
SCOTTISH STATUTORY INSTRUMENTS

2022 No. 373

**AGRICULTURE
FOOD**

**The Food and Feed (Miscellaneous
Amendments) (Scotland) Regulations 2022**

Made - - - - 13th December 2022
Laid before the Scottish
Parliament - - - - 15th December 2022
Coming into force - - 9th February 2023

The Scottish Ministers make these Regulations in exercise of the powers conferred by Articles 9(1), 13(6) and 18A(3) of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition⁽¹⁾ and paragraph 1(1) and (3) of schedule 2 and paragraph 21(b) of schedule 7 of the European Union (Withdrawal) Act 2018⁽²⁾ and all other powers enabling them to do so.

There has been consultation as required by Article 9 of Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽³⁾.

PART 1

Introduction

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Food and Feed (Miscellaneous Amendments) (Scotland) Regulations 2022 and come into force on 9 February 2023.

(2) These Regulations extend to Scotland only.

(1) EUR 1831/2003 as relevantly amended by S.I. 2019/654 and 2022/377. Article 9 was substituted by S.I. 2019/654 and amended by S.I. 2022/377. Article 13 was substituted and article 18A was added by S.I. 2019/654. The terms “prescribe” and “appropriate authority” are defined in Article 2 of EUR 1831/2003.

(2) 2018 c. 16. Section 8 was amended by section 27 of the European Union (Withdrawal Agreement) Act 2020 (c. 1); paragraph 21 of schedule 7 was amended by paragraph 53 of Part 2 of schedule 5 of that Act.

(3) EUR 178/2002 as amended by S.I. 2019/641. S.I. 2019/641 was amended by S.I. 2020/1504.

PART 2

Amendment of feed additives authorisations legislation

Amendment of Commission Implementing Regulation (EU) No. 787/2013

2.—(1) Commission Implementing Regulation (EU) No. 787/2013 concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Kemin Europa N.V.)(4) is amended in accordance with this regulation.

(2) In the Annex, in the table, in the column headed “Additive”, for “*Bacillus velezensis*” substitute “*Bacillus velezensis*”.

Amendment of Commission Implementing Regulation (EU) 2015/1020

3.—(1) Commission Implementing Regulation (EU) 2015/1020 concerning the authorisation of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying (holder of the authorisation Kemin Europa NV)(5) is amended in accordance with this regulation.

(2) In the Annex, in the table, in the column headed “Additive”, for “*Bacillus velezensis*” substitute “*Bacillus velezensis*”.

Amendment of Commission Implementing Regulation (EU) 2017/2276

4.—(1) Commission Implementing Regulation (EU) 2017/2276 concerning the authorisation of a new use of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for sows (holder of the authorisation Kemin Europa N.V.)(6) is amended in accordance with this regulation.

(2) In the Annex, in the table, in the column headed “Composition, chemical formula, description, analytical method”, for “*Bacillus velezensis*” substitute “*Bacillus velezensis*”.

Amendment of the Feed Additives (Authorisations) (Scotland) Regulations 2022

5.—(1) The Feed Additives (Authorisations) (Scotland) Regulations 2022(7) are amended in accordance with this regulation.

(2) In regulation 8(3) (transitional provision: *Saccharomyces cerevisiae* (identification number 4b1702)) after “the prior authorisation” means” insert “an authorisation contained in”.

(3) In regulation 9(5) (transitional: *Bacillus velezensis* (identification number 4b1823)) after “the prior authorisation” means” insert “an authorisation contained in”.

(4) In regulation 10(2) (transitional: Decoquate (Deccox®) (identification number 51756i (formerly E756))) after “the prior authorisation” means” insert “an authorisation contained in”.

(5) In schedule 1 (authorisation of a preparation of manganese chelate of lysine and glutamic acid (identification number 3b509) as a feed additive for all animal species), in the table—

(a) in column 2, in the eighth row—

(i) in paragraph 1—

(aa) in the first bullet point, for “6869:2000” substitute “6869:2001”,

(4) EUR 787/2013.

(5) EUR 2015/1020.

(6) EUR 2017/2276.

(7) S.S.I. 2022/288.

- (bb) at the end of the second bullet point, omit “or”,
- (cc) at the end of the third bullet point, omit “.”,
- (dd) at the end, insert—
- “; or
- Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) in accordance with international standard BS EN 17053: 2018 entitled “Animal feeding stuffs: Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS (multi-method)”⁽⁸⁾.”,
- (ii) in paragraph 2—
- (aa) at the end of the third bullet point omit “or”,
- (bb) in the fourth bullet point, after “15621” insert “: 2017”,
- (cc) at the end of the fourth bullet point, omit “.”,
- (dd) at the end, insert—
- “; or
- Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) in accordance with international standard BS EN 17053: 2018.”,
- (iii) in paragraph 3, at the end of the bullet point, insert “in accordance with BS EN ISO 13903:2005 entitled “*Animal feeding stuffs. Determination of amino acids content*”⁽⁹⁾”,
- (iv) in paragraph 4, for “For proving the chelated structure” substitute “For determination of the chelated form”,
- (b) in column 1, in the penultimate row, for “*Manganese chelate of lysine and glutamic acid*” substitute “*element (Mn)*”.
- (6) In schedule 3 (authorisation of a preparation of serine protease produced by *Bacillus licheniformis* DSM 19670 (identification number 4a13) as a feed additive for chickens for fattening) in the table, in column 2—
- (a) in the first row, after “Serine protease” insert “(EC 3.4.21-)”,
- (b) in the third row, for “in Switzerland” substitute “(Switzerland)”,
- (c) for “3.4.21.⁻¹”, in each place it occurs, substitute “3.4.21.-”.
- (7) In schedule 4 (renewal of authorisation of pyridoxine hydrochloride (vitamin B6) (identification number 3a831) as a feed additive for all animal species), in the table, in column 2, in the sixth row, for “C₈H₁₁NO₃·HCl” substitute “C₈H₁₁NO₃·HCl”.
- (8) In schedule 5 (renewal of authorisation (with modification) of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 (ACTISAF® Sc 47) (identification number 4b1702) as a feed additive for calves for rearing)—
- (a) in the heading—
- (i) omit “(with modification)”,
- (ii) omit “(ACTISAF® Sc 47)”,

⁽⁸⁾ Under reference BS EN ISO 17053: 2018, it was published as a UK standard by the British Standards Institution on 28 February 2018 (ISBN 978 0 580 94471 0).

⁽⁹⁾ This standard was approved by the European Committee for Standardization (CEN) on 19 April 2005. Under reference BS EN ISO 13903:2005, it was published as a UK standard by the British Standards Institution on 24 October 2005 (ISBN 0 580 46218 8).

(b) in the table, in the first row, in column 2, after “CNCM I-4407” omit “(ACTISAF® Sc 47)”.

(9) In schedule 6 (renewal of authorisation (with modification) of a preparation of *Bacillus velezensis* (ATCC PTA-6737) (identification number 4b1823) as a feed additive for chickens for fattening, chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches, and its authorisation as a feed additive extending existing uses to cover all minor poultry species (except for laying), ornamental birds, sporting birds and game birds), in the table, in column 2—

(a) in the eighth row, in paragraph 1—

- (i) after “(colony count)” insert “in the feed additive, premixtures, feed materials and compound feed”,
- (ii) for “feed samples” substitute “feed samples(10)”,

(b) in the final row—

- (i) after “Lasalocid” insert “A sodium”,
- (ii) for “Maduramycin” substitute “Maduramicin ammonium”,
- (iii) after “Monensin” insert “sodium”,
- (iv) after “Robenidine” insert “hydrochloride”,
- (v) after “Salinomycin” insert “sodium”.

(10) In schedule 7 (authorisation of a preparation of *Bacillus licheniformis* DSM 28710 (identification number 4b1828) as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds), in the table, in column 2, in the eighth row, in paragraph 1 for “additive, premixture and feed” substitute “feed additive, premixtures, feed materials and compound feed”.

(11) In schedule 8 (renewal of authorisation of a preparation of *Clostridium butyricum* (FERM BP-2789) (identification number 4b1830) as a feed additive for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, and its authorisation as a feed additive for chickens for fattening, suckling pigs and suckling minor porcine species)—

(a) in the heading for “pigs” substitute “piglets”,

(b) in the table, in column 2—

- (i) in the eighth row, in paragraph 1, after “(colony count)” insert “in the feed additive, premixtures, feed materials and compound feed”,
- (ii) in the ninth row, for “piglets and piglets of minor porcine species” substitute “piglets (suckling and weaned) and minor porcine species (suckling and weaned)”,
- (iii) in the final row—
 - (aa) after “Lasalocid” insert “A sodium”,
 - (bb) after “Robenidine” insert “hydrochloride”.

