To: ACVM Programmes and Appraisals
Ministry for Primary Industries
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Submission on: Transparency and ACVM Registration Applications

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Submission on: Transparency and ACVM Registration Applications

1. Introduction

1.1 Agcarm welcomes the opportunity to comment on the Transparency and ACVM Registration Applications discussion document.

1.2 Agcarm is generally supportive of the direction of the proposed review findings. However, a number of the proposals outlined in the discussion paper require clarification, and in some cases are challenged as to whether they are necessary.

1.3 As an industry representative we understand the need for Government to provide greater clarity to the New Zealand public. At the same time the Ministry for Primary Industries (MPI) needs to consider greater transparency around its processes to stakeholders, applicants and registrants that engage with the ACVM group. We request that this factor is considered by MPI, and that it also adopts greater transparency with its applications assessment process.

1.4 As a general statement the content disclosed as part of the public notification process should be minimal to ensure confidentiality, but sufficient to provide the public an overview of what has been provided, along with the benefits of the product. Noting that, for example, the EPA holds a public notification and MPI also holds a public notification for the promulgation of MRLs. Therefore, the scope of this public consultation should add to the other public consultation processes.

2. Summary of the submission

i. Registrants currently have no visibility regarding what the ACVM process is in regards to their decision-making procedures. Given the commercial sensitivity, Intellectual Property and economic implications with registrant data – Agcarm request that the ACVM group provides an overview of their decision making process, including the release of product information to requests lodged by other registrants.

ii. To ensure applicant information is not compromised, Agcarm submits that the ACVM group assess the possibility of combining B1 and B2 categories.

iii. Agcarm submits that the ACVM group provide evidence/ reassurance that the administration involved with the outlined proposals will not lead to extended deadlines, and/or a decline in the speed of processing registrant applications.

iv. Agcarm submits that in some cases, e.g. label claims, that the ACVM group keep this type of information general at an early stage of the assessment process to ensure confidentiality from competitors. An option to overcome the confidentiality would be to use only the first sentence in the report key description (as proposed for manufacturing changes and shelf life/packaging).

v. Agcarm submits that the ACVM group clarify the transparency requirements around categories.

vi. To ensure that the public understand the decision-making process, Agcarm submits that MPI prepare guidance material outlining, for example, the difference between risk and hazard. This will assist in developing the public's awareness of how the system works, and why they should have faith in the expert assessors.

vii. As part of overall transparency improvements Agcarm request that MPI:

- Advise registrants/outline what is their process for review and decision making around general OIA requests i.e. what are considered typical grounds for release/refusal of information in accordance with the OIA 1982?
- Advise why this information has not been included in the discussion paper.

viii. The ACVM group should ensure that confidentiality is not breached when publishing a risk management rationale. Agcarm request clarification as to whether applicants will have access to a draft version prior to publication in the Register.

General comments

A summary of feedback received from Agcarm members is provided under each of the following questions.

3.1 Is the level of transparency and disclosure appropriate?

Agcarm members are questioning some of the proposed changes put forward by the ACVM group.

Specific comments follow:

3.1.1 Category combination

i. For generic type applications there are areas that have the potential to place confidential information at risk, specifically the distinction between B1 & B2 applications.

ii. Agcarm submits that the ACVM group assess the possibility of combining B1 and B2 categories. In that way any potential connection between the applicant and the registrant of the reference product is less likely to be compromised, while still allowing transparency to the public in terms of data considered, risk/benefits and other criteria required during the registration process.

iii. The code system and respective definitions (e.g. B1: Identical to a registered product) may work well for coding applications internally. The use of the same coding system for public notification proposes may create confusion.

iv. To the general public, a new product is a new product, regardless if the applicant is crossing reference or providing a 500 page dossier to support registration. It would be more appropriate to spell out the context (e.g. new product registration containing an active ingredient already approved in a registered product; or - New product registration containing an active ingredient new to New Zealand). No need to talk about the risk profile in the key description as the risk assessment is inherent to the registration process.

