

**Product:**

**Date:**

Checklist for Assessing Commercial Communication aimed at Health Professionals on Infant Formula in Ireland \*

The aim of this tool is to provide a practical means of assessing commercial communication for compliance with the legislation. The questions can be answered using the drop-down box available in the 'Finding' column. Guidance is offered to provide background to the question asked.

Section	Indicator	Finding (Please Indicate)	Guidance
Nutrition Claims	<p><b>Nutrition claim requirements as set out in Regulation 2016/127, Directive 2006/141 and Regulation 1924/2006</b></p> <p>Are unpermitted nutrition claims made on this piece of material?</p>		<p>Please note there are no approved nutrition claims for infant formula under Regulation 2016/127, although claims relating to DHA or an equivalent claim are allowed on infant formulas placed on the market before 22 February 2025. A nutrition claim related to lactose must meet the condition of use specified in Article 9 of 2016/127. Nutrition claims listed in Annex IV of Directive 2006/141: contains lactose, lactose free, LCP/DHA, Taurine, FOS and GOS, Nucleotides apply to a product made from protein hydrolysates until February 2021. Comparative nutrition claims can be made between two IF products if the following conditions are met:</p> <ol style="list-style-type: none"> <li>1. The first product of the claim is made from protein hydrolysates</li> <li>2. The claim must be listed in Annex IV of Directive 2006/141</li> <li>3. The claim must satisfy the conditions of use of comparative claims set out in Article 9 Regulation 1924/2006</li> </ol>
	<p>Is a non-compliant comparative claim made?</p>		

<p><b>Health Claims</b></p>	<p><b>Health claims requirements as set out in Regulation 2016/127, Directive 2006/141 and Regulation 1924/2006</b></p> <p>Are unpermitted health claims made anywhere on this material?</p>		<p>Health claims related to infant formula made from protein hydrolysates concerning the reduction of risk to allergy to milk proteins is the only health claim permitted until 22 Feb 2021.</p> <p>Article 8 Regulation 2016/127: No health claims to be made on infant formula under Regulation 2016/127, Scientific and factual information shall not take the form of a health claim. Objective scientific information on a <b>new scientific development</b> is <b>not</b> a health claim.</p>
<p><b>Misleading Information</b></p>	<p><b>Food information must not be misleading as per Article 7 (1)(C) of Regulation 1169/2011</b></p> <p>Are any misleading claims made about the product?</p>		<p>Food information shall not be misleading...by suggesting that any food possesses special characteristics when in fact all similar foods possess such characteristics.</p>
<p><b>Required additional information</b></p>	<p><b>Presence of Important Notice as set out in Article 6 (C) Regulation 2016/127</b></p> <p>Is a statement on the superiority and benefits of breastfeeding on this material?</p> <p>Is a statement recommending that the product only be used on the advice of independent persons having qualifications in medicine, nutrition, pharmacy, or professionals responsible for maternal and childcare from this material?</p>		<p>All materials relating to infant formula must have a statement concerning the superiority of breast feeding, and advice that it should only be used on appropriate recommendation of a relevant professional.</p>
<p><b>Source of References</b></p>	<p><b>Scientific and factual information as set out in Section 7 of the Guidance Document</b></p> <p>Are scientific and factual information in this material referenced appropriately?</p>		<p>Sources of references/evidence should be scientific and factual however accepted sources of scientific and factual material are outlined and agreed upon in the Guidance Document.</p> <p>Referencing should be relevant, accessible &amp; verifiable by the health professional. <a href="#">See section 7 of Guidance Document.</a></p>

<p><b>Appropriate Terms</b></p>	<p><b>Appropriate terms as set out Article 6.6 of Regulation 2016/127 and Article 13 (3) Directive 2006/141</b></p> <p>Does this material contain terms such as 'humanised, maternalised, adapted', or similar terms, or make comparisons to breastfeeding?</p>		<p>Article 6(6) Regulation 2016/127: The labelling, presentation and advertising of infant formula and follow on formula shall not use the terms 'humanised, maternalised, adapted', or terms similar to them. Terms that may discourage breastfeeding also shall not be used. Text shall not idealise infant formula, and shall not imply an equivalence or superiority to breast milk.</p>
<p><b>Pictures of Infants</b></p>	<p><b>Pictures of Infants as set out in Article 10(2) of Regulation 609/2013</b></p> <p>Does this material contain any imagery of infants/imagery that could discourage breastfeeding/idealise infant formula?</p>		<p>Neither pictures of infants nor pictures that may idealise infant formula are allowed on any infant formula materials.</p>
<p><b>Restriction of Information</b></p>	<p><b>Restriction of Information as set out in Section 8 of the Guidance document</b></p> <p>Is the statement "For Healthcare Professionals Only" or a similar statement present?</p> <p>Is the Status Confirmation Prompt or similar prompt present? (Websites/Apps only - leave blank if not applicable)</p>		<p>If the material is intended exclusively for health professionals, and not for the average consumer, a <b>statement or status confirmation prompt</b> (websites only) should be present to that effect.</p>
<p><b>New Scientific Developments (If applicable)</b></p>	<p><b>Scope of scientific information as set out in Section 5 of the FSAI / DII guidance document</b></p> <p>Is a nutrition or health claim made <b>with</b> objective information on a new scientific development?</p> <p>Is published scientific evidence available to support such a claim? (see section 5 of Guidance Document)</p>		<p>Nutrition and health claims are allowed when they refer to a new scientific development.</p> <p>The sources which would not qualify as support for a claim are unpublished data on file or company information such as marketing information or sales trends.</p>

\* In line with [Commission Delegated Regulation \(EU\) 2016/127](#), [Regulation \(EC\) No. 1924/2006](#), [Regulation \(EU\) 609/2013](#), [Regulation \(EU\) 1169/2006](#), [Commission Directive 2006/141/EC](#) & [European Court of Justice Ruling C-19/15](#)

For further Guidance for [compliance with food law when communicating with health professionals about infant formula products, see here.](#)