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## Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)

This guidance applies to the whole of the UK and was prepared by the Welsh Government, the Department of Health and Food Standards Agency in Scotland and Northern Ireland

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[www.wales.gov.uk/topics/health/improvement/index](http://www.wales.gov.uk/topics/health/improvement/index)

## Intended audience

This guidance is aimed at all companies that manufacture, process, distribute, use, sell or import infant formula and follow-on formula, and those local authorities who are responsible for enforcing the legislation in this area.

Legislation on infant formula and follow-on formula is implemented on a devolved basis; however this guidance applies across the UK.

## Executive summary

EU Directive 2006/141/EC of 22 December 2006 is implemented in the UK by The Infant Formula and Follow-on Formula (Wales) Regulations 2007 (as amended), and equivalent regulations in England, Scotland and Northern Ireland. The Regulations specify rules on the compositional labelling and advertising of infant formula and follow-on formula.

The information set out in this document aims to provide non-statutory guidance on the rules, which apply to infant formula and follow-on formula under these Regulations.

## REVISION HISTORY

Revision No.	Revision date	Purpose of revision
1	May 2008	Finalise Draft Guidance
2	March 2009	To take account of 2008 amending Regulations
3	March 2013	To take account of the transfer of responsibility from The Food Standards Agency to the Welsh Government. <b><u>Important.</u> No significant changes have been made beyond updating contact details and weblinks.</b>

## Contents

Introduction .....	1
Background .....	2
Interpretation (regulation 2) .....	3
Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met (regulation 3) .....	6
Regulations 5 to 11 .....	6
Listed substances and their purity criteria (infant formula and follow-on formula) (regulation 12) .....	6
Notification of infant formula (regulation 13).....	7
Labelling of infant formula (regulation 17).....	7
Labelling relating to the preparation, storage and disposal of infant formula and follow-on formula.....	7
Labelling relating to the 'Important Notice' requirement.....	8
Labelling about the appropriate use of infant formula and follow-on formula so as not to discourage breastfeeding.....	8
Labelling of infant formula to avoid idealising the product .....	8
Use of nutrition and health claims in relation to infant formula (Regulation 17(4)).....	9
Extending the list of permitted nutrition and health claims in relation to infant formula .....	11
Labelling of follow-on formula (regulation 18).....	11
The use of claims in relation to follow-on formula.....	11
General guidance with regard to infant formula and follow-on formula advertising .....	13
Avoidance of the risk of confusion between infant formula and follow-on formula (in relation to labelling, presentation and advertising) (regulation 19) .....	14
Presentation (infant formula and follow-on formula) (regulation 20) .....	14
Restrictions on advertising infant formula (regulation 21).....	15
The use of 'Important Notice' information in infant formula advertisements .....	15
Advertising in relation to the appropriate use of infant formula and follow-on formula so as not to discourage breastfeeding .....	15
The use of pictures of infants or any other picture or text which may idealise the use of the product.....	15
The use of nutrition and health claims in infant formula advertisements.....	16
Ensuring that there is a clear distinction between advertisements for infant formula and follow-on formula.....	16
Ensuring that advertisements do not imply or create the belief that bottle-feeding is equivalent or superior to breastfeeding .....	16
Promotion of company 'milks' or 'formulae' .....	16
Additional Notes in relation to infant formula advertising.....	16
Restrictions on advertising follow-on formula (regulation 22).....	17
Restrictions on promotion of infant formula (regulation 23).....	18
Provision of information and education regarding infant and child feeding (regulation 24).....	18
Third country exports (regulations 26 and 27) .....	20
Offences and enforcement (regulation 28) .....	20
Revocation and transitional arrangements (regulation 31) .....	21
General recommendations to formula manufacturers.....	22

<b>Monitoring and review .....</b>	<b>22</b>
<b>Appendix I - Interpretation of ‘advertising’ .....</b>	<b>23</b>
<b>Appendix II – Guidance on website information relating to infant formula, follow-on formula and infant feeding .....</b>	<b>25</b>
<b>Appendix III – Differentiating infant formula and follow-on formula.....</b>	<b>26</b>
<b>Appendix IV – Guidance on scientific publications and information of a scientific or factual nature.....</b>	<b>27</b>

## Introduction

The content of these Guidance Notes was originally prepared by the Food Standards Agency (FSA) and reflects the interpretation of the Infant Formula and Follow-on Formula Regulations 2007 at that time. Other than those references to listed substances and their purity criteria, no significant changes have been made to these guidance notes following the move of responsibility for nutrition policy in Wales, from the FSA in Wales to the Welsh Government on 1 October 2010. The FSA Devolved Administrations of Scotland, and Northern Ireland are responsible for national legislation in their own administrations where separate but similar regulations apply. The responsibility for the policy area of infant formula and follow-on formula legislation in England has moved to the Department of Health.

These guidance notes aim to help industry, enforcement officers and other interested parties interpret the provisions of The Infant Formula and Follow-on Formula (Wales) Regulations 2007 (SI No. 3573 (W. 316) as amended by the Infant Formula and Follow-on Formula (Amendment) (Wales) Regulations 2008 (SI No. 2602 (W. 228)) and equivalent Regulations in England, Scotland and Northern Ireland<sup>1</sup> (referred to in the rest of this document as 'the Regulations').

The guidance notes:

- focus mainly on the provisions of the Regulations which relate to labelling, notification, avoidance of risk of confusion between infant formula and follow-on formula, advertising, promotion, and the provision of information and education relating to infant and child feeding.
- replace any LACORS Guidance Notes<sup>2</sup> on infant formula and follow-on formula and supersede any previous views expressed by the FSA on the interpretation of the Regulations which relate to the issues mentioned above.
- apply to equivalent parallel Regulations in England, Scotland and Northern Ireland.
- These guidance notes reflect the Welsh Government's view on how the Regulations should be interpreted. They have been produced to provide advice on the legal requirements of the Regulations and should be read in conjunction with the legislation itself. The text should not be taken as an authoritative statement or interpretation

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<sup>1</sup>The Infant Formula and Follow-on Formula (England) Regulations 2007 (SI 2007/3521) as amended by the Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008 (SI 2008/2445)

The Infant Formula and Follow-on Formula (Scotland) Regulations 2007 as amended by the Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2008 (SI 2008/322)

The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007 as amended by the Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 2008 (SR 2008/405)

<sup>2</sup> [www.lacors.gov.uk](http://www.lacors.gov.uk)

of the law, as only the courts have this power. Every effort has been made to ensure that these guidance notes are as helpful as possible. However, it is ultimately the responsibility of individual businesses to ensure their compliance with the law. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority or Port Health Authority or district council.

