission appeals against HAD case

## Strategic Intentions of the EC

- 🌿 The EC may be using the appeal as a strategic move.
- 🌿 The EC is expected to submit a regulatory proposal on **alpha-lipoic acid** soon
- 🌿 The EC is expected to submit a regulatory proposal to **ban** the **HAD**-containing preparations in part C (according to the article 8 timeline, this should be done in the 1st semester of 2025, but the EC confirmed to EHPM that they will wait the issue of the appeal procedure)
- 🌿 EFSA is expected to publish safety conclusions end of 2025 on other Article 8 dossiers:
  - Berberine, bitter and sweet fennel, plants containing hydroxycitric acid (HCA).
- 🌿 HOA (Heads of Agencies) report: 1st phase – article 8 activated for 12 botanicals and substances





# Monacolins in Red Yeast Rice/RYR



## Reg. (EU) 2022/860 (01/06/2022)

- **Restriction** < 3 mg monacolins /day and warnings on the label
- **Scrutiny:** 21/06/2022 + 24 months to provide safety data = end date 21/06/2024

Project EHPM to prove safety submitted to EFSA:

- Collaboration University Bologna
- 12 companies in 3 countries: BE, IT, NL

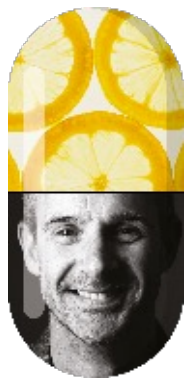
**EFSA concluded assessment of studies submitted during scrutiny**

Publication 28/02/2025: negative 😞 <https://www.efsa.europa.eu/en/efsajournal/pub/9276>

 **Decision EC: < 21/06/2026**

 **EC wants to ban Monacolins but should grant a transition period (↔ article 8 regulation)**





# Green tea extracts containing ECGC



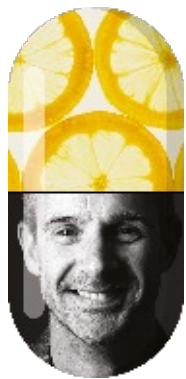
[R \(EU\) 2022/2340 \(30/11/2022\)](#)

## Restriction + warnings :

- in **PART B – RESTRICTED SUBSTANCES** of Annex III of Reg. (EC) 1925/2006: subjecting it to the following **condition of use**: *“Daily portion of food shall contain **less than 800 mg of (-)-epigallocatechin-3- gallate\***”*
- Additional requirements: the label shall provide the maximum numbers of portions of the food for daily consumption and a warning not to consume a daily amount of 800 mg of (-)-epigallocatechin-3- gallate or more.*
- The label shall indicate the content of (-)-epigallocatechin-3- gallate per portion of food.*
- The label shall include the following **warnings**:*
  - Should not be consumed if you are consuming other products containing green tea on the same day*
  - Should not be consumed by pregnant or lactating women and children below 18 years old*
  - Should not be consumed on an empty stomach*

**\* Excluding aqueous green tea extracts containing (-)-epigallocatechin-3- gallate which after reconstitution in beverages have a composition comparable to that of traditional green tea infusions**





# Green tea extracts containing EGCG



- Scrutiny : no safety data has been submitted
- EC wants to ban green tea!
- Disproportionate and challengeable at legal level
- ↔ Novel Foods autorisation

Epigallocatechin gallate as a purified extract from green tea leaves ( <i>Camellia sinensis</i> )	Specified food category	Maximum levels	The labelling shall bear a statement that consumers should not consume more than 300 mg of extract per day
	Food Supplements as defined in Directive 2002/46/EC	150 mg of extract in one portion of food or food supplement	
	Foods fortified in accordance with Regulation (EC) No 1925/2006		

Decision EC < 19/12/2026





# Alpha Lipoic Acid (ALA)

🌿 Initiative article 8 procedure: by Denmark

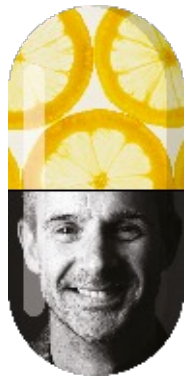
🌿 EFSA advice June 2021

- No safe dose can be established
- Problem: insulin autoimmune syndrome (IAS), also known as Hirata syndrome.
- Extremely rare in the European population (susceptibility by genetic polymorphism in Asian population)

🌿 **EC proposed first to place ALA in part A of ANNEX III to ban the use of ALA in food supplements**

🌿 **NEW: EC would now rather propose « scrutiny » (To be confirmed)**

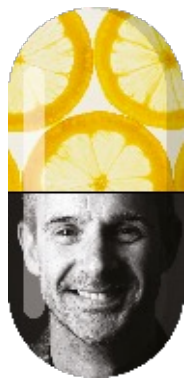




# Preparations of botanicals containing HCA (hydroxycitric acid)

- Ex: *Garcinia gummi-gutta* (*Garcinia cambogia*)
- Article 8 procedure initiated by Spain
- EFSA assessment ongoing
- Deadline: ~~15/05/2025~~ postponed
  - ~~December 2025~~ postponed
  - 31/03/2026

