Explanatory Memorandum to the Infant Formula and Follow-on Formula (Wales) Regulations 2007

This Explanatory Memorandum has been prepared by The Food Standards Agency Wales and is laid before the National Assembly for Wales.

Description

These regulations implement a European Commission Directive 2006/141/EEC on infant formulae and follow-on formulae which consolidate existing Community legislation on the composition, labelling and marketing of infant formulae and follow-on formulae. These Regulations also implement Council Directive 92/52/EEC laying down rules regarding the export of infant formulae and follow – on formulae to third countries.

Matters of special interest to the Subordinate Legislation Committee

None.

Legislative Background

The powers enabling the Regulations to be made are contained in sections 16 (1) (e),17(1), 26(1) (a) and (3) and 48(1) of The Food Safety Act 1990 and section 2(2) of the European Communities Act 1972 by virtue of them being designated in relation to measures relating to food (including drink). These are exercisable by Welsh Ministers. The Regulations are subject to the negative resolution procedure.

Purpose and intended effect of the legislation

These Regulations seek 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 whilst promoting and protecting breastfeeding;
- the rules on composition, labelling and advertising are in line with the principles and aims of the International Code of Marketing of Breast-Milk Substitutes ("the Code");
- information provided to carers about infant feeding does not counter the promotion of breastfeeding.

Implementation

It is intended that these Regulations will come in force on 11 January 2008, slightly later than the Commission deadline of 31 December 2007. Parallel legislation will also come into force in England, Scotland and Northern Ireland on 11 January 2008.

The implementation of these Regulations would fulfil the UK's obligations under the EC Treaty and will provide Local Authorities in Wales with the power to enforce against food business operators who are not in compliance with the new Regulations. The UK has a duty to implement these Regulations by 1 January 2008.

Consultation

Full details of the consultation undertaken are included in the Regulatory Impact Assessment below.

Regulatory Impact Assessment

Options

Option 1: Do nothing
Option 2: Implement the Regulations

Option 1 – Do nothing

This option would result in the continued application of the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77)[1].

Option 2: Implement EC requirements

This option would result in the implementation of the Directive by means of the Regulations. The Regulations would apply in Wales, with parallel Regulations being implemented in Scotland, England and Northern Ireland. The Regulations would be accompanied by Agency Guidance which would help industry, enforcement officers and other interested parties interpret the provisions of the legislation. The Guidance would, in particular, provide a detailed Agency view on the action that should be taken by formula manufacturers to ensure compliance with the labelling and advertising provisions of the Regulations.

The Nutrition Society supported Option 2, to implement the European Directive by means of the proposed Regulations.

In principle, the Infant and Dietetic Foods Association (IDFA) and Hipp UK Ltd support the implementation of the Directive, although they believe that the domestic Regulations should go no further than the provisions of the Directive. IDFA, Hipp and the National Pharmacy Assocoiation (NPA) object to the further tightening of the restrictions on infant formula advertising proposed in the Regulations.

The previous Regulations permit the advertising of infant formula in baby care publications circulated within the health care system. As a result, mothers and pregnant women could be exposed to infant formula advertising should they have access to baby care publications while under treatment within the health care system. This is not

[1] http://www.opsi.gov.uk/si/si1995/Uksi_19950077_en_1.htm

supportive of Government policy on the promotion of breastfeeding as infant formula advertising to the public has the potential to impact negatively on breastfeeding rates[3]. To ensure that mothers and pregnant women cannot be exposed to infant formula advertising by these means, the Regulations propose to remove the existing provision in domestic legislation which permits infant formula advertising in baby care publications circulated within the healthcare system. This brings into line the advertising restrictions which apply to all baby care publications, irrespective of where they are made available (either within, or outside the health care system).

