

Notes for Guidance on the Completion of an Application for an Import Licence/Authorisation for Animal Products or a Licence to Import an Animal Pathogen/Carrier into Great Britain

Ensure that:

- you read the appropriate Importer Information Note (IIN) which can be found at: http://apha.defra.gov.uk/official-vets/Guidance/bip/iin/index.htm
- you complete the application form in BLOCK LETTERS or typescript
- you allow at least 15 working days for the application to be processed and the licence/authorisation to be issued
- a separate form is used for each type of material (either animal product or animal pathogen/carrier) you wish to import.

If you wish to import a Specified Animal Pathogen (as defined by Article 3(1) of the Specified Animal Pathogens Order) please use the relevant General Licence (IV69). For further information see the guidance on GOV.UK: https://www.gov.uk/guidance/bringing-specified-animal-pathogens-into-gb

It is important that all relevant sections of the application form are completed as fully as possible to ensure your application is processed as quickly as possible. Failure to provide important information will only cause delays.

Section 1- Applicant's Details

Name and full postal address of importing company or individual.

- 1. Name and Address please ensure all sections are completed fully including the email address so we can contact you if we need to.
- 2. We need to know the exact destination of the samples so we can assess the degree of containment available. If we have any queries we will contact the 'person in charge'. The consignment must be sent directly to the user or approved laboratory, as appropriate, at this address.
- 3. We need the contact details of the Agent in case there are any problems at the place of landing in the Great Britain. We may be able to resolve the issue by contacting the Agent.
- 4. When importing any animal material (animal-derived product, substance or carrier) that contains biologically active microorganisms, including those that could be contaminated with pathogens, we will look at the laboratory containment level and the standards to which the laboratory operates. This is required in order to assess the ability of the laboratory to allocate appropriate containment and control measures including measures to minimise the risk to animal and human health of escape of organisms from laboratories. This could include the following considerations:
 - Laboratory is licensed to handle and store pathogens covered by the Specified Animal Pathogens Order 2008 (as amended)
 - laboratory containment level based on the Advisory Committee on Dangerous Pathogens (ACDP) approved list of biological agents.

In addition, application of good laboratory practice to avoid the spreading of diseases communicable to humans or animals during the handling of the materials is considered as part of the risk assessment, including the following:

- Adherence to the relevant Advisory Committee on Dangerous Pathogens (ACDP) and Health and Safety Executive (HSE) guidance for good practice
- Adherence to the Guidance notes on the containment requirements under the Specified Animal Pathogens
 Order (SAPO) (available at: http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/pathogens/index.htm)
- Application of quality assurance systems e.g. accreditation to relevant International Standards Organisation (ISO) standards such as ISO17025 and/or Good Laboratory Practice (GLP) principle

Importers/users of animal by-products should ensure that they are handled, stored, labelled, transported and used in accordance with the requirements of Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011. Premises must be registered for the use of animal by-products. Further information is available on the APHA website.

- 5. All laboratories should have a risk assessment for any material they handle. All staff working in the facility should be aware of its contents and we may ask to see the risk assessment in exceptional cases.
- 6. Direct contact with livestock, horses and poultry can present a risk of the animals becoming infected with disease or exposed to other hazards that may be in the material. The probability of the material coming into contact with other animals, even if unlikely to result in transmission of disease, must be carefully assessed and it is important that any potential exposure is declared. Unreasonable restrictions will not be placed on individuals e.g. pathogens that can only be spread by insect vectors are unlikely to result in restrictions on physical contact with susceptible species.
- 7. Contact of material indirectly via carriage on clothing, equipment, hands etc (fomites) with farm livestock, horses and poultry can also present a risk of disease transmission. Some pathogens/diseases can easily be transmitted by humans and contact with any livestock can increase the risk of disease incursion into the local animal population. Routine cleansing and a change of clothes may not be sufficient to prevent the transmission of some pathogenic organisms.
- 8. We need to know the intended use of the material not only as part of our risk assessment but also to ensure we issue the correct type of licence/authorisation.
- 9. Please complete the details of the testing, research etc. being carried out, providing any additional information on a separate sheet.
- 10. We need to know whether the product is for commercial use or not as this will determine what type of licence/authorisation to issue or what advice to give.
- 11. The import conditions for most animal products are laid down in European Union law. There are not always import conditions in place to allow imports of certain products from certain countries and as such some commercial imports into the EU/GB may not be possible.

Section 2 – Licence/Authorisation Details

- 12. Applications for import of animal pathogens are processed by a different team to those for non pathogenic material. Accurate completion of these sections will help us to ensure your application is sent to the appropriate Department.
- 13. The issue of a previous similar licence/authorisation may not always mean another licence/authorisation will be issued automatically. A number of issues need to be assessed and the circumstances since the previous licence/authorisation was issued can change. For example the disease status of the country of origin or our experience of the risk posed by a specific material can change, suggesting that the level of controls applied must be amended.
- 14. The validity period of the licence/authorisation varies on the type of material imported and the needs of the importer. We do not guarantee a licence/authorisation with a long validity will automatically be issued but we will try to accommodate specific requests.

