Ministry for Primary Industries
Manatū Ahu Matua

# Proposed changes to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011

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*Growing and Protecting New Zealand*

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# Contents

Page

# Part A

# 1 Submissions

The Ministry for Primary Industries (MPI) invites public comment on proposed changes to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 [the Regulations].

This document sets out the proposed changes. Your submissions will help us assess whether we need to amend these proposals in any way to better meet your needs, while still meeting the purpose of the legislation.

## 1.1 How to have your say

**The deadline for receipt of all submissions is 5pm on 19 October 2017**

Have your say by answering the questions in the boxes at the end of each of the three sections outlining the proposed changes. Note that the questions are prompts to get you thinking about the issues, but your comments are not restricted to answering these questions.

Please include the following information in your submission:

- a title line: 'Proposed changes to the ACVM Regulations';
- your name and title (if applicable);
- your organisation's name (if you are submitting on behalf of an organisation) and whether your submission represents the whole organisation or a section of it; and
- your contact details (such as phone number, address, and email).

MPI encourages you to make your submission electronically if possible. Please email your submission to: ACVM.Consultation@mpi.govt.nz

If you wish to make your submission in writing, these should be posted to:

ACVM Regulations Proposals
Ministry for Primary Industries
Food Policy Team
PO Box 2526
Wellington 6140

The following points may be of assistance in preparing comments:

- If your comments relate to a particular section in the document, please provide the section numbers used in the document so we can link your comments to the appropriate section;
- if where possible, reasons and/or data to support comments should be provided;
- the use of examples to illustrate particular points is encouraged; and
- as a number of copies may be made of your comments, please use a legible font and quality print, or make sure hand-written comments are clear in black or blue ink.

## 1.2 Your submission may be made public

Once you make your submission, anyone can ask for it under the Official Information Act 1982 (the OIA). If you don't want anything in your submission released, you should let us know what material you want withheld, and why, at the time you make your submission. Reasons for withholding information could include that the information is commercially sensitive or that you wish personal information, such as names or contact details, to be withheld. Note that an automatic confidentiality disclaimer from your IT system will not be considered as grounds for withholding information.

MPI will take your indications into account when determining whether or not to release information. The grounds for withholding information are outlined in the OIA, and we can only withhold information in accordance with those provisions. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman. Further information is available at www.legislation.govt.nz.

## 1.3 What happens next

Once the consultation period has closed we will analyse submissions and make recommendations to the Minister for Food Safety on the proposals contained in this document. A summary of submissions will be posted on the Ministry for Primary Industries website.

After Cabinet has approved the final proposals, The Parliamentary Counsel Office (the Government's legal drafters) will then prepare the regulations.

# 2 Executive summary

Agricultural compounds and veterinary medicines are subject to a system of regulatory oversight to prevent or manage risks associated with their use. This includes risks to public health, trade in primary produce, animal welfare, and agricultural security. The regulatory oversight also ensures that agricultural compound use does not result in breaches of domestic residue food standards, and that consumers are provided with sufficient information about agricultural compounds.

Any of these products authorised for sale and use under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 must either be registered, to ensure that any risks associated with their use are assessed and managed, or qualify for exemption. The main way that products are exempted is by meeting criteria specified in the Agricultural Compounds and Veterinary Medicines (exemptions and Prohibited Substances) Regulations 2011.

The proposals in this document relate to these Regulations, and are intended to reflect new knowledge of risk profiles, accommodate new novel products, and improve the clarity of exemption groups and conditions.

The objectives of the proposed changes are to:

- Improve accessibility of the Regulations;
- Create greater certainty and confidence in the Regulations;
- Reduce compliance and operational costs;
- Improve fairness by providing a more flexible and effective exemption regime;
- Reinforce the integrity of the ACVM regulatory environment.

The proposed changes to the Regulations fall into three categories:

- Amending several existing exemptions in Schedule 2. Some amendments are to rationalise entries and conditions in order to improve consistency and provide new consolidated groupings. Other amendments are proposed to better align with re-assessed risk profiles for the compound groups;
- Adding new categories of compounds exempt from registration. These have a risk profile that indicates they do not require a higher level of regulatory oversight;
- Amending some specific regulations. Most of the changes are to definitions in Regulation 3, and are consequential to the amendments to Schedule 2.

The proposed changes are intended to facilitate access to new products, which will benefit both industry and users, without compromising public health, trade in primary produce and animal welfare. These changes are also intended to reduce costs for businesses, through less products requiring registration, and increased clarity and certainty about which products are exempt.

Your responses to the questions in this document will enable MPI to better understand the effects of the proposed changes on you or your business before final recommendations are made to Cabinet. MPI is particularly keen to hear from industry about any possible impacts, including where the proposed changes could mean that some currently exempt products may require changes in their conditions of use or formulation in order to remain exempt, or may require registration.

# 3 How ACVM substances are regulated

Agricultural compound and veterinary medicine (ACVM) products are important inputs to New Zealand's primary production systems. They include fertilisers, agricultural chemicals for crop protection, veterinary medicines for animal health, and animal feed and other nutritional compounds. ACVM products are also used widely in non-farm applications including veterinary medicines and feeds for pets, and plant production and protection for home and commercial gardens.

Without proper use these products may pose risks to public health, trade, and animal welfare. Hence ACVM products are subject to a system of regulatory oversight.

## 3.1 Agricultural Compounds and Veterinary Medicines Act 1997

All agricultural compounds used in New Zealand (including imported, manufactured, sold or used) must be authorised by or under the Agricultural Compounds and Veterinary Medicines Act 1997 (the Act) and associated regulations. The purpose of the Act is to:

1. prevent or manage risks associated with the use of agricultural compounds. This covers risks to public health, trade in primary produce, animal welfare, and agricultural security;
2. ensure that agricultural compound use does not result in breaches of domestic food residue standards; and
3. ensure that consumers are provided with sufficient information about agricultural compounds.

The ACVM framework reflects a risk-based approach to managing the use of agricultural compounds, with regulations set at a level commensurate to the risk the compounds pose. The framework provides for three categories of use (Figure 1):

1. Prohibited from being used as an agricultural compound. These substances are specified in Schedule 1 of the Regulations.
2. Able to be used but requires registration (as a trade name product) subject to specifically imposed conditions.
3. Able to be used and exempt from requiring registration. Exemption may be provided by one of three routes under section 8A(1) of the Act:
    a. regulations made under section 75;
    b. listed as a substance generally recognised as safe (GRAS) for use under section 8B of the Act;
    c. approved on the basis of special circumstances under section 8C of the Act.

