Groups of agricultural compounds are exempt from registration under the ACVM (Exemptions and Prohibited Substances) Regulations 2011. This means that a product that fits one of the group definitions in Schedule 2 of the Regulations can be imported, manufactured, sold or used without regulatory assessment and further authorisation.

Agricultural compounds are exempt from registration only if the risks specified in section 4 of the ACVM Act can be managed without regulatory assessment prior to the compound’s authorisation. Although regulatory assessment is not necessary for exempt agricultural compounds, it is essential that the person(s) responsible for an exempt compound product takes steps to ensure that it always complies with the conditions of exemption specified in the Regulations.

To ensure that this care is taken, certain minimum requirements have been prescribed in the Regulations regarding:

• design and specification of a product that will not cause harm
• careful and reliable manufacture of the product to its specifications, and
• adequate labelling to facilitate identification and proper use.

Among other things, to meet these prescribed conditions, exempt agricultural compound products must be:
• fit for their intended purpose
• manufactured in accordance with a documented system, and
• supplied with certain information.

In addition to the general requirements prescribed in the body of the Regulations there are group-specific conditions specified for each entry in Schedule 2. These must also be complied with.

Amendment to the Regulations
The Regulations have not been amended for five years. Over that time amendments have been suggested to refine the Regulations and to add groups that could safely be exempt from registration.

MPI is preparing a public discussion document to seek comment on proposals for additional product groups that could...
Proposals for change concluded from page 1

be exempt from registration and to clarify misunderstandings and uncertainties regarding some of the existing entries in Schedule 2. Some examples of the issues are:

• There are products that do not contain any biologically active ingredients, such as diatomaceous earth used as veterinary medicines and as agricultural compounds, that could safely be exempt.

• There are naturally occurring or synthetic pheromone-type products used to control the behaviour of animals, including insects, that could safely be exempt.

• There are overlaps in the definitions of some entries. The conditions are not consistent across the overlapping entries. In some cases the regulatory effect could be different depending on which entry is considered to be relevant. This is particularly noticeable in the entries relating to topical veterinary preparations. Both the overlaps and the inconsistency of the conditions need to be addressed.

• There are agricultural chemical products that are exempt on the condition that they are not used on plants used for food for humans or feed for animals. However, the conditions do not seem to be explicit enough to make this clear.

• There is uncertainty regarding the obligation on parties using therapeutic or pharmacological substances in exempt animal nutrition products, particularly therapeutic premix products.

The discussion document will address these issues and others to refine the Regulations.

Exempt agricultural compounds notice

The ACVM (Exemptions and Prohibited Substances) Regulations 2011 specify requirements for exempt compounds, but the Regulations are not explicit about what must be done and by whom.

To make the regulatory requirements on people more explicit, MPI is preparing a discussion document proposing that a notice be made under section 76A to specify the requirements on persons who import, manufacture, sell or use an exempt compound product to ensure that the product is:

• fit for its intended purpose

• manufactured in accordance with a documented system, and

• supplied with at least the minimum information needed to use the product safely and correctly, and to trace it back to the person responsible for it.

The notice will include requirements that must be met by the manufacturer or importer and by any person who is responsible for the care of an exempt product during any stage of transport, storage, sale and use to ensure that the product conforms and continues to conform to the product’s specifications and that it is used only as intended.

Decision Making Transparency

The Ombudsman has received two complaints challenging MPI’s decision to withhold information relating to the technical assessment of a number of products.

While the decision to withhold all information has been upheld in the past, there is a clear indication that ACVM may not be transparent enough when it comes to publicising its decisions and the information used to make them. We will examine two aspects as part of the registration review:

• the detail that is reported to the web register on assessment types and outcomes

• the information reported on the delegate decision document.

We will look at how we can show what has been considered to support the decision made and associated controls applied to a registered product. This will include details of any variations to registered products. Papers will be presented to AVMAC to open discussion on this matter.

Systems Audits

The following audits are proposed for the 2016/17 period:

• Manufacturing of Agricultural Chemicals (info gathering to inform regulatory controls)

• Research, Training and Testing Operating Plans (fitness for purpose)

• Agricultural Chemical Shelf Life Management (compliance)

• Sale and Use of Restricted Veterinary Medicines (compliance with conditions and authorisations)

• Manufacture and Sale of Fertilisers (compliance with exemption regulations and information gathering)

• Biosecurity Clearance of Agricultural Compounds (compliance, understanding of and capability/competency at border).

