New Zealand Food Safety

Haumaru Kai Aotearoa

ACVM Overview

ACVM 101 Workshop

October 2018

Karen Booth

Topics

1. ACVM – who we are and what we do
2. Legislation
3. Website and resources
4. Interactive session - quiz

Who we are and what we do - MPI

Biosecurity NZ
Tiakitanga Pūtaiao Aotearoa

Fisheries NZ
Tini a Tangaroa

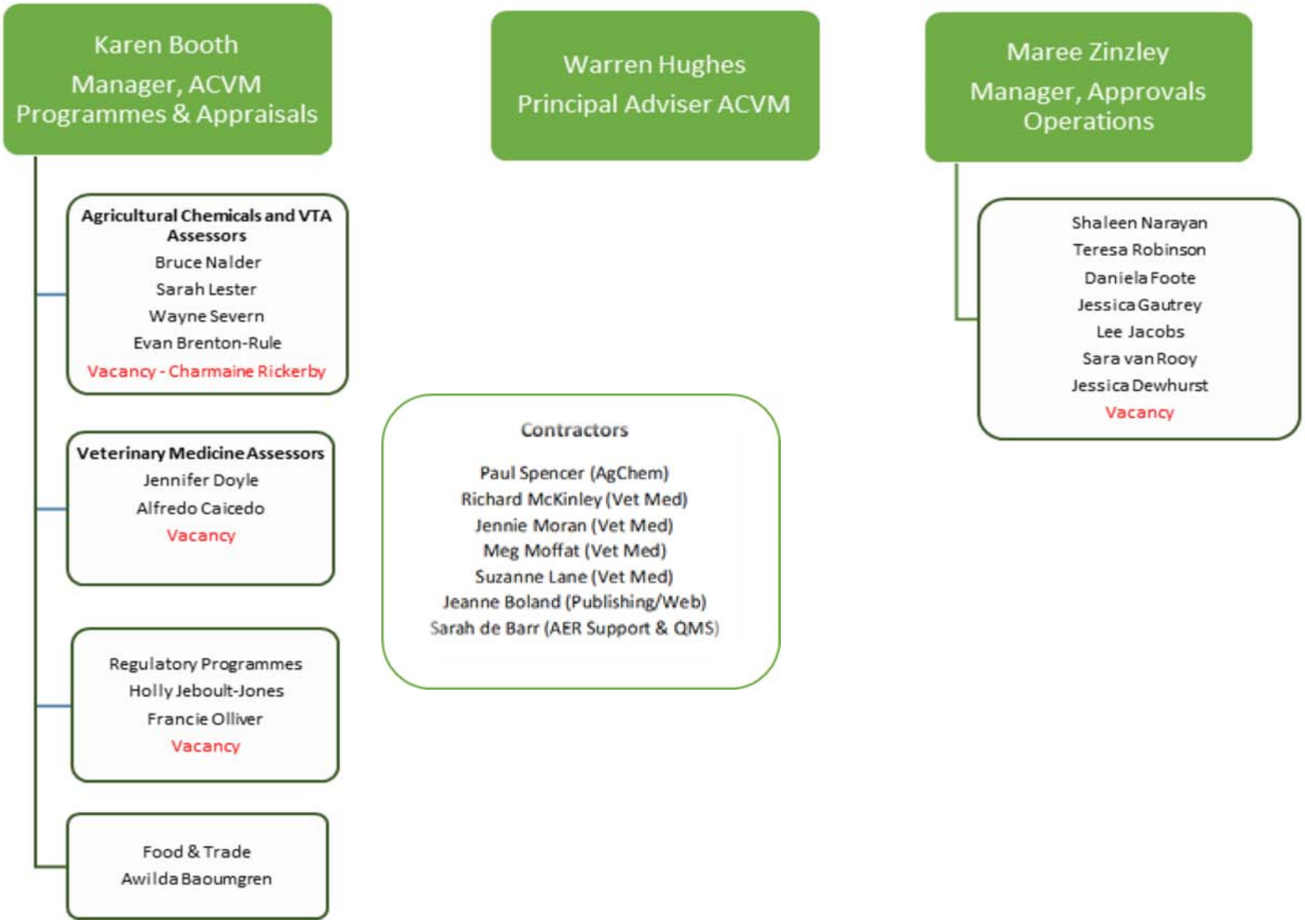
NZ Food Safety
Haumaru Kai Aotearoa

Te Uru Rākau
Forestry New Zealand

Who we are and what we do – Regulation & Assurance

- Assurance Directorate
  - ACVM Team
- Performance Oversight & Approvals Directorate
  - Operations Advisers
- Verification Services Directorate
- Food Regulation Directorate
- Animal Health & Welfare Directorate
- Science & Risk Assessment Directorate
- Plants & Pathways Directorate

ACVM Staff


Karen Booth
Manager, ACVM Programmes & Appraisals
Warren Hughes
Principal Adviser ACVM
Maree Zinzley
Manager, Approvals Operations
Agricultural Chemicals and VTA Assessors
Bruce Nalder
Sarah Lester
Wayne Severn
Evan Brenton-Rule
Vacancy - Charmaine Rickerby
Veterinary Medicine Assessors
Jennifer Doyle
Alfredo Caicedo
Vacancy
Regulatory Programmes
Holly Jebouit-Jones
Francie Olliver
Vacancy
Food & Trade
Awilda Baoumgren
Contractors
Paul Spencer (AgChem)
Richard McKinley (Vet Med)
Jennie Moran (Vet Med)
Meg Moffat (Vet Med)
Suzanne Lane (Vet Med)
Jeanne Boland (Publishing/Web)
Sarah de Barr (AER Support & QMS)
Shaleen Narayan
Teresa Robinson
Daniela Foote
Jessica Gautrey
Lee Jacobs
Sara van Rooy
Jessica Dewhurst
Vacancy

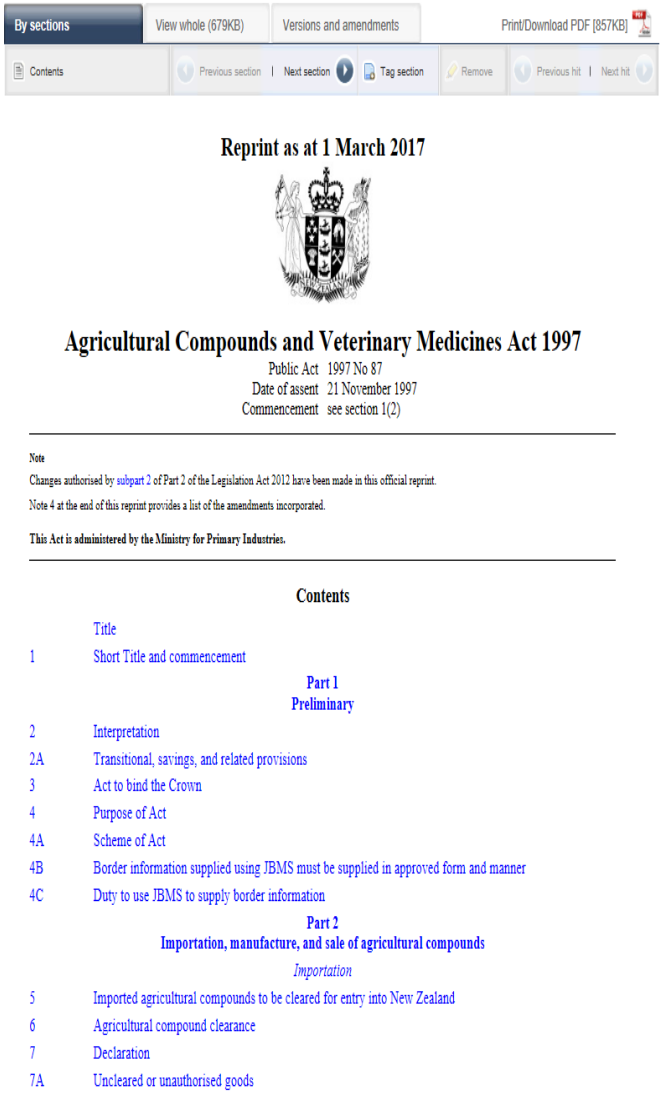
Who we are and what we do

MPI administers the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the ACVM (Exemptions and Prohibited Substances) Regulations 2011

The ACVM Act manages the importation, manufacture, sale, and use of all veterinary medicines, agricultural chemicals, vertebrate toxic agents, animal feeds, fertilisers etc.

ACVM Regulatory Framework

- Only relevant to substances that are defined as agricultural compounds
- No person may import, manufacture, sell or use in New Zealand any agricultural compound without authorisation (Section 8)
- Can not register a trade name product unless it has HSNO approval (if required) or DG of Ministry of Health where it is also a prescription human medicine



By sections | View whole (679KB) | Versions and amendments | Print/Download PDF [857KB]

Contents | Previous section | Next section | Tag section | Remove | Previous hit | Next hit

Reprint as at 1 March 2017

Agricultural Compounds and Veterinary Medicines Act 1997

Public Act 1997 No 87
Date of assent 21 November 1997
Commencement see section 1(2)

Note

Changes authorised by subpart 2 of Part 2 of the Legislation Act 2012 have been made in this official reprint.

Note 4 at the end of this reprint provides a list of the amendments incorporated.

This Act is administered by the Ministry for Primary Industries.

Contents

Agricultural Compounds

An agricultural compound is “Any substance, mixture of substances, or biological compound, **used or intended for use in the direct management of plants and animals**, or to be applied to the land, place or water on or in which plants and animals are managed.”