## Background

The Regulations implement European Commission Directive 2006/141/EC on infant formulae and follow-on formulae (referred to in the rest of this document as ‘the Directive’) which consolidates existing Community legislation on the composition, labelling and marketing of infant formulae and follow-on formulae. The Directive reflects the latest scientific advice on the essential composition of infant formulae and follow-on formulae and discussions at an international level in the Codex Alimentarius forum. The Directive also gives effect to the principles and aims of the 1981 WHO Code on the Marketing of Breastmilk Substitutes dealing with marketing, information and responsibilities of health authorities. The Directive regulates labelling and restricts advertising and presentation of infant and follow on formula so as not to discourage breastfeeding. The Regulations also implement Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries.

The Regulations were made in December 2007 and contain provisions relating to:

- The provisions relating to the notification of infant formula
- advertising of infant formula and follow-on formula
- presentation in so far as it relates to the way in which infant formula and follow-on formula are arranged and the setting in which they are displayed
- provision of informational and educational material dealing with the feeding of infants which came into force in early 2008.

The Regulations also put in place certain transitional arrangements until 2010 for products complying with the Infant Formula and Follow-on Formula Regulations 1995 (SI 1995/77)<sup>3</sup>, as amended (referred to as ‘the previous Regulations’ in the rest of this document). These transitional arrangements are explained further in paragraph 86.

In these Guidance Notes, references to ‘Annexes’ refer to the Annexes of Directive 2006/141/EC. Links to the Regulations and Directives 2006/141/EC and 92/52/EEC can be found below:

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<sup>3</sup> In Northern Ireland, the Infant Formula and Follow on Formula Regulations (NI) 1995 SR No. 85

2007 Regulations:

<http://www.legislation.gov.uk/wsi/2007/3573/contents/made>  
[http://www.opsi.gov.uk/si/si2007/pdf/uksi\\_20073521\\_en.pdf](http://www.opsi.gov.uk/si/si2007/pdf/uksi_20073521_en.pdf)  
<http://www.legislation.gov.uk/ssi/2007/549/contents/made>  
<http://www.legislation.gov.uk/nisr/2007/506/contents/made>

2008 Regulations:

<http://www.legislation.gov.uk/wsi/2008/2602/contents/made>  
<http://www.legislation.gov.uk/uksi/2008/2445/contents/made>  
<http://www.legislation.gov.uk/ssi/2008/322/contents/made>  
<http://www.legislation.gov.uk/nisr/2008/405/contents/made>

2006/141/EC:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:401:0001:0033:EN:PDF>

92/52/EEC:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31992L0052:EN:HTML>

## Interpretation (regulation 2)

Regulation 2(1) provides certain definitions.

Regulation 2(2) provides that, subject to regulation 2(3), any expression other than one defined in regulation 2(1) that is used both in the Regulations and in the Food Safety Act 1990<sup>4</sup> (referred to for the purposes of these Guidance Notes as ‘the Act’) has the meaning it bears in the Act.

Regulation 2(3) provides that any expression used in the Regulations and in the Directive has the meaning that it bears in the Directive. The definitions of the following terms set out in the Directive apply for the purposes of the Regulations:

- ‘infants’ means children under the age of 12 months;
- ‘young children’ means children aged between one and three years;
- ‘infant formulae’ means 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;
- ‘follow-on formulae’ means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding

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<sup>4</sup> In Northern Ireland, the corresponding legislation is the Food Safety (NI) Order 1991.  
[http://www.opsi.gov.uk/acts/acts1990/Ukpga\\_19900016\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900016_en_1.htm).



is introduced and constituting the principal liquid element in a progressively diversified diet of such infants. This definition should be read in conjunction with Regulation 18(1)(a), which clarifies that follow-on formula is only suitable for infants over the age of six months;

- 'pesticide residue' means the residue in infant formulae and follow-on formulae of a plant protection product, as defined in point 1 of Article 2 of Directive 91/414/EEC, including its metabolites and products resulting from its degradation or reaction.

The definitions of the following terms set out in Regulation (EC) No. 1924/2006 (the European Nutrition and Health Claims Regulation) apply for the purposes of the Regulations: 'claim', 'nutrition claim', 'health claim', 'reduction of disease risk claim' (refer to paragraph 33 for further details).

The term 'third country' has the meaning that it has in EC legislation. Thus, a third country is any country which is not part of the European Union.

The term 'advertisement' has not been defined in the Regulations (a definition was given in the previous Regulations). The term 'advertising' is used in the Directive but is not defined. It is considered that any attempt to define the term runs the risk of limiting its scope bearing in mind the wide range of forms that advertising has taken in recent years. Guidance relating to the interpretation of 'advertising' in the context of the Regulations is provided in Appendices I and II.

The terms 'sell' and 'market' have not been defined in the Regulations (the previous Regulations provided a definition of the term 'sell'). These terms, when used in the Regulations, will have the same meaning as in the Directive.

The term "place infant formula on the market" has not been defined in the Regulations and is not defined in the Directive. The term "placing on the market" is defined in Regulation 178/2002.

Wording to reflect the meaning given to the term 'presentation' in Article 13(8) of the Directive is included in the Regulations at regulation 20(3). Regulation 20(3) defines "presentation" as "includes the shape, appearance or packaging of the products concerned, the packaging materials used, the way in which they are arranged and the setting in which they are displayed."

Regulation 2(6)<sup>5</sup> provides that the Regulations will refer 'automatically' to the amended Annexes to the Directive without the need to introduce new amending regulations each time the Annexes to the Directive are updated. The Regulations will be amended by further regulations if the main Articles of the Directive are updated. The information in the Annexes to the Directive is summarised below:

- Annex I – The essential composition of infant formula when reconstituted as instructed by the manufacturer.

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<sup>5</sup> In the Scotland and Northern Ireland Regulations regulation 2(5)

- Annex II - The essential composition of follow-on formula when reconstituted as instructed by the manufacturer.
- Annex III – The list of nutritional substances that can be added to infant formula and follow-on formula for particular nutritional uses.
- Annex IV – The lists of nutrition and health claims that are permitted for use in relation to infant formula, with details of the conditions warranting the claims.
- Annex V – The list of indispensable and conditionally indispensable amino acids in breast milk.
- Annex VI – Specification for the protein content and source and the processing of protein used in the manufacture of infant formula with a protein content less than 0.56 g/100 kJ (2.25 g/100 kcal) manufactured from hydrolysates of whey proteins derived from cows' milk protein.
- Annex VII – Reference values for nutrition labelling for foods intended for infants and young children.
- Annex VIII – List of pesticides which shall not be used in agricultural production intended for the production of infant formulae and follow-on formulae.
- Annex IX – List of the specific maximum residue levels of pesticides or metabolites of pesticides in infant formula and follow-on formula.
- Annex X – Repealed Directive with a list of subsequent amendments, and the list of time limits for transposition into national law.
- Annex XI – Correlation table between Directive 91/321/EEC and Directive 2006/141/EC.

