Risk Management under the Agricultural Compounds and Veterinary Medicines Act 1997: Overview

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Contents

Goal of ACVM risk management

The goal of risk management under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 is to manage the risks posed by the use of agricultural chemicals, veterinary medicines, vertebrate toxic agents and other related compounds (collectively referred to as agricultural compounds) to an acceptable level to support the overall Government goal of growing and protecting New Zealand.

These compounds are in common use to produce primary produce such as arable and horticultural produce, meat, natural fibres and dairy products. They are also used on the domestic scene for home production, amenity gardening, and for treating companion animals. While agricultural compounds make primary production, gardening and the care of animals more effective and efficient, they can also cause harm (or any other negative effect) to people, animals and plants and the environment in general. The aim is to gain the benefits from their use while keeping the risks of harm down to an acceptable level. Finding that acceptable level and managing risk to that level is the purpose of regulatory control of agricultural compounds.

This management role is undertaken by the Ministry for Primary Industries (MPI) and, in particular, by the ACVM Group.

Statutory basis for ACVM risk management

The statutory authority to regulate agricultural compounds is provided in the ACVM Act. The purpose of that Act is to prevent or manage the following risks associated with the use of agricultural compounds:

- risks to public health
- risks to trade in primary produce
- risks to animal welfare
- risks to agricultural security.

While managing these risks regulatory decisions must also ensure that:

- the use of agricultural compounds does not result in breaches of domestic food residue standards; and
- sufficient consumer information is provided when agricultural compounds are sold so people can use them without causing harm.

To achieve the purpose of the ACVM Act, no agricultural compound may be used (including imported, manufactured or sold) in New Zealand unless that use is authorised by or under the Act.

The two main mechanisms for authorising use of an agricultural compound are:

- registration subject to specifically imposed conditions; or
- exemption from the requirement to register the compound, so long as any prescribed conditions are met.

A range of conditions may be imposed to manage the risks associated with agricultural compounds. These conditions may relate to substances, products, systems, or people's behaviour, and may be imposed:

- directly by the Director-General of MPI when an agricultural compound is registered; or
- generally, via Regulations.

To clarify Regulations, the Director-General may also issue notices that set out the technical detail of how compliance with conditions is to be achieved.

Because the ACVM Act is concerned with the acceptable level of risks it has a relationship with other Acts such as the Animal Products Act 1999, the Food Act 2014, the Wine Act 2003, the Animal Welfare Act 1999, the Biosecurity Act 1993, the Medicines Act 1981, and the Hazardous Substances and New Organisms Act 1996. Generally, the ACVM Act regulates for risk management outcomes that are set under these other related Acts. For example, maximum residue levels (MRLs) for food products are set under the Food Act while the ACVM Act assesses and controls agricultural compounds to ensure the Food Act MRLs are not breached.

ACVM risk management framework

The ACVM risk management framework is based on MPI's risk management framework, which is aligned with the AS/NZS Standard 31000:2009 Risk Management. It has two components:

- setting acceptable levels of risks in the areas specified in the Act and developing appropriate statutory intervention; and
- appraising the risk analyses provided by regulated parties in support for an application for authorisation and imposing necessary and sufficient conditions to maintain the acceptable levels of risk.

The context for the management of risks is defined by the provisions of the ACVM Act, which specify the risks that are relevant. (Note that, in regard to the provisions of the Act, veterinary medicines are a subset of agricultural compounds.)

The Act defines what an agricultural compound is by specifying the relevant uses of a compound. If a compound is used for a purpose that is not listed in the definition, that compound/use combination is not relevant to the ACVM Act and this risk management framework does not apply. For example, humans and organisms that affect only humans are not relevant to the ACVM Act. Compounds used on humans or used exclusively to control human pests or pathogens are not within the scope of the Act. Compounds used in processing food are not agricultural compounds and are not managed under the ACVM Act. (Although post-harvest treatment of produce is an agricultural compound use, this ends at the point food processing begins.)

