

Summary of Audit Report

MAF Quarantine Service Clearance of Agricultural Compounds and Veterinary Medicines

Background

The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, which repealed the Stock Foods Act 1946, the Fertilisers Act 1960 and 1982, and the Animal Remedies Act 1967, and (with the hazardous substances part of the Hazardous Substances and New Organisms [HSNO] Act 1996) the Pesticides Act 1979, has provided a new legislative framework for agricultural compounds and veterinary medicines in New Zealand. This includes imported ACVM products. Such items are 'cleared' at the border by MAF Quarantine Service (MAFQS), acting on behalf of the New Zealand Food Safety Authority (NZFSA)'s ACVM Group, which administers the ACVM legislation.

In 2003 the ACVM Group Director commissioned the NZFSA's Compliance and Investigation Group (CIG) to carry out an audit of MAFQS procedures for clearance of ACVM products at the border. MAFQS has worked closely with the ACVM Group in the development of clearance procedures and this was the first audit since the procedure's introduction. As such, it was an opportunity to look at what is currently happening, to evaluate its effectiveness, and to make recommendations for improvement if required.

The June-July 2003 audit covered products arriving by air, sea and mail, and examined MAFQS operations in Auckland and Christchurch. Observers from the ACVM Group accompanied the auditor.

Legislative regime

Legislation and procedures with requirements relevant to the audit included:

- Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997
- Agricultural Compounds and Veterinary Medicines Regulations 2001
- Register of Veterinary Medicines and Plant Compounds, and
- MAFQS procedures/work instructions, including PP82: *Clearance of Imported Veterinary Medicines and Plant Compounds*, and other related MAFQS process procedures.

AUDIT

The key topics

The following emerged as ‘key topics’, i.e. subjects of particular interest, during the audit:

- Process Procedure 82
- Review Data Agreement
- Quancargo
- Cargo clearance
- Mail clearance
- Clearance of accompanied ACVM products
- Cost recovery
- Powers of an inspector
- Competency review/training.

Process Procedure 82

MAFQS’s Process Procedure 82 was developed in conjunction with the ACVM Group and was introduced for MAFQS inspection and clearance of imported veterinary medicines and plant compounds. (Although the term refers to clearance of imported veterinary medicines and *plant* compounds, the procedure more accurately describes the clearance of veterinary medicines and *agricultural* compounds, which includes plant compounds.)

The clearance process begins with importers, or their customs brokers, lodging entries with New Zealand Customs (NZC). Identified commodities are listed with NZC by tariff code, and importers of these commodities are referred to MAFQS for a clearance. PP82 describes the clearance requirements and instructs inspectors that if there is any doubt whether product(s) should be cleared, they are to refer the importer to the ACVM Group.

Throughout PP82 there are references to ‘release’, ‘cleared’ and ‘clearance’; however, there are no definitions for what constitutes a ‘release’ or ‘clearance’.

The auditor found that Quarantine Officers (QOs) were issuing a Biosecurity Authority/Clearance Certificate (BACC) as a mechanism for release of consignments that were referred to them by NZC. A legal opinion on using this mechanism of the Biosecurity Act 1993 to provide a ‘clearance’ for agricultural compounds indicated that:

as the definition of ‘risk goods’ can cover agricultural compounds, agricultural compounds may be considered for clearance under this Act. However, ‘risk goods’ would not include an agricultural compound that contains no risk items of those matters referred to in (a) and (b) of the definition.

The auditor understands this to mean that only those ACVM products that fit into the definition of ‘risk good’ in the Biosecurity Act may be given a clearance under that Act. All others may need a clearance under the ACVM Act. This could confuse clearance management on an operational basis.

Some QOs indicated that the procedure is quite complex to follow. Possibly they were not too familiar with the process because they cleared such small volumes of ACVM products. Other QOs, who were more familiar with ACVM clearances, found the procedure reasonably easy to follow. In working through the procedure, the auditor found the format to be more or less consistent with other MAFQS procedures but found several items that should be reviewed to improve clearance instructions or to act within legal requirements. These are:

PP82, section 6.1.1

The procedure requires an inspector only to examine documentation rather than inspect the product/consignment. In some circumstances, an inspection of the consignment, to compare product with that described and/or to check labels for accuracy with those on the ACVM registers, may be required. There are no instructions for inspection of the product in the procedure.

PP82, section 6.2.2

The procedures for clearance of private and commercial consignments could be reworded to indicate that the importer does not need to be the registrant, and that the labelling must be exactly as listed in the ACVM register. The procedure could also include a prompt to the QO to refer to the ACVM Group if there are any discrepancies with the label.