“…Direct management of plants and animals…”

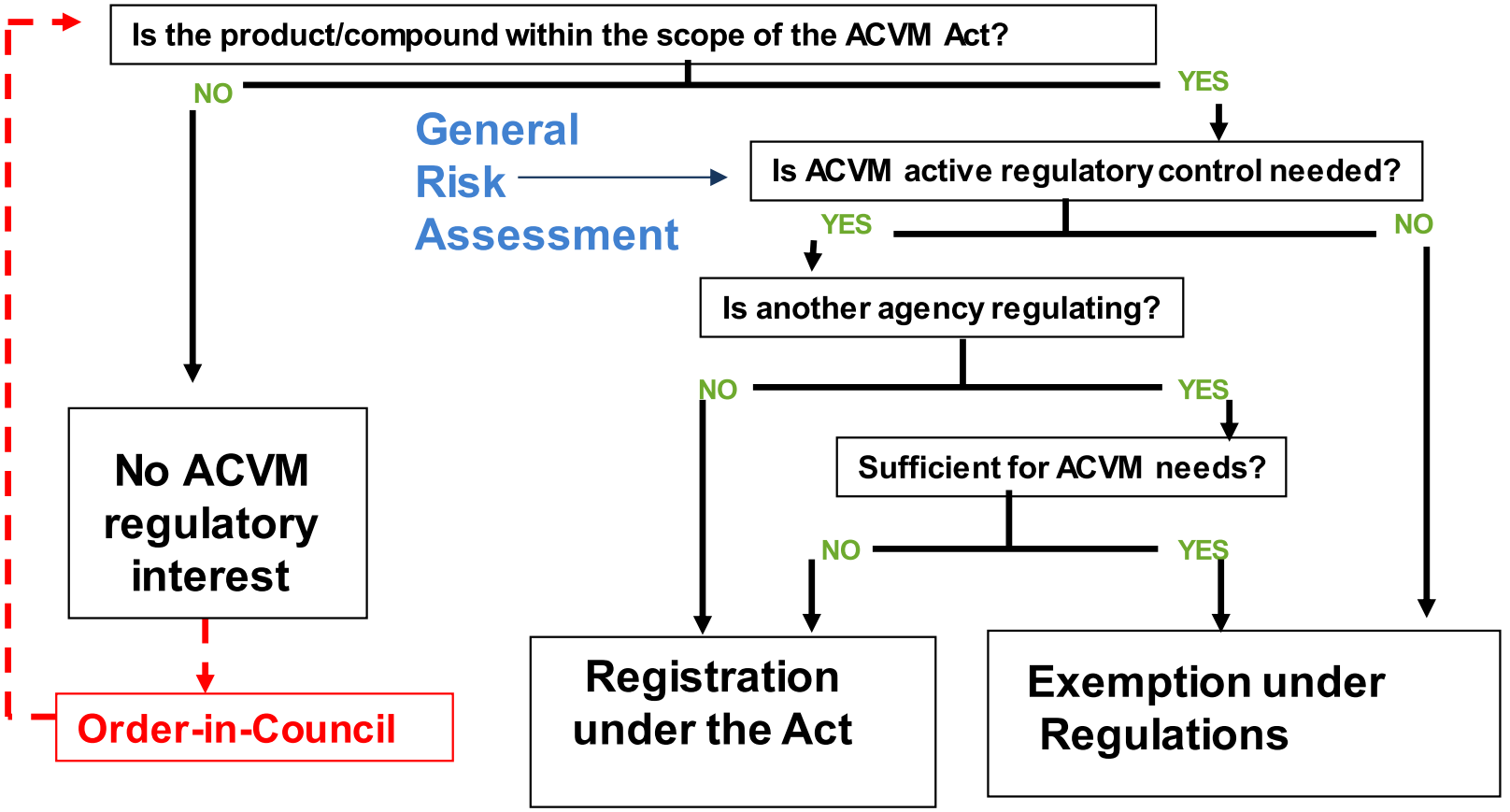
- Managing or eradicating pests, including vertebrate pests
- Maintaining, promoting, or regulating plant or animal productivity and performance or reproduction
- Fulfilling nutritional requirements
- The manipulation, capture, or immobilisation of animals
- Diagnosing the condition of animals
- Preventing or treating conditions of animals
- Enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals
- Marking animals
- **Other**

Authorisation types

If you want to import, manufacture, sell, or use an ACVM in New Zealand, it must be authorised under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and Regulations.

- Registration (section 21)
- Provisional Registration (section 27)
- Exempt from Registration (section 8A)
  - ❖ Exempt under section 75(1)(a)
  - ❖ Listed as GRAS (section 8B)
  - ❖ Approved in special circumstances (section 8C)

- Authorisation only granted if risks can be managed by applying conditions


Is the product/compound within the scope of the ACVM Act?
NO
YES
General Risk Assessment
Is ACVM active regulatory control needed?
YES
NO
Is another agency regulating?
NO
YES
Sufficient for ACVM needs?
NO
YES
No ACVM regulatory interest
Order-in-Council
Registration under the Act
Exemption under Regulations

Registration

- All trade name products are assessed prior to registration
- Risk areas outlined in the Act
    - Risks to trade in primary produce
    - Risks to agricultural security
    - Risks to the welfare of animals
    - Risks to public health
- Prevent breaches of domestic food residues standards
- Ensure the provision of sufficient consumer information

Exemption from Registration

- Low risk and/or non therapeutic products - no ongoing regulatory management is required
  - Includes oral nutritional compounds, herbal products, non-medicated shampoos, compounding by Veterinarians, fertilisers, surfactants
- Exempted by product groups - listed in the ACVM (Exemptions & Prohibited Substances) Regulations 2011

- Manufacturers and users are legally required to ensure exempt products are fit for purpose, and meet the conditions of exemption applied to each group

Risk Management Tools

- The registration process, information requirements and guidance documents
- The application of conditions
- Operating Plans
- Recognised persons
- Annual renewal fee
- Re-registration period (up to 5 years)
- Responsive compliance : complaints and adverse event reports
- Active compliance : system audits, product testing, reports of sales, notification of use

Verification

ACVM Group has a number of feedback routes

- Food Residue Surveillance Programme (vegetables, fruit etc)
- National Chemical Contaminants Programme (milk)
- National Chemical Residues Programmes (meat)
- Total Diet Study
- Exporter Survey
- Sector Analysis Audits
- Commercially run monitoring programmes

Regulatory Controls

- ACVM Act provides for **suspension** of registration (s30A) where conditions are not complied with
- It also provides for a **re-assessment** of TNP's where there is "significant new information" (s29)
- There is provision (s31) to **prohibit** or **restrict** products under S29 or s30 consideration

Enforcement

S55 provides a wide range of offences under the ACVM Act

S56 provides penalties

Up to 2 years jail or a fine up to $30,000 for individuals

Up to $150,000 for a company

Enforcement of MRL breaches is usually done via a breach of ACVM registration conditions

Options range from general education, through to active programmes (paid for by the regulated parties) and prosecution

Links with Other Legislation

Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997

Links with:

MPI – Biosecurity, Food, Animal Products, and Animal Welfare Acts

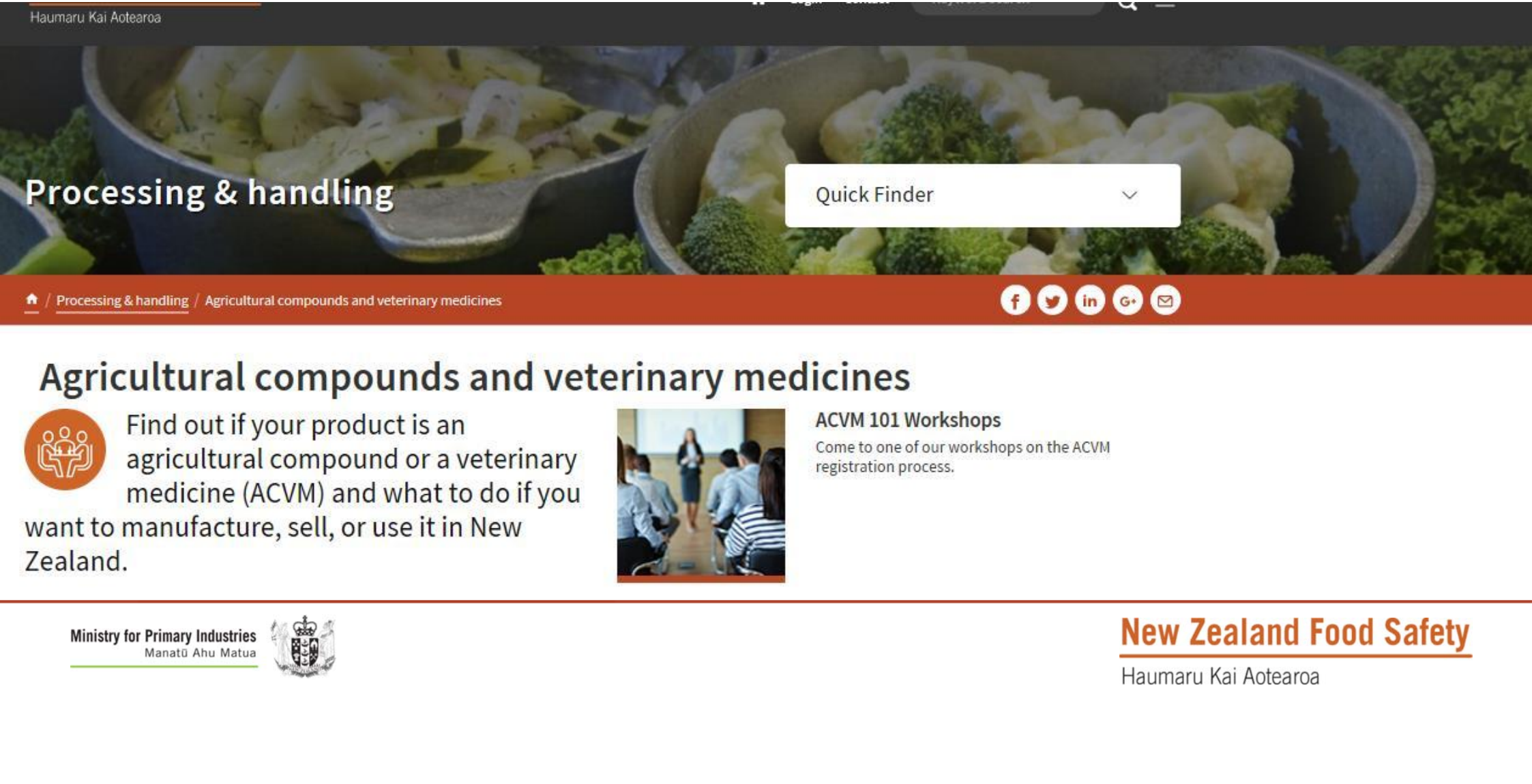
EPA – Hazardous Substances and New Organisms

MoH - Misuse of Drugs, Controlled Substances and Medicines Acts

WORKSAFE – Health & Safety at Work Act

External – Veterinarians Act

Website


Haumaru Kai Aotearoa
Processing & handling
Quick Finder
Processing & handling / Agricultural compounds and veterinary medicines
Agricultural compounds and veterinary medicines
Find out if your product is an agricultural compound or a veterinary medicine (ACVM) and what to do if you want to manufacture, sell, or use it in New Zealand.
ACVM 101 Workshops
Come to one of our workshops on the ACVM registration process.
Ministry for Primary Industries
Manatū Ahu Matua
New Zealand Food Safety
Haumaru Kai Aotearoa


Quiz

1. What does the ACVM Act do?

A. Manages the manufacture, sale, and use of all veterinary medicines, agricultural chemicals, vertebrate toxic agents, animal feeds, fertilisers etc.

B. Manages the importation, manufacture, sale, and use of all veterinary medicines, agricultural chemicals, vertebrate toxic agents, animal feeds, fertilisers etc.

