Food Safety
AUTHORITY OF IRELAND

6

GUIDANCE NOTE

Guidance on the Implementation of European Communities (Infant Formulae and Follow-on Formulae) Regulations 2007 and 2009 (Revision 1)

Guidance Note No. 6: Guidance on the Implementation of European Communities (Infant Formulae and Follow-on Formulae) Regulations 2007 and 2009 (Revision 1)

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1. INTRODUCTION

This guidance note updates and replaces the Food Safety Authority of Ireland's (FSAI) *Guidance Note No. 6 on the implementation of European Communities (Infant Formulae and Follow-on Formulae) Regulations* 1998 to 2000 published in 2001.

This has been developed by agreement between the FSAI, the environmental health officers' service of the Health Service Executive (HSE), the Dairy Controls and Certification Division of the Department of Agriculture, Food and the Marine (DAFM) and in consultation with the Irish infant nutrition industry.

2. BACKGROUND

The International Code of Marketing of Breast-Milk Substitutes was published by the Executive Board of the World Health Organization at the end of 1980 and passed as a recommendation to the Member Governments by the 34th World Health Assembly in May 1981. The aim of the International Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast milk substitutes when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

The International Code recognises that when a mother chooses to breastfeed she should be encouraged to do so. However, for those mothers who choose not to breastfeed or do so partially, or for those mothers and/or infants for whom it is medically contraindicated, alternatives to human breast milk must be made available. The Code also recognises that it is the right of the mother to make an informed choice about how she wishes to feed her infant.

Information on the benefits of breastfeeding and the risks associated with choosing not to breastfeed must be provided in order for a mother to make an informed choice. A mother may then choose to breastfeed or not breastfeed, rather than choosing between formula milk and breast milk.

EU and national legislation relating to the composition, labelling, presentation and advertising of infant formulae and follow-on formulae is in conformity with the principles and aims of the WHO International Code of Marketing of Breast Milk Substitutes.

3. PURPOSE

The purpose of this guidance note is to provide competent authorities, infant formulae and follow-on formulae manufacturers and retailers with guidance on the implementation of the legislation governing the composition and marketing of infant formulae and follow-on formulae as provided for in the European Communities (Infant Formulae and Follow-on Formulae) Regulations 2007 and 2009.

The principal purpose of the legislation and this guidance note is to contribute to the health of infants, bearing in mind that the encouragement and protection of breastfeeding is an important aspect of health care. It takes account of international discussions, in particular, those in Codex Alimentarius in relation to the timing of the introduction of complementary foods into the diet of infants.

For the most part, the EU and national legislation is self explanatory. This guidance note focuses on key areas of the legislation where advice is required:

- Marketing requirements including labelling, presentation, advertising and promotion of infant formulae and follow-on formulae
- Notification of infant formulae
- Export of infant formulae and follow-on formulae to Third Countries

Note: This guidance note is not a legal interpretation of the legislation. It should be read in conjunction with the applicable legislation.

4. SCOPE

This guidance note applies in the Republic of Ireland to the composition, labelling, presentation and advertising of infant formulae and follow-on formulae. Infant formulae and follow-on formulae are those formulae intended for use by infants in good health.

This guidance does not cover:

- Milk intended for young children or similar products intended for young children between one and three years
- Processed cereal-based foods and baby foods for infants and young children
- Foods for special medical purposes intended for use by infants and young children

Note: The FSAI's *Guidance Note No 22: Information relevant to the development of Guidance Material for the Safe Feeding of Reconstituted Powdered Infant Formula (Revision 2)* provides practical information on the use of infant formula.

