



# Compliance

ACVM Operational Policy No 165

May 2008

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## Introduction

This policy provides a framework for compliance activities under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and Regulations.

This policy makes a distinction between the types of compliance activities and describes the relationship between them.

## 1 Purpose of compliance

Compliance is the specific area of regulatory control consisting of those activities that are carried out to confirm that a product, process, person, organisation or premises conforms to, or complies with, the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. The purpose of compliance activities is to ensure that in an 'over-arching' sense the purpose of the ACVM Act is being met and it contributes to the credibility of the New Zealand Food Safety Authority (NZFSA) as a whole. Specifically it means that the regulatory conditions are met. The outcome is assurance to the public of New Zealand and other interested and affected parties that the use of agricultural compounds and veterinary medicines will not breach the agreed ACVM thresholds.

## 2 Compliance funding

Funding for ACVM Group compliance activities comes from a variety of sources. Crown funding is provided for activities where there is no clear beneficiary<sup>1</sup> or no identifiable party causing the compliance activity, or where the preliminary work investigating an allegation identifies that there is no cause for concern. Crown funding is also applied to investigations leading to prosecutions and actual prosecutions.

There is a compliance component charged in the fees for registration and in annual fees<sup>2</sup>. This funding is used to cover the costs of the reality checks undertaken by the Compliance and Investigation Group (CIG) of the NZFSA and survey or monitoring work carried out by (or on behalf of) the Approvals and ACVM Group). These fees also cover the costs of any initial activity, such as the undertaking of a class determination by the ACVM Group where a concern turns out to be unfounded.

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<sup>1</sup> A beneficiary can be a group of people or organisations

<sup>2</sup> Annual fees applied to registered products and to some groups of exempted products

Regular monitoring activity and short-term programmes are funded directly by the parties that are the subject of the activity. ACVM Group and third party agencies' (TPAs) actual time and any associated costs are recovered under the ACVM Act.

### 3 Relationship with other agencies

In order to maximise effectiveness, the ACVM Group will cooperate to the maximum extent possible with other parts of NZFSA (the Science Group, Verification Agency and NZ Standards Group), and with other regulatory agencies. There is a clear interface with other legislation. Memoranda of Understanding (MoUs) will be used to clarify operational roles and responsibilities with:

- MAF Biosecurity (Animal, Plants and Forestry Groups)
- MAF Animal Welfare Group
- The Environmental Risk Management Authority (ERMA NZ)
- The Ministry of Health
- The Veterinary Council of New Zealand.

It is also expected that operational agreements will clarify the interface roles and responsibilities with MAF Biosecurity New Zealand (MAFBNZ) (who provide border services) and with NZFSA Verification Agency (who provide some on farm services).

In addition to working closely with other regulatory agencies in New Zealand, the ACVM Group will cooperate fully with the regulatory agencies from other countries wherever this is appropriate. The ACVM Group has an operational agreement with the Australian Pesticides and Veterinary Medicines Authority (APVMA) to cover GMP compliance issues.

New Zealand already has a mutual recognition agreement (MRA) with the European Union that covers the area of Good Manufacturing Practice (GMP) for the manufacture of veterinary medicines. New Zealand has an MoU with Australia for GMP. VICH<sup>3</sup> is also working on a number of standards to harmonise pharmacovigilance activities. New Zealand will seek opportunities to work with other regulatory agencies to align in the area of compliance.

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<sup>3</sup> VICH is an international process to harmonise the data requirements for veterinary medicines between the member countries (Japan, the United States and the European Union) and the observer countries (Australia, New Zealand and Canada).

## 4 Scope of compliance

Compliance is about checking on an ongoing basis that the purpose of the ACVM Act is being achieved as effectively as possible. It covers the whole supply chain for agricultural compounds and veterinary medicines from importation or manufacture, distribution, sale and use.

### 4.1 Authorisations

The main activity under the ACVM Act is the provision of authorisations (approvals). We provide authorisations for people, places, organisations or premises, processes and for product(s).