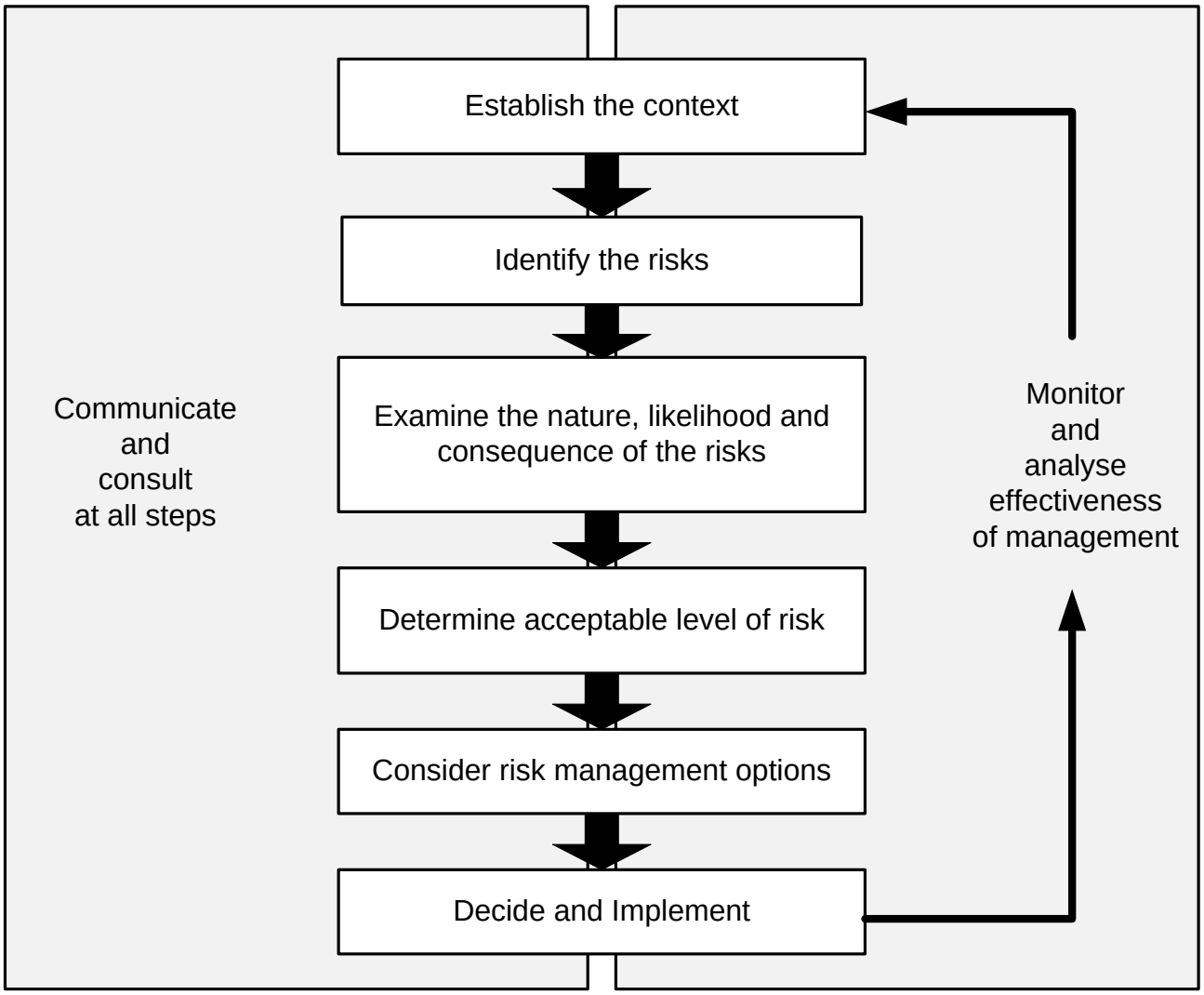
There is provision in the Act to declare by Order in Council that a substance, mixture of substances or biological compound is an agricultural compound. This would be done if it is considered that risks that might not otherwise be managed would be best managed under the ACVM Act.

