EXECUTIVE NOTE

THE FOOD FOR PARTICULAR NUTRITIONAL USES (ADDITION OF SUBSTANCES FOR SPECIFIC NUTRITIONAL PURPOSES (SCOTLAND) AMENDMENT REGULATIONS 2006 SSI/2006/556

The above instrument is being made in exercise of the powers conferred by sections 16(1)(f), 17(1) and 48(1) of the Food Safety Act 1990, and is subject to negative resolution procedure.

Policy Objectives

The purpose of this instrument is to implement, in Scotland, Commission Directive 2006/34/EC of 21 March 2006 amending Directive 2001/15/EC laying down particular requirements regarding substances that may be added for specific nutritional purposes to certain foods for particular nutritional uses ('parnuts' foods). The key proposals of the instrument amend The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 [SSI 2002/397] as follows:

- To update the definition of "Directive 2001/15" (regulation 3)
- To add calcium-L-methylfolate (under the vitamins category) and ferrous bisglycinate (under the minerals category) to the list of substances which may be added to all parnuts foods (regulation 4). Regulation 4 also changes the heading "FOLIC ACID" to "FOLATE" in the vitamins category
- To add magnesium-L-aspartate to the list of additional substances which may be added for special nutritional purposes in foods for special medical purposes (regulation 5)

Parallel implementing legislation will be made in England, Wales and Northern Ireland.

Policy background

Parnuts foods include infant formulae and follow-on formulae, processed cereal-based foods and baby foods for infants and young children, certain weight reduction products, and foods for special medical purposes[1].

EC legislation requires that parnuts foods are both safe and meet the nutritional requirements of the persons they are intended for. To facilitate consumer choice, the widest possible choice of substances such as vitamins, minerals and amino acids should be available for use in parnuts foods; and to ensure consumer protection, the safety of these substances must be scientifically proven before being used in the manufacture of parnuts foods.

Commission Directive 2001/15/EC lists in its Annex certain chemical substances allowed in the manufacture of parnuts foods. Any chemical substance listed in the Annex will have received a favourable scientific evaluation either by the European Food Safety Authority (EFSA), or its forerunner, the Scientific Committee on Food (SCF). Any new substance to be added to the Annex of Directive 2001/15/EC must first receive a positive safety assessment

[1] Provisions regarding the addition of substances to infant formulae, follow-on formulae, processed cereal-based foods and baby foods for infants and young children, are laid down in specific separate Directives.

from EFSA, then the European Commission Standing Committee on the Food Chain and Animal Health (SCoFCAH) must agree it.

After receiving positive opinions from EFSA on the safety of **calcium-L-methylfolate**, **magnesium-L-aspartate** and **ferrous bisglycinate**, SCoFCAH subsequently agreed to the addition of these substances. Commission Directive 2006/34/EC adds these three new substances to the Annex of Directive 2001/15/EC. Consequently, the number of substances that can be added to certain parnuts foods will increase, thereby increasing consumer choice and reducing the impact on industry of Directive 2001/15/EC.

Consultation

Article 9 of EC Regulation 178/2002 requires open and transparent public consultation, save in respect of measures made in circumstances of urgency. These Regulations were not made in such circumstances, therefore, a full 12- week public consultation was undertaken by the Agency as follows:

The Agency in Scotland consulted with stakeholders informally on the draft European Directive 2006/34/EC, and formally on these draft Regulations. Stakeholders consulted included consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals, and other government departments. During the consultation on the draft European Directive, one written response was received in Scotland which supported the proposed amendment to the European Directive. During the formal consultation on these draft Regulations, two responses were received in Scotland. One had no comment and one was supportive. No changes were made to the text of the SSI as a result of the consultation.

Regulatory Impact

There are no costs to consumers, businesses or enforcement authorities associated with the implementation of Directive 2006/34/EC. A final Regulatory Impact Assessment is attached to this Executive Note.

