Post-ACVM Authorisation Risk Management: Overview

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Risk management under the ACVM Act

Agricultural compounds and veterinary medicines are regulated under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. The intent of regulatory control is to manage the risks[1] posed by these products down to acceptable levels. The risk management framework is explained in *Risk Management under the Agricultural Compounds and Veterinary Medicines Act 1997: Overview*.

This document describes ACVM risk management after authorisations have been prescribed or issued under the ACVM Act for importation, manufacture, sale or use of agricultural compounds and veterinary medicines.

Purpose of post-authorisation control

Post-authorisation control of agricultural compounds and veterinary medicines is carried out for four purposes:

1. to confirm that parties are complying with the ACVM Act
2. to investigate suspicions or allegations of non-compliance that would prompt regulatory intervention
3. to measure the effectiveness of the risk management decisions and ensure that conditions imposed on authorisations are necessary and sufficient to achieve the risk management objectives; and
4. to provide assurances that agricultural compounds and veterinary medicines available in New Zealand can be used as intended without causing harms in any of the risk areas specified in the Act.

Statutory basis for post-authorisation control

The Ministry for Primary Industries (MPI) is the regulatory authority responsible for administering the ACVM Act. Under the Act agricultural compounds and veterinary medicines must be authorised before they can be imported,

[1] The risk areas specified in the ACVM Act (section 4) are: public health, trade in primary produce, animal welfare and agricultural security.

manufactured, sold or used in New Zealand (ref: section 8, ACVM Act). Conditions are imposed on those authorisations to manage risks down to acceptable levels. It is an offence under the Act to knowingly:

- carry out any of these activities if the compound is not authorised; or
- not comply with the conditions imposed on the authorisation.

Provisions in the ACVM Act provide the power to issue a range of authorisations to suit the circumstances and type of agricultural compound. In addition to authorisations on compounds and trade name products, the Act provides powers to regulate the activity of people who are importing, manufacturing, selling or using agricultural compounds via links to the conditions on authorisations and approval of operating plans.

There are statutory powers to investigate non-compliance and to intervene. Registrations and provisional registrations can be suspended, revoked or cancelled. Registrations can also be reassessed and conditions changed. Product can be recalled. ACVM Officers have the power to prevent the importation of agricultural compounds. They have powers of entry, search and seizure; and to take samples and examine records. They can issue prohibition notices preventing further activity.

All of these powers can be used to achieve the purpose of the ACVM Act in regard to post-authorisation control of agricultural compounds. (Note that veterinary medicines are a sub-set of agricultural compounds.)

The Act also specifies offences (section 55) and penalties (section 56) for non-compliance.

Authorisations and approvals

Post-authorisation activity varies for different kinds of products and different groups of regulated parties. The following describes the types of authorisations and approvals issued under the ACVM Act that have post-authorisation implications.

Authorisations are issued for agricultural compounds to allow their importation, manufacture, sale or use. They include:

- registration of trade name products (section 21);
- provisional registration of trade name products (section 27);
- prescribed exemption from registration (section 75(1)(a);
- exemption from registration due to listing as generally recognised as safe (GRAS) (section 8B); and
- approval in special circumstances (section 8C).

Approvals are issued to allow specified people to carry out specified activities. They include:

- border clearance (section 6); and
- approval of operating plans (section 28).

Also, parties can be recognised to carry out a specified function for the purpose of the ACVM Act (Part 3A).

Registration

Registration is a trade name product-specific authorisation. To obtain a registration a person must provide a risk analysis with comprehensive supporting data. MPI appraises the risk analysis and decides whether or not the product can be registered and what conditions should be imposed to manage the risks down to an acceptable level.

Once registered, anyone can import, sell or use the product in accordance with the conditions of the registration. Manufacture of the product is limited to the manufacturer specified in the registration.

The product and manufacturing specification approved at the time the product is registered uniquely defines the product. The conditions imposed on a registration are applied individually because each condition is considered

necessary to manage the risks. The product and manufacturing specification and the conditions of registration become the points of reference for post-authorisation compliance verification and investigation of non-compliance.

The registrant has overall responsibility for the product until it is sold[2] to another party. If a condition of registration imposes requirements related to specific activities such as importing, manufacturing, distribution, sale or use, the party responsible for carrying out that activity must comply with the relevant condition.

Compliance to the conditions on the registration is subject to review and inspections at any time, and all suspicions or allegations of non-compliance to conditions are investigated to determine if there are non-compliances. Formal compliance audit can be imposed if it is necessary to manage risks or to provide assurances that the risks are being managed.

Provisional registration

A provisional registration is an authorisation that is specific to the product, the registrant and the circumstances in which it can be imported or manufactured and used. It is issued to allow an agricultural compound that is in its final trade name product form to be used to gather additional data that could be used for risk analysis purposes. The conditions impose restrictions on the use and the circumstances under which that use can occur to minimise the potential and uncertain risks.

Because a provisional registration is specific to the registrant, the product can be imported or manufactured and used only by the registrant. Sale of the product is prohibited. Use is governed by approved security and research/trial protocols that must be followed. The registrant is responsible for the product, all activities and compliance to all conditions of the provisional registration.

Compliance to the conditions on the provisional registration is subject to review and inspections at any time, and all suspicions or allegations of non-compliance to conditions are investigated to determine if there are non-compliances. Formal compliance audit is imposed if it is necessary to manage risks or to provide assurances that the risks are being managed.

Prescribed exemption from registration

Some kinds of agricultural compounds are exempt from registration under the ACVM (Exemptions and Prohibited Substances) Regulations 2011. These are groups of products for which individual product registration is considered unnecessary to manage the risks, and exemption from registration is not inconsistent with international expectations[3].

