Impact Summary: Amendments to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 [ACVM Regulations]

Section 1: General information

Purpose

The Ministry for Primary Industries (MPI) is solely responsible for the analysis and advice set out in this Regulatory Impact Summary. This analysis and advice has been produced for the purpose of informing final decisions to proceed with a policy change to be taken by Cabinet.

Key Limitations or Constraints on Analysis

The Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) specifies that where the likely cost of assessing and registering an agricultural compound is greater than the likely risks from the use of that agricultural compound without registration, or the risks are already adequately managed under other legislation, then the Minister must recommend that the compound be exempt from registration. MPI is not proposing any changes to the ACVM Act or to the risk thresholds used to assess new exemption groups.

This Impact Summary proposes only two options to address the problems with the ACVM Regulations - the status quo, and amending the ACVM Regulations to add new exemption groups. There are no other non-regulatory options available to solve the problem identified. MPI is constrained by the ACVM Act 1997 when assessing and adding additional exemption groups. The proposed exemption groups have been individually assessed as having a risk profile not requiring registration.

Responsible Manager (signature and date):

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/ /2019

Section 2: Problem definition and objectives

2.1 What is the policy problem or opportunity?

Background

Agricultural Compounds and Veterinary Medicines Act 1997

The purpose of the ACVM 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 biosecurity;
2. ensure that agricultural use does not result in breaches of domestic food residue standards; and
3. ensure the provision of sufficient consumer information about agricultural compounds, so that they are used wisely and appropriately.

The sale, manufacture, importation or use of agricultural compounds in New Zealand is prohibited unless the compound is either a registered trade name product subject to conditions or exempt under the ACVM Regulations. The ACVM Act takes a risk-based approach to regulating agricultural compounds and veterinary medicines and recognises that these compounds should be regulated at a level commensurate to the risk they present.

Many of these compounds are in common use to produce primary products such as arable and horticultural produce, meat, natural fibres, and dairy products. They are also used domestically for home food production, amenity gardening, and treating companion animals.

Costs of registering a product

In order to achieve its purpose, the ACVM Act requires all agricultural compounds to be registered with MPI, or to be specifically granted exemption from registration. Initial registration for each individual product costs approximately $4500 (depending on how long it takes to process the application) plus an annual levy of $540 that is used for monitoring and review activities, and administration of the registration regime.[1]

In addition to direct registration costs, there are also substantial indirect costs associated with registering a product. Anyone who wants to market a product that requires registration in New Zealand must provide MPI with data that shows that the product is safe. It is estimated that generating the data required to support a registration can cost anywhere from $10,000 to $500,000. These costs may be passed onto the consumer at the point of sale. However, these costs may be offset by use for registration in other countries, which often require the same information.

How products are exempted and risks managed under the ACVM Regulations 2011

The ACVM Act allows for exemption from registration through the inclusion of exempt 'groups' (e.g. fertiliser and fertiliser additives) in the ACVM Regulations. These are groups of products for which individual product registration is considered unnecessary to manage the risks. Such exemptions are consistent with international practice.

Exempt compounds could still present a risk (to public health, trade in primary products, animal welfare, or biosecurity) if not used correctly or appropriately. These risks are

[1] Fees are currently being reviewed and a small reduction in costs is being proposed.

managed by setting conditions in the ACVM Regulations on the manufacture, sale or use of the compound. By satisfying these conditions compounds are able to retain their exempt status.[2]

How it is determined if a compound is exempt or not

Chemical compounds are assessed according to their chemical and structural properties to find out whether a compound fits into an exempt group or alternatively requires registration before it can be imported, manufactured, sold or used in New Zealand. These assessments of the properties can provide industry with certainty about whether a compound qualifies for exemption and would fit within current exemption groups.

A manufacturer or importer may do their own assessments of chemical properties or ask MPI to do one. Fees apply for this service and it may take up to 15 days to complete. After a determination has been made by MPI, MPI will provide an outcome letter that is valid for three years. MPI receives many such requests each year.