3.1.2 Administration of the proposed requirements – extended application deadlines

i. Agcarm submits that there is a risk that the increasing level of administration for ACVM staff, e.g. weekly uploads of data, will take valuable resource away from the processing of applications. We request that the ACVM group provides reassurance that increased timeframes for processing applications will not be the result of implementation of the proposed transparency requirements.

ii. On a similar theme, the suggestion of notifying manufacturing variation in the NZ Gazette may lead to longer timelines for approval of these applications. Currently only the high risk applications requiring change in withholding period, or use pattern, or for new product/new active, are notified in the NZ Gazette. The assessment of the application starts only after completion of the 30 working day notice period. Therefore, even for minor manufacturing variations registrants will be required to factor in the notification period for completion of the assessment of applications.

iii. Agcarm requests that MPI provide a commitment/evidence that application deadlines will not be extended and/or compromised due to the proposed transparency requirements. A key factor being to keep to agreed Key Performance Indicators and/or to within statutory timeframes as set in the legislation.

3.1.3 The additional information that is proposed to share in the new Applications Received Report

i. Agcarm highlights that the additional information will inadvertently provide competitors with a more precise view on what registrants are considering to introduce into the New Zealand market, earlier and in quite specific terms.

ii. The proposal being to move from the current "General Use Claim" published in the NZ Gazette, to a more specific and detailed Applications Received Report, particularly for changes to "Target Host", "Pest/Disease" and/or "Dose/Rate".

iii. The proposal suggests that for these types of changes the new Report would specify "existing and proposed label claims" - there is good reason to believe that this will actively encourage off-label use prior to risks being fully assessed by ACVM/EPA.

iv. Agcarm submits that due to the points raised under 3.1.3 i. to iii, that the ACVM group keep this type of information general at the early stage of the assessment process. There is a possibility, for example, that this could lead to off label use, or a competitor could be prompted to also submit an application confusing the data protection situation if/when both claims are registered.

3.1.4 Data generation

i. The ACVM group propose to distinguish between 1A Chemical and manufacturing data generated in NZ and 1B data generated (not NZ). Why is this disclosure necessary? There is no difference in risk assessment or public benefit from what is currently company confidential information.

ii. Taking that point further, disclosure of NZ vs non NZ data should only be relevant where it might affect the risk assessment. That in essence is efficacy or maybe AMR – where NZ pathogens, for example, may be different. For chemicals, safety, residues, toxicology the data are usually generated in very standard conditions.

iii. Some forms of data, e.g. toxicology data, will seldom be generated in NZ, and as was raised at prior consultation meetings, the public may form perceptions about applicability of residue and efficacy/safety data generated outside NZ.

iv. The use of residue and efficacy/safety data generated outside NZ is dealt with in the residue and efficacy/safety guidance material as to proportionality and justification for its applicability to the NZ situation. Further to that it is assessed by both independent data assessors and ACVM for its applicability. Therefore, Agcarm submits that in example 2 on page 8, A and B should be combined.

v. Similarly, F and G could be combined – does it matter if the regulatory agency is NZ based or not as ACVM will be making an assessment as to credibility of information provided? What public interest is served by this if the information provided by the regulatory agency is based on similar sound science? It could go either way in terms of public thinking NZ or non-NZ source is more relevant/credible. Also, because expert opinion and technical arguments are often based on information in the public domain, Agcarm submits that D, E and H could be put in one box labelled as "Other; public domain information, expert opinion, technical argument".

3.2 Is the proposed categorical description of information provided by an applicant in an application suitable?

i. The categorical description could cause some concern amongst the general public, particularly for generic applications where it may appear that there is less information considered relevant to the application. In the example given, the Residues, Efficacy & Crop safety and Toxicology should have 1C against them, as this information would be cross referenced from the reference product.

ii. Agcarm submit that the ACVM group clarify the transparency requirements around categories.

3.3 Is the proposed information on aspects considered in an application, and risk management outcomes stated in the Public Record of Delegate Decision appropriate?

Agcarm is supportive of the information aspects highlighted.

3.4 Are there any other areas of the ACVM product registration process that require more (or less) transparency?

Yes, issues are highlighted as below.

