Ministry for Primary Industries
Manatū Ahu Matua

2018 Group Update
ACVM Workshop

23 February 2018

Holly Jeboult-Jones

Agricultural Compounds and Veterinary Medicines (ACVM) Group
Systems Audit, Assurance and Monitoring

Growing and Protecting New Zealand

www.mpi.govt.nz

ACVM Staff

Glen Bradbury
Manager, ACVM Programmes & Appraisals

Agricultural Chemicals and VTA Assessors
- Bruce Nalder
- Vacancy
- Sarah Lester
- Wayne Severn
- Evan Brenton-Rule

Veterinary Medicine Assessors
- Richard McKinley
- Alfredo Caicedo
- Jennifer Doyle

Regulatory Programmes
- Holly Jeboult-Jones
- Francie Olliver
- Christian Morales Orea

Food and Trade
- Awilda Baoumgren

Warren Hughes
Principal Adviser ACVM R&A

Maree Zinzley
Manager, Approvals Operations

- Teresa Robinson
- Shaleen Narayan
- Vu Mpofu
- Daniela Foote
- Jessica Gautrey
- Lee Jacobs
- Sara Van Rooy

Contractors
- Paul Spencer (Ag Chem.)
- Jennie Moran (Vet)
- Meg Moffat (Vet)
- Suzanne Lane (Vet)
- Chris Boland (Projects)
- Jeanne Boland (Documents)
- Karen Booth (Reg. Review)
- Sarah De Barr (Reg. Review & QMS)

Our Team













2017 Achievements

- Registration Review (Near Completion)
- Data Protection Implementation
- Antimicrobial Resistance Project
- Manufacturing & Data Assessor Workshops
- Ag Chem Residue Guidance – Published
- Efficacy of Anthelmintics – Published
- Exempt Ag Compounds Notice – Published

2018 Work Plan (Projects)

Projects

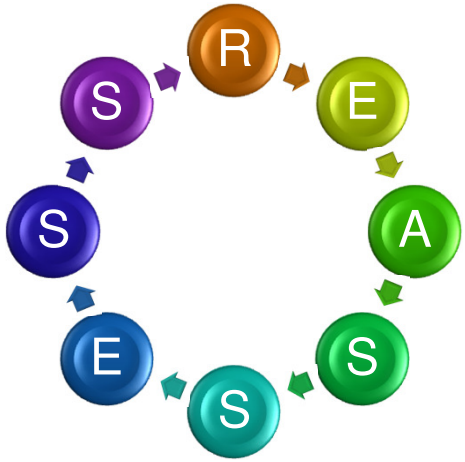
- Registration Review (completion/review of actions)
- VTA Anticoagulants Reassessment
- Post Registration Programme Evaluation
  - GMP
  - Compliance and Monitoring Systems
  - Pharmacovigilance
  - Conditions of registration
- AMR
- On-Farm Inputs
- MRL Review
- ACVM Regulation Changes
- Trans-Tasman Co-operation

2018 Work Plan (Priority Documents)

- **MRL notice amendment** – Ongoing
- **RTT OPs Guideline and Application Form (Renewals)** – Progressing
- **Equivalence of Vet Meds – Final Draft** – nearly completed
- **Vet Med Chemistry and Manufacturing** – Second Draft
- **Vet Med WHPs** – Prioritised for 2018
- **Vet Med Efficacy Guidance Consolidation** – Prioritised for 2018
- **Compounding** – Final Draft
- **Ag Chem Chemistry and Manufacturing Guidance** – On hold

2018 Reassessments

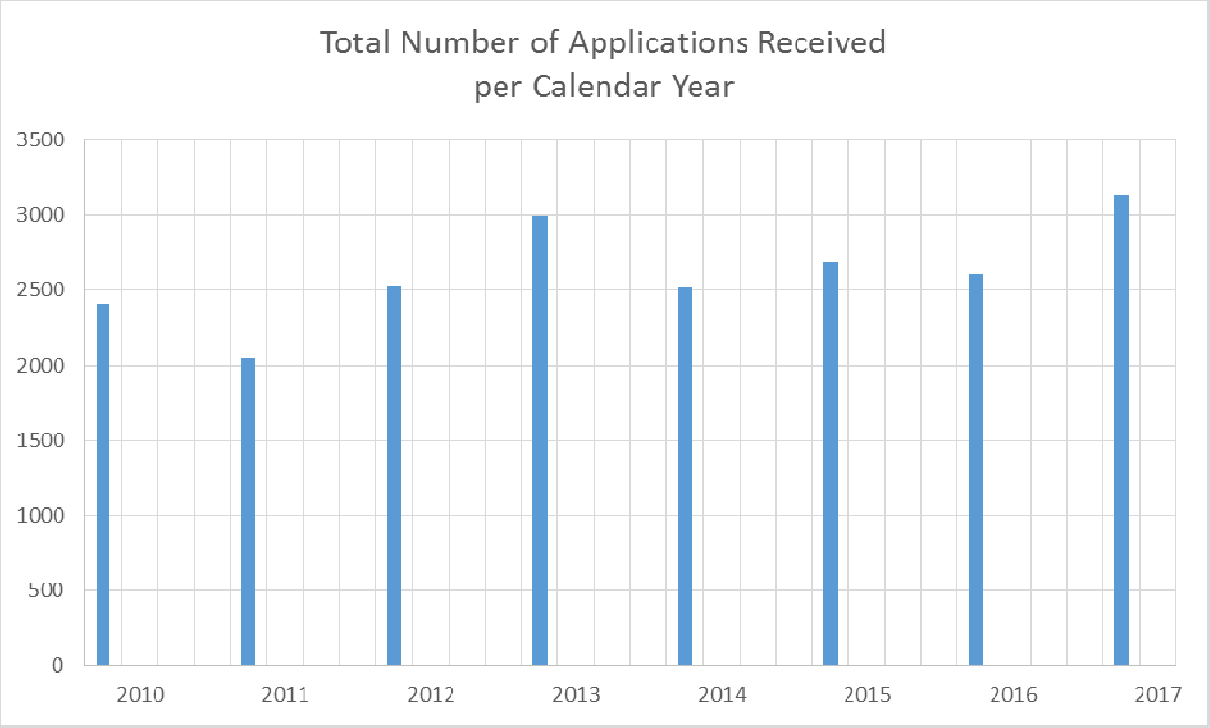
- Amitraz
- Carbadox
- Dimetridazole
- Glyphosate
- Brodifacoum
- Lasalocid/Monensin/Decoquinate