Consequently, the initial consideration in this risk management framework is whether or not a compound and the way it is to be used fits the definition of an agricultural compound.

Acceptable levels of risk and appropriate statutory regulatory intervention

In line with Government policy, MPI tries to avoid unnecessary regulatory intervention. It administers the ACVM Act in the context of no more regulatory intervention than is 'necessary and sufficient' to maintain acceptable levels of risk. It must establish what those levels are and when it is appropriate to impose regulatory control. It

must also ensure that the controls are necessary and sufficient, and impose the least cost to the nation. To achieve this delicate balance the ACVM Group applies the MPI risk management framework below, which involves dialogue with government agencies, affected industry sectors (both production sectors and those involved in developing and marketing agricultural compound products) and the public.



The first step is to establish the context. Exactly what is the negative consequence that is of concern and what might cause it. Then the relevant risks need to be identified and examined to create a clear picture of the nature, likelihood and consequences of the negative effect.

Interested and affected parties have to come to an understanding of the level of risk that is acceptable. If the risks are too high (or uncomfortably uncertain), the next step is to consider risk management options with the goal to reduce the level of risk (or manage the uncertainty) to an acceptable level of risk. Then risk management decisions made by MPI have to be implemented. Parameters for effectiveness of those decisions have to be set.

Importation, manufacture, sale and use of agricultural compounds must be monitored and intelligence collected and analysed. The process is iterative and development is informed by both incoming analyses and ongoing communication and consultation.

This framework is applied in the context of the risk areas specified in the ACVM Act. Use of agricultural compounds could cause harm in other risks areas, but regulatory control using the powers specified in the ACVM Act must always be within the scope of the Act as stated in its purpose (ref: section 4, ACVM Act).

Regulatory intervention may take the form of regulations (such as the ACVM Exemptions and Prohibited Substances Regulations 2011), notices (such as the ACVM Feed Commodities Notice 2014), authorisations, information requirements to support authorisations, or any other public statement of expectations, obligations or requirements.

These provide the context and foundation for statutory intervention to know when and how to intervene and what kinds of interventions would be effective and acceptable under the ACVM Act.

ACVM risk areas

One of the fundamental building blocks in this framework is the clarification of the relevant risk areas. Note that a risk is made up of the likelihood (probability) of a harm/negative effect occurring and the impact (magnitude) of that harm/negative effect. The specified risk areas are:

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

The relevant risk areas are specified in the ACVM Act, but they are not all the risks that an agricultural compound might pose. For example, risks of commercial or financial losses incurred by consumers due to faulty or misleading products are not managed under the ACVM Act. These are managed under separate consumer protection legislation. Risks of general harm to the environment are not managed under the ACVM Act. These are managed under the HSNO Act.

ACVM risk thresholds

Statements of thresholds (below) can be readily stated and provide a context for a shared understanding on what is of interest and what is at stake.

Public health

Public health as a risk area is defined as the health of:

- all of the people of New Zealand; or
- a community or section of such people.

In New Zealand, aspects of public health are managed by a number of government departments under different legislation (i.e. Ministry of Health under the Health Act 1956, the Medicines Act 1981 and the Misuse of Drugs Act 1975, WorkSafe under the Health and Safety in Employment Act 1992, and the Environmental Protection Authority [EPA] under the HSNO Act). Consequently, to avoid overlap, the public health risk area under the ACVM Act specifically relates to aspects that fall outside the scope of the other legislation dealing with public health.

In other words, the hazards and negative effects to the health and safety of people that would be relevant to the ACVM Act are those that are directly attributable to the use of agricultural compounds and not considered (or not able to be considered) under any other legislation. This includes negative effects on public health programmes (or the health and safety of individual people) caused by characteristics of the agricultural compound that are not hazard characteristics as defined under the HSNO Act and are not medicines under the Medicines Act and are not matters that can be addressed under the Health Act. Treatment of humans and control of human diseases are specifically excluded from the scope of the ACVM Act.

