Adopted 39th AMAF Meeting (28/9/2017)

PROTOCOL FOR RECOGNITION OF ASEAN REFERENCE LABORATORIES FOR ANIMAL VACCINE TESTING

CONTENT

PROTOCOL FOR RECOGNITION OF ASEAN REFERENCE LABORATORIES FOR ANIMAL VACCINE TESTING

1. INTRODUCTION

The ASEAN Sectoral Working Group on Livestock (ASWGL) has established standards for animal vaccines used in ASEAN Member States as well as procedures for registration of animal vaccines, requirements for good manufacturing practices for animal vaccines, criteria for accreditation of animal vaccine testing laboratories and code of practice for commercial storage, transportation and handling of animal vaccines. These have been published in the following manuals, which were launched at the Twentieth ASEAN Ministers on Agriculture and Forestry (20thAMAF) in Hanoi on 17-18 September 1998.

i. Manual of ASEAN Standards for Animal Vaccines,
ii. Manual of ASEAN Rules and Procedures for the Registration of Animal vaccines,
iii. Manual of ASEAN Standards for Good Manufacturing Practices (GMP) for Animal Vaccines,
iv. Manual of ASEAN Accreditation Criteria for Animal Vaccines Testing Laboratories, and
v. Manual of ASEAN Code of Practice for the Commercial Storage, Transportation and Handling of Animal Vaccines.

The Manual of ASEAN Accreditation Criteria for Animal Vaccine Testing Laboratories outlines the criteria for accreditation of ASEAN Animal Vaccine laboratories.

At the Fifth and Sixth Meetings of the ASWGL, it was agreed that the animal vaccine testing laboratories of Member States could apply for ASEAN accreditation to be recognized as ASEAN accredited animal vaccine testing laboratories. Furthermore, an audit team should be established to conduct the assessment of the applicant in accordance with the ASEAN Accreditation Criteria for Animal Vaccine Testing Laboratories and the ASEAN Standards for Animal Vaccines.

At the 25th meeting of ASWGL AMS concern that the definition of Accreditation is defined by ILAC as the independent evaluation of conformity assessment bodies against recognized standards to carry out specific activities to ensure their impartiality and competence but ASEAN mechanism is a self-assessment type and no Accreditation Body. The meeting agrees to change the terminology of “Accreditation” to “Recognition” for the Protocol for ASEAN Accreditation of Animal Vaccine Testing Laboratory to “Protocol for Recognition of ASEAN Reference Laboratories for Animal Vaccine Testing”

Protocol for Recognition of ASEAN Reference Laboratories for Animal Vaccine Testing is as follows:

2. APPLICATION FOR RECOGNITION

2.1 A Member State wishing to recognize an animal vaccine testing laboratory in its territory as an ASEAN Reference Laboratories Animal Vaccine Testing may submit an application to the ASEAN focal point for veterinary products with copies to all Member States in the format which appears as *ANNEX 1*.

2.2 The application for ASEAN recognition can be for specific type of vaccine or scope of testing methods whichever is applicable.

2.3 For recognition as ASEAN reference laboratories animal vaccine testing, the concerned Member State shall likewise submit an application to the ASEAN Focal Points for Veterinary Products.

2.4 The application shall be discussed at the next meeting of the ASWGL. For initial recognition, the application shall be submitted at least two (2) months prior to the meeting of the ASWGL. However, the application for recognition shall be submitted one year before the expiry date.

2.5 The ASWGL shall either accept the application or seek further clarification with regards to the application.

2.6 Once the application is accepted, the ASWGL shall create an audit team to assess the laboratory for its compliance/conformance to the ASEAN requirements. The guidelines for the audit team appear as ANNEX 2.

2.7 Applicant shall send the latest Quality Manual electronically (in PDF form) to the Audit Team at least1month before the assessment schedule.

3. ENDORSEMENT OF APPLICATION

3.1. The Audit Team shall conduct an assessment of the animal vaccine-testing laboratory in accordance with the ASEAN Recognition Criteria for Animal Vaccine Testing Laboratories as well as the ASEAN Standards for Animal Vaccines. The assessment would involve the evaluation of information submitted in the application as well as an audit inspection of the applicant.

3.2. The Audit Team shall report its findings and recommendations to the ASWGL. The ASWGL shall either endorse or reject the application for recognition of reference laboratories for animal vaccine testing (for specified types of animal vaccines and scope of testing methods, where applicable, or recommend that a further evaluation by another Audit Team be undertaken.

3.3. The Chairman of the ASWGL shall convey the decision for adoption at the next SOM-AMAF meeting. If SOM-AMAF endorses the decision of the ASWGL to recognized the applying animal vaccine-testing laboratory, the recommendation shall be submitted to AMAF for their approval to recognized the laboratory as an

ASEAN Reference Laboratories for Animal Vaccine Testing for scope of testing methods and/or specified type of animal vaccines.

4. VALIDITY

The recognition will be valid for a period of five (5) years from the date of issue of the certificate.

Annex 1

APPLICATION FORM
PROTOCOL FOR RECOGNITION OF ASEAN REFERENCE LABORATORIES
FOR ANIMAL VACCINE TESTING

To: ASEAN Focal Point for Veterinary Product

The Veterinary Authority of ……. (Name of ASEAN Member State) wishes to submit the following animal vaccine-testing laboratory for recognition by the ASEAN Sectoral Working Group on Livestock (ASWGL) in accordance with the Manual of ASEAN Recognition Criteria for Animal Vaccine Testing Laboratories.

Laboratory seeking recognition:

I. Institution

1. Name of Laboratory : …….
2. Address : …….
3. Phone and Fax No. : …….
4. Country : ……..

II. Contact person

1. Name : …….
2. Qualification and authority : …….
3. Phone and Fax. No. : …….
4. E-mail address : ……..

III. Scope of Recognition : (attached and completed)

IV. Quality Manual and Related Document:(should be attached)

The aforesaid laboratory has provided and certified the information in the attached checklist of ASEAN Recognition Criteria for Animal Vaccine Testing Laboratories.