Exemption from registration is by product group, so there are no product-specific conditions that must be complied with. Instead, the requirements and conditions are specified in the Regulations. This creates regulatory obligations equivalent to registration without imposing unnecessary product-specific compliance costs.

Exempt agricultural compounds are not subject to regular compliance verification audits to maintain certificates of compliance. However, they are subject to review and inspections at any time, and all suspicions or allegations of non-compliance to the Regulations are investigated to determine if there are non-compliances. Formal audit may be imposed if necessary to correct non-compliance or to re-establish confidence that product will conform and people will comply with the requirements and conditions.

GRAS listed compounds

MPI can list certain substances as generally recognised as safe (GRAS) for use as, or in, agricultural compounds. Any specification of the substance and conditions on sale or use is specified in the GRAS listing.

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[2] Under the ACVM Act sale is broadly defined and includes any kind of transaction that transfers ownership to another party.

[3] The scope of veterinary medicines in New Zealand is much more inclusive than it is internationally. For example, animal feeds are included in New Zealand but are not considered veterinary medicines in other countries.

GRAS status and conditions are substance–specific and everyone must comply. There is no specific party who is responsible, so use of GRAS substances is only intermittently the focus of review. Because the substances are considered safe, their use poses very little risk.

Approval in special circumstances

Agricultural compounds that are not otherwise authorised can be approved in special circumstances. Such an approval is issued to a specific party and limits how much of the substance can be used and how, when, where and by whom it can be used. Sale is prohibited. Security and use protocols are approved at the time the approval is issued and these must be complied with.

Approvals in special circumstances are subject to review and inspections at any time, and all suspicions or allegations of non-compliance to the approval are investigated to determine if there are non-compliances. Formal compliance audit may be imposed if necessary.

Border clearance

Imported agricultural compounds and veterinary medicines initially arrive into New Zealand at border check points. These are usually biosecurity transitional facilities, and the biosecurity staff are also appointed as ACVM Officers with the power to issue (or refuse) clearance (section 6). The imported product and or import documents are examined to confirm that:

- the goods are agricultural compounds
- they are properly authorised for importation; and
- there is no reason to suspect that they do not comply with requirements and conditions.

If the ACVM Officer is not certain that the agricultural compounds are properly authorised, or are suspected of not complying, clearance is refused and the goods are reshipped, destroyed or held until the Officer can confirm that the goods can be cleared. The cost of inspection and clearance is funded by government appropriation. However, the importer must meet the costs associated with dealing with non-compliant goods (reshipment, disposal or holding).

Unfinished agricultural compounds that require further processing in New Zealand before they comply with ACVM requirements enter via an approved pathway that allows the goods to be transferred to the approved manufacturer.

Raw materials and commodities that cannot be used as agricultural compounds without further processing are not regulated under the ACVM Act. However, if they could be used without further processing (such as a feed commodity) they are regulated under the ACVM Act and must comply before clearance or enter under one of the approved pathways.

Interceptions of non-compliant agricultural compounds (including goods entering under approved pathways) are recorded and the data is used to assess the nature and magnitude/significance of the risks due to importation.

Approved operating plans

MPI can approve operating plans that describe:

- who is responsible for certain activities
- how those activities will be carried out; and
- what critical control steps must be monitored and performance recorded to confirm that the operating plan is being followed.

If an ‘approved operating plan’ is specified in a condition on an authorisation, pre-approval of such a plan is compulsory. If MPI is asked to provide certification of compliance, pre-approval of an operating plan is necessary but it is not compulsory. Regulated parties may, for their own reasons, wish to have their operating systems pre-

approved by MPI. In all these cases, ongoing approval of the operating plan is dependent on a party operating in accordance with their approved plan. MPI can revoke the approval if the party fails to follow the approved plan.

The approved operating plan becomes the point of reference for compliance verification and investigation of non-compliance. Whether or not performance is subject to formal compliance audit depends on the level of harm that could be caused by non-compliance and the need for MPI to give assurances that parties are complying with regulatory conditions and risks are being managed.

Recognition

MPI can recognise persons, agencies and classes of persons to carry out specified functions and activities for the purposes of the ACVM Act (Part 3A). The relevant functions and activities are those that support or augment MPI's capacity to carry out regulatory duties such as monitoring and surveillance, compliance auditing, investigation of non-compliance, verification and calibration, sample testing, authorising certain actions.

The specified duties are set out in the recognition. The requirements that the recognised entity must comply with while carrying out the activities are specified in notices issued under section 44ZN. The recognition and the notices become the points of reference when reviewing or verifying compliance.

Under certain circumstances there may be a requirement for the recognised party to have an approved operating plan and, possibly, to be subject to formal compliance audit.

Non-compliant performance could result in suspension or withdrawal of the recognition.

Listing persons as competent

Listing is a form of non-statutory approval that simply expresses MPI's confidence that a party is competent to carry out a particular activity. Expectation of competency and performance are expressed with the understanding that ongoing listing is dependent on confirmation that a party is performing as expected.

Listing does not confer any rights or impose any duties or obligations on parties.

Certification of compliance

If compliance verification is compulsory or if MPI is asked or expected to provide assurances of compliance, MPI implements a compliance audit regime and issues certificates of compliance.

Conditions provide focus for risk management

The conditions imposed on the authorisations of agricultural compounds, approved operating plans or recognitions of persons provide the focus for post-authorisation risk management.

For registration of trade name products the conditions are imposed under section 23, which lists the kinds of conditions that can be applied. They are applied individually to each authorisation because each condition is considered necessary to manage particular hazards.

Some of the conditions relate to the product itself, such as the approved product specifications that characterise the compound, its packaging and the information that must be provided with it when it is offered for sale.

Other conditions place obligations on people when they carry out particular activities and specify limitations on those activities. If it is considered necessary, the conditions impose a requirement to have (and comply with) an approved operating plan (section 28) governing the activity. Compliance verification and non-compliance investigation uses these conditions as points of reference, aligning each condition to the party who must comply and reviewing the relevant activity.