PP82, section 6.3.1

The procedure indicates that, if a product cannot be categorised, the importer can be given the option to 'Hold' the consignment while a Class Determination is made, or application for registration is completed. The procedure does not indicate how consignments are to be held. The wording suggests that the importer 'holds' the consignment, but the auditor doubts this is the intention.

PP82, section 6.3.2

The procedure mentions that an inspector may request the importer to apply to the ACVM Group for a Class Determination. In so doing, the procedure implies that the consignment is detained, and that a Notice of Detainment must be issued to the importer. It was noted that in some locations the Notice of Detainment was not used or incorrect forms had been issued. Although the correct forms were immediately substituted, at the time of the audit there was no indication of actions taken to prevent recurrent use of the incorrect forms.

NB 1:

The ACVM Act does not provide the legal means for products, other than those defined as a 'risk good' under the Biosecurity Act 1993, to be detained other than under the provisions of s70, Powers of entry with a warrant.

NB 2:

A legal opinion on the detention of ACVM products suggests that, if the product is not given a clearance, then: *detention flows as a consequence of non-clearance at the border. The agricultural compound is detained, the customs broker notified that the product was not being given a clearance. It is envisaged that MAFQS would then advise the ACVM Group of what has occurred. Then NZFSA could order a further 'hold' of that product for five days in accordance with s64 of the ACVM Act. If the matter was not sorted within the five-day period then an inspector would seek a warrant under s69, seize the goods and those goods dealt with under s71.*

PP82, section 6.3.2

The procedure does not indicate that a Class Determination is valid for two years from date of issue.

PP82, Appendix 2

Notice of Detainment. This is located in the appendices, but lacks the identifier 'Appendix 2'.

Review Data Agreement

MAFQS and the ACVM Group have signed a Review Data Agreement. The purpose of the document is to define expectations and agree a review data period with respect to PP82.

In regard to expectations, the document identifies the roles of MAFQS and the ACVM Group:

- MAFQS: to ensure that it consistently operates in accordance with the requirements within PP82, as relevant to the ACVM Act;
- ACVM Group: to provide consistent and credible feedback to MAFQS on any operational changes with respect to the importation of veterinary medicines and plant compounds.

A key agreement within the document is an annual review of PP82. The last review of PP82 was undertaken in December 2002.

Quancargo

The MAFQS database for monitoring and facilitating clearance for identified commodities is Quancargo. This database, which is linked to the NZC clearance process for commercial consignments, is used to record details of consignments and to provide a MAFQS clearance number that may be used to facilitate a NZC clearance for commodities that are identified as requiring MAF clearance or control.

The examination of import documents revealed that each line within a consignment could be listed and tracked, as required. PP82 also provides some instruction for use of Quancargo to facilitate ACVM clearances.

While observing an ACVM clearance in Quancargo, it was noticed that a 'drop down list' of trade names was available to inspectors to check the status of registration. The ACVM Group observers expressed concern that the drop down list must be current at all times. Follow-up checks revealed that the drop down list is emailed from the ACVM Group on a regular basis, and is entered into Quancargo. The auditor suggests that MAFQS documents the procedure for renewal of the drop down list to ensure that it is consistently received and entered appropriately.

It was noticed that QOs sometimes select 'not on list' or 'exempt registration' from within the drop down list when entering trade names into Quancargo. MAFQS may need to develop some business rules around the use of these selections.

It was also noticed that, under Line Details (2), QOs are currently selecting 'Animal Remedies' or 'Pesticides' from a list of four options. These terms are now outdated and should be removed.

Several examples of clearances for ACVM consignments were examined. It was found that, in each case, a BACC was issued, complete with links to the MAFQS cost recovery process. Currently the BACC is issued pursuant to sections 25 and 26 of the Biosecurity Act 1993. However, where the agricultural compound does not constitute a risk good under the Biosecurity Act, then the issue

of a BACC under sections 25 and 26 may not be appropriate, i.e. the BACC in these instances may need to be pursuant to sections 5 and 6 of the ACVM Act (see discussion above).

MAFQS staff advised that, in conjunction with the ACVM Group, they are currently reviewing Quancargo, and the clearance documents (and supporting systems) that it generates, to ensure that the clearance process meets the requirements stipulated in the relevant legislation.

