





Overview of regulatory framework and guidance documents to prepare an application on food additives, food enzymes and flavourings

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
Food additives	<p><u>Common authorisation procedure:</u></p> <p>Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings</p> <p>Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common</p>	<p>EC practical guidance for applicants  on the submission of applications on food additives, food enzymes and food flavourings (September 2011- updated 26 January 2015)</p>	<p>Guidance for submission for food additive evaluations (July 2012). EFSA Journal 2012;10(7):2760 (EFSA-Q-2010-00675)</p> <p>EFSA Data requirements for the evaluation of food additive applications (August 2009). EFSA Journal 2009;1188 (EFSA-Q-2007-188)</p> <p>Guidance on submission for food additive evaluations by the Scientific Committee on Food (SCF/CS/GEN/26 Final - July 2001) </p>

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Food additives	<p>authorisation procedure for food additives, food enzymes and food flavourings</p> <p>Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives</p> <p>Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives</p> <p>Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients</p> <p>Commission Regulation (EU)</p>		<p>Food additives intake model (FAIM) template – Version 1.1 (Updated on: 25 July 2013) </p> <p>FAIM template 'Instructions for use' – Version 1.0 (Dec 2012) </p>

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Food additives	<p>No 1131/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides</p> <p>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council</p> <p><u>Re-evaluation:</u></p> <p>Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives</p> <p>Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food</p>		


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Food additives	<p>information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004</p>		

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Food enzymes	<p><u>Common authorisation procedure:</u></p> <p>Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings</p> <p>Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings</p> <p>Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC,</p>	<p>EC practical guidance for applicants  on the submission of applications on food additives, food enzymes and food flavourings (September 2011- updated 26 January 2015)</p> <p>Administrative Guidance to applicants on the suitability check of applications for authorisation of food enzymes submitted under Regulation (EC) No 1332/2008</p>	<p>EFSA Guidance of the Scientific Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes (May 2013 - replacing earlier version published on 23 July 2009). doi:10.2903/j.efsa.2009.1305 (EFSA-Q-2007-080)</p> <p>Explanatory Note for the Guidance of the Scientific Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes (July 2011, last updated 14 November 2014). (EFSA-Q-2014-00750)</p> <p>EFSA Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use (June 2011) (EFSA-Q-2009-00521) EFSA Journal 2011;9(6):2193 [54 pp.]. doi:10.2903/j.efsa.2011.2193</p>

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Food enzymes	<p>Council Directive 2001/112/EC and Regulation (EC) No 258/97</p> <p>Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes</p> <p>Commission Regulation (EU) No 1056/2012 of 12 November 2012 amending Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes with regard to transitional measures</p>		

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Flavourings	<p><u>Common authorisation procedure:</u></p> <p>Regulation (EC) No 1331/2008 of 16 December 2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings</p> <p>Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings</p> <p>Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation</p>	<p>EC practical guidance for applicants  on the submission of applications on food additives, food enzymes and food flavourings (September 2011- updated 26 January 2015)</p>	

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Flavourings	<p>(EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC</p> <p>Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC</p> <p>Commission Regulation (EU) No 873/2012 of 1 October 2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council</p> <p>Commission Regulation (EU) No 246/2014 of 13 March 2014 amending Annex I to Regulation</p>		

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	(EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances		
Flavourings	<p><u>Group evaluation:</u> Regulation (EC) No 2232/96 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs; sets out the basic rules for the use of flavouring substances in or on foodstuffs in the EU</p> <p>Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council</p> <p>1999/217/EC: Commission Decision of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of</p>		<p>EFSA Guidance on the data required for the risk assessment of flavourings to be used in or on foods (June 2010). EFSA Journal 2010; 8(6):1623 [53 pp.]. doi:10.2903/j.efsa.2010.1623 (EFSA-Q-2009-00004)</p> <p>EFSA Proposed template to be used in drafting scientific opinion on flavouring substances (explanatory notes for guidance included) (November 2011) (EFSA-Q-2011-01133)</p>

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Flavourings	Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 EU Register of food flavourings		

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