



ACVM Workshop

23 February 2017

Growing and Protecting New Zealand



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Presentations

- ACVM manufacturing workshop (slides 3-5)
- International activities (slides 6-28)
- ACVM risk analysis in applications (slides 29-47)
- ACVM Amendment Act (slides 48-64)
- Protection of confidential information (slides 65-78)
- Veterinary medicine chemistry and manufacturing documentation and guidelines (slides 79-111)

ACVM Manufacturing Workshop 2017

Proposed Date(s):

- Wellington - Friday 28th July
(day following winter AGCARM conference)
- Auckland - TBD

Venue(s):

- TBD

ACVM Manufacturing Workshop – Draft Agenda

Topic	Presenter	Time
Arrive and Network (08:30 - 09:00)		
➤ Welcome & Introductions	TBD	09:00-09:05
➤ ACVM Update	TBD	09:05-09:15
➤ Quality Management	TBD	09:15-10:00
➤ Common Deficiencies & Associated Risks	TBD	10:00-10:30
Morning Tea (10:30 - 11:00)		
➤ Deviations & Associated Risk Assessment	Industry Speaker	11:00-11:30
➤ Adverse Event Reporting (AERs)	TBD	12:00-12:15
➤ APIs	TBD	12:15-12:30
Lunch (12:30 - 13:30)		
➤ Validation (Concept, Process & Cleaning)	TBD	13:30-14:15
➤ Contract Manufacturing	TBD	14:15-14:30
➤ Chem. & Manufacturing Information Req.	TBD	14:30-15:00
Afternoon Tea (15:00 - 15:30)		
➤ Case Studies & Questions - Split into two groups (Registrants & Manufacturers)		15:30-16:30
• Manufacturers		
- Discuss ideas for investigating product separation, sterility failures		
- TBD		
• Registrants		
- Discuss what to do when notified of product separation issue, stability issue		
- Application variations, what data to supply and why		
➤ GMP Programme Review	TBD	16:30-16:45
➤ Closing Summary	TBD	16:45-17:00
Closing (16:45-17:00)		

Topics of Interest - Suggestions

If you have any suggestions for topics, please email:

holly.jeboult-jones@mpi.govt.nz

When registrations are open and the dates/venues confirmed, details will be provided in the ACVM News and Views newsletter. If you would like to be notified when registrations are open or have any questions, please email Holly.



International Activities

ACVM Group

Systems Audit, Assurance and Monitoring

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Topics

- **OECD**
- **VICH**
- **Codex**
- **Benefits**

What is OECD?

Forum for Governments to work together, established in 1961

- **Mandate**
 - to promote policies to improve economic and social well-being of people
- **Current membership**
 - 35 countries

OECD Structure

Who drives the OECD's work?



OECD Committees – EPA and MPI

Two Committees

- **Joint Meeting of the Environment Directorate**
- **Working Group of Pesticides (WGP)**

Joint Meeting:

- **Umbrella Committee for chemicals, biotechnology, and pesticide working groups**
- **EPA lead as it covers chemicals per se**

Working Group on Pesticides

- **Focus on agricultural pesticides**

OECD WGP

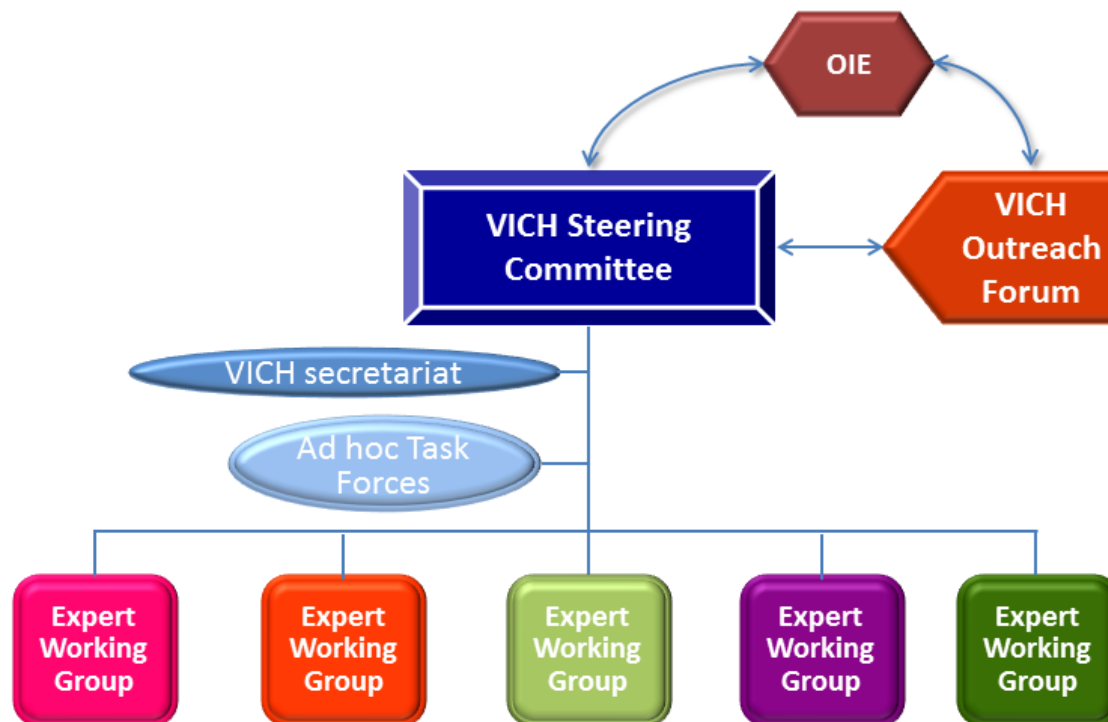
- **WGP commenced in 1992 and MPI attended the first meeting**
- **Strategy is:**
 - Harmonised requirements
 - Mutual recognition of pesticide reviews
 - Working sharing
 - IPM
 - Illegal trade

What is VICH?

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), established in 1996

- **Mandate**
 - to establish and implement technical requirements for registration of VMs
- **Current membership**
 - EU, Japan, and USA
 - NZ, Australia, Canada and South Africa (observers)

VICH Structure



VICH Objectives

- **Harmonised technical requirements for registration of veterinary medicines**
- **Promote the above to the wider international arena**
- **Ensure there is consistent interpretation of the technical requirements**
- **Forum for discussions on global and science issues relating to veterinary medicines**

VICH Process

- **Members propose areas of new work via concept papers**
- **Utilises electronic Working Groups to develop technical requirements**
- **A 9 step process is followed for development of the technical requirements**
 - **Includes public consultation step**

What is Codex?

**International Food Standards body
set up in 1962 by FAO/WHO**

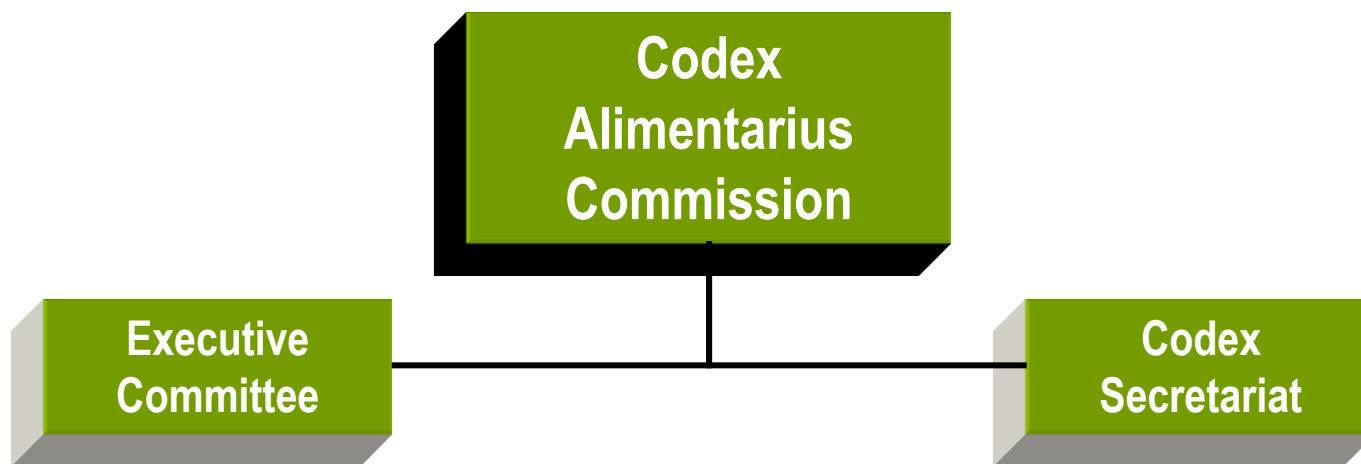
- **Mandate**
 - to promote international standards for health protection and fair practices in food trade
- **Current membership**
 - 187 countries and growing

Codex Structure

Codex Alimentarius Commission (CAC)

