

Remarks from Directorate of Animal Health

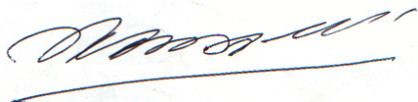
With the membership of Nepal in World Organization for Animal Health (OIE) and World Trade Organization (WTO), we have to comply with the obligations that were made for the membership. In this regard we have to prepare and implement appropriate legislations including acts, regulations, orders, SOPs, directives etc so that the activities carried out by Nepal can be compatible as per WTO/OIE standards.

In this era of globalization, we cannot live alone and our activities are also interconnected with the activities and standards set by other agencies/countries. Equally our national capacity has to be enhanced so that the veterinary service in Nepal can be uplifted as per the international standards.

Department of Livestock Services has been issuing different standards based on the legal power given by the Animal Health and Livestock Services Act, **2055 and its regulation 2056**. In this regard **Veterinary standards and Drug Administration Office** has compiled the standards approved by Department of Livestock Services and published in this booklet.

In this booklet, **standard for import risk analysis of live animal, animal product and veterinary biologicals, national microbial standard for meat, milk, egg and MRL of vet drugs, standard for the transfer and biocontainment of hazardous animal pathogens, and biosecurity manual for commercial poultry production has been compiled**. Implementation of above said documents will help to maintain quality of livestock, livestock products and production materials. Also this standard will be helpful for the people involved in regulatory activities giving them legislative support for the activities carried out by them.

I want to express my sincere thanks to all the individuals involved in the preparation of this standard and special thank goes to entire VSDAO family for their tireless effort in preparation, compilation, editing and finalizing this manuscript.



Dr Vijay Kant Jha
Program Director

Foreword

National and transnational factor has given severe impacts both in animal and human health throughout the world. To cope with the situation sincere and committed attention needs to be paid towards veterinary services in the country. The first step, we believe, in it, is to standardise the veterinary practices and enforce them to mitigate the risk. For this standards and benchmarks needs to be set and implemented properly by drafting appropriate manuals and guidelines. Though Nepal has made important progress in last few years, still there is a dearth of adequate standards.

The standards developed so far are being implemented but still much needs to be done to increase awareness about their existence. To overcome these challenges Veterinary Standards and Drug Administration Office (VSDAO) has taken initiatives to publish the set standards so that awareness among the users can be attained which will help to fulfil the mission of the national veterinary services as per the international standards.


Veterinary Standards and Drug Administration Office (VSDAO) has taken role to compile the standards approved by Department of Livestock Services and publish it in a booklet form for easy access and reference.

The booklet contains standards relating to: import risk analysis of live animal, animal product and veterinary biologicals, national microbial standard for meat, milk, egg and MRL of vet drugs, standard for the transfer and biocontainment of hazardous animal pathogens, and biosecurity manual for commercial poultry production.

We all hope the booklet will facilitate in disseminating and implementing standards to improve the quality and status of veterinary services in the country.

We need to work to bring new standards which will help to improve the quality of the veterinary services and also we need to change the existing standards as per the national and global scenario to make them compatible internationally. VSDAO will continue to work in the above said area.

I want to take this opportunity to thank all those who have contributed by developing and approving standards and encouraging us to bring out them in the present form. Special thanks are due to my colleagues, for their efforts in compiling and publishing this booklet in this form.



Dr. Salina Manandhar
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Veterinary Standards and Drugs
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Standard For Import Risk Analysis Of Live Animal, Animal Product And Veterinary Biologicals

Approved By Department of Livestock Service (DLS)-2069/4 /24 Nepal

Scope: Whereas it is expedient to safeguard the animal, public and environmental health by preventing entry, spread and establishment of animal pathogens through the import of live animal, animal product or veterinary biological. The Department of Livestock Services of the Government of Nepal, using the power conferred in the section 17 of the Animal Health and Livestock Services Regulation, 2000 enacted this generic standard of import risk analysis for importation of commodities.

1. Short Title and Commencement

- a. This standard may be called "Standard for Import Risk Analysis of Live Animal, Animal Product and Veterinary Biological, 2012"
- b. The standard shall come into force from the date of public notification by the Department of Livestock Services.
- c. The document shall be the generic sanitary standard for importation of specified live animal, animal product or veterinary biological.
- d. The standard may be reviewed, amended or revoked if there are changes in Nepal's import policy or for any other lawful reason, at the discretion of the Director General of the Department of Livestock Services (DG-DLS) of the Government of Nepal.

2. Definition

In this standard, unless the subject or context otherwise requires:

- a. **“Act”** means Animal Health and Livestock Services Act, 1998.
- b. **“Biologicals”** means bacterial or viral vaccines, medicines or biological chemicals used for the development of livestock and animal health.
- c. **“Competent authority”** (CA) means the Department of Livestock Services of the Government of Nepal.
- d. **“Disease”** means clinical or non-clinical infection with one or more of the etiological agents of the disease referred to in the Animal Health and Livestock Services Act, 1998.
- e. **“Hazard”** associated with the imported live animal, animal products and biologicals may be viral, bacterial, rickettsial, prion, fungal, protozoan, metazoan parasites and their toxins.
- f. **“Pathogen”** means an organism that causes or contributes to the development of a disease in animal or human.
- g. **“Regulation”** means Animal Health and Livestock Services Regulation, 2000.
- h. **“Risk”** indicates the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health and to environment by the disease.
- i. **“Risk Analysis Core Group”** means a team of specialists composed under the clause 5 of this standard.

3. Import Permit

- a. It is the responsibility of importer to ensure that they shall comply with the current version of the relevant import standard at the time of importation into Nepal.
- b. The importer seeking import permit for import of live animal, animal product or veterinary biological shall apply to the VSDAO in a prescribed form accompanying with necessary documents and sample as specified.
- c. The importer shall furnish the details of specified requirement to the competent authority before 30 days but not later than the date of import.
- d. The VSDAO shall verify the requirement and submit the valid application to the risk analysis core group for further processing.
- e. Documentation shall be written in English /Nepali language.

4. Eligibility

- a. The imported live animal, animal product or veterinary biological shall be free from animal quarantine pathogen (Annex IV).
- b. The international veterinary or sanitary certificate shall ensure that the commodity (live animal, animal product or veterinary biological) subjected to import shall be produced from a WHO or ISO-GMP certified manufacturer.
- c. The product shall be in its original sealed packaging on arrival
- d. All consignments of imported commodity shall carry a declaration document from the concerned exporter on the dispatch documents that the consignment does not contain the prohibited item in any form.

5. Determining the need for and type of risk analysis

- a. After receiving an import proposal, VSDAO shall consider whether a new risk analysis is required and, if so, whether there is sufficient information to proceed.
- b. If the required information is not available, the IRA Core Group shall initiate IRA.

6. The Risk Analysis (RA) Core Group

- a. The DG-DLS shall constitute a RA Core Group of specialists and concerning other experts as follows:
 - i. Program Director, Directorate of Animal Health: Chairperson
 - ii. Chief, Central Animal Quarantine Office: Member
 - iii. Chief, Veterinary Public Health Office: Member
 - iv. Chief, VEC: Member
 - v. Chief, CBPL: Member
 - vi. Chief, CVL: Member
 - vii. Subject Matter Specialist : Invitee Member
 - viii. Chief, VSDAO: Member Secretary
- b. The VSDAO shall act as the secretariat of the RA Core Group, and shall manage for necessary logistics required for the committee.
- c. The RA Core Group committee meeting will be organized as required.
- d. Chairperson shall exercise the power to invite subject matter specialist (SMS) as and when required
- e. The RA Core Group shall follow the standard procedure of risk analysis of each animal quarantine pathogen (Annex I) in a prescribed form as described in Annexs.

7. Determination of Animal Quarantine Pathogen

- a. The risk associated with a pathogen shall be analysed based on following criteria:
 - i. Absent in country (on the basis of laboratory diagnosis),
 - ii. If present, control program enforced,
 - iii. Pathogen related to public health,
 - iv. Pathogen related to environmental hazard and,
 - v. Economic loss.
- b. The list of animal quarantine pathogens for Nepal are given in Annex I.

8. Determination of Risk Analysis Process

- a. The IRA Core Group shall determine for necessary risk analysis when relevant risk management measures has not been established or do exist, but the likelihood and or consequences of entry, establishment or spread of disease could differ significantly from those previously assessed.
- b. The risk analysis process shall be:
 - i. continued if the pathogen meets the definition of a quarantine pathogen,
 - ii. continued if there is insufficient information and the uncertainties are identified,
 - iii. discontinued or stopped if the pathogen does not meet the definition of a quarantine pathogen.

9. Method of Risk Analysis

Nepal shall adopt a system of qualitative import risk analysis method including hazard identification, release assessment, exposure assessment, consequence assessment and risk estimation for import of live animal, animal product and veterinary biologicals.

a. Release Assessment

- i. As a part of risk analysis, the concerned Animal Quarantine Check-post shall initiate and assist to carryout cross border preliminary qualitative risk assessment process and especially the risk release assessment for import of live animals, animal products and veterinary biologicals in the prescribed model (Annex II).
- ii. An assessment for possible entry, establishment and spread of animal quarantine pathogen in a cross border area shall be carried out by the concerned Animal Quarantine Check post in a prescribed model using the standard risk indicators as described in a generic model (Annex III).
- iii. The concerned Animal Quarantine Check-post shall inform the finding of the preliminary qualitative risk assessment and submit the report to the RA Core Group.
- iv. The risk release assessment shall be done on the basis of the probability of the 'release' of each of the potential hazards (the pathogenic agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events, measures and factors. These factors shall include:
 - (1) Biological factors (species, age and breed of animals, agent predilection sites, vaccination, testing, treatment and quarantine),
 - (2) Country factors (incidence/prevalence, evaluation of Veterinary Services, surveillance and control programs and zoning systems of the exporting country)and

- (3) Commodity factors (quantity of commodity to be imported, ease of contamination, effect of processing and effect of storage and transport).
- v. The concerned Animal Quarantine Check-post shall collect information and score the value based on qualitative import risk analysis.
- vi. The spread of infectious diseases in cross border area posing the threat to the imported live animals, animal products and veterinary biologicals shall be assessed by analyzing the risk indicators.
- vii. The likelihood of risk release shall be assessed using the likelihood score board for release assessment as described in Annex IV.

b. Exposure Assessment

- i. The exposure assessment shall be done on the basis of the probability of exposure to the identified hazards for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure (e.g. ingestion, inhalation, or insect bite), and the number, species and other characteristics of the animal and human populations exposed.
- ii. The other characteristics or factors to be considered include:
 - 1. biological factors (properties of the agent);
 - 2. country factors (presence of potential vectors, human and animal demographics, customs and cultural practices, geographical and environmental characteristics); and
 - 3. commodity factors (quantity of commodity to be imported, intended use of the imported animals or products, disposal practices).
- iii. While performing the exposure assessment, the possible pathways or exposing points shall be identified and evaluated.
- iv. The likelihood of risk exposure shall be assessed using the likelihood score board for exposure assessment as described in Annex V.

