

## **PARTIAL REGULATORY IMPACT ASSESSMENT**

### **PROPOSAL FOR A RECAST COMMISSION DIRECTIVE ON INFANT FORMULAE AND FOLLOW-ON FORMULAE**

#### **PURPOSE AND INTENDED EFFECT OF MEASURE**

1. This Commission proposal for a recast Directive on infant formulae and follow-on formulae consolidates existing Community legislation on the composition and labelling of infant formulae and follow-on formulae and the marketing of infant formulae. It also introduces changes that update the text taking into account the latest scientific advice on the essential composition of infant formulae and follow-on formulae and ongoing discussions at the international level in the Codex Alimentarius forum.

#### **The background**

2. European Community controls on the composition and labelling of infant formulae and follow-on formulae were introduced in 1991 through Commission Directive 91/321/EEC which also introduced restrictions on the marketing of infant formulae. Directive 91/321/EEC has since been amended by Directive 96/4/EC which modified the compositional requirements and clarified rules on nutrition labelling; by Directive 1999/50/EC which laid down a very low common limit of 0.01 mg/kg for any individual pesticide in infant formulae and follow-on formulae and most recently by Directive 2003/14/EC which placed tighter restrictions on a number of very toxic pesticides with Acceptable Daily Intakes (ADIs) lower than 0.0005 mg/kg/body weight.
3. The aims of Directives 91/321/EEC, 96/4/EC, 1999/50/EC and 2003/14/EC were to ensure that
  - the essential composition of infant formulae and follow-on formulae satisfy the nutritional requirements of infants in good health as established by generally-accepted scientific data;
  - the labelling of infant formulae and follow-on formulae allows the proper use of such products and is such that it promotes and protects breastfeeding;
  - the rules on composition, labelling and advertising are in conformity with the principles and aims of the International Code of Marketing of Breast-Milk Substitutes ("the Code");
  - Member States (MS) may take appropriate measures in order that information about infant feeding given to pregnant women and mothers of infants ensures appropriate use of infant formulae and follow-on formulae and is not counter to the promotion of breastfeeding.
4. These aims are given effect by the main provisions of the Directives which:

- Define the terms 'infant', 'young children', 'infant formulae', 'follow-on formulae', 'pesticide residue';
- Set out detailed requirements for the essential composition of infant formulae and follow-on formulae;
- Introduce a general requirement that infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children;
- Introduce a general limit on the level of any individual pesticide residue that may be present in infant formulae and follow-on formulae and specific lower limits for a few, very toxic pesticides;
- Set out mandatory and non-mandatory particulars for the labelling of infant formulae and follow-on formulae;
- Place restrictions on the nutrition and health claims that can be made in the labelling of infant formulae;
- Place restrictions on the advertising of infant formulae;
- Set out rules on the provision of information on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition

### **Implementation of the Directives**

5. In Great Britain these Directives have been implemented through the Infant Formula and Follow-on Formula Regulations 1995, the 1997 amendment and separate but parallel amending Regulations for England, Scotland and Wales dated 2000 and 2003. Northern Ireland has similar legislation.

### **The recast Directive**

6. The recast Directive (Commission working document, preliminary draft, 5 April 2004) introduces the following additional aims

- to ensure that ingredients, other than those specified in the Annexes to the Directive, used in the manufacture of infant formulae and follow-on formulae are suitable for the particular nutritional use of infants, that their suitability has been demonstrated, when necessary, by appropriate studies and to give guidance on the design and conduct of appropriate studies;
- to permit statements on products that reflect ethical or religious considerations and which might influence dietary choices.

7. In order to give effect to these new aims and in order to update the provisions of the earlier Directives, the recast Directive includes the following important amendments or additions:

- the definition of 'infant formulae' is amended from 'means foodstuffs intended for particular nutritional use by infants during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons' to "*means foodstuffs intended for particular nutritional use by infants during the first months of life up to the introduction of appropriate complementary feeding and satisfying by*

*themselves the nutritional requirements of this category of persons'. In conjunction with this, Article 3 includes wording that is amended from 'No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.' to 'No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life up to the introduction of appropriate complementary feeding.';*