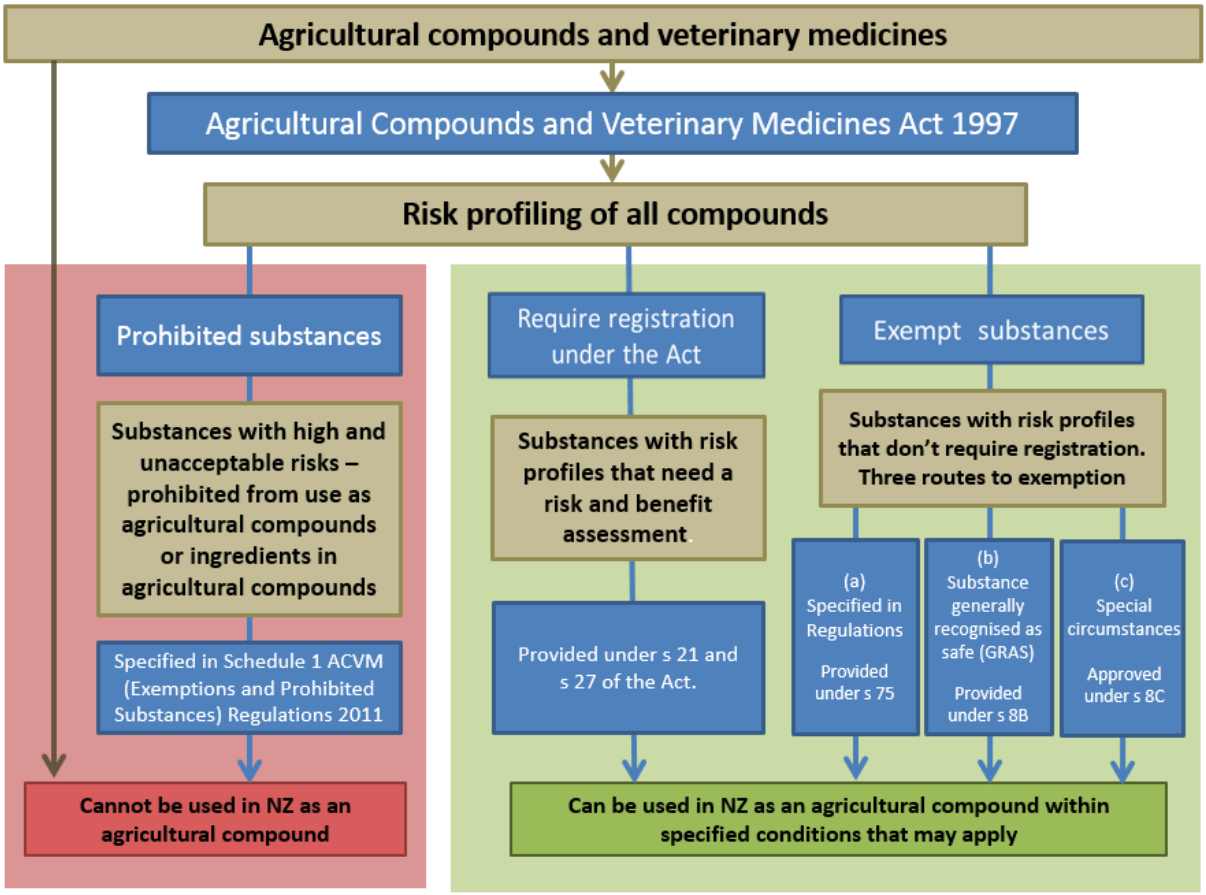


**Figure 1. Framework for the use of agricultural compounds**

## 3.2 Risk thresholds

In line with Government policy, MPI tries to avoid unnecessary regulatory intervention. This means that MPI administers the Act with no more regulatory intervention than is 'necessary and sufficient' to maintain acceptable levels of risk. Those levels of risk are specified through MPI establishing ACVM risk thresholds.

Risk thresholds underpin the setting of appropriate levels of regulatory oversight of agricultural compounds. They are instrumental in deciding the groups of agricultural compounds that should be exempt from registration, and the conditions that should apply to each group.

MPI carries out collective risk analyses within each group of compounds. Part of that analysis is to determine prescribed conditions sufficient to manage risks across all the products in an exempted group without the need for individual risk-benefit analysis as required for registered products. The risks associated with some products are managed under other legislation, such as the Hazardous Substances and New Organisms (HSNO) Act 1996.

## 3.3 Obligations and responsibilities applying to exempt agricultural compounds under the Regulations

Some agricultural compounds pose a low risk, and are exempt from registration under the Act. To determine which products are exempt, the Regulations specify 41 different compound groups (set out in Schedule 2 of the Regulations). All compounds are subject to a set of general conditions, which are specified in Regulations 7-13. In addition, particular exempt compound groups may have specific conditions imposed to manage risks. The conditions are use-related and may apply to substances, products, systems, or people's behaviour.

The general conditions are designed to move the regulatory emphasis away from a regulator-defined prescriptive approach to an outcomes-based set of obligations and responsibilities that apply to importers, manufacturers, sellers and users of exempt compounds. In particular:

- Regulation 7 sets out a set of "fitness for purpose" criteria that applies to any exempt compound imported, manufactured or sold in New Zealand.
- Regulation 8 places similar obligations on users of exempt compounds.
- Regulation 12 specifies information that must be provided with the product or preparation (that is, labelling requirements).

## 3.4 Process required to change the Regulations

The Act sets out a process for changing the Regulations, including changing categories or conditions of exemption.

An agricultural compound must be recommended for exemption if the Minister considers that:

- the likely cost of assessing and registering an agricultural compound as a trade name product is greater than the likely risks of use; or
- the likely risks of use are already adequately managed by conditions imposed under any other Act.

Consultation with affected parties must be undertaken prior to making any recommendation to the Minister for regulatory change. Once Cabinet has agreed final policy decisions, Changes to the Regulations will be made by Order in Council.

# 4 The changes proposed

## 4.1 Scope of the change proposals

The proposed changes to exemptions outlined in this consultation document are limited to those specified in the Regulations (route 'a' in Figure 1). By far the largest number of agricultural compounds gain exemption under the Act by this route.

## 4.2 Issues – the rationale for change

In the time since the last significant amendments to the Regulations in 2011, MPI has new knowledge and experience in working with the Regulations, and new products have been developed that do not neatly fit into existing categories. These issues mean that a review of the Regulations is timely to ensure they are effective and efficient.

A number of issues provide a focus for the review:

1. Some regulations are unclear and do not provide sufficient certainty for both industry and government. For example, it is uncertain where some products fit within the regulatory framework.
2. The Regulations have not been kept up to date with the changing risk profile of some agricultural compounds or some evolving agricultural practices.
3. Novel products that have not previously been considered by regulators are entering the market. Some of these products have a risk profile that indicates they could be managed by exemption, yet do not fit any of the current Schedule 2 exemption categories. This is potentially causing delays in bringing these products to market, and/or is imposing costs on industry players and users as they have to meet the requirements of registration.

Changes are needed in order that the Regulations remain fit for purpose, and that the appropriate level of regulatory oversight is applied to ACVM products.

## 4.3 Objectives of the proposed changes

The objectives of the changes proposed are to:

- Improve accessibility of the regulations for regulated parties by simplifying regulatory requirements where appropriate;
- Create greater certainty and confidence in the regulations both for industry and for MPI by making exemption groupings clearer and easier to understand;
- Reduce compliance and operational costs for industry and MPI where appropriate;
- Improve fairness by providing a more flexible and effective exemption regime;
- Reinforce the integrity of the ACVM regulatory environment by regulating according to risk, and emphasising the obligations and responsibilities of those importing, manufacturing, selling, or using ACVM compounds.

## 4.4 What we are proposing

The changes aim to address the issues outlined above and give effect to the objectives. We are proposing to:

- Amend several existing exemptions in Schedule 2. Some amendments are to rationalise entries and conditions in order to improve consistency and provide new consolidated groupings. Other amendments are proposed to better align with re-assessed risk profiles for the compound groups;
- Add new categories of compounds exempt from registration. These have a risk profile that indicates they do not require a higher level of regulatory oversight;
- Amend some specific regulations. Most of the changes are to definitions in Regulation 3, and are consequential to the amendments to Schedule 2.

## 4.5 How the proposed changes have been identified and assessed

The proposed changes must be consistent with the broader purpose of the Act, which are:

- preventing or managing risks associated with the use of agricultural compounds (risks to public health, trade in primary produce, animal welfare, and agricultural security);
- ensuring no breaches of food residue standards; and
- providing consumers with sufficient information about agricultural compounds.

Changes proposed to exemptions need to meet section 76(a) requirements to justify not registering agricultural compounds - that the "likely cost of assessing and registering an agricultural compound as a trade name product is greater than the likely risks from the use of that agricultural compound without registration".

The costs of assessing and registering an agricultural compound include costs to affected parties and to government. Affected parties incur costs for registration fees, annual levies and costs associated with generating and collecting data required for registration (the latter can be the largest cost by far). Costs to government are mainly for staff time and administration. However, there are large uncertainties in quantifying some costs, particularly because the number of products impacted is unknown. Hence the cost assessment on whether a group of products should be exempt from registration has been largely qualitative.

