HFMA UPDATE
by Graham Keen, Executive Director

Our regulatory environment

It will come as no surprise that following the UK's exit from the EU in a couple of years' time, in terms of the regulatory environment that our industry operates within, there will be virtually no change from the current prevailing situation.

We know this will be the case because of something generally known as the Repeal Bill. The Repeal Bill was announced in the Queen's Speech back in June and was subsequently published under its official title of the European Union (Withdrawal) Bill on July 13. Its 19 clauses and eight schedules enable three main things to happen; it repeals the European Communities Act 1972, brings all EU laws onto the UK books (crucially meaning that laws and regulations made over the past 40 years while the UK was a member of the EU will continue to apply after we leave the EU), and gives Ministers power to make secondary legislation.

On the one hand, this provides the stability that everyone wants in order to continue to manage their businesses in an orderly fashion, but also it remains the case that, post-exit, we may have the opportunity to correct some of the calamities resulting from certain aspects of EU legislation. But crucially, it should also mean that any future legislative howlers (for example, the imposition of restrictive harmonised maximum levels for nutrients used in food supplements) will not automatically be transposed into UK law.

But, for the foreseeable future, what we have is what we will have, and I therefore thought it might be helpful to provide an overview summary of the key pieces of existing legislation that most impact this great industry. You should note that the following list is not exhaustive; it only represents the primary directives/regulations for health products, including food supplements.

- **General Principles and Requirements for Food Law** [Regulation 178/2002]
This Regulation lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. It also stipulates that food must not be injurious to health or unfit for human consumption and that the labelling, advertising and presentation of food shall not mislead customers. *[Related UK pieces of legislation: The Food Safety Act 1990, The General Food Regulations 2004, The Food Safety and Hygiene Regulations 2013].*
- **Food Information to Consumers** [Regulation 1169/2011]
This Regulation establishes the general principles, requirements and responsibilities governing food information, in particular, food labelling. It applies to any food business operator supplying food to the public or mass caterers as well as 'business-to-business' transactions. *[UK implementing Regulations: The Food Information Regulations 2014].*
- **Addition of Vitamins, Minerals and Other Substances** [Regulation 1925/2006]
This Regulation harmonises the provisions regarding the addition of vitamins and minerals and of certain other substances to foods. For example, it defines the purpose for which addition of vitamins and minerals is permitted and lays down criteria for the control of other substances (by way of prohibition or restriction or by placing 'under scrutiny'), lists permitted vitamins and minerals and their authorised sources substances, lays down purity criteria for vitamin and mineral substances, and provides specific labelling requirements, including compulsory nutrition labelling. *[UK implementing Regulations: The Addition of Vitamins, Minerals and Other Substances Regulations].*
- **Food for Specific Groups** [Regulation 609/2013]
This Regulation establishes compositional and information requirements for food intended for vulnerable groups of the population – infants and young children, people with specific medical conditions and people undertaking energy-restricted diets to lose weight. It also aims to increase legal clarity for business and to facilitate correct application of the rules. The Food for Specific Group Regulation came into force on July 20, 2016, repealing Directive 2009/39/EC (PARNUT). *[UK implementing Regulations: The Food for Specific Groups Regulations 2016].*
- **Food Supplements** [Directive 2002/46]
This Directive establishes the general framework and safety rules for food supplements, including a list of permitted vitamins and minerals and their authorised sources substances. It also defines what constitute a food supplement and provides specific labelling requirements (in addition to the labelling provisions set by Regulation 1169/2011). However, not all areas have been harmonised by the Directive (for example, maximum levels for vitamins and minerals). *[UK implementing Regulations: The Food Supplements Regulations 2003 (and as amended)].*
- **Nutrition and Health Claims Regulation** [Regulation [1924/2006]
This Regulation establishes the legal framework for all nutrition and health claims made in commercial communications, which includes all forms of labelling and promotion material. It also established a list of permitted nutrition claims and authorised/non-authorised health claims. *[UK implementing Regulations: The Nutrition and Health Claims Regulations 2007].*
- **Food Additives** [Regulation 1333/2008] and Food Flavourings [Regulation 1334/2008]
These two Regulations lay down rules on food additives and flavourings, respectively, used in foods, providing a list of authorised food additives/flavourings and their condition of use and specific labelling requirements for certain food additives/flavourings. *[UK implementing Regulations: The Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations 2013].*
- **Novel Foods and Novel Food Ingredients** [Regulation 258/97]
This Regulation applies to foods and food ingredients that have not been consumed to a significant degree within the EU prior to May 15, 1997 and lays out the procedures and requirements to authorise the use of a novel food in the EU. This Regulation will be repealed on January 1, 2018 and replaced by Regulation 2015/2283, which aims to provide a simpler, faster and more efficient authorisation procedure, fully centralised at EU level. *[UK implementing Regulations: The Novel Foods and Novel Food Ingredients Regulations 1997].*
- **Traditional Herbal Medicinal Products** [Directive 2004/24]
This Directive amends the Medicinal Products Directive [2001/83/EC] and introduces a simplified registration procedure for herbal medicinal products with a long tradition of use (sufficient evidence of the medicinal use throughout a period of at least 30 years, including at least 15 years in the EU). *[UK implementing Regulations: The Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005].*

We operate within one of the world's most regulated industries and the HFMA exists to help its members fully understand and work with these and many other pieces of legislation. Our members have access to a gold-standard network of specialist advisers to help with this process, so to learn more about our activities visit our website www.hfma.co.uk, or contact philippa@hfma.co.uk. **hfb**