- the definition of 'follow-on formulae' is amended from 'means foodstuffs intended for particular nutritional use by infants aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons' to '*means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of this category of persons*' and the labelling is amended to indicate suitability for use from the age of 6 months rather than 4 months;
- Article 4 includes new text the purpose of which is to ensure that when food ingredients not specified in the Annexes are used in the manufacture of infant formulae and follow-on formulae their suitability for particular nutritional use by infants as established by generally accepted scientific data shall be demonstrated through a systematic review of the available data relating to the expected benefits and safety considerations including, as necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies;
- Deletion of nutrition claims relating to "adapted protein", "low sodium", "sucrose-free" and "iron-enriched" from the list of claims permitted for infant formulae;
- Addition of nutrition claims relating to addition of docosahexanoic acid, addition of taurine, addition of fructo-oligosaccharides and galacto-oligosaccharides and addition of nucleotides to the list of claims permitted for infant formulae;
- New text permitting, in the labelling of infant formulae, statements concerning the suitability of the product for use in a diet whose composition is influenced by ethical or religious considerations;
- detailed changes to the essential composition of infant formulae and follow-on formulae;
- changes to the reference values for nutrition labelling for foods intended for infants and young children;

## **Risk assessment**

8. Since Directive 91/321/EEC was adopted in 1991, there have been advances in scientific knowledge relating to infant feeding and nutrition. While there is no change in the view that 'breast is best', recent reviews of relevant scientific data indicate that changes to the essential composition and labelling of infant formulae and follow-on formulae are warranted. Relevant reports are the Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae<sup>1</sup> and the Opinion of the Scientific Committee on Food on the revision of reference values for nutrition labelling<sup>2</sup>. The SCF's recommendations for changes to the essential composition of infant formulae and follow-on for are based on a review of all relevant up-to-date scientific information and aim to improve the nutrition of infants and young children receiving infant formula or follow-on formula.
9. The text of the recast Directive reflects the recommendations in these two reports of the former Scientific Committee on Food (SCF) and aims to address the risk that provisions on the composition and labelling of infant formulae and follow-on formulae may not have been up-to-date before the proposed revisions to the text and therefore may not have provided the best basis for the nutrition of infants and young children receiving infant formula or follow-on formula.
10. A large number of babies consume infant formulae and follow-on formulae. According to the 2000 infant feeding survey<sup>3</sup> 30% of mothers in the UK did not breastfeed at all and gave infant formula as the sole source of nutrition from birth. The 2000 survey selected a sample of 13,112 births from all births occurring in the UK in the period 19 August to 19 October 2000. The total number of live births in the UK in 2000 was 679,000<sup>4</sup>. By the time babies were around four to ten weeks old, 58% had switched entirely to infant formula. Some breastfeeding mothers were also using infant formula making a total of 75% of mothers who were using infant formula at least to some extent for babies four to ten weeks old.

## **OPTIONS**

11. The current status of the Commission's document dated 5 April 2004 is that it is a working document, preliminary draft recast Directive. This document has so far been discussed at one working group (WG) meeting of Member States' experts in Brussels on 7 May 2004. The Commission has indicated that it aims to hold the next such meeting in September this year. The Commission has not yet set out its timetable for further meetings.

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<sup>1</sup> SCF/CS/NUT/IF/65/Final 18 May 2003.

<sup>2</sup> SCF/CS/NUT/GEN/18 Final 6 May 2003.

<sup>3</sup> Infant Feeding 2000. A survey conducted on behalf of the Department of Health, the Scottish Executive, the National Assembly of Wales and the Department of Health, Social Services and Public Safety in Northern Ireland. The Stationery Office, 2002.

<sup>4</sup> Mintel report on Baby Food Drinks and Milk, October 2002.

12. The following discussion addresses the UK's options in approaching the new and amended provisions proposed by the Commission in its 5 April document as well as those issues that were raised at the 7 May WG meeting.

**Option 1:** suggest making no changes to current European legislation on infant formulae and follow-on formulae.

**Option 2:** support the Commission's proposal for amendment to the legislation and consider the UK position on specific elements in light of the facts set out below. Each of these elements could contribute to the overall goal of improving the nutrition of infants and young children receiving infant formula or follow-on formula.