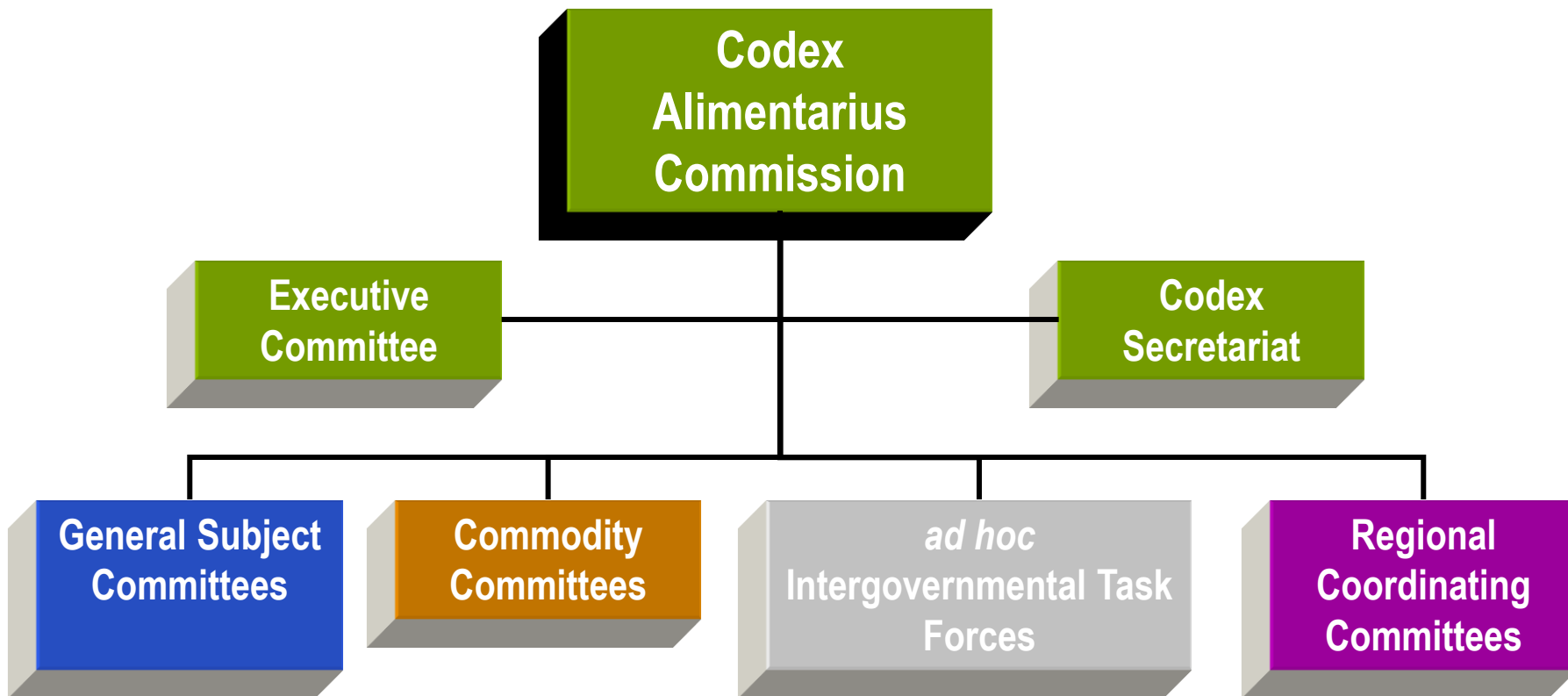
- high level decision making body
- meets annually (in July) to adopt standards and approve work programme
- NZ attends with reps from Policy and R&A Branches

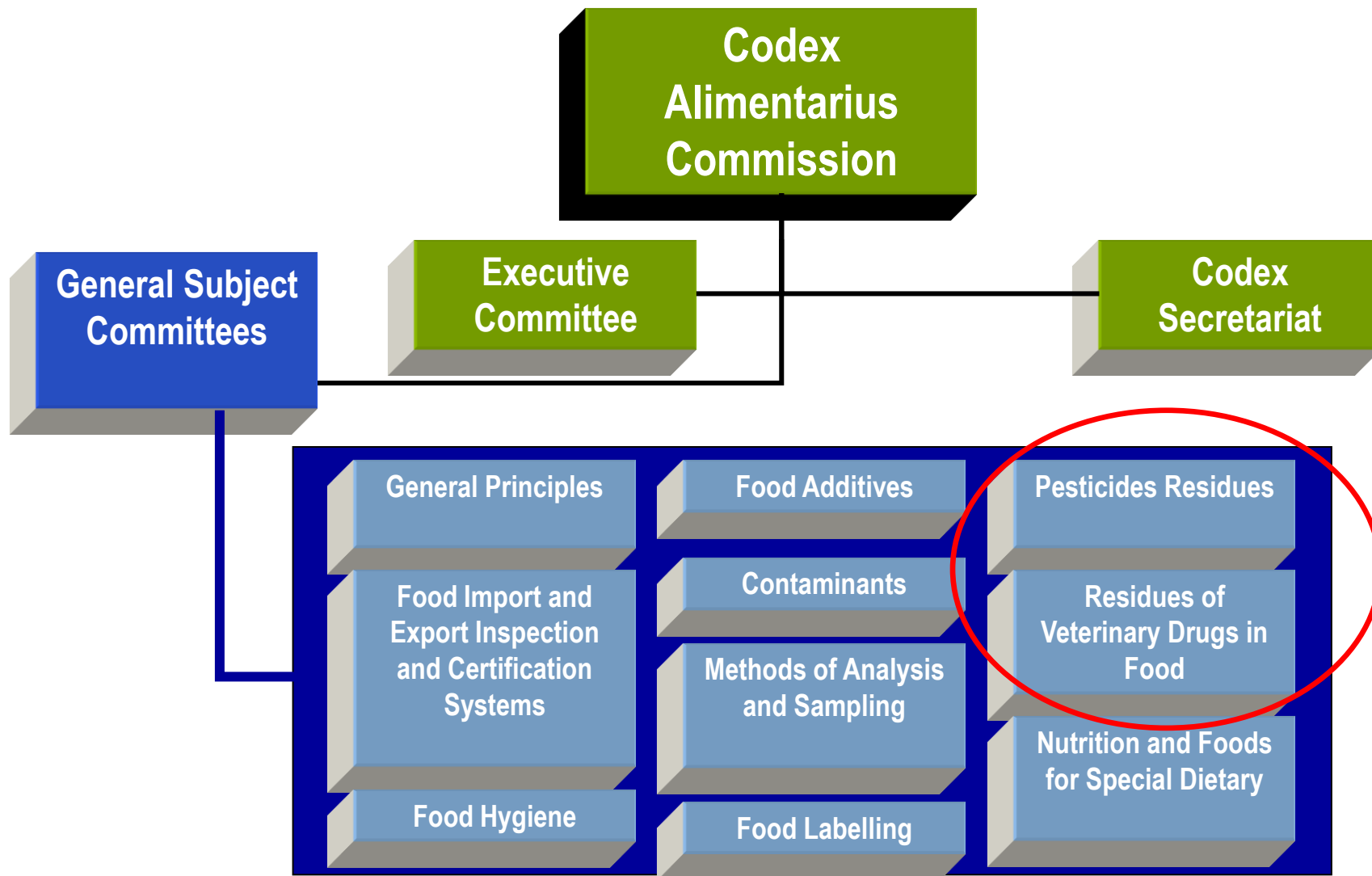
Codex Structure



Executive Committee

- **Management committee**
- **Advises the CAC**
- **Regions represented through Regional members and Regional Coordinators**





Codex Outputs

Standards/guidelines for

- Food hygiene
- Food labelling
- Food additives and contaminants
- Residues of pesticides and veterinary drugs
- Inspection and certification systems
- Commodities
(e.g. milk, meat, fruits and vegetables, processed foods)
- Foods derived from biotechnology

Codex – New Zealand

- MPI is lead agency for Codex
- Codex Contact Point located in International Policy
- We are responsible for managing New Zealand's participation in Codex activities
- Involves a lot of routine tasks that require systematic action

Codex Committees – ACVM Team

Two Committees

- **Codex Committee on Pesticide Residues (CCPR)**
- **Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)**

Both Committees have a similar function:

- **Establish Codex Maximum Residue Limits**
- **Establish Priority List**
- **Use FAO/WHO Committees as risk assessors**

Codex Committee on Pesticide Residues (CCPR)

- **First meeting in 1966 (one of the oldest committees)**
- **The Netherlands original host country, now China**
- **Meets once a year**
- **Busy committee**
 - **Full schedule of compounds for the next 3-4 years**

Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

- **First meeting in 1986**
- **USA host country**
- **Meets every 18 months**
- **Low activity**

Codex Committees

Operation of CCRP and CCRVDF:

- **Countries nominate compounds and commodities**
- **Committee confirms they meet criteria and go on the Priority List**
- **Countries submit toxicological and residue data to appropriate FAO/WHO committee**
- **A Step process is used to progress MRLs**
- **Use FAO/WHO Committees as risk assessors**
- **Both Committees make recommendations**