An important input to the assessment has been collated feedback from 'class determinations'. Class determinations are undertaken by MPI on request. They provide industry with certainty about where a compound, if potentially qualifying for exemption, would fit within current entry groups. MPI receives a large number of such requests each year. Class determinations provide a useful indication of the comparative numbers of products falling within exempt groups, and hence the potential impact that changes to entry descriptions or conditions might have. They can also indicate difficulties with existing group boundaries; for example, if potentially-exempt compounds fall between different groups or overlap existing groups.

## 4.6 Potential impacts of proposed changes

The changes proposed to the Regulations are of a technical nature in that they align with the intent of the Act and are not substantive changes to policy. While some changes are minor, with little anticipated impact (for example minor wording changes), other changes are more material.

For the proposed new exemption groups, the expectation is that the changes will result in cost savings to government, industry and users, and overall yield positive net benefits. These savings include reduced administrative time for all parties, and avoided opportunity costs by enabling new products to be brought to market without further delay, or without the need to embark on a potentially costly registration process.

The potential impacts from proposed amendments to existing exempt groups and conditions (as set out in Schedule 2 of the Regulations) will be specific to the particular group. Many of the changes are designed to improve clarity and certainty of the exemptions, with both industry and MPI benefitting. For example, MPI will be better placed to judge risk when assessing products within the regulatory framework.

It is possible that the proposed changes could mean that some currently exempt products may require changes in their conditions of use or formulation in order to remain exempt, or may require registration. Since it is difficult to quantify products or groups of products that may be impacted in this manner, MPI is particularly keen to hear from industry about any such possible impacts.

| What do you think? |
| --- |
| 1. Do you agree with the rationale and need to change the Regulations?<br>2. What is your view on the size/scale of issues identified? (This could include views on the numbers of products potentially affected, or the potential costs of a change to the status quo, for example). |

# Part B

# 5 Proposed amendments to existing Schedule 2 exemptions

Schedule 2 sets out the exemption groups and any specific conditions that apply to those groups. These are set out in two columns:

- Column 1:'Agricultural compound' provides an entry number (from 1 to 41) and a description for each exempt compound group
- Column 2: 'Conditions' sets out the specific conditions that apply to each compound group.

As a guide to the discussion in this section, the exemption groups are referred to either as their descriptive title (or their short descriptive title if appropriate), or as their entry number (e.g. entry 1).

## 5.1 Giving effect to Regulation 7 "fitness for purpose" and other general conditions

A number of the current exemption groups and conditions have not been changed since the Regulations were first enacted in 2001.

The 2011 amendments created the sub-heading 'Conditions of general application to exempt agricultural compounds'. This included a new Regulation 7, along with some other new and amended regulations. The changes proposed in 5.1.1 and 5.1.2 are designed to give better effect to the intention of these regulations.

### 5.1.1 Reference to substances generally recognised as safe (GRAS)

Being listed as a GRAS substance is one of three means under the Act by which an agricultural compound is exempt from the requirement to be registered. Entry 25 in Schedule 2 relates to oral nutritional compounds fed to animals and contains a condition that if feed additives are used they must be GRAS substances.

Entry 26 relates to orally fed microflora-enhancing compounds with the condition that the compounds must contain only ingredients that are GRAS substances.

#### Proposed change

**Conditions** – we propose to remove reference to GRAS substances in the conditions of entries 25 and 26.

#### Rationale

Requiring GRAS status as a condition of exemption in entries 25 and 26 is problematic because feed additives are only one type of ingredient in these compounds. Regulation 7 requires all ingredients to be fit for purpose; singling out specific types of ingredient may create the perception that others are not important.

Attempting to manage risks using section 8B of the Act is not efficient or practical for either entry since additives/substances can change as innovative additives are developed. MPI

considers that it would be better to remove the requirement for feed additives to be GRAS substances and focus the obligation on meeting Regulation 7 requirements for all ingredients.

### 5.1.2 Schedule 3: Plants not to be included in oral and topical preparations

Schedule 3 specifies a list of plants that must not be used in oral and topical preparations. The Regulations contain a sole reference to Schedule 3 – entry 11 Oral and topical preparations for use on animals - which relates to herbal preparations used as veterinary medicines. Entry description 11(a) states "being prepared from either any part of a plant or an unrefined extract from a plant, except a plant listed in Schedule 3; and…"

#### Proposed change

**Description** - we propose to change the description for entry 11 by removing reference to Schedule 3 and deleting Schedule 3.

#### Rationale

MPI considers that the need to have a list of plants has been superseded by the broader duty of care inherent in Regulations 7-13, especially the fitness-for-purpose obligations of Regulation 7. However, regulated parties may be overlooking the obligations inherent in Regulation 7 in preference to simply referring to the Schedule 3 list. There is a further concern in that the list of plants in Schedule 3 is unchanged from 2001, and so is potentially outdated.

In order to maintain the integrity of the Regulations and the overarching fitness for purpose obligations, and to remove any ambiguity that may exist between the Schedule 3 list and the requirements of Regulation 7, it is proposed to delete Schedule 3 and reference to it.

The labelling requirements in Regulation 12 provide a level of public scrutiny by requiring all active ingredients to be listed. In this group of products, the plant is the active ingredient.

## 5.2 Rationalising entries and standardising conditions

Schedule 2 currently contains 41 different exempt groups of agricultural compounds. Having a large number of groups has both benefits and downsides in relation to clarity and scope. The main benefit is that specifically formulated substances requiring precise conditions for exemption status can be readily accommodated. However, specifically and narrowly defined groups may exclude new products from the exemption if these products vary in some small way from the specific group description, even if, in other respects, they have a similar low risk profile.

Some class determinations have been difficult to make because a particular product could fit more than one entry. Experience has shown that the boundaries between some exemption groups are not precise. Because conditions can sometimes be different, the regulatory impact is different depending on which entry is considered more relevant.

MPI has therefore considered the need to rationalise some existing groups and conditions so that categories sharing some common factors are treated consistently. This rationalisation would improve readability, clarity, and understanding of the Regulations. These changes are also intended to provide flexibility to accommodate new products not requiring registration.

### 5.2.1 Topical veterinary preparations

Entry 16 relates to topical veterinary preparations for animals to treat minor injuries or skin problems. The entry description also includes a list of 4 types of ingredients the preparations must not contain. Entries 12, 13, 15, 17 and 21 are also topical veterinary preparations but with specifically defined uses and conditions.

#### Proposed changes

We propose to consolidate solely topical veterinary preparation entries (current entries 12, 13, 15, 16, 17 and 21) under a single entry with a common set of conditions. Proposed changes to the entry description and conditions are as follows:

**Entry description** - The proposed relevant uses for the consolidated entry would cover:

*(a)* *treatment or prevention of minor wounds or dermatological abnormalities;*

*(b)* *cleaning teeth, skin, hair, fur or hooves;*

*(c)* *maintaining skin, hair, fur, or hoof health/condition.*

**Conditions** –it is proposed that this entry would have conditions, to the effect, as follows:

*i.* *Ingredients the compounds must not contain:*

- *antibiotic substances*
- *hormones*
- *pharmacological substances*
- *solvents or penetrating agents*
- *active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981)*
- *substances that are prohibited by countries importing New Zealand primary produce;*

*ii.* *The compound must not be used in the eyes or ears;*

*iii.* *The compound must not be used on the udders and teats of animals whose milk is being collected for human consumption* (see 5.2.4);

*iv.* *Label information to include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice* (also see 5.2.2).

Make a consequential change to Regulation 3 to insert a definition of antibiotic substance.

#### Rationale

Having multiple entries dealing with topical veterinary preparations, some with differing conditions, is not justified by the risk profile of the compounds and can result in inconsistent risk management. Providing a single, more encompassing, entry description should provide greater robustness in considering new topical products. It should also address problems where exemption eligibility might be possible under more than one entry.

The changes would also provide certainty around other conditions that currently are either inconsistently applied or have been unclear. Currently the entry 16 description contains a list of ingredients that must not be used. Having the list in the entry description prompts assessment of full formulations to confirm the exemption; this is inconsistent with the intention of the exemption, which is to eliminate the need for regulatory assessment. Specifying a more comprehensive list as a condition, rather than a matter of definition, simplifies class determinations because it avoids the problem of forcing regulated parties to supply full

formulations of their products for assessment to confirm the exemption. Note that these substances would all be active ingredients, which must be listed on the label.