5. DEFINITIONS FOR THE PURPOSE OF THIS GUIDANCE

Advertising:	The making of a representation in any form in connection with any trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations (Directive 2006/114/EC)
Authorised Officer:	An authorised officer appointed under Section 49 of the Food Safety Authority of Ireland Act, 1998
Dietary Foods for Special Medical Purposes	A category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two (Directive 1999/21/EC)
Follow-on Formulae:	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 for such infants. Cognate words shall be construed accordingly (Directive 2006/141/EC)
Follow-on Milk:	Follow-on formula manufactured entirely from cows' milk proteins (Directive 2006/141/EC)
Health Care System:	Includes institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or child-care institutions, and includes health workers in private practice (S.I. No. 852 of 2007)

Health Claim, Nutrition Claim and Reduction of Disease Claim:	Defined in accordance with Article 2.2 of Regulation (EC) No 1924/2006
Infant Formulae:	Foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants, until the introduction of appropriate complementary feeding. Cognate words shall be construed accordingly (Directive 2006/141/EC)
Infant Milk:	Infant formula manufactured entirely from cows' milk proteins (Directive 2006/141/EC)
Infants:	Children under the age of 12 months (Directive 2006/141/EC)
Labelling:	Any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a product and placed on any packaging, document, notice, ring or collar accompanying or referring to such product (Directive 2000/13/EC)
Pesticide Residue:	The residue in infant formulae and follow-on formulae of a plant protection product, as defined in Article 2 of Directive 91/414/EEC, including its metabolites and products resulting from its degradation or reaction
Placing on the Market:	The holding of food for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves (Regulation EC No 178/2002)
Presentation:	Includes the shape, form, aspect, appearance or packaging of the product concerned, the packaging materials used, the way in which the product is arranged when it is exposed for sale and/or the setting in which the product is displayed with a view to sale (Regulation EC No 178/2002)
Young Children:	Children aged between one and three years (Directive 2006/141/EC)

6. LEGAL FRAMEWORK

In Ireland, the rules for the composition and marketing of infant formulae and follow-on formulae are based on European Union legislation.

6.1 EUROPEAN LEGISLATION

Infant formulae and follow-on formulae are foods intended for infants and young children in good health. These are foods for particular nutritional uses (PARNUTs). PARNUTs are 'foodstuffs which, owing to their special composition or manufacturing processes are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability'. Specific rules have been introduced for infant formulae and follow-on formulae.

For ease of reading, this section is focussed on the specific rules for infant formulae and follow-on formulae only. For completeness, the context in which this legislation is framed is set out in Appendix I.

All legislation referenced in this guidance note is available on the FSAI website at:
http://www.fsai.ie/legislation/food_legislation.html

Note: Please consult the Legislation Section on the FSAI website regularly where the current legislation is available.

6.1.1 Infant formulae and follow-on formulae

- Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC amended by:
  - Commission Regulation (EC) No 1243/2008 of 12 December amending Annexes III and IV to Directive 2006/141/EC as regards compositional requirements for certain infant formulae
  - Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries
  - Council Recommendation of 18 June 1992 on the marketing of breast-milk substitutes in third countries by Community-based manufacturers

6.2 NATIONAL LEGISLATION

6.2.1 Infant formulae and follow-on formulae

- European Communities (Infant Formulae and Follow-on Formulae) Regulations, 2007 [S.I. No. 852 of 2007]
- European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations, 2009 [S.I. No. 209 of 2009]

The two sets of Regulations are known collectively as European Communities (Infant Formulae and Follow-on Formulae) Regulations, 2007 and 2009.

These transpose:

- Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC
- Commission Regulation (EC) No 1243/2008 of 12 December amending Annexes III and VI to Directive 2006/141/EC as regards compositional requirements for certain infant formulae into Irish law
- Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries

6.3 ENFORCEMENT AND COMPLAINTS

The FSAI, the HSE and DAFM are responsible for the enforcement of food legislation including European Communities (Infant Formulae and Follow-on Formulae) Regulations, 2007 and 2009. The manufacture of infant formulae and follow-on formulae is supervised by the Dairy Controls and Certification Division of DAFM. Once infant formulae and follow-on formulae are placed on the market, they are supervised by the environmental health service of the HSE.

