

SUMMARY TABLE OF RESPONSES TO THE PUBLIC WRITTEN CONSULTATION
Guidance notes for The Infant Formula and Follow-on Formula Regulations 2007

Respondent	Comments	FSA response
Advertising and promotion		
Co-operative	Do not think interpretation of regulation 20 would necessarily mean that such absolute separation is needed to comply with those sections of the regulations; provided it is clear that these are two distinctive products and there is no confusion between the two. We think that the first bullet point in relation to shelf talkers for follow-on formula should suffice. If it is considered some point should be included on actual display, we consider that separation could be put forward as one option to comply and that this should be further qualified with "where practicable".	Noted
The British Retail Consortium	<p>While we understand the reason for developing a document following the same structure as the piece of legislation, in this case it is confusing and has resulted in several provisions (e.g. advertising) being covered several times.</p> <p>We also feel that the guidance goes beyond the legislation suggesting best practice guidance. The purpose of the guidance should be made clear. We are specifically concerned about paragraph 49 of the guidance which suggests that 'shelf-talkers' and other in-store promotional devices for follow-on formulae are not used in the vicinity of infant formulae. We are especially concerned about the unreasonable suggestion that a follow-on formula has to be located in a different part of the store to infant formula. This is gold plating, as this is not laid down in the legislation. As best practice this proposal is completely unjustified.</p> <p>The regulation states that infant formulae and follow-on formulae should not be presented in a manner that results in confusion between the two products; this can be done without having to separate the products on shelf. Retailers have no record of any customer complaints indicating difficulties distinguishing between the two products. We therefore urge the Agency to remove such provisions from this guidance document.</p>	<p>Noted</p> <p>Noted. The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency's view on how to comply with those requirements.</p> <p>Regulation 20(2) applies the provisions of Regulation 19 to the provision of follow on formula. Regulation 19 requires a clear distinction between infant formula and follow on formula so</p>

		as to avoid any risk of confusion. The Agency has provided its view on how this should be achieved.
PPA	<p>The PPA welcomes sensible guidelines on the advertising of a product such as infant and follow-on formula when health concerns are involved.</p> <p>The PPA calls on the FSA to:</p> <ul style="list-style-type: none"> • Incorporate a transitional period into the guidelines in order that campaigns already being carried do not breach them unwittingly • Incorporate a ‘publisher’s defence’ into the guidelines to cover unintentional breaches • Interpret the term ‘scientific publications’ less narrowly than it does in the current draft • Allow the advertising of infant formula online where it appears in journals not available to the general public which would be entitled to carry this advertising in their offline publications • Clarify what it means by editorial content and if possible work with publishers to reach a sensible conclusion in this area • Give general principles which must be followed when advertising infant and follow-on formulas rather than an overly detailed and potentially confusing list 	<p>The Guidance notes help interpret the Regulations. The Regulations, which implement the EC Directive, do not put in place a transitional period.</p> <p>Noted.</p> <p>The Agency will consider all comments received and will review the guidance on “scientific publication” accordingly.</p> <p>Noted</p> <p>Noted</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p>
Advertising Association	<p>AA is concerned that:</p> <p>The guidance notes seem to go further than the European Commission Directive 2006/141/EC “on infant formulae and follow-on formulae and the Infant Formula</p>	<p>The Guidance notes aim to help interpret the requirements the Regulations introduce and</p>

	<p>and Follow-on Formula Regulations 2007;</p> <p>Timing for implementation</p> <p>The AA is concerned that the immediate application of the guidelines in their current form will incur considerable loss for advertisers and publishers who will have to revise and/or stop advertisements already scheduled to run over the next 6 months. It is also unclear whether advertisers would be retrospectively liable for those campaigns already in print that do not comply with the guidance.</p> <p>Definition of scientific journals</p> <p>The Infant Formula and Follow-on Formula Regulations 2007 state that ‘no person shall advertise infant formula except in a scientific publication’. The FSA draft guidance notes take this statement further by adding ‘where such publications report the results of original scientific research and reviews’. This extends the terms of the regulations unnecessarily, removing the right to advertise infant formula in professional journals and specialist publications aimed at healthcare practitioners.</p> <p>Detail of rules</p> <p>The AA is also concerned by the excessively detailed nature of the rules relating to the advertising of both infant and follow-on formulae and could lead to inadvertent breaches of the guidance.</p> <p>Furthermore, the call for advertisers to submit planned campaigns to the FSA in advance of their implementation seems unnecessary, especially since this service is already available to the industry via its own self-regulatory bodies.</p> <p>Guidance on website information</p> <p>The AA would like to seek clarification on appendix III of the draft guidance since it removes the right to advertise and/or include editorial content in online scientific publications that would otherwise be allowed in print. The AA also considers that it would be reasonable for the FSA to make provisions for online advertising to be</p>	<p>provide the Agency’s view on how to comply with those requirements.</p> <p>The Regulations were consulted on in July 2007, have been in place since January 2008 and the draft guidance has been out to consultation since November 2007.</p> <p>The Agency will consider all comments received and will review the guidance on “scientific publication” accordingly.</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p> <p>Noted</p> <p>Noted</p>
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	<p>allowed in specialist publications and professional journals online provided they are password protected and cannot be accessed by the general public.</p> <p>Offences and enforcement</p> <p>It is common practice to incorporate a ‘publisher’s defence’ within Regulations creating an advertising offence. The objective of this is to reflect the fact that publishers take advertising in good faith and should not be held liable for breaches of the Regulations by advertisers.</p> <p>Monitoring and review</p> <p>The AA requests that the industry is consulted prior to the review of these guidance notes. The AA considers that the ‘Monitoring and review’ section of the draft guidance would benefit from further detail.</p>	<p>Noted.</p> <p>The Guidance will be reviewed when either the Regulations or Agency advice changes.</p>
Hipp	<p>We feel there is inadequate guidance on what constitutes ‘advertising’ and what may actually just be the provision of ‘information’ about a product. Without such a definition and greater guidance it could be difficult to write ‘informative copy’ without this possibly being interpreted as ‘advertising’, and thereby breaking the law. Hipp feel there could be confusion over leaflets, which provide information on both feeding and suitable products that may be used.</p> <p>With regards to Appendix I, we have interpreted ‘transactional decisions’ to mean ‘decisions to buy’ – is this correct?</p> <p>Guidance Note 42 - List of scientific journals considered acceptable for infant formula advertising</p> <p>Under the legislation (Regulation 21) and guidance notes, advertising of Infant formulas to health professionals is not considered acceptable unless this is in scientific publications which relate original scientific research and reviews. Midwives and other health professionals need to be able to give informed advice</p>	<p>The Agency will consider all comments received and will be reviewing the guidance on “advertising” accordingly. Ultimately whether or not a specific leaflet constitutes advertising will depend on the nature of the information it contains and this should be considered by manufacturers developing such material.</p> <p>Yes</p> <p>The Agency will consider all comments received and will be reviewing the guidance on “scientific publication” accordingly. A list of acceptable publications would quickly become out of date and is not</p>

	<p>on milk products to their clients, and their professional journals act as a useful reference source. A list of scientific publications currently available which are considered acceptable for infant formula advertising should be given, and an indication of what makes them acceptable so that future new publications can be assessed for suitability.</p> <p>Guidance Note 49 – presentation of follow-on formulas in stores The positioning of follow-on formulas in a different part of the store to the infant formulas is unlikely to be practical in retail outlets.</p> <p>Guidance Note 65 – positioning of advertisements for follow-on formulas in publications The positioning of advertisements for formula milks in printed publications by publishers and producers and their awareness of the Regulations is not the manufacturer’s responsibility.</p> <p>Guidance Notes 68-70 and Appendix II – provision of information and education regarding infant and child feeding (Regulation 24) We feel more guidance is needed than has been given in this draft as this is an area where there is a risk of misinterpretation or differing interpretation by different interested parties. For example, does ‘private correspondence’ and ‘oral communications’ mean that feeding information that has been requested by the customer in these contexts must not include any specific product information that might encourage the customer to use one product over any other?</p> <p>Also, does the approval of the Secretary of State need to be sought for all existing informational and educational equipment and materials or just for all new materials?</p>	<p>feasible for inclusion in the guidance.</p> <p>Noted. The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p> <p>Noted.</p> <p>Noted.</p> <p>This was a requirement of the 1995 Regulations and so existing informational and educational equipment and materials should already have Secretary of State approval. Paragraph 71 of the draft guidance provides contact details for companies wishing to</p>
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IDFA	<p>Two elements of the guidance notes are outside the control of the Infant and Follow-on formula industry. The two particular elements are, Point 49 and point 65.</p> <p>42 and 50 Healthcare Professional (HCP) Journals are scientific publications that enable HCPs to keep up to date with infant formula information. Healthcare Professional journals do not present the results of original research and reviews per se but present relevant scientific information for their target audience. Preventing infant formula advertising and information provision in these journals would restrict important factual, and accurate information about infant formulas getting to HCPs with infant feeding responsibilities.</p> <p>49 Goes beyond the legislation, the proposal to locate infant and follow-on formula in different parts of store may readily lead to confusion amongst parents who may start to introduce inappropriate foods and drinks to the diet of a six month old infant e.g. cows' milk etc if the existence of follow-on formula is not clear to them. In addition, this is simply not practical in small stores like convenience stores, corner shops and pharmacies.</p> <p>54 As stated previously, we agree that a reference to breast milk or breast feeding should not be made on follow-on formula, in such a way that implies equivalence or superiority to breast milk or unless required by legislation. However, infant formula is a breast milk substitute and as such it may be appropriate to refer to breast milk in certain circumstances to provide necessary information to enable an informed choice. We agree that any reference to breastfeeding must not discourage breastfeeding.</p> <p>58 Goes beyond the legislation, the requirement for scientific and factual information on advertisements is mandatory, however we consider that any comment about style (ie no subjective or emotive language) is beyond the requirement of these guidance notes.</p>	<p>Noted.</p> <p>The Agency will consider all comments received and will be reviewing the guidance on “scientific publication” accordingly.</p> <p>Noted. The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p> <p>The provision of information about follow on formula must comply with the requirements of the Regulation. Regulation 21(3) makes it a requirement that any reference to breastmilk in association with infant formula must not undermine Breastfeeding</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p>

