

SUMMARY TABLE OF RESPONSES TO THE PUBLIC WRITTEN CONSULTATION
The Infant Formula and Follow-on Formula (England) Regulations 2007

Please note that this is a summary document - Where possible we have assigned comments *verbatim*, however similar comments may be attributed to more than one respondent, this makes it possible to gauge at a glance the opinion of the majority / minority of respondents.

| | Respondent | Comments | FSA response |
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| Advertising and provision of information regarding infant and child feeding | | | |
| Industry | IDFA | <p>We do not believe that there is any need for further restrictions in the UK and our reasons are laid out in this document. Our comments relate specifically to Regulations 17, 18, 19, 21 and 23 as contained in the Draft Regulations.</p> <p>Under Decision 3052/95/EC, national authorities must notify the European Commission of steps preventing the free movement of products lawfully produced or marketed in another member state. This appears to be an important procedural requirement and we would like to know what steps, if any, FSA has taken to comply. We believe that just as companies from other member states should be able to trade in a free and fair manner within the UK market, so those companies who are UK-based should be able to trade in a reciprocal manner.</p> <p>There is no definition of 'advertising' in the Directive. It is our view that advertising does not need defining here. Where necessary this is a matter for the courts to decide when interpreting the provisions of the Directive. However, should government decide to include a definition of 'advertisement/advertising' in the Regulations and/or in accompanying guidance notes, it would be vital for any such definition to be reasonable and proportionate.</p> <p>Under the draft Regulations, the labelling of infant formula must not include any picture or text which idealises use of products. However, the draft Regulations expressly permit the use in labelling of graphic representations for easy identification of products. We consider that the word 'idealise' does not require further definition either in the Regulations or in any accompanying guidance. Where necessary, this is a matter for the courts to decide when interpreting the provisions of the Directive.</p> | <p>Noted</p> <p>The UK will notify the European Commission when the Directive is implemented by means of the domestic Regulations.</p> <p>The Directive does not include a definition of 'advertising', and therefore neither will the Regulations. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> <p>The Directive and therefore the Regulations do not include a definition of 'idealise'. The Guidance Notes set out a number of representations which should not be included on infant formula in relation to 'idealise'. The Agency is consulting separately on the Guidance Notes.</p> |

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| | | <p>We appreciate the consistent approach presented in the proposal to restrict advertising of infant formula in publications specialising in baby care and distributed only through the health care system. We would object to any further restrictions as we consider that advertising is an effective means of keeping healthcare professionals up to date with information on infant and follow on formula products and the science supporting them. Indeed, we are not aware of any evidence suggesting that advertising infant formulae to healthcare professionals in such journals affects breast feeding rates.</p> <p>Evidence shows that mothers turn to health professionals for advice on feeding their baby. The two main sources of information for breastfeeding mothers who experienced feeding problems were midwives and health visitors. Ideally these health professionals would be able to assist mothers in breastfeeding, but are also ideally placed if the mother chooses not to breastfeed to give detailed advice about bottle-feeding.</p> <p>We are unaware of any evidence for the statement in the first sentence of Paragraph 4.1 of the PRIA 'The Regulations would have potential benefits regarding breastfeeding rates due to the increased restrictions on the advertising of infant formula.' We call on the FSA to demonstrate that this is the case.</p> | <p>Regulation 17 of the previous¹ Regulations permits the advertising of infant formula in publications 'specialising in baby care and distributed only through the health care system' scientific publications and trade journals. Regulation 21 of the new Regulations permits the advertising of infant formula in scientific publications and trade journals only. This brings into line the advertising restrictions which apply to all baby care publications, irrespective of where they are made available (either within, or outside the health care system). The Directive allows EU Member States to take such action at a national level.</p> |
| Industry | Hipp UK Ltd | <p>We believe that Infant milk advertising should be allowed according to the conditions set out in Art 14.1 of Directive 2006/141/EC, to restrict advertising further to just scientific publications will limit the availability of factual information about the brands of milk available on the market for both parents and health professionals alike. Placing such restrictions could be both anti-competitive and anti-innovative.</p> <p>With the tighter restrictions on the claims permitted on infant milks packaging in this new Directive (Art. 13.6 and Annex IV), there will be less information on the labels to help parents understand the differences between the different formulas on the market if they have decided to bottle feed their baby. They will need, therefore, to get this information from other sources i.e. from health professionals, company literature, websites and information lines, and possibly</p> | <p>Please see response to IDFA.</p> <p>Noted. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> |

¹ Infant Formula and Follow-on Formula Regulations 1995 S.I. 1995/77 (as amended)

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| | | <p>advertisements in baby care publications, in order to understand what the different formula products could offer their baby. These factors should be taken into consideration when deciding what constitutes ‘an advertisement’ when preparing the FSA Guidance Notes for these Regulations.</p> <p>It is important that the use of the word ‘idealise’ should always be interpreted in the context of breastfeeding. We believe that the use of stylised logos and images on packs of infant formulas do not, in themselves, idealise the use of the products, but that it is important that the words chosen to accompany them do not imply that the product is equivalent to or superior to breast milk.</p> | <p>The Directive, and therefore the Regulations do not include a definition of ‘idealise’. The Guidance Notes will set out a number of representations which should not be included on infant formula in relation to ‘idealise’. The Agency is consulting separately on the Guidance Notes.</p> |
| Industry | National Pharmacy Association | <p>The EC Directive and the implementing regulations do not provide a definition of advertising in order to allow flexibility in legislative interpretation now and in the future.</p> <p>Guidance documentation should ensure that newer forms of advertising such as email, internet and electronic adverts are covered.</p> <p>The NPA would oppose the further restriction of advertising of infant formula. Under current legislation (infant formula and follow on formula regulations 1995) advertising is restricted to specialist baby care magazines, scientific publications and trade publications not intended for the general public.</p> <p>We see no information, data or evidence provided by the proposal document that suggests that the restrictions need to be tightened further and we would oppose the removal of the exemption to advertising for specialist baby care publications.</p> | <p>The Directive and therefore the Regulations do not propose a definition of ‘advertising’. Guidance relating to the characteristics of ‘advertising’ in the context of the Regulations is provided in the draft Guidance Notes, which the Agency is consulting on separately.</p> <p>Regulation 17 of the previous² Regulations permits the advertising of infant formula in publications ‘specialising in baby care and distributed only through the health care system’ scientific publications and trade journals. Regulation 21 of the new Regulations permits the advertising of infant formula in scientific publications and trade journals only. This brings into line the advertising restrictions which apply to all baby care publications, irrespective of where they are made available (either within, or outside the health care system). The Directive allows EU Member States to take such action at a national level.</p> |

² Infant Formula and Follow-on Formula Regulations 1995 S.I. 1995/77 (as amended)

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| Industry | FTSE, The Index Company | <p>We would like to emphasise our support for these regulations which we believe will bring the UK closer to the interpretation of the WHO Code. One aspect where we feel there may be a gap in the proposed Regulations is the labelling, advertising and promotion of complementary foods. It would be helpful if the UK Regulations could reflect the WHO Code and associated WHA resolutions. The harmonising of national Regulations to better match the WHO Code facilitates an international playing field that makes it easier for multinational companies to set globally applicable standards to the benefit of child nutrition globally.</p> <p>There is a danger in defining what advertising is as it may limit legitimate commercial activities of an industry that is both legal and what are in many cases valuable products. However, there is a need for clear guidelines that are widely accepted by stakeholders which have not, to date, been provided by the WHO.</p> <p>Idealise is a highly subjective term and as such will potentially become a cause for unhelpful and continuing debate. We recommend that the term is not used for the purposes of the Regulations.</p> | <p>The Regulations will implement the Directive which itself gives effect to the principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, information and responsibilities of health authorities.</p> <p>The Directive and therefore the Regulations regulate the advertising of follow-on formula and impose restrictions on the advertising of infant formula. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> <p>The Regulations do not include a definition of 'idealise'. The Guidance Notes will set out a number of representations which should not be included on infant formula in relation to 'idealise'. The Agency is consulting separately on the Guidance Notes.</p> |
| NGO | The Baby Feeding Law Group | <p>The Baby Feeding Law Group proposes a third option for implementation: to implement the WHO Code on the Marketing of Breastmilk Substitutes.</p> <p>The Baby Feeding Law Group is calling for the following safeguards to be included in the Infant Formula and Follow-on Formula Regulations 2007 to implement some aspects of the Code. The law should:</p> | <p>The Regulations will implement the Directive which itself gives effect to the principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, information and responsibilities of health authorities.</p> |

