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REQUIREMENTS AND GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF VETERINARY BIOLOGIC MANUFACTURING AND REPACKING INSTITUTIONS IN THE PHILIPPINES

BAI ADMINISTRATIVE ORDER NO. 15, July 11, 1991

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Pursuant to Republic Act No. 3101, Republic Act No. 3720, Republic Act No. 1071, and A.O. No. 9, Series of 1982, A.O. No. 138 Series of 1990 the following guidelines, criteria, standards and requirements governing the establishment and operation of veterinary biologic manufacturing and repacking institution in the Philippines are hereby promulgated for the guidance of all concerned.

Article I
General Provisions

SECTION 1. Title - This order shall be known as the Philippine Rules and Regulations on the Establishment and Operation of Veterinary Biologics Manufacturing and Repacking Institutions of 1991

SECTION 2. Scope - This order shall apply to all establishments, public or private which manufacture, produce or repack, rebottle or reconstitute any veterinary biologics either for sale, experiment and distribution for the purpose of treating, preventing and diagnosing livestock and poultry diseases in the Philippines.

SECTION 3. Objectives - This order shall have the following objectives.

a. Set standards and criteria for the production or manufacture and repacking of veterinary biologics in the Philippines.

b. Provide criteria and guidelines on the establishment of operation of veterinary biologics manufacturing and repacking concerns and institutions in the Philippines.

c. Ensure the veterinary biologics manufactured, repacked or otherwise processed in the Philippines are safe and of high quality.

SECTION 4. Definition of Terms - For the purpose of this order the following terms and phrases as herein used shall mean:

a. Veterinary Biologic Establishment License refers to an establishment license issued by the BAI authorizing the use of the designated premises for production of biological products specified for one or more unexpired, unsuspended and unrevoked product licensed establishment.

b. Veterinary Biological Product License. A document referred to as a product license issued to the holder of an establishment license which authorizes production of a specified biological product in the license establishment.

c. Veterinary Biological Product. These words also referred to as veterinary biologics or biological products shall mean all viruses, bacteria, live microorganisms, killed microorganisms, components or product of microorganisms, antisera and other similar substances whether of natural or synthetic origin, intended for use in the diagnosis, therapy for prophylaxis of diseases of animals, prevention, or for identification of the causative

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organisms of a disease of animals.

d. Microorganism - also referred to as organisms, shall mean any virus , bacteria, protozoa, and other minute parasites which cannot be seen by naked eye and have the capability of causing or disseminating disease in animals.

e. Preparation of microorganisms veterinary for veterinary use - also referred to as "preparation" or production" means the processes through which an organism is rendered innocuous and made usable for the treatment, diagnosis and prophilaxis of animal diseases.

f. Animals refers to horses, mules, cattle, carabao, buffaloes, sheep, goats, swine, cats, dogs, poultry; wild animals such as deer, wild hogs, zoo animals; show and circus animals; household pets; specialty pets; aquatic animals; laboratory animals use for diagnostic and experimental purposes; and other species not including humans, wherein biological products are used.

g. Autogenous Biologic - also referred to as autogenous vaccine or autogenous biological product means any vaccine processed or manufactured from microbial isolates from a specific animal source and/or the infected tissues of the same, and thereafter used as treatment or prophylaxis for the same disease conditions) of animals belonging to the same farm herd of flock as the original source of the products and for exclusive use of the farm and not for sale or commercial distribution. Autogenous biological is classified as experimental biological product.

h. Experimental Biological Product refers to new biological product which is being evaluated to substantiate an application for a product license, the composition of which is different from that of already licensed biological product.

i. Pure or purity - refers to the quality of a biological product prepared in its final form of being free of extraneous microorganisms or other materials (organic or inorganic), as determined by quality control test.

j. Safe or safety refers to a quality of a biologic of being free from properties that cause undue local or systemic reactions when used as recommended or in standard Quality Control test.

k. Sterile or sterility refers to freedom from viable contaminating microorganisms as demonstrated by standard procedures and criteria of LSD Quality Control.

l. Potent or potency refers to the relative strength of a biological product as measured by standard Quality Control test of the LSD.

m. Efficacious or efficacy refers to specific ability or capability of biological product to effect or produce the result for which it is offered when used under conditions recommended by the manufacturer.

n. Stable or stability refers to the quality of a biological product of maintaining an assured degree of potency and efficacy within a specified amount of time after the production date, usually defined as its viable shelf life. Stability is usually measured under normal storage conditions; however, stability under room temperature and at 37 C may also be required.

o. Identity refers to the quality of biological product of containing only the specifically declared organisms or antigens, as determined by the quality control tests. This can be analogous to purity in some instances.

p. Duration of immunity refers to the length of time that a certain vaccine given to an animal according to recommended conditions would afford sufficient protection against virulent challenge of homologous or specifically related organisms.