C. Manages the importation, manufacture, sale, and use of all agricultural substances.

D. Manages the sale and use of all veterinary medicines, agricultural chemicals, vertebrate toxic agents, animal feeds, fertilisers etc.

1. Answer

B. The ACVM Act manages the

importation,

manufacture,

sale, and

use

of all veterinary medicines, agricultural chemicals, vertebrate toxic agents, animal feeds, fertilisers etc.

2. What is an Agricultural Compound?

A. Anything **used or intended for use in the direct management of plants and animals**, or to be applied to the land, place or water on or in which plants and animals are managed

B. Any substance, mixture of substances, or biological compound, **used or intended for use in the management plants and animals,** and the environment in which they are managed

C. Any product **used or intended for use in the direct management of plants and animals**, or to be applied to the land, place or water on or in which plants and animals are managed

D. Any substance, mixture of substances, or biological compound, **used or intended for use in the direct management of plants and animals**, or to be applied to the land, place or water on or in which plants and animals are managed

2. Answer

An agricultural compound is

D. “Any substance, mixture of substances, or biological compound, **used or intended for use in the direct management of plants and animals**, or to be applied to the land, place or water on or in which plants and animals are managed.”

3. What types of products are ag compounds?

A. veterinary medicines – substances used for animals, including companion animals
B. pasture
C. agricultural chemicals – substances used for plants, including herbicides, fungicides, insecticides, plant growth regulators, surfactants, and adjuvants
D. vertebrate toxic agents – substances that kill or limit the viability of animals, such as possums, rodents, and other unwanted mammals
E. chemicals used in animal premises (e.g. dairy sheds) and processing plants for the purpose of sanitisation and disinfection
F. human medicines
G. fertilisers and soil conditioners
H. pet food and animal feed – including dietary supplements

3. Answer

A. veterinary medicines – substances used for animals, including companion animals

~~B. pasture~~

C. agricultural chemicals – substances used for plants, including herbicides, fungicides, insecticides, plant growth regulators, surfactants, and adjuvants

D. vertebrate toxic agents – substances that kill or limit the viability of animals, such as possums, rodents, and other unwanted mammals

~~E. chemicals used in animal premises (e.g. dairy sheds) and processing plants for the purpose of sanitisation and disinfection~~

~~F. human medicines~~

G. fertilisers and soil conditioners

H. pet food and animal feed – including dietary supplements

4. What risks are managed by the Act?

A. Risks to trade in primary produce, agricultural security, the welfare of animals and public health

B. Risks to trade in primary produce, food safety, biosecurity, and the welfare of animals

C. Risks to trade in primary produce, food safety, the welfare of animals and public health

D. Risks to biosecurity, food safety, the welfare of animals and public health

4. Answer

- All trade name products are assessed prior to registration
- Risk areas outlined in the Act
- A:
    - Risks to trade in primary produce
    - Risks to agricultural security
    - Risks to the welfare of animals
    - Risks to public health

- Prevent breaches of domestic food residues standards
- Ensure the provision of sufficient consumer information

5. What are the types of product authorisations?

A. Registration
B. Import Permit
C. Provisional Registration
D. Containment approval
E. Risk Management Plan (RMP)
F. Exempt from Registration
G. Approved in special circumstances

5. Answer

If you want to import, manufacture, sell, or use an ACVM in New Zealand, it must be authorised under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and Regulations.

A. Registration
~~B. Import Permit~~
C. Provisional Registration
~~D. Containment approval~~
~~E. Risk Management Plan (RMP)~~
F. Exempt from Registration
G. Approved in special circumstances


Questions?

Session 2

The Application Process

ACVM workshop 101

October 2018

- Types of ACVM Approvals
- What application forms do I need to submit?
- What happens once I've submitted?
- Manufacturing requirements

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Registration Application Type	Forms to use	Other Documentation
A1: New Active Ingredient	ACVM 1 + 1DP	PDS, Label, Technical Dossiers, Data Assessments, Application summary, EPA, ± Biosecurity.
A2: Known Active with New Risk Profile	ACVM 1 + 1DP	
B1: Identical to registered TNP	ACVM 1	
B2: Similar to Registered TNP	ACVM 1, + 1DP	
Registration renewal	ACVM1R	PDS, Label, GMP
Variation to Registration	ACVM1V +(6-14)	PDS, Label
C1: Change in Formulation	ACVM 6 + 1V	PDS, Label, EPA
C2: Change in active ingredient manufacturer	ACVM 7 + 1V	PDS, Label, Batch Analysis
C2: Change in formulation manufacturer	ACVM 8 + 1V	PDS, Label, GMP, batch analysis, validation
C2: Change in manufacturing (specifications or manufacturing process)	ACVM 9 + 1V	PDS, Label, ± method validation
C3: Change in packaging	ACVM 10 + 1V	PDS, Label, ± stability data
C3: Change in shelf life	ACVM 11 + 1V	PDS, Label, stability data
C4: Additional Target Species	ACVM 12 + 1V + 1DP	PDS, Label, technical dossier, data assessment
C5: Additional Disease/condition	ACVM 12 + 1V + 1DP	PDS, Label, technical dossier, data assessment
C6: Change in Dose regime	ACVM 13 + 1V + 1DP	PDS, Label, technical dossier, data assessment
C7: Change in Method of Administration	ACVM 13 + 1V + 1DP	PDS, Label, technical dossier, data assessment, data protection
C8: Change in WHP	ACVM 14 + 1V + 1DP	PDS, Label, technical dossier, data assessment, data protection
C9: Administrative Change	ACVM 1V	PDS, Label, outline change in section 7 in ACVM1V

Registration-obtaining authorisation under section 21 of the Act

Minimum Requirements for Registrations

- ACVM 1 / ACVM 1V / ACVM1R
- All relevant variation forms (C1-C8)
- PDS
- Label
- Application summary
- Data assessment package
- Data protection form
- EPA +/- biosecurity

Application summary

- Outline the purpose of the application
- Index- what's been submitted and where it can be found
- Risk analysis on how the product (change) could affect animal welfare, trade, agricultural security, public health
- Address all data-assessment non-conformances

Registration Renewal

Required every 5 years unless another variation has been made.

Must supply

- Complete label
- Complete PDS
- Current GMP certification (VM & VTA)

Provisional/Research Approvals

Research (ACVM 5 form)

- To enable use of non-registered products in plants or animals that have potential to enter the food chain.
- Required under Section 8C(1) of the Act

Provisional (ACVM 4 form)

- To enable trial work on a fixed formulation
- Allows 5 years data protection
- Required under section 27 of the Act

Other Approvals

- **Special Circumstances (**AVCM 3 form)

  - to allow use of unregistered products due to unavailability in NZ

- **Operating Plans**

  - RVM sellers (ACVM 28 form)
  - Research testing and teaching (ACVM 26A)
  - Product specific OPs(HGPs) (ACVM 27 form)
  -GMP and Manufacturing related OPs

Interactive session

Forms on your table include

ACVM 1
ACVM 1V
ACVM 1R
ACVM 6 Change formulation
ACVM 7 Change/Add AI manufacturer
ACVM 8 Change/Add formulation manufacturer
ACVM 9 Change manufacturing
ACVM 10 Change packaging
ACVM 11 Change shelf life
ACVM 12 Change/add target crop/species/claim/disease/condition
ACVM 13 Change dose/application rate/timing/method of administration
ACVM 14 Change WHP
ACVM1DP form for data protection

PDSs for VTA / VM /Ag Chem + label

Interactive Session

You want to submit an A2 application

- **Vet med parasiticide**
- **Known active but new risk profile**
- **Used as a pour-on in sheep but application is to register a tablet for use in dogs**

- What application **forms** do you need to submit?

Interactive Session

Application forms to submit for an A2 vet med

- ACVM1
- PDS for vet meds
- Label
- ACVM1DP Data Protection form

Interactive Session

You have a registered Agricultural Chemical and you want to make the following changes:

A) Change in specifications for the active ingredient manufacturer

B) Change in manufacturing process for the formulation manufacturer

C) Administrative change to the label

D) Registration for the product expires in 2 months

1) What application types are you making?

2) What application forms do you need?

Interactive session

If registration lapses within 3 months, you need to submit an RR without any variations first. Once RR approved, submit your variation.

Q1:

C2, C2, C9

Q2:

ACVM1V – fill in section 7 of the form

ACVM 9 – for both C2 changes

PDS (Ag chem) & Label

Interactive Session

You have a registered veterinary medicine and want to make the following changes:

A) New type of primary packaging

B) Changes to the formulation

1) What application forms do you need?

2) What other information might you need to submit?

Interactive session

Q1:

ACVM1V

ACVM10

ACVM6

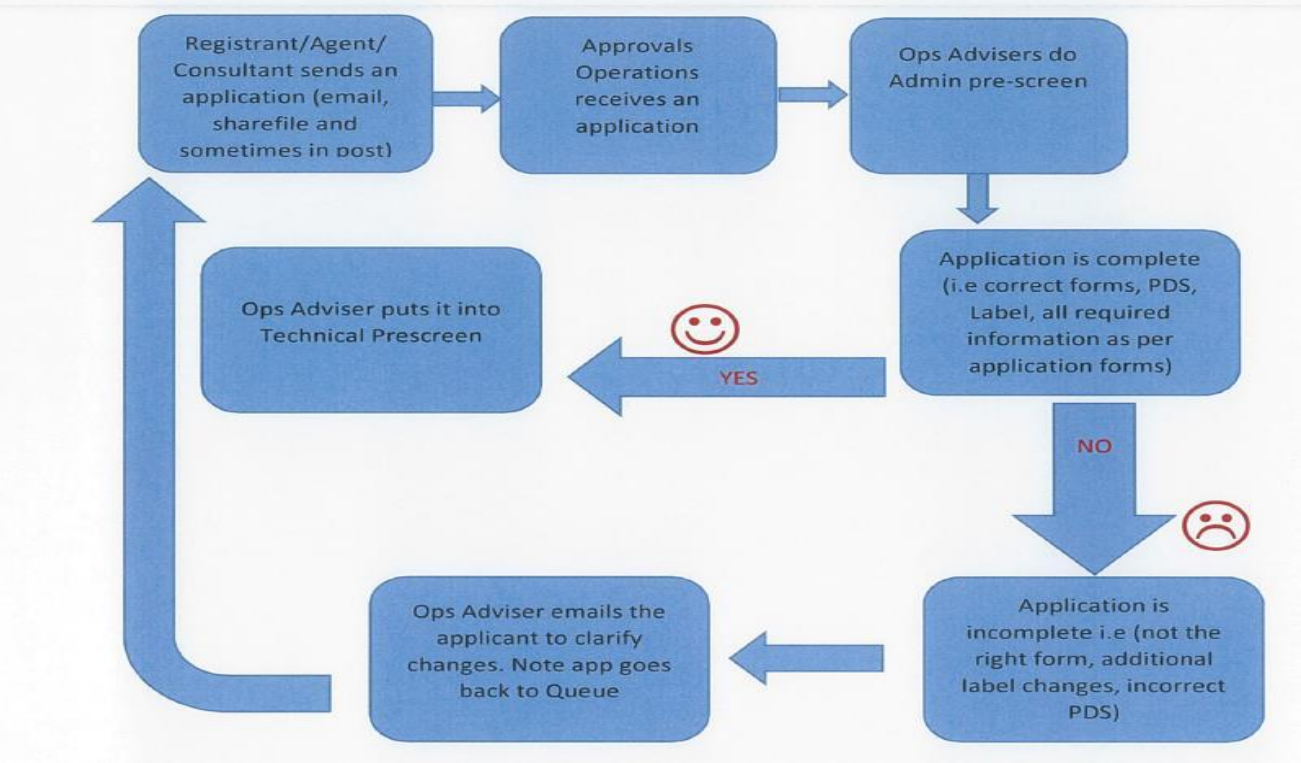
PDS (vet med) & Label

Q2:

Stability data

EPA approval

What happens at MPI- **Approvals Operations**



Deadline for submission to Operations team is 12 pm Friday

What happens at MPI?