While the Baby Feeding Law Group is supportive of the proposal to further tighten the restrictions on the advertising of infant formula, they propose a 'third option' for the wider implementation of the Regulations. Their proposed option involves the implementation of a number of provisions which, they contend, would implement the WHO Code on the Marketing of Breastmilk Substitutes (referred to in this document as the 'WHO Code'). As part of this approach, the BFLG propose a ban on the advertising of follow-on formula to remove the role of such advertising being taken by consumers as advertising infant formula and thereby undermining breastfeeding. In support of their proposal, the BFLG cite a legal opinion which formed part of the UNICEF submission to the Agency consultation on the draft Regulations, and two other opinions from legal academics. The following groups submitted comments to the Agency consultation in support of the 'third option' proposed by the BFLG: Baby Milk Action, Breastfeeding Manifesto Coalition, Association of Breastfeeding Mothers, The Breast Feeding Network, NCT, UNICEF UK, Royal College of Nursing, Save the Children, IBFAN-GIFA, La Leche League Great Britain, Unite-CPHVA, Royal College of Midwives. In addition, over 1300 individuals wrote to the Agency and/or the UK Health Departments calling for domestic UK formula legislation to be based on the WHO Code. The Subgroup on Maternal and Child Nutrition of the Scientific Advisory Committee on Nutrition also supported a prohibition on the advertising of follow-on formula.

From an enforcement perspective, LACORS UK supports a prohibition on the advertising of follow-on formula. 'Trading Standards South-East' (TSSE), a group representing the views of 19 enforcement authorities, recognise that such a prohibition would mean that there would be no opportunity to cause confusion between infant formula and follow-on formula. However, TSSE also state that they support the principle of informed consumer choice, and that any ban on follow-on formula advertising would run counter to this principle.

The Directive represents the EU view on how the recommendations of the WHO Code should be incorporated into European law with respect to the composition, labelling and advertising of infant formula and follow-on formula. Regulation 19 of the Regulations which itself applies to labelling as applied to presentation by regulation 20(1) and applied

to advertising by regulation 21, in combination with Agency Guidance Notes, will address the issue of confusion between infant formula and follow-on formula labelling, presentation and advertising. The Agency will monitor the impact of the new rules and after 12 months of application set up an independently chaired review, with stakeholder participation, to check that they are working effectively.

With regard to Regulation 19, stakeholders were asked, as part of the Agency consultation, to suggest how manufacturers can ensure that infant formula and follow-on formula are appropriately differentiated. IDFA responded by stating that they are not aware of any reliable evidence of confusion between these products. The National Childbirth Trust and Trading Standards South East made a number of suggestions about the packaging/advertising of these products, which have been addressed in the draft Guidance Notes.

Consultation in Wales

The Food Standards Agency Wales carried out a 12-week consultation between 6 July and 28 September 2007 on proposed Regulations to implement Commission Directive 2006/141/EC.

Welsh stakeholders, including industry, enforcement, consumer representatives and the Assembly's Breastfeeding co-ordinator and nutrition adviser were invited to comment on the draft Regulations, and the draft Regulatory Impact Assessment. The consultation package was posted on the Agency's website.

A number of key stakeholders responded to the FSA Wales consultation exercise, namely: the National Childbirth Trust, Save the Children UK and Unicef UK; the National Pharmacy Association, The Breastfeeding Network, the Breastfeeding Manifesto Coalition, the Royal College of Midwives, and the Baby Feeding Law Group. The National Childbirth Trust also wrote to the Assembly Minister for Health and Social Services, Edwina Hart, AM, who subsequently wrote to the Public Health Minister in England urging her to take a robust approach to restricting the advertising of follow-on formula, so as not to undermine breastfeeding.

Flexibility

The Commission Directive does not offer any flexibility on the implementation of its provisions.

Costs and Benefits

Sectors and groups affected

The main sectors and groups of stakeholders that would be affected by the implementation of the Regulations are listed below.

- Consumers (infants in the UK, throughout the EU and in third countries)
- Carers of infants
- Professionals involved in maternal and infant health
- Charities and the voluntary sector involved in maternal and infant health
- Manufacturers of infant formula and follow-on formula
- Manufacturers and suppliers of ingredients used in infant formula and follow-on formula.
- Companies involved in the marketing and distribution of infant formula and follow-on formula (e.g. wholesalers and retailers)
- Companies, organisations and institutions which benefit from the advertising of infant formula and follow-on formula.
- Enforcement authorities
- Government

Benefits of option 1

Continuing to apply the current Regulations would not bring any additional benefits to any of the sectors or groups listed above.