	<p>In addition, subjective language can legitimately be used as part of advertising, providing it does not mislead, is factual, decent, honest and true and does not idealise the use of an infant formula or undermine breastfeeding.</p> <p>59 In an advertisement scientific and factual information will be provided and if that includes clinical study results from a breast fed group, the opportunity to communicate such results needs to be available. The important notice will always clearly state the superiority of breastfeeding.</p> <p>60 We do not agree with the recommendation to avoid the use of generic references to formula milks or formulae in advertising. In communications and advertisements to health care professionals, the term 'formulae' may be used to refer to the range of 'special' formulae for infants with particular nutritional needs. Used appropriately we believe these terms are informative.</p> <p>63 Goes beyond the legislation, we believe that parents and carers have a right to request and receive information from a company that makes products being fed to their child. This information is always sent following a request. The statement that the examples quoted are advertising and therefore prohibited is an interpretation that is not warranted by the regulations.</p> <p>We believe that a brand name not uniquely associated with a specific infant formula is not an infant formula brand name.</p> <p>65 (point 5) Goes beyond the legislation, Bullet 1. It is a manufacturers responsibility to decide on the compositional elements (colour, font etc) that will best achieve the identification of the product as being follow-on formula. Bullet 2. We agree that infants featured in follow-on formula advertisements must be over the age of six months, however we do not agree that a clear indication of the age of the child is required. Bullet 5. These notes represent an interpretation beyond the legislation.</p> <p>70 This guideline requires further details to outline the practical aspects of how this</p>	<p>Regulation 21(2) states "advertisement for infant formula shall only contain information of a scientific or factual nature."</p> <p>Regulation 21(3) states "Shall not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding".</p> <p>Noted, however, where generic references are made to formula milks all information provided would need to comply with the requirements of the Regulation.</p> <p>Ultimately whether or not a specific leaflet constitutes advertising will depend on the nature of the information it contains and this should be considered by manufacturers developing such material.</p> <p>Noted</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency's view on how to comply with those requirements.</p> <p>Materials to be circulated to</p>
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Boots	<p>Confusion is partly created by the prohibition on the use of images on infant formula which would, if used carefully, assist in distinguishing between infant and follow-on formula. We object to the restrictions because they add to the law rather than assist in the interpretation of the law.</p> <p>To state that shelf talkers for follow-on formula must not be used in the vicinity of infant formula is an unnecessary, and to suggest that infant formula must be displayed in another store location to follow-on formula is impractical and unnecessary. These additional restrictions would only exist within the UK not, as the Directive contemplates, harmonised across the European Community.</p>	<p>Regulations 19 and 22 require the labelling and advertising of infant formula and follow on formula to be sufficiently clear so as to avoid any risk of confusion.</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p>

	<p>Paragraph 60, generic references to formula milks must be allowed otherwise this will undermine clear signposting for customers with the intent of avoiding the confusion. We accept that a reference to a brand of formula milks may contravene the requirements of Regulation 21 generic references must not be treated as a contravention of this requirement.</p> <p>Paragraph 65, in our experience manufacturers and retailers act responsibly in advertising follow-on formula and work within the confines of the law, such responsible practices are the norm when it comes to advertising. However, the guidance should not place an unreasonable burden on advising and educating organisations whose business it is to know and understand the rules that control its sector.</p> <p>Appendix III. This must not be applied to the simple featuring of formula milks for sale in the same way as in store. It has been a view long held that featuring infant and follow-on formula on websites is no different to product featured on sale in store. Providing the information given is factual and confined only to that contained on the labelling, with no special emphasis being given to any of the information, then this must not be treated as a breach of the requirements. The guidance fails to recognise that this information may be given by someone other than the brand owner. To feature an intermediate page before purchase is something we would resist. Furthermore, this has to promote consistency across the European Community which I fear is currently not the case.</p>	<p>Noted</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p> <p>Noted. Any information provided would need to comply with Regulations 17,18 and 21.</p>
The Nutrition Society	<p><i>Paragraph 49, bullet point 2.</i> This is the responsibility of the retailer. The Society would like to highlight that they – the retailer - will need to be made aware of this Regulation.</p> <p><i>Paragraph 63.</i> Guidance is given that specific, named infant formula should not be included in the advertising of feeding products. The Society suggests this be extended to include that infant formula should not be referred to at all, and mention that equivalence or superiority to breastfeeding be advised against.</p> <p>Paragraph 65, bullet point five. The Society advises that this be extended to include ‘or could possibly be perceived as being under six months of age’.</p>	<p>The BRC have been consulted on the Regulations and Guidance.</p> <p>Noted</p> <p>Noted</p>
LACORS	<p>Paragraph 8 With regard to the 4th bullet point it would be desirable to indicate that all practices should be deemed to be “advertising or promotion” unless they can be</p>	<p>It is not appropriate to deem something to have legal effect in</p>

	<p>demonstrated to fall outside these controls; thus reversing the burden of proof for enforcement authorities.</p> <p>Paragraphs 50 & 51 With regard to Appendix II it would be helpful to include a further bullet point to cover the placement of infant formula in print publications and TV broadcast situations.</p> <p>Paragraphs 66 & 67 It would be helpful to include a reference to the prohibitions of sales of infant formula in store loyalty/reward card schemes, price reductions or mark downs, buy one get one free etc.</p>	<p>guidance.</p> <p>Noted. Placement of infant formula that constitutes advertising or promotion would need to comply with Regulations 21,22,23 and 24.</p> <p>Noted</p>
<p>Trading Standards South East</p>	<p><u>Paragraph 8</u> Disappointed that the Regulations do not contain a statutory definition of advertisement, the Guidance on what is considered to be advertising for the purposes of these Regulations given in Appendices I, II and III, is sufficiently broad to cover both current and future practices. The guidance in paragraph 8 says that 'Placing on the market' will have the same meaning as in the Directive. It would be helpful to repeat here what that is, so that one does not have to refer to another document.</p> <p><u>Paragraph 44.</u> In addition to the advice in paragraph 44, it should be pointed out that Article 5.5 of The International Code states that marketing personnel should not seek direct or indirect contact of any kind with pregnant women or mothers. Companies should be advised to ensure that carelines, websites, baby clubs etc do not contravene this article by, for example, providing details of customers for marketing purposes</p> <p><u>Paragraph 63</u> Manufacturers should be reminded again in this section that there is a prohibition in the International Code on direct or indirect contact by marketing personnel.</p>	<p>The Agency will consider all comments received and will be reviewing the guidance on “advertising” accordingly.</p> <p>Noted</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide Guidance on its application. Regulation 21 restricts advertising of infant formula and Regulation 24 controls the provision of information.</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide</p>