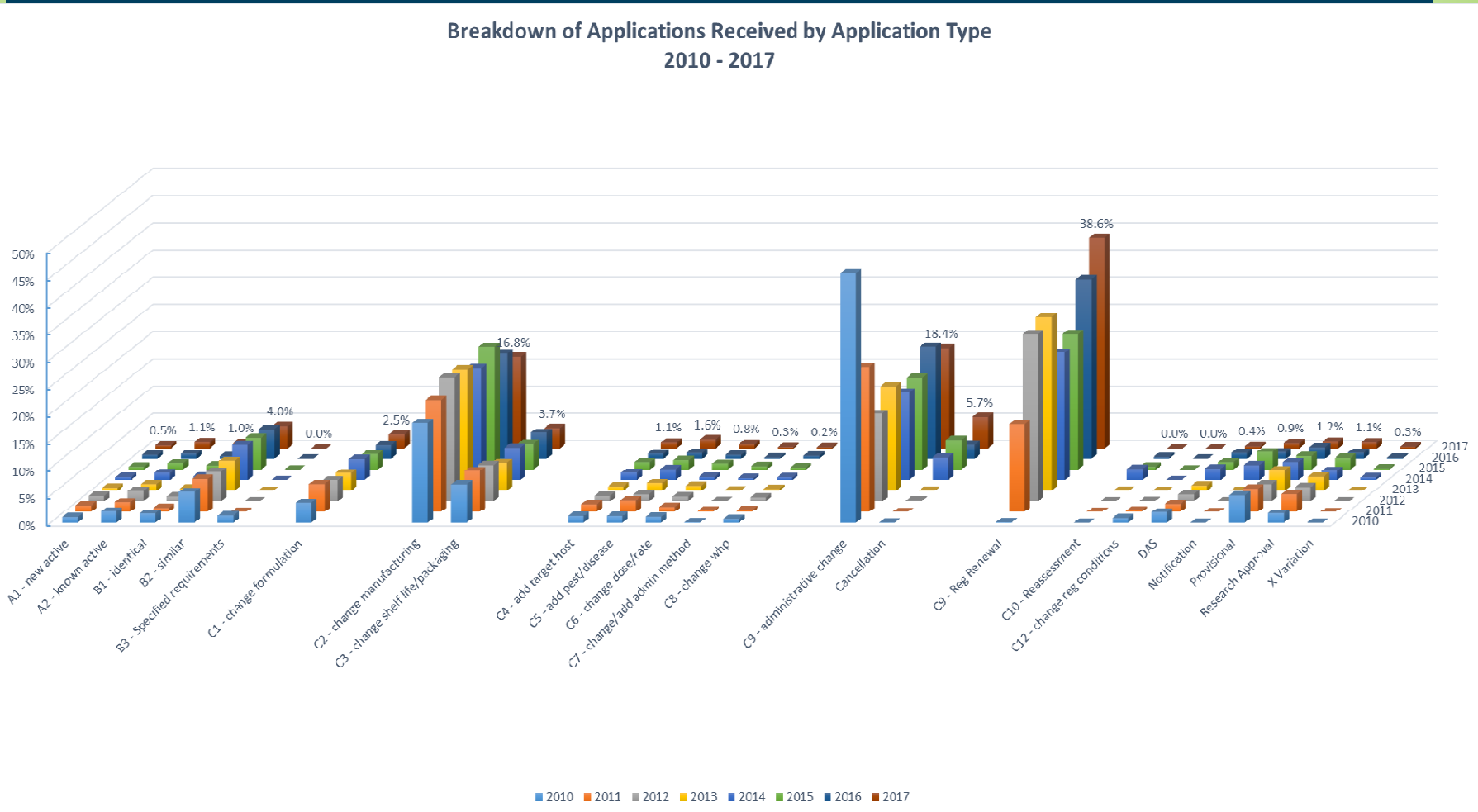
ACVM in Numbers - *Registrations*

- ACVM receives ~2,600 applications/year
- 3,148 in 2017

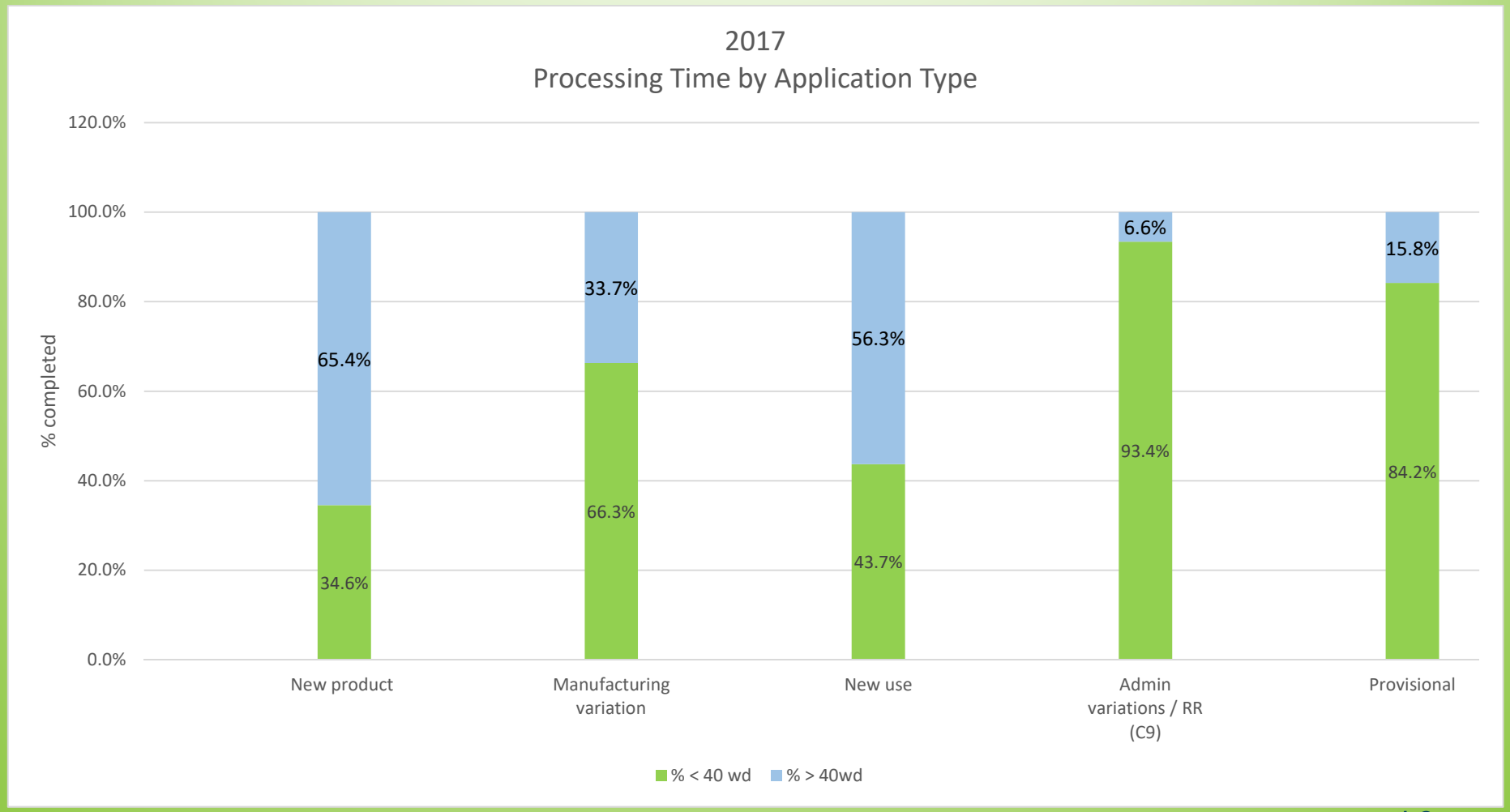
3328 Currently Registered

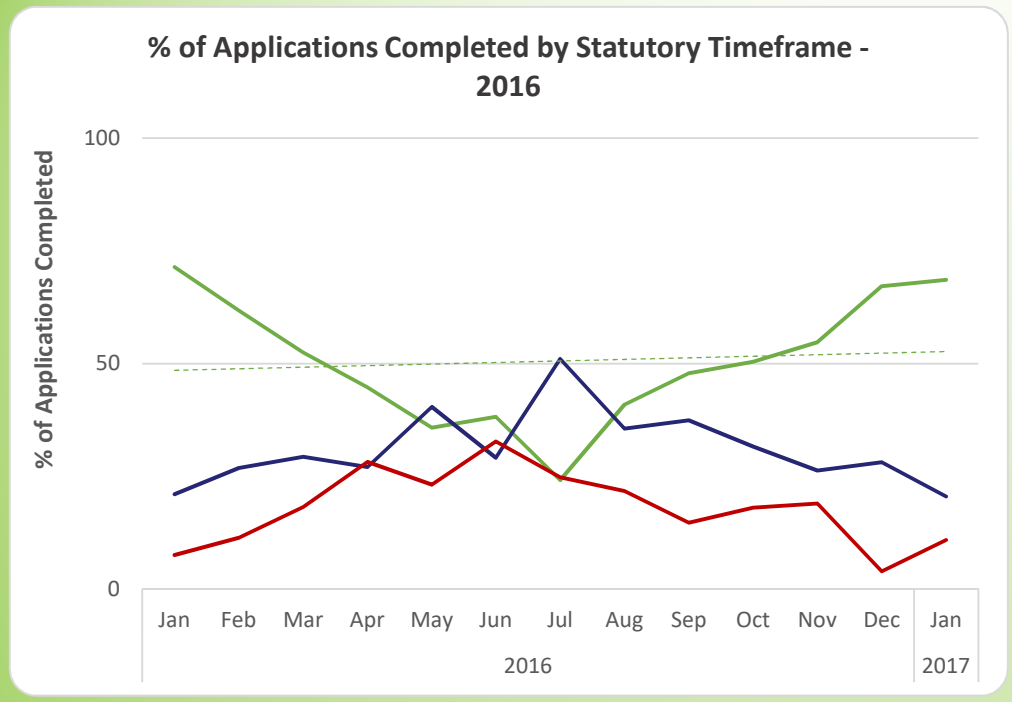


ACVM in numbers – *App. types*

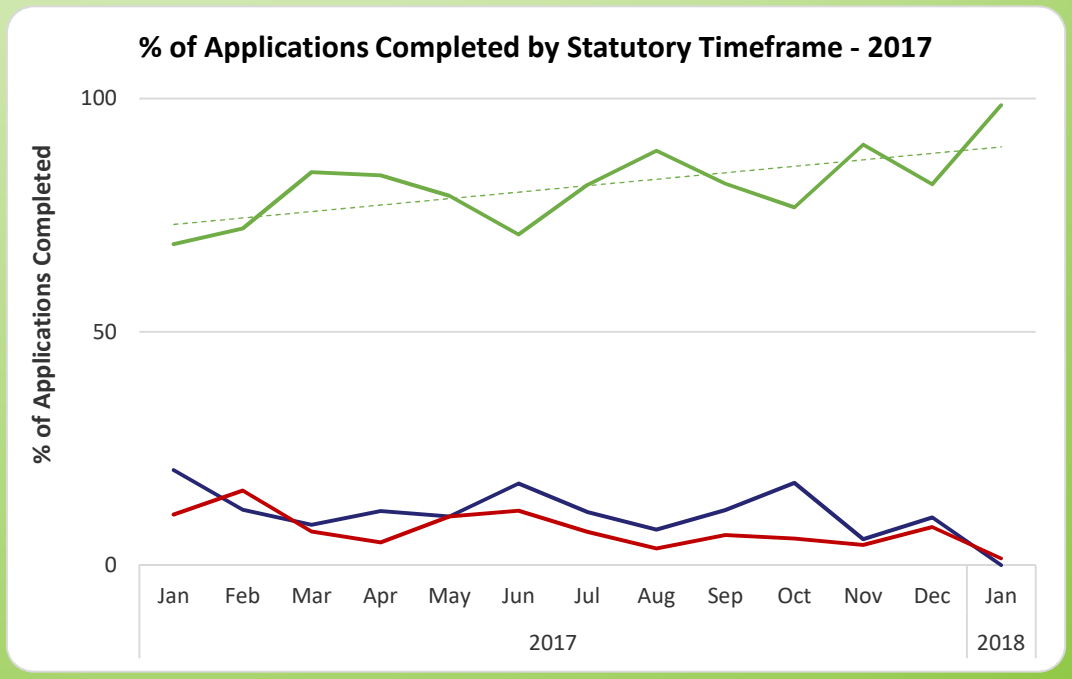


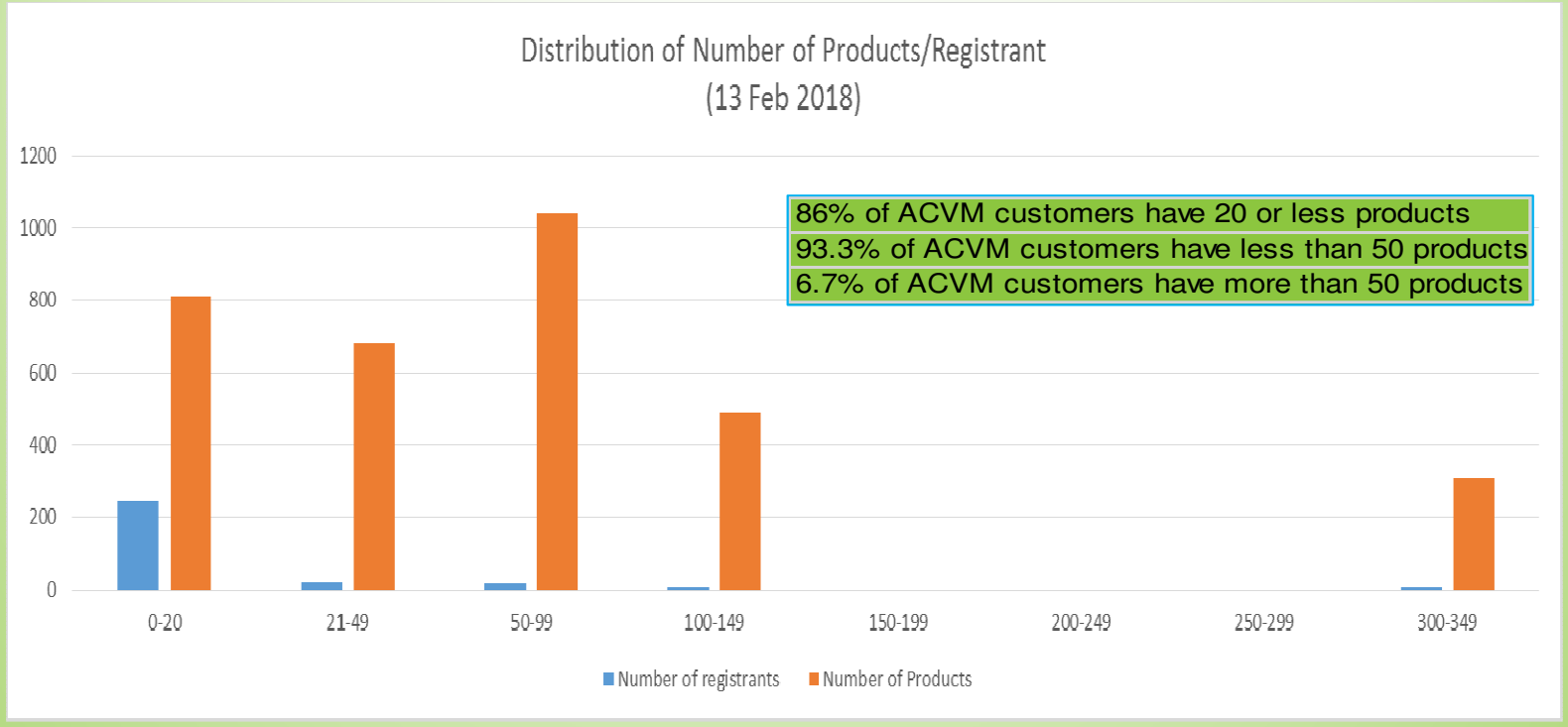
ACVM in numbers – *Processing Time*

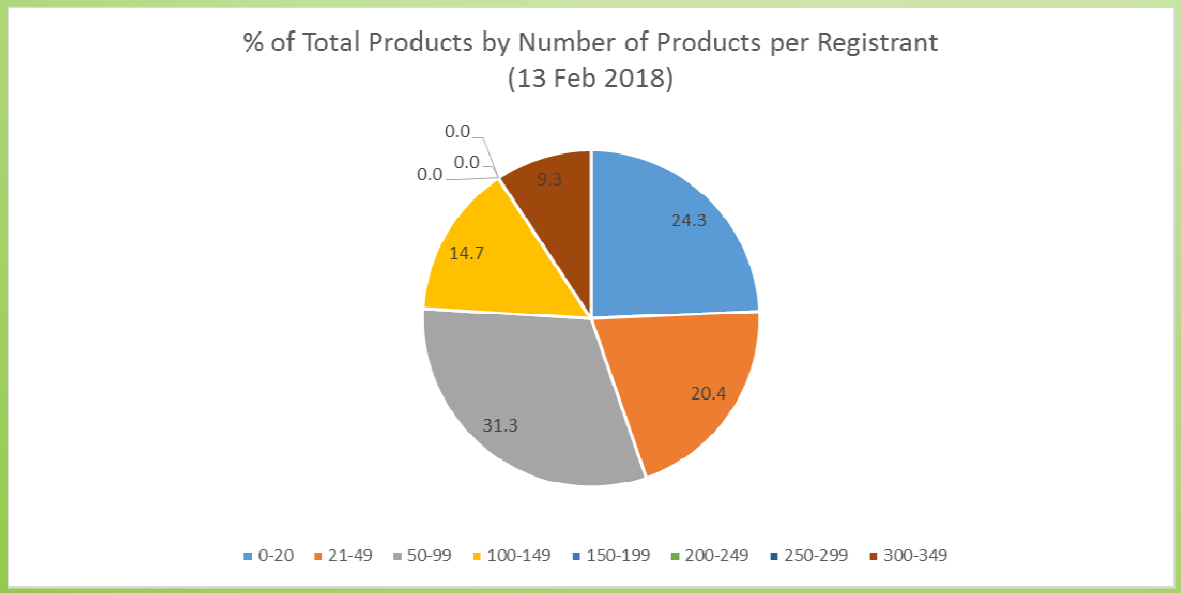




- < 40 working days
- 41 – 79 working days
- 80+ working days







Bayer New Zealand Limited	309
Zoetis New Zealand Limited	146
Adria New Zealand Ltd	121
Merial New Zealand Limited	117
Orion Agriscience Limited	106
Nufarm Limited	95
Agpro (NZ) Ltd	92
Schering-Plough Animal Health Ltd	91
Shandong Rainbow International Co., Ltd.	89
Virbac New Zealand Ltd	89

ACVM in Numbers – *Other Authorisations*

	2016	*2017*	*2018 (to date)*
Special Circumstances	138	138	6
Maintenance Compounds (non-dairy)	558	789	47
GMP Audits (site days)	24 (57)	22 (46)	33 (50)
PS & RTT OPs	15	12	1
RVM Seller OPs	5	33	1
Data Assessments	28	11	0
Deviations	40	22	1

ACVM in Numbers – *Post Registration*

	2016	*2017*	*2018 (to date)*
Compliance Matters	50	91	14
- Recalls	5	8	0
Batch Variations	20	21	2
Rapid Alerts	33	15	1
AERs	1222	1192	110
Ministerials	43	41	17
Residue Investigations	19	17	16

Admin Reminder - Contacting ACVM

- 1st point of call –

  Contact your Operations Adviser for any questions/application updates/meeting requests etc.

- Please don't email the manager for questions about your application (progress report), meeting requests, general issues unless you have a specific personnel complaint.

  approvals@mpi.govt.nz

- There are also email addresses for dealing with compliance/RVM sale/AERs – to be provided later on.

Admin Update

- Building Move
- Branding changes
  - Fisheries New Zealand
  - Forestry New Zealand
  - Biosecurity New Zealand
  - New Zealand Food Safety

ACVM Workshop - Winter 2018

Proposed Date:

- Friday 27th July
  (Te Papa, Wellington)

Ideas for topics are welcome

Please email your suggestions for topics to your ACVM contact or discuss with one of us today


Thank
you!

Ministry for Primary Industries
Manatū Ahu Matua

Approvals Operations Team Update
ACVM Workshop

23 February 2018

Shaleen Narayan & Teresa Robinson

Approvals Operations

Branch planning, systems & support

www.mpi.govt.nz

Approvals Operations Team

- Approvals Operations Team - overview
- Application changes as of 1 January 2018
- Submission Errors
- Electronic Submissions
- General update

ACVM Operations Staff

Maree Zinzley
MANAGER APPROVALS OPERATIONS
Approvals Operations

Daniela Foote
Adviser
Approvals Operations

Jessica Gautrey
Adviser
Approvals Operation

Teresa Robinson
Adviser
Approvals Operations

Vuyisile Mpofu
Adviser
Approvals Operations

Shaleen Narayan
Adviser
Approvals Operations

Lee Jacobs
Adviser
Approvals Operations

Sara Van Roy
Adviser (Enquires)
Approvals Operations

Approvals Operations Team

We work across four different pieces of legislation:

- Food Act 2014
- Wine Act 2003
- Animal Products Act 1999
- Agricultural Compounds and Veterinary Medicines 1997

Approvals Operations Team - ACVM

- First point of contact for the registrants
- Administrative pre-screen of ACVM applications
- Pre and post application work for all types of approvals
- RR/C9s are now completed by Operations Team, if any technical expertise is required we consult the technical team.
- Carry out day to day invoicing functions for all applications

Approvals Operations Team - ACVM

- Upload approved labels and Delegate Decisions to the web register
- Peer review applications to ensure trade name products are compliant with their conditions of registration
- Follow-up on all correspondence, complaints and enquiries
- Support Border control for ACVM products

Application changes as of 1 January 2018

- In the September news "What is changing?" we advised that MPI is changing the registration expiry period for trade name products from **3 years to 5 years** (unless a shorter period is required for risk management purposes).
- MPI is changing the processing of **Variation** and **Renewal** applications, so that all applications (when granted) will be issued with a new registration expiry date.
- This became effective for all applications formally received after the 1st January 2018

Application changes as of 1 January 2018

- Simultaneous Renewal and Variation applications will **not** be accepted.

- If you wish to submit a C2 and RR Application and the product is due to expire within 3 months of submission, you must submit a RR first (with NO changes). Once the RR is finalised, then you can submit the C2 application.

- Some **minor** C9 (purely admin) changes can still be accepted with renewal applications.

Application changes as of 1 January 2018

- For **every** application you will need to submit a PDS and label along with the applicable form(s).

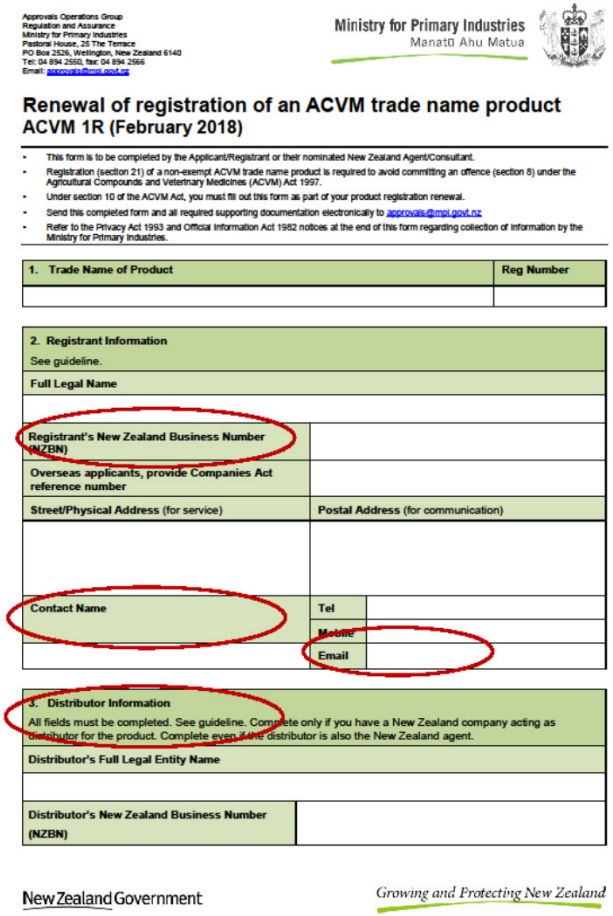
- Please note the application forms are currently being updated, please check out our website to ensure the latest version is submitted.

In addition:

We will be charging for time taken to assess information submitted to satisfy Conditions 86 or 101, where the assessment occurs outside of an application.