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q. Consistency of production refers to the quality of a biological product which has been processed through the same procedures, or having relatively the same degree of stability, safety, efficacy, potency and general physical properties.

r. Batch - the total quantity of completed product which has been thoroughly mixed in a single container and identified by a batch number.

s. Batch number - number or numbers and letters used to identify and distinguish one serial from another.

t. Manufacturing process refers to the complete chain of procedural events which a biological preparation undergoes starting from the propagaton from seed stock up to the final packaging.

u. Repacking orrepackaging - also referred to as rebottling means the filling and bottling procedures used with regards to biological preparation that was previously processed and standardized in another establishment other the Biological Establishment presently handling it. This process could essentially involve reconstitution of the processed product.

v. Quality control refers to the test and services performed in the Biological Standards Section of the Laboratory Services Division to determine and ascertain the purity, safety, sterility, potency, efficacy and other desirable characteristics of the biologics.

w. Standard requirements refer to the test, methods procedures and criteria established or prescribed by the LSD in evaluating the various qualities and characteristics of a biological product to ensure its purity, safety, potency, and efficacy and to determine that such product is not worthless, contaminated, adulterated dangerous or harmful to animals as construed in the provisions of this Order and others related to it.

x. Establishment refers to the buildings and premises or place where veterinary biological products are being produced, manufactured, stored, or processed or any place where the object of business is veterinary biological products.

y. Director refers to the Director of the Bureau of Animal Industry.

z. Laboratory Services Division (LSD) refers to the Laboratory Services Division of the Bureau of Animal Industry.

Article II
Licensing Requirements and Procedures

SECTION 5. Persons Qualified to Apply for Licenses - No person shall be granted license for the handling repacking or manufacture of any veterinary biological product in the Philippines unless he meets the following qualifications and conditions.

a. He must be a Filipino Citizen or a permanent resident of the Philippines.

b. He has no records of previous violations of Bureau of Animal Industry regulations or similar regulations of other government agencies regarding production, manufacture, handling, distribution or marketing of veterinary biologics or similar products in the Philippines.

c. He has no court record of previous conviction for illegal production, manufacture, handling, distribution or marketing of veterinary biologics or similar products in the Philippines.

d. His establishment or place of business is in accordance with the standard and criteria prescribed by the BAI and it shall be operated under the direction and supervision of a licensed veterinarian or microbiologist sufficiently

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trained in the prescribed techniques for preparation and testing of such veterinary products specified in the application for registration; and

e. If he operates a branch, subsidiary or franchised establishment of a foreign-based company, such person shall have a valid contract or memorandum of agreement with the foreign mother company.

SECTION 6. Licenses - Every person who intends to prepare or repackage veterinary biological products shall make a written application to the Director of Animal Industry for a Veterinary Biologics Establishment License and a Veterinary Biologics Products License for each individual product.

a. Veterinary Biologic Establishment License

- Initial application for a Veterinary Biologics Establishment License shall be accompanied by a request for a Veterinary Biological Product License including all document requirements for both, as outlined in this set of guidelines of an Application for Veterinary Biologics Establishment License.

- No establishment license shall be granted until at least one biological product prepared therein meets all required standards of BAI.

- When a person operates more than one establishment a separate application shall be made for each establishment. A new application shall also be made when a change of ownership, operation or location of an establishment occurs.

- When partnerships of different establishment are involved in single operation, or if one establishment operates as a subsidiary of another, copies of formal contracts between said establishment should be submitted with the other requirements.

- A Veterinary Biologics Establishment License expires at the end of the year and can be renewed 90 days but not less than 30 days before expiration in accordance with Section 9 of BAI, A.O. No. 9, subject to the results of an annual inspection and examination of other requirements set by the BAI.

b. Veterinary Biological Product License

- An establishment that prepares or repackages biological products shall hold an unexpired, unsuspended and unrevoked Veterinary Biologics Establishment License and at least one Vet. Biologics Product License issued by the Director of Animal Industry.

- A Veterinary Product License shall specify authorization for production or repacking of a single biological product. This is renewed on a yearly basis upon approval of the BAI Director, based on recommendation of authorized BAI personnel. Renewal can be applied for anytime before the license expiry date. This license will not be issued without prior or simultaneous issuance of a Veterinary Biological Establishment License. A processing fe shall be collected upon filing of Application for Veterinary Biological Product License.

- A change or modification of the method of production of a particular product shall be a cause for requiring a separate product license for such a product.

- any establishment that wishes to prepare an autogenous biologic must have at least one licensed non-autogenous biological product.