	<p><u>Paragraph 66</u> This section omits reference to Regulation 23(2) which prohibits gifts designed to promote the sale of an infant formula. The guidance notes should advise manufacturers not to use practices such as providing toys to doctors or midwives bearing a company logo to promote their names and brands.</p>	<p>Guidance on its application. Regulation 21 restricts advertising of infant formula and Regulation 24 controls the provision of information.</p> <p>Noted</p>
<p>Advertising Standards Authority</p>	<p>Point 41 suggests that upheld ASA decisions on unsubstantiated claims would be enforceable in labelling and all advertising. The ASA will only take and enforce decisions on advertising that falls within the scope of the Advertising Codes. The FSA’s interpretation of an advertisement is broader than the Advertising Codes, the ASA has no role in maintaining standards in these areas.</p> <p>The FSA’s definition appears to capture editorial content or communications that are not disseminated and/ or paid for by the manufacturer of formula milks or their agents (e.g. an advertising agency or retailer). European law clearly considers that what constitutes an advertisement is restricted to materials disseminated by or on behalf of a commercial interest.</p> <p>The FSA appears to have used some of the concepts used within the Unfair Commercial Practices Directive, however the Directive very clearly defines that its provisions apply only to business-to-consumer commercial communications.</p> <p>Appendix II – 1st bullet point, “electronic and printed material (including editorial content and advertorials); 9th bullet point, “press releases and other public relations material and activities)</p> <p>Appendix II – 7th bullet point, “private correspondence” and 8th bullet point “oral communications, including telephone calls”</p>	<p>Noted</p> <p>The Agency will consider all comments received and will be reviewing the guidance on “advertising” accordingly.</p> <p>Noted</p>

<p>The British Dietetic Association</p>	<p>We are pleased to see that there have been some commendable changes made which include banning all promotion on infant formula, prohibiting all idealising text and images, not permitting any health claims and regulating all nutritional claims made, adding clear warnings about the fact that infant formula is not a sterile product and restricting promotion of the products to information of a scientific factual matter only.</p> <p>Advertisement</p> <p>There is uncertainty over why the term ‘advertisement’ and ‘sell’ were defined in the previous Regulations but have been omitted in the new guidance notes and Regulations. Many of the general public will continue to associate the brand of infant formula with that of follow-on formula, in our opinion it will be extremely difficult for manufacturers to ensure that their adverts are for exclusively follow-on formula, and not promoting the brand name which produces the infant formula.</p>	<p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p> <p>The provision at Regulation 22 tackles concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective and if not we’ll consider if further action needs to be taken and if not we’ll consider if further action needs to be taken.</p>
<p>Manchester PCT</p>	<p>Advertising:</p> <ul style="list-style-type: none"> • Why are you not prohibiting the advertising of infant formula to health professionals? Why does the government not prohibit all infant formula advertising in the same way it prohibited tobacco • Why are the companies able to continue to advertise follow-on milk to the public? Why are you not banning this in order that parents can make a fully informed choice free from commercial pressure? 	<p>Only where there is a specific requirement in the Regulation can the Agency provide Guidance on its application. Regulation 21 allows advertising in scientific publications.</p> <p>The Regulations implement the Directive and the provision at Regulation 22 addresses concerns regarding the advertising of follow on formula. The independently chaired review of the new controls will</p>

		<p>assess whether this has been effective and if not we'll consider if further action needs to be taken.</p>
<p>Baby feeding Law Group This submission was supported by 434 individual responses</p>	<p>The Regulations - section 4, page 2 It is stated: <i>"The term 'advertising' is used in the Directive but is not defined. The term, when used in the Regulations, has the same meaning as in the Directive."</i> It is confusing to reference a document that does not define the word 'advertising' to explain its meaning. Advertising should be considered to include any form of promotion of products, including in a publication directed at any target, on the internet, as a product placement, on a telephone careline or on product labelling.</p> <p>Labelling of follow-on formula - section 30 - 41, page. It is a serious failing of the Regulations and the Guidance Notes that they treat infant formula and follow-on formula differently. It has been well documented that the industry attempts to overcome restrictions on the marketing of infant formula by using the same tactics for follow-on formula. The ASA is extremely reluctant to investigate complaints regarding follow-on formula due to the way it is treated differently in UK law from infant formula.</p> <p>General guidance with regard to infant formula and follow-on formula advertising - section 42 - 44, page 9. This section of the Guidance Notes is fundamentally flawed as it legitimises the advertising of follow-on formula in breach of the <i>International Code of Marketing of Breastmilk Substitutes</i>. The Guidance Notes should remind companies of their obligation under Article 11.3 of the Code and the outright prohibition of all forms of promotion of breastmilk substitutes contained in the Code - which includes follow-on milks. The Guidance Notes implicitly authorise carelines, websites and mother</p>	<p>The Agency will consider all comments received and will be reviewing the guidance on "advertising" accordingly.</p> <p>The provision at Regulation 22 addresses concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective and if not we'll consider if further action needs to be taken.</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency's view on how to comply with those requirements.</p>

and baby clubs, though these are prohibited by Article 5.5 of the *International Code*. The Guidance Notes call for companies to ensure that only 'factual information' is supplied through these channels and advertisements for them. However, it has been documented and brought to the attention of the FSA and the government repeatedly that company information is not factual, but promotional and idealising and sometimes contradicts the information provided by the FSA and Chief Medical Officer.

Health workers have independent, accurate information to provide to parents and should be given greater government support to do so. If the government is to go the route of allowing companies to violate the Code in this way, then it should put significant resources into routine monitoring of company materials and telephone 'carelines' and must examine this evidence carefully in the review of the regulations. Pending stronger regulations the Guidance Notes could remind companies of the prohibition on seeking direct or indirect contact with pregnant women and mothers contained in the Code and Resolutions.

Avoidance of the risk of confusion between infant formula and follow-on formula (inrelation to labelling, presentation and advertising) - section 45 - 47, page 11.

This section of the Guidance Notes would have been unnecessary had the FSA accepted the advice of LACORS, the Scientific Advisory Committee on Nutrition, BFLG and individuals who made submissions to the consultation on the Regulations and prohibited the advertising of all breastmilk substitutes. The approach taken by the FSA also ignores the fact that promotion of follow-on formula by baby food companies in itself undermines public health. If follow-on formula advertising is to be permitted then the changes required by sections 45 -4 7 will have to be vigorously pursued. Members of the public associate company brand names with the full range of products. Accordingly, the Guidance Notes should make it clear that follow-on formula should not prominently feature a company name and logo if these are used prominently on infant formula labels and materials. The simple way for companies to comply with this requirement is to brand the products with different names as was the case before the *Infant Formula and Follow-on Formula Regulations 1995*.

The Department of Health cannot commit to regular monitoring but will work with Local Authorities and PCTs to ensure that materials made available through the health care system are in accordance with the guidance.

The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency's view on how to comply with those requirements. The provision of information must comply with Regulations 21,22 and 24.

The provision at Regulation 22 addresses concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective

	<p>The Guidance Notes should make it clear that if follow-on formula labels, presentation or advertising refers to websites or telephone ‘carelines’ or invite mothers to join mother and baby clubs, then these means of communication must not include information relating to the care of babies under 6 months of age and must not contain information about products for babies under 6 months of age. (Section 63 requires amending). Again, resources should be put into monitoring these means of communication and the evidence considered carefully in the review of the Guidance Notes and Regulations.</p> <p>Presentation (infant formula and follow-on formula) - section 48 - 49, page 11.</p> <p>The BFLG welcomes the provisions in the Guidance Notes that infant formula and follow-on formula be placed in different parts of a retail outlet and that shelf talkers and other promotion for follow-on formula, if it is still permitted, must not appear alongside the infant formula. The Guidance Notes should go further, however, and prohibit any form of promotion with breastmilk substitutes.</p> <p>This point can be made more strongly as the vast majority of advertisements that should be restricted to factual and scientific matters are dominated by graphics and text that are not scientific or factual, but purely promotional. The Guidance Notes can address this point by stating that the area of an advertisement containing scientific and factual information (not including pack shots, headlines or highlighted claims) should make up at least 75% of the area of the advertisement. It is currently the case that scientific and factual information may be totally nonexistent or make up less than 10% of the area of an advertisement.</p> <p>The invitation in section 63 for companies to place advertisements encouraging members of the public and carers to request information on infant formula completely undermines the earlier provisions attempting to stop advertising from promoting infant formula. As suggested previously the Guidance Notes should prohibit companies from promoting infant formula through this route as it is inconsistent with the Regulations prohibiting the advertising of infant formula.</p> <p>Restrictions on advertising follow-on formula - section 64 - 65, page 12.</p> <p>The Guidance Notes also miss the point of the concern raised by the BFLG that not only does follow-on formula advertising acting as a de facto advertisement for infant formula. Follow-on formula is an unnecessary product that was introduced in</p>	<p>and if not we’ll consider if further action needs to be taken.</p> <p>Noted. The provision of information must comply with Regulations 21 and 24.</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provides the Agency’s view on how to comply with those requirements.</p> <p>Noted. Regulation 21 controls the provision of information.</p> <p>The provision of information via such routes must comply with</p>
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	<p>an attempt to overcome advertising restrictions and its promotion undermines breastfeeding, which is recommended into the second year of life and beyond. Follow-on milk advertising is also misleading and does not provide those parents and carers who use formula with the necessary information they need on selecting a product. The Guidance Notes should require that follow-on formula advertisements, if they are permitted, contain no idealizing text or images and are restricted to scientific and factual matters and the review should examine these and perceptions of them carefully.</p> <p>Provision of information and education regarding infant and child feeding - section 68 - 71 page 15.</p> <p>The Guidance Notes should be changed to reflect BFLG's position that: <i>"The government should, as clear policy, neither request nor accept donations of materials from companies that manufacture products within the scope of the legislation, nor permit them to produce materials for pregnant women or mothers or other carers of infant and young children.</i> Specifically, companies should be informed that it is not their role to provide information through websites and this will be taken to be illegal promotion of brand names. Rather than inviting companies to submit requests for permission to distribute company-produced or sponsored materials the Guidance Notes should make it clear that as a matter of policy all requests will be refused, as is the government's right under the Regulations.</p>	<p>Regulations 21 and 24. Advertisements for follow on formula must comply with Regulations 19 and 22. The independently chaired review of the new controls will assess whether this has been effective and if not we'll consider if further action needs to be taken.</p> <p>Materials to be circulated to mothers or healthcare professionals should conform to DH policy on breastfeeding and the promotion and advertising of Infant and Follow-on formula. The main criteria will be a check on consistency with current DH policies.</p>
<p>National Childbirth Trust</p>	<p>p3. We recognise FSA concern that any attempt to define the term runs the risk of limiting its scope bearing in mind the wide range of forms that advertising has taken in recent years.' However, we believe it is better for the guidance to be clear, and therefore recommend a definition for advertising is included. The discussion in Appendix 1 is helpful. It is important for accurate interpretation and implementation of the Regulations that this is clear. We suggest this would include advertisements in any media covering infant formula or milks for babies.</p> <p>Advertising of any form of formula (follow on or the newly invented growing up milks) in magazines serves only to promote use of infant formula and risks mothers using follow on in babies under 6 months. Advertising of FoMs should be excluded from all publications targeted at those who are pregnant or caring for a baby under 6 months.</p>	<p>The Agency will consider all comments received and will be reviewing the guidance on "advertising" accordingly.</p> <p>The provision at Regulation 22 addresses concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine</p>

	<p>23. Add at the end of the first line of the first sentence: ‘or follow on milk’. As manufacturers have argued that follow on milk is not a breastmilk substitute, and it should not be idealised, there should be no reference to ‘breastmilk’, ‘breastfeeding’, or the ‘ideal method of feeding’ on labelling or advertising for follow on milk. This is line with Regulation 18.</p> <p>24 and 25. add follow on milk and advertising It would not be helpful if restrictions on advertising or labelling for infant formulae, such as pictures of infants or young children were allowed on advertising or labelling for follow on formulae, as this might increase the chance that they would be used for babies younger than 6 months. This is also in line with Regulation 18.</p> <p>29. Claims are regulated wherever they appear on the labelling, ADD ‘in promotional messages, websites, and any other company materials, whether available to the public or to health professionals.’</p> <p>In the final bullet point, third line, add after group of formulae, ‘or follow on formulae.’</p> <p>40. Any research conclusions cited by companies in support of their claims should represent the balance of independent published evidence.</p>	<p>breastfeeding. The independently chaired review of the new controls will assess whether this has been effective and if not we’ll consider if further action needs to be taken.</p> <p>The Agency will consider all comments received together with Regulations 17 and 18 before finalising the guidance.</p> <p>Regulation 18 does not include the same requirements as Regulation 17(3)</p> <p>Noted</p> <p>Regulation 1924/2006 controls the use of nutrition and health claims in relation to follow on formula. Please see the Agency’s specific guidance on this Regulation.</p> <p>The European Food Safety Authority (EFSA) has produced guidance on the evidence that should be provided in support of a claim.</p>
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	<p>ADD “Advertising (in print, broadcast, electronic or other media) marketing and other promotional practices including the use of generic or brand names or corporate logos or imagery which could infer that the benefits referred to could also be ascribed to infant formula ... is prohibited.”</p> <p>41. add at end: ‘websites, and any other promotional materials.’</p> <p>42. add at the end of the second bullet. This means that brand names associated with infant formula and with carelines run under the same name should not be promoted.</p> <p>To comply with Regulation 18(2), and so that Follow-on formula advertisement do not discourage breastfeeding, advertisements will require a clear statement of the superiority of breastfeeding, including for babies older than 6 months.</p> <p>43. Add after formula ‘or follow on formula’ advertising or any other form of promotion. These points are all relevant to the promotion of follow on formula.</p> <p>In addition we would add a bullet point preventing the suggestion that babies should ‘move on’ or progress from breastfeeding to either formula milk or Follow on formula.</p> <p>44. delete ‘consumers’. There is no need for direct contact between parents or carers and manufacturers, it is not in line with the WHO Code, and the provision of information contravenes Article 14(3) and 15 (3) of Directive 2006/141/EC as therefore Regulation 24 4(d) which states that a donation of informational or</p>	<p>The provision at Regulation 22 tackles concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective.</p> <p>Noted. The Agency will consider all comments received before finalising the guidance.</p> <p>The Regulations do not control brand names.</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application. This is not a requirement of the Regulations.</p> <p>Noted</p> <p>The Agency will consider all comments received together with Regulations 17 and 18 before finalising the guidance.</p> <p>Regulations 24 (1), (2) and (3) allow informational and educational material to be provided where it is not a</p>
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	<p>educational equipment or materials shall only be distributed through the health care system. Carelines, mother and baby clubs, public meetings, etc run by manufacturers of infant formula are run for the purpose of promoting their products. As such they will contravene the regulations.</p> <p>49. We support this helpful suggestion, while remaining convinced that preventing the promotion of follow on formula is needed.</p> <p>50. Add in the first bullet point after original ‘, peer reviewed’</p> <p>58. In line with the spirit of the Regulations, particularly 18 (2) and the need to avoid confusion, advertising and promotion for follow on formula should only include information of a scientific and factual nature and should not include subjective or emotive language.</p> <p>59. Add in each case, after infant formula ‘or follow on formula’.</p> <p>63. ‘Infant formula brand name’ requires a definition which includes manufacturers’ names/logos where these feature strongly on the labels.</p> <p>Add after ‘must not feature an infant formula brand name ‘or logo’ After ‘Attempting to solicit requests for information’, ADD ‘including advertising carelines and similar incentives for parents to call manufacturers for information’.</p>	<p>donation. The provision of information will also need to comply with Regulations 21 and 22</p> <p>The provision at Regulation 22 addresses concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective.</p> <p>The Agency will consider all comments received and will be reviewing the guidance on “scientific publication” accordingly.</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p> <p>These are not requirements for follow-on formula.</p> <p>Noted</p> <p>Noted</p>
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	<p>The company telephone line numbers should only be published on company websites and on formula packaging. They must not be advertised or promoted using PR or handed out to parents by the companies, their agents or via the health service. No attempts to solicit visits to company websites for parent related information should be made through any media. Information lines should only list their services as being product information such as clarification on sources of ingredients.</p> <p>64. last bullet point. Add after publishers or producers, 'their agents, or distributors'</p> <p>Insert a new point below 67. to clarify that under Regulation 23 (2) manufacturers of formula or follow on milks are not permitted to send out gifts or incentives for parents who join baby clubs or similar activities.</p> <p>68. It should be clarified that gift incentives and materials are not permitted to be given out at healthcare professional conferences under Regulations 23(2) and 24 4(d).</p> <p>70. ADD exhibitions, booklets, study days, meetings arranged for children, parents to be, parents or health professionals, flyers, handouts, downloads, wallcharts and similar materials. ADD Materials or equipment must not carry an infant formula brand name or logo associated with formula milk and milks for babies as this would constitute advertising.</p> <p>68-70. Manufacturers' website information is not always in line with current departments of health and FSA recommendations. This leads to confusion for parents, and increased risk of ill health for babies.</p>	<p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application. The provision of information about infant and follow on formula must comply with Regulations 21,22 and 23.</p> <p>Noted</p> <p>Noted</p> <p>Regulation 23(2) does not control gifts given to healthcare professionals. It does however control the distribution of such gifts through the health care system. Regulation 24(4)(d) controls donations of informational and educational equipment.</p> <p>Noted. The provision of materials will need to comply with Regulations 21, 22, 23 and 24.</p> <p>Noted. The provision of information on websites will need to comply with Regulations 21,22,23 and 24.</p>
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	<p>Appendix II Need to add product placement in websites, electronic communication and all other media, particularly broadcast media, not just commercials.</p> <p>Eighth bullet point, needs to be clarified. While consumers may contact manufacturers for further information on the ingredients of formula or follow on milks, for instance, carelines which provide information are prohibited.</p> <p>Appendix III We understand that general website information from manufacturers of infant formula and follow on formula is prohibited under Regulation 24 4(d). We suggest that a list of ingredients and other information permitted on the labels of products are provided on websites for partially sighted or blind people, in addition to the information covered by 24(1), 24(2) and 24(3).</p> <p>In addition to the above NCT submitted a range of internet screen shots of various formula milk products which they believe are illegal or misleading. and an article on infant mortality.</p>	<p>Noted where this constitutes advertising.</p> <p>Regulations 21, 22 and 24 allow the provision of information that complies those requirements.</p> <p>The provision of information on websites must comply with the Requirements of the Regulations.</p>
UNICEF UK	<p>- We are concerned that this document cannot compensate for the Regulations being unfit for purpose. Our main concern remains that the advertising of follow-on formula is still permitted.</p> <p>42 Bullet 2 can only be achieved if the infant formula and follow-on formula brands and their presentations are wholly separate from each other – i.e. that they are not recognisable as being from the same family of brands.</p> <p>To deliver the aim of ensuring that follow-on formula advertisements do not discourage breastfeeding (Regulation 22 as applied to regulation 18(2)), any advertisement will require a clear statement of the superiority of breastfeeding, including for babies older than 6 months.</p> <p>43</p>	<p>The provision at Regulation 22 addresses concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective and if not we'll consider if further action needs to be taken.</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p>

