

Supplementary status

Sally Shorthose and Dr Justin Penman of Eversheds LLP examine the EU proposals to unify the laws in member states with regard to the regulation of food supplements.

The nutraceutical market is expanding rapidly in Europe, with millions of related products consumed daily. Although not defined by any EU legislation, nutraceuticals are foodstuffs, food additives or dietary supplements that make health claims; for example, margarines that claim to help reduce cholesterol levels. They are also called 'functional foods'. With boundaries between foods and medicines blurring, there is often uncertainty about the classification of products intended to enhance health. Furthermore, the sale of these products is regulated in member states by differing national rules, which impedes their movement across the EU.

In its white paper on Food Safety (COM, 1999, 719) the European Commission set out its proposal to unify the EU regulation of nutraceuticals. On 10 June 2002 the European Parliament and Council adopted a directive on the approximation of laws of the member states relating to food supplements (2002/46/EC, the Directive). Subsequently, the European Commission proposed a new regulation in July 2003 to govern the use of health and nutritional claims made on foods.

Given the provisions of the new directive and the principal changes contained within proposed regulations, there are bound to be significant implications for the nutraceutical industry. In short, while some functional foods may be marketable in the EU as food supplements, those that do not comply with new legislation may still be regulated by national laws, in the same way as medicines.

Current directives

Until the directive was adopted, there was no EU legislation to specifically regulate food supplements. Products had to comply with EU food law and national laws (if any) relating to supplements. Due to discrepancies between national requirements, it became almost impossible for companies to market food supplements consistently across Europe.

The directive, which came into force on 12 July 2003, was proposed as a move towards establishing a harmonious regulatory framework for the marketing of food supplements containing vitamins and minerals. It applies to any food

supplement marketed and presented as a foodstuff, and also defines the term 'food supplements' for the first time. It provides a positive list of the forms in which vitamins and minerals may be used in the manufacture of dietary supplements. Trade in products complying with the directive is permitted from 1 August 2003, and member states must prohibit the sale of non-compliant products from 1 August 2005 at the latest. Further guidance regarding the forms of vitamins and minerals currently omitted from the positive list is expected from the commission by July 2003.

Food supplements are defined as: 'foodstuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, and marketed in dose form'. Dose form includes capsules, pills and sachets of powder. Medicines, as defined by the community code relating to medicines for human use (Directive, 2001/83/EC, the Community Code), are excluded from its scope.

Confirming composition

According to the directive, food supplements may only contain the vitamins and minerals listed in annex I, in the formulations listed in annex II. Under transitional provisions, member states may permit the use of vitamins and minerals outside the positive list until 31 December 2009, provided that:

- ❖ The substance in question was used in one or more food supplements marketed in the EU on 12 July 2002
- ❖ A dossier supporting use of the substance is submitted to the European Commission no later than 12 July 2005
- ❖ The European Food Safety Authority has not given an unfavourable opinion on the use of that substance or its form in the manufacture of food supplements

In future, the EU will set maximum amounts of vitamins and minerals permitted in food supplements per daily dose. This will be done by taking into account the upper safety levels, established by scientific risk assessment, and data on vitamin and

mineral intake from other dietary sources. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily dose will also be set.

Trading standards

The directive will introduce mandatory labelling requirements for food supplements, in addition to the general EU provisions on food labelling. Products must be sold as 'food supplements' and their labels must include:

- ❖ The category name of nutrients and the quantities present in the product given in numerical form
- ❖ The recommended daily dose of the product, plus a warning that this amount should not be exceeded
- ❖ A statement that food supplements should not be used as a substitute for a varied diet
- ❖ A statement that the product should be stored out of the reach of young children

In correspondence with food law, nutraceutical labelling and advertising must not refer to properties of preventing, treating or

curing human diseases. It is also prohibited to state or imply that adequate amounts of nutrients cannot be obtained from a balanced and varied diet.

The directive will be implemented in England by secondary legislation (the Regulations), which will come into force on 1 August 2005. Parallel legislation has been enacted in Scotland, Wales and Northern Ireland. The regulations are more prescriptive than the directive. For example, the sale of any food supplement to the ultimate customer will be prohibited unless it is in a pre-packaged form. Breach of this requirement will be a criminal offence, unless the product is to be exported to a country with similar legislation and – in the case of member states – the legislation complies with the directive.

UK regulations

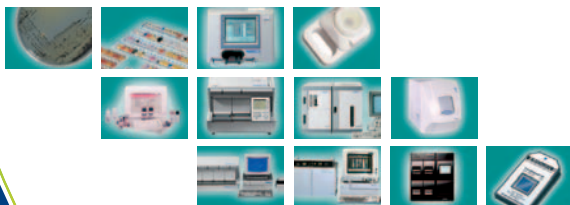
At present, food supplements are regulated by the Food Safety Act (1990), the Food Labelling Regulations (1996, as amended) and the Trade Descriptions Act (1968). It is an offence to sell food that is not safe for consumption, or that is misleadingly described or labelled. The Food Labelling Regulations prohibit the use of medicinal claims in food labelling or advertisements.