Compounds being imported may also require a biosecurity assessment under the Biosecurity Act 1993. Approval may also be needed under the Hazardous Substances and New Organisms Act 1996 (HSNO Act), which includes an assessment of risks to human health and to the environment before it can be cleared for entry into New Zealand.

How MPI has identified new groups of exempt compounds

The ACVM risk thresholds (Section 4 ACVM Act 1997) provide the basis for determining what groups of agricultural compounds can be exempted from registration. The risks that need to be considered as stated in the ACVM Act are risks associated with the use of agricultural compounds to:

- public health;
- trade in primary produce;
- animal welfare; and
- biosecurity.

The MPI ACVM technical team has identified groups of agricultural compounds that could be exempt from registration by applying the MPI risk assessment framework as set out in **Appendix One**. This involved dialogue with government agencies, affected industry stakeholders (both production sectors and those involved in developing and marketing agricultural compound products) and the public. Industry groups like the Agricultural Compounds and Veterinary Medicines Advisory Council (AVMAC) were also consulted.

Information used in the assessment of risk included information supplied by the marketer about the product such as label and formulation information. Experts were consulted as well as overseas regulatory authorities, to give a full picture of the hazards and risks of the product associated with the risk thresholds. MPI's technical team has also done their own research including whether other New Zealand legislation may cover the products.

Only those agricultural compounds with risks that can be managed appropriately are considered for exempted from registration. MPI has carried out collective risk analyses on each group of agricultural compounds that, because of similarities, pose similar risks and should be regulated in a similar way. The conditions imposed are equally relevant to every compound in the group and are sufficient to manage the risks.

[2] For example fertiliser and fertiliser additives can be used (without registration) on the condition "the label must specify nutrient content and modifying pH value, if applicable."

A risk is calculated by combining the probability that the use of a product or compound will cause harm with the magnitude of that harm. As the probability and magnitude increases, the acceptability of the level of risk decreases. There are established thresholds for these risk areas:

The threshold that is used to determine an acceptable level of risk to <u>public health</u> is an unacceptable probability (and magnitude of harm) that the use of the agricultural compound would: • Reduce effectiveness of human health care • Reduce the safety of food and food related products • Fail to achieve claims to maintain or improve human health status or health care via its use as an agricultural compound, including the management of pests • Reduce the effectiveness of public health programmes • Be inconsistent with any written ministerial direction on public health	**The <u>Biosecurity</u> threshold is an unacceptable probability (or impact) that:** • Use would allow exotic pests, unwanted organism or undesirable organisms to become established in NZ • Inefficacy would allow pests, unwanted organisms or undesirable organisms to become established in NZ • Use would undermine control measures • Inefficacy would undermine control measures • Unintended harm to non-target plants or animals would jeopardise control measures • Use would be inconsistent with any written ministerial direction on biosecurity
The <u>Animal welfare</u> threshold is an unacceptable probability (or impact) that: • The use of the agricultural compound would result in unnecessary/unreasonable pain or distress in the target animal • The product would fail to achieve claims to prevent or cure conditions characterised by significant pain or distress • The use of the agricultural compound would be inconsistent with any written ministerial directions on animal welfare	**The <u>trade risk</u> threshold is an unacceptable probability (or impact) resulting in non-conformance to:** • International trade requirements • Bilateral trade requirements • Requirements imposed to give effect to a written New Zealand ministerial direction

The framework does not lead to zero risk in any of these areas as that is neither practical nor affordable. The most desirable outcome is a balance between potential harm and potential benefit.

Current Situation/Problem

The ACVM Regulations were last amended in 2011. The Regulations have not kept pace with the evolving nature of the agricultural compound market. The majority of the agricultural compound products used in New Zealand are owned by off-shore companies, and products are largely driven by overseas developments and the advances in technology. Some of these advances involve novel technologies not previously considered by New Zealand regulators.