Agricultural Compounds and Veterinary Medicines (Fees, Charges, and Levies) Regulations 2015 Schedule 1 (21)

Changes to the ACVM 1R Form



Approvals Operations Group
Regulation and Assurance
Ministry for Primary Industries
Pastoral House, 25 The Terrace
PO Box 2526, Wellington, New Zealand 6140
Tel: 04 894 2550, fax: 04 894 2566
Email: approvals@mpi.govt.nz

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Manatū Ahu Matua

Renewal of registration of an ACVM trade name product
ACVM 1R (February 2018)

- This form is to be completed by the Applicant/Registrant or their nominated New Zealand Agent/Consultant.
- Registration (section 21) of a non-exempt ACVM trade name product is required to avoid committing an offence (section 8) under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- Under section 10 of the ACVM Act, you must fill out this form as part of your product registration renewal.
- Send this completed form and all required supporting documentation electronically to approvals@mpi.govt.nz
- Refer to the Privacy Act 1993 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

1. Trade Name of Product	Reg Number

2. Registrant Information See guideline.	
Full Legal Name	
Registrant's New Zealand Business Number (NZBN)	
Overseas applicants, provide Companies Act reference number	
Street/Physical Address (for service)	Postal Address (for communication)
Contact Name	Tel
	Mobile
	Email

3. Distributor Information All fields must be completed. See guideline. Complete only if you have a New Zealand company acting as distributor for the product. Complete even if the distributor is also the New Zealand agent.	
Distributor's Full Legal Entity Name	
Distributor's New Zealand Business Number (NZBN)	

New Zealand Government

Growing and Protecting New Zealand

Submission Errors

- Please ensure the applicant statement on the PDS and application form(s) is signed and dated with the **submission date**.

- Note: if an updated PDS or label is provided after the application has been submitted, name the file correctly and update the date.

- Submit all the required documentation
  - Renewal: Updated ACVM 1R form, complete PDS and Label
  - Variation: ACVM 1V form, complete PDS and Label (with tracked changes) and any other relevant forms and data.

Submission Errors

- Identification of Confidential Information for the Purpose of Data Protection (ACVM1DP) should be submitted for **all A1, A2, B2, Prov's, C4-C8 applications**

- Every time MPI requests further information, your application becomes 'pending' and remains at the bottom of the queue with the following outcomes:
  - Delayed approval – (the 40 working day regulatory timeframe starts once we receive a complete application (for RR or C9's) or is formally received (accepted at pre-screen)
  - Increased cost - we do charge for extra time taken on applications and application withdrawals.
  - Re-Work – causing additional time spent

Electronic Submissions

- ACVM is now paperless as of 1st November 2017

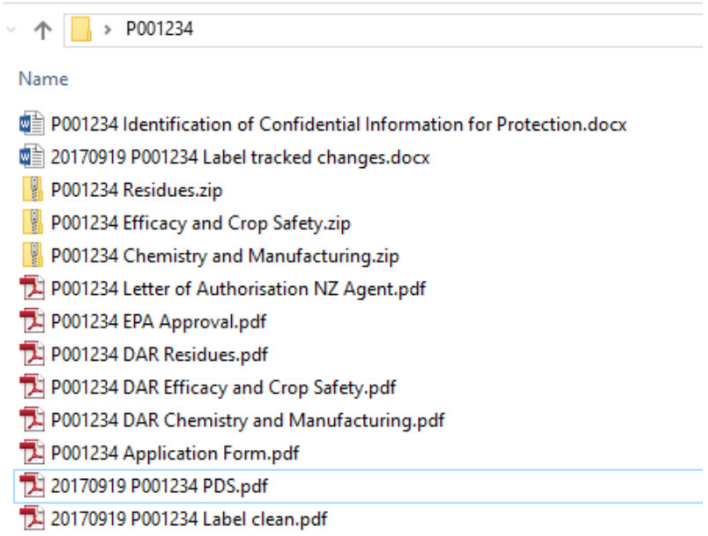
- Please have a read of our guideline for E-files, it covers the requirements below:
  - Methods used for submission of E-Files
  - Language
  - File format and source
  - Requirements for creating PDF files for electronic submission
  - ACVM E-File naming convention
  - Structuring E-Files for submission
  - Submission of confidential E-Files by third parties

Electronic Submissions

- These are common submission errors:
- Files names:
  - ‘Special’ characters impede search capability in the MPI system. File name cannot contain the following characters:

/	\	*	&	:	?	(	)	<	>	{	}

  - Dates are required for PDS and Label file names e.g. 20170919 P001234 PDS



Electronic Submissions

- We accept electronic signatures - we no longer require documents to be printed off, signed and then scanned back to us.

- PDF documents should be preferably created directly from their electronic source documents.

General update

In Summary:

- All applications receive a **5 year** expiry date unless a shorter period is required for risk management purposes.
- Simultaneous renewal and variation applications are **no longer** accepted.
- Renewal reminder emails are sent 3 months prior to the expiry date, followed by a warning email if renewal is not received.
- We are now publishing Delegate Decisions for RR and C9 approvals on the register.

Thank you

Ministry for Primary Industries
Manatū Ahu Matua

Changes to the ACVM Regulations
ACVM Workshop 23 February 2018

Warren Hughes

ACVM Group
Systems Audit, Assurance and Monitoring

www.mpi.govt.nz

Background

The Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011:

- Set out rules for products exempt from registration
- List products exempt from registration in schedules
- List prohibited substances

Why change was required

- Some regulations are **unclear and lack certainty** for both industry and government
- Some regulations have not kept up to date with **changing risk profile** of some agricultural compounds, or evolving agricultural practices
- **Novel products are entering the market** that are low risk and should not require registration, but they **don't fit existing exempt categories**.

Snapshot of changes:

- **Consolidate existing exempt groups** from 41 currently to 34:
  - Amalgamate 6 groups related to topical veterinary preparations
  - Combine 3 groups related to compounds to protect plants from climate
- **Amend entry descriptions and/or conditions** of a further 15 groups
  - Create standardised conditions to apply across several groups
  - Remove some specific conditions in favour of ‘fitness for purpose’ obligations

Snapshot of changes (cont):

- **Create 6 new categories** of exempt compound groups
- **Amend specific regulations** – in particular definitions (Regulation 3)

Public Consultation

- The public discussion document was consulted on between 7 September 2017 to 19 October 2017
- 15 submissions were received
- Key points from submissions:
  - No major concerns
  - Points of clarification eg defintions
  - Support for majority of proposed changes

Current and Next Steps

Current

- Submissions have been summarized
- Considering relevant submissions for further discussion

Next

- Develop a paper on recommendations for Cabinet
- If Cabinet supports the recommendations, then PCO will be asked to draft amendment regulations

Timeline

- Difficult to determine
  - New Government
  - Legislative programme

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Registration Conditions ACVM Workshop 23 February 2018

Sarah Lester & Rich McKinley

ACVM Group

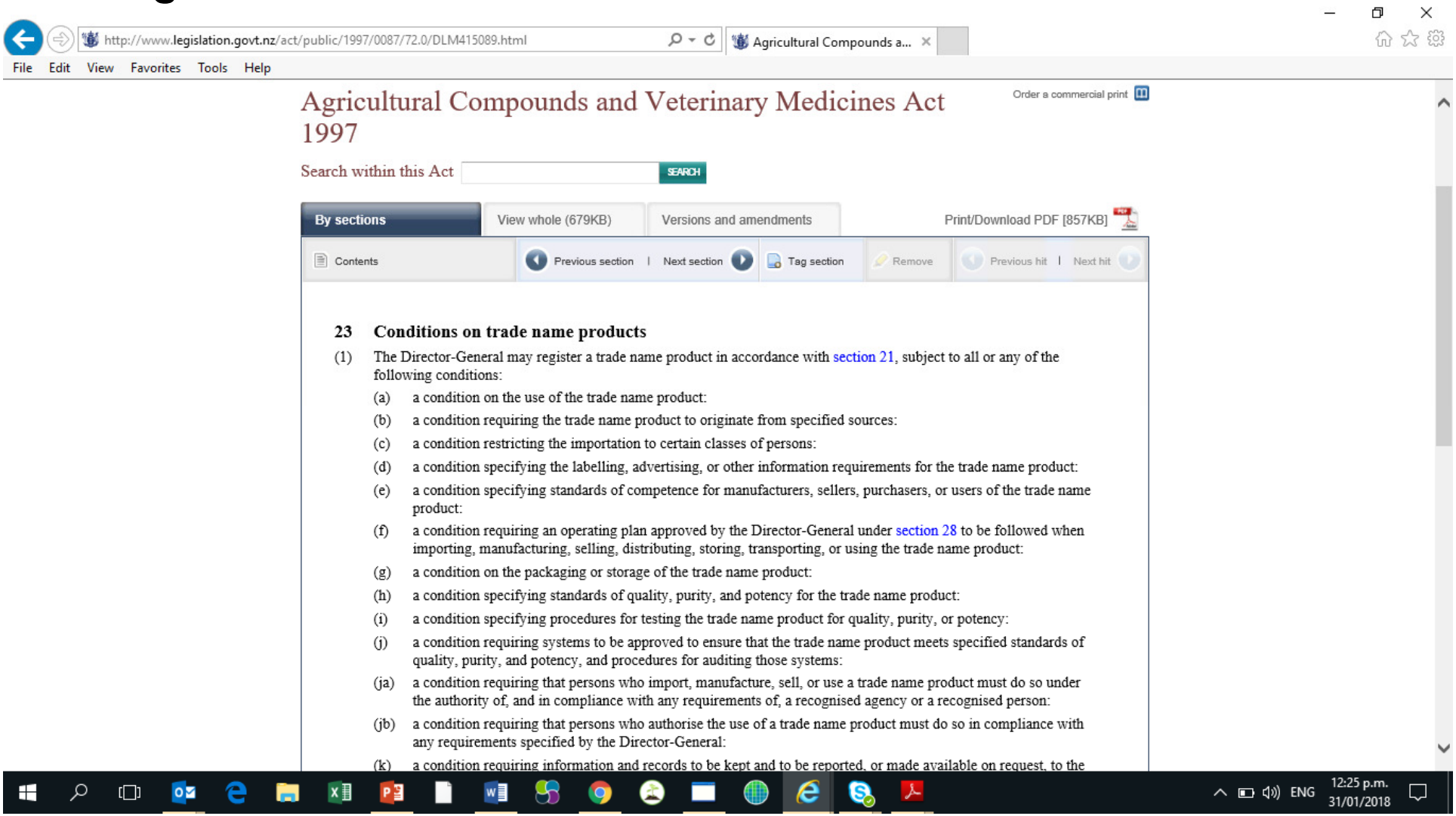
Systems Audit, Assurance and Monitoring

www.mpi.govt.nz

The purpose of conditions

- The main way for ACVM to manage risks associated with agricultural compounds
- May relate to substances, products, systems, or people's behaviour
- May be imposed:
  - directly by the Director-General of MPI when an agricultural compound is registered; or
  - generally, via Regulations.

Legislative basis: Section 23 of ACVM Act 1997



http://www.legislation.govt.nz/act/public/1997/0087/72.0/DLM415089.html

Agricultural Compounds a...

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Agricultural Compounds and Veterinary Medicines Act 1997

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

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

23 Conditions on trade name products

(1) The Director-General may register a trade name product in accordance with section 21, subject to all or any of the following conditions:

(a) a condition on the use of the trade name product:

(b) a condition requiring the trade name product to originate from specified sources:

(c) a condition restricting the importation to certain classes of persons:

(d) a condition specifying the labelling, advertising, or other information requirements for the trade name product:

(e) a condition specifying standards of competence for manufacturers, sellers, purchasers, or users of the trade name product:

(f) a condition requiring an operating plan approved by the Director-General under section 28 to be followed when importing, manufacturing, selling, distributing, storing, transporting, or using the trade name product:

(g) a condition on the packaging or storage of the trade name product:

(h) a condition specifying standards of quality, purity, and potency for the trade name product:

(i) a condition specifying procedures for testing the trade name product for quality, purity, or potency:

(j) a condition requiring systems to be approved to ensure that the trade name product meets specified standards of quality, purity, and potency, and procedures for auditing those systems:

(ja) a condition requiring that persons who import, manufacture, sell, or use a trade name product must do so under the authority of, and in compliance with any requirements of, a recognised agency or a recognised person:

(jb) a condition requiring that persons who authorise the use of a trade name product must do so in compliance with any requirements specified by the Director-General:

(k) a condition requiring information and records to be kept and to be reported, or made available on request, to the

ENG 12:25 p.m. 31/01/2018

Ministry for Primary Industries
Manatū Ahu Matua

Certificate of Registration

This Certificate of Registration is issued to:

J Bloggs Ltd

Of **Level 1 Footrot Flats, High Street, Waipukurau**

The agricultural chemical known by the trade name of: No. **P012345**

Herbicide G

Is hereby registered under the Agricultural Compounds and Veterinary Medicines Act 1997 on the 19th day of February 2018

The conditions placed on this approval are attached.

This Registration expires on the 19th day of February 2023

(Date of first registration was 20 October 2000)

Maree Zinzley
Manager Approvals Operations
Regulation and Assurance

Signed:

Certificate Issued on 19/02/2018

This certificate is a record of the product approval that was current on the date the certificate was issued. It reflects the public register entry for the product at that time. From time to time the wording of registration conditions may change, resulting in a change on the public register for that product. As a certificate is not necessarily re-issued for such changes, consult the public register for the current approval of the product

Page 1 of 3

19/02/2018

New Zealand Government Growing and Protecting New Zealand

Maree Zinzley
Manager Approvals Operations
Regulation and Assurance

CONDITIONS

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

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

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.

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.

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.

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 continued use of the product.