……..

Name of endorser (National Focal Point for Veterinary Product)

……..

Name and Address of National Veterinary Authority:

……
……

Phone and Fax. No. : ……..
E-mail : ……..

Date : …….

…….
Signature of National Coordinator on behalf of
National Veterinary Authority

RECOGNITION CRITERIA FOR

ASEAN REFERENCE LABORATORIESFOR ANIMAL VACCINE TESTING

Please indicate (X) if the following are in place at time of application:

No.	Description	Remarks
A. BUILDING AND FACILITIES		
1.	**Laboratory Facility** **(Essential requirements for all laboratory works) (Follow up OIE Terrestrial Manual 2008)**	
1.1	The laboratory should be easy to clean, with surfaces that are impervious to water and resistant to chemicals;	
1.2	There shall be a wash-hand basin and emergency shower, including an eye bath, in each laboratory suite as appropriate for the chemicals and other hazards present;	
1.3	Procedures shall be established for frequent cleaning and disinfection during and at the end of the work period;	
1.4	Personnel access to the work area should be restricted;	
1.5	Personal protective equipment such as long-sleeved lab coats or gowns, closed-toe footwear, disposable gloves, masks, safety glasses, face shields, and oro-nasal respirators, as appropriate, shall be worn in the laboratory and removed when leaving the laboratory;	
1.6	The laboratory door should be closed when work in the progress and ventilation should be provided by extracting air from the room. (Where biosafety cabinets are used, care shall be taken to balance ventilation systems.);	
1.7	Food (including chewing gum, candy, throat lozenges and cough drops) and/or drink shall not be stored or consumed in laboratories;	
1.8	Smoking and/or application of cosmetics shall not take place in the laboratory;	
1.9	Pipetting shall not be done by mouth;	
1.10	Care shall be taken to minimize the production of aerosols;	
1.11	Emergency response plans should be developed to deal with the biohazard of spills. Some of the items addressed in the plans should include having effective disinfectant available for cleaning spills, removal of and decontamination of contaminated protective clothing, washing of hands, and cleaning and disinfection of bench tops;	
1.12	Used laboratory glassware and other contaminated material shall be stored safely;	
1.13	Materials for disposal shall be transported without spillage in strong containers;	
1.14	Waste material should be autoclaved, incinerated or otherwise	

No.	Description	Remarks
	decontaminated before disposal;	
1.15	Reusable material shall be decontaminated by appropriate means;	
1.16	No infectious material shall be discarded down laboratory sinks or any other drain;	
1.17	Any accidents shall be recorded and reported to the Safety Officer.	
2.	**Requirements of the laboratory/animal facility for Containment Group 2**	
	Laboratory/animal facility setting and structure	
2.1	Not next to known fire hazard;.	
2.2	Workplace separated from other activities;	
2.3	Personnel access limited;	
2.4	Protected against entry/exit of rodents and insects;	
2.5	Incinerator, pressure steam steriliser or renderer for disposal of carcasses and waste available;	
2.6	The laboratory/animal facility should be easy to clean, with surfaces that are impervious to water and resistant to chemicals. There shall be a wash-hand basin and emergency shower, including an eye bath, in each laboratory suite as appropriate for the chemicals and other hazards present. Procedures shall be established for frequent cleaning and disinfection during and at the end of the work period;	
	Additional Laboratory facility requirements	
2.7	Class I or II microbiological safety cabinet available;	
2.8	HEPA filters shall be verified regularly (usually annually);	
2.9	Direct access to autoclave/pressure steam sterilizer;	
2.10	Specified pathogens stored in laboratory;	
2.11	Personal protective clothing and equipment not worn outside laboratory;	
2.12	Safety Officer responsible for containment;	
2.13	Staff receive special training and demonstrate competence in the requirements needed;	
	Laboratory discipline	
2.14	Warning notices for containment area to indicate the hazard present and the name and telephone number of the person(s) responsible;	
2.15	Emergency protocols should be posted within the laboratory to advise personnel of procedures to follow in case of a pathogen spill or the need to evacuate the laboratory in the event of a fire or other emergency;	

No.	Description	Remarks
2.16	Laboratory must be lockable;	
2.17	Authorised entry of personnel;	
2.18	Protective clothing, including gloves, masks, eye shields, and oro-nasal respirators, as appropriate, shall be worn in the laboratory and removed when leaving the laboratory;	
2.19	The laboratory door should be closed when work is in progress and ventilation should be provided by extracting air from the room. (Where biosafety cabinets are used, care shall be taken to balance ventilation systems.);	
2.20	Food and/or drink shall not be stored or consumed in laboratories;	
2.21	Smoking and/or application of cosmetics shall not take place in the laboratory;	
2.22	Pipetting shall not be done by mouth;	
2.23	Care shall be taken to minimise the production of aerosols;	
2.24	No infectious material shall be discarded down laboratory sinks or any other drain;	
2.25	Used laboratory glassware and other material shall be stored safety before disinfection. Materials for disposal shall be transported without spillage in strong containers. Waste material should be autoclaved, incinerated or otherwise made safe before disposal. Reusable material shall be decontaminated by appropriate means;	
2.26	Any accidents or incidents shall be recorded and reported to the Safety Officer;	
	Handling of specimens	
2.28	Packaging requirements to be advised prior to submission;	
2.29	Incoming packages opened by trained staff in appropriately contained reception area;	
2.30	Movement of pathogens from an approved laboratory to another requires a license;	
2.31	Standard Operating Procedures covering all areas must be available.	
3.	**Requirements of the laboratory/animal facility for Containment Group 3**	
	Laboratory/animal facility setting and structure	
3.1	It is advisable that the laboratory/animal facility be in an isolated location;	
3.2	Not next to known fire hazard;	
3.3	Workplace separated from other activities;	
3.4	Personnel access limited;	
3.5	Protected against entry/exit of rodents and insects;	