### **Option 1**

13. The European Commission is proposing changes to the essential composition of infant formulae and follow-on formulae on the basis of recommendations made by the SCF. The SCF's recommendations are based on a review of all relevant up-to-date scientific information and aim to improve the nutrition of infants and young children receiving infant formula or follow-on formula. To make no changes to the current legislation would risk failing to take the opportunity to improve the nutrition of a particularly vulnerable group within the population i.e. consumers of infant formulae and follow-on formulae. The Food Standards Agency would be failing in its statutory objective to protect the health of these consumers if it were to support this option.

### **Option 2**

14. The following discussion addresses the main issues that have been raised and outlines the Food Standards Agency's current thinking on each.

#### **New definition of 'infant formulae'**

15. At the expert WG on 7 May, Food Standards Agency officials suggested amending the wording of this definition to bring it closer to the definition in the Codex draft standard on infant formula. Stakeholders have not raised any particular concerns over the proposed definition set out in the Commission's document dated 5 April.

#### **New definition of 'follow-on formulae and amendment to the labelling to indicate that it is suitable for use from the age of 6 months rather than 4 months'**

16. Breastfeeding promotion groups support this labelling change as a means of supporting the World Health Assembly (WHA) recommendation that infants be exclusively breastfed up to six months of age. Other stakeholders argue that the effect of such a change, and the anticipated change to the labelling of weaning foods to indicate suitability from 6 months rather than 4 months, on the health of European infants has not been adequately assessed. However, this proposed change is based on a

WHA recommendation and is supported by the UK Department of Health which leads on infant feeding policy. The Food Standards Agency therefore supports the Commission's proposed labelling change.

**Explicit requirement, in Article 4, that the suitability of ingredients other than those in the Annexes should be demonstrated through a systematic review of the available data relating to the expected benefits and safety considerations including, as necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies**

17. This text in the new Article 4, which is similar to that in Article 3 of 91/321/EEC, places the onus on manufacturers to ensure that the use of new ingredients is safe; Member States may request and assess supporting data if they consider this necessary. In practical terms this means that products containing new ingredients are not currently subject to any form of authorisation or independent scrutiny before they are placed on the market.
18. Following discussion at the 7 May WG meeting the Commission asked for views on four options: 1) to keep Article 4 as currently drafted i.e. no change to current arrangements; 2) to introduce a requirement that manufacturers notify MS of a new ingredient / product containing a new ingredient akin to the current notification procedure for medical foods; 3) to introduce a prior approval process with Commission having the power to provide temporary authorisation; 4) to introduce a prior approval process involving an opinion from the European Food Safety Authority (EFSA).
19. The Agency consulted stakeholders on this question following the WG meeting. Manufacturers' representatives supported Article 4 as currently drafted on the grounds that current arrangements ensure the safety and efficacy of innovation in infant formula products and that it is not necessary to introduce additional procedures into the existing food safety framework. One local authority supported a notification procedure. An individual member of SACN's subgroup on Maternal and Child Nutrition strongly supported review of the suitability of new ingredients by an independent body.
20. A notification procedure could pose some difficulties to the Food Standards Agency. Data supporting such a notification would need to be assessed by the relevant scientific advisory committee and the process could be lengthy, taking into account the fact that additional experts might need to be invited to contribute and that the committees tend to have full agendas and a limited number of meetings per year. In the past the UK has indicated to the Commission (in relation to LCFAs) that it is concerned that new ingredients can be used in infant formulas without prior approval, and needs to take that into account in forming its view now. There is also a precedent of prior approval systems in place under existing European food law.

21. The Directive's requirements for essential composition, including the suitability of specific sources of certain ingredients, are based on the recommendations of an independent expert body (the former Scientific Committee for Food). A logical extension of this process would be to require a process of independent review for new ingredients prior to their introduction to the market in order to ensure their suitability and safety for this vulnerable population group. EFSA is the most appropriate body to undertake this task. Any such approval system should be proportionately constructed and it would be possible to get specific timetables and confidentiality provisions written into the Directive. The Food Standards Agency is considering which of the four options to support.

**Deletion of claims relating to "adapted protein", "low sodium", sucrose-free" and "iron-enriched" from the list of nutrition claims permitted on infant formulae**

22. Breastfeeding promotion groups support these deletions and would like to see a general prohibition on nutrition claims on infant formulae on the grounds that they are not helpful to parents. Manufacturers' representatives want nutrition claims to continue to be allowed and would like to see the development of a specific procedure for the approval of claims on infant formulae. Deletion of these claims is proposed on the basis of recommendations in the SCF report. The Food Standards Agency supports these recommendations.

