Australian Government
Department of Agriculture, Fisheries and Forestry

Production questionnaire: Veterinary therapeutics including those for use as a stockfeed additive

Form approved under the *Biosecurity Act 2015*

Section A: General information

Purpose of this form	To support an import permit application by an Australian business to import veterinary therapeutic products into Australia. Veterinary therapeutic products are those which are used for the purpose of preventing, treating, alleviating or curing animal diseases. They have a therapeutic index with a clear dosing schedule. This form covers products that are used as veterinary therapeutics to be added to stockfeed, to be mixed into the water rations of livestock animals, or to be dispersed within a livestock holding facility. Please also complete this form if the intended use is for in vivo use in non-laboratory organisms.
Who should complete this form	An authorised representative of the manufacturer of the veterinary therapeutic products must complete this form. The manufacturer is the facility where the products are manufactured. This includes buildings and areas where the products are stored or processed and any other buildings or areas within the boundary of the site.
To complete this form	Answer all questions truthfully and accurately. Failure to complete questions or provide supporting documentation will result in delays in the processing of the import permit application. **Electronically** Download the document to your computer and save any changes. **Manually** Use black or blue pen Print in BLOCK LETTERS Mark boxes with a tick ☑ or a cross ☒ Attach additional sheets if space is insufficient

You must submit these documents with this form

English language versions of the manufacturer's:

☐ Package label or tag for each product. Where applicable these should include instructions for use.

☐ Certificate of Analysis for each product that has been manufactured in the last 6 months (on manufacturer's letterhead, and signed and dated)

☐ Flowchart detailing processing of raw material into each finished product (on manufacturer's letterhead, and signed and dated)

☐ Current approval or certification against a code of Good Manufacturing Practice (GMP), if available

☐ Current approval or certification against quality systems (for example, ISO or HACCP), if available

☐ Evidence of the Australian Pesticides and Veterinary Medicines Authority (APVMA) registration of the product or API contained in the product, if relevant.

Any additional documents must be:

- on manufacturer's letterhead (including company address and country)
- signed by a senior company employee from the site of manufacture, whose name, title and contact details also appear
- dated within the last 6 months, free from erasures and uncertified alterations (all alterations must be initialled by the senior company employee responsible for signing the declaration).

All documentation supplied in support of an import permit application is required to meet the department's minimum documentary and import declaration requirements policy

To submit this form	**Option 1 (preferred)** Submit your completed, signed questionnaire and all additional documents and attachments to the Australian importer for inclusion in their import permit application. **Option 2 Questionnaires containing commercial-in-confidence information** Commercial-in-confidence information made available to the department is protected against unauthorised disclosure to any other party under Australian Federal Law. Post or email (preferred) the completed questionnaire and all additional documents and attachments (referencing the import permit application number and marked 'commercial-in-confidence' where relevant) to: Biosecurity Import Support Team Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601 Email Imports@agriculture.gov.au
More information	Phone 1800 900 090 (within Australia) +61 3 8318 6700 (outside Australia) Web agriculture.gov.au/import/goods/biological/checklist/vet-products

Section B: Contact details

1. Manufacturer's head office

Name of manufacturer (legal entity name)			
Authorised person to sign this form ***(must be an employee of the facility)***	**Full name:**	**Position in company/Job title:**	
Address			
Phone (include area code):		**Fax:**	
Email:			

2. Facility where products are manufactured (if the same as question 1, write 'As above'). Include multiple facilities if required e.g. secondary packaging site.

Name of manufacturer (legal entity name)			
Authorised person to sign this form ***(must be an employee of the facility)***	**Full name:**	**Position in company/Job title:**	
Address			
Phone (include area code):		**Fax:**	
Email:			

3. Exporter's details (if exporter and manufacturer details are the same, write 'As above')

Name of exporter (legal entity name)			
Authorised person to sign this form ***(must be an employee of the facility)***	**Full name:**	**Position in company/Job title:**	
Address			
Phone (include area code):		**Fax:**	
Email:			

Section C: Product to be exported to Australia

If you are exporting multiple products, provide a separate version of this section for each product.