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| | | <ul style="list-style-type: none"> • ban all promotion of breastmilk substitutes (including follow-on formula, specialised formulas and other bottle-fed products) • prohibit baby feeding companies from seeking direct or indirect contact with pregnant women and mothers and carers of infants and young children and other members of the public (including a clear ban on company ‘carelines’, pamphlets, mailshots, emails and promotional websites), • prohibit baby feeding companies from offering sales incentives and bonuses or setting sales quotas linked to breastmilk substitutes for personnel employed by or on behalf of the company, • prohibit company-produced or sponsored materials on pregnancy, maternity, infant feeding or care (the Government must provide objective information on infant feeding, avoiding conflicts of interest in funding infant feeding programmes), • prohibit the promotion of names associated with breastmilk substitutes and their use on other products. | <p>The Directive and therefore the Regulations regulate the advertising of follow-on formula and impose restrictions on the advertising of infant formula. Guidance relating to the characteristics of ‘advertising’ in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> <p>The new provision at Regulation 22 tackles concerns that advertising for FOF could be taken as advertising for IF and undermine BF. The Government will work with enforcement bodies to ensure robust enforcement in line with Guidance Notes issued by the FSA.</p> <p>The Directive and therefore the Regulations lay down restrictions in relation to written or audiovisual informational and educational materials, dealing with infant feeding, produced by manufacturers.</p> <p>This is beyond the scope of the Directive and has not been included in the domestic Regulations.</p> <p>The Directive and therefore the Regulations allow such materials subject to certain conditions which reflect those detailed in the WHO Code which specifically permits the donation of informational or educational equipment or materials by manufacturers or distributors.</p> <p>The labelling of infant formula and follow-on formula is strictly controlled by Regulations 17 and 18 and all labelling</p> |
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| | | <ul style="list-style-type: none"> • prohibit the promotion of any product in a way that could lead to it being used for babies under 6 months (complementary foods should not be marketed in ways that undermine breastfeeding). • restrict information for health professionals to scientific and factual matters with no idealising text or images, • prohibit promotion in healthcare facilities and gifts to health workers (allowing only single samples for evaluation), • introduce regulations for the marketing of feeding equipment, feeding bottles, teats, dummies etc. in line with the International Code. • We recommend that the safeguards on packaging and presentation of follow-on outlined above covers specialised formulas also. <p>Legal Arguments surrounding the UK's ability to implement the international Code: The proposals for the Regulations put forward by the UK Food</p> | <p>must comply with these provisions.</p> <p>These Regulations relate only to infant formula and follow-on formula only, and do not extend to complementary foods which are regulated separately³.</p> <p>The Regulations prohibit the use of idealising text or images in any information relating to infant formula.</p> <p>The Regulations propose restrictions on the promotion of infant formula to the general public, pregnant women, mothers and their families, either directly or indirectly through the health care system or health workers. The Regulations do lay down restrictions on gifts to health workers and they provide restrictions on the donation of informational or educational equipment or materials by manufacturers or distributors of infant formula.</p> <p>The promotion of feeding equipment is outside of the scope of the Directive and cannot be accommodated in the domestic Regulations.</p> <p>This goes beyond the scope of the Directive and has not been incorporated in the domestic Regulations.</p> <p>The Regulations will implement those provisions of the WHO Code and subsequent WHA resolutions which are</p> |
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³ The Processed Cereal based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 (SI 2003 No 3207)

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| | | <p>Standards Agency reflect the provisions, though not the aims of the Directive more or less as it is, going further only where the text specifically permits and in some sections falling short.</p> <p>The BFLG has sought several legal opinions about the options open to the Government. The legal arguments are summarised here:</p> <ol style="list-style-type: none"> 1. The margin of discretion available to Member States is determined by the Directive itself and must be inferred from its wording, purpose and structure. Article 1 of the Directive not only permits, but could be said to require, Member States to act in accordance with the International Code. As such it should not matter greatly whether a Directive is a Total or Partial harmonisation measure – states should act in accordance with the Code in either case. 2. There is a horizontal duty in the EC Treaty to promote public health through all the activities of the Union. Article 152 (1) indicates that any interpretation of this Directive should favour compliance with the International Code. | <p>incorporated into the European Directive.</p> <ol style="list-style-type: none"> 1. The Agency does not consider that the second paragraph of Article 1 of the Directive imposes a legal duty on the Member States to introduce domestic legislation giving effect to the Code. If that were the intention of the Directive, it would have been set out clearly and explicitly (particularly taking account of the breadth of the provisions of the Code). The Agency considers that the correct interpretation of the second paragraph of Article 1 is that it merely explains what the Code does. 2. The Agency considers that the Directive should be interpreted in the light of the Code. The guidance seeks to do this. |
| <p>NGO</p> | <p>The National Childbirth Trust</p> | <p>Glad to see the Agency’s summary of the Directive as the NCT supports these aims. However, the proposed Regulations are not fully in line with the Code and Resolutions, and fully endorse the Baby Feeding Law Group position.</p> <p>We have contributed to detailed comments provided by the Baby Feeding Law Group and the Breastfeeding Manifesto Coalition, which we fully endorse. The NCT have also provided several examples of advertising that blurs the distinction between infant formula and follow-on formula, ASA rulings on particular adverts, outtakes from online discussion groups, job-advertisements for the infant formula industry, non-compliant product placement and labelling</p> | <p>See the Agency response to the Baby Feeding Law Group.</p> <p>The Agency has reflected on this material in the development of the guidance notes on which the Agency is consulting on separately</p> |

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| | | infringements. Unicef UK, the National Childbirth Trust and Save the Children have jointly published the document 'A Weak Formula for Legislation' ⁴ | |
| NGO | Baby Milk Action | Endorses the Baby Feeding Law Group Position | See the Agency response to the Baby Feeding Law Group. |
| NGO | UNICEF UK | <p>Key Recommendation: restrict the advertising of infant formula and follow-on formula. We welcome the restriction of infant formula advertising within Para 21. However, only a simultaneous restriction of follow on formula advertising would ensure that such choices are based on full information and are free from commercial pressures.</p> <p>We note that paragraph 3.58 to 3.61 of the Partial RIA concluded that the FSA is unable to impose further restrictions on the advertising of follow-on formula than provided for in the Directive. We disagree based on the following legal basis:</p> <ol style="list-style-type: none"> 1. It has been a long established Directive requirement that Member States give effect to the principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, information and responsibilities of health authorities. 2. That Member States are permitted to implement non-discriminatory selling arrangements which could include further restrictions or prohibitions on advertising going beyond those required by the Directives. 3. That depending on the measures proposed, statutory authority for such measures may well be found in existing legislation. | <p>The Directive includes some important restrictions relating to the advertising of follow-on formula and impose further substantial restrictions on the advertising of infant formula. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> <p>The Directive provides for Member States to give effect to the principles and aims of the Code. Many of the provisions of the Code are provided within the Directive and the Regulations.</p> <p>The Directive and therefore the Regulations include some restrictions relating to the advertising of follow-on formula and impose restrictions on the advertising of infant formula. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> |
| NGO | The Breastfeeding Manifesto | <p>Endorse the Baby Feeding Law Group position.</p> <p>We welcome the principles of paragraph 19 which aims to avoid any risk of</p> | <p>See the Agency response to the Baby Feeding Law Group.</p> <p>Noted.</p> |

⁴ http://www.savethechildren.org.uk/en/docs/babymilk_legislation.pdf

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| | <p>Coalition; Association of Breastfeeding Mothers</p> | <p>confusion between infant and follow-on formulas. This is essential to avoid potential risks to infant health resulting from the use of an age-inappropriate product, but also to ensure that advertising of follow-on formula cannot also promote infant formula. However, confusion between infant formula and follow-on formula seems unavoidable. This would appear to be due to the intrinsic similarity between the two products.</p> <p>We would like to draw your attention to the situation under the current Regulations which also prohibit the presence of an infant formula brand name on information materials, but which permit such materials to carry the name or logo of the donating company. The proposed regulations both permit and prohibit the same thing, making it impossible to enforce.</p> <p>To avoid confusion between infant formula and follow-on formula, and to achieve effective restriction of infant formula advertising, the references to infant formula in paragraph 24(2), 24(3) and 24(4) should be extended also to refer to follow-on formula.</p> | <p>The labelling of infant formula and follow-on formula is strictly controlled by the proposed Regulations⁵.</p> <p>The Directive and therefore the Regulations lay down restrictions in relation to written or audiovisual informational and educational materials, dealing with infant feeding, produced by manufacturers with particular requirements for infant formula. Guidance relating to avoidance of confusion between infant formula and follow-on formula in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> |
| <p>NGO</p> | <p>The Breast Feeding Network</p> | <p>Fully support the Baby Feeding Law Group submission</p> <p>Advertising should be considered as any promotion or activity which is aimed at inducing people to buy or use a particular product or brand.</p> <p>The term idealise should include and promotional activity which represents the product as ideal, perfection, excellence. Terms such as humanised, closest or closer to breastmilk ect should not be used.</p> | <p>Noted.</p> <p>The Regulations do not propose a definition of 'advertising'. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> |

