





Overview of regulatory framework and guidance documents to prepare an application on health claims, novel foods, infant formulae and food allergies

Submission of regulated products applications by electronic means only

Applications for regulated products should now be submitted to the European Food Safety Authority (EFSA) by electronic means only. Electronic mediums such as CD ROMS, DVDs or USB keys can be used to submit technical dossiers, updates to applications and to respond to requests for additional information.

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
<p>Health claims</p> <p>Chapter IV Reg. (EC) 1924/2006</p> <p>Art 13.5 New function health claims</p> <p>Art. 14 Claims referring to: reduction of disease risk and to children's development and health</p>	<p>Regulation (EC) No 1924/2006 of the European Parliament and of the council of 20 December 2006 on nutrition and health claims made on foods</p> <p>Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council</p> <p>Commission Regulation (EC) No 1169/2009 of 30 November 2009 amending Regulation (EC) No</p>	<p>EFSA Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1) (revised in May 2011) EFSA Journal 2011,9(5):2170</p> <p>Parts 1-4 of the application </p> <p>Appendix A – Application form </p> <p>Appendix B – Overall summary of the application </p> <p>EFSA General guidance for stakeholders on the evaluation of</p>	<ol style="list-style-type: none"> EFSA Guidance on the scientific requirements for health claims related to functions of the nervous system, including psychological functions (July 2012). EFSA Journal 2012;10(7):2816 (EFSA-Q-2010-01185) EFSA Guidance on the scientific requirements for health claims related to physical performance (July 2012). EFSA Journal 2012;10(7):2817 (EFSA-Q-2010-01186) EFSA Guidance on the


Area	Regulatory framework	Administrative Guidance	Scientific Guidance
<p>Health claims</p> <p>Chapter IV Reg. (EC) 1924/2006</p>	<p>353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council</p> <p>2013/63/EU: Commission Implementing Decision of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council</p> <p>Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health</p> <p>EU Register of Nutrition and health claims made on food</p>	<p>Article 13.1, 13.5 and 14 health claims EFSA Journal 2011;9(4):2135 (published April 2011) (EFSA-Q-2011-00216)</p> <p>EC Guidance  on the implementation of Regulation (EC) N° 1924/2006 on Nutrition and Health Claims made on food approved by the Standing Committee on the Food Chain and Animal Health on 14 December 2007</p>	<p>scientific requirements for health claims related to bone, joints, skin, and oral health (May 2012) EFSA Journal 2012;10(5):2702 (EFSA-Q-2010-01184)</p> <p>4. EFSA Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations (March 2012) EFSA Journal 2012;10(3):2604 (EFSA-Q-2010-01183)</p> <p>5. EFSA Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (December 2011) EFSA Journal 2011;9(12):2474 (EFSA-Q-2010-01182)</p> <p>6. EFSA Guidance on the scientific requirements for health claims related to gut</p>

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
			and immune function (April 2011) EFSA Journal 2011;9(4):1984 (EFSA-Q-2010-01139)
Nutrition claims Chapter III Regulation Reg. EC 1924/2006	<p>Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods</p> <p>Commission Regulation (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims</p> <p>EU Register of Nutrition and health claims made on food</p>		

[\(Top\)](#)

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
<p>Novel foods</p>	<p>Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients</p> <p>Novel Food Catalogue of authorised Novel Foods and Novel Food Ingredients</p> <p>Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97</p>	<p>97/618/EC: Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council</p>	

[\(Top\)](#)

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
Infant formulae	Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC	EC Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae  (Adopted on 4 April 2003)	

[\(Top\)](#)

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
Food allergies	Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs		<p>Guidance on the preparation and presentation of applications pursuant to Article 6 Paragraph 11 of Directive 2000/13/EC, as amended (October 2013) EFSA Journal 2013;11(10):3417 (EFSA-Q-2013-00221)</p> <p>Outcome of a public consultation on the Draft Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on Scientific and technical guidance for the preparation and presentation of applications pursuant to Article 6 Paragraph</p>

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
			11 of Directive 2000/13/EC, as amended (October 2013) EFSA-Q-2013-00430

[\(Top\)](#)