

L.N. 59 of 2025

**FOOD SAFETY ACT
(CAP. 449)**

**Extraction Solvents for Foodstuffs
(Amendment) Regulations, 2025**

IN EXERCISE of the powers conferred by article 10 of the Food Safety Act, the Minister responsible for public health has made the following regulations:-

1. (1) The title of these regulations is the Extraction Solvents for Foodstuffs (Amendment) Regulations, 2025 and these regulations shall be read and construed as one with the Extraction Solvents for Foodstuffs Regulations, hereinafter referred to as the "principal regulations".

Citation and
scope.
S.L. 449.23.

(2) The scope of these regulations is to transpose 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.

2. In the Maltese version only, in regulation 1 of the principal regulations the words "fi Hwejjeġ ta' l-Ikel" shall be substituted by the words "f'Oggetti tal-Ikel".

Amends
regulation 1 of
the principal
regulations.

3. Regulation 2.1 of the principal regulations shall be substituted by the following new regulation:

Substitutes
regulation 2.1 of
the principal
regulations.

"Interpret-
ation.

2.1. In these regulations, unless the context otherwise requires:

"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 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin;

"extraction solvent" means a solvent which is used in an extraction procedure during the processing of raw materials, foodstuffs or of components or ingredients of such products and which is removed but which may result in the unintentional but technically unavoidable presence of residues or derivatives in the foodstuff or food ingredient;

"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 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin;

"hexane" means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C;

"solvent" means any substance for dissolving a foodstuff or any component thereof, including any contaminant present in, or on that foodstuff."

Deletes regulation 3.2 of the principal regulations.

4. Regulation 3.2 of the principal regulations shall be deleted.

Deletes regulation 3.3 of the principal regulations.

5. Regulation 3.3 of the principal regulations shall be deleted.

Deletes regulation 3.4 of the principal regulations.

6. Regulation 3.4 of the principal regulations shall be deleted.

Amends regulation 4.5 of the principal regulations.

7. In regulation 4.5 of the principal regulations the words "in regulations 3.2, 3.3 or 3.4" shall be substituted by the words "in Part I, II and III of the Schedule".

Amends regulation 5.1 of the principal regulations.

8. In regulation 5.1 of the principal regulations the words "in regulations 3.2, 3.3 and 3.4" shall be substituted by the words "in Part I, II and III of the Schedule".

Amends regulation 5.1.1 of the principal regulations.

9. In regulation 5.1.1 of the principal regulations the words "in regulations 3.2, 3.3 and 3.4" shall be substituted by the words "in Part I, II and III of the Schedule".

10. In regulation 6.1 of the principal regulations, the words "in regulations 3.2, 3.3 and 3.4" shall be substituted by the words "in Part I, II and III of the Schedule".

Amends regulation 6.1 of the principal regulations.

11. Immediately after regulation 6.2 of the principal regulations there shall be added the following new Schedule:

Adds new Schedule to the principal regulations.

"SCHEDULE
(regulations 4.5, 5.1, 5.1.1 and 6.1)

Extraction Solvents which may be Used during the Processing of
Raw Materials, Foodstuffs, Food Components or Food Ingredients

PART I

Extraction solvents to be used in compliance with good manufacturing
practice for all uses (*)

Propane
Butane
Ethyl acetate
Ethanol
Acetone (**)
Nitrous oxide
Carbon
(*) An extraction solvent is considered as being used in compliance with good manufacturing practice if its use results only in the presence of residues or derivatives in technically unavoidable quantities presenting no danger to human health.
(**) The use of Acetone in the refining of olive-pomace oil is forbidden.

PART II

Extraction solvents for which conditions of use are specified

Name	Conditions of use (summary description of extraction)	Maximum residue limits in the extracted foodstuff or food ingredient
Hexane (*)	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 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
2-methyloxolane	Production or fractionation of fats and oils and the 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
Methyl acetate	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
	Production of sugar from molasses	1 mg/kg in the sugar
Ethylmethylketone (**)	Fractionation of fats and oils	5 mg/kg in the fat or oil
	Decaffeination of, or removal of irritants and bitterings from coffee and tea	20 mg/kg in the coffee or tea
Dichloromethane	Decaffeination of, or removal of irritants and bitterings from coffee and tea	2 mg/kg in the roasted coffee and 5 mg/kg in the tea
Methanol	For all uses	10 mg/kg
Propan-2-ol	For all uses	10 mg/kg

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
(*) The combined use of Hexane and Ethylmethylketone is forbidden.		
(**) The level of n-Hexane in this solvent shall not exceed 50 mg/kg. This solvent may not be used in combination with Hexane.		

PART III

Extraction solvents for which conditions of use are specified

Name	Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials
Diethyl ether	2 mg/kg
Hexane (*)	1 mg/kg
2-methyloxolane	1 mg/kg
Cyclohexane	1 mg/kg
Methyl acetate	1 mg/kg
Butan-1-ol	1 mg/kg
Butan-2-ol	1 mg/kg
Ethylmethylketone (*)	1 mg/kg
Dichloromethane	0,02 mg/kg
Propan-1-ol	1 mg/kg
1,1,1,2-tetrafluoroethane	0,02 mg/kg
Methanol	1.5 mg/kg
Propan-2-ol	1 mg/kg
(*) The combined use of Hexane and Ethylmethylketone is forbidden.	

PART IV

Specific purity criteria for the extraction solvents

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)".