Entries 10 and 11, homeopathic and herbal preparations respectively, are for oral as well as topical use. These groups would not be subsumed into the consolidated topical preparation exemption.

### 5.2.2 Labelling information requirements for animal preparations

One condition common to several Schedule 2 entries relating to animal preparations (entries 10, 11, 18, 19, 20 & 21) is a requirement for the label information to "include a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice". This condition is to ensure that users are made aware of their responsibility for the welfare of their animals.

Two other exemption groups relate to animal preparations (entry 22 Oral urinary tract modifiers; and entry 23 Respiratory tract modifiers) but do not carry this condition.

#### Proposed change

**Conditions** – we propose to add to the conditions of entries 22 and 23 a requirement that the label information includes a statement that, if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice.

#### Rationale

Extending the condition to include entries 22 and 23 would provide a consistent approach to risk management and animal welfare across the entry groups relating to animal preparations.

### 5.2.3 Use of term 'non-medicated'

Three exemption group descriptions (entry 18 Locally acting anti-diarrhoeal preparations; entry 19 Orally and rectally administered laxatives and lubricants; and entry 20 Moist or dry poultice preparations) are each prefaced by use of the term 'non-medicated'. Non-medicated products are currently defined in Regulation 3 to mean "a product that does not contain any pharmacological or therapeutic substances".

#### Proposed changes

We propose to change the entry description and conditions of entries 18, 19 and 20 as follows:

**Description** – remove the words "non-medicated" and delete the definition of non-medicated from Regulation 3.

**Conditions** - add as a condition a list of ingredients the compounds must not contain, the same as proposed for the consolidated topical veterinary preparations entry (see 5.2.1).

#### Rationale

Use of the term 'non-medicated' is problematic because the entry descriptions are not using the term in ways that are fully consistent with the definition. Also, by using the term 'non-medicated' in the entry description, an assessment of full formulations is needed to confirm the exemption. To do so undermines the intention of the exemption, which is to eliminate this level of regulatory assessment.

The changes would remove uncertainty about the meaning of 'non-medicated' while being more specific about the excluded substances. Putting the list of substances in the conditions rather than in the description would remove the need for MPI to require and assess full formulations. Transparency would be maintained because all the listed substances would be active ingredients that must be stated on the label (ref: Regulation 12).

### 5.2.4 Treatment of teats of lactating animals

Three exemption groups relating to topically applied preparations (entry 11 Oral and topical herbal preparations; entry 15 Over-the-counter first aid preparations; entry 16 Topical preparations for animals), have a condition that the compounds "must not be used on the teats of lactating animals if the milk of the animals is intended for human consumption". The reason for the condition is to prevent possible contamination of milk, or organoleptic changes in the milk (i.e. changes in sensory perceptions such as taste), as a result of the compound being drawn from the teats into the milk during milking.

#### Proposed changes

**Conditions** – we propose to:
- amend the condition to the effect that the compound must not be used on the udders and teats of animals whose milk is being collected for human consumption.

- add as a condition to entry 11 a list of ingredients the compounds must not contain, the same as proposed for the consolidated topical veterinary preparations entry (see 5.2.1).

#### Rationale

The existing condition carries some risk because it does not explicitly exclude herbal and other preparations being used on the udders of an animal. Gravity and surface tension effects could draw the preparation down onto the teats and into the milk. The condition is also not sufficiently clear that the risk is to the suitability of milk collected for human consumption. The proposed amended condition would address these concerns.

This amended condition would also apply to the proposed consolidated group for topical preparations, under which entries 15 and 16 would be subsumed (see 5.2.1).

### 5.2.5 Agricultural chemical compounds used to protect plants from climatological conditions

Three existing entries (entry 32 Anti-transpirants used solely to prevent drying of plants; entry 33 Frost protectants; and entry 34 Sunblocks) provide exemption for compounds used for specific types of protection from climatological conditions.

None of the entries have specific conditions, although each entry describes their use as being "solely" for the protection outcome sought.

#### Proposed changes

We propose to change the entry description and conditions as follows:

**Description** - consolidate entries 32, 33 and 34 into a single group covering compounds used for protecting plants from climatological conditions.

**Conditions** - insert a condition to the effect that *compounds must not contain biologically active ingredients.*

#### Rationale

Consolidating the entries by creating an inclusive single category would provide a consistent approach for dealing with exemptions for compounds that provide protection from climatological hazards. Also, current entry groups do not provide sufficient flexibility to accommodate potentially innovative climate protection products that meet criteria for exemption from registration, but that do not precisely meet the descriptions of the three current entries.

It is proposed to manage potential risks by inserting a condition that the compounds must not contain biologically active ingredients.

## 5.3 Clarifying entries in Schedule 2 and improving risk management

### 5.3.1 Substances with no agricultural compound claims

Entry 2 provides exemption for a "Substance or compound (not being an agricultural compound described elsewhere in this schedule)-….". These exemptions are for generic substances, with no agricultural compound claims, but that are bought and used as such. The exemption is needed to ensure that:

- users are subject to Regulation 8 and are obliged to take responsibility for the risk management; and
- if certain substances are used, those uses are subject to regulatory approval (that is, used within the scope of an approved operating plan under section 28 of the Act).

#### Proposed changes

We propose to change the entry description and conditions as follows:

**Description** - delete the bracketed phrase "not being an agricultural compound described elsewhere in this schedule" from the entry description.

**Conditions** - add as a condition a list of ingredients the compounds must not contain, the same as proposed for the consolidated topical veterinary preparations entry (see 5.2.1) to replace existing conditions (a)-(e), prefaced by the words "unless there is an approved operating plan".

#### Rationale

The phrase "not being an agricultural compound described elsewhere in this schedule" is confusing and creates uncertainty about the appropriate exemption group for some compounds. This could mean a substance that should be solely subject to entry 2 (and its conditions) could be subject to other entries. This is not the intention. For example, the exemption allows a person to buy a shampoo sold for human use and use it to wash their dog as long as they take care not to harm the dog and the shampoo is not medicated with, for example, a prescription medicine. However, because cleaning products, including shampoos, are described in entry 13, entry 2 might not apply, which is not the intention.

The phrase does not contribute any risk management advantage and may prevent people from safely taking advantage of entry 2.

### 5.3.2 Compounds used in research, testing and training activities

Entry 3 provides an exemption to persons and organisations to use agricultural compounds for research, testing and training activities as long as they are operating within the scope of an approved operating plan. The approved operating plan dictates the security measures necessary to minimise the risks from those activities.

A condition on the exemption obliges the person or organisation to notify the Director-General if a substance or compound is to be used that has not previously been notified in the operating plan.

#### Proposed change

We propose to change the entry description and conditions as follows:

**Description** - replace the phrase "substances or compounds" with the term *"active ingredients"*

**Conditions** - replace the phrase "substance or compound" with the term *"active ingredient"*.

#### Rationale

The phrase "substance or compound" is imprecise. It could mean an ingredient or a full formulation. However, only active ingredients are of significant interest, so full formulations are not needed.

This change would simplify the obligation on the person or organisation while still providing adequate information to the regulator on what is being used.

### 5.3.3 Sterilisers, sanitisers, and disinfectants

Entry 7 provides exemption for compounds used for hygiene in housed environments. The entry description is stated as follows:

> "Sterilisers, sanitisers, and disinfectants (excluding fumigants) used to maintain hygienic conditions for the purposes of hygiene and pest management in places where animals and plants are housed or cultivated".

#### Proposed change

**Description** – we propose to amend the entry description to remove reference to "pest management".

#### Rationale

Reference to "pest management" in the description of entry 7 is problematic. Compounds relevant to this exemption (that is, sterilisers, sanitisers and disinfectants) are not used for 'pest management' as the term is commonly understood and used. Pest management normally refers to control of macro-organisms, not hygiene-related purposes.

