

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2023/175

of 26 January 2023

amending Directive 2009/32/EC of the European Parliament and of the Council as regards 2-methyloxolane

(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 points (a) and (d) 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 6 January 2020, an application was submitted by Pennakem Europa requesting the authorisation of 2-methyloxolane as an extraction solvent. According to the applicant, 2-methyloxolane could be used as an alternative to the currently permitted hexane. In particular, for the extraction processes in the production or fractionation of fats, oils or cocoa butter, in the preparation of defatted protein products, defatted flours, and in the preparation of defatted cereal germs and flavourings from natural flavouring materials. The application was subsequently made available to the Member States.
- (3) The European Food Safety Authority ('the Authority') evaluated the safety of the proposed use of 2-methyloxolane as a food extraction solvent. In the Authority's opinion ⁽²⁾ adopted on 26 January 2022, a tolerable daily intake ('TDI') of 1 mg/kg bw per day was established. The Authority noted that the established TDI is not exceeded in any of the population groups at the mean and the 95th percentile exposure and concluded that the extraction solvent 2-methyloxolane does not raise a safety concern when used as intended and when respecting the proposed maximum residue limits (MRLs). 2-methyloxolane, as evaluated by the Authority, is obtained with a purity superior to 99,9 %. Furan and 2-methylfuran, the impurities with the highest potentially hazardous properties, do not pose a safety concern if present at their maximum limits of 50 mg/kg and 500 mg/kg respectively, in accordance with the specifications.
- (4) Therefore, it is appropriate to authorise the use of 2-methyloxolane as an extraction solvent in the production or fractionation of fats, oils or cocoa butter, in the preparation of defatted protein products, defatted flours, preparation of defatted cereal germs and flavourings from natural flavouring materials. It is also appropriate to establish specific purity criteria for 2-methyloxolane.
- (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,

⁽¹⁾ OJ L 141, 6.6.2009, p. 3.

⁽²⁾ EFSA Journal 2022;20(3):7138

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 2 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, 26 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex I to Directive 2009/32/EC is amended as follows:

(a) In Part II, the following new entry is inserted after the entry for hexane:

'2-methyloxolane	Production or fractionation of fats and oils and production of cocoa butter	1 mg/kg in the fat or oil or cocoa butter
	Preparation of defatted protein products and defatted flours	10 mg/kg in the food containing the defatted protein products and the defatted flours
		30 mg/kg in the defatted soya products as sold to the final consumer
	Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germs'

(b) In Part III, the following new entry is inserted after the entry for hexane:

'2-methyloxolane	1 mg/kg'
------------------	----------

(c) A new Part IV is added:

PART IV

Specific purity criteria for the extraction solvents listed in Annex I

2-methyloxolane	
CAS number	96-47-9
Assay	Content not less than 99,9 % expressed on dry basis
Purity	
Furan	Not more than 50 mg/kg (expressed on dry basis)
2-methylfuran	Not more than 500 mg/kg (expressed on dry basis)
Ethanol	Not more than 450 mg/kg (expressed on dry basis)'