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www.food.gov.uk

FOOD STANDARDS AGENCY
SCOTLAND
Buidheann Inbhe-Bìdhe an Alba

REGULATORY IMPACT ASSESSMENT (RIA)

1. Title of Proposal

1.1 The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Amendment Regulations 2006 SSI/2006/556

2. Purpose and Intended Effect

Objective

2.1 These Regulations implement, in Scotland, Commission Directive 2006/34/EC of 21 March 2006 amending Directive 2001/15/EC to include certain substances in the Annex. These new regulations amend The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 [SSI 2002/397]. Parallel implementing legislation will be made in England, Wales and Northern Ireland.

Provisions in the new Regulations

2.2 The key proposals of these Regulations are:

- To update the definition of "Directive 2001/15" (regulation 3)
- To add calcium-L-methylfolate (under the vitamins category) and ferrous bisglycinate (under the minerals category) to the list of substances which may be added to all parnuts foods (regulation 4). Regulation 4 also changes the heading "FOLIC ACID" to "FOLATE" in the vitamins category
- To add magnesium-L-aspartate to the list of additional substances which may be added for special nutritional purposes in foods for special medical purposes (regulation 5)

Background

2.3 Directive 2001/15/EC, which is implemented in Scotland by The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002, lays down certain requirements regarding substances that may be added for specific nutritional purposes to certain foods for particular nutritional uses.

2.4 A food for a particular nutritional use (a parnuts' or ‘PNU’ food) is a food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and is sold in such a way as to indicate its suitability for its claimed nutritional purpose. A particular nutritional use means the fulfilment of the particular nutritional requirements of certain categories of persons a) whose digestive processes or metabolism are disturbed or b) whose physiological condition renders them able to obtain special benefit from controlled consumption of certain substances in foodstuffs or c) of infants or children in good health.

2.5 Parnuts foods include infant formulae and follow-on formulae, processed cereal-based foods and baby foods for infants and young children, certain weight reduction products, and foods for special medical purposes. Provisions regarding the addition of substances to infant formulae, follow-on formulae, processed cereal-based foods and baby foods for infants and young children are laid down in separate Directives which apply to those specific categories of parnuts foods.

2.6 Foods intended for particular nutritional uses are regulated by framework Directive 89/398/EEC and by specific Directives adopted under that framework. Nutritional substances e.g. vitamins, minerals and amino acids may be added to foods for particular nutritional uses in order to ensure that the particular nutritional requirements of the persons for whom those foods are intended are fulfilled and/or in order to satisfy legal requirements laid down in specific directives adopted pursuant to Article 4 of framework Directive 89/398/EEC.

2.7 Directive 2001/15/EC was adopted pursuant to Article 4(2) of Directive 89/398/EEC which provides for the future adoption of a Directive containing a list of substances for specific nutritional purposes intended for addition to parnuts foods together with the purity criteria applicable to those substances. This practice of adopting a so-called “positive list” is characteristic of EU food law.

2.8 The 2002 Regulations limit the sources of several categories of substances that may be added to certain parnuts foods to those sources listed under the relevant category in Schedule 1 or, in the case of foods for special medical purposes, Schedule 1 or 2 to the Regulations. The list of substances in the Annex to Directive 2001/15/EC currently does not include a number of substances that are used in the manufacture of certain parnuts foods currently on the market.

2.9 At the time of adoption of 2001/15/EC, a number of substances added to Parnuts foods could not be included in the Annex because they had not been assessed by the Scientific Committee on Food (SCF), the forerunner of the European Food Safety Authority (EFSA). Thus, Commission Directive 2004/6/EC implemented a derogation which permitted the use of these substances in parnuts foods until 31st December 2006. The list of these substances is given in the Annex to Directive 2004/6/EC. Each substance listed in 2004/6/EC must be approved by EFSA and must be included in the Annex to 2001/15/EC before 31st December 2006 in order to permit their continued use in parnuts foods within the EC.

2.10 Directive 2004/6/EC and Directive 2004/5/EC (a further amendment which added a number of substances to several categories of Directive 2001/15/EC) were implemented in UK law *via* The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Amendment Regulations 2004 [SSI 2004/90].

Rationale for government intervention

2.11 The new legislation will increase the number of substances that can be added to certain parnuts foods, thereby enabling wider consumer choice and reducing the impact of Directive 2001/15/EC on industry.

3. Consultation

3.1 Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments were consulted informally on the draft European legislation, and formally on these draft Regulations.