Benefits

- **The ability to influence international standards that impact on New Zealand**
 - Ensures those standards we adopt or utilise are fit for purpose for New Zealand
 - Our guidance documents are heavily influenced by those produced by OECD, VICH and Codex
- **Assists in maintaining our good reputation as a regulator internationally**
- **Reduces costs to industry**

Benefits

- **Contributes to the effective resource at ACVM**
- **Facilitates the export of both products and produce**
- **Provides the opportunity for regulators to collaborate more on range of matters, particularly on assessment of registrations**
- **Networking opportunities**

Revised application requirements

ACVM risk analysis in applications

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New focus in registration applications

- TNP, application type, registrant information
- Biosecurity authorisation, EPA approval
- Documentation
 - Complete product data sheet (PDS)
 - Draft label
 - Risk analysis
 - Supporting documentation index
 - Public summary of information

ALL SUPPORTING DOCUMENTATION

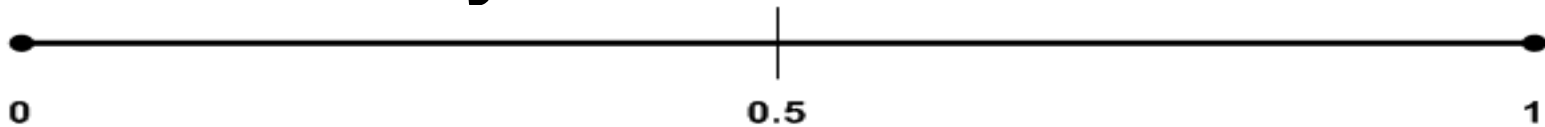
ACVM Act 1997



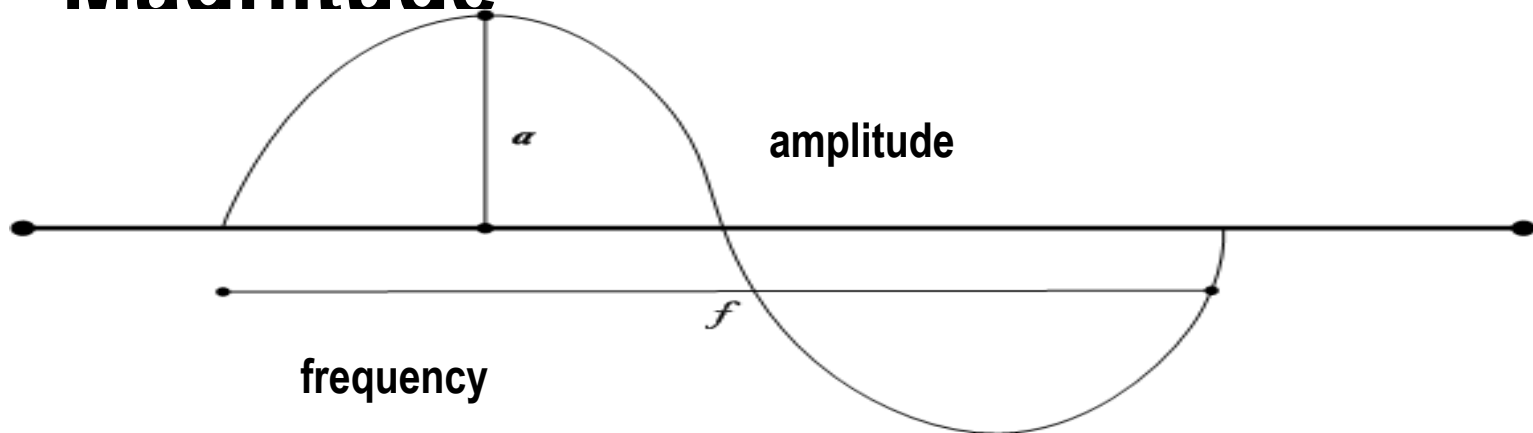
**Risk
Analysis**

What is risk?

- **Probability**



- **Magnitude**



$$\text{Risk} = [P] [M]$$

What can be hazards?

- **Ingredients**
- **Contaminants, impurities, metabolites**
- **Formulations**
- **Innovative technologies**
- **Application/administration systems**
- **Use directions and other label information**

Anything that can cause harm

ACVM risk areas

- **Public health**
- **Trade in primary produce (domestic and export)**
- **Animal welfare**
- **Agricultural security (exotic and endemic organisms)**

Risk management under the ACVM Act

How many risks can there be?

Hazard = h

Harm = H

Hazard harm pathway = h/H

Probability = P

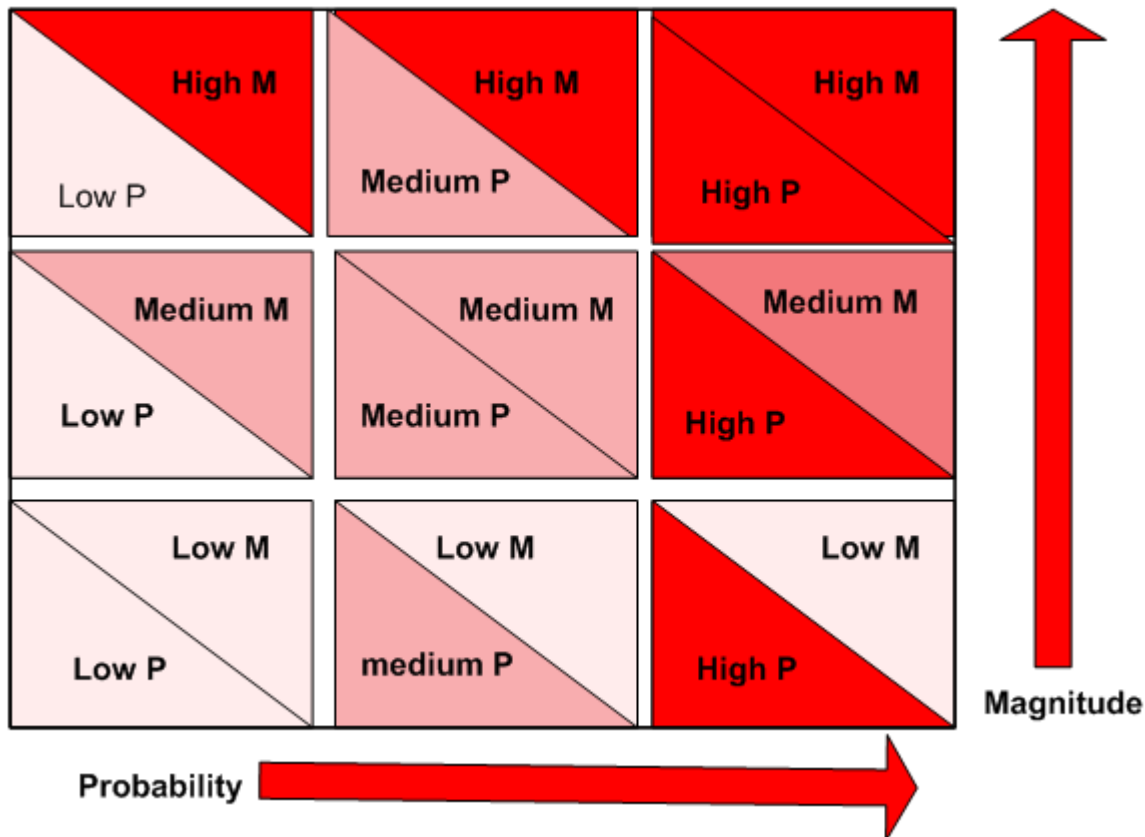
Magnitude = f - a

Risk area = RA

Number of risks = n

$$R_n / RA = [h/H]^n \cdot [P]^n \cdot [f + a]^n$$

How accurate does the calculation of the risk have to be?



Required areas of analysis

	Public health	Trade in primary produce	Agricultural security	Animal welfare
Residues				
Target animal safety				
Target plant safety				
Efficacy				
Environmental impact				
Public health impact				

What is the starting point of all risk analyses?

- **Product identity**
- **Confidence that the product conforms to the product identify**
- **Evidence that all the registration information is relevant to the product identity**

**When is chemistry and manufacturing
information required?**

ALWAYS!!!

Statutory registration information requirement

**Include in the application
technically sound analyses of all
the relevant risks**

Can an applicant deviate from this requirement?

