Ensuring safe food supplements in the EU

SUMMARY OF: Directive 2002/46/EC — food supplements

SUMMARY

WHAT DOES THIS DIRECTIVE DO?
It harmonises rules on food supplements* to protect consumers from potential health risks and to ensure that they are not provided with misleading information.

KEY POINTS

• The law lays down a harmonised list of vitamins and minerals that may be used to make food supplements.
• Manufacturers recommend maximum and minimum levels of daily consumption.
• Food supplements must not be labelled, presented or advertised as being able to prevent, treat or cure a disease. Nor should it be suggested that a balanced and varied diet cannot provide appropriate quantities of nutrients.
• Labels must give details of:
the nutrients and substances that the foodstuffs contain;
recommended daily consumption with a warning as to not exceed that dose; and
advice to store the product out of reach of young children.

- National authorities may require that manufacturers notify them by providing a copy of the label when they place a product on the market.
- National authorities may suspend or restrict the sale of a supplement if they believe that it could endanger human health. They immediately inform the European Commission and all countries in the European Economic Area – an area comprising the 28 EU countries (1), Iceland, Liechtenstein and Norway in which there is free movement of persons, goods, services and capital.
- The legislation does not apply to medicinal products.

In addition:
- Regulation (EU) No 609/2013 lays down rules on the content and accompanying information of baby formula, processed cereal-based food, baby food, food for special medical purposes and total diet replacement for weight control;
- Regulation (EC) No 1924/2006 harmonises rules on nutrition and health claims for food sold to the public, including food supplied to restaurants, hospitals, schools, canteens and other mass caterers;
- Regulation (EC) No 1925/2006 harmonises rules on the addition of vitamins, minerals and certain other substances to food.

FROM WHEN DOES THE DIRECTIVE APPLY?
It entered into force on 12 July 2002. EU countries had to incorporate it into national law by 31 July 2003.

BACKGROUND
- Food supplements
- European Food Safety Agency

KEY TERM
* Food supplements: concentrated sources of nutrients or other substances with nutritional or physiological benefits to supplement a normal diet. They may be sold as capsules, lozenges, tablets and sachets or in bottles.

ACT

Successive amendments and corrections to Directive 2002/46/EC have been incorporated into the basic text. This consolidated version is of documentary value only.

RELATED ACTS

(¹) The United Kingdom withdraws from the European Union and becomes a third country (non-EU country) as of 1 February 2020.

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