No.	Description	Remarks
3.6	Liquid effluent must be sterilised and monitored;	
3.7	Isolated by airlock. Continuous internal airflow;	
3.8	The laboratory/animal facility shall be under negative pressure and the pressure differentials should be monitored;	
3.9	Input air to be filtered using HEPA or equivalent such as gas tight damper; exhaust air to be single HEPA filtration for laboratories and double HEPA filtration for animal facilities (Single on extract);	
3.10	HEPA filters shall be verified regularly (usually annually);	
3.11	Mechanical air supply system with fail-safe system and an alarm provided if there is a problem;	
3.12	Laboratory/animal facility sealable to permit fumigation;	
3.13	There are incinerator, pressure steam steriliser or renderer for disposal of carcasses and waste;	
3.14	The laboratory/animal facility should be easy to clean, with surfaces that are impervious to water and resistant to chemicals. There shall be a wash-hand basin and emergency shower, including an eye bath, in each laboratory suite as appropriate for the chemicals and other hazards present. Procedures shall be established for frequent cleaning and disinfection during and at the end of the work period;	
	Additional Laboratory facility requirements	
3.15	Class I or II biological safety cabinet available;	
3.16	Class III biological safety cabinet available;	
3.17	HEPA filters shall be verified regularly (usually annually);	
3.18	Direct access to double doors autoclave/pressure steam sterilizer;	
3.19	Specified pathogens stored in laboratory;	
3.20	Double-ended dunk tank is preferable;	
3.21	Personal protective clothing and equipment not worn outside laboratory;	
3.22	It may be necessary for staff to shower on exit from the laboratory and they must wear dedicated laboratory clothing that is left in the laboratory before leaving the building;	
3.23	Safety Officer responsible for containment;	
3.24	Staff receives special training and demonstrates competence in the requirements needed.	
	Laboratory discipline	
3.25	Warning notices for containment area to indicate the hazard present and the name and telephone number of the person(s) responsible.	
3.26	Emergency protocols should be posted within the laboratory to advice personnel of procedures to follow in case of a pathogen spill or the need to evacuate the laboratory in the event of a fire or other emergency.	

No.	Description	Remarks
3.27	Laboratory must be lockable	
3.28	Authorised entry of personnel	
3.29	Protective clothing, including gloves, masks, eye shields, and oro-nasal respirators, as appropriate, shall be worn in the laboratory and removed when leaving the laboratory;	
3.30	The laboratory door should be closed when work is in progress and ventilation should be provided by extracting air from the room. (Where biosafety cabinets are used, care shall be taken to balance ventilation systems.);	
3.31	Food and/or drink shall not be stored or consumed in laboratories;	
3.32	Smoking and/or application of cosmetics shall not take place in the laboratory;	
3.33	Pipetting shall not be done by mouth;	
3.34	Care shall be taken to minimise the production of aerosols;	
3.35	No infectious material shall be discarded down laboratory sinks or any other drain;	
3.36	Used laboratory glassware and other material shall be stored safety before disinfection. Materials for disposal shall be transported without spillage in strong containers. Waste material should be autoclaved, incinerated or otherwise made safe before disposal. Reusable material shall be decontaminated by appropriate means;	
3.37	Any accidents or incidents shall be recorded and reported to the Safety Officer;	
3.38	On entering all clothing removed and clean clothes put on.	
3.39	On exiting all laboratory clothes removed, individual shall wash and transfer to clean side;	
	Handling of specimens	
3.40	Packaging requirements to be advised prior to submission;	
3.41	Incoming packages opened by trained staff in appropriately contained reception area;	
3.42	Movement of pathogens from an approved laboratory to another requires a license;	
3.43	Standard Operating Procedures covering all areas must be available.	
4.	**Requirements of the laboratory/animal facility for Containment Group 4**	
	Laboratory/animal facility setting and structure	
4.1	It is advisable that the laboratory/animal facility be in an isolated location;	
4.2	Not next to known fire hazard;	

No.	Description	Remarks
4.3	Workplace separated from other activities;	
4.4	Personnel access limited;	
4.5	Protected against entry/exit of rodents and insects;	
4.6	Liquid effluent must be sterilised and monitored;	
4.7	Liquid effluent from steam steriliser's shall be sterilised and monitored;	
4.8	Isolated by airlock. Continuous internal airflow;	
4.9	The laboratory/animal facility shall be under negative pressure and the pressure differentials should be monitored;	
4.10	Input air to be filtered using HEPA or equivalent such as gas tight damper; exhaust air to be single HEPA filtration for laboratories and double HEPA filtration for animal facilities (Single for input, double for extract);	
4.11	HEPA filters shall be verified regularly (usually annually);	
4.12	Mechanical air supply system with fail-safe system and an alarm provided if there is a problem;	
4.13	Laboratory/animal facility sealable to permit fumigation;	
4.14	Incinerator, pressure steam steriliser or renderer for disposal of carcasses and waste are on site;	
4.15	The laboratory/animal facility should be easy to clean, with surfaces that are impervious to water and resistant to chemicals. There shall be a wash-hand basin and emergency shower, including an eye bath, in each laboratory suite as appropriate for the chemicals and other hazards present. Procedures shall be established for frequent cleaning and disinfection during and at the end of the work period;	
	Additional Laboratory facility requirements	
4.16	Class I or II biological safety cabinet available;	
4.17	Class III biological safety cabinet available;	
4.18	HEPA filters shall be verified regularly (usually annually);	
4.19	Direct access to double doors autoclave/pressure steam sterilizer;	
4.20	Specified pathogens stored in laboratory;	
4.21	Double-ended dunk tank is required;	
4.22	Personal protective clothing and equipment not worn outside laboratory;	
4.23	Full body shower and change of clothing required before exiting laboratory;	
4.24	Safety Officer responsible for containment;	
4.25	Staff receive special training and demonstrate competence in the requirements needed.	
	Laboratory discipline	
4.26	Warning notices for containment area to indicate the hazard present and the name and telephone number of the person(s)	

