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# SAAM News & Views

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## Expanded Content

In case you missed seeing the June issue, please note that *ACVM News and Views* has been expanded to include information from other parts of MPI's Systems Audit, Assurance and Monitoring (SAAM) Directorate. ID tags in the top corner of each page tell you what team has provided the news on that page.

## New Zealand Business Number

As part of MPI's commitment to the Government's Better for Business Programme and making it easier for businesses to deal with MPI, we are pleased to say we can now receive your NZBN.

**What is NZBN?**
It stands for New Zealand Business Number. It is a single unique number that business can use when dealing either with other business, or with Government organisations.

**Who has a NZBN now?**
All registered companies that already have a company number have been issued a NZBN. To find out what yours is, you can search for it here: www.nzbn.govt.nz

**When will we ask you for your NZBN?**
As part of our standard registration or renewal processes, you will notice a new field for a NZBN.

**What does MPI do with your NZBN?**
We store the number in our internal MPI systems. We check we have the right NZBN for the right legal company name. In the future, if your business address changes, having your NZBN will help us recognise there has been a change.

**What if you don't have a NZBN?**
You do not need to have one, but to help MPI provide the best service to our customers, any other customer type can apply for one on the NZBN Website (e.g. If you are a sole trader, a partnership or a trust).

**Is there any cost?**
No, there is no cost to get a NZBN.

**Why should you get a NZBN?**
At MPI, like most large organisations, we have multiple systems and multiple processes. If all of our customers have a NZBN, we can ensure we keep accurate records across all our systems and processes, meaning you only have to tell MPI once, if some details change. If you have any questions, you can email nzbn@mpi.govt.nz.

Ministry for Primary Industries
Manatū Ahu Matua

# Proposed changes to ACVM Regulations

Public consultation on proposed changes to the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 is underway.

The proposed changes seek to:
- add new compound groups to enable more products to be exempt
- provide more clarity to existing exemptions, and
- amend some individual regulations to incorporate new information such as definitions.

MPI expects that the proposed new exempt groups will facilitate access to new products, which will benefit both industry and users. Managing these products by exemption will also benefit industry by avoiding registration costs.

MPI is particularly interested in understanding if any additional costs may be imposed through these changes, especially where risk profiles for some product groups are proposed to change. Your responses will enable MPI to better understand the effects of the proposed changes on you or your business before final recommendations are made.

Email your feedback on the consultation document by 5pm on **19 October 2017** to ACVM.Consultation@mpi.govt.nz

Make sure you include in your submission:
- the title of the consultation document in the subject line of your email
- your name and title (if applicable)
- your organisation's name (if applicable)
- your address.

While we prefer email, you can send your submission by post to:
ACVM Regulations Proposals
MPI Food Policy Team
PO Box 2526
Wellington 6140, New Zealand

# ACVM registration renewal process

*A registration renewal application is made to renew the registration period and set a new registration expiry date for a trade name product.*

**What is changing?**
MPI is changing the registration expiry period for trade name products from 3 years to 5 years.

MPI is changing the processing of variation applications, so that all variation applications (when granted) will be issued with a new registration expiry date. If a variation application is submitted within the 5 year expiration period, the new expiry date will be set for a further 5 years from the date the application is granted. A new certificate of registration will be issued with the new expiration date, along with the approval of the submitted product datasheet (PDS) and label. A renewal application will not be required until 3 months prior to that registration expiring.

**The changes below will come into effect for all applications formally received (accepted at pre-screen) from 1 January 2018:**
- The registration expiry period will be 5 years (except for those trade name products requiring a shorter registration period to manage risk).
- Registrations will be renewed for 5 years from granting of every variation or renewal application.
- Simultaneous renewal and variation applications will not be accepted.

More detailed guidance and updated application forms will be made available on our website prior to January 2018.

**Annual fees and registration renewal**
MPI wishes to remind registrants that annual fees are separate from renewal of product registrations. Payment of annual fees does not renew a product registration.