Audit in progress:

• Imported Feed Commodities Notice (implementation).
**Fertilisers**

MPI has met with organisations who made submissions regarding our public discussion document on fertilisers. At the meeting, there was general support for oversight of fertilisers with differing views of the level of oversight. However, a majority supported the MPI preferred option of a fertiliser notice.

One of the issues that requires attention is the scope of the regulatory oversight, i.e. the definition of a fertiliser. In particular, how some products do not meet the current definition, yet the outcome is the same (facilitate growing of the plant). This is important in relation to a fertiliser notice as some requirements would be specific to certain groups of compounds and not others. MPI agrees that definitions are important for the scope of the fertiliser notice. We will work on a definition or definitions and circulate to submitters as soon as possible.

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**Maximum Residue Limits**

MPI plans to issue a public consultation document on the next round of MRLs in July. There will be 19 new or amended MRLs, six new or amended exemptions from compliance with an MRL, and three revised residue definitions proposed in this round.

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**ACVM Registration Review**

The Registration Review Project has completed the information gathering and gap analysis phases, and is now in the design phase. A Business Technology and Information Services (BT&IS) Requirements Review is also in progress, reviewing the current IT applications against the ACVM needs. This review is expected to be completed soon, and will inform the senior management team re possible BT solutions and options going forward. In parallel with the BT&IS piece of work, the following process initiatives are being developed and tested internally:

- streamlining the pre-screen process
- developing alternate pathways for C1 (Change formulation, C2 (Change manufacturing/manufacturer), and C3 (Change packaging/shelf life) variation applications
- developing a process for 'right of review of decisions made under delegated authority' (section 77A of the ACVM Act)
- testing the concept of an ACVM Review Committee
- reviewing information provided in the Delegate’s Decision.
Staff

Farewells
We are sorry to announce that Teresa Robinson and Gabi Hidvegi, two valued Ops team members, are leaving us—Teresa for a big OE and Gabi for a new career opportunity. We will be training new staff as quickly as possible, and we ask for your patience during the time it takes for them to get up to speed.

On a happier note
We welcomed Joy O’Connor back from Maternity Leave at the end of April. She is settling back into her role in the Ag Chem team, where they are keeping her busy with the backlog of applications. She’s definitely made a dent in them. At home, her now one-year-old daughter Evelyn is keeping Joy on her toes getting into mischief as she learns to walk. Joy is a smitten new mum, even with Evelyn’s first word being “bum” (not sure who she learned that from, but it must’ve been her Dad…).

Biosecurity

Assessment for Registration Renewal
When registration comes up for renewal, MPI needs assurance that the product still carries no biosecurity risks. Production systems, suppliers, ingredients and manufacturing processes may have changed, possibly impacting on the risks.

At time of registration renewal, please provide either a signed declaration on company letterhead stating that there have been no changes since the last assessment was done, or an outline of the changes that have taken place so we can update the biosecurity assessment.

If you have questions, contact animalimports@mpi.govt.nz

Documents

Completed and now available on our website:
Risk Management under the ACVM Act Overview
This document explains the framework to manage risks associated with the use of agricultural compounds and veterinary medicines.

Post-ACVM Authorisation Risk Management Overview
This document describes risk management after authorisations have been issued for importation, manufacture, sale or use of ACVM products.

Operating Plans for Restricted Veterinary Medicines Sellers
This guidance document explains the information that needs to be in an operating plan to sell RVMs. Such a plan must be approved by MPI under section 28 of the ACVM Act so that the seller can meet the condition of RVM registration relating to sale.

Antimicrobial Agents for Teat Disinfection
This document specifies the minimum study and reporting requirements for efficacy and host safety studies submitted in support of an application to register a teat disinfectant.

Preparing for final approval:
• Microbial Agricultural Chemicals
• Bioequivalence of Veterinary Medicines

Drafting:
Agricultural Compounds Exempt from Registration Notice (see page 2 for details).