Referring to "pest management" in this context may cause confusion and mislead. It may also lead to a perception that products that fall into this category should also be capable of 'pest management'. This can lead to 'scope creep' - broadening the scope of the entry to include substances beyond that intended for exemption.

The change would refocus the entry description unambiguously on hygiene, and remove the potentially misleading reference to pest management.

### 5.3.4 Compounded veterinary preparations

Entry 9 provides exemption for compounded veterinary preparations, prepared and used by, or under the instruction of, veterinarians. The first condition states the compounded veterinary preparation "must not be used on animals except under the direct care, or with the authorisation, of the compounding veterinarian".

This exemption group is intended to allow veterinarians the ability to prepare specific formulations that they can use on animals under their direct care.

#### Proposed change

We propose to change the description and conditions as follows:

**Description** – delete the words "…used by veterinarians" from the description.

**Conditions** – delete the words "or with the authorisation" in the first condition.

Add a condition *"Must not be advertised for sale for use on animals"*

#### Rationale

The proposed changes are to clarify the intention and focus of the exemption. The exemption is to provide for specific situations where registered brand name products, or other available recognised products, are not suitable for the particular treatment proposed by the veterinarian. It is not the intention of the exemption to allow a veterinarian to supply or sell the compounded veterinary preparation more broadly. The veterinarian is able to prepare specifically formulated compounds, but the application is limited to animals directly under the compounding veterinarian's care.

Removing the phrase "or with the authorisation" eliminates the current potential interpretation that a compounding veterinarian could provide authority for use of the compounded preparation for animals not under his/her direct care. Furthermore, by adding the proposed new condition, it makes it explicit that a compounded veterinary medicine preparation is only in relation to animals under the direct care of the compounding veterinarian.

### 5.3.5 Homeopathic preparations used as veterinary medicines

Entry 10 Oral and topical preparations for use on animals relates to homeopathic preparations used as veterinary medicines.

#### Proposed changes

**Description** – we propose to:
- amend the entry description to specifically state that these are homeopathic oral and topical preparations.

- amend para (a) to the effect that these preparations "are prepared by a process of solution, extraction or titration of an active ingredient followed by strictly regimented dilution *to the point that the active ingredient is no longer practically detectable*;"

### Rationale

The changes clarify two issues. First, the term "homeopathic" is not currently used in the entry description, although this entry relates specifically to homeopathic preparations. This has caused some confusion. Second, the current wording in 10(a) that finishes with "…strictly regimented serial dilution" is considered to leave some uncertainty about the extent of dilution required. Adding additional wording to the effect that serial dilution must continue until the active ingredients are no longer able to be practically detected, avoids uncertainty. This change reinforces consistency with the principles and practice of homeopathy.

## 5.3.6 Entry 11 reference to unrefined extract

The term "unrefined extract" appears in entry 11 Oral and topical preparations for animals, but is currently not defined in the Regulations.

### Proposed change

We propose to insert a definition of 'unrefined extract' in Regulation 3 (see 7.1).

### Rationale

The current lack of a definition for unrefined extract leaves the term open for interpretation from industry, and has led to some ambiguity for MPI in assessing class determinations. Providing a formal definition would provide clarity and certainty.

The definition proposed for 'unrefined' in 7.1 allows for some degree of processing, but this would be limited to actions related only to achieving a material of acceptable quality (for instance, filtering or drying), without modifying any other properties of the material.

## 5.3.7 Entry 18 antidiarrhoeal preparations

The entry is specific to preparations that are used solely as gastrointestinal adsorbent or protective agents and do not make claims in relation to binding any specific micro-organism or toxin.

**Proposed change**

**Description** - we propose to add a qualifier on the entry description to the effect that the product must *"have only a local, surface-acting effect on the gastrointestinal tract"*.

**Rationale**

The proposed change reinforces in the entry description the limited applicability and use for these preparations. The current conditions also do not make it sufficiently clear that the only products included in this group are locally acting substances with no drug-like actions.

This change should also be read in conjunction with the changes noted earlier for entries 18, 19 and 20 (5.2.3) - removing the term 'non-medicated' and adding a list of substances the exempt products must not contain.

## 5.3.8 Entry 19 lubricants

The entry is specific to oral and rectal laxatives and lubricants.

### Proposed change

**Description** - we propose to delete the words "orally and rectally administered", and add a qualifier on the entry description so the description would read to the effect "Laxatives and lubricants used on animals, *having only a local, surface-acting effect on the gastrointestinal tract, vulva, and vagina"*.

### Rationale

The proposed change broadens the scope of the exemption to include vaginally administered lubricants, when used in small quantities. MPI considers that lubricants used in small quantities in the vagina have a risk profile equivalent to rectally-administered lubricants. Note that it is not intended that lubricants introduced into the uterus in large volumes during assisted calving would be included in the scope of this exemption.

This change should also be read in conjunction with the changes noted earlier for entries 18, 19 and 20 (5.2.3) removing the term 'non-medicated' and adding a list substances the exempt products must not contain.

## 5.3.9 Entry 25 Oral nutritional compounds

Entry 25 provides an exemption for animal nutritional compounds that are fed orally. One of the conditions allows oral nutritional compounds to be used as a carrier for therapeutic veterinary medicines when treating a herd or flock of animals. This is common practice, especially in intensive operations such as chicken and pig production, as it simplifies the treatment and is less intrusive to the animals.

The condition allows an animal feed to remain exempt from registration as long as only registered veterinary medicines are added and used in a manner consistent with registration conditions:

> "An agricultural compound that is a therapeutic or pharmacological substance or preparation may be incorporated into oral nutritional compounds only if—
> (a) the agricultural compounds are registered under the Act; and
> (b) the incorporation of the agricultural compounds is consistent with any conditions of their registration"

### Proposed change

**Conditions** – we propose to add clauses to the conditions to the effect that:

> *(c) incorporation of the registered veterinary medicine must be consistent with the indications, use patterns and target species approved for the registered product; and*
> *(d) the registered veterinary medicine must remain adequately distributed throughout the oral nutritional compound for the entirety of the claimed shelf life of the feed; and*
> *(e) the efficacy of the registered veterinary medicine must be maintained for the entirety of the claimed shelf life of the feed.*

### Rationale

The amendments would address concerns that current exemption conditions are insufficient with respect to the targeting, effectiveness and efficacy of the resulting animal feed/veterinary medicine mixture. The added conditions would expressly state that incorporating a registered veterinary medicine into an animal feed a) must be consistent with, and within the scope of, the

registration of that product, and b) must ensure that a medicated feed staying on the shelf for an extended length of time before use will not deteriorate or separate out.

Note that the proposed amendment would not alter the exempt status of any oral nutritional compound.

### 5.3.10 Reference to intra-ruminal device within the scope of oral nutritional compounds

Entry 25 applies to oral nutritional compounds but specifically excludes intra-ruminal devices from exemption. These devices contain, and provide slow release of, high-concentration nutrients, and are also used for some veterinary medicines. Some of these substances are toxic in high concentrations and inadvertent quick release would harm the animal. Because of the unique risks they pose, intra-ruminal devices are excluded from the oral nutritional compound exemption.

#### Proposed change

**Description** – we propose to change the bracketed phrase in the entry description from "not being an intra-ruminal device" to *"excluding agricultural compounds administered in an intra-ruminal device"*.

#### Rationale

Clarifying the wording would distinguish between the device and the agricultural compound that is administered. The current entry description could imply that the intra-ruminal device is an agricultural compound rather than a release mechanism for agricultural compounds.

### 5.3.11 Agricultural chemical products used on plants not to be used as food for people or animals

Entry 35 relates to agricultural chemical products used solely to manage plants not intended to be used as food for humans or animals. The exemption provides for situations where the compound used may leave residues, but as long as the residues do not enter the food chain the risks are minimal.

There is one current condition that states:

> "The label must clearly state that the product must not be used on crops intended for consumption by humans or animals".

