Agricultural Compounds and Veterinary Medicines Amendment Regulations 2007

Anand Satyanand, Governor-General

Order in Council

At Wellington this 2nd day of July 2007

Present:
His Excellency the Governor-General in Council

Pursuant to section 75 of the Agricultural Compounds and Veterinary Medicines Act 1997, His Excellency the Governor-General, acting on the advice and with the consent of the Executive Council and on the recommendation of the Minister for Food Safety, makes the following regulations.

Contents

Regulations

1 Title

These regulations are the Agricultural Compounds and Veterinary Medicines Amendment Regulations 2007.

2 Commencement

These regulations come into force on 2 August 2007.

3 Principal regulations amended

These regulations amend the Agricultural Compounds and Veterinary Medicines Regulations 2001.

4 Interpretation

(1) The definition of **antisapstain** in regulation 3 is revoked.

(2) The definition of **fertiliser additive** in regulation 3 is amended by—

(a) omitting from paragraph (a) "to land by itself" and substituting "by itself to land or plants"; and

(b) omitting from paragraph (a)(ii) "the biological activity of soil" and substituting "biological activity".

(3) Regulation 3 is amended by inserting the following definition in its appropriate alphabetical order:

"**oral gastrointestinal-acting microflora-enhancing compound** means a substance ingested by an animal, or a preparation intended for oral administration to an animal, solely to modify the conditions of the animal's gastrointestinal tract to maintain or produce a normal or favourable microflora population".

(4) Regulation 3 is amended by adding the following definition:

"**topical**, in relation to a substance or preparation, means the substance or preparation is applied only to the surface of the body, which—

"(a) includes the skin, hoof, nail, or hair; but

"(b) does not include the eye or the ear canal."

5 New regulation 8A inserted

The following regulation is inserted after regulation 8:

"**8A Oral gastrointestinal-acting microflora-enhancing compounds conditions**

Compounds may be imported, manufactured, sold, or used as oral gastrointestinal-acting microflora-enhancing compounds without registration under section 21 or 27 of the Act if the conditions in Schedule 4A are complied with."

6 New Schedules 1 and 2 substituted

Schedules 1 and 2 are revoked and the Schedules 1 and 2 set out in Schedule 1 of these regulations are substituted.

7 Schedule 3 revoked

Schedule 3 is revoked.

8 New Schedule 4A inserted

The Schedule 4A set out in Schedule 2 of these regulations is inserted after Schedule 4.

9 New Schedule 7 substituted

Schedule 7 is revoked and the Schedule 7 set out in Schedule 3 of these regulations is substituted.

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Schedule 1
New Schedules 1 and 2 substituted in principal regulations

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Schedule 1
Agricultural compounds exempt from registration under sections 21 and 27 of Act if applicable codes of practice complied with

1 Compounds (including homeopathic, herbal, chemical, and oral nutritional compounds) prepared by a person for use by the person as an agricultural compound on animals or plants owned by the person, or in any land, place, or water owned or occupied by the person.

The following compounds are excluded unless there is an applicable code of practice in force under section 28 of the Act:

(a) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981):

(b) antibiotic active ingredients:

(c) hormones:

(d) substances that are prohibited by countries importing New Zealand primary produce:

(e) vertebrate toxic agents.

2 Homeopathic plant compounds used commercially.

3 Non-medicated topical hoof preparations used solely to maintain or improve hoof condition.

4 Non-medicated topical skin preparations used solely to maintain or improve skin condition.

5 Non-absorbable masking agents used to disguise odours.

6 Topical non-absorbable and non-solvent cleaning products, including non-medicated shampoos, soaps, tear-stain removers, and toothpaste.

7 *In vitro* diagnostics used to confirm the presence or absence of disease or as an aid in the diagnosis of disease or abnormal conditions.

8 Compounds used in the production of plant tissue cultures.

Schedule 1—*continued*

9 Compounds (not containing biologically active ingredients) used to protect plant grafts or plant wounds.

10 Vertebrate and invertebrate attractants and repellants that are not applied directly to animals or plants.

11 Invertebrate mating disrupters that are not applied directly to animals or plants.

12 Compounds used in the post-harvest treatment of wood-producing crops.

13 A preparation of 2 or more ingredients if each ingredient is an agricultural compound described in this schedule and the combination of ingredients does not increase or change any of the risks described in section 19 of the Act.