Technical Prescreen

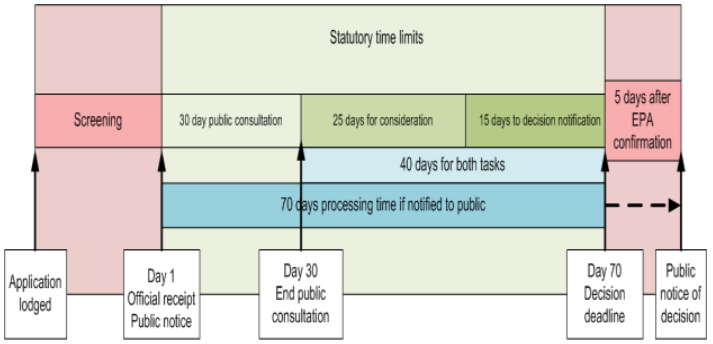
- Check all information required to make a decision has been submitted
- Technical prescreening starts Monday
- Discussion and decision is made the following Monday

What happens at MPI?

Technical assessment

- Public notification - 30 working days
- Technical appraisal - 25 working days
- bigger apps go for peer review

DD - 15 working days

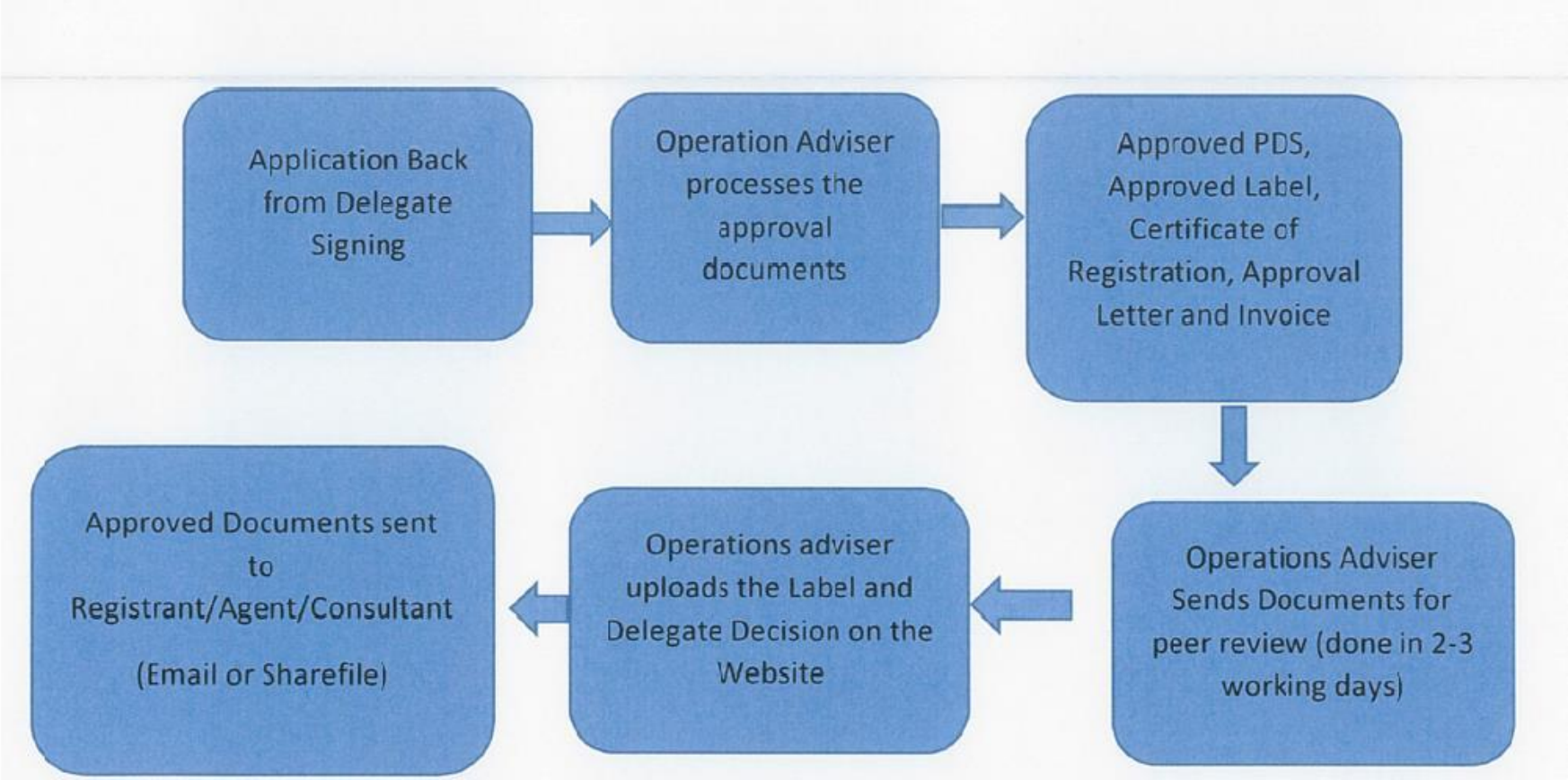


When might the applicant be questioned?

1) Administrative check
2) Prescreen
3) Technical assessment
4) Peer review
5) Delegate decision

Answers to questions may bring about new questions

Post Registration/Approval of Final Documents



All manufacturers must have:

A Quality Management System

- manages the risks associated with the product(s) manufactured
- ensures the products manufactured are of appropriate quality to be fit for purpose and pose no risks

The term ‘manufacture’ incorporates…

the entire process of producing a trade name product from…

the acquisition of starting materials

release for supply

Remember to include all steps in section B5 of the PDS

Manufacturing includes…

- Acquiring starting materials
- Preparation or extraction
- Dispensing
- Mixing / Blending
- In-Process Controls and Testing
- Filling
- Packing / Labelling
- Testing for release
- Re-packing / Re-labelling and filling from bulk

As a registrant you must:

- Use a manufacturer that is appropriate to manufacture your product

- List all entities performing any step of the manufacturing process on the PDS

AND

Ensure any ACVM registered product that is released is compliant with its registration particulars, including its conditions of registration

Manufacturers of VMs and VTAs

Must have independent approval of their QMS

<u>Vet Meds</u>

- this means verified compliance to GMP

<u>VTAs</u>

- this means verified compliance to GMP or another form of independent approval (for those manufacturers overseas)

GMP Compliance:

- NZ Manufacturers

Must be compliant with the ACVM Standard and Guideline for GMP.

Audited by an ACVM Auditor to verify compliance.

Applications for a manufacturer's GMP approval must be made prior to a registration application being made

GMP Compliance:

- International Manufacturers

- Equivalence arrangements exist between some countries, meaning alignment of GMP standard / programme between certain authorities

- Authorities that are deemed equivalent are considered ‘recognised’

- Manufacturers must be compliant with GMP and be verified by a ‘recognized’ authority

- Must hold a current GMP certificate/license or equivalent manufacturing authorisation

- Scope of activities approved must include the manufacturing activities performed in relation to the registered product.

- Current evidence of a manufacturer’s GMP compliance must be provided with every application (and variation)

Interactive Session 2

Task

On your tables are copies of an agricultural chemical PDS and a veterinary medicine PDS.

In groups, read through each PDS and mark the errors/discrepancies/mistakes.

You have 10 minutes

We'll then discuss some of the answers as a group.

Reg No	Trade Name	Authorised Person's Signature	Date
P	MINTY MOUSE CAT FLEA TREATMENT		17 Sep 18

ACVM Use	
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Reg No	Trade Name	Authorised Person's Signature	Date
A	Minty Mouse Insecticide		17 Sep 18

ACVM Use	
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See guideline.
Ectoparasiticide

A4 Formulation Type See guideline.
Aqueous Solution/Suspension

A5 Overseas Regulatory Status See guideline.

Part B. Product and Manufacturing Specifications-- Commercially Sensitive Information

B1 Active Ingredient Manufacturer See guideline.			
Active Ingredient	**Manufacturer's Name**	**Site Address**	**Postal Address (if different)**
Ingredient A	Triple A Manufacturing Ltd	186 Lambton Quay, Wellington, New Zealand	78 Queen Street, Auckland, 9028
Ingredient B	B-Bop Manufacturing Ltd		PO Box 86, Florence, Italy
Ingredient A	The Best Ltd	56 Nowhere Lane, Muswellbrook, NSW, Australia	Same as site address
Ingredient B	Captain X Ltd	89 Snizort Road, Snizort, IV51 9XQ Scotland	Same as site address

B2 Active Ingredient Minimum Purity and Impurities

See guideline.

Active Ingredient	Manufacturer	Grade	% Minimum Purity	Impurity and Amount
Ingredient A	Triple A Manufacturing Ltd	USP 36	* 98-103%	Heavy metals ≤0.005% Iron ≤0.001% Related cmpd A ≤0.5% Impurity B ≤0.1% LoD ≤0.8%
Ingredient A	The Best Ltd	BP	* 96%	Heavy metals ≤0.005% Iron ≤0.06% Impurity B ≤0.1% LoD ≤0.8%
Ingredient B	B-Bop Manufacturing Ltd	BP	≥98%	

B3 Formulation Details

See guideline.

