Understanding Food Supplements Regulations

Key Insights & Industry Support

THE VOICE OF UK NATURAL HEALTH

16 April 2025

Agenda

Industry Support

- Introduction to the HFMA
- HFMA Services to support health food industry
- Membership benefits

Key Insights

- Ashwagandha
- ‘Not for EU’ Labelling
- Article 8
- Novel Foods
  - New & Updated Entries
  - Consultations
  - EU vs UK Status (Examples)

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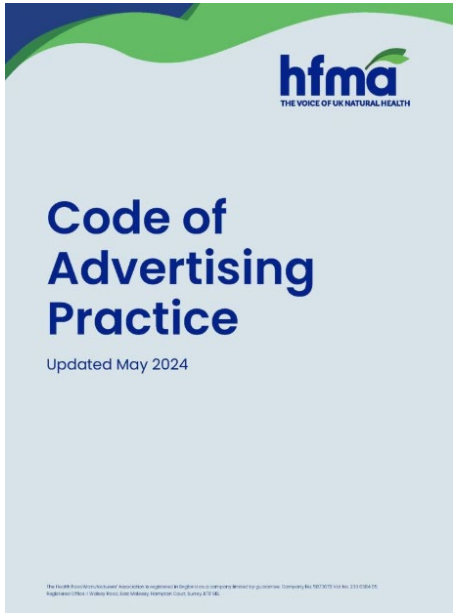
THE VOICE OF UK NATURAL HEALTH

Industry Support

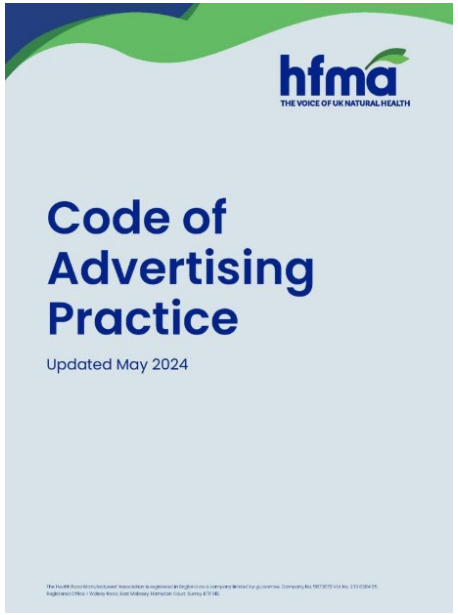
Who are we?

The Health Food Manufacturers Association (HFMA) is the **UK's leading voice for the health food industry**



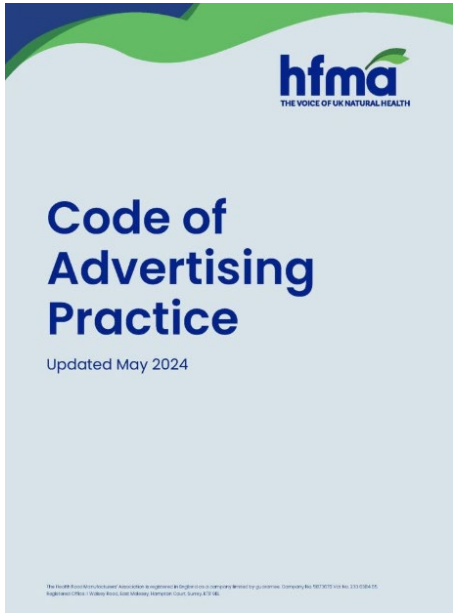
Who are we?

Founded in 1965, HFMA represents **UK manufacturers and suppliers of specialist health products**, advocating for industry interests and public health improvement through its 120 member companies



Who are we?

HFMA operates democratically with fair, turnover-based subscriptions, providing members with advice, **promoting quality standards**, and ensuring **positive public relations and education**



ehpm
European Federation of Associations of Health Products Manufacturers

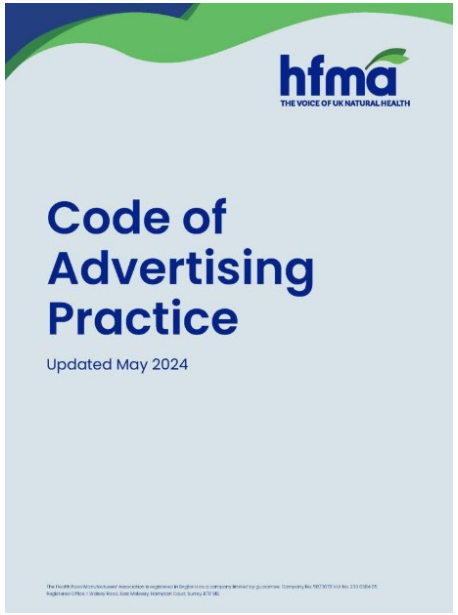
PRIMARY AUTHORITY PARTNERSHIP WITH
Buckinghamshire&Surrey trading standards

healthstoresUK

HEALTH FOOD INSTITUTE

Who are we?

