

Overview of regulatory framework and guidance documents to prepare an application on smoke 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
Flavourings - Smoke flavourings	<p>Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods</p> <p>Commission Regulation (EC) No 627/2006 of 21 April 2006 implementing Regulation (EC) No 2065/2003 of the European Parliament and of the Council as regards quality criteria for validated analytical methods for sampling, identification and characterisation of primary smoke products</p>		<p>EFSA Guidance on submission of a dossier on a Smoke Flavouring Primary Product for evaluation by EFSA (April 2005). doi:10.2903/j.efsa.2005.492 (EFSA-Q-2003-00240)</p> <p>EFSA Statement on the Safety Evaluation of Smoke Flavourings Primary Products: Interpretation of the Margin of Safety (January 2010). EFSA Journal 2010; 8(1):1325 [7 pp.] (EFSA-Q-2009-00764)</p> <p>EFSA Guidance on Dietary exposure assessment methods for smoke flavouring Primary</p>

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Flavourings - Smoke flavourings	<p>Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four</p> <p>Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings</p>		<p>Products (April 2009). doi:10.2903/j.efsa.2009.248r (EFSA-Q-2008-402)</p>

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