## **Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met (regulation 3)**

This regulation provides that no person shall:

- market infant formula which contravenes or fails to comply with the relevant provisions in the Regulations relating to its composition (regulations 6, 8, 11, 12), naming and labelling (regulations 15 and 17), preparation instructions (regulation 10), safety (regulation 5), pesticide residue levels (14), presentation (regulation 20, applying regulation 17 to presentation) and risk of confusion with follow-on formula (regulation 19).
- market follow-on formula which contravenes or fails to comply with the relevant provisions in the Regulations relating to its composition (regulations 7, 9, 11, 12), naming and labelling (16 and 18), preparation instructions (regulation 10) safety (regulation 5), pesticide residue levels (14), presentation (regulation 20, applying regulations 18 and 19 to presentation) and risk of confusion with infant formula (regulation 19).

## **Regulations 5 to 11**

These regulations relate mainly to compositional aspects of infant formula and follow-on formula. Infant formula and follow-on formula must comply with these compositional requirements. Detailed guidance is not provided on these provisions.

## **Listed substances and their purity criteria (infant formula and follow-on formula) (regulation 12)**

Regulation 12(3) provides that for the purposes of regulation 12(2), the relevant purity criteria for substances used in the manufacture of infant formula and follow-on formula are:

- the purity criteria for substances, as provided for in Community legislation concerning the use of substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by the Directive. The relevant EU legislation which deals with the purity criteria of food additives is Regulation (EC) No 1333/2008 and Commission Regulation (EU) No 231/2012. These are implemented in the UK by the Food Additives (Wales) Regulations 2009 (SI 2009/3378), the Food Additives (England) Regulations 2009 (SI 2009/3238), and the Food Additives (Scotland) Regulations (SI 2009/436), as amended. The relevant domestic legislation in Northern Ireland is the Food Additives Regulations (Northern Ireland) 2009 (SI 2009/416), as amended.

- In the absence of such purity criteria, generally acceptable purity criteria recommended by international bodies.

Other substances having a particular nutritional purpose must be listed in Annex III before they can be added to infant formula or follow-on formula products which are placed on the market.

### **Notification of infant formula (regulation 13)**

Regulation 13 provides that no food business operator may place an infant formula on the market, which has not yet been placed on the market in the United Kingdom, unless he has given prior notice to the Welsh Government by forwarding to it a model of the label used for the product.

Further guidance on how and when to notify the Welsh Government can be found at: <http://wales.gov.uk/topics/health/improvement/index>

### **Labelling of infant formula (regulation 17)**

Manufacturers must comply with the Food Labelling Regulations 1996 (as amended). Guidance on these Regulations can be accessed at:

<http://www.food.gov.uk/multimedia/pdfs/Fguidnot1.pdf>

Manufacturers are also encouraged to clearly state the age range that the product is suitable for on the front of the packaging. The font size for the age range declaration should be no smaller than that used for the term 'infant milk' or 'infant formula' on the front of the packaging.

### **Labelling relating to the preparation, storage and disposal of infant formula and follow-on formula**

Regulation 17 (1)(d) and 18(1)(d) require that instructions are provided for appropriate preparation, storage and disposal of the product. The Welsh Government recommends that these instructions should include information noting that:

- Powdered infant formulae and follow-on formulae are not sterile, and as such can contain harmful bacteria. It is therefore important to be very careful when preparing formula to reduce the risks. Boiled tap water (not bottled water) cooled for no more than 30 minutes should be used to prepare infant feeds.
- All equipment used for feeding and preparing feed must be thoroughly cleaned and sterilised before use, and bottles should be made up fresh for each feed, as storing made-up formula milk may increase the chance of a baby becoming ill.

Further advice about the preparation and storage of formula can be found in Chapter 1 of the Birth to 5 booklet on the Welsh Government website:

<http://wales.gov.uk/topics/health/improvement/index/earlyyears/?lang=en>

Regulations 17(1)(d) and 18(1)(d) require, in addition to instructions for appropriate preparation, storage and disposal of the product, a 'warning about the health hazards of inappropriate preparation and storage'. This statement should stress the importance to the baby's health of the correct preparation of infant formula without which there is an increased risk of the baby suffering from serious stomach upsets, diarrhoea, constipation etc. This statement should appear on the label in a conspicuous place and be clearly visible and easily understandable. The statement should include wording such as 'Failure to follow instructions may make your baby ill'.

### **Labelling relating to the 'Important Notice' requirement**

The Important Notice (concerning the superiority of breast feeding and advice on when infant formula should be used) is required on infant formula by virtue of regulation 17(1)(e) and should be afforded a high degree of prominence on the label. It should be clearly visible and understandable. Please refer to Appendix II for guidance on the presentation of 'Important Notice' information on websites.

### **Labelling about the appropriate use of infant formula and follow-on formula so as not to discourage breastfeeding**

Regulations 17(2) and 18(2) seek to ensure that the labelling of infant formula and follow-on formula provides the necessary information about the appropriate use of the products so as not to discourage breast feeding and does not contain the terms 'humanised', 'maternalised' and 'adapted' or any similar term. Non-mandatory text or pictures on infant formula and follow-on formula labelling must not make reference to 'breastmilk', 'breastfeeding', 'moving on from breastfeeding' or 'closer to/inspired by breastmilk'. Use of such terms would not comply with Regulation 17 (2) or 18(2).

Non-mandatory text or pictures on infant formula labelling must not make reference to terms such as 'the best' or 'the ideal method' of infant feeding. Use of such terms would not comply with regulation 17(3) in relation to idealisation of infant formula.

### **Labelling of infant formula to avoid idealising the product**

Regulation 17(3) provides that the labelling of infant formula shall not include:

- a) any picture of an infant; or
- b) any other picture or text which may idealise the use of the product,

but may include graphic representations for easy identification of the product or for illustrating methods of preparation.

The following are examples of representations which may be considered to 'idealise' the use of infant formula should they feature on infant formula labelling:

- Pictures of infants, young children or carers (e.g. mothers or fathers).
- Graphics that represent nursing mothers and pregnant women.
- Pictures or text which imply that infant health, happiness or well being, or the health, happiness and wellbeing of carers, is associated with infant formula.
- References to infant's or carer's emotions.
- Baby or child related subjects (e.g. toys, cots or young animals) and anthropomorphic characters, pictures and logos.
- Non-mandatory pictures or text which refers, directly or indirectly, to 'the ideal method' of infant feeding. References to such terms would not comply with regulation 17 (3).