No.	Description	Remarks
	responsible.	
4.27	Emergency protocols should be posted within the laboratory to advise personnel of procedures to follow in case of a pathogen spill or the need to evacuate the laboratory in the event of a fire or other emergency.	
4.28	Laboratory must be lockable	
4.29	Authorised entry of personnel	
4.30	Protective clothing, including gloves, masks, eye shields, and oro-nasal respirators, as appropriate, shall be worn in the laboratory and removed when leaving the laboratory;	
4.31	The laboratory door should be closed when work is in progress and ventilation should be provided by extracting air from the room. (Where biosafety cabinets are used, care shall be taken to balance ventilation systems.);	
4.32	Food and/or drink shall not be stored or consumed in laboratories;	
4.33	Smoking and/or application of cosmetics shall not take place in the laboratory;	
4.34	Pipetting shall not be done by mouth;	
4.35	Care shall be taken to minimise the production of aerosols;	
4.36	No infectious material shall be discarded down laboratory sinks or any other drain;	
4.37	Used laboratory glassware and other material shall be stored safety before disinfection. Materials for disposal shall be transported without spillage in strong containers. Waste material should be autoclaved, incinerated or otherwise made safe before disposal. Reusable material shall be decontaminated by appropriate means;	
4.38	Any accidents or incidents shall be recorded and reported to the Safety Officer;	
4.39	On entering all clothing removed and clean clothes put on;	
4.40	Individual shall shower prior to transfer to clean side;	
	Handling of specimens	
4.41	Packaging requirements to be advised prior to submission;	
4.42	Incoming packages opened by trained staff in appropriately contained reception area;	
4.43	Movement of pathogens from an approved laboratory to another requires a license;	
4.44	Standard Operating Procedures covering all areas must be available.	
5.	**Animal Facility**	
5.1	Poultry facility	

No.	Description	Remarks
	5.1.1 Facility for Containment Group 2 available	
	5.1.2 Facility for Containment Group 3 available	
	5.1.3 Facility for Containment Group 4 available	
5.2	Swine facility	
	5.2.1 Facility for Containment Group 2 available	
	5.2.2 Facility for Containment Group 3 available	
	5.2.3 Facility for Containment Group 4 available	
5.3	Small laboratory animal facility	
	5.3.1 Facility for Containment Group 2 available	
	5.3.2 Facility for Containment Group 3 available	
	5.3.3 Facility for Containment Group 4 available	
5.3	Large animal/ ruminant facility	
	5.3.1 Facility for Containment Group 2 available	
	5.3.2 Facility for Containment Group 3 available	
	5.3.3 Facility for Containment Group 4 available	
B. QUALITY ASSURANCE		
1.	**QA Manager**	
1.1	Name	
1.2	Qualification	
1.3	Responsibility and authority	
2.	**Assistant QA Manager**	
2.1	Name	
2.2	Qualification	
2.3	Responsibility and authority	
3.	**Technical Manager**	

No.	Description	Remarks
3.1	Name	
3.2	Qualification	
3.3	Responsibility and Authority	
4.	**Assistant Technical Manager**	
4.1	Name	
4.2	Qualification	
4.3	Responsibility and Authority	
C. QUALITY MANUAL		
1.	Quality manual and related document attached	
2.	Quality manual consist of :	
2.1	Quality policy	
2.2	Organization chart of laboratory	
2.3	Personnel	
	2.3.1 Qualification/ education	
	2.3.2 Training course	
	2.3.3 Experiences	
	2.3.4 Job descriptions, responsibilities and authorities	
2.4	Methods and procedures :	

No.	Description	Remarks
	2.4.1 Validation procedure	
	2.4.2 Sampling, handling, storing, recording and procedures of stamping out of samples	
	2.4.3 All analytical methods Standard Operating Procedures (SOP)	
	2.4.4 Protocol Testing	
	2.4.5 Flows diagrams and working instructions	
	2.4.6 Sample preparation	
	2.4.7 Details of equipment and calibration	
	2.4.8 Reagents and biological standard/ calibration	
	2.4.9 Data handling, calculation and checking of results, data transfer, estimation of uncertainty	
2.5	Producing certificates of analysis, reports and records	
2.6	Procedure for handling, taking recording corrective action	
2.7	Procedures for sub contracted laboratories (if used)	
2.8	Procedures for claim of result testing	
2.9	Procedures for inter-laboratory collaborative studies	
2.10	Document control	
	2.10.1 Handling and storage	
	2.10.2 Person holding master copy of QA manual	
	2.10.3 System for control of documents	
2.11	Equipment	
	2.11.1 Documentation of equipment	
	2.11.2 List of all equipment	
	2.11.3 Procedures and programme of equipment requiring calibration and maintenance	
	2.11.4 Working instruction / Standard Operational Procedures	
2.12	Audit and Reviews	

No.	Description	Remarks
	2.12.1 Procedure of Internal Audit Body appointed	
	2.12.2 Procedure of Regular Review of QA System	
	2.12.3 System for keeping/ filling all raw data, records and report in place	

Attachment

RECOGNITION FOR SCOPE OF TESTING METHODS

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		

No.	Description and Parameters	Remarks
B. Testing Methods		
1	Characteristic test	
	1.1 General appearance	
	1.2 Vacuum test	
	1.3 Moisture content test	
	1.4 pH measurement	
	1.5 Protein content test	
	1.6 Preservative content test	
	1.6.1 Thimerosal content test	
	1.6.2 Phenol content test	
	1.6.3 etc.	
	1.7 Inactivant content test	
	1.7.1 Formalin content test	
	1.7.2 Beta-propionate content test	
	1.7.3 BEI content test	
	1.7.4 etc.	
	1.8 etc.	
2	Purity test	