3.2 During the negotiations of the amendment to European Directive, the Agency in Scotland consulted informally with the above stakeholders, including SMEs. We received one written response to our informal consultation, from the Scottish Committee for Public Health Medicine and Community Health, who supported the proposed amendment to the European Directive.

3.3 The Food Standards Agency received five responses to the formal consultation on the draft Regulations. Responses from The Royal College of Nursing and East Ayrshire Council in Scotland, the British Medical Association (Northern Ireland) and the Wales Centre for Health either offered no specific comments, or outlined support for the implementation of the proposed Regulations. In their response, The Health Foods Manufacturers Association (HFMA) raised a question about the effect of the Regulations on the labelling requirements for parnuts foods. The Agency responded to the HFMA, noting that the proposed Regulations would have no effect on the relevant labelling requirements. None of the respondents offered any comments on the drafting of the Regulations so no changes were made to the text of the SSI as a result of the consultation.

4. Options

4.1 Options for transposing the provisions of the amending Directive 2006/34/EC are as follows:

Option 1: do nothing i.e. fail to implement the Directive

Option 2: implement the provisions of the Directive by 31 December 2006 as required according to Article 2 of the Directive.

4.2 Option 1: failure to implement would bring risks and disbenefits to consumers, industry, enforcement authorities and Government. Failure to implement would represent an unjustified restriction on consumer choice and would disadvantage industry by preventing the use of a number of substances that

could be used in the manufacture of parnuts foods. Failure to implement would also be a risk to Government in that it would result in a serious breach of the UK's obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and the likelihood of heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement.

4.3 Option 2: there are no risks or disbenefits attached to option 2.

Flexibility

4.4 The Directives do not offer any implementation flexibility.

5. Costs and Benefits

Sectors and Groups Affected

Business sectors

5.1 Businesses that benefited by the amending Directives, and hence the new Regulations, are food businesses producing/distributing certain parnuts foods. The parnuts food sector in the UK is dominated by approximately 10 large companies. Approximately 40 small companies are also involved in the production/distribution of parnuts products in the UK.

Consumers

5.2 The legislation will benefit consumers of parnuts foods. We do not envisage any differential effect of the legislation on consumers because of gender, age, health or income. We do not envisage that the legislation would have differential effects on disabled people or those living in different regions or in rural communities. We consider that the proposal will have no impact on racial equality issues.

Voluntary organisations and charities

5.3 We are not aware of any charities or voluntary organisations that would be affected by the legislation.

Public sector

5.4 Government and enforcement authorities would be affected by the legislation.

Regional impact

5.5 Any regional differences in benefit due to the new legislation would depend upon the location of the relevant businesses. We are not aware of any differential impact.

6. Benefits

6.1 Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or Government.

6.2 Option 2: implementation brings benefits to consumers, industry, enforcement authorities and Government. It benefits consumers by increasing consumer choice; benefits industry by permitting the safe use of a wider choice of substances when manufacturing parnuts foods; and benefits Government by removing the risk of incurring infraction proceedings.

7. Costs

7.1 There are no costs to consumers, businesses, enforcement authorities or Government associated with implementation of these new Directives apart from administrative costs to Government.

7.2 The environmental impact of the new Regulations is likely to be negligible.

8. Small Firms' Impact Test

8.1 The new Regulations will allow companies to continue using certain products in these foods. This will allow small businesses to continue to market these foods along with bigger businesses. Views of small businesses in Scotland, including the Forum of Private Business (Scotland) Ltd and the Federation of Small Businesses were sought prior to and during formal consultation and they have not indicated that they will be put at any disadvantage as a result of the Regulations. In reality, it will bring benefits to industry.

9. Test run of business forms

9.1 There are no forms associated with this piece of legislation.

10. Competition Assessment

10.1 As Option 2 does not have a cost impact on industry, neither will it have a significant negative impact on competition in the parnuts industry. Indeed, the maintenance of the UK situation is likely to allow continued innovative product formulation in this industry. There are no further competition issues to be considered for the amendments proposed over and above those identified in the RIA for the principal Regulations – the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002. A copy of the RIA for the 2002 Regulations is attached at the end of this document.