(12) In schedule 9 (authorisation of a preparation of 6-phytase (EC 3.1.3.26) (identification number 4a32) as a feed additive for all poultry species, ornamental birds, piglets, pigs for fattening, sows and minor porcine species for fattening or reproduction), in the table, in column 2, in the seventh row, before “*Komagataella phaffi*” insert “fermentation with”.

(13) In schedule 10 (authorisation of Decoquinat (Deccox®) (identification number 51756i) as a feed additive for chickens for fattening), in the table, in column 2—

(10) This method is not suitable for the detection of *Bacillus velezensis* ATCC PTA-6737 in feed materials and compound feed at concentrations below the minimum content level.

- (a) in the eighth row—
 - (i) in paragraph 1 for “and feed” substitute “, feed materials and compound feed”,
 - (ii) in paragraph 2 for “(RP-HPLC-MS/MS)” substitute “(RP-HPLC-MS/MS(11))”,
 - (b) in the final row, in paragraphs 1 and 2, before “additive” insert “feed”.
- (14) In schedule 11 (authorisation of Decoquinat (Avi-Deccox® 60G) (identification number 51756ii) as a feed additive for chickens for fattening), in the table, in column 2—
- (a) in the seventh row for “CAS No: 185-7-89-6” substitute “CAS No: 18507-89-6”,
 - (b) in the eighth row, in paragraph 1, for “and feed” substitute “, feed materials and compound feed”,
 - (c) in the final row, in paragraphs 1 and 2, before “additive” insert “feed”.

PART 3

Amendment of miscellaneous food and feed legislation

Amendment of the Animal Feed (Scotland) Regulations 2010

- 6.—(1) The Animal Feed (Scotland) Regulations 2010(12) are amended in accordance with this regulation.
- (2) In regulation 2 (interpretation and scope)—
 - (a) in paragraph (1)—
 - (i) omit the definition of “Directive 82/475”,
 - (ii) omit the definition of “Directive 2002/32”,
 - (b) in paragraph (3) omit “Directive 82/475, Directive 2002/32”.
 - (3) In regulation 4(2) (enforcement of requirements of Regulation 767/2009) for “the Annex to Directive 82/475” substitute “schedule 3”.
 - (4) In regulation 8 (interpretation of Part 4 of the Regulations) omit paragraph (a).
 - (5) In regulation 9 (control of animal feeds containing undesirable substances)—
 - (a) in paragraph (1)—
 - (i) in sub-paragraph (a) for “feed that is specified in column 2 of Annex I” substitute “products intended for animal feed that are specified in column 2 of a table in schedule 4”,
 - (ii) in the words after sub-paragraph (b), for “Annex” substitute “table”,
 - (b) in paragraph (2)—
 - (i) in sub-paragraph (a) for “Annex I” substitute “a table in schedule 4”,
 - (ii) in sub-paragraph (b) for “Annex” substitute “table”,
 - (c) in paragraph (3)—
 - (i) for “Annex I” substitute “a table in schedule 4”,
 - (ii) for “Annex”, in the second place it occurs, substitute “table”,

(11) “Safety and efficiency of Deccox (decoquinat) for chickens for fattening”. Published by the European Food Safety Authority (EFSA) in the EFSA Journal, Volume 17, Issue 1 on 14 January 2019. This document is available at the following address: <https://www.efsa.europa.eu/en/efsajournal/pub/5541>.

(12) S.S.I. 2010/373, last amended by S.S.I. 2020/467.

- (d) in paragraph (5)—
 - (i) for “Annex I” substitute “a table in schedule 4”,
 - (ii) for “Annex”, in the second place it occurs, substitute “table”,
- (e) in paragraph (7)—
 - (i) omit the “and” at the end of sub-paragraph (c),
 - (ii) after sub-paragraph (d) insert—
 - “; and
 - (e) peat; leonardite”,
- (f) after paragraph (8) insert—
 - “(9) In order to reduce or eliminate sources of undesirable substances in products intended for animal feed, the feed authority must, in cooperation with feed business operators(13), carry out investigations to identify the sources of undesirable substances, in cases where the maximum levels are exceeded and in cases where increased levels of such substances are detected, taking into account background levels; for the purpose of ensuring a uniform approach in cases of increased levels, action thresholds to trigger investigations are set out in table in schedule 5.”.
- (6) Schedule 1 has effect.

Amendment of the Materials and Articles in Contact with Food (Scotland) Regulations 2012

7.—(1) The Materials and Articles in Contact with Food (Scotland) Regulations 2012(14) are amended in accordance with this regulation.

- (2) In regulation 2 (interpretation)—
 - (a) in paragraph (1)—
 - (i) omit the definition of “Directive 84/500/EEC”,
 - (ii) omit the definition of “Directive 2007/42/EC”,
 - (b) in paragraph (3)—
 - (i) omit “or to any Annex to Directive 2007/42/EC”,
 - (ii) omit “or that Annex”.
- (3) In regulation 11(interpretation of this part) omit paragraph (3).
- (4) In regulation 12 (controls and limits)—
 - (a) in paragraph (1)—
 - (i) in both places where it occurs, for “Annex II” substitute “schedule 6”,
 - (ii) for “that Annex” substitute “that schedule”,
 - (b) in paragraph (2) for “Annex II” substitute “schedule 6”.
- (5) Schedule 2 has effect.

Amendment of the Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013

8.—(1) The Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013(15) are amended in accordance with this regulation.

(13) See article 3(2)(a) of EUR 2009/767 for the meaning of “feed business operator”.

(14) S.S.I. 2012/318 as relevantly amended by S.S.I. 2019/52.

(15) S.S.I. 2013/266 as relevantly amended by S.S.I. 2019/53 and S.S.I. 2020/372.

- (2) In regulation 2 (interpretation)—
 - (a) in paragraph (1) omit the definition of “Directive 2009/32”,
 - (b) in paragraph (2) omit “EU”,
 - (c) in paragraph (3) omit “EU”,
 - (d) in paragraph (4) for “EU instruments are Directive 2009/32,” substitute “instruments are”,
 - (e) in paragraph (5) in the definition of “the EU Regulations” before “EU” insert “retained”.
- (3) Omit regulation 7 (controls on extraction solvents).
- (4) In regulation 8(a), for “Annex I” substitute “schedule 6”.
- (5) In regulation 9(a)—
 - (a) in sub-paragraph (i), for “Annex I” substitute “schedule 6”,
 - (b) in sub-paragraph (ii), for “that Annex” substitute “schedule 6”,
 - (c) in sub-paragraph (iii), insert “and” at the end,
 - (d) in sub-paragraph (iv), omit “and” at the end,
 - (e) omit sub-paragraph (v).
- (6) In regulation 12(1)(a), for “Annex I” substitute “schedule 6”.
- (7) In regulation 14 (enforcement authorities), before “EU Regulations” insert “retained”.
- (8) In regulation 17(2) (application of various provisions of the Food Safety Act 1990), before “EU Regulations” insert “retained”.
- (9) Schedule 3 has effect.

Amendment of the Food Information (Scotland) Regulations 2014

9.—(1) The Food Information (Scotland) Regulations 2014(16) are amended in accordance with this regulation.

(2) In schedule 3 (specified provisions of FIC, Regulation 828/2014 and Regulation 2018/775), in the table in Part 1 (specified FIC provisions applying on and from 13th December 2014), omit—

- (a) the entry relating to Article 17(2) (use of the name used for food in member State of production in another member State: need for other descriptive information in addition to the name of the food in certain cases),
- (b) the entry relating to Article 17(3) (prohibition in certain exceptional cases of the use of a name used for a food in a member State of production when marketing that food in another member State).