HFMA leads in representing the natural health products industry, engaging with key UK and European decision-makers to advocate for industry interest & Representation through regular dialogue, negotiation and relationships with legislators (government, parliamentarians), regulators (DEFRA, MHRA) and enforcement agencies (FSA, CAP/ASA)



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HEALTH FOOD INSTITUTE

Member Benefits

INFORM

Mailouts & Bulletins

Frequent e-mail alerts and updates direct to your business

Website

Information-rich, password-protected Members' section

Webinars & Networking seminars

On current issues with internal and external experts

Media summaries & Research Updates

REPRESENTATION & EDUCATION

Representation

Through regular dialogue & relationships with legislators, regulators & enforcement agencies

Initiatives

Legal opinions, legal action, public petitions etc. have been used to achieve member industry objectives

Expert advice

Through on-demand Technical and Regulatory support with short queries by email, telephone or video call

Member Benefits

CLEAR CHECK

CLEAR CHECK

CLEAR CHECK specialized, and highly cost-effective service is Primary Authority-accredited

Members Rate

Label renewal service for longstanding members with a 20% reduction on member rates

New Members

New members are credited two free hours with our CLEAR CHECK service

HFMA's Code & Guidance Notes

SUPPORT

Regulatory Complaint Procedure

Issue resolution including the RCP to handle concerns confidentially and internally

Expert Resources

Political, scientific, technical advisers, & key partnerships and active international involvement through EHPM and IADSA

Events

A regular programme of practical, educational events

HFMA's General Principles & Role in Regulatory Engagement

- HFMA acknowledges that authorities set and enforce the law
- HFMA helps members navigate regulations, as seen in ClearCheck's guidance notes; an inherent membership benefit
- HFMA seeks clarity from authorities and updates members on regulatory changes
- Medicinal Judgements: Assessed case-by-case
- Intervention Policy: HFMA intervenes with authorities only on broader industry issues

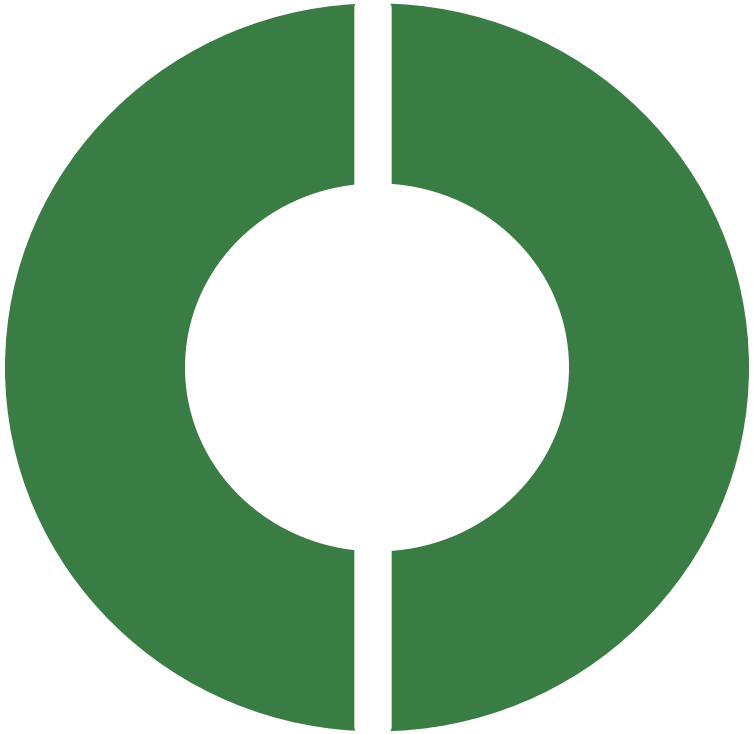
Key Insights

Ashwagandha
Novel Food Status

Non-concentrated aqueous infusion from the roots

Not novel in food*

Evidence that a significant history of consumption as a food in the UK/EU prior to 15 May 1997



