

Partial RIA

1. Title of Proposal

The Tryptophan in Food (England) Regulations 2005 (“the draft Regulations”)

2. Purpose and intended effect of measure

(i) The objective

2.1 The draft Regulations consolidate, with amendments, the Tryptophan in Food Regulations 1990 as amended¹, in relation to England.

2.2 These draft 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.

2.3 The main changes affected by the draft regulations are:

- (a) the addition of a new exception from the prohibitions of the original Regulations in respect of laevorotatory tryptophan (L-tryptophan) added to food supplements if certain conditions are met with regard to purity and recommended daily dose;
- (b) 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.

2.4 The 1990 Regulations extended to England and Wales, parallel provision being made in Scotland and Northern Ireland. Separate parallel legislation will be made in Scotland, Wales and Northern Ireland.

(ii) The background

2.5 Tryptophan 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 (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.

Current controls on foods containing added tryptophan

2.6 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.

¹ S.I. 1990 No. 1728
S.I. 1990 No. 2480
S.I. 2002 No. 1817
S.I. 2003 No. 3207

Why are we considering an amendment to the Tryptophan in Food Regulations (1990)?

2.7 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).

2.8 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.

2.9 The COT 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.

2.10 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.

(iii) Risk assessment

Health Risk

2.11 The COT published their opinion on L-tryptophan-containing food supplements in August 2004 (2.9).

2.12 Allowing L-tryptophan-containing food supplements 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 to a significant extent, as there are currently many alternative products available. These include St Johns Wort, S-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

2.13 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.

The limited data currently available make the assessment of the impact on the current sector difficult. We are keen to hear from industry regarding and views of the potential level of latent demand for L-tryptophan-containing food supplements and any likely displacement effects their re-introduction may

have. We would particularly welcome information regarding the financial impact of the draft regulations on the industry.

Risk of doing nothing

2.14 Given COT conclusions, 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.

2.15 In light of the COT view, the existing prohibitions on L-tryptophan containing food supplements could be viewed as a barrier to trade amongst Member States.

Risks posed by not removing prohibitions on all tryptophan forms

2.16 Not going further and relaxing prohibitions on all tryptophan forms may attract criticism from some stakeholders and interested parties. However, the COT opinion applies only to L-tryptophan-containing food supplements.

3. Options

Option 1 *Do nothing.* This is not a favoured option. See risk assessment.

Option 2 *Re-cast 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 (Recommended option) *Re-cast the Tryptophan in Food Regulations 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 dose does not exceed 220mg/day. 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.*

4. Benefits

Option 2

4.1 Economic - None identified.

4.2 Environmental - None identified

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

Option 3

4.4 Economic - This Option would allow producers to put on to the market L-tryptophan-containing food supplements. The chemical-supply industry may also see an increased demand for L-tryptophan.

Contributions would be welcomed from industry on how this Option might affect the sector.

4.5 Environmental - None identified

4.6 Social / Health- This Option would providing consumers with the option to purchase L-tryptophan-containing food supplements.

5. Costs

Option 2

5.1 Economic - Under this Option, foods for particular nutritional uses would need to meet purity criteria.

Contributions are welcomed from industry regarding the economic impact of this Option.

5.2 Environmental - None identified

5.3 Social - None identified

Option 3

5.4 Economic - This Option would incur all of the costs of Option 2 with regard to foods for particular nutritional uses. The sales of some other food supplements may be displaced.

5.5 Environmental - None identified

5.6 Social - None identified

6. Equity and Fairness

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

7. Consultation with small business: the Small Firms' Impact Test

The SBS have been consulted regarding the draft Regulations and have agreed to provide a view on the impact the draft regulations might have on small business.

Contributions are welcomed from the small business sector on this issue.

8. Competition Assessment

8.1 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.

8.2 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.

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

Contributions are welcomed from industry on how the proposal might effect competition and on what would be a sensible transitional period before the legislation comes into force.

9. Sustainable Development

9.1 The Food Standards Agency does not consider that implementing these Regulations will have any impact on sustainability issues.

10. Enforcement and Sanctions

10.1 Port Health Authorities (in relation to imported food) and Local Authorities will be responsible for the enforcement of the draft Regulations.

10.2 Persons convicted of an offence under the draft Regulations would be liable to a fine not exceeding level 5 on the standard scale (currently £5,000).

11. Public Services Threshold Test

11.1 The test will be completed at the end of the consultation period when a better understanding of potential Local Authority and Port Health Authority testing costs has emerged.

Contributions are welcomed from enforcement authorities on this issue.

12. Monitoring and Review

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

13. Consultation

i) Within government

13.1 The devolved administrations were consulted on the draft Regulations. The draft Regulations do not directly impact upon the work of any other Government department.

ii) Public Consultation

13.2 The draft regulations, a consultation letter and a partial Regulatory Impact Assessment were issued for a 12 week consultation on w.b. 28 February. The consultation was issued to interested parties from industry, enforcement and consumer groups, and was available on the Food Standards Agency website (www.food.gov.uk).

14. Summary and Recommendation

14.1 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.

14.2 Purity criteria for foods for particular nutritional uses and purity criteria / recommended daily dose for food supplements recommended under Options 2 and 3 are unlikely to be onerous on industry and will provide better protection to consumers.

14.3 Taking into account COT's opinion, Option 3, to revise prohibitions on L-tryptophan, with enhanced safety criteria, is the recommended option.

Table 1

Option	Total cost per annum Economic, environmental, social	Total benefit per annum Economic, environmental, social
1 Do nothing		
2 Require EP purity criteria to be met for L-tryptophan-containing foods for particular nutritional uses.		
3 Require EP purity criteria to be met for L-tryptophan-containing foods for particular nutritional uses. 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 dose does not exceed 220mg.		

We would welcome information regarding the financial impact for options 1,2, and 3.

15. Declaration

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed

Date

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