St Andrew’s House,
Edinburgh
13th December 2022

MAREE TODD
Authorised to sign by the Scottish Ministers

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SCHEDULE 1

Regulation 6(6)

Insertion of schedules 3, 4 and 5 of the Animal Feed (Scotland) Regulations 2010

1. After schedule 2 (revocations) of the Animal Feed (Scotland) Regulations 2010 insert—

“SCHEDULE 3

Regulation 4(2)

Categories of feed materials which may be indicated in place of individual feed materials on the packaging, container or label of compound feedingstuffs for pet animals

Description of the category	Definition
1. Meat and animal derivatives	All the fleshy parts of slaughtered warm-blooded land animals, fresh or preserved by appropriate treatment, and all products and derivatives of the processing of the carcase or parts of the carcase of warm-blooded land animals
2. Milk and milk derivatives	All milk products, fresh or preserved by appropriate treatment, and derivatives from their processing
3. Eggs and egg derivatives	All egg products fresh or preserved by appropriate treatment and derivatives from their processing
4. Oils and fats	All animal and vegetable oils and fats
5. Yeasts	All yeasts, the cells of which have been killed and dried
6. Fish and fish derivatives	Fish or parts of fish, fresh or preserved by appropriate treatment, and derivatives from their processing
7. Cereals	All types of cereal, regardless of their presentation, or products made from the starchy endosperm
8. Vegetables	All types of vegetables and legumes, fresh or preserved by appropriate treatment
9. Derivatives of vegetable origin	Derivatives resulting from the treatment of vegetable products, in particular cereals, vegetables, legumes and oil seeds
10. Vegetable protein extracts	All products of vegetable origin in which the proteins have been concentrated by an adequate process to contain at least 50% crude protein, as related to the dry matter, and which may be restructured (textured)
11. Minerals	All inorganic substances suitable for animal feed
12. Various sugars	All types of sugar

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Description of the category	Definition
13. Fruit	All types of fruit, fresh or preserved by appropriate treatment
14. Nuts	All kernels from shells
15. Seeds	All types of seeds as such or roughly crushed
16. Algae	Algae, fresh or preserved by appropriate treatment
17. Molluscs and crustaceans	All types of molluscs, crustaceans, shellfish, fresh or preserved by appropriate treatment, and their processing derivatives
18. Insects	All types of insects and their stages of development
19. Bakery products	All bread, cakes, biscuits and pasta products

SCHEDULE 4

Regulation 9

Maximum levels of undesirable substances

Table 1: INORGANIC CONTAMINANTS AND NITROGENOUS COMPOUNDS

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%
1. Arsenic ⁽¹⁾	Feed materials	2
	with the exception of:	
	— meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp,	4
	— palm kernel expeller,	4
	— peat; leonardite,	5
	— phosphates, calcareous marine algae,	10
	— calcium carbonate; calcium and magnesium carbonate ⁽²⁾ ; calcareous marine shells,	15
— magnesium oxide; magnesium carbonate,	20	
— fish, other aquatic animals and products derived from them,	25	

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	— seaweed meal and feed materials derived from seaweed.	40
	Iron particles used as tracer.	50
	Feed additives belonging to the functional group of compounds of trace elements with the exception of:	30
	— cupric sulphate pentahydrate; cupric carbonate; dicopper chloride trihydroxide; ferrous carbonate; dimanganese chloride trihydroxide,	50
	— zinc oxide; manganous oxide; cupric oxide.	100
	Complementary feed with the exception of:	4
	— mineral feed,	12
	— complementary feed for pet animals containing fish, other aquatic animals and products derived from them and/or seaweed meal and feed materials derived from seaweed,	10
	— long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed,	30
	Complete feed with the exception of:	2
	— complete feed for fish and fur animals,	10
	— complete feed for pet animals containing fish, other aquatic animals and products derived from them and/or seaweed meal and	10

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	feed materials derived from seaweed.	
2. Cadmium	Feed materials of vegetable origin.	1
	Feed materials of animal origin.	2
	Feed materials of mineral origin	2
	with the exception of:	
	— phosphates.	10
	Feed additives belonging to the functional group of compounds of trace elements	10
	with the exception of:	
	— cupric oxide, manganous oxide, zinc oxide and manganous sulphate monohydrate.	30
	Feed additives belonging to the functional groups of binders and anti-caking agents.	2
	Premixtures. ⁽³⁾	15
	Complementary feed	0.5
	with the exception of:	
	— mineral feed	
	— containing < 7% phosphorus ⁽⁴⁾	5
	— containing ≥ 7% phosphorus ⁽⁴⁾	0.75 per 1% phosphorus ⁽⁴⁾ , with a maximum of 7.5
	— complementary feed for pet animals,	2
	— long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed.	15
	Complete feed	0.5
	with the exception of:	

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	— complete feed for cattle (except calves), sheep (except lambs), goats (except kids) and fish, — complete feed for pet animals.	1 2
3. Fluorine ⁽⁵⁾	Feed materials with the exception of: — feed materials of animal origin except marine crustaceans such as marine krill; calcareous marine shells, — marine crustaceans such as marine krill, — phosphates, — calcium carbonate, calcium and magnesium carbonate, ⁽²⁾ — magnesium oxide, — calcareous marine algae. Vermiculite (E 561). Complementary feed: — containing ≤ 4% phosphorus ⁽⁴⁾ , — containing > 4% phosphorus ⁽⁴⁾ . Complete feed with the exception of: — complete feed for pigs, — complete feed for poultry (except chicks) and fish, — complete feed for chicks, — complete feed for cattle, sheep and goats — in lactation, — other.	150 500 3 000 2 000 350 600 1 250 3 000 500 125 per 1% phosphorus ⁽⁴⁾ 150 100 350 250 30 50
4. Lead ⁽⁶⁾	Feed materials with the exception of:	10

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	<ul style="list-style-type: none"> — forage⁽⁷⁾, — phosphates, calcareous marine algae and calcareous marine shells, — calcium carbonate, calcium and magnesium carbonate⁽²⁾, — yeasts. 	<ul style="list-style-type: none"> 30 15 20 5
	<p>Feed additives belonging to the functional group of compounds of trace elements with the exception of:</p> <ul style="list-style-type: none"> — zinc oxide, — manganous oxide, ferrous carbonate, cupric carbonate, copper (I) oxide. 	<ul style="list-style-type: none"> 100 400 200
	<p>Feed additives belonging to the functional groups of binders and anti-caking agents with the exception of:</p> <ul style="list-style-type: none"> — clinoptilolite of volcanic origin; natrolite-phonolite. 	<ul style="list-style-type: none"> 30 60
	<p>Premixtures.⁽³⁾</p>	<ul style="list-style-type: none"> 200
	<p>Complementary feed with the exception of:</p> <ul style="list-style-type: none"> — mineral feed, — long-term supply formulations of feed for particular nutritional purposes with a concentration of trace elements higher than 100 times the established maximum content in complete feed. 	<ul style="list-style-type: none"> 10 15 60
	<p>Complete feed.</p>	<ul style="list-style-type: none"> 5
5. Mercury ⁽⁸⁾	<p>Feed materials with the exception of:</p> <ul style="list-style-type: none"> — fish, other aquatic animals and products derived from them intended for the 	<ul style="list-style-type: none"> 0.1 0.5

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	<p>production of compound feed for food producing animals,</p> <p>— fish, other aquatic animals and products derived from them intended for the production of compound feed for dogs, cats, ornamental fish and fur animals,</p> <p>— fish, other aquatic animals and products derived from them as canned wet feed material for direct feeding of dogs and cats,</p> <p>— calcium carbonate, calcium and magnesium carbonate⁽²⁾.</p> <p>Compound feed with the exception of:</p> <p>— mineral feed,</p> <p>— compound feed for fish,</p> <p>— compound feed for dogs, cats, ornamental fish and fur animals.</p>	<p>1.0⁽⁹⁾</p> <p>0.3</p> <p>0.3</p> <p>0.1</p> <p>0.2</p> <p>0.2</p> <p>0.3</p>
6. Nitrite ⁽¹⁰⁾	<p>Feed materials with the exception of:</p> <p>— fishmeal,</p> <p>— silage,</p> <p>— products and by-products from sugar beet and sugarcane and from starch and alcoholic drink production.</p> <p>Complete feed with the exception of:</p> <p>— complete feed for dogs and cats with a moisture content exceeding 20%.</p>	<p>15</p> <p>30</p> <p>—</p> <p>—</p> <p>15</p> <p>—</p>
7. Melamine ⁽¹¹⁾	<p>Feed with the exception of:</p> <p>— canned pet food,</p>	<p>2.5</p> <p>2.5⁽¹²⁾</p>

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	<ul style="list-style-type: none"> — the following feed additives: — guanidino acetic acid (GAA), — urea, — biuret. 	<ul style="list-style-type: none"> 20 — —