- When a licensee no longer holds a product license authorizing preparation of non-autogenous biological product, any establishment license and any product license(s) for autogenous biologic shall be considered terminated and will be submitted to the BAI office for cancellation.

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SECTION 7. Supporting Documents - The following are the supporting documents required before issuance of licenses for manufacturing establishment, or a biological product, is considered. Documents will be treated confidential.

a. Documents for Veterinary Biologics Establishment License

- Preliminary plot plans, blueprints and legends shall be submitted at least in duplicate, clearly indicating functions performed in each building electrical outlets, water outlets, drains, doors and windows in designated establishment address. A standard specified scale should be used, which should be clearly indicated in the drafts. Date of preparation and signature of the responsible officer of the firm shall be indicated.

- Suggested alteration in preliminary drawings will be indicated by the authorized LSD personnel, and these shall be returned for subsequent revision.

- Acceptable submissions shall be stamped and filed, and the date noted. One copy shall be returned and another filed in the BAI-LSD.

b. Documents for a Veterinary Biological Product License

- Each written application for a Veterinary Product License shall be accompanied with at least two copies of complete and detailed production and quality control methods including methods for maintenance of vaccine seed strains and the origin of such strains.

- At least two copies of test reports and research data sufficient to establish purity, safety, potency, efficacy, duration of immunity, stability, identity and consistency of production of the product, according to current standard requirements shall be submitted. Signature of the person(s) who conducted and supervised the test shall accompany the test results.

- A copy of the field trial studies conducted on the vaccine accompanied by data from a practicing veterinarian who used the vaccine should be submitted. The field trial studies should establish that the vaccine is safe for use in target animals.

- Legends submitted together with the application for a Veterinary Biologics Establishment License shall designate which facilities are to be used for preparation of each biologics fraction or type.

- Labels in finished form or sketched facsimile shall be submitted together with information regarding all claims to be made on the labels and in advertising matter to be used in connection with or related to the biological product as prescribed in Sec. 27 of this order.

c. Other relevant requirements as stated in BAI A.O. No. 9 Sec. 7, 13 and 15 shall also be submitted.

d. Written assurance is filed with the BAI office, together with the license application, that the bilogical product(s) which are to be licensed and produced or repacked in the establishment shall not to be so adverised as to mislead or deceive the purchasers and that the packages or containers in which the same, are to be marketed shall not bear any statement, design or device which is false or misleading in any way. The written assurance also precludes advertising distribution and marketing of the product without official approval of the BAI.

SECTION 8. Inspection and Evaluation - the following requirements should be met before a license can be issued for a Veterinary Biological Establishment or Product:

a. Before a license is issued by the BAI for any establishment, inspection should be made to determine whether the site, condition, equipment, facilities and the like of the establishment, and the methods used to prepare biological products are in conformity with the requirements of BAI regulations.

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b. At least three inspection tours will be made prior to granting of a biological license, the initial one is to evaluate the site and general layout of the establishment, the second to observe standard manufacturing procedures and lastly to observe bottling/packaging procedures.

c. The BAI Director or his authorized representatives shall decide to issue a license based on inspection reports and evaluation of technical data that the condition of the technical data that the condition of the establishment including its facilities, and the establishment including its facilities, and the methods of preparation and testing of biological products are such that it is reasonable to assure that the products shall accomplish the purpose for which they are intended.

d. A license shall not be issued unless the BAI Director or his authorized representative(s) is satisfied on the basis of information before them that the establishment shall be operated in compliance with the BAI regulations and be under the supervision of person(s) competent in the preparation of biological products as defined in the next section.

e. Other pertinent provisions regarding inspection of biological establishments as detailed in AO. No. 9 Sec 37-39 will likewise be implemented.

Article III
General Requirements, Criteria
and Standards

SECTION 9. Personnel and Staff Standards -The following are the standards and criteria for the personnel and staff being employed or hired by the biologics manufacturing institutions.

a. The persons in-charge of manufacturing the biologics must :

- be sufficiently trained on the techniques used in the production of biologics to be manufactured by the institution.

- have demonstrated fitness to produce biological products in compliance with BAI regulations.

- have adequate knowledge of the scientific basis of the manufacture of the biologics being produced.

- have the authority to enforce discipline among all employees involved in the manufacturing process, including hired specialist assigned to the manufacture of specific product lines.

b. All hired specialists involved in product manufacture and quality control testing must:

- be a licensed and registered veterinarian with a valid graduate level of specialization in microbiology.