Existing
relevant
regulatory
decisions

Relevant
public
domain
information

Relevant
Technical
support
argument/
information

Specific
product trials
and data

Equivalence

- **No cross-reference without equivalence**
- **Different equivalence cases**
 - **Chemical equivalence**
 - **Pharmacological equivalence**
 - **Therapeutic equivalence**
 - **Bioequivalence**

Relevance

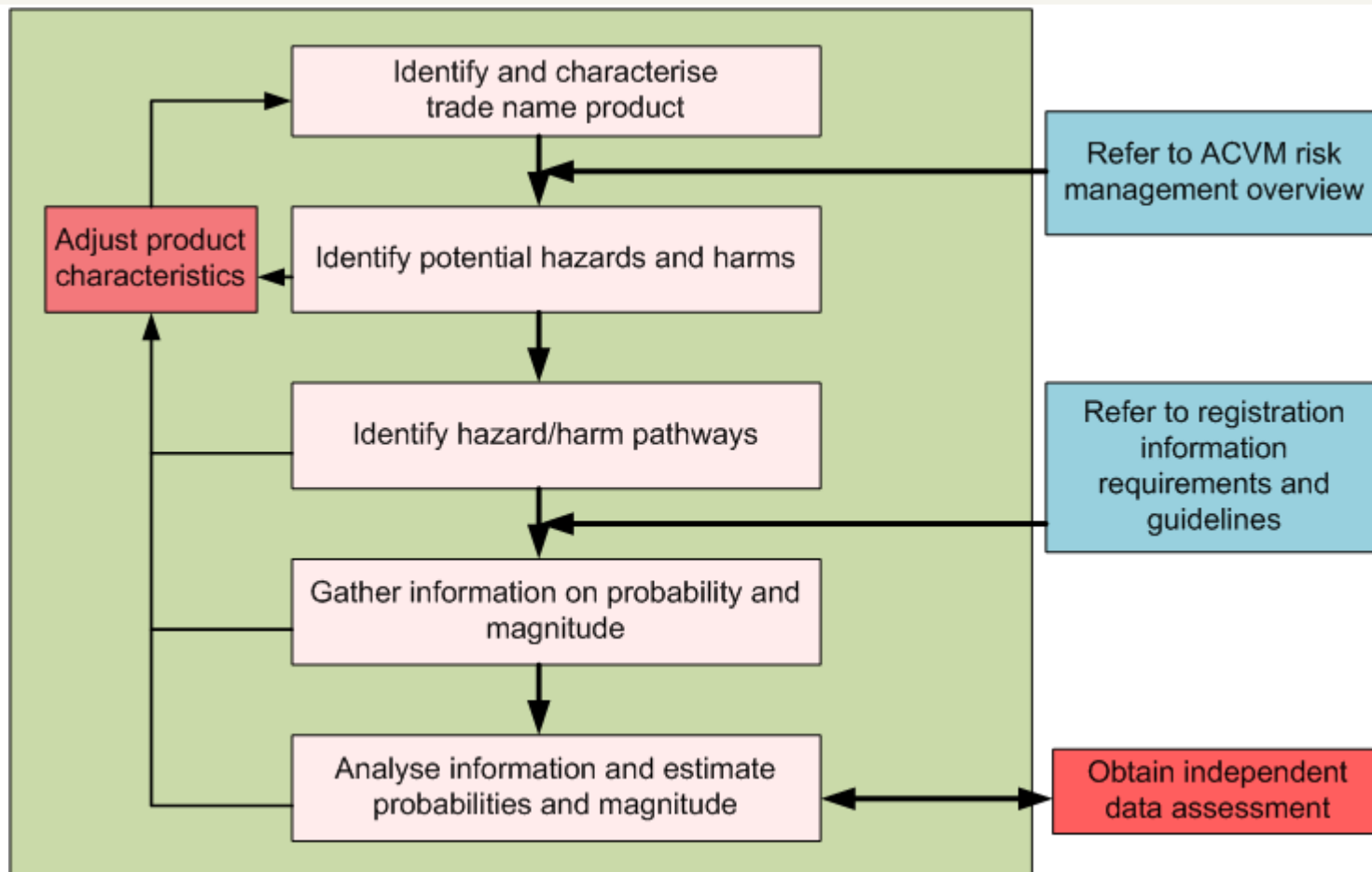
Cannot refer to other information without presenting a case as to why it is relevant

Applicant

- **Specifies the product**
- **Identifies the hazard/harm pathways for the product (risk = probability and magnitude of harm)**
- **Gathers information and data to characterise and estimate each risk**

Provides a robust and technically supported analysis of all relevant risks

Risk analysis process



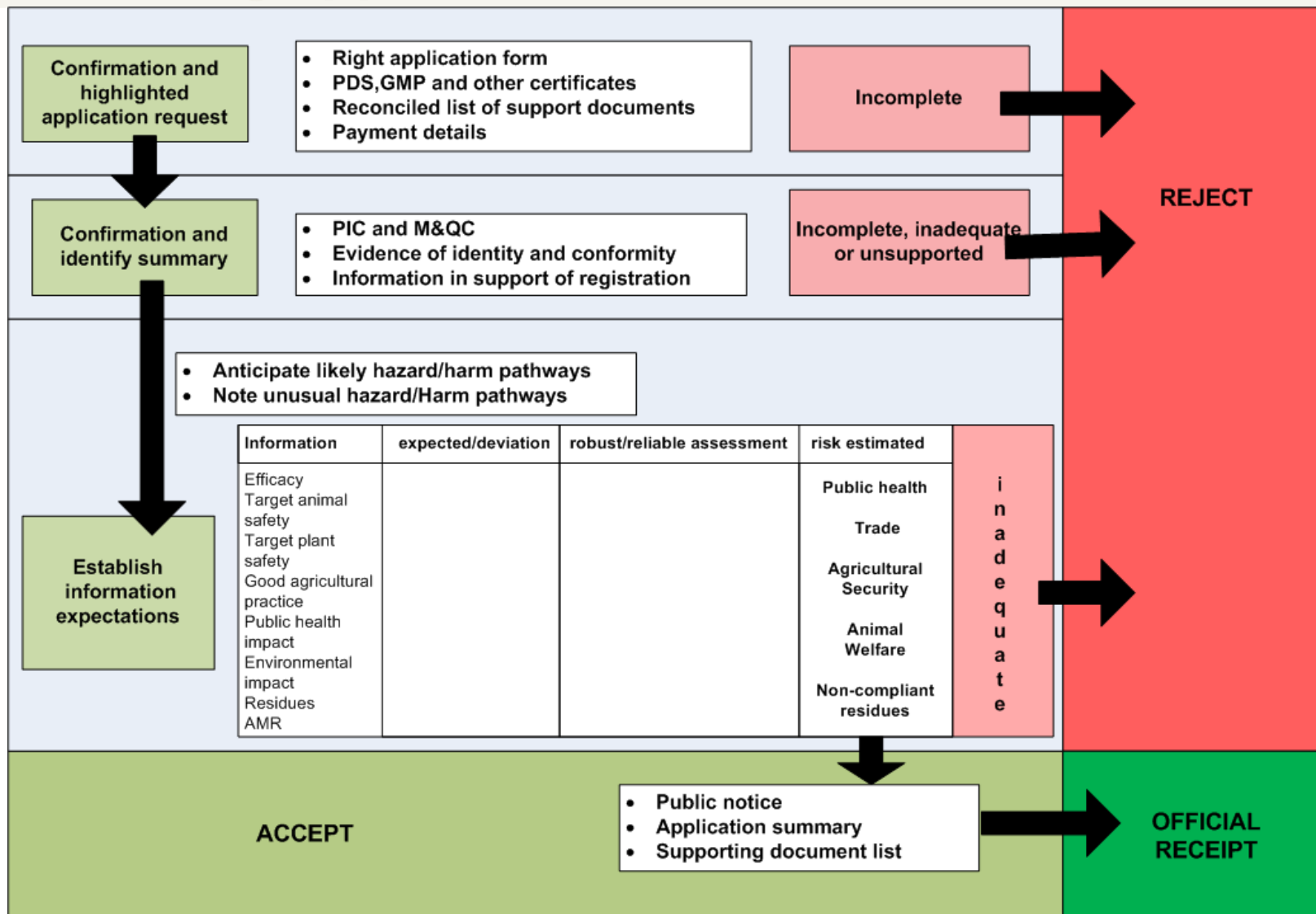
Estimate the risks

Independent data assessor

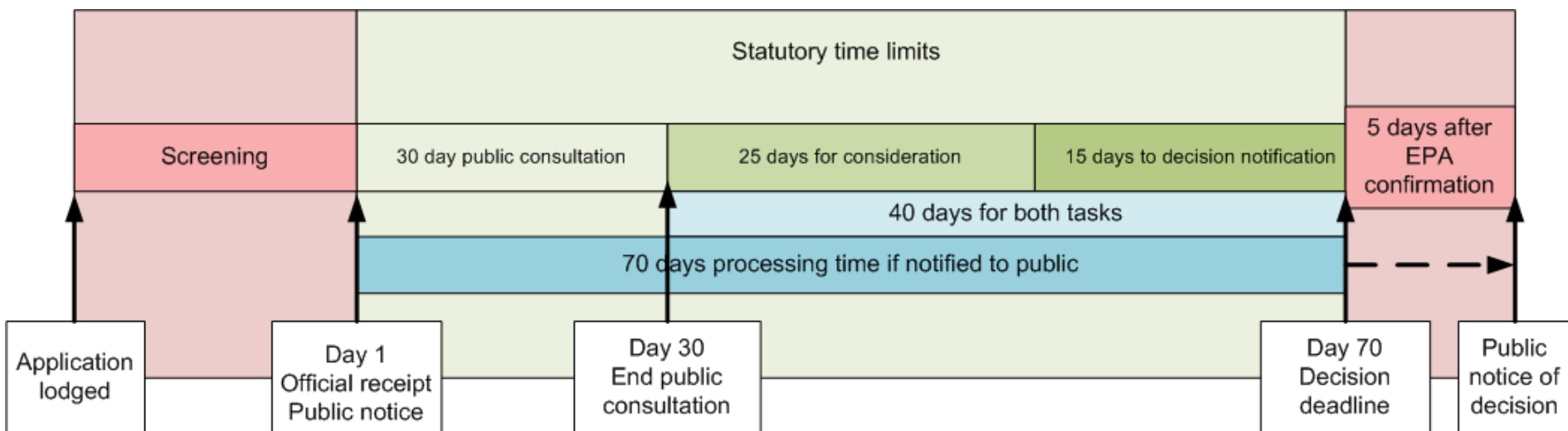
- Reviews the applicant's risk analysis and identifies where data was generated to estimate risks
- Examines the data and how it was generated
- Compares what has been provided with the ACVM information guidelines
- Reports on the reliability and relevance of the data

