The Health Claims and Article 13.5 Issue
Can a Pre-submission System offer a Solution?

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EHPM

- European federation of National Associations of **Health Product Manufacturers**
- Established 1975, 14 members, from 14 Member States
- 1,750 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

Key Impacts of Health Claims Regulation

- A regulation designed to improve consumer protection has been successful in removing many fraudulent claims from labelling

BUT

- It has also led to the removal of many health claims widely accepted in scientific community which continue to be used with the support of regulators in other regions of the world
- Implementation to date has made it impossible for SMEs to secure approval for innovative health claims

Key EHPM Points

- EHPM fully accepts and supports the fact that robust scientific evidence is required to justify health claims
- EHPM fully supported the health regulation when it was proposed
- EHPM simply considers that the requirements currently being applied are:
  - Over and above the rules applied by various EU Member States prior to harmonisation
  - Resulting in the prohibition of health claims for substances that other regions in the world continue to recognise as having health benefits
  - Making it impossible for SMEs to satisfy and in many cases equally impossible for large companies to satisfy – see probiotics example later.

General Statistics

Claim Type	Approvals	Rejections	% Rejection
Article 13(1) General Function Health Claims	229* (Real Figure 58)	1,875	89% (Real Rate 97%)
Article 13(5) New/Emerging Science	6	115	95%
Article 14(1)(a) Disease Risk Factor Reduction	14	24	63%
Article 14(1)(b) Children's Development	12	44	79%
Total	261	2,058	89%

* It should be noted that as Article 13(1) health claims for essential nutrients, vitamins & minerals (165), protein (3), essential fatty acids (2)carbohydrates (1) were subjected to a lighter assessment process. Only 58 approved Article 13(1) health claims can really classified as meeting the standard EFSA Criteria

Within Article 13.5 procedure

- 6 approvals (1 in 2014, 1 in 2015, 2 in 2016 and 2 in 2017)
- 8 companies involved for the 6 approvals
- Collaboration of 3 companies involved collectively 1150 employees
- Size of the other 5 companies : from 1,400 to 6,800 employees
- Very high rejection rate of 95%
- Cost estimation : if 3 clinical trials x 500K€ = €1.5 million
- Cost estimation for 121 applications up to date : €70 million

Some Simple Conclusions

- With high current rejection rate, less and less companies will apply for claims
- High budget involved means only large multinationals can afford the risk (and the cost) of rejection
- The current situation is a brake on innovation and hostile to SMEs
- The only way to change the situation is to do 2 things:
  1. Introduce a pre-submission meeting system
  2. Assess whether the criteria being applied is appropriate

Why a pre-submission procedure?

- If written guidance was sufficient, a probiotic health claim would have been approved seen:
  - The resources that have been invested
  - The general acceptance in the scientific community of the beneficial effects of probiotics
- If the current situation is maintained the number of applications will decrease and only multinationals will apply

Why a pre-submission procedure?

- Companies would agree to pay a reasonable pre-submission fee to get clarity on requirements rather than blindly spend 1.5 million and hope for the best
- Beside its consumer protection role the health claims regulation also had the objective of encouraging innovation.
- Pre-submission meetings would improve the situation, not only for SMEs.

What Changes to the Criteria?

- EFSA could be asked to provide opinions that indicate if the evidence submitted is enough to satisfy different categories of claims – examples:
  - Contributes to ……
  - Can contribute to ……..
  - Traditionally used for ……..

General Conclusions

- No level of generic written guidance can make the requirements affordable
- Even for multinationals, the current requirement are not always achievable
- With a 95% rejection rate, would you invest with those odds?
- Foods are not drugs and should not be assessed as if they are

General Conclusions

- EFSA's attempts at greater stakeholder engagement in recent years are appreciated and will help improve the situation to a degree
- However, more is still needed to make this regulation function effectively
- Overseeing the effective implementation of legislation is the responsibility of the European Commission
- For any problem to be fixed, its existence first needs to be acknowledged