The EU and your Product: Decoding Market Access

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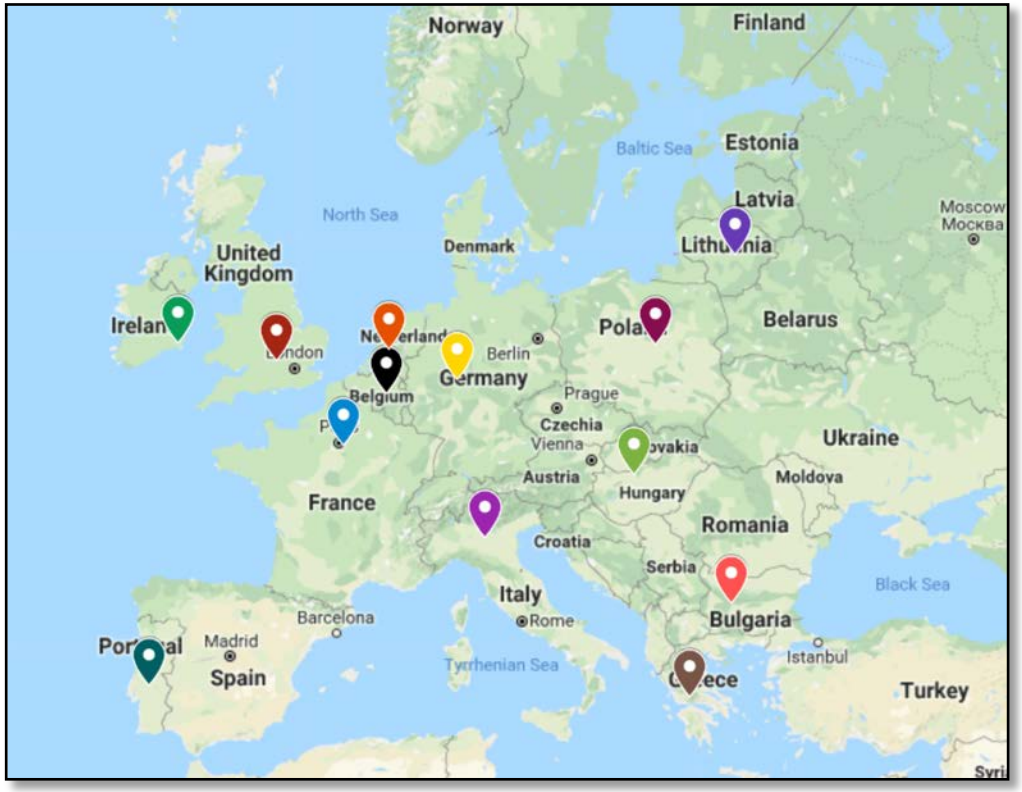
Director General EHPM

EHPM



- European federation of National Associations of **Health Product Manufacturers**
- Established 1975, 13 members, from 13 Member States
- 1600+ Manufacturers and distributors of food supplements
- 100,000 jobs, turnover of €13 billion, 98% SMEs

EHPM Vision

In a modern health maintenance system, there is a legitimate place for physiologically active health enhancing products

National health systems reduce costs by preventing diseases thanks to the consumption of food supplements

Food supplements deserve an appropriate legal environment to deliver well-informed access for consumers to **safe** and **efficient** products

EHPM will back and help to build any feasible legislation project which offers coherence and legal security for serious & responsible operators

The Current Situation

The Current Situation
Key Questions
Country Profiles Document
Methodology
Key Findings
Expected Changes
User Benefit

- While EU legislation has harmonised requirements when placing a product on the market to a certain extent, there are still significant regulatory differences between countries.
- Any company seeking to operate across multiple Member States needs to consider this information and remain up to date with the dynamic regulatory environment within which we operate.

Key Questions asked by Manufacturers

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- Can I get this product to market?
- Can I enter the market with my entire range?
- How easily can I do so?
- How quickly can I do so?
- Will I need approval before launching?