### **Use of nutrition and health claims in relation to infant formula (Regulation 17(4))**

The labelling of infant formula can only bear nutrition or health claims when:

- a) the claim is listed in the first column of Annex IV and is expressed in the terms set out there; and
- b) the condition specified in the second column of Annex IV in relation to the relevant claim made in the first column is satisfied.

A link to the Directive and Annex IV (the list of permitted nutrition and health claims) is provided below:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:401:0001:0033:EN:PDF>

The following definitions, which are set out in European Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, apply for the purposes of these Regulations:

- 'claim' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;
- 'nutrition claim' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- (a) the energy (calorific value) it:
- (i) provides
  - (ii) provides at a reduced or increased rate; or
  - (iii) does not provide; and/or
- (b) the nutrients or other substances it:
- (i) contains
  - (ii) contains in reduced or increased proportions; or
  - (iii) does not contain;
- ‘health claim’ means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;
  - ‘reduction of disease risk claim’ means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

Annex IV provides lists of the nutrition and health claims that can be made in relation to infant formula. **All other nutrition and health claims in relation to infant formula or its ingredients are therefore prohibited.**

The following points should be noted in relation to regulation 17(4):

- Claims are regulated wherever they appear on the labelling, on a website or in advertising or presentation. It is not the case that statements constitute claims only when they appear in headings or banners.
- European Commission Guidance clarifies that claims which refer to functionality or an implied effect on health are considered as health claims and as such cannot be used in relation to infant formula unless they are included in Table 2 of Annex IV. For example, claims relating to ‘prebiotics’, such as ‘contains prebiotics’, are considered health claims because they describe a function and are not permitted. The term prebiotic can not be used as an alternative wording for the nutrition claim “contains fructo-saccharides/oligo-saccharides” and must be specifically listed as specified in Table 2 of Annex IV to be used on infant formula.
- Permitted nutrition claims cannot be used in conjunction with additional statements, where those additional statements would make the claim a health claim or implied health claim. For example, ‘contains added LCPs’ is permitted, whereas ‘with LCP care’ is not.

- Nutrition or health claims about named, patented, mixtures of ingredients can be used only if the composition of the patented mixture is explained on the labelling. Thus, it would not be permitted to include claims such as 'contains LCPmix' on infant formula packaging if terms such as 'LCPmix' are not further explained on the labelling. Claims such as 'contains LCPmix - a patented mixture of long chain polyunsaturated fatty acids' would be permitted on the labelling (subject to the relevant conditions in Table 1 of Annex IV). Nutrition claims can be made only in relation to patented mixtures of the substances included in the left hand column of Table 1 in Annex IV of the Directive. Health claims other than those listed in Table 2 of Annex IV of the Directive, cannot be used. Thus, claims such as 'Contains LCPmix for brain and eye development' cannot be used.
- The definition of a health claim is "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health." Therefore consideration should be given to whether information that is provided suggests or implies a health relationship. For example if the labelling of 'formula brand x' refers to the health properties of 'substance y' in breastmilk, and the same labelling contains a nutrition claim for substance y in relation to a brand x formula or group of formulae, then this may constitute an implied health claim for formula brand x and is considered non-compliant. This would also apply in the case of claims such as 'Breastmilk contains ingredient y which helps fortify the immune system. Formula brand x contains ingredient y.'

### **Extending the list of permitted nutrition and health claims in relation to infant formula**

The European Food Safety Authority (EFSA), is likely to be consulted on any changes to Annex IV<sup>6</sup>. These Guidance Notes will be updated if the Commission publish guidance on the process whereby new claims may be added to Annex IV.

### **Labelling of follow-on formula (regulation 18)**

Manufacturers must clearly state the age range that the product is suitable for on the front of the packaging. The font size for the age range declaration should be no smaller than that used for the terms 'follow-on milk' or 'follow-on formula' and the font size for those terms should be no smaller than the font of the brand name.

The statement required on follow-on formula labelling by virtue of regulation 18(1)(a) should be afforded a high degree of prominence on the label. It should be clearly visible and understandable.

For guidance relating to regulation 18(2), refer to paragraph 28.

### **The use of claims in relation to follow-on formula**

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<sup>6</sup> [http://ec.europa.eu/food/committees/regulatory/scfcah/general\\_food/summary21\\_en.pdf](http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/summary21_en.pdf)



## Guidance Notes on The Infant Formula and Follow-on Formula Regulations 2007

Claims made in relation to follow-on formula are controlled by European Regulation (EC) No 1924/2006, on nutrition and health claims made on foods.

A weblink to the Guidance and compliance to Regulation 1924/2006 is given below:

<http://wales.gov.uk/topics/health/improvement/index/nutrition/?lang=en>

European Commission Guidance on the implementation of Regulation 1924/2006 on nutrition and health claims made on foods can be accessed at the following website address:

[http://ec.europa.eu/food/food/labellingnutrition/claims/guidance\\_claim\\_14-12-07.pdf](http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf)

The Annex to Regulation 1924/2006 contains the list of permitted nutrition claims which may be used on foods, including follow-on formula, and the criteria for using them. The list of permitted health claims is still to be compiled and there are various ways in which claims can be authorised and added to this list. The European Commission guidance classifies health claims made on follow-on formula as claims referring to children's development and health. Only health claims for which an application for authorisation was submitted by 19th January 2008 can be used on follow-on formula during the transitional period. The transitional period lasts until the Commission's Standing Committee reach a decision on the application. Until such time the Consumer Protection from Unfair Trading Regulations and the Food Safety Act 1990, will apply to health claims made on follow-on formula and make it an offence to falsely describe a food or mislead as to its nature, substance or quality.

The Food Labelling Regulations 1996 also make it an offence to make medicinal claims which state or imply that a product can prevent, treat or cure a human disease. Regulation 1924/2006 allows disease risk reduction claims to be made, but only once they have been authorised.

More information about applications for the authorisation of nutrition and health claims to be used on follow-on formula can be found in the Welsh Government's guidance to compliance with 1924/2006:

<http://wales.gov.uk/topics/health/improvement/index/nutrition/?lang=en>

Claims about follow-on formula which the Advertising Standards Authority (ASA) have found to be unsubstantiated should not be used in advertising. Manufacturers should also consider such judgements when developing their labelling, websites and other promotional materials.