c. Consequence Assessment

- i. The consequence assessment shall be done on the basis of the relationship between specified exposures to a biological agent and the consequences of those exposures which may produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences.
- ii. The consequences shall include:
 - 1. direct consequences (animal infection, disease, and production losses, public health consequences); and
 - 2. indirect consequences (surveillance and control costs, compensation costs, potential trade losses, adverse consequences to the environment).
- iii. The direct and indirect consequences of risk shall be assessed adopting the process outlined in likelihood score board for consequence assessment as outlined in Annex VI.
- iv. The summary result of the assessment of risk release, exposure and consequences shall be evaluated using the summary score board for release, exposure and consequence assessment as described in Annex VII.
- v. The magnitude or severity of consequence of the risk shall be determined as described in Annex VIII.

d. Risk Estimation

- i. Nepal shall follow the approach of Office of Gene Technology Regulator's Approach (OGTRA) as described in Annex IX for risk estimation.
- ii. Risk estimation shall be done on the basis of integration of the results from the release assessment, exposure assessment and consequence assessment to produce overall measures of risks associated with the identified hazards.
- iii. The estimated risk shall be categorized adopting the model outlined in Annex X.
- iv. Nepal shall follow the internationally recognized checklist for qualitative risk estimation and categorization of risk associated with the import of live animal, animal product and veterinary biological by multiplying the values of release, exposure and consequence assessment. The possible risk estimation outcomes shall also be based on the internationally recognized tools of the integration of release, exposure, and consequence assessment rankings. The estimated risk outcomes shall be further scored and categorized as demonstrated in Annex XI

10. Role of Competent Authority for Risk Management

- a. The competent authority (DLS), shall:
 - i. Develop the necessary risk management measures to achieve the ALOP for Nepal.
 - ii. Decide to issue or restrict the import permit for the importation of live animals, animal products and veterinary biologicals in question based on the recommendation of the Risk Analysis Core Group.
 - iii. Assess implementation status of risk management measures
 - iv. Regulates the risk management measures.
 - v. Monitor and manage the evaluation and reevaluation of the action taken.
 - vi. Validate and verify the risk management and control measures designed.
 - vii. Maintain a strong link with the risk assessors and related stakeholders.

11. Risk Management

- a. Nepal shall adopt the science based risk management measures to reduce the risk associated with the import of live animals, animal products and veterinary biologicals in question.
- b. Nepal may develop the separate Acceptable Level of Protection (ALOP) measures for different countries depending upon the geographical, socioeconomic, cultural and epidemiological situation of the exporting country.
- c. Nepal shall adopt the risk management measures by implementing:
 - i. Standard method for pathogen transfer
 - ii. Standard animal quarantine measures
 - iii. Measures developed in the domestic legislation in compliance with the international (OIE/WHO/CAC) standards and guidelines,
 - iv. Scientific measures based on zonation/compartmentalization.

12. Risk Communication

- a. The competent authority shall exchange all the information and communicate all the decisions made to the concerned stakeholders including risk assessors, managers, consumers, industries, institutions etc through appropriate channel.
- b. The response and information received from the stakeholders shall be taken into consideration by the competent authority and processed for taking optional decision as and when necessary.

13. Termination of an IRA

- a. Work on an IRA may be terminated at any time if:
 - i. A proponent notifies IRA Core Group in writing that the concerning party no longer wishes to precede with an import proposal.
 - ii. IRA Core Group believes that insufficient information is available to complete the IRA satisfactorily.
- b. If an IRA is terminated IRA Core Group shall notify to the concerning party.

14. Risk Analysis and Report Preparation

- a. The draft IRA report shall :
 - i. Confirm the disease and pest being assessed,
 - ii. Describe the main pathway by which VEC considers the disease could enter, establish or spread in Nepal,
 - iii. Determine the likelihood pathway of entry, establishment or spread and the possible harm (consequences) for each risk factor,
 - iv. Specify whether the resulting risks exceed Nepal's ALOP,
 - v. Identifies, in cases where the risk exceeds the Nepal's ALOP, potential risk management measures and determine whether application of the measures could reduce the risk to achieve Nepal's ALOP,
 - vi. Include a preliminary review of the preferred options for risk management,
 - vii. Relevant regions and districts are consulted about disease status and risk.

15. Determination by the Director General of DLS

- a. The making of a determination is an administrative process undertaken by DG-DLS. The determination provides a policy framework for decisions on whether or not to grant an import permit any conditions that may be attached to a permit.
- b. In making the determination, the DG-DLS shall consider:
 - i. The final IRA report and recommendations of IRA Core Group,
 - ii. The outcome of any appeal.

Annex I. List of Proposed Animal Quarantine Pathogen for Nepal

Multiple Species Diseases	Diseases of Bovidae	Diseases of Equidae
New and Old World Screwworm (<i>Cochliomyia hominivorax</i> and <i>Chrysomya bezziana</i>)	Bovine brucellosis	African horse sickness
Rift Valley fever	Bovine genital campylobacteriosis	Contagious equine metritis
Rinderpest	Bovine spongiform encephalopathy	Dourine
Tularemia	Bovine viral diarrhoea	Epizootic lymphangitis
West Nile fever	Contagious bovine pleuropneumonia	Equine encephalomyelitis (Eastern and Western)
Diseases of Aves	Dermatophilosis	Equine infectious anaemia
Avian chlamydiosis	Enzootic bovine leukosis	Equine influenza
Highly pathogenic avian influenza		Equine piroplasmosis
Duck virus enteritis	Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis	Equine rhinopneumonitis
Duck virus hepatitis	Lumpy skin disease	Equine viral arteritis
Turkey rhinotracheitis (avian metapneumovirus)	Malignant catarrhal fever	Glanders
Diseases of Suidae	Trichomonosis	Horse mange
African swine fever	Trypanosomosis (Tsetse-transmitted)	Horse pox
Atrophic rhinitis of swine	Ovidae and Capridae	Venezuelan equine encephalomyelitis
Nipah virus encephalitis	Border disease	Other Diseases
Porcine brucellosis (NB: Version adopted in May 2009)	Caprine and ovine brucellosis (excluding <i>Brucella ovis</i>)	Bunyaviral diseases of animals (excluding Rift Valley fever)
Porcine cysticercosis	Caprine arthritis/encephalitis and Maedi-visna	Camel pox.

Multiple Species Diseases	Diseases of Bovidae	Diseases of Equidae
Porcine reproductive and respiratory syndrome	Contagious agalactia	<i>Campylobacter jejuni</i> and <i>Campylobacter coli</i>
Swine influenza	Contagious caprine pleuropneumonia	Cryptosporidiosis
Swine vesicular disease	Enzootic abortion of ewes (ovine chlamydiosis)	Hendra and Nipah virus diseases
Teschovirus (Teschen/Talfan disease)	Nairobi sheep disease	<i>Listeria monocytogenes</i>
Transmissible gastroenteritis	Ovine epididymitis (<i>Brucella ovis</i>)	Toxoplasmosis
Nipah virus	Ovine pulmonary adenocarcinoma (adenomatosis)	Verocytotoxigenic <i>Escherichia coli</i>
Hanta virus	Scrapie	Diseases of Apidae
Hendra virus	Lagomorpha	Acarapisosis of honey bees
	Myxomatosis	American foulbrood of honey bees
	Rabbit haemorrhagic disease	European foulbrood of honey bees
List of Eradicated or Controlled Diseases of Nepal		Nosemosis of honey bees
Disease	Status	Small hive beetle infestation (<i>Aethina tumida</i>)
Rinderpest	Eradicated	Tropilaelaps infestation of honey bees (<i>Tropilaelaps</i> spp.)
PPR	Controlled	Varroosis of honey bees
HPAI	Controlled	
Foot Rot	Eradicated	

Annex II. Questionnaire Format for Risk Release Assessment at the Animal Quarantine Check Post.

Name of Pathogen:		
Risk Assessment		
Likelihood of entry	Rating	Summary Note
What level of risk does the number of intended consignments represent?		
What is the likelihood of the pest being associated with the pathway at origin?		
What is the likelihood of the pest surviving during transport?		
What is the likelihood of the pest surviving or evading existing risk management practices?		
Consider any previous interceptions. What level of risk do they represent?		
Consider pathway destinations. What level of risk do they represent?		
What level of risk does the intended use of the commodity represent?		
Summary		
Likelihood of establishment	Rating	Summary Note
What is the likelihood of suitable hosts being available?		
If transmitted by vectors, what is the likelihood of suitable vectors being available?		
How suitable is the environment?		
What is the likelihood that existing control measures for other pathogen are unable to provide adequate control?		
What level of risk does the biology of the pathogen represent?		
Summary		
Likelihood of spread	Rating	Summary Note
How suitable is the natural and/or managed environment for the pathogen?		
If vectored, how likely are vectors to spread the pathogen in the PRA area?		
How likely is the pathogen to be transported with commodities or conveyances in the PRA area?		

What is the likelihood of the pathogen spreading to an area of higher economic importance than the area of introduction?		
What level of risk does the intended use of the commodity represent?		
What is the likelihood of natural enemies being unable to control spread of the pathogen?		
Summary		
Likelihood of economic or environmental damage	Rating	Summary Note
What level of economic loss is associated with this pathogen in its existing geographical range?		
What is the level of potential economic loss to agriculture in the PRA area?		
What is the level of potential loss associated with non-agricultural factors?		
Summary		
Risk Management		
Options for consignments	Rating	Summary Note
Inspection or testing		
Prohibition of (parts of) the host		
Pre- or post-entry quarantine		
Conditions for preparing and packing		
Restrictions on end use, distribution and periods of entry		
In-transit treatment		
Other (specify in note):		
Options to prevent or reduce infestation in the crop	Rating	Summary Note
Treatment of crop, field or place of production		
Specially protected growing conditions		
Specified harvesting time		
Certification scheme		
Other (specify in note):		
Options to ensure that the production area is free from the pathogen	Rating	Summary Note
Sourcing from designated pathogen-free areas		
Other (specify in note):		
Prohibition of commodities:		
Sanitary certificate requirement:		

Annex III: Risk Indicators to Determine the Spread of Infectious X-disease in Cross Border Area

Risk Indicator	0 = no risk	1 = low risk	2 = medium risk	3 = high risk
1. Current status of infectious X disease in the area				
2. History of the presence of X disease in the area				
3. Surveillance activities in the area and effectiveness of the implementation of the control measures where applicable				
4. Presence of high-risk species, high-risk spots or high-risk husbandry practices				
5. Movements of live susceptible animal or animal products within the area, across the border/s and to other destinations				
6. Production clusters of susceptible species of animal or animal products				
7. Presence of movement corridors and current or past presence of X disease in the areas of origin of susceptible animal and animal products in the corridor				
8. Presence of local and/or regional live animal markets and/or animal product markets and their regulatory framework				
9. Presence of hubs for live animal hubs and animal products				
10. Presence of highly-populated human areas				
11. Regulatory framework, enforcement and controls at border points and markets				
12. Permanent or temporal driving forces for cross-border trade				

Note: X-disease means any suspected AQP

Annex IV: The likelihood score board for release assessment

Likelihood	Highly unlikely	Unlikely	Likely	Highly likely
Pathway 1				
Pathway 2				
Pathway 3				
Average release score				

Pathway: Possible entry points (land, sky, legal, informal, illegal ...)