⁵ The Infant Formula and Follow-on Formula (England) Regulations 2007

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| | | Evidence shows that the general public does not understand or recognise the difference between infant formula and follow on formula. Follow on formula should be treated the same as infant formula bearing in mind that follow on formula exploits loopholes in the law on the promotion of infant formula. We welcome the proposal to further restrict the advertising of infant formula and would welcome the inclusion of follow on milk. | The Directive and therefore the Regulations include some restrictions relating to the advertising of follow-on formula and impose further restrictions on the advertising of infant formula. Guidance relating to avoidance of confusion between infant formula and follow-on formula in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consult on separately. |
| NGO | Save the Children | Save the Children broadly supports the comments made in the Baby Feeding Law Group's consultation response. | See the Agency response to the Baby Feeding Law Group. |
| NGO | IBFAN-GIFA | We are writing in support of the coalition of UK health worker organisations and mother support groups which is calling for the UK law on the marketing of formula to be strengthened and enforced. We support the coalition's view that every mother has the right to accurate information about infant feeding free from commercial pressure and should be supported to breastfeed as long as she wishes. We therefore urge the UK Government to strengthen the provisions of the law and enforce the law, and thus to set a clear example to other countries in Europe and beyond. | See the Agency response to the Baby Feeding Law Group. The Regulations proposed and the guidance, on which the Agency is consulting separately, strengthen the controls relating to the marketing of infant formula. |
| NGO | La Leche League, Great Britain | <p>The recent tightening of the rules over the claims the companies are permitted to make for their milks has been ineffective because the companies continue to make the prohibited claims openly on their websites without restriction.</p> <p>La Leche League believes that all mothers are entitled to accurate objective information on how to feed their babies, no matter whether or not they choose to breastfeed. To protect mothers and babies we support the Baby feeding Law Group comments.</p> | <p>Claims relating to infant formula and follow-on formula that appear on labelling are regulated. Regulation 21 requires that any advertisement for infant formula complies with the labelling requirements irrespective of whether it is on the internet.</p> <p>See the Agency response to the Baby Feeding Law Group</p> |
| | Unite-CPHVA | The CPHVA represent the majority of Health Visitors within the United Kingdom and are members of the Baby Feeding Law Group and support the group's collective submission to this consultation in all four countries within the United Kingdom. | See the Agency response to the Baby Feeding Law Group. |

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| <p>Public health group</p> | <p>The British Dietetic Association</p> | <p>In general we welcome option 2 of the Partial Regulatory Impact assessment but would wish to see the UK Government establishing an additional case to further restrict the advertising of Follow on Formula. Infant formula and follow on formula products should be considered as breast feeding substitutes and we would call for the same labelling and advertising restrictions to apply to both products.</p> <p>We welcome the principle of clarifying the labelling of these products to enable consumers to make a clear distinction between infant formula and follow on milks. Common branding by the companies through their range of milks makes it more difficult for the consumer to identify differences especially when advertising one product (follow on formula) with clear brand recognition.</p> <p>We welcome formally recognising the change in the age (to 6 months) at which follow on formula can be introduced.</p> <p>We recognise the difficulty in attempting to define the term ‘advertising’ and the danger of limiting its scope by so doing but would like to see a control on product placement in ‘news’ journalism. It is unacceptable to see a celebrity bottle feeding a baby with the brand of milk clearly visible. Advertising should include promotional websites, care lines and baby clubs, welcome packs and mailshots of any sort whether printed or electronic that could be accessed by the general public.</p> <p>However, these additional restrictions make it vital that health professionals provide adequate, timely and factual information to enable a mother, who chooses to use an infant formula, to have access to sufficient information to allow her to make an informed choice on the product and how to make up the product safely. This requires health professionals to be well informed on availability within the market of different products and requires adequate non</p> | <p>The Directive and therefore the Regulations include some restrictions relating to the advertising of follow-on formula and imposes further restrictions on the advertising of infant formula. Guidance relating to the characteristics of ‘advertising’ in the context of the Regulations is provided in the draft Guidance Notes, which the Agency is consulting on separately.</p> <p>Noted.</p> <p>Noted.</p> <p>The Directive and therefore the Regulations regulate the advertising of follow-on formula to a certain extent, as well as imposing substantial restrictions on the advertising of infant formula. Further guidance on this issue is given in the draft Guidance Notes on which the Agency is consulting on separately.</p> <p>Noted.</p> |

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| | | <p>promotional literature from an independent source to be available for mothers.</p> <p>The BDA would support the WHO resolution that carers should be informed through an explicit warning on packaging that powdered infant formula may contain pathogenic micro organisms. We would recommend that this is a mandatory requirement rather than a voluntary one.</p> | <p>The Agency is working with formula manufacturers to agree a suitable form of words for voluntary labelling which would inform consumers that infant formula and follow-on formula are non-sterile.</p> |
| Public health group | Royal College of Nursing | <p>As members of the Breastfeeding Manifesto Group, the UNICEF Baby Friendly Steering Group and the UK Infant Feeding Group we have contributed to the [BFLG] responses and do not intend on submitting a detailed response to the above consultation, however our key recommendations are those set out in the Baby Feeding Law group response.</p> | <p>See the Agency response to the Baby Feeding Law Group.</p> |
| Public health group | The Nutrition Society | <p>The Nutrition Society supports the Food Standards Agency's proposal to implement the EC directive.</p> <p>The Society welcomes the directive's aim to ensure that 'information provided to carers about infant feeding does not counter the promotion of breastfeeding. The Society is of the opinion that women who are unable or choose not to breastfeed their infant, should be supported. However, breastfeeding provides health benefits to both the mother and the baby, which all pregnant women should be made aware of, to ensure they can make a fully informed choice.</p> | <p>Noted.</p> <p>Noted.</p> |
| Public health group | Royal College of Midwives | <p>The RCM believes that the proposed new regulations should seek to :</p> <ul style="list-style-type: none"> • ban all promotion of breast milk substitutes (including follow-on formula and bottles and teats) • prohibit baby feeding companies from seeking direct or indirect contact with mothers (including a clear ban on company 'carelines', pamphlets, mailshots, emails and promotional websites), • prohibit sales incentives for marketing personnel employed by manufacturers of distributors of breast milk substitutes, • prohibit all idealising text and images from all breast milk substitutes • prohibit the use of the image of a feeding-bottle to indicate baby changing areas in public places • ban the use of pictures of bottle-feeding babies in magazines aimed at pregnant women and new mothers • prohibit company-produced or sponsored materials on infant feeding), • prohibit the promotion of names associated with breast milk substitutes | <p>See the Agency response to the Baby Feeding Law Group.</p> |

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| | | <p>(i.e. brand names and company names),</p> <ul style="list-style-type: none"> • restrict information for health professionals to scientific and factual matters with no idealising text or images, • prohibit promotion in health care facilities and gifts to health workers (samples for evaluation only), • prohibit the promotion of any product targeting babies under 6 months (complementary foods should not be marketed in ways that undermine breastfeeding). | |
| Individual | Tracy Morter | <p>It is my opinion that if the UK government was to adopt fully the WHO code on the marketing of infant formula milk and baby foods, then breast feeding and appropriate use of formula milks would be drastically improved.</p> <p>The problem is the unchallenged power of the infant formula milk industry to increase its 'market share' and therefore profits. Follow-on milk is an unnecessary product, produced as a cynical attempt to get round regulations on formula promotion. I am all for parents getting good, clear factual information regarding these products, but too often it is embedded in idealised advertising aimed at creating 'brand allegiance's from the earliest possible age. Please look to Norway, as an excellent example of providing factual product information for parents.</p> | See the Agency response to the Baby Feeding Law Group |
| Individual | Helen Nash RN (Child), IBCLC | <p>It is so important to stop advertising on follow on milks; mothering magazines are full of them as are professional journals. Most of the mothers I work with don't know the difference, and think babies must have them especially mother's in the lower income bracket who can ill afford them, all mothers recognise is the logos.</p> <p>An absolute ban on gifts to health professionals, pens, diary covers, free</p> | <p>The Directive and the Regulations include some restrictions relating to the advertising of follow-on formula impose further restrictions on the advertising of infant formula. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> <p>The Regulations include specific restrictions relating to donations. Further</p> |