4. What is the name of the product? The product name must match the name on the product label or tag.

_____

_____

5. What is the end-use of the product? (Select one or more boxes)

- ☐ Veterinary therapeutic
- ☐ In vivo in non-laboratory organisms
- ☐ Veterinary use as a stockfeed additive (please also complete section E)
- ☐ Other (provide details)

_____

6. Target species for the product (e.g., chickens)

_____

7. How will the product be used in Australia? (Select one or more boxes)

- ☐ Product is a fully finished and packaged product ready for retail sale in Australia
- ☐ Product will undergo further processing or packaging in Australia
- ☐ Product is intended to be used for research purposes in Australia
- ☐ Unsure
- ☐ Other (provide details)

_____

_____

8. If the product is a fully finished and packaged product that is ready for retail sale, is it registered or undergoing registration with the Australian Pesticides and Veterinary Medicines Authority (APVMA)?

No ☐ Go to question 9

Yes ☐ Attach evidence of APVMA registration and provide product registration numbers (Go to question 12)

N/A ☐ Product is not fully finished and retail ready (Go to question 10)

9. Explain why the product does not need APVMA registration.

_____

_____

10. If the product is an Active Pharmaceutical Ingredient, is it currently approved as an 'active constituent' by the APVMA?

No ☐ Go to question 11

Yes ☐ Attach evidence of manufacturer and importer APVMA approval with APVMA active constituent product numbers (Go to question 12)

N/A ☐ Product is not an Active Pharmaceutical Ingredient (Go to question 12)

11. Explain why the Active Pharmaceutical Ingredient does not require APVMA approval.

_____

_____

12. Is the product packaged in clean and brand-new packaging?

No ☐ Go to question 13

Yes ☐ Go to question 14

13. Provide details about the source of recycled packaging, including contents that were previously contained within the packages

14. Describe the type of packaging of the product, including the volume of each individually packaged unit (e.g., 600 gram tubes, 25 kg bags)

15. Is the product packaged for export immediately at the end of production?

Yes ☐
No ☐ Please provide details below.

16. Where is the product packaged?

At the manufacturing facility listed in question 2 ☐

At a different facility to the manufacturing facility ☐ A production questionnaire: third-party facility will need to be supplied by this facility.

Section D: Product details

Commercial-in-confidence information made available to the department is protected against unauthorised disclosure to any other party under Australian Federal Law. Protected information collected by the department will only be used or disclosed as authorised under the *Biosecurity Act 2015*. With this in mind, manufacturers may prefer to provide information directly to the department.

17. Provide details about all the ingredients in the product. Include all carriers used as ingredients in the ingredient list. (Insert more rows if required)

Product name	**Product formulation** *(e.g. granules, gel, liquid, powder etc)*	**Ingredient Name**	**Composition in product (%) Percentages must add up to 100%**	**Origin of ingredient** *(Animal, plant, microbial, mineral, synthetic, or chemical)*	**Species of origin** *Please provide genus and species name of biological ingredients e.g. Saccharomyces cerevisiae, Bos taurus*	**Country of origin of ingredient** *(where the plant/animal was grown, or the mineral ingredient is mined) Please note: EU is not a country*[a]	**Tissue of origin of all animal-derived ingredients (e.g. milk from bovine animals)**

a Country of origin is the country where the animals were born, raised and slaughtered. This may be different to the country of manufacture.

18. Do the animal-derived ingredients in the product receive any heat, chemical or ionising radiation treatments before they are used in the manufacturing process to produce the product? For example, has the milk in the product been heat pasteurised?

Yes ☐ Go to question 19

No ☐ Go to question 20

N/A ☐ Product does not contain animal-derived ingredients (Go to question 20)

19. Provide details about all heat, chemical and ionising radiation treatments that are applied to each animal-derived ingredient prior to the manufacturing process to produce the product. For all heat treatments, provide the core temperature of the ingredient during the heat treatment, and duration of the heat treatment. Confirm whether the heat treatment is dry or moist. For all chemical treatments, provide the name of the chemical, the concentration, the duration of the treatment and pH of the treatment. For all ionising radiation treatments, provide the minimum absorbed dose. (Insert more rows if required)

Ingredient of animal origin	Describe all heat, chemical or ionising radiation treatments applied to the ingredient

20. Are any of the ingredients in the product derived from microbial propagation? Examples include bacteria, yeast, antibiotics, microalgae, mectin compounds and enzymes.

