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SAAM News & Views

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Expanded Content

Did you notice the difference in our newsletter name? We have expanded *ACVM News and Views* to include information from other parts of MPI's Systems Audit, Assurance and Monitoring (SAAM) Directorate.

This issue features a report from the Systems Audit Team and an introduction (including activity information) to the Food Assurance Team.

To make it easy for you to find information specifically related to your business, each page has an ID tag in the top corner to let you know what team has provided the news on that page.

Your feedback is always welcome, so if you have any comments, questions, or suggestions for articles, email the editor: jeanne.boland@mpi.govt.nz

ACVM Annual Fees Reminder

In May we sent letters reminding you to view your list of registered products on the public register and advise us if you wished to de-register any of your products. The deadline for notifying us has passed, so if you have not cancelled a product registration you will be invoiced for the annual fee.

Annual fees must be paid by 30 September 2017. If fees are not paid, products may be de-registered as per section 81J of the Agricultural Compounds and Veterinary Medicines Act 1997.

Please note that annual fees are separate from renewal of product registrations. See "Annual Fees & Registration Renewals" in our March 2017 issue if you are unsure about the difference.

If you have questions about annual fees, email approvals@mpi.govt.nz

Ministry for Primary Industries
Manatū Ahu Matua

Calf Milk Replacers

As we come into another calving season, MPI wants to remind manufacturers and consumers of the requirements for exempt agricultural compounds, specifically calf milk replacers, under the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.

Labelled milk replacers

If a product is labelled in any way as a calf milk replacer, or is intended to be fed to calves, the product must meet the full labelling requirements of an exempt product under Regulation 12 of the ACVM Exemption Regulations. This includes:

- the name (if any) under which it is sold or supplied
- a description of the product or preparation sufficient to enable the user to determine the nature and purpose of it
- the name and contact details of the manufacturer or importer
- the active ingredients
- directions for use
- use-by date or expiry date, if applicable
- details of precautions (if any) to be taken to prevent or manage any risks associated with the product
- the batch number or other information sufficient to allow the date and place of manufacture or preparation to be ascertained, and
- any information specified on the label of any registered veterinary medicines incorporated into the product.

Products that are supplied without this information, if they are not registered as veterinary medicines, are likely to be in breach of the ACVM Act and any manufacturer, distributor, seller, or user of the product could be held responsible.

'Brown bag' products

It is known to be common industry practice to sell powdered milk products with limited labelling as a 'brown bag' and usually labelled as "Stock Feed; Not for Human Consumption". While it is legal to manufacture and sell these products, they must not be marked in any way as intended as a feed for animals.

These products are usually sold as processing waste products and can be bought or sold as such. Anyone who buys this product with the intent to use or on-sell it as a stock feed or calf milk replacer should be aware that they are considered to be the manufacturer under the ACVM Exemption Regulations. It is therefore the responsibility of that person to ensure the product is fit for purpose under the Regulations, as well as being appropriately labelled as a calf milk replacer or animal feed if the product is sold by them.

To ensure a product is fit for purpose, the person who takes or buys processing waste and uses it as an animal feed must comply with Regulation 7 of the ACVM Exemption Regulations. This includes ensuring that the product will not cause any harm to the animal when used as directed, or when fed as the sole source of nutrition unless otherwise directed.

Manufacturing calf milk replacers

Any person who buys processing waste or any other item that was clearly not intended to be used as a calf milk replacer and then further processes, labels, sells, or uses the product as a feed for calves is considered to be a manufacturer under the ACVM Exemption Regulations. The person must have a documented system to ensure that the product is fit for purpose and is labelled according to Regulation 12. If the product causes any harm to animals that consume it, the person who 'manufactured' that stock feed may be held responsible, even if they are feeding it to their own animals.

Adverse events

Any adverse events associated with a product, including any disease or harm that appears to have been caused by the product, should be reported to the manufacturer or seller of the product in the first instance. It is the manufacturer's responsibility to ensure that such feedback is investigated and any issues in the manufacturing process or labelling information are corrected.

If problems continue, or there are any concerns regarding the ongoing fitness-for-purpose of the product when used as directed, an adverse event report should be filed with MPI. Forms are available on our website.