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| | | <p>lunches etc, the health professional carries all these logos into the mothers house, the 'rep' always spins a good story, about the latest developments. Reps should only see one person (the infant feeding coordinator would be best) and then information fed out to the rest of the staff.</p> <p>Some information on formula that is not from the formula milk companies should be available, so we can have unbiased information on the different types, so health professionals can see they are basically the same. Some unbiased information on the difference between first milks and hungry baby milks, on cow's milk protein allergy and the difference between this and lactose intolerance, very different things, and how Soya milk is not the answer.</p> <p>Finally can we talk about the disadvantages of formula instead of the advantages of breast milk, mother nature expected us to be breastfed so she expected us to be naturally protected against eczema, asthma, cancer, diabetes, obesity etc. health professionals need to stop feeling guilty when they talk about formula and how it is unhealthy for babies, after all that is what they are there for.</p> | <p>guidance on donations is provided in the Guidance Notes on which the Agency is consulting on separately. The number of healthcare professionals contacted by a company is outside of the scope of these Regulations.</p> <p>Noted</p> <p>The Regulations require companies to provide information regarding the benefits and superiority of breastfeeding and the possible negative impact of bottle feeding in breastfeeding.</p> |
| Individual | Michael Joffe | <p>I am very pleased that Government intends to strengthen the Infant Formula and Follow-on Formula Regulations and hope that the new law will be fully in line with the International Code of Marketing of Breastmilk Substitutes and subsequent, relevant Resolutions of the World Health Assembly. In particular I support the Baby Feeding Law Group requests.</p> | <p>See the Agency response to the Baby Feeding Law Group.</p> |
| Individual | Sue Cardus | <p>I am extremely pleased to see that the Government intends to strengthen the Infant Formula and Follow-on Formula Regulations and hope that the new law will be fully in line with the International Code of the Marketing of Breastmilk Substitutes and subsequent, relevant Resolutions of the World Health Assembly. I endorse the Baby Feeding Law group position.</p> <p>Mothers and babies desperately need to be protected from these cynical promotions, and provided with accurate information about the composition of such milks, accurate information on how to prepare them safely and accurate information on the risks associated with their use. Has the Government considered whether these products should be packaged with the sort of information leaflet that comes with medications, listing all possible problems,</p> | <p>See the Agency response to the Baby Feeding Law Group</p> <p>The Regulations require manufacturers to include some information regarding the superiority of breastfeeding and the possible negative impact of bottle feeding.</p> |

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| | | risks and side-effects, as well as information on use? | |
| Individual | Lucy Best | I believe that the Jordan advert in OK magazine are an infringement of the law. Breast fed babies have lower incidents of health problems. | Noted. The Directive and therefore the Regulations regulate the advertising of follow-on and imposes further restrictions on the advertising of infant formula. Formula advertising must comply with these provisions. Further guidance on this issue is given in the Draft Guidance Notes which the Agency is consulting on separately. |
| Individual | Calvin Davies | I am working to tighten the law to prevent baby milk companies from promoting infant formula. At the moment they are using their advertising of follow-on formula to promote their infant formula by using the same logos and brand names. This contributes to the UK having one of the lowest rates of breastfeeding in Europe hence reduces the health and future well-being of our nation. | The Directive and therefore the Regulations regulate the advertising of follow-on formula and impose further restrictions on the advertising of infant formula. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately. |
| Individual | Anonymous | I have many friends who breastfed their children and many who did not. I am absolutely certain that the decision not to was not taken lightly by any of them and was certainly not influenced by advertising. I have twins and breastfed them for several weeks but because they were very premature and in hospital for a long time I eventually had to admit defeat. My milk supply was not sufficient as they grew because I didn't have enough physical contact with them. Stopping was the hardest thing I have ever done and I still feel huge guilt about it. I am incredibly angry by the suggestion that I may have done so on a whim because I saw an advert on television. Of course I knew that formula existed, but that was from seeing it on Supermarket shelves – how many new Mums have time to watch television? | Noted |
| Individuals | Letter to Secretary of State for | I am writing to draw your attention to a matter that is of great concern to me. The law in the UK is supposed to protect parents' right to receive objective and accurate information about feeding their babies and young children. It is meant to do this by prohibiting the promotion of formula milks to parents. The law, | The Regulations will implement the Directive which itself gives effect to the principles and aims of the International Code of Marketing of Breast-milk |

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| | <p>Health (1301 individual letters received in total) Reverend HP Barkham Mr Rob Ager Ruth Ker Kirsty Hymers Valerie Monk Paul Greenwood Deirdre O'Reilly Roy St. Pierre Daraius Master Lucy Best Beverley Beech Barbara Higham Sue Sauders Shirley-Anne Hunter JayneCollins</p> | <p>however, is not doing what it was designed to do.</p> <p>This undermines breastfeeding as the healthiest way of feeding a baby, and leaves those parents who formula feed confused about which sort of formula is suitable for their child. I believe that protecting breastfeeding and making formula feeding less unsafe is essential to protecting the health of the nation as a whole.</p> <p>The law as it stands leaves open loopholes, which have allowed baby milk companies to continue to promote formula milks unhindered. It is not coincidental that the UK has one of the lowest breastfeeding rates in Europe. This is unacceptable. Following the government's excellent work in ensuring that there were no loopholes in the law banning tobacco advertising, it is clear that the loopholes in the formula legislation also need to be closed if parents and babies are to receive the protection the law intended. There is already a model upon which the law in the UK could and should be based, and that is the WHA International Code of Marketing of Breastmilk Substitutes.</p> <p>This is an issue the UK should be leading on. I urge you to tighten the law to stop baby milk companies from putting profit before babies' health. Parents need reliable information based on evidence, not commercial pressure from baby milk companies.</p> | <p>Substitutes dealing with marketing, information and responsibilities of health authorities.</p> <p>The Directive and therefore the Regulations regulate the advertising of follow-on formula and impose further restrictions on the advertising of infant formula. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> |
| <p>Individuals</p> | <p>Letter to Minister for Public Health (7 received in total)</p> | <p>I am writing because I am pleased that the Government intends to strengthen the Infant Formula and Follow-on Formula Regulations. I am always shocked to hear some of the claims that the formula milk companies are allowed to make. Being a new mum is confusing enough without all these biased claims being made. I breastfed both of my children and found it rewarding for all concerned. I hope that the new law will be fully in line with the International Code of Marketing of Breast milk Substitutes and subsequent, relevant Resolutions of the World Health Assembly.</p> <p>I am really hoping that it will include the following:- ban promotion of breast milk</p> | <p>Noted. See the Agency response to the Baby Feeding Law Group</p> |

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| | | <p>substitutes including ridiculous “follow on” milks, put a ban on all these so called care lines and all the free information you get given in “bounty packs” and similar from the hospitals.</p> <p>The Government must provide objective information on infant feeding, avoiding conflicts of interest in funding infant feeding programmes i.e. not inaccurate by cow and gate!</p> <p>The following should also be included: there should be clear warnings about the fact infant formula is not a sterile product and may contain harmful bacteria, the promotion of names associated with breast milk substitutes (i.e. brand names and company names) should be prohibited and information for health professionals should be limited to scientific and factual matters with no idealising text or images, other “foods” should not be labelled as suitable for under 6 months as this undermines breastfeeding.</p> | |
| Individual | Costanza De Toma | As a mother I think that this form of direct promotion to mothers is misleading and shocking and should not be allowed. I have submitted a selection of emails regarding information sent to me from Cow & Gate ‘mums club’ | The Directive lays down substantial restrictions in relation to written or audiovisual informational and educational materials, dealing with infant feeding, produced by manufacturers and these are included in the Regulations. |
| Health worker | Sue Saxey | Provided information on the ‘Jordan’ article in OK magazine and believes the placement of the article was a deliberate article placement which constitutes illegal advertising. | Noted. The Directive regulates the advertising of follow-on formula and imposes further restrictions on the advertising of infant formula. Any advertising of formula must comply with these provisions. Further guidance on this issue is given in the Draft Guidance Notes which the Agency will consult separately |
| Individual | Angela Cartwright | I hope that all those harmed by your failure in this matter will be on your conscience for life. | Noted |
| Individual | Abigail Salehi | May I suggest the Food Standards Agency takes this opportunity to adopt the WHO Code in its entirety to protect the health of mothers and babies in the UK | The Regulations will implement the Directive which itself gives effect to the principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, |