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Schedule 2
Agricultural compounds exempt from registration under sections 21 and 27 of Act if conditions in column 2 and requirements in regulation 6 complied with

Column 1 Agricultural compound	Column 2 Conditions
Oral and topical preparations— (a) prepared by a process of solution, extraction, or titration of an active ingredient followed by strictly regimented serial dilution; and (b) that do not claim to prevent, control, or cure a specific disease characterised by pain or distress in animals	If used as a veterinary medicine, the label information must— (a) identify the compound as a homeopathic preparation; and (b) include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice
Oral and topical preparations— (a) prepared from either any part of a plant or an unrefined extract from a plant, except a plant listed in Schedule 6; and (b) that do not claim to prevent, control, or cure a specific disease characterised by pain or distress in animals; and (c) that do not claim to have pharmacological or anabolic effects, or to modify the physiological function of an animal	If used as a veterinary medicine, the label information must— (a) identify the compound as a herbal preparation; and (b) include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice Must not be used on the teats of lactating animals if the milk of the animals is intended for human consumption
Markers, paints, and dyes used as pigments or colourants for topical application to identify animals temporarily	
Over-the-counter first aid preparations, including general disinfectants, antiseptics, and sanitisers	Must not be used on the teats of lactating animals if the milk of the animals is intended for human consumption
Preparations scheduled as pharmacy-only, prescription, or restricted medicines under the Medicines Act 1981, and used as veterinary medicines	Preparations must not be used on animals except under the direct care, authority, or prescription of a veterinarian The veterinarian must act in accordance with any applicable code of practice in force under section 28 of the Act

Schedule 2—*continued*

Column 1 Agricultural compound	Column 2 Conditions
Preparations compounded and used by veterinarians	Preparations must not be used on animals except under the direct care, authority, or prescription of a veterinarian The veterinarian must act in accordance with any applicable code of practice in force under section 28 of the Act
A substance or biological compound or a mix of substances or biological compounds (to which this schedule does not otherwise apply) to be used as a veterinary medicine	May be imported only if the Director-General is satisfied that— (a) there is no equivalent veterinary medicine registered under the Act; and (b) it is required to ensure the immediate welfare of animals Must not contain any substance or biological compound that is prohibited from use as an agricultural compound Must not be used on animals except under the direct care, authority, or prescription of a veterinarian The veterinarian must act in accordance with any applicable code of practice in force under section 28 of the Act
Topical preparations— (a) containing ingredients not able to be absorbed through the skin; and (b) used solely to treat minor injuries or to prevent dermatological abnormalities; and (c) that do not include any of the following ingredients: (i) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981): (ii) antibiotic active ingredients: (iii) hormones: (iv) substances that are prohibited by countries importing New Zealand primary produce	Must not be used on the teats of lactating animals if the milk of the animals is intended for human consumption Must be manufactured in accordance with good manufacturing practice

Schedule 2—*continued*

Column 1 Agricultural compound	Column 2 Conditions
Topical hoof preparations— (a) containing ingredients that act only on the surface to which they are applied; and (b) used solely to treat or prevent minor injuries or abnormalities of the surface of the hoof; and (c) that do not include any of the following ingredients: (i) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981): (ii) antibiotic active ingredients: (iii) substances that are prohibited by countries importing New Zealand primary produce	Must be manufactured in accordance with good manufacturing practice
Non-medicated antidiarrhoeal preparations that— (a) are used solely as gastrointestinal adsorbent or protectant agents; and (b) do not make claims in relation to binding any specific micro-organism or toxin	Must be manufactured in accordance with good manufacturing practice The label information must include statements that— (a) the preparation is suitable for use without veterinary advice only in the treatment of minor cases of diarrhoea; and (b) the preparation will not treat dehydration; and (c) if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice
Non-medicated orally and rectally administered laxatives and lubricants	Must be manufactured in accordance with good manufacturing practice The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice

Schedule 2—*continued*

Column 1 Agricultural compound	Column 2 Conditions
Non-medicated moist or dry poultice preparations that— (a) are used to treat or prevent inflammation, swelling, or pain solely by heating or cooling, or drawing fluid from, the affected area; and (b) are intended for use on intact skin or minor wounds	Must be manufactured in accordance with good manufacturing practice The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice
Cauterising preparations used or applied superficially	Must be manufactured in accordance with good manufacturing practice The label must include a statement that, if the preparation fails to stop bleeding, the user should seek veterinary advice
Urinary tract modifiers (acidifiers and alkalisers) that are oral preparations used solely for modification of urinary pH	Must not be used on animals from which animal material is intended to be used for the production of human food or human pharmaceutical products Must be manufactured in accordance with good manufacturing practice Must be packaged for sale in dosage-size packages (not in bulk or concentrated form) appropriate for the animals for which the agricultural compound is recommended
Respiratory tract modifiers (expectorants and cough suppressants) that— (a) have only a locally acting, superficial effect on the respiratory tract; and (b) are given orally, applied topically to the nose, or inhaled; and (c) are used solely in companion animals to promote mucolysis, for cough suppression (by alleviating only irritation), and to relieve compromised airways and upper respiratory tract congestion	Must not be used on animals from which animal material is intended to be used for the production of human food or human pharmaceutical products Must be manufactured in accordance with good manufacturing practice Must be packaged for sale in dosage-size packages (not in bulk or concentrated form) appropriate for the animals for which the agricultural compound is recommended
Compounds used to extend animal semen or to be used as media for animal ova	An applicable code of practice must be in force under section 28 of the Act and must be complied with

Schedule 2—*continued*

Column 1 Agricultural compound	Column 2 Conditions
Spray markers that are coloured indicators to show where liquid agri-chemicals have been applied to help prevent overlaps	Must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment
Plant compound adjuvants, including wetting and sticking agents, pH buffers, drift retardants, and water conditioners	Must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment
Repellants applied directly to plants and used solely to repel vertebrates or invertebrates	Must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment
Attractants applied directly to plants and used solely to attract vertebrates or invertebrates	Must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment
Mating disrupters applied directly to plants and used solely to interfere with the reproduction of invertebrates	Must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment
Anti-transpirants used solely to prevent drying of plants	Must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment
Frost protectants of a chemical nature used solely to prevent frost damage	Must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment
Sunblocks used solely to prevent or reduce sunburn in plants	Must not be used on food crops unless they do not produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment

Schedule 2—*continued*

Column 1 Agricultural compound	Column 2 Conditions
Plant compounds used solely— (a) in home gardens or amenity horticulture; and (b) on plants that are not intended to be used as food for humans or animals	The label must clearly state that the product must not be used on crops intended for consumption by humans or animals

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Schedule 2
New Schedule 4A inserted in principal regulations

r 8A

Schedule 4A
Oral gastrointestinal-acting microflora-enhancing compounds exempt from registration under sections 21 and 27 of Act if following conditions complied with

1 The compounds must be supplied with a label containing the following information:

(a) trade name:

(b) the name and address of the producer, if applicable:

(c) the name and address of the manufacturer, if applicable:

(d) ingredients:

(e) directions for use, including the species, type, and class of animal for which use is intended:

(f) details of any precautions to be taken to prevent or manage risks described in section 19 of the Act when being used, particularly potential hazards to animals fed with or exposed to them:

(g) batch number, if applicable:

(h) manufacturing date, if applicable:

(i) use-by date or expiry date, if applicable.

2 The compounds must be fit for the purpose of feeding or administering to the species, type, and class of animal specified under clause 1(e).

3 The compounds are fit for their purpose only if they are used as recommended and do not do any of the following:

(a) produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment:

(b) result in toxic reactions causing pain or distress in the animal:

(c) result in malnutrition causing pain or distress in the animal:

(d) result in physical harm causing pain or distress in the animal:

Schedule 4A—*continued*

(e) contain pathogenic micro-organisms at levels that could cause disease resulting in pain or distress in the animal.

4 The compounds must not make therapeutic or pharmacological claims to prevent, treat, or cure any disease characterised by pain or distress in animals.

5 The compounds must contain only ingredients that—

(a) are described in Schedule 7; and

(b) comply with any relevant limitations specified in that schedule.

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Schedule 3
New Schedule 7 substituted in principal regulations

Schedules 4, 4A

Schedule 7
Substances generally recognised as safe feed additives in oral nutritional compounds or safe ingredients in oral gastrointestinal-acting microflora-enhancing compounds

Interpretation

A reference to a substance is to all forms of the substance unless a chemical abstract (CAS) number is specified or otherwise stated. Where the first column refers to an organism (including plants), the reference means the whole or any part or any extract of the organism.

General limitations

Each substance in this schedule is subject to the following limitations:

- that it is included in a trade name product formulated in accordance with good manufacturing practice; and
- that it is of an appropriate grade, and the amount added to the product must not exceed the amount reasonably required to accomplish the intended technical effect.