## **General guidance with regard to infant formula and follow-on formula advertising**

When advertising to the public or health care professionals, formula manufacturers must comply with the requirements of regulations 18, 19, 21 and 22 together. Read together, the aims of these regulations are to ensure that:

- infant formula is advertised only in scientific publications or for trade purposes (regulation 21).
- consumers recognise that advertisements for follow-on formula relate exclusively to products for older babies and not infant formula. Such advertisements should not promote, either directly or indirectly, infant formula, or formula milks/bottle-feeding in general. (regulations 18, 19 and 22)

In order to achieve compliance, companies will therefore need to ensure that formula advertising does not:

- promote a range of formula products by making the brand the focus of the advert, rather than specific products (e.g. where specific products are mentioned only in a footnote or in a picture of a tin of formula within the advertisement);
- feature text or images which relate to pregnancy (e.g. pregnancy test kits) or the feeding or care of infants under six months;
- include pictures or text which directly or indirectly relate or compare products to breastmilk;
- focus on carers emotions in relation to the feeding or care of infants under six months;
- feature babies which consumers may perceive as being under six months (even if they are over six months);
- focus primarily on the promotion of ingredients, or the effect of ingredients, which are common to both follow-on formula and infant formula.

Companies will also need to ensure that carelines, websites or mother and baby clubs, and any advertisements for these means of communication, supply only factual information to consumers and health care professionals and, where they constitute advertising comply, with those controls outlined in paragraphs 47, 48 and 54 -70.

## **Avoidance of the risk of confusion between infant formula and follow-on formula (in relation to labelling, presentation and advertising) (regulation 19)**

Manufacturers must ensure that infant formula and follow-on formula are labelled in such a way that it enables consumers to make a clear distinction between infant formula and follow-on formula so as to avoid any risk of confusion. Regulations 20(1), 20(2), 21(1)(b) and 22 make this a requirement relating to the presentation and advertising of infant formula and follow-on formula.

In the light of this requirement, manufacturers should ensure the following when drafting infant formula and follow-on formula labelling:

- the specific terms ‘infant formula’ and ‘follow-on formula’ should be clearly featured on the packaging, in a font size no smaller than the brand name.
- Infant formula and follow-on formula are fundamentally different and information on labels, such as pictures and blocks of text should differentiate between them (Appendix III).
- The colour scheme used for infant formula packaging should be clearly different to the colour scheme of follow-on formula packaging. Using different shades of the same colour is not acceptable as it may lead to confusion.
- Non-mandatory references to breastmilk or breastfeeding should not be made on follow-on formula packaging as consumers may associate these terms with feeding infants from birth, whereas follow-on formula should be used only from six months.

## **Presentation (infant formula and follow-on formula) (regulation 20)**

Regulation 20(3) notes that for the purposes of this regulation, which specifically applies regulation 19 to presentation; “presentation” includes the shape, appearance or packaging of the products concerned, the packaging materials used, the way in which they are arranged and the setting in which they are displayed.

The aspects of presentation which relate to labelling of infant formula and follow-on formula have been discussed previously. In relation to in-store presentation, companies must ensure that they are clearly differentiated in order to avoid any risk of confusion and that:

- ‘shelf-talkers’ (attachments that add a company’s logo or sales message to the edge of a shelf) and other in-store promotional devices for follow-on formula must not be used in the vicinity of infant formula.
- Follow-on formula should be located at a different part of the store to infant formula. If this is not possible they should be clearly separated in physical location.

## **Restrictions on advertising infant formula (regulation 21)**

Regulation 21 provides that infant formula can be advertised only in:

- scientific publications or
- trade publications (prior to the retail stage), where the intended readership of the publications is other than the general public, and only if subject to the conditions outlined in regulation 21(b), which provides that any advertisement for infant formula must not contravene or fail to comply with the provisions of regulations 17(1)(e), (2), (3), (4) or regulation 19. Regulation 21 (2) and (3) require that infant formula advertisements must also:
- only contain information of a scientific and factual nature
- not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding

Further guidance on what is a scientific publication and what information can be provided in infant formula advertisements can be found in Appendix IV.

Guidance on what constitutes advertising is given in Appendices I and II.

### **The use of 'Important Notice' information in infant formula advertisements**

The 'Important Notice' which must appear in any advertisement for infant formula by virtue of regulation 17(1)(e), should be afforded a high degree of prominence in the advertisement. It should be clearly visible and understandable.

### **Advertising in relation to the appropriate use of infant formula and follow-on formula so as not to discourage breastfeeding**

Regulations 21(b) and 22 apply regulations 17(2) and 18(2) in relation to infant formula and follow-on formula advertising. As a result, advertisements for these products must provide the necessary information about the appropriate use of the products so as not to discourage breast feeding and must not contain terms such as 'humanised', 'maternalised' or 'adapted'. Non-mandatory text or pictures in infant formula and follow-on formula advertisements must not make reference to 'breastmilk', 'breastfeeding', 'moving on from breastfeeding' or 'closer to/inspired by breastmilk'. Use of such terms would not comply with Regulation 17(2) or 18(2).

In the light of these provisions, non-mandatory text or pictures in infant formula and follow-on formula advertisements must not make reference to terms such as "the best" or 'the ideal method' of infant feeding. Use of such terms would not comply with regulation 17(3) in relation to idealisation of infant formula.

### **The use of pictures of infants or any other picture or text which may idealise the use of the product**

Regulation 21(1)(b) applies regulation 17(3) in relation to advertisements for infant formula. As a result, the guidance detailed in paragraphs 30 and 31 should be applied to infant formula advertisements.

### **The use of nutrition and health claims in infant formula advertisements**

Regulation 21(1)(b) applies regulation 17(4) in relation to advertisements for infant formula. As a result, the considerations detailed in paragraphs 32 to 35 should be applied to infant formula advertisements.

### **Ensuring that there is a clear distinction between advertisements for infant formula and follow-on formula**

Regulation 21(b) applies regulation 19 in relation to advertisements for infant formula and follow-on formula. To comply with this provision, companies should follow the guidance detailed in paragraphs 50 – 51.

### **Ensuring that advertisements do not imply or create the belief that bottle-feeding is equivalent or superior to breastfeeding**

Regulation 21(3) provides that information in advertisements for infant formula shall not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. Advertisements should therefore not include pictures or text which relate or compare infant formula to breastmilk.

### **Promotion of company 'milks' or 'formulae'**

Consumers may understand that generic references to a brand of 'formula milks' or 'formulae' in advertisements refer to a number of formula products including infant formula. In order to achieve compliance, companies will need to ensure that such terms are not used in advertising, subject to the exceptions detailed in regulation 21, as explained in paragraph 54.

### **Additional Notes in relation to infant formula advertising**

Whilst trade to trade advertisements are allowed under regulation 21, they must comply with the provisions which control advertisements.

The regulations cover infant formula and follow-on formula and do not extend to the advertising of products related to feeding infants and young children, provided advertisements of these products do not contain references to a named infant formula. For example breast pads, sterilising equipment, bottles and teats etc.

