Ministry for Primary Industries
Manatū Ahu Matua

Transparency and ACVM Registration Applications

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1 Introduction

MPI has been reviewing the level of transparency to the general public and stakeholders of the current trade name product* registration procedures and processes managed under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

The drivers for this review are:

1. New Zealand government policy directive of Open and Transparent Government. MPI as a central government agency is, and has been, actively working to improve the level of transparency. The four key benefits of releasing open government data are:
   a. improving government
   b. empowering citizens
   c. creating opportunity
   d. solving public problems.
2. Management of, and provision of, information in response to Official Information Act 1982 (OIA) requests.
3. Awareness of differences in the level of disclosure of registration application information by other comparable regulatory authorities (European Medicines Agency [EMA], US Food and Drug Administration [FDA], Australian Pesticides and Veterinary Medicines Authority [APVMA]).
4. Increasing focus on providing an appropriate level of information about the registration of agricultural compounds and veterinary medicines to the New Zealand general public and primary industry sectors to support a robust decision-making process. The level of disclosure must be balanced with the statutory requirement to protect Commercially Sensitive Information (CSI) and personal data. (CSI is defined as any information not in the public domain or publicly available and where public disclosure may undermine the economic interest or competitive position of the owner of the information.)
5. The requirement to comply with the relevant legislation (ACVM Act, OIA).

* Trade name product is defined as an agricultural compound identified and packaged under a trade name for a specified use or uses.

2 Background

Historically, transparency of applications made and approved in the product registration process under the ACVM Act has been achieved by notification under section 14 of the Act, and publication of the decision to register in the ACVM Register of Trade Name Products. Notification under section14 requires the Director-General of MPI to notify all applications upon receipt by publishing a notice in the *NZ Gazette*. However, under section 15 of the Act, the Director-General may waive the requirement to publicly notify.

Operationally, MPI has set the criteria for public notification to include applications for products with new active ingredients, new formulations, new use patterns or changes to the product's risk profile deemed to be significant. Applications constituting manufacturing changes or minor changes have not been publicly notified.

Public notification occurs upon formal receipt of an application (i.e. accepted at technical pre-screen). Public notification is a 100% cost recovered activity, with the applicant charged the Department of Internal Affairs fee for gazettal, plus an administrative fee.

The information disclosed currently in a *NZ Gazette* notice is of the type shown below:

Trade Name:	**Reference:**
Active Ingredient(s) and Concentration(s):	
Formulation Type:	
General Use Claim:	

See links below to view examples of actual notices:
New trade name product application (A1) CYTOPOINT: Gazette notice
Vary the conditions of a trade name product VIVANDO: Gazette notice

The purpose of the notice is to provide sufficient information to enable a member of the general public to understand the purpose of the application to write a submission. It is debatable whether or not this is the case currently.

3 Proposed changes

MPI proposes to improve the transparency of the registration process with the following three changes:

3.1 APPLICATIONS RECEIVED REPORT

A list of applications formally received (passed pre-screen) for:

- registration of a new trade name product, and
- variations to trade name products, excluding C9-administrative changes and registration renewals. (These will be excluded as they are deemed to be of low public interest.)

will be published on the MPI website.

This publication will be a regular (e.g. weekly) upload of a report to the ACVM Register web page, which can be found on the MPI website at https://eatsafe.nzfsa.govt.nz/web/public/acvm-register. The report will include those applications received that will also be published in the *NZ Gazette*.

The report will provide transparency of the registration process to members of the general public, as well as other interested parties, without prejudicing the security of information provided by applicants.

MPI proposes to provide the following information in the report:

- Registration reference number
- Trade name
- Applicant name
- Application type description
- Date formally received by MPI
- In the future, it may be possible to also inform whether there is protected confidential information associated with the application, with a Data Protection column entry of either YES or NO.

MPI proposes that the application type description is the same as that used by the registrant in their submission and recorded in the ACVM information database, and is augmented by provision of a key in the report with a more complete description, as in the table below:

