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Summary Report: Review and recommendations for approval & registration of biopesticides for use in plant protection in New Zealand

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1. Summary report

New Zealand (NZ) farmers and growers require access to the most appropriate portfolio of plant protection products to support them growing consistent acceptable quality crops, cost effectively and thereby remain competitive on home markets and to maintain or open access to global markets. Given the desire for NZ farmers to grow crops sustainably with few or no unacceptable adverse effects for people and the environment, biopesticides are a useful and desired range of plant protection products. Currently, NZ has around 50 biopesticides active substances, (compared to 445 in USA, 214 in the EU) that are available in products for farmers and growers and as such, the registration of such products is considered a barrier. This review aimed to identify barriers, make a comparative assessment of biopesticide registration provisions in other jurisdictions, and subsequently make recommendations for consideration for improvements for approval/ registration of biopesticides in NZ.

The aspiration of developing a facilitating system for biopesticides is to remove unnecessary barriers to their approval and registration thereby providing more products available to NZ growers to allow them to implement good plant protection practices, IPM and to remain competitive nationally and internationally.

Regulation of plant protection products has three aspects: a) policy framework, b) application and assessment process and c) data requirements (dossier fulfilment). The interviews and consultation with other stakeholders (research organisations, applicants, innovators, Appendix 1) for this project were conducted to explore these three aspects. Depending on the role of the organisation being interviewed, they had a different depth of experience for each of the three aspects. The information gathered from these interviews informed the considerations and is provided in terms of good practice and facilitation for biopesticide regulation.

This review has focussed on the regulation for the main types of biopesticides. This includes 1) microorganisms, 2) plant extracts/botanicals, nature identical substances/natural substances and 3) semiochemicals (Figure 1). As they are relatively new technologies, this report has not addressed technologies such as dsRNAi, peptides and proteins and gene technologies, although it is recognised that in some organisations and countries, regulatory provisions for these technologies have been or are currently under consideration and development.

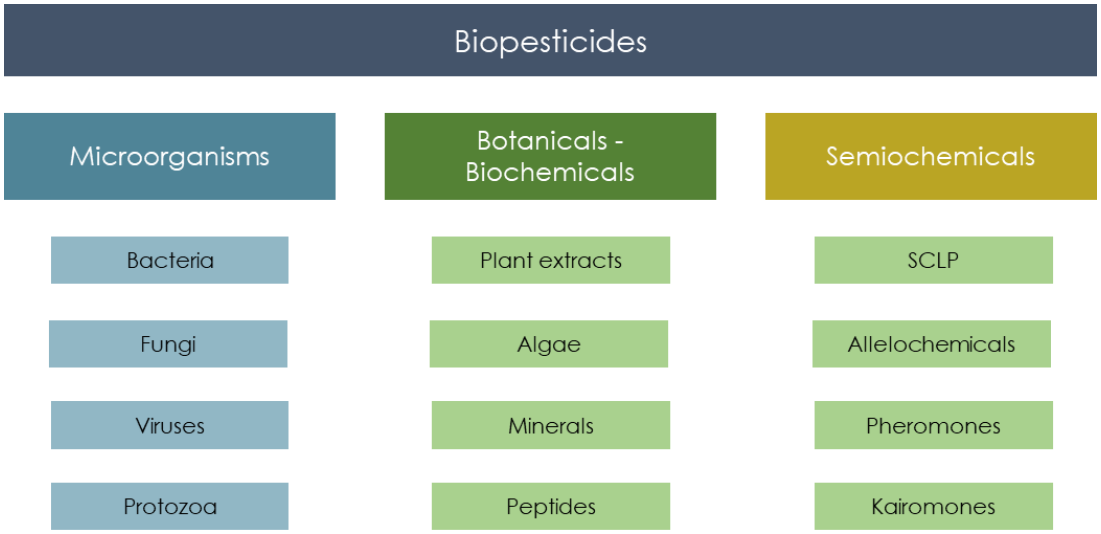

Figure 1. Definitions of biopesticide types with examples of active substances.
(SCLP = short chain Lepidopteran pheromones)

A typical process to develop a microorganism-based biopesticide with conservative timelines needed for a well-funded and managed product development process and regulatory process indicates this process takes at least 6 years (Figure 2). By the time a dossier is prepared, innovators and companies have invested significant resources in developing their product and preparing its regulatory dossier then, for the period of regulatory review, the company cannot generate any revenue from the new development. This causes significant financial stress to a business.

