ehpm
European Federation of Associations of Health Products Manufacturers

A Pragmatic Approach Towards The Regulation of Botanical Food Supplements

Overview

1. Botanicals
2. Basic Principles
3. Current Situation
4. Safety
    1. Quality standards
    2. Inventory of the products on the market
    3. Ingredients
    4. Possible approach
5. Health Claims
6. Conclusion

1. Botanicals

- Issues linked to food supplements to be addressed?
- What does the food supplement industry need to thrive?
- What do consumers need in order to be confident in our products?

2. Basic Principles

- Consumers need safe, effective and non-misleading products
- What does this mean?
    1. SAFETY: Safe and manufactured to high quality standards products
    2. HEALTH CLAIMS: Claimed benefits delivered

3. Current Situation

At EU Level:

- Regulation (EC) No 178/2002 → framework for food safety in general
- Directive 2002/46/EC → additional safety and labelling rules
- Regulation (EC) No 1925/2006 → other substances to foods
- Regulation (EC) No 1924/2006 → health and nutrition claims on labelling

4. Safety

4.1. Quality standard

- Rapid alert on FS only from imports from third countries (internet sales)
- Excellent safety record for the European FS industry thanks to national best practice & industry developed standards

→ A model for harmonization?

4. Safety

4.1. Quality standard

Examples of Best Practice

- EHPM Quality Guide
- Belgium: sectorial Quality Guide (NAREDI): reference standard for audit by authorities/certified auditors
  - Official licence needed for manufacturing supplements
- Poland: Self-Regulation system based on EHPM Quality Guide

→ Possible model: EHPM quality guide base for CEN Standard (European Committee for Standardization)?

4. Safety

4.2. Inventory of products on the market

- Optional notification system foreseen by Directive 2002/46/EC → applied differently by Member States

4. Safety

4.2. Inventory of products on the market

Examples:

- Some Member States have online systems for notification
- Some Member States have no notification procedure
- Belgium: test automated monitoring of internet sales to detect illegal products.

4. Safety

4.3. Ingredients

- Different systems for safety:
  - positive/negative list
  - case by case assessment

Some Examples:

1. BELFRIT List – Positive list developed in collaboration between authorities: Belgium, France & Italy, to be implemented into national law in each country

2. Germany: Stoffliste (informal) – 3 categories:
   - Not recommended (List A)
   - Permitted with conditions (List B)
   - Under Scrutiny (List C)

3. Some approaches (Belgium, France) include dosage rules that can help address borderline issues etc.

4. Safety

4.4. Possible Approach

- Regulation (EC) No 1925/2006: lists of substances that can be added to food (permitted, prohibited, under scrutiny)
- Similar approach legitimate for botanical food supplements?
  - Positive list: plants all MS agree can be used based on safety
  - Negative list: plants all MS agree are unsafe because of safety concerns
  - If no agreement by all MS:
    - Placed on "under scrutiny" list
    - National rules apply plus Regulation (EC) 764/2008 on **mutual recognition** until agreement is found

5. Health Claims

- The assessment of 2,000 botanical health claims is pending
- It is important to have a system that:
  - Ensure only credible claims are used
  - Is accessible to SMEs
- One does not exclude the other

5. Health Claims

- Need for a proportionate evidence based system that takes tradition into account
- Directive 2004/24/EC on herbal medicines accepts tradition of use as a factor in assessment
- Why accept tradition as:
  - proof of efficacy for the therapeutic effect of a medicine
  - NOT for the physiological effect of a food?
- Existing national best practice can provide the answer → many Member States already had functioning systems in place to control the use of health claims

5. Health Claims

- EFSA's model on clinical trials is not working resulting in reduced investment in innovation
- Disproportional decision: claims rejected despite trials showing benefits in majority of trial subjects

Examples:

- *Prune: bowel maintenance effect claim first rejected then approved following challenge*
- *Probiotics: many trials evidenced positive effect but claim still rejected*

→Rules could be created for different categories of claims to recognise tradition and allow for innovation by SMEs

→Need to adapt approach allowing for assessed-tradition based health benefits understood thanks to modern science.

5. Health Claims

- Industry is not seeking a free for all on botanicals health claims
- Assessment can include:
  - Identification of the history and tradition of use on the market for a specific health benefit
  - Review of existing recognitions by national authorities
  - High Quality Scientific Assessment based on a comprehensive review of the scientific literature:
    - Study of constituents for active substances;
    - Review of *In vitro* and *In vivo* studies into mode of action;
    - Critical Appraisal of Human Studies
- SMEs should be allowed to innovate

6. Conclusion

- New regulatory structure must work for consumers, regulators and industry
- Approach will be crucial for the future growth and development of the food supplement sector
- A solution may come from existing best practices
- EHPM will be an active and constructive partner:
  - In developing a pragmatic solution
  - Working for all parties