Is not asked to make a judgement on the use of other kinds of information in the risk analysis

Screening application



Time line





ACVM Amendment Act

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Background

- ACVM Amendment Act 2016 on confidential information protection commenced in November 2016
- Made changes to Part 6 of the ACVM Act on confidential information protection

Definitions

- **Innovative TNP application** (both regn and provisional) means the application contains an active ingredient not previously in:
 - TNP registered under section 21 of ACVM Act; or
 - TNP registered under the Pesticides Act; or
 - TNP licensed under the Animal Remedies Act
- **Innovative TNP** means the TNP registered on granting of the above.

Definitions

- **Non Innovative TNP application** (both regn and provisional) means an application for registration for a TNP that is not an innovative TNP application
- **Non Innovative TNP** means the TNP registered on granting of the above

Definitions

- Application to authorise a new use or method of use means an application to vary a registration for:
 - One of the purposes outlined in the definition of an agricultural compound; or
 - One or more of the following:
 - Application rate;
 - When the product must or must not be applied;
 - How the product is applied;
 - The withholding period

Protection Periods - Innovative

- **Innovative TNP Application for registration**
 - Protected period starts when MPI receives the application; and
 - Ends 10 years after the date on which MPI grants or refuses to grant the application

Protection Periods - Innovative

- **Innovative TNP application for provisional registration**
 - Protected period starts when MPI receives the application; and
 - Ends 5 years after the date on which MPI grants or refuses to grant the application

There is a exception to this.

Protection Periods - Innovative

- **Innovative TNP Application for provisional registration**
 - Except when the following applies:
 - An application for registration for the same TNP is made prior to the above period expires; and
 - The confidential information under the provisional registration is used to support the application for registration
 - Then protection period carries on for the 10 year period for the innovative TNP application for registration

Protection Periods – Innovative

- **Application new use or method of use**
 - Protected period starts when MPI receives the application; and
 - Ends on the later of:
 - End date of the protected period for the TNP application; or
 - 5 years after the date on which MPI grants or refuses to grant the application

Protection Periods – Non Innovative

- **Non Innovative TNP Application for registration**
 - Protected period starts when MPI receives the application; and
 - Ends 5 years after the date on which MPI grants or refuses to grant the application

Protection Periods – Non Innovative

- **Non Innovative TNP Application for provisional registration**
 - Protected period starts when MPI receives the application; and
 - Ends 5 years after the date on which MPI grants or refuses to grant the application

Protection Periods – Non Innovative

- **Non Innovative TNP Application for provisional registration**
 - Except when the following applies:
 - An application for registration for the same TNP is made prior to the above period expires; and
 - The confidential information under the provisional registration is used to support the application for registration
 - Then protection period carries on for the 5 year period for the non innovative TNP application for registration

Protection Periods – Non Innovative

- **Application new use or method of use**
 - Protected period starts when MPI receives the application; and
 - Ends 5 years after the date on which MPI grants or refuses to grant the application

Protection Periods - Reassessment

- **Section 29 & 30**
 - The same rules apply as for non innovative TNP applications

HSNO Act

- Consequential amendments required to Hazardous Substances and New Organisms Act
 - Net effect is no change to scope of confidential information protected, i.e. remains for innovative TNP applications only.

Transitional Provisions

- New rules on innovative and non innovative TNP applications only apply on or after commencement
- Active ingredients still under confidential information protection retain their confidential information protection
- Applications to authorise new use or method of use:
 - Products already registered (either innovative or non innovative) there will be 5 years protected period

Other Changes

- The amendment makes minor changes to terminology in the ACVM Act for consistency purposes and/or to clarify the existing law
 - Refusal or Granting now used instead of declining or registering



Protection of Confidential Information – how it works

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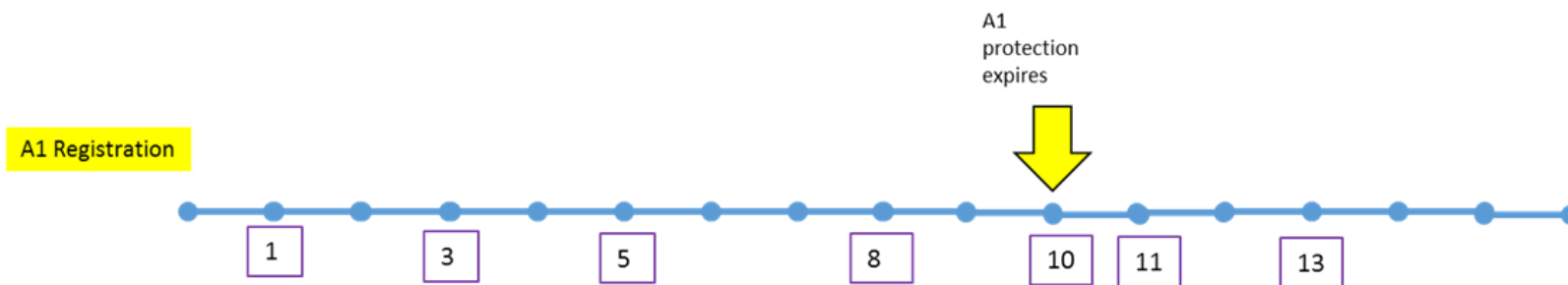
What happens from 8 November 2016 when you make an application?

- If your application fits the criteria for protection of your confidential information under Part 6 and section 29 (Reassessments), you must provide a completed form where information to be protected is listed
- Your application files must follow the file naming conventions in the E-File Guidance to Registrants (this is being updated)
- Mark all your information as In-Confidence

Innovative New Product Registrations

A1 New product with new active ingredient
Confidential information supplied for an Innovative trade name product containing a new Active Ingredient.

Protected period starts when application is received, ends 10 years after the date the application is granted or refused.



Note: Innovative Trade Name Product refers to a product containing an innovative active ingredient, which means that the active ingredient is not in any previous registered product registered either under section 21; or a pesticide registered under the Pesticides Act 1979; or an animal remedy licensed under the Animal Remedies Act 1967

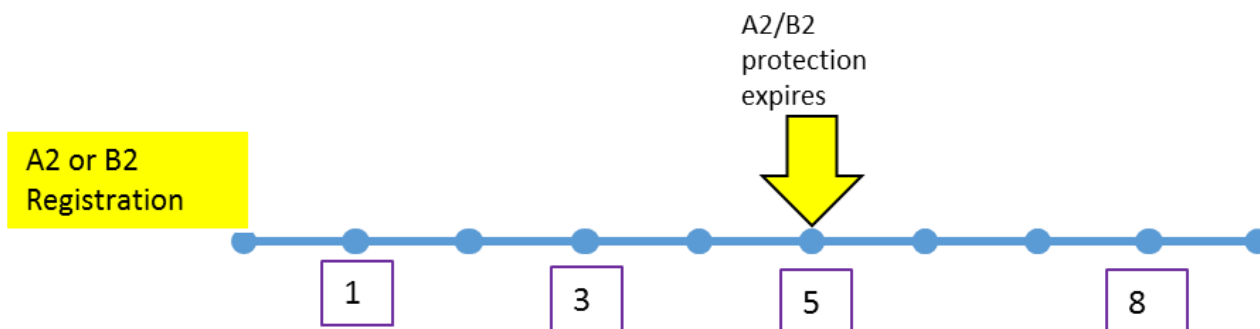
Non-Innovative New Product Registrations

A2 New product containing known active ingredient with new risk profile
Confidential information supplied for a new product that does not contain a new active ingredient.

Protected period starts when application is officially received, ends 5 years after the date the application is granted or refused.

B2 Similar to a registered TNP
Confidential information supplied for a new product that does not contain a new active ingredient.

Protected period starts when application is officially received, ends 5 years after the date the application is granted or refused.