Any general advertisement placed by a manufacturer must not feature a brand name, trade mark, business name or logo uniquely associated with an infant formula or mention breastfeeding. If this advertisement includes a response mechanism this must be of an 'opt-in' type, so that only parents or carers actively requesting information on infant formula milks can be sent this information and nothing else. Attempting to solicit requests for information, providing information on products outside the scope of the initial enquiry or making undue references to proprietary

infant formula brand names in a response to a request for product information is considered advertising and is not permitted under regulation 21.

The provision of information in response to requests from parents or carers via telephone carelines or mother and baby clubs must comply with regulation 21 and 24 and must provide the information outlined in paragraphs 74 and 75 of these guidance notes.

### **Restrictions on advertising follow-on formula (regulation 22)**

This regulation provides that no person shall advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions of regulation 18(2) or 19.

As a result, to comply with these provisions, companies should follow the guidance in paragraphs 28 and 47-50 in addition to the guidance detailed below.

In advertisements for follow-on formula, the term 'follow-on formula' should feature conspicuously, in a font size similar to the main copy of the advertisement. The font size for the term 'follow-on formula' should be no smaller than the brand name. The term 'follow-on formula' should not feature solely in:

- the text of the 'Important Notice' where provided; or
- pictures of follow-on formula packaging which are featured in the advertisement.

The inclusion of the information below in any follow-on formula advertisement may help consumers understand that it relates exclusively to follow-on formula, and does not relate to infant formula:

- Follow-on formula is suitable only for particular nutritional use by infants over the age of six months.
- A clear indication that any infants featured in follow-on formula advertisements are over six months.
- The colour scheme of follow-on formula advertisements should clearly differ from that used in infant formula advertisements.
- To minimise the risk of consumers making a connection between follow-on formula and the act of feeding infants from birth, information in advertisements for follow-on formula should not include pictures or text which relate or compare follow-on formula to breastmilk.
- Manufacturers are encouraged to make publishers, producers, their agents and distributors involved in the advertising of infant formula and follow-on formula aware of the Regulations with regard to the marketing and presentation of an infant formula. In addition, manufacturers should ensure that publishers and producers are aware that any advertisement for follow-on formula in print should

not be placed within or adjacent to any article or photo spread featuring the feeding of babies under six months of age or babies that could be perceived as being under 6 months.

### **Restrictions on promotion of infant formula (regulation 23)**

Regulation 23(1)(b) prohibits 'any special display designed to promote sales'. As a result, companies should not use prominent shop window displays, free standing displays or 'shelf-talkers' which relate to infant formula products.

Regulations 23(1)(d), (e) and 23(2) prohibit 'special sales' to promote the sale of an infant formula or any other special activity at any place where any infant formula is sold by retail to induce the sale of an infant formula. For example multi packs (bulk packs), loyalty/reward card schemes, free formula, price reductions, discounts or mark downs and buy one get one free.

Regulation 23(2) prohibits manufacturers or distributors from providing any gift designed to promote the sale of an infant formula to the general public, pregnant women, mothers, and members of their families. In the Welsh Government's view this would prohibit such gifts being provided via baby clubs or similar activities.

### **Provision of information and education regarding infant and child feeding (regulation 24)**

Regulation 24 requires information and educational material, whether this is written or audiovisual, that deals with feeding of infants and intended to reach pregnant women, to include certain information. Regulation 24 states that the following information must be included:

- the benefits and superiority of breast-feeding;
- maternal nutrition;
- the preparation for and the maintenance of breast-feeding;
- the possible negative effect on breast-feeding of introducing partial bottle-feeding;
- the difficulty of reversing the decision not to breast-feed; and
- where needed, the proper use of an infant formula.

When the material referred to in paragraph 74 contains information about the use of an infant formula regulation 24 states that the following information is included:

- the social and financial implications of its use;
- the health hazards of inappropriate foods or feeding methods; and
- the health hazards of improper use of infant formula.

Guidance on information which is provided by means of websites is provided in Appendix II.

The following is a list of some of the types of materials which, if they provide information or are educational, would be controlled by regulation 24(4) and require approval from the Secretary of State<sup>7</sup> (for Health) before formula manufacturers donate them to third parties:

- CDs and DVDs
- Wallcharts, posters
- Booklets or leaflets which are designed for reference purposes
- Electronic files that can be downloaded directly from a website

To gain Secretary of State approval, such materials should contain information which is consistent with current Welsh Government's<sup>8</sup> policies on breastfeeding and the promotion and advertising of infant formula and follow-on formula. Such materials must not be marked or labelled with the name of a proprietary brand of infant formula and must only be distributed through the healthcare system, such as via GPs, nurses, midwives etc.

Companies who wish to seek approval from the Secretary of State for their donation should write to:

### **In Wales**

Health Improvement Division  
Welsh Government  
Cathays Park  
Cardiff  
CF10 3NQ  
Tel: 02920 825953  
Email: [Lifestyles@wales.gsi.gov.uk](mailto:Lifestyles@wales.gsi.gov.uk)

### **In England**

Nutrition Legislation Team  
Health and Wellbeing  
Department of Health  
Wellington House  
133-155 Waterloo Road  
London SE1 8UG  
Tel: 020 7972 4340  
Fax No. 020 7972 4227  
E-mail: [parnutnotification@dh.gsi.gov.uk](mailto:parnutnotification@dh.gsi.gov.uk)

### **In Scotland**

Food Standards Agency (Scotland)

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<sup>7</sup> In Scotland, this would be Scottish Ministers.

<sup>8</sup> And equivalent departments and directorates in Scotland, Wales and Northern Ireland



Parnuts Food Notification  
Professional Advice Branch  
6th Floor  
St Magnus House  
25 Guild Street  
Aberdeen AB11 6NJ  
Tel: 01224 285175  
Fax: 01224 285110  
E-mail: [parnutnotification@foodstandards.gsi.gov.uk](mailto:parnutnotification@foodstandards.gsi.gov.uk)

### **In Northern Ireland**

Northern Ireland:  
Food Standards Agency (Northern Ireland)  
Parnuts Food Notification  
Professional Unit  
10c Clarendon Road  
Belfast BT1 3BG  
Tel: 028 9041 7714  
Fax: 028 9041 7726  
E-mail: [parnutnotification@foodstandards.gsi.gov.uk](mailto:parnutnotification@foodstandards.gsi.gov.uk)

### **Third country exports (regulations 26 and 27)**

Regulations 26 and 27 require that exports of infant formula or follow-on formula from the UK to third countries (i.e. non-EU countries) meet the compositional requirement of these Regulations as set out in regulations 5-12 and 14 as appropriate and the labelling requirements of regulations 17-19 as appropriate. In addition the exported products must meet the requirements of the Food (Lot Marking) Regulations 1996 (S.I. 1996/1502)<sup>9</sup> and the Codex Standard for Infant Formula or the Codex Standard for Follow-up Formula.