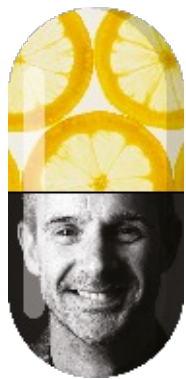




# Berberine

- Article 8 procedure asked by France
- EFSA assessment ongoing
- Deadline: ~~15/05/2025~~ postponed
  - ~~September 2025~~ postponed
  - 30/04/2026





# Sweet and Bitter Fennel

- Article 8 procedure asked by Germany
- EFSA assessment: ongoing
- Deadline ~~15/05/2025~~ postponed
  - ~~December 2025~~ postponed
  - 31/01/2026





# Heads of Agencies (HOA) report



# Rapport HOA: Status November 2025

## Priority substances:

1. *Coumarin in plant preparations*
2. *Curcumin in Curcuma spp. preparations*
3. *Hypericum perforatum*
4. *Melaleuca spp. essential oils*
5. *Piperine*
6. *p-Synephrine in Citrus spp. Preparations*
7. *Tryptophan*
8. *Actaea racemosa*
8. *Lepidium meyenii*
9. *Ocimum tenuiflorum*
10. *Tribulus terrestris*
11. *Withania somnifera*

## COM EU:

- Asked EFSA for a preliminary study
- Sent EFSA's questions to authorities D and NL





# Current developments in Belgium





# **New royal decree to replace royal decrees NUT/PL/AS**

Entry into force, implications and actions



# What is new?

1. The FPS wants to unilaterally change the **European definition** for "food supplements" by removing the words "concentrated source" from the definition
2. The FPS wants to grant itself the **right to refuse notification numbers**
3. The FPS **does not want Belgian notification numbers to be used in the context of an application for mutual recognition** (MUT REC)
4. The FPS wants to make **food supplements for children** compulsorily subject to the opinion of the **Superior Health Council (CSS/HGR)**
5. The FPS wants **essential oils in capsules** to be compulsorily "approved" by the Plant Advisory Committee





# Legal analysis: important infringements

- 🍃 Hampering the **free movement of food supplements** in Belgium and the EU through additional restrictions.
- 🍃 **Unilateral modification** of the **EU definition** of food supplements
- 🍃 A notification system that increasingly resembles a **marketing authorisation procedure**, contrary to the provisions of the EU directive.
- 🍃 **New requirements**, such as the obligation to carry out frequent analyses, make the notification procedure more complex, creating **obstacles** for both Belgian and foreign manufacturers.
- 🍃 Contrary to the principle **of mutual recognition** of goods between Member States.





# New Royal Decree replacing the RD on nutrients, botanicals and substances

## Be-sup asked annulment state council

- Be-sup gave the mandate to our lawyers to file an annulment demand with the Council of State. (<60 days after publication)
- Gregory Sorreaux (Thales) + specialized lawyer in administration law, Fabien Hans.
- Significant financial commitment for be-sup, but a crucial step to protect our member's interests.
- FEVIA** joined our court case (for fortified nutrition)
- Timeline Council of State annulment action:**
  - An opinion from the auditor is expected in the **first half of 2026**.
  - Annulment could take place in the **second half of 2026**.
  - During the procedure, the Royal Decree remains into force...**





**Use of German on labels:**

**Last call! Be ready for the  
1st January 2026**





# The use of German on the labelling of food supplements

- 🍃 **The legislation (Law of 24 January 1977) states:**
- 🍃 "The information appearing on the label, which is compulsorily prescribed in implementation of this law, shall at least be in the language or languages of the language area where the products are made available on the market."
- 🍃 The language on the label of a food product must correspond to the language of the community where the product is sold, in other words:
  - Bilingual (French/Dutch) in the Brussels region
  - Dutch in Flanders
  - French in Wallonia (except in the German-speaking community)
  - German in the German-speaking community (**Eupen, Kelmis, Lontzen, Raeren, Amel, Büllingen, Burg-Reuland, Bütgenbach, Sankt Vith**)
- 🍃 **BUT: While transposing the FIC legislation, an error happened which left a gap in the legislation. FAVV/AFSCA could not enforce the law as a result.**





# Correction of the legal flaw: 22/09/22

- 🌿 Law published on 22/09/2022
- 🌿 The law on the use of languages of 24 January 1977 remains applicable
- 🌿 The next amendments are made:
- 🌿 Former Art. 8. [§ 1.]