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| | | <p>This would also be an opportunity to prevent the advertising of complementary feeds as suitable from 4 months. The Department of Health recommends infants should start solid foods from 6 months. All manufacturers of baby foods produce products which they claim are suitable from 4 months and this is very confusing for parents.</p> | <p>information and responsibilities of health authorities.</p> <p>Noted. These Regulations require that follow-on formula is labelled as suitable from six months which is in line with the Department of Health recommendations regarding weaning. There are separate requirements relating to baby food.</p> |
| Parliamentarian | Dr Lynne Jones MP | <p>Supports strengthening the law to ban all infant formula adverts (not just for babies under 6 months) to avoid any possibility of grey areas for the companies to exploit. The government is trying to increase breastfeeding rates as it costs the NHS millions each year treating sick artificially feed babies. Formula companies must not be allowed to inaccurately portray formula feeding as a beneficial choice.</p> <p>The EU Directive allows the full WHA Code to be implemented in the UK and the measures in the WHA Code are vitally important to ensure that mothers are provided with only non-emotive, impartial and independent information, free from the subtle marketing techniques currently used.</p> | <p>The Directive and therefore the Regulations regulate the advertising of follow-on formula and impose further restrictions on the advertising of infant formula. Guidance relating to the characteristics of ‘advertising’ in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consult on separately.</p> <p>The Regulations implement the Directive which itself gives effect to the principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, information and responsibilities of health authorities.</p> |
| Academic | Professor Mark Bell, Centre for European Law and Integration University of Leicester | <p>In my opinion, there are several aspects of the Directive which favour a broad interpretation permitting Member States to restrict such advertising.</p> <ol style="list-style-type: none"> 1. There is ambiguity within the Directive regarding its intended effects on the advertising of follow-on formulae. The approach of the Court of Justice to the interpretation of legislation is commonly described as ‘purposive’ in nature. In other words, the Court does not follow the literal approach which is characteristic of English law; instead it searches for the underlying goals of the legislation and interprets its provisions accordingly. 2. Arguably, the key provision is Article 1. This clarifies that the Directive ‘provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-milk Substitutes ...’. This is reaffirmed in Recital 27, which specifies that ‘the rules of composition, | <p>The Directive provides for Member States to give effect to the principles and aims of the Code and many of the provisions of the Code are provided within the Directive. This has been developed via the Regulations and the Guidance Notes.</p> <p>The Agency does not consider that the second paragraph of Article 1 of the Directive imposes a legal duty on the Member States to introduce domestic legislation giving effect to the Code. If</p> |

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| | | <p>labelling and advertising laid down in this Directive should be in conformity with the principles and the aims of the International Code ...'. In the light of these provisions, there seems a legal basis for arguing that provisions within domestic legislation which are designed to implement the International Code will not be in breach of the Directive.</p> <ol style="list-style-type: none"> 3. This conclusion fits with Recitals 22 and 28 which further emphasise the importance of promoting and protecting breast-feeding. 4. Article 3 of the Directive states that 'infant formulae and follow-on formulae may be marketed within the Community only if they comply with this Directive'. This provision needs to be read in the light of Article 1. Rules relating to follow-on formulae which are consistent with the International Code should be compatible with the Directive. 5. With regard to the legal basis for domestic legislation implementing the Directive, even if the Regulations are based purely on the European Communities Act 1972, this should not prevent the adoption of measures restricting the advertising of follow-on formulae. Given that the Directive expressly invokes the implementation of the International Code by Member States in Article 1, then measures taken to this end would appear to fall within the scope of the Directive. | <p>that were the intention of the Directive, it would have been set out clearly and explicitly (particularly taking account of the breadth of the provisions of the Code). The Agency considers that the correct interpretation of the second paragraph of Article 1 is that it merely explains what the Code does.</p> |
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| Academic | Tonia Novitz | <p>Firstly, I am not convinced that they reflect adequately the stated purpose of Directive 2006/141/EC, which is to 'give effect to principles and aims of the International Code of Marketing of Breast-milk Substitutes' (Article 1 - Reaffirmed in Recital 27). This indicates that any measures taken by the UK Government to comply with the Code could not be regarded to be in violation of the Directive. This is not, therefore, a harmonisation Directive setting minimum standards above which the UK cannot go. Instead, it lies at the discretion of the UK government to take all appropriate steps to ensure implementation of the Code. The Regulations therefore do not go as far as they might. Moreover, the ability to market infant formulae and follow-on formulae (arising under Article 3) can be read in the light of Article 1. Provision for marketing such goods without provision for compliance with the Code would arguably be in breach of the Directive.</p> <p>Secondly, while Article 18(1) obliges Member States to 'permit trade in products complying with this Directive by 1 January 2008', there remains scope for the UK to place restrictions on advertising. See Case C-267/91 Keck [1993] ECR I-6097.</p> | <p>The Directive provides for Member States to give effect to the principles and aims of the Code and many of the provisions of the Code are provided within the Directive.</p> <p>The Agency does not consider that the second paragraph of Article 1 of the Directive imposes a legal duty on the Member States to introduce domestic legislation giving effect to the Code. If that were the intention of the Directive, it would have been set out clearly and explicitly (particularly taking account of the breadth of the provisions of the Code). The Agency considers that the correct interpretation of the second paragraph of Article 1 is that it merely explains what the Code does.</p> <p>The Regulations will restrict advertising of infant formula from 1st January 2008 in accordance with the requirements of Directive.</p> |
| Individual | Ann Watts | <p>I understand that the government is reviewing the regulations with respect to baby milk or infant formula.</p> <p>I believe that all new and prospective parents should have unbiased information to help them come to an informed decision about how to feed their children. Any advertising of artificial baby milk may tip the scales and make the parents even subconsciously think that formula is a good substitute for breast milk. Breast feeding has many advantages to bottle feeding, and parents need the confidence their abilities to be able to breastfeed babies for as long as they want to. Please rethink the advertising regulations in the UK to help parents make informed choices.</p> | <p>The Directive and therefore the Regulations regulate the advertising of follow-on formula and impose further restrictions on the advertising of infant formula. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> |
| Individual | Dani Dinwoodie | <p>I urge you to tighten the law in line with the WHO Code and subsequent resolutions to stop baby milk companies from putting profit before babies' health. Parents need reliable information based on evidence, not commercial pressure from baby milk companies.</p> | <p>Noted. See the Agency response to the Baby Feeding Law Group</p> |

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| Individual | Gerald Hingley | Advertising of formula should be permitted, the same standards of honesty and empirical impartiality should be imposed on both commercial advertisers and on the charities and other organisations who supply information on the feeding of infants to prospective and new mothers. | Noted |
| Breastfeeding Counsellor | Hazel Jones | Pleased that Government intends to strengthen the Infant Formula and Follow-on Formula Regulations and hope that the new law will be fully in line with the International Code of Marketing of Breastmilk Substitutes and subsequent, relevant Resolutions of the World Health Assembly. I support the Baby Feeding Law Group request: | Noted. See the Agency response to the Baby Feeding Law Group |
| Government Advisory Committee | Subgroup on Maternal and Child Nutrition (SMCN), Scientific Committee on Nutrition | <p>The Regulations do not give effect to the 'International Code of Marketing of Breast Milk Substitutes' in its entirety because they are inadequate in scope. They refer only to two 'breast milk substitutes' as defined by the Code: infant formula and follow on formula. Other products marketed to infants (for example bottled water and drinks) are not included.</p> <p>There is no case for allowing the "advertising" of follow-on formula. It is our opinion that infant formula and follow-on formula should be subjected to the same marketing restrictions.</p> <p>The Regulations should also ensure that infant formula and follow-on formula are clearly distinguishable to consumers who are currently confused by similarity of labelling and package design.</p> <p>In addition, free samples do not appear to be adequately prescribed by the Regulations.</p> | <p>The Directive and therefore these Regulations lay down provisions in relation to infant formula and follow-on formula.</p> <p>The Directive and the Regulations regulate the advertising of follow-on formula and impose further restrictions on the advertising of infant formula. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in the draft Guidance Notes which the Agency is consulting on separately.</p> <p>Article 13 of the Directive and Regulation 19 requires that infant formula and follow-on formula are labelled in such a way to enable consumers to distinguish between the two. Further guidance on this aspect will be provided in the Guidance Notes which the Agency is consulting on separately.</p> <p>Article 14 of the Directive and Regulation 23 prohibits the provision of free samples of infant formula and Article 25 of the Directive and Regulation 25 lays down controls relating to distribution of infant</p> |

