

Amendments to the Agricultural Compounds & Veterinary Medicines Regulations 2001 (March 2007)

Regulatory Impact Statement

Statement of the nature and magnitude of the problem and the need for government action

The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 is enabling legislation. It works on the assumption that all agricultural compounds must be registered, unless they have been exempted from registration by regulation. The term agricultural compound has a wide definition and includes substances that pose little or no risk, through to high-risk pesticides and veterinary medicines.

The purpose of the ACVM Act is to manage or prevent risks from agricultural compounds to trade, animal welfare, and agricultural security and to ensure their use does not breach domestic food residue standards. It does not cover risks to the environment or human health, which are covered by the Hazardous Substances and New Organisms Act 1996. However, the ACVM Act does provide for the provision of consumer information about agricultural compounds and veterinary medicines, including environmental and human health information.

The ACVM Act requires the Minister to recommend the making of an Order in Council (to exempt compounds from registration) if the Minister considers that 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. Compounds that fall into this category are those that:

- do not pose any risk; or
- the risk can be managed through conditions (e.g. conditions of use) prescribed under the ACVM Act; or
- the risks posed can be managed adequately under other legislation.

The average cost of registration is estimated at \$5,000 in government charges; the applicant's time in preparing an application (which is estimated at \$5,000) and a time period of several months to complete the registration process before the product can be marketed.

The ACVM Regulations 2001 exempt certain substances from the registration requirements of the ACVM Act. They also prescribe conditions on certain exempted agricultural compounds and veterinary medicines and list the substances that have been prescribed as generally recognised as safe (GRAS).

There are seven Schedules in the ACVM Regulations which list agricultural compounds that are exempt from registration and the applicable conditions of exemption. Of these, four Schedules are intended to be amended by the proposals, including:

- Schedule One lists agricultural compounds exempt from registration if an applicable 'code of practice' is complied with. Where there is no applicable code of practice then there are no conditions that must be complied with.
- Schedule Two lists agricultural compounds exempt from registration if prescribed conditions in Column Two and Regulation Six are complied with.
- Schedule Three lists ingredients that must not be included in topical preparations.
- Schedule Seven lists substances generally recognised as safe if used in accordance with any applicable conditions in Schedule Four.

Key problems with the current regulations

Currently some products are required to be registered when the risks they pose do not warrant such registration. The likely cost of assessing and registering these products is considered greater than the likely risks posed from the use of those products without registration.

In contrast, some products are currently exempt from registration when the risks they pose mean that they should be registered. Some exemption groups require amendment to expand the scope of the exemption, while others require further clarification to ensure industry understands the intent of the exemption.

1. Substances which are currently required to be registered when they should be exempt:
 - Poultices are a distinct group of products that are not included under the current topical product group exemption because there are usually therapeutic or pharmacological claims made that would require registration in other kinds of topical products. However, poultices achieve those claims via a mechanism (physical action rather than via biologically active ingredients) that is of low regulatory interest. Consequently, poultices can be safely put into a group on their own and still make claims consistent with that mechanism that, otherwise, would not be allowed. As such the registration requirement for poultices is considered unnecessary.
 - Home garden and amenity horticulture was originally considered "non-agricultural", but has recently been reclassified as "agricultural". As a consequence home garden and amenity horticulture is covered by the requirements of the ACVM Act. However, registration of products used in these situations is not considered commensurate with the level of risk they pose.

- Oral gastro-intestinal-acting microflora enhancing compounds are a group of compounds being increasingly used as veterinary medicines. These products are not currently included under an exemption group and therefore are required to be registered when such registration is not commensurate with the level of risk they pose.
- The current limitations placed on the types of ingredients that can be added to topical hoof preparations is considered unnecessarily restrictive for products applied to the hoof for the treatment or prevention of superficial disease.
- The list, in Schedule Seven of substances generally recognised as safe is out of date.

2. Problems requiring the scope of current exemptions to be extended or restricted:

- There are a small number of insecticide products used post-harvest on wood-producing crops that do not fall under the antisapstain (fungicide) exemption, but have the same risk profile.
- The current definition of a fertiliser additive in Regulation 3 specifies a purpose limited to increasing biological activity in the soil. However, there are products that meet the definition of a fertiliser additive, but are not applied to soil.
- There is lack of clarity as to whether or not cleaning products with an absorbent action (including toothpastes) are included in the sixth entry of Schedule One "Topical non-absorbent and non-solvent cleaning products".
- It is unclear that the non-medicated anti-diarrhoea preparations exemption is intended to be limited to substances that claim to have non-specific protectant and, or absorbent actions in the gastro-intestinal tract.
- The exemption for compounds used to protect plant grafts refers solely to products used to protect grafts and therefore products used for protection following thinning or pruning are excluded, despite having the same risk profile.