- (1) The maximum levels refer to total arsenic.
- (2) Calcium and magnesium carbonate refers to the natural mixture of calcium carbonate and magnesium carbonate as described in [Commission Regulation \(EU\) No 68/2013](#) on the Catalogue of feed materials¹⁷.
- (3) The maximum level established for premixtures takes into account the additives with the highest level of lead and cadmium and not the sensitivity of the different animal species to lead and cadmium. As provided in Article 16 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition, in order to protect animal and public health¹⁸, it is the responsibility of the producer of premixtures to ensure that, in addition to compliance with the maximum levels for premixtures, the instructions for use of the premixture are in accordance with the maximum levels for complementary and complete feed.
- (4) The % of phosphorus is relative to a feed with a moisture content of 12%.
- (5) Maximum levels refer to an analytical determination of fluorine, whereby extraction is performed with hydrochloric acid 1 N for 20 minutes at ambient temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.
- (6) For the determination of lead in kaolinitic clay and in feed containing kaolinitic clay, the maximum level refers to an analytical determination of lead, whereby extraction is performed in nitric acid (5% w/w) for 30 minutes at boiling temperature. Equivalent extraction procedures can be applied for which it can be demonstrated that the used extraction procedure has an equal extraction efficiency.
- (7) Forage includes products intended for animal feed such as hay, silage, fresh grass, etc.
- (8) The maximum levels refer to total mercury.
- (9) The maximum level is applicable on wet weight basis.
- (10) The maximum levels are expressed as sodium nitrite.
- (11) The maximum level refers to melamine only. The inclusion of the structurally related compounds cyanuric acid, ammeline and ammelide in the maximum level will be considered at a later stage.
- (12) The maximum level is applicable to canned pet food as sold.

Table 2: MYCOTOXINS

<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
1. Aflatoxin B1	<ul style="list-style-type: none"> Feed materials Complementary and complete feed with the exception of: <ul style="list-style-type: none"> — compound feed for dairy cattle and calves, dairy sheep and lambs, dairy goats and kids, piglets and young poultry animals, 	<ul style="list-style-type: none"> 0.02 0.01 0.005

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	— compound feed for cattle (except dairy cattle and calves), sheep (except dairy sheep and lambs), goats (except dairy goats and kids), pigs (except piglets) and poultry (except young animals).	0.02
2. Rye ergot (<i>Claviceps purpurea</i>)	Feed materials and compound feed containing unground cereals.	1 000

Table 3: INHERENT PLANT TOXINS

<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
1. Free gossypol	Feed materials with the exception of: — cottonseed, — cottonseed cakes and cottonseed meal. Complete feed with the exception of: — complete feed for cattle (except calves), — complete feed for sheep (except lambs) and goats (except kids), — complete feed for poultry (except laying hens) and calves, — complete feed for rabbits, lambs, kids and pigs (except piglets).	20 6 000 1 200 20 500 300 100 60
2. Hydrocyanic acid	Feed materials with the exception of:	50

(1) The maximum levels are expressed as allyl isothiocyanate.

(2) Upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of total glucosinolates is lower than 30 mmol/kg. The method of analysis of reference is EN-ISO 9167:2019 (Rapeseed and rapeseed meals — Determination of glucosinolates content — Method using high-performance liquid chromatography); published by the International Organization for Standardization in May 2019, edition 1. Available from the ISO website <https://www.iso.org>.

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	— linseed, — linseed cakes, — manioc products and almond cakes. Complete feed with the exception of: — complete feed for young chickens (< 6 weeks).	250 350 100 50 10
3. Theobromine	Complete feed with the exception of: — complete feed for pigs, — complete feed for dogs, rabbits, horses and fur animals.	300 200 50
4. vinyl thioxazolidone (5-vinyloxazolidine-2-thione)	Complete feed for poultry with the exception of: — complete feed for laying hens.	1 000 500
5. Volatile mustard oil ⁽¹⁾	Feed materials with the exception of: — Camelina seed and products derived from it ⁽²⁾ , products derived from mustard seed ⁽²⁾ , rape seed and products derived from them. Complete feed with the exception of: — complete feed for cattle (except calves), sheep (except lambs) and goats (except kids), — complete feed for pigs (except piglets) and poultry.	100 4 000 150 1 000 500

(1) The maximum levels are expressed as allyl isothiocyanate.

(2) Upon request of the competent authorities, the responsible operator must perform an analysis to demonstrate that the content of total glucosinolates is lower than 30 mmol/kg. The method of analysis of reference is EN-ISO 9167:2019 (Rapeseed and rapeseed meals — Determination of glucosinolates content — Method using high-performance liquid chromatography); published by the International Organization for Standardization in May 2019, edition 1. Available from the ISO website <https://www.iso.org>.

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Table 4: ORGANOCHLORINE COMPOUNDS (EXCEPT DIOXINS AND PCBs)

<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
1. Aldrin ⁽¹⁾	Feed materials and compound feed with the exception of: — fats and oils, — compound feed for fish.	0.01 ⁽²⁾ 0.1 ⁽²⁾ 0.02 ⁽²⁾
2. Dieldrin ⁽¹⁾	Feed materials and compound feed with the exception of: — fats and oils, — compound feed for fish.	0.01 ⁽²⁾ 0.1 ⁽²⁾ 0.02 ⁽²⁾
3. Camphechlor (toxaphene) – sum of indicator congeners CHB 26, 50 and 62 ⁽³⁾	Fish, other aquatic animals and products derived from them with the exception of: — fish oil. Complete feed for fish.	0.02 0.2 0.05
4. Chlordane (sum of cis- and trans-isomers and of oxychlordane, expressed as chlordane)	Feed materials and compound feed with the exception of: — fats and oils.	0.02 0.05
5. DDT (sum of DDT-, DDD- (or TDE-) and DDE-isomers, expressed as DDT)	Feed materials and compound feed with the exception of: — fats and oils.	0.05 0.5
6. Endosulfan (sum of alpha- and beta-isomers and of	Feed materials and compound feed	0.1

(1) Singly or combined expressed as dieldrin.

(2) Maximum level for aldrin and dieldrin, singly or combined, expressed as dieldrin.

(3) Numbering system according to Parlar, prefixed by either CHB or 'Parlar':

CHB 26: 2-endo,3-exo,5-endo,6-exo,8,8,10,10-octochlorobornane,

CHB 50: 2-endo,3-exo,5-endo,6-exo,8,8,9,10,10-nonachlorobornane,

CHB 62: 2,2,5,5,8,9,9,10,10-nonachlorobornane.

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Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%
endosulfansulphate expressed as endosulfan)	with the exception of: — cotton seed and products derived from its processing, except crude cotton seed oil, — soybean and products derived from its processing, except crude soybean oil, — crude vegetable oil, — complete feed for fish except for <i>Salmonids</i> , — complete feed for <i>Salmonids</i> .	0.3 0.5 1.0 0.005 0.05
7. Endrin (sum of endrin and of delta-ketoi-endrin, expressed as endrin)	Feed materials and compound feed with the exception of: — fats and oils.	0.01 0.05
8. Heptachlor (sum of heptachlor and of heptachlorepoxyde, expressed as heptachlor)	Feed materials and compound feed with the exception of: — fats and oils.	0.01 0.2
9. Hexachlorobenzene (HCB)	Feed materials and compound feed with the exception of: — fats and oils.	0.01 0.2
10. Hexachlorocyclo-hexane (HCH) — alpha-isomers	Feed materials and compound feed	0.02

(1) Singly or combined expressed as dieldrin.

(2) Maximum level for aldrin and dieldrin, singly or combined, expressed as dieldrin.

(3) Numbering system according to Parlar, prefixed by either CHB or 'Parlar':

CHB 26: 2-endo,3-exo,5-endo,6-exo,8,8,10,10-octochlorobornane,

CHB 50: 2-endo,3-exo,5-endo,6-exo,8,8,9,10,10-nonachlorobornane,

CHB 62: 2,2,5,5,8,9,9,10,10-nonachlorobornane.

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
— beta-isomers	with the exception of: — fats and oils.	0.2
	Feed materials	0.01
— gamma-isomers	with the exception of: — fats and oils.	0.1
	Compound feed	0.01
	with the exception of: — compound feed for dairy cattle.	0.005
	Feed materials and compound feed	0.2
	with the exception of: — fats and oils.	2.0

(1) Singly or combined expressed as dieldrin.

