HFMA UPDATE

by Graham Keen, Executive Director

The 'H' word: Harmonisation

Harmonisation: 'An objective of the European Union to achieve uniformity in laws of member states to facilitate free trade and protect citizens'. Source: Wikipedia, Feb 2013.

In February, I attended an impressive two-day conference in Brussels entitled 'EU Regulations for Food Supplements'. A total of 17 speakers included Basil Mathioudakis, from the Commission's DG SANCO, six Member State officials (including Dr Chris Jones of the UK's FSA), a very senior EFSA official, Brussels-based food law expert Jean Savigny, and a number of industry representatives, including Steve Mann from HFMA member company Nelsons. So, an extremely strong speaker line-up and a well-organised event.

In general, the tone of the conference was very balanced, but with a major emphasis on all of the current discussion around the future regulatory 'home' for botanicals, and the destiny of the more than 2,000 botanical health claims currently on-hold. As we all know, the Commission has created a very challenging dilemma for itself by introducing two concurrent pieces of legislation (i.e. the Traditional Herbal and Medicinal Products Directive (THMPD), and the Nutrition and Health Claims Regulation (NHCR) that have different criteria for the scientific evaluation of the same herbal substances. Speakers throughout the two days spoke of the challenge of scientifically assessing these substances with or without the inclusion of evidence of decades of traditional and safe use.

An announcement from the Commission on a way forward is expected imminently, but as I write this there is simply no indication of what this is likely to be.

Crucially, although there were some calls for the implementation of maximum levels under the Food Supplements Directive, it was clear from the comments of Mr Mathioudakis that this subject is not on the Commission's current work agenda, nor is it likely to be in the short or medium term. There will be a new Commission in 2014, so there is every chance that MLs will remain off the agenda until after the new Commission is in place, but we remain ever vigilant for this resurfacing.

But the overriding message I took from this event was that there exists what is little short of a desperate clamouring for the 'Holy Grail' that is the 'H' word – harmonisation. But ironically, I've come to see that this is only in part because it will help foster cross-border trade and reduce regulatory burdens.

Speaker after speaker made calls for further harmonisation, but the common thread was that these speakers were, in the main, Member State regulatory authority officials, for example from Sweden, Austria and the Netherlands, where harmonising law would simply make their life a lot more clear and straightforward. Which, of course, is understandable other than for the fact that even in a 'harmonised' market, if the individual Member State authorities opt to interpret and enforce the harmonised legislation in their own individual and different ways, then where is the 'harmony' or more importantly fairness in that?

Another Wikipedia reference further defines 'harmonisation' as aiming to:

- Create consistency of laws, regulations, standards and practices, so that the same rules will apply to businesses that operate in more than one Member State, and so that the businesses of one State do not obtain an economic advantage over those in another as a result of different rules.
- Reduce compliance and regulatory burdens for businesses operating nationally or trans-nationally.

I'm not sure that HFMA member companies, over 75 per cent of which are Small and Medium-sized Enterprises (SMEs), and all of those independent health food stores that are the bedrock of our industry would agree that this drive for harmonisation has resulted in reduced compliance and regulatory burdens for businesses. On the contrary, our industry, which is driven by the enterprise and passion of a vast number of SMEs across Europe, is sagging under the weight of additional regulatory burden!

We are told that all of the activities of the Commission and Brussels generally are underpinned by two basic tenets; to protect the citizens of the EU, and to protect the interests of SMEs operating in the EU. We have been saying to anyone that will listen that the SMEs we represent will certainly not benefit from the drive for more regulation and pan-EU harmonisation.

The EU-wide Economic Impact Assessment carried out by the European Health Claims Alliance investigates the impact of the worst excesses of the health claims regulation, and this anticipated a total loss of sales of €1billion, resulting in lost profits of €242million, additional costs of implementation of €291million and 13,300 lost jobs. So much for reducing compliance and regulatory burdens for SMEs.

And where is the protection for the consumer? You cannot simply say that what is good for a consumer in one part of the EU is exactly the same as for one in another country 2,500 miles away. It is just plain daft to presuppose that the dietary requirements of someone living in Glasgow are the same as for someone living in Athens, when the lifestyle, diet, climate and environmental conditions in those two cities are so fundamentally different.

Harmonisation is not always the answer. And one size does not always fit all. **hfb**

If you want to know more, or would like to join the HFMA or learn more about our activities, please contact me at graham@hfma.co.uk.