11. Enforcement Sanctions and Monitoring

11.1 Local Authority Environmental Health Departments are responsible for enforcing the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002. Therefore, enforcement, sanctions and monitoring for these new Regulations are the same

as those set out in the RIA for the 2002 legislation i.e. persons convicted of an offence under these new Regulations would be liable to a fine not exceeding level 5 on the standard scale (currently £5000).

12. Implementation and Delivery Plan

12.1 The Directives do not provide for any specific review date and there is no provision in the main Directive for a review. However, it is likely that further amendments to the Annex of 2001/15/EC will be made by further amending Directives following future scientific evaluation of more substances by the EFSA.

13. Post-Implementation Review

13.1 In line with Scottish Executive guidance we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

14. Summary and Recommendation

14.1 In summary, making these Regulations will enable us to fulfil our Community obligations and will benefit consumers and industry. Failure to make these Regulations would result in a serious breach of the UK's obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK and the likelihood of heavy fines.

14.2 For these reasons, it is recommended that the Agency in Scotland should implement the provisions of Directive 2006/34/EC *via* The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) (Amendment) Regulations 2006.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister: **LEWIS MACDONALD**……..

Date:. **22nd November 2006**.....……

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ANNEX 2

FOOD STANDARDS AGENCY SCOTLAND
Buidheann Inbhe-Bìdhe an Alba

FULL REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSED MEASURE

The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002

1. The Regulations implement Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

The issue

2. Reflecting Article 1(3) of Directive 2001/15/EC, which requires that the use of nutritional substances in foods for particular nutritional uses (a PNU food) must result in safe products that fulfil the particular nutritional requirements of the intended consumer as established by generally accepted scientific data, the Regulations seek to protect the consumer.

3. The Regulations would also promote the free movement of goods as, currently, harmonised rules on nutritional substances for most types of PNU foods do not exist. Introducing harmonising legislation on nutritional substances would work to eliminate the barriers to the free movement of goods.

The objectives

4. The Regulations would implement European Commission Directive 2001/15/EC, which lists substances that may be used in PNU foods. The list includes sources of vitamins, minerals, amino acids, 'carnitine and taurine', nucleotides, and 'choline and inositol', which have been cleared for safety and bioavailability. Other substances not belonging to one of these categories may be used subject

to the general provisions laid down. Article 1.4 of the Directive also allows member states to verify that the foods are safe.

5. These provisions apply to most PNU foods, including medical foods, slimming foods, sports foods and foods for diabetics. Substances added for nutritional purposes to infant formulae and baby foods are controlled in the legislation that covers their composition and labelling.

6. The proposed Regulations would, from 1 April 2004, prohibit the sale of the relevant PNU foods containing nutritional substances in the defined categories unless they are specifically permitted.

7. The permitted list includes tryptophan, whose use in these foods is currently prohibited under national legislation, The Tryptophan in Food (Scotland) Regulations 1990. The new Regulations include an amendment to these Regulations and would also require prior notification to the Food Standards Agency of first marketing of certain PNU foods to which tryptophan has been added for a specific nutritional purpose. The sale of such foods where the notification requirement has not been met would be prohibited.

3 RISK ASSESSMENT

8. The range of foods for particular nutritional uses is diverse and the technological processes used in their manufacture are varied. In drafting the Directive it was the Commission's intent to allow the widest possible choice of substances for addition to such foods. However, ultimately these foods must be safe when used as instructed by the manufacturer. To this end, the Annex to the Directive lists substances that may be added and states that relevant purity criteria must be met. The list of substances is based on advice from the EU Scientific Committee on Food which has evaluated their safety and bioavailability.

9. Thus the Directive and the implementing Regulations address the risk that the addition of substances for specific nutritional purposes to PNU foods could result in the production of unsafe products. This is particularly important given that PNU foods may be manufactured to meet the particular nutritional needs of groups of vulnerable consumers.

10. As noted above in paragraph 7, the Regulations also prohibit the sale by the manufacturer or importer of certain designated PNU foods to which L-tryptophan

has been added for a specific nutritional purpose, unless prior notification has been given to the Food Standards Agency before the first marketing of food of that particular type. The national Tryptophan in Food (Scotland) Regulations 1990 have prohibited the addition of tryptophan to foods, with certain exemptions.