(2) Maximum level for aldrin and dieldrin, singly or combined, expressed as dieldrin.

(3) Numbering system according to Parlar, prefixed by either CHB or 'Parlar':

CHB 26: 2-endo,3-exo,5-endo,6-exo,8,8,10,10-octochlorobornane,

CHB 50: 2-endo,3-exo,5-endo,6-exo,8,8,9,10,10-nonachlorobornane,

CHB 62: 2,2,5,5,8,9,9,10,10-nonachlorobornane.

Table 5 (Part 1): DIOXINS AND PCBs

<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt)⁽¹⁾ relative to a feed with a moisture content of 12%</i>
1. Dioxins (sum of polychlorinated dibenzo- <i>para</i> -dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005) ⁽²⁾)	Feed materials of plant origin	0.75
	with the exception of: — vegetable oils and their by-products.	0.75
	Feed materials of mineral origin.	0.75

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Undesirable substance	Products intended for animal feed	Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt)⁽¹⁾ relative to a feed with a moisture content of 12%
	Feed materials of animal origin: <ul style="list-style-type: none"> — Animal fat, including milk fat and egg fat, 1.50 — Other land animal products including milk and milk products and eggs and egg products, 0.75 — Fish oil, 5.0 — Fish, other aquatic animals, and products derived from them with the exception of fish oil, hydrolysed fish protein containing more than 20% fat⁽³⁾ and crustacea meal, 1.25 — Hydrolysed fish protein containing more than 20% fat; crustacea meal. 1.75 Feed additives belonging to the functional groups of binders and anti-caking agents. ⁽⁴⁾ 0.75 Feed additives belonging to the functional group of compounds of trace elements. 1.0 Premixtures. 1.0 Compound feed 0.75 with the exception of: <ul style="list-style-type: none"> — compound feed for pet animals and fish, 1.75 — compound feed for fur animals. — 	
Undesirable substance	Products intended for animal feed.	Maximum content in ng WHO-PCDD/F-PCB-TEQ/kg (ppt)⁽¹⁾ relative to a feed with a moisture content of 12%.
2. Sum of dioxins and dioxin-like PCBs (sum of polychlorinated dibenzo- <i>para</i> -dioxins (PCDDs),	Feed materials of plant origin	1.25

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt)⁽¹⁾ relative to a feed with a moisture content of 12%</i>
<p>polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors), 2005⁽²⁾</p>	<p>with the exception of:</p> <ul style="list-style-type: none"> — vegetable oils and their by-products. 1.5 Feed materials of mineral origin. 1.0 Feed materials of animal origin: <ul style="list-style-type: none"> — Animal fat, including milk fat and egg fat, 2.0 — Other land animal products including milk and milk products and eggs and egg products, 1.25 — Fish oil, 20.0 — Fish, other aquatic animals, and products derived from them with the exception of fish oil and fish protein, hydrolysed, containing more than 20% fat,⁽³⁾ 4.0 — Fish protein, hydrolysed, containing more than 20% fat. 9.0 Feed additives belonging to the functional groups of binders and anti-caking agents. ⁽⁴⁾ 1.5 Feed additives belonging to the functional group of compounds of trace elements. 1.5 Premixtures. 1.5 Compound feed 1.5 <p>with the exception of:</p>	

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt)⁽¹⁾ relative to a feed with a moisture content of 12%</i>
	— compound feed for pet animals and fish, — compound feed for fur animals.	5.5 —
Undesirable substance	Products intended for animal feed.	Maximum content in µg/kg (ppb) relative to a feed with a moisture content of 12%.⁽¹⁾
3. Non-dioxin-like PCBs (sum of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153 and PCB 180 (ICES – 6) ⁽¹⁾)	Feed materials of plant origin.	10
	Feed materials of mineral origin.	10
	Feed materials of animal origin:	
	— Animal fat, including milk fat and egg fat,	10
	— Other land animal products including milk and milk products and eggs and egg products,	10
	— Fish oil,	175
	— Fish, other aquatic animals and products derived from them with the exception of fish oil and fish protein, hydrolysed, containing more than 20% fat, ⁽⁵⁾	30
	— Fish protein, hydrolysed, containing more than 20% fat.	50
	Feed additives belonging to the functional groups of binders and anti-caking agents. ⁽⁴⁾	10
	Feed additives belonging to the functional group of compounds of trace elements.	10
Premixtures.	10	
Compound feed	10	
with the exception of:		

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in ng WHO-PCDD/F-TEQ/kg (ppt)⁽¹⁾ relative to a feed with a moisture content of 12%</i>
	— compound feed for pet animals and fish, — compound feed for fur animals.	40 —

- (1) Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.
- (2) Table 5 (Part 2): Table of TEF (toxic equivalency factors) for dioxins, furans and dioxin-like PCBs: WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation (WHO) – International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organisation Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)).
- (3) Fresh fish and other aquatic animals directly delivered and used without intermediate processing for the production of feed for fur animals are not subject to the maximum levels, while maximum levels of 3.5 ng WHO-PCDD/F-TEQ/kg product and 6.5 ng WHO-PCDD/F-PCB-TEQ/kg product are applicable to fresh fish and 20.0 ng WHO-PCDD/F-PCB-TEQ/kg product is applicable to fish liver used for the direct feeding of pet animals, zoo and circus animals or used as feed material for the production of pet food. The products or processed animal proteins produced from these animals (fur animals, pet animals, zoo and circus animals) cannot enter the food chain and cannot be fed to farmed animals which are kept, fattened or bred for the production of food.
- (4) The maximum level is also applicable to the feed additives belonging to the functional groups of substances for the control of radionuclide contamination and substances for reduction of the contamination of feed by mycotoxins which also belong to the functional groups of binders and anti-caking agents.
- (5) Fresh fish and other aquatic animals directly delivered and used without intermediate processing for the production of feed for fur animals are not subject to the maximum levels, while maximum levels of 75 µg/kg product are applicable to fresh fish and 200 µg/kg product are applicable to fish liver used for the direct feeding of pet animals, zoo and circus animals or used as feed material for the production of pet food. The products or processed animal proteins produced from these animals (fur animals, pet animals, zoo and circus animals) cannot enter the food chain and cannot be fed to farmed animals which are kept, fattened or bred for the production of food.

Table 5 (Part 2): Table of TEF (toxic equivalency factors) for dioxins, furans and dioxin-like PCBs

<i>Congener</i>	<i>TEF value</i>
Dibenzo-<i>para</i>-dioxins ('PCDDs') and Dibenzo-<i>para</i>-furans (PCDFs)	
2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0003
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.03
2,3,4,7,8-PeCDF	0.3

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Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%
2. <i>Crotalaria</i> spp.	Feed materials and compound feed.	100
3. Seeds and husks from <i>Ricinus communis</i> L., <i>Croton tiglium</i> L. and <i>Abrus precatorius</i> L. as well as their processed derivatives ⁽¹⁾ , separately or in combination	Feed materials and compound feed.	10 ⁽²⁾
4. Unhusked beech mast — <i>Fagus sylvatica</i> L.	Feed materials and compound feed.	Seeds and fruit as well as their processed derivatives may only be present in feed in trace amounts not quantitatively determinable.
5. Purguera — <i>Jatropha curcas</i> L.	Feed materials and compound feed.	Seeds and fruit as well as their processed derivatives may only be present in feed in trace amounts not quantitatively determinable.
6. Seeds from Ambrosia spp.	Feed materials ⁽³⁾ with the exception of: – Millet (grains of <i>Panicum miliaceum</i> L.) and sorghum (grains of <i>Sorghum bicolor</i> (L) Moench s.l.) not directly fed to animals. ⁽³⁾ Compound feed containing unground grains and seeds.	50 200 50
7. Seeds from — Indian mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>integrifolia</i> (West.) Thell. — Sareptian mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>juncea</i> — Chinese mustard — <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>juncea</i> var. <i>lutea</i> Batalin — Black mustard — <i>Brassica nigra</i> (L.) Koch	Feed materials and compound feed.	Seeds may only be present in feed in trace amounts not quantitatively determinable.

