Ministry for Primary Industries
Manatū Ahu Matua

Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines

ACVM Guidance (Version 3; Dated: 12/2020)

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], such as:
  - 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.

5. The biosecurity approval process

Depending on the type of imported agricultural compounds, the biosecurity approval process will fall into one of the following pathways:

- biosecurity approval for imported agricultural chemicals, VTAs, and veterinary medicines
- biosecurity approval for:
  - imported biological ingredients intended for use in the manufacture of agricultural compounds in New Zealand
  - imported exempt agricultural compounds.

[1] Exempt agricultural compounds are those products 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.

6. Biosecurity approval for imported agricultural chemicals, VTAs, and veterinary medicines

This biosecurity approval process is applied to imported agricultural chemicals, VTAs, and veterinary medicines and authorised under the ACVM Act in one of the following ways:

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

For biosecurity assessment, 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.

6.1. Imported agricultural chemicals and VTAs

Imported agricultural chemicals and VTAs authorised via registration, provisional registration, research approval, and special circumstances approval will need to be biosecurity assessed if they contain biological ingredients other than those included in the Negligible Risk Ingredient Schedule (see Section 13 of this guidance document for details).

Agricultural chemicals and VTAs containing viable microorganisms must be imported under an import permit in accordance with the requirements of the *Import Health Standard: Microorganisms from All Countries (MICROIC.ALL)*. These requirements include providing a Quality Control Test Declaration relating to threshold levels of any contaminating organisms that may be present. See section 8 of this document for more details on import permits.

For most purposes, information provided in the Product Data Sheets is sufficient for the biosecurity assessment of agricultural chemicals and VTAs.

The Plant Product Imports team does the biosecurity assessment for agricultural chemicals and VTAs.

6.2. Imported veterinary medicines

Imported veterinary medicines authorised via registration, provisional registration, research approval, and special circumstances approval will need to be biosecurity assessed if they contain biological ingredients other than those included in the Negligible Risk Ingredient Schedule (see Section 13 of this guidance document for details).

Veterinary medicines that are blood plasma products must be imported under an import permit. The applicant will be advised of the permit requirement at the time of a blood plasma product's ACVM authorisation. See section 8 of this document for more details on import permits.

The Animal Imports team does the biosecurity assessment for veterinary medicines.

6.2.1. Imported veterinary medicines authorised via registration

For imported veterinary medicines that contain biological ingredients other than those included in the Negligible Risk Ingredient Schedule and are authorised via registration, the Animal Imports team will issue a biosecurity approval letter if the product meets the requirements of biosecurity assessment. The AO team will forward the biosecurity approval letter to the registrant. The purpose of the biosecurity approval letter is to inform the applicant of their obligations under the Biosecurity Act with respect to conditions of 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.

For most veterinary medicines, information provided in the Product Data Sheets and the chemistry & manufacturing dossiers is sufficient for the biosecurity assessment. For vaccines, additionally complete the *Biosecurity Approval of Imported Veterinary Vaccines: Summary of Information Provided Form*.

6.2.2. Imported veterinary medicines authorised via provisional registration, or research approval, or special circumstances approval

For imported veterinary medicines that contain biological ingredients other than those included in the Negligible Risk Ingredient Schedule and are authorised via provisional registration, or research approval, or special circumstances approval and meet the requirements of biosecurity assessment, the Animal Imports team will advise the ACVM team of the biosecurity approval via internal communication. The ACVM team's authorisation letter will reflect, where applicable, that biosecurity assessment was completed and approved for the veterinary medicine. The ACVM authorisation letter will facilitate the biosecurity clearance of the product at the border.

For imported veterinary medicines authorised via provisional registration or research approval, information provided in the Product Data Sheets should be sufficient for the biosecurity assessment.

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

6.2.3. Imported veterinary vaccines not in approved marketing label

To be eligible for biosecurity clearance at the border, vaccines registered under s21 must be in their ACVM-approved marketing label with the ACVM registration number printed on it. Occasionally, overseas-manufactured veterinary vaccines that are not in their ACVM-approved marketing label may need to be imported, such as for potency testing in New Zealand prior to release for use and sale. In such cases an import permit will be required. See section 8 of this document for more details on import permits.

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

The below biosecurity approval process applies to:

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

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

[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.

For most of these biological ingredients an import permit is not required. Where an import permit is required the IHS will specify that. For example, a permit is required for importing live microorganisms. An import permit is also required for importing ingredients derived from microbial fermentation (such as antibiotics).

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

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).

8. 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 the permit is '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. Examples of goods issued with multiple entry permits are viable microorganisms and microbial fermentation ingredients.

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*

9. 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.

10. 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.

11. 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).

12. Products containing antigens 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.

13. Negligible Risk Ingredient Schedule

For imported agricultural chemicals, VTAs, and veterinary medicines authorised via registration, or provisional registration, or 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 (a) imported biological ingredients intended for use in the manufacture of agricultural compounds in New Zealand and (b) 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	
Galactose	
Glucosamine (all forms)	
Lactalbumin	
Lactose	
Lanolin and lanolin-derived ingredients	
Liver powder	Biosecurity approval not required if used in oral veterinary medicines for dogs and cats.
Stearic acid and stearates (all forms)	