EHPM Country Profiles Document

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- A synthesis of country profiles providing information to assist in an initial pre-market entry assessment.

Focused Questions to Generate Country Profiles

- General Details and Point of Contact

Germany

Competent National Authority(ies):
Bundesamt fur Verbraucherschutz und Lebensmittelsicher-heit (BVL)
Bundesallee 50, 38116, Braunschweig

Email: poststelle@bvl.bund.de

Address: Radetzkystraβe. 2, A-1031, Vienna

Website: https://www.bvl.bund.de/DE/Home/homepage_n-ode.html

Telephone: +49 (0)531 21497-0

National Food Supplement Association: BDIH
Address: L11, 20-22, 68161 Mannheim

Telephone: +49 621 30 98 08 60
Website:https://www.bdih.de/

Notification Procedures

- **Do you have a notification procedure in place for food supplements? Please specify.**
  - *Yes, before placing on the market, form to be submitted online - see BVL website*

If you have a notification procedure in place in your country, can you place products on the market immediately once they are notified or do you need to receive approval from the authorities?	Products can be put on the market immediately once their notification has been duly completed. Confirmation is received upon receipt and should be kept for future reference.
Do your authorities issue a formal decision regarding whether to accept a notification and allow you to place a product on the market? Is there a system in place whereby you can legally challenge a negative decision?	No decision about marketability of the products

Maximum Levels

- **Is there national legislation in place establishing maximum levels of vitamins and minerals for use in food supplements?**
  - *No list, but a food supplement shall not contain substances in a dose that has been shown to have a pharmacological effect (in order to avoid classification as a medicinal product/pharmaceutical)*

Does your country have specific rules for "other substances" that can/can't be used in food supplements or special conditions, warnings or minimum/maximum levels?	No, but supplements must not contain substances in a dose that has been to have pharmacological effects. There is, however, a list of substances (not formally binding) of the Competent Federal Government and Federal State Authorities which are created to facilitate the classification and assessment of substances regarding their use as a food or food ingredient.

Fees

Are there any charges/ fees for notifying a product?	No
Is there an annual fee that is charged by the authorities for keeping a product on the market?	No

Online Systems

Does your country have an online system for notifying food supplements?	No
Does your country have a food supplement vigilance system in place?	No
Is there an online list operated by the national authorities of the food supplement products legally on the market in your country?	No

Mutual Recognition

Do your authorities accept and fully apply the principle of mutual recognition? i.e. if a product is legally on the market in another EU Member State, it can be placed on the market in yours.

Yes, restrictions and procedures available at http://www.gesetze-im-internet.de/lfgb/