Some of these novel technologies have a risk profile that indicate registration is not appropriate for them, but because their novel use does not fit any of the existing exempt groups in the ACVM Regulations, they require registration. Furthermore, both the domestic and international landscape have evolved on risk thresholds on agricultural compounds. This means that adjustments to the ACVM Regulations to identify new groups of exempt products are needed to ensure the ACVM Regulations remain fit for purpose and set the appropriate level of regulatory oversight of agricultural compounds.

If the ACVM Regulations are not updated, this could result in:

- Delays in bringing the products to market as they require registration, which involves compiling a submission package and obtaining data to support the submission.
- Costs – both in terms of the registration fees, but more substantially the research data required to support the registration that are not justified given the risks.

2.2 Who is affected and how?

The main impacted group are manufacturers and importers of agricultural compounds that are currently required to register their products before importing and selling their products in New Zealand. Once products are exempt from registration, manufacturers and importers are able to bring those products to market without having to develop and provide the data necessary for registration.

End users of agricultural compounds and veterinary medicines including home gardeners, pet owners, farmers and growers of primary produce, are affected as they have less choice of products, or a greater range of products but at increased costs.

2.3 Are there any constraints on the scope for decision making?

The purpose of the ACCM Act is to prevent or manage risks associated with the use of agricultural compounds, being risks to public health, trade, animal welfare, and biosecurity. Changes to these four risk areas are not proposed.

This places a constraint on the decision making in relation to the ACVM Regulations. The only two options are that evidence shows the criteria for exemption is met and new groups are recommended for exemption (and the regulations are updated to include them) or the status quo remains (and products will need to continue to be registered even though their risk profile does not indicate that this is necessary).

As the ACVM Act is concerned with acceptable levels of risk, it has a relationship with other Acts. All authorised compounds or products that contain ingredients of biological origin (whether registered or exempt from registration) need to have Biosecurity Act 1993 clearance to import. Approval may also be needed under the Hazardous Substances and New Organisms Act 1996.

Section 3: Options identification

3.1 What options have been considered?

The ACVM Act only enables new exemption groups to be added through a regulatory process. Therefore, we do not consider there to be any non-regulatory options to address the problem.

The two options are:

- Option 1: status quo where products require registration; or
- Option 2: Amend the ACVM Regulations to add new groups for exemption from registration

Option 1: status quo where products require registration

The status quo fails to implement the purpose and process of the ACVM Act where agricultural compounds and veterinary medicines are to be regulated at a level commensurate to their risks.

Option 2: Amend the Regulations to add new groups for exemption from registration.

Six new exemption groups have been identified and have had a collective risk assessment done based on the risk thresholds identified in the ACVM Act. The assessment found that each of the proposed new groups meet the criteria for exemption, posing risks similar to other exempt groups and can be regulated in a similar way. The conditions imposed on each group are sufficient to manage the risks. The proposed new exemption groups are:

Agricultural compound description	**Examples of products that would fit under this new exempt group**
Agricultural compounds that act mechanically to control pests in the environment	Diatomaceous earth causes insects to die by dehydration.
Semiochemical preparations that modify animal behaviour	Pheromones used to disrupt a pest's mating cycle, or to attract an insect to a trap.
Biologically active agricultural compounds, applied to the contained environment in which non-food producing animals are kept, to control invertebrate pests of animals	Flea treatment.
Topically absorbable animal nutrient substances	Ointment applied to iguanas and other reptiles in a housed environment in a zoo.
Substances with a purely mechanical mechanism of action used on animals	Putty hoof repair products; tissue glue.
Agricultural chemical products used in empty structures to remove infestations of diseases or pests of plants	For use in empty glasshouses and storage barns that store raw agricultural commodities.

