Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Becoming a Data Assessor for ACVM Products

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Title

Guidance Document: Becoming a Data Assessor for ACVM Products

About this document

This guidance document is to provide information on the process of becoming an MPI-listed data assessor to carry out independent data assessment in specified areas and to prepare data assessment reports concerning trade name products for registration (or variation) applications under the ACVM Act.

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Disclaimer

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1 Purpose

This guidance document explains the process and minimum requirements for persons to be listed by the Ministry for Primary Industries (MPI) as acceptable persons to carry out independent data assessments for trade name products (TNPs) for registration (or variation of registration) applications under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Note: Data assessors are responsible for the management of their own intellectual property and confidentiality agreements with the organisation or person contracting their services.

2 Background

Because of the tight statutory timeframe for making decisions on applications to register (or to vary registration of) trade name products and the limited technical resources, the ACVM Group is unable to carry out all the necessary data assessment required for the technical appraisal of registration applications.

To overcome this, it is an ACVM Group operational requirement that data assessment must be done before an application for registration (or variation) is made under the ACVM Act. Such an application must include appropriate data assessment reports from a competent and independent data assessor (DA).

The purpose of listing DAs is to give a clear, transparent and predictable view on the acceptability of data assessment reports. This allows applicants to make an informed decision in regard to the supply of the data assessment reports that are essential for the appraisal of an application to register (or to vary registration of) a trade name product.

It is not mandatory for persons completing data assessment reports to be listed. However, MPI's expectation is that data assessment reports completed by non-listed persons will be subject to greater scrutiny and the ACVM Group may require peer review.

3 Definitions

ACVM
means agricultural compounds and veterinary medicines.

ACVM Group
means the Group in MPI that is responsible for the regulatory control, including registration, of agricultural compounds and veterinary medicines under the Agricultural Compounds and Veterinary Medicines Act 1997.

Conflict of interest
means a real or seeming incompatibility between one's private interests (e.g. financial interest) and public or fiduciary duties (as applies to data assessors).

Data assessment report
means a report on the validity, reliability and credibility (measured by compliance to ACVM registration information requirements documents) of data provided by an applicant in support of registration (or variation) application of a trade name product, and a documented assessment of the data to determine whether hazards have been identified and risks relevant to the ACVM Act have been adequately addressed.

Fiduciary
means a person who is required to act for the benefit of another person on all matters within the scope of their relationship.

Independent
means a person who has not been associated with:

- the applicant (in a personal or business capacity) – i.e. who does not have a conflict of interest
- designing or undertaking trial work or
- collating, preparing or writing of reports, data, or information

in relation to the data assessment reports prepared by that person.

Listed data assessor
means a person listed by MPI as suitable to carry out independent data assessment in specified areas and to prepare data assessment reports concerning trade name products for registration (or variation) applications under the ACVM Act.

Registration consultant
means a person employed by the applicant to prepare and/or provide advice on an application to register or vary registration of a trade name product under the ACVM Act in order to facilitate ACVM registration.

Statement of conflict of interest
means a statement signed by the DA regarding whether he/she:

- has or has not had any other interest (financial or contractual)
  - in the trade name product in question, and
  - with any person who has any interest in that trade name product, and/or
- has or has not participated in any way in the conduct of trials or the collection of the data that is to be assessed.

The statement is specific to a circumstance, so one is required for each report or set of reports in an application.

4 The Listing Process

4.1 Initial listing

Applicant
If you wish to become an MPI-listed DA, you should:

- provide required information as set out in the 'Data Assessor Application Pack'. This includes a completed application form (ACVM 29), completed form for consent to disclosure of convictions[1], written answers to the assessment questions and/or the required evidence, a *curriculum vitae* (CV) with a history of qualifications and training, experience and expertise relevant to the general and specific competencies requested, and the application fee
- be prepared to be interviewed by MPI, if necessary
- be prepared to attend an ACVM training workshop at your own expense.

MPI
Data assessor listing by MPI is based initially on the information provided by an applicant, which must indicate satisfactory competency of the person for the specific area or areas of expertise.

[1] Convictions that may impede listing are those that are against the ACVM Act, relating to fraud or dishonesty or relating to management control, or business activities in relation to this Act or a similar one overseas.

MPI may request further information or material before making a determination on whether to list or not. (If no timeframe has been specified, the application will lapse if this information is not supplied within three months.)

MPI reserves the right to:

- judge whether or not a person should be listed as a DA
- determine the scope of the listing.

At any point during the process MPI can refuse all or part of an application. The applicant, who will be notified in writing, can request a review of the decision.

4.2 Provisional listing

Five data assessment reports of sufficient complexity within the scope of listing should be supplied to MPI within the registration application process. These data assessment reports will be reviewed in detail to confirm that the reports meet the expected quality.

Further reports may be monitored to allow MPI to gain confidence in the consistency and reliability of that person.

MPI will provide feedback to the DA on their data assessment reports. The DA is expected to respond appropriately to feedback.