11. Directive 2001/15/EC, and earlier Directives 91/321/EEC and 96/5/EC (on infant and follow-on formulae and baby foods respectively) allow the use of L-tryptophan in most PNU foods. With the implementation of the Directive it becomes necessary to remove the restrictions contained in the Tryptophan in Foods (Scotland) Regulations 1990, but at the same time it is considered appropriate to monitor the use of L-tryptophan in order to protect public health. For this reason the new Regulations not only amend the Tryptophan in Foods (Scotland) Regulations 1990 to remove the restriction, but also contain a requirement that manufacturers/importers of certain PNU foods containing added L-tryptophan notify the Food Standards Agency three months before placing such a product on the market in order that the Food Standards Agency can verify compliance with the requirement in Article 1.3 of Directive 2001/15/EC that PNU foods with added substances are safe.

4 BENEFITS AND OPTIONS

12. The benefit of these Regulations is that they will contribute to consumer protection by ensuring that substances added for specific nutritional purposes in foods for particular nutritional uses have been evaluated for safety and bioavailability.

4(i) Options

13. The UK is obliged to implement Commission Directive 2001/15/EC and to prohibit trade in products that do not comply with the Directive with effect from 1st April 2004; the Directive does not allow for any flexibility in timing. Failure to implement would risk infraction proceedings from the Commission. In implementing the Directive, it is also necessary to deal with the conflict between the Tryptophan in Food (Scotland) Regulations 1990 and Directive 2001/15/EC and also, incidentally, with the conflict between the Tryptophan in Food (Scotland) Regulations 1990 and Article 5 of Commission Directive 91/321/EEC (on infant formulae and follow–on formulae) and Article 5 of Commission Directive 96/5/EC (on processed cereal–based foods and baby foods for infants and young children).

14. The options are:

Option 1: do nothing i.e. fail to implement Commission Directive 2001/15/EC.

Option 2 – introduce a voluntary code on the prohibition of sales of relevant PNU foods.

Option 3: implement Directive 2001/15/EC and, at the same time, amend the Tryptophan in Food (Scotland) Regulations 1990 to disapply the prohibitions as far as they apply to certain Directives. At the same time, introduce a requirement prohibiting the manufacturer or importer from selling certain PNU foods to which L-tryptophan has been added for a specific nutritional purpose unless the Food Standards Agency has been notified at least three months prior to the placing on the market of food of that particular type.

Option 4: implement Directive 2001/15/EC and leave the Tryptophan in Food (Scotland) Regulations 1990 unamended, thereby retaining the previous national prohibition on the addition of tryptophan (including L-tryptophan which features in the list of amino acids in the Annex to the Directive) to PNU foods as well as to other foods. This would result, necessarily, in incomplete implementation of the Directive.

Option 5: implement Directive 200115/EC and revoke the Tryptophan in Food (Scotland) Regulations 1990.

4(ii) Benefits and disbenefits of options

15. Option 1: failure to implement the Directive would result in failure to prohibit trade in products that have not been specifically evaluated for safety and bioavailability, hence would fail to provide consumer protection.

16. Option 2 – introduction of a voluntary code would not guarantee compliance and would fail to gain public confidence and consumer protection.

17. Option 3: this would remove the risk of incurring infraction proceedings from the Commission while at the same time allowing national safety controls to be maintained on other foods containing added tryptophan. In the case of certain

PNU foods containing added L-tryptophan the Food Standards Agency would have the opportunity to assess the safety of any such product before it was put on the market.

18. Option 4: while, on the face of it, this would allow the national safety measures to be maintained in their entirety, it would result in two inconsistent legislative provisions and the courts would give effect to the provisions implementing the Directive.

19. Option 5: this would remove the national provisions prohibiting the addition of tryptophan to foodstuffs. While this would remove a constraint on food manufacturing practice and would be the least restrictive option it would carry the greatest risk to public health. It also goes further than required by the Directive.

5 COMPLIANCE COSTS ESTIMATES

20. Businesses affected by the Regulation will be food businesses manufacturing PNU foods. The legislation could also have knock-on effects on importers and suppliers of such foods including charities and voluntary organisations.