	<p>We welcome all these requirements. It is suggested that a further requirement be added which prohibits any suggestion that parents need to ‘move on’ from breast feeding to follow-on formula</p> <p>44 It is strongly suggested that the advertising of carelines be prohibited. Over the past 10 years, UNICEF has received numerous enquires and complaints from health professionals concerned about misleading and inaccurate information / advertising given to parents who have used these facilities.</p> <p>49 We welcome the requirement that follow-on formula be located in a different part of the store to infant formula.</p> <p>60 We welcome this requirement but suggest that it be extended to acknowledge that customers may understand that manufacturers’ logos which feature prominently on formula labels refer to a number of formula products including IF and should therefore not be used in advertisements.</p> <p>62 It is suggested that ‘do not contain’ is replaced with ‘cannot be understood by consumers as containing’.</p> <p>Appendix II Bullet 2 – It is suggested that ‘scientific publication’ be defined. Such publications would include publications which exist for the dissemination of peer-reviewed research papers, but not publications providing information for the members of trade unions or professional bodies, nor those which contain largely a mixture of</p>	<p>The Agency will consider all comments received together with Regulations 17 and 18 before finalising the guidance.</p> <p>The Regulations do not prohibit carelines, however the information provided must comply with Regulations 21,22 and 24.</p> <p>Noted</p> <p>The provision at Regulation 22 addresses concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective and if not we’ll consider if further action needs to be taken. The Regulation does not put in place specific controls relating to brand advertising.</p> <p>This is not a requirement of the Regulation.</p> <p>The Agency will consider all comments received and will be reviewing the guidance on “scientific publication”</p>
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	<p>news, views and opinion.</p> <p>Appendix III We welcome the inclusion of all web content here.</p> <p>Appendix IV The proposed revised treatment may, as is stated, be less likely to confuse consumers, but will not prevent advertisements for the companies' follow-on formula being used to promote the infant formula.</p>	<p>accordingly.</p> <p>The provision at Regulation 22 addresses concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective and if not we'll consider if further action needs to be taken.</p>
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Labelling

<p>IDFA</p>	<p>We welcome the inclusion of these points and stress that we will continue in this practice.</p> <p>17. & 32. Age suitability is stated on front of packs</p> <p>18 Already state on packs 'Failure to follow instructions may make your baby ill' as agreed with FSA previously.</p> <p>33 & 34 Name 'Follow-on formula' is afforded a high degree of prominence on packs. The information required by virtue of regulation 18(1) (a) has been present on the labels of follow-on formula for many years. It has been placed under the words 'Important Notice'.</p> <p>43. Advertising of follow-on formula does not include pictures or text that compare products to breastmilk, and only babies over six months of age are used in advertising.</p> <p>44. Careline staff are highly trained, and provide factual support to parents and carers on request.</p> <p>45 Infant and follow-on formula products are clearly labelled with suitable age for use, and designed with different colour or numerical schemes to ensure simple identification by parents and carers.</p>	<p>Noted</p>
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	<p>52. The important notice is clearly visible and understandable on advertisements</p> <p>65. Advertising of follow-on formula is conducted in a manner to ensure that the nature of the product is clear, as is the suitability from six months.</p> <p>67. There is no promotion of products in multi-packs where they are not the normal form in which the product is offered for sale. The reference to multi-packs is not warranted by the wording of the regulation.</p> <p>80. Discussions with Home Authority officers are already undertaken on a courtesy basis where appropriate.</p> <p>Detailed comments</p> <p>16/ 17 goes beyond the legislation, the suitable age range is always stated clearly on the front of packaging. Manufacturers must decide on the compositional elements (colour, font etc) that will best achieve this. However, we would like to express concern whether legibility guidance set by the FSA could be met on all pack sizes, particularly small tetra paks, as legibility is a function of pack size. Minimum font sizes are not always possible, and the focus should be on clarity rather than prescriptive guidance.</p> <p>18 & 20 The statement ‘Failure to follow instructions may make your baby ill’ is commonly included on packaging currently. We are not aware of any evidence that the above statement has been inadequate. Similar statements have been used since the mid 1970s.</p> <p>We do not support the alternative wording proposed in the guidance notes on the grounds that this may be alarmist and not easily understood by the consumer. Such a warning statement could lead consumers to use inappropriate products such as other powdered milk or other liquids (not infant or follow-on formulae) which do not have such warnings.</p>	<p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements. The Agency’s “Clear Food Labelling” guidance contains best practice advice on minimum font size, choice of font and contrast etc, which if followed, will assist labelling and clarity on all pack sizes.</p> <p>FSA-funded focus group research found that caregivers were concerned that powder formula was not sterile. Overall, as it poses a potential risk to babies, parents and healthcare professionals agreed that information about non – sterility and what it means should be clearly communicated to parents, so that they can make informed decisions and choices.</p> <p>Some manufacturers of infant</p>
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	<p>25 goes beyond the legislation (except pictures of infants) We do not agree that the items quoted would idealise the use of an infant formula, and are aware of no evidence to support that view. The law specifically refers to pictures of infants only (Reg 17(3)(a)).</p> <p>29 (point 2) goes beyond the legislation health claims are regulated under the Nutrition and Health claims legislation, and this needs to be reflected in the guidance notes</p> <p>31 goes beyond the legislation, we consider that it is the responsibility of the industry to provide clear labelling on packaging, consulting sources of information, which include the FSA 'Clear Labelling Guidance' amongst other information, as appropriate.</p> <p>32 We already state the age range clearly on the front of packaging. We believe it should be the responsibility of manufacturers themselves to determine the appropriate size of the font in relation to other elements of the packaging including pack size. We are unaware of any case in which a product has been used inappropriately because of a lack of clarity over the appropriate age range.</p> <p>47 Goes beyond the legislation, we are not aware of any evidence to show that consumers are confused between infant formula and follow-on formula as our packs already differentiate using clear notices about age suitability and different colour schemes.</p>	<p>formula products are already labelling their products to indicate that these are non sterile. We are not aware of any evidence of caregivers turning to inappropriate products as a result of the non-sterile message being used.</p> <p>Regulation 17(3) (b) refers to any other picture or text which may idealise the use of the product.</p> <p>Paragraph 29 (point 2) relates to claims made on infant formula, which are controlled by the Regulation 17(1).</p> <p>Noted.</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency's view on how to comply with those requirements.</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency's view on how to comply with those requirements.</p>
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	<p>We consider that the proposal that infant and follow-on formula should feature different labelling elements (such as pictures and blocks of text) in differing spatial arrangements to be above and beyond the requirements of the EU Directive. We do not believe it is in the interest of consumers to change labels if there is no clear evidence of any confusion.</p> <p>We agree that a reference to breast milk or breast feeding should not be made on follow-on formula in such a way that implies equivalence or superiority to breastmilk or unless required by legislation.</p>	<p>The provision at Regulation 22 addresses concerns that advertising of follow on formula could be taken as advertising for infant formula and undermine breastfeeding. The independently chaired review of the new controls will assess whether this has been effective and if not we'll consider if further action needs to be taken.</p> <p>Noted.</p>
<p>Baby Feeding Law Group. This submission was supported by 434 individual responses.</p>	<p>Labelling of infant formula and follow-on formula - section 16, 17, page 5</p> <p>The only information needed on formula labels is:</p> <ul style="list-style-type: none"> • Brand name and formula generic name (with the brand name no bigger than the generic name and not incorporating a claim e.g. Advanced, Humana, HA). • Warnings and preparation instructions (in accordance with FSA and WHO guidance to parents). • Ingredients. • Permitted nutritional claims (which should be with the list of ingredients on back of pack). • Batch number, use by date, manufacturers details. • Specific independent certification on kosher/organic etc. (using the independent authorities' stamp or wording). Any other information is unnecessary and likely to be promotional and so should be prohibited. Images should only be allowed in the preparation instructions. The language used in the Guidance Notes is very weak, stating that "Manufacturers are encouraged...". Companies refuse to take advice to change labels if they will be able to argue they were 'encouraged' but not 'required' to comply. <p>Those who use formula are being misled by companies</p>	<p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p> <p>Noted</p>

The FSA published new guidance to parents in November 2005 in response to growing concerns over possible contamination of powdered formula with *Enterobacter Sakazakii*. BFLG state that manufacturers are not reflecting this guidance.

