Food Supplement Regulation: EU Requirements and Commercial Realities in EU 28

Alban Maggiar
EHPM Chairman

8 May 2014

Presentation Objective

Highlight some of the issues faced by the Food Supplement Industry as a consequence of :

- The implementation of EU legislation
- The lack of implementation of EU legislation
- The absence of EU legislation

Presentation Overview

1. Introduction to EHPM
2. Key pieces of EU legislation
3. Issues due to implementation
4. Issues due to lack of implementation
5. Issues due to lack of legislation
6. The importance of effective industry representation in Brussels ?
7. Conclusion

1. Introduction to EHPM

General Info

- European Federation of Associations of Health Product Manufacturers (EHPM)
- Representing the industry since 1975
- Gathering national associations of food supplement manufacturers, distributors & retailers
- 1,750 Enterprises (Over 90% SMEs)
- 13 Member States

1. Introduction to EHPM

European Federation of Associations of Health Product Manufacturers

Food Supplement Products

- Vitamins & Minerals (55% of sales)
- Botanicals
- Combination Products
- Other substances (fish oil, probiotics, etc.)

Examples of botanicals used in FS:

Artichoke, Gingko, Chamomile, Borrage

2. Key Pieces of EU Legislation

- Directive 2002/46/EC on food supplements
  - Provides definition for food supplements
  - Harmonises labelling requirements
  - Provides a process for label notification
  - Lists vitamins and minerals that can be used in food supplement
- Regulation (EC) No 1924/2006 on nutrition and health claims
  - Led to list of approved EU wide nutrition and health claims
  - Provides for ‘Generic Descriptor’ status for terms describing certain categories of products

2. Key Pieces of EU Legislation

- Regulation (EC) No 764/2008 on mutual recognition
  - Intended to implement the principle that if a product is on the market legally in one Member States then it should be allowed on the market in another
- Regulation (EC) No 1169/2011 on food information to consumers
  - Provides mandatory font size (with exemptions) for product in a container of a certain size
  - Replaces the term Recommended Daily Allowance (RDA) currently used on labelling

3. Issues due to implementation

- Directive 2002/46/EC on food supplements
  - Label notification system provided for in the Directive is applied in differently depending on the Member State
  - In some Member States the notification system has evolved into an authorisation system. A dossier has to be submitted for each product and approval needed before a product is placed on the market (Example: Greece)

3. Issues due to implementation

- Regulation (EC) No 1169/2011 on food information to consumers
  - It is not clear whether by 13 December 2014, the term RDA should be replaced on food supplement labelling by Nutrient Reference Value (NRV) or Reference Intake (RI)
  - Some national authorities say NRV some say RI
  - Likely Result = confusion for both consumers and industry

3. Issues due to implementation

- Regulation (EC) No 1924/2006 on nutrition and health claims
  - Numerous health claims dismissed for substances with health benefits that have long been recognised (example: Glucosamine)
  - Rules for ‘Generic Descriptors’ provide for country by country decision on whether terms like ‘probiotic’ can be used on labelling as generic descriptors in the absence of approved health claims
    - Result = difficulty in communicating to consumers on the main characteristic of a product

4. Issues due to lack of Implementation

- Regulation (EC) No 764/2008 on mutual recognition
  - Due to lack of harmonisation at EU level on other substances, national rules can mean that a substance that can be used in a food supplement in one country can only be used in a medicine in another (example: melatonin)
  - Mutual recognition regulation intended to resolve this as if legal in one Member State, a product should be accepted in others
  - Unfortunately not all Members States fully implement mutual recognition
  - Fully applied in Spain for example but this is not the case in all Member States
  - Result: Market access issues for companies seeking to sell product in all EU Member States

5. Issues due to lack of EU legislation

- No EU rules in place to harmonise the use of ‘other substances’ in food supplements in the EU
- Permitted use of vitamins and mineral provides a level of commercial certainty for industry
- The use of botanicals in food supplements is subject to different rules in different Member States – approved for Food Supplement in one country but considered a medicine in another
- Melatonin approved for food supplement use in Italy but considered a medicine in Ireland
- European Commission is considering creating specific regime for botanicals that recognises tradition in assessing health claims and also harmonising quality and safety rules
- Some countries already working on botanicals harmonisation (example: Belgium, France and Italy have developed BELFRIT list)

6. Why have a presence in Brussels?

- Influence EU decision making by lobbying:
  - European Commission
  - European Parliament
  - Member State governments
- Get immediate updates on key policy decisions
- Contribute to shaping a coherent regulatory structure

7. Conclusion

- It is important to recognise the benefits EU legislation has delivered for industry and consumers
- Areas for improvement remain
- There is a need to:
  - Improve implementation and address flaws in existing legislation
  - Increase dialogue between regulators (EFSA, European Commission) and industry to create workable regulation that promotes growth and innovation and also ensures food safety and consumer protection

European Federation of Associations of Health Product Manufacturers

Thanks for Your Attention