The threshold that is used to determine an acceptable level of risk to public health 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 (commercial, non-commercial/home grown and recreationally gathered produce/food)
- 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.

Public health negative consequences would include failure to achieve the level of human health protection expected from the use of an agricultural compound product (e.g. a product does not produce the immunity in animals to prevent the spread of zoonotic organisms from animals to people). Another negative consequence would be reduction in the effectiveness of human health care. The obvious example of this is the possible development of resistance to antimicrobial active ingredients and the transfer of resistant bacteria from animals to people.

Because of the diffuse responsibilities for public health, it is useful to know what negative consequences are **not** relevant to the ACVM public health risk area. For example, health problems in people caused by exposure via spray drift to agricultural compound products are not relevant to the ACVM Act. Such problems are managed under the HSNO Act and the Health and Safety in Employment Act 1992.

Potentially, this can cause gaps in regulatory oversight. For example, if a particular commercial product has only one intended use and that is to kill mosquitoes to prevent the spread of vector-borne human diseases, that product would not be an agricultural compound. It is not likely to be a human medicine either. In practice, these gaps are very unusual because products usually have multiple use claims and, if any one of the claims fits the definition of an agricultural compound, it is subject to the ACVM Act. Therefore, the management of risks for ACVM Act reasons usually manages similar public health risks.

In the very rare case in which the gap would significantly jeopardise public health and all parties agree that regulatory control under the ACVM Act would be the most practical way to manage the risk, an Order in Council could be made to declare the product (or products like it) an agricultural compound.

Trade in primary produce

This risk area involves both international and domestic trade in New Zealand primary produce. In the ACVM Act primary produce is defined as “any animal or plant, or any derivative of any animal or plant, intended for sale”. The relevant immediate negative consequences are ones that would prevent the produce from conforming to official overseas import requirements or New Zealand minimum requirements. A downstream negative consequence is rejection (or delay in acceptance) of New Zealand primary produce in the overseas marketplace.

Market preferences for quality of the produce are not relevant to this risk area unless the preferences are specified in official requirements (i.e. required under New Zealand law or specified in importation requirements by other countries, or specified in a direction from the Minister). For example, there are no official requirements for wool to meet any residue limits for agricultural compounds, so agricultural compound residues do not jeopardise the official acceptability of wool overseas or in the New Zealand market, even though some consumers would prefer to buy wool that is known to be free of residues.

The trade risk threshold is an unacceptable probability (or impact) resulting in non-conformance to:

- international trade requirements
- bilateral trade requirements
- agreed New Zealand requirements
- requirements imposed to give effect to a written New Zealand ministerial direction.

Downstream negative effects could be any official government action taken against New Zealand exported primary produce. However, the immediate consequences of concern are findings that would lead to sanctions against primary produce. For example, the European Union import requirements prohibit animal produce from animals that have been treated with hormonal growth promotants (HGPs). A rejection of an export consignment of

New Zealand beef because some animals had been treated with such products would be a negative effect. Even a delay in processing the consignment to confirm that animals had not been treated would be a negative effect.

Other actions, such as ongoing restrictions, delays or rejections, are due to a failure to comply with any other international standard, bilateral import requirement, control programmes or restrictions/ prohibitions on the use of certain substances or types of agricultural compound product. MPI attempts to maintain up-to-date information on those import requirements.

There are also negative effects closer to home. Failure to conform to New Zealand minimum requirements could result in restrictions, delays, rejections, or even statutory offences when nonconforming primary produce is offered for sale here.