Labelling relating to the preparation, storage and disposal of infant formula and follow-on formula - section 18 - 20, page 5.

In the consultation on the Regulations, various organisations called for explicit warnings on labels that powdered formula is not sterile and improved instructions with the simple steps required to reduce the risk of possible contamination with harmful bacteria. While the Directive did not make an explicit call for improved labelling in this area, the World Health Assembly has done so with UK Government support. The suggestion that a voluntary agreement will be pursued and the wording in the Guidance Notes that the FSA is '*recommending*' relevant information be included is inadequate. Similar wording to that in section 20 which sets out what '*should*' be included in other warning text is required.

Labelling about the appropriate use of infant formula and follow-on formula so as not to discourage breastfeeding and to avoid idealising the product - section 22 - 25, page 6.

Breastfeeding is undermined by other forms of idealising text such as claims that formula is '*close to breastmilk*', '*inspired by breastmilk*', claims that it contains ingredients found in breastmilk, that it is advanced, '*the best*' and images such as pictures of mothers, stylised pictures of breastfeeding, pictures of infants, teddy bears or cartoon figures that make formula appear like a children's toy rather than the nutritional medicine it really is. A clearer approach is to give a lead in the Guidance Notes that any non-mandatory text or images should be presumed to be unnecessary and possibly idealizing. The review of the effectiveness of the Guidance Notes and Regulations should examine how fully labels are brought into line.

Use of nutrition and health claims in relation to infant formula - section 26 - 29, page 7.

The efforts made in section 29 to address some of the ways in which companies attempt to idealise their products through the use of claims are very welcome. Again, the review should consider very carefully if the many examples of breaches of these provisions are brought to an end.

Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.

Noted. Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application. The Regulations allow non-mandatory text and images that comply with the controls in Regulations 17,18 and 19.

Noted

<p>The British Dietetic Association</p>	<p>Welcome the guidance on the manufacturer clearly having to state the age range that the product is suitable for on the front of the packaging, and would also like to see guidance on all companies using the same colour labels for each stage of infant formulas. Disappointed that there was going to be no further restriction on advertising of follow-on formula in the UK.</p> <p>We would like to see Regulation 17 amended to ‘requires’ the need to label the products as possibly containing harmful bacteria.</p> <p>The important notice concerning the superiority of breast feeding should be afforded by a high degree of prominence on the label’ – could this be defined a little more in terms of size of wording (para 21)?</p> <p>We would like to see the guidance for labelling of follow-on formula be exactly the same as for infant formula as we consider these products both to be breast milk substitutes.</p>	<p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p> <p>The Agency is working with formula manufacturers to agree suitable form of words for voluntary labelling which would inform consumers that infant formula and follow-on formula are non-sterile.</p> <p>Noted</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p>
<p>National Child Birth Trust</p>	<p>Page 2</p> <p>8. The definitions of the following terms set out in Regulation (EC) No. 1924/2006 (the European Nutrition and Health Claims Regulation) apply for the purposes of the Regulations: ‘claim’, ‘nutrition claim’, ‘health claim’, ‘reduction of disease risk claim’ (refer to paragraph B, INSERT 27, p7 for further details).</p> <p>16. Manufacturers should are encouraged to use the Agency ‘Clear labelling’ . These statements need to be stronger and clear to aid interpretation. (In line with point 31)</p>	<p>Noted</p> <p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency’s view on how to comply with those requirements.</p>

	<p>18. To be effective, these Guidance Notes need to be stronger than recommendations. We suggest that the second sentence is reworded: The Agency recommends that These instructions should include information ...or These instructions must include the following information:</p> <p>The first bullet point should be stronger eg It is therefore important to be very careful rather than to take care</p> <p>Information on the correct way to minimise the risks of contamination of formula milk and follow on milk (PIF).</p> <p>An additional bullet point advising on the appropriate temperature to reduce the risk of bacterial growth in formula milks should be added. Water at 70°C should be used to reconstitute powdered infant formula and follow on formula milks. Not to insist on the inclusion of this information, or updated versions in line with FSA guidance, risks the current confusion among parents and carers continuing to the detriment of babies.</p> <p>Having the same required wording for all brands would also avoid the confusion for parents arising from different manufacturers giving different guidance. We suggest the FSA <i>Guidance on preparing infant formula</i> which states:</p> <p>Infant formula powder is not sterile; the risks associated with using powdered infant formula milk are reduced if:</p> <ul style="list-style-type: none"> • feeds are made up using boiled water that is greater than 70°C; in practice, this means using water that has been left to cool for no more than half an hour would be suitable. <p>26. ADD: Claims that are permitted under the Directive should be carried in the same size text as, and next to the ingredients panel.</p>	<p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency's view on how to comply with those requirements.</p> <p>Noted</p> <p>The Agency would like to see manufacturers providing consistent advice on preparation that fully takes into account the microbiological risks associated with these products and reflects the advice issued by Department of Health.</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p> <p>The labelling of infant formula and follow on formula is strictly controlled by Regulations 17 and 18 and all labelling must comply with these provisions. The Guidance reflects the controls in Regulations 17 and 18.</p>
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	<p>27. It should be clarified that the name of the product should not be a health, nutrition or other claim. This would include Stay Down, Easy Digest, Good Night, Sleep Tight, Comfort, Night Time, Grow More, etc.. These claims are not allowed under the Directive and have not been substantiated, but play on parents' common concerns. Anything implying better sleep for babies is likely to attract mothers of young infants when sleep deprivation of the parents is a common issue and parents become desperate for anything that will get their babies to sleep.</p> <p>Similarly other words or phrases which imply a health benefit, such as "Immunofortis," "improved protein balance" "without colouring" should not be used.</p> <p>Further clarity is needed on formula milks which are available both on prescription and are sold over the counter, or from the shelf. Some may be classified as FSMP but claims on these products are at least as damaging as claims on infant formula, and particularly so when they are available directly to the general public.</p> <p>33. It is very important that the phrase in the follow-on milk Important Notice should not be phrased: 'Not to be used as a breastmilk substitute before 6 months' as this implies that it should be used as a breastmilk substitute after six months. This is not FSA or the health departments' position and therefore the notice could be misleading. The notice should state that follow on milk should not be used instead of breastmilk and should not be given to babies younger than 6 months.</p> <p>Or: Follow on milks must only be used for babies older than 6 months. Follow on milk should only be used when a mother is not breastfeeding.</p> <p>34. Regulation 18(2)(a) states that Follow-on formula labels should be designed so as not to discourage Breastfeeding. The labels therefore require the 'Important Notice' statement and guidance notes 21, 24 and 25 should apply to FOMs as well as Regulation 22.</p>	<p>FSMPs are not within the scope of the infant formula and follow on formula Regulations 2007. These are controlled by The Medical Food (England) Regulations 2000</p> <p>The important notice requirement in Regulation 17(2) is not repeated in Regulation 18. The provision of information within follow on formula labelling will need to comply with Regulation 18.</p> <p>The important notice requirement in Regulation 17(1)(e) is not repeated in Regulation 18.</p> <p>Noted</p> <p>Noted</p> <p>The transitional periods set out in the Regulations will apply.</p>
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	<p>37. (last line) It would be helpful to specify which existing national legislation is relevant here.</p> <p>47. These suggestions are helpful, in the last bullet point, references to breastfeeding ADD ‘in non-mandatory text’, in line with Guidance note 23.</p> <p>79. second and third bullets need to ensure that new products are not placed on the market that comply with the 1995 Regulations rather than the 2006 Regulations.</p>	
UNICEF UK	<p>16,31 It is stated in 31 that manufacturers ‘should’ use the clear labelling guidelines when designing the labels of FUMS. However, they are only ‘encouraged’ to use the guidelines for IF labels. The stronger wording should apply to both.</p> <p>18 It is suggested that parents be advised to ‘take care’ when preparing feeds. This wording does not convey the importance of careful preparation. It is suggested that this wording be amended to: ‘It is therefore important that the instructions on preparing feeds are followed very carefully to reduce the risks as much as possible’</p> <p>20 This warning implies that the risks to babies health come merely from the incorrect preparation of feeds. It is suggested that this warning be strengthened to make clear that not breastfeeding increases the risk of serious illness and that this risk is even greater if instructions are not followed.</p> <p>21 The ‘Important notice’ requirement has not fulfilled its intended purpose in the past because of a lack of strict guidance on the wording which may be used. It is suggested that manufacturers be required to select from a prescribed list of options and that these options be kept simple and unambiguous.</p>	<p>Noted that consistency in wording is needed. This is not a requirement of the Regulation, but Agency advice on its application.</p> <p>Noted.</p> <p>Only where there is a specific requirement in the Regulation can the Agency offer Guidance on its application.</p> <p>The Regulation does not require specified wording to be used.</p>