No.	Description and Parameters	Remarks
	2.1 Test for bacterial contamination	
	2.2 Test for fungal contamination	
	2.3 Test for Mycoplasma contamination	
	2.4 Test for Salmonella contamination	
	2.5 Test for extraneous viruses	
	2.6 Test for extraneous microorganisms	
	2.7 etc.	
3	Safety test	
	3.1 Animal inoculation test	
	3.1.1 Mouse inoculation test	
	3.1.2 Guinea pig inoculation test	
	3.1.3 Rabbit inoculation test	
	3.1.4 Rat inoculation test	
	3.1.5 Chicken inoculation test	
	3.1.6 Duck inoculation test	
	3.1.7 Goose inoculation test	
	3.1.8 Pig inoculation test	
	3.1.9 Cattle inoculation test	

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	3.1.10 Buffalo inoculation test	

	3.1.11 Goat inoculation test	
	3.1.12 Sheep inoculation test	
	3.1.13 Dog inoculation test	
	3.1.14 Cat inoculation test	
	3.1.15 etc.	
	3.2 Inactivation test	
	3.2.1 Cell culture inoculation test	
	3.2.2 Egg inoculation test	
	3.2.3 Animal inoculation test	
	3.2.4 Medium culture test	
	3.2.5 etc.	
	3.3 Turn virulence test	
	3.4 Transmissibility test	
	3.5 Virulence test	
	3.5.1 ICPI test	
	3.5.2 Score lesion test	
	3.6 Toxicity test	
	3.7 Pyrogen test	
	3.8 etc.	
4	Potency test	

	4.1 Virus content test	
	4.2 Bacterial viable count test	
	4.3 Antigen content test	
	4.3.1 Haemagglutination test	
	4.3.2 Agglutination test	
	4.3.3 ELISA	
	4.3.4 etc.	
	4.4 Nucleic acid content test	
	4.5 Challenge test	
	4.5.1 Mouse inoculation test	
	4.5.2 Guinea pig inoculation test	
	4.5.3 Rabbit inoculation test	
	4.5.4 Rat inoculation test	
	4.5.5 Chicken inoculation test	
	4.5.6. Duck inoculation test	
	4.5.7 Goose inoculation test	
	4.5.8 Pig inoculation test	
	4.5.9 Cattle inoculation test	
	4.5.10 Buffalo inoculation test	
	4.5.11 Goat inoculation test	
	4.5.12 Sheep inoculation test	
	4.5.13 Dog inoculation test	

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	4.5.14 Cat inoculation test	

	4.5.15 etc.	
	4.6 Pathology / Histopathology	
	4.7 Virus isolation	
	4.8 Bacterial isolation	
	4.9 Mycoplasma isolation	
	4.10 Salmonella isolation	
	4.11 Humoral Immune response (HIR) titration test	
	4.11.1 Serum neutralisation test	
	4.11.2 Haemagglutination inhibition test	
	4.11.3 Agar gel immunodiffusion test	
	4.11.4Indirect fluorescent antibody test	
	4.11.5 Indirect immunoperoxidase test	
	4.11.6 Enzyme-linked immunosorbant assay (ELISA)	
	4.11.7 Modified direct complement fixation test	
	4.11.8 Rapid agglutination test	
	4.11.9 Tube agglutination test	
	4.11.10 Microscopic agglutination test (MAT)	
	4.11.11 etc.	
	4.12 Cell Mediated Immune Response (CMIR) titration test	
	4.13 etc.	
5	Identity test	

	5.1 Virus identity test	
	5.2 Bacterial identity test	
	5.3 Antigen identity test	
	5.4 Antibody identity test	
	5.5 etc.	
6	Stability test (Samples are tested at the expiry date)	
	6.1 Virus content test	
	6.2 Bacterial viable count test	
	6.3 Challenge test	
	6.4 Antibody titration test	
	6.5 Stability of oil emulsion	
	6.6 etc.	
7	etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Poultry Viral Vaccines**	
1.	Newcastle disease vaccine (Live / Lyophilized)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Vacuum test	
	1.1.3 Moisture content test	
	1.1.4 Preservative content test	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 Test for Mycoplasma contamination	
	1.2.4 Test for Salmonella contamination	
	1.2.5 Test for extraneous viruses	
	1.2.6 etc.	
1.3	Safety test	
	1.3.1 Chicken inoculation test	
	1.3.2 Virulence test	
	1.3.3 etc.	
1.4	Potency test	
	1.4.1 Virus content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Virus isolation test	
	1.4.5 Antibody titration test	
	1.4.6 etc.	
1.5	Identity test	
	1.5.1 Virus identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test (Samples are tested at the expiry date)	
	1.6.1 Virus content test	
	1.6.2 Challenge test	
	1.6.3 Antibody titration test	
	1.6.4 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Poultry Viral Vaccines**	
1.	Newcastle disease vaccine (Killed / Inactivated)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Preservative content test	
	1.1.3 Inactivant content test	
	1.1.4 Stability of oil emulsion	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 etc.	
1.3	Safety test	
	1.3.1 Chicken inoculation test	
	1.3.2 Inactivation test	
	1.3.3 etc.	
1.4	Potency test	
	1.4.1 Antigen content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Virus isolation test	
	1.4.5 Antibody titration test	
	1.4.6 etc.	
1.5	Identity test	
	1.5.1 Antigen identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test (Samples are tested at the expiry date)	
	1.6.1 Antigen content test	
	1.6.2 Challenge test	
	1.6.3 Antibody titration test	
	1.6.4 Stability of oil emulsion	
	1.6.5 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Poultry Bacterial Vaccines**	
1.	Salmonella vaccine (Live / Lyophilized)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Vacuum test	
	1.1.3 Moisture content test	
	1.1.4 pH measurement	
	1.1.5 etc.	
1.2	Purity test	
	1.2.1 Test for fungal contamination	
	1.2.2 Test for extraneous microorganisms	
	1.2.3 etc.	
1.3	Safety test	