Complaints about infringements of the legislation should be brought to the attention of either the FSAI or the local environmental health service of the HSE.

6.4 FOODS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR USE BY INFANTS

Some dietary foods for special medical purposes (FSMPs) are intended specifically for use by infants. If a food which is intended to be used by infants is deemed to be a FSMP, it must comply with the rules for dietary foods for special medical purposes. These foods do not come within the scope of the rules relating to infant formula and follow-on formula. Commission Directive 1999/21/EC sets out the rules for dietary foods for special medical purposes. These are transposed into Irish legislation by European Communities (Dietary Foods for Special Medical Purposes) Regulations, 2009 [S.I. No. 187 of 2009].

See FSAI *Guidance Note No. 19: Notification of Dietary Foods for Special Medical Purposes.*

7. GENERAL REQUIREMENTS

The European Communities (Infant Formulae and Follow-on Formulae) Regulations, 2007 [S.I. No. 852 of 2007] as amended, is presented in five Parts with associated Schedules

- Part 1: Preliminary. This includes the title, date(s) of coming into operation and definitions
- Part 2: Infant Formulae and Follow-on Formulae to be placed on the market in a Member State
- Part 3: Infant Formulae and Follow-on Formulae for export to Third Countries
- Part 4: Enforcement
- Part 5: Revocations

Note: For ease of reading, legal references in this guidance note will be to the Irish legislation. This guidance should be read in conjunction with the Irish and European legislation.

PART 1: PRELIMINARY

Part 1 sets out the title and the citation of the Regulation as amended and definitions used in the Regulation.

Sampling and analysis required to verify compliance with the Regulation is carried out by the Dairy Controls and Certification Inspectorate, DAFM and the environmental health service, HSE. Chemical analysis is carried out by the Dairy Science Laboratory, Backweston (DAFM) and the Public Analysts Laboratories, HSE. Microbiological testing is carried out by the Dairy Science Laboratory, Backweston, Dairy Science Laboratory, Limerick and the Public Health Microbiology Laboratories, HSE.

The definition of follow-on formulae has been changed in light of international discussions on the timing of the introduction of complementary feeding. Follow-on formula is now defined as '*when appropriate complementary feeding is introduced*….' However, the labelling on follow-on formulae must have a statement to the effect that the product is suitable only for use by infants over the age of six months as part of a diversified diet. It is not suitable as a substitute for breast milk during the first six months of life. The decision on when to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent suitably qualified persons.

PART 2: INFANT FORMULAE AND FOLLOW-ON FORMULAE INTENDED TO BE PLACED ON THE MARKET IN A MEMBER STATE

Part 2 of the Regulation sets out the conditions under which infant formulae and follow-on formulae must be sold. Products which do not meet the criteria cannot be placed on the market as infant or follow-on formulae. A product which is not an infant formula cannot be represented as being suitable for satisfying by itself, the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding.

Description

Infant formulae and follow-on formulae manufactured from protein hydrolysates or soya protein isolates must use the descriptions 'infant formula' or 'follow-on formula' respectively. Infant formula or follow-on formula manufactured entirely from cows' milk proteins must be described as 'infant milk' and 'follow-on milk' respectively.

Composition

Infant formulae and follow-on formulae must be manufactured in accordance with strict compositional rules. These are set out in Schedules 1 (infant formulae) and Schedule 2 (follow-on formulae) of the Regulations. The compositional criteria for infant formulae and follow-on formulae are outlined in Table 1.