Substance	Identification (CAS number)	Limitations
Acacia (gum arabic)	9000-01-5	
Acetaldehyde	75-07-0	
Acetic acid	64-19-7	
Acetoin	513-86-0	
Acetophenone	98-86-2	
Adipic acid	124-04-9	
Aldehyde C-18	104-61-0	
Allura red	25956-17-6	
Almond shell meal		
Aloe vera	8001-97-6	
alpha-galactosidase	9025-35-8	From the following sources: *Aspergillus niger* var, *Morteirella vinaceae* var *raffinoutiliser*, *Saccharomyces* spp

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
alpha-pinene	7785-70-8	No more than 2% of a pesticide formulation
Aluminium hydroxide	21645-51-2	
Amaranth	915-67-3	
Ammonium chloride	12125-02-9	
Ammonium formate	540-69-2	
Ammonium hydroxide	1336-21-6	
Ammonium phosphate (dibasic)	7783-28-0	
Ammonium phosphate (monobasic)	7722-76-1	
Ammonium propionate	17496-08-1	
Ammonium sulphate	7783-20-2	
Amyl butyrate	540-18-1	
Amylase	9000-92-4	From the following sources: animal pancreatic tissue, *Aspergillus oryzae* var, *A. niger* var, *Bacillus amyloliquefaciens*, *B. lentus*, *B. licheniformis*, *B. licheniformis* containing a *B. stearothermophilus* gene for alpha-amylase, *B. stearothermophilus*
Anethole	4180-23-8	
p-Anisaldehyde	123-11-5	
Aniseed oil	8007-70-3	
Anisole	100-66-3	
Ascorbic acid	50-81-7	
Ascorbyl palmitate	137-66-6	
Aspartame	22839-47-0	
Aspergillus niger	68038-55-1	
Aspergillus oryzae	68038-56-2	
Astaxanthin	472-61-7	
Bacillus licheniformis	68038-66-4	
Bacillus subtilis	68038-70-0	Non-pathogenic strains
Baliospermum montanum		
Beeswax	8012-89-3	
Beetroot		
Bentonite	1302-78-9	
Benzaldehyde	100-52-7	
Benzoic acid	65-85-0	No more than 0.1% of final feed

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Benzyl acetate	140-11-4	
Benzyl alcohol	100-51-6	
Benzyl benzoate	120-51-4	
Benzyl paraben	94-18-8	
beta-apo-8-carotenoic acid, ethyl ester	1109-11-1	
beta-carotene		
beta-glucanase	9074-98-0	From the following sources: *Aspergillus niger* var, *Bacillus lentius*, *B. subtilis*, *B. amyloliquefaciens* var, *Humicola insolens*, *Trichoderma longibrachiatum*, *Penicillium funiculosum*
Betaine hydrochloride	590-46-5	
Bifidobacterium spp		
Birch oil	8001-88-5	
Boerhavia diffusa		
Brilliant black BN	2519-30-4	
Brilliant blue FCF	3844-45-9	
Bromolain	9001-00-7	
Bronopol	52-51-7	
Brown HT	4556-89-3	
Butyl paraben	94-26-8	
Butylated hydroxy-anisole	25013-16-5	Total content of antioxidants to be no more than 0.02% fat content of final feed
Butylated hydroxy-toluene	128-37-0	Total content of antioxidants to be no more than 0.02% fat content of final feed
Butylidenephthalide	551-08-6	
Butyric acid	107-92-6	
Calcium carbonate	471-34-1	
Calcium caseinate	9005-43-0	
Calcium chloride	10035-04-8	
Calcium disodium EDTA	62-33-9	
Calcium formate	544-17-2	
Calcium hydroxide	1305-62-0	
Calcium lactate	814-80-2	
Calcium lignosulfonate	8061-52-7	
Calcium methyl paraben	40167-95-1	

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Calcium oxide	1305-78-8	
Calcium propionate	4057-81-4	
Calcium propyl paraben	83542-69-2	
Calcium silicate	1344-95-2	
Calcium sulphate	7778-18-9	
Camphor	76-22-2	No more than 5% of any premix used in production of animal feeds
Candida pintolepesii		
Canthaxanthin	514-78-3	
Capric (decanoic) acid	334-48-5	
Caproic acid	142-62-1	
Caprylic acid	124-07-2	
Capsanthin	465-42-9	
Capsicum oleoresin	8023-77-6	
Caramel		
Caraway		
Carbon black	1333-86-4	
Carminic acid (cochineal)	1260-17-9	
Carmosine	3567-69-9	
Carnauba wax	8015-86-9	
Carophyll pink	514-78-3	
Carrageenan	9000-07-1	
Cassia gum	5373-11-5 or 8013-11-4	
Cayenne pepper		
Cedrus deodara		
Cellulase	9012-54-8	From the following sources: *Aspergillus niger* var, *Bacillus lentus*, *Humicola insolens*, *Trichoderma longibrachiatum*, *T. reesei*
Cellulose	9004-34-6	
Charcoal, activated	16291-96-6	
CharSol C 10	87139-45-5	
Chitosan	9012-76-4	
Chlorophyll	1406-65-1	
Choline chloride	67-48-1	
Chromium proprionates		
Chymotrypsin	9004-07-3	
Cinnamic aldehyde	104-55-2	
Cinnamon		