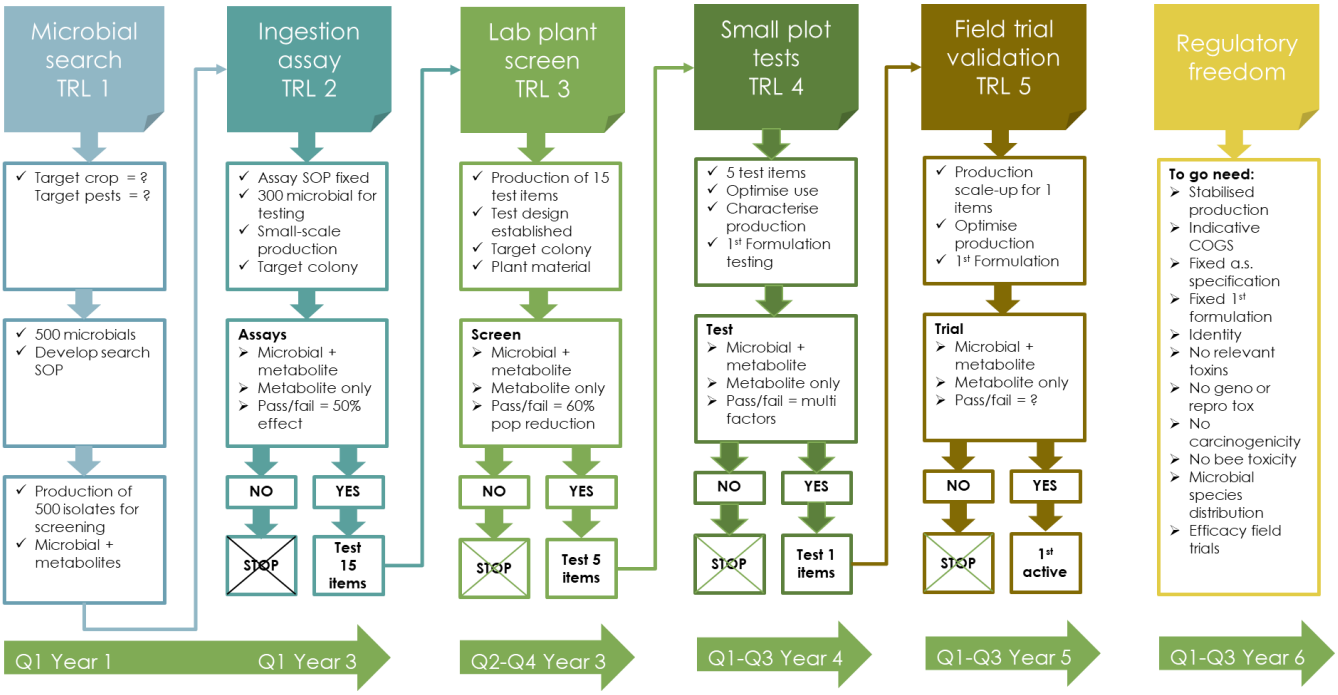

Figure 2. Optimistic product development plan for a microorganism-based biopesticide

Following this optimistic 6-year product development there is usually a 3 to 5 years regulatory process. Timely, proportionate regulation can have a positive impact of development of new technologies and support movement of innovative ideas and technologies into products that farmers

and growers can use to support them to remain competitive in New Zealand and international markets.