Benefits of option 2

Adopting the Regulations would bring benefits to:

Consumers

As the Regulations require companies to ensure that infant formulae and follow-on formulae are manufactured in accordance with the most current independent expert scientific recommendations regarding infant nutrition. Thus, option 2 would improve the nutrition of infants who are not breastfed.

Carers and health professionals

The Regulations provide increased protection because they:

- clarify the rules which apply to the use of claims in relation to infant formula.
- the labelling, presentation and advertising of infant formula and follow-on formula will ensure that carers and healthcare professionals can adequately differentiate between these products.
- potential exposure to direct infant formula advertising will be reduced as a result of the further restriction proposed in the Regulations.

These measures may potentially help to improve breastfeeding rates/duration. It is difficult to quantify any resulting beneficial effect. However, the Howard study demonstrated that reducing exposure to infant formula advertising can have a significant positive effect on breastfeeding rates/duration[3].

Infants/health services

Improved breastfeeding rates/duration would bring health benefits to those infants who would otherwise not have been breastfed[5]. Improved breastfeeding rates/duration would also potentially bring savings to the health service, as discussed above.

Manufacturers

Manufacturers would be able to market the same compositions of their products throughout the EU (the three biggest selling companies in the UK infant formula and follow-on formula sectors are multi-nationals).

Government

In addition, by introducing the new regulations, the UK would avoid the risk of infraction proceedings brought by the European Commission for not implementing the requirements in the Directive.

In addition, the Food Standards Agency would be failing in its duty to implement EU law and could possibly face the cost of infraction procedures.

Costs of option 1

Maintaining the status quo would bring costs to stakeholders as discussed below:

Consumers

Without changes to the current UK legislation, the nutrition of a particularly vulnerable group of the population, i.e. consumers of infant formulae and follow-on formulae, would not be in line with the latest scientific advice on infant nutrition.

Industry

Failing to implement the Regulations could lead to a lack of harmony between the compositional criteria of formulae marketed in the UK when compared to formulae marketed throughout the rest of the EU. This may disadvantage industry which may have to make special formulations of infant and follow-on formula specifically for UK consumers.

Costs of option 2

Adopting the Regulations would bring costs to stakeholders as discussed below:

Consumers and carers

Implementing the Regulations would bring no new direct costs for consumers (infants). However, a proportion of any cost increase which manufacturers may face as a result of the Regulations could be passed on to carers who purchase formula products, in the form of higher prices.

Industry

New provisions affecting the composition, labelling and marketing of infant formulae and follow-on formulae would affect manufacturers and other businesses involved in the marketing and distribution of these products as well as those involved in the production of ingredients. The Agency requested comments and evidence from stakeholders about the policy or administrative[2] compliance costs associated with the new mandatory reformulation, notification or re-labelling requirements of the Regulations.

The Infant and Dietetic Foods Association (IFDA) noted that it is difficult to quantify these policy and administrative costs as formula companies have been working towards compliance with the compositional provisions of the new Directive for a long period of time (since 2003). IDFA also highlighted concerns that the imposition of labelling/packaging restrictions which go beyond what is required in the Directive may make Europe-wide distribution more difficult and will have a negative impact on competition and potentially could result in increased costs to consumers. None of the formula manufacturers, or their representatives provided any monetised estimates of compliance costs, or provide any quantified evidence to support their views on the impact of the proposed options.

In the absence of monetised information from stakeholders, the Agency estimates that Option 2 will incur the following costs on formula manufacturers:

Notification of infant formula

The Agency considers that the administrative costs associated with notifying infant formula are similar to those associated with notifying Article 9 parnuts food or foods for special medical purposes (FSMPs). As such, the Agency estimates that the administrative cost to a company, over and above what it would do commercially, of completing and submitting a notification form on marketing of a new infant formula

[2] 'Administrative costs' are the costs of the administrative activities that a business incurs when it complies with information obligations in legislation (ie procuring or preparing information and making this information available to a public authority or third party) excluding costs that would be incurred during the normal course of business; 'Policy costs' are all the costs of complying with regulation, excluding administrative burdens.

product will be approximately in the region of £70-£130. The Agency estimates that it may receive in the region of 12 notifications per year. The resulting total additional administrative cost to industry of complying with this new requirement is therefore likely to be in the region of £840-£1560 per annum.