MPI will give provisional listing to a person based on their training, expertise and experience. If MPI is satisfied that the person qualifies for provisional listing, then he/she will be placed on a website list of DAs with a provisional status to be used by applicants for TNP registration or variation.

During this provisional period, MPI will accept a data assessment report from that person including:

- new active ingredients
- novel uses where there is no previous knowledge that would be relevant.

MPI may still carry out its own full audit of such reports. The cost of this audit will be borne by MPI unless it indicates significant concerns over the quality of the report to support the registration application. In such instances, the cost will be recovered.

If MPI is not satisfied with the quality and acceptability of the provisionally listed DA at the end of this period, MPI may extend the provisional period or remove the DA from the provisional list. Note: this step will not be taken without consultation.

4.3 Full listing

Once MPI is confident that a provisionally listed DA is competent in a scope, he/she will be notified of the decision to list. (No additional information is required from the DA for this step.)

At this point, the status of the scope will change to 'Full' on the Data Assessor List on MPI's public website. (Note: if a DA is listed for more than one scope, he/she may have Provisional listing status in some areas and Full listing status in other areas.)

Listed DA's responsibilities
The listed DA must comply with the following:

- carry out independent data assessment within the scope of those areas specified (when acting in their capacity as a listed DA)

- maintain all competency requirements applicable to the listing
- maintain an appropriate degree of impartiality and independence.

A listed DA can submit reports under areas outside the scope of their listing, but they must not do so in their capacity as a listed DA or while purporting to act as a listed DA.

A listed DA must notify MPI of any changes to the information supplied during the application process.

4.4 Ongoing listing

Data assessor listing will expire after five years. (For a DA's first five years, this period starts from the date of provisional listing.) An application for renewal must be made at least one month before expiry, using the specified application form (ACVM 29). If the DA has provided regular and acceptable data assessment reports, then the information required for renewal will be minimal.

Ongoing listing is based on the following:

- consistent acceptability of data assessment reports prepared by the listed DA for inclusion in applications to register (or to vary registration of) TNPs
- a history of responding appropriately to formal and informal feedback from the ACVM Group
- ongoing professional development, in terms of keeping up-to-date with changes in the ACVM requirements and in the DA's area(s) of expertise. This may be shown by subscribing to notification of ACVM website updates, attending relevant workshops/conferences, and/or provision of an updated CV
- compliance with the responsibilities as a listed DA.

If a listed DA does not prepare any assessment reports for a protracted period (between 1-3 years), confidence in the DA and future reports may have to be reconfirmed.

4.5 Extending scope of listing

A listed DA can apply to extend the scope of their listing by applying for additional data assessment areas. The requirements outlined above for initial and provisional listing will apply for the new area of listing. However, as general competencies have already been shown, the minimum number of audited reports required will be reduced to three.

The date of expiry of the new listing will remain the same as per the original listing unless the application coincides with a renewal application.

4.6 De-listing

DA request
If a DA no longer wishes to be listed, he/she may request to be removed from the list by written notice to MPI. MPI will acknowledge the request and will remove the DA from the public list on the date specified in the written notice.

MPI decision
MPI will have serious concerns about a DA and will consider de-listing if:

- the performance of the DA is unsatisfactory when considering the requirements of listing. For example:

  - the reports are not of a consistently acceptable quality, given the expected level of expertise of the DA
  - the reports are found to contain statements that cannot be relied upon, or

- the DA fails to comply with the responsibilities of a listed DA. For example:

  - it is suspected the statement of conflict of interest cannot be relied upon or a subsequent conflict of interest develops that cannot be resolved, and that affects the work of the DA
  - the DA has failed to comply or maintain any criteria or competency that led to listing
  - the DA has failed to pay an ongoing listing (application) fee within 30 days after the due date.

Other reasons for de-listing are:

- The DA is no longer able to carry out data assessment activity.
- The DA has ceased to operate as a listed DA.

After consultation MPI will notify the DA of the decision to de-list by written notice and specify the following:

- the reason(s) for de-listing
- the date and time the de-listing takes effect.

MPI will also provide the DA with a copy of all material information MPI relied on in proposing to de-list.

The DA can request a review of the decision.

5 Provision of Feedback and Ongoing Support

MPI will undertake to provide constructive feedback directly to the DA. This will be done both formally, as a result of audits during the provisional listing period, and informally, at any time MPI notices an instance where feedback on the data assessment report would be appropriate.

Any feedback, which will be given in writing using a feedback template, will be saved by MPI for review at the next renewal.

The ACVM Group will hold Data Assessor Workshops (probably at two yearly intervals) in order to maintain familiarity with ACVM requirements.

A website page to support DAs will include relevant links to useful tools and information.

DAs should subscribe to the website list for ACVM updates and MPI website feeds.