19/02/2018

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Growing and Protecting New Zealand

Maree Zinzley
Manager Approvals Operations
Regulation and Assurance

CONDITIONS

ensure that residues of any substance in the product that may occur in:

human consumption produced from plants or plant material treated with

Animal Products Act 1999 intended for human consumption
plants or plant material treated with the product to food producing
either:

ent Food Notice: Maximum Residue Levels for Agricultural

he current Food Notice: Maximum Residue Levels for
residue level for that substance has not been specified"

less the use is approved as part of this registration.

er advice about the on-going stability of the product for use

e market place where evidence shows it is no longer
to its use, when stored in line with the manufacturers

19/02/2018

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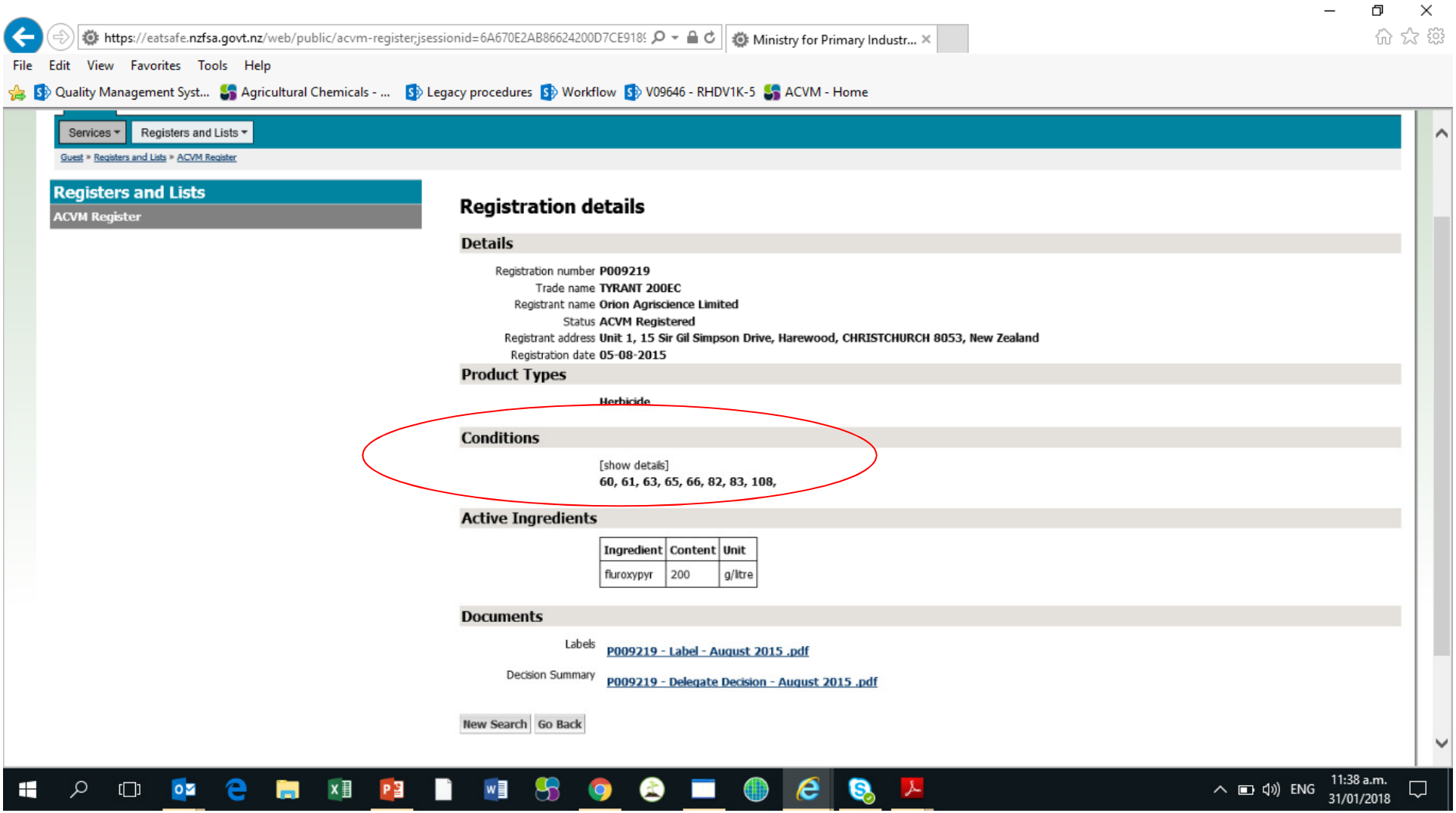
Conditions can also be found on our web register:



Registrant's responsibilities

- Check conditions on registration
- Comply with them - throughout the whole registration period!

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Common Conditions
Ag Chem & Vet Med

Growing and Protecting New Zealand

www.mpi.govt.nz

Product Manufacturing:

- Condition 60: *"the manufacture of the product must, at all times, conform to the product and manufacturing specifications approved as part of this registration"*

- Condition 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."*

Examples:

- *Can't change manufacturing sites, formulation. Must meet release specifications.*
- *Retailers can't decant product and resell*
- *Distributors and retailers should keep product under approved storage conditions*

In summary, conditions 60 and 63 are imposed to ensure that PRODUCT complies with the ACVM approved particulars throughout shelf-life and retail sale.

Labelling and Advertising:

- Condition 61: *"the product must be labelled in accordance with the product and manufacturing specifications approved as part of this registration"*

- Condition 66: *"No advertisement for the product may:*
  - *include content or be presented in a manner that does not conform to the approved product and manufacturing specifications (this includes approved uses);*
  - *contain false or misleading claims, statements or information in relation to the product; or*
  - *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."*

Examples:

- *Don't make label changes without prior approval*
- ***All** advertising and marketing material must comply with the registration – can't infer additional claims etc on website.*
  - *If selling through retail chains, exercise good product stewardship throughout product life.*

New Information

- Condition 65: "*The registrant must, as soon as practicable after becoming aware of new information, advise MPI 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.*"

- For example, additional trial work suggests that product is not safe on a particular cultivar.
- Adverse Events are covered under different conditions.

New Information – Report to ACVM

- **Product Quality** – Manufacturing or quality issue impacting product safety, efficacy, quality
- **Out of Specification** (OOS)
- **New trial work** which contradicts registered information

  Condition 65 (AC + VM)

  Condition 37 (VTA)

- **Must be reported to ACVM as soon as practicable**

New Information – AE Trends

- **International AE** trends or label changes due to AEs are considered '**new information**'
- **Any trends identified** during Product Quality reviews – indicating a potential impact to quality which could impact profile of product
- **Report to ACVM as soon as practicable**

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Agricultural Chemical Conditions

Growing and Protecting New Zealand

www.mpi.govt.nz

Adverse Events

Condition 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 MPI 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.

Definition AE - Agricultural Chemicals

Any observation in target crop, species, claim or disease or non-target plants that is unintended, and that occurs after the use of an agricultural chemical. This may include:

- unintended effects
- unacceptable residues
- **lack of efficacy**
- Good Agricultural Practice (GAP) issues
- application issues (faulty sprayers, poor quality product, sedimentation, and compatibility issues).

Conditions on Users

Condition 83: *Any person using the product must ensure that residues of any substance in the product that may occur in: plant material or animal material must not exceed the specified residue level in the current Food Notice: Maximum Residue Levels for Agricultural Compounds;*

(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 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.

Conditions on Users

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

At registration, the registrant is required to use a ‘By law…’ label statement.

Note: Even though these conditions are for users, good product stewardship means that you should make users aware of obligations.

Stability

Condition 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".

Stability

In summary, condition 108 is imposed to ensure the PRODUCT complies with the ACVM approved specifications throughout the product's retail sale.

As long as the product is on the shelf, the product must comply with the approved specifications

The registrant should have processes in place to ensure that the product meets the shelf life requirements.

Note: if the registrant cannot ensure the product meets the shelf-life requirements by any means – expiry date should be provided

Stability

Examples of how shelf life could be managed without a label statement to ensure compliance with condition 108:

- testing batches of the product already in the market place
- establish an ongoing product stability programme, where manufactured samples are retained and re-tested

Note: this requires that distribution records of batches sold are kept so that appropriate action can be taken if required.

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Veterinary Medicine Conditions

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GMP

- Condition #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.*

- *For vet meds this means GMP*

Adverse Events

- Condition #64
- *The registrant must investigate the significance of every adverse event associated with the use of the product; and report to MPI within 20 working days the outcome of this investigation.*
- *The registrant must notify MPI 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.*

Definition AE - Vet Medicines

An **adverse event** is any:

- negative physiological or pharmacological side effect
- target animal safety issue
- residue issue
- **lack of efficacy**
- or alleged interactions with other products or compounds

Definition AE – Vet Medicines

Includes all **unfavourable** and **unintended** events associated with the use of the product in an on-label or off-label manner.

- Residues – IS grades
- Suspected lack of efficacy (note: product may or may not be the cause)
- Multiple product use/interactions

Residues

- Condition #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

Examples

- This condition places the residue requirement on the person using the product.
- Whether on label use or not

- Important for all end users to understand their responsibility
- Withholding periods help to reduce residue risk
- Off label use is ‘at risk’

Animal Welfare

- Condition #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.*

Examples

- This condition allows for off-label use

BUT

Any use of this product off label must be supported by an appropriately qualified person.

- Use of sheep anthelmintics in goats/deer
- Combination therapy

Restricted Veterinary Medicines

- Conditions #69-72

- A range of conditions placed on the products restricting:
  - Who to sell the product to
  - Who can sell the product
  - Who can purchase and use the product

Examples (#69-72)

Note – restriction is not only to Veterinarians

- Conditions specifically allow for RVM's to be:
  - Sold to
  - Sold by
  - Used by

  A person acting in accordance with a relevant operating plan approved under section 28

- ACVM group assess and approve Operating Plans which allow for use of restricted products
- Usually Universities, research facilities

Additional Conditions – AgChem & VetMed

- Condition #34

An annual report of sales by month must be supplied by the registrant to the Ministry for Primary Industries

Commonly applied to antibiotic products.

Additional Conditions – AgChem & VetMed

- Condition #86

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 MPI for approval prior to sale of product from this new site.

- Condition #101

The registrant must provide additional information specified by the ACVM Group at or before the expiry of the current product registration period.

Consequences

- It is an offence under the Act to knowingly not comply with the conditions imposed on the authorisation.

- If you fail to comply with the relevant conditions, MPI may place a prohibition on the importation, manufacture, and sale of the product.

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Maintaining Registrations
ACVM Workshop

23 February 2018

Awilda Baoumgren

ACVM Group

Systems Audit, Assurance and Monitoring

www.mpi.govt.nz

Maintaining Registrations: Overview

- Product maintenance and variation applications
- Managing new information
- Adverse Event Reporting

The Purpose of the ACVM Act

a) Prevent or manage risks associated with the use of agricultural compounds, being –

   (ia) risks to public health; and

   (i) risks to trade in primary produce; and

   (ii) risks to animal welfare; and

   (iii) risks to agricultural security

b) Ensure that the use of an agricultural compound does not result in breaches of domestic food residue standards

c) Ensure the provision of sufficient consumer information about agricultural compounds.

The Purpose of the ACVM Act

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**

The Product is Registered – Now What?

Registered Trade Name Product

- Product manufacture established and approved
- Product identity and risk profile characterised
- Risk management controls in place

→Product Data Sheet

→Product Label

→Registration Conditions

→MRLs (where applicable)

Product Maintenance and Variation Applications

Changes to the Product Manufacturing or Identity

Application Type		Data Volume				
		Chemistry & Manufacturing	Residue	Efficacy	Safety	Toxicology
C1:	Change in formulation	◆	◆	◆	◆	
C2:	Change in manufacturing process	◆				
C3:	Change in shelf life or packaging	◆				

Changes that impact the PDS (current state)

Changes to the Product Manufacturing or Identity

<u>ALL proposed changes</u> must be explained for both chemistry/stability of the product AND impact on the risk profile

It is not sufficient to state that efficacy, safety and residues are not impacted

- Must at least provide a technical discussion of why they are not impacted

Administrative Changes

Application Type	Data Volume				
	Chemistry & Manufacturing	Residue	Efficacy	Safety	Toxicology
C9: Administrative changes	Explain the changes in a letter				

Changes that impact the administrative content of the PDS and label (current state)

Changes to the Product Manufacturing or Identity

Administrative Variation Applications (C9)

- For changes to the **product documentation including registration renewal**, this includes:
  - An updated PDS and/or product label where changes are proposed that affect them → always with RR
  - As appropriate: authorisation letters, new GMP certificates, other documentation
- **Important to ensure the proposed change is administrative**
  - Example: Label changes to reword claims or safety warnings may need assessment

Changes to the Product Use Risk Profile

Application Type		Data Volume				
		Chemistry & Manufacturing	Residue	Efficacy	Safety	Toxicology
C4:	Additional target species		◆	◆	◆	
C5:	Additional disease/condition			◆		
C6:	Change of dose regime		◆	◆	◆	
C7:	Change to method of administration		◆	◆	◆	
C8:	Change in withholding period		◆			

Changes that impact the efficacy, safety, or residue profile

Changes to the Product Use Risk Profile

- For changes to the **target species/crop, approved use patterns,** and **approved claims**:
  - Technical discussion of the impact on efficacy, safety and residue profiles
  - All supporting data and documentation including any literature references

➢ **Remember that most changes will affect more than one risk category – discuss accordingly!**

Changes to the Product Use Risk Profile

- For changes to the **withholding period**:
  - All associated data and references, with technical discussion
  - Discussion of any trade impacts known
  - If the application involves a change in the MRL(s), the new MRL(s) should be explained and discussed
  - ➢ Can consider alignment to overseas MRLs but must be supportive of New Zealand GAP

A Variation Application Will NOT Be Accepted If…

- Changes made that have not been identified/discussed
- Data is absent, incomplete, or does not adequately address the risks
- No deviation request or explanation for lack of data
- References not provided when argument relies on them
- Risk areas stated to be “not applicable”
- Data assessment non-conformances not addressed
- Administrative errors that impact the assessment
  - Incorrect or missing information in the PDS or label
  - Incorrect or missing application forms and documents
- VMs/VTAs: Lack of evidence of current GMP approval

New Information

Managing New Information

- Registrants are conditionally required to report any new information that could impact the risk profile of the product or the validity of product registration as soon as they become aware of it
- May trigger the need for variations to registration, changes to the product itself (formulation, etc.), or a reassessment of the product or group of products affected
- New information can also be obtained by MPI by direct review of literature or other information sources, from industry, and from other domestic or international regulatory authorities

Managing New Information: Registration Conditions

Condition 65 (ACs and VMs):

*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.*

Managing New Information: Registration Conditions

Condition 37 (VTAs):

Ongoing obligations:

The registrant must provide an annual summary of adverse events to the Ministry for Primary Industries. Adverse events which have serious implications for the continued use of the product must be notified immediately.

*The registrant must also advise the Ministry for Primary Industries of **any new studies or data** that contradict information previously supplied.*

What is ‘New Information’?

“… relevance, reliability or correctness of information provided at the time of registration and upon which the decision to register the product was made.”

- This can relate to any information used to inform the decision
  - Product chemistry and manufacturing information
  - Stability data
  - Packaging and distribution information
  - Any other content in the PDS or dossiers

What is ‘New Information’?

Risks to public health

- New studies to suggest there is a previously undiscovered risk of a compound being a risk
- HSNO reassessment for user/operator/consumer safety
- Antimicrobial resistance

What is ‘New Information’?

Risks to trade in primary produce

- New data to suggest residue profile was not adequately characterised at initial assessment – research into new use patterns, AERs
- Residue detections despite use as per label
- Overseas changes that impact trade
- Can trigger review of ‘does not result in breaches of domestic food residue standards’ risk area – MRL compliance

What is 'New Information'?

Risks to animal welfare

- Safety or inefficacy issues identified in domestic AERs
- Safety or inefficacy issues identified in overseas authorities where products are similar or identical

Risks to agricultural security

- Biosecurity risks arising from use such as contamination
- Failure of the product to protect against a biosecurity threat

What is ‘New Information’?

Ensuring the provision of sufficient consumer information

- Must provide enough information to use a product safely and effectively in all situations
- This includes compliance with MRLs (WHP advice)
  - Label **does not** do this → label needs to be revised
  - Label **cannot** do this → additional restriction may be required (e.g. RVM status, use only under an operating plan)

New Information has been Submitted: Now What?

- The outcome of the review of new information depends on what area(s) of the risk profile is impacted
  - Update information on file for the product
  - Variation application to re-evaluate risk profile and affect changes to the registration
  - Reassessment of the product to establish new risk profile and management controls
  - Reassessment of an entire group of products to establish new risk profile and management controls

Adverse Event Reporting

Adverse Event Reporting

- An **adverse event** is any observation in animals or plants that is **unfavourable** and **unintended**, including:
    - Side effects after application or treatment
    - An animal or crop safety issue
    - A residue issue
    - Lack of efficacy
    - Interactions with other products

Adverse Event Reporting Conditions

Condition 82 (Agricultural Chemicals)

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 Event Reporting Conditions

Condition 64 (Veterinary Medicines)

*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.***

Adverse Event Reporting Conditions

Condition 37 (VTAs):

Ongoing obligations:

*The registrant must **provide an annual summary of adverse events** to the Ministry for Primary Industries. Adverse events which have **serious implications** for the continued use of the product must be **notified immediately.***

The registrant must also advise the Ministry for Primary Industries of any new studies or data that contradict information previously supplied.

