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Standard for Recognising ACVM Data Assessors

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Endorsement:

Date:

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Standard for Recognising ACVM Data Assessors

1 Introduction

1.1 Purpose

This standard sets out the minimum requirements for persons to be recognised by the Approvals and ACVM Group as acceptable persons to carry out independent data assessments for trade name products for registration (or variation of registration) applications under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, and to provide data assessment reports concerning applications to register (or to vary registration of) such products.

Recognition of data assessors is not a statutory approval. The purpose of recognition is to give a clear, transparent and predictable view on the acceptability of data assessment reports from particular persons. 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 that persons completing data assessment reports will require recognition. However, the Approvals and ACVM Group's expectation is that data assessment reports completed by non-recognised persons will be subject to greater scrutiny.

There will be no charge for any person expressing interest in becoming a recognised ACVM data assessor.

1.2 Scope

This standard contains specifications for:

- requirements for data assessment reports
- requirement for recognising ACVM data assessors
- initial recognition
- ongoing recognition
- withdrawal of recognition
- competencies for data assessors.

1.3 Out of scope

Data assessors will be responsible for the management of their own intellectual property and confidentiality agreements with the organisation or person contracting their services

1.4 Definitions and abbreviations

ACVM: Agricultural compounds and veterinary medicines

ACVM Group: The Approvals and ACVM Group in NZFSA that is responsible for the regulatory control, including registration, of agricultural compounds and veterinary medicines.

Data assessment report: Report on the validity reliability and credibility (measured by compliance to ACVM registration standards) of data provided by an applicant in support of registration (or variation) application of an agricultural compound or veterinary medicine 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.

Independent: A person who has not been associated with:

- 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.

Recognised ACVM data assessor: A person recognised 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.

Statement of conflict of interest: A statement signed by the data assessor that he/she:

- has or has not had any 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.

1.5 References

Agricultural Compounds and Veterinary Medicines Act 1997

ACVM registration standards for research, residues, animal safety, efficacy, chemistry, and manufacturing

Hazard Identification and Risk Analysis under the ACVM Act 1997

Guidelines for Data Assessment under the ACVM Act (to be developed)

2 Background

2.1 Requirement for independent data assessment reports

Because of the tight statutory time frame for making decisions on applications to register (or to vary registration of) trade name products and the limited technical resources, the Approvals and ACVM Group is unable to carry out all the necessary data assessment under these circumstances. 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. An application for registration (or variation) of a trade name product must include appropriate data assessment reports from a competent and independent data assessor.

2.2 Requirement for recognising ACVM data assessors

Data assessment undertaken by the ACVM Group is not a core function; it is a discretionary service. This function is more appropriately undertaken by third parties.

However, the ACVM Group will continue to undertake data assessment as supplier of last resort. The expectation is that applicants will utilise third parties to undertake data assessments rather than rely on the ACVM Group.

In order to avoid extensive reassessment of applications, data assessment reports must be completed and signed by a person who has made a statement of conflict of interest. Usually, applications that do not contain data assessment reports prepared by appropriate data assessors will be either:

- returned to the applicant unprocessed with advice to include data assessment reports or
- processed with a likely decline for the registration.

The expectation by the ACVM Group is that recognised ACVM data assessors are less likely to have their data assessment reports rejected than those undertaken by a person not recognised by the ACVM Group.

There are circumstances in which the nature and complexity of the assessment does not warrant data assessment reports, or reports undertaken by a recognised ACVM assessor. In the latter case, the ACVM Group reserves the right to accept the application with the data assessment reports from a non recognised ACVM data assessor and process it or to contract an independent data assessor at the expense of the applicant. The ACVM Group will discuss this with the applicant before proceeding.

For data assessment reports to be acceptable they must meet the minimum requirements listed under section 4. The ACVM Group expects recognised ACVM data assessors, when undertaking

data assessment reports on behalf of an applicant, not to engage in a consultancy capacity when addressing issues identified in preparing the data assessment reports.

It is expected that recognised ACVM data assessors should declare any possible conflict of interest with the party contracting their services prior to accepting the contract. The ACVM Group recognises in some instances it may be difficult to obtain the services of an independent recognised ACVM data assessor having no conflict of interest. This may be due to the small number of, or lack of availability of, recognised ACVM data assessors in a particular area.

Where a recognised ACVM data assessor has declared a conflict of interest, the party wishing to contract their services should consult with the ACVM Group on whether that person is an appropriate assessor to undertake the assessment. The acceptability or otherwise in such circumstances will be dependent on a number of factors such as the level of involvement by the recognised ACVM data assessors, the pool of recognised ACVM data assessors with appropriate skills and expertise and their availability, or whether a non-recognised ACVM data assessor could be an acceptable alternative.

2.3 Initial recognition of data assessors

Recognition of a data assessor by the ACVM Group is based initially on the acceptability of the level of competency of the person for the specific area or areas of expertise. Independence in general is important, but a statement of conflict of interest is expected to be specific for each application in which an assessment report is included. The recognition is restricted to the areas of competency of the person, and reports from that person are acceptable only if they are related to those areas of competency.

The ACVM Group reserves the right to:

- i. judge whether or not a person should be recognised as a data assessor
- ii. determine the scope of recognition
- iii. process applications for registration (or variation of registration).

These are based primarily on data assessment reports from that person. The ACVM Group is prepared to give initial recognition to a person based on their training, expertise and experience. To gain initial recognition as a data assessor the person must:

- provide a *curriculum vitae* (CV) containing a history of qualifications and training, experience and expertise relevant to the general and specific competencies listed in 3.1 and 3.2
- be interviewed by the ACVM Group.

If the ACVM Group is satisfied that the person has sufficient experience, then they will be recognised.