The registration of a trade name product includes a product data sheet that contains the approved product and manufacturing specifications and label content. The product data sheet and label content along with the conditions of registration constitute the point of reference for the product itself.

For compound groups that are prescribed as exempt from registration in the ACVM (Exemptions and Prohibited Substances) Regulations 2011 certain requirements are imposed on all groups in the body of the Regulations and additional conditions are imposed on particular groups in Schedule 2 of the Regulations. The general requirements include:

- ensuring that the compound is fit for its intended purpose (Regulations 7 and 8)
- having a documented system governing manufacturing, complying with that system and keeping record of compliance (Regulations 9 or 10 and 14)
- providing specified information with the compound when it is offered for sale (Regulation 12)
- avoiding misleading statements about the compound (Regulation 13); and
- keeping records of imported compounds (Regulation 15).

The conditions in Schedule 2 are specific to each exempt group and relate to the particular hazards that are likely to be present in that group.

If particular requirements or conditions have been clarified or expanded in notices issued under section 76A, those notices are used as points of reference to examine compliance. If the condition specifies that there must be an approved operating plan in certain circumstances, then that plan is also used as a point of reference.

The conditions imposed on substances listed as generally recognised as safe (GRAS) are specified in the public listing. These relate to the definition of the substance itself and possible limitation on the circumstances and concentration relevant to its use.

Conditions on approval in special circumstances under section 8C are specified in the approval and are specific for the compound, the person approved to use it and the circumstances under which it can be used. Sale of the substance is prohibited. The approval is the point of reference for compliance verification and non-compliance investigation.

Impact assessment and risk analysis

The Act imposes a responsibility on MPI to manage risks in section 4. In addition, section 36 imposes a responsibility to:

- encourage and facilitate the reporting of any adverse effects from the use of agricultural compounds or veterinary medicines; and
- disseminate information and advice on products and compounds.

These roles are essential post-authorisation components of MPI's risk management model. Besides issuing authorisations and ensuring compliance, post-authorisation risk management also focuses on gathering information and assessing the effectiveness of authorisations /conditions on managing risks down to acceptable levels without imposing unnecessary intervention or compliance costs. Assessment of the impact then informs risk management decisions when issuing subsequent authorisations or reassessing existing ones. It also provides the evidence to underpin assurances to bolster public confidence and facilitate market access and trade in New Zealand primary produce.

Assurances

As the regulatory authority MPI provides compliance certification (section 35A) and other specific and general assurances that parties are complying with conditions and ACVM risks are being managed. MPI's surveillance and monitory programmes underpin its assurances.

Scope of post-authorisation activities

Post-authorisation activities are a combination of education and awareness, voluntary or compulsory monitoring and surveillance, regulatory intervention, and the application of sanctions and/or prosecution.

Education and awareness

MPI provides general advice to groups of interested or affected parties and the general public. It uses its own website, public media, industry communication channels and educational institutions to communicate ACVM risk information on innovations, trends, changing production practices, adverse events, regulatory requirements and national/international standards regarding agricultural compounds and veterinary medicines.

Compliance verification

Some authorisations attract compulsory compliance verification. In other cases the regulated parties request MPI certification. In both cases MPI carries out regular programmed audits to verify compliance. The frequency and 'depth' (for example, documentation review versus a physical field audit) of checking is set on the basis of the level of risk or need for verification of compliance.

Compliance reviews

If compliance verification or compliance certification is not required, MPI programmes compliance reviews that focus on areas of particular interest or concern, or to underpin assurance that parties are complying and risks are being managed. The focus of interest or concern is informed by the intelligence gathered in MPI surveillance and monitoring programmes such as adverse event reporting, industry feedback, and monitoring and analysis of allegations of non-compliance.

Non-compliance investigations

MPI investigates all suspicions or allegations of non-compliance. This is done in a stepwise and proportionate fashion based on an assessment of the risks posed by the non-compliance. The initial investigation is to gather relevant information to determine the validity and significance of the suspicion or allegation and the nature of the non-compliance. If non-compliance is confirmed or considered to be likely, a warning is issued to the non-compliant party. The warning specifies:

1. the non-compliance in the context of the statutory requirements
2. advice on how to correct the non-conformance
3. warning of the consequence of not complying with the advice; and
4. description of subsequent regulatory action and cost implications.

If the circumstances warrant it because the non-compliance is potentially a serious breach of the ACVM Act or Regulations or the party involved fails to comply with the remedial action direction (see below), then the case is investigated further to secure evidence in support of a prosecution.

Remedial action direction

Remedial action directions specify what must be done (and by when) to remedy a non-compliance. They also state what the consequences may be for not complying with the direction.

If necessary, they can be issued to the non-compliant party during a compliance verification audit or compliance review. They are also issued during an investigation of non-compliance.

Sanctions

The ACVM Act provides a toolbox of sanctions to draw from depending on the circumstances. Sanctions may be applied at any stage of the compliance process if statutory requirements are not complied with or if they are considered necessary to manage the risks.

Authorisations on agricultural compounds can be suspended, cancelled or revoked if there are reasonable grounds to consider that:

- the compound does not conform to approved product specifications or its manufacture does not comply with approved manufacturing specifications
- the conditions or requirements on the authorisation are not being complied with; or
- changes in circumstances bring into question the appropriateness of the authorisation or the adequacy of the conditions imposed on it.

Further import, manufacture, sale or use can be restricted (section 31) and products/compounds can be recalled (section 35G).

Authorisations, approvals and recognitions can be withdrawn, making any further activity an offence. Certificates of compliance can be revoked.

ACVM Officers can refuse to give border clearance to agricultural compounds that are being imported if they are not properly authorised or are suspected of not complying with the conditions on the relevant authorisation.

