EXECUTIVE NOTE

The Tryptophan in Food (Scotland) Regulations 2005 SSI/2005/479

The above instrument was made in exercise of the powers conferred by sections 6(4), 16(1)(a) and (f), 26(1) and (3) and 48(1) of the Food Safety Act 1990. The instrument is subject to negative resolution procedure.

Policy Objective

The purpose of the instrument is to consolidate with amendments the Tryptophan in Food (Scotland) Regulations 1990, as amended.

Background

Tryptophan was used in food supplements until 1990. The Tryptophan in Food (Scotland) Regulations 1990 were put in place following the occurrence of Eosinophilia-Myalgia Syndrome (EMS) in people taking dietary supplements containing tryptophan in the US and UK.

The 1990 Regulations prohibit, in most cases, the addition of tryptophan to foods intended for human consumption. There are some exemptions for foods for particular nutritional purposes and for uses under supervision of healthcare professionals.

Discussion

In October 2002, the Institute for Optimum Nutrition (ION) submitted to the Food Standards Agency a report entitled "The case for the removal of the ban on tryptophan as a food supplement" in support of their request for the reintroduction of tryptophan-containing food supplements onto the UK market. While the data in the ION report alone were insufficient to support a review of the Regulations, they indicated that a formal review of data by the Committee on Toxicology of Chemicals in Food, Consumer Products and the Environment (COT) was warranted.

The COT published a statement on tryptophan and EMS on 4 August 2004. They concluded that L-tryptophan as a dietary (food) supplement would not present an appreciable risk to health provided that it met the purity criteria specified in the European Pharmacopoeia (EP) and that the maximum recommended intake for an adult was 220mg/day. Given COT's conclusions, it was decided that there was a case for introducing a requirement that where L-tryptophan (or any of its salts) is added to infant formulas, follow-on formulas, processed cereal based baby foods and baby foods intended for infants and young children or other foods for particular nutritional uses it should also, in these cases, comply with EP purity criteria.

The main changes effected by the new Regulations are that they now permit the addition of L-tryptophan to food supplements provided that the added tryptophan complies with EP purity criteria and provided that the recommended daily dose does not exceed 220mg/day. They also require that where L-tryptophan (or any of its salts) is added to foods for particular nutritional uses it must comply with EP purity criteria.

The new Regulations continue to prohibit the addition of tryptophan to food, and the sale, offer for sale and exposure for sale of food containing tryptophan, subject to exceptions.

Parallel legislation will be or has been introduced in England, Wales and Northern Ireland.

Consultation

Article 9 of EC Regulation 178/2002, laying down the general principles and requirements of food law, requires open and transparent public consultation on the revision of food law, save in respect of measures made in circumstances of urgency. These regulations are not made in circumstances of urgency and therefore full public consultation was undertaken by the Agency as follows.

In Scotland the draft Regulations, a consultation letter and a partial Regulatory Impact Assessment were issued for a 12 week consultation on 7 March 2005. A circulation list of the bodies that were consulted during the preparation of the instrument is attached to the Regulatory Impact Assessment. The Food Standards Agency Scotland received two responses to the twelve-week consultation. One respondent had no comments and the other supported the provisions of the new Regulations.

Parallel consultations were carried out in England, Wales and Northern Ireland.

A technical notification was submitted to the European Commission. The standstill period ended on 6 July 2005 and no comments or opinions were received.

Financial Effects

No information was received on the financial implications for industry or enforcement bodies, during the Scottish consultation.

Contact

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Food Standards Agency Scotland
28 September 2005