#### Proposed change

**Conditions** – we propose to amend the conditions to add clauses to the effect that:

- *the product must not be used on plants that are intended to produce food for consumption by humans or animals;*
- *the product must not be applied to areas that may be grazed by food-producing animals.*

#### Rationale

Adding the further conditions directly addresses the main risk issue with this group of products; concern with residues entering the food chain. The proposed changes would also clarify problems with how this exemption has been interpreted.

Some regulated parties have argued that when their product is intended to be used, the plant would not be used for human consumption, or the part of the plant intended to be used for food

has not yet been formed. Consequently, they consider that the exemption applies to their products. This was not the intention. If, following treatment, any plant material is to be used for human or animal consumption, the potential risk of residues needs to be assessed via the registration process. The residue uncertainty is too great to allow exemption for food-producing plants or for plants used to feed food-producing animals.

Requiring a label warning is considered a reasonable and practical approach, rather than imposing a more stringent condition that would be difficult to enforce. Users also have responsibilities to comply with Regulation 7 Fitness for purpose.

### 5.3.12 Entry 41 Fertilisers and fertiliser additives

This entry covers a broad group of compounds that directly or indirectly enhance plant productivity. 'Fertilisers' and 'fertiliser additives' are defined in Regulation 3 Interpretation.

#### Proposed actions

We propose to change the entry description and conditions as follows:

**Description** - amend entry 41 to read *"Fertilisers and plant biostimulants"*.

**Conditions** - amend to the effect that the label must specify plant nutrient content, *active ingredients*, and modifying pH value, as applicable.

Make consequential changes to Regulation 3; amend the definition of 'fertiliser', delete 'fertiliser additives', add definitions of 'plant biostimulant' and 'plant nutrient', and amend the definition of nutrient to read 'animal nutrient' (see 7.1).

#### Rationale

New knowledge has become available on the range of substances and organisms that can have a positive impact on the growth and productivity of plants. In view of this it is proposed to update this exemption category with new terms and conditions, and to update and clarify relevant definitions.

Changing the entry description provides a more consistent group of compounds to better reflect the current understanding of plant growth and productivity. The proposed amendment to the labelling conditions would ensure any active ingredients are identified.

These changes flow through to a consequent need to clarify and update definitions. It is proposed to amend the definition of fertiliser. The current fertiliser definition contains details relating to nutrients; these details are moved to a new definition, 'plant nutrient'. A definition is proposed for the newly introduced term of 'plant biostimulant'. The current definition of nutrient relates specifically to nutrients for animals; this definition will now be stated as 'animal nutrient' and will be amended to clarify that it also includes topically applied nutrients. The specific changes proposed to definitions are set out in 7.1 of this document.

Deleting specific reference to fertiliser additives is not to imply removal of exemption status for such compounds; it is considered that these types of compounds are included in entry 28 of Schedule 2.

| What do you think? |
| --- |
| 3. What do you think of the proposed changes? Please comment in detail on proposed changes where you have specific knowledge and insights.<br>4. What impact do you anticipate the proposed change(s) will have? Please comment, if applicable, on the impact the proposed changes will have on your business. Do you think the current exempt status of any products will change as a result of the proposed changes?<br>5. Are there alternative options to the proposed changes that you believe would be preferable? If so, what are they and why do you prefer them?<br>6. Should MPI be considering changes to any other existing compound groups? If so, what ones, and why? |

# 6 Proposed new Schedule 2 exemption groups

A number of emerging products have been subject to class determinations by MPI but, despite meeting the criteria for exemption (that is, section 76 analysis), have proven difficult to allocate to existing exemption groups. This means some products are currently not formally exempt from registration when they should be. As a consequence, they currently require registration.

New groups have been identified by sub-headings to provide a working description of the groups. Substances in these categories have been determined as carrying a risk profile not requiring their registration when used in compliance with the Regulations (the general provisions as well as any specific conditions proposed).

## 6.1 Part A exemptions - agricultural compounds used in relation to animals and plants

### 6.1.1 Proposed exemption for agricultural compounds acting mechanically to control pests in the environment

Compounds that act mechanically to control pests are those whose properties exert control over pests by mechanical constraint or constriction. An example is diatomaceous earth, which effects control of insects by causing dehydration.

#### Entry description

Agricultural compounds with solely a mechanical mode of action applied to the environment in which animals or plants are kept, to control invertebrate pests of animals or plants.

#### Conditions

Must not contain any biologically active ingredients.

#### Rationale

MPI considers that these types of products have a risk profile not requiring their registration and are unlikely to cause residue issues. The condition would make it explicitly clear that if the compound contains a biologically active ingredient it would no longer be considered to have a mechanical mode of action and would not qualify for exemption within this group.

However, MPI is keen to hear the views of interested parties on whether further conditions should be applied, in particular to reduce harm to animals who may be exposed to these substances.

## 6.2 Part B exemptions - agricultural compounds used in relation to animals

### 6.2.1 Proposed exemption for semiochemical preparations to modify animal behaviour

Semiochemicals are chemicals that carry communication signals that affect the behaviour of animals. Semiochemical preparations utilise these chemicals to modify animal behaviour. Their advantages include being relatively nontoxic and non-persistent in the environment.

#### Entry description

Semiochemical preparations used to modify animal behaviour.

#### Conditions

- They must not claim to prevent, control, or cure a specific disease characterised by pain or distress in animals.
- The proposed conditions to apply to topical preparations (5.2.1) would also apply.

Make consequential change to Regulation 3 to insert a definition of semiochemical preparations.

#### Rationale

MPI considers that this proposed exemption is consistent with other exemptions for repellents and attractants. All these exemptions have a risk profile not requiring their registration.

### 6.2.2 Proposed exemption for biologically active agricultural compounds, applied to the contained environment in which non-food producing animals are kept, to control invertebrate pests of animals

This proposed exemption group would cover situations where invertebrate pests are causing issues for animals in buildings. An example would include a flea treatment used in homes to protect companion animals from fleas.

#### Entry description

Biologically active agricultural compounds applied to the contained environment in which non-food producing animals are kept to control invertebrate pests of animals.

#### Conditions

- Must not be used when any animal is present.
- The label must state a safe re-entry period for non-food producing animals.
- The label must state that food-producing animals must not be exposed to this product.

#### Rationale

MPI considers that these types of products have a risk profile not requiring their registration and are unlikely to cause residue issues if the proposed conditions are complied with.

### 6.2.3 Proposed exemption for topically absorbable animal nutrient substances

This emerging group of products use a novel method to provide nutrients to animals – absorbable through the skin. An example of potential use is for reptiles in housed environments such as zoos.

#### Entry description

Topically absorbable animal nutrient substances.

#### Conditions

- The directions for use on the label must specify the species, type, and class of animal for which use is intended.

#### Rationale

MPI considers that the risk profile of these substances is similar to those under entry 25 for oral nutritional compounds but these products do not meet the criteria under that exemption. Because of the different method of administering these products, it is not considered appropriate to amend entry 25 to include them. A new group is therefore proposed.

### 6.2.4 Proposed exemption for substances with a purely mechanical mechanism of action used on animals

This exemption would cover products considered to be agricultural compounds (because they are considered compounds or biological substances), but for which there is no specific exemption based on their mechanical mode of action. The type of products would include tissue glue and putty hoof repair products.

#### Entry description

Substances with a purely mechanical mechanism of action used on animals.

#### Conditions

- Must not contain any biologically active ingredients.
- Must not be absorbable.

#### Rationale

These products provide similar outcomes to products not considered agricultural compounds, such as sutures and hoof blocks, in that their intention is to provide a physical barrier or constraint. However, they differ in the form in which they are applied, and so need to have conditions to ensure they do not contain a biologically active ingredient and are non-absorbable.

MPI is keen to hear the views of interested parties on whether the scope and/or conditions proposed for this new entry should be further prescribed. As currently proposed, the group could encompass compounds such as diatomaceous earth products.

## 6.3 Part C exemptions - agricultural compounds used in relation to plants

### 6.3.1 Proposed exemption for agricultural chemical products used in empty structures to remove infestations of diseases or pests of plants

This exemption group would cover products that are applied to, or within, empty structures to remove pests prior to growing plants or storing grains or other raw agricultural commodities. The structures would include empty glasshouses, silos, storage barns or similar such contained structures.

