Exporting pesticide to Australia and New Zealand? Compliance Overview and Strategies

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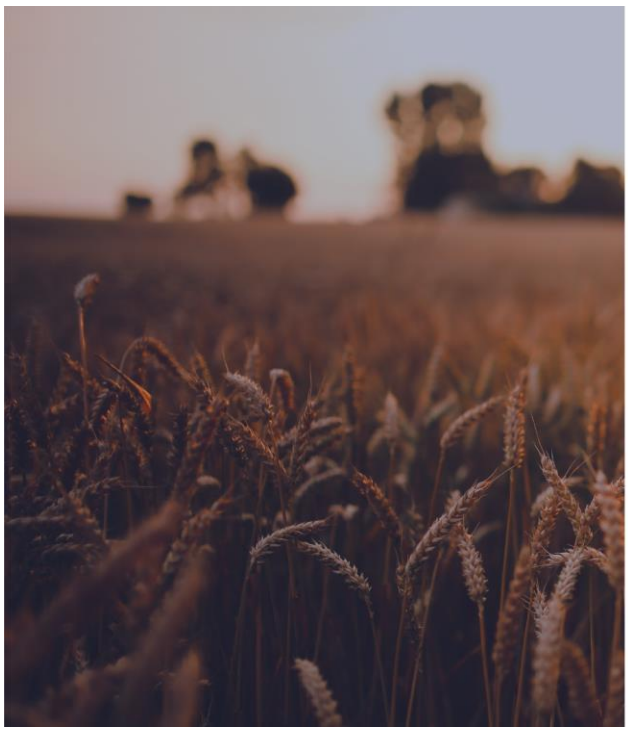

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Why are pesticides registered?

- To provide safe crop protection products for farmers
- To protect the health of users of the pesticide
- To protect the environment
- To ensure that the pesticide does not damage the treated crop
- To ensure that the pesticide performs as claimed (efficacy)
- To protect the health of consumers of treated food
  - Residues expected from use pattern
  - Establish Standards for Maximum Residue Limits
  - Dietary exposure assessments

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The agrochemical market in Australia

- The agricultural chemical imports is rising up considerably in Australia.
- The increase in imports reflects rising cost pressures faced by manufacturing in Australia and increasingly competitive pricing of overseas suppliers.
- Manufacturers in Australia are outsourcing an increasing proportion of production or have left and set up international operations (IBISWorld Australia 2018b).
- Earlier the imports consisted mostly of active ingredients, with manufacturers in Australia formulating products in Australia. However the reduction in local manufacturing and the rise of imports has resulted in increasing import of formulated products (IBISWorld Australia 2018b).
- China, the United States, New Zealand and Malaysia supply over 70 per cent of all imported product (United Nations 2019).

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The agrochemical market in New Zealand

- According to Food and Agricultural Organization (FAO) data, the value of pesticide imports in New Zealand is significant in relation to agricultural exports.
- In 1996 our annual imports of pesticides increased to approximately 1% of export earnings and since then have been relatively stable at this level. In 2003, New Zealand imported pesticides valued at US$72 million.
- More than 300 pesticides are approved for use on fruit and vege grown in New Zealand.

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Export requirements – AU and NZ

- Presence of your organization in country of interest or the authorized agent in the country
- Import permit or approval
- A proposed Good Agricultural Practice (GAP)
  - The GAP includes nationally authorized safe uses of pesticides under actual conditions necessary for effective pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable (JMPR).
- A data package addressing the national requirements (as per OECD & JMPR guidance)

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AUSTRALIA

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Agrochemical Registration In Australia (1/3)

1. The APVMA (Australian Pesticides and Veterinary Medicines Authority) evaluates, registers and regulates agricultural chemicals. Agricultural and Veterinary Chemicals Act 1994 is the base for pesticide regulation for APVMA.
2. The states and territories are responsible for control of use. Chemical companies wishing to register a product are required to provide extensive data supporting the safe and environmentally friendly status of the product.
3. Evaluations of variations to available products can be shorter. The active constituent of a product must be registered before or with the registration of the product.

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Agrochemical Registration In Australia (2/3)

4. Evaluations for completely new products can be lengthy in Australia.
5. As part of the assessment process, the APVMA receives input from other Commonwealth agencies, including:
   - Australian Government Department of Health
   - Australian Government Department of the Environment
   - Food Standards Australia New Zealand (FSANZ)
   - Office of the Gene Technology Regulator (OGTR)
   - Biosecurity

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Agrochemicals Registration in Australia (3/3)

A. Active substance registration
B. Plant protection product registration

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Types of Product Registration in Australia (1/2)

Types of active ingredient and PPP registration

1. New product with an existing active or new combination of approved actives (new agvet chemical product containing an existing active)
2. New product which contains a new active constituent (new agvet chemical product that contains a new active constituent)
3. A product that is based on an existing registered reference product (new product based on that product being similar or closely similar to a registered reference product)

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Types of Product Registration in Australia (2/2)

