Residue data information requirements for agricultural chemicals: Q + A

ACVM information paper

1. Introduction

Information requirements for residue data in support of an application to register an agricultural chemical under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 were revised in October 2011. The following should answer any questions you may have about the differences between the old and new requirements. If you do have other questions, contact the ACVM Group (details at end).

2. When will the new residue data information requirements come into effect?

The new version of the information requirements is in effect now. All residue data will be assessed against this document. However, we know that trials are underway or have been recently concluded using the requirements of the previous standard, so a transition period of 3 years will be adopted. During this time, residue data submitted with trial components conducted prior to 1 July 2013 will be considered against the old requirements.

3. Why is the document content less detailed than the previous standard?

Our residue requirements are now more closely aligned to those established by OECD. As a result, it seemed appropriate to reference the OECD individual guidelines directly rather than attempting to repeat or summarise them within our document. Therefore, only the minimum general information requirements are stated.

4. Why has the required trial number increased?

The minimum trial number for a crop type is now 3 trials, with trial numbers for major crops increased in proportion to this. Three trials represent a more statistically robust basis for determining a residue population and allocating an accurate MRL.

5. Why is the document split into 2 sections?

The general residue information requirements (Section A) relate to the overarching conduct of trials and the minimum information requirements for these to be appropriate for assessment under the ACVM Act. These are harmonised with the OECD guidelines.

The New Zealand specific requirements (Section B) are additional guidance or requirements over that currently in the OECD guidelines. These are necessary for establishing GAP in New Zealand conditions.

6. Why is data from OECD countries given more weight than other countries?

Data submitted to OECD countries have to meet the requirements of the OECD guidelines to be accepted in that country. Data submitted to non-OECD signatory countries may not have this requirement, so a more comprehensive package must be provided to demonstrate the accuracy of the results.

7. Is Good Laboratory Practice (GLP) approval required for lab work?

GLP approval of analytical work is no longer mandatory. However, in its absence sufficient data should still be generated by the residue laboratory to detail that quality procedures are in place to support the accuracy of the results.

8. What is Good Agricultural Practice (GAP) and how do I demonstrate this for my use pattern?

OECD defines GAP as follows:

> Good Agricultural Practice in the use of pesticides (GAP) includes the nationally authorised safe uses of pesticides under actual conditions necessary for effective pest control. It encompasses a range of levels of pesticide applications up to the highest authorised use, applied in a manner which leaves a residue which is the smallest amount practicable.

To show a use pattern as being GAP in New Zealand, demonstrate that the application timing and intervals are in accordance with the common cultivation practices and relevant pest/disease control key timings for the crop. The application rate is no more than necessary for an acceptable level of efficacy (as demonstrated in the efficacy data submission), and the withholding period fitting to an appropriate duration for retaining pest control and allowing normal harvest or animal feeding practices.

For plant commodities, management of the harvested crop to a ‘no detectable residue level’ for the purpose of meeting overseas residue standards would not be considered to represent GAP if this results in significant changes to the use pattern or withholding period.

9. Can I submit data electronically?

Electronic data submission is acceptable. We prefer the OECD format for data submission with all studies accessible though a transmittal (electronic contents) document.

10. Where do I find information about residue levels in animal feeds?

We do not set residue limits for animal feeds, but every use of an agricultural chemical on a feeding source is assessed for the potential for the residues to transfer to animal tissues. From this assessment appropriate grazing withholding periods or slaughter intervals are set to mitigate accumulation of residues in animal tissues. Because of the requirements for many animal products to meet overseas MRLs, agricultural chemical residues in animal tissues and in plant commodities are regulated separately. The appropriate limits for residues in animal tissues to meet the most conservative overseas

markets are established in the Animal Products (Contaminants Specification) Notice. The current version and general information on MRLs can be found at the following link: Maximum Residue Limits (MRLs) for Agricultural Compounds.

11. How do I get an MRL promulgated?

We manage the MRL setting process internally because of the requirement to undertake dietary intake assessment of all new MRLs proposed. Once a residue data assessment has been accepted as part of an application for registration, we will consider the conclusions and propose the most appropriate level for regulating GAP.

For more information, contact us (approvals@mpi.govt.nz).