Provisional Registrations – Innovative TNPs

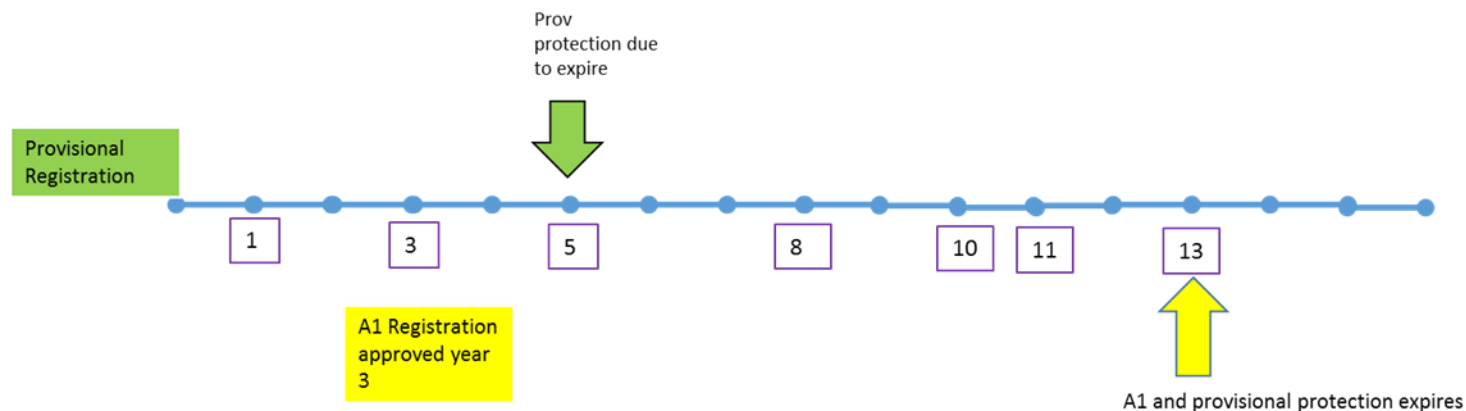
Provisional Registration

(innovative - new active ingredient) - Confidential information supplied for a provisional registration of an innovative product.

Protected period starts when application is received, ends 5 years after the date the application is granted or refused

Note: the protected period for the information supplied in the provisional application can be extended a further 10 years from the date of refusal/granting of an Innovative new product (A1) registration, if:

- it is the same innovative trade name product
- the A1 registration is officially received before the provisional protected period expires
- the information supplied in the Provisional is also supplied in the A1 application



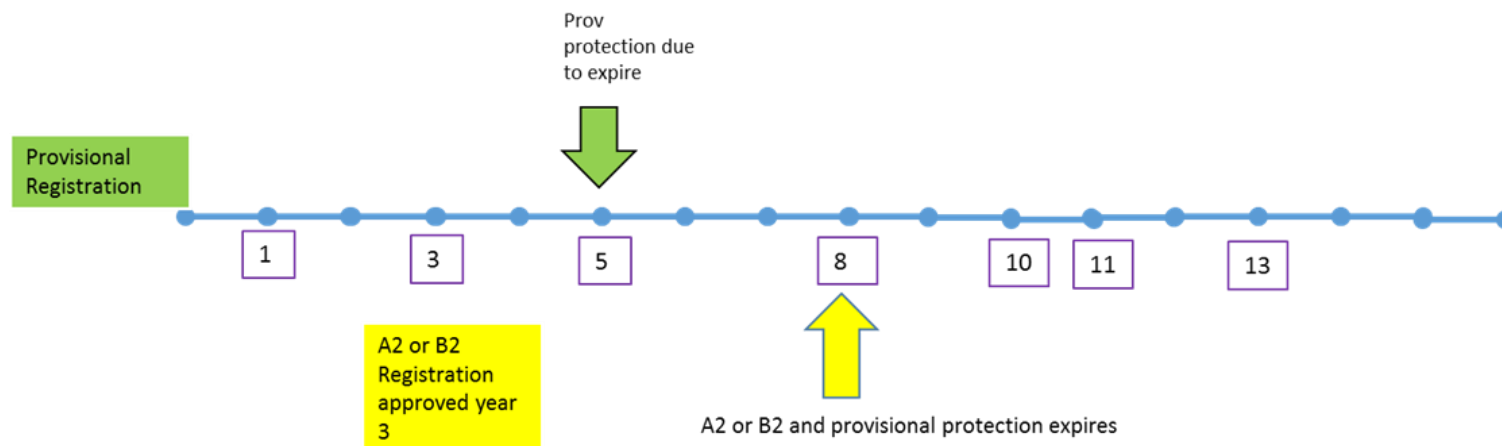
Provisional Registrations – Non-Innovative TNPs

Provisional Registration
(non-innovative) - Confidential information supplied for a provisional registration of an innovative product.

Protected period starts when application is received, ends 5 years after the date the application is granted or refused

Note: the protected period for the information supplied in the provisional application can be extended a further 5 years from the date of refusal/granting of an Innovative new product (A1) registration, if:

- it is the same innovative trade name product
- the A2/B2 registration is officially received before the provisional protected period expires
- the information supplied in the Provisional is also supplied in the A2/B2 application



Variations to Innovative TNPs

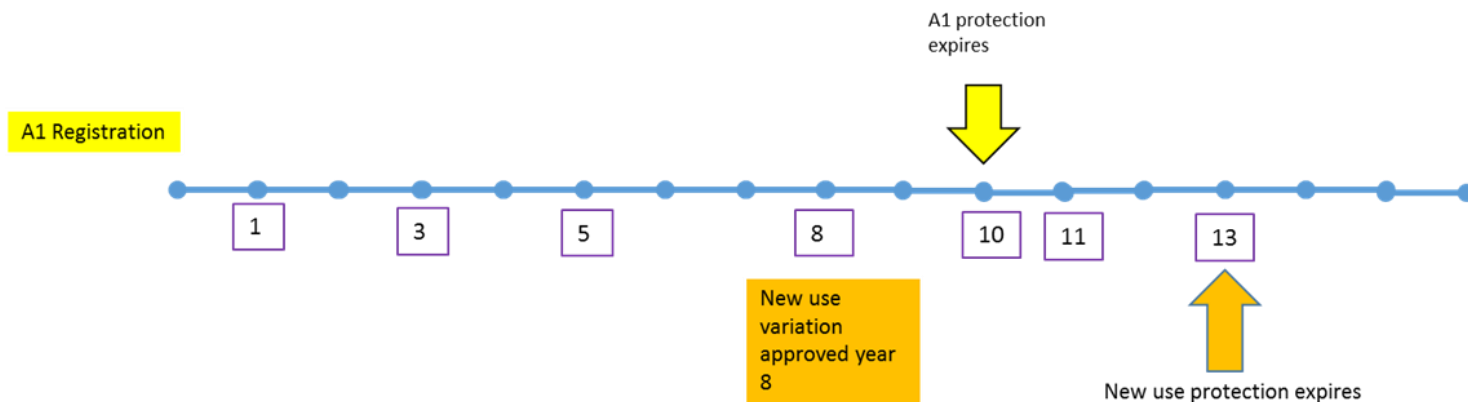
Confidential information supplied for a new use or method of use for an Innovative product:

- ☐ C4: AC/VM/VTAs: Extension of use to include an additional situation or target host
- ☐ C5: AC Addition of another disease, pest or weed;
VM Addition of another disease/ condition;
VTA Addition/ variation to the use situation for an existing target species.
- ☐ C6: AC/VTA Change of application rate or timing;
VM Change of dose regime.
- ☐ C7: AC Change or addition of a method of application;
VM/VTA Change to or addition of method of administration.
- ☐ C8: Change in withholding period.

Protected period starts when application is received.
Ends either the later of the two periods of:

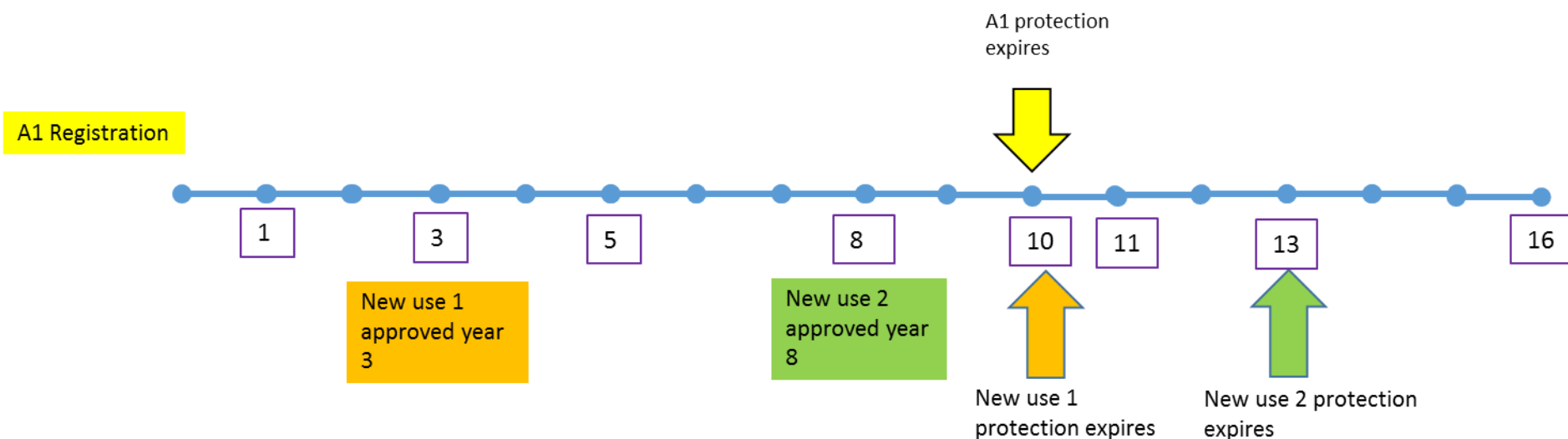
- a) End date for the protected period for confidential information supporting the innovative TNP application that resulted in the registration of the product (i.e. 10 years); or
- b) 5 years from the granting or refusing the variation.