Table 1: Overview of Compositional Requirements for Infant Formulae and Follow-on Formulae*

Ingredient	Values	Conditions
Energy	Minimum and maximum set	
Protein	Minimum and maximum set for: • Cows' milk protein • Protein hydrolysates • Soya protein isolates	Addition of amino acids for nutritional purposes only, only in proportions necessary for the purpose
Taurine	Maximum set if added	
Choline	Minimum and maximum set	Applies to infant formula only
Lipids • Lauric acid and myristic acid • Linoleic acid	Minimum and maximum set • Maximum set • Minimum and maximum set	Sesame and cotton seed oil is prohibited
Phospholipids	Maximum set	
Inositol	Maximum and minimum set	Applies to infant formula only
Carbohydrates • Lactose • Sucrose • Glucose • Pre-cooked starch and/ or gelatinised starch	Minimum and maximum set • Minimum set, if added except where soya protein isolates >50% of total protein content • Maximum set if added • Maximum set if added • Maximum set	Only listed forms may be added to infant formulae Use of ingredients containing gluten are prohibited in infant formulae and follow-on formulae Sucrose and glucose may only be added where protein hydrolysates are used Fructose and honey may be used in follow-on formulae.
** Saccharides Fructo-oligosaccharides and galacto-oligosaccharides	Maximum set if added with 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharides	May be added Other combinations and maximum levels may be used in accordance with Regulations 4(1) and 4(2)
Minerals	Maximum and minimum set for specific minerals	Lists minerals which may only be added to infant formula and follow-on formulae manufactured from: • Cows' milk or protein hydrolysates • Soya protein isolates alone or mixed with cows' milk proteins
Vitamins	Minimum and maximum set for specific vitamins	
Nucleotides	Maximum set if added	May be added

* This table is an overview only and must be read in conjunction with Schedules 1, 2 and 5.

** While saccharides are listed with carbohydrates in the EU Directive 2006/141/EC they are separated in S.I. No. 852 of 2007.

The source of protein may only be cows' milk, protein hydrolysates or soya protein isolates. The use of any other animal protein source, such as goats' milk, is prohibited. When determining the composition of infant formula and follow-on formulae, account must be taken of the specifications for indispensible and conditionally indispensible amino acids in breast milk. These are set out in Schedule 5 of the Regulation.

Where the infant formula is manufactured from protein hydrolysates of whey proteins derived from cows' milk protein with a protein content between the minimum 0.45g/100kJ (1.8g/100kcal) and 0.56g/100kJ (2.25g/100kCal), it must comply with the specifications set out in Schedule 6.

The food ingredients used in infant formulae and follow-on formulae can only be used in accordance with the prohibitions and limitations set out in Schedules 1 and 2 respectively.

Only minerals, vitamins, amino acids and other nutritional substances set out in Schedule 3 of the Regulations can be used in infant formulae and follow-on formulae.

Purity criteria

The purity criteria for substances listed in Schedule 3 must be in accordance with Community legislation where criteria have been set for those substances, i.e. food additives. Where no such criteria have been set in Community legislation, then criteria generally recommended by international bodies will apply.

Pesticides residues

In general, infant formula and follow-on formulae must not contain residues of individual pesticides at levels exceeding 0.01mg/kg in the final product as it is intended to be consumed. Certain pesticides cannot be used in agricultural products intended for the production of infant formulae or follow-on formulae. These are listed in Schedule 8 of the Regulation. To be considered absent, they must not be present at levels above 0.003mg/kg. Certain other pesticides are permitted in infant formula and follow-on formulae once the maximum levels, as listed in Schedule 9 of the Regulation, are not exceeded.

Marketing

The requirements for the labelling, presentation, advertising, promotion and donations of infant formulae are detailed in Section 8 of this guidance note.

Nutrition and health claims

There are only six nutrition claims and one health claim allowed on infant formulae and these are set out in Schedule 4 of the Regulation.

Permitted claims must be in accordance with the Schedule and comply with the conditions of use set out.

As for all food, the requirements regarding nutritional or health claims made on infant formulae include what appears on the label and any associated presentation or advertising.

Reduction of disease risk claims are not permitted on infant formulae.