Methodology Used

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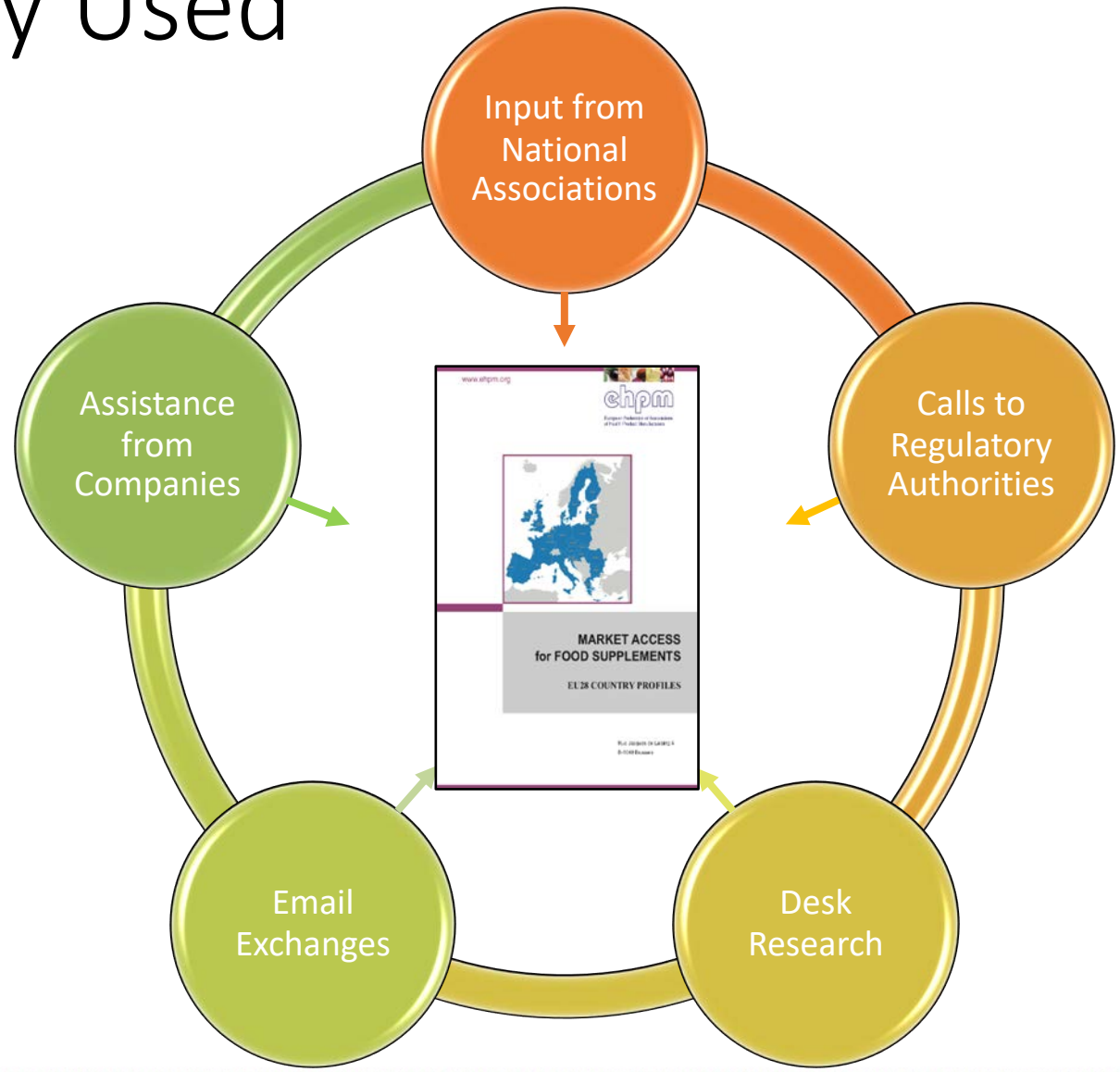

Key Findings

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- Twenty-three Member States have notification systems, 5 do not
- Maximum Levels of Vitamins and Minerals:
  - Ten Member States have clear levels in place
  - Remaining 18 Member States appear to operate on a case-by-case basis
- Mutual Recognition
  - 14 Member States fully apply the principle
  - 12 Member States do not
  - The situation with 2 Member States is unclear

Key Findings

- Online Notification
  - 11 Member States have online notification systems

- Notification Fees
  - 14 Member States charge fees
  - Greece has the most expensive fee per product, €614.40
  - Malta has the cheapest, €10

- Online List of notified products
  - 11 Member States have an online list of notified products

Key Findings

- Notification versus Authorisation
  - Of the 23 Member States that have notification systems in place, 8 actually apply what in essence is a pre-marketing approval system at least for certain types of supplements

- Negative/Positive Plant Lists
  - 7 out of 28 have positive lists
  - 8 out of 28 have a negative list
  - 4 out of 28 have both

