

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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients⁽¹⁾, and in particular point (a) of the first subparagraph of Article 4 thereof,

Whereas:

- (1) Directive 2009/32/EC applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients. That Directive does not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives, unless such food additives, vitamins or nutritional additives are listed in its Annex I.
- (2) On 19 August 2014, an application was submitted by Akzo Nobel Industrial Chemicals BV requesting a change in the maximum residual limit (MRL) for dimethyl ether (DME) as an extraction solvent in defatted animal protein products, in particular collagen and collagen derivatives, from 0,009 mg/kg to 3 mg/kg, and a new use for the extraction of protein products to yield gelatine with a MRL of 0,009 mg/kg. That application was subsequently made available to the Member States.
- (3) The European Food Safety Authority ('the Authority') re-evaluated the safety of DME as an extraction solvent for the preparation of defatted animal protein products — collagen and gelatine — and issued its opinion on 14 July 2015⁽²⁾. The Authority concluded that the use of DME as an extraction solvent, under the intended conditions of use and with the proposed MRLs of 3 mg/kg in collagen and collagen derivatives and 0,009 mg/kg in gelatine, is of no safety concern.
- (4) Therefore, it is appropriate to authorise the use of dimethyl ether as an extraction solvent to remove fat from animal protein raw materials under the condition of maximum

*Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After
IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

residual limits of dimethyl ether of 3 mg/kg in collagen and collagen derivatives and of 0,009 mg/kg in gelatine.

- (5) Directive 2009/32/EC should therefore be amended accordingly.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DIRECTIVE:

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (1) [OJ L 141, 6.6.2009, p. 3.](#)
- (2) EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2015. Scientific Opinion on the safety of use of dimethyl ether as an extraction solvent under the intended conditions of use and the proposed maximum residual limits. EFSA Journal 2015;13(7):4174, 13 pp.