Annex V: The likelihood score board for exposure assessment

Likelihood	Highly unlikely	Unlikely	Likely	Highly likely
Exposure area 1:				
Exposure area 2:				
Exposure area 3:				
Average release score				

Exposure area: Possible area where the pathogen may be exposed (farm, community, slaughterhouse, industry,)

Annex VI: The likelihood score board for consequence assessment

Likelihood	Highly unlikely	Unlikely	Likely	Highly likely
Direct: (a) (b) (c)				
Indirect: (a) (b) (c)				
Average				

Note:

Highly unlikely : may occur only in very rare circumstances
 Unlikely : could occur in some circumstances
 Likely : could occur in many circumstances
 Highly likely : expected to occur in most circumstances

Annex VII: Summary score board of release, exposure and consequences assessment

	Negligible	Low	Medium	High
Risk release assessment				
Exposure assessment				
Consequences assessment				
Average score				

Note:

Negligible – probability is extremely low or negligible
 Low – probability is low but clearly possible
 Medium – probability is likely
 High – probability is very likely or certain

Annex VIII: The likelihood score board for magnitude assessment of consequence

Magnitude / severity	Marginal	Minor	Intermediate	Major
Consequence				

The magnitude or severity of consequence of the risk is determined by assessing the qualitative indicators in the consequence score board. The findings of the severity of consequence are expressed as marginal, minor, intermediate and major and are explained as follows:

Marginal Minimal or no negative impact,
 Minimal or no injury except to a few individuals that may require first aid,
 Minimal or no degradation of the environment,
 Disruption to biological communities that is reversible and limited in time and space or number of individuals/populations affected,
 Disruption to biological communities that is widespread but reversible or of limited severity,
 Extensive biological and physical disruption of whole ecosystems, communities or an entire species that persists over time or is not readily reversible.

Annex IX: Qualitative risk estimation matrix board

Mathematically,

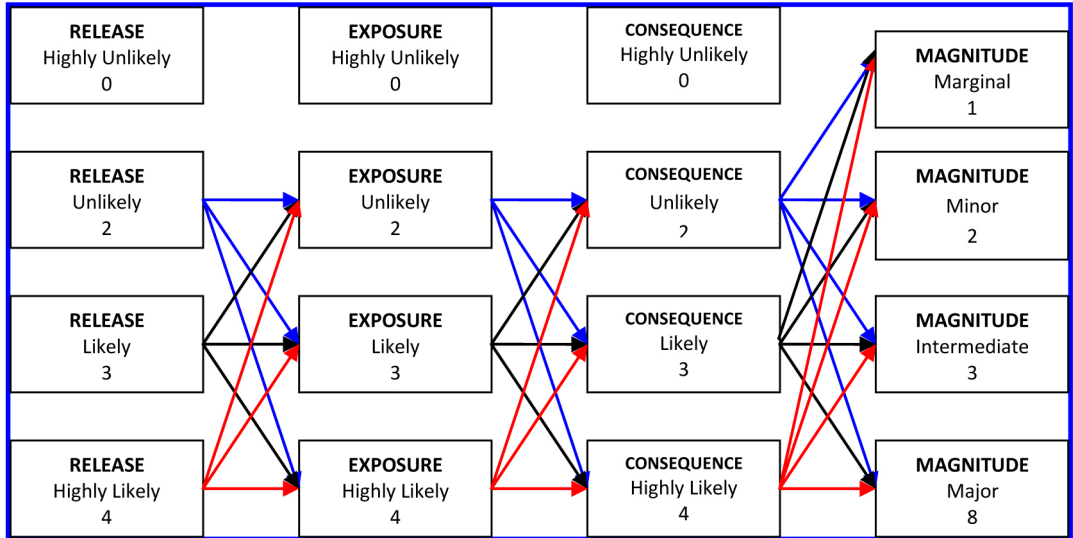
$$\text{Risk estimation} = \text{Release assessment} \times \text{Exposure assessment} \times \text{Consequence assessment}$$

RISK ESTIMATE MATRIX					
Likelihood	Highly likely	Low	Moderate	High	High
	Likely				
	Unlikely				
	Highly unlikely				
		Marginal	Minor	Intermediate	Major
	CONSEQUENCE				

Source: Office of Gene Technology Regulator's Approach for the estimation of risk

Annex X: Categorization of estimated qualitative risk

Possible risk estimation outcomes based on the integration of the release, exposure, and consequence assessment rankings



Category of Risk Estimate

Negligible	0-16	Low	24-36
Moderate	54-81	High	108-512

Source: Gene Technology Regulator's Approach for the estimation of risk

Annex XI: Internationally recognized qualitative risk estimation outcome checklist based on the integration of the release, exposure, and consequence assessment rankings

The qualitative risk estimation outcomes based on the integration of the release, exposure, and consequence assessment rankings can be expressed as low, medium and high as expressed in the table below:

Release	Exposure	Consequence	Risk Estimation
low	low	important	low
low	medium	important	low
medium	low	important	low
low	low	highly important	low
low	high	important	medium
high	low	important	medium
medium	medium	important	medium
medium	high	important	medium
high	medium	important	medium
high	high	important	medium
low	medium	highly important	medium
low	high	highly important	medium
medium	medium	highly important	medium
medium	low	highly important	medium
medium	high	highly important	medium
high	low	highly important	medium
high	medium	highly important	medium
low	low	critically important	high
high	high	highly important	high
low	medium	critically important	high
medium	low	critically important	high
low	high	critically important	high
high	low	critically important	high
medium	medium	critically important	high
medium	high	critically important	high
high	medium	critically important	high
high	high	critically important	high

Source: Gene Technology Regulator’s Approach for the estimation of risk

National Microbial standard For Meat, Milk, Egg and MRL of Veterinary Drugs

Approved By Department of Livestock Service (DLS)-2069/4 /24 Nepal

It is an obligatory responsibility of any government to safeguard the public health controlling the microbial load in meat, milk and egg. In this context in pursuance of section 33 of Animal Health and Livestock Services Act, 1999, this standard is developed for the use of VPHO/DLS to monitor microbial load in meat, milk and egg. It should have regular revision to comply international standard as when necessary.

Chapter I National Microbial standard of Meat

Scope

The scope of this standard covers microbial load of some of the important bacteria in raw meat, meat preparations from the time of live animal production up to the point of retail sale. **Being a member of WTO, the national veterinary Services of Government of Nepal has the obligation in developing necessary standards that are required for WTO/SPS measures.** On the other hand, these standards will help in facilitating trade and play a major role in the protection of public from microbial hazards. These standards provide a space for the competent veterinary authority in the inspection of meat for the limit of microbial load. While meat hygiene consideration involves a wide range of activities starting from raw meat to processing and cooking until it is consumed by human beings. However, this standard **refers mainly to fresh meat** within the scope of Slaughter House and Meat Inspection Act, 1999 and Animal health and Livestock Services Act, 1998. In the context of unspecified standards, other recommendations developed elsewhere in the Codex system and OIE Terrestrial Animal Health Code specified for zoonoses control, will be followed. These standards are also in consistence with the research, guidelines available in the country and neighboring countries.

Proposed National Standards

Interpretation of the test results

- Satisfactory, if all the values observed are $\leq m$ (minimum),
- Acceptable, if a maximum values are between m and M (Maximum),
- Unacceptable, if one or more of the values observed are $> M$.

Definition

“**Aerobic plate Count**” means total number of bacteria comprising all microbial groups.

Carcass: means the body of an animal after slaughter and dressing.

“**Enterobacteriaceae**” means the specific bacterial groups, which are the part of the intestinal microflora. They are present in high numbers in the faeces of humans and animals. Most of the harmful food poisoning bacteria belong to this group. *E.g. E.coli, Salmonella spp.*

“**Meat**” can be defined as it is mentioned in Animal Slaughterhouse and Meat Inspection Act, 2055.

“**Fresh meat**” means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere.

“**Minced meat**” means meat that has been minced into fragments and contains less than 1% salt.

“**Post-mortem inspection**” means any procedure or test conducted by a competent person (as defined by Slaughterhouse and Meat Inspection Act, 2055) on all relevant parts of slaughtered/killed animals for the purpose of judgment of safety and suitability and disposition.

“**Primary production**” means all those steps in the food chain constituting animal production and transport to the abattoir, or hunting and transporting wild food animals to a slaughter place.

“**Process control**” means all conditions and measures applied during the production process that are necessary to achieve safety and suitability of meat.

“**Sanitary measure**” means a measure, such as those described in various chapters of the Terrestrial Code, destined to protect animal or human health or life within the territory of Nepal from risks arising from the entry, establishment and/or spread of a hazard.

“**Slaughter**” means any procedure which causes the death of an animal by bleeding.

“**Animal Slaughterhouse**” shall mean the house or premises for the purposes of slaughtering animals for meat.

Chapter II

National Microbial Standard of Milk

Scope

The scope of this standard covers microbial load of some of the important bacteria in raw milk and milk products from the time of milk collection up to the point of retail sale. Being a member of WTO, the National Veterinary Services of Government of Nepal has the obligation in developing necessary standards that are required for WTO/SPS measures. On the other hand, these standards will help in facilitating trade and play a major role in the protection of public from microbial hazards. These standards provide a space for the competent veterinary authority in the inspection of milk for the limit of microbial load. While hygienic milk production involves a wide range of activities starting from raw milk production to collection, transportation, processing until it is consumed by human beings. However, this standard refers mainly to raw milk within the scope of Animal health and Livestock Services Act, 1998. In the context of unspecified standards, other recommendations developed elsewhere in the Codex system and OIE Terrestrial Animal Health Code specified for zoonoses, control will be followed. These standards are also in consistence with the research, guidelines available in the country and neighboring countries.

Proposed National Standards

SN	Microorganism	Analytical reference	Raw milk
1	Aerobic plate count	ISO 4833	<5x10 ² cfu/g
2	Coliform		Absent/0.1g
3	E.coli	ISO 16649-1&2	Absent/1g
4	Salmonella	ISO 6579	Absent/25g
5	Shigella		Absent/25g

SN	Microorganism	Analytical reference	Raw milk
6	Staph. aureus	ISO 6888-1 or 2	<10 ² cfu/g
7	Yeast and mould		Absent/1g
8	Anaerobic spore count		<5 cfu/g
9	Listeria monocytogenes	ISO 11290	Absent/1g

Definition

Milk: means the normal mammary secretion of milking animals obtained from one or more milking without either addition to it or extraction from it.