Adverse Event Reporting: Investigation

- **Gather as much detailed information as possible**
  - Use pattern, number affected, concurrent use, etc.
  - Beware of false assumptions
- **Characterise the event**
  - Is it product related?
  - If product related, is it a known effect or something novel?
  - ➢ Will help establish causality and predict whether other adverse events are expected

Adverse Event Reporting: Investigation

- **Determine if the event is manufacturing related**
  - Review the manufacturing records for any variations or faults that may result in an issue
  - If something is found, may need to go back to the manufacturer (or contract manufacturer) to investigate further
- **Ensure investigation includes the entire life cycle including manufacturing, distribution, and end use**
  - The problem could stem from manufacture, transport, or user error → investigate all possibilities

Adverse Event Reporting: Causality

Probable – reasonable association no other plausible explanation

Possible – one of the possible plausible explanations

Unlikely – sufficient evidence for other more likely explanation

Unknown – insufficient information or evidence to draw a conclusion

Adverse Event Reporting: Reporting

- **Include all details of investigation and causality are reported in the AER form**
- **Provide any additional detail relevant to the manufacturing investigation and outcomes**
- **Remember the time frame and content requirements in the conditions**

Adverse Event Reporting: Reporting

- **Remember that the responsibility to manage AERs and ensure MPI receives a report sits with the registrant**
  - Conditional requirement of registration that a report is submitted
  - Don’t assume the manufacturer or another entity will investigate and/or report the issue

Adverse Event Reporting: Outcomes

Review risk management

- Registrant: is this a “one-off” or an ongoing issue?
- MPI: are the controls on the product still adequate?

Identify and implement corrective actions

- May include update to label warnings, change to manufacturing process/controls, change in storage conditions
- Can be actioned immediately or at the next update, depending on level of risk and adequacy of current controls

Adverse Events: Ongoing Obligations

Ongoing product management

- Product stewardship programme is up to date and is adaptable

Trend Analysis

- Regular review and trending - is there an increase in number or change in type of reports received?

Action Change

- Submit product variations and/or label changes as required
- Action any internal changes needed to better manage risk

In Summary…

The ACVM Team Expect…

Product Maintenance and Variations

- All information needed for an assessment is complete and included in the application package
- The information provided is clear, logical, and explains all changes with respect to the risk profile
- The registrant is practising good product stewardship at all times

The ACVM Team Expect…

New Information

- The registrant is seeking out new information on products and their actives to ensure they have the most up to date information
- Any new information is assessed relative to the ingredient's or product's risk profile to determine if action is required
- Any significant new information is reported to MPI as soon as practicable

The ACVM Team Expect…

Adverse Event Reporting

- All adverse events are monitored and reviewed, with all significant adverse events reported to MPI immediately
- Investigations will be complete and detailed, and causality determinations will be evidence-based and objective
- The registrant will action corrective actions where appropriate, and continue to monitor and trend adverse events

Thank You!

Ministry for Primary Industries
Manatū Ahu Matua

Contracting Third Parties ACVM Workshop

23 February 2018

Francie Olliver

ACVM Group
Systems Audit, Assurance and Monitoring

www.mpi.govt.nz

Responsibilities - Ag Compounds

All Agricultural Compounds (registered or exempt) must:

- Be fit for their intended use
- Comply with the requirements of the product registration (or exemption conditions)
- Not pose an undue risks (safety, efficacy, residues etc)

Responsibilities under ACVM act

Registrant

- **Ultimately responsible** for product compliance with registration

Other parties

- Manufacturers, Distributors, Vets, Wholesalers, Retailers & Users
  (Advertising, storage, prescribing, using)

All have obligations under the ACVM act and regulations

Responsibilities – Third Parties

Contracting an activity to a 3rd Party does not absolve responsibility

- 3rd Party must be carefully chosen
- Each party's responsibilities should be clearly defined
- **Hands-on oversight is required**

Obligations under the ACVM Act remain when 3rd Parties contracted

Commonly Contracted Activities

- Active & Raw Material Manufacture
- **Formulated Product Manufacture**
- Stability Testing
- **QC Laboratory Testing**
- **Packing and Labelling**
- **Warehousing and Dispatch**
- **Distribution (Sales and Marketing)**

Specific Activities Covered

- **Manufacturing**
  - Finished Product (Formulator)
  - Quality Control/Testing
  - Labelling/packing
- **Distributor (sales & marketing)**
- **Warehousing (storage & dispatch)**

ACVM Expectations

Contracted 3rd Party has:

- The required facilities, equipment & expertise
- Applicable licensing or **ACVM approval** (e.g. current GMP certificate for relevant category & scope)
- **Approval by ACVM (Registration Product Data Sheet (PDS)**

Multiple Contracted Parties

More than 1 party can perform different aspects of manufacturing e.g.:

- Manufacture at A/ Testing at B
- Manufacture & testing A/ labelling/packing at B
- Manufacture A, QC testing at C

Responsibilities and relationships between each party must be clearly specified

Sourcing – Supply vs Manufacture

Supplier Vs Manufacturer

- **Supplier (trader/agent)** - commonly source raw materials, active ingredients or finished products from multiple manufacturers
- **Manufacturer –** Actual manufacturing site (ACVM registration of Manufacturer)

Manufacturing Site (physical address) should be qualified and specified in your PDS

Registrant to Specify - Manufacturing Details

The approved product details/particulars must be provided to 3rd Party:

- Active (Technical) material supply
- Raw material, specifications & quality
- Manufacturing methods & equipment
- Packaging Materials/Labelling
- QC Testing methods

ACVM Expectations - 3rd Party Management

3rd Party Oversight includes:

- Qualification of the Company
- Technical Agreements
- Monitoring of Performance

Qualification Process

- Process used to **provide an appropriate level of confidence** that suppliers, vendors and contractors are able to supply consistent quality of materials, components and services in compliance with (regulatory) requirements.
- Prior to outsourcing & until confidence established

Qualification

Includes:

- Due Diligence
- Facility/Capability/Expertise
- Compliance with Regulations/ Licenses
- QMS and QA systems
- Inspections/Audits (by registrant)
- Independent testing
- Other (Safety, Environmental, Social)

Technical (Quality) Agreements

- Sets out responsibilities for each party in relation to Regulatory and Quality (GMP) requirements
- Sits alongside Commercial contract (reference to the other)

Quality & Commercial Agreements must be consistent - both applicable to the same activities.

Quality Agreements - Purpose

- Each Party understands requirements and obligations – no confusion
- Ensure full (& ongoing) compliance with the particulars in the product registration
- Defined responsibilities
- Reporting channels & timelines for communications
- Ensure consistent quality of product

GMP - Manufacturing

GMP/Quality Agreements required for Vet Medicine & VTA manufacturing:

- Compliance to registration (Conditions 60 – 63)
- GMP (ACVM GMP Guide)

Note: Under GMP both **Registrant** & **Manufacturer** required to have Quality Agreement

GMP – Registrant

Required to:

- Assess competence of 3rd Party
- Provide all necessary information (registration details)
- Technical information & any potential hazards communicated
- Ensure product received complies with specifications

GMP - 3rd Party Manufacturer

Required to:

- Hold appropriate licenses (e.g. GMP) and have capability
- Ensure all products & materials are fit for purpose
- Refrain from any activity which may adversely affect quality of product
- Cannot subcontract the activity

Content of Agreements

Should also include responsibilities for:

- **Release for Sale**
- Records/Documentation
- Validation
- Stability studies
- **Change Control**
- What to do if something goes wrong
- Complaints & Recalls
- Allow Audit/inspections by Contract giver

Examples of GMP contracts

Link to examples of Quality contracts:

- http://www.pharmtech.com/quality-agreement-templates
- https://www.gmp-compliance.org/guidelines/gmp-guideline/apic-quality-agreement-guideline-template

Manufacturing workshop slides – examples

Quality Agreements - AgChems & Exempt Products

- GMP not required, but QMS expected
- Technical/Quality Agreement is expected to be in place to ensure quality and conformance
- Minimum requirements of a Documented System for Ag Compounds are stated in Exemption Regs (7- 15)

Agreements – Warehousing & Dispatch

- If 3rd Party is taking Sales orders – then any relevant conditions of registration apply (e.g. **RVM Seller approval** may be required)
- If only Storage, Dispatch etc then still need to agreement to ensure that **storage temperature, security of product is maintained.**

Agreements - Distribution/Marketing

Minimum requirements:

- Relevant aspects of Registration Conditions (e.g. RVMs, AB sales reporting)
- Complaints, Product Recalls
- Storage conditions
- Advertising etc

3rd Party - Monitoring of Performance

Important to monitor 3rd Party performance through various ways:

- Check of product received
- Annual Product Reviews
- Audits/inspections
- Communication
- Review of contract, KPIs etc

Summary – ACVM Expectations

When Contracting 3rd Party:

- Exercise due diligence – qualify the company
- Gain necessary approvals
- Quality Agreements – appropriate controls
- Monitor performance

Wellington on a good day

Ministry for Primary Industries
Manatū Ahu Matua

Reporting Potential or Known Non-Conformances ACVM Workshop

23 February 2018

Francie Olliver

ACVM Group

Systems Audit, Assurance and Monitoring

www.mpi.govt.nz

Non-Conformances – What are they?

Product on the market (or intended for the market) that has been identified (or with cause for concern) that:

- **May not** meet approved release specifications
- Is not of the appropriate quality
- **May not** be fit for purpose
- **May not** represent the data assessed as part of the product registration with respect to animal safety, product efficacy, stability or residues

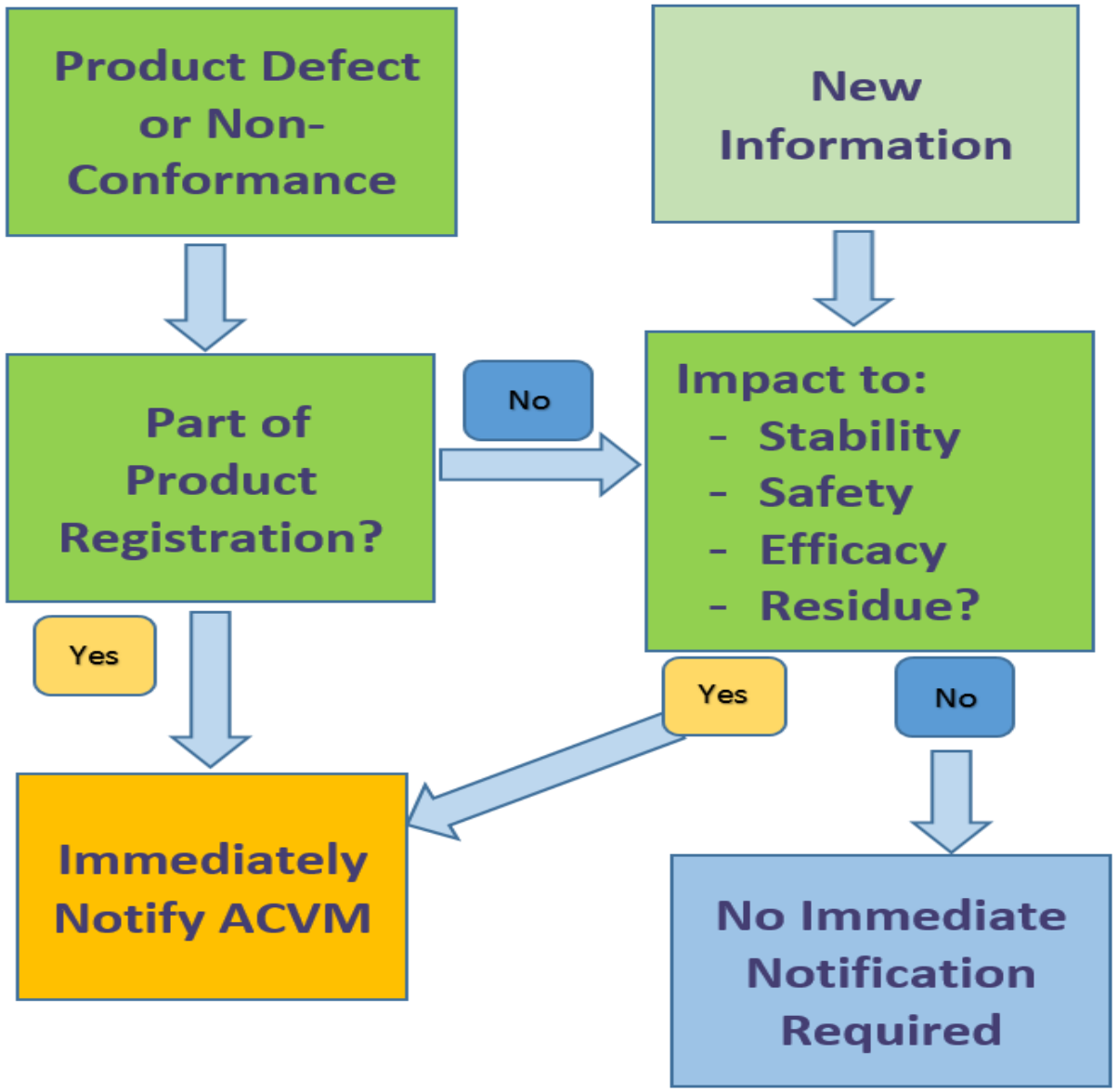
Reporting Potential Non-Conformances

Potential Non-Conformance

- Suspected product issue where there is potential for serious consequences (e.g. safety, residue or efficacy concerns)

- Refer to conditions of registration – as discussed earlier (64, 65, 82)

Decision Tree



Product Quality Defects

Always need to consider the **potential for negative impact to the safety or efficacy** profile of the product e.g.:

- Changed appearance/odour/colour
- Product flowability – ease of administration
- Change in pH (injectable products)
- Sterility/contamination

Examples of Non-Conformances

- Unapproved manufacturing process
- Unapproved AI or FP manufacturer
- Unapproved pack size/packaging
- Product separation - during filling, shipment and storage
- Cross-contamination/Contamination
- Precipitation

Examples of Non-Conformances

- OOS identified during ongoing stability trials
- Incorrect Label used (old version)
- Labelled with unapproved Shelf life
- Decanted into smaller unregistered pack size
- Inefficacy in the field

If in doubt – Communciate with ACVM

Please contact ACVM to discuss

– Operations Adviser or approvals@mpi.govt.nz

- Communicate early - keep us updated

Demonstrate to ACVM you are taking compliance and stewardship seriously

Reporting Timeframes

Report as soon as practicable:

- Non-Conformance with Registration
- Product Quality Concerns (safety or efficacy etc)
- New Information

Product Recalls:

Contact ACVM **immediately** (1 working day) **Prior to initiation (where possible)**.

How to Report?

New reporting form will be available on the website:

- Defective/Non-Conforming Product Notification Form
- Use for Non-Conformances and Recalls
- Email to:

ACVM-recallsandcompliance@mpi.govt.nz

Recall – Information Needed?

- Product/s affected (type/s, actives)
- Summary of the problem and any hazards
- Batches and Quantity
- Distribution channels – Quantity in market
- Risk assessment
- Is it sold internationally
- Intended actions to be taken

ACVM Expectations - Recalls

- All required notifications & information **provided in a timely manner** to meet ACVM Act obligations and registration conditions

- **Information must not be withheld or unduly delayed** due to company legal processes

Product Recall Decisions

Voluntary – Decision made by company or in consultation with ACVM

Mandated (under 35G ACVM Act)

35 (a) the compound **does not comply** with any requirements of … Act …or regulations; and

(b) the non-compliance **could result in serious or significant risk** to the matters referred to … (public health, trade, animal welfare, agricultural security)

ACVM – Powers to Act

Offences under ACVM Act 1997 (s55)

55 (c) Knowingly contravening any conditions which apply to any trade name product registered …

(l) Knowingly withholds relevant information...

Where insufficient actions taken or information is delayed/withheld

ACVM can issue Recall Notice (s35G) or Prohibition Notice (s65)

Recall Plan – All Registrants

Recall Procedure/plan:

- Assessment of risk & recall decision
- ACVM Notification
- Level of recall - distributor/retailer/consumer
- Communication plan
- Recall actions
- Quarantine, return & storage of product
- Root Cause analysis, investigations etc

Non-Conforming Batches

Batches still held on site

- Can request a **batch variation** (specific release) with technical explanation and supporting data

Batches already in the market

- Submit NC Product form with assessment of whether a recall is necessary with data to support decision

Batch Variation - Request for Release

Batch Variation Requests

- Exception – Case by Case!