Adverse events and any questions can be emailed to ACVM-AdverseEvents@MPI.govt.nz.

Further information

Further information regarding obligations under the ACVM Regulations can be found on our website class determination page.

The Agricultural Compounds and Veterinary Medicines Act 1997 can be found here.

The Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 can be found here.

FYI

Requirements update

ACVM Act Notice: Agricultural Compounds Exempt from Registration
Public consultation on this new notice ended on 19 May (see the March issue for details about the notice). Our thanks to those who submitted comments and suggestions. The submissions have been analysed and some changes have been made to the draft, which is now going through the final approval process.

ACVM Registration Information Requirements
The information requirements for ACVM registration are being revised and the draft has been cleared by MPI Legal for public consultation. Watch your website notifications.

Agricultural Chemical and Veterinary Medicine Labelling Requirements
The labelling requirements documents have been updated to reflect the previously announced change to the regulatory statement for management of residues, which is: "It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels of Agricultural Compounds."

Confidential information

The ACVM form 'Identification of Confidential Information for the Purpose of Data Protection' has been revised to enable provision of information from third parties. Please use the revised form (dated June 2017) from now on.

E-files for ACVM applications

The guideline for submitting electronic files has been revised to include more specific examples, and more information on how and when to use different types of files, such as Share Files. It has been sent out for targeted consultation. Watch your website notifications for when the final version is uploaded.

Codex Committee on Pesticides Residues (CCPR)

The 49th meeting of CCPR was held in Beijing, China in late April 2017. Warren Hughes and Dave Lunn from MPI, and Rebeca Fisher from Market Access Solutionz attended.

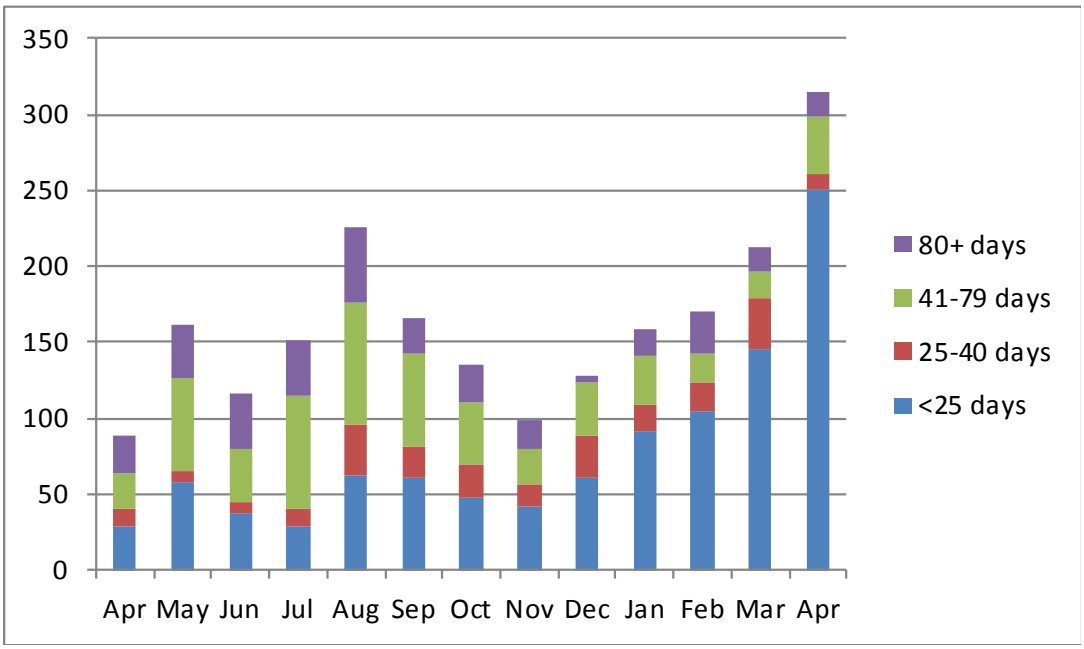
Items of interest include:

- The maximum residue level (MRL) for kiwifruit for acibenzolar-S-methyl, which New Zealand sponsored, was supported by the Committee and will go for adoption at the next Codex Alimentarius Commission meeting. In addition, all of the 490 or so draft MRLs proposed for 26 pesticides by the JMPR were progressed to Step 5/8.
- The Committee supported the Canadian proposal (and funding) for an extra meeting of JMPR (Joint Meeting on Pesticide Residues) to assess MRL proposals. This meeting will be held in 2019 and will assist in alleviating the backlog of MRL proposals being requested by members at CCPR.
- The draft guidance document entitled 'Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues' was approved.
- The revision of the Codex classification of foods and feeds made good progress -- the groups and sub-groups for vegetables, pulses, cereal grains and sugar/syrup grasses were finalised. Work continues on the revision of the classification of 'Seeds for beverages and sweets' and 'Herbs and spices' and to start revising the current 'Primary animal feeds' group.
- The Committee is reviewing the IESTI equations (used to assess short-term exposure to consumers from pesticides in food) and whether they require amendment. Part of the review will consider the implications of any changes on both existing and new Codex MRLs.

Food Notice: Maximum Residue Levels for Agricultural Compounds

Public consultatation on the latest round of MRLs closed 30 May 2017. MPI is working through some issues raised in the submissions.

ACVM registration applications update



The chart at left shows a snapshot of ACVM registration applications from April 2016 - April 2017. The columns indicate processing times of applications from passing pre-screen to issuing registration.

Baselining Food Safety Behaviours

What are we doing?
MPI's Systems Audit Team is currently carrying out work to identify the food safety practices and behaviours in food sectors that are required to transition to the Food Act between 1 July 2017 and 30 June 2018 (Tranche 2 sectors).

Why are we doing it?
Knowing what current practices are being used by food businesses will allow us to:

- identify key areas for improvement
- target resources and communications to areas that need it most.

By better understanding industry practices now we will be able to assess whether the activities undertaken by Territorial Authorities (TAs), verifiers and MPI have helped to improve performance. This work also helps MPI to ensure the standards are delivering the intended outcomes and provide opportunities for improvement.

Scope of work
The work will involve reviewing audit reports from verification of deemed Food Control Plan (FCP) businesses and conducting a reality check of a sample of businesses operating under the Food Hygiene Regulations.

We hope to visit 60-70 businesses in total over the manufacturing, retail and bakery sectors. We want to make sure this sample is as representative as possible of each sector.

Additionally 30 importers will be audited to consider behaviours in relation to how these businesses meet their obligations under the Food Act 2014.

Auditor
The work is being undertaken by an experienced MPI Systems Auditor, Ruth Houston, who will visit businesses in several regions of the country. Ruth will be working directly with TA staff to identify and work in with routine inspections of businesses that are scheduled where possible.

Included areas
Areas that will be included in the audit are as follows, although this is subject to change to align with other planned activities and travel for cost efficiency:

- Hauraki
- New Plymouth
- Dunedin
- Wellington
- Auckland
- Christchurch.

Opportunity for businesses
This is an excellent opportunity for businesses to contribute to ensure the requirements are fit for purpose and provide for future innovation. We would therefore appreciate TAs supporting this work, letting their businesses know about it, and actively encouraging businesses selected for audit to take part.

ACVM Manufacturing Workshops

Two workshops on manufacturing, which were announced in the March issue, will be held as follows:

- Wellington workshop -- Friday, 28 July, 9.00 - 4.30, Te Papa
- Auckland workshop -- Thursday, 10 August, 9.00 - 4.30, Sudima Hotel

Entry is by ticket only to ensure catering and facilities are adequate for attendees.
As of 15 June, the Wellington workshop still had 57 tickets available and the Auckland workshop had 28.

We are happy to announce that the guest speaker for the workshops will be Bob Tribe, Chief Good Manufacturing Practice (GMP) Auditor at the Australian Therapeutic Goods Administration for 23 years, who now consults to many GMP regulators around the world.

