HFMA UPDATE

by Penny Viner, Vice-President

HFMA European update on botanicals

In a year dominated by Covid-19, it's easy to forget that the clock is ticking inexorably towards our exit from the EU – and there are numerous outstanding EU regulatory issues that will inevitably influence future regulation in the UK after we leave.

One such example is the Nutrition and Health and Claims Regulation 1924/2006 EC (NHCR) and botanical health claims. The food supplement industry currently continues to benefit from the 'on hold' list of claims and, for nearly 10 years, the European Commission (EC) has reflected on how these claims should be reviewed. Now, under its 'REFIT' procedure – a rolling programme aimed at keeping all EU legislation under review and ensuring it is *'fit for purpose'* – the Commission has published an Evaluation Report on the effectiveness, efficiency, coherence, relevance and EU added-value of two areas where implementation of the NHCR are incomplete; nutrient profiles, and health claims on plants and their preparations used in foods.

The report is comprehensive, with a wide variety of stakeholder opinions, which sometimes, as with the pharma and food industries, are diametrically opposed. In addition, it highlights areas where the implementation of the regulation has failed to meet its aims – but it also fails to offer firm conclusions/pointers to the way forward. For nutrient profiles, the report sees them as still necessary to ensure a high level of consumer protection, but their setting *'needs to be further considered'*.

For health claims on plants and their preparations, i.e. botanicals, and their regulatory framework for foods, the overall conclusion is that the objectives of the NHCR have not been fully obtained and that the current rules do not take into account tradition of use linked to health benefits. Therefore, and perhaps significantly, it states: *'It could be appropriate to explore the notion of 'traditional use in the efficacy assessment of health claims on plants and their preparations used in foods together with the effects of the co-existence, on the EU market, of THMPs on the same plant substances'*, and that, *'....there are merits for further studying the potential harmonisation of the field of plants and their preparations, including the safety aspect'*.

Commenting on the report, the European Federation, EHPM, of which HFMA was a founder member over 40 years ago, notes that its content:

- Strongly reflects the pharmaceutical industry's position that the lower costs and regulatory restrictions of plant food supplements mean unfair competition in relation to claims between manufacturers of plant food supplements and manufacturers of traditional herbal medicines.
- Acknowledges that the regulation has failed fully to fulfil its purpose in terms of harmonisation, and exposes consumers to the risks of unsubstantiated claims on the on-hold list of botanical claims, but also suggests that the list provides an EU-level reference for Member States (MS), contributing to improving consumer protection.
- Frequently refers to safety issues and identifies Article 8 of Regulation 1925/2006 as the legislative tool to establish a list of plants and other ingredients whose use is prohibited in food supplements – thereby enhancing industry's concerns about the potential overuse of Art. 8.

EHPM is preparing its response to the report and is particularly seeking further information from its member associations on harmonisation – the pros and cons of positive/negative lists; on the BELFRIT project and whether it helps to market products in EU MS, and whether the Novel Foods Regulation helps or hinders marketing food in the EU.

While no immediate changes to EU and UK botanicals regulation are anticipated, the EC's eventual decisions will inevitably affect UK legislation. A UK committee to review health claims has already been formed and is ready to start work in January 2021. A consultation on botanical health claims has also been proposed. Needless to say, the HFMA remains fully engaged with this important regulatory area, at both EU and UK level.

The contamination of botanical substances with pyrrolizidine alkaloids (PAs) has long been a regulatory concern. Now, a draft Commission Regulation and Annex lists proposed maximum levels for herbal teas/infusions, dried herbs, and food supplements, where the maximum level is 400µg/kg, with the exception of 500µg/kg for pollen-based products. Acknowledging the problems of the analytical methodology and co-elution, the transition period is extended to 18 months after the legislation's entry into application. This will be long after the UK has left the EU, but as the FSA has consistently said that it is waiting on the EU before taking action on pyrrolizidine alkaloids, it would seem probable that, as with the other regulatory issues discussed, the UK will, initially at least, follow the EU line. hfb

To help us in our efforts to protect this industry and benefit from the gold-standard advice we provide, join the HFMA at the earliest opportunity. To learn more about our activities, please contact me at graham@hfma.co.uk