5(i) Compliance costs for a typical business

21. The PNU food sector is dominated by thirteen large companies (e.g. Nutricia, Boots, Abbott Laboratories) that manufacture medical foods. Although all of the manufacturing takes place in England, the majority of these companies have markets and retail outlets in Scotland. Therefore, the new Regulations would have only a very limited impact in Scotland because they stipulate what substances may be added to PNU foods for specific nutritional purposes, an issue that affects the manufacturing rather than the retail stage of product development. Any increased costs for retailers in Scotland resulting from implementation are likely to be passed on to their customers. Other PNU foods on sale in Scotland (such as many sports foods) are manufactured in the United States thus the impacts of the new Regulations are most likely to be felt, in this country, by businesses importing and supplying such foods.

22. As it stands, the Annex to Directive 2001/15/EC excludes a number of nutritional substances (primarily amino acids) that are added to PNU foods currently on the market. The Directive requires that trade in products not complying with the Directive be prohibited with effect from 1 April 2004. The Commission recognises

that the list of permitted substances in the Annex requires updating and has stated its intention to expand the list before 1 April 2004. Industry, long aware of the Directive, has already submitted dossiers to the Scientific Committee on Food for assessment with a view to getting those substances included in the Annex.

23. There will be no implementation costs for companies that do not currently use substances excluded from the list. Those companies which do use these substances will only incur costs if the permitted list is not extended by 1 April 2004, the date from which trade in products not complying with the Directive is prohibited. A Regulatory Impact Assessment is attached at Annex 2.

24. Based on the information received through consultation, we estimate that, at worst, the upper limit for implementation costs across the sector as a whole might be around 2% of turnover. One micro-business responded to our UK-wide consultation and stated that the regulations would not affect it in any way other than could be reasonably passed on in any increased costs to its own customers.

5(ii) Small business litmus test

25. The Agency identified and contacted four small businesses within the UK involved in supplying sports foods; of these, two were micro businesses (one employee and two employees respectively). Only one business responded and stated that the implications of any controls on manufacturing would not affect the business in any way other than that it would pass on any increased costs to its own customers.

6 ENFORCEMENT AND SANCTIONS

26. Enforcement of the Regulations will be the responsibility of local food authorities. The Food Standards Agency will also play a role with regard to the notification requirement in regulation 4. Persons convicted of an offence under these Regulations would be liable to a fine not exceeding level 5 on the standard scale (currently £5,000).

7 RESULTS OF CONSULTATIONS

27. A wide range of interested parties across Scotland were consulted on the draft regulations including consumer and health professional groups, industry groups, enforcement bodies and individuals. Three replies were received from Scottish

interests who either made no comment or were supportive of the measures. Across the UK the Food Standards Agency received 35 written responses.

28. Consumers' organisations generally welcomed the Regulations and their contribution to ensuring the safety of PNU foods. Enforcement authorities also supported the new measures but requested clarification on some details in order to aid enforcement. The Agency is currently preparing guidance notes to clarify the requirements of the Regulations to businesses and local authorities. The main concern expressed by businesses was that the list of permitted substances does not include seven substances currently used in products on the UK market, and that the use of such a list would stifle innovation. However, as mentioned at paragraph 22 above, additions can be made to the list.

8 SUMMARY AND RECOMMENDATIONS

29. It is recommended that **option 3** (section 4(i) above) **is supported**. This will allow the UK to fulfil its Community obligation to implement the provisions of Directive 2001/15/EC while still allowing the retention of national safety measures relating to the addition of tryptophan to most foods. The Scottish Statutory Instrument implements option 3.

9 MONITORING AND REVIEW

30. Officials will maintain close and regular contact with Local Authorities and the relevant trade associations to monitor compliance with the Regulations, in particular compliance with the requirement of prior notification provided for in Regulation 4.

31. We are committed to ensuring that all regulations introduced are, and remain, proportionate and fit for purpose. In line with Scottish Executive guidance we will review the continued effectiveness of this regulation through the use of a Review Regulatory Impact Assessment that will be completed before 23 September 2012.

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister: Mary Mulligan

Date: 30-9-02

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