No.	Description and Parameters	Remarks
	1.3.1 Chicken inoculation test	
	1.3.2 Mouse inoculation test	
	1.3.3 Turn virulence test	
	1.3.4 Transmissibility test	
	1.3.5 etc.	
1.4	Potency test	
	1.4.1 Bacterial viable count test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Bacterial isolation test	
	1.4.5 Antibody titration test	
	1.4.6 etc.	
1.5	Identity test	
	1.5.1 Bacterial identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test (Samples are tested at the expiry date)	
	1.6.1 Bacterial viable count test	
	1.6.2 Challenge test	
	1.6.3 Antibody titration test	
	1.6.4 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Poultry Bacterial Vaccines**	
1.	E. Coli (Killed / Inactivated)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Protein content test	
	1.1.3 Inactivant content test	
	1.1.4 Stability of oil emulsion	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 etc.	
1.3	Safety test	

No.	Description and Parameters	Remarks
	1.3.1 Chicken inoculation test	
	1.3.2 Mouse inoculation test	
	1.3.3 Inactivation test	
	1.3.4 Toxicity test	
	1.3.5 Pyrogen test	
	1.3.6 etc.	
1.4	Potency test	
	1.4.1 Challenge test	
	1.4.2 Pathology / Histopathology	
	1.4.3 Bacterial isolation test	
	1.4.4 Antibody titration test	
	1.4.5 etc.	
1.5	Identity test	
	1.5.1 Antigen identity test	
	1.5.2 Antibody identity test	
	1.5.4 etc.	
1.6	Stability test	
	1.6.1 Challenge test	
	1.6.2 Antibody titration test	
	1.6.3 Stability of oil emulsion	
	1.6.4 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Swine Viral Vaccines**	
1.	Aujeszky's disease vaccine (Live / Lyophilized)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Vacuum test	
	1.1.3 Moisture content test	
	1.1.4 Preservative content test	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 Test for Mycoplasma contamination	
	1.2.4 Test for Salmonella contamination	
	1.2.5 Test for extraneous viruses	
	1.2.6 etc.	
1.3	Safety test	
	1.3.1 Pig inoculation test	
	1.3.2 Turn virulence test	
	1.3.3 Transmissibility test	
	1.3.4 etc.	
1.4	Potency test	
	1.4.1 Virus content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Virus isolation test	
	1.4.5 Antibody titration test	
	1.4.6 etc.	
1.5	Identity test	
	1.5.1 Virus identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test (Samples are tested at the expiry date)	
	1.6.1 Virus content test	
	1.6.2 Challenge test	
	1.6.3 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Swine Viral Vaccines**	
1.	Aujeszky's disease vaccine (killed/Inactivated)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Preservative content test	
	1.1.3 Inactivant content test	
	1.1.4 Stability of oil emulsion	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 etc.	
1.3	Safety test	

No.	Description and Parameters	Remarks
	1.3.1 Pig inoculation test	
	1.3.2 Inactivation test	
	1.3.3 etc.	
1.4	Potency test	
	1.4.1 Antigen content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Virus isolation test	
	1.4.5 Antibody titration test	
	1.4.6 etc.	
1.5	Identity test	
	1.5.1 Antigen identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test	
	1.6.1 Antigen content test	
	1.6.2 Challenge test	
	1.6.3 Antibody titration test	
	1.6.4 Stability of oil emulsion	
	1.6.5 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Swine Bacterial Vaccines**	
1.	E. Coli (Killed / Inactivated)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Protein content test	
	1.1.3 Inactivant content test	
	1.1.4 Stability of oil emulsion	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 etc.	
1.3	Safety test	

No.	Description and Parameters	Remarks
	1.3.1 Pig inoculation test	
	1.3.2 Mouse inoculation test	
	1.3.3 Inactivation test	
	1.3.4 Toxicity test	
	1.3.5 Pyrogen test	
	1.3.6 etc.	
1.4	Potency test	
	1.4.1 Challenge test	
	1.4.2 Pathology / Histopathology	
	1.4.3 Bacterial isolation test	
	1.4.4 Antibody titration test	
	1.4.5 etc.	
1.5	Identity test	
	1.5.1 Antigen identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test	
	1.6.1 Challenge test	
	1.6.2 Antibody titration test	
	1.6.3 Stability of oil emulsion	
	1.6.4 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Bovine Viral Vaccines**	
1.	Infectious bovine rhinotracheitis vaccine (Live / Lyophilized)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Vacuum test	
	1.1.3 Moisture content test	
	1.1.4 Preservative content test	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 Test for Mycoplasma contamination	
	1.2.4 Test for Salmonella contamination	
	1.2.5 Test for extraneous viruses	
	1.2.6 etc.	
1.3	Safety test	
	1.3.1 Cattle inoculation test	
	1.3.2 Turn virulence test	
	1.3.3 Transmissibility test	
	1.3.4 etc.	
1.4	Potency test	
	1.4.1 Virus content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Virus isolation test	
	1.4.5 Antibody titration test	
	1.4.6 etc.	
1.5	Identity test	
	1.5.1 Virus identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test (Samples are tested at the expiry date)	
	1.6.1 Virus content test	
	1.6.2 Challenge test	
	1.6.3 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Bovine Viral Vaccines**	
1.	Foot and mouth disease vaccine for cattle and buffaloes (Killed / Inactivated)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Preservative content test	
	1.1.3 Inactivant content test	
	1.1.4 Protein content test	
	1.1.5 Stability of oil emulsion	
	1.1.6 pH measurement	
	1.1.7 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 etc.	
1.3	Safety test	
	1.3.1 Cattle inoculation test	
	1.3.2 Inactivation test	
	1.3.3 etc.	
1.4	Potency test	
	1.4.1 Antigen content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Antibody titration test	
	1.4.5 etc.	
1.5	Identity test	
	1.5.1 Antigen identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test	
	1.6.1 Antigen content test	
	1.6.2 Challenge test	
	1.6.3 Antibody titration test	
	1.6.4 Stability of oil emulsion	
	1.6.5 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Bovine Bacterial Vaccines**	
1.	Brucella abortus vaccine(Live / Lyophilized)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Vacuum test	
	1.1.3 Moisture content test	
	1.1.4 pH measurement	
	1.1.5 etc.	
1.2	Purity test	
	1.2.1 Test for fungal contamination	
	1.2.2 Test for extraneous microorganisms	
	1.2.3 etc.	
1.3	Safety test	