No ☐ Go to question 24

Yes ☐ Go to question 21

21. Provide details about all ingredients that are derived from microbial propagation. (Insert more rows if required)

Ingredient name	List all components in this ingredient, including carriers, cryoprotectants and residual fermentation media	Genus and species of microorganism used to manufacture ingredient (e.g. *Escherichia coli*)	Source of the microorganism (e.g culture collection, isolation from mother culture stock or microorganisms drawn from a previous production batch)	Describe the method of harvest, extraction and/or purification of the ingredient from the culture media

22. List the ingredients contained in each culture media used to propagate each of the microorganisms you listed in question 21. If different culture media are used for storage, mother stock, working seed and production of the microorganism, provide a different table for each of these media. Percentages must add up to 100%. (Insert more rows if required)

Culture media name (e.g. seed media of *Escherichia coli*)	Culture media ingredient	Composition in media (%)	Origin of ingredient (e.g. plant, animal, microbial, mineral, synthetic or chemical)	Tissue and species of origin of animal-derived ingredients	Country of origin of all animal-derived ingredients (EU is not a country) [a]

a Country where the animals were born, raised and slaughtered.

23. Provide details of the sterilisation of the culture media, including method, minimum temperatures and durations. (Insert more rows if required)

Culture media name (e.g. seed media of *Escherichia coli*)	Sterilisation parameters used (e.g. autoclave sterilisation at 121˚C for 20 minutes)

24. Have materials of animal origin been used at any stage during manufacturing of the product, or during manufacturing of any ingredients contained in the product? This includes the use of animal-derived materials as carriers of ingredients derived from microbial propagation, and ingredients in the fermentation culture media, cell line storage media, and cryopreservation media.

No ☐ Go to question 27

Yes ☐ Go to question 25

25. Have you listed all the animal-derived materials used to manufacture the product in your answers to questions 17 or questions 21 and/or 22?

No ☐ Go to question 26

Yes ☐ Go to question 27

26. Provide details of all additional materials of animal origin that are used during manufacture of the product, or during manufacture of any ingredients contained in the product. Only include information that has not been included in the preceding pages. (Insert more rows if required)

Material of animal origin [a]	Describe how the material is used during manufacture of the product or manufacture of any ingredients contained in the product (e.g. calf rennet is used to produce lactose contained in the product)	Describe all heat, chemical or ionising radiation treatments applied to the material [b]

a Include information about the species, tissue and country of origin of the animal-derived material.
b For all heat treatments, provide the core temperature of the material during the heat treatment, and duration of the heat treatment. Confirm whether the heat treatment is dry or moist. For all chemical treatments, provide the name of the chemical, the concentration, the duration of the treatment and pH of the treatment. For all ionising radiation treatments, provide the minimum absorbed dose.

27. Does the final product contain microalgae?

No ☐

Yes ☐ If you're applying to import veterinary therapeutic containing microalgae, please ask the relevant parties to complete our microalgae questionnaire and then submit the completed questionnaire with your application.

28. Does the final product contain whole seeds or viable plant material?

No ☐

Yes ☐

29. Provide information about the processing or treatments applied to all grain- and plant-based ingredients that render them non-viable and incapable of germinating. Non-viable means incapable of living, reproducing, replicating or germinating. This may include milling or grinding the grain, heat treatments or ionising irradiation applied to the ingredient. For any heat treatment, please provide minimum times and core product temperatures.

30. **Have you attached a Certificate of Analysis (or equivalent quality system document) for the product? This is an authenticated document, supported by an effective quality management system, and attesting to critical parameters of the product.**

    Yes ☐ Attach a copy

    No ☐

31. **Have you attached a flowchart that outlines the manufacturing process for the product? This should describe each stage of the manufacturing process, from the processing of raw materials to the finished product. Include all mechanical, heat, chemical, physical and ionising radiation treatments and their respective measurement parameters (for example core temperatures during heat treatments, pH or concentration of chemicals, durations of treatments or filter pore size).**

    No ☐ Attach a copy

    Yes ☐

Section E: Veterinary therapeutics to be added to stockfeed, to be mixed into the water rations of livestock animals, or to be dispersed within a livestock holding facility

32. Do you store, handle or process any material of terrestrial (including avian) or marine animal origin (e.g. dairy, oils, protein meals)? Include ingredients for products that are not intended for export to Australia.

Yes ☐ Please provide details below (Insert additional rows if required)
No ☐ Continue to question 33 below.