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Citranaxanthin		
Citric acid	77-92-9	
Clove oil	8000-34-8	
Cobalt carbonate	513-79-1	
Copper carbonate	1184-64-1	
Cryptoxanthin	465-42-9	
Curcuma domestica		
Curcuma longa		
Cyperus scarriosus		Specify source
Dandelion		
Diacetyl	431-03-8	
Diatomaceous earth	7631-86-9	
Dicalcium phosphate	7757-93-9	
2,4-Dichlorobenzyl alcohol	1777-82-8	To be used as a preservative only
Didecyl dimethyl ammonium bromide	2390-68-3	
Dimethyl polysiloxane	9016-00-6	
Disodium EDTA	139-33-3	No more than 240 mg/kg in final feed
Disodium guanylate	5550-12-9	
Disodium inosinate	4691-65-0	
Disodium succinate	150-90-3	
Dolomite	16389-88-1	
Echinacea		
Elephantopus scaber		
Embelia ribes		No more than 5% of any premix used in production of animal feeds
Enterococcus faecium		
Erythorbic acid	89-65-6	
Erythrosine	16423-68-0	
Ethoxyquin	91-53-2	No more than 0.015% of final feed
Ethyl acetate	141-78-6	
Ethyl alcohol	64-17-5	No more than 10% of the formulation
Ethyl butyrate	105-54-4	
Ethyl cellulose	9004-57-3	
Ethyl formate	109-94-4	
Ethyl heptanoate	106-30-9	
Ethyl lactate	97-64-3	
Ethyl paraben	120-47-8	
Ethyl phenylacetate	101-97-3	

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Ethyl propionate	105-37-3	
Ethyl sorbate	2396-84-1	
Ethyl vanillin	121-32-4	
Ethylene diamine tetra-acetic acid (EDTA)	60-00-4	
Ethyl-o-aminobenzoate	87-25-2	
Eugenol	97-53-0	
Fennel	8006-84-6	
Fenugreek		
Ferric chloride	7705-08-0	
Ferrous oxide	1345-25-1	
Ferrous sulphate	7720-78-7	
Food starch and modified food starch	9005-25-8	Use at a level not in excess of the amount reasonably required to accomplish the intended effect
Formaldehyde	50-00-0	No more than 0.25% of final feed
Formic acid	64-18-6	
Fumaric acid	110-17-8	
Furaneol	3658-77-3	
gamma nonalactone	104-61-0	
gamma undecalactone	104-67-6	
Garlic	8000-78-0	
Ginger	8007-08-7	
Glucose	50-99-7	Includes dextrose and its hydrated and anhydrous forms
Glutamic acid	56-86-0	
Glycerides (mono and di)		
Glycerine	56-81-5	
Glycerol	56-81-5	
Glycerol monooleate	25496-72-4	
Glycerol monostearate	31566-31-1	
Glycerol poly-ethyleneglycolricin-oleate		
Glycerol triacetate	102-76-1	
Green S	3087-16-9	
Guar gum	9000-30-0	
Gypsum	10101-41-4	
Haematococcus algae		

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Hemicellulase	9025-56-3	From the following sources: *Aspergillus niger* var, *A. aculeatus*, *Bacillus lentus*, *B. subtilis* var, *Humicola insolens*, *Trichoderma longibrachiatum*
2-Hexenal	505-57-7	
Holarrhena antidysenterica	90045-74-2	
Hydrogenated palm stearine	11099-07-3	
Hydroxypropyl cellulose	9004-64-2	
i-carrageenan	9062-07-1	
Indigo carmine (indigotine)	860-22-0	
Inulin	9005-80-5	
Iron oxides (black)	1317-61-9	
Iron oxides (red)	1309-37-1	
Iron oxides (yellow)	51274-00-1	
Isoamyl acetate	123-92-2	
Isoamyl isovalerate	659-70-1	No more than 1 ppm in final feed
Iso-eugenol	97-54-1	
Isopropyl alcohol	67-63-0	
Kaolin	1332-58-7	
k-carrageenan	11114-20-8	
Kombu seaweed		
Konjac gum	9000-36-6	
Lactic acid	50-21-5	
Lactobacillus acidophilus	68333-16-4	
Lactobacillus bifidus		
Lactobacillus bulgaricus	68333-15-3	
Lactobacillus casei	68333-14-2	
Lactobacillus delbrueckii subsp *lactis*	68919-91-5	
Lactobacillus fermentum		
Lactobacillus plantarum		
Lactobacillus rhannosus		