Chapter III National Microbial Standard of Eggs

Scope

This standard applies to the primary production, sorting, grading, storing, transport, processing, and distribution of eggs in shell and egg products of such eggs produced by domesticated birds and intended for human consumption. The scope of this standard covers microbial load of some of the important bacteria in egg and egg products from the time of laying up to the point of retail sale. Being a member of WTO, the National Veterinary Services of Government of Nepal has the obligation in developing necessary standards that are required for WTO/SPS measures. On the other hand, these standards will help in facilitating trade and play a major role in the protection of public from microbial hazards. These standards provide a space for the competent veterinary authority in the inspection of milk for the limit of microbial load. While hygienic egg production involves a wide range of activities starting from primary production, sorting, grading, storing, transport, processing, and distribution of eggs until it is consumed by human beings. However, this standard refers mainly to table egg within the scope of Animal health and Livestock Services Act, 1998. In the context of unspecified standards, other recommendations developed elsewhere in the Codex system and OIE Terrestrial Animal Health Code specified for zoonoses, control will be followed. These standards are also in consistence with the research, guidelines available in the country and neighboring countries.

Proposed National Standards

Category	Microorganism	Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory result
		m	M			
Non Pasteurized egg	Enterobacteriaceae	≤10 cfu/g or ml	≤100 cfu/g or ml	ISO 21528-2	End of the primary production	Checks on the efficiency of good hygienic practices
	Salmonella	Absent 25g		ISO 6579	End of the primary production	Checks on the efficiency of good hygienic practices
	Aerobic Plate Count	≤10 ⁵ cfu/g	≤10 ⁶ cfu/g	ISO 4833	End of the primary production	Checks on the efficiency of good hygienic practices
	Coliform	≤10 ² cfu/g	≤10 ³ cfu/g		End of the primary production	Checks on the efficiency of good hygienic practices

Interpretation of the Test Results

- Satisfactory, if all the values observed are $\leq m$ (minimum),
- Acceptable, if a maximum values are between m and M (Maximum),
- Unacceptable, if one or more of the values observed are $> M$.

Definition

Egg: means the fresh edible portion of the spheroid body produced by female birds, especially domestic fowl. Portion of the commodity to which the MRL applies: The edible portion of the egg including the yolk and egg white after removal of the shell.

Chapter IV

Maximum Residue Limit of Veterinary Drugs in Meat, Milk And Eggs

Scope

The scope of this standard covers Maximum Residue limit (MRL) of some of the important Veterinary drugs or antimicrobial agents in meat, milk and eggs. Being a member of WTO, the national veterinary Services of Government of Nepal has obligation in developing necessary standards that are required for WTO/SPS measures. One the other hand, these standards will help in facilitating trade and play a major role in the protection of public from antimicrobial resistance. These standards provide a space for the competent veterinary authority in the inspection of meat, milk and eggs for MRL that is allowable. This standard refers to only those animal products that are under the scope of veterinary services given by the Animal health and Livestock Services Act, 2055. In the context of unspecified standards, texts and other recommendations developed elsewhere in the Codex system will be followed. This standard is developed based on the available research, guidelines available in the country and neighboring countries. The Veterinary Public Health Office in coordination with Veterinary Standards and Drug Administration Office (VSDAO) will be responsible institution to check, verify and recommend the action to be taken in case of any deviation from the standard. This standard will be revised periodically as when necessary in compliance with the international standards.

Maximum Residue Limit of Veterinary Drugs in Meat, Milk and Eggs

Drugs	category	MRLs @ $\mu\text{g}/\text{Kg/L}$
Albendazole	milk	100
	Muscle	100
	Liver	5000
	Kidney	5000
	Fat	100
Benzyle Penicillin/Procaine Penicillin	milk	4
	Muscle	50
	Liver	50
	Kidney	50

Drugs	category	MRLs @ µg/ Kg/L
Ceftiofur	milk	100
	Muscle	1000
	Liver	2000
	Kidney	6000
	Fat	2000
Colistin	milk	50
	Muscle	150
	Liver	150
	Kidney	200
	Fat	150
Chloramphenicol	M,L,K,F	100
	milk	50
	Eggs	50
	M,L,K,F	100
Cypermethrin	milk	100
	Muscle	50
	Liver	50
	Kidney	50
	Fat	1000
Deltamethrin	milk	30
	Muscle	30
	Liver	50
	Kidney	50
	Fat	500
	Eggs	30
Dexamethasone	milk	0.3
	Muscle	1.0
	Liver	2.0
	Kidney	1.0
Erythromycin	M,L,K,F	100
	milk	50
	Eggs	50

Drugs	category	MRLs @ µg/ Kg/L
Fenbendazole/ Oxfendazole	Milk	100
	Muscle	100
	Liver	500
	Kidney	100
	Fat	100
Gentamycin	milk	200
	Muscle	100
	Liver	2000
	Kidney	5000
	Fat	100
Ivermectin	milk	10
	Liver	15
	Fat	20
Levamisole	milk	10
	Muscle	10
	Liver	100
	Kidney	10
	Fat	10
Spectinomycin	milk	200
	Muscle	500
	Liver	2000
	Kidney	5000
	Fat	2000
	Eggs	2000
Spiramycin	milk	200
	Muscle	200
	Liver	600
	Kidney	800
	Kidney	300
	Fat	300
Sulfadimidine	M,L,K,F	100
	milk	25

Drugs	category	MRLs @ µg/ Kg/L
Tetracycline (Oxy, Chlor)	milk	100
	Muscle	200
	Liver	600
	Kidney	1200
	Eggs	400
Thiabendazole	M,L,K,F	100
	milk	100
Triclabendazole	milk	200
	Muscle	200
	Liver	300
	Kidney	200
	Fat	100
Tylosin	M,L,K,F	100
	milk	100
	Eggs	300
Streptomycin	milk	200
Neomycin	milk	1500
Ampicillin	milk	10

M=Muscle; L=Liver; K=Kidney; F=Fat

Definitions

“**Antimicrobial agent**” means a naturally occurring, semi-synthetic or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

“**Antimicrobial Resistance (AMR)**” means the ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial relative to the susceptible counterpart of the same species

“**Egg**” means the fresh edible portion of the spheroid body produced by female birds, especially domestic fowl. Portion of the commodity to which the MRL applies the edible portion of the egg including the yolk and egg white after removal of the shell.

“**Fat**” means the lipid-based tissue that is trimmable from an animal carcass or cuts from an animal carcass. It may include subcutaneous, omental or perirenal fat. It does not include interstitial or intramuscular carcass fat or milk fat. Portion of the commodity to which the MRL applies the whole commodity. For fat-soluble compounds the fat is analyzed and MRLs apply to the fat. For those compounds where the trimmable fat is insufficient to provide a suitable test sample, the whole commodity (muscle and fat but without bone) is analyzed and the MRL applies to the whole commodity (e.g., rabbit meat).

“Maximum Residue Limit for Veterinary Drugs”(MRLVD) means the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or ug/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food. It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects. When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

“Milk” means the normal mammary secretion of milking animals obtained from one or more milking without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.

“Muscle” means the skeletal tissue of an animal carcass or cuts of these tissues from an animal carcass that contains interstitial and intramuscular fat. The muscular tissue may also include bone, connective tissue, tendons as well as nerves and lymph nodes in natural portions. It does not include edible offal or trimmable fat

“Veterinary Drug” means any substance applied or administered to any food-producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic, or diagnostic purposes, or for modification of physiological functions or behavior.

Standards For The Transfer And Biocontainment of Hazardous Animal Pathogens, 2012

Approved By Department of Livestock Service (D/S)-2069/4 /24 Nepal

Scope

Whereas it is obligatory to safeguard the animal, public and environmental health by preventing entry and establishment of hazardous animal pathogens through accidental release during domestic or international transfer or through inappropriate containment during handling, storage and disposal, Department of Livestock Services (DLS) of government of Nepal using the power conferred in the section clause 17 of Animal Health and Livestock Services Regulation 2000 enacted this transfer of infectious animal pathogens standard protocol on 2012.

The proposed standards shall provide the requirements on transfer and bio-containment of hazardous animal pathogens in the pure form or in the biological samples while shipping from the field to the diagnostic laboratory or from one laboratory to other referral laboratories and disposal at the laboratories. Both the public and private veterinary laboratories shall be the users of this standard in Nepal.

1. Name and Commencement:

- i) The name of this standard is "Transfer and bio containment of hazardous animal pathogens, 2012".
- ii) This standard shall come into force from the date of public notification by the DLS.

2. Application:

This standard applies to all persons who collect, handle, ship, transport, receive, store and dispose hazardous (infectious) animal pathogens and bio-medical waste in any form.

3. Definitions

For the purposes of these regulations:

- 3.1. **“Hazardous Materials or Dangerous Goods”** are defined as any substances or materials that could adversely affect the safety of the public, handlers or carriers during transportation. There are nine classes of hazardous materials as listed in the Annex 1, Table 1.
- 3.2. **“Pathogens”** are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.
- 3.3. **“Infectious Substances”** are substances which are known or are reasonably expected to contain pathogens. Infectious substances shall be divided into two categories.
 - 3.3.1 **“Category A Infectious Substances”** An infectious substance which is transported in a form that, when exposure to the environment, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Indicative examples of substances that meet these criteria are given in the table in Annex 2. Category A poses a higher degree of risk than Category B.
 - 3.3.2 **“Category B Biological Substances”** An infectious substance not in a form generally capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs or an infectious substance which does not meet the criteria for inclusion in Category A (formerly referred to as

diagnostic specimens). Category B infectious substances have included any human or animal material including but not limited to excreta, blood and its components, tissue and tissue fluids transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.

- 3.4. **“Biological Products”** are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related there to. They include, but are not limited to, finished or unfinished products such as vaccines and diagnostic products. Examples of biological products include certain viruses, therapeutic serums, antitoxins, vaccines, blood, and blood products.
 - 3.5. **“Cultures”** are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined below in 3.6. Cultures may be classified as Category A or Category B, depending on the microorganism involved.
 - 3.6. **“Patient Specimens”** are human or animal materials collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.
 - 3.7. **“Genetically Modified Microorganisms and Organisms” (GMMO)** are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. Those genetically modified microorganisms and organisms that do not meet the definition of an infectious substance but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction.
 - 3.8. **“Biomedical or Clinical Waste”** means any waste, which is generated during the diagnosis, treatment or immunization of animals or human beings or in research activities pertaining thereto or in the production or testing of biologicals.
 - 3.9. **“Overpack”** is the term used when several packages are combined to form one unit and sent to the same destination by a single shipper.
 - 3.10. **“Biomedical Waste Treatment Facility”** means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment or disposal is carried out.
 - 3.11. **“Competent Authority”** means the Veterinary Authority or other Governmental Authority of Nepal having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international health certification and other standards and recommendations in the act in the whole territory.
 - 3.12. **“Laboratory Officer”** means any laboratory technologist or technical officer working in the veterinary laboratory assigned with the job of handling and containing animal pathogens.
4. **Policy and Legislation for the Shipment of Animal Pathogens**
- a) GON shall formulate a mandatory policy for recruiting or designating a biosafety officer in all veterinary laboratories within the country.
 - b) GON shall develop a policy for the compulsory capacity development training of technical staffs dedicated to shipping, handling and containing infectious pathogens of Category A in every two years.