Types of active ingredient and PPP registration

4. The product same as a reference product (repack)
5. Approval of a new source of active
6. Variations to registered products (minor/major changes in existing registered product)
7. Timeshift applications (staged submission of supporting data packages allowing commencement of longer assessments (such as toxicology and environment) while other supporting data packages (such as efficacy and crop safety) are being completed)

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Registration requirements (1/2)

To meet the application requirements, you will require:

1. An online application form
2. The application fee plus any amount that is due to the APVMA
3. Supporting information
4. APVMA product number(s) for your nominated reference product(s) (in case the product is similar or closely similar to the already registered product in Australia)

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Registration requirements (2/2)

To meet the application requirements, you will require:

5. An information list
6. Consent for use (if any of the information provided is subject to limits on use)
7. e-label of the product

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Data requirements (1/3)

Modules

1. Preliminary assessment
2. Chemistry
3. Toxicology
4. Residues and trade
5. Work health and safety

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Data requirements (2/3)

Modules

6. Environment
7. Efficacy and safety
8. Non-food trade
9. Special data assessment
10. Finalization
11. Limits on use of information

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Data requirements (3/3)

Modules

12. Risk assessments in the area of
    - Chemistry and manufacture
    - Environment
    - Human health
    - Residues and trade
    - Spray Drift Risk Assessment Manual

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Renewal of registration (1/2)

- The product is granted registration up to 5 years after that period the product need to re-register.
- An email advising that applications are open to renew product registrations will be sent out towards the beginning of April each year.
- An application to renew a registration must be made online through the APVMA Online Services Portal. Either a one year or a 5-year renewal can be selected when making the application to renew the product.

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Renewal of registration (2/2)

- Any products not renewed by the last day of the registration period (June 30) will be de-registered. After this point should you wish to register a product, you will be required to lodge a new application for product registration.
- The Australian Pesticides and Veterinary Medicines Authority (APVMA) may only accept a late renewal application in 2 circumstances:

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Renewal of registration (3/3)

1. Prior to May 30th - If prior to May 30th each year a registrant write to the APVMA to request that the APVMA accept a late renewal application. If the APVMA agrees to the request, the registrant can then make the late renewal application prior to June 30th.
2. Prior to June 30th but after May 30th - If the APVMA agrees to the request, the registrant can pay a late renewal application fee of $50 per product. The late renewal application will not be accepted without payment of the late fee.

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Timeline and fees

Application type	Timeline	Fees
new product with an existing active or new combination of approved actives	18 months	$83 511
new product which contains a new active constituent	18 months	$116 501
a product that is based on an existing registered reference product	8 months	$7 566
Product same as a reference product	8 months	$6 406
approval of a new source of active	Up to 13 months	Vary as per the assessment required
Variations to registered products	1 – 10 months	$175 to $36 205
Timeshift applications	Up to 13 months	Vary as per the assessment required
Renewal of application	before the registration end date	- $3 650 (renewal for 5 year) - $600 (renewal for 1 year)

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Points to consider (1/4)

- To apply for registration of agrochemicals in Australia, the applicant should be a resident of Australia, in case the applicant does not belong to Australia, there must be a local nominated agent appointed on applicant's behalf.
- A nominated agent may at any time give a signed written request to the APVMA to withdraw from being the nominated agent. The APVMA must be satisfied the nominated agent has notified the holder of the withdrawal before the request can be completed.
- To facilitate changes to nominated agents, a separate application and fee are not needed to appoint or vary an agent if the change is made in conjunction with the lodgment of an application to approve, register or vary an active constituent, agvet chemical product or permit.

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Points to consider (2/4)

Product Efficacy requirements -

- Applicants wishing to register a product, vary the particulars or conditions of registration, or hold a permit to use a chemical product, shall satisfy the APVMA that the product meets the efficacy and safety requirements.
- The statutory criteria to address the efficacy of product is as following:
  1. Nominating a relevant reference product (and demonstrating that the applicant obtained consent for us to access any protected data associated with the reference product).
  2. Providing trial data to the APVMA.
  3. Providing valid scientific argument.
  4. Using overseas data assessments or decisions.
  5. Using previously provided reports from the APVMA (provided they meet the validity criteria).

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Points to consider (3/4)

Product Efficacy requirements – No. of trial requirements

- If it's a new agricultural chemical products with new active ingredients or the first use of an active ingredient in a major crop may require up to **10 fully supportive separate trials** per crop–major pest combination to demonstrate efficacy, depending on how widely the crop is grown and on the crop's economic importance.
- Some trials may be used for multiple pests if there is adequate pest pressure for all species.

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Points to consider (4/4)

Product Efficacy requirements – No. of trial requirements

- New formulations of existing active ingredients, or extensions of registered products to new minor crops or minor pests in a major crop, would need fewer trials to demonstrate efficacy (generally 3 as a minimum) under the use direction on the label.
- A similar reduction would apply if a similar pest species is already present on the label.
- The quality of the trials and the consistency of results may also determine how many trials are needed to satisfactorily demonstrate efficacy.