The information appearing on the **label** that is compulsorily prescribed in implementation of this law shall be written at least in the language or languages of the language area where the products are made available on the market

- 🌿 **New Art. 8. [§ 1.]**

The information which appears on **the labelling** and which is compulsorily prescribed in implementation of this law or by the relevant European regulations and decisions or decrees shall be written at least in the language or languages of the language area where the products are made available on the market





# Tolerance period: no fines (but controls possible)

- Use of languages = sensitive issue
- No transitional period, but a “tolerance period” - tolerance period was extended until the end of **2025!**
- Thanks to the joined advocacy of Fevia/**be-sup** and Comeos
- Tolerance period: controls possible, no fines





# Practical solutions

## Peel off labels are accepted

- Expensive
  - Not sustainable (PPWR-compliant ???)
  - “For German, see inside”

## QR-codes?

- Task Force Minister Clarinval
- Legal services cabinet: “QR-codes are not a legal solution” 😞

## Outer packaging

- **All mandatory indications must be on the outer packaging.** Except for the use-by date (R EU 1169/2011: Annex X, 2, d), there is no specific regulatory provision regarding the information to be repeated on the inner packaging.
- **Therefore, for a product sold in the German-speaking area, German is mandatory for all mandatory information on the outer packaging.**





# What will happen in practice on 01/01/2026?

- 🍃 **Until 31/12/2025:** controls by FAVV/AFSCA are possible, but no fines (Be-sup received written confirmation from FAVV/AFSCA)
- 🍃 **As from 01/01/2026:**
  - 🍃 Controls (sensitive issue + 3 years “tolerance period”)
  - 🍃 Labels will have to mention German (if POS in German speaking region)
  - 🍃 Recalls? No, no food safety issue
  - 🍃 Withdrawals: possible.
  - 🍃 Advice: contact FAVV to show goodwill (i.e. new labels provide German information)





# Nutrivigilance scheme



# Nutrivigilance

🍃 The Belgian NUTRIVIGILANCE scheme was launched on 11 January 2024

🍃 General information on the FOD/SPF website: click [here](#)

🍃 Royal Decrees (published in December 2023)

[Notification of adverse reactions linked to the use of foodstuffs](#)

[Nutrivigilance Commission](#)

🍃 Forms for reporting adverse reactions :

[Reporting undesirable effects online](#)

[Reporting undesirable effects via PDF](#)

If reporting via PDF: e-mail: [nutrivigilance@health.fgov.be](mailto:nutrivigilance@health.fgov.be)



# Nutrivigilance

- ✔ Nutrivigilance is a food vigilance system managed by the FPS Public Health
- ✔ Main objective: to **protect consumer health** by rapidly identifying undesirable effects linked to the consumption of certain foodstuffs.
- ✔ Types of food covered: **food supplements - fortified foods - foods intended for specific groups - novel foods.**
- ✔ Reporting adverse reactions is **compulsory for operators**
- ✔ The report must concern **products purchased on Belgian territory (also valid for products purchased on the Internet and received in Belgium).**
- ✔ Operators must report **ALL adverse reactions, regardless of their nature or degree of seriousness.**





# Our concerns

- 🌿 Lack of methodology to assess the admissibility, analyzability, and assignability of a case
- 🌿 No scale to evaluate the severity
- 🌿 Absence of methodology to determine causality
- 🌿 Risk that a "light" nutriviigilance system undermines the objectivity and usefulness/purpose of nutriviigilance
- 🌿 Risk of misuse/abuse: a single case could be enough to trigger risk management measures, such as dosage reduction or prohibition, for an entire category of ingredients.





# Nutrivigilance Commission

- Established, but still not complete (no publication in Belgisch Staatsblad/ Moniteur belge until Commission will be complete)
- Members of the Commission are evaluating the different methodologies and will decide upon which system to use





# Nutrivigilance: How are the received cases treated?

- 🌿 FOD/SPF receives a case.
  - If from a company: it is dealt with
  - If not from a company (operator, citizen, hcp): FOD/SPF informs the company that they have received a case and additional information may be requested.
- 🌿 Is the file complete?
- 🌿 Has the FS been notified? If not, FAVV/AFSCA is informed.
- 🌿 If problem: Superior Council for Health or Advisory Board for Botanicals will be asked for advice
- 🌿 Before taking risk management measures, the industry will be consulted
- 🌿 For the moment: no alarming problems with a product or ingredient.





# Nutrivigilance: Reporting of cases

- Frequency: 1 x year
- Click [here](#) to download the report





# Other actual topics

Contaminants

Additives

Guidelines for  
influencer marketing

Scientific  
substantiation

Mutual recognition

G-011 Guide for GMP  
and autocontrol system

Food Safety  
Culture

Food Safety  
Culture

SUP Directive  
MOSH/MOAH

Unit pricing

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