Variations to Innovative TNPs



Variations to Innovative TNPs

Innovative TNP with New Product (A1) Registration, followed by a variation at year 3 and a variation at year 8



Variations to Non-Innovative TNPs

Confidential information supplied for a new use or method of use for an Innovative product:

☐ C4: AC/VM/VTAs Extension of use to include an additional situation or target host

☐ C5: AC Addition of another disease, pest or weed; VM Addition of another disease/condition;

VTA Addition/ variation to the use situation for an existing target species.

☐ C6: AC/VTA Change of application rate or timing; VM Change of dose regime.

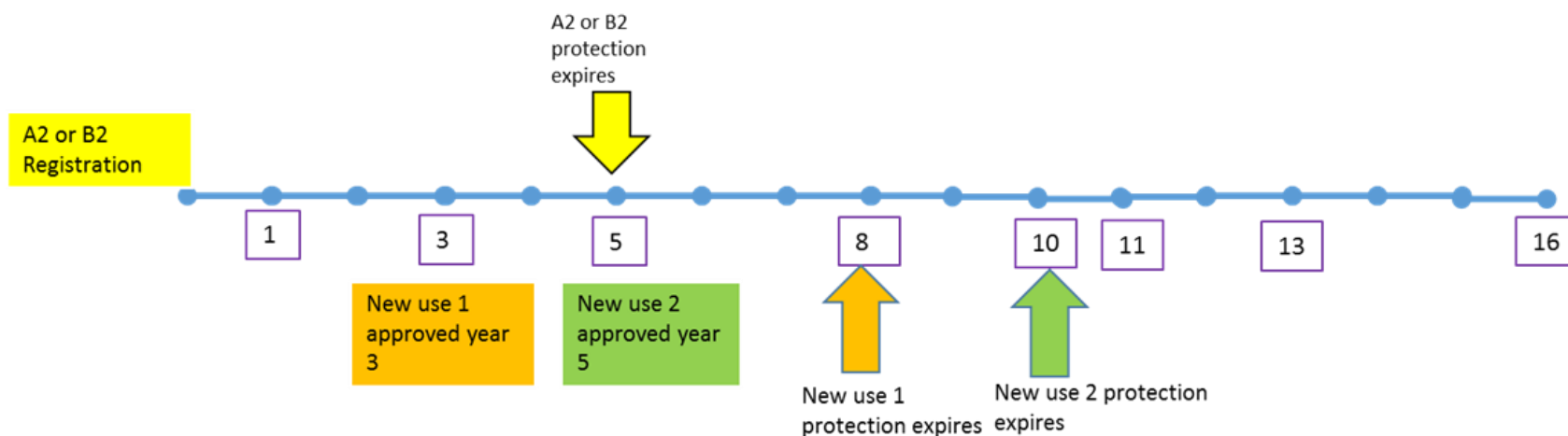
☐ C7: AC Change or addition of a method of application; VM/VTA Change to or addition of method of administration.

☐ C8: Change in withholding period.

Protected period starts when application is received. Ends 5 years from the granting or refusing the variation.

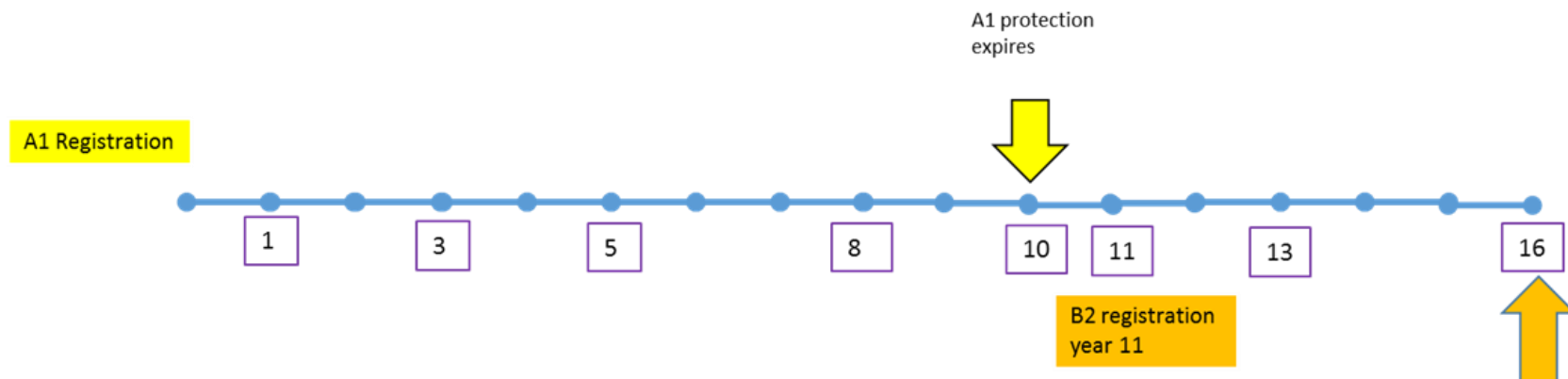
Variations to Non-Innovative TNPs

Non-Innovative TNP with New Product (A2 or B2) Registration, followed by a new use variation at year 3 and a new use variation at year 5:

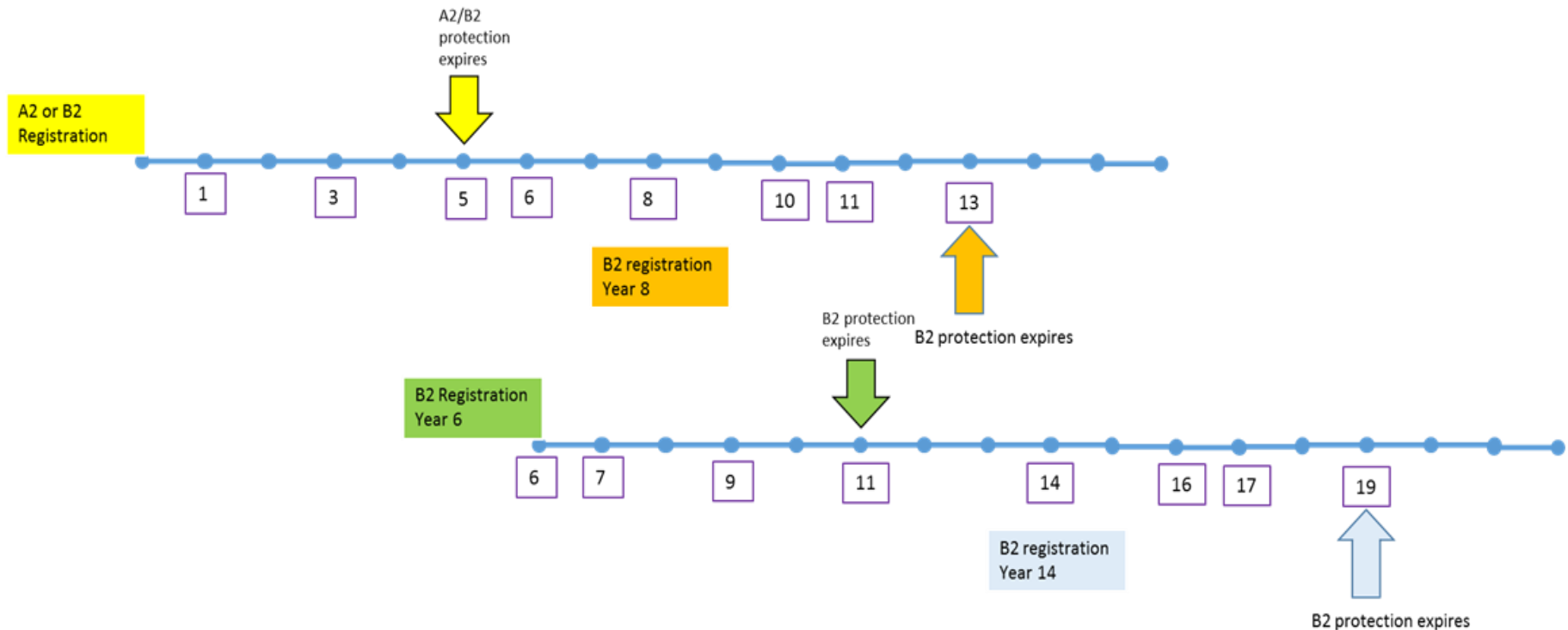


New TNP followed by B2 applications

The confidential information supplied in the A1 registration cannot be cross-referenced until the protection period expires at 10 years from the registration approval. Cross-referencing can only occur after that time. The B2 registration will receive confidential information protection for 5 years on all confidential information supplied in that application, but not for any confidential information cross-referenced from the pioneer (A1) registration.