The table below provides more detail on how the proposed new groups have meet the criteria for exemption, the types of products that would be exempt under the categories, and the conditions imposed on their use to manage any risks:

Proposed new exemption groups

Used in relation to…	Agricultural compound description	Assessment of proposed exemption group against criteria for exemption	Ways that risks are managed
Plants and animals	**1. Invertebrate pest control by mechanical action** Agricultural compounds that act mechanically to control pests. They do this by mechanical constraint or constriction. *Examples*: Diatomaceous earth	**Public health**: The human health risk profile of products in this group does not meet the requirements for registration under the ACVM Act. The mechanical actions of these products and the fact that the products are not biologically active or absorbable present little risks to human health. Therefore, these products are not of sufficient concern to require strong regulation. **Animal welfare**: The use patterns are through mechanical actions (using diatomaceous earth to prevent insect access to plants), that are also not absorbable or biologically active, and thus pose no animal welfare concerns. **Biosecurity**: The group of products is not of a sufficient biosecurity risk to require registration of the product. Any imported products within this group that might contain ingredients of biological origin will still require a biosecurity assessment and biosecurity clearance under the Biosecurity Act 1993. **Trade risk**: These products, being mechanical modes of action do not have active ingredients of toxicological concern and will not cause residues or present a trade risk.	<u>Conditions</u> • Must not contain any biologically active ingredients. • Must not be absorbable.
Animals	**2. Modifying behaviour with chemicals** Semiochemical preparations modify an animal's behaviour by sending communication signals through chemicals. *Example:* Pheromones used to disrupt a pest's mating cycle, or to attract an insect to a trap.	**Public health**: Semiochemicals and their use patterns do not pose a discernible risk to human health as they primarily work at very low concentrations on the chemical receptors of insects. **Animal welfare**: The chemicals in this group are intended to modify animal's behaviour through means other than therapeutic chemicals and are therefore of low animal welfare concern. In addition, one of the conditions required will be to ensure there are no claims for a therapeutic purpose, to treat a specific disease or condition. **Biosecurity**: The group of products is not of a sufficient biosecurity risk to require registration of the product. Any imported products containing ingredients of biological origin require a biosecurity assessment and biosecurity clearance under the Biosecurity Act 1993. HSNO approval will also be required. **Trade risk**: There is a specific condition to ensure that the compound must not contain substances that are prohibited by countries importing New Zealand primary produce.	<u>Conditions</u> • Must not claim to prevent, control or cure a particular disease characterised by pain or distress in animals. • Must not contain antibiotic substances, hormones, pharmacological substances, solvents, penetrating agents or substances that are prohibited by countries importing

			New Zealand primary produce.
	3. Killing invertebrate pests Biologically active agricultural compounds applied to the contained environment in which non-food producing animals are kept to control invertebrate pests of animals. *Example:* Flea treatment.	**Public health**: The specific biological agents are focused on invertebrates for use in non-food producing animals, do not pose a threat to human health. The products are created to specifically target pests, and are not being used in a way that exposes humans using the product. **Animal welfare**: These products are considered low risk as it deals with pests. However, imposing the condition that the products not be used when animals are present will manage these small risks. **Biosecurity**: Biologically active products can pose a biosecurity risk. However, any imported products will require a biosecurity assessment and biosecurity clearance under the Biosecurity Act 1993. HSNO approval will also be required. **Trade risk**: Products will not cause residue issues if conditions are complied with (food producing animals not to be exposed to product).	Conditions • Must not be used when any animal is present. • Label must state safe re-entry period for non-food producing animals. • Label must state that food producing animals must not be exposed to product.
	4. Nutrients in ointments A new way to supply nutrients to animals – through a topically absorbable ointment containing nutrients. *Example:* Ointment applied to reptiles in a housed environment in a zoo.	**Public health**: The use of ointments to supply nutrients does not pose a risk to human health as the nutrients are the same as those found in comparable human supplements. **Animal welfare**: The products are similar to oral nutritional compounds that are also currently exempt. They are there to provide nutrients to the animals which helps animal welfare not hinder it, and does not meet the threshold for registration. **Biosecurity**: Nutrients in ointment do not pose a biosecurity risk as there is no aspect of biological activity to the nutrients in question to present a biosecurity concern. **Trade risk**: Topical nutrients share similar risk profiles to oral nutritional compounds in that they are unlikely to lead to residues that could cause trade issues.	Conditions • Directions for use on label must specify the species, type and class of animal for which use is intended.
	5. Substances with a purely mechanical mode of action Covers products considered to be agricultural compounds because they are compounds or biological	**Public health**: Substances with a purely mechanical mode of action, such as common glues, do not present a risk to human health, particularly those substances that are not absorbable. **Animal welfare**: These products provide similar outcomes to barrier products that are not agricultural compounds (e.g. sutures and hoof blocks), and treat conditions not requiring a therapeutic product, and hence of low animal welfare concern.	Conditions • Must not contain any biologically active ingredients. • Must not be absorbable.