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Lactose	63-42-3	
Lauric acid	143-07-7	
Lecithin	8002-43-5	
Lemon grass		
Lemon oil	8008-56-8	
Licorice (*Glycyrrhiza*)		Includes all licorice derivatives. No more than 0.1% of final feed
Lignosulphonate	8062-15-5	
Lime oil	8008-26-2	
Limonene	138-86-3	
Linalool	78-70-6	
Lipase	9001-62-1	From the following sources: animal pancreatic tissue, *Aspergillus niger* var, *A. oryzae* var, *Candida rugosa*, *Rhizopus* spp, edible forestomach of calves, kids, and lambs
Locust bean gum	9000-40-2	
Lutein	57-83-0	
Lycopene	502-65-8	
Macrogol esters (polyethylene esters)	9000-99-3	
Magnesium acetate	142-72-3	Includes hydrated forms. Only added to the levels needed
Magnesium aluminium silicate	1327-43-1	Includes hydrated forms. Only added to the levels needed
Magnesium aspartate	18962-61-3	Includes hydrated forms. Only added to the levels needed
Magnesium carbonate	546-93-0	Includes hydrated forms. Only added to the levels needed
Magnesium chloride	7791-18-6	Includes hydrated forms. Only added to the levels needed
Magnesium citrate	3344-18-1	Includes hydrated forms. Only added to the levels needed
Magnesium gluconate	3632-91-5	Includes hydrated forms. Only added to the levels needed
Magnesium glutamate	64407-99-4	Includes hydrated forms. Only added to the levels needed
Magnesium glycerophosphate	927-20-8	Includes hydrated forms. Only added to the levels needed
Magnesium hydroxide	1309-42-8	Includes hydrated forms. Only added to the levels needed

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Magnesium hypophosphite	13446-24-7	Includes hydrated forms. Only added to the levels needed
Magnesium orotate	34717-03-8	Includes hydrated forms. Only added to the levels needed
Magnesium oxide	1309-48-4	Includes hydrated forms. Only added to the levels needed
Magnesium phosphate	10043-83-1	Includes hydrated forms. Only added to the levels needed
Magnesium silicate	1343-88-0	Includes hydrated forms. Only added to the levels needed
Magnesium stearate	557-04-0	Includes hydrated forms. Only added to the levels needed
Magnesium sulphate	7487-88-9	Includes hydrated forms. Only added to the levels needed
Magnesium trisilicate	14987-04-3	Includes hydrated forms. Only added to the levels needed
Malic acid	6915-15-7	
Maltodextrin	9050-36-6	
Maltol	118-71-8	Use at a level not in excess of the amount reasonably required to accomplish the intended effect
Mannan endo-1,4-beta-mannosidase	37288-54-3	From the following sources: *Aspergillus niger* var, *Bacillus lentus*, *Trichoderma longibrachiatum*. For use in poultry feed only
Mannitol	87-78-5	
Marigold (Aztec)		
Menthol	89-78-1	Not for use in cats
Metalloproteinase		From *Bacillus subtilis* var
Methyl alcohol	67-56-1	
6-Methyl-5-hepten-2-one	110-93-0	
Methyl paraben	99-76-3	
3-Methyl-3-phenyl glycidic acid, ethyl ester	77-83-8	
Methyl salicylate	119-36-8	
Mineral oil (high viscosity)		
Mineral oil (medium and low viscosity)	8012-95-1	No more than 0.06% of final feed
Monoisopropyl citrate	1321-57-9	