Ingredient Name (Common or Chemical)	CAS Number	Standard	Quantity (g/kg or g/L)	Function
Ingredient A	1235-12-3	Ph Eur	45	Active Ingredient
Ingredient B	123-45-3	USP	10	Excipient
Ingredient C	-	In-house	2.5	Excipient
Ingredient D	N/A	CP	20	Active Ingredient
Ingredient E	5746-45-1	BP	75	Excipient

B4 Manufacturer(s) of the Formulated Product See guideline.			
Company name	**Street address of manufacturing site**	**Manufacturing step/Function**	**Approval (A, B or C)**
Gary Goose Ltd	45 Gander Way California, USA	ALL	A
Shaun Sheep Pty	97 Flock Avenue Florida, USA	QC Testing	A
Perry Packaging Ltd	53 Cardboard Lane Timaru, New Zealand	Re-packing/Re-labelling	B
Colin Catt Ltd	1001 Kitten Road Taupo, New Zealand	QC Testing	C

B5 Manufacturing Process	
State typical batch size or range	10L – 1000L
Provide a flowchart (either within this box or as an electronic attachment to this document) representative of the manufacturing process from beginning of the process until release.	
(refer attached)	

B6 Specifications of the Formulated Product		
Release Specifications See guideline.		
Parameter	**Range (include units if appropriate)**	**Method**
Appearance	Green	MS - Visual
Viscosity	< 180,000	Viscometer
Assay (Ingredient A)	95%-105%	MS - HPLC
Assay (Ingredient D)	90%-105%	MS - HPLC
Filled Weight	9.89g – 9.99g 4.77g - 4.89g	Weight using scale
pH	5.0	EP
Expiry Specifications See guideline.		
Parameter	**Range (include units if appropriate)**	**Method**
Appearance	Green	MS - Visual
Viscosity	< 180,000	Viscometer
Assay (Ingredient A)	95%-105%	MS - HPLC

B7 Packaging Details See guideline.
10mL plastic syringe 5mL plastic syringe

Part C: Statement and Notices

Applicant Statement			
I confirm that: ▪ I am authorised to make this application as the registrant OR a person with legal authority to act on behalf of the registrant noted in section A2; and ▪ the information supplied in and with this application is truthful and accurate to the best of my knowledge; and ▪ I understand that, if this product is registered, any change to the information provided in this application must go through MPI's 'variation to registration' process or I will be in breach of the product's registration conditions.			
Name	Minty Mouse	**Tel**	04 126 9287
		Email	minty@mousemansion.com
Signature		**Date**	17 Sept 2018


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Session 3: Assessing an Application

Evan Brenton-Rule

Roadmap

Expectations of data and information to support registration

- Ag Chem Considerations
- Vet Med Considerations
- VTA Considerations

Applications that may not required full data

- B1 Registrations
- B2 Registrations
- Variation Applications
- Administrative changes (C9 type applications)

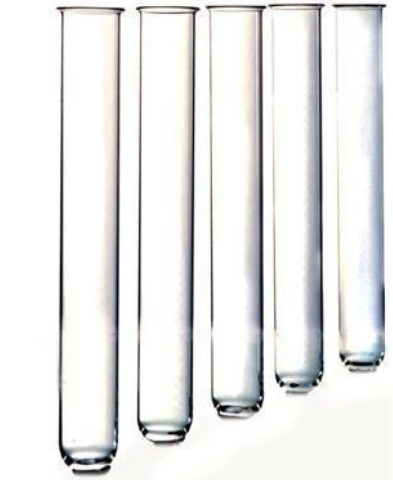
General expectations

- Data and information follows guidance
    - Be thorough
- Product specific

Ag Chem Expectations

Product identity and characteristics

- Chemistry and manufacturing guideline
- Concern is that you are able to accurately characterise and manufacture your product
- Quality, purity and stability



Vet Med expectations

Product and identity

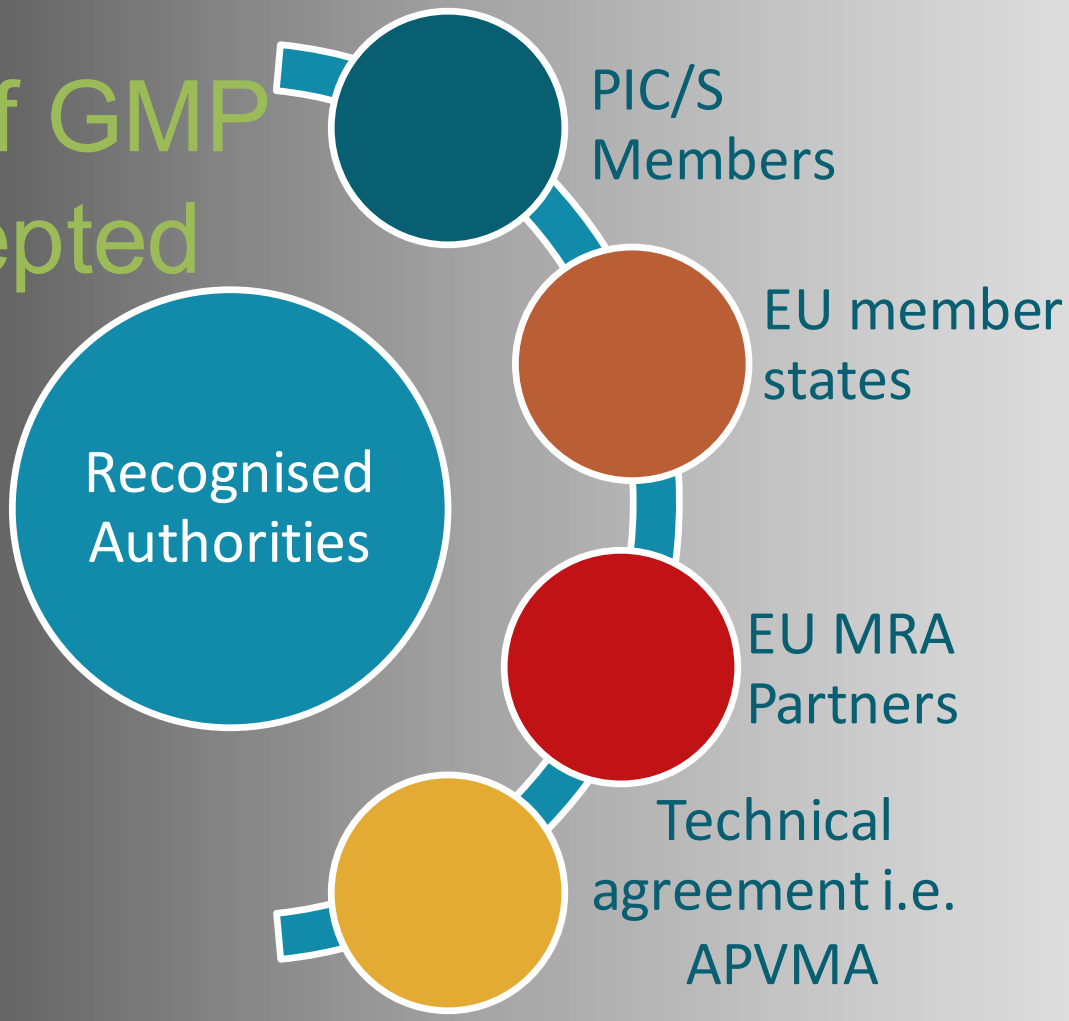
- Same requirements: need to be able to characterise the formulation chemistry and manufacturing processes **AND**
- Evidence of GMP
    - Required for anyone performing any step in the manufacturing process (acquisition of starting materials to release for supply)
        - Formulated product manufacturers
        - Repacker/relabellers
        - QC laboratories

Vet Med expectations

Product and identity

- AI manufacturers and specifications must be identified
- Manufacturing process validation required to verify the manufacturing processes for all vet meds
    - All critical control points must be included
    - Validation must verify the batch size/range in the PDS using equipment intended for market manufacture

Evidence of GMP will be accepted from:



Providing...

International GMP evidence must…

- Specify the applicable scope/approval for the product type and/or function being performed

AND

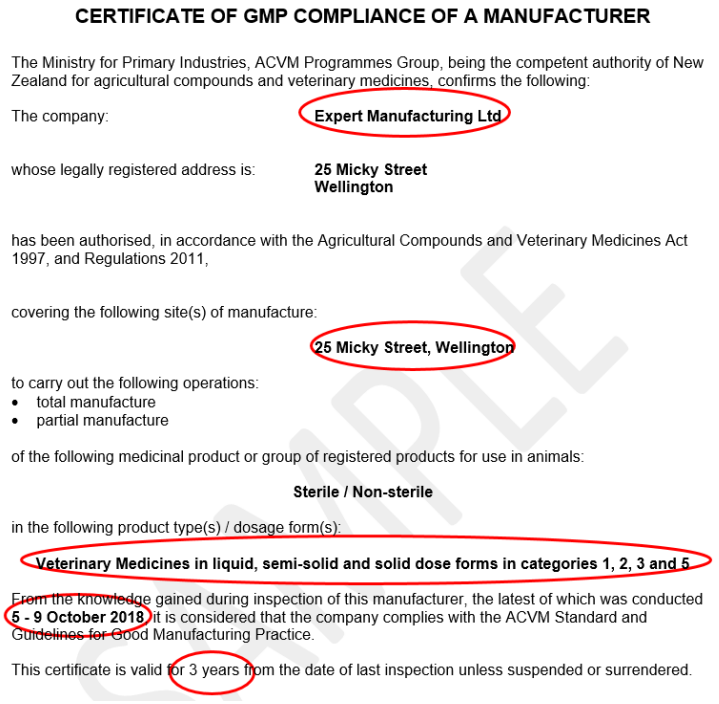
- Detail the manufacturer's name and site address

AND

- Identify that an audit has been conducted within the last 2 years where there is no validity period specified

OR

- have been issued within the last 3 years



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

The Ministry for Primary Industries, ACVM Programmes Group, being the competent authority of New Zealand for agricultural compounds and veterinary medicines, confirms the following:

The company: **Expert Manufacturing Ltd**

whose legally registered address is: **25 Micky Street Wellington**

has been authorised, in accordance with the Agricultural Compounds and Veterinary Medicines Act 1997, and Regulations 2011,

covering the following site(s) of manufacture:

25 Micky Street, Wellington

to carry out the following operations:
- total manufacture
- partial manufacture

of the following medicinal product or group of registered products for use in animals:

Sterile / Non-sterile

in the following product type(s) / dosage form(s):

Veterinary Medicines in liquid, semi-solid and solid dose forms in categories 1, 2, 3 and 5

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted **5 - 9 October 2018** it is considered that the company complies with the ACVM Standard and Guidelines for Good Manufacturing Practice.

This certificate is valid for 3 years from the date of last inspection unless suspended or surrendered.

SAMPLE

SCOPE OF APPROVAL MUST MATCH ACTIVITY CONDUCTED / PRODUCT

i.e.

