Ministry for Primary Industries
Manatū Ahu Matua

Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines

ACVM Guidance (Version 4; Dated: 07/2022)

Contents

1. Who is this document for?

This guidance document is for those who import:

- agricultural compounds containing biological ingredients
- biological ingredients intended for use in the manufacture of agricultural compounds in New Zealand.

2. What is an agricultural compound?

An agricultural compound is as defined in section 2 of the *Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997*. The term 'agricultural compound' covers the following classes of products:

- agricultural chemicals: substances used for plants, including herbicides, fungicides, insecticides, plant growth regulators, surfactants, and adjuvants
- veterinary medicines: substances used for animals, including companion animals
- vertebrate toxic agents (VTAs): substances that kill or limit the viability of vertebrate animals
- exempt agricultural compounds[1], which include:
  - fertilisers and soil conditioners
  - oral nutritional compounds, such as pet food and livestock feed
  - semen extenders.

3. What is a biological ingredient?

A biological ingredient is an ingredient that is derived from an organism, such as a plant, animal, or a microorganism. A biological ingredient may have a synthetic and a biological component. Examples of such composite biological ingredients are amoxycillin and ampicillin, which are manufactured by chemical addition of synthetic side chains to their parent biological molecule 6-aminopenicillanic acid that is obtained by culturing *Penicillium* species.

If there is doubt whether an ingredient is of biological origin, contact the relevant MPI Imports team or, if unsure which team to contact, the MPI Customer Enquiries Centre.

- Animal Imports team (animal.imports@mpi.govt.nz) for products administered to animals.
- Plant Product Imports team (plantimports@mpi.govt.nz) for products applied to plants.
- MPI Customer Enquiries Centre (info@mpi.govt.nz) for all other enquiries.

4. Biological ingredients and the Biosecurity Act

Under the Biosecurity Act 1993, imported biological ingredients are considered risk goods[2], which require effective management of the risks associated with them before they can be given biosecurity clearance at the border. This management of risks also applies to imported agricultural compounds if they contain biological ingredients.

[1] Exempt agricultural compounds are those product categories specified in column 1 of Schedule 2 of the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.

[2] The Biosecurity Act 1993 defines risk goods as any organism, organic material, or other thing, or substance, that (by reason of its nature, origin, or other relevant factors) it is reasonable to suspect constitutes, harbours, or contains an organism that may:
(a) cause unwanted harm to natural and physical resources or human health in New Zealand; or
(b) interfere with the diagnosis, management, or treatment, in New Zealand, of pests or unwanted organisms.

5. The biosecurity approval process

The biosecurity approval process will depend on the category of biological ingredient being imported. The categories are:

- ACVM-assessed agricultural compounds, namely agricultural chemicals, VTAs, and veterinary medicines (see section 6 of this document for details)
- Exempt agricultural compounds (see section 7 of this document for details)
- Biological ingredients intended for use in the manufacture of agricultural compounds in New Zealand (see section 7 of this document for details).

6. Biosecurity approval for ACVM-assessed agricultural compounds

ACVM-assessed agricultural compounds (agricultural chemicals, VTAs, and veterinary medicines) authorised under the ACVM Act in one of the following ways will need to be biosecurity assessed if they are imported and they contain biological ingredients other than those included in the Negligible Risk Ingredient Schedule (see section 18 of this document for details).

- Registration (under s21)
- Provisional Registration (under s27)
- Research Approval (under s8C)
- Special Circumstances Approval (under s8C).

The Plant Product Imports team does the biosecurity assessment for agricultural chemicals and VTAs, while veterinary medicines are assessed by the Animal Imports team.

7. Information required for biosecurity assessment and approval

7.1. Agricultural chemicals and VTAs

Information provided in the Product Data Sheets (PDS) is generally sufficient for the biosecurity assessment of agricultural chemicals and VTAs authorised via registration, provisional registration, and research approval.

For products authorised via special circumstances approval the *Special Circumstances: Import Approval Request Form: ACVM 3* has instructions for providing the type of information required for biosecurity assessment.

7.2. Veterinary medicines

For veterinary medicines authorised via provisional registration and research approval, information provided in the PDS is generally sufficient for the biosecurity assessment.

For veterinary medicines authorised via registration, the chemistry & manufacturing dossier is required. For vaccines, additionally complete the *Biosecurity Approval of Imported Veterinary Vaccines: Summary of Information Provided Form*.

For veterinary medicines imported via special circumstances approval the *Special Circumstances: Import Approval Request Form: ACVM 3* has instructions for providing the type of information required for biosecurity assessment.

8. Submitting information for biosecurity assessment and approval

For biosecurity assessment and approval of ACVM-assessed agricultural compounds, submit all biosecurity information along with the ACVM documents to the Approvals Operations (AO) team (approvals@mpi.govt.nz). The AO team will forward the biosecurity information to the relevant Imports team.

9. Biosecurity approval letter

9.1. Veterinary medicines

For veterinary medicines that are authorised via registration, provisional registration, and research approval, the Animal Imports team will issue a biosecurity approval letter if the outcome of the biosecurity assessment for the product is favourable.