Information required:

- Summary of issue & request for release
- Risk assessment - include all supporting data (e.g. relevant test results)
- What can be done to mitigate risks
- Comparison to other batches (if applicable)

SUMMARY - Post-Registration

ACVM Expects Registrants to:

- Pro-actively monitor conformance with registration particulars & conditions
- Control product manufacture & distribution etc (including 3rd Parties)
- Monitor product quality
- Report all non-conformances in timely manner
- Notify recalls (including potential) urgently


Have an Umbrella!

Ministry for Primary Industries
Manatū Ahu Matua

Registration Review Project
ACVM Workshop

23 February 2018

Karen Booth

ACVM Group

Systems Audit, Assurance and Monitoring

www.mpi.govt.nz

Introduction

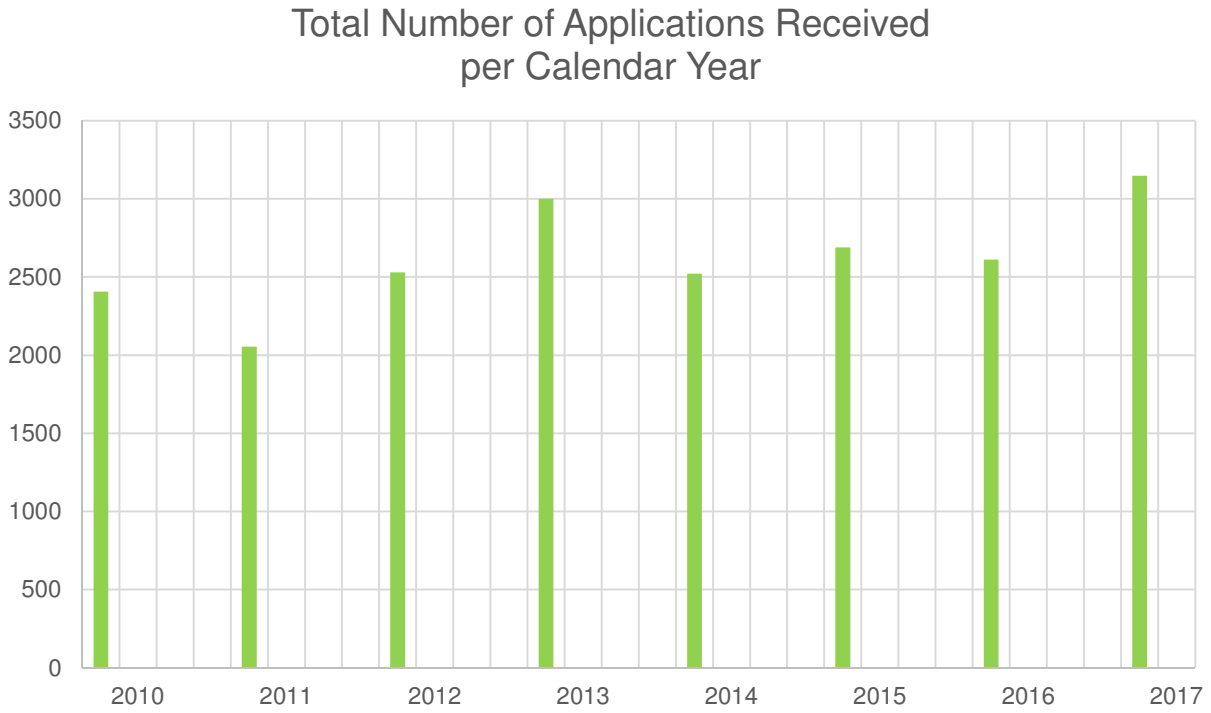
- Initiated late 2015 in response to:
  - performance against statutory timeframes
  - industry feedback and lobbying
  - changing landscape of ACVM activities
- Scope - end to end review of the registration process

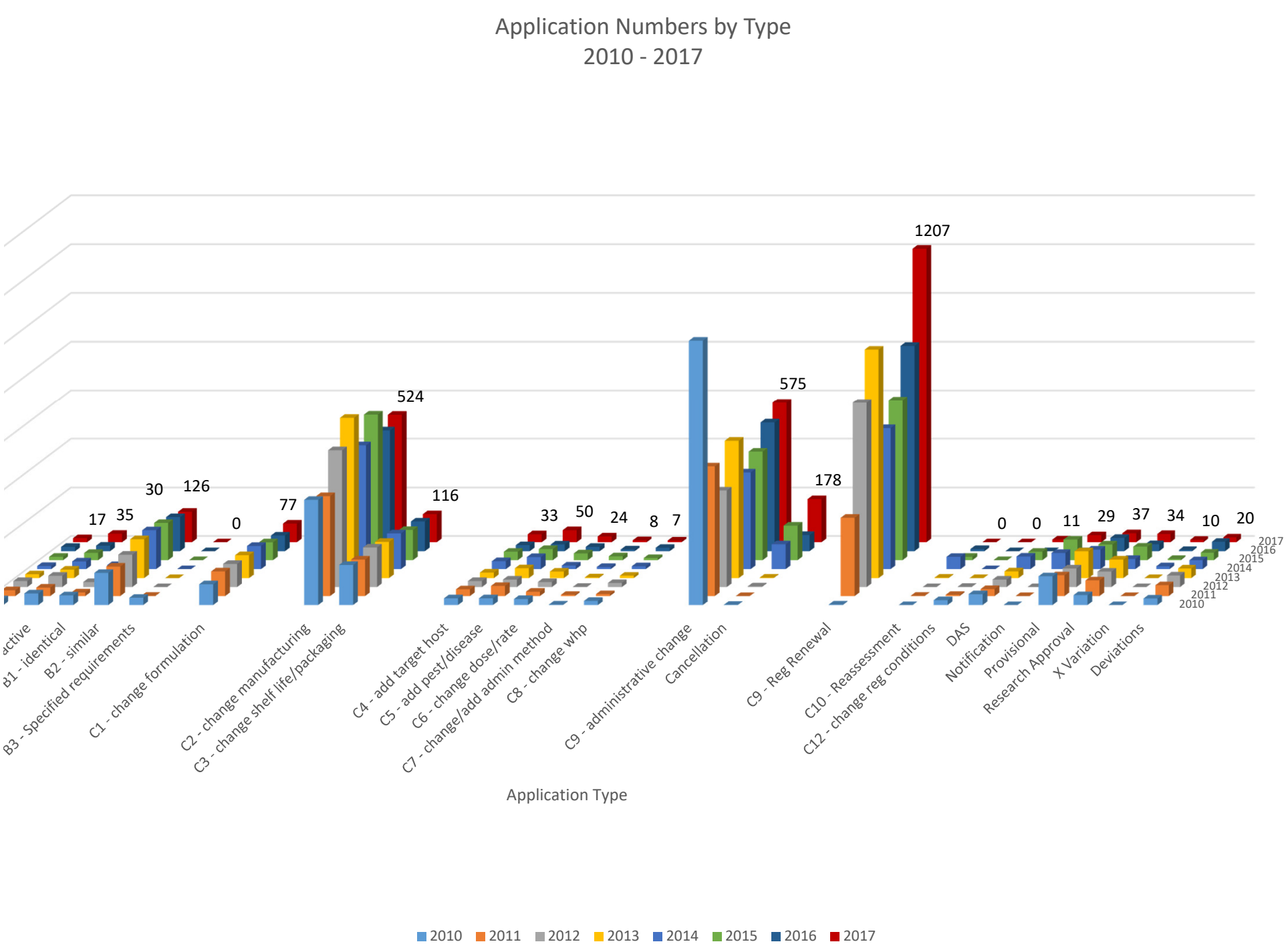
Project Objectives

Objectives	Critical Success Factors
Robust process where regulatory effort is commensurate with risks being managed & meets legal requirements.	A decrease or no increase in post-authorisation non-conformance issues/events.
Maximise benefits to registrants: timeliness, transparency, consistency, simplicity.	Meet both statutory timeframes and AVCM-Industry agreed KPI metrics Improved ratings in customer survey
Improve efficiency & flexibility of process, reporting capability, ability to manage increased application volumes & complexity. Enable ACVM to work proactively with industry to mitigate future risks and adapt to changing risk management needs of the primary sector.	Meet internal KPIs
Appropriate use of ACVM resources. Free up capacity to progress ACVM work programme, resource response activities with minimal operational negative impacts, resource activities in post-authorisation space.	Increased internal capacity for staff deployment into other ACVM work streams

Metrics – then and now

- ACVM receives ~2,600 applications/year
- 3,148 in 2017

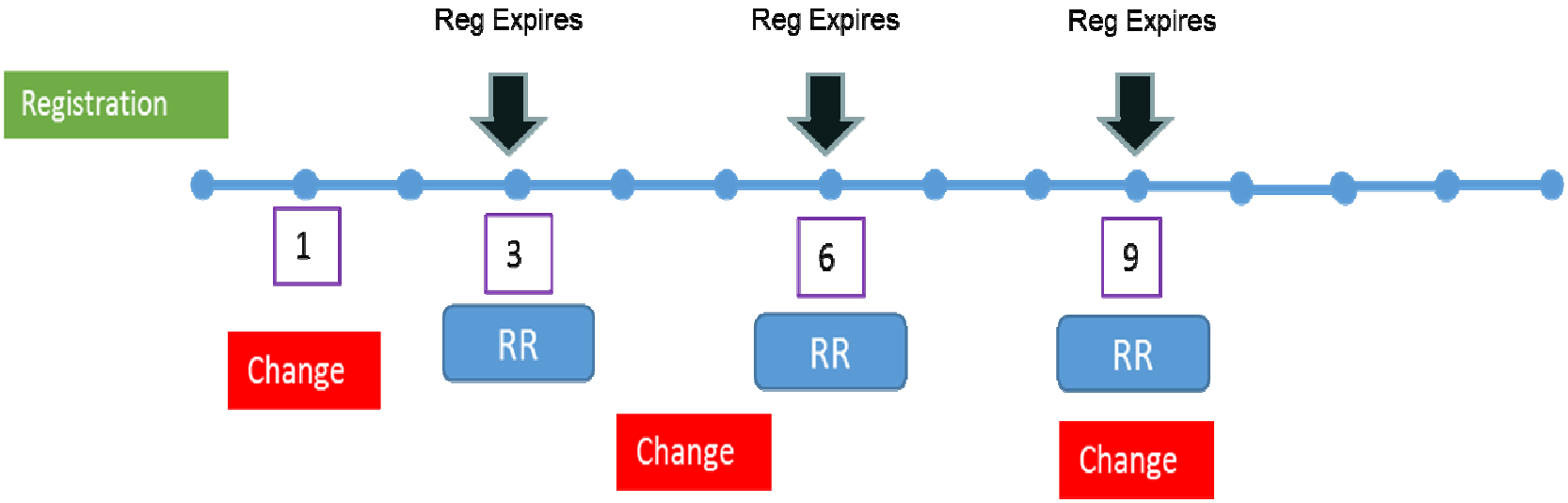



Application Numbers by Type
2010 - 2017
17
35
30
126
0
77
524
116
33
50
24
8
7
1207
575
178
0
0
11
29
37
34
10
20
2017
2016
2015
2014
2013
2012
2011
2010
active
B1 - identical
B2 - similar
B3 - Specified requirements
C1 - change formulation
C2 - change manufacturing
C3 - change shelf life/packaging
C4 - add target host
C5 - add pest/disease
C6 - change dose/rate
C7 - change/add admin method
C8 - change whp
C9 - administrative change
Cancellation
C9 - Reg Renewal
C10 - Reassessment
C12 - change reg conditions
DAS
Notification
Provisional
Research Approval
X Variation
Deviations
Application Type
2010
2011
2012
2013
2014
2015
2016
2017

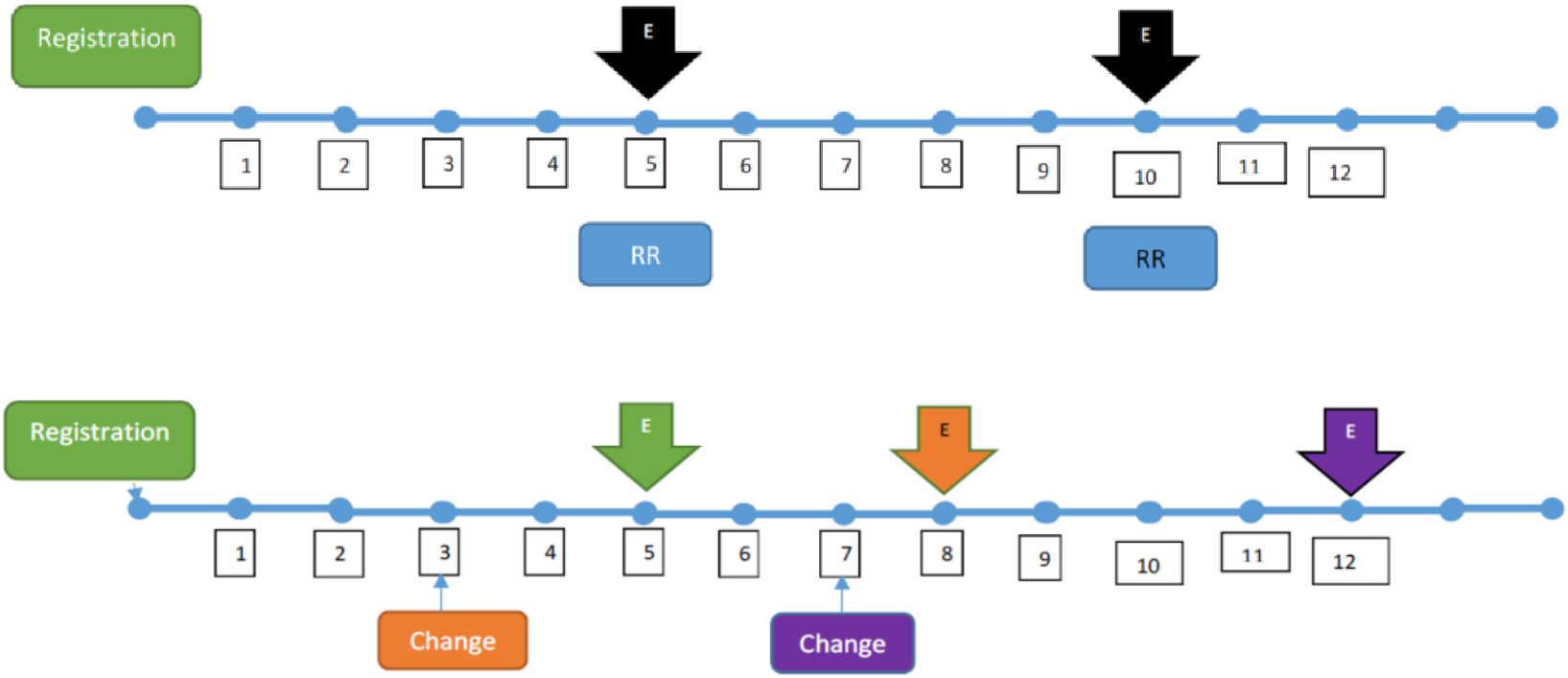
Project Initiatives

1. Paperless processing of applications - completed
2. Rework registration renewal process - completed
3. Improve transparency of registration process to public and interested parties – in progress
4. MPI one process for ACVM and Biosecurity approval applications – soon to be implemented
5. Recalibrate screening of applications – in progress
6. Rework product & manufacturing specifications – in progress
7. Develop, consult on, test and implement alternate pathways for chemistry and manufacturing variations (pending finalisation of Chem & Manufacture Guidance)