- c) Nepal shall adopt the standard international protocol for the transfer of infectious animal pathogens and biological materials based on United Nations Model Regulation in compliance with the International Air Transport Association (IATA) Agreement (Annex 2).
- d) Nepal shall implement and regulate her policy for shipment of animal pathogens standard under the Animal Health and Livestock Services Act,1998.
- e) No hazardous animal pathogens or veterinary vaccines/biological shall be shipped without following international standard irrespective of having import/shipping permit. However, veterinary vaccines/biological that are not risking health hazard for humans, animals or environment shall be allowed to import within the country.
- f) There shall be legal authority to destroyed consignment breaching Nepalese standards.
- g) Government of Nepal (GON) shall constitute a core group of specialists to carry out the import risk analysis to hazardous animal pathogens/ veterinary vaccines/ biologicals within the country. The permit import of animal pathogens, biologicals/ vaccines and Genetically Modified Micro organisms and Organisms (GMMO) shall be granted on the basis of import risk analysis .

5. Roles and Responsibilities of Shipper, Carrier and Receiver

5.1 The Shipper (Sender, Consignor)

- a) When preparing shipments of animal pathogens the shipper shall:
 - i. Identify the hazard,
 - ii. Classify the hazard,
 - iii. Properly pack the hazard,
 - iv. Properly mark and label the shipping containers.
- b) Shipper shall make advance arrangements with the receiver, including investigating the need for import/export permits and inquire about legal boundaries prevailing in that country.
- c) Shipper shall make advance arrangements with the carrier to ensure:
 - i. That the shipment will be accepted for appropriate transport,
 - ii. That the shipment (direct transport if possible) is undertaken by the most direct route.
- d) Shipper shall prepare necessary documents, including permits, dispatch and shipping documents.
- e) Shipper shall notify the receiver (consignee) of transportation arrangements once these have been made, well in advance of the expected arrival time.

5.2 The Receiver (Consignee) of the Sample (S)

- a) Shall obtain the necessary authorization(s) from national authorities for the importation of the material,
- b) Shall provide the sender with the required import permit(s), letter(s) of authorization, or other document(s) required by the national authorities,
- c) Shall arrange for the most timely and efficient collection ,on arrival,
- d) Shall acknowledge receipt to the sender as soon as possible.

5.3 Shipments of the Sample (S) Shall not be Dispatched until:

- a) Advance arrangements have been made between the sender, carrier and receiver.
- b) The shipper has confirmed with the national authorities that the material may be legally exported in case of international shipments.

- c) The receiver has confirmed with the national authorities that the material may be legally imported.
- d) The receiver has confirmed that there will be no delay incurred in the delivery of the package to its destination.

5.4 Requirements for Packaging

- a) Category A Infectious substances shall comply with Packing Instruction given in Annex 3, with all marking and labels as depicted in Figures 1, 1a-1f and 2.
- b) Packaging used to ship Category A Infectious substances shall be used as tested and certified (Annex 6, Tables 5 and 6).
- c) Category B Infectious substances shall comply with Packing Instruction 650 and Figure 3 as given in Annex 4.
- d) Exempt patient specimens (exempt animal specimens) packaging (Annex 5, Figure 4) shall consist of:
 - i. a leak-proof primary receptacle(s), with absorbent materials for liquid specimens,
 - ii. a leak-proof secondary packaging,
 - iii. an outer packaging with at least one surface 100 mm x 100 mm.
- e) Biological samples suspected to contain infectious pathogens of unknown etiology, shall be shipped as Category A Infectious Substances with all precautions as in Annex 3, Figures 1, 1a -1f and 2.
- f) Biological samples known to contain non-infectious substances or non dangerous goods such as anticoagulated blood for hematology and blood chemistry shall be shipped by road or air with several ice packs within the cool box or Styrofoam box with tightly tapped lid as shown in Annex 5.
- g) Packing materials meeting the test standards shall be marked by their manufacturers with an international specification mark (Annex,3 Figure 1a) for international shipping.
- h) An overpack may be used to consolidate several smaller packages.
 - i. All overpack shall display the following:
 - 1. Orientation arrow on two opposing sides,
 - 2. The word "Overpack" (may be a label),
 - 3. The proper shipping name, UN Number and Technical Name if shipping infectious substances,
 - 4. The total volume (gm or ml) of all the containers within the overpack,
 - 5. The Dry Ice/ice-pack Proper Shipping Name and quantity, if applicable,
 - 6. The name and phone/fax number of the person responsible for the shipment of infectious pathogens,
 - 7. Complete information on the shipper and consignee.
 - ii. Each individual inner package may contain, but shall not exceed, the maximum quantity allowed under the List of Dangerous Goods.

5.5 Marking & Labelling

- a) Labeling and marking shall include the content of the shipment and the nature of the hazard (Annexs 2 and 3).
- b) Category A Infectious Substance shipments shall include the following markings:
 - i. UN Number 2900 diamond-on-point marking at least 50mm x 50mm and no larger than 100mm x 100mm for Infectious Substances affecting animals only,

- ii. UN Number 2814 diamond-on-point marking at least 50mm x 50mm and no larger than 100mm x 100mm for Infectious Substances affecting humans only or affecting both humans and animals,
- iii. Technical name in parentheses; i.e. a recognized name used in scientific and technical handbooks, texts or journals (Example: *Coxiella burnetii*).
- c) Biological Substance, Category B Infectious Substance shipments shall include the following markings:
 - i. Proper shipping name (PI 650, Biological substance, Category B),
 - ii. UN Number 3373 diamond-on-point marking at least 50mm x 50mm and no larger than 100mm x 100mm,
 - iii. Volume (gm/ml),
 - iv. Name and address of shipper and consignee,
 - v. Name and phone/fax number of persons responsible for shipment.
- d) Exempt patient specimens shall be marked as “Exempt animal specimen”. Do not use the UN 3373 diamond-on-point marking.
- e) Shipments containing dry ice/ice pack shall be marked as Class 9 Miscellaneous Dangerous Goods (Annex3) and bear label:
 - i. The Nature and Quantity of Goods box on the Air Waybill shall show in sequence:
 - 1. The Proper Shipping Name “Dry Ice”,
 - 2. The Class or Division Number “9”,
 - 3. ID Number “UN 1845”,
 - 4. Packing Group “III”,
 - 5. Subsidiary risk: if None, leave blank,
 - 6. Number of packages,
 - 7. Net quantity per package.
 - ii. Ventilation shall be provided at all times. Dry ice shall never be shipped in a sealed container.
 - iii. If there are no other dangerous goods in the package, a Shipper’s Declaration for Dangerous Goods shall not be required when shipping UN 3373 samples with Dry Ice.

5.6 Documentation

- a) An itemized list of contents shall be included between the secondary container and outer packaging for both Category A and Category B shipments.
- b) When shipping Category A Infectious Substances, a Shipper’s Declaration of Dangerous Goods is required (Annex 3, Figure 2).
 - i. It shall be typed, accurate, legible and free of spelling errors. White-out shall not be permitted on Shipper’s Declaration!
 - ii. A 24-hour emergency response number shall be included and should be monitored at all times by a person who is knowledgeable about the shipment.
 - iii. Printed Shipper’s Declarations must have red side bars.
 - iv. Shippers should create five copies of this document:

- 1) Two signed copies shall be sent with the shipment,
 - 2) One signed copy shall be retained by the carrier,
 - 3) One signed copy shall be retained by the recipient,
 - 4) The fifth signed copy shall be retained by the sender.
- c) Shipments of Category B Infectious Substances or Patients specimens do not require a Shipper's Declaration.
 - d) Air Waybills shall also be completed by the shipper or operator. Sender may check with individual couriers for information on their specific requirements.

5.7 Quality Control Methods

- a) Only trained personnel shall prepare packages for shipping.
- b) Transport media shall be used according to the nature of organism and tissue collected
- c) Packing and shipping shall be monitored by biosafety officer.

6. Transport by Hand Carry

6.1 Within or Between Laboratories

- a) Hazardous materials containing infectious animal pathogens shall be transported in leak-proof containers with lids or covers to reduce potential incidents of spillage.
- b) Specimens shall be placed in leak proof and breakage-resistant receptacles. It should be closed with screw caps rather than snap caps whenever possible.
- c) Use unbreakable leak proof secondary containers for light loads that are to be carried, ensure that the secondary containers have solid handgrips. Small tubes can be sealed inside zipper-lock freezer bags, which are leak proof and will not break if dropped.
- d) All other containers such as autoclave or other bags which may contain hazardous materials shall be transported on a cart and contained in a plastic tray to capture any leakage. For heavier items, a cart with guard rails or raised edges shall be used. Load so that the contents will not dislodge if the cart should bump into a wall or door.

Note - All containers must be decontaminated on the outside, prior to leaving the laboratory, so that gloves are not required.

- e) The transport route of hazardous materials shall be restricted to service corridors/elevators or those areas less frequented by members of the general public. The shortest route is not necessarily for this purpose.
- f) Transport of hazardous materials that must go through publicly accessible areas may only occur when there shall be a minimum of public present (i.e. no transport during class change times or in a full elevator).
- g) The movement of hazardous materials shall be prohibited in the following areas:
 - i. Food and beverage consumption areas
 - ii. Recreational facilities
 - iii. Washrooms
 - iv. Meeting rooms
 - v. Carpeted areas
 - vi. Mailrooms
 - vii. Libraries
 - viii. Common areas accessible or used as a gathering location by the public
 - ix. Patient Waiting and Treatment areas
 - x. Stores (except where hazardous materials are purchased)
 - xi. Personal and Administrative Offices

6.2 Between Buildings

- a) The same principles as listed in 6.1.a) to 6.1.e) may apply if laboratory buildings are situated within the same premises, whereas to laboratory located in other premises, one shall use special vehicle for carrying laboratory utilities and which can be disinfected easily on the event of spillage or breakage.
- b) Ensure that the substance is in a closed and sealed primary receptacle such as a test tube, vial or flask.
- c) Place cushioning absorbent material around the primary container.
- d) Use a secondary leakproof container that can withstand dropping or crushing while in transit.
- e) If the material must be kept refrigerated or frozen during transport, place the coolant (e.g., dry ice, crushed ice) inside an insulated tertiary vessel. To prevent rupture of the package, ensure that dry ice is able to release carbon dioxide gas.