- **People and/or organisations** authorisations cover:
  - ‘users’ of certain groups of products, eg hormone growth promotants (HGP), vertebrate toxic agents (VTAs)
  - suppliers of certain groups of products, such as the approval of traders in restricted sale products
  - ACVM Officers and recognised persons who can be appointed or authorised under the ACVM Act to undertake a range of functions from regulatory compliance activities to data assessment as a commercial service for applicants.
- **Places or premises** authorisations under the ACVM Act includes sites approved for levels of GMP and responsible manufacture, and certain research facilities to carry out trials.
- **Process** authorisations include the recognition of Operating Plans. For example:
  - GMP
  - restricted sale products.
- **Product** authorisations include:
  - exemption by regulation (from the requirement to be registered) of groups of trade name products
  - registration of products
  - import clearances
  - approval under special circumstances
  - listing as generally recognised as safe (GRAS).

## 4.2 Prohibitions

The ACVM Act provides the power to prohibit the use of certain products or substances as agricultural compounds. This is done by regulation but it is not commonly used as most concerns can be managed by varying the conditions on an authorisation.

## 4.3 Suspensions

The ACVM Act provides the power to suspend an approval of products or substances as agricultural compounds or approvals/recognitions of people and/or organisations, places or premises.

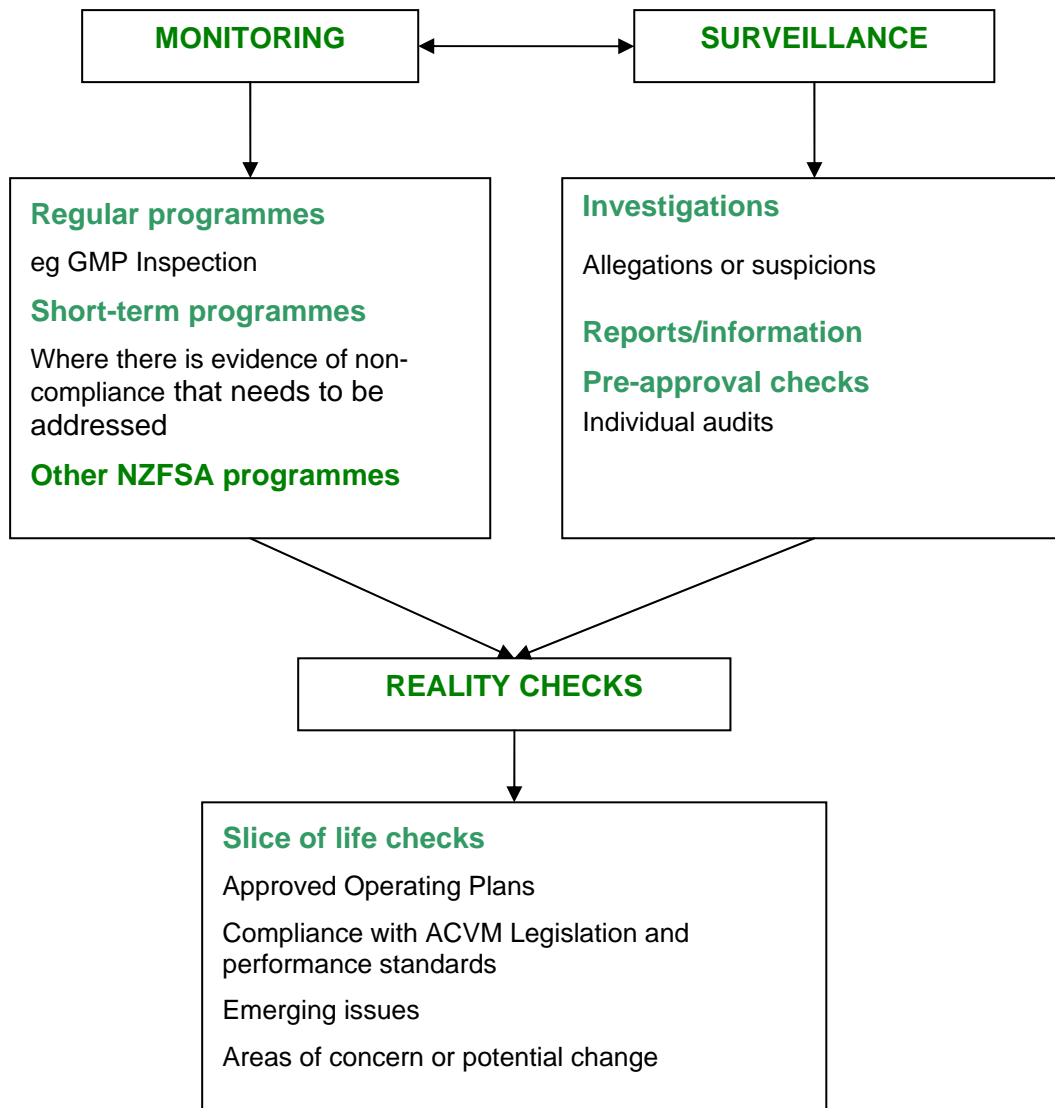
## 4.4 Pre-approval checks

In some cases a 'pre-approval' step is required before approval. This usually consists of the provision of information rather than a physical check, but physical checks are undertaken where needed. GMP provides examples of this -- where a product is being added to the list of products of a similar type to be manufactured at an already approved facility, approval is usually given on the basis of previous knowledge of the site and its systems. If it were a brand new manufacturing facility, there would be a series of physical and/or verification checks prior to approval.

## 4.5 Post-approval checks

This is the area most commonly referred to as 'compliance'. It consists of information collection and collation as well as a range of physical checks. It covers the activities already outlined under approvals and prohibitions. Checks can be of specific products across the whole supply chain or of specific parts of the supply chain for a range of products. The components (monitoring, surveillance and reality checks) are more fully explained below.

The following figure is a model of the interrelationship of the traditional compliance activities.



## 4.6 Application of Sanctions

The ACVM Act provides a range of sanctions and powers that can be applied at the various stages in the process.

- **Reassessment of approvals:** The Act provides criteria for the reassessment of registered products and the actions that can be taken. As groups of products are exempted by regulation, changes to exemptions are also by regulation.
- **Suspension of approvals:** Trade name products registered under section 21 of the Act can be suspended for a period of up to 3 months on the basis that any conditions imposed on the

registration are not being complied with. The Act also provides the power to suspend/revoke an appointment/recognition of persons or places.