The AO team will forward the biosecurity approval letter to the registrant.

The purpose of the biosecurity approval letter is to inform the registrants of their obligations under the Biosecurity Act with respect to the conditions for the biosecurity approval, i.e., requirements for biosecurity reassessment.

Biosecurity reassessment will be required if one or more of the following occurs:

- There is a change in the formulation, source and/or manufacturing process of any biological ingredient, other than those listed in the Negligible Risk Ingredient Schedule.
- There is an extension of use to include additional target species.
- Five years have elapsed since the date of issue of the biosecurity approval letter.
- The ACVM authorisation status is changed to registration under Section 21 of the ACVM Act 1997 [*This condition is added for veterinary medicines authorised via provisional registration and research approval.*]

For veterinary medicines authorised via special circumstances approval, the Animal Imports team will not issue a biosecurity approval letter. Instead, the biosecurity approval, if one is required, is communicated to the AO team internally.

9.2. Agricultural chemicals and VTAs

Biosecurity approval letter is not issued for agricultural chemicals and VTAs. If a product is successfully authorised under the ACVM Act, it means that it has been biosecurity approved.

10. Biosecurity approval for imported biological ingredients and exempt agricultural compounds

Biological ingredients imported for use in the manufacture of agricultural compounds in New Zealand and imported exempt agricultural compounds must meet the requirements in the applicable import health standard[3] (IHS) to be eligible for biosecurity clearance at the border.

Detailed information on importing various categories of products and biological ingredients is available here and the complete IHS library is available here.

[3] An IHS is a document issued under section 24A of the Biosecurity Act 1993 which states the requirements that must be met before risk goods can be imported into New Zealand.

Importers are encouraged to do their own due diligence to ascertain the biosecurity import requirements for the products and ingredients they are importing. Contact the relevant Imports team for clarification on the IHS requirements (see section 3 of this document for contact details).

11. Import permit

An import permit is a document that is issued when required by an IHS. Issuing an import permit means an assessment has been made for the imported risk goods in relation to managing the biosecurity risks.

Permits are issued as either single entry or multiple entry documents.

- Single entry permits are used for high-risk goods, such as plant nursery stock and live mammals. Once the goods arrive in New Zealand single entry permits are 'spent' and cannot be used again.

- Multiple entry permits are used for goods which are imported recurrently and may be used more than once over a specified time period, usually a year. Import permits for inanimate goods are usually of the multiple entry type.

Import permit application forms are specific to the Imports teams. Contact the relevant Imports team for advice on the right application to use if the below forms are not appropriate for your products (see section 3 of this document for contact details).

- Animal Imports team: *Application for permit to import biologicals, microorganisms and cell cultures*

- Plant Product Imports team: *Application for permit to import plant derived material, microorganisms associated with plants, soil or water*

There is a cost for issuing an import permit (see details in section 14 of this document).

12. Product categories that require an import permit

Below are some major product categories that will require an import permit to be eligible for biosecurity clearance. Please check with the relevant Imports team to know if an import permit will be required for your specific product.

12.1. Blood plasma products

Veterinary medicines that are blood plasma products must be imported under an import permit. Registrants of blood plasma products will be advised of the permit requirement at the time of the product's ACVM authorisation.

12.2. Veterinary medicines not in approved marketing label

Veterinary medicines not in their ACVM-approved marketing label will need a permit to import unless an ACVM x-variation authorisation has been granted.

12.3. Exempt agricultural compounds that contain live microorganisms

Exempt agricultural compounds that contain live microorganisms will require an import permit. For example, petfoods that contain probiotics require import permits.

13. Assessed agricultural compounds do not require an import permit

Imported agricultural chemicals, veterinary medicines, and VTAs authorised via registration can be imported without an import permit (see sections 12.1 and 12.2 of this document for exceptions).

The listing of registered agricultural compounds on the publicly available ACVM Register informs MPI Border that biosecurity assessment for the product has been completed and so can be cleared without an import permit.

Imported agricultural chemicals, veterinary medicines, and VTAs authorised via provisional registration, research approval, or special circumstances approval can also be imported without an import permit. The AO team's authorisation letter for these products will reflect that biosecurity assessment, where applicable, was completed, which informs MPI Border to clear the product without an import permit.

14. Cost for biosecurity assessment

For imported agricultural chemicals, VTAs, and veterinary medicines authorised via registration, provisional registration, research approval, and special circumstances approval, the cost of biosecurity assessment is $117.61 (inclusive of GST) per hour. The fee will be invoiced in conjunction with the ACVM authorisation charges and will be managed by the AO team.

For imported biological ingredients intended for use in the manufacture of agricultural compounds in New Zealand and for exempt agricultural compounds that require an import permit, the biosecurity assessment charge is built into the cost for issuing the permit. The cost for this assessment is $220.74, provided the administrative processing of the import permit application and biosecurity assessment can be completed within 90 minutes. For applications requiring more than 90 minutes the charge out rate of $117.61 (inclusive of GST) per hour applies.