Assessment of new claims

The cost of preparing scientific dossiers to submit to the European Food Safety Authority (EFSA) for assessment in order to substantiate claims is difficult to calculate because we do not know the level of information that EFSA will require, or the number of dossiers that are likely to be submitted to EFSA to substantiate claims on infant formula, or over what timescales.

Costs of relabelling

In their submissions to the Agency consultation on Signpost labelling[3], the British Retail Consortium (BRC) estimated the cost of relabelling a product line at £1000 per product, whereas the equivalent figure estimated by the FDF was £50,000. The Agency considers that approximately 25 infant formula and follow-on formula product lines marketed by Nutricia, H.J. Heinz and SMA Wyeth (whose products account for 97% of formula sales in the UK, according to the market research company, Mintel) may need to be relabelled as a result of the new Regulations. Thus, the total cost of this relabelling is estimated at between £25,000 which the Agency considers the most realistic estimate, and £1,250,000.

Charities and the voluntary sector

The Breastfeeding Network noted in their response to the consultation that their workload would be reduced if women were not undermined by the commercialisation of infant feeding. None of the other charities or voluntary organisations who responded to the Agency consultation noted specific impacts of either option on their work.

Enforcement and health professionals

LACORS UK is not able to quantify the impact that implementing the proposed Regulations would have in resource terms on enforcement authorities.

Government

Implementing the Regulations will lead to a small increase in costs mainly due to the administrative burden of the notification requirements regarding infant formula.

[3] http://www.food.gov.uk/foodindustry/regulation/ria/ria2006/signpostingria

Small Firms Impact Test

The supply structure for infant formulae and follow-on formulae in the UK is heavily concentrated, with three multi-national manufacturers accounting for 97% of sales. None of the other suppliers of infant formula in the UK are small businesses. As a result, the Regulations are unlikely to have a significant impact on small firms in the UK.

Sustainable development

A sustainability assessment has been carried out on options 1 and 2, in the light of the information we have received concerning the costs and benefits listed above.

Option 1 does not create any new economic or social benefits. It may, however, incur economic disadvantages to industry, who may have to make specific formulae to market in the UK, and to the Government, which may be subject to infraction proceedings for not implementing the updated European Directive. Option 1 may also bring social disbenefits (in terms of infant health) as formulae placed on the market in the UK would not be required to be manufactured in accordance with the latest expert scientific recommendations in relation to infant nutrition. Option 2 may bring new economic costs to industry due to reformulation and relabelling. Option 2 also brings social benefits in terms of improving infant health by ensuring that formulae are manufactured in accordance with the latest expert scientific recommendations in relation to infant nutrition.

On the basis of the information available, there appears to be no significant differences between the environmental costs of Options 1 and 2.

None of the stakeholders who responded submitted quantitative estimates of the economic, environmental or social costs and benefits associated with options 1 or 2. As a result, the sustainability assessment with respect to the Regulations cannot be further quantified.

Enforcement, sanctions and monitoring

Local food authorities are responsible for enforcing the Regulations in Wales. The amending Regulations bring no new enforcement responsibilities.

Competition assessment

As noted above, the infant and follow-on formulae sectors are currently characterised by significant concentration with three firms, Nutricia, H.J. Heinz and SMA Wyeth, accounting for 97% of sales in the UK.

It is not considered that the Regulations are likely to either directly or indirectly limit the number or range of suppliers to these sectors nor will they reduce the incentives for competitive action. The ability of firms to enter these sectors is already greatly dictated by the complexity of producing infant and follow-on formulae. Whilst these regulations may impact upon product specifications, any such impacts will be marginal compared with the existing commercial complexities involved. This commercial entry barrier also makes issues such as the proposed marginal reduction in promotional scope secondary in importance. As such the Agency does not consider that the Regulations have the scope to significantly effect competition adversely in these sectors.

Post-implementation review

The Agency will monitor the impact of the new rules and after 12 months of application set up an independently chaired review, with stakeholder participation, to check that they are working effectively. The UK would also participate in any future review of the Directive that may be taken forward at an EU level.

Summary

In summary, these Regulations will benefit consumers and enable the UK to fulfil Community obligations. Failure to make these Regulations would result in a serious breach of the UK’s obligations under the EC treaty which would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.