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Advertising of food supplements is additionally controlled by industry self-regulation through codes of practice. The Independent Television Commission (ITC) Advertising Standards Code regulates television advertising, while the British Code of Advertising, Sales Promotion and Direct Marketing, (administered by the Advertising Standards Agency) regulates non-broadcast advertisements. The general principle behind these codes is that advertisements should be legal, decent, honest and truthful.

Medicines or foodstuffs?

The nutraceutical industry is positioned somewhere between the food and pharmaceutical sectors. Understandably, there is uncertainty over whether to classify and regulate these nutritional/pharmaceutical hybrids as foodstuffs or medicines. In terms of industry, this ambiguity can significantly affect the timing and cost of placing products on the market.

Under the European Community Code, a medicine is defined as: 'any substance or combination of substances presented for treating or preventing disease in humans, or which may be administered to humans with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions'. Products making these claims fall within the scope of authorities regulating medicines, and must meet the strict standards of quality, safety and efficacy to be marketed under the Community Code. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) does not consider claims to maintain, help to maintain or 'support health or a healthy lifestyle' as being medicinal.

Food is defined by the Community Code as: 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans (Regulation (EC) 178/2002)'. It includes any vitamins or minerals intentionally incorporated into food during its manufacture, preparation or treatment, but excludes medicines. Therefore, any ingested product that is not a medicine, but which qualifies as food, must comply with food law regarding its content, labelling, sale and advertising.

European projections

Nutraceuticals will be classified as food supplements, as long as they meet the compositional and labelling requirements prescribed by the directive. If quantitative levels of vitamins or minerals are not complied with, or other substances with a nutritional or physiological effect are used as ingredients in food supplements, nutraceutical products will either have to be authorised as medicines or be forced to comply with existing national laws relating to supplements. Functional foods will have to be sold in dose form to fall within the prescriptions of the directive. They will also have to comply with certain mandatory labelling and advertising requirements, avoid

claims relating to the prevention, treatment or cure of human diseases, and only include the vitamins and minerals currently on the positive list. According to the new regulations, nutraceuticals must only be sold to UK consumers in pre-packaged form. It is anticipated that many functional foods will not be available as 'food supplements' across the EU, following the European Commission's approximation of national laws.

Market reactions to the regulation of food supplements have been strong. Initially, there was concern among consumers that the directive would ban certain functional foods. Many health-food retailers producing their own food supplements feared that increased safety-testing costs could put them out of business, or lead to the withdrawal of many popular products. Following extensive publicity, the European Commission issued a statement that the directive was not designed to ban food supplements but to promote consumer protection and informed choice, and to solve the problems manufacturers face when marketing their products in the EU. Despite these assurances, neither the directive nor the regulations seem to solve the nutraceutical industry's key issue regarding the consistent EU-wide marketing of products. Although the new compositional standards may prevent some functional foods being classed as food supplements in the short-to-medium term, the positive list remains open and other sources of vitamins and minerals may be included in the future.

Harmonious proposals

Currently, there is a lack of coordinated rules regarding the use of beneficial claims for food products. In July 2003, the European Commission adopted a proposed regulation on the use of health and nutrition claims on foods (COM, 2003, 424). This prohibits the use of claims that are either difficult to substantiate or potentially misleading, and recommends the creation of a positive list of acceptable, well-established health claims. However, scientific evidence and pre-marketing approval would be required for more novel health claims (for example, claims that a functional food may help to reduce cholesterol). The proposed regulation will also provide a list of permitted nutritional claims, such as high fibre, low fat or sugar free, that may be used when a product satisfies specific criteria.

The nutraceutical industry is currently undergoing a period of change, driven by EU legislation. As with all new legislation, the implications of its introduction will become clearer with time. One certain outcome is that food supplements will finally have official EU status. However, given that the proposals are closer to strict pharmaceutical guidelines than those for general foodstuffs, some nutraceutical companies are bound to find the EU definitions restrictive. ●

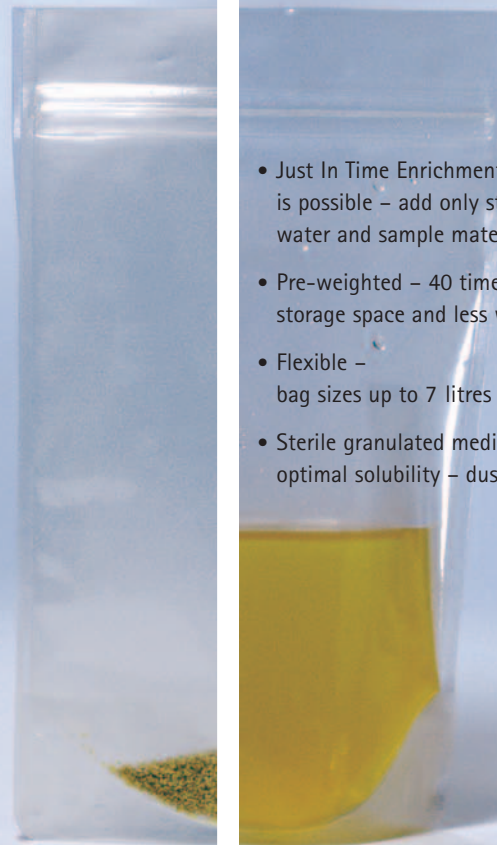
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