New TNP followed by multiple B2 applications



Reassessments

Reassessment

Protected period starts when confidential information is received, ends 5 years after the date the application is granted or refused.



Veterinary Medicine Chemistry and Manufacturing Documentation and Guidelines

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Veterinary Medicine Chemistry and Manufacturing Guidelines

- Product Identity Characteristics and Manufacturing and Quality Characteristics
- Feedback on PIC/MQC proposal
- Planned changes to the VM Guidelines

Product Identity Characteristics and Manufacturing and Quality Characteristics

Product Identity Characteristics and Manufacturing and Quality Characteristics

- Presented PIC and MQC concept to AVMAC, Agcarm and ARPPA Oct-Dec 2016
- Restructure of the information necessary to achieve and maintain a registration
- Only some of this information is captured by the current PDS

Product Identity Characteristics and Manufacturing and Quality Characteristics

- **Product Identity Characteristics**
- Parameters that identify the TNP as a unique product
 - Product itself – formulation characteristics, specifications, physicochemical parameters, shelf life
 - Presentation of the product – packaging, labelling (ACVM-approved aspects)

Product Identity Characteristics and Manufacturing and Quality Characteristics

- **Manufacturing and Quality Characteristics**
- How the unique TNP is produced
 - Manufacturers and manufacturing processes
 - Quality control and analytical procedures
 - Post-registration management

Product Identity Characteristics and Manufacturing and Quality Characteristics

- **Drivers for change**

- Ensure that processes are in place to manage risk
- Ensure all information being requested is important to the risk management of the product
- Eliminate the need for unnecessary applications and administrative work

Product Identity Characteristics and Manufacturing and Quality Characteristics

- **Drivers for change**

- Ensure more efficient and complete post-registration management
- **Benefit to registrants**
 - Ability to self-assess certain changes
 - More “black and white” information requirements
 - Faster variation appraisal

Product Identity Characteristics and Manufacturing and Quality Characteristics

- **Drivers for change**

- Ensure more efficient and complete post-registration management
- **Benefit to ACVM Team**
 - Clearer at-a-glance picture of a product
 - Fewer variation applications
 - Information more readily available for GMP audits

Product Identity Characteristics: New Concepts

- Presentation Type
- Label Information
- Chemical and Physical Characteristics
- Information on Biologicals

Product Identity Characteristics: New Concepts

- **Presentation Type**

- More detailed classification of the product
- Examples: sterile lyophilised powder for reconstitution, chewable tablet, coated bolus

- **Risk being managed:** Informs at a glance what other product-specific risk parameters are needed for the product and helps characterise the product

Product Identity Characteristics: New Concepts

- **Label Information**

- Includes all details of the ACVM-approved parts of the label
- Claims, use patterns, WHPs, warnings, storage

➤ **Risk being managed:** Limits approval to only aspects managed by MPI

Note: up to date marketed label will still be required for the product record, but not approved

Product Identity Characteristics: New Concepts

- **Chemical and Physical Characteristics**

- Details of those characteristics critical to the risk profile
- Can include any or all of the following: pH, hydrolytic properties, photolytic properties, isomeric content, pKa

➤ **Risk being managed:** Identifies those aspects of the product impacted by associated changes

Product Identity Characteristics: New Concepts

- **Information on Biologicals**

- Will allow for further characterisation of biological products where needed
- Includes such details as whether the product is sterile, organism status (live vs live attenuated vs killed), antigen/strain detail, other critical parameters

- **Risk being managed:** Allows for concise review of product-specific critical parameters unique to biologicals

Manufacturing and Quality Characteristics: New Concepts

- Critical Ingredients and Components
- Product Release Analytical Procedures
- Entity Responsible for Ongoing Stability Programme
- Entity Responsible for Release to Market in New Zealand
- Entity Responsible for Pharmacovigilance Programme and Adverse Event Reporting

Manufacturing and Quality Characteristics: New Concepts

- **Critical Ingredients and Components**

- Those ingredients and/or components in the final formulation that have a direct impact on the risk profile of the product
- Change in those ingredients/components would change the risk profile
 - Active Ingredients
 - Vaccine adjuvants, penetrants in pour on products, bolus delivery mechanism that regulates payout, ingredients triggering other risk areas (e.g. NPE)

Manufacturing and Quality Characteristics: New Concepts

- **Critical Ingredients and Components**
 - Moving away from simple binary active vs excipient designation – not all excipients are inert!
 - Allows regulation to focus on components that have a direct impact on the risk profile of the product post-registration
 - Registrant justifies what is and is not critical

Manufacturing and Quality Characteristics: New Concepts

- **Critical Ingredients and Components**
- **Risk being managed:** Allows for a true picture of the risk-related parameters, not just active ingredients

Manufacturing and Quality Characteristics: New Concepts

- **Product Release Analytical Procedures**

- Requires more detail on the analysis of the product prior to product release, and ongoing management
- Identifies validated analytical procedures being used, testing sites (QC labs), testing intervals

- **Risk being managed:** Ensures that all aspects of QC are being effectively managed and maintained

Manufacturing and Quality Characteristics: New Concepts

- **Entity Responsible for Ongoing Stability Programme**

- Ongoing stability programme is important for managing risks under the Act and maintaining products
- International requirement and GMP requirement
- Identifies stability issues during product life

➤ **Risk being managed:** Ensures programme is in place

Manufacturing and Quality Characteristics: New Concepts

- **Entity Responsible for Release to Market in New Zealand**

- Will require identity of the entity responsible (can be a person or company) and the responsibilities assigned to that entity
- Currently, responsible entity inconsistently identified or not identified

➤ **Risk being managed:** Ensure better visibility of responsible entities and their roles in product manufacture and supply for all products

Manufacturing and Quality Characteristics: New Concepts

- **Entity Responsible for Pharmacovigilance Programme and Adverse Event Reporting**
 - Important to identify who is responsible for these programmes
 - Although often the registrant, these responsibilities can be contracted out
 - These functions may be auditable in future
- **Risk being managed:** Ensure a clear regulatory understanding of who is responsible and how they are managed

Feedback on the PIC/MQC Proposal

Feedback on the PIC/MQC Proposal

- PIC/MQC proposal was presented to AVMAC, Agcarm, and ARPPA in three separate workshops
- Feedback was received from five registrant companies
- Key learnings from feedback:
 - **Keep requirements focused on risk management**
 - **Focus on improving the system**
 - **Align with other international regulatory authorities**
 - **Look at all possible tools to achieve the most efficient end**

Feedback on the PIC/MQC Proposal

- **Keep requirements focused on risk management**
 - Changes proposed are the key components necessary for ACVM Act risk management
 - Additional product identity characteristics are further detail on existing requirements
 - Additional manufacturing and quality control detail in line with international expectations
 - Eliminates detail not necessary to the product risk profile from product documentation

Feedback on the PIC/MQC Proposal

- **Focus on improving the system**

- Proposed changes align with Registration Review efficiency strategies
- Limiting review and variation to only risk-affecting parameters will reduce workload and regulatory burden
- Allowing self-assessment of certain changes will further reduce workload
- New requirements will “even the playing field”

Feedback on the PIC/MQC Proposal

- **Align with other international regulatory authorities**
 - In developing the new structure, chemistry and manufacturing information requirements and manufacturing/GMP requirements in Australia, the US, Canada, and the EU were reviewed
 - Striving for alignment has driven the requirement for more detail
 - Must always keep the NZ risk assessment model and NZ-specific risks in mind at all times – alignment is not always appropriate.

Feedback on the PIC/MQC Proposal

- **Look at all possible tools to achieve the most efficient end**
 - Will continue to consult with industry to ensure the risks are being managed in a way that is achievable and practical
 - Registration Review project looking at efficiencies at application management end
 - Chemistry and Manufacturing risk management can include other tools where appropriate, such as operating plans for pharmacovigilance programmes

Veterinary Medicine Chemistry and Manufacturing Guidelines

Chemistry and Manufacturing Guidelines

- New guidelines being drafted to include detail informing PIC/MQC concept
- Guidance will be divided into three sections:
 - New Registrations
 - Variations
 - Notifications

Chemistry and Manufacturing Guidelines

- **New Registrations** guidance will include all information necessary for a full C+M dossier
 - **Variations guidance** will include information on what is expected for each type of variation
 - **Notifications guidance** will include what is and is not considered a notification, and what is expected of the registrant when can just be notified
- Guidance detail level will be comparable to EU

Chemistry and Manufacturing Guidelines

- **Final PIC/MQC will not be rolled out until the new guidelines have been completed (probably via AVMAC)**
- **Industry will be consulted before draft guidelines, PIC/MQC document, and associated application form are finalised**
- Expect guidance to be completed at or before Q3 2017

Any Questions?