**Addition, to the list of permitted claims for infant formulae, of nutrition claims relating to addition of docosahexanoic acid (DHA), addition of taurine, addition of fructo-oligosaccharides (FOS) and galacto-oligosaccharides (GOS), addition of nucleotides**

23. Some infant formulae on the market contain added taurine (a non-protein amino acid found in breastmilk), DHA (a long chain polyunsaturated fatty acid), FOS or GOS (sugars formed of a small number of monosaccharide residues) or nucleotides (components of DNA and RNA) and these ingredients are, in some cases, the subject of claims on the label. Some stakeholders take the view that neither nutrition nor health claims should be permitted in relation to infant formulae and follow-on formulae on the grounds that they can be used to promote these products in a way that could undermine breastfeeding. Breastfeeding promotion groups take the view that new ingredients should only be permitted where a need has been demonstrated by independent assessment of appropriately-designed studies using exclusively breastfed babies as controls.

24. As to claims relating to ingredients added voluntarily to these products e.g. taurine, nucleotides, FOS or GOS - if claims on the benefits of non-mandatory ingredients are substantiated, then there may be a question as to why these ingredients are not required as part of the essential composition. If such ingredients were to become mandatory, then it would not make sense to permit related claims.

25. While the Agency's view is that, in general, health claims should be permitted if they are substantiated, it would consider modifying this view

with respect to infant and follow-on formulae if these claims were thought to undermine breastfeeding. The Agency will be seeking the views of Department of Health on this issue.

**Introduction of text permitting, in the labelling of infant formulae, statements concerning the suitability of the product for use in a diet whose composition is influenced by ethical or religious considerations**

26. This could include, for example, use of terms indicating suitability for vegan, Kosher or Halal diets. Breastfeeding promotion groups oppose the use of such terms on the grounds that they could act as claims and so undermine breastfeeding; they suggest that an alternative would be to require all ingredients, especially those that have a particular ethical or religious significance, to be disclosed using 'quid' labelling, that is ingredients listing that quantifies ingredients. Manufacturers' representatives support the specific inclusion of a provision permitting the use of these terms. The Agency's current thinking is that the use of terms indicating suitability for diets whose composition is influenced by ethical or religious considerations should be permitted providing this is not done in a way that could undermine breastfeeding.

**Changes to the reference values for nutrition labelling for foods intended for infants and young children**

27. The proposed changes are based on recommendations in the Opinion of the Scientific Committee on Food on the revision of reference values for nutrition labelling. Stakeholders have not made the Agency aware of any concerns about the proposed revised values. The Agency supports the proposed changes in the Commission's proposal.

**Restrictions on advertising of follow-on formulas**

28. The International Code of Marketing of Breast-Milk Substitutes recommends restricting the advertising and other forms of promotion of products within the scope of the Code. The current text of the Directive places restrictions on the advertising and promotion of infant formulae but not follow-on formulae. It is the Food Standards Agency's view that follow-on formulae fall within the scope of the Code.

29. The Agency is aware of concerns that, in some cases, current practices in the advertising and promotion of follow-on formulae could be argued to blur the distinction between these two types of products. At the 7 May WG meeting there was discussion of this issue which is also of concern to other MS. The Food Standards Agency is therefore considering pressing for the text of the Directive to be amended to place restrictions on the advertising and promotion of follow-on formulae as well as infant formulae.

**Labelling of soya-based infant formulas**

30. At the 7 May WG meeting there was discussion of whether to continue to permit the sale of soy protein-based formulas given the lack of benefit to healthy infants and the long-term health concerns. Given that feeding soya-based formulas is an issue of choice for some consumers it was suggested that it might be useful to improve the labelling of such formulas

in order to alert parents and carers to the need to expert advice on their use. As a starting point for discussion, the UK suggested that text be inserted within Article 8(5)(b) to require that soya-based infant formulas bear a statement that they 'should only be used in exceptional circumstances and only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care'. The Commission has since indicated that it is unlikely to accept this wording and the Agency is currently considering what other wording to propose.

