Veterinary Biologics Guideline 3.25E

Guidelines for Importation of Veterinary Biologics

Information Sheet - Importation of Veterinary Biologics into Canada

The manufacture and importation of veterinary biologics in Canada is regulated by the Canadian Food Inspection Agency (CFIA) under the authority of the *Health of Animals Act and Regulations*. Veterinary biologics include veterinary vaccines, diagnostic tests for the diagnosis of animal infectious diseases and antibody products used to treat or prevent animal infectious disease. Veterinary biologics do not include veterinary drugs (which are assigned a DIN number) and are primarily regulated by Health Canada (Veterinary Drugs Directorate) under the authority of the *Food & Drugs Act and Regulations*.

Veterinary biologics are regulated to ensure that the products used in animals in Canada are safe, effective, pure and potent. The manufacture of these products frequently involves (at some stage) the use of live infectious disease agents that are modified or killed during the manufacturing process. It is critical that credible processes with appropriate controls are utilized and validated during the manufacture of these products to ensure a safe end-product. All manufacturers of approved veterinary biologics that are allowed to be licensed and/or imported for use in Canada, must first provide detailed information about the effectiveness, safety and manufacturing to the CFIA-Veterinary Biologics Section (VBS) for careful assessment and review by scientific experts. CFIA inspectors also conduct on-site inspection of manufacturing facilities as part of this review process.

Requirement for an Import Permit

A significant number of animal vaccines and diagnostic kits used in Canada, are imported from other countries, including the United States, Europe, Australia and New Zealand. Prospective importers must demonstrate that they utilize appropriate facilities and expertise to manufacture veterinary biologics to conform with Canadian licensing requirements, and that the country of origin has the required animal disease freedom and/or surveillance systems to meet Canadian import requirements for animal products and veterinary biologics.

The importation of any veterinary biologic into Canada requires a valid import permit issued by the CFIA - VBS in Ottawa. There is no exemption from the import permit requirement for small shipments, “personal use” or for emergency or research use. (Reference *Health of Animals Regulations* Part XI Veterinary Biologics, Section 121.(1) "No person shall import a veterinary biologic into Canada unless he does so under and in accordance with a permit issued by the Minister".)

Commercial Import Permits

Commercial import permits are only issued by the CFIA-VBS (Ottawa) for products which are registered/licensed for use in Canada. For a list of veterinary biological products licensed for use in Canada (please note that this list may not be completely up-to-date) see the following web link (copy & paste into your browser): http://active.inspection.gc.ca/eng/anima/vetbio/vetbio_dbe.asp

Each product listed on a commercial import permit for veterinary biologics, has undergone a scientific regulatory review. A detailed product file must be prepared by the manufacturer and submitted to the CFIA-VBS for review. Furthermore, the product must be an approved product (licensed/registered by the regulatory authorities) in the country of origin. The product file contains research data, proprietary information concerning production, testing, formulation and materials of animal origin as well as specifications for storage, use, labelling, packaging, etc. The safety, purity, potency and efficacy of the product must be demonstrated by the data and information submitted for review. Cost recovery fees must be paid for the preliminary application review, in-depth consideration of the application, and issuance of the initial commercial import permit (if the product is accepted for registration by the CFIA). A satisfactory inspection of the manufacturing facility and the proposed Canadian importer by a CFIA veterinary inspector is also a requirement for product registration in Canada. These inspections are subject to fees for service, as well as full recovery of inspection travel expenses.

The commercial import permit(s) for the product are issued only to the importer or importers, designated by the manufacturer. Once the initial product review is completed and the product is licensed/registered in Canada, subsequent renewal of the import permit does not require the above in-depth review of the product file however the manufacturer must submit data for on-going review to CFIA-VBS, to support any significant changes to the production outline, label claims, designated importer, etc. and also must report any suspected adverse events associated with the use of the product (post market surveillance). In addition to the initial premises inspections, Canadian importers and foreign manufacturers are subject to subsequent periodic facility inspections by CFIA veterinary inspectors. The inspection frequency is determined by program requirements.

Frequently, the designated Canadian commercial importer is a subsidiary of the manufacturer located in Canada. They usually provide distribution, marketing and technical support to customers in Canada and may act as the regulatory affairs contact with the CFIA on behalf of the manufacturer for reporting suspect adverse events, product recalls and market withdrawal. A manufacturer may designate more than one importer and in this case each importer is subject to inspection and must pay for and be issued an import permit. Product must be shipped directly from the manufacturer to the designated importer. The importer is subject to inspection and is responsible for complying with all conditions stipulated on the import permit as well as the regulatory requirements related to veterinary biologics in the *Health of Animals Act and Regulations*.