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| | | <p>Lastly, the Committee states that the term ‘advertising’ is too narrow and must include promotion and other marketing communications.</p> | <p>formula through institutions or organisations.</p> <p>The Directive and the Regulations do not propose a definition of ‘advertising’. Guidance relating to the characteristics of ‘advertising’ in the context of the Regulations is provided in the draft Guidance Notes on which the Agency is consulting on separately.</p> |
| Enforcement bodies | Trading Standards South East | <p>The 1995 regulations provided a definition of advertisement, which was linked to that in the Food Safety Act 1990. This definition has proved to be inadequate. The proposed regulations do not include a definition of advertisement.</p> <p>The Partnership is of the opinion that a definition of ‘advertisement’ is necessary in the <u>Infant Formula and Follow-on Formula (England) Regulations</u>, to prevent ambiguity and difficulties of enforcement. The Partnership wants the definition to encompass internet advertising. The provision of website links either to pieces of research or other advertisements should also be considered in the context of ‘advertising’, either in the Regulations or any accompanying guidance.</p> <p>The term marketing is not defined in Regulation 2. There is no definition of marketing in the Directive either.</p> <p>The Directive and this proposed regulation do not deal with use of brand names and logos which appear on both formula and follow on milks. The Partnership would like to see a reference in Regulations to any statement being “clear and uninterrupted”, in a minimum stipulated font size, on the front of the pack which faces the consumer.</p> <p>An alternative approach would be to ban the advertising of all breast milk substitutes, including follow on milks. This would mean there would be no opportunity to cause confusion. However, this Partnership supports the principle of informed consumer choice and this approach would run counter to this principle.</p> | <p>The Regulations do not propose a definition of ‘advertising’ relating to the characteristics of ‘advertising’ in the context of the Regulations is provided in the Guidance Notes on which the Agency is consulting on separately.</p> <p>The Regulations provide at regulation 2(3) that expressions used both in the Regulations and in the Directive have the meaning they bear in the Directive. Accordingly, the term ‘marketing’ has the meaning it does in the Directive.</p> <p>The labelling of infant formula and follow-on formula is strictly controlled by these Regulations.</p> <p>The Directive and the Regulations regulate the advertising of follow-on formula and impose further restrictions on the advertising of infant formula. Guidance relating to the characteristics of</p> |

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| | | <p>Regulation 21 restricts advertisements of infant formula to scientific publications or a publication prior to the retail stage whose readership is other than the general public. The Partnership is of the opinion that the lack of definition of scientific publication will give rise to ambiguity and difficulties with enforcement. Is a scientific publication only one where research papers are published, or would a magazine published by a professional organisation, such as the Royal College of Midwives, be considered a scientific publication? Is New Scientist, (a general science magazine aimed available to the general public), a scientific publication? The directive and regulations provides no definition, but the Partnership feels this could be included in the guidance notes.</p> <p>Potential problems include a 'product guide' booklet on infant feeding inserted loose in a healthcare professionals' magazine and manufacturers' websites with information on infant feeding. Is this information or is it an advertisement? Is this the donation of material? In the absence of a clear definition of advertisement and what is meant by donation, it may be legally possible for a manufacturer to present its products in such a way that it could be argued that it is providing (but not donating) information which then allows it to refer to composition and other details which are prohibited in an advertisement.</p> <p>To prevent enforcement problems, the Partnership is of the opinion that clear guidelines on what is informational or educational material is needed. The Code and Directive seem to imply that information and educational material should only originate from government sources. If this is the case the guidelines should explain this.</p> <p>The interpretation of the term 'idealise' for the purposes of these Regulations: If the intention of legislators is to have a broad scope, it would be helpful to have a definition which makes this clear. For example, 'idealising pictures and text includes symbolic representation, images, text, graphics, logos of items, people, or products usually associated with young babies.</p> | <p>'advertising' in the context of the Regulations is provided in the Guidance Notes which the Agency is consulting on separately.</p> <p>Noted. The Agency will provide further guidance on this issue in the Guidance Notes on which it is consulting on separately.</p> <p>Noted. The Agency will provide further guidance on this issue in the Guidance Notes on which it is consulting on separately.</p> <p>Noted. The Agency will provide further guidance in the Guidance Notes, on which it is consulting on separately.</p> <p>The Regulations do not propose a definition of 'idealise', as any attempt to define the term runs the risk of limiting its scope. The Regulations do not include a definition of 'idealise'. The Guidance Notes set out a number of representations which should not be included on infant formula in relation to 'idealise'. The Agency is consulting</p> |
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| | | | separately on the Guidance Notes. |
| Enforcement bodies | LACORS | <p>LACORS believes that there is sufficient legal authority contained within EC Directive 2006/141 to enable greater implementation within the UK legislation of the controls set out in the International Code.</p> <p>LACORS supports the view that the same advertising and marketing and promotional controls which currently apply to infant formula should also apply to follow-on formulae.</p> <p>It would be helpful to define the terms “ advertise “ , “ advertising “ and “ advertisement “ for the purposes of Regulations 20, 21 and 22. If these terms can not be defined within the Regulations themselves they should be addressed and defined within the proposed accompanying FSA guidance notes. The same principle applies also in relation to the terms “ promotion “ and “ promote “ in relation to Regulation 23.</p> <p>LACORS recommends that the Regulations are extended to address the issues of website advertising; product placement in publications and advertorials</p> <p>With regard to Regulation 23(1)(a) – (e) the accompanying guidance notes should clearly set out, with examples, the types of advertising, display or promotional activity prohibited by the Regulations.</p> <p>LACORS considers that the proposed FSA accompanying guidance should define “ advertising “ for the purposes of these Regulations as widely as possible given the enforcement problems caused by the blurring of the line</p> | <p>The Directive regulates the advertising of follow-on formula imposes further restrictions on the advertising of infant formula.</p> <p>The Regulations will implement the Directive which itself gives effect to the principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, information and responsibilities of health authorities.</p> <p>The Regulations do not propose a definition of ‘advertising’. Guidance relating to the characteristics of ‘advertising’ in the context of the Regulations is provided in the Guidance Notes which the Agency is consulting on separately.</p> <p>Guidance relating to the characteristics of ‘advertising’ in the context of the Regulations is provided in the Guidance Notes.</p> <p>Noted</p> <p>Noted</p> |

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| | | <p>between infant formula and follow-on formulae.</p> <p>LACORS view is the term “idealise” should be defined or explained within the accompanying FSA guidance notes.</p> <p>LACORS suggests that the packaging and presentation of infant formula and follow-on formula should be visually and stylistically distinctive. To achieve this any aspects, which also include generic brand/company names and/or logos should be removed and replaced or substantially modified.</p> <p>LACORS supports the FSA proposal to further restrict the advertising of infant formula.</p> | <p>The Regulations do not include a definition of ‘idealise’. The Guidance notes will set out a number of representations which should not be included on infant formula in relation to ‘idealise’. The Agency is consulting separately on the Guidance Notes.</p> <p>The labelling of infant formula and follow-on formula is strictly controlled by these Regulations and all labelling must comply with these provisions. The Regulations cannot prohibit generic brand names/company names as they are allowed by the Directive. Further guidance will be provided in the Guidance Notes on which the Agency is consulting separately.</p> <p>Noted</p> |
| Notification | | | |
| Industry | IDFA | <p>It would be useful to have a definition of a re-formulated brand so as to exclude <i>de minimus</i> changes. We propose that a ‘re-formulated brand’ of infant formula be a brand whose formula has changed to the degree that there is a consequential labelling change. Any change in the formula that did not require a labelling change would be ignored.</p> | <p>The Agency will consider this view when finalising the Guidance Notes on the procedures for notifying the marketing of infant formula.</p> |
| NGO’s | Baby Feeding Law Group | <p>require a pre-authorisation procedure for all new ingredients and addition of authorised ingredients to the annex of EU Directive 2006/141 rather than the proposed notification system.</p> | <p>The European Commission has indicated that pre-authorisation procedures will be examined as part of future revisions of 89/398/EC (the framework Directive on Foods for Particular Nutritional Uses). The Agency will keep stakeholders informed as appropriate.</p> |

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| NGOs | Baby Milk Action; The NCT; The Breastfeeding Manifesto Coalition; Association of Breastfeeding Mothers; Save the Children; IBFAN-GIFA; La Leche League; UNITE CPHVA | Support the Baby Feeding Law Group | See Agency response to Baby Feeding Law Group |
| Public Health groups | Royal College of Nursing | Support the Baby Feeding Law Group | See Agency response to Baby Feeding Law Group |
| | The Royal College of Midwives | The RCM believes that the proposed new regulations should seek to require a pre-authorization procedure for all new ingredients and listing in EU Directive 2006/141. | See the Agency response to the Baby Feeding Law Group. |
| Individuals | Tracy Morter; Michael Joffe; Sue Cardus | Support the Baby Feeding Law Group | See Agency response to Baby Feeding Law Group |
| Enforcement bodies | Trading Standards South East | The Partnership felt it important that the Agency informs the relevant Local Authority of any notifications that they receive under these Regulations concerning businesses in their area, so they may carry out their duties effectively. | The Agency will use procedures which will ensure that the relevant Local Authority is informed of a notification at the same time as acknowledging the notification from the food business operator. |
| Labelling | | | |
| Industry | IDFA | We are not aware of any reliable evidence of confusion between these products. Indeed, the Infant Feeding Survey 2005 showed that at stage 2 the | The labelling, presentation and advertising of infant formula and follow-on |