3.4.1 Providing guidance material to the wider public

i. The proposal to include a summary of risk management conclusions in the Public Record of Delegate Decision is generally supported. It is proposed that this should include the type of information that was considered by the ACVM group in the appraisal and any risk management rationale.

ii. The challenge here is the low level of understanding in the wider community in relation to the principles of risk management, i.e. the difference between hazard and risk.

iii. To ensure that the public understand the decision-making process, Agcarm submits that MPI prepare guidance material outlining, for example, the difference between risk and hazard. If this is not provided there is a real risk that as with Europe, technical information will be misrepresented through lack of understanding by the media, general public, NGOs and others.

iv. As an industry leader, Agcarm is willing to assist MPI in the task of preparing information for the general public and other interested parties.

3.4.2 System integrity – deviating from guidance

i. The ACVM group must be careful with the proposed general references in relation to "Technical information/argument supplied by application, e.g. requests to deviate from MPI Guidance Documents".

ii. With argumentation a critical element of the process and scientifically warranted, the idea of MPI "deviating from Guidance" has the potential to be misrepresented by those looking to undermine the integrity of the system. Once again it comes back to building the public's awareness of how the system works, and why they should have faith in the expert assessors.

3.4.3 Official Information Act (OIA) Requests

i. MPI have noted that a driver for their proposed changes is other country regulatory authorities currently supply varying/greater information regarding product registrations as below:
Awareness of differences in the level of disclosure of registration application information by other comparable regulatory authorities.

ii. However, within NZ –The OIA 1982 is the overarching guidance on what information can be shared publicly. The Act lists multiple legitimate exceptions where government entities can refuse to release information.

iii. See examples below, with the majority relevant to industry members.
Conclusive reasons under the Act for agencies to refuse OIA requests include the below

- *protecting personal privacy;*
- *protecting trade secrets;*
- *protecting information given in confidence;*
- *protecting public health and safety;*
- *protecting New Zealand's economic interests, or members of the public from material loss;*
- *commercial confidentiality;*
- *preventing the use of official information for "improper gain or improper advantage"*
- *the requested information is already publicly available or will soon be made publicly available.*

All the registrations 'will soon be publically available' in the form of the label on the database, so why the need for increased transparency?

iv. As part of overall transparency improvements Agcarm request that MPI:

- Advise registrants/outline what is their process for review and decisions making around general OIA requests i.e. what are considered typical grounds for release/refusal of information in accordance with the OIA 1982?

- Advise why this information has not been included in this discussion paper.

3.5 General Feedback

3.5.1 It is not clear if the new 'regular publication system' will be equivalent to the current public notification process (30 days). This needs to be clarified as no application can be completed until public notification has elapsed and submissions accounted for during assessment (if any). If so, this proposal goes against the ongoing process review targeting fast track assessments. Under the current procedure, certain application types are quickly assessed and signed off. This will be no longer possible if the proposed 'regular publication system' is equivalent to the current public notification process.

3.5.2 The ACVM group should ensure that confidentiality is not breached when publishing a risk management rationale. Will applicants have access to a draft version prior publication in the Register?

3.5.3 Some members are uncertain as to how the information in the summary tables will favour transparency. It seems this summary aims to facilitate the use of confidential information to support cross reference (after data protection has expired), and not transparency. It seems more appropriate to make generic statements against the ACVM risk management framework (e.g. The applicant has provided sufficient information to support efficacy of product X for the control of pest Y; or the applicant has cross referenced efficacy information from product X to support efficacy of product Z for the control of pest Y).

4. About Agcarm

Agcarm is the industry association for manufacturers and suppliers of crop protection and animal health products. For further information and a full list of members, see www.agcarm.co.nz.

Agcarm member products protect public health, improve animal welfare and help environmental management. They:

- Play a pivotal role in growing high yield, sustainable food and fibre products;
- Help supply healthy, nutritional and affordable food;
- Keep New Zealand's agriculture, horticulture and forestry sectors internationally competitive.

Our members are committed to safety, innovation and product stewardship.