15. Products containing new organisms, including GMOs

MPI enforces the legislation relating to 'new organisms', defined as such under the Hazardous Substances and New Organisms (HSNO) Act 1996. As well as genetically modified organisms (GMOs), new organisms are those that were not present in New Zealand immediately prior to 29 July 1998.

Biosecurity assessment of products that are, or contain, viable new organisms can only progress after appropriate authorisation has been provided by the Environmental Protection Authority (EPA), which administers the HSNO Act.

Before importing products containing new organisms, please contact the relevant Imports team for advice (see section 3 for contact details). Importers should also contact the New Organisms (NO) team at the EPA, especially if they are unsure of the status of an organism. The NO team may be contacted by email at neworganisms@epa.govt.nz, or by phone at +64 4 474 5591.

16. Unwanted organisms

Before importing or manufacturing in New Zealand agricultural compounds containing viable unwanted organisms[4] contact the relevant Imports team for advice. Under the Biosecurity Act, it is an offence to breed, sell, or release unwanted organisms, unless MPI grants permission. You can search unwanted organisms in the Official New Zealand Pest Register (ONZPR).

17. Products containing antigens of exotic diseases or making claims relating to exotic diseases

New Zealand is free from many animal and plant pests and/or diseases. Before submitting applications to the AO team for importation and use of agricultural chemicals and veterinary medicines containing antigens, and/or that make claims relating to diseases not present in New Zealand, contact the relevant Imports team for advice (see section 3 of this document for contact details). MPI will first need to evaluate the impact that importation, and use of such products, might have on New Zealand's disease surveillance programmes or overseas market access.

18. Negligible Risk Ingredient Schedule

For imported agricultural chemicals, VTAs, and veterinary medicines authorised via registration, provisional registration, research approval, or special circumstances approval, biosecurity assessment is not required if all the biological ingredients in them are from the Negligible Risk Ingredient Schedule and the ingredients meet the requirements where stated (see table below).

New biological ingredients will be added to the Negligible Risk Ingredient Schedule from time to time. Before submitting ACVM applications check the MPI website for the latest version of this guidance document.

NOTE: The Negligible Risk Ingredient Schedule is not applicable to:

- imported biological ingredients intended for use in the manufacture of agricultural compounds in New Zealand
- imported exempt agricultural compounds.

[4] An unwanted organism is any organism that is capable of causing harm to natural or physical resources (like forests and waterways) or human health.

NEGLIGIBLE RISK INGREDIENT SCHEDULE

This Schedule is applicable to biological ingredients in imported agricultural chemicals, vertebrate toxic agents, and veterinary medicines authorised under the ACVM Act via registration, or provisional registration, or research approval, or special circumstances approval.

This Schedule is not applicable to (a) imported biological ingredients intended for use in the manufacture of agricultural compounds in New Zealand and (b) imported exempt agricultural compounds.

Negligible Risk Ingredient	Requirements
Extracts from plants, yeast, algae, lichen, and fungi Examples include but not limited to: alginate (alginic acid), brans, flavourings, flours, gums, powders, vegetable oils and fats, syrups, waxes, aloe vera extract, brewer's yeast (inactivated), cellulose, chlorophyll, citric acid, corn steep liquor, dextrin, dextrose, glycerol/glycerine, glucose, hydrolysed vegetable, hypromellose, lactic acid, lecithin, lectins, limonene, malic acid, maltitol, maltodextrin, maltose, molasses, oleic acid, sorbitol, palm stearin, pyrethrin, starch, sucrose, sugar.	
Ingredients biosynthesised by microorganisms and their semi-synthetic versions Examples include but not limited to: abamectin, amoxicillin, ampicillin, apramycin, avilamycin, bacitracin, bambermycin, cefovecin, cefpodoxime, cefquinome, ceftiofur, cefuroxime, cephalexin, cephalonium, cephapirin, chlortetracycline, clavulanic acid, clindamycin, cloxacillin, colistin, dextran, doramectin, doxycycline; emamectin, eprinomectin, erythromycin, framycetin, fusidic acid, gentamicin, ivermectin, kasugamycin, lasalocid, lincomycin, maduramicin, milbemectin, milbemycin, monensin, moxidectin, narasin, neomycin, nystatin, oleandomycin, oxytetracycline, penicillin, polymyxin, salinomycin, selamectin, spectinomycin, spinosad, spiramycin, streptomycin, tiamulin, tilmicosin, tulathromycin, tylosin, virginiamycin, xanthan gum.	If used in veterinary medicines, include with the ACVM application a declaration from the manufacturer of the biological ingredient that no animal origin components were used in the medium for growing the microorganism. Biosecurity approval will be required if this declaration is not included.
Casein	
Cholecalciferol (Vitamin D3)	
Ethanol	
Histidine	
Galactose	
Gelatine	Biosecurity approval not required if used in oral veterinary medicines for dogs and cats.
Glucosamine (all forms)	
Methionine	
Lactalbumin	
Lactose	
Lanolin and lanolin-derived ingredients	
Liver powder	Biosecurity approval not required if used in oral veterinary medicines for dogs and cats.
Pancreatic powder	Biosecurity approval not required if used in oral veterinary medicines for dogs and cats.
Stearic acid and stearates (all forms)	