In these examples the requirements (export or domestic) are government imposed official requirements. Market preferences or industry set targets do not prompt trade risks relevant to the ACVM Act, unless there is a ministerial direction that makes it relevant. For example, maximum residues levels (MRLs) of agricultural compounds are prescribed. The MRLs are based on an assessment of the potential for harm to humans with a very significant margin of safety. If screening tests are particularly sensitive, residues of substances that do not exceed these limits (and do not pose safety risks) can be found. This should not prompt regulatory intervention. However, if it were in the best interest of the nation, the Minister could issue a direction, which in effect would become an official requirement, which would prompt regulatory intervention.

A market preference for zero residues is not a relevant prompt for regulatory intervention under the ACVM Act.

Animal welfare

The definition of animal in the ACVM Act is "any living stage of any member of the animal kingdom except human beings". This definition is broader than the definition in the Animal Welfare Act 1999, which includes all vertebrate animals and a few specified invertebrate animals. Because the scope for animal welfare risks is set within the context of the Animal Welfare Act, particularly in regard to the definition of an animal for which there are welfare concerns, the target animal must be included in the Animal Welfare Act definition. (A target animal is defined as the animal purposefully treated with the agricultural compound and, in the case of a pregnant animal, the foetus or neonate potentially affected by the compound administered.)

Pain and distress are the parameters for animal welfare and unnecessary/unreasonable has become the point of unacceptability for those parameters. This takes into consideration the fact that some pain or distress may be necessary to achieve a benefit to the animal.

The intended outcome in managing risks to animal welfare under the ACVM Act is to prevent unnecessary and unreasonable pain or distress in the target animal. In many cases involving agricultural compounds, animal welfare is a question of balance between the unavoidable pain and distress caused and the benefit to be realised for the animal(s). The balance must be in favour of benefit to the animal.

The animal welfare risk area is not generally relevant to the use of agricultural chemical products because animals are not the intended target. Some welfare issues are associated with subsequent and inadvertent exposure, but these non-target effects are addressed under the HSNO Act (as negative impacts on the environment rather than as animal welfare per se).

In regard to vertebrate toxic agents (VTAs), death of the target animal is the intended outcome so the animal welfare concern is that death is achieved in the most humane manner possible, minimising the associated pain or distress. Once again, effects of VTAs on non-target species is a HSNO Act matter (as negative impacts on the environment rather than as animal welfare per se).

The animal welfare 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, treat or cure conditions characterised by significant pain or distress

- the use of the agricultural compound would be inconsistent with any written ministerial direction on animal welfare.

Animal welfare negative effects include chronic pain or distress or delayed development of symptoms or abnormalities in the animal treated as well as immediate pain and distress in the treated animal. The negative effects can be divided into two kinds. The first kind relates to pain or distress to the animal due to treatment with, or exposure to, the agricultural compound. The negative effect could take the form of death, toxicity, physical injury, infection, abnormal or unintentional physiological responses or functions, undesirable pharmacological effects, carcinogenicity, teratogenicity, or any other abnormality that can be related to treatment or exposure to the agricultural compound.

The second kind of consequence relates to pain or distress caused by failure of the product to achieve the claimed effects. Consequently, the animal suffers the pain or distress that the agricultural compound was intended to prevent or alleviate.

Agricultural security

The term 'agricultural security' refers to the zoosanitary and phytosanitary safety of animal and plant populations respectively. It relates to:

- eradication or control of pests or unwanted organisms as per the Biosecurity Act 1993; and
- management of organisms that may be undesirable to certain parties.

In the first bullet point the terms 'pest' and 'unwanted organism' have the specific meanings used in the Biosecurity Act 1993, which relate to organisms in risk goods or ones specified in official pest management plans. However, the scope of the ACVM Act is broader and includes any organism that is undesirable by a sector managing the productivity of the national herd/flock. For example, the endemic contagious bovine leukaemia virus is not a pest or unwanted organism in terms of the Biosecurity Act but it is considered an undesirable organism by the dairy industry and dairy farmers. Consequently, regulatory intervention on agricultural security grounds is carefully considered in light of disease or pest control programmes of other affected parties as well as the incursion of exotic organisms and national and regional pest management goals.