### **Detailed changes to the essential composition of infant formulae and follow-on formulae**

31. The Commission has proposed detailed changes to the essential composition of infant formulae and follow-on formulae based on the recommendations of the former SCF in its May 2003 report. The Agency has consulted stakeholders, including the SACN subgroup on Maternal and Child Nutrition, on the SCF report. The SACN subgroup fully supports the recommendations in the report and Breastfeeding promotion groups are broadly in support too. Manufacturers' representatives do, however, have concerns about recommendations relating to specific ingredients. Where these concerns relate to safety and are supported by new scientific evidence the Agency will consider pursuing these concerns with the Commission. Where industry has concerns that certain changes may be technically difficult to achieve, the Agency will consider pressing for a longer implementation period for these particular ingredients; the Commission has already indicated that it may be open to such an approach.

### **Extension of the Directive's provisions to bring them fully into line with the recommendations of the Code**

32. Breastfeeding promotion groups are pressing for the text of the Directive to be extended so that it covers foods for special medical purposes for infants as well as breastmilk substitutes for healthy infants. These groups are also of the view that the Directive should give effect to the recommendations of the Code which include restrictions on the advertising and promotion of other breastmilk substitutes such as follow-on formulae; teas, juices and waters and weaning foods marketed as being suitable for infants below 6 months of age; and bottles and teats. They also want the Directive to take into account those elements of the Code that deal with the way breastfeeding and formula feeding are presented within healthcare systems and by health workers. The Agency is considering views on this issue.

### **Establishment of microbiological criteria**

33. The current text of the Directive states that microbiological criteria (that is rules on the permitted microbiological load of infant formulae and follow-on formulae) shall be established as necessary. Breastfeeding promotion groups are pressing for immediate amendments to the labelling of (powdered) infant formulae and follow-on formulae to include statements

that these products are not sterile. The Agency is considering views on this issue.

### **Timing of implementation of revisions to the Directive**

34. Manufacturers' representatives state that the proposed changes to the essential composition of infant formulae and follow-on formulae would necessitate the reformulation of most products currently on the market and that this is a long, difficult and costly process. They state that the process involves changes to raw materials (e.g. proteins and vitamin premixes), manufacturing procedures, production lines and packaging as well as to quality management measures (e.g. stability testing, possible clinical trials). Where the Agency believes that there are health implications for infants or good technical reasons, it will argue for appropriate transition periods. Article 11 of the recast Directive already includes a provision which would permit the continued sale of products not in conformity with the new requirements but which were labelled before a certain date (yet to be decided) while stocks last.

## **COST BENEFIT ANALYSIS**

### **BUSINESS SECTORS AFFECTED**

35. New provisions affecting the composition and labelling of infant formulae and follow-on formulae would affect businesses involved in the manufacture and sale of these products as well as those involved in the production of ingredients. Any charities and voluntary organisations that sell or supply such formulae in the course of their business could be affected by these new provisions; we are not aware of any charities or voluntary organisations that would be so affected.

36. According to Mintel<sup>5</sup> UK retail sales of baby foods and drinks in 2000 totalled £369.8 million with £167.5 million (45.3% of the total) accounted for by sales of infant formulae and follow-on formulae. The supply structure for infant formulae and follow-on formulae in the UK is heavily concentrated with three manufacturers accounting for 97% of sales. Infant formulae and follow-on formulae are distributed via a wide range of retail outlets, with around 25% sales by volume being through clinics.

## **EQUITY AND FAIRNESS**

37. New provisions on composition and labelling of infant formulae and follow-on formulae in the recast Directive would be equally applicable to all relevant business involved in the manufacture of such products.

## **BENEFITS**

38. The proposed changes to the essential composition of infant formulae and follow-on formulae are based on assessment of new scientific evidence

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<sup>5</sup> Mintel report on Baby Food Drinks and Milk, October 2002

and are designed to ensure that the composition of these products provides the best nutrition for infants that are receiving infant formula or follow-on formula. The benefits of the changes under discussion are to the health of infants.

## **COSTS**

### **Compliance costs for businesses**

39. Policy costs would be in the form of costs to businesses having to comply with new compositional and labelling requirements in the recast Directive. These costs would be incurred by all relevant businesses involved in the manufacture of such products.