	substances but for which there is no specific exemption based on their mechanical mode of action. *Example:* Putty hoof repair products, or tissue glue.	**Biosecurity**: The conditions restrict this group to those products that are not biologically active, and do not pose a biosecurity risk. **Trade risk**: The products do not contain a biological active ingredient and hence will not lead to residues that could cause trade concerns.	
Plants	**6. Dealing with infestations of pests in empty silos** Products applied to, or within, empty structures to remove pests prior to growing plants. *Example:* For use in empty glasshouses, empty grain silos or storage barns, or other places that store raw agricultural commodities.	**Public health**: The specific use patterns of treating empty structures does not present a large enough human health risk to require registration. The products will not be used when food items are present and the labels will prevent humans from coming into contact with the products. **Animal welfare**: These products are not used on animals and present no animal welfare risks. **Biosecurity**: These products do not pose biosecurity risks as the products do not contain any biologically active substances. HSNO approval will also be required however. **Trade risk**: The conditions imposed on the use of these products in relation to exposure to food will ensure residues will not cause trade issues. The condition of requiring a re-entry label will prevent the introduction of food items prior to the reduction of any residues that might pose a trade risk.	<u>Conditions</u> • Must not be used when plants or produce are present. • Label must state re-entry period before plants or produce are re-introduced (to avoid non-compliant residues).

3.2 Which of these options is the proposed approach?

MPI considers the proposed approach to be option two, to amend the ACVM Regulations to add six new exemption groups. Each group has been individually assessed against the criteria in the ACVM Act to indicate that any costs imposed on the use of the products (through registration) would outweigh any risks. Conditions on their use will limit further any residue risks as well as other Acts including the Biosecurity Act 1993.

Section 4: Impact Analysis (Proposed approach)

4.1 Summary table of costs and benefits

Creating six new exemption categories

Affected parties Marketers of products, importers, distributers, retailers and end users of agricultural compounds.	**Comment**: There are some uncertainties in quantifying some costs because the number of products impacted is unknown however an approximate number of products is used.	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*

Additional costs of proposed approach, compared to taking no action		
Regulated parties (Manufacturers and importers of ACVM compounds)		Not applicable
Regulators (MPI)	MPI will lose the revenue collected from the levy payable when 5-15 products will no longer have to be registered.	$0.05 million ongoing
Wider government		Not applicable
Other parties		Not applicable
Total Monetised Cost		$0.05 million ongoing
Non-monetised costs		Not applicable

Expected benefits of proposed approach, compared to taking no action		
Regulated parties (Manufacturers and importers of ACVM products)	The proposals would result in benefits for some regulated parties whose products could be made exempt as they would not need to register their products before importing and selling in New Zealand. These figures are based on roughly 60-90 products being exempt based on average registration fees of $4,500 plus a $540 annual levy. This saving would be ongoing. It is expected 5-15 products will become exempt within one year after the Regulations come into force with the remaining products (55-75) becoming exempt within 2-3 years. It does not take into account the indirect benefits from not having to generate data and the completion of documentation which can cost anywhere from $10,000 to $500,000 per product.	$0.30 – 0.45 million over 1 – 3 years[3].