3. Substances that are currently exempt from registration when the risks they pose mean they should be registered:

- The term 'topical' is included in several exemption groups in Schedules One and Two of the Regulations. The intention was that the exemptions would apply solely to products that are applied to the surface of the skin, hair, nail or hoof. The intention was never to include products that are instilled into the ear or eye as being covered by any exemption for topically applied products.
- Currently there are no restrictions applied to the type of pharmacological claims that can be made for herbal oral and topical preparations. As a

consequence, some products are being marketed in association with significant unproven pharmacological claims that could compromise animal welfare and have a deleterious impact on trade in animal products.

- The limitations placed on the types of substances which can be used as ingredients in topical preparations are not sufficient and are inconsistent with the limitations placed on other exemption groups, including substances that may be used in the treatment of own animals. This is despite topical preparations being eligible for general sale and therefore having a wider distribution and use.
- There are no restrictions placed on the manner of lubricant used, or the mode of action. As a consequence, lubricants intended for intra-uterine administration can be considered exempt from the requirement for registration. The risks associated with the use of these products are not adequately managed by the current exemption.

Statement of the public policy objective(s)

The objective is to ensure that agricultural compounds and veterinary medicines are subject to controls, where appropriate, commensurate with the level of risk they pose.

Statement of feasible options (regulatory and/or non-regulatory) that may constitute viable means for achieving the desired objective(s)

Status Quo:

The key features of status quo are set out in the statement of the nature and magnitude of the problem and the need for government action.

Maintaining the status quo does not meet the public policy objective as the agricultural compounds and veterinary medicines would not be subject to the appropriate level of control commensurate with the level of risk they pose.

Amend the ACVM Regulations 2001 – (preferred option):

1. Substances which are currently required to be registered when they should be exempt:
 - Add an exemption group to Schedule Two for 'non-medicated poultices'.
 - Add an exemption group to Schedule Two for 'home garden and amenity plant compounds that are used solely on non-food crops'.
 - Add an exemption for the group of products known as oral gastro-intestinal-acting microflora enhancing compounds as they are currently not well represented by an exemption group.

- Add an exemption group to Schedule Two for ‘topical hoof preparations’. The restriction that topical products must not be able to be absorbed through the skin is not applicable to products applied to the hoof.
- Update the Schedule Seven list of substances generally recognised as safe.

2. Problems requiring the scope of current exemptions to be extended or restricted:

- Broaden the scope of the Schedule One entry for ‘antispasmodics’ to cover all agricultural compounds used in the post-harvest treatment of wood-producing crops.
- Amend the definition of a fertiliser additive to broaden the scope of the definition to capture fertiliser additives not added to the soil.
- Clarify the intent of the Schedule One entry for ‘topical non-absorbent and non-solvent cleaning products’ to ensure that products which are absorbed through the skin are not exempt from the registration requirement.
- Broaden the scope of the Schedule One entry for ‘compounds used to protect plant grafts’ to include compounds used to protect all plant wounds, regardless of the cause of the wound.
- Amend the Schedule Two entry for ‘non-medicated oral laxatives and lubricants’ to make it clear that lubricants intended for intra-uterine administration are not included in the exemption group.

3. Substances that are currently exempt from registration when the risks they pose mean they should be registered:

- Add a new definition for the word ‘topical’ to clarify that products instilled into the eye or ear are not considered topical.
- Amend the Schedule Two entry for ‘oral and topical preparations’ to prevent unregistered herbal preparations being marketed in association with pharmacological claims that could result in compromised management under the ACVM Act.
- Amend the Schedule Two entry for ‘topical preparations’ to ensure consistency between the types of ingredients that can be added to compounds in different exemption groups. The amendment will amalgamate Schedule Three with the topical preparations entry in Schedule Two, allowing Schedule Three to be repealed.
- Amend the Schedule Two entry for ‘non-medicated anti-diarrhoea preparations’ to clarify what types of products are covered by the exemption group.

Statement of the net benefit of the proposal, including the total regulatory costs (administrative, compliance and economic costs) and benefits (including non-quantifiable benefits) of the proposal, and other feasible options

The table below sets out the general impacts of each of the proposed amendments to the ACVM Regulations.