7. Surface (Land) Transport

7.1 Trekking Route

- a) Carrying infectious materials collected in the field outbreaks through trekking route from the remote regions to DLSO shall comply with biohazardous materials packaging and following shipping requirements accordingly.
- b) All known infectious and suspected materials containing infectious pathogens, collected in the fields shall be packed in the triple packages as described below so that there will be no leakage during transport:
 - i. Place the specimen inside an appropriately labeled leakproof primary (inner) container; close with screw caps or seal with stoppers and tape or other suitable material.
 - ii. Wrap the container in enough absorptive material (e.g. paper towels, tissue, cotton wool) to absorb all fluid in the event of a leak.
 - iii. Several samples or cultures can be sent together provided each is inside a primary container, packed to prevent contact with each other, and surrounded by sufficient absorbent in case of breakage.
 - iv. Place the wrapped container inside a secondary watertight receptacle, using enough absorbent material to cushion the primary container.
 - v. Place the secondary container inside a third (outer) package for protection from physical damage and water while in transit.
- c) If the shipment must be kept cold or frozen, notification to that effect should appear on the accompanying documents and on the outer package.
- d) Send all transportation documentation to the receiving lab provided that it is safely packaged and accompanied by a suitably trained person.
- e) Should there be any leakage, appropriate containment measures shall be taken.

7.2 Through Road/Rail Transport

- a) Infectious substances shall be packaged and transported as described in 7.1. a).
- b) Sender shall communicate with carrier and consignee to coordinate transport and receipt.
- c) Obtain and complete shipping documents, submission and declaration forms.
- d) Arrange dispatch by the most direct route whenever possible.

- e) Send all transportation documentation to the receiving lab provided that it is safely packaged and accompanied by a suitably trained person.
- f) The person packing the goods must have received appropriate training so that she/he is aware of the nature of the hazard and how to deal with any emergency. The vehicle must have a 2 kg fire extinguisher. The vehicle must be suitably supervised or securely parked when the load is on board. The goods shall not require approved UN packaging but the packaging must be of suitable quality and labelled UN 3373.
- g) Suitable information and contact details should be affixed to the package in event of an emergency.
- h) If there is any leakage, appropriate containment measures shall be taken by disinfecting with 5% bleach solution. If leakage occurs while shipping or in the lab, appropriate disinfectant (5% bleach solution) shall be applied concentrically beginning at the outer margin of the spill area, working towards the centre.

8. Domestic Air Transport of Animal Pathogens/Infectious Substances

From the service centre (field outbreak) to DLSO; DLSO to RVL and RVL to CVL:

- a) Known biological samples containing infectious pathogens of Category A shall be packaged and shipped as described in 5.5, Annex 3 and Figure 1.
- b) Known biological samples containing infectious pathogens of Category B shall be packaged and shipped as described in 5.6, in Annex 4 and Figure 3.
- c) Specimens with unknown infection potential shall be shipped in triple packages as “Suspected Category A substance” as described in Annex 3 and Figure 1 with all precautions.
- d) Exempt biological samples shall be shipped in a triple package as shown in Annex 5, Figure 4.
- e) Ice cubes and ice packs shall be replaced depending on their melting status in every 4-6 hours to maintain the cool temperature.
- f) Potentially hazardous biological materials shall be packaged to withstand leakage of contents, shocks, temperature, pressure changes and other conditions that can occur during ordinary handling in transportation.
- g) If leakage occurs while shipping or in the lab, appropriate disinfectant (5% bleach solution) shall be applied concentrically beginning at the outer margin of the spill area, working towards the centre.
- h) Permit
 - i) Permits/import licence issued by DLS shall be required for the importation of any animal pathogen, pathological material or organisms carrying the pathogen into Nepal.
 - ii) Laboratories that intend to import animal or zoonotic pathogens, import permits shall be required authorization from competent veterinary as per the rules of importing country.

9. International Shipment, Packaging, Labelling and Documentation Requirements for Infectious Substances in Category A and Category B

- a) Permit
 - i) Permits/import licence issued by DLS shall be required for the importation of any animal pathogen, pathological material or organisms carrying the pathogen into Nepal.
 - ii) Laboratories that intend to import animal or zoonotic pathogens, import permits shall be required authorization from competent veterinary as per the rules of importing country.
- b) Sample transfer agreement shall be made before shipment of Category A and Category B, suspected biological materials (Annex 7).
- c) Infectious substances of Category A and Category B, suspected biological materials containing infectious pathogens and exempt samples shall be packaged, labelled, documented and shipped as stated in 5.5 -5.7.
- d) In case of leakage while shipping or in the lab, appropriate disinfectant (5% bleach solution) shall be applied concentrically beginning at the outer margin of the spill area, working towards the centre.

10. Shipment of Biomedical or Clinical Wastes

- a) Biomedical or clinical wastes containing Category A infectious substances shall be assigned to UN 2814 or UN 2900 as appropriate.
- b) Biomedical or clinical wastes containing Category B infectious substances, or which are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN 3291.
- c) Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these regulations unless they meet the criteria for inclusion in another class.

11. Laboratory Containment of Animal Pathogens

a) Specimen Containers

Specimen containers shall be preferably of plastic and they shall be correctly labelled to facilitate identification. Specimen request or specification forms shall not be wrapped around the containers but placed in separate, preferably waterproof envelopes.

b) Receipt of Specimens

Laboratories that receive large numbers of specimens shall designate a particular person and sample receiving desk/room for this purpose.

c) Opening Packages

- i. Primary specimen containers shall be opened in a biological safety cabinet (BSC) level I or II.
- ii. A BSC shall be routinely inspected and tested by trained personnel, following strict protocols, to verify that it is working properly.
- iii. Special technical precautions shall be taken while opening of ampoules containing lyophilized infectious materials.

d) Movement of Hazardous Materials Within Buildings

- i. Transportation of biohazardous materials within laboratory shall be done in closed, leak proof containers. A trolley or cart shall be used whenever possible.

e) Storage of Pathogens

- i. A complete inventory of the pathogens in storage shall be kept up to date.
- ii. Ampoules containing infectious materials shall never be immersed in liquid nitrogen because cracked or imperfectly sealed ampoules may break or explode on removal
- iii. Infectious materials shall be stored separately in mechanical deep-freeze cabinets or on dry ice according to the nature of pathogens.
- iv. Laboratory workers shall wear protective gears (apron, gloves and eye glasses) for eye and hand protection when removing ampoules from cold storage.
- v. The outer surfaces of ampoules shall be disinfected when the ampoules are removed from storage.
- vi. Specified pathogens shall be stored in the laboratory and in suitable containers (depending on the mode of storage, frozen or freeze-dried) in a cabinet reserved for specified pathogens and shall keep under lock and key by an authorized person.

12. Responsibilities of Organization

- a) Only a designated and trained personnel working in the public and Private Veterinary Laboratories, Animal quarantine Offices, District Veterinary Services Office shall be responsible for the proper collection (Refer Table 3, Annex 2), handling, storage, shipping and containment of animal pathogens.

13. Cleaning and Disinfection of Laboratory

- a) Cleaning and disinfection of a veterinary laboratory shall be done according to the standard protocol.

14. Disposal of Biomedical Wastes

- a) Biomedical wastes shall be segregated into containers/bags at the point of generation.
- b) Biomedical wastes shall be transported only in such vehicle as may be authorized for the purpose by the competent authority as specified by the government.
- c) No untreated biomedical wastes shall be kept stored beyond a period of 48 hours.
- d) Animal tissues, organs, body parts, carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary laboratories, animal houses shall be incinerated or disposed in a biological pit.
- e) Wastes from laboratory cultures, stocks or specimens of micro-organisms liver or attenuated vaccines, animal cell culture used in research and infectious agents from research laboratories, wastes from production of biologicals, toxins, dishes and devices used for transfer of cultures shall be decontaminated by microwaving/incineration/autoclaving or by either treating with disinfectants or autoclaving before incinerating or disposing off in the biological pits or any other appropriate measures.
- f) Waste sharps (needles, syringes, scalpels, blades, glass, etc. that may cause puncture and cuts) shall be collected in a puncture resistant-bin placed in each laboratory room, marked with red color biohazard label and decontaminated by chemical treatment/autoclaving/micro-waving and mutilation/shredding.

- g) Solid waste (items contaminated with blood, and body fluids including cotton, dressings, soiled plaster casts, lines, beddings, other material contaminated with blood, disposable items other than waste sharps such as catheters, intravenous sets, etc.) shall be decontaminated by incineration/autoclaving/microwaving.
- h) Liquid waste (waste generated from laboratory and washing, cleaning, housekeeping and disinfecting activities) shall be decontaminated by at least 1% hypochlorite solution or any other equivalent chemical reagent before discharging into drains. Liquid infectious wastes shall be disposed in the sanitary sewer only when volumes are so large as to preclude the feasibility of autoclaving and when using the precautions listed:
 - i) a sink must be dedicated for this purpose and set aside from other uses through appropriate signs;
 - ii) personnel must wear gloves, goggles, face shield and splash protection;
 - iii) personnel shall be trained in the techniques to minimize the risk of exposure and contamination; in particular, the infectious waste shall be poured in a manner so as to minimize, as much as possible, the generation of aerosols;
 - iv) the sink and surrounding surfaces shall be decontaminated with a 1:100 solution of bleach in water and the drain shall be flushed with the same solution each time it is used;
 - v) plumbers servicing drain pipes used for infectious waste disposal shall be informed of the potential hazard of liquid infectious waste being retained in the lines and advised to wear suitable personal protective equipment.

Annex- 1

Table 1: List of dangerous goods

Proper Shipping Name	UN No.	Class or division	Labels	Packaging instruction	Max. quantity per package
Aviation regulated liquid	3334	9	Miscellaneous	906	100 Litres
Biological Substance Category B	3373	6.2		650	See 650
Biomedical waste	3291	6.2	Infectious substance	602	No limit
Carbon dioxide, solid Dry ice	1845	9	Miscellaneous	904	200 Kg
Clinical waste unspecified, not otherwise specified (n.o.s.)	3291	6.2	Infectious substance	622	No limit
Ethanol	1170	3	Flammable liquid	305	5 Litres
Ethyl alcohol solution				309	60 Litres
Formaldehyde solution	2209	8	Corrosive	818	5 Litres
Genetically modified micro-organism	3245	9	Miscellaneous	913	No limit
Infectious substance affecting human (liquid)	2814	6.2	Infectious substance	602	50 ml
Infectious substance affecting human (solid)	2814	6.2	Infectious substance	602	50 gm
Infectious substance affecting animal only (liquid)	2900	6.2	Infectious substance	602	50 ml
Infectious substance affecting animal only (solid)	2900	6.2	Infectious substance	602	50 gm
Medical waste, n.o.s.	3291	6.2	Infectious substance	622	No limit
Methanol	1230	3	Flammable liquid	305	1 Litre
Nitrogen, refrigerated liquid	1977	2.2	Nonflammable gas & cryogenic liquid	202	50 Kg
Regulated medical waste, n.o.s.	3291	6.2	Infectious substance	622	No limit

Source: <http://www.who.int/ihr/biosafety/transport/en/index.html>

Table 2. Specimen submission form

1. Submitter Name	2. Officer ID, if any	3. Name of owner			
				<input type="checkbox"/> Check if wildlife	
Phone:					
		Address:			
Email:					
		4. Location of animals			
		VDC/Municipality:			
Mailing address:					
		District:		Region:	
5. Herd/Flock Size	8. Examination Requested			9. Collected by	
6. No. in herd/flock affected				10. Date collected:	