Annual fees are a fixed fee payable by registrants, based on the number of products registered to them. They are paid in advance e.g. the current annual fees run from 1 October 2017 through to 30 September 2018. Reminder letters are sent to registrants each year, with payment due by 30 September. Please note it is the responsibility of the registrant to ensure that their contact details are current, and advise MPI of any change.

# ACVM Manufacturing Workshops

The latest ACVM Manufacturing Workshops, successfully held on 28 July (Wellington) and 10 August (Auckland), were attended by more than 160 people. Participants came from a wide range of agricultural chemical and veterinary medicine manufacturers and registrant companies, as well as consultants and others involved in the import, manufacture, distribution and sale of agricultural compounds including exempt products.

*MPI presentations during the recent ACVM Manufacturing Workshops in Wellington (top photo) and Auckland.*

Topics of discussion included:

- ACVM Good Manufacturing Practice (GMP) Programme
- Administration issues
- Common deficiencies
- Quality management
- Validation
- GMP in Asia and beyond
- Proposed amendments to the Veterinary Medicines Chemistry and Manufacture Registration Information Requirements
- Agricultural chemical manufacturing, and
- Requirements for contract manufacturing.

There was a general consensus that the workshops were of benefit. We received positive feedback as well as suggestions for making future workshops focused and directed towards specific groups. This will be considered for any future workshops to ensure content is structured accordingly.

The workshop presentations are available at the following links:

ACVM Manufacturing Workshop Presentation: Auckland

ACVM Manufacturing Workshop Presentation: Wellington

Please note that these are large (13-14 MB) PDF files.

## Reminder to ACVM registrants

**Annual fees must be paid by 30 September.**

**If fees are not paid, products may be de-registered.**

# ACVM Data Assessor Workshop

MPI hosted a workshop for 15 independent data assessors on 8 September in Wellington.

The workshop was an opportunity for us to inform data assessors about upcoming changes to the ACVM registration process and to answer questions. We also asked the data assessors for their opinions on a range of issues, including proposed changes to the data assessor's role.

## Heads Up: Electronic Documentation

**MPI proposes to provide ACVM approval documentation for TNP registrations, Provisional Registrations and Special Circumstances approvals (including Research approvals) electronically (by email or through SharePoint) rather than in hard copy form in the near future.**

**No starting date has been decided, but we want you to be aware of the proposal.**

**If you prefer to receive your approval documentation in hard copy, please either advise your account manager or the Approvals team at approvals@mpi.govt.nz before the end of October 2017.**

FYI

## On-farm veterinary medicine issues

We are working to get the MPI On-Farm Verifiers (OFVs) and Residue Programmes Coordinators (RPCs) warranted under the ACVM Act. This is to allow them to take action if there are veterinary medicine-related issues that crop up on-farm in either routine verification or residues traceback visits without the need for additional visits. OFV findings will be investigated by ACVM as needed.

The findings will also allow us to trend the information and relay any significant trends or issues related to veterinary authorisation and/or product use to the New Zealand Veterinary Council and the New Zealand Veterinary Association. We have not previously had any direct formal link into on-farm verification and their findings, any way to evaluate and trend these reports, or any formal pathway to relay significant findings to the veterinary council. It's a great step forward.

## Requirements and guidance update

**Food Act Notice: Maximum Residue Levels for Agricultural Compounds (July 2017)**
The latest MRL notice was signed and came into effect on 28 July 2017. It is available on our website at this link.

**ACVM Act Notice: Agricultural Compounds Exempt from Registration**
This notice specifies certain requirements for ensuring conditions of exemption from ACVM registration are met. It was signed on 1 August 2017 and came into effect on 1 September 2017. It is available on our website at this link.

**ACVM Registration Information Requirements**
Public consultation on this document and the related Risk-Benefit Analysis guidance, which was extended at industry request, has now finished and submissions are being analysed.