Nutrition, health or disease reduction claims made in respect of follow-on formulae must comply with Regulation (EC) No 1924/2006 on nutrition and health claims made on food.

Notification

The notification of infant formulae is detailed in Section 9 of this guidance note.

PART 3: INFANT FORMULAE AND FOLLOW-ON FORMULAE INTENDED FOR EXPORT TO THIRD COUNTRIES

The requirements are detailed in Section 10 of this guidance note.

PART 4: ENFORCEMENT

This part sets out the provisions for enforcement which are similar to those provided for in other national food legislation introduced by the Department of Health. These include provisions for:

- Sampling
- Retention of batches for a period not exceeding 15 days from the taking of the sample pending the results of analysis where the product is suspected not to be in compliance
- Sampling provisions apply equally to products which are not infant formulae or follow-on formulae but which are placed on the market as such or any other products which the authorised officer suspects are being treated, manufactured or placed on the market in contravention of the Regulations
- Seizure, removal, detention and withdrawal of products suspected not to comply with the Regulations

PART 5: REVOCATIONS

The European Communities (Infant Formulae and Follow-on Formulae) Regulations, 2004 [S.I. No. 242 of 2004] and its amendment [S.I. No. 242 of 2007] are now revoked in their entirety. The time periods for all transitional arrangements has now passed.

8. MARKETING OF INFANT FORMULAE AND FOLLOW-ON FORMULAE

The rules on general labelling and nutrition and health claims apply to both infant formulae and follow-on formulae. References to these rules are set out in Appendix 1.

8.1 MARKETING OF INFANT FORMULAE

In addition, certain restrictions apply to the labelling, advertising, presentation, distribution, donation and promotion of infant formulae. The legislation stipulates that the requirements, prohibitions and restrictions relating to the labelling of infant formula also apply to advertising and presentation.

- **Consumers** must be able to clearly distinguish between infant formula and follow-on formula products through their labelling, advertising or presentation.
- **Labels** carried on infant formulae should provide information about the product as well as its safe storage, handling and preparation in particular a warning against the hazards of inappropriate preparation and storage (FSAI Guidance Note 22). Certain mandatory statements about the benefits of breastfeeding are required by law on product labels and any additional information must not discourage breastfeeding.
- **Advertising** includes information about infant formula disseminated through various media outlets, electronic communication (internet websites, email etc) and social media (facebook, twitter, blogs, etc). Advertising of infant formula is restricted to publications specialising in baby care or scientific publications and may only contain information of a scientific and factual nature.
- **Presentation** includes the product shape and appearance, the packaging materials used as well as the product arrangement and the setting in which it is displayed.
- **Donations** or low price sales of infant formula by manufacturers and distributors to organisations or institutions and its distribution or use by these bodies is acceptable only where infant formula is the only source of nutrition available to an infant and only for as long as required by such infants.
- **Informational or educational equipment or materials** dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children must contain clear information on the benefits and superiority of breastfeeding; the importance of maternal nutrition; the preparation for and maintenance of breastfeeding; the possible negative effects on breastfeeding of introducing partial bottle feeding; the difficulty of reversing the decision and where needed, the proper use of infant formulae. Informational or educational material must not use pictures or text that may idealise the use of infant formula. Information about the use of infant formulae must include the financial and social implications of its use, the health hazards of inappropriate foods or feeding methods and in particular the improper use of infant formulae.

- **Manufacturers and distributors** may donate informational or educational equipment or materials upon request and with the prior written consent of the FSAI. Such equipment and materials may bear the donating company's logo but must not refer to a proprietary brand of infant formula, and may only be distributed through the health care system.
- **Promotions** of infant formula including point-of-sale advertising, giving of samples (free or reduced price) or any other promotional device to induce sales of infant formulae directly to the consumer at the retail level are prohibited. The use of special displays, specific discounts and sales, premiums, loss-leaders and tie-in sales are not permitted at retail level. The awarding of points on loyalty cards by retailers for the purchase of infant formula is not permitted.