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<i>Undesirable substance</i>	<i>Products intended for animal feed</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
— Ethiopian mustard — <i>Brassica carinata</i> A. Braun		

- (1) Insofar as determinable by analytical microscopy.
- (2) Includes also seed husk fragments.
- (3) Where unequivocal evidence is provided that the grains and seeds are intended for milling or crushing, there is no need to perform a cleaning of the grains and seeds containing non-compliant levels of seeds of *Ambrosia* spp. before milling or crushing on the condition that:

—the consignment is transported as a whole to the milling or crushing plant, and the milling or crushing plant is informed in advance of the presence of high levels of *Ambrosia* spp. seeds in order to take additional prevention measures to avoid dissemination into the environment,

—solid evidence is provided that prevention measures are taken to avoid dissemination of *Ambrosia* spp. seeds into the environment during transport to the crushing or milling plant, and

—the competent authority agrees to the transport, after having ensured that the abovementioned conditions are fulfilled.

In case these conditions are not fulfilled, the consignment must be cleared before any transport into the country and the screenings must be appropriately destroyed.

Table 7: AUTHORISED FEED ADDITIVES IN NON-TARGET FEED FOLLOWING UNAVOIDABLE CARRY-OVER

<i>Coccidiostat</i>	<i>Products intended for animal feed⁽¹⁾</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
1. Decoquinatate	Feed materials. Compound feed for: — laying birds and chickens reared for laying (> 16 weeks), — other animal species. Premixtures for use in feed in which the use of decoquinatate is not authorised.	0.4 0.4 1.2 (2)
2. Diclazuril	Feed materials. Compound feed for: — laying birds and chickens reared for laying (> 16 weeks), — rabbits for fattening and breeding for the period before slaughter in which the use of diclazuril is prohibited (withdrawal feed),	0.01 0.01 0.01

(1) Without prejudice to the authorised levels pursuant to Regulation (EC) No 1831/200319.

(2) The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50% of the maximum levels established in the feed when the instructions for use of the premixture are followed.

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<i>Coccidiostat</i>	<i>Products intended for animal feed⁽¹⁾</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	<p>— other animal species other than chickens reared for laying (< 16 weeks), chickens for fattening, guinea fowl and turkeys for fattening.</p> <p>Premixtures for use in feed in which the use of diclazuril is not authorised.</p>	0.03 ⁽²⁾
3. Halofuginone hydrobromide	<p>Feed materials.</p> <p>Compound feed for:</p> <p>— laying birds, chickens reared for laying and turkeys (> 12 weeks),</p> <p>— chickens for fattening and turkeys (< 12 weeks) for the period before slaughter in which the use of halofuginone hydrobromide is prohibited (withdrawal feed),</p> <p>— other animal species.</p> <p>Premixtures for use in feed in which the use of halofuginone hydrobromide is not authorised.</p>	0.03 0.03 0.03 0.09 ⁽²⁾
4. Lasalocid A sodium	<p>Feed materials.</p> <p>Compound feed for:</p> <p>— dogs, calves, rabbits, equine species, dairy animals, laying birds, turkeys (> 16 weeks) and chickens reared for laying (> 16 weeks),</p> <p>— chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 16 weeks) for the period before slaughter in which the use of lasalocid A sodium is prohibited (withdrawal feed),</p>	1.25 1.25 1.25

(1) Without prejudice to the authorised levels pursuant to Regulation (EC) No 1831/2003¹⁹.

(2) The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50% of the maximum levels established in the feed when the instructions for use of the premixture are followed.

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<i>Cocidiostat</i>	<i>Products intended for animal feed⁽¹⁾</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	<p>— pheasants, guinea fowl, quails and partridges (except laying birds) for the period before slaughter in which the use of lasalocid A sodium is prohibited (withdrawal feed),</p> <p>— other animal species.</p> <p>Premixtures for use in feed in which the use of lasalocid A sodium is not authorised.</p>	<p>1.25</p> <p>3.75</p> <p>⁽²⁾</p>
5. Maduramicin ammonium alpha	<p>Feed materials.</p> <p>Compound feed for:</p> <p>— equine species, rabbits, turkeys (> 16 weeks), laying birds and chickens reared for laying (> 16 weeks),</p> <p>— chickens for fattening and turkeys (< 16 weeks) for the period before slaughter in which the use of maduramicin ammonium alpha is prohibited (withdrawal feed),</p> <p>— other animal species.</p> <p>Premixtures for use in feed in which the use of maduramicin ammonium alpha is not authorised.</p>	<p>0.05</p> <p>0.05</p> <p>0.05</p> <p>0.15</p> <p>⁽²⁾</p>
6. Monensin sodium	<p>Feed materials.</p> <p>Compound feed for:</p> <p>— equine species, dogs, small ruminants (sheep and goat), ducks, bovine, dairy cattle, laying birds, chickens reared for laying (> 16 weeks) and turkeys (> 16 weeks),</p> <p>— chickens for fattening, chickens reared for laying (< 16 weeks) and turkeys (< 16</p>	<p>1.25</p> <p>1.25</p> <p>1.25</p>

(1) Without prejudice to the authorised levels pursuant to Regulation (EC) No 1831/200319.

(2) The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50% of the maximum levels established in the feed when the instructions for use of the premixture are followed.

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<i>Cocidiostat</i>	<i>Products intended for animal feed⁽¹⁾</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	weeks) for the period before slaughter in which the use of monensin sodium is prohibited (withdrawal feed), — other animal species. Premixtures for use in feed in which the use of monensin sodium is not authorised.	3.75 ⁽²⁾
7. Narasin	Feed materials. Compound feed for: — turkeys, rabbits, equine species, laying birds and chickens reared for laying (> 16 weeks), — other animal species. Premixtures for use in feed in which the use of narasin is not authorised.	0.7 0.7 2.1 ⁽²⁾
8. Nicarbazin	Feed materials. Compound feed for: — equine species, laying birds and chickens reared for laying (> 16 weeks), — other animal species. Premixtures for use in feed in which the use of nicarbazin (alone or in combination with narasin) is not authorised.	1.25 1.25 3.75 ⁽²⁾
9. Robenidine hydrochloride	Feed materials. Compound feed for: — laying birds and chickens reared for laying (> 16 weeks), — chickens for fattening, rabbits for fattening and breeding and turkeys for the period before slaughter in which the use of robenidine	0.7 0.7 0.7

(1) Without prejudice to the authorised levels pursuant to Regulation (EC) No 1831/200319.

(2) The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50% of the maximum levels established in the feed when the instructions for use of the premixture are followed.

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<i>Cocidiostat</i>	<i>Products intended for animal feed⁽¹⁾</i>	<i>Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12%</i>
	hydrochloride is prohibited (withdrawal feed), — other animal species. Premixtures for use in feed in which the use of robenidine hydrochloride is not authorised.	2.1 ⁽²⁾
10. Salinomycin sodium	Feed materials. Compound feed for: — equine species, turkeys, laying birds and chickens reared for laying (> 12 weeks), — chickens for fattening, chickens reared for laying (< 12 weeks) and rabbits for fattening for the period before slaughter in which the use of salinomycin sodium is prohibited (withdrawal feed), — other animal species. Premixtures for use in feed in which the use of salinomycin sodium is not authorised.	0.7 0.7 0.7 2.1 ⁽²⁾
11. Semduramicin sodium	Feed materials. Compound feed for: — laying birds and chickens reared for laying (> 16 weeks), — chickens for fattening for the period before slaughter in which the use of semduramicin sodium is prohibited (withdrawal feed), — other animal species. Premixtures for use in feed in which the use of semduramicin sodium is not authorised. ⁽²⁾	0.25 0.25 0.25 0.75 ⁽²⁾

(1) Without prejudice to the authorised levels pursuant to Regulation (EC) No 1831/2003¹⁹.