Report listing description	Report key description		
Registration reference number:	P = agricultural chemical, A = veterinary medicine, V = vertebrate toxic agent		
A1: New active	New product registration - contains a new active ingredient. Specifying active ingredient and proposed use		
A2: Known active	New product registration - contains a known active ingredient with a new risk profile. Specifying proposed use		
B1: Identical	New product registration - identical to a registered product. Specifying proposed use		
B2: Similar	New product registration - similar to a registered product. Specifying proposed use		
C1: Formulation C2: Active	Variation - manufacturing change(s) *(this will include change in formulation, change in active ingredient manufacturer, change in formulation manufacturer, change in specifications for active ingredient, change in specifications for formulation, change in manufacturing process)*		
C3: Shelf life/packaging	Variation - change in shelf life and/or packaging		
C4: Target host	Variation - extension in use to include additional target host. Specifying existing and proposed label claim	Variation - extension in use to include an additional target species. Specifying existing and proposed label claim *(if the product is a Veterinary Medicine or Vertebrate Toxic Agent)*	
C5: Pest/disease	Variation - extension of use to include control of additional pests / weeds / diseases. Specifying existing and proposed label claim *(if the product is an Agricultural Chemical)*	Variation - extension of use to include additional disease / condition. Specifying existing and proposed label claim *(if the product is a Veterinary Medicine)*	Variation - extension of use to include addition/variation to the use situation for an existing target species. Specifying existing and proposed label claim *(if the product is a Vertebrate Toxic Agent)*
C6: Dose/rate:	Variation - change in application rate or timing. Specifying existing and proposed label claim *(if the product is an*	Variation - change in dosage regime. Specifying existing and proposed label claim	Variation - change in application rate or timing. Specifying existing and proposed label claim *(if the product is a*

	Agricultural Chemical)	*(if the product is a Veterinary Medicine)*	*Vertebrate Toxic Agent)*
C7: Admin method	Variation - change in the method of application. Specifying existing and proposed label claim *(if the product is an Agricultural Chemical)*		Variation - change in the method of administration. Specifying existing and proposed label claim *(if the product is a Veterinary Medicine or Vertebrate Toxic Agent)*
C8: WHP	Variation - change in withholding period. Specifying existing and proposed label claim		
C10: Reassessment	Reassessment. Specifying purpose of reassessment		

3.2 PUBLIC RECORD OF DELEGATE DECISION

MPI proposes changing the information provided on the Public Record of the Delegate Decision document that appears on the ACVM Register of Trade Name Products, which can be found on the MPI website at https://eatsafe.nzfsa.govt.nz/web/public/acvm-register.

This will improve transparency of registration process outcomes to members of the general public, as well as other interested parties, without prejudicing the security of information provided by applicants. It complements changes made to the Public Record of the Delegate Decision document in January 2018, to include the registration expiry date and Protected Confidential Information status. (See Protection of Confidential Information about ACVM Trade Name Products on the MPI website for an explanation of what information is protected.)

Proposed changes

- Application Type will be more descriptive than the current Public Record of Delegate Decision document, which is stated as either New Registration or Variation.

MPI proposes to use the Application Type descriptions as set out in the second column of the table below:

Current description	Proposed description
New product registration	New product registration - contains a new active ingredient. Specifying active ingredient and proposed use
New product registration	New product registration - contains a known active ingredient with a new risk profile. Specifying proposed use
New product registration	New product registration - identical to a registered product. Specifying proposed use
New product registration	New product registration - similar to a registered product. Specifying proposed use
Variation	Variation - manufacturing change(s)

	(this will include change in formulation, change in active ingredient manufacturer, change in formulation manufacturer, change in specifications for active ingredient, change in specifications for formulation, change in manufacturing process)		
Variation	Variation - change in shelf life		
Variation	Variation - change in packaging		
Variation	Variation - extension in use to include additional target host. Specifying approved label claim	Variation - extension in use to include an additional target species. Specifying approved label claim *(if the product is a Veterinary Medicine or Vertebrate Toxic Agent)*	
Variation	Variation - extension of use to include control of additional pests / weeds / diseases. Specifying approved label claim *(if the product is an Agricultural Chemical)*	Variation - extension of use to include additional disease / condition. Specifying approved label claim *(if the product is a Veterinary Medicine)*	Variation - extension of use to include addition/variation to the use situation for an existing target species. Specifying approved label claim *(if the product is a Vertebrate Toxic Agent)*
Variation	Variation - change in application rate or timing. Specifying approved label claim *(if the product is an Agricultural Chemical)*	Variation - change in dosage regime. Specifying approved label claim *(if the product is a Veterinary Medicine)*	Variation - change in application rate or timing. Specifying approved label claim *(if the product is a Vertebrate Toxic Agent)*
Variation	Variation - change in the method of application. Specifying approved label claim *(if the product is an Agricultural Chemical)*	Variation - change in the method of administration. Specifying approved label claim *(if the product is a Veterinary Medicine or Vertebrate Toxic Agent)*	
Variation	Variation - change in withholding period. Specifying approved label claim		
Variation	Variation - administrative change		
Variation	Registration renewal		

- Summary of risk management conclusions. Historically, the summary of conclusions and recommendation to register information in the Delegate Decision document have been brief and generic in nature.

MPI proposes to provide a more informative precis of the risk management considerations posed by the application, including (but not limited to):

- Type of information that was considered in the appraisal of the application (see section 3.3 below)
- Risk management rationale for the conditions of registration imposed on the registration of the product.