Prohibition notices can be issued to immediately stop further importation, manufacture, sale or use until non-compliances are addressed.

Prosecution

If necessary, offending parties can be prosecuted.

All offences (section 55) are subject to prosecution with penalties upon summary conviction (section 56). In order for an action to be an offence, the ACVM Act requires the party to know that what he or she is doing is contrary to the legal requirements. Therefore, on confirmation of a possible non-compliance, the party is warned, in writing, of the problem and what needs to be done to rectify it (or a prohibition notice is issued). This constitutes the evidence that the party knows that they are not complying. Subsequent non-compliance in regard to the same matter can then be considered a prosecutable offence. This two-step process influences the principles and process governing post-authorisation regulatory control.

Principles for post-authorisation control

1. **Compliance and enforcement activity is based on an assessment of the risks posed by the non-compliance.**

The higher the risks (i.e. the probability that the product will not conform to approved specifications or the parties will not comply with conditions and the magnitude of the harm in any of the relevant risk areas that may be caused by the non-compliance), the greater the regulatory interest and the greater the need for assurances about compliance.

2. **The level and depth of post-authorisation compliance activity is proportionate to the risks posed.**

The higher risks attract compulsory compliance verification and more intense regulatory oversight and intervention. Compulsory compliance verification, active regulatory oversight, and imposition of invasive and disruptive sanctions or prosecution may not be justified for lower risk products and situations.

3. **Expressly-stated, transparent and predictable points of reference govern compliance reviews and investigation of suspicions or allegations of non-compliance.**

The regulated parties must have a clear knowledge of their regulatory obligations. That understanding must be the same for regulator and regulated parties. By using the same points of reference, both MPI and the regulated parties can maintain predictability, fairness and consistency.

4. Proactive oversight of compliance is imposed to manage high risks or provide assurances of compliance.

Obligatory compliance verification is imposed when the risks warrant active oversight or when MPI is expected to provide assurances to maintain public confidence or to facilitate trade in primary produce. However, it may not be necessary to impose formal compliance verification in all cases. If formal compliance verification is not considered necessary, regular overall compliance reviews are programmed with the type of product and the participants selected on a rolling random sampling basis. Adverse events, number of complaints, stated public and industry concerns are all prompts that assist MPI to focus its review programme.

5. Timely remediation of non-compliant product or behaviour is the primary intent of post-authorisation control.

Voluntary compliance is the preferred state. In the first instance MPI provides clarification and directions to regulated parties to assist them in remediating non-compliance. Only very high risk situations or failures to remediate non-compliance prompt MPI to impose sanctions and take prosecutions.

6. Response is stepped, based on the risks posed.

All suspicions or allegations of non-compliance are subject to initial investigation to confirm the validity and significance of the suspicion or allegation. All investigations are recorded and used for reference when identifying repeat offending or trends in non-compliance and to inform subsequent regulatory action.

It is not efficient or even practical to do a comprehensive investigation of all suspicions or allegations of non-compliance. MPI applies a risk appraisal rationale to prioritise cases and decide what level of follow-up and intervention is necessary to get the most cost-effective risk management. The form and extent of further regulatory action is considered in light of the estimated risk and likely risk reduction.

Step 1 is for MPI to issue non-compliant parties with a written warning that will be the point of reference for any subsequent regulatory action.

Repeated suspicions or allegations of continued non-compliance or confirmed failure to comply with any remedial action direction are reviewed, and a report and recommendation on further investigation and additional regulatory action are sent to MPI's compliance and response directorate (MPI C&R). The response is escalated if the risks warrant it.

7. If practical, the costs of assuring compliance are recovered.

Costs incurred by MPI to confirm compliance must be recovered. If specific beneficiaries or regulated parties prompting compliance verification or investigation of non-compliance can be identified, the costs are recovered from them. If this cannot be done, and it is in the public interest to monitor overall compliance to the ACVM Act, the cost is met through government allocation. Compliance reviews inform risk management and requirement setting so they are funded from general risk management and standard setting budgets.

The effectiveness of risk management is monitored and adjusted as needed.

8. Compliance activity is carried out in a fair and consistent manner.

MPI encourages parties to report adverse events and suspicions of non-compliance, and to assist in investigations. To this end, MPI endeavours to act fairly and consistently when carrying out compliance verification and investigation of non-compliance. MPI does not want to inadvertently disadvantage parties or damage business reputations. All information gathered is held in confidence and is not released unless it is

necessary for the public good. The circumstances of exemption under the Official Information Act are considered carefully.

9. **ACVM compliance activity is consistent and compatible with regulatory requirements imposed under other legislation.**

The primary focus of post-authorisation activity must be the requirements and conditions imposed under the ACVM Act, but MPI keeps in mind statutory requirements imposed under the Biosecurity and Animal Products Acts and by other agencies such as the Ministry of Health, Environmental Protection Authority and the Veterinary Council of New Zealand.

Compliance verification and investigation of non-compliance

Compliance verification

A formal compliance verification audit regime is imposed if:

- the risks (either probability or magnitude of harm) posed by non-compliance are unacceptably high or uncertain otherwise
- international agreements or conventions expect formal regulatory oversight
- bilateral trade requirements require assurances of compliance or assurances that some event will or will not occur
- domestic expectations require assurances of compliance or assurances that some event will or will not occur
- MPI certification of compliance is required or requested.

The conditions on an authorisation specify if formal compliance verification audit is required. MPI maintains a list of parties who are subject to formal compliance verification audit. Audit frequency is specified based on an assessment of what is necessary and sufficient to:

- meet oversight requirements
- manage risks down to an acceptable level
- produce credible assurances of compliance.

Audit frequencies are adjusted up or down in light of changing risk profiles and confidence that the regulated party will comply with conditions.