(2) The maximum level of the substance in the premixture is the concentration which shall not result in a level of the substance higher than 50% of the maximum levels established in the feed when the instructions for use of the premixture are followed.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

SCHEDULE 5

Regulation 9(9)

Action thresholds triggering investigations: dioxins and PCBs

Table 1: DIOXINS AND PCBS

<i>Undesirable substances</i>	<i>Products intended for animal feed</i>	<i>Action threshold in ng WHO-PCDD/F TEQ/kg (ppt)⁽²⁾ relative to a feedingstuff with a moisture content of 12%</i>	<i>Comments and additional information (e.g. nature of investigations to be performed)</i>
1. Dioxins (sum of polychlorinated dibenzo- <i>para</i> -dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005) ⁽¹⁾)	Feed materials of plant origin	0.5	(3)
	with the exception of: — vegetable oils and their by-products.	0.5	(3)
	Feed materials of mineral origin.	0.5	(3)
	Feed materials of animal origin: — Animal fat, including milk fat and egg fat,	0.75	(3)
	— Other land animal products including milk and milk products and eggs and egg products,	0.5	(3)
	— Fish oil,	4.0	(4)
	— Fish, other aquatic animals and products derived from them, with the exception of fish oil, hydrolysed fish protein containing	0.75	(4)

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<i>Undesirable substances</i>	<i>Products intended for animal feed</i>	<i>Action threshold in ng WHO-PCDD/F TEQ/kg (ppt)⁽²⁾ relative to a feedingstuff with a moisture content of 12%</i>	<i>Comments and additional information (e.g. nature of investigations to be performed)</i>
	<p>more than 20% fat and crustacea meal,</p> <p>— Hydrolysed fish protein containing more than 20% fat, crustacea meal.</p> <p>Feed additives belonging to the functional groups of binders and anti-caking agents.</p> <p>Feed additives belonging to the functional group of compounds of trace elements.</p> <p>Premixtures.</p> <p>Compound feed with the exception of:</p> <p>— compound feed for pet animals and fish,</p> <p>— compound feed for fur animals.</p>	<p>1.25</p> <p>0.5</p> <p>0.5</p> <p>0.5</p> <p>0.5</p> <p>1.25</p> <p>—</p>	<p>(4)</p> <p>(3)</p> <p>(3)</p> <p>(3)</p> <p>(3)</p> <p>(4)</p>
<p>2. Dioxin-like PCBs (sum of polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 2005)⁽¹⁾)</p>	<p>Feed materials of plant origin</p> <p>with the exception of:</p> <p>— vegetable oils and their by-products.</p> <p>Feed materials of mineral origin.</p>	<p>0.35</p> <p>0.5</p> <p>0.35</p>	<p>(3)</p> <p>(3)</p> <p>(3)</p>

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Undesirable substances	Products intended for animal feed	Action threshold in ng WHO-PCDD/F TEQ/kg (ppt)⁽²⁾ relative to a feedingstuff with a moisture content of 12%	Comments and additional information (e.g. nature of investigations to be performed)
	Feed materials of animal origin:		
	— Animal fat, including milk fat and egg fat,	0.75	(3)
	— Other land animal products including milk and milk products and eggs and egg products,	0.35	(3)
	— Fish oil,	11.0	(4)
	— Fish, other aquatic animals and products derived from them, with the exception of fish oil and fish protein, hydrolysed, containing more than 20% fat, ⁽³⁾	2.0	(4)
	— Fish protein, hydrolysed, containing more than 20% fat.	5.0	(4)
	Feed additives belonging to the functional groups of binders and anti-caking agents.	0.5	(3)
	Feed additives belonging to the functional group of compounds of trace elements.	0.35	(3)
	Premixtures.	0.35	(3)
	Compound feed	0.5	(3)
	with the exception of:		
	— compound feed for pet animals and fish, ⁽⁴⁾	2.5	(4)

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Undesirable substances	Products intended for animal feed	Action threshold in ng WHO-PCDD/F TEQ/kg (ppt)⁽²⁾ relative to a feedingstuff with a moisture content of 12%	Comments and additional information (e.g. nature of investigations to be performed)
	— compound feed for fur animals.	—	

- (1) Table 2: Table of TEF (toxic equivalency factors) for dioxins, furans and dioxin-like PCBs: WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation (WHO) – International Programme on Chemical Safety (IPCS) expert meeting which was held in Geneva in June 2005 (Martin van den Berg et al., The 2005 World Health Organisation Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. Toxicological Sciences 93(2), 223–241 (2006)).
- (2) Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.
- (3) Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination.
- (4) In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc., shall be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.

Table 2: Table of TEF (toxic equivalency factors) for dioxins, furans and dioxin-like PCBs

Congener	TEF value
Dibenzo-<i>para</i>-dioxins ('PCDDs') and Dibenzo-<i>para</i>-furans (PCDFs)	
2,3,7,8-TCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0003
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.03
2,3,4,7,8-PeCDF	0.3
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01

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<i>Congener</i>	<i>TEF value</i>
OCDF	0.0003
‘Dioxin-like’ PCBs: Non-ortho PCBs + Mono-ortho PCBs	
Non-ortho PCBs	
PCB 77	0.0001
PCB 81	0.0003
PCB 126	0.1
PCB 169	0.03
Mono-ortho PCBs	
PCB 105	0.00003
PCB 114	0.00003
PCB 118	0.00003
PCB 123	0.00003
PCB 156	0.00003
PCB 157	0.00003
PCB 167	0.00003
PCB 189	0.00003
Abbreviations used: ‘T’ = tetra; ‘Pe’ = penta; ‘Hx’ = hexa; ‘Hp’ = hepta; ‘O’ = octa; ‘CDD’ = chlorodibenzodioxin; ‘CDF’ = chlorodibenzofuran; ‘CB’ = chlorobiphenyl.”.	

SCHEDULE 2

Regulation 7(5)

Insertion of schedule 6 of the Materials and Articles in Contact with Food (Scotland) Regulations 2012

1. After schedule 5 of the Materials and Articles in Contact with Food (Scotland) Regulations 2012 insert—

“SCHEDULE 6

Regulation 12(1)

LIST OF SUBSTANCES AUTHORISED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM

1. In this schedule “regenerated cellulose film” means a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

2. Notes—

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—The percentages in this schedule, in the first and second parts, are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film.

—The usual technical denominations are given in square brackets.

—The substances used shall be of good technical quality as regards the purity criteria.

First Part: Uncoated regenerated cellulose film

Denominations	Restrictions
A. Regenerated cellulose	Not less than 72% (w/w).
B. Additives	
1. Softeners	Not more than 27% (w/w) in total.
—Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foodstuffs which are not moist, namely which do not contain water which is physically free at the surface. The total amount of bis(2-hydroxyethyl)ether and ethanediol present in foodstuffs that have been in contact with film of this type may not exceed 30 mg/kg of the foodstuff.
—Ethanediol [= monoethyleneglycol]	
—1.3-butanediol	
—Glycerol	
—1.2-propanediol [= 1.2 propyleneglycol]	
—Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1200.
—1.2-polypropylene oxide [= 1.2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1.3-propanediol content not greater than 1% (w/w) in substance.
—Sorbitol	
—Tetraethyleneglycol	
—Triethyleneglycol	
—Urea	
2. Other additives	Not more than 1% (w/w) in total.
First class	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film.
—Acetic acid and its NH ₄ , Ca, Mg, K and Na salts	
—Ascorbic acid and its NH ₄ , Ca, Mg, K and Na salts	

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Denominations	Restrictions
—Benzoic acid and sodium benzoate	
—Formic acid and its NH ₄ , Ca, Mg, K and Na salts	
—Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and the NH ₄ , Ca, Mg, K, Na, Al, Zn salts of these acids	
—Citric, d- and l-lactic, maleic, l-tartaric acids and their Na and K salts	
—Sorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
—Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids	
—Natural edible starches and flours	
—Edible starches and flours modified by chemical treatment	
—Amylose	
—Calcium and magnesium carbonates and chlorides	
—Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
—Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
—Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
—Mono-and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol	
—Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium	
—Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1200 and 4000.
—Sodium propionate	
Second class	The total quantity of the substances may not exceed 1 mg/dm ² of the uncoated film and the quantity of the

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Denominations	Restrictions
	substance or group of substances in each indent may not exceed 0.2 mg/dm ² (or a lower limit where one is specified) of the uncoated film.
—Sodium alkyl (C8-C18) benzene sulphonate	
—Sodium isopropyl naphthalene sulphonate	
—Sodium alkyl (C8-C18) sulphate	
—Sodium alkyl (C8-C18) sulphonate	
—Sodium dioctylsulphosuccinate	
—Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0.05 mg/dm ² of the uncoated film.
—Ammonium, magnesium and potassium lauryl sulphates	
—N,N'-distearoyl diaminoethane, N,N'-dipalmitoyl diaminoethane and N,N'-dioleoyl diaminoethane	
—2-heptadecyl-4,4-bis(methylene-stearate) oxazoline	
—Polyethylene-aminostearamide ethylsulphate	Not more than 0.1 mg/dm ² of the uncoated film.
Third class — Anchoring agent	The total quantity of substances may not exceed 1 mg/dm ² of the uncoated film.
—Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products: butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine	Free formaldehyde content not greater than 0.5 mg/dm ² of the uncoated film. Free melamine content not greater than 0.3 mg/dm ² of the uncoated film.
—Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0.5 mg/dm ² of the uncoated film. Free melamine content not greater than 0.3 mg/dm ² of the uncoated film.
—Cross-linked cationic polyalkyleneamines: (a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin, (b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine, (c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia,	In accordance with relevant legislation.