Annex- 2

Table 3: List of infectious substances included in Category A*

UN # and Proper Shipping Name	Microorganism	
UN 2814 Infectious substance affecting humans	Bacillus anthracis (cultures only) Brucella abortus (cultures only) Brucella melitensis (cultures only) Brucella suis cultures Burkholderia mallei - Pseudomonas mallei Glanders (cultures only) Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only) Chlamydia psittaci - avian strains (cultures only) Clostridium botulinum (cultures only) Coccidioides immitis (cultures only) Coxiella burnetii (cultures only) Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) Escherichia coli, verotoxigenic (cultures only)I Ebola virus Flexal virus Francisella tularensis (cultures only) Guanarito virus Hantaan virus Hantaviruses causing hantavirus pulmonary syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only)	Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus Mycobacterium tuberculosis (cultures only) I Nipah virus Omsk hemorrhagic fever virus Poliovirus cultures Rabies virus (cultures only) Rickettsia prowazekii (cultures only) Rickettsia rickettsia (cultures only) Rift Valley fever virus (cultures only) Russian spring-summer encephalitis virus (cultures only) Sabia virus Shigella dysenteriae type 1 (cultures only) I Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) Yersinia pestis (cultures only)

UN 2900 Infectious substance affecting animals	African horse sickness virus African swine fever virus Avian paramyxovirus Type 1 - Newcastle disease virus Bluetongue virus Classical swine fever virus Foot and mouth disease virus Lumpy skin disease virus Mycoplasma mycoides - Contagious bovine pleuropneumonia Peste des petits ruminants virus Rinderpest virus Sheep pox virus Goat pox virus Swine vesicular disease virus Vesicular stomatitis virus	
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* This list is not exhaustive.

Source: http://www.iata.org/SiteCollectionDocuments/dgr50_InfectiousSubstancespdf.pdf
(Based on 15th Edition of the United Nations Model Regulations)

Category B Infectious substances are diagnostic specimens or clinical specimens that do not meet the criteria of Category A infectious substances and are shipped for diagnostic purposes. They are assigned to UN 3373 and designated as BIOLOGICAL SUBSTANCES CATEGORY B.

Annex- 3

Packing Instruction P620

Infectious substances in Category A and designated as UN 2814 or UN 2900 may only be transported in packing that meets the United Nations class 6.2 specifications and complies with Packing Instruction P620 (PI602 for the air mode), which is reproduced below. The various provisions mentioned are set out in the United Nations Model Regulations.

P620 (PI 602 for the air mode) PACKING INSTRUCTION P620

This instruction applies to UN Numbers 2814 or UN 2900.

The following packagings are authorized provided the special packing provisions are met:

- | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">a) Inner packagings comprising:<ul style="list-style-type: none">i. Leakproof primary receptacle(s);ii. a leakproof secondary packaging,iii. other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them;b) An itemized list of contents enclosed between the secondary packaging and the outer packaging. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A, the words “suspected category A infectious substances” shall be shown in parenthesis, following the proper shipping name on the document inside the outer packaging.c) A rigid outer packaging of adequate strength for its capacity mass and intended use. The smallest external dimension shall be not less than 100 mm (4 inch). |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Additional requirements:

- | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">1. Inner packagings containing infectious substances shall not be consolidated with inner packagings containing unrelated types of goods.2. Other than for exceptional consignments, e.g., Whole organs which require special packaging, the following additional requirements shall apply:<ul style="list-style-type: none">i. Substances consigned at ambient temperatures or at a higher temperature: Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g. a heat seal, a skirted topper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g. tape, paraffin sealing tape or manufactured locking closure;ii. Substances consigned refrigerated or frozen: Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used; |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

- iii. Substances consigned in liquid nitrogen: Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacles individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen;
- iv. Lyophilized substances may also be carried in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

3. Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing pressure differential of not less than 95 kPa and temperature in the range -40°C to +55°C (-40°F to +130°F).

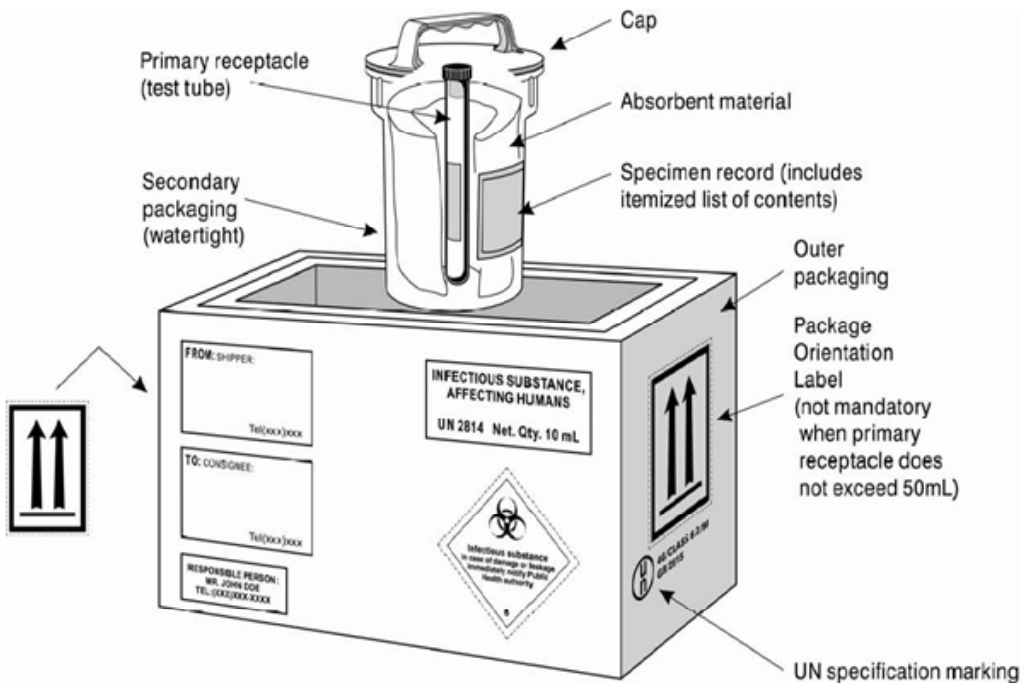


Figure 1. Example of triple packaging system for the packaging and labelling of Category A infectious substances (Figure Adopted from IATA, Montreal, Canada)



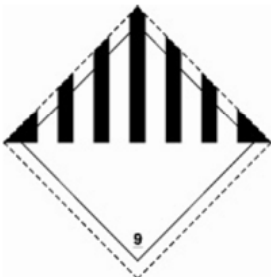
4G/Class 6.2/05/GB/2470

This marking comprises:
the United Nations packaging symbol
an indication of the type of packaging (in this example a fibreboard box (4G))
an indication that the packaging has been specially tested to ensure that it meets the requirements for Category A infectious substances (Class 6.2)
the last two digits of the year of manufacture (in this example 2005)
competent state authority that has authorized the allocation of the mark (in this example GB, signifying Great Britain)
the manufacturer's code specified by the competent authority (in this example 2470)
Users shall be provided with clear instructions as to how the package should be filled and prepared for transport.

Figure 1a. Package specification marking for Category A infectious substance

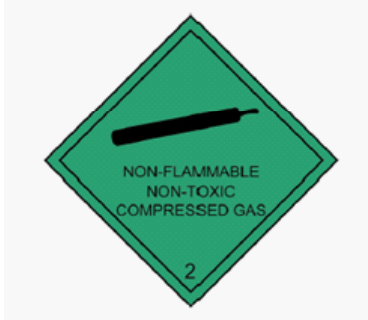


Figure 1b. Hazard label for Category A infectious substances and for genetically modified microorganisms and organisms that meet the definition of an infectious substance, Category A.



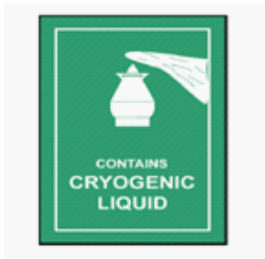
Label name: Non flammable, non-toxic gas
Minimum dimensions: 100 × 100 mm
(For small packages: 50 × 50 mm)
No. of labels per package: 1
Colour: Green and white or green and black

Figure 1c. Hazard label for certain noninfectious genetically modified microorganisms and organisms (UN 3245) and for carbon dioxide, solid (dry ice) (UN 1845); substances packed in dry ice shall bear this label in addition to the primary risk label.



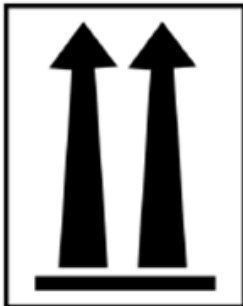
Label name: Miscellaneous dangerous substances
 Minimum dimensions: 100 × 100 mm
 (For small packages: 50 × 50 mm)
 No. of labels per package: 1
 Colour: Black and white

Figure 1d. Hazard label for liquid nitrogen; substances packed using liquid nitrogen shall bear this label in addition to the primary risk label.



Label name: Cryogenic liquid
 Minimum dimensions: Standard A7: 74 × 105 mm
 No. of labels per package: 1
 Colour: Green and white

Figure 1e. Handling label for cryogenic liquids; for transport by air, where cryogenic liquids (deeply refrigerated liquefied gases) are used this label shall be affixed to insulated vessels or flasks used as outer packaging in addition to the labels or markings shown in Figures 1b-1d as appropriate



Label name: Orientation label
 Minimum dimensions: Standard A7: 74 × 105 mm
 No. per package: 2 on opposite sides
 Colour: Black and white or red and white

The words “THIS SIDE UP” or “THIS END UP” may also be displayed on the top cover of the package.

Figure 1f. Orientation label to indicate position of closures on the primary receptacles; for the air transport of quantities of liquid infectious substances in Category A that exceed 50 ml per primary receptacle, this label shall be affixed to two opposite sides of the package with the arrows pointing in the right direction, in addition to the label shown in Figure 1b.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Hôpital des enfants 5, Rue des Mimosas 05234 Rivière Fleurie - Primance Dr Bedikian tel +0789 456 123	Air Waybill No. 543 7654 9876 Page 1 of 1 Pages Shipper's Reference Number <small>(optional)</small>
Consignee Laboratorios Biovirobact 5, Calle Escherichia 98675 Eproveta - Polotos Dr Guarguir tel +0520 36 009 832	

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

TRANSPORT DETAILS	
This shipment is within the limitations prescribed for: <small>(delete non-applicable)</small>	Airport of Departure: VILLEBELLE
PASSENGER AND CARGO AIRCRAFT <input type="checkbox"/>	CARGO AIRCRAFT ONLY <input checked="" type="checkbox"/>

Airport of Destination: VIALIS	Shipment type: <small>(delete non-applicable)</small> <input checked="" type="checkbox"/> NON-RADIOACTIVE <input type="checkbox"/> RADIOACTIVE
---------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division <small>(Subsidiary risk)</small>	Pack- ing Group	Quantity and type of packing	Packing Inst.	Authorization
UN 2814	Infectious substance, affecting humans, (Ebola virus)	6.2		50 mL	602	
UN 1845	Dry ice	9	III	20 kg All packed in one fibreboard box	904	

Additional Handling Information
Emergency contact: Dr Bedikian Tel +0789 456 123

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.	Name/Title of Signatory Dr Bedikian, Goods Receipt & Dispatch
	Place and Date Rivière Fleurie, 18 May 2005
	Signature <small>(see warning above)</small>

Figure 2. Example of a completed Shipper's Declaration for Dangerous Goods

Annex- 4

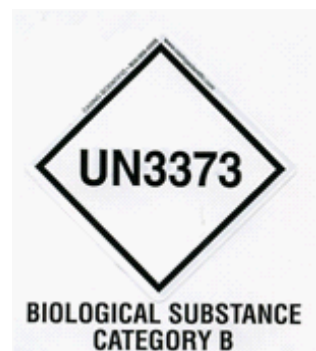
Packing Instruction P650

The text of United Nations Packing Instruction 650, in use for the transport of infectious substances in category B assigned to UN 3373 by all surface modes of transport in reproduced below. The various provisions mentioned are set out in the United Nations Model Regulations.