Audits are programmed and carried out with the cooperation of the audited parties and in accordance with established audit protocols, using the appropriate points of reference (i.e. conditions on authorisations, approved operating plans, performance standards etc.) accepted by both parties.

Remedial action directions are issued and followed up. Appropriate sanctions are applied to address major non-compliances or to address failure to take remedial action.

Audit reports are kept confidential, but audit summaries suitable for public release are prepared and filed. Summaries are compiled and analysed to produce an annual report to provide monitoring information for:

- adjusting individual authorisations and approvals
- adjusting MPI's risk management of agricultural compounds
- supporting MPI assurances.

Agricultural compounds that attract formal compliance verification audit are:

Product type	Activity audited	Reason
Registered veterinary medicines	Manufacturing	Manage risks and meet mutual

		recognition agreement requirements and domestic expectations for regulatory oversight
Vertebrate toxic agent products	Manufacturing	Manage risks and meet domestic expectations for regulatory oversight
Hormonal growth promotants for cattle	Sale and use	Meet bilateral trade access requirements

Formal compliance verification audit is imposed if non-compliance has been identified and confidence in ongoing compliance has to be re-established. Frequency and duration of the additional oversight is adjusted to restore confidence that the party is complying with conditions. Consequential audit reports are compiled, analysed and reported in a general way to maintain confidentiality, if appropriate.

Compliance reviews

Compliance reviews are checks on the level of compliance of a sector or in regard to a certain kind of agricultural compound.

Programmed compliance reviews

Some compliance reviews are regularly programmed into annual work plans. Agricultural compounds and systems that attract programmed compliance reviews are:

Product type	Activity reviewed	Reason
Restricted veterinary medicines	Selling	Manage risks and meet domestic expectations for regulatory oversight, trade access requirements, Ministry of Health expectations for regulatory oversight of prescription medicines
Restricted veterinary medicines	Supply and use under approved operating plans	Manage risks and meet Ministry of Health expectations for regulatory oversight of prescription medicines
Restricted access vertebrate toxic agent products	Selling	Manage risks and meet domestic expectations for regulatory oversight
Animal feeds	Import, manufacture, sale and use	Manage risks and meet domestic expectations for regulatory oversight and market access expectations
Research testing and training organisation	Use of unregistered agricultural compounds	Manage risks and meet domestic expectations for regulatory oversight
Own use of unregistered agricultural compounds containing restricted access substances	Use under approved operating plans	Manage risks and meet domestic expectations for regulatory oversight

Response compliance reviews

If intelligence suggests that there might be significant non-compliance within a sector or adverse events suggest that risks are not being managed adequately, compliance reviews are commissioned. These reviews put the situation into perspective so that risk management efforts can be refined or assurances given that people are complying and risks are being managed. Commissioned reviews can focus on the agricultural compounds (or

group of compounds) or any aspect of their management. The criteria used to decide if a review would be informative are.

- Are there repeated concerns expressed that some sector or kind of agricultural compound is causing adverse events (or an actual increase in the frequency of adverse events)?
- Have risk profiles or management practices changed to the point that risk management decisions may no longer be relevant?
- Are there international or bilateral pressures to alter conditions on authorisations or to increase or formalise regulatory oversight?
- Has there been a Ministerial directive to investigate a sector or the regulatory control of a type of agricultural compound?

Each year response reviews are added to the programmed reviews to make up the compliance verification workplan for the year.

Investigation and intervention

All suspicions or allegations of non-compliance are investigated to confirm the validity and circumstances of the case. Possible regulatory responses in an investigation include:

- sending an educational or awareness letter
- issuing a warning of possible non-compliance
- recalling non-complaint product
- issuing a prohibition notice on further activity
- suspending or revoking the relevant authorisation
- prosecution.

The focus of the initial investigation is to confirm the details of the case such as:

- who is involved
- what agricultural compound is involved
- what is the relevant authorisation and conditions
- what is the likely non-compliance.

Confirmation of the details of the case is handled by ACVM advisers. Often the suspicions or allegations of non-compliance are unfounded and intervention of any kind is not required. Even so MPI may send out an educational/awareness letter to reinforce the obligation to comply with conditions. Such cases are still recorded as useful background information.

If it is reasonable to consider that non-compliance is involved, a warning letter is sent to the potentially offending party stating the conditions that must be complied with and how they may be in contravention of those conditions. The party is warned to address the matter and comply with the conditions. This ensures that the party is aware of the conditions and subsequent non-compliance is likely to be a prosecutable offence. The case is recorded and a report is sent to MPI C&R describing the case and stating a judgement as to the significance of the non-compliance.

Regulatory intervention taken by MPI C&R varies according to the circumstances and the significance of the non-compliance.

The criteria used to decide whether or not intervention beyond issuing a warning is required are:

- the non-compliance significantly undermines efforts to manage risks down to an acceptable level
- international, bilateral or domestic expectations dictate the need for intervention under the circumstances
- the Minister issues a directive to intervene
- there is likely to be reliable evidence of non-compliance and justification to take a prosecution.

If it is considered necessary to remove the product from the marketplace to prevent significant adverse events, MPI C&R issues a product recall under section 35G.

Sometimes the product itself may be compliant but the activities of people are causing risks. In these cases a prohibition notice under section 65 is issued to stop that activity.

If a party is not complying with an operating plan approved under section 28, approval of the plan can be suspended or withdrawn. If the operating plan approval is withdrawn, the party will likely be in breach of the conditions on the authorisation and further compliance action can be taken.

If a party is not complying with requirements imposed on the recognition of an agency, person of class of persons, the recognitions can be suspended or withdrawn.

Remedial action directions are issued to the non-compliant parties in any of the circumstance described above. Remedial action is reviewed to confirm that it has been taken. Failure to do so may result in further regulatory intervention and possibly prosecution.