[3] These figures are based on the current charges (charges are proposed to change from 1 July 2019 with a decrease in the base hourly rate charged for ACVM fees).

Regulators (MPI)	Would save time in being able to provide certainty about what is exempt and what requires registration.	Neutral
Wider government		Not applicable
Other parties	End users will have a wide range of new and different products to choose.	Low
Total Monetised Benefit		$0.30 – 0.45 million
Non-monetised benefits		Low

4.2 What other impacts is this approach likely to have?
The levy funds the trade name product regime standard, development and maintenance work of registered products. As new exempt products do not require this maintenance it will not impact on the amount available to spend on registered products.

Section 5: Stakeholder views

5.1 What do stakeholders think about the problem and the proposed solution?

In September 2017, MPI released a discussion document for public consultation (Link: here). Consultation closed in October 2017 and MPI received 15 submissions (four of which were out of scope). Three submitters explicitly mentioned they supported the proposed new exemption groups while the remaining submitters submitted on other proposals not in scope of this Impact Summary Template.

Before consultation began, MPI engaged with AVMAC which consists of industry groups and producer sectors involved in the sale or use of agricultural compounds as well as a consumer representative. AVMAC's purpose is to provide comprehensive and balanced advice to MPI on matters relating to the regulatory control of agricultural compounds and veterinary medicines. AVMAC was provided a draft discussion document for comment and they supported the draft proposals. Seeking comment from AVMAC before the public discussion document was released, was a vital part of the consultation and risk management framework communication process.

To further inform the assessment of the proposed exemption groups, MPI specifically asked for feedback in the consultation document on two of the proposed six new exempt product groups. During consultation MPI asked if further conditions should be applied to 'agricultural compounds that act mechanically to control pests in the environment' and 'substances with purely mechanical mechanisms of action used on animals'.

An example of a product that would fit under the two proposed exemption groups is diatomaceous earth, which effects control of insects by causing dehydration. Diatomaceous earth was singled out as this substance is a well-known compound for insect control and is likely to be one of the main type of substances fitting into these proposed categories.

One submitter noted that these groups would encompass diatomaceous earth products that contains silica. They said silica is dangerous when inhaled, causes lung disease in workers exposed to silica dust and can also irritate the nose, nasal passages, and eyes. They said a condition should be added to the exemption groups stating that the product must be non-irritant and non-toxic to the target species, and used in a way that limits its potential harm.

MPI's view is that such concerns are appropriately addressed already through the ACVM Regulations and current legislation including the Hazardous Substances and New Organisms Act 1996 whose purpose is to protect the environment, and the health and safety of people and communities. Therefore, MPI felt the concerns raised where not significant enough to add further conditions to the exemption category.

Section 6: Implementation and operation

6.1 How will the new arrangements be given effect?

It is intended that the Regulations be implemented as soon as they are promulgated.

MPI would ensure the changes are communicated directly to those that may be impacted through key industry groups via AVMAC and through industry groups such as 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 the MPI website and sent out to stakeholder email lists. MPI will provide support and guidance to stakeholders to ensure the new regulations are implemented smoothly.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

MPI will monitor implementation of the regulatory changes to ensure they remain up to date and fit for purpose as part of its ongoing programmes and processes. This includes a number of ongoing methods of assessing the impact of the regulatory system including:

- Food monitoring programmes to ensure food produced in New Zealand is safe and suitable by establishing safe levels for residues, contaminants and other hazards;
- Stakeholder engagement forums including AVMAC (which meets quarterly) and feedback from industry;
- Information gained from requests at the border to determine if a product is exempt or not; and
- Site audits to check compliance and evidence of good manufacturing practice.

7.2 When and how will the new arrangements be reviewed?

There is no plan to conduct a formal review of the amendments within a particular timeframe. However, as has always been the case, stakeholders will raise issues to do with the application of the ACVM Regulations and feedback from the sector will provide information about whether and when to review the ACVM Regulations again.

Appendix one: MPI Risk Management Framework