

## REGULATORY APPRAISAL

### FOOD, WALES

#### THE TRYPTOPHAN IN FOOD (WALES) REGULATIONS 2005

##### Background

1. The Regulations amend the Tryptophan in Food Regulations 1990 as amended<sup>1</sup>, in relation to Wales.
2. Tryptophan<sup>2</sup> was used in food supplements until 1990. The Tryptophan in Food Regulations were put in place in 1990 following the occurrence of Eosinophilia-Myalgia Syndrome<sup>3</sup> (EMS) in people taking dietary supplements containing tryptophan in the US and UK. During the 1998 outbreak of EMS in the US, more than 1500 cases were reported and 37 deaths occurred. The first UK case occurred in a body builder taking supplements of individual amino acids including tryptophan.
3. The Tryptophan in Food Regulations 1990 as amended prohibit, in most cases, the addition of tryptophan (defined in the Regulations as Dextrorotatory-tryptophan, Laevorotatory-tryptophan, racemic tryptophan or any salt or peptide prepared from any of those forms) to foods intended for human consumption. There are some exemptions for foods for particular nutritional purposes and for uses under supervision of healthcare professionals.
4. 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. (Tryptophan-containing supplements became illegal in the UK with the introduction of the 1990 Regulations).
5. 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, stating 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.

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<sup>1</sup> S.I. 1990 No. 1728  
S.I. 1990 No. 2480  
S.I. 2002 No. 2939 (W.280)  
S.I. 2004 No. 314 (W.32)

<sup>2</sup> An essential amino acid, that is needed by the body to synthesise the proteins needed for its growth and functioning. The body is unable to manufacture this amino acid which has to be obtained through food and drink.

<sup>3</sup> A complex systemic syndrome with inflammatory and autoimmune components that affect the skin, fascia, muscle, nerve, blood vessels, lung, and heart.

6. 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 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<sup>4</sup> (EP) and that the maximum recommended intake for an adult was 220mg/day.
7. Given COT's conclusions, there is 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.

### **Purpose and intended effect of the measure**

8. These 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 the exceptions in paragraph nine below.
9. The main changes affected by the regulations are:
  - (i) the addition of a new exception from the prohibitions of the original Regulations in respect of laevorotatory tryptophan<sup>5</sup> (L-tryptophan) added to food supplements if certain conditions are met with regard to purity and recommended daily dose of 220mg/day; and
  - (ii) the insertion of a qualification to the existing exception in respect of L-tryptophan or its salts added to foods for a particular nutritional use in that the added substance must comply with specific purity criteria.
10. The 1990 Regulations extended to England and Wales, parallel provision being made in Scotland and Northern Ireland. Separate parallel legislation will be made in England, Scotland, and Northern Ireland and is expected to come into force, simultaneously on 11 November 2005.

### **Risk assessment**

#### Health risk

11. Allowing food supplements containing L-tryptophan- to be marketed could have positive health effects for those choosing to consume them. However, prohibiting the sale of these supplements would be unlikely to risk disadvantaging consumers as there are currently many alternatives to traditional antidepressant products available. These include St John's Wort, S-

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<sup>4</sup> European publication created to harmonize specifications for medicinal substances which are of general interest to the peoples of Europe and to hasten the drawing-up of specifications for the growing number of new medicinal substances appearing on the market.

<sup>5</sup> The biologically active form of the amino acid tryptophan, which is capable of being incorporated into proteins, such as the neurotransmitter serotonin.

Adenosyl-L-methionine (SAME), 5-Hydroxytryptophan (5-HTP) and Melatonin. Both 5-Hydroxytryptophan and Melatonin are products of the metabolism of tryptophan.

#### Risk of destabilising the current sector

12. Allowing L-tryptophan to be marketed in food supplements may potentially challenge the commercial position of the alternative products mentioned above. This sector is supplied by many companies, including a few sizeable suppliers who have interests in consumer medicines, as well as several smaller companies who specialise in these products.

### **Options**

#### Option 1: Do Nothing

13. Given COT conclusions referred to above, the Government would be open to strong criticism from stakeholders for not re-addressing the prohibitions on L-tryptophan containing food supplements. In addition, whilst the potential displacement effects are as yet unclear, the re-introduction of this class of food supplement is likely to provide at least some consumer choice benefit. Furthermore the existing prohibitions on L-tryptophan containing food supplements could be viewed as a barrier to trade amongst Member States.

#### Option 2: Partial Amendment

14. Amend the Tryptophan in Food Regulations to require that where L-tryptophan (or any of its salts) is added to foods for particular nutritional uses it should comply with EP purity criteria.

#### Option 3: Make the Legislation

15. Amend the Tryptophan in Food Regulations to require that where L-tryptophan (or any of its salts) is added to foods for particular nutritional uses it should comply with EP purity criteria and with the COT recommended daily dose of 220mg/day.

### **Benefits**

#### Option 2

16. This option would benefit consumers, ensuring that L-tryptophan in foods for particular nutritional uses met minimum purity criteria.

#### Option 3

17. The economic benefits would be realised by producers who could re-introduce food supplements containing L-tryptophan on to the market. The chemical-supply industry may also see an increased demand for L-tryptophan. The social and health benefits would be that consumers would have the option to purchase food supplements containing L-tryptophan.

### **Costs**

18. Foods for particular nutritional uses would need to meet purity criteria. In addition, the sales of some other food supplements may be displaced.