Impact assessment

Impact assessment is gathering the existing information (or commissioning projects to generate additional information) concerning the positive and negatives impacts that the use of agricultural compounds is having in the risk areas specified in the ACVM Act. Impact assessments help MPI to carry out risk analyses and to communicate risk management intelligence. The information comes from analysis and reporting of:

- compliance verification findings
- investigation and intervention results
- programmed or responsive compliance review findings
- qualitative and quantitative data on importation, manufacturing, sale and use
- adverse events
- qualitative and quantitative information on industry and public concerns
- international and bilateral requirements or expectations
- primary produce monitoring findings.

Data and information are collated, analysed and recorded. The information is then used to appraise the effectiveness of risk management and to underpin assurances that legal requirements are being complied with and the intent of the ACVM Act (i.e. to manage the risks) is being achieved.

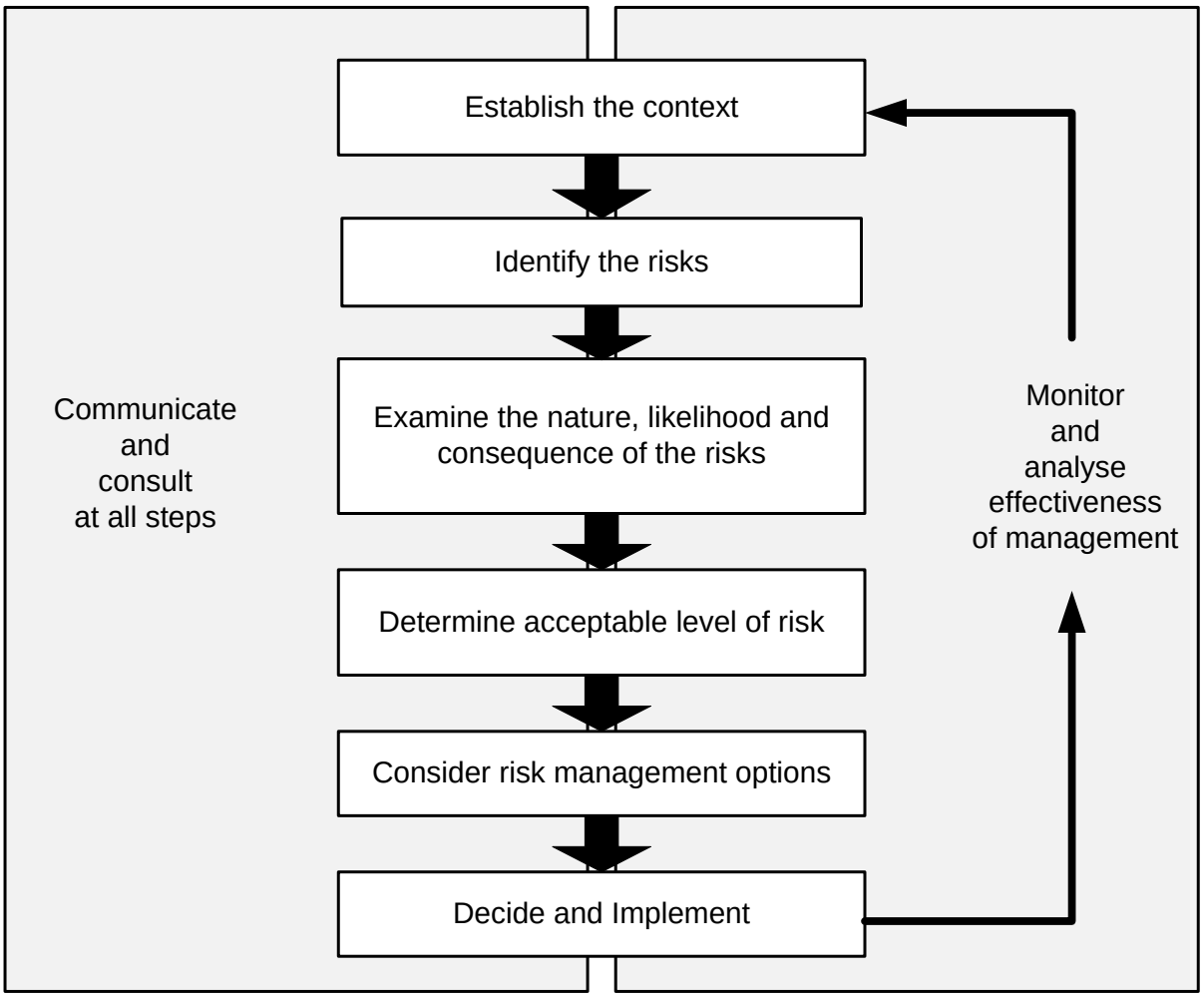
Impact assessment takes advantage of a number of sources of surveillance information including:

- complaints and concerns advised by the public, industry stakeholders or other regulatory bodies
- information from MPI programmes, which include residue monitoring programmes for meat, poultry, honey, dairy, feral game etc as well as monitoring programmes run under the science strategy
- information from other Directors within MPI
- information from other regulatory bodies in New Zealand (such as the Ministry of Health, MedSafe, Environmental Protection Authority (EPA), Veterinary Council of New Zealand
- information from the regulatory authorities in other countries (such as authorisation statistics, compliance verification and investigation of non-compliance, international/bilateral conventions and standards)
- information from ACVM surveillance and monitoring programmes including adverse event reporting (AER), compliance reviews and border clearance statistics
- information from inspections and audits or from pre-approval checks
- industry sector intelligence.

MPI's risk management framework

Compliance verification and non-compliance investigation are important feedback inputs into MPI's risk management process.

The MPI risk management framework, 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 is set out below.



Risk management decisions are made using the information available at the time. Circumstances and the information about the characteristics of products and the impact of their use change over time. Changes may prompt a re-examination of the risks and the risk management decisions that seemed necessary and sufficient when authorisations were issued. Authorisations and approvals are subject to review in light of new information.