Cargo clearance

Sea cargo

Sea cargo clearances are document-based, which means that (unless specifically required) no inspections of sea cargo consignments are made to reconcile documents with contents. Shipping manifests are screened and, although ACVM commodities are described, import containers are not stopped at the port of entry.

All sea cargo consignments must be cleared through the NZC clearance system, and identified ACVM commodities are referred to MAFQS for clearance. Most ACVM commodities arriving by sea are imported in FAK containers (i.e. multiple consignee general cargo).

The process of sea cargo clearance is as follows:

1. The importer/broker applies to MAFQS for a biosecurity clearance. (Application forms examined during the audit revealed a number of formats/types with varying terminology are used.)
2. The application and supporting import documentation (e.g. Bill of Lading, Commercial Invoice, and Class Determination) are scrutinised.
3. Commodity details are checked against the ACVM registers (as appropriate) for accuracy/status.
4. If the commodity details and the supporting import documentation details match, then a BACC is issued.

From time to time, a physical inspection of the consignment may be requested by MAFQS. This may follow an 'alert' to MAFQS from the ACVM Group requesting an inspection to provide further details of a particular consignment(s) imported by a particular company. On occasion, an inspection to check the consignment against import documentation for general cargo has been undertaken as a result of discrepancies detected. One such inspection revealed undeclared ACVM products within a consignment of pet food and accessories. As a result of these inspections and findings, subsequent consignments for these importers were targeted for inspection.

Alerts

During the audit it was found that the Quancargo Database Manager had received a recent 'alert' to MAFQS. This alert was for an importer who (it was thought) was illegally importing ACVM commodities. The information in the alert was forwarded to several MAFQS cargo offices in the Auckland area. While it was likely that limiting distribution of the alert information to Auckland only was appropriate in this instance, the possibility that an importation may occur at another port cannot be ignored.

There was no evidence that the information was received by the MAFQS Quality Manager responsible for changes to procedures and issuing Standing Orders. (Standing Orders are used to

provide immediate changes to specifications, or important new instructions, pending changes to process procedures.) It is important that the correct notification pathway is used for alerts and that changes to specifications are appropriate at all times to manage the potential for an application for clearance of a consignment being made at alternative locations, irrespective of the port of arrival or unloading.

Second company

The auditor was advised that commercial consignments of ACVM products are sometimes imported by a company other than the one that holds the product registration. In these cases, the importer is advised to refer to the ACVM Group in order to produce evidence of approval for importation.

Air cargo

Airwaybills are screened by MAFQS to identify risk goods, including ACVM products. Any Master Airwaybill or House Airwaybill that has an ACVM commodity declared is stamped 'Hold For MAF'. Any Airwaybill stamped 'Hold for MAF' must be accompanied by a BACC or over-stamped 'Release' by MAFQS before the consignment can be released from the controlling agency.

MAFQS clearances of ACVM commodities are completed by checking import documentation and/or visual inspection. Although the same document clearance process used for sea cargo is followed, air cargo ACVM products are regularly inspected to compare documents against product because the packages are usually small and are easily presented to MAFQS as part of the clearance process.

In other cargo clearances, particularly fresh produce imported by sea and air, MAFQS operates a physical commodity inspection process. In some cases, for approved importers, consignments are selected at random and samples of the contents are inspected and checked against import documentation. Consignments from non-approved importers are fully unloaded from containers and made available for sampling and inspection. Samples for inspection are selected only when the entire consignment has been unloaded. By not comparing the consignment with import documentation, there is the potential for importers to import any number of ACVM goods without any apparent redress.

Mail clearance

Both NZC and MAFQS, using a combination of x-ray, detector dogs and checking declarations, screen all international mail into New Zealand. Mail that has a declaration indicating ACVM products, or is thought to contain ACVM products, is referred to MAFQS for inspection/clearance.

The inspection and subsequent clearance of a parcel containing possible ACVM products was observed during the audit. The process that is followed uses the electronic links to the ACVM registers. When details are provided on the packaging, the manufacturer's website is often visited to check technical details of manufacture (e.g. ingredients). In this instance, the QO referred the details to the ACVM Group for a decision on its status, and was advised that the package could be released.

Examples of detained ACVM commodities were examined during the audit. It was found that several parcels had been detained and that incorrect Notices of Detainment had been used. The Group Leader advised that all out of date notices would be reissued with correct Notices of Detainment, and that the remaining unused forms would be destroyed (within two weeks). This

finding indicates that the MAFQS document control process may not have been applied in this work area.

Clearance of accompanied ACVM products

Clearance of passengers' products

All passengers' luggage is screened by either x-ray or physical examination. Any ACVM products detected are then checked against the ACVM registers to determine the status and clearance conditions.

