Mar 2018

SAAM News & Views

ISSN 2538-1059

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Changes to MPI

On 13 December 2017, MPI Ministers announced changes to MPI to align our structure to Ministerial portfolios, ensure accountability, and increase visibility of some of our core business.

Since Cabinet agreed to establish four branded business units, MPI has made good progress to establish:

- Biosecurity New Zealand
- Fisheries New Zealand
- Forestry New Zealand, and
- New Zealand Food Safety.

Consultation with all MPI staff on structural changes closed 20 March, and we expect to have a final decision in mid-April. From late April, MPI will start to make structural changes to enable the establishment of the four new branded business units. This will involve moving to new premises for some groups, but we are focused on minimising disruption to services and the way we work with stakeholders.

After branded business units have been established, the MPI brand will continue to be used in association with some of MPI's functions, such as compliance, trade and corporate services. Our trade and market access functions will remain part of MPI's core business. MPI remains the competent authority for all trade activity in the primary industries and work carried out internationally will remain associated with the MPI brand.

ACVM Winter Workshop

The next ACVM workshop for registrants and consultants will be held on 27 July at Te Papa, Wellington.

We are preparing the agenda now, so if you have suggestions please email us with the subject heading 'winter workshop': approvals@mpi.govt.nz

Ministry for Primary Industries
Manatū Ahu Matua

ACVM applications for 2017

In 2017, we received 3,148 applications -- over 500 more than 'normal'. (This was mainly a result of the expired registrations work where 541 products were either renewed or removed from the register.) You will see from the graph at right that the percentage of applications completed within the statutory timeframe rose throughout the year.

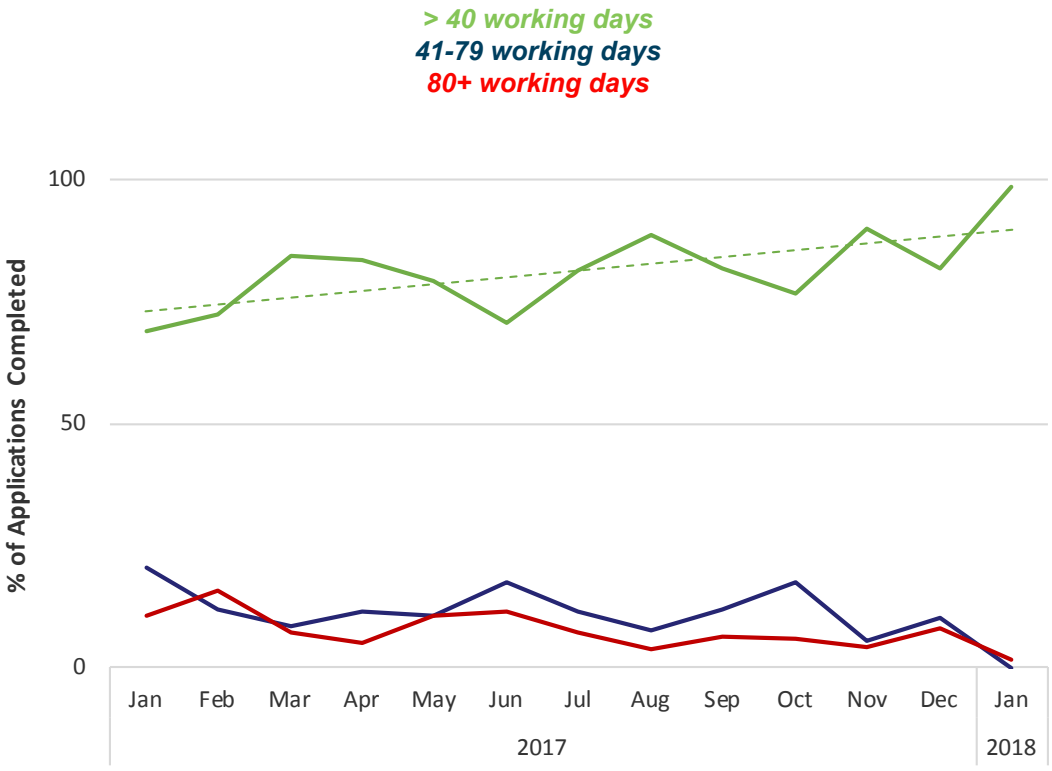
New screening process
The new screening process, in place since August 2017, has made a significant positive impact on processing time for minor variations (93.4% were processed in under 40 working days). These are now screened and processed at the same time to reduce double handling.

