

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		
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</p>

		requirements.
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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	<p>proposal will be managed, what industry will be required to do and in turn what process the approval system will follow. Guidance on what ‘donations’ means in this context would be useful. Any system for the approval of materials must be transparent, have published criteria as to which materials are approvable, have defined and practicable timelines, and provide for a right of appeal.</p> <p>80 Due to timelines involved in producing material such as advertisements, it would be impractical to discuss every piece with the Home Authority. However, we will continue to strive to consult the Home Authority on advertising and labeling where appropriate.</p> <p>Appendix II Several points in this appendix require clarification, in particular bullet points 2 and 7. Responding to requests for product information (orally or in writing) is a duty of manufacturers. This includes private correspondence between companies and their customers (such as retailers or wholesalers) and consumers. It is essential that infant formula brand names are used in communication pieces such as recall notices, safety notices and factual statements – this is not advertising and should not be treated in the same way.</p>	<p>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>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. Ultimately whether or not this constitutes advertising will depend on the nature of the information provided and this should be considered by manufacturers developing such material.</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</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>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>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</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</p>

advertising of follow-on formula in breach of the *International Code of Marketing of Breastmilk Substitutes*. 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 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 -47 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

how to comply with those requirements.

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

	<p>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 <i>Infant Formula and Follow-on Formula Regulations 1995</i>.</p> <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>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. 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>
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	<p>Restrictions on advertising follow-on formula - section 64 - 65, page 12. 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 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. 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>The provision of information via such routes must comply with 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>The Agency will consider all comments received and will be reviewing the guidance on “advertising” accordingly.</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>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</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 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</p>
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	<p>represent the balance of independent published evidence.</p> <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>Authority (EFSA) has produced guidance on the evidence that should be provided in support of a claim.</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>
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	<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 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>Regulations 24 (1), (2) and (3) allow informational and educational material to be provided where it is not a 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>
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	<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>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>Noted</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>
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	<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>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. The provision of information on websites will need to comply with Regulations 21,22,23 and 24.</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>
<h2>Labelling</h2>		
<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</p>	<p>Noted</p>

on the labels of follow-on formula for many years. It has been placed under the words 'Important Notice'.

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.

44. Careline staff are highly trained, and provide factual support to parents and carers on request.

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.

52. The important notice is clearly visible and understandable on advertisements

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.

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.

80. Discussions with Home Authority officers are already undertaken on a courtesy basis where appropriate.

Detailed comments

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.

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.

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.

FSA-funded focus group research found that caregivers were concerned that powder formula was not sterile. Overall,

	<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>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</p>	<p>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 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</p>
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	<p>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>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>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> <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). 	<p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p>

- 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.

Those who use formula are being misled by companies

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

Noted

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.

	<p>unnecessary and possibly idealizing. The review of the effectiveness of the Guidance Notes and Regulations should examine how fully labels are brought into line.</p> <p>Use of nutrition and health claims in relation to infant formula - section 26 - 29, page 7.</p> <p>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.</p>	<p>Noted</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>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</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> <p>Noted</p> <p>The Agency would like to see manufacturers providing consistent advice on preparation that fully takes into account the</p>

	<p>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>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</p>	<p>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> <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</p>
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	<p>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>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>	<p>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>Western Trust</p>	<p>Information on labels</p> <p>Attempts to regulate this are welcome, in particular in relation to information on hazards of artificial feeding and on so-called Carelines.</p> <p>Hazards of artificial feeding</p> <p>At present, both on labels and in patient information literature produced by the milk companies, the information on the hazards of artificial feeding (to the mother as well as the infant) is minimal and quite unreflective of the research evidence now available.</p> <p>On labels in particular, information on hazards is often given in very small print.</p> <p>The consequences of offering formula, in terms of its detrimental effect on maternal milk production, are not made clear, with phrases such as 'for hungrier babies' contributing to the confusion.</p> <p>Carelines</p> <p>The Code explicitly recognizes that parents have a right to approach milk companies for information about their products. This is not the same thing as parents being advertised to by companies with offers of 'Carelines.'</p> <p>In the spirit of the Code, milk companies should only be allowed to give contact details on where information may be sought: emotive terms such as 'Careline' and 'support' should not be allowed. Phrasing should be limited to words such as 'Information may be obtained from ...'</p> <p>Milk company contact details should not be allowed on information materials ostensibly promoting breastfeeding.</p> <p>The content of 'Careline' information is in practice very difficult to monitor. What is permissible should be carefully described, so that breaches are clearly identifiable.</p>	<p>Noted</p> <p>Noted with regards to informational and education material.</p> <p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application. However the information provided via carelines must comply with the Regulations 21,22 and 24.</p>
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Other issues

<p>IDFA</p>	<p>43 Note: Growing up milks are not within the scope of the regulations and therefore should not be referred to in the guidelines.</p> <p>Perception of babies under six months of age is very subjective. Manufacturers always ensure the babies are over the chronological age of six months. Final bullet: we are concerned that this would restrict communication about key elements of formulae (For instance iron, which is common to both infant and follow-on formula. It is an important element in follow-on formula and its presence offers a proven benefit for infants over six months of age and communication about the presence of iron is an important feature.)</p>	<p>Noted</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>Baby feeding Law Group. This submission was supported by 434 individual responses.</p>	<p>Background - section 3, page 1</p> <p>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</p> <p>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, 	<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</p>

	<p>respond to and take appropriate action over concerns reported.</p> <ul style="list-style-type: none"> • Accurate, independent information on new ingredients and products should be prepared for communication to health workers by the Food Standards Agency, or 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>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>to the Home Authority.</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</p> <p>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</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</p>

	<p>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 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>been up-dated to cover infant formula and follow on formula.</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>
Western Trust	<p>Follow-on formula</p> <p>While the attempts to regulate the marketing of follow-on formula (FOF) are welcome, they do not go far enough and will allow continuing abuse.</p> <p>It is important to have a joined-up approach to infant feeding recommendations, with consistency between Departmental recommendations on infant feeding and approaches allowed to FOF producers. For example, DoH literature makes clear that FOFs are not nutritionally necessary for the majority of children; their chief function is to provide a marketing opportunity for milk companies to associate their other formulas with FOFs by brand-imaging. Current UK law allows vigorous marketing of FOFs which is also used to create public awareness of other, ostensibly unadvertised, items in the milk companies' lines of formulas.</p> <p>The current UK recommendation is that breastfeeding should be continued to at least 12 months. FOF used before 12 months is therefore a breast milk substitute, and logically should be subject to the same marketing restrictions as other infant formula, ie it should not be allowed to promoted directly to the public.</p> <p>The wording 'follow-on formula is not a breast milk substitute' should not</p>	<p>Only where there is a specific requirement in the Regulation can the Agency provide guidance on its application.</p>

be allowed on labels or other information.

FOF is recognised to be unnecessary for the majority of children. This information should be included on labels, with information on which children might benefit. It is reasonable to give parents this information, to allow informed choice and protection from financial exploitation.

The current UK recommendation is that infants should use cups, rather than bottles, from 12 months. This information should be included on FOF labels.