At the Auckland International Terminal Building (ITB), hard copy handwritten BACCs are issued for ACVM products rather than computer generated clearances. Any products that are detained are recorded on an MAFQS Action Record sheet. For example, six tubes of Equimec paste were detained by MAFQS pending completion of the clearance process. Instead of a Detainment Notice being issued, a BACC was completed and a copy given to the passenger. The accompanying Action Record indicated that the importer was advised that an application for a Class Determination was required. While the use of the BACC and the Action Record achieved the same result, their use was contrary to the requirements outlined in PP82.

Staff at the Auckland ITB expressed their confusion over clearance specifications. There were at least two interpretations for clearance of private importations of ACVM products. Some staff were not aware of what constituted a seizure, and were not familiar with the requirements, if any, for recording ACVM products in Quanpax (MAFQS's passenger clearance database).

Auckland ITB staff were not as familiar with PP82 as would be expected. Staff at Christchurch International Airport advised that they were not familiar with clearance specifications either because they encounter so few ACVM products.

Groom kits

Grooms (or veterinarians) who accompany livestock (particularly horses) on aircraft often have their own groom kits that contain a range of medicaments and associated equipment.

MAFQS at the Auckland ITB has established a simple process for the control of groom kits that may contain ACVM products. The control process used allows for the groom kits to be retained by MAFQS at the airport and a log book/register completed. The groom (or veterinarian) surrenders their kit to MAFQS and collects it when they next depart New Zealand with a consignment of animals.

In Christchurch, the MAFQS veterinarian advised that he was not very familiar with the clearance process for ACVM products. He tended to follow what he considered good quarantine practice rather than a specified process. He indicated that he had inspected groom kits in the past when he attended animal charter flights. All ACVM products were checked to see that they were registered, approved for importation and (in the case of veterinary medicines) were in an unopened state. Any product that did not comply was destroyed.

It is apparent that there are at least two processes operating for the clearance of accompanied groom kits. Although the Auckland process ensures possible ACVM products do not enter the country, it is not a documented procedure that is outlined in PP82. The Christchurch procedure appears to be more appropriate, but the veterinarian was unsure of the correct process.

It was noted that the ACVM Group is developing a specification for groom kits. At the time of the audit, the document had not been presented to MAFQS for comment or development of a process procedure, but the document should be finalised as soon as possible. Its implementation will help MAFQS to develop a consistent national clearance practice.

Infringement Notices

The auditor discussed the use of Infringement Notices at international airports with an Enforcement Officer in Christchurch.

The Enforcement Officer indicated that the Passenger Arrival Card had the necessary information to inform passengers of the requirement to declare ACVM products. The auditor was advised that, if a passenger made a false declaration regarding an ACVM product, then an Infringement Notice might be issued. The Enforcement Officer had to judge the passenger's intent and decide whether to issue an Infringement Notice or recommend a prosecution be taken.

The Enforcement Officer indicated that no formal training had been provided regarding Infringement Notices in relation to ACVM products.

Cost recovery

When checking the process for applying cost recovery for the clearance of ACVM products, the auditor found that correct fees for clearance activities had been applied. However, the QOs questioned did not understand that fees were applicable under the Agricultural Compound and Veterinary Medicines (Fees and Charges) Regulations 2002, as well as under the Biosecurity Costs Regulations 1993.

Fees for clearance of ACVM products are clearly set out in the MAFQS PP10 Cost Recovery of Fees.

Powers of an inspector

Under the Biosecurity Act 1993, the power of entry for inspection is well defined. Similarly, the Act clearly establishes the power of an inspector to dispose of any restricted goods. The powers of entry to inspect under the Biosecurity Act can be used to determine the presence of risk items, and so may also be used to determine the presence of agricultural compounds and veterinary medicines.

However, the powers of an inspector to dispose of any restricted goods under the ACVM Act are not so clear. Section 64 of the ACVM Act outlines the powers of entry for inspection and specifies that an inspector under powers of entry may:

- a) open containers and packages to inspect the contents;
- b) request, gather, or secure evidence, take samples for testing and analysis, or arrange for testing or analysis;
- c) inspect, inquire about, copy documents or other records, or remove documents and records, including in an electronic format;
- d) order the person in charge of the place to hold any agricultural compound for up to 5 working days.

Unlike the powers under the Biosecurity Act 1993, an inspector under the ACVM Act does not have the power to seize or detain agricultural compounds or veterinary medicines (other than as samples or evidence) from the place of inspection, not including a dwelling house or marae.