You will find more information and a link to the registration page here.
If you have any questions, email Holly Jeboult-Jones (holly.jeboult-jones@mpi.govt.nz)

Introducing...
THE FOOD ASSURANCE TEAM

Exporter Non-Conformances

The Food Assurance Team manages Exporter Non-Conformances (ENCs). Under the Animal Products Act 1999, exporters are required to notify MPI within 24 hours of any issues relating to export of product.

Exporters can encounter many issues in the process of exporting. Knowing about these issues, what markets or products they relate to, where and why they occurred, can be valuable information for MPI as market intelligence.

In some cases exporters may have sent product to customers that is not fit for purpose. MPI (particularly the Market Access Team) also needs to know about these events. Sometimes the only notification the team receives about new import requirements is when a series of ENCs is received, highlighting unexpected changes.

ENCs can include events such as documentation issues that prevent clearance of product at the border, or product being not fit for intended purpose due to foreign matter or microbiological.

Data collected
The Food Assurance Team collects data from these ENCs. It is then analysed and reported to identify potential trends, by country of destination or specific issues, to several industry groups (e.g. Dairy Product Safety Advisory Council, Strategic Direction Group), to senior management, or to the Minister.

The Food Assurance Team's role is critical to give confidence and trust that our food safety systems are working. The team:

- *sets general requirements for export and import of food*
- *maintains the electronic certification system for export of animal products*
- *manages food safety problems before and after the border*
- *monitors the performance of food sectors (mainly animal products)*
- *works with recognised verification agencies and verifiers to maintain or improve their competency.*

There are currently two team members in Auckland and seven in Wellington.

These reports enable MPI to ensure that the requirements and systems in place are effective at protecting the international reputation of 'Brand New Zealand' and provide the best basis from which to facilitate market access for New Zealand products.

Legal notices

The Food Assurance Team issues legal notices for regulating the export of New Zealand animal products. This is part of its role in ensuring that New Zealand animal products meet market access demands and continue to be regarded by overseas authorities and consumers with a higher degree of assurance, confidence and trust. The team is currently working on a number of legal notices, including the following:

General Export Requirements Notice for Bee Products
This proposed Notice is intended to give legal effect to the regulatory science definition for monofloral and multifloral manuka honey. It also proposes other general requirements for strengthening the bee products export system. (Public consultation closed 13 June 2017.)

Inspection of Imported Animal Products and Returned Exports
Current requirements relating to the inspection and clearance of imported animal products and returned New Zealand animal products are being reviewed.

Halal Export Requirements for Dairy Products
The Food Assurance Team is currently leading a project to establish a halal export regime for dairy exports with the objective of maximising value in halal markets. This is a joint MPI-industry initiative and involves internal collaboration with various MPI teams and external collaboration with approved halal certifiers and dairy companies. The proposed Notice is scheduled for public consultation in July so keep an eye out on the MPI website consultation page.

Verifier Calibration Workshops

The dairy and bee product sectors are the only animal product sectors that have multiple verifying agencies auditing their Risk Management Programmes (RMPs). Because of this, there is a need for 'calibration days'.

The Food Assurance team has been running dairy verifier calibration workshops twice a year since October 2013. Bee products verifier calibration workshops have also been run by the team yearly since November 2014.

Combined workshops

Last year we ran our first combined calibration workshop for dairy and bee products and held our second combined workshop, the 11th workshop run by the Food Assurance Team, in March this year. The day involved a combined session in the morning and separate dairy and bee product sessions in the afternoon. These workshops are now getting over 100 attendees, including presenters.

The latest workshop, held in Auckland, was affected by the fog in Wellington and staff from the team as well as several other presenters couldn't make it to Auckland. Our Systems Audit Team as well as other MPI staff chipped in to ensure the workshop was a success and all presentations and exercises were completed.

These workshops are a mixture of updates, informative presentations, calibration exercises and general discussions between MPI and the differing verifying agencies. The last two workshops have included guest presenters from the dairy industry with representatives from the Tatua Cooperative Dairy company speaking at the latest workshop.

Presentation

A special presentation (see photo below) was also made at this workshop by the AsureQuality CEO John McKay. Ian Morrison, an AsureQuality verifier and evaluator, was recognised for his 40 years of service with AsureQuality.

Food Assurance Team's Core Functions