Compliance and risk management assurances

Specific certificates of compliance may be issued for matters such as the manufacture of veterinary medicines or vertebrate toxic agents, or when any regulated party requests certificates of compliance. MPI will only certify what it can verify. If a party who is not subject to formal MPI compliance verification wishes a certificate of verification that party must voluntarily submit their systems to compliance verification.

MPI provides general assurances that risks are being managed and parties are complying with regulatory requirements. Annual reports on compliance audits and compliance reviews, investigations of non-compliance, adverse events and other MPI monitoring programmes form part of MPI assurances.

Appendix: Control of ACVM products by product type

ACVM registered products

The registration of every agricultural compound trade name product is issued to a specific registrant and is based on approved product specifications that uniquely characterise the product. How (and by whom) the product is manufactured is also critical to the identity of the product. Therefore, every registration includes a condition that the product must comply with the approved product and manufacturing specifications. This condition is the common point of reference for post-authorisation risk management.

Each person responsible for a registered product at each stage in the chain from importation/manufacture through to the sale of the product to the end user must take due care to ensure that the product always complies with this condition. Compliance verification or investigation of non-compliance examines the evidence that due care was taken to meet this condition. Whether or not formal compliance verification is required depends on the risks posed by the type of product and the international/bilateral or domestic expectations of proactive oversight by the regulator.

The variations in post-registration activity can best be described by referring to product types. These are:

- veterinary medicines (both restricted and unrestricted)
- vertebrate toxic agents (both restricted and unrestricted)
- agricultural chemicals.

Veterinary medicines

Veterinary medicines are products administered to or applied directly to animals to achieve any of the purposes listed in the definition of an agricultural compound (ref: section 2, ACVM Act). Because all veterinary medicines are administered (or applied) directly to animals they pose immediate-to-long-term animal welfare risks. In addition, if the animals are food production animals, the hazards can be transmitted to people via consumption of animal products. Veterinary medicines can also have hazards that pose significant agricultural security and public health risks, and jeopardise trade in primary produce.

Importation

Importation of registered veterinary medicines is managed via ACVM clearance at the border.

Manufacture

Internationally and domestically there is an expectation that, because of the potential risks, the competent authority will impose proactive compliance verification oversight over the manufacture of veterinary medicines. To manage the risks and to meet this expectation, the registration of a veterinary medicine hinges on identification of the manufacturer and confirmation that there is a current ACVM certificate of compliance (section 35A) to good manufacturing practices (GMP) for competency and capacity for manufacturing veterinary medicines.

The requirements are modelled on and consistent with the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S). Commitment to this international convention underpins New Zealand's commitment to its mutual recognition agreements with the European Union and Australia, which govern oversight of the manufacture of veterinary medicines and facilitate trade in primary produce and in veterinary medicines themselves.

The registration of each trade name veterinary medicine also includes a condition requiring the manufacturer to have an approved product-specific operating plan (section 28) governing the manufacture of that product and to manufacture it in accordance with that plan.

Manufacturers of registered veterinary medicines are subject to regular compliance verification audits to maintain their certificates of compliance. Concurrently, compliance to the approved operating plans is reviewed. Between audits, all suspicions or allegations of non-compliance are investigated.

Distribution

If the manufacturer remains responsible for distribution, then that step is also included in their GMP system. Otherwise, compliance verification of distribution is not subject to regular audit. Compliance to conditions is an aspect that is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that product continues to conform to the approved product specifications.

Sale and authorisation

Registered veterinary medicines are placed in unrestricted and restricted categories depending on the risks posed by unrestricted access. Unrestricted veterinary medicines can be sold, bought and used by anyone. These can be used safely and effectively without specific training by following the information provided with the product.

On the other hand, safe and effective use of restricted veterinary medicines requires expert diagnosis and professional discretionary judgement, and may require specialist training. Consequently, they are subject to restricted access. They can be sold only by persons who have an approved operating plan (section 28) governing the sale of restricted veterinary medicines or by a veterinarian with a current practising certificate issued by the Veterinary Council of New Zealand (ref: Veterinarians Act 2005). With a few regulated exemptions, restricted veterinary medicines can be purchased and used only by a veterinarian with a current practising certificate issued by the Veterinary Council of New Zealand or a person with written authorisation[4]. (The regulated exceptions involve specific approved operating plans.)

Compliance verification of the sale of unrestricted veterinary medicines is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that the product continues to conform to the approved product specifications and that no promotion or advertising is contrary to the conditions of registration. Compliance verification for sale of restricted veterinary medicines also includes evidence that they are supplied only to authorised persons and only in accordance with the instructions of the authorising veterinarian, and that the seller is identified so that the product can be traced back to that party.

Use

Use of registered veterinary medicines is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that either the product is used as directed or, if it is used in an off-label manner, that due care was taken to avoid non-compliant residues in animal products and veterinary advice was sought to minimise risks to the welfare of the treated animals.

Vertebrate toxic agents

Vertebrate toxic agents are products used to kill vertebrate pests or hinder their capacity to survive or reproduce. There is an expectation in New Zealand that, even though vertebrate toxic agents are intended to kill the pest, the products must be humanely effective, causing the least amount of pain or distress as possible. In addition to animal welfare considerations, vertebrate toxic agents can pose significant risks to trade in primary produce via indirect exposure of production animals. They could also pose significant agricultural security risks. All vertebrate toxic agents must be registered.

[4] Veterinarians are recognised (section 44G) to issue authorisations to purchase and use restricted veterinary medicines.

Importation

Importation of vertebrate toxic agents is managed via ACVM clearance at the border.