'Idealising' the use of infant formula

'The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. It may, however, include graphic representations for easy identification of the product and for illustrating methods of preparation'.

'Idealise' is a subjective term that is difficult to define and therefore any relevant pictures and text will need to be assessed on a case-by-case basis. However, experience shows that any human likeness, as portrayed in pictures, cartoons or other graphic representations, can be construed by the general public as idealising the use of infant formula and therefore should not be used in the labelling or advertising of infant formulae, even to demonstrate optimal preparation, handling or storage.

8.2 MARKETING OF FOLLOW-ON FORMULAE

In addition to the general labelling requirements, certain mandatory information must be provided on the labels of follow-on formula, including: a statement to the fact that the follow-on formula is only suitable for infants over six months; specific composition and nutrition information and the appropriate use so as not to discourage breastfeeding. The use of the terms 'humanised', maternalised', 'adapted' or similar terms are not permitted. Follow-on formula must also be clearly labelled to ensure that the distinction between infant formulae and follow-on formulae is clear and unambiguous.

9. NOTIFICATION OF INFANT FORMULA

9.1 GENERAL

To facilitate the efficient official monitoring of infant formulae, the Regulations require the food business operator placing infant formula on the market in Ireland to notify the FSAI by forwarding a model of the label used for the product. Any changes to the labelling should also be notified.

This requirement applies when the product is manufactured in or imported into Ireland and is being first placed on the market by an individual, i.e. manufacturer, distributor, importer or retailer, irrespective of the country of origin of the product.

All infant formula which is to be placed on the market in Ireland must be notified regardless of whether the product has already been notified in another Member State.

This notification procedure applies to all infant formulae covered by the Regulation. If the product is a dietary food for special medical purposes intended for use by infants, it must be notified as a dietary food for special medical purposes rather than as an infant formula.

Notification of follow-on formulae is not required.

Products already on the market prior to 1st January, 2008, the date the Regulations came into operation, do not need to be notified unless the label has been changed or the product has been reformulated since the 1st January, 2008. A single notification will suffice for product which is sold in a variety of sizes, once the same information is supplied on the label for each size. The variety of sizes of packs must be declared on the notification form. A separate form is required for each product.

9.2 HOW TO NOTIFY THE FSAI

The Regulations require that a model of the label of any product requiring notification is forwarded to the FSAI. The FSAI has developed a template for notification of infant formulae to assist infant formulae manufacturers or importers. This is available from the FSAI website at: http://www.fsai.ie/legislation/notification_form/ifnotification.html.

Notification is made by forwarding a completed form along with a model of the product label and any associated packaging as available at point-of-sale.

9.3 FURTHER INFORMATION REQUIRED BY THE FSAI

The FSAI may require the manufacturer (or where appropriate, the importer) to produce additional information to demonstrate compliance with relevant legislation.

10. EXPORT TO THIRD COUNTRIES

Part 3 of the Regulation sets out the requirements for exporting infant formulae and follow-on formulae to Third Countries, i.e. countries outside of the European Union.

Infant formula intended for export to Third Counties must meet the requirements of Regulation 12. Infant formulae for export must comply with the appropriate compositional criteria set out in Regulation 4, i.e. Schedule 1 or the equivalent set out in Codex Alimentarius. The labelling and presentation of infant formula for export must also comply with the requirements set out in Regulation 6, paragraphs 1-7.

Follow-on formulae intended for export to Third Countries must meet the requirements of Regulation 13. Follow-on formulae for export must comply with the appropriate compositional criteria set out in Regulation 5, i.e. Schedule 2 or the equivalent set out in the Codex Alimentarius. The labelling and presentation of follow-on formulae for export must also comply with the labelling requirements set out in Regulation 7, paragraphs 1 – 4.