No.	Description and Parameters	Remarks
	1.3.1 Cattle inoculation test	
	1.3.2 Guinea pig inoculation test	
	1.3.3 etc.	
1.4	Potency test	
	1.4.1 Bacterial viable count test	
	1.4.2 Antibody titration test	
	1.4.3 etc.	
1.5	Identity test	
	1.5.1 Bacterial identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test (Samples are tested at the expiry date)	
	1.6.1 Bacterial viable count test	
	1.6.2 Antibody titration test	
	1.6.3 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Bovine Bacterial Vaccines**	
1.	Haemorrhagic Septicaemia for cattle and buffaloes (Killed / Inactivated)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Protein content test	
	1.1.3 Inactivant content test	
	1.1.4 Stability of oil emulsion	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 etc.	
1.3	Safety test	
	1.3.1 Cattle inoculation test	
	1.3.2 Mouse inoculation test	
	1.3.3 Inactivation test	
	1.3.4 Toxicity test	
	1.3.5 Pyrogen test	
	1.3.6 etc.	
1.4	Potency test	
	1.4.1 Challenge test	
	1.4.2 Pathology / Histopathology	
	1.4.3 Bacterial isolation test	
	1.4.4 Antibody titration test	
	1.4.5 etc.	
1.5	Identity test	
	1.5.1 Antigen identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test	
	1.6.1 Challenge test	
	1.6.2 Antibody titration test	
	1.6.3 Stability of oil emulsion	
	1.6.4 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Canine Viral Vaccines**	
1.	Canine distemper vaccine (Live / Lyophilized)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Vacuum test	
	1.1.3 Moisture content test	
	1.1.4 Preservative content test	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 Test for Mycoplasma contamination	
	1.2.4 Test for Salmonella contamination	
	1.2.5 Test for extraneous viruses	
	1.2.6 etc.	
1.3	Safety test	
	1.3.1 Dog inoculation test	
	1.3.1 Mouse inoculation test	
	1.3.2 Turn virulence test	
	1.3.3 Transmissibility test	
	1.3.4 etc.	
1.4	Potency test	
	1.4.1 Virus content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Virus isolation test	
	1.4.5 Antibody titration test	
	1.4.6 etc.	
1.5	Identity test	
	1.5.1 Virus identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test (Samples are tested at the expiry date)	

No.	Description and Parameters	Remarks
	1.6.1 Virus content test	
	1.6.2 Challenge test	
	1.6.3 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Canine Viral Vaccines**	
1.	Rabies vaccine (Killed / Inactivated)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Preservative content test	
	1.1.3 Inactivant content test	
	1.1.4 Protein content test	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 etc.	
1.3	Safety test	
	1.3.1 Dog inoculation test	
	1.3.2 Mouse inoculation test	
	1.3.3 Inactivation test	
	1.3.4 etc.	
1.4	Potency test	
	1.4.1 Antigen content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Antibody titration test	
	1.4.5 etc.	
1.5	Identity test	
	1.5.1 Antigen identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test	
	1.6.1 Antigen content test	
	1.6.2 Challenge test	
	1.6.3 Antibody titration test	
	1.6.4 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Feline Viral Vaccines**	
1.	Feline panleucopenia vaccine (Live / Lyophilized)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Vacuum test	
	1.1.3 Moisture content test	
	1.1.4 Preservative content test	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 Test for Mycoplasma contamination	
	1.2.4 Test for Salmonella contamination	
	1.2.5 Test for extraneous viruses	
	1.2.6 etc.	
1.3	Safety test	
	1.3.1 Cat inoculation test	
	1.3.1 Mouse inoculation test	
	1.3.2 Turn virulence test	
	1.3.3 Transmissibility test	
	1.3.4 etc.	
1.4	Potency test	
	1.4.1 Virus content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Virus isolation test	
	1.4.5 Antibody titration test	
	1.4.6 etc.	
1.5	Identity test	
	1.5.1 Virus identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test (Samples are tested at the expiry date)	

No.	Description and Parameters	Remarks
	1.6.1 Virus content test	
	1.6.2 Challenge test	
	1.6.3 etc.	