The agricultural security threshold is an unacceptable probability (or impact) that:

- use would allow exotic pests, unwanted organisms or undesirable organisms to become established in New Zealand
- inefficacy would allow pests, unwanted organisms or undesirable organisms to become established in New Zealand
- 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 agricultural security.

Consideration of benefits

The framework does not lead to zero risk being the optimal threshold. In fact, extreme risk aversion is unsustainable because aiming for zero risk is neither practical nor affordable. The most desirable outcome must be a balance between potential harm, potential benefit and affordability to the nation. Although the ACVM Act does not specify what benefits are relevant, benefits (and costs to the nation) must be factored into the risk analysis along with the probability and magnitude of impact of the harms (negative effects).

So far the only mention of benefits has been the explanation of the balance between the potential harm to an animal and the potential benefit with regard to animal welfare. However, there are other benefit considerations that relate to the potential positive outcome or gain that could be expected and the relative costs of alternative

intervention options and the likely consequences of the public not having access, or having restricted access, to an agricultural compound or group of compounds.

MPI considers that, if the risks of harm can be managed, having a choice of safe, effective products is a significant benefit to the public. MPI usually does not ask for a detailed analysis of the benefits because the focus on managing the harms (negative effects), and applying the principle of no more regulatory intervention than is necessary to manage the risks down to an acceptable level, is adequate without extensive analysis of the benefits.

Utilisation of ACVM risk thresholds

The establishment of ACVM risk thresholds underpins the level of regulatory oversight of agricultural compounds. As stated earlier, two important areas based on these risk thresholds are deciding:

- what groups of agricultural compounds should be exempt from registration; and
- what information must be provided to support registration.

Exemption from registration

The ACVM risk thresholds provide the basis for determining what groups of agricultural compounds can be exempted from registration, as specified in the ACVM (Exemptions and Prohibited Substances) Regulations 2011. This exemption from registration:

- supports the general principles of no more regulatory intervention than is necessary and sufficient to maintain acceptable levels of risk and least cost to the nation; and
- eliminates considerable compliance cost because individual applications for registration do not have to be lodged and appraised.

MPI carries out collective risk analyses (utilising the risk thresholds above) on each group of compounds that, because of similarities, pose similar risks and can be regulated in a similar way. The conditions imposed are equally relevant to every compound in the group and sufficient to manage the risks. If necessary, further clarification in the form of a notice on an exempted group of agricultural compounds and associated conditions can be developed and issued under the authority of the Director-General.

A key point is that the risk analysis for a group of agricultural compounds indicates the prescribed conditions that can manage the risks across all the products in an exempted group without pre-registration risk assessment of each product and individual registration.

Any person can import, manufacture, sell or use a product that fits the definition of one of the exempted groups as long as they comply with the relevant regulations and the conditions imposed on that group.

Setting information requirements for authorisation

For products that do not fit in one of the exempted groups authorisation at an individual trade name product level is necessary. The general risk management framework applies, but it focuses on MPI risk appraisal of individual applications for registration.

MPI is required to outline its expectations, in the form of information requirements, to ensure it receives the appropriate information to determine the acceptable level of risks and to impose conditions that are necessary and sufficient to manage those risks. The information requirements must be sufficient to allow an adequate appraisal of the risks posed by a product but not more than is needed, which would create added compliance costs for the applicant.

Information requirements are designed to focus the applicant's attention on the most likely hazard-negative effects pathways based on kinds of products previously considered. Requirements are consistent with international common best practice for analysing similar kinds of products in regard to the kinds of data that are relevant, the kinds of trials that would generate that data, the most useful parameters to use in the risk analysis and the most

significant tests to carry out. However, this guidance cannot address hazard-negative-effects pathways that have not been seen before that may be posed by innovative products. So the information requirements do not alter the applicant's responsibility to address the risks comprehensively.

