EXPLANATORY MEMORANDUM TO

THE TRYPTOPHAN IN FOOD (ENGLAND) REGULATIONS 2005

2005 No. 2630

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations continue to prohibit the sale of food containing tryptophan, subject to some exceptions. The Regulations now allow the sale of food containing laevorotatory tryptophan (L-tryptophan) added to food supplements if certain conditions are met. The Regulations also adjust the exception regarding L-tryptophan added to certain foods for particular nutritional uses.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 These Regulations consolidate with amendments the Tryptophan in Food Regulations 1990, as amended, in relation to England. Those Regulations extended to England and Wales.

5. Extent

5.1 This instrument applies in relation to England only.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Tryptophan is recognised as having calming properties and was used in food supplements until 1990. The Tryptophan in Food Regulations, prohibiting the use of tryptophan in food, were put in place in 1990 following the occurrence of Eosinophilia-Myalgia Syndrome[1] (EMS) in people taking dietary supplements containing tryptophan in the US and UK. During the 1989 epidemic of EMS in the US, more than 1500 cases were reported and 37 deaths occurred. The Tryptophan in Food Regulations (1990) 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.

7.2 Between July 2003 and August 2004, the COT reviewed current literature on tryptophan and EMS. A statement by COT was published on 4 August 2004, that on the balance of evidence, it is likely that L-tryptophan per se was not causal for EMS, and that EMS was due to one or more contaminants. However

there are uncertainties and it cannot entirely be ruled out that the apparent epidemic may have been due to the increased use of L-tryptophan supplements and the recognition of EMS. The statement concluded that laevorotatory tryptophan (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.

7.3 In light of COT's opinion, the Tryptophan in Food Regulations 1990 are being re-cast to:

(a) exempt L-tryptophan-containing food supplements from the prohibitions provided that they meet purity and recommended daily dose criteria;

(b) insert a qualification to the existing exemption in respect of L-tryptophan added to some foods for particular nutritional uses in that the added substance must comply with specific purity criteria.

7.4 A technical notification has been submitted to the European Commission. The standstill period was completed on 6 July 2005. No comments were received.

7.5 A public consultation involving 300 stakeholders was carried out between 2 March and 25 May 2005, 5 responses were received. These are summarised in the Regulatory Impact Assessment and will also be summarised and published on the Food Standards Agency website.[2]

8. Impact

8.1 A Regulatory Impact Assessment is attached to the Submission (Annex B).

8.2 The impact on the public sector is the cost of enforcement.

9. Contact

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