Since this project started, the review of the regulatory system for agricultural and horticultural products in New Zealand has been released[1]. The regulatory system review gives a good overview of NZ regulatory systems and details provisions for biopesticides - Chapter 2, 2.3 onwards in the document gives a good review of NZ regulatory practice and the respective roles of the ACVM and EPA in managing the potential risks associated with pesticides in general. The complicated process that an applicant must follow to obtain a substance approval under the HSNO Act and registration of a tradename product under the ACVM Act in NZ is transparent from the report.

It was not in scope of this report to review the existing regulatory system as that had already been done by A Lighter Touch project.

2. Recommendations for good practice biopesticide regulation in New Zealand

The recommendations in this report consider regulatory approaches that can be used to speed-up biopesticide registration but essentially maintain a good level of safety for people and the environment.

2.1 General recommendations

1. Develop biopesticide specific regulation for each category of biopesticides with accompanying data requirements and good interpretive notes that support assessors and applicants. As part of this it will be necessary to develop and adopt definitions for substances within the broader definition of biopesticide technologies. Plus, establish a glossary of terms for biopesticides to provide clarity for applicants and assessors for the data requirements.
2. For biopesticide registrations, with or without legal changes for biopesticides, create a collaborative working group to make a 'Biopesticide Hub' (Figure 3) that integrates ACVM and EPA roles into a combined assessment process.
3. Establish effective communications between assessors from both regulatory organisations that is clear and transparent within a defined scope agreed via the new Biopesticide Hub. This system will facilitate the regulatory agencies and the applicants to track progress and anticipate when their inputs will be required. This allows everyone involved to plan what resources are needed and when; and serve to minimise lost administrative time and create transparency.
4. Develop clear, written, and shared policy on the relevant protection goals for NZ for biopesticides. A clear standard will ensure there is alignment of assessments between technology types. Clarity on the protection level for no unacceptable effects for biopesticides will support assessors to know when sufficient information is provided for the risk assessment and support applicants to understand when they have provided sufficient information.
5. Develop biopesticide expert capacity in NZ:
    a. Develop and share information about biopesticides, what the technologies are, and their value to horticulture and agriculture production.

[1] Agricultural and Horticultural Products Regulatory Review, Ministry of Regulation, https://www.regulation.govt.nz/regulatory-reviews/agricultural12-and-horticultural-products-regulatory-review/

b. Train regulators in biopesticides and encourage engagement internationally such as via OECD, FAO and developing partnerships with parallel regulators to share knowledge and experience.
c. Set up a biopesticide regulatory network amongst regulators to support experts, compare practice (benchmarking standards), validate risk assessments etc. This would be a mechanism for creating continuity of expertise when there are staff changes and facilitates continued learning for biopesticide specialists.
d. Identify, recruit and/or train suitable biopesticide experts into Biopesticide Hub, including those based outside NZ.
e. Sub-contracting work to specialists (nationally and internationally). Sub-contract assessment to relevant specialists to provide capacity to manage workflow effectively and not to have paused assessments. Depending on the specialism (biopesticide type, risk assessment category), the specialists could be situated globally. This would speed up workflow and demonstrate assessments, which NZ regulators can use for training.
f. Provide training for applicants for preparation of critical aspects for biopesticide dossiers.

6. Make a clear fee structure: amounts and timing of payments. For cash flow and to survive, many small companies need to spread fees across the assessment period. It would be supportive to small companies to have such a provision and encourage the registration of new technology from NZ-based companies. It is understood that currently this is separated into HSNO approvals and MPI tradename registrations, an approach to align this would be beneficial to applicants.
7. NZ has established a list of 'trusted' countries, who's evaluations for biopesticide are considered a comparable standard to those of NZ. This information needs to be made a priority and made transparent to applicants as it confirms that NZ takes a 'Peer Review' rapid assessment approach. In addition, NZ could consider greater reciprocity of data with trusted assessments from other countries and add to the already-established list with other countries whose assessments match the standard applied in NZ. Care should be taken not to create an unjustified, from a risk perspective, higher standard in NZ than in other countries as this will significantly reduce applications and approvals. This consideration includes efficacy, where it is important to be clear when there are points of relevant differences in uses, climate and agronomic conditions such that additional, NZ-specific testing is needed.
8. Explore options for work sharing with Australia who already have a well thought-out and facilitating regulatory process for biopesticide active substances.
9. Efficacy for where there are differences in proposed uses or for new applications:
    a. Make the needs clear and transparent for applicants, including the list of regions, countries or climates that are comparable to NZ and therefore acceptable for efficacy trials.
    b. Provide clear guidance on aspect of comparable agronomy that are acceptable.
    c. Training of NZ efficacy trialists in biopesticide trial design, statistical methodology, assessment, application etc.
    d. Clear adoption of EPPO[2] General Standards, particularly identifying those applicable to biopesticides.
    e. Clear guidance on number of acceptable trials required to support uses.
    f. Clear guidance on acceptable quality of biopesticides trials to support uses.