New registrations and new use applications require far more assessment, so there has been little positive impact in processing times for these categories. In regard to provisional registrations, 84.2% were processed in under 40 working days. Also in the 40 working day timeframe, 66.3% of manufacturing variations were processed.

Other authorisations
Other authorisations/ approvals in 2017 included:

- 138 Special circumstances
- 789 Maintenance compounds (non-dairy)
- 45 Operating plans.

Percentage of applications completed by statutory timeframe in 2017



Products for Teats of Lactating Animals

Recently MPI has had reports of exempt products being advertised or promoted for use on the teats of lactating animals. There have also been a number of class determination requests for products with claims involving application of products to the teats of lactating animals.

Please note that all steriliser, sanitiser, and disinfectant products, herbal oral or topical products, first aid and antiseptic preparations, and topical preparations applied to the teats of lactating animals MUST BE REGISTERED before they can be imported, sold, or used in New Zealand as all associated exemptions specifically prohibit such use. In addition, any exempt product that makes a claim for or promotes the application of such products to the teats of lactating animals is no longer in compliance with the conditions of exemption and can be considered in breach of the ACVM Regulations and subject to compliance action.

If you know of a product that is being sold or promoted in this manner, please contact the ACVM team.

One Stop Shop for ACVM and Biosecurity Approvals

Following on from the 2017 ACVM Workshop, we are pleased to announce that the application for Biosecurity approvals has been integrated into the ACVM application process.

In response to your feedback, applicants will no longer be required to make separate submissions to the Animal Imports team and the ACVM Group to obtain the relevant approvals for trade name products imported into New Zealand that contain ingredients of biological origin (plant or animal).

New streamlined process

MPI has created a new internal process to streamline the receipt, technical appraisal and issuing of Biosecurity approvals. The new process requires applicants to supply all required application forms and information directly to the Approvals Operations team. This team will manage the receipt and issuance of all application and approval documents/invoices.

The example at right shows how the process will work for new trade name product (TNP) registrations requiring Biosecurity approvals. The process will be the same for registration renewals or variations aside from the ACVM form submitted in step 1:

- renewals = form ACVM 1R
- variations = form ACVM 1V.

To obtain a Biosecurity approval **prior** to submitting an ACVM registration application, the process will be a little different. The applicant (step 1) will only submit a Biosecurity Summary of Information Provided form and supporting information to the Approvals Operations team. Assuming approval of the application, the outcome at step 4 is a Biosecurity approval letter that the applicant can supply when submitting an ACVM registration application for the product.

Example: New Product Registration Requiring Biosecurity Approval

1. Applicant
- Biosecurity Summary of Info Provided form
- ACVM 1 form
- Label and PDS
- PCI form
- Supporting information (DARs, dossiers etc)

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2. ACVM Operations
- Receives application documents
- Sets up application in MPI system
- Sends Biosecurity approval application docs to Imports team

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3. Technical Appraisal
- Imports team risk assessment: approves or declines application
- ACVM technical team appraises application to register the TNP

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4. ACVM Operations
- Issues Biosecurity approval letter
- Issues ACVM approval letter and registration documents
- Issues invoice

Biosecurity approvals for trade name products will remain valid for the registration period of the product. Note it is the registrant's responsibility to advise MPI if any change in the formulation or sourcing of ingredients of biological origin occurs prior to registration renewal.

Updated forms

To facilitate the new process, the Registration (ACVM 1), Variation to Registration (ACVM 1V), and Registration Renewal (ACVM 1R) application forms, product data sheet (PDS) forms, and guidelines have been updated and will be available on the MPI website as soon as they are signed off (early April).

We are also revising the Special Circumstances (ACVM 3), Provisional Registration (ACVM 4), and Research Approval (ACVM 5) forms, which will be available soon.

Additionally, a new guidance document and form will be available for Biosecurity approval applications on the MPI website, in both the Animal Imports and ACVM pages:

- Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines – ACVM Guidance
- Biosecurity Summary of Information Provided form.