- have appropriate training regarding the product he is handling. In dealing with problems of production, training is needed, in some or all of the following fields, biometry, chemistry, medicine, virology, immunology, microbial genetic and relative disciplines.

c. All staff engaged in manufacture, testing and animal care should be vaccinated with appropriate specific vaccines and should undergo annual medical and physical check-ups.

d. The specialist staff and other personnel performing house quality control tests should be separate and different from those performing the manufacturing and should not be responsible the person in charge of production.

e. The names and qualifications of all specialist and technical personnel should be registered with the BAI. The complete biodata should be submitted together with the signatures of the concerned personnel. In case of major changes in personnel incharge of manufacture and testing, e.g those at the supervisory level, the BAI will be

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notified and files will be updated regarding names and qualifications of replacement personnel.

SECTION 10. Buildings and Rooms - The following are the criteria and standards for all the buildings and other infrastructures used or involved in manufacture, quality control of biologics a care upkeep of test animals:

a. Laboratories, workrooms, laboratory animal rooms and all other rooms and buildings used for the manufacture, repacking and quality control procedures shall be designated and constructed in such a way that high standards of sanitation and cleanliness can be maintained and freedom from insects and vermin ensured.

b. All buildings and rooms shall be kept clean and sanitary at all times.

c. Adequate drainage should be provided for all buildings. Due care and precaution shall be taken to avoid contamination of the drainage system with dangerous affluent, by having a treatment system of affluent prior to release into the environment.

d. The buildings should be equipped with an efficient system and supply of running water.

e. Precautionary measures shall be installed in all buildings used for manufacture, quality control and laboratory animal quarters to avoid airborne dissemination of pathogenic microbes and viruses and leakages thereof to the surrounding atmosphere.

f. Staff office rooms, changing rooms, dressing rooms, comfort rooms and other similarly necessary rooms should provided for with adequate space so as to ensure comfort for the users of such areas. Such rooms should be situated so as not to pose a possible source of contamination of the biological products nor adversely affect production and other related processes.

g. The rooms routinely used for the biological products, when used to manufacture other biologics, shall be cleaned, thoroughly and sterilized prior to resumption manufacture of the former biologics. The process(es) used shall be indicated in the documents and submitted together with the application for licenses, and approved as satisfactory by the authorized BAI personnel.

h. Any person not concerned with the production or other activities within a section of the building, who may enter that section for the purposes of inspection shall be supplied with sterile protective clothing.

i. There should be adequate scientific library facilities equipped with scientific books and updated journals particularly those relevant to the production and testing processes undertaken within the facilities.

SECTION 11. Outer Premises - The following are the criteria and standards for the outer premises of a biological manufacturing establishment.

a. The outer premises of biological manufacturing establishment including docks, driveways, approaches, yards, pens, chutes and alleys shall be drained properly and kept in a clean and orderly condition. No nuisance shall be allowed in any such establishment or its premises.

b. Every practical measure shall be taken to keep biological manufacturing establishments free of flies, rats, mice and other vermin. The accumulation on the premises of establishments of any material in which flies or other vermin may breed is strictly forbidden

c. A complete perimeter fencing shall enclose every biological manufacturing establishment to ensure security of the facility and of the surrounding areas.

d. The location of the manufacturing facility should be such that it poses no risks of infection or contamination to residential centers or animal production centers.

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SECTION 12. Water Quality and Pollution Control - A certification from the appropriate Water and Environmental Pollution Control Agency that the establishment is in compliance with government regulations, shall be filed with the BAI before the final approval for licensing is granted.

SECTION 13. Sterile Rooms -The following are the criteria and standards for sterile rooms:

a. The number of sterile processing rooms should be as many as possible according to the number and kind of biological products being manufactured therein.

b. They should be of a minimum size of their functions and have ceiling and smooth surface to permit through cleaning before and after their use.

c. These rooms should be essentially dust-free and preferably supplied with filtered air at a pressure higher than the adjacent rooms.

d. Before entering these rooms, staff personnel should change their outer garments in designated changing areas and wear sterile gowns.

e. Sterilizable inoculation hoods and/or laminar flow cabinets should be available for critical microbiological procedures e.g. preparation of seed inoculum, test for product quality and similar procedures.

SECTION 14. Animal Quarters and Houses -The following are the standards and requirements for cages and quarters of all tests and laboratory animals being used in connection with the manufacture and quality control assays of biological product.

a. The quarters for animals shall be designed and constructed with such materials that permit maintenance of cleanliness, sanitation and freedom from insects and vermin.

b. The food storage for the laboratory animals should be vermin free.

c. Animal inoculation rooms, isolation units for non-infected animals, quarantine area for incoming animals and post mortem examination rooms shall be provided and shall be separate and distinct from each other.

d. A separate area for production and maintenance of a supply of uninfected healthy test animals should be located as to exclude risk of contamination from probable source of infection. A facility such as this could be maintained as part of the Veterinary Biological Production Establishment, or could be duly approved and specifically designated commercial source(s) identified in the documents submitted with the license applications.

e. There should be provisions for the disinfection of cages and utilities used for feeding, drinking and upkeep of animals. Preferably, sterilization with steam under pressure should be used for this purposes.