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| | | use of follow-on milk is very low and the reasons given for early introduction did not include information from manufacturers but a significant proportion cited 'advised by doctor/health. This suggests that there is a need to address the matter of education of health professionals about infant feeding and the roles of the products available and we are happy to work with the Agency to address this point. | formula must be differentiated to ensure that consumers can make a clear distinction between these products. The Agency has provided guidance on the relevant provisions of the Regulations (regulations 19, 20, 21 and 22 and Articles 13 and 14 of the Directive) in the Guidance Notes, on which the Agency is consulting separately. |
| Industry | National Pharmacy Association | In regulation 19 and 20 of the regulations, implementing articles 7 and 8 of the Directive, there is a requirement that labelling and presentation of infant and follow on formula is such as to avoid confusion between the two types. The FSA has requested suggestions for inclusion in the accompanying guidance notes covering these regulations. The NPA would suggest that the FSA consult a detailed reference document published by the National Patient Safety Agency designed for improving packaging and labelling of medicines, as many of the recommendations could help in the development of guidance for the packaging and labelling of infant and follow on formula. | Noted |
| Industry | HIPP | We request that "the definitions of 'claim', 'nutrition claim', 'health claim' and 'reduction of disease risk claim' in Article 2(2)(1), (4), (5) and (6) of Regulation (EC) No 1924/2006 shall apply" should be inserted into The Infant Formula and Follow-on Formula (England) Regulations 2007. | The Directive makes a direct reference to these definitions and as such these definitions would apply to claims on infant formula and follow-on formula. |
| NGO | Baby Feeding Law Group | <ul style="list-style-type: none"> • where possible prohibit all health and nutrition claims on foods for infants and young children. Require any permitted claims to be placed at the back of the package near the nutrition panel, • require clear warnings about the fact that powdered formula is not a sterile product and may contain harmful bacteria, alongside clear instructions on how | <p>Only those claims that are listed in Annex IV of the Directive can be made on infant formula. Claims on follow-on formula are controlled by the Nutrition and Health Claims Regulation and would have to be included in the relevant Annex of that Regulation before they can be used on follow-on formula. The Regulations cannot specify where claims must be placed on formula packaging because no such detailed rules are included in the Directive.</p> <p>The Regulations do not require such labelling as there is no requirement to do</p> |

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| | | <p>to reduce risks from possible contamination,</p> <p>prohibit all idealising text and images from all breastmilk substitutes,</p> <p>To avoid confusion and to prevent inappropriate use of the products, the requirements for the labelling of infant formula in paragraphs 17(1) (e) and 17(3) should be repeated in paragraph 18 in order that they also apply to the labelling on follow-on formula. This would ensure that follow-on formula also carries information about the superiority of breastfeeding, the recommendation that the product be used only on the advice of an independent health professional, and that it does not carry images which idealise the use of the product.</p> | <p>so in the Directive. The Agency is working with formula manufacturers to agree a suitable form of words for voluntary labelling which would inform consumers that infant formula and follow-on formula are non-sterile.</p> <p>The draft Regulations prohibit the use of idealizing text and images in relation to infant formula. The use of certain words such as ‘humanised’ and ‘maternalised’ is prohibited in relation to follow-on formula by the Regulations. These prohibitions are provided for in the Guidance Notes which the Agency is consulting on separately.</p> <p>The Regulations require the recommendation that follow-on formula be used on the advice of an independent health professional. Guidance relating to the avoidance of risk of confusion between infant formula and follow-on formula is provided in the Guidance Notes which the Agency is consulting on separately.</p> |
| <p>NGO’s</p> | <p>Baby Milk Action; The NCT; The Breastfeeding Manifesto Coalition; Save the Children; IBFAN-GIFA; La Leche League; UNITE</p> | <p>Support the Baby Feeding Law Group</p> | <p>See Agency response to Baby Feeding Law Group</p> |

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| | CPHVA | | |
| Public Health group | Royal College of Nursing | Support the Baby Feeding Law Group | See Agency response to Baby Feeding Law Group |
| Individuals | Tracy Morter; Michael Joffe; Sue Cardus | Support the Baby Feeding Law Group | See Agency response to Baby Feeding Law Group |
| NGO | Association of breastfeeding Mothers | <p>To avoid confusion and to prevent inappropriate use of the products, the requirements for the labelling of infant formula in paragraphs 17(1) (e) and 17(3) should be repeated in paragraph 18 in order that they also apply to the labelling on follow-on formula. This would ensure that follow-on formula also carries information about the superiority of breastfeeding, the recommendation that the product be used only on the advice of an independent health professional, and that it does not carry images which idealise the use of the product.</p> <p>We note from Appendix 4 of the Partial Regulatory Impact Assessment that the FSA is considering asking the formula industry to agree a voluntary approach to warning parents and health professionals about the risks of pathogenic contamination of formula powders. We are sceptical about the effectiveness of a voluntary agreement in this aspect since it has such significant implications for infant health. We therefore believe that paragraphs 17 and 18 should, in line with WHO and FSA recommendations require labels to carry explicit warnings that the product may contain pathogenic micro-organisms and that following the preparation instructions carefully is essential to protect babies' health.</p> | <p>The Regulations require follow-on formula be used on the advice of an independent health professional. Guidance relating to the avoidance of risk of confusion between infant formula and follow-on formula is provided in the Guidance Notes which the Agency is consulting on separately.</p> <p>The Agency is working with formula manufacturers to agree a suitable form of words for voluntary labelling which would inform consumers that infant formula and follow-on formula are non-sterile.</p> |
| NGO | The Royal College of Midwives | <p>The RCM believes that the proposed new regulations should seek to :</p> <ul style="list-style-type: none"> • where possible prohibit all health and nutrition claims on foods for infants and young children. Require any permitted claims to be placed at the back of the package near the nutrition panel in specified text, • require clear warnings about the fact that infant formula is not a sterile product and may contain harmful bacteria, alongside clear instructions on how to reduce risks from possible intrinsic contamination. | See the Agency response to the Baby Feeding Law Group |
| OGD | Sub-group on Maternal and Child | We find the case for labelling infant formula or follow on formula with health or nutrition claims entirely unsupportable. | Only those claims that are listed in Annex IV of the Directive can be made on infant formula. Claims on follow-on formula are |

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| | Nutrition (SMCN) of Scientific Advisory Committee on Nutrition | <p>If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods.</p> | <p>controlled by the Nutrition and Health Claims Regulation and would have to be included in the relevant Annex of that Regulation before they can be used on follow-on formula.</p> <p>The European Commission has indicated that pre-authorisation procedures will be examined as part of future revisions of 89/398/EC (the framework Directive on Foods for Particular Nutritional Uses). The Agency will keep stakeholders informed as appropriate.</p> |
| Enforcement bodies | Trading Standards South East | <p>Regulation 17(2) (b) of the new regulations does not include the phrase 'or any similar term suggesting that the product is equivalent or superior to breast milk' which appears in the Regulation 15(b) of the 1995 regulations. This phrase may not now be needed following the recent EU ruling on terms such as closer to breast milk, inspired by breast milk, but it would be helpful to have clearer guidance on the how broad the definitions of humanise and maternalise should be.</p> | <p>No terms that may discourage breastfeeding should be used on labelling of infant formula. Further advice on this is given in the Guidance Note.</p> |
| | LACORS | <p>With regard to Regulation 17(1)(d) LACORS is aware that current FSA/Department of Health guidance is that minimum water temperature required to safely prepare infant formula is 70deg C. LACORS suggest that this figure is specifically included in the Regulations.</p> <p>With regard to Regulations 17(2)(b) and 18(2) (b) these should be amended, in terms of its intention, to prohibit the use of phrases such as " closer to breast milk ", " inspired by breast milk " and any other phrase having the same impact on purchasers. With regard to Regulation 18(2) (b) see comments made above in relation to Regulation 17(2) (b).</p> <p>With regard to Regulation 17(3)(a) this should be expanded to cover pictorial and stylised representation of " an infant " as well as just pictures</p> | <p>The Agency is working with formula manufacturers to agree a suitable form of words for voluntary labelling which would inform consumers that infant formula and follow-on formula are non-sterile.</p> <p>No terms that may discourage breastfeeding should be used. The Regulations seek to ensure that the labelling of infant formula and follow-on formula does not discourage breast feeding. Further advice is given in the draft Guidance Notes which are being consulted on separately.</p> <p>Further advice on this will be provided in Guidance Notes.</p> |