If you have any questions contact: approvals@mpi.govt.nz or animal.imports@mpi.govt.nz

ACVM Workshop

We welcomed 88 registrants, consultants, and data assessors to the latest ACVM workshop in Auckland.

These presentations were made:

- ACVM update
- Operations update
- Conditions of registration
- Regulation changes
- Contracting 3rd parties
- ACVM expectations: managing registrations
- Reporting non-conformances
- Antimicrobial resistance (AMR) update
- Registration review project.

In early April, the Power Points will be available as a single PDF file on the ACVM Resources section of the MPI website, which is currently under construction.

Attendees who participated in the Survey Monkey evaluation following the workshop provided valuable feedback. We were pleased to see that most participants found the content of the presentations extremely relevant (10.53%) or very relevant (57.89%) to them and gave the workshop a rating of excellent (15.56%), very good (60%), or good (22.22%). We will use the comments from this survey, both positive and negative, to plan future workshops, including the one scheduled for July (see page 1).

staff update staff update staff update

We are very pleased to welcome our new ACVM Technical Adviser, **Evan Brenton-Rule.** By way of introduction, Evan says:

"I was born in Corpus Christi, Texas, but have spent most of my life in Wellington as well as stints working in Australia and England. My undergraduate study involved degrees in science and law, and I am currently putting the finishing touches (hopefully!) on a PhD focussed on legal regulation of pest species and their pathogens. Prior to joining MPI I worked in a variety of roles, including biosecurity work on Pacific atolls and laboratory research of animal pest genetics.

Outside of work I like participating in and following virtually all sports. Travel is also an interest and I try to escape Wellington for somewhere warmer and less windy in July or August each year."

Evan (pre-MPI) examining a common wasp nest dug out near Lake Rotoiti.

FYI

MRL Notice

Food Act Notice: Maximum Residue Levels for Agricultural Compounds
The latest round of new and amended maximum residue levels (MRLs) were signed off and came into effect on 16 February 2018. This round included new and amended MRL entries for eight agricultural compounds, three proposals for new or amended exceptions from compliance with a MRL, and the addition of a definition for 'active ingredient' into Part 1 of the Notice.

More information on MRLs can be found on our website; the revised MRL Notice is linked on that page, or you can access it directly here.

The next amendments to the Notice are currently being assessed.

ACVM 101 workshop

MPI has a large number of registrants with a small number of products registered under the ACVM Act, and who commonly need assistance with or have questions about the registration process. We propose to hold an 'ACVM 101 Workshop' -- a one-day workshop focused on the registration process, and MPI's expectations of registrants. The content will be tailored for people with minimal experience in submitting ACVM applications.

To enable us to gauge interest in an ACVM 101 workshop, would you please indicate:
1. if you would be interested in attending
2. how many of your staff would be likely to attend, and
3. your preference for city location of workshop.

Email by 5 April: approvals@mpi.govt.nz

Transparency consultation

Public consultation on proposed changes to improve transparency of the ACVM product registration process closed 16 March. (The three proposals are: regular website publication of an 'applications received' report, changes to the information on the public record of the delegate decision document, and a summary listing of information supplied with an application.) The six submissions received are being considered before any changes to the current process are implemented.

Monitoring Compliance of Food Businesses

The Food Act 2014 requires most food businesses to either:

- register a Food Control Plan or
- manage food safety and suitability under a National Programme.

Verification and enforcement

It also requires that these businesses be verified (the frequency is dependent on the risk of the activity and the outcome of the verification).

The verification of food businesses is conducted by verifiers at each of the 67 territorial authorities (TAs) and at Third Party Verification Agencies.

Mānuka Honey Notice

On 29 January 2018, MPI issued the Animal Products Notice: General Export Requirements for Bee Products. This Notice establishes a regulatory definition for New Zealand monofloral and multifloral mānuka honey intended for export.

Bee product processors and exporters are required to test their honey at an MPI-recognised laboratory in order to ascertain compliance with the definition. Honey intended for export cannot be labelled as monofloral or multifloral mānuka honey unless the test results show that the relevant applicable definition has been met.

The Notice also specifies requirements for strengthening the traceability of bee products intended for export and for ensuring that such products are fit for purpose. For more information, refer to the MPI website.