- Immunobiologicals
- Steriles
- Non-steriles
- Ectoparasiticides
- Secondary Re-packing/Re-labelling
- Testing
- Sterilisation
- Vertebrate Toxic Agents (VTAs)
- API manufacturing

Recognition of International GMP Certificates - Other Evidence

For regulatory authorities that don't issue a regular license, and the current license was issued over 3 years ago, the license needs to be supported with evidence of recent audit, such as:

- Audit closure letter
- Audit report
- Letter from regulatory authority specifying when an audit has last been conducted

Recognition of International Certificates - Feeds and Supplements

- If evidence of GMP cannot be supplied, FAMI-QS (Feed Additives and Premixtures Quality System) can be accepted providing:
  - The certificate is issued by an established certification body
  - The certificate is accompanied by the most recent audit report
  - The manufacturer (or NZ product registrant), declared that QC testing will be performed on every batch prior to sale in NZ

Recognition of International Certificates - VTAs

- Evidence of independent approval of a manufacturer's QMS must be supplied along with the following:
  - Completed application form
  - Site Master File / Summary of activities conducted on site
  - Organisational Chart
  - Copy of Batch Record
  - Procedure outlining the manufacturing process
  - Current Certificate identifying that the company's QMS has been audited. e.g. ISO accreditation

Ag Chem Expectations

Product efficacy

- Data that supports all label claims of a product
- Any information necessary to interpret or understand data is should be included
- Overseas data acceptable if applicable to NZ
    - NZ confirmatory trials usually required
- Optimal rates: 0.5x, label rate, 2x

Ag Chem Expectations

Product efficacy

- Trial number – depends
    - Nature of product, importance of crop, importance of pest
    - A1 more → C5 less
- Locations(s)
- Cultivars – resistant and susceptible
- Application method
- Pest abundance

Vet Med Expectations

Product efficacy

- Data/information must support all label claims, target pathogens, and target species/class to be treated

- Overseas data can be acceptable if applicable to NZ use
    - Relevance should be confirmed for
        - NZ target species/class
        - NZ pathogens
        - NZ farming practices

Vet Med Expectations

Product efficacy

- Data requirements depend on how novel the compound/use is
    - Bioequivalence can be considered
- Dose confirmation should be addressed with data or information relative to the species/class
- Efficacy must be supported at the lowest on-label dose
- If multiple administration methods, all need to be supported

Ag Chem Expectations

Safety

- Varietal susceptibility
- Crop size, age, physiological condition

<u>Report symptoms such as:</u>

- Thinning through loss of whole plants
- Modifications in colour (chlorosis, intensity)
- Necrosis
- Deformations such as curling, rolling or twisting

Ag Chem Expectations

Safety

- Safety to following crops can be relevant for persistent herbicides
    - Rotational crop or carry over experiments
- Bioequivalence: Generic products

Vet Med Expectations

Safety

- Animal Welfare one of the four main risk areas for ACVM
- Trial work/information needs to establish:
    - Safety of the product when used as directed (highest 1x)
    - Margin of safety (3x, 5x, >5x)
        - ➢ Margin of safety evaluated relative to toxicity risk
- Parameters tested must be dictated by tox/safety profile and use pattern for the product
- All species must be represented
- The most at-risk class(es) must be represented

Ag Chem Expectations

Residues

- Residue Data for Agricultural Chemical Guidance Document
- Residue data required to determine levels of residue in produce and animal transfer residues in edible tissue or animal products
- Use this to recommend a WHP
- WHP is used to manage compliance with MRL
- If an MRL is required, must propose this in data package
    - MRL based on GAP and trade risk

Ag Chem Expectations

Residues

- Product chemistry
- Proposed use pattern
- Residue analysis
- Metabolism studies
- Supervised crop residue trials
- Processing studies
- Animal transfer studies
- Environmental fate data
- Rotational crop studies

Vet Med Considerations

Residues

- *ACVM Registration Standard and Guideline for Determination Of A Residue Withholding Period for Veterinary Medicines*
    - Outlines expectations for trial design and data reporting for vet med residue trial work
- WHPs used to manage compliance with MRLs, MRLs based on GAP and trade risk
- Registrants must propose WHPs and, when required, MRLs as part of the data package

Vet Med Expectations

Residues

- Represents proposed use pattern – all species and classes, highest doses
- Analytical validation including sample storage
- PK profile
- Data from at least three time points – point of expected MRL compliance
- Proposed WHPs

  Meat: Single day up to 21 days, then weekly;

  Milk: In both hours and milkings; DCT: PNTIs in weeks, post-calving in hrs/milkings

  Eggs: one day intervals

Applications that may not require full data

B1 Applications

- B1 applications are applications that are *identical* to a registered product

Applications that may not require full data

B2 Applications (Ag Chems and Vet Meds)

- A letter of authority is required when you are cross-referencing another company's product
- We will accept a confidential PDS sent by the other company

Applications that may not require full data

B2 Applications (Ag Chems and Vet Meds)

- B2 applications are application that are *similar* to a registered product
- Technically requires full suite of data
- Can cross-reference to already existing products… provided they no longer have data protection
    - Must reference pioneer product

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Applications that may not require full data

B2 Applications

- Must be NZ registered, same formulation type, same active content, same application rate, same application methods, same claims
- May be as a separate deviation or deviation incorporated in an application
- C&M data always required

	Application type	Data volumes				
		Chemistry & Manufacturing	Residue	Efficacy	Safety	Toxicology
A1	New active ingredient	◆	◆	◆	◆	◆
A2	Known active ingredient with a new risk profile	◆	◆	◆	◆	
B1	Identical to a registered trade name product	Dev	Dev	Dev	Dev	
B2	Similar to a registered trade name product	◆	◆	◆	◆	
C1	Change in formulation	◆	◆	◆	◆	
C2	Change in manufacturing process	◆				
C3	Change in shelf life or packaging	◆				
C4	Extension of use to include an additional situation or target host		◆	◆	◆	
C5	Addition of another disease, pest or weed			◆		
C6	Change of application rate or timing		◆	◆	◆	
C7	Change or addition of a method of application		◆	◆	◆	
C8	Change in withholding period		◆			
C9	Administrative change	Fully explain change(s) in a letter.				

Key

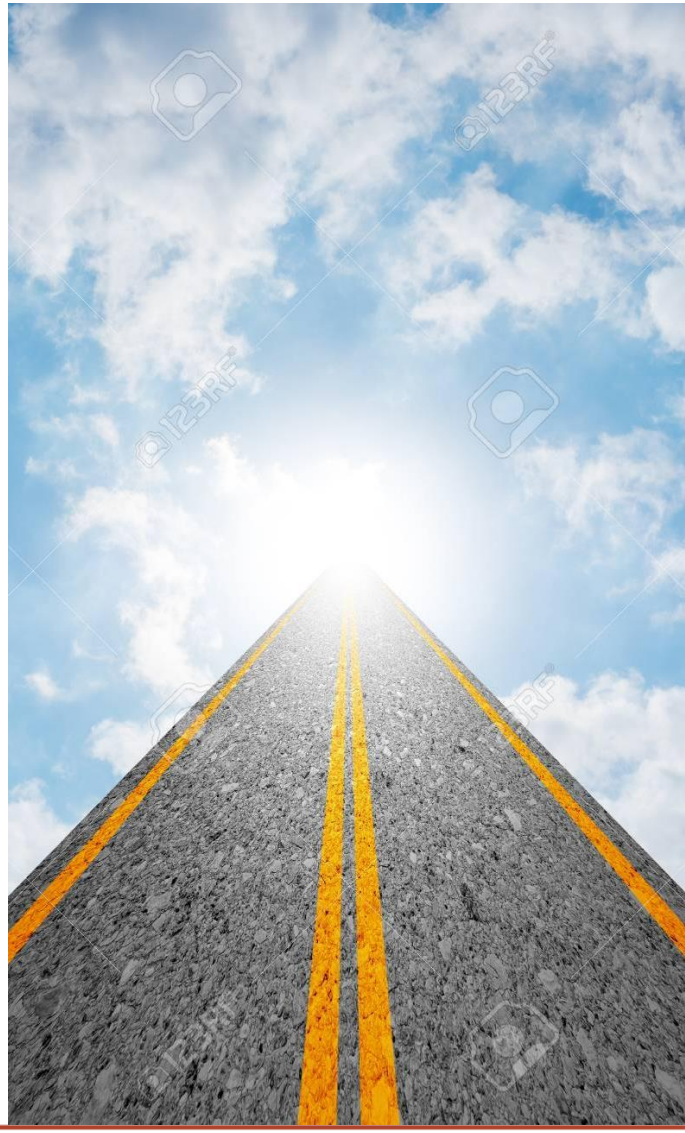
◆ Information must be provided or a deviation from the information requirements be submitted

ACVM information Requirements 2

Administrative changes

- Strictly changes to administrative information on PDS and/or label
- Do NOT affect risk profile
    - Wording changes, visual changes on label, registrant address change
- Processed by Operations, but often sent to technical team if change may impact risk profile
- All applications reset registration period so full PDS and label required

Thank you…



New Zealand Food Safety

Haumaru Kai Aotearoa

Post-Authorisation Registrant Responsibilities

ACVM 101 Workshop

October 2018

Ministry for Primary Industries

Post-Authorisation Registrant Responsibilities

- Managing compliance with the conditions of registration
    - Maintaining product registrations over time
    - Adverse event reporting
    - Significant new information
- Managing temporary conditions

ACVM Registration Assessment

The key outcomes of the ACVM risk assessment and product appraisal are:

- To determine whether sufficient information has been provided to ensure the benefits of registration always outweigh the risks, and
- To determine whether the risks can be managed with the application of conditions

ACVM Registration Assessment

A recommendation to register means:

- Product identity and risk profile characterised
- Product manufacturing processes are consistent and appropriate to manage product quality
- Claims and all other label information sufficiently supported
- All associated risks can be managed
    - public health, trade, animal welfare, and agricultural security

Registration Granted….Now What?

Conditions of Registration

- Registration conditions on all registered agricultural compounds
- Control risks associated with product importation, manufacture, sale and use
    - Permanent conditions– remain for the life of the product
    - Temporary conditions – applied for a specified period and reason
- All conditions subject to regular review, usually at each variation

Managing compliance with the conditions of registration:

Common Permanent Conditions

Product Identity and Characteristics

60. The manufacture of the product **must at all times conform to the product and manufacturing specifications** approved as part of the registration.

61. The product must be **labelled in accordance with the product and manufacturing specifications** approved as part of this registration.

Product Manufacture and Distribution

62. The product must be manufactured by a **person specified to manufacture it** and **acting in accordance with an operating plan approved under section 28.** **[Vet Meds]**

63. Persons responsible for the product at each stage throughout its **distribution** must **maintain the product** in a manner that ensures it **conforms to the approved product and manufacturing specifications through to the product's retail sale**.