Emergency & Research Use Import Permits

Under certain special circumstances, Canadian veterinarians can apply to VBS for a permit to import veterinary biologics which are unlicensed in Canada, for use under the importing veterinarian's supervision, in research or emergency situations. These permits may or may not be issued by CFIA-VBS, after a review of the rationale for use submitted by the importing veterinarian and a case-by-case evaluation of specified minimum product information. The permit (if granted) would specify conditions and requirements based on a risk assessment of the product and its proposed use. This provision is restricted to specific serials in the case of injectable products. Applications to import unlicensed products are reviewed on a case-by-case basis and a decision is made to either allow or refuse the importation. Imported products must then be shipped directly from the manufacturer, and used under the supervision of the importing veterinarian.

In a covering letter sent to VBS along with the application and appropriate fee, the importing veterinarian must briefly explain the rationale for importing and using unlicensed product in Canada by providing the following information:

1. The name and address of the farm(s) for which the product is being imported;

2. The history of the disease situation - the incidence of disease on the farm(s); test results of the affected animals on those farms; information on other vaccines/treatments tried (or diagnostic kits used) and the success or failure rate.

3. The reason for deciding to use this imported vaccine (or diagnostic kit)

4. State the number of doses or vials (or diagnostic tests or kits) to be imported.

The veterinarian's letter must also confirm:

1. That the product will be used under the supervision of the importing veterinarian
2. That the veterinarian and clients are aware that the product is not licensed and has not been evaluated as a veterinary biologic in Canada and will be used at their own risk
3. That the product is being imported for investigational or emergency use

All forms and more information concerning the above is available at the following web site: http://www.inspection.gc.ca/english/anima/vetbio/info/vb321e.shtml

Completed permit applications may be sent to:

Dr. Glen Gifford, National Manager
Canadian Food Inspection Agency, Animal Health & Production Division
Veterinary Biologics Section
2 Constellation Crescent, 8th Floor
Ottawa, ON K1A 0Y9
For General Inquiries: Tel: (613) 221-7566 Fax: (613) 228-6612
Web contact: http://www.inspection.gc.ca/english/anima/vetbio/conpere.shtml
Information concerning import permits and the veterinary biologics program in Canada may be obtained from the following Area contacts:

For Western Canada (Manitoba, Saskatchewan, Alberta & British Columbia):

Dr. Denis Anderchek
Veterinary Biologics Veterinarian
Veterinary Biologics-Operations-West
Canadian Food Inspection Agency
CFIA Box 28, 247 - 111 Research Drive
Saskatoon, SK S7N 3R2

Telephone: 306-975-6027 Fax: 306-975-6613
E-mail: anderchekd@inspection.gc.ca

For Ontario:

Dr. Ann West
Veterinary Biologics Veterinarian
Veterinary Biologics-Operations-Ontario
Canadian Food Inspection Agency
118071 Jackson Road, R. R. # 5
Owen Sound, ON N4K 5N7

Telephone: 519-371-4272 Fax: 519-371-7047
E-mail: westa@inspection.gc.ca

For Quebec:

Dr. Michel Morier
Veterinary Biologics Veterinarian
Veterinary Biologics-Operations-Québec
Canadian Food Inspection Agency
3100, Laframboise, bureau 206
St-Hyacinthe, QC J2S 4Z4

Telephone: 450-773-6639, ext : 119 Fax: 450-773-8338
E-mail: morierm@inspection.gc.ca

For Atlantic Canada (Newbrunswick, Newfoundland & Labrador, Nova Scotia, Prince Edward Island):

Dr. Thomas Wright
Veterinary Biologics Veterinarian
Veterinary Biologics-Operations-Atlantic
Canadian Food Inspection Agency
690 University Avenue
Charlottetown, PEI C1E 1E3

Telephone: 902-566-7290 Fax: 902-566-7334
E-mail: wrightt@inspection.gc.ca

Veterinary Drugs

Frequently there is confusion regarding the regulation of veterinary drugs. This information is being provided to attempt to clarify the regulation of these drugs and re-direct enquiries concerning these products. Veterinary drugs (which are not veterinary biologics and can be readily identified as drugs by the presence of a DIN or Drug Identification Number) are regulated by the Veterinary Drugs Directorate (VDD) of Health Canada.

The Emergency Drug Release Program allows veterinarians to obtain limited quantities of drugs not approved for sale in Canada, for emergency treatment under their direct medical supervision. Veterinarians may ask the VDD, which may then recommend to the Health Products & Food Branch, that the manufacturer be authorized to sell them a limited quantity of the drug for emergency use. The manufacturer must provide adequate evidence to the VDD that the drug poses no known health risk to the animals being treated or to humans. The veterinarian assumes full responsibility for the safety of the animals treated with the emergency drug and for any residue violations in food-producing animals as a result of this use. More information concerning this is available on the VDD website at http://www.hc-sc.gc.ca/dhp-mps/vet/index_e.html.