#### Entry description

Agricultural chemical products used in empty structures to remove infestations of diseases or pests of plants.

#### Conditions

- Must not be used when plants or produce are present.
- To avoid non-compliant residues, the label must state a re-entry period that should pass before plants or produce are re-introduced.

#### Rationale

MPI considers that these types of products have a risk profile not requiring their registration and are unlikely to cause residue issues if used in compliance with the proposed conditions.

| What do you think? |
| --- |
| 7. Do you agree with the proposed changes? Please comment in detail on proposed changes where you have specific knowledge and insights.<br>8. What impact do you anticipate the proposed change(s) will have? (for example, the scale or range of new products that could become available). Please comment, if applicable, on the impact the proposed changes will have on your business.<br>9. Should MPI be considering exemption for any other new compound groupings? If so, what ones, and why? |

# 7 Proposed changes to specific regulations

## 7.1 Regulation 3 Interpretation

All changes to definitions have been noted and discussed in sections 5 and 6 of this document as part of the Schedule 2 proposed changes (see 5.2.1, 5.2.3, 5.3.6, 5.3.12 and 6.2.1). The following collates and specifies these proposed changes.

**animal nutrient - amend** the current definition of "nutrient" to read "animal nutrient" to clarify that this applies only to animals. **Add** the words "or topically" so the definition reads "**animal nutrient** means a nourishing substance given orally *or topically*, …"

**antibiotic substance –insert** a definition to read (to the effect):

means a substance that kills or stops the growth of bacteria

**fertiliser – amend** the current definition of fertiliser to read (to the effect):

(a) means a substance or biological compound or plant material or 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 or, indirectly, animals through the application to plants or soil of plant nutrients; and

(b) includes non-plant nutrient attributes of the materials used in fertiliser; but

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

**fertiliser additive - delete** the term

**non-medicated - delete** the term

**plant biostimulant - insert** a definition to read (to the effect):

contains substance(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural growth processes or enhance/benefit plant nutrient uptake, plant nutrient efficiency, tolerance to abiotic stress, or crop quality. It does not include substances that are plant growth regulators that modify the physiological functions of plants

**plant nutrient - insert** a definition to mean:

chemical elements and compounds necessary for plant growth, including, but not limited to—

a) macronutrients (nitrogen, phosphorous, potassium, calcium, sulphur and magnesium); and

b) micronutrients (boron, chlorine, manganese, iron, zinc, copper, molybdenum, and nickel)

**semiochemical preparation –insert** a definition to read (to the effect):

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

**unrefined extract - insert** a definition to read (to the effect):

plant material not subjected to purification processes that result in the isolation of or alteration of the proportions of specific chemical constituents of the plant

Some consequential changes would be required in the regulations where 'nutrient' is currently used. Either 'animal nutrient' or 'plant nutrient' would be used as appropriate.

## 7.2 Regulation 10 Documented system for compounded veterinary preparations

Regulation 10 specifies that compounded veterinary preparations must be prepared in accordance with a documented system for that preparation, and sets out a number of requirements that must be contained in the documented system.

### Proposed change

Amend Regulation 10, adding words to the effect that the compounding veterinarian must be satisfied that the documented system is suitable and fit for purpose.

### Rationale

The proposed change would address concerns that the current regulation is silent on who should take responsibility for ensuring the documented system is fit for purpose. Currently the regulation only specifies that the compounding veterinarian must be involved in monitoring compliance with requirements of the documented system (Regulation 10(e)).

By limiting the proposed change to specifying an oversight role for the compounding veterinarian, the preparation of the documented system is left flexible. This enables a documented system to be prepared by, for example, a product manufacturer, an agent under the supervision of a compounding veterinarian, or the compounding veterinarian.

## 7.3 Regulation 12 Information requirements

Regulation 12 outlines the circumstances where information must be supplied with the exempt compounded product, and specifies the information requirements (that is, information that must be on the label).

The regulation imposes a requirement to supply information when an exempt compound product is supplied to a user where the intention is that the compound is to be administered by the user.

Regulation 12 does not require labelling when people use exempt compounds themselves and do not offer them for sale (i.e. anyone using compounds under entries 2 or 3 of Schedule 2 or the compounding veterinarian under entry 9 of Schedule 2).

### Proposed change

Amend Regulation 12 to clarify that:

a) if a compounded veterinary product is administered by the compounding veterinarian, regulation 12(2) does not apply.
b) if a compounded veterinary product is to be supplied and authorised for use by someone other than the compounding veterinarian it must be accompanied by a label or other document that includes the information set out in Regulation 12

### Rationale

The proposed change would clarify confusion around the circumstances when labelling is not required. The particular situation where label information is not required will be specified. In all other circumstances label information will be required.

## 7.4 Schedule 3

As discussed in relation to entry 11 of Schedule 2, it is proposed to delete Schedule 3 *Plants not to be included in oral and topical preparations* from the Regulations. This would remove any potential conflicts between the list of plants in Schedule 3 and the broader obligations and responsibilities on importers, manufacturers, sellers and users of agricultural compounds contained in Regulations 7 and 8.

| What do you think? |
| --- |
| 10. Do you agree with the proposed changes to the definitions? Are the proposed changes clear, and will they be easy to work with?<br>11. Are there any other definitions you consider to be unclear or difficult to interpret? If so what changes would you like to see?<br>12. Do you agree with the proposed changes to Regulations 10 and 12, and the deletion of Schedule 3? If not please tell us why. If there are other regulations you consider should be changed, please tell us what they are and why you would like changes.<br>13. Please comment, if applicable, on the impact the proposed changes will have on your business. |

# 8 Implementation

After the consultation period finishes, MPI will analyse the submissions and refine the proposals, taking account of the feedback received. The Minister for Food Safety will then submit the final proposals to Cabinet for approval. Once the final proposals have been agreed, the Parliamentary Council Office will draft the amendments to the ACVM Regulations.

MPI will ensure the changes will be communicated directly to those who may be impacted through key industry groups via the Agricultural Compounds and Veterinary Medicine Advisory Council (AVMAC) and through industry groups the Agricultural Chemical and Animal Remedy Manufacturers Association (Agcarm) and the Animal Remedy and Plant Protection Association (ARPPA). Information about these changes will also be made available on MPI's website.

MPI will provide support and guidance to stakeholders to ensure the new regulations are implemented smoothly. A 24 months transition period is proposed to allow sufficient time to comply with the revised ACVM Regulations. This will allow for the collection of data and other relevant information to support registration and to make an application with MPI for registration should this be required.

# 9 Monitoring and evaluation

MPI will monitor implementation of the regulatory changes as part of its ongoing programmes and processes. This includes:

- general food safety monitoring and evaluation;
- annual regulatory scanning and planning;
- stakeholder engagement forums and feedback from industry;
- information gained from class determination requests;
- audit processes and verifications.