The intent is to provide a more informative summary of what MPI considered when making the decision to register, the specific risks posed, and how these will be managed.

3.3 SUMMARY LISTING OF INFORMATION SUPPLIED IN SUPPORT OF AN APPLICATION

MPI proposes that applicants will be required to provide a summary listing of the information provided with their application. This will be less detailed than the Application Summaries published by the Australian Pesticides and Veterinary Medicines Authority, and will comprise a categorical description of the information provided. It will be a requirement to provide the data listing in the specified format (i.e. as a table in a specific section of the application form) as part of the application.

The intent is that this information summary table can in the future be included in Applications Received notification reports and Public Record of Delegate Decision documents that are published in the ACVM Register of Trade Name Products.

The categorical descriptions applicants would use to summarise the type of information provided are:

A Data generated in New Zealand
B Data generated (not in New Zealand)
C Cross reference to information held by MPI
D Information in the public domain
E Information supplied as expert opinion
F Information supplied by other regulatory agencies (New Zealand)
G Information supplied by other regulatory agencies (non-New Zealand)
H Technical information / argument supplied by applicant (e.g. requests to deviate from MPI guidance documents)
I Other information.

The alphabetic category will be preceded by a number relating to the relevant dossier section (as in the table below) to provide an overall summary of the type of information provided.

Veterinary Medicines	Agricultural Chemicals	Vertebrate Toxic Agents
1 Chemistry & Manufacturing 2 Residues 3 Efficacy 4 Target Animal Safety 5 Toxicology 6 Antimicrobial resistance (AMR)	1 Chemistry & Manufacturing 2 Residues 3 Efficacy & Crop Safety 4 Toxicology	1 Chemistry & Manufacturing 2 Residues 3 Efficacy 4 Target Animal Welfare 5 Toxicology

Here are two examples of information summary tables:

Example 1: A Veterinary Medicine A2 application (known active ingredient)

Vet Meds		Dossier Volume Reference					
		1 Chem & Manuf	**2 Residues**	**3 Efficacy**	**4 Target An Safety**	**5 Toxicology**	**6 AMR**
	A Data generated in NZ	1A	2A	3A	4A	-	-
	B Data generated (not NZ)	1B	2B	3B	4B	-	-
	C Cross reference information held by MPI	1C	2C	3C	4C	-	-
	D Information referenced in public domain	1D	2D	3D	-	-	-
	E Information supplied as expert opinion	1E	-	3E	-	-	-
	F Information supplied by other regulatory agencies (NZ)	1F	-	-	-	-	-
	G Information supplied by other regulatory agencies (non-NZ)	1G	-	-		-	-
	H Technical information / argument supplied by applicant	1H	-	3H	4H	-	-

Example 2: An Agricultural Chemical B1 application (identical to a registered product)

Ag Chems		Dossier Volume Reference			
		1 Chem & Manuf	**2 Residues**	**3 Efficacy & Crop Safety**	**4 Toxicology**
	A Data generated in NZ	-	-	-	-
	B Data generated (not NZ)	-	-	-	-
	C Cross reference information held by MPI	1C	-	-	-
	D Information referenced in public domain	-	-	-	-
	E Information supplied as expert opinion	-	-	-	-
	F Information supplied by other regulatory agencies (NZ)	-	-	-	-
	G Information supplied by other regulatory agencies (non-NZ)	-	-	-	-
	H Technical information / argument supplied by applicant	-	-	-	-

4 Request for submissions

MPI requests you to comment on the changes proposed in this document.

MPI is particularly interested in your feedback on these questions:

- Is the level of transparency and disclosure appropriate?
- Is the proposed categorical description of information provided by an applicant in an application suitable?
- Is the proposed information on aspects considered in an application, and risk management outcomes stated in the Public Record of Delegate Decision appropriate?
- Are there any other areas of the ACVM product registration process that require more (or less) transparency?

Submissions close at **5pm on Friday, 16 March 2018**.

Send your comments to:
Transparency and ACVM Registration Applications
ACVM Programmes and Appraisals
MPI Systems Audit, Assurance and Monitoring Directorate
PO Box 2526, Wellington 6140
Email: ACVM.Consultation@mpi.govt.nz

Please include your name and address on your submission. If you are making comments on behalf of an organisation, also include your title and the name of the organisation.
Make sure your comments can be clearly read, as a number of copies of your submission may be made.

The Official Information Act
The Official Information Act 1982 (the OIA) states that information is to be made available unless there are grounds for withholding it. The grounds for withholding information are outlined in the OIA. Submitters may wish to indicate any grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. MPI will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.