### **Offences and enforcement (regulation 28)**

Regulation 28(1) provides that any person who contravenes or fails to comply with regulations 3, 4, 13, 21(1), 22, 23, 24, 25, 26 or 27 shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Regulation 28(2) provides that each food authority shall enforce and execute these Regulations within its area.  
For the purposes of these Regulations, the term “food authority”, is defined to reflect the provisions of section 5 of the Food Safety Act 1990. For the purposes of the England and Wales Regulations, food authorities are :

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<sup>9</sup> In Northern Ireland, the Food (Lot Marking) Regulations (NI) 1996 (S.R. 1996 No. 384)

- the London Boroughs
- metropolitan districts
- unitary authorities
- where there is two-tier local government, both non-metropolitan districts and non-metropolitan counties.

Where there is two-tier local government, the Food Law Code of Practice (England)<sup>10</sup> specifies whether the District Council or the County Council Food Authority is to act in particular cases.

For the purposes of the Scotland Regulations, food authorities are the local authorities.

In Northern Ireland the regulations made under the Food Safety (NI) Order 1991 are enforced by the “district councils” to the extent specified in Article 26 of the Order.

### **Revocation and transitional arrangements (regulation 31) This no longer applies but is retained for historical purposes**

The Regulations provide certain transitional arrangements for products that are compliant with the previous Infant Formula and Follow-on Formula Regulations 1995 (SI 1995/77)<sup>11</sup>, as amended (referred to as ‘the previous Regulations’ here and elsewhere in this document). The transitional arrangements allow:

- Infant formula and follow-on formula to use labelling, which is compliant with the previous Regulations, until 1st January 2010.
- Infant formula and follow-on formula to be presented in a way, which is compliant with the previous Regulations, until 1st January 2010. The transitional arrangements only apply to presentation in so far as it relates to the shape, appearance and packing of the infant formula or follow-on formula
- The composition of infant formula and follow-on formula to be compliant with the previous Regulations, until 1st January 2010.

From 1st January 2010 all products must now comply with the entirety of the 2007 Regulations.

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<sup>10</sup> [Food Standards Agency - Food Law Code of Practice](#)

<sup>11</sup> In Northern Ireland, the Infant Formula and Follow on Formula Regulations (NI) 1995 SR No. 85

## **General recommendations to formula manufacturers**

Although they are not requirements of the Regulations, the Welsh Government would encourage formula manufacturers to:

- discuss, with their Home Authority/Primary Authority, draft labelling, informational material, website content and any other material designed for the public and/or health care professionals before such material is finalised for use.
- discuss advertising with the Committee of Advertising Practice's Copy Advice Team or for broadcast advertising Clearcast.
- Recommend to parents/carers that they discuss any questions about infant feeding issues with their health visitor, a member of the health visiting team or a family nurse. Referral to the family GP should be made if the query is identified as requiring medical intervention.

## **Monitoring and review**

Due to the pace of change in marketing, these Guidance Notes will be reviewed and updated periodically to ensure that they remain applicable.

## Appendix I - Interpretation of 'advertising'

The Regulations follow the Directive in restricting the advertising of infant formula and follow-on formula; however the production and publishing of informational and educational material is permitted. Informational and educational material will therefore not be considered to constitute advertising, but must comply with the requirements of regulation 24. Whether a representation is informational or educational material or advertising will depend on its content, regardless of whether it is claimed to be informational or educational material.

The Welsh Government considers the term "advertising" to mean:

**Any representation that is made in connection with a trade, business, or company in order to promote, either directly or indirectly, the supply, including sale or transfer, of infant and/or follow-on formula.**

The above paragraph includes the term "representation". The following list includes some examples of the means by which a representation can be made within the context of advertising. The list is not definitive due to the fact that the nature of advertising is always changing.

- newspapers, magazines, brochures, leaflets, circulars, direct mailings, e-mails, text transmissions, fax transmissions, catalogues, follow-up literature and other electronic and printed material (including advertorials)
- publications for healthcare professionals which are not scientific publications
- posters and other promotional media in public places, including moving pictures
- cinema and video commercials
- non-broadcast electronic media, (refer to Appendix II for further guidance with regard to the internet)
- television and radio broadcast commercials
- correspondence between a trade, business or company and their customers, in writing, orally (including telephone calls and company carelines), electronically or by other means
- press releases and other public relations material and activities that can be accessed by consumers
- tickets, timetables and price lists
- celebrity endorsements in connection with a trade, business, or company
- product placement in websites

All advertising of infant and follow on formula must comply with the requirements of the Regulations, in particular regulation 21, which restricts infant formula advertising

## Guidance Notes on The Infant Formula and Follow-on Formula Regulations 2007

to scientific publications and between trade, and regulation 22 which applies regulations 19 and 18(2) to follow on formula advertising.

## Appendix II – Guidance on website information relating to infant formula, follow-on formula and infant feeding

- All website content, including editorial text or pictures that constitute an advertisement, is subject to the Regulations. Editorial website content, must not advertise infant formula, unless it is in a password protected scientific publication or for trade purposes and complies with the requirements of Regulation 21 (see paragraph 54 - 68)

### Presentation for sale

- In the case of websites where infant formula can be purchased, only the information that would be allowed on the label should be provided, with no particular emphasis being given to any of that information. The information provided must comply with the controls on labelling (see paragraphs 22-35).