	<p>23 The prohibition of references to breast milk, breast feeding and ‘ideal method’ is very much welcomed. It is suggested that this paragraph be strengthened to also prohibit such claims as manufacturers describing themselves as ‘experts in infant nutrition’.</p> <p>23 refers back to 22 which in turn refers to regulations 17 and 18. However, the wording in 23 refers only to infant formula. Regulation 18 relates to follow-on formula and therefore 23 should read ‘..or pictures on infant formula or follow-on formula labelling..’.</p> <p>24, 25 These restrictions are welcomed. We are particularly pleased to see that the restrictions now include reference to emotions and baby related subjects.</p> <p>29 The restrictions on health claims relating to particular substances are welcomed.</p> <p>31,32,33,34 Regulation 18(1)(a)(ii) requires that follow-on formula labels carry a statement that the product should form only part of a diversified diet. Optimum health would be promoted if this clarified that breast milk forms the main component of the diet for babies of 6-12 months and that follow-on formula should only replace this if the mother is no longer breastfeeding.</p> <p>Regulation 18(2)(a) states that follow-on formula labels should be designed so as not to discourage breast feeding. The labels therefore require the ‘Important Notice’ statement and guidance notes 21, 24 and 25 should also apply to follow-on formula.</p> <p>47 It would be helpful if a clear statement was added to ensure that the design of the labels for infant formula and follow-on formula are fundamentally different, so that the two products are not identifiable as being part of the same stable or family of products.</p> <p>Bullet 2 is welcomed. However, the wording is not reinforced by Appendix IV which shows identical spatial arrangements.</p>	<p>The Agency will consider all comments received together with Regulations 17 and 18 before finalising the Guidance.</p> <p>Noted</p> <p>Noted</p> <p>Regulation 18 does not require these details to be included. Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p> <p>The important notice requirement in Regulation 17(1)(e) is not repeated in Regulation 18.</p> <p>Noted</p> <p>Noted</p>
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	<p>Bullet 3 is welcomed. However, this should be clarified to state that a different shade or tone of the same colour is not permitted.</p> <p>Bullet 4 as it stands would prevent a manufacturer from including a statement on the superiority of breast feeding on a follow-on formula label. This could be reworded using the ‘non-mandatory text’ terminology used in 23 and 54.</p> <p>63 ‘Infant formula brand name’ requires a definition which includes manufacturers names/logos where these feature strongly on the labels.</p> <p>65 We welcome the requirement that an ‘Important Notice’ is required for follow-on formula and suggest that this be brought into line with the suggestions made under 21, 31-4, 42 and 44.</p>	<p>Noted. This is not a requirement of the Regulation, but would be Agency advice on its application.</p> <p>Noted</p> <p>Reference to Infant formula brand names would need to comply with Regulation 21 and 22.</p> <p>The Agency will consider all comments received and will revise paragraph 65 accordingly.</p>
HIPP	<p>Guidance Note 47 – references to breast milk or breastfeeding on follow-on formula packaging</p> <p>Provided the usage of a follow-on milk is clearly differentiated from infant formula usage (in relation to labelling, presentation and advertising), we feel that reference to breast milk and breastfeeding can be made on follow-on formula packaging without risk of causing confusion.</p> <p>Guidance Notes 22, 23, 47 - use of statements on infant and follow-on formula labels that may discourage breastfeeding</p> <p>We believe that use of phrases such as ‘to complement breastfeeding’ can be used on formula labels to provide customers with useful information without discouraging them from breastfeeding.</p>	<p>Regulation 19 and 22 require a clear distinction between infant formula and follow on formula so as to avoid any risk of confusion. The Agency has provided guidance on how this should be achieved.</p> <p>The labelling of infant formula must comply with Regulation 17 and in particular 17(2) and (3).</p>
The Nutrition Society	<p>In addition to actively encouraging and supporting exclusive breastfeeding until infants are six months of age, the Society believes that the continuation of breastfeeding for as long as the mother wishes after this point should also be supported (alongside the introduction of appropriate solid foods). This is in line with</p>	<p>The important notice requirement in Regulation 17(1)(e) is not repeated in Regulation 18. Only where there is a specific</p>

	<p>the recent draft guidance from NICE on infant feeding. The Society therefore suggests that the recommendation to industry outlined in Regulation 17(1)(e) (guidance Paragraph 21) is extended to include the labelling and advertising of follow-on formula.</p> <p><i>Paragraph 32.</i> The Society recommends stating that age range, ‘infant formula’/‘follow-on formula’, AND brand name should all be of a similar font size, and that guidance as to what size that should be, as a minimum, be given.</p> <p><i>Paragraph 47, bullet point 2.</i> The Society is of the opinion that there is not enough guidance to ensure labelling of infant formula and follow-on formula are clearly distinguishable.</p>	<p>requirement in the Regulation can the Agency provide guidance on its application.</p> <p>Noted</p> <p>Noted.</p>
VEGA	<p>We note that the regulations and guidance notes are primarily aimed at the general suitability of infant formulas vs breast-feeding and the distinction between different types of formula. However, we believe that some attention needs to be given to labelling for specific aversions, eg to cows milk or other proteins. It would be helpful to parents if any such labelling follows a standard format.</p>	<p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p>
LACORS	<p>Paragraphs 18 & 19 LACORS assumes that the references to instructions for appropriate preparation will refer to the current DoH recommendation that the minimum water temperature to prepare infant formula is 70 deg C. It would be desirable to add a further reference to the fact that instructions relating to lower temperature are totally unacceptable on the grounds of protecting infant health and well being.</p> <p>Paragraph 22 It would be helpful to include a reference here to indicate that the “similar terms” would also include “closer to/ inspired by breastmilk” etc.</p> <p>Paragraph 24 & 25 In addition to the examples listed it would be desirable to include graphics such as those stylistically depicting nursing mothers etc.</p>	<p>The Agency would like to see manufacturers providing consistent advice on preparation that fully takes into account the microbiological risks associated with these products and reflects the advice issued by Department of Health.</p> <p>The Agency will consider all comments received together with Regulations 17 and 18 before finalising the guidance.</p> <p>Noted</p>

	<p>Paragraph 28 Suggest the second sentence appears in bold type to highlight this important prohibition.</p> <p>Paragraphs 45 – 47 The guidance notes (and Appendix IV) address the issue of labelling but the same provisions should be extended to cover all forms of advertising and promotional practices.</p>	<p>Noted</p> <p>Noted</p>
<p>Trading Standards South East</p>	<p><u>Paragraph 16</u> It would be appropriate at this point to state that the whereas clause 22 in Directive 2006/141/EC makes it clear that infant formula and follow on products are subject to the general rules of labelling which are contained in Directive 2000/13/EC. The Agency 'Clear labelling' guidance should assist manufacturers produce labels which comply with these rules.</p> <p><u>Paragraph 19</u> In the advice to consumers section, there is a signpost to an Agency news page. It would be more appropriate to signpost consumers to the Department of Health leaflet as this is the definitive guidance.</p> <p><u>Paragraph 21</u> The guidance states that the notice should be afforded a high degree of prominence. However, there is no practical advice on how this is achieved. It would be helpful to give guidance on how to achieve prominence.</p> <p><u>Paragraph 38</u> This paragraph refers to controls on misleading descriptions in the Trade Descriptions Act 1968. This Act is about to be repealed and replaced by the Consumer Protection from Unfair Trading Regulations 2007 and Business Protection from Misleading Marketing Regulations 2007 which are enforceable via part 8 of the Enterprise Act 2002</p> <p><u>Paragraph 47</u> The final bulletpoint in this paragraph states that references to breastmilk should not be made on follow on formula packaging. However, there is a required statutory statement which contains this term. (The labelling must contain a</p>	<p>Noted</p> <p>Noted</p> <p>Noted</p> <p>Noted</p> <p>Noted</p>