[2] https://gd.eppo.int/

g. Provision for acceptable label descriptions to reflect biopesticide efficacy data.

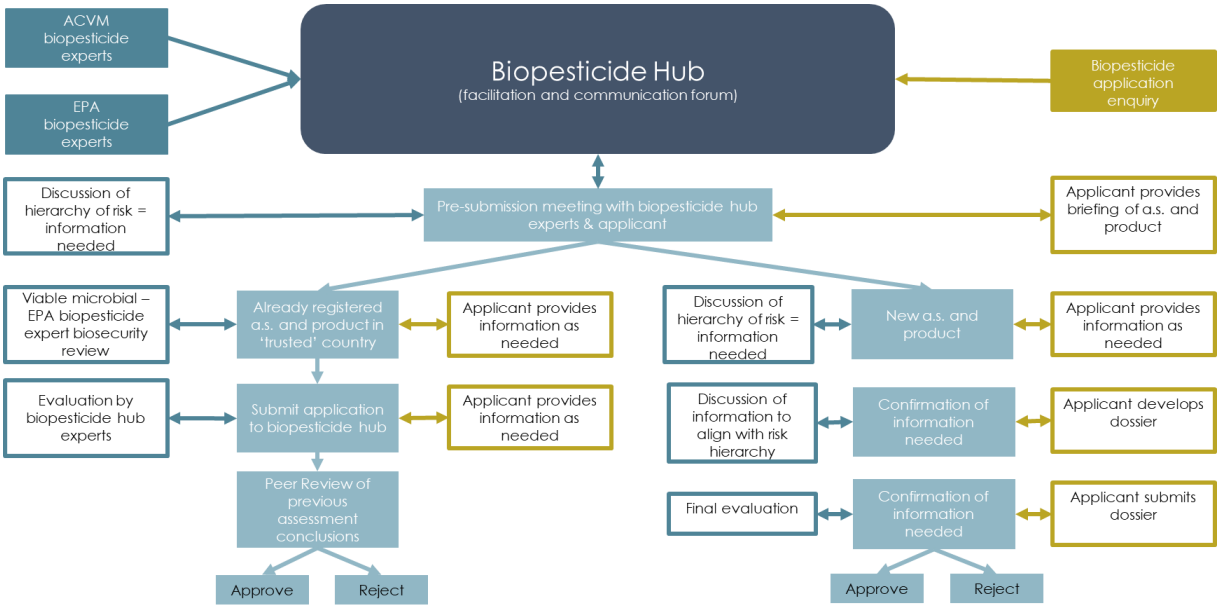

Figure 3. Proposed system of a Biopesticide Hub

2.2 Specific recommendations to optimise the NZ regulatory process and assessment

2.2.1 Regulatory policy

1. **Develop biopesticide specific regulations**
   For all technology types develop a specific regulation with provisions for new technologies to future-proof the effort.
2. **Create mechanism for, and establish a Biopesticide Hub (collaborative working group)**
   A Biopesticide Hub would bring together and align the different responsibilities that ACVM and EPA assessors have, onto the same timelines and assessment quality and to work collaboratively. This can also serve as a knowledge base for assessors and applicants.
3. **Government support** for:
   a. Reduced fees for applicants with biopesticides.
   b. Free pre-submission meetings (applicants can access advice and assessors get pre-notification of expected workload).
4. **Prioritise biopesticide dossiers for assessment.**
   Establish the principles and mechanisms to allow regulators to prioritise biopesticide dossier assessments.

