

DIRECTIVES

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 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:

Article 1

Annex I to Directive 2009/32/EC is amended in accordance with the Annex to this Directive.

⁽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.

Article 2

1. 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. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 19 October 2016.

For the Commission
The President
 Jean-Claude JUNCKER

ANNEX

In Part II of Annex I to Directive 2009/32/EC, the row for 'Dimethyl ether' is replaced by the following:

'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.'