6 Performance and Technical Requirements for Listed Data Assessors

6.1 General competencies

To be acceptable as a DA a person must:

- have critical analytical skills for the assessment of scientifically generated data
- have written communications skills sufficient to produce reports that are understandable and prepared in acceptable and grammatically correct English
- be able to demonstrate sound judgement and decision making

- show a sound and informed level of knowledge of the general application and use of agricultural, horticultural or veterinary products
- show a sound and informed level of knowledge (as appropriate for the areas of expertise) of the proper conduct of field trials for agricultural chemicals, or clinical trials for veterinary medicines, or trials for vertebrate toxic agents
- show a sound and informed level of knowledge of hazard identification and risk analysis.

In regard to training and expertise, a listed DA must:

- have tertiary qualification(s) or relevant experience in the science specialty(ies) for which listing as a DA is sought
- have a minimum of five years of relevant experience in regulatory affairs or in the industry sector relevant to the scope of listing sought, or
- be able to show that they have developed the necessary experience in the time they have worked in a relevant area.

A listed DA must have a working knowledge of the ACVM Act and its regulations, sufficient to focus the data assessments on what is relevant under the Act. This includes a sound understanding of:

- the relevant ACVM risk areas
- the ACVM registration information requirements and guidelines, and
- relevant operational policies.

A listed DA must have general knowledge of relevant MPI-administered legislation, particularly the Animal Products and Food Acts.

A listed DA must also have general knowledge of other legislation relevant to ACVM assessments, such as the Misuse of Drugs Act (for veterinary medicines) and the Hazardous Substances and New Organisms Act.

6.2 Specific competencies

Depending on the scope of listing sought, the person may have to show a sound grounding in the following:

- assessment of target animal safety relevant to animal welfare risks for veterinary medicines
- assessment of efficacy relevant to animal welfare risks for veterinary medicines and vertebrate toxic agents
- assessment of efficacy relevant to determining good agricultural practice for agricultural chemicals
- assessment of the pharmacology and fate of pharmaceutical and biological compounds for veterinary medicines
- assessment of chemical metabolic pathways, the effect and fate of chemical compounds for agricultural chemicals, assessment of potential residues and requirements for appropriate withholding periods relevant to trade and New Zealand food standards risks for veterinary medicines, agricultural chemicals or vertebrate toxic agents
- knowledge of the development, manufacturing and quality management processes for agricultural chemicals, veterinary medicines, or vertebrate toxic agents.

7 Data Assessor Output

Data assessment reports provided in support of an application for registration (or variation to registration) will include:

- the report
- a statement regarding conflict of interest

- the listing status of the DA at the time the report was completed

7.1 Data assessment reports

To be acceptable data assessment reports must:

- be prepared and signed by a DA who has also made a statement of conflict of interest
- be written in coherent, understandable English in the appropriate, current ACVM DA report format
- show an attention to detail in the analysis of data and presentation of data assessment results
- make a comprehensive assessment of compliance (or lack of) to the relevant ACVM registration information requirements
- address whether or not the methodology for collecting the data was likely to identify hazards relating to the product and describe and quantify relevant ACVM risks in an accurate and robust manner
- address whether or not the data itself supports the conclusions drawn from it, and
- identify deficiencies or non-conformances in methodology or its implementation that has jeopardised the relevance or reliability of the data presented.

Confidence in listed DAs is based on the consistent quality of reports received from that person.

Some areas of expertise that pertain to a particular risk area which the ACVM Group considers may require knowledge held by the regulator may require additional evaluation by MPI. These types of assessments will generally require peer review of the data assessment reports, even though the DA may be listed. For example, residue assessments will in most cases require peer review by MPI.

It is understood that for efficacy assessments, some listed DAs are likely to be generalists rather than experts in the specific area. In these cases, expert opinions may be used to support the data assessment report. This may be especially important if, for example, the data assessment relies to an extent on extrapolation or overseas data, or a statistician is used. If an expert opinion is used to support the data assessment report, the CV of the expert must be supplied to MPI.

7.2 Conflict of interest expectations

MPI expects each registration application with a data assessment report to include a statement of conflict of interest specific to that application.

A possible conflict of interest may not necessarily disqualify a listed DA from undertaking an assessment.

As a guide to the ACVM Group's expectations in this area, a listed DA should consider the following:

- Have you been involved in trials or other research and development sponsored by the registrant or applicant?
- Have you been involved in trials or other research and development in relation to the product being assessed?
- Do you hold shares in the registrant's or applicant's company, or have any other personal financial involvement with the registrant or applicant?
- Are you involved in trials or other research and development work with another registrant or applicant who has a chemical product that is in direct competition with the product that will be assessed?
- Are you aware of a conflict of interest between the application, including the material being assessed and any other review or research work that could adversely impact on an objective review of the material?

7.3 Listing status

When DAs sign reports, they must specify if the report was done in their capacity as a listed DA (that is, in an area of their listed expertise) or not.

8 Public List

MPI will keep and maintain an electronic public list of all listed DAs. This list will be available to the public free of charge.

The purpose of the public list is to enable the public and stakeholders regulated under this Act to know who is listed to carry out data assessment. It will also facilitate the compliance, audit, and other support/ administration functions of MPI.

The public list will include the following information:

- full name and contact information of the DA
- the scope of the DA
- the commencement date and duration of listing.