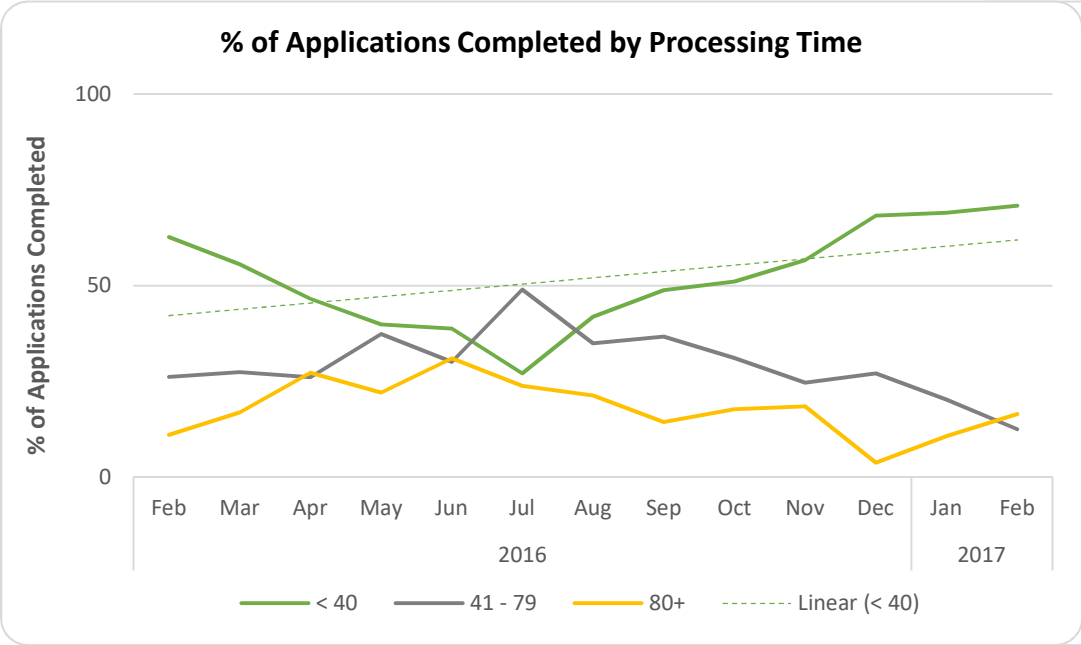
Registration Renewal – old process

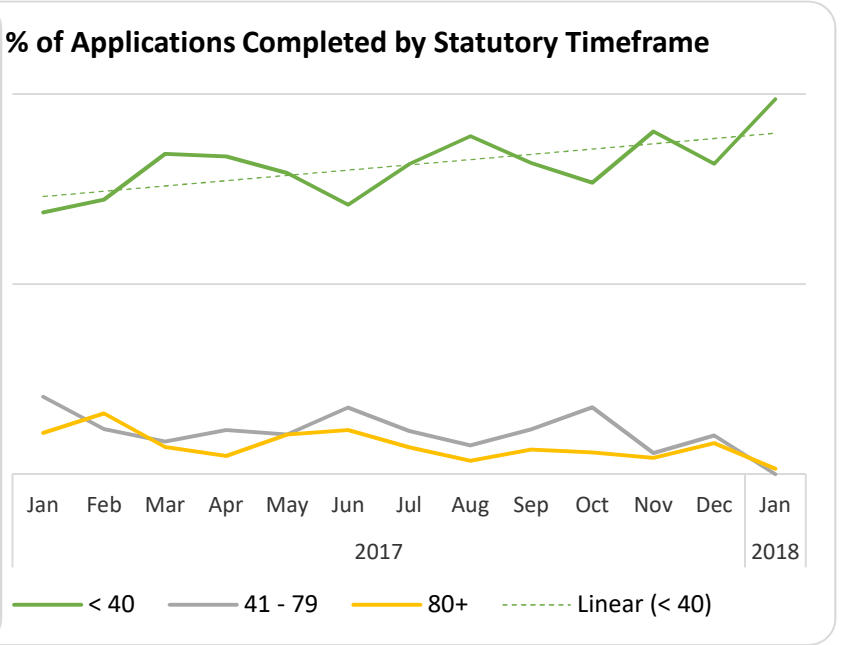


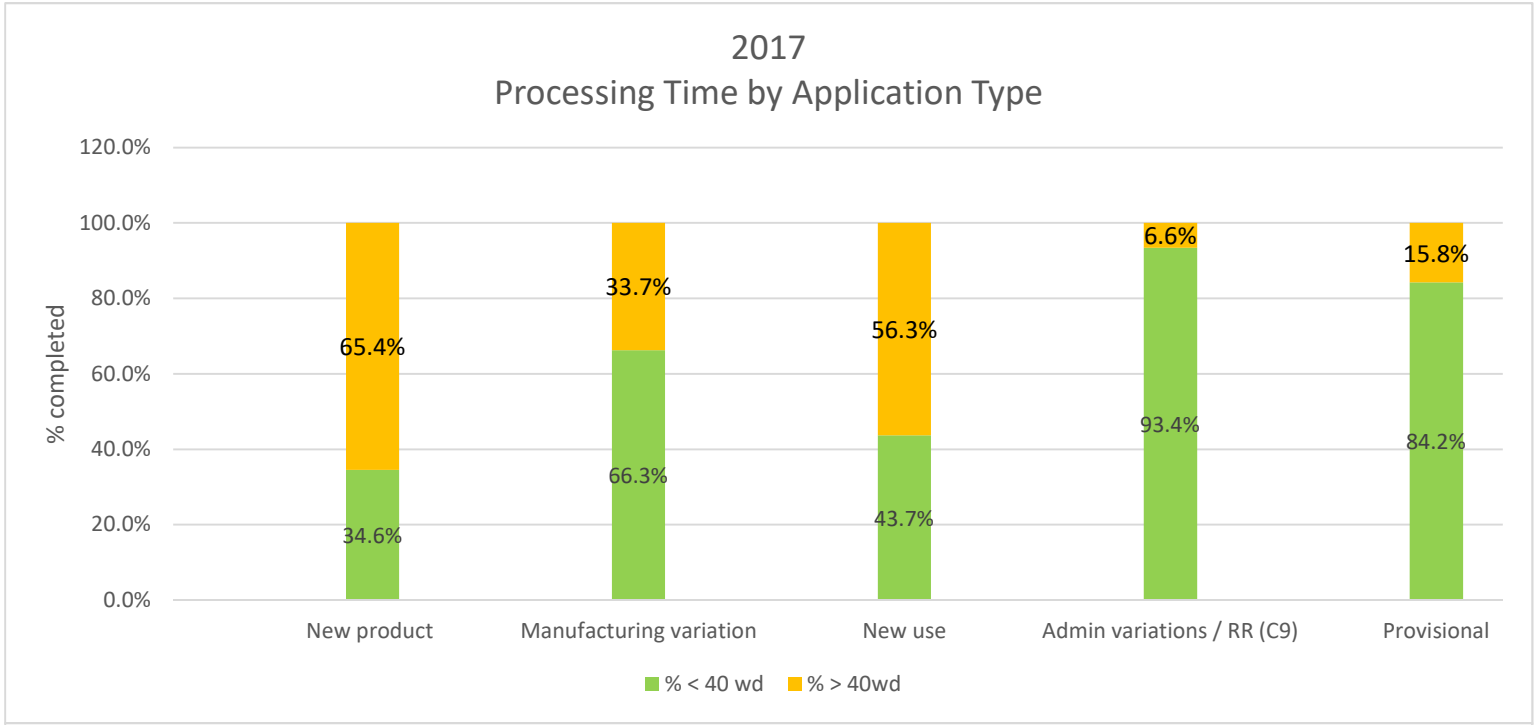
Registration Renewal /Variations – new process

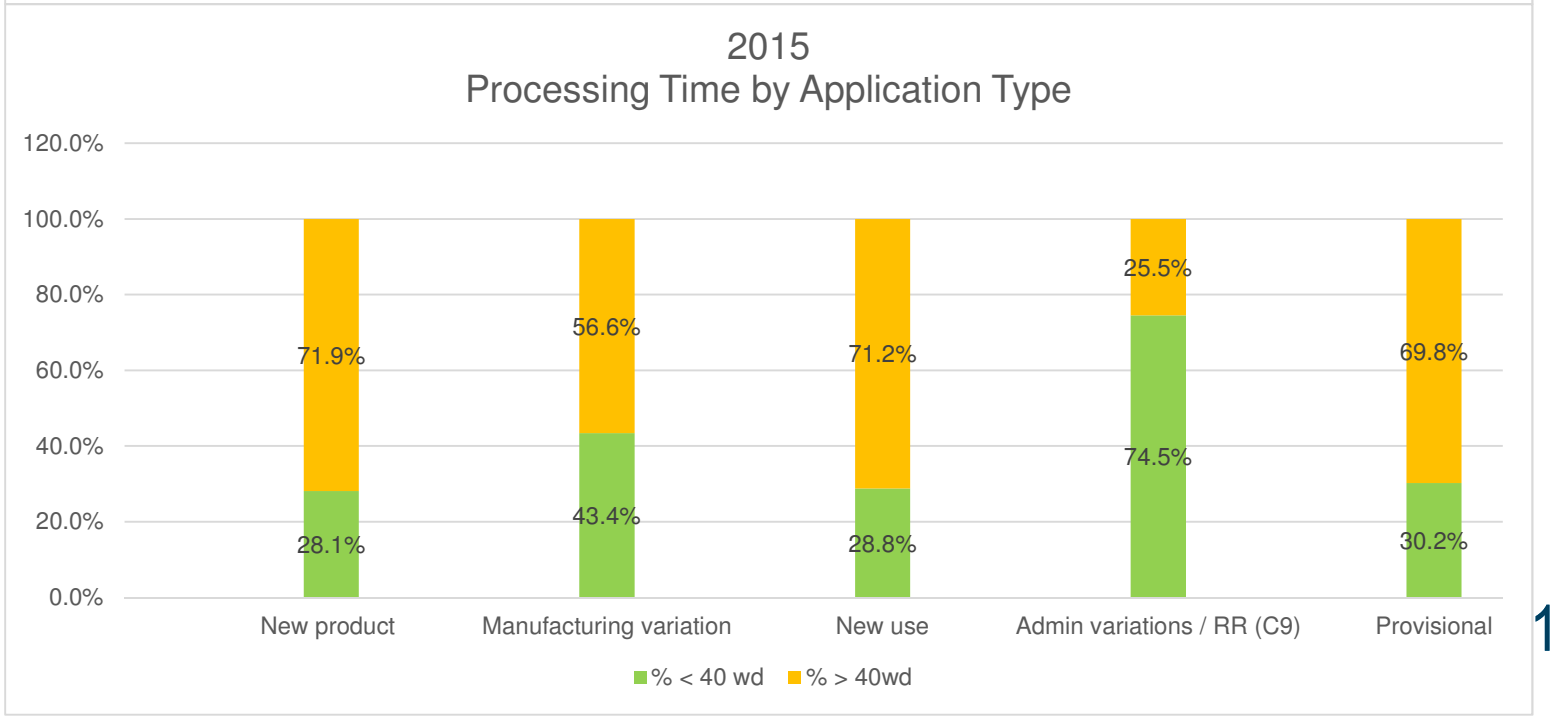


Performance against statutory timeframe

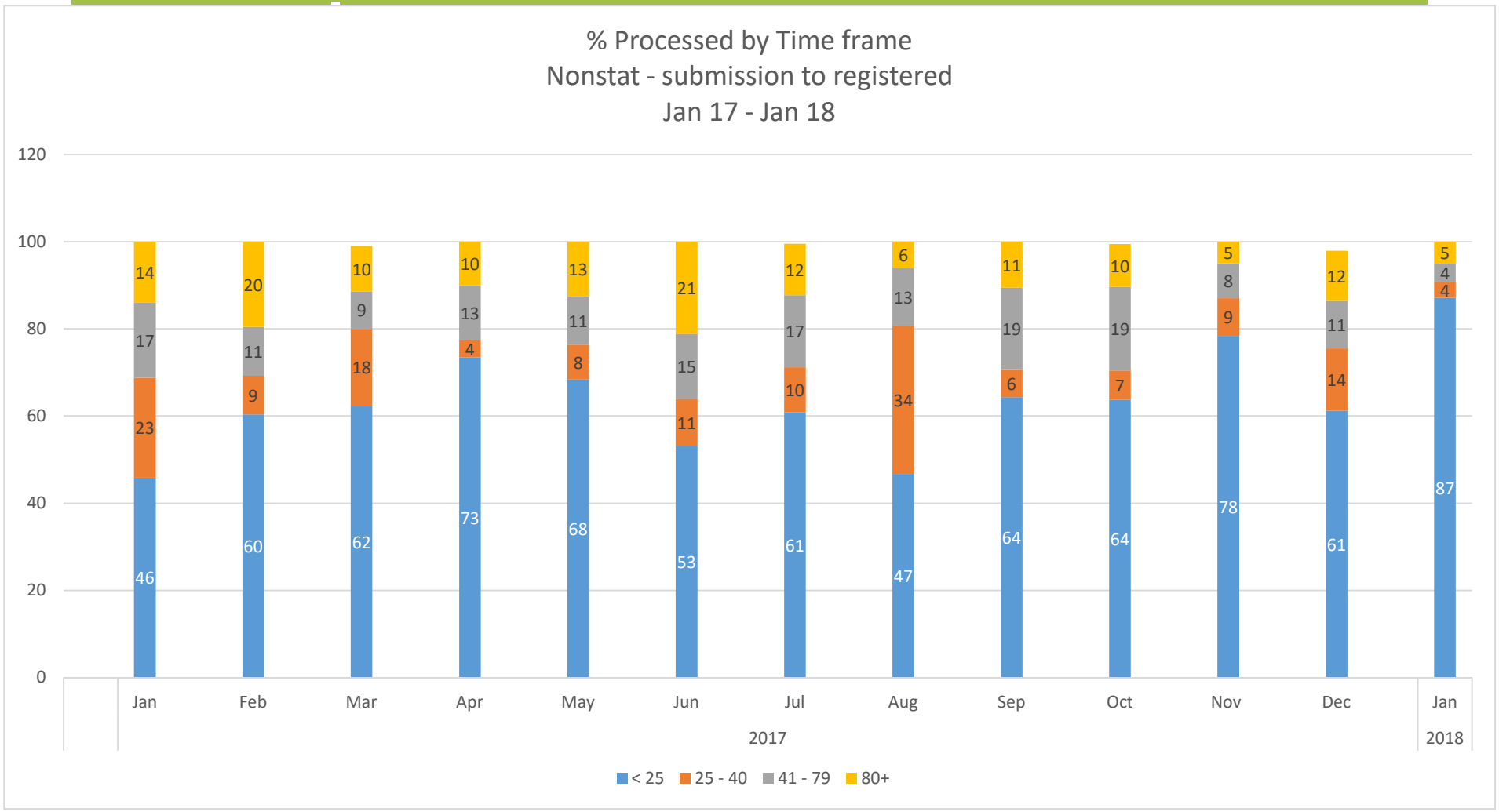





2017
Processing Time by Application Type
120.0%
100.0%
80.0%
60.0%
40.0%
20.0%
0.0%
% completed
65.4%
34.6%
33.7%
66.3%
56.3%
43.7%
6.6%
93.4%
15.8%
84.2%
New product
Manufacturing variation
New use
Admin variations / RR (C9)
Provisional
% < 40 wd
% > 40wd


