Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Amendment Regulations 2020

Patsy Reddy, Governor-General

Order in Council

At Wellington this 22nd day of June 2020

Present:
Her Excellency the Governor-General in Council

These regulations are made under section 75 of the Agricultural Compounds and Veterinary Medicines Act 1997—

(a) on the advice and with the consent of the Executive Council; and

(b) on the recommendation of the Minister for Food Safety made in accordance with section 78 of that Act.

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Schedule
Schedule 2 replaced

Regulations

1 Title

These regulations are the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Amendment Regulations 2020.

2 Commencement

These regulations come into force on 23 July 2020.

3 Principal regulations

These regulations amend the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 (the **principal regulations**).

4 Regulation 3 amended (Interpretation)

(1) In regulation 3, revoke the definitions of **fertiliser additive**, **non-medicated**, and **nutrient**.

(2) In regulation 3, insert in their appropriate alphabetical order:

animal nutrient means a nourishing substance, including, but not limited to,—

(a) a constituent substance of feed that is necessary for, or contributes to, the natural and normal physiological function and metabolic homeostasis of an animal; and

(b) proteins, carbohydrates, fats, oils, minerals, vitamins, water, and their naturally occurring components

antibiotic means a naturally occurring, semi-synthetic, or synthetic antimicrobial substance that kills or inhibits the growth of bacteria to prevent or treat bacterial infections in or on an animal or a plant

plant biostimulant—

(a) means a substance or biological compound or plant material, or a mix of substances or biological compounds or plant material, whose function when applied to plants, the rhizosphere, or soil is to stimulate natural processes to enhance or benefit plant nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality traits; but

(b) does not include substances that are plant growth regulators that modify the physiological functions of plants

plant nutrient means an essential element necessary for plant growth, including, but not limited to,—

(a) a macronutrient (nitrogen, phosphorus, potassium, calcium, sulphur, or magnesium); and

(b) a micronutrient (boron, chlorine, manganese, iron, zinc, copper, molybdenum, or nickel)

semiochemical preparation means a preparation containing a volatile substance that conveys a signal to an animal to modify the behaviour of the recipient animal

soil conditioner means a substance or biological compound or plant material, or a mix of substances or biological compounds or plant material, that is added to soil to improve its physical or chemical qualities including, but not limited to, structure, porosity, water retention, pH, and cation-exchange capacity

unrefined extract means plant material that has not been subjected to purification processes that result in the isolation of, or alteration of the proportions of, specific chemical constituents of the plant

(3) In regulation 3, in the definitions of **intra-ruminal device**, **nutritional benefit**, **nutritional preparation**, and **therapeutic substance**, replace "nutrients" with "animal nutrients" in each place.

(4) In regulation 3, replace the definition of **fertiliser** with:

fertiliser—

(a) means a substance or biological compound or plant material, or a mix of substances or biological compounds or plant material, that is described as, or held out to be suitable for, sustaining or increasing the growth, productivity, or quality of plants through the delivery to plants or soil of plant nutrients; and

(b) includes any—

(i) non-nutrient attributes of the materials used in fertiliser; and

(ii) animal nutrients used in fertiliser; but

(c) does not include a substance or biological compound or plant material, or a mix of substances or biological compounds or plant material, that is intended for use as a plant growth regulator that modifies the physiological functions of plants

5 Regulation 10 amended (Compounded veterinary preparation to be prepared in accordance with documented system)

(1) In regulation 10, insert before paragraph (a):

(aaa) a statement of the purpose of the preparation; and

(2) In regulation 10, insert as subclause (2):

(2) The compounding veterinarian must ensure that the documented system—

(a) complies with the conditions of exemption applicable to a compounded veterinary preparation under these regulations; and

(b) is sufficient to provide a compounded veterinary preparation that is fit for its intended purpose.

6 Regulation 12 amended (Information requirements)

After regulation 12(1), insert:

(1A) This regulation does not apply to a veterinarian who prepares a compounded veterinary preparation and administers the preparation to an animal.

7 Regulation 14 amended (Recording of documented system and of actions taken in accordance with documented system)

In regulation 14(3)(a), replace "regulation 10(a)" with "regulation 10(1)(aaa)".

8 Schedule 2 replaced

Replace Schedule 2 with the Schedule 2 set out in the Schedule of these regulations.

9 Schedule 3 revoked

Revoke Schedule 3.