All plant parts

Not novel in food supplements*

Novel food in other food categories*

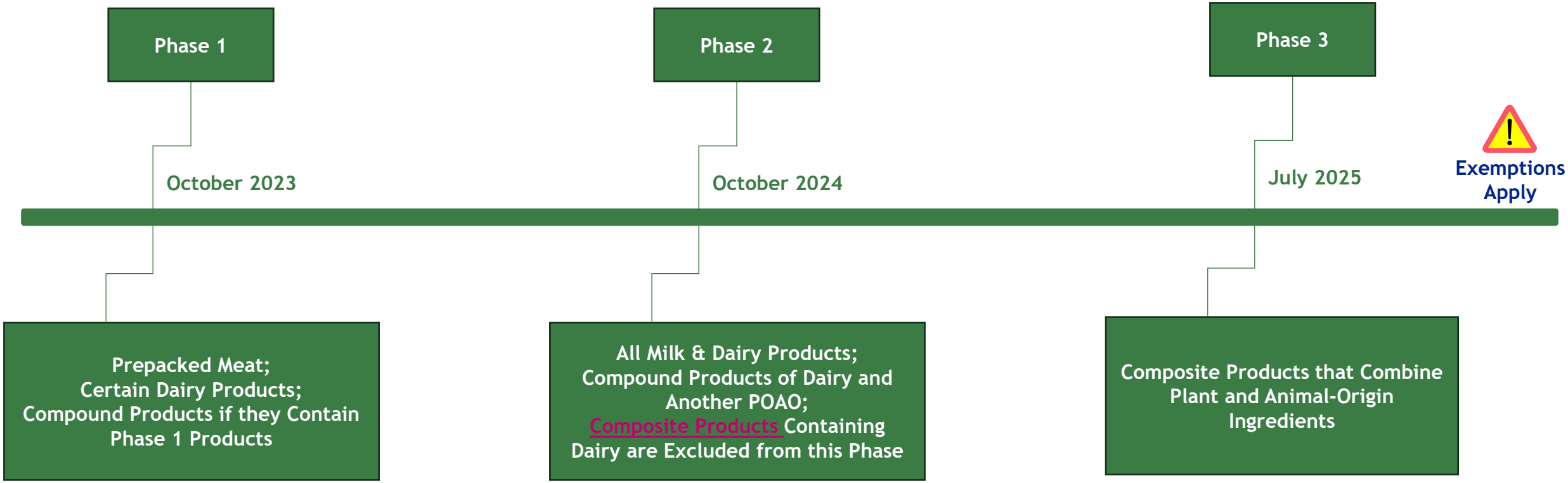
**possible other EU or national restrictions*

Ashwagandha

UK vs EU Developments

UK	EU
FSA Call for Evidence (July-September 2024) Launched to assess risks and determine potential safe levels for ashwagandha in food supplements	**Potential Article 8 Listing (June 2024)** A report from the HoA Food Supplements Working Group identified *Withania somnifera* as a candidate for restrictions under Regulation 1925/2006
HFMA's Involvement (October 2024) Collected anonymous data from members, provided safety and scientific research to support FSA's assessment	**Dutch Proposal (February-March 2025)** The Netherlands proposed a national ban on ashwagandha, with public consultation open until 24 March 2025
Current Status FSA is reviewing submitted data, with a risk assessment planned for February 2025 No established safe levels in the UK No confirmation on a final report, but possible follow-up after the risk assessment	**EHPM & HFMA Action (March 2025)** HFMA supported EHPM's request for safety data collection EHPM is considering a statement urging national authorities to pause restrictions until an EU-wide decision is made Industry stakeholders were asked to submit safety data by 12 March 2025

‘Not for EU’ Labelling



‘Not for EU’ Labelling Exemptions	Examples
All processed fruits & vegetables	Mixed fresh fruits, baked beans, salad boxes
Most dried fruit and vegetable products	Dried herbs & spices, vegetable crisps
All deregulated fruits in any form *except where a phytosanitary certificate is required*	Pineapples, bananas, dates
Most frozen products without POAO	Frozen fruits, frozen chips, ice lollies
Most spreads	Peanut butter, vegetables spreads
Table sauces and condiments	Mustard, vinegar, soy sauce
Grains, pulses and cereals	Quinoa, flour, bread mixes
Snacks	Crackers, popcorn, biscuits
Cooking oils	Olives oil, cooking sprays
Sugars & confectionary, sweets & chocolate products *including those containing milk*	Hot chocolate drinks and mixes, gelatine-based sweets
Most alcoholic and most non-alcoholic drinks	Gin, wine, soft drinks
All hot drinks that do not contain milk	Tea, coffee
Other products	All food supplements that are packaged for the final consumer, whether or not they contain any animal products (including whey-based supplements)