In addition, infant formulae and follow-on formulae for export must meet the requirements of Council Directive 89/396/EEC on identifications or marks identifying the lot to which a foodstuff belongs. The infant formulae or follow-on formulae for export must be labelled in an appropriate language, i.e. the language understood by the consumers in the country in which it is to be marketed. The infant formulae or follow-on formulae for export must be labelled in such a way as to avoid the risk of confusion between them.

Infant formula which does not comply with these requirements must not be exported unless a deviation from this requirement is requested or stipulated by the Third Country and subject to Article 12 of Regulation 178/2002, i.e. general requirements for food exported from the EU.

DAFM is responsible for the certification of infant formulae and follow-on formulae for export to Third Countries.

11. RELATED DOCUMENTS

The FSAI has published *Guidance Note No. 22 (Revision 2): Information Relevant to the Development of Guidance Material for the Safe Feeding of Reconstituted Powdered Infant Formula*. This document provides the basis for the development of suitable guidance material on the safe preparation and feeding of powdered infant formula.

APPENDIX I: LEGISLATION

Legislation relating to Infant Formulae and Follow-on Formulae

	EU Legislation	National Legislation
[1]General Food Law	Council Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety as amended	S.I. No. 747 of 2007 (HSE) S.I. No. 498 of 2010 (HSE) S.I. No. 500 of 2011 (HSE) S.I. No. 432 of 2009 (DAFM) S.I. No. 164 of 2012 (DAFM)
General Labelling	Council Directive 2000/13/EC of 20 March 2000 on the approximation of laws of the member States relating to the labelling, presentation and advertising of foodstuffs as amended	S.I. No. 483 of 2002 as amended
Lot Identification	Council Directive 2011/91/EU of 13 December 2011 on indication or marks identifying the lot to which a foodstuff belongs	S.I. No. 110 of 1992
Foods for Particular Nutritional Uses (PARNUTs)	Council Directive 2009/39/EC of 06 May 2009 on foodstuffs intended for particular nutritional uses Commission Regulation (EC) No 953/2009 as amended by Commission Regulation (EU) No 1161/2011	S.I. No. 169 of 2012
Infant Formulae and Follow-on Formulae	Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC Regulation (EC) No 1243/2008 of 12 December amending Annexes III and IV to Directive 2006/141/EC as regards compositional requirements for certain infant formulae Council Directive 92/52/EC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries Council Recommendation of 18 June 1992 on the marketing of breast-milk substitutes in third countries by Community based manufacturers	S.I. No. 852 of 2007 S.I. No. 209 of 2009
Nutrition and Health Claims made on Food	Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food as amended	

[1] Council Regulation (EC) No 2000/13 has been replaced by Regulation (EU) No 1169/2011. While Regulation (EU) No 1169/2011 came into effect in 13th December 2011 its date of application is 13th December 2014 with the exception of point (l) of Article 9(1) (mandatory nutrition declaration), which will apply from 13th December 2016, and Part B of Annex VI (specific requirements regarding the designation of minced meat), which will apply from 1 January 2014.

European Legislation

General provisions for foods for particular nutritional uses are set out in the framework Directive 2009/39/EC. This Directive requires that specific rules are introduced for certain categories of foods including infant formulae and follow-on formulae in addition to the general provisions set out in Directive 2009/39/EC.

The European legislation dealing with the regulation of infant and follow-on formulae is as follows:

FOODS FOR PARTICULAR NUTRITIONAL USES

- Council Directive 2009/39/EC of 06 May 2009 on foodstuffs intended for particular nutritional uses
- Commission Regulation (EC) No 953/2009 of 13 October 2009 as amended by Commission Regulation (EU) 1161/2009 of 14 November 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses

Note: The PARNUTS framework Directive is under review by the European Commission with a proposed completion date by the end of 2012.