Manufacture

To manage the risks posed by vertebrate toxic agents and to meet public expectations for control of potentially dangerous agricultural compounds, their registration hinges on identification of the manufacturer and confirmation that there is a current ACVM certificate of compliance (section 35A) to GMP for competency and capacity for manufacturing vertebrate toxic agents.

The registration of each trade name vertebrate toxic agent product also includes a condition requiring the manufacturer to have an approved product-specific operating plan (section 28) governing the manufacture of that product and to manufacture it in accordance with that plan.

Manufacturers of vertebrate toxic agent products are subject to regular compliance verification audits to maintain their certificates of compliance. Concurrently, compliance to the product-specific approved operating plans is reviewed. Between audits, all suspicions or allegations of non-compliance are investigated.

Distribution

If the manufacturer remains responsible for distribution, then that step is also included the GMP system. Otherwise, compliance verification of distribution is not subject to regular audit. Compliance to conditions is an aspect that is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that the product continues to conform to the approved product specifications.

Sale and authorisation

Vertebrate toxic agent products are placed in unrestricted and restricted categories depending on the risks posed by unrestricted access. Unrestricted vertebrate toxic agent products can be sold, bought and used by anyone. These can be used safely and effectively without specific training by following the information provided with the product.

Safe and effective use of restricted vertebrate toxic agent products requires expert discretionary judgement, and may require specialist training. They must be kept securely away from the general public and used only as instructed, with appropriate safety precautions. Consequently, they are subject to restricted access. They can be sold only by persons who have an approved operating plan (section 28) governing the sale of restricted vertebrate toxic agents. With a few regulated exemptions, restricted vertebrate toxic agents can be purchased and used only by persons with a controlled substance licence issued by the Environmental Protection Authority (EPA).

Compliance verification of the sale of unrestricted vertebrate toxic agent products is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that:

- the product continues to conform to the approved product specifications
- it is supplied only to an authorised person
- the seller is identified
- no promotion or advertising is contrary to the conditions of registration.

Use

Use of vertebrate toxic agent products is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that the purchase and use has been authorised and the product is used as directed.

Agricultural chemicals

Agricultural chemicals are products used to either:

- manage plants for any of the purposes listed in the definition of an agricultural compound; or
- indirectly, manage animals for any of the purposes listed in the definition of an agricultural compound by applying the product to plants, land, air, water or premises.

Because agricultural chemicals are not applied directly to animals, the animal welfare concerns relate to subsequent and inadvertent exposure. Agricultural chemicals can and often do pose significant risks to trade in primary produce, usually as a result of non-compliant residues. They could also pose significant agricultural security risks and, sometimes, public health risks.

Importation

Importation of registered agricultural chemical products is managed via ACVM clearance at the border.

Manufacture

There is no international convention governing the manufacture of agricultural chemical products but there are international guidelines for GMP that encourage responsible manufacturing or formulation. New Zealand aligns its manufacturing requirements to these guidelines. Agricultural chemical registrations include the condition requiring the product to always comply with the approved product and manufacturing specifications. Compliance verification of manufacture is not subject to regular audit. Compliance to conditions is an aspect that is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated.

Distribution

Compliance verification of distribution is not subject to regular compliance verification audit. Compliance to conditions is an aspect that is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that the product continues to conform to the approved product specifications.

Sale

Compliance verification of the sale of agricultural chemicals is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that the product continues to conform to the approved product specifications and that no promotion or advertising is contrary to the conditions of registration.

Use

Use of agricultural chemical products is intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated. The focus is on taking due care to ensure that the product is used as directed.

ACVM products exempt from registration

Veterinary medicines and agricultural chemicals

Some kinds of veterinary medicines and agricultural chemicals are exempt from registration under the ACVM (Exemptions and Prohibited Substances) Regulations 2011. These are groups of products for which individual product registration is considered unnecessary to manage the risks.

Exemption from registration is by product group, so there are no product-specific registration conditions that must be complied with. Instead, the requirements and conditions are specified in the Regulations. Among other things these include:

- ensuring that the product is fit for its intended purpose (Regulation 7)
- having a documented system[5] governing manufacturing, and manufacturing the product in accordance with that system (Regulation 9)
- ensuring the specified information is provided with the product (i.e. minimum labelling requirements) (Regulation 12).

This creates equivalent regulatory obligations as registration without imposing unnecessary product-specific approval and compliance costs.

Exempt products are not subject to regular compliance verification audits. However, they are subject to review and inspections at any time, and all suspicions or allegations of non-compliance to the Regulations are investigated. Formal audit may be imposed if necessary to correct non-compliance or to re-establish confidence that product will conform and people will comply. They are intermittently the subject of general compliance reviews, and all suspicions or allegations of non-compliance are investigated.

Importation of products exempt from registration is managed via ACVM clearance at the border.

Animal feeds and fertilisers are particularly common agricultural compounds that are exempt from registration. Their use is so frequent and widespread that their use has the potential to cause significant problems for animal welfare and trade in primary produce. Consequently, compliance reviews of animal feeds and fertilisers should be regularly programmed.

Off-label use of ACVM products

Unless specifically prohibited in the conditions of registration, products can be used for off-label purposes. However, the user is obliged to ensure that the off-label use will not cause harm in any of the ACVM risk areas, particularly residues that are breaches in the domestic food residue standard. The residue avoidance information provided with the product related to the intended use is not sufficient to support off-label use so the user has to be cautious.

Off-label use is not subject to regular compliance verification audit. It is intermittently the subject of general compliance reviews and all suspicions or allegations of non-compliance are investigated. The focus is on examining the user's effort to avoid negative effects from that off-label use.

Risk analysis intelligence is combined with regular residue surveys to decide if certain off-label uses need to be controlled or if product registrations need to be adjusted to manage the risks.

[5] The documented system governing manufacture must include product and manufacturing specification equivalent to the ones imposed on registered veterinary medicines.