Threats and Opportunities

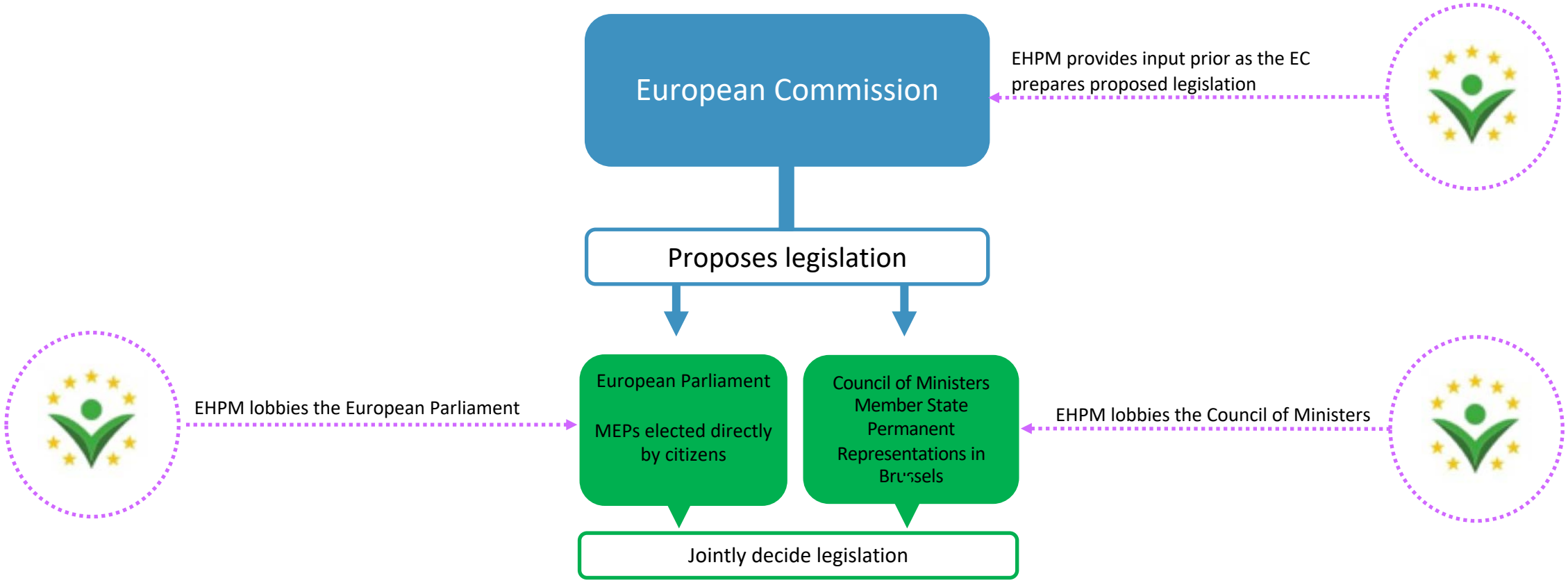
Threats

- Technical implementing legislation linked to safety issues – Additives, risk assessments for specific functional ingredients