**Veterinary Medicine Chemistry and Manufacturing Guidance**
The first draft of this guidance document was shared with industry and it generated a high level of interest. Our intention was to get early feedback on the overall changes from a requirement standard to a guidance document, but this must not have been stated clearly enough. Following extensive discussion with industry, the second draft is being written.

# STAFF STAFF STAFF STAFF STAFF

*We are pleased to introduce two new Approvals Operations Team advisers who are working with ACVM applications...*

## Jessica Gautrey

"Hi I'm Jess! I was born in the sunny Hawke's Bay, then ventured to Hamilton to study Business Management at Waikato University. In my 4th year of university I started my career in Logistics -- this led to a move to Wellington in 2015.

After a couple of years it was time for a change. I've now been at MPI for 5months, and I'm looking forward to building my knowledge of the ACVM Act."

## Daniela Foote

"I was born and bred in Hamilton, where I studied Animal Behaviour at Waikato Uni. My degree and my involvement volunteering at the Hamilton Zoo during my early student years led me more into the zoological side of animal science. My move to Windy Welly has been a big step, coming from a family-oriented Polish heritage, and being my first career move after graduating, but I'm enjoying the change. My love of travel makes me appreciate the social and cultural life Wellington has to offer – when the weather allows it!"

# Vacancies

**Veterinary medicine assessor Justin Mercier has joined the Response Team of MPI. We thank Justin for his contribution to ACVM during his time with us and wish him well in his new challenge.**

**Our best wishes also go to Joy O'Connor, agricultural chemical assessor, who is expecting her second child and will be on parental leave from 1 November.**

**As a result of these departures, we are looking for a senior veterinary medicine assessor and we have a 12-month position in the agricultural chemical team.**

**Email any queries or expressions of interest to Glen.Bradbury@mpi.govt.nz**

# Introducing... THE CHEMICAL AND MICROBIOLOGICAL ASSURANCE (CMA) TEAM

This team is accountable for major chemical and microbiological food monitoring programmes. These programmes are designed to provide confidence to the New Zealand consumer and our trading partners that good agricultural practice is in place in the use of agricultural compounds and veterinary medicines, as well as good hygienic processes in meat and poultry production. (see programmes at right). This is an area that requires significant technical expertise in chemistry, microbiology, veterinary medicine and data management, as well as an understanding of agricultural practices, international pathogen and residue issues, emerging risks and changing market access requirements.

It is essential that our chemical and microbiological monitoring and surveillance programmes are robust and inspire confidence in our control systems. This means that:

- our programmes are well-designed and adapt to changes in the environment, country requirements, new animal treatments and farming practices, and
- our laboratories and test methods meet international standards and any exception event is followed through to resolution.

In addition to robust programmes, MPI must have a database that can manage a huge amount of monitoring information so that it is easily retrieved, readily analysed and able to be provided to industry, consumers and our trading partners. Over 500,000 test results are analysed annually.

Ten years ago, this team developed the Sample Attribute Management Database (SAMD), which was a significant advancement in management of food residue data.

Things don't stay static in the IT world. Platforms become obsolete so CMA is now working on a project to develop a new database, E*STAR (Electronic Sampling, Tracking, Analysis and Reporting), which will continue to harmoniously manage critically valuable data.

There is significant public interest in the work of this team in looking after the population of New Zealand. Reports are published on the MPI website regularly.

## Current monitoring programmes

**National Microbiological Database Programme**
This programme monitors the microbiological profile of meat produced in New Zealand and is critical to our access to the US market. In addition, we use this programme to inspire confidence within many other markets. The poultry monitoring is core to our pathogen strategy for New Zealand to reduce the incidence of campylobacter infection in the New Zealand population, with great success.

**National Chemical Residues Programme (NCRP)**
This programme monitors meat, seafood, poultry, honey and wild fish for chemical and environmental contaminants. Every overseas audit investigates this programme, and results to date have been extremely favourable.

