SCHEDULE 2

Regulation 3(9)

New Schedule 4A to the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013

"SCHEDULE 4A

Regulations 10, 11 and 14

Extraction solvents which may be used during the processing of raw materials, of food, of food components or of food ingredients

Table 1

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

Name:
Propane
Butane
Ethyl Acetate
Ethanol
Carbon dioxide
Acetone ⁽²⁾
Nitrous oxide

- (1) 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.
- (2) Acetone is not permitted for use in the refining of olive-pomace oil.

Table 2 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 ⁽¹⁾	Production or fractionation of fats and oils and production of cocoa butter	

- (1) Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. Combined use of Hexane and Ethymethylketone is not permitted.
- (2) The level of n-Hexane in this solvent should not exceed 50 mg/kg. Combined use of Hexane and Ethymethylketone is not permitted.
- (3) '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 laying down specific hygiene rules for food of animal origin.
- (4) '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.

0

Name	Conditions of use (summary description of extraction)	Maximum residue limits in the extracted foodstuff or food ingredient
	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 ⁽²⁾	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 ⁽³⁾	0.009 mg/kg in the defatted animal protein products including gelatine
	Preparation of collagen ⁽⁴⁾ and collagen derivatives, except gelatine	3 mg/kg in the collagen and collagen derivatives, except gelatine

⁽¹⁾ Hexane means a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C. Combined use of Hexane and Ethymethylketone is not permitted.

⁽²⁾ The level of n-Hexane in this solvent should not exceed 50 mg/kg. Combined use of Hexane and Ethymethylketone is not permitted.

^{(3) &#}x27;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 laying down specific hygiene rules for food of animal origin.

^{(4) &#}x27;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.

Table 3

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⁾	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⁾	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"

⁽¹⁾ Combined use of Hexane and Ethymethylketone is not permitted.