### **Implementation costs for enforcement authorities and others in the public sector**

40. We are seeking information on costs to enforcement authorities that could arise as a result of changes to the Directive. Having identified the potential for increased costs to manufacturers we note that some of these costs may be transferred through to consumers. As a significant buyer of these products the NHS/Healthy Start may face increased prices; this issue will be considered further in the light of more information.

### **Research and development costs**

41. Manufacturers' representatives have indicated that manufacturers will undertake research into the safety and stability of products that are reformulated in order to bring them into line with the new compositional requirements of the Directive.

### **Costs to consumers**

42. A proportion of any cost increases which manufacturers would face as a result of the regulations may be passed on to the consumer in the form of higher prices. However, as this represents a transfer of the costs that have already been discussed they are not considered further in this appraisal.

### **Compliance Costs for Charities and the Voluntary Sector**

43. Future implementation of the Directive is not expected to result in additional costs for any charity or voluntary sector organisation.

### **Costs for a typical business**

44. We will be seeking costs for a typical business as part of this consultation process.

## **SMALL FIRMS' IMPACT TEST**

45. This is not particularly salient as the supply of infant formulae and follow-on formulae is characterised by a small number of large firms which account for 97% of sales<sup>6</sup>. However, we will continue to include the Small Business Service in our consultations.

### **Impact on Regions**

46. We are seeking information on this as part of our consultation with stakeholders.

## **COMPETITION ASSESSMENT**

47. New provisions in the legislation on infant formulae and follow-on formulae will affect two sectors of the UK supply for such products. Infant formulae which are suitable for babies from birth onwards (70.8% of sales) and follow-on formulae designed for babies from six months to 24 months (22.0% of baby milk sales). Three companies, Heinz/Farley's, Cow & Gate and SMA Nutrition are the main manufacturers of infant formulae and follow-on formulae products. Together these companies have a 97%<sup>7</sup> of sales. These companies are multinational in nature with a portfolio of established brands, they benefit from scale in both distribution promotion and manufacturing.

48. Implementation of changes to the legislation will bring up-front and ongoing costs. However, it is not anticipated that these costs will have an appreciable impact on competition as they will equally affect each manufacturer, neither will they have any disproportionate effects on firms in the relevant sector. Although the increased costs to manufacturers may act to raise entry barriers, it is not anticipated that this effect will be significant compared to the existing costs of market entry.

49. Option 1, under which current legislation is retained would not have an impact on competition within the UK, as it would maintain the status quo.

## **ENFORCEMENT AND SANCTIONS**

50. When, in due course, the text of the recast Directive is adopted it will have to be transposed into UK law through implementing legislation. Such legislation will be enforced by food authorities in their areas except where they are enforced by port health authorities in their districts in relation to imported food.

51. It is likely that, as in the current Regulations on infant formulae and follow-on formulae, any person committing an offence under the new national

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<sup>6</sup> Heinz/Farley's (11%), Nutricia Baby Care who own both the Cow and Gate (31%) and Milupa (10%) brands, and SMA Nutrition (45%).

<sup>7</sup> Figures obtained from Mintel report on Baby Food Drinks and Milk, October 2002 and include the total milk sector which also includes Soya Milk (3.0% of sector) and Ready to Feed (4.3% of sector).

implementing Regulations would be liable on summary conviction to a fine not exceeding level 5 on the standard scale. The Home Office's view on the offence and level of penalty proposed will be sought in the normal way.

## **MONITORING AND REVIEW**

52.No specific review date is provided for within the Directive.

## **CONSULTATION**

53.The Food Standards Agency has already consulted interested parties including consumers organisations, individuals, health professional groups, manufacturers and retailers of baby foods and enforcement authorities on the SCF's report on revisions to the Directive, on the Commission's preliminary draft working document for a recast Directive and on specific questions arising from the MS expert WG meeting on 7 May 2004. Other Government Departments were also consulted.

54.Summaries of the responses are available on the Food Standards Agency's website. The lengths of these consultations were tailored to meet timetables imposed upon us by the European Commission. While substantive responses from key stakeholders have already been received, a formal written consultation lasting 12 weeks will now be undertaken to solicit any additional views.

## **SUMMARY AND RECOMMENDATION**

55.To support the Commission's proposal for amendment to the legislation and consider the UK position on specific elements in light of the facts set out above and any further views and information provided in response to this consultation.

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