Schedule
Schedule 2 replaced

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Schedule 2
Agricultural compounds exempt from registration under sections 21 and 27 of Act

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Column 1 Agricultural compound	Column 2 Conditions
Part A. Exemptions relating to agricultural compounds that could be used in relation to either animals or plants	
1 *In vitro* diagnostics used to confirm the presence or absence of disease or as an aid in the diagnosis of disease or abnormal conditions	
2 Substance or compound— (a) prepared by a person (**person A**) for use on animals or plants owned by person A, or in any land, place, or water owned or occupied by person A (and not for sale); or (b) used by person A, or a person employed or engaged by person A, or another person expressly authorised by person A, as described in paragraph (a)	If the substance or compound is used by a person employed or engaged by person A or another person expressly authorised by person A, the use must be in accordance with written instructions from person A about— (a) how the substance or compound is to be stored, prepared for use, administered, applied, and (if applicable) disposed of; and (b) how the safety and welfare of any person or animal who may come into contact with the active ingredient is to be protected and how any pain or distress of an animal is to be mitigated; and (c) how third parties are to be contacted or advised of the use of the substance or compound and warned of any hazards relating to its use The following substances or compounds may be prepared or used as described in column 1 only in compliance with an approved operating plan: (a) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981): (b) antibiotic substances: (c) animal hormones: (d) substances that are prohibited by countries importing New Zealand primary produce: (e) vertebrate toxic agents

Column 1 Agricultural compound			Column 2 Conditions
3	Agricultural compounds used for—		An operating plan covering the type or class of agricultural compounds the person or organisation wishes to use for research, testing, or training, and the nature of the activities contemplated, must have been approved and must be complied with
	(a)	any investigative, analytical, experimental, or diagnostic work or toxicity or potency testing work that involves any agricultural compounds; or	
	(b)	any work that is carried out for the purpose of testing the safety or efficacy of any agricultural compound; or	The person or organisation subject to the operating plan must, on an ongoing basis, notify the Director-General if an active ingredient is to be used that was not notified to the Director-General as being used or contemplated for use at the time the operating plan was approved, even where the active ingredient to be used is within the scope of agricultural compounds approved for use under that operating plan
	(c)	any training or teaching of persons, of a kind specified in the approved operating plan, involving agricultural compounds, within the scope of the active ingredients specified in the plan	
4	Vertebrate and invertebrate attractants and repellents that are not applied directly to animals or plants		
5	Invertebrate mating disrupters that are not applied directly to animals or plants		
6	Agricultural compounds used to control the characteristics of water where—		
	(a)	the water is used on or in relation to animals or plants; and	
	(b)	the characteristic must be controlled to maintain the animals or plants in a healthy state or to facilitate the management of the animals or plants	
7	Sterilisers, sanitisers, and disinfectants (excluding fumigants) used to maintain hygienic conditions for the purposes of hygiene in places where animals and plants are housed or cultivated		Animals and plants must not be exposed to the substance or compound
8	Agricultural compounds with a solely mechanical mode of action applied to the environment in which animals or plants are kept, to control invertebrate pests of animals or plants		Must not contain any biologically active ingredients
Part B. Exemptions relating to agricultural compounds that could be used in relation to animals			
9	Preparations scheduled as medicines under the Medicines Act 1981, and used as veterinary medicines		Must not be used on animals except under the direct care, or with the authorisation, of a veterinarian The conditions in regulations 9 to 13 do not apply Must not be advertised for sale for use on animals The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice

Column 1 Agricultural compound	Column 2 Conditions
10 Compounded veterinary preparations	Must not be used on animals except under the direct care of the compounding veterinarian Preparations may be used only on animals specified by the compounding veterinarian or animals of a type specified by the compounding veterinarian Must not be advertised for sale for use on animals The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice
11 Homeopathic oral and topical preparations for use on animals— (a) prepared by a process of solution, extraction, or titration of an active ingredient followed by strictly regimented serial dilution to the point that the active ingredient is no longer practically detectable; and (b) that are not claimed 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
12 Topical veterinary preparations (non-absorbable) for— (a) treatment or prevention of minor wounds or dermatological abnormalities; and (b) cleaning teeth, skin, hair, fur, or hooves; and (c) maintaining skin, hair, fur, or hoof health/condition; and (d) disguising odours	Must not contain the following ingredients: (a) antibiotic substances: (b) hormones: (c) pharmacological substances: (d) solvents or penetrating agents: (e) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981): (f) substances that are prohibited by countries importing New Zealand primary produce The compound must not be used on the udders and teats of animals whose milk is being collected for human consumption For the preparation described in paragraph 12(a), the label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice
13 Oral and topical preparations for animals— (a) prepared from either any part of a plant or an unrefined extract from a plant; and	If used as a veterinary medicine, the label information must,— (a) if applicable, identify the compound as a herbal preparation; and (b) include a statement that, if the preparation fails to alleviate the