SECTION 15. Equipment and Facilities - The minimum requirements of a vaccine laboratory are listed in Annex A. Additional specifications requirements are hereby listed.

a. Constant temperature rooms and/or cabinets such as refigerator spaces, incubator spaces or warm rooms capable of being maintained at a uniform constant temperature within a required range shall be available and maintained in a clean and sanitary conditions.

b. Other equipment such as aeration tanks, gyratory shakers and the like, which are utilized for propagation of certain microbes used in biologicals preparation in the establishment and are specified for use in procedures submitted together with the license application should also be available.

c. Additional storage equipment such as - 20 C and - 70 C freezers, liquid nitrogen tanks and similar equipment essential for specified standards operations of the Veterinary Biological Standards facility should also be

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available.

d. Such equipment as mentioned in the preceeding paragraphs of this section should, whenever possible, be equipped with appropriate recording thermometers and suitable alarm signals to ensure optimal control and maintenance of production systems.

e. An adequate supply of deionized and distilled water of a grade appropriate for specified procedures of the laboratory should be available.

f. For sterilizing supplies, media and the like, the following cleaning and sterilization equipment should be available.

- washing set-up or washing apparatus

- dry heat sterilizers and/or drying ovens

- bacteria retaining filters and other similar sterilization devices, if production procedures specify the use of these.

g. There should also be incinerators of similar equipment for disposal of infectious materials including animal carcasses used in the production or testing procedures. These shall be constructed and located so as not to pose a potential source of contamination to the production and testing operations and shall have been demonstrated to be capable of complete incineration of material for which its use is intended.

h. There should be additional means of sterilization such as ultraviolet irradiation and chemical sterilization if these are needed in specific processes and procedures used in the laboratory. The appropriate precautions with regards to the use of these shall be observed.

i. Adequate bottling, sealing and packaging equipment set-ups appropriate to specified products and operation processes shall be available.

j. An emergency power supply source(s) shall be available if the regular electrical power supply is not stable. These should preferably be equipped with automatic power-on switches and connected with the most critical laboratory equipment (e.g. storage equipment containing seed cultures etc.)

k. All apparatus, equipment and instruments used in the establishment should be high precision and shall be calibrated and checked at regular intervals to maintain optimal running conditions at all times.

Furthermore, these shall be adequate and appropriate for the requirements of the laboratory as specified in the procedures submitted with the licensing requirements.

Article IV
Production Control Standards,
Criteria and Requirements
SECTION 16 Production Methods - The following criteria, standards and measures shall be observed with regards to production manufacture or repacking of any veterinary biological product.

a. All methods used in the manufacture and testing of veterinary biologics shall be submitted to the BAI Director or his authorized representatives for evaluation before any product is manufactured or repacked. A written procedure shall be prepared for each product, describing each step in the process of production and quality control testing including data specified in section 25 (a) of this order. The projected production capacity for the prescribed process(es) shall also be stated.

b. Any subsequent modification of the initially submitted production and testing methods shall likewise be

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submitted for approval by the BAI Director before implementation of a full scale production process.

c. At any time, manufacture or repacking of each biological product shall take place in a separate area using separate equipment.

d. Only the strain of microorganisms used for the production of a particular biological product or fraction shall be permitted or allowed in the manufacturing area.

e. All production procedures should conform with the standard requirements set and approved by the BAI-LSD as based on the most current available methods applicable.

SECTION 17. Cleanliness of Apparatus and Equipment - Apparatus equipment and materials used in manufacturing biologics shall be kept clean and if necessary sterile and should be kept free from pyrogenic contamination.

SECTION 18. Orderliness and Identifications - All containers of biological substances regardless of the stage of manufacture shall be identified by securely attached labels.

SECTION 19. Precautions Against Contamination - The following precautionary measures shall be observed and followed strictly in any establishment, manufacturing or repacking veterinary biologics.

a. All procedures performed with regard to spore forming microorganisms shall be confined to separate and distinctly secured areas with equipment used exclusively in and for areas these areas.

b. Separate facilities shall be provided for work with each virus or distinct virus type and precautions shall be taken to prevent formation of infectious aerosol (especially by configuration and blending) which might lead to transfer of virus from one production unit to another.

c. Adequate staff shall be provided to avoid the necessity fot the staff to work in any one working day in different areas in which different products are being manufactured or repacked.

d. Sequential manufacture or repacking of different products in the same area may be allowed provided that the method of sterilization of the area between the manufacture of the different product is found satisfactory and has the prior approval of the BAI Director or his authorized representative.