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New Zealand

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Agrochemical Registration New Zealand (1/2)

- To be imported, manufactured, sold, or used in New Zealand, an agricultural chemical must be registered under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
- Registration authorizes your product for import, manufacture, sale, or use in New Zealand. It is an approval to market a trade name product.
- Other legislation controlling their use includes the:
  I. Hazardous Substances and New Organisms Act 1996 – NZ Legislation website
  II. Biosecurity Act 1993 – NZ Legislation website
- Registration is normally for 5 years, after this you'll need to renew.

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Agrochemical Registration in New Zealand (2/2)

A. Active substance registration
B. Plant protection product registration

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Types of Product Registration in New Zealand

Types of active ingredient/product registration

1. Registration of product containing known active ingredient with a new risk profile
2. Registration of Identical to a registered trade name product
3. Product Similar to a registered trade name product
4. Product variation authorization
5. Renewal of registration
6. Provisional registration

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Process of registration

1. Pre-screening to make sure your application is complete
2. Public notification (if needed)
3. Technical appraisal and risk assessment
4. Registration decision

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Pre-screening to make sure your application is complete

There are 2 pre-screening stages.

1. Administrative pre-screen
   - Checks required supporting documents
   - create an electronic product file to hold the documents and give your application a number.
2. Technical pre-screen
   - Verification of technical data and required information

If the information is missing as per the requirements authorities will contact the applicant and gives 40 working days to address the deficiency.

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Public notification (if needed) (1/2)

MPI (Ministry of Primary Industries) will publish a public notice for:

- Applications with a new risk profile.
- New product registrations with new risk profiles:
- New active ingredient (A1 application), or
- Registered active ingredient with a new risk profile (A2 application)
- New use

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Public notification (if needed) (2/2)

The public notification may not require if:

- There is a registered product with the same active ingredients and an equivalent formulation as per the registered product
- The variation to an existing registration doesn't affect the evaluation of risks for that product.
- The public notification of the application is completely decided by the authority and conveyed to client beforehand.
- The notification period is 30 days

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Technical appraisal and risk assessment

- The timeframe for this phase is 25 working days.
- During this stage, authority may contact the applicant for extra information or clarification.
- If applicant can't provide the information within 5 working days, authority does not approve more than 20 working days for submission.
- If authority accept your request, the 'clock' pause for appraisal of your application until authority receive the extra information. If applicant don't ask for a waiver – or if applicant do and don't accept it – authority will complete the appraisal based on available information.

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Data requirement (1/4)

1. Provide the product (PPP) data sheet (PDS document)

Information required under PDS is;

- Part A: General Information and general Product and Manufacturing Specifications
- Part B. Commercially Sensitive Information Product and Manufacturing Specifications-

2. The technical data requirements

- Chemistry and manufacturing
- Residues
- Efficacy and crop safety, and
- Toxicology

The application requirement varies as per the application type. Explained in fig. 1

3. Draft label

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Data requirement (2/4)

The risk assessment

The risk to following sections need to be address while completing the application.

1. Chemistry and manufacturing
2. Residues
3. Efficacy
4. Toxicity and
5. Environment

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Data requirement (3/4)

The risk assessment

- MPI (Ministry of primary Industries) requires data assessment to be done before an application for registration (or variation to registration) by a competent and independent data assessor.
- The MPI assesses residues, chemistry, manufacture, efficacy and trade implications of agvet products.
- The EPA (NZ Environment Protection Agency) assesses the risk pertaining to toxicity and environment.

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Data requirement as per application type (4/4)

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

Key

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

🏴 See toxicology data requirements

Dev Deviation from the Information Requirements

Source - https://www.mpi.govt.nz/dmsdocument/1423-ACVM-registration-information-requirements-for-agricultural-chemicals-in-New-Zealand

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Timeline and fees

Application type	Timeline	Fees
Pre assessment of application	40 days	$77.63 + 155.25/hr AC
To register a trade name product or vary one or more conditions on a trade name product (new active/new product)	12 – 15 hrs	$155.25 + $155.25/hour AC
New risk profile or change in the risk profile	12 – 18 hrs	$155.25 + $155.25/hour AC And additional charge of approximately $150
Registration	12 – 15 hrs	$465.75
Annual Fees		$621.00

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Registration decision

- The appraiser will recommend that authority either grant or refuse your application. They may make a split recommendation for applications with multiple changes.
- A delegate from the Director-General of MPI then decides whether to grant or refuse your application. This decision must be made within 15 working days.
- The appraiser may recommend granting the application along with changes to the original product data sheet (PDS) or label content. If this happens, authority ask the applicant to submit the revised PDS or label content. The delegate's decision won't be made until all outstanding issues have been addressed.

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Points to consider (1/2)

- If your substance contains the same active ingredient as an approved substance and has the same classification and use as that substance, the registration may be covered by the existing approval.
- If your product is not covered by an existing approval, an application for an approval must be made.

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Points to consider (2/2)

- If your product contains active ingredients that are present in existing substances in New Zealand, it may be eligible for rapid assessment. This will be the case if it has a similar composition or has a reduced hazard compared to another substance that is already approved or meets the least degrees of hazard criteria.
- If your substance is not eligible for rapid assessment or contains active ingredients that are new to New Zealand, a full assessment is required.

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