Amendment	Benefits	Costs
<ul style="list-style-type: none"> • Amend definition of a 'fertilizer additive' • Amend clause 12 in Schedule One 'Antisapstains' to broaden the scope of the exemption. • Amend the clause 9 to Schedule One 'Compounds used to protect plant grafts'. • Add an exemption group to Schedule Two 'non-medicated poultices'. • Add an exemption group to Schedule Two 'topical hoof preparations'. • Add an exemption group to Schedule Two 'home garden and amenity horticulture'. • Add exemption group for 'Oral Gastro-intestinal-Acting Microflora Enhancing Compounds'. 	<p>A broader range of products would not attract unnecessary regulatory cost associated with registration. This would provide benefits to both industry and consumers.</p>	<p>Zero cost.</p>
<ul style="list-style-type: none"> • Add definition for 'topical' to clarify scope of products exempted from registration as topical preparations. • Amend clause 6 in Schedule One 'topical non-absorbable and non-solvent cleaning products'. • 	<p>Clarity regarding which products are eligible for exemption, giving industry greater certainty.</p> <p>Protection from deleterious animal welfare outcomes and potential impacts on trade in primary products.</p>	<p>Zero cost. This amendment reflects current administrative procedures regarding the eligibility for exemption.</p>
<ul style="list-style-type: none"> • Amend second entry in Schedule Two herbal 'oral and topical preparations'. 	<p>Consumers will benefit as products with pharmacological claims will have to be registered and therefore prove their efficacy.</p> <p>Protection from deleterious animal welfare outcome and potential impacts on trade in primary products.</p>	<p>Manufacturers who wish to continue to make pharmacological claims in relation to their products will have to register such product and meet the associated cost.</p>
<ul style="list-style-type: none"> • Amend eighth entry in Schedule Two 	<p>Consistency with regard to the</p>	<p>Topical preparations</p>

'topical preparations'.	restrictions placed on exempted products. Protection from deleterious animal welfare outcome and potential impacts on trade in primary products.	containing active ingredients that are prescription medicines or restricted medicines, hormones or substances prohibited by New Zealand's trading partners will be required to register.
<ul style="list-style-type: none"> Amend ninth entry in Schedule Two 'non-medicated anti-diarrhoeal preparation'. 	<p>Clarity regarding which products are eligible for exemption, giving industry greater certainty.</p> <p>Protection from deleterious animal welfare outcome and potential impacts on trade in primary products.</p>	This amendment reflects current administrative procedures regarding the eligibility for exemption. There will be additional labelling requirements.
<ul style="list-style-type: none"> Amend tenth entry in Schedule Two 'non-medicated oral laxatives and lubricants'. 	<p>Clarity regarding which products are eligible for exemption, giving industry greater certainty.</p> <p>Protection from deleterious animal welfare outcomes and potential impacts on trade in primary products.</p>	Intra-uterine products will need to be registered and the associated costs meet by industry. Less than a dozen products are affected.

The following paragraphs are structured by the parties impacted by the proposals.

Government

Overall the net benefit of the proposals will ensure that the controls on agricultural compounds, if any, are commensurate with the level of risk they pose to ACVM Act outcomes. This will help ensure compounds are regulated efficiently so that costs can be kept to the minimum necessary to manage the risks.

There may be a reduction in government workload in terms of processing and assessing ACVM Act registrations, resulting from more products being exempt from the registration requirements. Government costs related to the time spent assessing and processing registrations are cost recovered. There may also be a reduction in government workload associated with the time spent responding to industry queries as a result of amendments to clarify the intent of some exemption groups.

Industry

Some products will need to be registered when previously they did not, while others will not need to be registered, when previously they were required to be.

The proposals are designed to ensure agricultural compounds and veterinary medicines are regulated efficiently so that costs to industry can be kept to the minimum necessary to manage the risks.

Importers, manufacturers and users of agricultural compounds and veterinary medicines will benefit from lower costs, if they import or use one of the products which will no longer be required to be registered. The average cost of registration is estimated at \$5,000 in government charges, plus the applicant's time in preparing an application (which is estimated to be on average \$5,000). Government charges are made up of a combination of set fees and an hourly rate. Set fees have been calculated based on an hourly rate and the estimated time required.

Both importers and users of such products will benefit from improved availability of products. In addition, importers and manufacturers of products no longer requiring registration will benefit from being able to market their products earlier, as a consequence of not having to go through the registration process. The registration process can take several months, during which time the product can not be marketed.