Such approval must be applied for in writing and granted in writing.

e. Pathological specimens shall never be allowed in the areas used for manufacturing biological products. Bacterial and viral isolation work should be done in separate areas away from the manufacturing areas.

f. Employees should stay in specific work area during scheduled working periods and wear protective clothing which should not be worn outside said working areas.

g. Visitor during work period shall be limited and should not normally be permitted to enter sterile work areas.

SECTION 20. Experimental Biological Products - The following precautions and requirements shall be applied with regards to the handling of experimental biological products (including autogenous biologics) in a Veterinary Biological Product facility.

a. Experimental Biological products which are neither composed of nor prepared with organism or antigens used in biologicals already licensed shall not be prepared in the production facilities of licensed establishment. Autogenous vaccines are also classified as experimental biological products.

b. The BAI Director may authorize the preparation of such experimental products if it has been determined that

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such preparation will not result in contamination of a licensed product(s).

c. Each request for permission to prepare an experimental product in licensed premises shall indicate the nature of the unlicensed product, designate facilities to be used and specify precautions which will be taken to prevent contamination or licensed products. Such request will be submitted together with other requirements stated in section 16 (a) and (b) and section 25 (a) to the BAI Director for evaluation.

d. Research facilities that are entirely separate and apart from facilities used for the preparation of licensed biological products will not be considered part of the licensed premises and shall also be licensed if intended for use in preparing biological product(s).

SECTION 21. Autogenous Biologics -

a. Autogenous biologics shall be prepared from a culture of microorganisms which has been inactivated and is non-toxic.

b. Unless otherwise authorized by the BAI Director, the autogenous biologics shall be prepared for emergency use only. Organisms shall not be used for production more than twelve months from isolation.

c. The microorganisms used as seed shall be isolated from sick and dead animals and Judged to be causative agent of the current disease affecting such animals. More than one isolate from the same specimen(s) may be used.

d. Under normal circumstances, isolates from one herd or flock shall not be used to prepare an autogenous biologics for another herd or flock. However, the Director or authorized representative may authorize preparation of an autogenous biologics for use in adjacent herds or flocks which are considered to be at risk.

e. The Director may authorize the preparation of autogenous biologics for use in other (not adjacent) herds or flocks which is considered to be at risk with written concurrence of local veterinary officers responsible for the affected areas.

f. Isolates used to prepare autogenous biologics shall not be maintained in the licensed establishment beyond the time required to prepare authorized amounts.

g. Expiration date shall not exceed six (6) months from harvest.

h. The autogenous biologics shall be tested for purity, sterility and safety according to standard methods, except that:

- Serials which are satisfactory after the fifth day observation of purity/sterility test and safety test in animals may be released for shipment to the customer and the tests continued throughout the required period, and

- Serials released on the basis of satisfactory results of 5th day observation shall be immediately recalled if evidence of contamination occurs in the test cultures or if any of the safety test animals sicken or die during the observation period.

SECTION 22. Selection Care and Disposal of Laboratory and Test Animals

a. The animals used for production purposes or for test purposes shall show no signs of communicable disease. When necessary (e.g. when preparing seed stocks) specific pathogen free (SPF) animals should be utilized.

b. They should be provided with adequate housing areas, comfortable environmental conditions, well balanced diet and should be kept clean and sanitary.

c. Animal and/or animal carcasses capable of transmitting disease should not be removed from the establishment.

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d. Animals that died of infectious diseases should be completely incinerated.

e. Surviving test animals, including challenged control animals shall not be removed from the premises of which the tests are conducted at least 14 days after administration of a biological product or live organisms provided that this holding period may be increased or decreased as permitted by the BAI Director or his authorized representative(s) following review of all relevant information or data available.

f. The test control officer shall maintain adequate records relative to the disposition of each animal administered biological products. These records shall be maintained for a minimum period of two years. However, that the test control officer may be exempted from these record keeping requirements by authorized BAI personnel, on the basis of acceptable date demonstrating that the use of the biological products will not result in the presence of any unwholesome condition in the edible parts of animals subsequently presented for slaughter.

SECTION 23. Filing and Containers - The following shall be observed and followed with regards to filling procedures and the room and containers used for such procedures.

a. Filling shall be performed in a room(s) reserved exclusively for this purpose. They shall be maintained as close to sterile conditions possible and equipped with special equipment and apparatus for transferring measured quantities of finished products from bulk containers. Strict dust control measures and aseptic techniques shall be enforced to ensure that the product is not contaminated during the filling process.

b. Filling operations shall be conducted in such a way as to avoid any contamination or alteration of the product. These shall be done in areas completely separated from those in which living microorganism are handled.

c. The filling process should be checked at least twice each year at the end of working day, by filling not less than 500 ampules or 100 vials with nutrient medium containing no antibiotics or bacteriostatic substances and incubating the first batch at 37 C for one week. Not more than 1% of the containers should show signs of contamination and all contaminants should be identified.

d. Final containers should be sealed as soon as possible after filling. Closures shall be made of materials that does not have a deleterious effect upon the biological substances and be designed to maintain a hermetic seal throughout the guaranteed shelf life of the products.