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Monopotassium phosphate	7778-77-0	
Monosodium glutamate	142-47-2	
Myrica nagi (bayberry)	8006-78-8	
Neohesperidine dihydrochalcone	20702-77-6	No more than 30 ppm in final feed
Neotame	165450-17-9	
Nonyl phenol ethoxylate	9016-45-9 or 26027-38-3	
Octyl gallate	1034-01-1	
Onion oil	8002-72-0	
Operculina turpethum		
Orange oil	8008-57-9	
Oregano		
Pancreatin	8049-47-6	
Papain	9001-73-4	
Paprika		
Para-formaldehyde	30525-89-4	*See* formaldehyde
Patent blue V	129-17-9 or 3536-49-0	
Pectinase	9032-75-1	
Pediococcus acidilactici		
Pediococcus pentosaceus		
Peppermint oil	8006-90-4	Not for use in cats
Pericol black	2519-30-4	
Phenylacetic acid	103-82-2	
Phosphoric acid	7664-38-2	
Phyllanthus emblica		
Phytase	9001-89-2	From the following sources: *Aspergillus niger* var, *A. oryzae* var, *Schizosaccharomyces pombe*
Picrorhiza kurroa		
Piper longum		
Piper nigrum		
Piper officinarum		
Pistacia integerrima		
Plumbago zeylanica		
Polyethylene oxide, polypropylene glycol block copolymer	9003-11-6	

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Polyoxethylene nonyl phenyl ester	9016-45-9	Only to be used as a wetting agent. No more than 0.5% of formulated product
Polyoxyethylene (20) sorbitan mono-laurate	9005-64-5	
Polyoxyethylene (20) sorbitan monooleate	9005-65-6	
Polyoxyethylene (35) castor oil	61791-12-6	
Polyoxyethylene sorbitan monopalmitate	9005-66-7	
Polyoxyethylene sorbitan mono-stearate	9005-67-8	
Polyvinylpyrrolidone	9003-39-8	
Ponceau 4R	2611-82-7	No more than 50 mg/kg in final feed
Potassium carbonate	584-08-7	
Potassium chloride	7447-40-7	
Potassium hydroxide	1310-58-3	
Potassium lactate	996-31-6	
Potassium lactate/sodium lactate mixture	996-31-6 and 72-17-3	
Potassium sorbate	590-00-1	
Propionic acid	79-09-4	
Propyl acetate	109-60-4	
Propyl alcohol	71-23-8	No more than 55 g/head/day
Propyl benzoate	2315-68-6	
Propyl gallate	121-79-9	Total content of antioxidants to be no more than 0.02% fat content of final feed
Propyl paraben	94-13-3	
Propylene glycol	57-55-6	
Protease	9001-92-7	From the following sources: *Aspergillus niger* var, *A. oryzae* var, *Bacillus amyloliquefaciens*, *B. licheniformis*, *B. subtilis* var, *B. subtilis* containing a *B. amyloliquefaciens* gene for protease, *Rhizopus* spp
Pumice	1332-09-8	

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Raffinase		
Rapeseed oil	8002-13-9	Includes hydrated forms
Rennet	9042-08-4	
Rosemary	8000-25-7	
Rosemary oleoresin		
Rum ether	8030-89-5	
Rutin	153-18-4	
Saccharin sodium	128-44-9	
Saccharomyces cerevisiae	68876-77-7	
Sage oil	8022-56-8	
Saponified marigold extract		
Saponified paprika extract		
Silica (silicon dioxide)	7631-86-9	
Silicone antifoam	63148-62-9	
Skatole	83-34-1	
Sodium acid pyrophosphate	7758-16-9	
Sodium alginate	9005-38-3	
Sodium alkyl benzene sulphonate	25155-30-0	No more than 0.2% in solution
Sodium aluminosilicate	1344-00-9	No more than 2% of final feed
Sodium ascorbate	134-03-2	
Sodium benzoate	532-32-1	No more than 0.1% of final feed
Sodium bicarbonate	144-55-8	
Sodium butyl paraben	36457-20-2	
Sodium carbonate	497-19-8	
Sodium carboxy methylcellulose	9004-32-4	
Sodium chloride	7647-14-5	
Sodium citrate	68-04-2	
Sodium cyclamate	139-05-9	
Sodium erythorbate	6381-77-7	
Sodium formate	141-53-7	
Sodium fumarate	7704-73-6	
Sodium hexametaphosphate	10124-56-8	
Sodium hydroxide	1310-73-2	No more than 0.5% of final feed

