

Extraction Solvents (Dimethyl Ether)
Amendment to Directive 2009/32/EC

Directive 2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients has been amended by Commission Directive (EU) 2016/1855. Conditions of use of Dimethyl ether in defatted animal protein products (gelatine and collagen) are modified.

 **Background**

Directive 2009/32/EC applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients. On 19 August 2014, the EU Commission received an application submitted by an operator requesting a change in the maximum residual limit (MRL) for dimethyl ether (DME) as an extraction solvent in defatted animal protein products. EFSA was requested to re-evaluate the safety of DME under the proposed intended conditions of use. EFSA concluded that the modification is of no safety concern.

 **Modification of Directive 2009/32/EC**

Commission Directive (EU) 2016/1855 has been adopted on 19 October 2016 and published in the Official Journal on 20 October 2016 (L 284/19):

- o **Commission Directive (EU) 2016/1855 of 19 October 2016 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients**
<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478793623388&uri=CELEX:32016L1855>

NB: A consolidated version of Directive 2009/32/EC which takes into account this latest amendment is available on Eur-lex: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478793623388&uri=CELEX:02009L0032-20161109>

This Commission Regulation entered into force on the 20th day following its publication, i.e. on 9 November 2016. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than two years after the date of entry into force of this Directive, i.e. on 9 November 2018.

Modifications applied to Part II of Annex I to Directive 2009/32/EC ('Extraction solvents for which conditions of use are specified'). Directive (EU) 2016/1855 defines a new use of dimethyl ether for the extraction of protein products to yield gelatine with a MRL of 0,009 mg/kg. At the same time the MRL for the use of DME as extraction solvent for the preparation of collagen and collagen derivatives is increased from 0,009 mg/kg up to 3 mg/kg.

Former conditions of use of dimethyl ether:

Dimethyl ether	Preparation of defatted animal protein products	0,009 mg/kg in the defatted protein product
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New conditions of use of dimethyl ether (as set by Directive 2016/1855):

Dimethyl ether	Preparation of defatted animal protein products including gelatine(*)	0,009 mg/kg in the defatted animal protein products including gelatine
	Preparation of collagen(**) and collagen derivatives, except gelatine	3 mg/kg in the collagen and collagen derivatives, except gelatine

(*) 'Gelatine' means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals, in accordance with the relevant requirements of Regulation (EC) No 853/2004.

(**) 'Collagen' means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of Regulation (EC) No 853/2004.'

If you have further questions, please do not hesitate to contact EFFA at info@effa.eu or your respective national association.

EFFA Secretariat – 14 November 2016

Enclosures:

Commission Directive (EU) 2016/1855 of 19 October 2016 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. (FL/16/37)