Article 8
Overview

Article 8 of Regulation (EC) 1925/2006 on the addition of vitamins, minerals and certain other substances to foodstuffs

Allows for classification of substances with safety concerns

Possible outcomes:

Prohibition (Annex III, Part A)

Restriction (Annex III, Part B)

Union scrutiny (Annex III, Part C)

Article 8
Substances likely moving towards prohibition (Part A)

Alpha-lipoic acid (ALA)

EFSA opinion (June 2021)

EC proposal: Ban without transition period

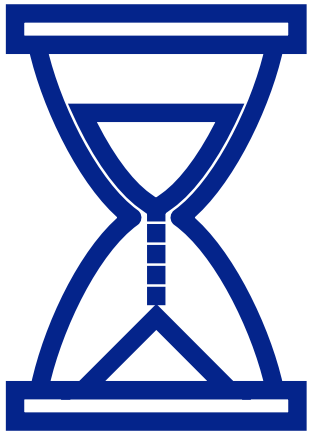
Possible final regulation by end of 2025

Monacolins from red yeast rice

Currently in part C (< 3 mg/day)

New EFSA opinion (Feb 2025)

High risk of full ban (Part A) decision within 1 year



Article 8
Substances awaiting regulatory decisions

Plant preparations with hydroxyanthracene derivatives (HAD)

Awaiting CJEU appeal decision (Jan 2025) before regulatory action

Green tea extracts (EGCG < 800 mg/day)

Currently in part C

No new data submitted

Decision expected within 2 years

Article 8
Ongoing EFSA evaluations (Opinions pending)

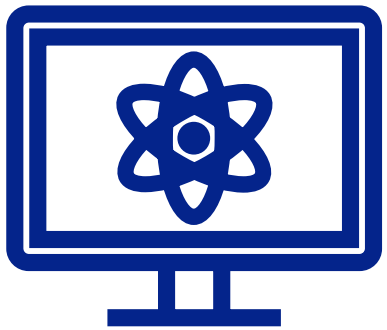
By September 2025

Berberine containing plant preparations

By December 2025

Hydroxycitric acid (HCA) & Garcinia Cambogia preparations

Sweet & bitter fennel preparations



Article 8
New upcoming EFSA mandates (June 2024 HoA report)

EFSA will assess safety under Article 8 for:

- Actaea racemosa
- Coumarin in plant preparations
- Curcumin in Curcuma spp. Preparations
- Hypericum perforatum
- Lepidium meyenii
- Melaleuca spp. essential oils
- Ocimum tenuiflorum
- Piperine
- P-Synephrine in Citrus spp.
- Tribulus terrestris
- Tryptophan
- Withania somnifera

Novel Foods

New & Updated Entries

Consultations

EU vs UK Status (Examples)

Novel Food Catalogue
New Entries

Ingredient	Status	Food Category
Native Guar Gum Form & Partially Hydrolysed Guar Gum	✅ Not Novel	🥄 Food Supplements 💊 Foods for Special Medical Purposes
	❌ Novel	🥦 Other Food Categories
Wax Gourd (Fruits of Benincasa hispida)	❌ Novel	🥦 All Food Categories
Calcidiol Monohydrate as a Source of Vitamin D	✅ Not Novel	🥄 Food Supplements ⚠️ Conditions Apply
Choline, Succinate (2:1) Salt Solution	✅ Not Novel	🥦 All Food Categories

Authorizations published after 1rst January 2021 (Brexit), may not be authorized in Great Britain

Novel Food Catalogue
Updated Entries

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Ingredient	Status	Food Category
Mumijo, Shilajit	✅ Not Novel	🥄 Food Supplements
	❌ Novel	🥦 Other Food Categories
Fruiting Body & Aqueous Extract Powder from the Fruiting Body of Chaga Mushroom	✅ Not Novel	🥄 Food Supplements
	❌ Novel	🥦 Other Food Categories
Fruiting Body & Aqueous Extract Powder from the Fruiting Body of Lion's Mane Mushroom	✅ Not Novel	🥦 All Food Categories
Dehydrated Mycelium Powder of Lion's Mane Mushroom	❌ Novel	🥦 All Food Categories

Note on Aqueous Extracts: The term aqueous extraction usually refers to water-based methods, and it would most likely mean that an ethanol/water extraction could be novel unless there is documented historical use of ethanol extraction prior to 15 May 1995