19. The enforcement of food labelling legislation is the responsibility of Local Authority Public Protection Departments and Port Health Authorities. These Regulations do not specify any additional levels of inspection. Therefore it is not anticipated that there will be any additional costs for Local Authorities. Enforcement authorities were invited to identify and comment on any additional costs they thought might arise.
20. Neither the Local Authorities Co-ordinators of Regulatory Services (LACORS) (the Co-ordinating body for Local Authority Trading Standards departments in England and Wales), nor the Welsh Local Government Association, responded to the consultation. No additional costs to Welsh Local Authorities nor to the Assembly have been identified.
21. Persons convicted of an offence under the Regulations would be liable to a fine not exceeding level 5 on the standard scale (currently £5,000).
22. Information from a manufacturer's association in England explains that since it is 15 years since L-tryptophan food supplements were available it will take some time to re-build consumer sales. A Health Food Manufacturers' Association questionnaire was issued to companies seeking sales estimates for L-tryptophan. Sales prospects are highly sensitive to the maximum potency limit (MPL) allowed – sales for 5 companies questioned would total £140k assuming the COT MPL of 220mg. A further £265k would be added if the MPL were to be 1000mg. On average, half the sales for the companies would be incremental. Sales will be evenly balanced between use in single-nutrient supplements and multiple formulas. The modest impact of sales of L-tryptophan supplements on existing products will be diffuse.

### **Equity and Fairness**

23. It is not expected that the regulation will have a negative impact on any specific groups of the community.

### **Consultation with small business: the Small Firms' Impact Test**

24. The FSA has consulted the Small Business Service (SBS) who agree that the addition of a new exemption from the prohibitions of the original Regulations in respect of L-tryptophan added to food supplements may be beneficial to small firms.
25. The SBS have also agreed that there is no requirement to carry out further small firms impact test analyses.

### **Competition Assessment**

26. The proposal is likely to contribute towards the range of comparable products on sale. However, little is known about this sector, or the level of latent demand for tryptophan-containing products, which makes it difficult to assess the effect on competition.
27. The requirement for foods for particular nutritional use to meet EP purity criteria will apply to all producers but are not considered to be onerous. The

requirement for L-tryptophan-containing food supplements to meet EP purity and recommended daily dose criteria will apply equally to all producers.

28. Businesses wishing to import products affected by the Regulation would be required to meet the same safety criteria. This could have potential trade affects.

### **Public Services Threshold Test**

29. As a result of the consultation no information was received from Local Authorities or Port Health Authorities regarding costs for analysis.

### **Consultation**

#### With Stakeholders

30. The Food Standards Agency Wales carried out a 12-week consultation from 7 March to 30 May 2005. Stakeholders, including industry, enforcement authorities, consumer representatives and the National Assembly for Wales, were invited to comment on the draft regulations and the draft Regulatory Appraisal. A copy of the consultation package was posted on the Agency's website. A list of those consulted in Wales is attached at Annex 1. Parallel consultations were carried out in England, Scotland and Northern Ireland.
31. Five responses were received to the consultation in England. All the respondents supported the lifting of the ban, however, three specified that the ban should only be lifted providing the purity criteria was adhered to, and two questioned whether the recommended daily allowance of 220mg/day was adequate, or whether the threshold should be higher. Two were received in Scotland, and three were received in Wales (from the Welsh Consumer Council, ADAS- the UK's largest provider of rural and environmental solutions and policy advice and the Wales Centre for Health), all of whom made no comment.

#### With Subject Committee

32. The Regulations were notified to the Health and Social Services Committee via the list of forthcoming legislation on 12 January 2005 (HSSC (2) —01-05 (p.2b) Item FS 27 (04)). The Regulations were not identified for detailed scrutiny.

### **Review**

33. The Food Standards Agency will consult with enforcement authorities, industry and other stakeholders to evaluate the effectiveness of the legislation.

### **Summary**

34. Option 1 is not a realistic option. Given COT's favourable opinion, the Government would be likely to attract strong criticism from stakeholders and interested parties for not revising the prohibitions on L-tryptophan and would risk contravening EU rules on free trade.
35. It is considered that purity criteria for foods for particular nutritional uses and purity criteria / recommended daily dose for food supplements as

recommended under Options 2 and 3 will not be onerous on industry and will provide better protection for consumers.

36. It is recommended that the Option 3 is implemented to permit the addition of L-tryptophan in food supplements provided that the added tryptophan complies with EP purity criteria and provided that the recommended daily does not exceed 220mg/day. This will be achieved by making The Tryptophan in Food (Wales) Regulations 2005.

## **Annex 1**

### **List of Consultees**

Abergavenny Fine Foods Ltd  
ADAS Wales  
Biotrace Limited  
Brewster et Huguette White  
British Institute for Allergy & Environmental  
Therapy  
Chairman, Welsh Food Advisory Committee  
Chartered Institute of Environmental Health in  
Wales  
Co-operative Group (CWS) Ltd  
Dairy Strategy Group  
DEE DAIRY SERVICES  
Department of Food Science & Technology  
Farmer's Union of Wales  
Federation of Small Businesses (North Wales)  
Food Quality Panel  
Food Safe  
Health & Social Services Committee  
Iceland Frozen Foods PLC  
International Federation for Home Economics  
Local Authorities Co-ordinators or Regulator  
Services  
Welsh Food Advisory Committee  
Monmouthshire Food Initiatives Officer  
National Farmers Union (Wales)  
National Federation of Women's Institutes  
PRP Training Ltd  
Rachel's Dairy  
RED STAR BIOPRODUCTS  
RUDDOCK & SHERRATT  
School of Environmental Sciences  
The Association of Public Analysts  
UWIC  
Vydex Nutrition  
Wales Centre for Health  
Wales Young Farmers' Club  
Welsh Consumer Council  
Welsh Food Alliance  
Welsh Food Laboratories  
Welsh Food Microbiological Forum  
Welsh Local Government Association