**National Chemical Contaminants Programme (NCCP)**
This programme monitors dairy raw milk and processed dairy products for chemical contaminants, with similarly successful results.

**Independent Verification Programme**
This programme serves to validate extensive industry testing of processed dairy products through MPI microbiological and compositional testing.

**Food Residues Survey Programme (FRSP)**
This programme tests primarily produce, both domestically produced and imported, to assure the New Zealand public that the produce they consume meets good agricultural practice in the use of pesticides and herbicides.

**Total Diet Survey (TDS)**
This programme tests the average New Zealand diet every 5 years, primarily looking for chemical contaminants. Currently designed by MPI Science and the Institute of Environmental Science and Research (ESR), the data is managed via SAMD (see left).

# Codex Committee on Methods of Analysis and Sampling

*Susan Morris, CMA Team's Principal Adviser (Residues), headed the New Zealand delegation to the 37th CCMAS session in Budapest, Hungary.*

## Background

New Zealand, primarily an exporting country, wants science-based rules that support our export activities without compromising the 'safety' of the consumer.

Countries importing food from New Zealand need a sampling and testing plan that protects their consumers, and gives our producers a scientific framework to work in to protect them. The importing country sets the bar. As an exporting country we need to meet that bar and use sampling plans that have those limits built in to them.

Codex is important to New Zealand because of our trade in food products. Harmonising scientifically robust standards is a key role for Codex. International standards are expected around the world and we want them to work for us, both as a consumer and an exporter.

The roles of the Codex Committee on Methods of Analysis and Sampling (CCMAS) include defining appropriate criteria for methods of analysis and sampling, as well as reviewing and endorsing methods of analysis and sampling proposed by Codex commodity committees, providing direction of sampling plans and procedures, and working with other international groups working in methods of analysis and sampling and quality assurance systems for laboratories.

***"Leading the working group will enable New Zealand to identify and guide the improvements needed to implement fit-for-purpose sampling plans in today's international trading environment."***

The CCMAS mandate does not include methods of analysis and sampling for pesticides or veterinary drugs in food, microbiological quality and safety or food additives.

CCMAS is trying to put in place statistically and scientifically robust sampling and testing decisions, so both trading countries and the importing/exporting businesses can operate sampling and testing programmes for international food trade under the Codex framework. New Zealand is visibly influential in this.

## 37th session

New Zealand's participation in the 37th CCMAS session was very successful in progressing the key technical areas relevant to our interests.

New Zealand will lead an electronic working group identifying potential improvements leading to a review of the Codex General Guidelines on Sampling. These guidelines are extremely important for international trade to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard.

New Zealand's involvement came at the invitation of the CCMAS 37 Chair and followed discussion out-of-session on the New Zealand position -- a strategic approach to undertake a review of the General Guidelines on Sampling. This review would provide clarity for Commodity Committees that own various Codex standards and need to consider consumers' and producers' risk when selecting sampling plans that are fit-for-purpose.

This opportunity is potentially highly significant in terms of New Zealand's strategic objective to strongly influence Codex standards to reflect New Zealand's interests in food safety, public health and trade.

Leading the working group will enable New Zealand to identify and guide the improvements needed to implement fit-for-purpose sampling plans in today's international trading environment. This work will require the input of experts from different New Zealand government agencies as well as some of New Zealand's key export trading businesses. In addition, the membership of the working group is open to representatives from all countries participating in CCMAS.

# Animal Product Export Certification System

New Zealand relies on its reputation as a trusted supplier of safe and suitable food when negotiating and maintaining access to international markets. This reputation is based on:

- our robust but risk-based regulatory requirements across the food chain
- checks that these requirements are being met, and
- the integrity of MPI's export certification system.

MPI has been highly involved in the development of international standards to ensure consistency across international certification systems and acceptance of New Zealand's certification model.