- **Requirements to provide information:** ACVM Officers can request samples and information where there are concerns about compliance. They can also issue 'hold' notices on products for up to five days.
- **Inspection:** ACVM Officers have the power to undertake inspections when there are reasonable grounds to believe there is non-compliance with the ACVM Act.
- **Prohibition notices:** ACVM Officers have the power to prohibit the manufacture, sale, import and/or use of a product by any party where there are reasonable grounds to believe that there is non-compliance with the ACVM Act. Prohibition notices need to include the actions that are to be taken to remedy the non-compliance to the satisfaction of the ACVM Officer. Prohibition notices will be issued following an inspection.
- **Search warrants:** Inspectors may be issued search warrants that provide further powers of entry and the power to seize and detain products of concern.
- **Import clearance:** Where there are concerns about non-compliance of products at the point of importation, clearance will not be granted and regulatory action will be taken in the biosecurity transitional facilities

## 4.7 Investigation

All complaints or allegations of non-compliance will be investigated by the ACVM Group. Should there be a breach of the ACVM Act and/or ACVM Regulations 2001, the ACVM Group's immediate goal is to return the breach to compliance as soon as possible. The ACVM Group will not shy away from prosecution where it is required. A range of sanctions are available under the ACVM Act--declining clearance at the border, suspension and withdrawal of registration approval and the use of prohibition notices which detail requirements that must be complied with before normal business can resume.

As a result of the investigation, the ACVM Group has the power under section 35G to direct an agricultural compound to be recalled for rectification, disposal or destruction if the compound does not comply with the requirements of the Act and/or Regulations or the non-compliance would result in serious or significant breaches to the ACVM risk areas.

## 4.8 Prosecution

Cases are investigated, documented and prepared by CIG. The decision to prosecute and the process of taking prosecutions are conducted in accordance with NZFSA prosecution policies. The

ACVM Group and CIG will work to the following principles in considering prosecutions under the ACVM Act:

- The prime purpose of prosecution is to act as a deterrent for the parties concerned and for others in related industries. It is therefore important that successful prosecutions are given the maximum possible exposure in relevant media, and that agreements providing protections or confidentiality are not entered into without due consideration.
- New or revised legislation will need to be 'tested' in the courts. An initial prosecution will set the legal precedent for penalties in the future in the specific legislation and in any related legislation.
- NZFSA will cooperate with other regulatory agencies in New Zealand to the maximum extent possible to ensure the most effective use of Crown monies and of NZFSA people resources. Wherever possible NZFSA will work on complementary investigations from the outset.
- NZFSA will have an open dialogue with overseas regulators where there is a likely impact from a breach of New Zealand legislation.
- Prosecutions will be considered against the NZFSA CIG Prosecution Policy.