SECTION 24. Test and Test Procedures

a. All test on specific biological products involving the use of living microorganisms should be carried out in rooms separate from those use in the production or repacking procedures. When practicable, entirely separate facilities should be available for this purpose.

b. The description of the test procedures necessary to ascertain the safety, purity, potency and other relevant standard qualities of each lot of biologics produced should be submitted to the Director or his authorized representative for approval and for reference purposes.

SECTION 25. Record Keeping

a. Records shall be maintained on the complete passsage history of all cultures kept in the establishment including origin of all isolates. Cultures and seed stock shall be labeled and stored in a safe, orderly manner so as to ensure maintenance of stable antigenic characteristics critical to the efficacy of the biological product. Maintenance of specific seed stocks shall be done in accordance with international standard and if possible and equipped with special apparatus for transferring measured quantities of finished product from the bulk containers to final containers. Strict dust control measures and aseptic techniques shall be enforced to ensure that the product is not contaminated during the filling process.

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b. Permanent production record shall be maintained and should clearly indicate all steps, dates and quantities produced, repacked, tested, bottled and distributed. The format of each records should be approved by the Director.

c. Written records of all test performed should be kept, irrespective of their results. These should be retained and made available at all times for inspection by authorized agents of the BAI.

d. Records of the manufacturing or repacking and testing processes of each batch should be maintained. These records should include sterilization of all apparatus and materials used.

e. Records of production and distribution must be submitted to BAI on a monthly basis in the manufacture, repacking and testing of the product(s).

f. Distribution records must be in such form that it is easy to trace the whereabouts of any particular batch distributed and recall these should the need arise.

SECTION 26. Samples

a. Samples from each lot shall be taken in sufficient quantity to enable enough test to be done as required by the BAI. Additional samples shall be retained throughout the guaranteed shelf life of the product as reference.

b. Such samples shall be kept in such a manner as to ensure the identity of the lot and such quantity as to permit repetitions of each control test when such need arises.

c. In particular, samples for purity and sterility test should represent a statistically significant quantity in relation to the volume of each production batches.

SECTION 27. Labelling - The following standards shall be observed in labelling the finished product(s).

a. All products shall be clearly identified by labels.

b. The label on the container shall indicate at least the following information:

- The name of the product (i.e. the generic name alone or international name or with the brand name);

- Name and complete address of manufacture if possible.

- Pharmacologic category;

- Dosage form and strength

- Rx symbol

- Batch No. and Lot No.

- Recommended Mode of Administration/ Directions for use

- Registration Number

- For Veterinary use only

- Expiration date

- Storage condition

- Indication

- Net content

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c. The label on the package shall in addition to the information shown on the container label show at least.

- The nature and amount of any preservative or added substance present in the product;

- A description of any substance likely to cause any adverse reaction and recommended antidotes;

- Any conta-indications regarding the use of the product and;

- Recommended booster vaccination

SECTION 28. Distribution and Sale - The following requirements and conditions should be followed and observed in releasing veterinary biologics for distribution.

a. A biological product shall not be released for distribution or sale until all the required quality tests have been performed and reviewed by the authorized representative(s) of the BAI Director. The product has passed the quality control test conducted by Veterinary Biologics Standard Section of the BAI. These test shall include an identify test performed on the final product if possible.

b. No new biological product shall be released for commercial use until consistency of production has been established. Such consistency in production of product quality has to be stablished in a minimum of three (3) and a maximum of five (5) consecutive production batches as determined to be appropriate by the representative of the Director.

c. No batches or portion thereof shall be released for sale to the public until so authorized by the BAI Director or his authorized representatives.

d. Failure of single batch to meet the requirement for product quality as determined by the BAI-LSD shall be considered a breakdown in production and cause for stopping product release.

e. In the event that the above breakdown happens, consistency of production shall be reestablished to the satisfaction of the Director or his authorized representative before any further batches are released.

f. All batches that fail should be submitted to BAI-LSD for destruction and condemnation.

SECTION 29. Shipping - Biologics shall be shipped with precautions to ensure that the product retains its potency upon arrival at its destination.

SECTION 30. Storage Conditions - Biologics shall be stored at controlled temperature environments at all times, within a range which ensures and maintains optimal data.