**Electronic export certification**

One of New Zealand's key mechanisms to facilitate market access is to provide Official Assurances (government to government statements) for products being exported. An export certificate is a vehicle for providing an official assurance to an importing country that the product meets certain standards and requirements. These requirements are likely to include those relating to food safety, wholesomeness, accuracy of labelling, and risk to animal health.

An export certificate is essentially a consignment's passport to help products clear importing country borders. It facilitates communication of assurances about a consignment of animal product from the regulatory authority in New Zealand (MPI) to the equivalent authority of an importing country.

MPI's export certification system for animal products is an electronic system known as AP Ecert. It was designed to meet international standards, including those of the United Nations Centre for Trade Facilitation and Electronic Business and the needs of our trading partners.

**Why is AP Ecert important?**

AP Ecert is an internet-based system that was developed by MPI in the 1990s to:

- provide a more secure means of delivering export certification than the paper-based process that was used at the time
- minimise the ability of others to misuse MPI's certificates (e.g. fraud)
- improve the ability to update, replace and deliver certificates to market in real-time
- provide flexibility so that certificates can be tailored and updated to meet market needs
- be able to trace individual consignments and batches of products and ingredients backwards and forwards through the food chain when there is a food safety issue or response
- be able to report on the status of deliveries, acceptance of product and rejections.

**How does it work?**

The legal basis for certification is provided through notices and specifications under the Animal Products Act, in particular Official Assurance Specifications.

Export certificates are issued by MPI as an assurance to other governments that the product was produced under MPI's regulatory control, and that the attestations made on the certificate are true and are supported by evidence.

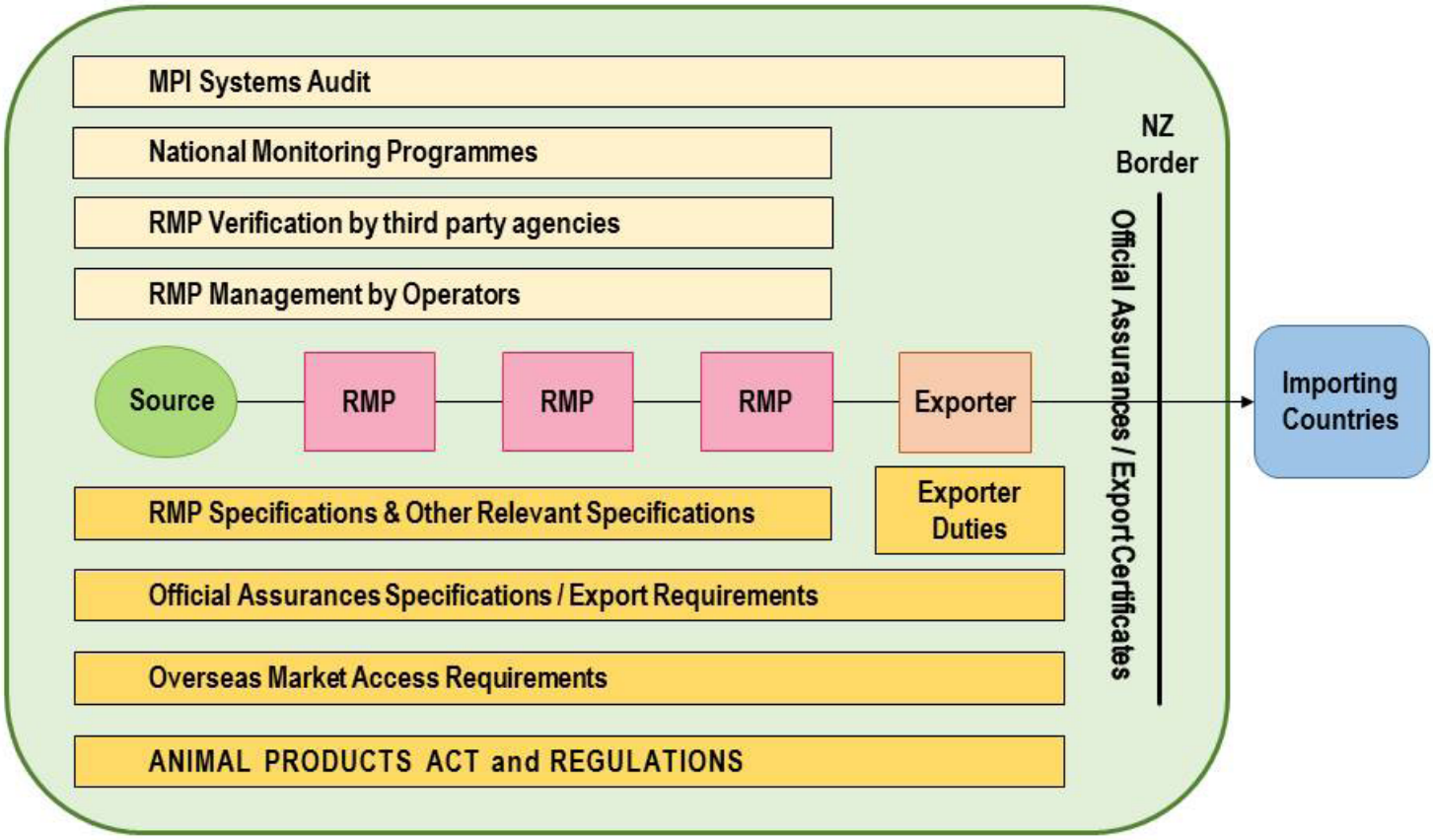
In order to certify a particular consignment, MPI must have evidence that each operator in each part of the food chain has met the legal requirements as well as any market access requirements. Each operator has to record information demonstrating that the product is eligible for export as it moves along the chain.