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Sodium lignosulphonate	8061-51-6	
Sodium metabisulphite	7681-57-4	
Sodium methyl paraben	5026-62-0	
Sodium nitrite	7632-00-0	No more than 1% of final feed
Sodium propionate	137-40-6	
Sodium propyl paraben	35285-69-9	
Sodium thiosulfate	7772-98-7	
Sodium tri-polyphosphate	7758-29-4	
Sorbic acid	110-44-1	
Sorbitan fatty acid esters (fatty acids limited to C12, C14, C16, and C18 containing minor amounts of associated fatty acids) and poly(oxyethylene) derivatives of sorbitan fatty acid esters		
Sorbitan monooleate	1338-43-8	
Sorbitan monostearate	1338-41-6	
Sorbitol	50-70-4	
Streptococcus (*Enterococcus*) *salivarius* subsp *thermophilus*		
Sulphamic acid	5329-14-6	
Sulphuric acid	7664-93-9	
Sunflower oil	8001-21-6	
Sunset yellow	2783-94-0	
Tagetes oil	8016-84-0	
Tangerine oil	8008-31-9	
Tartaric acid	87-69-4	
Tartrazine	1934-21-0	
Terminalia belerica *Terminalia chebula*		
Tertiary butylhydroquinone (TBHQ)	1984-33-0	
Tetra potassium pyrophosphate	7320-34-5	

Schedule 7—*continued*

Substance	Identification (CAS number)	Limitations
Tetra sodium pyrophosphate	7722-88-5	
Thaumatin	53850-34-3	
Thyme oil	8007-46-3	
Thymol	89-83-8	When added at levels consistent with good feeding practice
Titanium dioxide	13463-67-7	
Tocopherols (extracts of natural origin)	1406-66-2	
Tricalcium phosphate	7758-87-4	
Trimethylamine	75-50-3	
Trisodium phosphate	7601-54-9	
Trypsin	9002-07-7	
Turmeric	8024-37-1	
Undecylenic alcohol	112-43-6	
Urea	57-13-6	
Valerian		
Valeric acid	109-52-4	
Vanillin	121-33-5	
Vermiculite	1318-00-9	
Vitamin B1	59-43-8	
Vitamin B12	68-19-9	
Xanthan gum	11138-66-2	
Xanthophyll	127-40-2	
Xylanase	9025-57-4	From the following sources: *Aspergillus oryzae* containing a *Thermomyces lanuginosus* gene for xylanase, *Penicillium funiculosum*, *Trichoderma longibrachiatum*, *T. viride*
Yucca schidigera		
Zeaxanthin		
Zinc oxide	1314-13-2	
Zinc proprionate	557-28-8	
Zingiber officinale		

Diane Morcom,
Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations come into force on 2 August 2007. They amend the Agricultural Compounds and Veterinary Medicines Regulations 2001 (the **principal regulations**). The principal regulations are made under the Agricultural Compounds and Veterinary Medicines Act 1997 (the **Act**).

The definition of fertiliser additive is amended. A fertiliser additive may now be applied directly to a plant and may simply increase biological activity.

A definition of topical is inserted. The definition excludes the application of substances to the eye or the ear canal.

A definition is inserted for oral gastrointestinal-acting microflora-enhancing compounds. A new regulation is inserted that allows these compounds to be exempt from registration under the Act if certain conditions are complied with. The conditions are set out in a *new Schedule 4A*.

Schedule 1 of the principal regulations specifies agricultural compounds that are exempt from registration if applicable codes of practice are complied with. It is replaced with a revised schedule, in which—

- clauses 5 and 6 specify certain non-absorbable masking agents and cleaning products:
- clause 9 now specifies certain compounds used to protect plant grafts or plant wounds:
- clause 12 now specifies compounds used in the post-harvest treatment of wood-producing crops.

Schedule 2 of the principal regulations specifies agricultural compounds that are exempt from registration if certain conditions and requirements are complied with. It is replaced with a revised schedule, which now specifies (amongst other things)—

- certain oral and topical preparations that are prepared from a plant or unrefined plant extract and that do not claim to have pharmacological or anabolic effects, or to modify the physiological function of an animal:
- certain topical preparations that contain ingredients not absorbed through the skin and that do not include certain ingredients:

- certain topical hoof preparations that contain ingredients that act only on the surface to which they are applied and that do not include certain ingredients, with a condition applied to these preparations:
- non-medicated antidiarrhoeal preparations that are used solely as gastrointestinal adsorbent or protectant agents, and that do not make claims about binding any specific micro-organism or toxin, with more labelling conditions applied to these preparations:
- non-medicated orally and rectally administered laxatives and lubricants:
- certain non-medicated moist or dry poultice preparations, with conditions applied to these preparations:
- plant compounds that are used solely in home gardens or amenity horticulture on plants that are not intended to be used as food for humans or animals, with a labelling condition applied to these compounds.

Schedule 7 of the principal regulations specifies substances that are generally recognised as safe if used in accordance with certain conditions. It is replaced with a revised and updated schedule, which now specifies substances that are generally recognised as safe feed additives in oral nutritional compounds or safe ingredients in oral gastrointestinal-acting microflora-enhancing compounds.

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