2015
Processing Time by Application Type
120.0%
100.0%
80.0%
60.0%
40.0%
20.0%
0.0%
71.9%
28.1%
56.6%
43.4%
71.2%
28.8%
25.5%
74.5%
69.8%
30.2%
New product
Manufacturing variation
New use
Admin variations / RR (C9)
Provisional
% < 40 wd
% > 40wd

Performance from time of submission to



Transparency

- Document out for public consultation – closes 16 March

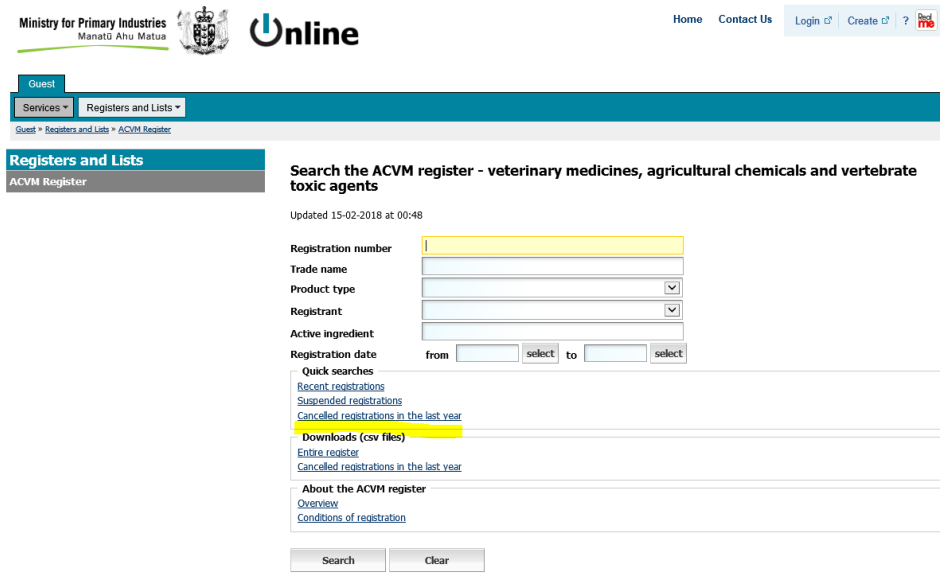
  https://www.mpi.govt.nz/dmsdocument/27393-transparency-and-acvm-registration-applications

- Proposed changes:
  - Public notification of applications received
  - Changes to Public Record of Delegate Decision
  - Summary listing of information supplied in an application

Transparency – applications received

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.



Transparency – delegate decision

Current

Ministry for Primary Industries
Manatū Ahu Matua

Public Record of Delegate's Decision

For granting an application for registration under section 21 of the Agricultural Compounds and Veterinary Medicines Act 1997

Product details

Trade name		**Ref No**	
Applicant			
Application type	New Product Variation		
Date of Delegate Decision			
Registration Expiry Period	This registration will expire X years from the date of this Delegate's Decision.		
Protected Confidential Information	YES or NO		

Transparency – delegate decision

Ministry for Primary Industries
Manatū Ahu Matua

Delegate's Decision

For granting an application for registration under section 21 of the Agricultural Compounds and Veterinary Medicines Act 1997

Product details

Trade name		**Ref No**	
Applicant			
Application type	New registration *<description of use>* Variation *<description of application, e.g. manufacturing change, addition of use in sheep to existing label claims.>*		
Registration Expiry Period	This registration will expire X years from the date of this Delegate's Decision.		
Protected Confidential Information	Protected CI – New Use – Non-innovative Trade Name Product		

Summary of type of information provided

Chemistry & Manufacturing	A – H as relevant
Residues	A – H as relevant
Efficacy & Crop Safety (AgChem)	A – H as relevant
Efficacy (VetMed & VTA)	A – H as relevant
Target Animal Safety (VetMed)	A – H as relevant
Target Animal Welfare (VTA)	A – H as relevant
Toxicology	A – H as relevant
Antimicrobial Resistance	A – H as relevant

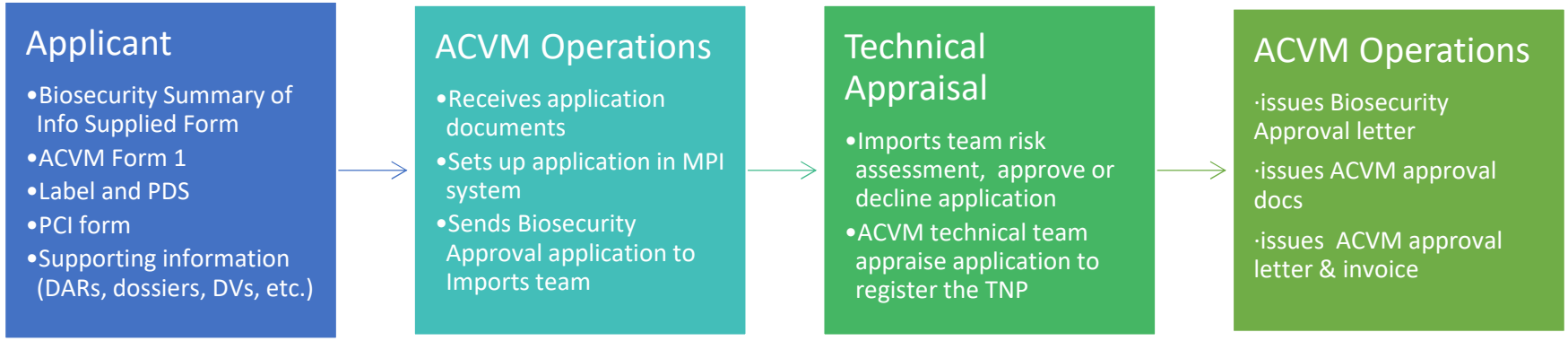
Key:

A: Data generated in New Zealand
B: Data generated overseas
C: Request to cross reference information held by MPI
D: Information referenced in the public domain
E: Information supplied as an 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 the applicant

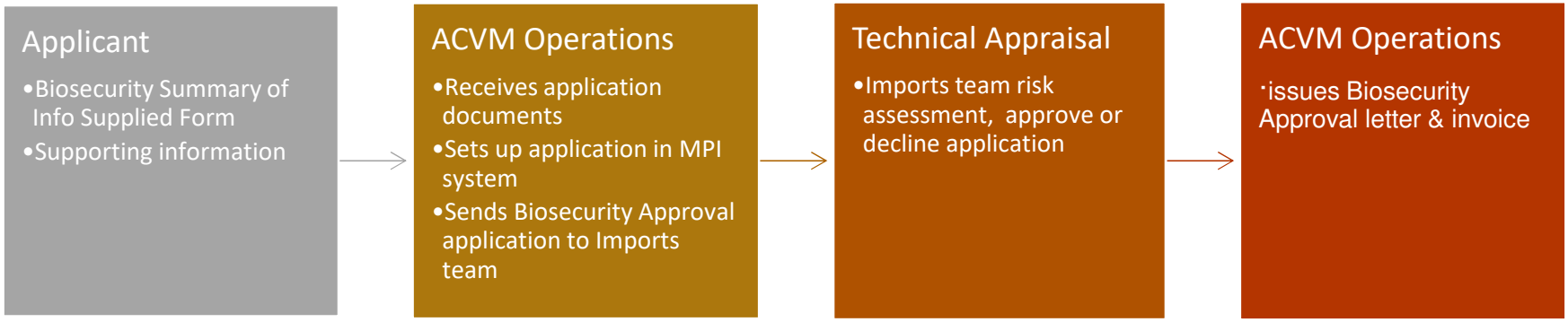
ACVM-Biosecurity integrated application process

- New internal process to streamline receipt, appraisal and issuing of Biosecurity Approval applications
- Applications made via Approvals Operations team
- Following documents are being updated:
  - ACVM Form 1
  - ACVM Form 1V
  - ACVM Form 1R
  - Product Datasheets (for Agricultural Chemicals, Veterinary Medicines and Vertebrate Toxic Agents)
  - Product Datasheet guidelines
- New Biosecurity guidance and form

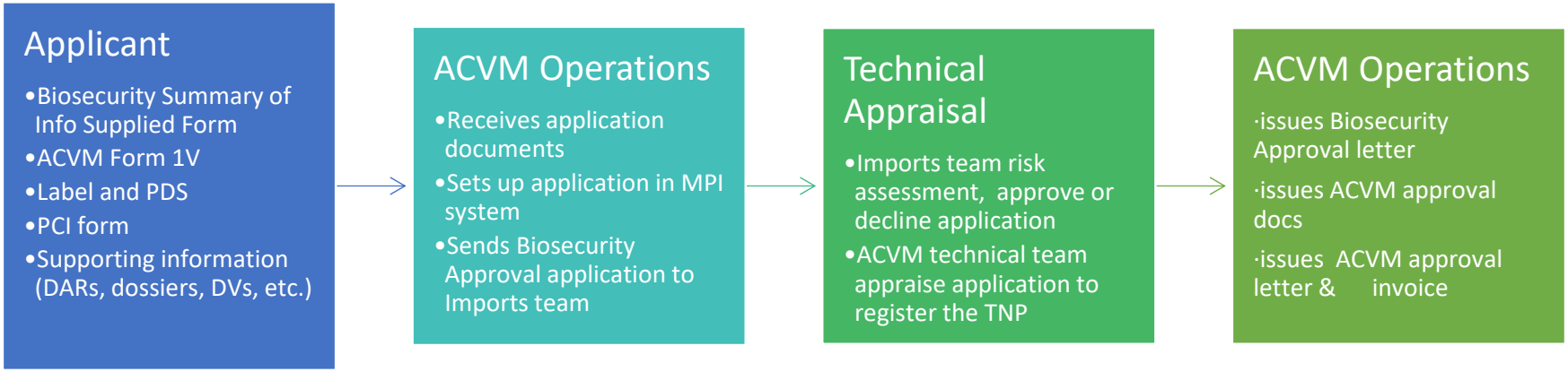
New Product Registration requiring Biosecurity Approval



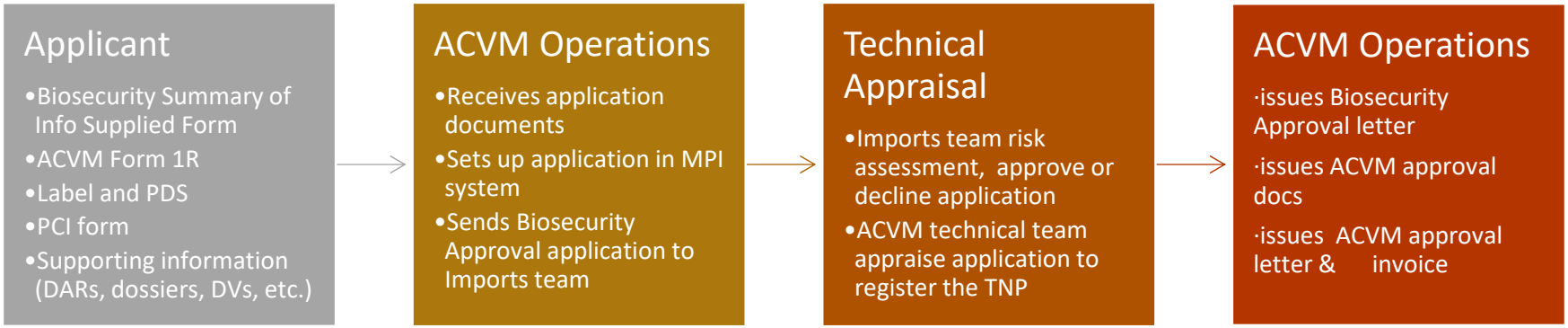
Obtaining Biosecurity Approval prior to submitting ACVM application (optional)



Variation to Registration requiring Biosecurity Approval process



Registration Renewal requiring Biosecurity Approval process



Project Next Steps

1. Finalising screening process
2. Rework product & manufacturing specifications – likely more changes to PDS
3. Develop, consult on, test and implement alternate pathways for chemistry and manufacturing variations

Navigating the new MPI website

MPI website architecture

Consultations

Importing

Processing

Registers

Subscribing to the MPI website

Ministry for Primary Industries
Manatū Ahu Matua

Antimicrobial Resistance (AMR) Update
ACVM Workshop

23 February 2018

Warren Hughes

ACVM Group

Systems Audit, Assurance and Monitoring

www.mpi.govt.nz

Domestic Activities

New Zealand Antimicrobial Resistance Action Plan

- The World Health Assembly (WHA) asked all members to develop a national action plan on AMR outlining priorities of activities under 5 objectives
- New Zealand advised the WHA in May 2017 that it had developed its plan
- Ministers of Health and for Food Safety announced the publication of this document in August 2017
- A copy can be found at:

  https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/antimicrobial-resistance/

Domestic Activities

New Zealand Antimicrobial Resistance Action Plan (cont)

- MPI and Ministry of Health have established a Governance Group to monitor to the implementation of the Action Plan
- The priorities relating to animals, plants and food safety have been incorporated into our existing work programme on AMR

Domestic Activities

MPI AMR Work Programme

- Items of Priority are:
  - Monitoring and surveillance for AMR bacteria in foods
  - Prudent Use Guidance
  - Review of controls and labels
  - Antimicrobial classification
  - Reassessment programme
  - Update and new guidance documents for registration
  - AMR Co-ordination Group

Domestic Activities

MPI AMR Work Programme

- Monitoring and surveillance
  - A number of activities
    - An update on the 2009 baseline survey
    - Establish a MPI specification for laboratory testing
    - Establish a national system for veterinary laboratories to report to MPI on AMR findings from samples

Domestic Activities

MPI AMR Work Programme

- Prudent Use
  - Focus on the regulatory touch points
    - Regulatory Requirements (including labelling)
    - Registrants
    - Resellers
    - Veterinarians
    - Sector Groups
    - End Users
  - Has been released and can be found on our website at:

https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/antimicrobial-resistance

Domestic Activities

MPI AMR Work Programme

- Regulatory Controls and Labelling
  - Conditions of Registration
    - Wording of current conditions
    - Advertising
    - Sales v Use data
  - Labelling
    - Prudent use statements
    - Update of ACVM labelling requirement document

MPI Activities - AMR Work Programme

MPI AMR Work Programme

- Antimicrobial Classification System
  - Expert Report 2005 recommended regular reviews
  - Our review will inform on whether the appropriate conditions are being applied
- Reassessments
  - Develop a programme to regularly review antimicrobials
  - Review will cover all aspects

MPI Activities - AMR Work Programme

MPI AMR Work Programme

- AMR Co-ordination Group
  - Replaced the AMR Steering Group
  - Membership covers regulators, industry sectors, researchers
  - Focus on sharing of information and co-ordination of activities
  - 4 meetings held

International Activities

Codex

- Member countries requested CAC review and refresh the existing Codex AMR documents
- CAC agreed in 2016 to establish an Ad Hoc Task Force to:
  - review and revise as appropriate the Code of Practice to Minimise and Contain Antimicrobial Resistance (CAC/RCP 61-2005)
  - To consider the development of Guidance on Integrated Surveillance of Antimicrobial Resistance

International Activities

Codex

- Two Electronic Working Groups established for each of the two activities
  - New Zealand is co-chairing the surveillance EWG
- Republic of Korea is the host country
- A physical meeting was held November 2017
  - New Zealand co-chaired the session on the surveillance activity
  - The meeting agreed that both documents needed further work (particularly the Code of Practice) before progressing them further

International Activities

OIE

- Since 2015, OIE has asked member countries to provide information on sales (or use) of antimicrobials
  - Currently excludes ionophores
  - The first two OIE reports can be found at:

    http://www.oie.int/en/our-scientific-expertise/veterinary-products/antimicrobials/
- It is possible that OIE may ask in the future member countries to supply use data
  - This would be a significant change for NZ