SECTION 31. Expiry Date - The expiry date of a biological product shall be defined and fixed with the approval of the Director as based on valid and adequate experimental.

SECTION 32. Advertising - Biological products which have not been duly licensed by the BAI-LSD shall not be advertised nor in any way promoted for use or distribution to the public.

Article V
General Requirements for
In-House Quality Control

SECTION 33. In-House Quality Control is Required - Any establishment or institution engaged in the manufacture or repacking of veterinary biologics in the Philippines is required to set up an in- house quality control laboratory within its compound or property.

SECTION 34. Staff of In-House Quality Control Laboratory - The staff performing the quality control tests

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should be separate from those performing the manufacturing process and should not be responsible to the person(s) in charge of production. The quality control tests shall be done in areas distinctly separate from those devoted to the manufacturing processes.

SECTION 35. Authority of the In-House Quality Control - The chief quality control officer should have sufficient authority to order a staff in manufacturing operations when a breakdown in production is detected.

SECTION 36. Building and Equipment - The building and equipment for the in-house quality control should be essentially similar to those basically required for manufacturing although on a suitably smaller scale.

SECTION 37. Test Animal - The following shall be observed:

a. Healthy animals of various species and specific strains shall be available in adequate number for an effective performance of the tests.

b. Animals should be maintained under optimum nutritional environmental conditions before and during tests and should be maintained free from extraneous infectious processes/disease.

SECTION 38. The Quality Control Tests - The following guidelines shall be observed regarding quality control tests:

a. Tests procedures used shall have been approved by the Director or his representative(s) and adequate data should have been obtained to satisfy requirements as mentioned in Section 7, b-11.

b. Personnel performing quality control tests should be familiar with international assay standards and approved national standard assays, additional specialized training in disciplines as mentioned in Art. III, Sec 9 b, is desirable.

c. The quality control laboratory shall devise effective internal control measures to permit objective interpretation and evaluation of all processes and results.

Article VI
Schedule of Fees

The following non-refundable fees will be collected by the Bureau of Animal Industry, upon application of the license.

INITIAL

RENEWAL
(Yearly)

a. Processing fee

P 1,000

b. Establishment License

4,000

5,000

c. Product License

2,500

2,500

Article VII
Administrative Sanctions
SECTION 39. Suspensions and Revocations of Veterinary Biologic Establishment License -Violation by the licensee of any of the prescribed standards and criteria or the terms or condition for registration and any pertinent provision of this order shall constitute a ground for the suspension or revocation of the Veterinary Biologic Establishment License. See A.O. No. 138 Series of 1990 for other Sanction. However, a licensee shall be given opportunity to be heard before the suspension or revocation of this license and the Director may assign a committee of responsible officials of the BAI for the purposes. The suspension order may be lifted after correction of the deficiency which is the cause for suspension.

In case of failure to correct the deficiency within the period prescribed by the Director, the license shall be deemed automatically revoked.

SECTION 40. Grounds for Cancellation of Veterinary Biological Product License - Any product license shall be cancelled under any of the following conditions.

a. When the biological product is withdrawn from the market by the manufacturer or producer, or when the biologic is no longer available in the normal channels of trade and commerce in the Philippines for a period of two years.

b. When the veterinary biologics has been verified by authorized investigators of the BAI to have caused damages to livestock and other animals in the Philippines, or when the meat of food animals treated there will become unfit for human consumption because the residues found in such meat are injurious to human beings.

c. When the veterinary biologic has been found to have deteriorated in quality as proven by findings of the BAI-LSD.

d. When the veterinary biologic has been found to be ineffective in prevention of the disease for which the vaccine was intended for as proven by findings of the BAI.

Article VIII
Penalties Repealing Provisions and
Effectivity

SECTION 41. a. Penalties - Any person found violating any of the provisions of Act No. 3101, Republic Act No. 1071 and/or this Order or any other rules and regulations that may be issued in accordance with the said laws, shall be deemed, guilty of misdemeanor and shall be punished by imprisonment or fine or both, as the Court may decide in accordance with the penal provisions of either Act 3101 or Republic Act No. 1071, whichever may be applicable.

b. The BAI reserves the right to order and effect closure of any establishment found to be operating in violation of this similar orders and to issue public advertisement to protect the public from unlicensed products and the distribution of such products.

SECTION 42 Repealing Provisions -All laws, rules and regulations or parts thereof in conflict with the provisions

of this Order are hereby repealed and modified accordingly.

SECTION 43. Effectivity - This Order shall take effect immediately.

Adopted: 11 July 1991

(SGD.) SENEN C. BACANI
Secretary of Agriculture

Approved:

(SGD.) ROMEO N. ALCASID
Director, Bureau of Animal Industry

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