Attachment

RECOGNITION FOR SPECIFIED TYPE OF ANIMAL VACCINES

Please indicate (X) if the following are in place at time application

No.	Description and Parameters	Remarks
A. Laboratory		
B. Product Testing		
I.	**Feline Viral Vaccines**	
1.	Feline panleucopenia vaccine (Killed / Inactivated)	
1.1	Characteristic test	
	1.1.1 General appearance	
	1.1.2 Preservative content test	
	1.1.3 Inactivant content test	
	1.1.4 Protein content test	
	1.1.5 pH measurement	
	1.1.6 etc.	
1.2	Purity test	

No.	Description and Parameters	Remarks
	1.2.1 Test for bacterial contamination	
	1.2.2 Test for fungal contamination	
	1.2.3 etc.	
1.3	Safety test	
	1.3.1 Cat inoculation test	
	1.3.2 Mouse inoculation test	
	1.3.3 Inactivation test	
	1.3.4 etc.	
1.4	Potency test	
	1.4.1 Antigen content test	
	1.4.2 Challenge test	
	1.4.3 Pathology / Histopathology	
	1.4.4 Antibody titration test	
	1.4.5 etc.	
1.5	Identity test	
	1.5.1 Antigen identity test	
	1.5.2 Antibody identity test	
	1.5.3 etc.	
1.6	Stability test	
	1.6.1 Antigen content test	
	1.6.2 Challenge test	
	1.6.3 Antibody titration test	
	1.6.4 etc.	

Annex 2

GUIDELINES FOR THE AUDIT TEAM

1. COMPOSITION OF AUDIT TEAM

The Audit Team shall be composed of a representative from each of the ASEAN Member State, other than the applying country. It can be regarded as constituted if at least four (4) countries and two (2) countries are represented during the assessment and reassessment process, respectively.

The members of the Audit Team should be competent and qualified to conduct assessment in accordance with the Recognition ASEAN Criteria for Animal Testing Laboratories as well as the ASEAN Standards for Animal Vaccines. The assessors should have an academic degree in the field of veterinary medicines, veterinary science, veterinary microbiology (virology and bacteriology), biomedical sciences and other related disciplines, and b) at least three (3) years experience in testing animal vaccines or related work. Those with experience in ISO17025 or equivalent are preferable. No member of the Audit Team shall participate in the assessment of animal vaccine testing laboratories in his own country.

National Focal Point for Veterinary Product of each ASEAN Member State should submit the list of not more than four (4) assessors who have the qualifications as mentioned above.

2. TERMS OF REFERENCE FOR THE AUDIT TEAM

The Audit Team shall have the following duties and responsibilities:

1.To assess the application for recognition as an ASEAN Reference Laboratories for Animal Vaccine Testing by an animal vaccine testing laboratory in a Member State (i.e. host country) and to obtain any additional technical information before planning a visit.

2. To conduct an audit inspection of the animal vaccine testing laboratory in the host country applying for recognition as an ASEAN Reference Laboratories for Animal Vaccine Testing.

3.To assess the building, facilities and quality assurance systems of the applying animal vaccine testing laboratory (for scope of testing methods and/or specified type of animal vaccines)in accordance with the ASEAN Recognition Criteria for Animal Vaccine Testing Laboratories as well as the ASEAN Standards for Animal Vaccines.

4. To report its finding and make recommendations to the ASWGL on the recognition of applying laboratory as an ASEAN Reference Laboratories for Animal Vaccine Testing for scope of testing methods and/or specified type of animal vaccines.

3. ROLE OF THE COORDINATOR FOR THE AUDIT TEAM

The Coordinator for the Audit Team shall be a representative from the Lead Country (Indonesia), which holds the appointment as ASEAN focal point for veterinary product.

However, when the lead country is to be audited, the coordinator shall be designated from among the rest of Member States and shall be decided during the ANFPVP Meeting.

Once approval has been given by the ASWGL, the Coordinator shall coordinate the formation of an Audit Team, by writing to request all ASEAN Member States (other than the host country) attached with the list of qualified assessors of each selected country to the National Veterinary Authority to nominate one person from the list of qualified person to ASEAN Secretariat, then the ASEAN Secretariat will inform to the Coordinator for the Audit Team. The request should be copied to the Chairman of the ASWGL and the host country. The Coordinator should provide details on the outstanding applications accepted by the ASWGL so far (i.e. number of countries and laboratories to be recognized in each country.

The Coordinator shall coordinate requests for additional technical information by any member of the Audit Team. Any request should be submitted by the members of the Audit Team to the Coordinator within 1 month of dispatch of the applications by the Coordinator. The Coordinator shall then compile these requests and forward them to the host country with a copy to each member of the Audit Team. The host country shall provide the requested information to the Coordinator and all members of the Audit Team within 1 (one) month of dispatch of the request for information by the Coordinator.

The Coordinator shall then finalize schedule for the audit inspection of the vaccine testing laboratories in the host country (or host countries) in consultation with the members of the Audit Team and the host country or countries. If there is a time and cost constraints, it may necessary to schedule visits to only one or two host countries at a time. The schedule of host countries to be visited shall be in accordance to the order of acceptance of the applications by the ASWGL.

The Coordinator shall liaise with the team leader on submission of the report of the findings and recommendations of the Audit Team to the ASWGL for consideration.

4. ASSESSMENT AND REASSESSMENT PROCESS

The members of the Audit Team shall elect amongst themselves a leader to lead the Audit Team.

The Audit Team shall assess the animal vaccine-testing laboratory in accordance with the ASEAN Recognition Criteria for Animal Vaccine testing Laboratories as well as the ASEAN Standards for Animal Vaccines. The assessment would involve the evaluation of information provided in the application as well as an audit inspection of the animal vaccines testing laboratory. The team leader on behalf of the Audit Team shall report its findings and recommendations on the recognition of the applying laboratory as a recognized ASEAN Reference Laboratories for Animal Vaccine Testing (for specified scopes of testing methods) to the ASWGL. In an event when corrective actions are recommended during the assessment process, the animal vaccine testing laboratory applying for certification shall be reassessed based upon measures taken to address the recommended corrective actions. The procedures for the reassessment and the report thereof of its findings shall follow the procedures applied during the assessment process.

5. FINANCIAL ARRANGEMENTS

The host country shall also bear the costs of international and domestic official travel, accommodation and food for the Audit Team assessing the applying laboratory or laboratories within the host country.

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