2.2.2 Regulatory process

1. **Formalise Peer Review processes for already-assessed dossiers from trusted countries.**
   Establish specific to biopesticides, which parts of the dossier need to be reviewed, and which parts must be re-assessed or need new data to meet NZ standards. This can be a fast 'triage' approach specific to the biopesticide type, so applicants quickly understand resources needed and whether to proceed (see Point 3 below). This links to the establishment of clear protection goals, to ensure that NZ does not implement artificially higher standards than needed to maintain human and environmental safety. This can be supported by developing biopesticide-specific guidance that encompasses both ACVM and EPA requirements.
2. **Formalise full reciprocity with Australia AVPMA for Biopesticide Registration**

Australia AVPMA operate a biopesticide registration system that is a good model to use for how to work with biopesticide applicants and how to evaluate biopesticide applications in a hierarchy of risk approach that is pragmatic, maintains close dialogue with applicants and is proportional to the risk biopesticides represent. This approach is explained in a well-designed online resource where needs for biopesticides are specifically addressed and there is the option of consultation with suitably qualified regulatory experts. APVMA have developed biopesticide expertise in all areas for risk assessment and for efficacy. Given the geographical proximity, the proposed NZ Biopesticide Hub could include APVMA.

A shared working relationship would make the region more attractive for applicants (easier to access the markets) as a single application would mean approval in both countries. This approach would also allow building of expertise across the region and potentially create a system that other countries in the region could use. Again, this would increase the market attractiveness of the region, the lack of which is one of the reasons for a low number of biopesticide applications (the cost of and time to registration, versus the regions market value, does not align).

3. **Formalise a 'triage' pre-submission meeting for new, unassessed applications.**
   To create an optimised assessment system, apply a staged approach that is taken to the Biopesticide Hub, which has combined experts from both ACVM and EPA. Hold a formal pre-submission meeting for which applicants provide specific information about their active substance and product (this could easily be applicable to both Peer Review dossiers, already assessed and new substance dossiers). The specific information to be provided at such a first-stage meeting would be sufficient for assessors to understand what a substance is but it is not intended that a risk assessment is made at this stage. Information that an applicant could include:
   a. Active substance identity.
   b. Biological properties including what is known of the mode of action
   c. Product formulation.
   d. Good Agriculture Practice table of intended uses for target and crops and situation (field, greenhouse, indoors).

   The output from this meeting would be to provide the scope of the information needed for preparing a suitable dossier. It should lead onto the step below. The advantage of this approach is that an applicant is not spending money to develop information for all the data requirements but can be directed to providing information critical to make a good risk assessment for NZ.
4. **Use a Hierarchy of Risk approach.**
   Based on the above stage move on to a Decision Tree approach. To determine the information needed for a risk assessment, there are two published peer-reviewed papers [3,4,] on how to work through the risk associated with microorganisms and natural substances (semiochemicals is under preparation), these can be used as the model or basis to guide assessors and applicants to determine the information that is relevant, and needed, to allow a good risk assessment for human and environmental safety. Importantly it will also highlight information not needed. This approach would be applicable to both Peer Review (already assessed dossiers) and for new, unassessed substances. This Decision Tree approach is used well by Australia and USA and considered to support an efficient regulatory process.