### Informational and educational material

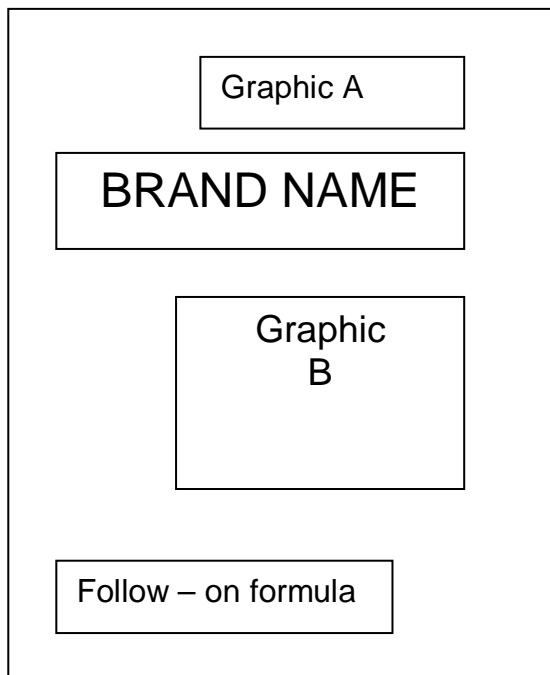
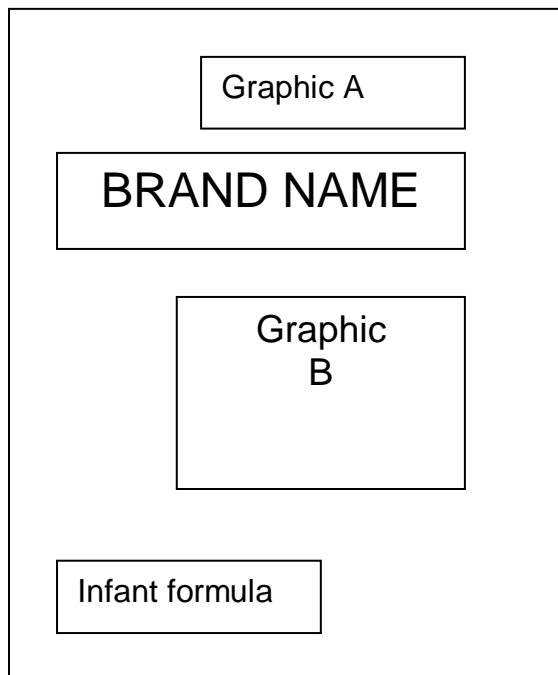
- Any additional information about infant formula, or infant feeding, should be accessed only by means of an intermediate page which includes statements highlighting to the viewer that:
  - by proceeding, they will be able to view information about ‘Brand X’ infant milks and other formula products and that if they choose to proceed, they are accepting that ‘Brand X’ is supplying this information at their individual request.
- Those responsible for preparing the website are legally obliged to ensure that the content relating to infant formula may not constitute advertising and may only constitute information.
- Where informational and educational about infant formula is provided by means of a website, such information should comply with the requirements of regulation 24(1), 24(2) and 24(3).
- The information described in the above paragraphs should have the same readability as the main text of the website. Any button which must be clicked to progress beyond the information described above should be positioned at the end of the text.

**The Advertising Standards Authority (ASA) regulates advertising across all media. Since September 2010, this also includes advertiser’s own marketing communications on their own websites and in other non-paid-for space under their control, such as social networking sites like Facebook and Twitter.**

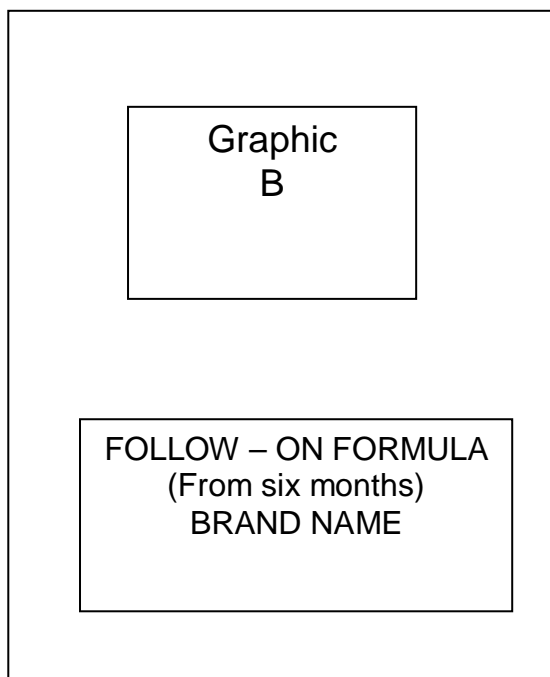
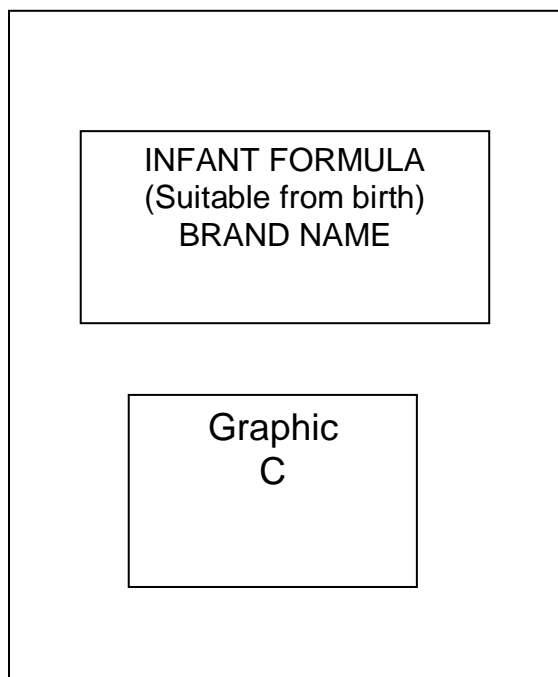
**For more information on the ASA and rulings relating to infant formula, please visit their website at: [www.asa.org.uk](http://www.asa.org.uk)**

**Appendix III – Differentiating infant formula and follow-on formula**

May be more likely to confuse consumers:



May be less likely to confuse consumers:



## **Appendix IV – Guidance on scientific publications and information of a scientific or factual nature**

Regulation 21 only allows infant formula to be advertised in scientific publications and trade publications and puts in place controls on the content of such advertisements. Below is Welsh Government guidance on what constitutes a scientific publication and also guidance on the nature of the information that can be included in advertisements for infant formula.

### **Scientific Publication**

Scientific publications are usually published periodically (at regular or irregular intervals) and aimed at academic and/or professionals in a scientific field, such as GPs, nurses and midwives. They consist of an aggregation of original articles by different authors published under an umbrella title. Articles include those that report new scientific research or review existing scientific research. They may also include editorials, opinion pieces and book or other reviews dealing with a scientific theme.

In addition, they

- are static, rather than dynamic (i.e. the core content is fixed at the time of publication),
- may have been assigned an ISSN

### **Content of Infant Formula Advertisements**

Advertisements for infant formula can only include information that is of a scientific and factual nature (regulation 21(2)). Where that information constitutes a nutrition or health claim, it must be listed in the first column of Annex IV and the product must meet the conditions specified in the second column. All other nutrition and health claims are prohibited. Paragraphs 32-35 provide information on what constitutes a nutrition or health claim.

In the Welsh Government's view, to comply with this requirement, it must be possible to support any further information provided, that is not a nutrition or a health claim, with an article from a peer-reviewed scientific journal.

Regulation 21 also requires advertisements for infant formula to comply with the controls in regulations 17(1)(e), (2) and (3), regulation 19 and regulation 21(3).