Column 1 Agricultural compound	Column 2 Conditions
(b) that are not claimed to prevent, control, or cure a specific disease characterised by pain or distress in animals; and (c) that are not claimed to have pharmacological or anabolic effects, or to modify the physiological function of an animal	condition being treated, the user should seek veterinary advice Must not be used on the udders and teats of animals whose milk is being collected for human consumption Must not contain the following ingredients: (a) antibiotic substances: (b) hormones: (c) pharmacological substances: (d) solvents or penetrating agents: (e) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981): (f) substances that are prohibited by countries importing New Zealand primary produce
14 Markers, paints, and dyes used as pigments or colourants for topical application to identify animals temporarily	
15 Antidiarrhoeal preparations that— (a) are used solely as gastrointestinal adsorbent or protectant agents; and (b) are not claimed to bind any specific micro-organism or toxin; and (c) have only a local, surface-acting effect on the gastrointestinal tract	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 Must not contain the following ingredients: (a) antibiotic substances: (b) hormones: (c) pharmacological substances: (d) solvents or penetrating agents: (e) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981): (f) substances that are prohibited by countries importing New Zealand primary produce
16 Laxatives and lubricants used on animals that have only a local, surface-acting effect on the gastrointestinal tract, vulva, and vagina	The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice Must not contain the following ingredients:

Column 1 Agricultural compound	Column 2 Conditions
	(a) antibiotic substances: (b) hormones: (c) pharmacological substances: (d) solvents or penetrating agents: (e) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981): (f) substances that are prohibited by countries importing New Zealand primary produce
17 Moist or dry poultice preparations used on animals 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	The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice Must not contain the following ingredients: (a) antibiotic substances: (b) hormones: (c) pharmacological substances: (d) solvents or penetrating agents: (e) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981): (f) substances that are prohibited by countries importing New Zealand primary produce
18 Cauterising preparations used or applied superficially	The label information must include a statement that, if the preparation fails to stop bleeding, the user should seek veterinary advice
19 Oral urinary tract modifiers (acidifiers and alkalisers) that are used solely for modification of urinary pH	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 The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice
20 Respiratory tract modifiers (expectorants and cough suppressants) for use on animals 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 animals to promote mucolysis, for cough suppression (by alleviating only irritation), and to	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 The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice

Column 1 Agricultural compound		Column 2 Conditions
	relieve compromised airways and upper respiratory tract congestion	
21	Agricultural compounds used to extend animal semen or to be used as media for animal sperm, cells, ova, and embryos	
22	Any agricultural compound (excluding agricultural compounds administered in an intra-ruminal device) ingested by an animal as feed, or a nutritional preparation intended for oral administration to an animal to achieve a nutritional benefit (an **oral nutritional compound**)	The directions for use on the label must specify the species, type, and class of animal for which use is intended An agricultural compound that is a therapeutic or pharmacological substance or preparation may only be incorporated into oral nutritional compounds if the agricultural compound is registered as a veterinary medicine under the Act and— (a) incorporation of the registered veterinary medicine is consistent with the indications, use patterns, and target species approved for the registered product; and (b) the registered veterinary medicine remains adequately distributed throughout the oral nutritional compound for the entirety of the claimed shelf life of the feed; and (c) the efficacy of the registered veterinary medicine is maintained for the entirety of the claimed shelf life of the feed Oral nutritional compounds that are feed commodities are not subject to the conditions in regulations 9 and 12 For the purpose of this special condition, **feed commodities** means plants (or any part or parts of those plants) that are raised and used as feed or for feed production for animals If an oral nutritional compound is incorporated with an agricultural compound the label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice
23	Oral gastrointestinal-acting microflora-enhancing compounds	The directions for use on the label must specify the species, type, and class of animal for which use is intended No therapeutic or pharmacological claims that the compound prevents, treats, or cures any disease characterised by pain or distress in animals may be made
24	Semiochemical preparations that modify an animal's behaviour by sending communication signals through chemicals and are not claimed	Must not contain the following ingredients— (a) antibiotic substances: (b) hormones:

Column 1 Agricultural compound		Column 2 Conditions
	to prevent, control, or cure a particular disease characterised by pain or distress in animals	(c) pharmacological substances: (d) solvents or penetrating agents: (e) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981) Label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice
25	Biologically active agricultural compounds applied to the contained environment in which non-food producing animals are kept to control invertebrate pests of animals	Must not be used when any animal is present The label information must state the safe re-entry period for non-food-producing animals and that food-producing animals must not be exposed to the product
26	Topically absorbable animal nutrients	Directions for use on the label must specify the species, type, and class of animal for which use is intended
27	Products with a solely mechanical mode of action applied topically, that are not claimed to prevent, control, or cure a particular disease characterised by pain or distress in animals	Must not contain any biologically active ingredients Must not be absorbable The label information must include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice Must not be an irritant
Part C. Exemptions relating to agricultural compounds that could be used to manage plants or plant production		
28	Products applied to, or within, empty structures to remove pests before— (a) introducing produce; or (b) growing plants	Must not be used when plants or produce are present The label information must state the re-entry period before plants or produce are re-introduced (to avoid non-compliant residues)
29	Products with a solely mechanical mode of action to control invertebrate pests on plants or plant produce	Must not contain any biologically active ingredients
30	Spray markers that are coloured indicators to show where liquid agricultural chemicals have been applied to help prevent overlaps	
31	Agricultural chemical synergists and other adjuvants, including wetting and sticking agents, pH buffers, drift retardants, and water conditioners	
32	Repellents applied directly to plants and used solely to repel vertebrates or invertebrates	
33	Attractants applied directly to plants and used solely to attract vertebrates or invertebrates	
34	Mating disrupters applied directly to plants and used solely to interfere with the reproduction of invertebrates	

Column 1 Agricultural compound			Column 2 Conditions
35	Agricultural chemical compounds used to protect plants from climatological conditions		Must not contain any biologically active ingredients
36	Agricultural chemicals used solely—		The label information must clearly state that the product must not be—
	(a)	in home gardens or amenity horticulture on plants that are not intended to produce food for consumption by humans or animals; or	(a) used on plants that are intended to produce food for consumption by humans or animals; and
	(b)	in commercial plant production on plants that are not intended to produce food for consumption by humans or animals; or	(b) applied to areas that may be grazed by food-producing animals
	(c)	for the post-harvest treatment of cut flowers and bulbs	
37	Homeopathic agricultural chemicals used commercially		
38	Agricultural compounds used in the production of plant tissue cultures		
39	Agricultural compounds (not containing biologically active ingredients) used to protect plant grafts or plant wounds		
40	Agricultural compounds (not containing biologically active ingredients) used to provide a physical barrier to infestation or infection of plants		
41	Agricultural compounds used in the post-harvest treatment of wood-producing crops		
42	Fertilisers		The label information must specify nutrient content value, as applicable The product must comply with any applicable notice issued under the Act
43	Plant biostimulants		The label information must specify mode of action, as applicable The product must comply with any applicable notice issued under the Act
44	Soil conditioners		The label information must specify mode of action, as applicable The product must comply with any applicable notice issued under the Act

Michael Webster,
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, which come into force on 23 July 2020, amend the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 (the **principal regulations**). The amendments—

- exempt specified new agricultural compound and veterinary medicine (**AVCM**) products from registration under the Agricultural Compounds and Veterinary Medicines Act 1997:
- update the risk status of certain existing ACVM products:
- improve the clarity of descriptions and conditions for certain ACVM products:
- make other technical improvements to the principal regulations.

Schedule 2 of the principal regulations is replaced. *New Schedule 2* includes 6 new ACVM product groups, and has been restructured to rationalise some exemption groups, and to standardise conditions across groups sharing common factors. *New Schedule 2* also updates the risk status of certain ACVM products.

Schedule 3 of the principal regulations is revoked.

Regulation 10 of the principal regulations is amended to strengthen the requirement for a fit for purpose documentation system. An amendment is made to regulation 12 of the principal regulations to clarify that labelling requirements do not apply if a veterinarian compounds a veterinary product and administers the compound to an animal.

Issued under the authority of the Legislation Act 2012.
Date of notification in *Gazette*: 25 June 2020.
These regulations are administered by the Ministry for Primary Industries.

Wellington, New Zealand:
Published under the authority of the New Zealand Government—2020