Appraising risk analyses and making decisions on registration

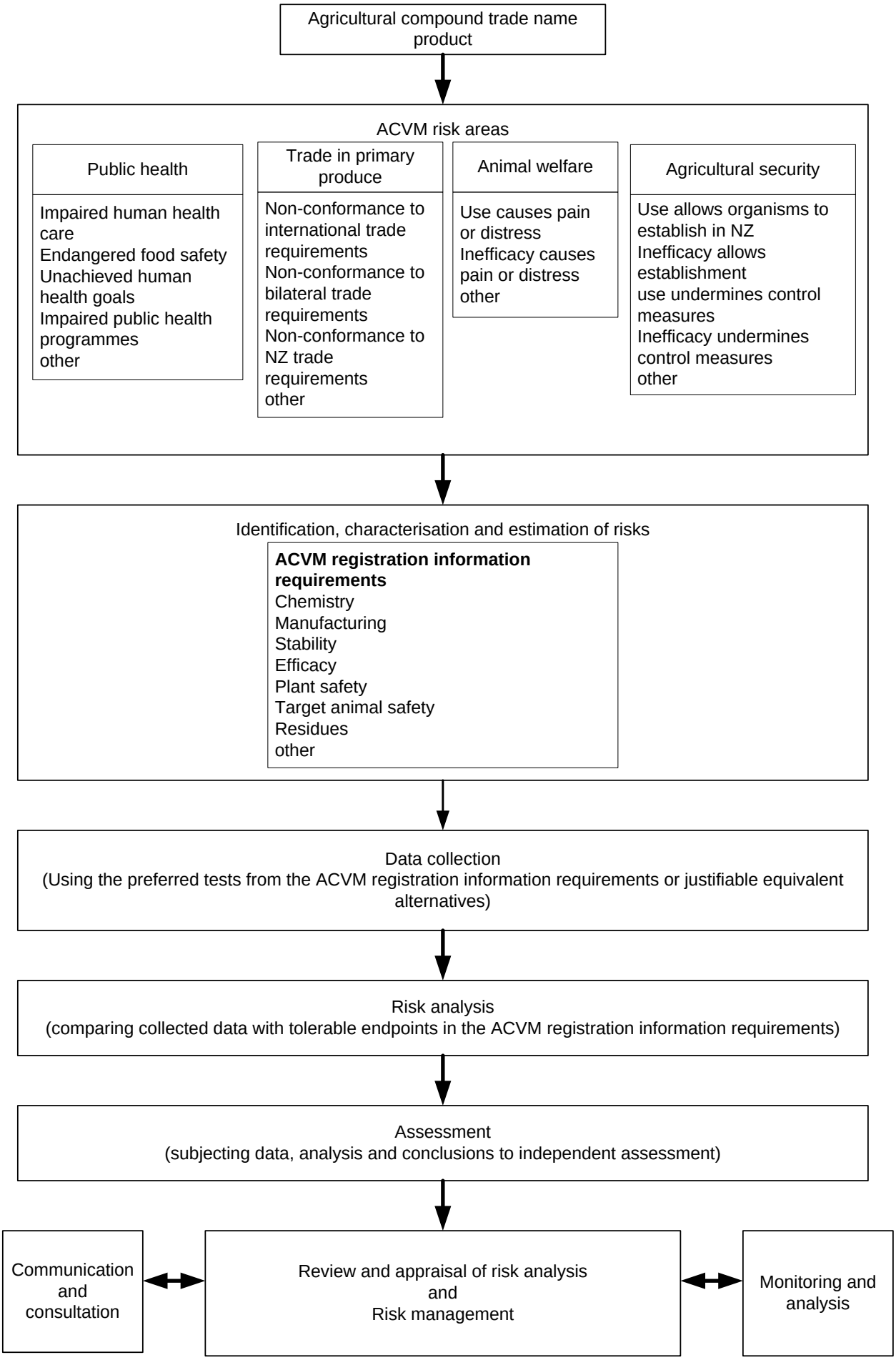
Applicants must provide all the required information that comprehensively specifies the product and analyses the potential harms/risk pathways, estimating the probability and likely magnitude of harm. They must show that the information they provide is reliable and accurately describes their risk analysis. They must also provide independent risk assessment reports.