[3] https://doi.org/10.1080/09583157.2025.2450414

[4] https://doi.org/10.1080/09583157.2023.2210268

5. **Provide waivers for viable microorganism substances already assessed for biosecurity**.
   For environmental risk assessment and non-target effects for viable microorganism that have undergone a plant health biosecurity assessment, additional assessment can be automatically waived.
6. **Develop a fast-track system for commonly used microorganisms.**
   When required, once a new organism has been approved for release by EPA, a simplified approach could be used. Some microorganism species have been approved for use and widely sold in many countries and for a long-time. These microorganisms usually have a defined mode of action and specificity to target and/or are known to be (through prior assessments) lower risk, for these microorganisms it should be possible to only require the following information (based on similar recommendation in WHO/FAO microbial, botanical and semiochemical guidelines[5]):
   a. Full and unequivocal taxonomic identification to species with strain designation, deposition of the strain in an internationally recognised culture collection and given an accession number.
   b. Confirmation of the microorganism production process including quality control steps, to clearly demonstrate that the active substance contains viable cells only and therefore an absence of significant levels of secondary compounds (metabolites).
   c. The active substance is formulated only with inert (non-toxic) co-formulants in the product.
   d. Confirmation of viability/potency as appropriate, in the final product following storage.
   e. Confirmation of formulated product relevant physical/chemical and technical properties.
   f. Confirmation that human pathogen contaminants are below accepted levels in the product.
   g. Sufficient efficacy data to confirm label claims but there can be extrapolation of uses between crops, for example for the same target pest.

   This list could also form the basis of relevant aspects to be confirmed for a Peer Review, already assessed application.

2..2.3 Data requirements

1. **Amend data requirements for HSNO substance approvals to match biopesticides substance types**.
   Adjust data requirements specifically to biopesticides so that the currently terms 'Required' or 'Conditionally Required' apply for the specific biopesticide types and provide clarity on which and how they are, or are not, applicable to biopesticides.
2. **Develop biopesticide-type specific** data requirements**.**
   A simplified set of data requirements could be developed for all sections, so that applicants do not provide more information than needed and for example undertake unnecessary testing. In Brazil, Canada, EU and USA, there are collectively over 1000 biopesticides approved over the past 30 plus years: this is a resource that NZ can use as much of the information about the assessment outcomes is in the public domain and can be considered in the context of any cases of problems that have arisen post approval (there are few problems identified post-approval, suggesting assessments have been good). Based on this body of experience, NZ can create groupings of substances and the data required for these can be made appropriate to the expected risk based on this body of information, this is the approach Brazil has taken. This approach is also advocated for microbials in the already referenced, FAO guidance.

[5] FAO/WHO Guidelines for the Registration of Microbial, Botanical and Semiochemical pest control agents for plant protection and public health uses. https://www.who.int/publications/i/item/WHO-HTM-NTD-WHOPES-2017.05

For example, based on the experience with microorganisms, for the environmental risk assessment, OECD developed a specific guidance[6] which provides a proposal for the environmental risk assessment for microorganism active substances. The same approach could be taken for other biopesticides. The system advocates a hierarchy approach.

Following this approach, it is clear what information is needed to identify the additional environmental risks that may arise following use of the product, the information needed to address the identified risks and the mechanisms to confirm that the use of the product will/will not result in an unacceptable effect or risk. This approach means that the data requirements can be adapted case-by-case so only the relevant information is provided by applicants.

3. **Establish relevant and specific guidance for registration requirements for each biopesticide type.**
   The OECD and FAO[7] have developed good guidance for areas of risk for microorganisms, natural substances and semiochemicals. In addition, countries such as USA-EPA BPPD, EU, Canada have also developed guidance documents to support applicants and assessors. These documents provide vital clarifications for both applicants and evaluators. In NZ, a single manual for biopesticide registration would provide a working framework for how to address and evaluate biopesticide data requirements. This guidance should follow a hierarchy of risk approach, indicating when information is not needed, where it is critical and how this can be assessed. It should include an explanation of the risk assessment goals. Such a document will also assist in training new assessors and to standardise assessments.
4. **Provide specific advice on biopesticide efficacy trials needed to support a label use.**
   Efficacy testing can be expensive and time-consuming therefore it can be a barrier to getting registration of biopesticides. Develop good quality, clear advice on the trials-based evidence that is essential to support a label use, provide clarity on acceptability of trials from other regions (based on similarity of agronomy and if needed climate). Make good use of EPPO[8] trials guidance.