ACVM commodities that pose a risk, as per the definition of the Biosecurity Act 1993, can be detained or seized under the powers of the Biosecurity Act. However, under the ACVM Act, an inspector may not seize or dispose of ACVM goods, unless those goods (which are not risk goods as defined under the Biosecurity Act) have been intercepted as a result of the issue of a warrant to search a dwelling or marae. Therefore, any attempted seizure or disposal of ACVM commodities, that are not risk goods as per the Biosecurity Act, may be *ultra vires*. Moreover, based on legal advice, the auditor doubts the validity of QOs exercising section 64 where a consignment legitimately arrives at the border to await a clearance.

Similarly, any ACVM that has been abandoned (as a result of a clearance not being issued) can be disposed of only if a warrant to seize has been obtained.

This has a major impact on the ability of MAFQS to undertake its duties in an effective manner. Clearly, MAFQS requires the ability to inspect, seize (or place on hold), or dispose of any abandoned ACVM commodity, using either or both pieces of legislation, but without the encumbrance of warrants to seize.

Quite possibly, the instructions allowing QOs to detain ACVM products and the use of the Notice of Detainment could embarrass MAF and the NZFSA if detention or disposal were challenged in court.

Competency review/training

MAFQS has been running a programme of competency review for each of its process procedures. Each involved staff member completes a review process (open book) and must attain a 90% pass rate. When the required pass is attained, information is passed on to the ACVM Group for warranting purposes, to qualify the successful officer as an inspector under the ACVM Act.

MAFQS was asked to provide an indication of which staff had completed a competency review in the clearance of ACVM products. In each location, it was demonstrated that most staff had completed a competency review at some stage in the past three years, and that warrants had been, or were in the process of, being attained.

The ongoing competency review process requires Group Leaders to keep all staff records in a proficiency log, which provides for the inclusion of ACVM clearance. Records examined did not indicate if all staff had undertaken a competency review since the current PP82 had been implemented. Some competency review records were at least three years old, and reflected an out of date review timeframe.

Some staff indicated that they had not received training in the new procedure and felt that this was definitely needed. They noted that staff working at regional airports had received recent training in the clearance of ACVM products.

RECOMMENDATIONS TO NZFSA

Procedures

MAFQS completes a review of Process Procedure 82 to include findings of this audit.

MAFQS develops a process for the receipt and entry of 'drop down lists' and removes out of date terms from the options available under Line Details (2) within the Quancargo database.

MAFQS advises the ACVM Group of correct notification pathways for changes to specifications and information contained in 'alerts'.

MAFQS introduces a system of inspection of consignments and reconciliation of documentation for all ACVM clearances.

MAFQS undertakes a review of its Quality System with regard to the document control process.

MAFQS provides training for all staff involved with the clearance of agricultural compounds and veterinary medicines, including legislation, cost recovery and the use of infringement notices, and reviews the competency review process for PP82.

ACVM Group/MAFQS response

The ACVM Group and MAFQS have agreed to the recommendations at a meeting held on 18 November 2003 and are addressing these recommendations together. The ACVM Group is considering the level of inspection needed at the Border as part of the Imports Review and will work with MAFQS on the outcomes from this.

In regard to Process Procedure 82, MAFQS has informed the ACVM Group that it is making several changes as recommended, e.g. the title will be changed from *Clearance of Imported Veterinary Medicines and Plant Compounds* to *Clearance of Imported Veterinary Medicines and Agricultural Compounds*. While PP82 is dated December 2002, we note that it has been the subject of regular review and amendment since then.

Some recommended changes have been deferred until the ACVM Act is amended, e.g. definitions for what constitutes a 'release' or 'clearance', and clarification of how consignments are to be held.

Groom kits

The ACVM Group completes the development of specifications for the clearance of groom kits and advises MAFQS accordingly.

MAFQS develops a national instruction for the clearance of groom kits.

ACVM Group response

A code of practice has been approved for grooms carrying on board prescription animal remedies for use in emergencies. An audit on the approved code of practice is planned within the next 12 months.

ACVM Act/Inspectors

NZFSA reviews the ACVM Act and makes recommendations for effective changes to enable appropriate inspection, seizure and disposal activities by inspectors to be undertaken.

ACVM Group response

NZFSA is in the process of reviewing the ACVM Act and will address the issue of powers at the border. The suggested changes align the ACVM Act powers with those in the Biosecurity Act.