2.3.1 Provisional recognition

Where the data assessor has little or no previous record or experience, then the recognition will be provisional. This allows that person to prepare data assessment reports in appropriate areas as part of an application to register (or to vary registration of) a trade name product. Furthermore, applicants will not be disadvantaged by using a provisionally recognised data assessor for the appropriate kind of application to register or to vary a registration.

As part of the assessment of the competency level of a provisionally recognised ACVM data assessor, the first five reports from that person will be reviewed in detail to confirm that the reports meet the expected quality. Further reports will be monitored to allow NZFSA to gain confidence in the consistency and reliability of that person.

During this provisional period, NZFSA 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.

However, the ACVM Group will carry out its own full audit of such reports. The cost of this audit will be borne by the ACVM Group unless it indicates significant concerns over the quality of the report. In such instances, the cost will be borne by the applicant. In addition, the ACVM Group will provide feedback to the data assessor on their data assessment reports, critiquing them to encourage quality improvement. It will also provide support to answer the data assessor's questions on what is required.

Reports concerning the above will be acceptable only when there is a history of consistent supply of at least five quality reports of sufficient complexity to make it clear that the data assessor can be relied on to carry out a competent assessment without the benefit of a body of existing relevant information.

Should the ACVM Group not be satisfied with the quality and acceptability of the provisionally recognised ACVM data assessor at the end of this period, the ACVM Group may extend the provisional period or withdraw their provisional recognition (see 2.4).

Where the ACVM Group is satisfied the person is competent, then the provisional endorsement will be removed.

In the situation where an already recognised ACVM data assessor wishes to change the scope of their recognition, then the requirements outlined above will apply.

2.4 Ongoing recognition

Ongoing recognition is based on the consistent acceptability of data assessment reports prepared by the recognised ACVM data assessor for inclusion in applications to register (or to vary registration of) trade name products. Continued confidence in a recognised ACVM data assessor will be based on ongoing monitoring of the quality of his or her reports.

Any deficiencies in assessment reports will be discussed with the recognised ACVM data assessor to make sure the ACVM requirements are clear. It is expected that the recognised ACVM data assessor will avoid such deficiencies in the future.

Where a recognised ACVM data assessor does not prepare any assessment reports for a protracted period (between 1-3 years), it is expected that confidence in the recognised ACVM data assessor and future reports may have to be reconfirmed.

The recognition of ACVM data assessors will be reviewed every five years from the date they were first recognised. Where the recognised ACVM data assessor has provided regular and acceptable data assessment reports, then the review will be minimal.

A register of recognised ACVM data assessors is maintained by the ACVM Group. It lists:

- the person
- whether the recognition is provisional or not
- the kinds of assessment reports (scope of the recognition) that are acceptable from that person.

2.5 Withdrawal of recognition

The ACVM Group will advise the recognised ACVM data assessor of any dissatisfaction with assessment reports and will work with them to avoid deficiencies. However, the ACVM Group reserves the right to withdraw recognition of a data assessor and to refuse to process applications based partially on assessment reports from that person if:

- the reports are not of a consistently acceptable quality, given the expected level of expertise of the data assessor
- the reports are found to contain statements that cannot be relied upon, or
- it is suspected the statement of conflict of interest cannot be relied upon.

If no applications containing reports from a data assessor are received for three years, the data assessor will be given an 'inactive' status on the register, and will be removed from the register after another year.

Reinstatement on the register will be done as if it is an initial recognition.

3 Requirements and Expectations for Recognised ACVM Data Assessors

3.1 General competencies for data assessors

To be acceptable as a data assessor 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 and products systems
- show a sound and informed level of knowledge (as appropriate for the areas of expertise) of the proper conduct of field trials for plant compounds, 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.

Training and expertise

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

ACVM specific knowledge

- have a basic 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 and the ACVM registration standards and guidelines, and relevant operational policies.

NZFSA legislation

- have general knowledge of relevant NZFSA legislation, particularly the Animal Products and Food Acts.

3.2 Specific competencies

Depending on the scope of recognition 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 plant compounds
- 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 plant compounds
- assessment of potential residues and requirements for appropriate withholding periods relevant to trade and New Zealand food standards risks for veterinary medicines, plant compounds or vertebrate toxic agents
- knowledge of the development, manufacturing and quality management processes for agricultural compounds, veterinary medicines, or vertebrate toxic agents.

3.3 Conflicts of interest expectations

As stated above, a possible conflict of interest may not disqualify a recognised ACVM data assessor from undertaking an assessment. As a guide to the ACVM Group's expectations in this area, recognised ACVM data assessor should take into consideration the following:

- Have they been involved in trials or other research and development sponsored by the registrant or applicant?
- Have they been involved in trials or other research and development in relation to the product being assessed?
- Do they hold shares in the registrant's or applicant's company, or have any other personal financial involvement with the registrant or applicant?
- Are they 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 they 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?

The above list is not exhaustive, but indicates the types of conflicts of interest they should be aware of. Should a recognised ACVM data assessor be aware of any of the above, or of any other concerns relating to a potential conflict of interest, either prior to accepting or during an assessment, they should contact the ACVM Group to discuss the situation. The ACVM Group will determine either that:

- The conflict of interest is negligible and the assessor may still conduct the assessment or
- There is a conflict of interest that would necessitate the data being returned and another assessor appointed.

4 Requirements for Data Assessment Reports

Confidence in recognised ACVM data assessors is based on the consistent quality of reports received from that person. To be acceptable reports must:

- be prepared and signed by a data assessor recognised by the ACVM Group who has also made a statement of conflict of interest
- be written in coherent, understandable English in the appropriate ACVM DAS 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 standards
- 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 in methodology or its implementation that has jeopardised the relevance or reliability of the data presented.