MPI can only certify products from registered businesses that have been subject to the required checks and balances. This is achieved by reviewing the data and supporting evidence that has been entered into MPI's electronic certification system by the business operators, the exporter and the verifiers who check that the businesses are complying with the requirements (see graphic next page).

AP Ecert is used to track this export eligibility information. For every movement of product from one business to another, an Eligibility Document (ED) is submitted with information about the product and the markets for which the product is eligible. AP Ecert enables all documents to be linked electronically to the export certificate.

Certifiers check the submitted documents and relevant information

# The MPI Export Assurance System




from MPI's assurance systems prior to issuing the export certificate.

**Why do we need to continuously improve it?**

Over the years AP Ecert has been expanded and updated, through continuous improvement and a number of rebuilds, to ensure that it has remained current with evolving international standards, and still provides an efficient service to New Zealand animal products businesses and exporters, and overseas authorities.

Overseas countries are continuing to require additional assurances for a wider range of products. AP Ecert has proven to be easy to adapt to meet these changing needs at a relatively low cost.

AP Ecert is currently being expanded to meet market needs as follows:

- Halal certificates are now produced using AP Ecert for most meat exports to Muslim markets.
- Work is underway to produce organic export certificates from AP Ecert for all types of organic produce.
- Assurances for general food produce (non-animal products) is being developed for specific markets including China and the United Arab Emirates.

In some of the above cases the underpinning legal requirements are not as rigorous as those under the Animal Products Act. In this case MPI sets up an administrative framework to ensure that we have a system that can still provide the integrity required for MPI to provide export certification.

One of the other key developments in the electronic certification area is work on a reciprocal system that will enable MPI to receive electronic certificates from overseas authorities. This development work has started in the plant certification area but is likely to move quickly to animal products as the pace of change to paperless certification increases internationally.

***Steve Collinson has recently joined the Food Assurance team to cover for Michelle Boston who is on maternity leave. Steve has a background in MPI Food Compliance in Christchurch as well as many years' experience in chocolate manufacture.***