Some products will be required to be registered when previously they did not and will be subject to additional cost as set out in the business compliance cost statement. The specific agricultural compounds and veterinary medicines affected are intra-uterine lubricants, oral and topical preparations that make pharmacological claims, and topical preparations, containing prescription medicines or restricted medicines, hormones or substances that are prohibited by countries importing New Zealand's primary produce. However, in the case of oral and topical preparations and topical preparations, registration will only be required when the manufacturer wishes to continue to make pharmacological claims or use ingredients which are no longer covered by the exemption. All intra-uterine lubricants will be required to be registered.

It is difficult to predict how many products will not need to be registered in the future as a consequence of the proposed amendments to clarify the scope of the exemption groups.

Society

The amendments to the ACVM Regulations 2001 were specifically designed to clarify the scope of some exemption groups, and decrease the number of products that attract unnecessary registration costs, thereby reducing the existing cost of products. They were also intended to ensure product efficacy claims are substantiated, and protect against negative animal welfare outcomes and potential deleterious impacts on the trade of primary produce, resulting from the use of agricultural compounds and veterinary medicines.

The amendments will continue to give assurance to individual members of society that agricultural compounds and veterinary medicines will be controlled so that any potential risks relevant to the ACVM Act are managed to an

acceptable level. It is recognised that the amendments to exempt some products from registration, when they were previously required to be registered, has the potential to increase the risk posed (albeit minor) by those products. However, the amendments have been proposed recognising that requiring these products to be registered is not commensurate with the level of risk they pose and that an exemption, in some cases with conditions, would manage risks to an acceptable level.

Users of these products may benefit from improved availability of agricultural compounds and veterinary medicines, and increased competition with the potential to reduce the price of such products.

Statement of consultation undertaken

Stakeholder consultation

NZFSA prepared a public discussion document regarding the proposed amendments to the current exemption groups and the addition of new exemption groups in the ACVM Regulations 2001. NZFSA alerted key stakeholders of the proposed amendments by letter and through the AgVetLink newsletter, and published the discussion document on the NZFSA website. A total of five submissions were received. The following three substantive issues of concern were raised.

One submitter objected to the amendment to non-medicated oral laxatives and lubricants which gave effect to removing intra-uterine lubricant products from the exemption group. It is recognised that as a result of the amendment intra-uterine lubricant products will be regulated more stringently, however, the NZFSA considers the risks are significantly greater for this kind of product because of the intra-uterine environment at the time of parturition and immediately post-parturition. The quantity of product used is much larger and the potential for bacterial invasion, subsequent incubation and infection are much greater than for lubricant products used to treat constipation or to facilitate rectal pregnancy exams. The NZFSA considers that, if products are intended to be used to facilitate the delivery of a new-borne animal, the product has to be registered and subject to chemistry and manufacturing assessment.

Another submitter raised concern regarding the proposed amendment to Schedule Two 'Topical Preparations' and the definition used to describe a non-medicated poultice, specifically with regard to the use of dry poultices. The NZFSA acknowledged that at times, the nature and consistency of a poultice may vary from the one described in the definition and the wording will be revised to make sure it was more flexible.

The same submitter did not support the proposed limitation on topical substances, to those which cannot be absorbed, suggesting that this limitation precludes those substances that are absorbed and treat conditions such as inflammation (e.g. Arnica). NZFSA considers that products must not make claims that they have a pharmacological anti-inflammatory effect unless they are

registered. This is to manage risks and to ensure that the efficacy of such claims is proven.

Government departments/agencies consultation

The following government departments were consulted: Ministry for the Environment, Agriculture and Forestry, DPMC, Treasury and ERMA New Zealand. No concerns or issues were raised.

Business compliance cost statement

There are expected to be one off compliance costs for importers and manufacturers of agricultural compounds, associated with becoming familiar with the new regulatory requirements, and in determining whether or not their products qualify for an exemption. These changes in cost are expected to be minimal.

There will be a reduction in compliance costs for businesses in association with the increased range of agricultural compounds and veterinary medicines that will no longer be required to be registered under the ACVM Act. However, there will be an increase in compliance costs for those importers or manufacturers of products that were exempt, but that are now required to be registered. The average cost of registration is estimated at \$5,000 in government charges and \$5,000 in costs associated with the time required to prepare an application. Government charges are made up of a combination of set fees for tasks such as pre-screening of an application or annual fees and an hourly rate for the assessment of an application. Set charges have been calculated based on an hourly rate and the estimated time undertaken to complete the task.

There will also be an increase in compliance costs for some exemption groups in relation to new, or altered labelling conditions. These changes in cost are expected to be minimal.

Importers and manufacturers of agricultural compounds and veterinary medicines will be advised through AgVetLink (which is circulated to all registrants and affected parties) about amendments to the Regulations. The changes will also be posted on the NZFSA website.