Applications are publically notified if the product poses risks that the public has not previously had the opportunity to consider. The applicant's risk analysis, supporting data, independent risk assessment reports and any public submissions are reviewed and appraised by MPI to determine if the product should be registered and what conditions would be necessary and sufficient to manage the risks down to an acceptable level. If the product is also a human medicine, then ACVM registration is subject to Ministry of Health consent. In addition, ACVM authorisation for products containing hazardous substances or new organisms cannot be issued unless there is an EPA approval under the HSNO Act.

Conditions can be imposed to reduce risks. The conditions focus on the point at which a particular hazard-negative effect can be efficiently managed. For example, risk management begins with certainty as to the identity and characteristics of the agricultural compound product itself, so a condition that requires the product to conform to the product and manufacturing specification approved at the time of registration is always imposed. This is to control risks associated with product design and manufacture. Conditions can also be imposed on products, people, places and processes--all of which might introduce hazards and pose risks.

The final decision is notified. The impact of the decision prompts post-registration compliance monitoring and non-compliance investigations. This intelligence is used to measure the effectiveness of the risk management decisions and inform the risk management cycle as a whole.

The following graphically shows the risk management framework as it applies to registration decisions, with the three boxes across the bottom showing the steps carried out by MPI (i.e. risk appraisal, monitoring compliance and investigating non-compliance and communication/consultation).


Agricultural compound trade name product
ACVM risk areas
Public health
Impaired human health care
Endangered food safety
Unachieved human health goals
Impaired public health programmes
other
Trade in primary produce
Non-conformance to international trade requirements
Non-conformance to bilateral trade requirements
Non-conformance to NZ trade requirements
other
Animal welfare
Use causes pain or distress
Inefficacy causes pain or distress
other
Agricultural security
Use allows organisms to establish in NZ
Inefficacy allows establishment
use undermines control measures
Inefficacy undermines control measures
other
Identification, characterisation and estimation of risks
ACVM registration information requirements
Chemistry
Manufacturing
Stability
Efficacy
Plant safety
Target animal safety
Residues
other
Data collection
(Using the preferred tests from the ACVM registration information requirements or justifiable equivalent alternatives)
Risk analysis
(comparing collected data with tolerable endpoints in the ACVM registration information requirements)
Assessment
(subjecting data, analysis and conclusions to independent assessment)
Communication and consultation
Review and appraisal of risk analysis and Risk management
Monitoring and analysis

Summary

The ACVM risk management framework is based on the wider MPI risk management framework which, in turn, is consistent with AS/NZS Standard 31000:2009 Risk Management. The ACVM framework is made up of two components:

- setting acceptable levels of risks and developing appropriate statutory intervention; and
- appraising the risk analyses provided by regulated parties in support of an application for authorisation and imposing necessary and sufficient conditions to maintain the acceptable levels of risk.

The framework limits the scope of relevant risks to those specified in the ACVM Act, which is the statutory tool for controlling the use of agricultural compounds in New Zealand.

MPI administers the ACVM Act and establishes the shared expectations and collective goals and objectives in regard to the management of risks posed by agricultural compounds. It ensures that statutory intervention is necessary and sufficient to manage risks down to an acceptable level while not imposing unnecessary costs to the nation. It either:

- oversees authorisation imposed generally via Regulations; or
- appraises product-specific applications for authorisation and imposes conditions on authorisation that are necessary and sufficient to manage the risks.

The loop in the MPI Risk Management Framework model is closed by maintaining processes to monitor and analyse data regarding the effectiveness of risk management decisions. The findings inform communication and consultation and further risk management decisions.