## **4.9 External review**

External review relates to government or overseas competent authority review of the New Zealand competent authority's activities. Such reviews are not usually targeted at ACVM Act activities specifically but they do usually cover the approval and controls of agricultural compounds and veterinary medicines in the scope of the overseas competent authority's review as a risk area to be managed.

# **5 Roles and responsibilities**

## **5.1 Regulator**

In the regulatory model it is the role of the regulator to set standards, and to confirm that the standards are being met. The Approvals and ACVM Group in this role has developed a range of standards and guidelines as well as documenting the decision making framework by way of operational policies and procedures.

## 5.2 Third party audit

Third party agencies or individuals carry out audits to assure that the regulated parties are in compliance with the Act, Regulations, standards or conditions applied to authorisations. Individuals or organisations may be recognised under the ACVM Act to carry out the appropriate audits. There may be oversight of this activity from time to time by the regulator. CIG would undertake this for NZFSA in most instances, although the ACVM Group may be involved where specialist knowledge is required.

## 5.3 Regulated parties or industries

Regulated parties cover the entire supply chain and include importers, manufacturers, distributors, wholesalers and traders of agricultural compounds and veterinary medicines, as well as specified user groups.

# 6 Compliance responses

The ACVM Group has the following range of responses to compliance concerns.

- **Education:** The provision of general advice on responsibilities under the ACVM legislation, usually to groups of interested or affected parties.
- **Specific advice/warnings:** The provision of specific advice to individuals or companies about their products or processes and their responsibilities under ACVM legislation.
- **Specific requirements for action to be taken:** The provision of information on what must happen and the timeframe for action by those found to be not in compliance with ACVM legislation. Actions required might include providing information so that a class determination can be done on a product, relabelling a product, updating advertising claims, changing processes to comply with a standard etc.
- **Initial Inspections or compliance checks:** These comprise a physical inspection or check to confirm if there is non-compliance. Such an inspection will likely result in specific requirements for action and may be enforced by way of a hold notice or a prohibition notice under the ACVM Act, a suspension of authorisation or recognition or even withdrawal of either type of approval. Specific requirements can be extended to other parts of the supply chain if the information gained from the initial inspection provides additional information. The objective of an inspection is to get a 'snapshot' of the activities of the person or company that is the object of a compliance concern.
- **Institution of short-term monitoring programmes or increased audit frequency:** This is essentially a check over time for ongoing compliance where there has been a previous breach.

This is likely to extend for a confidence building period and will mean increased audit frequency for those already part of regular programmes.

- **Regular compliance checks:** These programmes are put in place to confirm compliance on an ongoing basis against an ACVM standard or against the legislation. The frequency and 'depth' (for example, documentary confirmation versus a physical audit) of checking is set on the basis of the level of concern and risk.
- **Investigation of suspicions or allegations involving preliminary work to establish the facts of the event.**
- **Investigation leading to prosecution:** Usually undertaken where there is a potentially serious breach of the ACVM Act and Regulations, and NZFSA or MAF administered legislation in ACVM related areas.
- **Prosecution:** As already stated, this is considered and initiated in line with the NZFSA CIG Prosecution Policy.

The ACVM Act provides a toolbox of sanctions to draw from depending on the circumstances. Sanctions may be applied as a response at any stage of the compliance process, but it is the policy of the ACVM Group to concentrate on education and advice in the first instance unless the alleged breach is serious. Suspensions will be applied if continued operation is unacceptable during the time that a party is taking remedial action. Recalls will be used if justified from a risk management perspective and remedial action is not taken as instructed. Prosecutions will be taken if warranted and the matter meets public interest criteria.

## 7 Monitoring activity

Monitoring consists of programmes run for the purpose of the assessment of compliance with an ACVM performance standard, the ACVM Act, or its regulations. Compliance with ACVM requirements in most cases is implemented as a condition of an authorisation such as product registration. The condition is directed at the point where it is considered most appropriate and/or effective to manage identified risks and hazards down to an acceptable level. A specific regulated party (for example importers, manufacturers, sellers or users) is nominated in the condition.