Name of the animal material	**Country of origin of the animal material** [a]	**Product form** *(e.g. powder, liquid)*	**How is this animal material stored and handled at the site?**	**Is this animal material processed on the same production line as that used to produce goods for the Australian market?**	**If yes, provide information about any controls in place to prevent cross-contamination with product for Australia.**

a Country of origin is the country where the animals were born, raised and slaughtered.

33. Is water used in the manufacturing process, this includes for cleaning?

No ☐ Go to question 35

Yes ☐ Go to question 34

34. Is this water potable (safe to drink)

Yes ☐

No ☐ Please provide details below.

Before moving to Section F, ensure you have completed a separate version of Section D and if relevant Section E for each product intended for export to Australia.

Section F: Manufacturing facility

35. Are there any live animals (including domestic, wild and native) present on, or with access to, the manufacturing facility or site?

No ☐ Go to question 37

Yes ☐ Go to question 36

36. Describe the nature of the live animal access.

37. Describe how access by live animals is prevented.

38. Describe the system in place at the manufacturing facility that protects products, during and post-production, from contamination with extraneous materials, including soil, faeces, feathers, insects, viable seeds or bark. Include details about the enclosure of the production area, cleaning procedures and pest control.

39. Quality assurance and compliance certification

a) Provide copies of all certificates demonstrating current accreditation of the manufacturing facility to quality or safety assurance schemes (e.g. GMP+, ISO or HACCP if applicable).

b) Provide copies of all government certifications, licences, registration documents and/or approvals (if applicable).

List the names of each current certificate of registration or approval and attach copies. (Insert more rows if necessary)

Certification type (e.g. ISO 9001:2015)	Scope of certification

40. Describe each of the internal quality assurance, quality control and change control systems in place at the manufacturing facility.

- Quality assurance includes all aspects of a manufacturing process designed to ensure that products meet pre-determined quality standards.
- Quality control is the set of sampling and testing processes designed to ensure quality throughout a manufacturing process.
- Change control is the structured, formal process established to evaluate all proposed changes that may affect the production and quality of a product. Please confirm if the change control procedure includes processes for early notification of proposed changes and a requirement for formal endorsement from all affected stakeholders (including regulatory associates in the Australian market)

Section G: Manufacturer's declaration

This section is to be completed by the manufacturer's representative named in section B of this form.

It is a criminal offence under Division 136 of the *Criminal Code Act 1995* to knowingly give false or misleading information to a Commonwealth officer exercising powers under Commonwealth law. This offence carries a potential penalty of 12 months' imprisonment.

I declare that the information in this form is true and accurate to the best of my knowledge. I understand that giving false or misleading information is a serious offence.

If I become aware that the information I have provided is incomplete or incorrect, I will notify the Department of Agriculture, Fisheries and Forestry as soon as practicable.

If the department issues an import permit for products referred to in this form, I declare that the products exported to Australia will comply with all conditions on that import permit.

If manufacturing processes change so that products are no longer compliant with all conditions on the import permit, I will provide details of the change to the Australian importer so that a new application for an import permit (or an application to amend the current import permit) can be submitted to the department.

I have read and understood the privacy notice and Privacy Policy and the commercial-in-confidence notice.

Signature (type or sign your name) _____

Full name _____

Date (dd/mm/yyyy) _____

a. Section H: Privacy notice

Personal information means any information or opinion about an identified, or reasonably identifiable, individual. Personal information that is collected under or in accordance with the *Biosecurity Act 2015* is also 'protected information' under the Biosecurity Act.

The Department of Agriculture, Fisheries and Forestry is authorised under the Biosecurity Act to collect your personal information for the purposes of determining import conditions for your veterinary therapeutic products and for other related purposes. If you fail to provide some or all of the relevant personal information requested in this form, the department may be unable to process the import permit application that relates to this form.

Information collected by the department will only be used or disclosed under the Biosecurity Act. The department may disclose your personal information to the Department of Health and the Australian Pesticides and Veterinary Medicines Authority, and other Australian Government agencies, persons or organisations where necessary for these purposes. It will not usually be disclosed overseas. It will only be disclosed if authorised under the Biosecurity Act.

See our Privacy Policy to learn more about accessing or correcting personal information or making a complaint. Alternatively, telephone the department on +61 2 6272 3933 (or +61 3 8318 6700 outside Australia).

b. Section I: Commercial-in-confidence notice

Commercial-in-confidence information made available to the department is protected against unauthorised disclosure to any other party under Australian Federal Law.