Product Manufacture and Distribution

88. Random samples must be taken from each batch/lot imported into the country and tested for compliance with the provided Certificate of Analysis. This sampling must occur before the product is released for sale. This testing must be performed in a GMP or ISO 17025 accredited laboratory according to pharmacopeia or test methods quoted on the Certificate of Analysis. Completed assay results must be retained for Ministry for Primary Industries audit purposes.

    Material must be inspected on arrival to ensure it is labelled correctly and has traceability back to the Certificates of Analysis received.

Adverse Events

Any unexpected or negative outcome of product use

Can be:

- Product inefficacy
- Safety related side-effects
- Residue detections despite use according to label including WHP

Adverse Events: Agricultural Chemicals

82. For the purposes of this condition, **an adverse event is any event that brings into question the relevance or reliability of information** provided at the time of registration and upon which the decision to register the product was made.

The registrant must notify Ministry for Primary Industries of an adverse event in relation to the product, **immediately upon becoming aware of the event**, where the event has or may have significant implications for the continued use of the product.

Adverse Events: Veterinary Medicines

64. The registrant must investigate the significance of **every adverse event** associated with the use of the product; and **report to Ministry for Primary Industries within 20 working days** the outcome of this investigation.

    The registrant must notify Ministry for Primary Industries **immediately** upon becoming aware of an adverse event that seems to have **seriously jeopardised the health and welfare** of the treated/exposed animal(s); and may require the use of the product to be stopped or restricted to prevent similar adverse events.

New Information

65. The registrant must, **as soon as practicable** after becoming aware of new information, advise Ministry for Primary Industries of **any new information that relates to the relevance, reliability or correctness of information** provided at the time of registration and upon which the decision to register the product was made.

Advertising

66. No advertisement for the product may:

(a) **include content** or be presented in a manner **that does not conform to the approved** product and manufacturing specifications (this includes approved uses);

(b) **contain false or misleading claims**, statements or information in relation to the product; or

(c) without limitation to the generality of (b), directly or by implication make **false or misleading claims or statements about the regulatory status** of the product under the ACVM Act.

MRL Compliance: Agricultural Chemicals

83. Any person using the product must ensure that residues of any substance in the product that may occur in:

(a) Plant material intended for human consumption produced from plants or plant material treated with the product, or

(b) Animal material as defined in the Animal Products Act 1999 intended for human consumption produced from grazing or direct feeding plants or plant material treated with the product to food producing animals does not exceed the lower of either:

(i) the specified residue level in the current Food Notice: Maximum Residue Levels for Agricultural Compounds; or

(ii) the default maximum residue level in the current Food Notice: Maximum Residue Levels for Agricultural Compounds, when a maximum residue level for that substance has not been specified.

MRL Compliance: Veterinary Medicines

67. Any person using the product on any animal from which animal material as defined in the Animal Products Act 1999 is likely to be used for human consumption (whether that use is in accordance with the approved product label or not) must ensure that residues of any substance in the product that may occur in animal material produced from the treated animals, do not exceed the lower of either:

    (a) the specified residue level in the current Food Notice: Maximum Residue Levels of Agricultural Compounds; or

    (b) where a maximum residue level for that substance has not been specified, the default maximum residue level in the current Food Notice: Maximum Residue Levels of Agricultural Compounds.

MRL Compliance

- Any person using the compound must manage residues in:
    - Ag Chems: Plant material from treated crops AND animal material from food-producing animals that have grazed or been fed treated crops
    - Vet meds: Animal material from any treated animal
- Residues must conform to the lower of either the MRL specified in the Food Notice, or the default MRL of 0.1 mg/kg if no MRL has been set

→MRLs <u>always</u> apply to food producing crops and animals

MRL Compliance

90. This product must not be used on any animal producing, or intended to produce food for human consumption.

Common Ag Chem Specific Conditions

84. The product **must not be used on animals** unless the use is approved as part of this registration.

108. The registrant must provide sufficient consumer advice about the **on-going stability** of the product for use if requested by any purchaser of the product.

The registrant must withdraw the product from the market place where evidence shows it is no longer capable of meeting its expiry specifications prior to its use, when stored in line with the manufacturers recommendations.

Common Vet Med Specific Conditions

68. Any person using the product on any animal or in any manner **other than as specified in the approved product and manufacturing specifications** must, before using the product, seek advice from an appropriately qualified source and confirm that the intended use is not likely to cause unnecessary or unreasonable pain or distress in the animal treated

RVM Conditions: 69-73

- Manage who can sell (69), purchase (71), and use (72) RVMs, what a vet authorisation is (70), and the notice to which authorising vets must comply (73).

VTA Conditions

- GMP
- On-label use only
- AER reporting
- sale restrictions
- Availability/display restrictions
- Signage and notification requirements
- Advertising requirements
- Use Restrictions
- Security and control of product

Other Conditions

Condition 31: On-label use only

Condition 34: Annual sales reporting

Condition 42: Tuberculin specific condition

Condition 89: Requirement for an Operating Plan

Condition 129: Prohibition of growth promotion in ruminants

Managing compliance with the conditions of registration:

Temporary Conditions

Manufacturing

86. The registrant must provide a **batch analysis, which confirms that the product meets the approved release specifications, from the first production batch** at the new manufacturing site to Ministry for Primary Industries for approval prior to sale of product from this new site.

Additional Information

101. The registrant must provide **additional information specified** by the Ministry for Primary Industries at or before the expiry of the current product registration period.

MRL Promulgation

136. The product **must not be sold** until all proposed MRLs specific to the **use directions** on the product label are promulgated

138. The product **must not be advertised or sold** with **uses or claims** on the label that are subject to proposed MRLs until such MRLs have been promulgated.

Ongoing Registrant Responsibilities

Registrants Must….

Make sure the manufacturers are appropriate and their approvals are up to date

- Ensure evidence of GMP compliance (or equivalent) for all VM and VTA manufacturers are up to date and cover the appropriate scope
- Ensure all manufacturers have and are maintaining a robust quality management system
- Ensure manufacturers hold the applicable product particulars and registration information relevant to their responsibilities
- Have a manufacturing quality agreement with each manufacturer that outlines each parties responsibilities.

Registrants Must….

Ensure they are practicing good product stewardship

- Monitor product use in the field to ensure currently expectations around use and GAP are correct
- Maintain ongoing monitoring and compliance management for their products including an ongoing stability programme
- Monitor, report, and manage adverse events

Registrants Must….

Maintain each product's registration as current

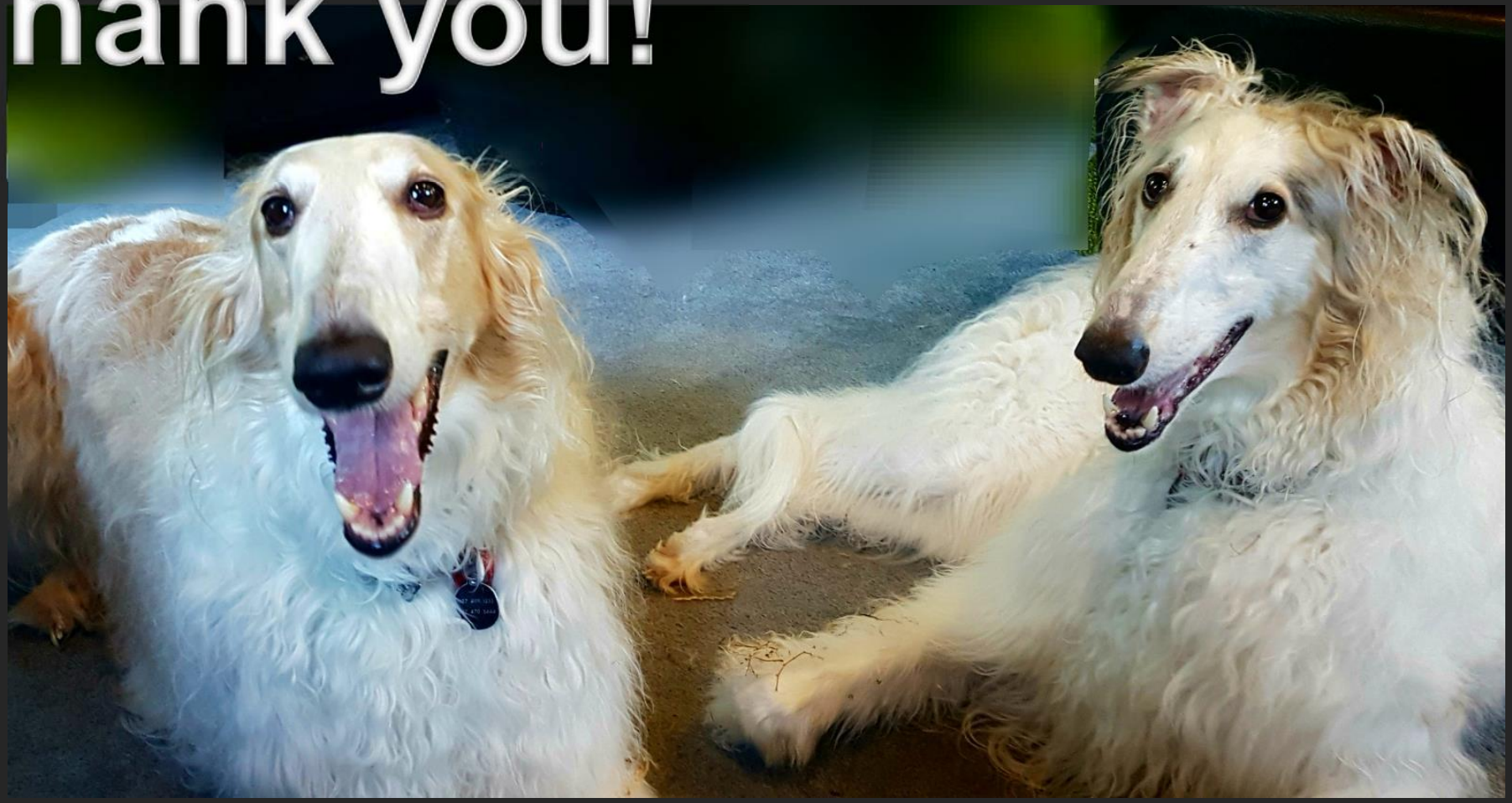
- Ensure all approved details in the PDS and label are accurate and up to date
- Apply for variations to update information throughout the product's life before implementing change
- Keep the product's registration current throughout the product's life span

