



Overview of regulatory framework and guidance documents to prepare an application on nutrient sources

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
Nutrient sources	<p>Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements</p> <p>Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods</p> <p>Commission Directive 2006/37/EC of 30 March 2006 amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council</p>	<p>EC Administrative guidance on submissions for safety evaluations of substances added for specific nutritional purposes in the manufacture of foods (February 2004 – Revised April 2012) </p>	<p>EC Guidance on submissions for safety evaluations of sources of nutrients or of other ingredients proposed for use in the manufacture of foods (July 2001) </p>

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
Nutrient sources	<p>as regards the inclusion of certain substances</p> <p>Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements</p> <p>Commission Regulation (EU) No 1161/2011 of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods</p>		

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
Nutrient sources	<p><u>Commission Regulation (EU) No 119/2014 of 7 February 2014 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards chromium enriched yeast used for the manufacture of food supplements and chromium(III) lactate tri-hydrate added to foods</u></p> <p><u>Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations</u></p>		

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
Nutrient sources	<p>(EC) No 41/2009 and (EC) No 953/2009</p> <p>Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses</p> <p>Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods</p> <p>EC list of authorised nutrient sources</p>		

[\(Top\)](#)