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| | | <p>With regard to Regulation 17(3) (b) the term “idealise “ should be defined if possible within the Regulations themselves or failing that within the accompanying FSA guidance notes.</p> <p>With regard to Regulation 17(4) the wording used should be amended to indicate that any claim relating to nutrition, health and composition are prohibited unless specifically included in Annex IV.</p> <p>This requirement to clearly distinguish between infant formula and follow-on formula should not be applied to labelling alone but be expanded to include all advertising and promotional activities.</p> | <p>The Regulations do not propose a definition of ‘idealise’, as any attempt to define the term runs the risk of limiting its scope.</p> <p>Article 13 of the Directive and Regulation 17(4) specifies that only those nutrition and health claims listed in Annex IV can be made on infant formula. All composition claims are subject to the provisions of the Food Labelling Regulations 1996 (as amended).</p> <p>The Regulations lay down strict restrictions with regard to advertising and promotion of infant formula. The Agency will give further advice on advertising of infant formula and follow-on formula in the Guidance Notes which the Agency is consulting on separately.</p> |
| Individual | Rob Ager | <p>The Regulations should require any permitted claims to be placed at the back of the package near the nutrition panel in specified text</p> <p>The Regulations should require clear warnings about the fact that infant formula is not sterile and contains harmful bacteria, alongside clear instructions on how to reduce risk from possible intrinsic contamination</p> | <p>Only those claims that are listed in Annex IV of the Directive can be made on infant formula. Claims on follow-on formula are controlled by the Nutrition and Health Claims Regulation and would have to be included in the relevant Annex of that Regulation before they can be used on follow-on formula.</p> <p>The Agency is working with formula manufacturers to agree a suitable form of words for voluntary labelling which would inform consumers that infant formula and follow-on formula are non-sterile.</p> |
| Costs, benefits and sustainability | | | |

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| Industry | IDFA | <p>costs associated with not implementing the Directive:</p> <p>It is difficult to quantify costs associated with the work that has been undertaken as this has been in progress for a long period of time, since the publication of the SCF report. Costs to other countries, such as Ireland and Malta could be significant as they rely on the UK for products. Should the UK not implement the Directive these member states would have to develop their own packaging at significant costs to them and potentially their consumers. We reiterate our view that the legislation should be pan-European to promote free and fair trade.</p> <p>policy and administrative costs which are over and above what a business would do commercially, with respect to the approval of new claims relating to infant formula:</p> <p>We accept that there are likely to be additional costs in this area.</p> <p>policy and administrative costs which are over and above what a business would do commercially, in relation to the other provisions of the Regulations:</p> <p>We would like to stress that should the UK Regulations go further than those set out in the above Directives there is likely to be a substantial financial impact on UK manufacturers.</p> <p>social and environmental costs and benefits of options 1 and 2:</p> <p>We are concerned that there will be a social impact and related cost in restricting access to information for mothers and carers. There would be significant cost associated with providing this information in a timely and accurate fashion to mothers via other routes.</p> | <p>Noted</p> <p>Noted</p> <p>Noted</p> <p>Noted</p> |
| | FTSE, The Index Company | <p>Option 2 would provide benefits to infant nutrition and health and help socially responsible investors differentiate between the practices of food/formulae companies.</p> | <p>Noted</p> |

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| NGO | Baby feeding Law Group | There are likely to be few health or cost benefits through implementation via options 1 or 2. The proposed Regulations are unlikely to have any positive benefit and could further harm infant health. However, implementing the International code could have a significant impact as it would mean that efforts to promote and support breastfeeding are more likely to succeed. Implementing the Code could have a significant impact on social and environmental costs, reduce maternal absenteeism from work, reduce obesity and will help to achieve carbon reduction targets. | Noted |
| NGO | Save the Children | The serious international situation provides one of the strongest rationales for going further than the proposed regulations and strengthening the rules in this country. While they would protect babies in the UK, stronger regulations would also provide global leadership in an international context where a strong institutional champion on this issue is absent. It would assist the work of Save the Children and our partners internationally to call governments and companies to account, and to help protect the health and lives of the world's most vulnerable children. Tightening the rules in the UK could therefore have ramifications for the lives of children globally. | Noted |
| NGO | The Breast Feeding Network | <p>Costs associated with not implementing the Directive The cost savings through continued breastfeeding have been widely acknowledged,</p> <p>Financial concerns should never be considered ahead of infant health. Allowing new claims without approval would allow industry to use them to induce sales. Any new claims should be regulated by government.</p> <p>New ingredients should be mandatory once scientifically and independently proven.</p> <p>The impact that implementing the Regulations may have on the charity and the voluntary sectors, enforcement authorities and healthcare professionals: We support a strengthening of proposals. It would reduce our workload if women were not constantly undermined by commercialisation of infant feeding. The positive effect on health in terms of increased breastfeeding and safer artificial feeding, will impact positively in the long term with much less use of</p> | <p>Noted</p> <p>Noted</p> <p>The European Commission has indicated that pre-authorisation procedures will be examined as part of future revisions of 89/398/EC (the framework Directive on Foods for Particular Nutritional Uses). The Agency will keep stakeholders informed as appropriate.</p> <p>Noted</p> |

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| | | <p>NHS resources. If loopholes were closed this would save enforcement authorities time as the companies would not be finding creative ways to advertise their products. Health professional's job would be made easier by the fact the information they give is not being constantly undermined by company promotion.</p> <p>It will reduce some of the environmental costs associated with formula feeding-status quo is not acceptable.</p> | Noted |
| Enforcement bodies | LACORS | LACORS is not able to quantify the impact that implementing the Regulations will have in resource terms. LACORS recognises the strongly held views of many stakeholder groups and particularly those representing consumer and health professional groups that the requirements should be vigorously and uniformly applied and enforced. Home authorities advising infant formula manufacturers and responding to complaints about their activities will bear a particular burden in terms of officer time and resources. However, many other local authorities may have a role to play in assessing and dealing with point of sale advertising or promotional activities. | Noted |
| Enforcement and transitional provisions | | | |
| Industry | Hipp Organic Ltd | We request clarification of the transitional provisions for these Regulations. We understand there may be differences in the interpretation of the dates published in Article 18.1 of the EC Directive in different Member States. Section 1(b) (i) states that these new Regulations come into force on 01.01.2010. Does this mean that you can produce milks according to the old Regulations until 31.12.2009, or does this mean that products at the retail level have to fulfil the new laws by 01.01.2010? | This will be clarified in the Guidance Notes |
| NGO | Association of breastfeeding Mothers, UNICEF UK | We were concerned to note that paragraph 28 does not apply to the regulations on labelling or risk of confusion and only partially to the regulation on advertising infant formula. It would seem reasonable to expect that this will make compliance less likely and enforcement more difficult. Paragraph 28 should therefore be extended to refer also to regulations 17, 18, 19, 21(2) and 21(3). | Article 3 of the Directive and Regulation 3 requires that any person marketing an infant formula or follow-on formula must comply with Article 13 of the Directive and Regulations 17, 18, or 19 and need not be listed specifically for enforcement purposes. |
| Enforcement bodies | Trading Standards South East | The Partnership found Regulation 31 confusing and were concerned that if enforcement agencies could not understand them, then businesses will also fail to understand the Regulations. | This will be clarified in the Guidance Notes |
| Other issues | | | |

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| Industry | IDFA | <p>We believe that the UK needs to implement the regulations as presented by the EU. The regulations as adopted in the UK should be in line with those in other EU member states to support the principle of free and fair trade between member states. The presence of specific UK regulations which go further than the wording in the EU recast directive may prove unduly and unfairly onerous for UK companies</p> <p>Regulation 2(6) provides for the 'automatic' updating of the annexes to the Regulations as the Annexes to Directive 141 are changed. We propose that we work with the Food Standards Agency to understand the practical applications related to this Regulation, including notification of changes and transitional provisions.</p> <p>Regulation 24</p> <p>The heading is "Provision of information and education regarding infant and child feeding". However, the regulation actually deals with the provision of informational and educational material dealing with the feeding of infants. The words "and child" should be deleted as they cause confusion.</p> | <p>Noted</p> <p>The Agency will ensure that any proposed changes to the Annexes of the Directive are highlighted to stakeholders when such changes are being considered at European level.</p> <p>The wording used in Regulation 24 reflects the text within the Directive which refers to both infants and young children.</p> |
| NGO | World Cancer Research Fund International | <p>The WCRF supports any move that protects and supports breastfeeding mothers according to the WHO global strategy for Health</p> | <p>Noted</p> |
| Individual | Ruth Ker | <p>I believe that it is your obligation, as a human being, to protect other innocent human beings from harm. Formula milk is harmful for all babies. Breast milk is their human right. You have the choice to harm or not harm infants. I hope that you will think deeply about your choice to allow the continuation of harm to infants and accept this harm as your responsibility.</p> | <p>Noted</p> |
| Compositional criteria | | | |
| NGO | Helen Nash RN (Child), IBCLC | <p>tougher regulations on what can and cannot be put in formula, and tests done by an independent body, not just the manufacturer, also a detailed list of ingredients on the tin.</p> | <p>The composition of both infant formula and follow-on formula is tightly controlled by the Regulations to ensure the suitability of these products for infants. The composition of infant formula and follow-on formula is given in Annex 1 and</p> |

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