### 7.1 Regular programmes

A number of regular programmes are already in place, such as the programme covering the *ACVM Standard and Guidelines for GMP*, which applies to manufacturers of registered veterinary medicines and vertebrate toxic agents.

Regular programmes will be added wherever:

- there is an international expectation or requirement (as in the case of GMP), or
- there is an agreed New Zealand expectation as in the manufacture of certain vertebrate toxic agents, or
- where information shows that there is a need for an ongoing oversight of the activity in order to effectively manage the risks or to provide regulatory assurances.

Where a regular programme is in place and there is a breach of the conditions of the legislation, it will be a standard response for the ACVM Group to require an increase in the frequency of the programme until the required level of confidence is restored.

## 7.2 Short-term programmes

While short-term compliance programmes may be used case by case for a variety of reasons, we expect them to be used mainly in two areas. The ACVM Group will institute short-term programmes for those areas where there are reasonably significant breaches that show a lack of awareness of roles and responsibilities under the ACVM Act. They will also be used where new conditions that rely on compliance to an operating plan are developed. This will ensure that the plan is understood and is adequate.

Short-term programmes are post-approval checks. They ensure that the conditions placed on an approval are understood and are having the desired effect. They act as confidence building checks to confirm that specific instructions are complied with over time.

In line with the regulatory model, the activity is likely to be outsourced to one of a number of TPAs<sup>4</sup>. In some cases, the staff will need to be specially trained (eg MAFBNZ staff at the border). They may also be given powers under the ACVM Act by way of being appointed as ACVM Officers<sup>5</sup>.

## 7.3 Other monitoring

Monitoring programmes run by other groups within NZFSA will provide information for ACVM Group compliance.

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<sup>4</sup> NZFSA has a number of service providers in this area including MAFBNZ, NZFSA Verification Agency, IANZ etc. It is expected that programmes will be tendered to one of the existing agencies on the basis of their ability to provide an effective service.

<sup>5</sup> ACVM Officers appointed under the ACVM Act must be State Sector employees.

## 8 Surveillance

Surveillance information is used to drive reviews of policy and the development and review of ACVM requirements, performance standards, conditions etc. The information provides a key element in the modification of overall regulatory control. In addition, surveillance information may be used for the non-regulatory modification of practices or processes by agreement between the ACVM Group and industry where this might be the appropriate course to follow.

Surveillance is about the receipt and evaluation of information and intelligence from a variety of sources. Information is collated in a way that enables decisions to be taken on the appropriate response (if any) required. Surveillance may be undertaken either in isolation of any regular or short-term monitoring programme, or addition to monitoring programmes to address specific concerns.

The ACVM Group has a number of sources of surveillance information including:

- Complaints and concerns advised by the public, industry stakeholders or other regulatory bodies
- Information from NZFSA programmes, which includes the residue monitoring programmes for meat, poultry, honey, dairy, feral game, etc as well as the monitoring programmes run under the science strategy
- Information from MAFBNZ and Animal Welfare Groups
- Information from other regulatory bodies in New Zealand such as the Ministry of Health, MedSafe, Veterinary Council of New Zealand, ERMA New Zealand etc
- Information from the regulatory authorities in other countries (such as residue violations or information sharing about compliance violations such as in the Pan Pharmaceuticals incident)
- Information from ACVM programmes including adverse event reporting (AER), 'slice of life' reviews and reporting from MAFBNZ at the border
- Information from inspections and audits or from pre-approval checks.

## 9 Reality checks

Reality checks or 'slice of life' reviews provide assurance that programmes are performing as expected. They also determine in broad terms where gaps in ACVM policy, requirements, performance standards and procedures might lead to a lower than desirable level of risk management under the Act, or where regulatory intervention is unnecessary.

Reality checks are not necessarily undertaken as a result of reported non-compliance but priority is likely to be given on the basis of identified concerns or of existing information gaps. Activity is carried out by CIG on behalf of the ACVM Group.

The output of a reality check will be a report and recommendations to the Director, ACVM Group. Recommendations might include a review of ACVM policy or standards or changes to the frequency of an existing regular programme.