Section 3 – Consignment Details

- 15. Please complete this section fully.
- 16. In order to complete our risk assessment we must know the country of origin of the material so we can check the disease status of the exporting country, relevant import conditions etc (please use a separate sheet if necessary).
- 17. It is possible for material to become contaminated whilst being transshipped so full details of any countries involved through which the material will pass during transport to the final destination are required (please use a separate sheet if necessary).
- 18. As part of our risk assessment we need to know the animal species from which the product is derived so that we can assess disease status of the specific animal population of the exporting country and the potential risk that may be posed by import of material/products derived from that specific animal species.
- 19. Some products may present a higher animal health risk or have specific import requirements. Also the type of licence/authorisation required may vary. We need to know the exporting country for each type of material e.g. milk from country A, egg from country B.

- 20. If the product has a specific name we can check precisely the contents and we may previously have completed a risk assessment for the material, which will speed up the process.
- 21. It is particularly important to give full details of all the animal products or pathogens involved. If it is an animal by-product, please state the Category (1, 2 or 3) in accordance with the requirements of Articles 8, 9 or 10 of Regulation (EC) No 1069/2009.
- 22. The rules on landing products in Great Britain vary and the port/airport of landing may have to be approved for the type of material concerned. If landed at the wrong airport or port the consignment could be delayed or even destroyed.
- 23. Specific rules apply to the carriage of goods and importers should contact the carrier to ensure the correct packaging and labeling is used.
- 24. We need to know the date of import as this helps us to determine the validity period of the licence/authorisation.
- 25. +26, 27 & 28. It is important for us to know the quantities of material imported as part of our risk assessment. For example very small quantities sealed in capillary tubes present a much reduced risk. We may also use this information to limit the total amount of material per consignment.
- 29. Testing for pathogens prior to dispatch will help reduce the need for additional precautions in the destination laboratory. It is important that full details are given including the name and status (National, OIE or World Health Organisation designation etc.) of the laboratory carrying out the testing.
- 30. Prior treatment of the sample can reduce the risk of importing material that may present a risk and may help us to determine the type of facility (e.g. containment) to which the material can be sent. It is important to give full details e.g. both time and temperature for heat treatment and volumes and concentrations of preservatives.
- 31. Heat treatment at 56°C for 30 minutes is considered to destroy certain viruses and may negate the need for containment at the destination.
- 32. There is always a risk of cross-contamination at a laboratory that handles a wide variety of pathogens and this will be considered when carrying out the risk assessment.
- 33. The origin of the material will affect the need for extra precautions. Material from a laboratory will generally be of lower risk than material from wild animals. Where a country is approved to export similar commercial material to the EU the risk will be considered much lower.
- 34. Material from the animals suspected of being infected with any notifiable disease to which the animals are susceptible according to European or other National Animal Health legislation will not normally be licensed except to a laboratory approved under the Specified Animal Pathogens Order.
- 35. The proportion of animal derived ingredients will help us to determine the risk the product may present. A complete breakdown of **all** ingredients must be supplied, particularly in respect of any animal derived material (if necessary please list these at Section VI or on a separate sheet of paper).

Section 4 – Animal Health Licence to Import an Animal Pathogen/Carrier

36 – 39. This information is needed specifically for applications for a Pathogens Licence and helps to assess the risk of escape of the pathogen and affecting domestic or wild animals in the vicinity of the laboratory

Section 5 – Disposal of Residues and Waste

40 – 43. Please indicate how and where the residues of the animal product, pathogen or carrier following testing and any packaging will be destroyed. In the case of incinerators please supply the full name and address.

Please note that the material must be disposed of in accordance with Environmental and Animal By-products legislation.

Section 6 - Declaration

After reading these Guidance Notes tick the appropriate box and sign the appropriate declaration(s). Then see below for where to send the completed application form.

Please note that if completed electronically and if the application is not signed, we will not be able to process it.

Section 7 – Additional Information

Please use this section for any additional information and attach additional sheets if necessary.

The completed application form should be sent to:

For applications for animal pathogens and carriers landing in England or Scotland, and for animal products landing in England or Wales:

Wales:

For applications for animal pathogens or carriers landing in

Animal and Plant Health Agency Centre for international Trade - Carlisle Eden Bridge House Lowther Street Carlisle Cumbria CA3 8DX

Tel: 03000 200 301

Email: Imports@apha.gov.uk

For applications for animal products landing in

Scotland:

EH11 3XD

Scottish Government **Exotic Animal Diseases**

Agriculture and Rural Economy Directorate Office of the Chief Veterinary Officer

Animal Health and Welfare Divison Welsh Government P Spur Cathays Park

Saughton House Cardiff **Broomhouse Drive** CF10 3NQ Edinburgh

Tel: 0300 244 9874

Tel: 0300 060 4400

Email: animal.health@gov.Scot Email: animaldiseaseslivestock@gov.wales

APHA is an Executive Agency of the Department for Environment, Food and Rural Affairs and also works on behalf of the Scottish Government, Welsh Government and Food Standards Agency to safeguard animal and plant health for the benefit of people, the environment and the economy.