If critical non-compliances are identified, then Food Safety Officers at MPI or the TAs follow these up with the business and conduct any enforcement activities.

With verification and enforcement activities happening at so many different places, it is difficult to get a national picture of how businesses are performing. This is something MPI would very much like to have as it allows for the prioritisation of resource and targeting of education to food businesses.

Monitoring and reporting framework development

With that in mind Food Assurance, along with other teams in MPI, has been working to develop a monitoring and reporting framework that will allow:

- national trends in business compliance to be determined, and
- monitoring of the consistency of verifiers and food safety officers.

In order to do this MPI first worked with verifiers to develop a common list of verification topics to be used when reporting verification scope and findings. These can be found under “Step 3: Decide what to check” at: https://www.mpi.govt.nz/food-safety/food-act-2014/information-for-regulators-and-verifiers/working-as-a-verifier/

The topics were developed some time ago and verifiers are now transitioning to using them. They will also be used to indicate areas of non-compliance when reporting enforcement activities. MPI is now building a software application called Titiro (a Maori word for inspection).

All verifiers and Food Safety Officers will have access to this system, which they will use to submit summary details of verification completed and enforcement actions undertaken.

Reporting trends

The Food Assurance team will be responsible for reporting trends from the data supplied. The team is closely involved in the development of Titiro to ensure it will deliver the data required to answer questions such as:

- Which are the verification topics where a large number of food businesses are noncompliant?
- Is there improvement in the compliance for topics that have been the subject of education efforts nationally?
- Are there particular regions struggling with compliance?
- Are verification activities, frequency and reporting appropriate?
- Are enforcement activities appropriate?

New Specialist Adviser

Retha Brandt has joined the team as a Specialist Adviser Food Assurance.

Retha is a registered veterinarian and has extensive regulatory experience. She has recently been working as a Senior Adviser in the Animal Exports team.

Correct Client Code for Registered Food Importers

In the last *SAAM News and Views* we explained the need for all food importers to be registered with MPI. Subsequently, we have been following up with businesses that we believe should be registered. During this exercise it has come to light that some registered importers are using the incorrect client code when importing food.

When importing food for sale it is important that:

- the importer is registered as a Food Importer with MPI, and
- an active Importer/Exporter client code is used rather than a General client code.

The active Importer/Exporter code is associated with the registration of a Food Importer under the Food Act 2014. Failure to use the correct code may mean that:

- the client may be identified as an unregistered food importer by MPI, and
- clearance may be withheld unintentionally by MPI.

For registered Food Importers the client code would have been notified by NZ Customs on approval of the client registration application (Customs 224 or 225 form).

If you are a registered importer but unsure what client code should be used, details are available in the Trade Single Window or you can contact approvals@mpi.govt.nz for help.

As the client code is used in the Joint Border Management System (JBMS) to facilitate clearance for businesses that hold NZ Importer Assurances (i.e. businesses that are able to demonstrate through verification that they manage the risks of importing High Regulatory Interest Food), it is important that the timing of any change in the use of client codes is managed in conjunction with MPI. MPI will therefore be writing directly to these businesses and their brokers.

Imported Foods Rejections Report (January - June 2017)

A report of imported foods that were rejected at the border for the first six months of 2017 has been posted on the MPI website. (See https://www.mpi.govt.nz/importing/overview/food-imports/ under the heading, “Foods of Regulatory Interest Stopped at the New Zealand Border”.)

These rejections were imported high risk food consignments stopped from entering New Zealand because they failed testing requirements.

Food Notice

To make sure food for sale is safe and suitable under the Food Act 2014, the Food Notice: Importing Food sets out categories of imported food for targeted testing. MPI conducts targeting testing of these foods before they are cleared for entry into New Zealand. The foods are tested by laboratories for hazards, as specified in the Food Notice: Importing Food.

The food that failed testing requirements was not distributed for sale in New Zealand. It was destroyed by the importer or returned to the country of origin. MPI is making this information available to meet its CODEX requirements and for public interest.

Export Non-Conformances

The Food Assurance Team has published a Guidance document and a decision tree that will provide more information on the Exporter Non-Conformance (ENC) process and assist exporters to determine whether issues should be reported as ENCs or not.

These are now available on the MPI website.