[6] https://www.oecd.org/en/publications/oecd-guidance-to-the-environmental-safety-evaluation-of-microbial-biocontrol-agents_9789264221659-en.html

[7] FAO/WHO Guidelines for the Registration of Microbial, Botanical and Semiochemical pest control agents for plant protection and public health uses. https://www.who.int/publications/i/item/WHO-HTM-NTD-WHOPES-2017.05

[8] https://gd.eppo.int/

Appendix 1: Organisations interviewed for this project and questions addressed

Interview framework shares with interviewees in advance of meetings

I would be interested in a discussion some ideas that your organisation has of what works well and ideas for:

- Policy
  - Ways that policy alters biopesticide facilitation, if at all
  - Processes for encouraging applications of products, what are the drivers?
  - Interdepartmental liaison and processes to manage timelines
  - Risk context
  - Capacity/resource availability
  - Readiness for new technology
- Applications/submissions:
  - Initiation of applications, examples of good communication/processes between applicant and authority,
  - Expertise of applicants
  - Experiences of good mechanisms for submitting applications (e.g. format, electronic etc.)
  - Data quality issues with applications – frequency of any problems and how they are resolved
  - Acceptability of reciprocity of prior assessments/parallel standards
  - Any study quality issues e.g. acceptability of studies from other regions
  - Quality of waivers/reasoned cases
- Evaluation
  - Authority's mechanisms to facilitate assessments and any relevant context for risk assessments specific to your country
  - Availability of suitable expertise, are some tasks sub-contracted as demand requires
  - End point of risk assessment – what is the target?
  - Mechanisms for assessing new technologies
- Ideas for what makes for good biopesticide registration processes for both applicants and authorities.

I appreciate this is a long list of points to consider but I have found that there will be areas that you may want to focus on because you consider these are either the greatest bottlenecks or the best solutions. While it is good to understand your processes, I would aim to be focussed on good practices and solutions for biopesticides.

List of interviewees

Organisation type	Country	Organisation	Roles and relevance
Regulator	Australia	APVMA	Efficacy and Safety
Regulator	Australia	APVMA	Director, Efficacy and Safety
Regulator	Australia	APVMA	Executive Director, Registration Management
Regulator	Australia	APVMA	Registration Management
Consultant	Brazil	Cesis	Biopesticide expert for South America
Regulator	EU	DG SANTE	Head of Pesticides DG SANTE. Develop regulations, DR, GD

Organisation type	Country	Organisation	Roles and relevance
Regulator	EU	DG SANTE	Microbial Specialist DG SANTE. Develop regulations, DR, GD
Regulator	EU	CTGB	NL Regulator and regulatory policy
Regulator	EU	MST	DK Regulator and regulatory policy
Regulator	EU	MST	DK Regulator and regulatory policy
Trade Association	EU	IBMA	Executive Director of IBMA
Efficacy	Global	EPPO	Efficacy Organisation
Consultant	NL	Independent	Ex: Regulator, Head of DG SANTE WGBP, CRO, IBMA advisor
Regulator	NZ	ACVM	NZ regulatory agency
Company	NZ	Biotelliga	Biopesticide developer
Research, industry	NZ	University of Lincoln	Import, development, registration, expert advice to regulators
CRO	UK	APIS	Lead CRO and testing for biocontrol in EU
Farmer	UK	AHDB	Grower organisation
Regulator	UK	CRD	Efficacy specialist, CRD, UK
Researcher	UK	University of Warwick	Regulatory policy
Company	USA	Lallemand, BPIA	Deep experience of USA biopesticides, BPIA
Company	USA	Agrospheres	Deep experience of USA biopesticides
Company	USA	ProFarm/Bioceres	VP Regulations, USA policy advisor
Farmer	USA	Western Growers	Grower organisation
Regulator	USA	EPA - BPPD	Deputy head of EPA BPPD, Chair of OECD EGBP
Regulator	USA	EPA - BPPD	Deputy head of EPA BPPD, Chair of OECD EGBP
Trade Association	USA	BPIA	Regulatory Specialist, BPIA