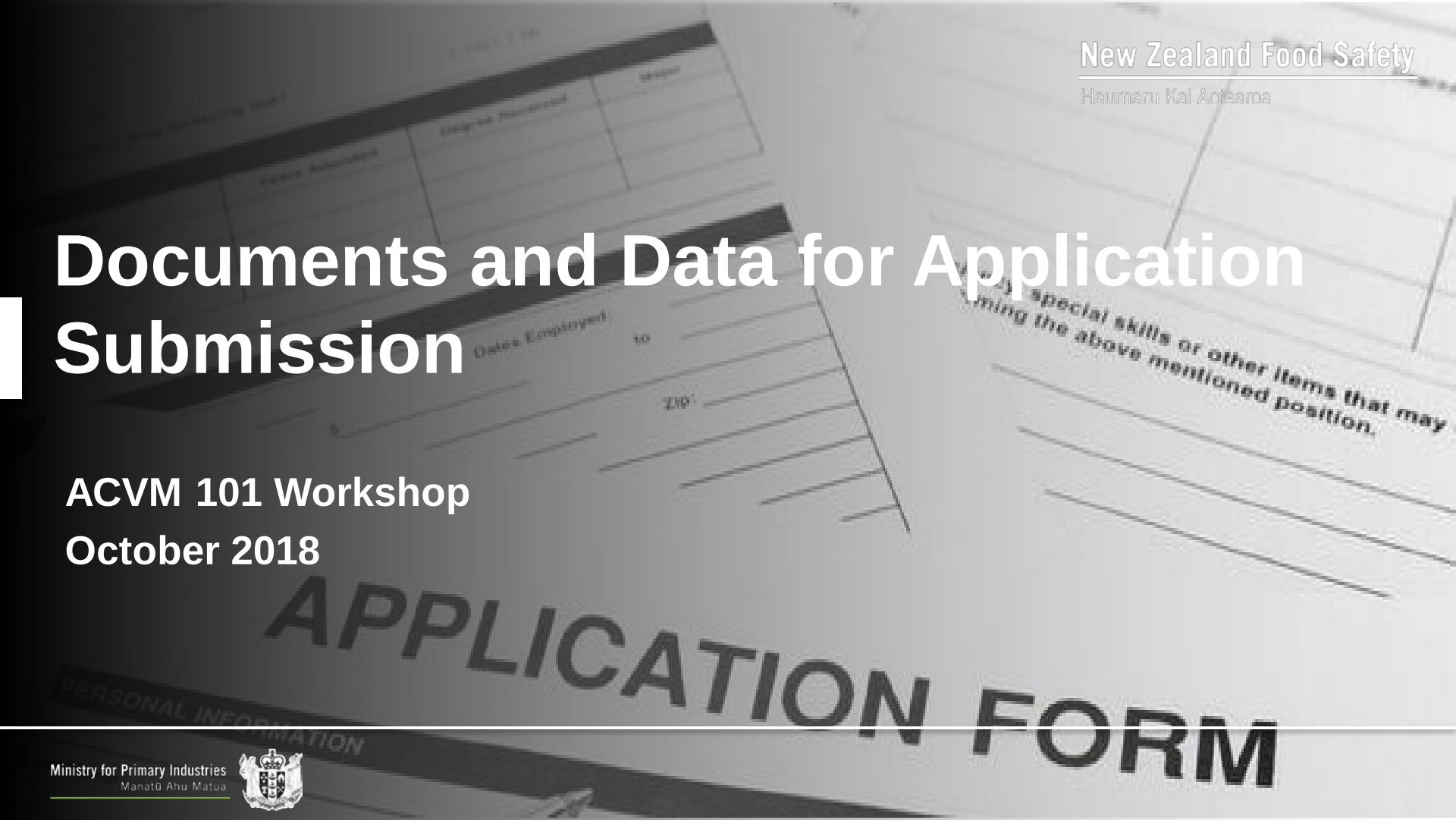
Registrants Must….

Not release product if:

- The registered specifications have not been met
- The AI or product has been sourced from a manufacturer not listed on the PDS
- There are questions raised about a batch's quality or consistency
- The overall product quality is uncertain

Thank you!





Documents and Data for Application Submission

ACVM 101 Workshop

October 2018

Compiling the Application

What to submit for different application types

- Data packages
- Data assessment reports
- EPA and Biosecurity approvals
- Other information

Compiling the Application

Note: For this exercise, submission of the PDS and label(s) with every application is a given.

Scenario 1

You are planning to register a new dog and cat wormer that is the same as one you already have registered. All details of the products are identical, and both products will be manufactured at the same overseas site.

The only difference between the registered product and the new product is the trade name.

The product is a chew that contains beef flavouring.

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

A1	Novel active ingredient
A2	Known active, new risk profile
B1	**Identical to registered TNP**
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

Scenario 1: B1 (Identical to a registered TNP)

• Application Summary	• Biosecurity Approval/Application

Scenario 1a

You are planning to register a new dog and cat wormer that is the same as one **that is already registered**. All details of the products are identical, and both products will be manufactured at the same overseas site.

The only differences between the registered product and the new product are the trade name **and that the registered product is owned by a different registrant**.

The product is a chew that contains beef flavouring.

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	**Similar to registered TNP**
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

Scenario 1a: B2 (Similar to a registered TNP)

<u>No longer identical</u> to a registered TNP because that product is owned by a different registrant

• Application Summary	• Biosecurity Approval/Application
• **Declaration Letter**	

Scenario 1b

You are planning to register a new dog and cat wormer that is the same as one you already have registered. All details of the products are identical, and both products will be manufactured at the same overseas site.

The only difference between the registered product and the new product is the trade name **and the formulated product manufacturer, which is a different overseas manufacturer**.

The product is a chew that contains beef flavouring.

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	**Similar to registered TNP**
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

Scenario 1b: B2 (Similar to a registered TNP)

• Application Summary	• Chemistry and Manufacturing Data
• Overall Data Assessment Report	• Batch Analysis
• Chemistry & Manufacturing Data Assessment Report	• Stability Data
• Manufacturing Process Validation Data	• Cross-Reference/Deviation Technical Discussion
• Evidence of GMP Approval	• Biosecurity Approval/Application

Scenario 1c

You are planning to register a new oral wormer that is the same as one that is already registered. You own the registered product.

The new product is a version of the registered one, with a few minor differences in the formulation to allow claims in dogs, cats, sheep, and goats. The dog and cat claims are identical to the registered product, and there are similar products with sheep and goat claims.

The beef flavouring has been removed in favour of a honey flavouring.

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	**Similar to registered TNP**
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

Scenario 1c: B2 (Similar to a registered TNP)

• Application Summary	• Chemistry and Manufacturing Data
• Overall Data Assessment Report	• Batch Analysis
• Chemistry & Manufacturing Data Assessment Report	• Stability Data
• **Safety Data Assessment Report**	• **Cross-Reference/Deviation Technical Discussion –AND/OR–**
• **Efficacy Data Assessment Report**	• **Bioequivalence Data –AND/OR–**
• **Residues Data Assessment Report**	• **Efficacy Data: NZ and/or overseas data with justification**
• Manufacturing Process Validation Data	
• Evidence of GMP Approval	• **Residues Data (+/-)**
• Biosecurity Approval/Application	• **Target Animal Safety Data (+/-)**

Scenario 2

You have a herbicide registered for post-emergence control of broadleaf weeds in a range of cereal crops. The withholding periods are 28 days in barley and 56 days in all other cereals.

You would like to submit an application to reduce the “all other cereals” withholding period to 42 days.

There are no changes to the product itself or its use patterns other than this change.

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	**Change in WHP**
C9	Administrative Change

Scenario 2: C8 (Change in Withholding Period)

• Application Summary	• Residues Data
• Overall Data Assessment Report	• Animal Transfer Data [or review existing]
• Residues Data Assessment Report	

❖ Also consider MRLs – may need revision

Scenario 2a

You have a herbicide registered for post-emergence control of broadleaf weeds in a range of cereal crops. The withholding periods are 28 days in barley and 56 days in all other cereals.

You would like to submit an application to reduce the “all other cereals” withholding period to 42 days. **This is based on a slight adjustment to the “other cereals” application rate.**

There are no other changes to the product or its use patterns.

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	**Change in WHP**
C9	Administrative Change

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	**Change in application rate or timing;**
C7	Change in the method of application/administration
C8	**Change in WHP**
C9	Administrative Change

Scenario 2a: C6 (Change in Application Rate or Timing); C8 (Change in Withholding Period)

• Application Summary	• Residues Data (+/- MRL proposal)
• Overall Data Assessment Report	• Animal Transfer Data [or review existing]
• Residues Data Assessment Report	• **Toxicology Data**
• **Efficacy Data Assessment Report**	• **Cross-Reference/Deviation Technical Discussion –OR–**
• **Safety Data Assessment Report**	• **Efficacy Data: NZ and/or overseas data with justification**
• **EPA Approval**	• **Crop Safety Data**

Scenario 3

You have a VTA product registered which uses palm oil as a binder. Concerned about deforestation, your company has decided to change the binder to sustainably sourced coconut oil.

There are no other aspects of the product's manufacture or use that is proposed for change. The product is manufactured overseas.

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	Change in formulation
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	**Change in formulation**
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

Scenario 3: C1 (Change in Formulation)

• Application Summary	• Chemistry and Manufacturing Data
• Overall Data Assessment Report	• Batch Analysis
• Chemistry & Manufacturing Data Assessment Report	• Stability Data
• Efficacy Data Assessment Report	• Cross-Reference/Deviation Technical Discussion
• EPA Approval	• Efficacy Data: NZ and/or overseas data with justification
• Biosecurity Approval/Application	

Scenario 3a

You have a VTA product registered which uses palm oil as a binder. Concerned about deforestation, your company has decided to change the binder to sustainably sourced coconut oil.

The new binder requires different equipment that the current manufacturer will not be getting, so a new formulated product manufacturer is also needed.

There are no other aspects of the product's manufacture or use that is proposed for change. The product is manufactured overseas.

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	**Change in formulation**
C2	Change in Manufacturing
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

A1	Novel active ingredient
A2	Known active, new risk profile
B1	Identical to registered TNP
B2	Similar to registered TNP
C1	**Change in formulation**
C2	**Change in Manufacturing**
C3	Change in Shelf life/Packaging
C4	Extension of Use/Additional target species
C5	Additional disease, pest or weed
C6	Change in application rate or timing;
C7	Change in the method of application/administration
C8	Change in WHP
C9	Administrative Change

Scenario 3a: C1 (Change in Formulation); C2 (Change in Manufacturing)

• Application Summary	• Chemistry and Manufacturing Data
• Overall Data Assessment Report	• Batch Analysis
• Chemistry & Manufacturing Data Assessment Report	• Stability Data
• Efficacy Data Assessment Report	• Cross-Reference/Deviation Technical Discussion
• EPA Approval	• Efficacy Data: NZ and/or overseas data with justification
• Biosecurity Approval/Application	• **Evidence of GMP Approval**