INFANT FORMULAE AND FOLLOW-ON FORMULAE

- Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC amended by
- Commission Regulation (EC) No 1243/2008 of 12 December amending Annexes III and IV to Directive 2006/141/EC as regards compositional requirements for certain infant formulae
- Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries
- Council Recommendation of 18 June 1992 on the marketing of breast-milk substitutes in third countries by Community based manufacturers

GENERAL FOOD LAW

- Council Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

LABELLING, PRESENTATION AND ADVERTISING

- Council Directive 2000/13/EC (OJ L109, p29, 06/05/2000) of 20 March 2000 on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs as amended
- Council Directive 89/396/EEC (OJ L186, p21, 30/06/89) of 14 June 1989 on indication or marks identifying the lot to which a foodstuff belongs

NUTRITION AND HEALTH CLAIMS

- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food as amended

National Legislation

FOODS FOR PARTICULAR NUTRITIONAL USES

European Communities (Foodstuffs for Particular Nutritional Uses) Regulations, 2006 [S.I. No.169 of 2012

These transpose:

- Council Directive 2009/39/EC of 06 May 2009 on foodstuffs intended for particular nutritional uses
- Commission Regulation (EC) No 953/2009 of 13 October 2009 as amended by Commission Regulation (EU) 1161/2009 of 14 November 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses

INFANT FORMULAE AND FOLLOW-ON FORMULAE

- European Communities (Infant Formulae and Follow-on Formulae) Regulations, 2007 [S.I. No. 852 of 2007]
- European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations, 2009 [S.I. No. 209 of 2009]

The two sets of Regulations are known collectively as European Communities (Infant Formulae and Follow-on Formulae) Regulations, 2007 and 2009.

These transpose:

- Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC
- Commission Regulation (EC) No 1243/2008 of 12 December amending Annexes III and IV to Directive 2006/141/EC as regards compositional requirements for certain infant formulae into Irish law.
- Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries

GENERAL FOOD LAW

- European Communities (General Food Law) Regulations, 2007 (S.I. 747 of 2007) as amended by the European Communities (General Food Law) (Amendment) Regulations, 2010 (S.I. No. 498 of 2010) and the European Communities (General Food Law) (Amendment) Regulations 2011 (S.I. No. 500 of 2011)
- European Communities (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009)

These transpose:

- Council Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

S.I. No. 747 of 2007 as amended applies to food businesses supervised by the HSE. S.I. No. 432 of 2009 applies to food businesses supervised by DAFM and to certain approved manufacturers of products of animal origin supervised by the HSE. For details of these manufacturers, see www.fsai.ie.

LABELLING, PRESENTATION AND ADVERTISING

European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, 2002 as amended, transpose Council Directive 2000/13/EC (OJ L109, p29, 06/05/2000) of 20 March on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs as amended

These transpose:

- Council Directive 2000/13/EC (OJ L109, p29, 06/05/2000) of 20 March 2000 on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs as amended

European Communities (Identification of Foodstuff Lot) Regulations, 1992

These transpose:

- Council Directive 2011/91/EU of 13 December 2011 on indication or marks identifying the lot to which a foodstuff belongs

Note: Regulation (EU) No 1169/2011 on the provision of food information to consumers replaces the current rules, i.e. Regulation (EC) No 2000/13 and its amendments, and sets out the requirements for the provision of food information for the consumer as well as the requirements for the provision of nutrition information on foodstuffs. The Regulation came into effect on the 13th December 2011. It will apply from 13 December 2014, with the exception of point (l) of Article 9(1) (mandatory nutrition declaration), which will apply from 13th December 2016, and Part B of Annex VI (specific requirements regarding the designation of minced meat), which will apply from 1 January, 2014.

This new Regulation maintains the original objectives and the core components of the current labelling legislation, but does introduce some new requirements in order to ensure easier compliance and greater clarity for stakeholders as well as modernising the legislation to take account of new developments in the field of food information.

NUTRITION AND HEALTH CLAIMS

This legislation awaits the introduction of national law to give effect to it.

NOTES

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