	statement to the effect that it must not be used as a substitute for breastmilk). The guidance should say this is the only exception.	
Manchester PCT	<p>Labelling:</p> <ul style="list-style-type: none"> • Will the companies be obliged to inform parents that their product is not sterile and highlight the risks associated with it's use? • While I recognise that your main concern is with formula milks, why are first weaning foods (manufactured by many of the formula milk companies) labelled as starting from 4-6 months when you state you follow WHO guidelines and support complementary feeding from 6 months? It has long been known that these foods are not necessary and the inconsistent message given by health workers (who are following WHO guidelines) and the companies cause confusion for parents. 	<p>The Agency would like to see manufacturers providing consistent advice on preparation that fully takes into account the microbiological risks associated with these products and reflects the advice issued by Department of Health.</p> <p>The Regulations relate only to infant formula and follow-on formula and do not extend to complementary foods which are regulated separately¹.</p>
Other issues		
British Dental Association	<p>It is accepted that feeding infants breast milk is the most complete form of nutrition for infants. Infants who get most of their nutrition from formula during the first 12 months will lower their risk of developing dental fluorosis if they have ready-to-feed formula rather than formula reconstituted with water containing fluoride.</p> <p>If liquid or powdered concentrate infant formula is the primary source of nutrition it should be diluted or reconstituted with water that is free of fluoride or contains low levels of fluoride (water containing 2parts per million or less would be considered to have low levels of fluoride) in order to decrease the risk of dental fluorosis.</p>	<p>The composition of infant formula is harmonised at EU level, and for fluoride reflects the recommendation of the EU Scientific Committee for Food that, on safety and nutritional grounds, no minimum level, but a maximum level of 100 micrograms of fluoride per 100 kcal, should be set. This advice</p>

¹ The Processed Cereal Based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 (SI 2003 No 3207)

	<p>compositional aspect of formulae as stated here. The Nutrition Society suggests guidance is required to aid compliance.</p> <p><i>Paragraph 12.</i> This is the only place the abbreviations IF and FOF are used in the guidance. For the sake of consistency it is suggested they be replacing them with 'infant formula' and 'follow on formula'.</p>	Noted
The British Dietetic Association	<p>General Recommendations Paediatric Dietitians can also be recommended by formula manufacturers to parents and carers who would like to discuss any issues regarding infant feeding. Para 81 – could there be a definitive review date set as periodically is not a defined time?</p>	The content of the Guidance will be reviewed when either the Regulations or Agency advice changes.
Baby feeding Law Group. This submission was supported by 434 individual responses.	<p>Background - section 3, page 1 It is stated that the <i>Infant Formula and Follow-on Formula Regulations 2007</i> come into force on 1 January 2008 and replace the existing regulations fully on 1 January 2010. There needs to be clear guidance to Trading Standards officers to continue to pursue cases of illegal activity under whatever Regulations were in force at the time of offences.</p> <p>Composition and notification of infant formula - sections 9-14, pages 3-5 Simply requiring companies to submit a label to the FSA before putting new formulations of infant formula on the market is woefully inadequate. The BFLG calls on the UK Government to vigorously pursue a pre-authorisation procedure in the discussion on this Directive. If it is not willing to include such a procedure in the Guidance Notes, the BFLG highlights two recommendations:</p> <ul style="list-style-type: none"> • The notification system, whatever form it takes, should include provision for health workers and others to report to the Food Standards Agency or other designated authority any concerns they may have about the health impact of the new ingredients and products. Manufacturers should not be relied upon to carry out this monitoring function. <p>breastfeeding and babies fed on formula</p> <ul style="list-style-type: none"> • The Food Standards Agency or other designated authority should investigate, respond to and take appropriate action over concerns reported. • Accurate, independent information on new ingredients and products should be prepared for communication to health workers by the Food Standards Agency, or 	<p>The transitional periods set out in the Regulations will apply.</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p> <p>If health workers or others have general concerns about the ingredients used in infant and follow on formula these should be directed to the Agency. If the concerns related to a specific product these should be reported to the Home Authority.</p>

	<p>other authority to equip them to advise parents. BFLG also supports the suggestion that <i>“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.”</i> As the BFLG specifically, and the public generally, are invited to report breaches of the law to Trading Standards officers where relevant, it would be beneficial to make the notifications publicly available on the FSA website.</p> <p>Third country exports - section 72 page 16. The Guidance Notes should reference the EU Export Directive 92/52/EEC and Council Resolution 92/C172/01 which require compliance with the <i>International Code of Marketing of Breastmilk Substitutes</i> when operating in or exporting to third countries. The Guidance Notes should make it clear that the government will evaluate any complaints received under the terms of the Directive against the International Code and subsequent, relevant Resolutions of the World Health Assembly and that the provisions apply to anyone exporting products from the UK, be it a company, Non-Governmental Organisation or member of the public.</p>	<p>The relevant section of Directive 92/52/EEC are reflected in Directive 2006/141/EC and therefore the Regulations.</p>
<p>National Child Birth Trust</p>	<p>Page 1 3. We disagree that the Regulations give effect to the principles and aims of the WHO Code dealing with marketing, information and responsibilities of health authorities and would like this to reflect a more honest position by including the words ‘some of the’ prior to ‘principles’.</p> <p>13. add at end: Substances with no health or nutritional purpose will not be permitted.</p> <p>15. Although the link may be provided for clarification, and the legislation is separate, the current document at: www.food.gov.uk/multimedia/pdfs/parnutsguidancenotes.pdf (point 5 (page 3) states that infant formula and follow on formula products do not need to be notified</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 the Marketing, information and responsibilities of health authorities.</p> <p>The substances in Annex III are to be used to meet the nutritional requirements of the Regulations laid down in Annex II and III.</p> <p>The guidance on notification has been up-dated to cover infant formula and follow on formula.</p>

	<p>to the FSA. This is confusing, we assume that it will be updated or clarified.</p> <p>81. We suggest that the Guidance is reviewed annually, at least for the first three years to ensure that their provisions are working as intended.</p>	<p>The content of the Guidance will be reviewed when either the Regulations or Agency advice changes. This review process is separate to the Agency's independently chaired review, which will assess whether the new controls have been effective.</p>
UNICEF UK	<p>2 This section should include a clear and unambiguous statement that the guidance is legally enforceable. 16,17,18,25,32 Words such as 'encouraged', 'may', 'recommend' are weak and likely to cause enforcement problems. Stronger wording such as 'should', as is used elsewhere in the document, is recommended.</p> <p>81 It would be helpful if a specific timescale for review of the review of the Guidance Notes was included. It is suggested that a bi-annual review would be appropriate.</p>	<p>The Guidance notes aim to help interpret the requirements the Regulations introduce and provide the Agency's view on how to comply with those requirements.</p> <p>The content of the Guidance will be reviewed when either the Regulations or Agency advice changes. This review process is separate to the Agency's independently chaired review, which will assess whether the new controls have been effective.</p>
LACORS	<p>Paragraph 3 It would be helpful if a short reference could be added to explain that these Regulations are significantly different to virtually all other food legislation and are intended to significantly prevent, restrict or control a wide variety of commercial practice which apply to most other foodstuffs. It would be helpful if the text could</p>	<p>Noted</p> <p>The Guidance notes aim to help interpret the requirements the</p>

	explain which elements of the WHO Code (those which extend beyond the provisions of EC Directive 2006/141/EC) are not reflected in these guidance notes.	Regulations introduce.
Trading Standards South East	<p>It is hoped that this guidance will remove many of the areas of disagreement between manufacturers and enforcement agencies. Practical guidance such as this is a useful tool. However, it will not necessarily make it any easier for an enforcement agency to prove to the satisfaction of a criminal court that there has been a contravention of some of the subjective provisions because the guidance notes do not have a statutory status.</p> <p><u>Notification of Infant Formula (regulation 13)</u> <u>Paragraph 15</u> These guidance notes have a link to the PARNUTS guidance on the notification procedure. The PARNUTS guidance needs updating to state that notification is now needed for Infant Formula under the Infant Formula Regulations</p>	The guidance on notification has been up-dated to cover infant formula and follow on formula.
Manchester PCT	It is frustrating that the government continues to fail to fully acknowledge the massive cost to the health of the poorest mothers and children (as well as the financial cost to the NHS) that results from giving formula instead of breastmilk.	This does not relate to the content of the Guidance.