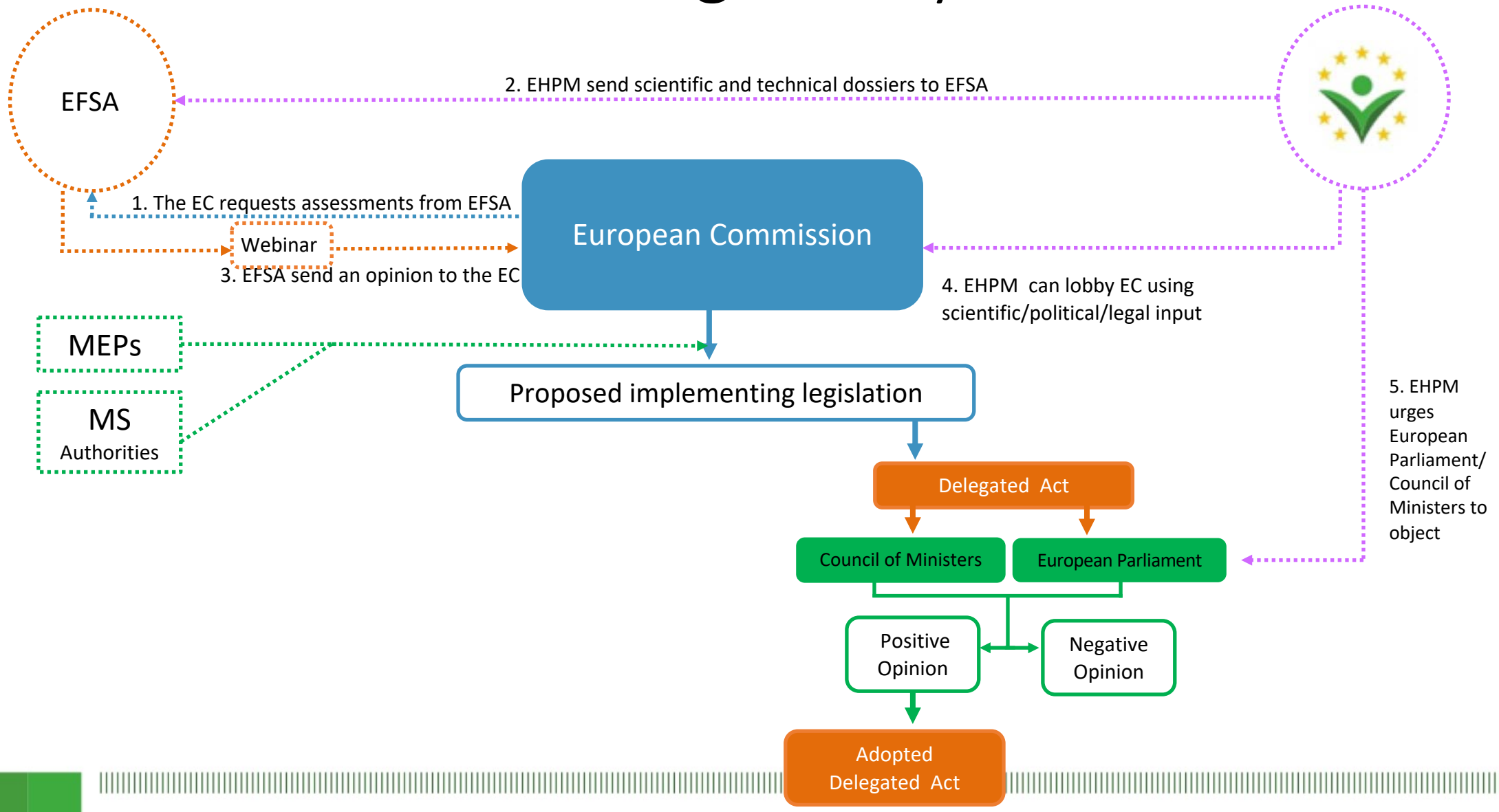
Opportunities

- Mutual recognition proposal published in December 2017 is the most positive development under the current Commission for the food supplement industry
- Revision of general food law regulation has considered EFSA pre-submission meetings but not in way that is effective for industry

Process for Opportunities - Legislative



Process for threats - Regulatory



What Changes Can Happen?

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- **At national Level**
  - Italy published a new Plant List
  - Belgium changed their maximum levels
- **At European Level**
  - The European Commission launched the Article 8 procedure
    - *Green Tea Catechins, Monacolin K, Hyrdroxyanthracene Derivatives*

User Benefit: More than just a document

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- Country Profiles act as a guide to help companies make an initial pre-market entry assessment of the regulatory environment of each Member State
- Although the profiles do not constitute a comprehensive assessment of legal pre-market entry requirements it helps companies to gain an understanding of the European Market and particular countries of opportunity for their product
- Country profiles are changing at a rapid pace and updates are needed on a yearly basis to reflect the most realistic view of the market