

**EVALUATION OF RISK POSED BY THE IMPORTATION
OF ANIMAL PATHOGENS INTO SINGAPORE**

To be completed by Applicant

This qualitative risk assessment is carried out to estimate the risks to animal health, and enable an assessment of impact on trade and economy, posed by the importation, use and handling of the following pathogen into Singapore:

[Name of pathogen]

This risk assessment describes the biology, host range and economic importance of the above agent and aims to estimate the risks for:

- a. Inadvertent release from the Applicant's facility
- b. Potential for the pathogen to become established in the local animal community, in event of such release
- c. Spread to susceptible hosts; and
- d. Adverse impact on trade, economy and animal health

1. Purpose of importation

- R&D Clinical Trial Product manufacture Diagnostic use Others

2. Brief description of project or intended use:

PART I: GENERAL INFORMATION

3. Applicant Information

Name: _____
Title: _____
Department: _____
Contact No: _____(O / HP) Fax: _____
Email: _____

4. Facility Information

Institution: _____
Address: _____
Facilities: BSL 1 2 3 ABSL 1 2 3
Licence to Possess Vet Biologics – Reference / Expiry : _____

5. Personnel involved:

Do personnel involved in this project handle or come in contact with animals susceptible to this pathogen?
 Yes No

6. Pathogen Information

- Full name (strain, serotype, genus, family, etc): _____
- Live, virulent strain Live, non-pathogenic Live, attenuated Live, recombinant
 Inactivated (Section 7)
- Source: _____
- History & Passage (or attach Product Information):

- Quantity & concentration to be imported: _____
- MSDS attached, if available
- Specimen type:
 - Purified form
 - Pure culture. State media / cell line:
 - Unpurified culture possibly containing unknown organisms
 - In tissue. State type & species:

7. Inactivated agent only

- Method of inactivation:

- Test performed to validate inactivation process:

Please attach letter from manufacturer (on letterhead, signed and dated) stating the preparation method / treatment process, and confirmation that treatment measures are acceptable to eliminate possible pathogens / confirmation of inactivation (please specify method of inactivation).

8. Biohazard

- Risk Group: RG1 RG2 RG 3 RG 4 (live agent not permitted)
- State reference for Risk Grouping eg NIH etc: _____
- BATA Schedule: 1 Part I 1 Part II 2 3 4 5
- Is this a animal pathogen? Yes No
- Is this a human pathogen? Yes No
- Is this a plant pathogen? Yes No
- Recommended biosafety level for handling: BSL 1 2 3 4
- For RG3 / Schedule 1 agents, attach IBC Approval:
- For a Live recombinant microorganism, has its use been approved by IBC / GMAC? Yes No
If Yes, attach IBC or GMAC approval.

9. Experimental procedures

9.1. Will pathogen be inoculated into animals?

Yes No

If Yes,

Species: _____

Location of animal facility to be used: _____

9.2. Will pathogen be cultured in vitro?

Yes No

If Yes,

Largest volume handled at any time: _____

Typical or estimated concentration per culture: _____

Will pathogen be concentrated?

Yes No

PART II: APPLICANT'S RISK ASSESSMENT

10. Biology, host range and economic importance of the pathogens:

Biology and economic importance of the organism:

Description of disease:

a. Is pathogen / disease endemic to Singapore?

Yes No

b. Is pathogen / disease endemic in the region (SE Asia)?

Yes No

c. Transmission (tick all applicable)

- Air-borne Aerosol Oral /Mucosal
- Blood-borne Parenteral (injection) Bites, scratches
- Vector-borne Others: _____

- Direct contact
- Formites

If vector-borne, state vector: _____

Is vector present in Singapore?

Yes No

d. Reservoir & Host Range

_____ Is/Are host species present in Singapore?

Yes No

e. **Infectious Dose:** _____ Not known

f. **Incubation period:** _____ Not known

g. Susceptibility to disinfectants

h. Survival outside host

i. Vaccination & treatment:

Is vaccination for personnel available in Singapore? Yes No

Is animal vaccination available in Singapore? Yes No

Is treatment for infected personnel readily available in Singapore? Yes No

If Yes to the above, name vaccine / treatment: _____

References for Section 10 :

11. Transport and Movement of Pathogen

Will live materials be transported out of the lab?

Yes No

Note: The animal pathogen can only be transported to a facility that is licensed to possess veterinary biologics. Transportation must be carried out according to national regulations for transportation of biological agents.

12. Decontamination & waste handling (Please attach institution SOPs)

13. Inadvertent Release potential: Negligible Low Medium High

Please describe highest risk activities and mitigating factors:

14. Establishment Potential: Negligible Low Medium High

Please provide facts/information on the organism's potential to establish in an area, information on hosts, temperature requirement for it to multiply, etc. Must provide info to support the rating given:

15. **Spread potential:** The potential for spread to susceptible species in the event of accidental release:
 Negligible Low Medium High

Please include information on the suitability of the natural and/or managed environment for natural spread of the organism. Must provide info to support the rating given:

16. Please attach the relevant SOPs, MSDS, IBC approvals, references, etc.