UK Regulatory Reform

Effective 1 April 2025, the UK introduced reforms to streamline the authorisation of regulated products (such as novel foods, additives, GMOs)

Aims to accelerate innovation and expand consumer choice without compromising food safety

Reform is part of the FSA and FSS strategy to create a more agile and efficient market authorisation system

Safety remains central: risk assessments still underpin decisions, and ministers in England, Wales, and Scotland retain the final say

UK Regulatory Reform

Key Changes Benefiting Novel Foods & Innovation:

No 10-year renewal required for authorisations of: Feed additives, Smoke flavourings, GMOs (including food/feed derived from them)

Products with long histories of safe use no longer need reassessment unless new risks arise

FSA/FSS can review authorisations at any time and act on new evidence

Authorisations now take effect after ministerial decision and are published in an online public register, replacing the need for legislation

This reduces delays, aligns with other UK regulators, and enhances transparency

EU Market Authorisation

Magnesium L-threonate

📌 Recent EU Authorisation

Approved on: 7 November 2024
Data protection: Until 7 November 2029 (proprietary data under **Article 26 of Regulation (EU) 2015/2283**)
Applicant: AIDP Inc., USA

🔎 Regulatory Conditions

Permitted in food supplements (Directive 2002/46/EC)
Maximum level of Magnesium: 250 mg/day
Restrictions: ⚠ Not for pregnant & lactating women

📌 EU Novel Food Catalogue Status

❌ **Still considered unauthorised**
Additional applications required for marketing beyond AIDP Inc.'s exclusive period

UK Novel Food Consultations

Magnesium L-threonate

📌 Current Status in the UK

Included in **FSA & FSS Consultation Pack on Market Authorisation** (Dec 2024)
Consultation closed: February 2025
Awaiting final outcome from UK authorities

📝 Application Details

Applicant: AIDP Inc., USA
Purpose: Use as a **novel food in food supplements**
Risk Analysis in Progress: FSA is assessing the impact before ministerial approval

🔎 Key Consideration

The UK decision is pending, with potential market authorisation upon approval

Regulatory Status of Saw Palmetto in the UK & EU

*Overview of its classification as a **food supplement vs. medicinal product***

*Differences in regulatory approaches across **UK, EU, and member states***

UK Status
Saw Palmetto

📌 UK Classification: Considered Medicinal by MHRA

MHRA Approach: Saw Palmetto is frequently deemed **a medicinal herb** if linked to medicinal claims

Impact on Sales:
Online platforms (e.g., **Amazon**) have removed/delisted products containing Saw Palmetto
Decisions are based on discussions between **Amazon and the MHRA**

MHRA's Case-by-Case Approach:
No official classification for the ingredient itself - only for finished products
Potential defense: A company must provide evidence that the **dose is sub-therapeutic** to justify food supplement use
High-risk herbs: MHRA has specifically categorized herbs like **valerian, black cohosh, and echinacea** as medicinal

🔎 Key Considerations

Any **on-pack claims** could impact MHRA's borderline decision
Companies should **consult the MHRA** borderline team for case-specific guidance:
📧 borderline_medicine@mhra.gov.uk

EU Status; EMA & Member States

Saw Palmetto

📌 **European Medicines Agency (EMA) Position**	**Saw Palmetto (*Serenoa repens*) is classified as a medicinal product** under: EMA Community Herbal Monograph Well-Established Use (WEU) Status **Permitted medicinal forms:** Soft extract (DER 7-11:1) Fatty acids (92%) & unsaponifiable part (2%) Dosage: 320 mg once daily or 160 mg twice daily
🔎 **Key Considerations**	Saw Palmetto **is not considered a novel food** but is categorized as a **medicinal product** under EMA guidelines

Saw Palmetto: EU Member States Variability

Country	Regulatory Status	Conditions & Warnings
Belgium	Authorized in Food Supplements	**Positive List (Royal Decree, updated 2025)** ✅ Must carry warning: *"Consult your physician or pharmacist"* ⚠ Liposoluble component intake ≤ **256 mg/day**
Italy	Authorized in Food Supplements	**Positive List (Decree, updated 2023)** ✅ Warning: *"Not recommended in women of child-bearing age & prepubertal children."* ⚠ Botanical claims regulated under **Annex 1 Decree of 10 August 2018**
Sweden	Typically Considered a Drug	🚫 **Swedish Medicines Agency (March 2023 Guide):** Saw Palmetto **usually classified as a medicinal product**

THANK YOU

Questions?

Get in touch: hfma@hfma.co.uk