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Denominations	Restrictions
(d) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine, (e) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine	
—Polyethyleneamines and polyethyleneimines	Not more than 0.75 mg/dm ² of the uncoated film.
—Condensation product of urea-formaldehyde unmodified, or which may be modified with one or of the following products: aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite	Free formaldehyde content not greater than 0.5 mg/dm ² of the uncoated film.
Fourth class	The total quantity of substances may not exceed 0.01 mg/dm ² of the uncoated film.
—Products resulting from the reaction of the amines of edible oils with polyethylene oxide,	
—Monoethanolamine lauryl sulphate	

Second Part: Coated regenerated cellulose film

Denominations	Restrictions
A. Regenerated cellulose	See first part.
B. Additives	See first part.
C. Coating	
1. Polymers	The total quantity of substances may not exceed 50 mg/dm ² of the coating on the side in contact with foodstuffs.
—Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
—Cellulose nitrate	Not more than 20 mg/dm ² of the coating on the side in contact with foodstuffs; nitrogen content between 10.8% (w/w) and 12.2% (w/w) in the cellulose nitrate.
2. Resins	The total quantity of substances may not exceed 12.5 mg/dm ² of the coating on the side in contact with foodstuffs and solely for the

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Denominations	Restrictions
	preparation of regenerated cellulose films with cellulose nitrate based coatings.
—Casein	
—Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C2 to C6 polyvalent alcohols, or mixtures of these alcohols	
—Colophony and/or its products of polymerization, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/or 2.2 bis (4-hydroxyphenyl) propane formaldehyde and esterified with methyl ethyl or C2 to C6 polyvalent alcohols or mixtures of these alcohols	
—Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene and/or dipentene and/or diterpene and maleic anhydride	
—Edible gelatine	
—Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
—Natural gum [= damar]	
—Poly-beta-pinene [= terpenic resins]	
—Urea-formaldehyde resins (see anchoring agents)	
3. Plasticisers	The total quantity of substances may not exceed 6 mg/dm ² of the coating on the side in contact with foodstuffs.
—Acetyl tributyl citrate	
—Acetyl tri(2-ethylhexyl) citrate	
—Di-isobutyl adipate	
—Di-n-butyl adipate	
—Di-n-hexyl azelate	
—Dicyclohexyl phthalate	Not more than 4.0 mg/dm ² of the coating on the side in contact with foodstuffs.
—2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2 ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate is not to exceed:

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Denominations	Restrictions
	(a) 2.4 mg/kg of the foodstuff in contact with this type of film, or (b) 0.4 mg/dm ² in the coating on the side in contact with foodstuffs.
—Glycerol monoacetate [= monoacetin]	
—Glycerol diacetate [= diacetin]	
—Glycerol triacetate [= triacetin]	
—Di-butyl sebacate	
—Di-n-butyl tartrate	
—Di-isobutyl tartrate	
4. Other additives	The total quantity of substances are not to exceed 6 mg/dm ² in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs.
4.1. Additives listed in the first part	Same restrictions as in the first part (however the quantities in mg/dm ² refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs).
4.2. Specific coating additives	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs.
—1-hexadecanol and 1-octadecanol	
—Esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
—Montan waxes, comprising purified montanic (C26 to C32) acids and/or their esters with ethanediol and/or 1.3 butanediol and/or their calcium and potassium salts	
—Carnauba wax	
—Beeswax	
—Esparto wax	
—Candelilla wax	
—Dimethylpolysiloxane	Not more than 1 mg/dm ² of the coating on the side in contact with foodstuffs.
—Epoxydised soya-bean oil (oxirane content 6 to 8%)	

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Denominations	Restrictions
—Refined paraffin and microcrystalline waxes	
—Pentaerythritol tetrastearate	
—Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0.2 mg/dm ² of the coating on the side in contact with foodstuffs.
—Aliphatic acids (C8 to C20) esterified with mono- or di-(2-hydroxyethyl)amine	
—2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA]	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.
—2.6-di-tert.butyl-4-methylphenol butylated hydroxytoluene — BHT] [=	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.
—Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.
5.Solvents	The total quantity of substances may not exceed 0.6 mg/dm ² of the coating on the side in contact with foodstuffs.
—Butyl acetate	
—Ethyl acetate	
—Isobutyl acetate	
—Isopropyl acetate	
—Propyl acetate	
—Acetone	
—1-butanol	
—Ethanol	
—2-butanol	
—2-propanol	
—1-propanol	
—Cyclohexane	
—Ethyleneglycol monobutyl ether	
—Ethyleneglycol monobutyl ether acetate	
—Methyl ethyl ketone	
—Methyl isobutyl ketone	
—Tetrahydrofuran	
—Toluene	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs. ”.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

SCHEDULE 3

Regulation 8(9)

Insertion of schedule 6 of the Food Additives, Flavourings,
Enzymes and Extraction Solvents (Scotland) Regulations 2013

1. After schedule 5 the Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 insert—

“SCHEDULE 6

Regulation 8(a)

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

Table 2: Extraction solvents to be used in compliance with good manufacturing practice for all uses

<i>Name⁽¹⁾</i>
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) The use of Acetone in the refining of olive-pomace oil is forbidden.

Table 3: Extraction solvents for which conditions of use are specified

<i>Name</i>	<i>Conditions of use (summary description of extraction)</i>	<i>Maximum residue limits in the extracted foodstuff or food ingredient</i>
Hexane ⁽¹⁾	Production or fractionation of fats and oils and production of cocoa butter	1 mg/kg in the fat or oil or 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. The combined use of Hexane and Ethylmethylketone is forbidden.
- (2) The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.
- (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 origin²⁰.
- (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 853/2004²¹.

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<i>Name</i>	<i>Conditions of use (summary description of extraction)</i>	<i>Maximum residue limits in the extracted foodstuff or food ingredient</i>
	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	1mg/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 and collagen derivatives, except gelatine ⁽⁴⁾	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. The combined use of Hexane and Ethylmethylketone is forbidden.
- (2) The level of n-Hexane in this solvent should not exceed 50 mg/kg. The combined use of Hexane and Ethylmethylketone is forbidden.
- (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 origin²⁰.
- (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 853/2004²¹.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Table 4: Extraction solvents for which conditions of use are specified

<i>Name</i>	<i>Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials</i>
Diethyl ether	2 mg/kg
Hexane (*)	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.”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

Regulations 2, 3 and 4 amend Commission Implementing Regulations (EU) No’s 787/2013, 2015/1020 and 2017/2276, respectively, to make minor corrections which relate to amendment to those Commission Implementing Regulations made by the Feed Additives (Authorisations) (Scotland) Regulations 2022.

Regulation 5 makes minor corrections to the Feed Additives (Authorisations) (Scotland) Regulations 2022.

Regulation 6 and schedule 1 amend the Animal Feed (Scotland) Regulations 2010 (2010 Regulations) with the effect that the Annex to Commission Directive [82/475/EEC](#) laying down the categories of feed materials which may be used for the purposes of labelling compound feeding stuffs for pet animals (OJ L 213, 21.7.1982, p. 27–28) is replicated as new schedule 3 of the 2010 Regulations and Annexes 1 and 2 to [Directive 2002/32/EC](#) of the European Parliament and of the Council on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10–22) are replicated as new schedules 4 and 5 of the 2010 Regulations.

Regulation 7 and schedule 2 amend the Materials and Articles in Contact with Food (Scotland) Regulations 2012 with the effect that Annexes 1 and 2 to Commission [Directive 2007/42/EC](#) relating

to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (OJ L 172, 30.6.2007, p. 71–82) are replicated in a new schedule 6 of those Regulations.

Regulation 8 and schedule 3 amend the Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013 with the effect that Annex 1 to [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 (OJ L 141, 6.6.2009, p. 3–11) is replicated in a new schedule 6 to those Regulations.

Regulation 9 amends the Food Information (Scotland) Regulations 2014 to remove redundant references to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.

A business and regulatory impact assessment has not been produced for this instrument as no significant impact on the private or voluntary sector is foreseen.