# 10 Appendix - snapshot of the proposed changes

## 10.1 Changes to existing exempt groups in Schedule 2

| Entry | Short title | Proposed change to entry description and conditions (includes reference to the section in this report where discussed) |
|---|---|---|
| 2 | Substance or compound that is not an exempt agricultural compound, but is used to achieve similar outcomes | Delete phrase “not being an agricultural compound described elsewhere in this schedule” from the entry description (5.3.1)<br>Add to conditions a list of substances the compounds must not contain (5.3.1 & 5.2.1) |
| 3 | Agricultural compounds used for research, testing or training | Amend entry description and conditions to replace the phrase “substance(s) or compound(s)” with the term “active ingredient(s)” (5.3.2) |
| 7 | Sterilisers, sanitisers, and disinfectants used for maintaining hygiene | Amend existing entry description to remove reference to “pest management" (5.3.3) |
| 9 | Compounded veterinary preparations used by veterinarians | Amend entry description by removing "used by veterinarians" (5.3.4)<br>Amend conditions to clarify that exemption applies only for veterinary preparations used on animals under the direct care of the compounding veterinarian, and that such preparations cannot be advertised for sale more broadly (5.3.4) |
| 10 | Homeopathic oral and topical preparations for use on animals | Amend entry description to specifically state that these are homeopathic oral and topical preparations (5.3.5)<br>Add a further explanation to entry description to clarify dilution expected from a homeopathic preparation (5.3.5) |
| 11 | Oral and topical preparations for use on animals | Remove reference to Schedule 3 and delete Schedule 3 from Regulations (5.1.2)<br>Add to conditions a list of substances the compounds must not contain (5.2.4 & 5.2.1)<br>Clarify the condition relating to milk for human consumption, and include udders as part of the animal where the preparation must not be used (5.2.4) |
| 12 | Non-absorbable masking agents | Consolidate together as a single topical veterinary preparation entry, specifying a set of relevant uses in the entry description (5.2.1)<br>Move some existing entry description phrases to conditions. Set out a consolidated list of substances the compounds must not contain (5.2.1)<br>Add amended condition relating to udders and teats of animals whose milk is being collected for human consumption (5.2.1 & 5.2.4) |
| 13 | Topical non-absorbable and non-solvent cleaning products | |
| 15 | Over-the-counter first aid preparations | |
| 16 | Topical preparations for animals | |
| 17 | Topical hoof preparations | |
| 21 | Cauterising preparations used or applied superficially | |

| | | |
|---|---|---|
| 18 | Non-medicated antidiarrhoeal preparations | Remove "Non-medicated" from entry description and delete the definition (5.2.3)<br>Add to entry description that product must have only a local, surface-acting effect on gastrointestinal tract (5.3.7)<br>Add to conditions a list of substances the compounds must not contain (5.2.3 & 5.2.1) |
| 19 | Non-medicated orally and rectally administered laxatives and lubricants used on animals | Remove "Non-medicated orally and rectally administered" from entry description (5.2.3 & 5.3.8)<br>Add to entry description that product must have only a local, surface-acting effect on gastrointestinal tract, vulva and vagina (5.3.8)<br>Add to conditions a list of substances the compounds must not contain (5.2.3 &5.2.1) |
| 20 | Non-medicated moist or dry poultice preparations used on animals | Remove "Non-medicated" from entry description (5.2.3)<br>Add to conditions a list of substances the compounds must not contain (5.2.3 & 5.2.1) |
| 22 | Oral urinary tract modifiers | Add a label statement to seek veterinary advice if the preparation fails to alleviate the condition (5.2.2) |
| 23 | Respiratory tract modifiers for use on animals | Add a label statement to seek veterinary advice if the preparation fails to alleviate the condition (5.2.2) |
| 25 | Oral nutritional compounds fed to animals | Amend description to clarify wording on the exclusion of intra-ruminal devices from exemption (5.3.10)<br>Remove reference to GRAS substances in the conditions (5.1.1)<br>Add three new conditions applying to feed additives used in oral nutritional compounds (5.3.9) |
| 26 | Oral gastrointestinal-acting microflora-enhancing compounds | Remove reference to GRAS substances in the conditions (5.1.1) |
| 32 | Anti-transpirants to prevent drying of plants | Combine into single entry - compounds used for protecting plants from climatological conditions (5.2.5)<br>Add condition that compounds must not contain biologically active ingredients (5.2.5) |
| 33 | Frost protectants to prevent frost damage | |
| 34 | Sunblocks to prevent or reduce sunburn in plants | |
| 35 | Agricultural chemicals used on plants not intended for human and animal consumption | Add conditions that the compounds must not be used on plants intended to produce food for consumption by humans or animals, or applied to areas grazed by food-producing animals (5.3.11) |
| 41 | Fertilisers and fertiliser additives | Amend entry description to read fertilisers and plant biostimulants (5.3.12)<br>Amend label to require specification of active ingredients (5.3.12) |

## 10.2 Proposed new exempt groups

| **Proposed exempt group** | **Comment and conditions** |
|---|---|
| Agricultural compounds with a solely mechanical mode of action applied to the environment in which animals or plants are kept, to control | These types of products have a risk profile not requiring registration.<br>Must not contain any biologically active ingredients. |

| | |
|---|---|
| invertebrate pests of animals or plants | |
| Semiochemical preparations used to modify animal behaviour | Preparations utilising natural chemicals to modify animal behaviour.<br>Conditions proposed to state the limitations on any outcome claims.<br>Would also adopt conditions proposed for consolidated topical preparations entry in Schedule 2. |
| Biologically active agricultural compounds applied to the contained environment in which non-food producing animals are kept to control invertebrate pests of animals | These types of products considered to have a low risk profile so long as conditions complied with.<br>Must not be used when any animal is present;<br>Label must state a safe re-entry period for non-food producing animals;<br>Label must state that food producing animals must not be exposed to this product |
| Topically absorbable animal nutrient substances | Emerging group of products providing nutrients to animals by absorbing through the skin.<br>Would require label condition that must specify species, type, and class of animal for which use is intended |
| Substances with a purely mechanical mechanism of action used on animals | Products provide similar outcomes to products not considered agricultural compounds, such as sutures and hoof blocks, but are applied in a different form.<br>Conditions need to ensure they do not contain a biologically active ingredients and are non-absorbable |
| Agricultural chemical products used in empty glasshouses or silos to remove infestations of diseases or pests of plants | Products considered to have low risk profile so long as conditions complied with.<br>Must not be used when plants or produce are present, and label must state a re-entry period that should pass before plants or produce are re-introduced |

## 10.3 Proposed changes to specific regulations

Regulation 3 Interpretation: changes are proposed to several definitions – animal nutrient, antibiotic substance, fertiliser, fertiliser additive, non-medicated, plant biostimulant, plant nutrient, semiochemical preparation, unrefined extract.

Regulation 10 Documented system for compounded veterinary preparations – it is proposed to amend this regulation to specify that the compounding veterinarian has responsibility for ensuring the documented system is suitable and fit for purpose.

Regulation 12 Information requirements– it is proposed to amend this regulation in order to clarify when labelling is not required for an exempt agricultural compound.

Schedule 3 – it is proposed to delete Schedule 3 Plants not to be included in oral and topical preparations from the Regulations.

## 10.4 The questions we would like you to address

| Issues and rationale - what do you think? |
|---|
| 1. Do you agree with the rationale and need to change the Regulations? |
| 2. What is your view on the size/scale of issues identified? (This could include views on the numbers of products potentially affected, or the potential costs of a change to the status quo, for example). |
| **Proposed changes to Schedule 2 - what do you think?** |
| 3. What do you think of the proposed changes? Please comment in detail on proposed changes where you have specific knowledge and insights. |
| 4. What impact do you anticipate the proposed change(s) will have? Please comment, if applicable, on the impact the proposed changes will have on your business. Do you think the current exempt status of any products will change as a result of the proposed changes? |
| 5. Are there alternative options to the proposed changes that you believe would be preferable? If so, what are they and why do you prefer them? |
| 6. Should MPI be considering changes to any other existing compound groups? If so, what ones, and why? |
| **Proposed new exempt groups - what do you think?** |
| 7. Do you agree with the proposed changes? Please comment in detail on proposed changes where you have specific knowledge and insights. |
| 8. What impact do you anticipate the proposed change(s) will have? (For example, the scale or range of new products that could become available). Please comment, if applicable, on the impact the proposed changes will have on your business. |
| 9. Should MPI be considering exemption for any other new compound groupings? If so, what ones, and why? |
| **Proposed changes to specific regulations - what do you think?** |
| 10. Do you agree with the proposed changes to the definitions? Are the proposed changes clear, and will they be easy to work with? |
| 11. Are there any other definitions you consider to be unclear or difficult to interpret? If so what changes would you like to see? |
| 12. Do you agree with the proposed changes to Regulations 10 and 12, and the deletion of Schedule 3? If not please tell us why. If there are other regulations you consider should be changed, please tell us what they are and why you would like changes. |
| 13. Please comment, if applicable, on the impact the proposed changes will have on your business. |