Packing Instruction P650

This packing instruction applies to UN 3373 on passenger and cargo aircraft only.

- 1) The packing shall be of good quality, strong enough to withstand the shocks and loading normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses as well as any removal from a pallet or over-pack for subsequent manual or mechanical handling. Packaging shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.
- 2) The packaging shall consist of three component:
 - a) a primary receptacle,
 - b) a secondary packaging, and
 - c) an outer packaging of which either the secondary or the outer packaging shall be rigid.
- 3) Primary receptacles shall be packed in secondary packaging in such as way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging shall be secured in outer packaging with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.
- 4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm, the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high. The proper shipping name “BIOLOGICAL SUBSTANCE, CATEGORY B” in letters at least 6 mm high must be marked on the outer package adjacent to the diamonds-shaped mark.
- 5) At least one surface of the outer packaging must have minimum dimension of 100 mm x 100 mm.
- 6) The completed package shall capable of successfully passing the drop test from a height of 1.2 m. Following the drop sequence, there shall be no leakage from the primary receptacle (s) which shall remain protected by absorbent materials when required in the secondary packaging.



- 7) For liquid substances
 - a) The primary receptacle(s) shall be leak proof and must not contain more than 1 litre.
 - b) The secondary packaging shall be leakproof.
 - c) If multiple fragile primary receptacles are placed in single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.
 - d) Absorbent materials shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent materials shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging.
 - e) The primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure of 95 kPa (0.95 bar) and temperature in the range -40°C to + 55°C (-40°F to + 130°F).
 - f) The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.
- 8) For solid substances
 - a) The primary receptacle (s) shall be siftproof and must not exceed the outer packaging mass limit.
 - b) The secondary packaging shall be siftproof.
 - c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.
 - d) Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.
 - e) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport, then packaging suitable for liquids, including absorbent materials shall be used.
- 9) Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen
 - a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports shall be provided to secure the secondary packaging in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings and the package (the outer packaging or the overpack) shall be marked “Carbon dioxide, solid” or “Dry ice”.
 - b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.

- 10) When packages are placed in an overpack, the package markings required by this packing instruction shall either be clearly visible or be reproduced on the outside of the overpack.
- 11) Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Instructions except for the following:
 - a) The proper shipping name, UN number and the name, address and telephone number of a person responsible must be provided on a written document (such as an air waybill) or on the package;
 - b) Passengers and crew members are prohibited from transporting infectious substances either as or in carry-on baggage or checked baggage or on their person.
- 12) Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.
- 13) Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3 (flammable liquids), 8 (corrosive) or 9 (miscellaneous dangerous substances and articles) may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements in these Instructions need to be met.

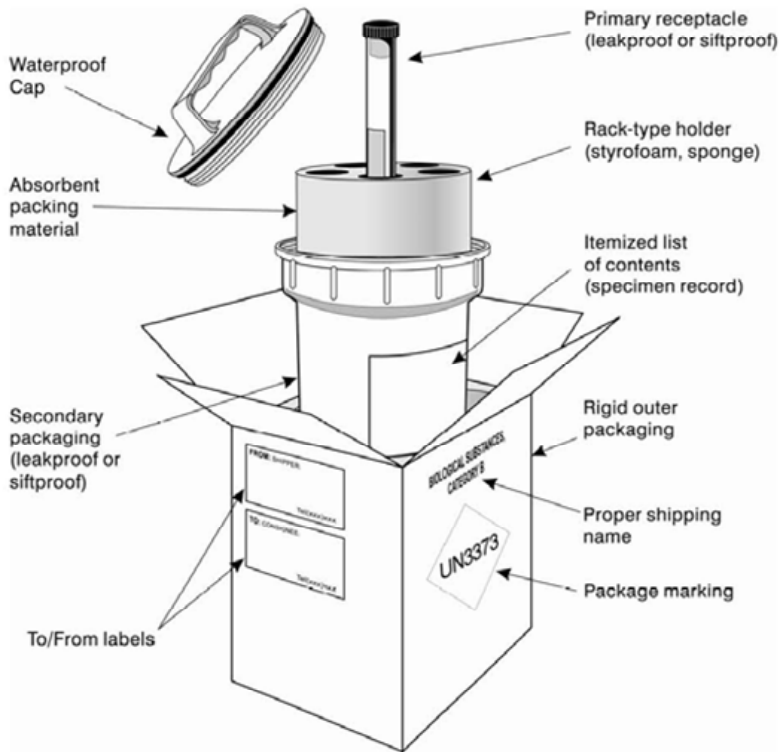


Figure 3. Showing example of the triple packaging system for packing and labelling of Category B infectious substances (Adopted from IATA, Montreal, Canada)

Annex- 5 Packaging for Exempt Specimens

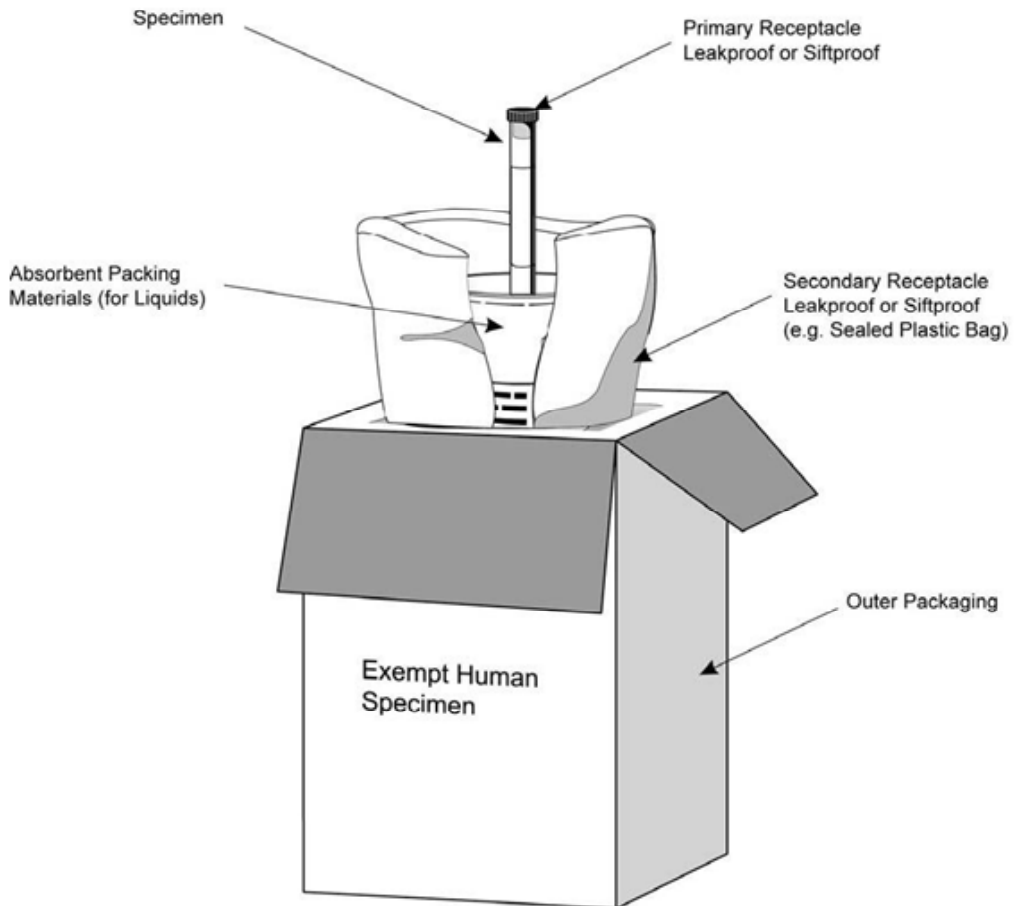


Figure 4. Showing example of the triple packaging system for packing and labelling of exempt substances (Adopted from IATA, Montreal, Canada)

Note:

1. At least one surface of the outer packaging must have a minimum dimension of 100 x 100 mm;
2. The outer packaging must be of adequate strength for its capacity, mass and intended use.

Annex- 6

Summary of Packagings

Table 5. Summary of differences in packaging requirements

Category A (PI602) UN 2814- Infectious Substances affecting Humans UN 2900- Infectious Substances affecting Animals only	Category B (PI650) UN 3373-Biological Substance, Category B	Exempt Exempt Animal Exempt Human
Primary container is leakproof	Primary container is leakproof	Primary container is leakproof
Secondary container is leakproof	Secondary container is leakproof	Secondary container is leakproof
Outer container is rigid	Either secondary or outer container must be rigid*
Pressure tested at 95 kPa	Pressure tested at 95 kPa
Drop tested from 9 m	Drop tested from 1.2 m
UN symbol must be on page
Puncture tested at 7 kg
Shipper must be trained

* If shipment is transported by air, the outer container must be rigid.

Table 6. Summary requirement for shipping samples with dry ice

Category A (PI602) UN 2814- Infectious Substances affecting Humans UN 2900- Infectious Substances affecting Animals only	Category B (PI650) UN 3373-Biological Substance, Category B	Exempt Exempt Animal Exempt Human
Packing Instruction 602	Packing instruction 650	Minimal triple packaging
Shipper must be trained	Shipper must be trained	Shipper must be trained
Markings and labels	Markings and labels	Markings and labels
Shipper's Declaration of Dangerous Goods
Airway bill for air transport	Airway bill for air transport	Airway bill for air transport
Import/export permit (if required)	Import/export permit (if required)	Import/export permit (if required)
Weight and volume limitations for infectious substances, Category A	Weight and volume limitations for infectious substances, Category B

Annex- 7

A Format of Sample Transfer Agreement

Between:

The Central Veterinary Laboratory (CVL), Kathmandu, Nepal represented by its Chief

Dr.....and.....

NAME, Institute, Country (Beneficiary)

1 Scope

The CVL performs laboratory diagnostic on infectious diseases of animals. The Parties agree that the CVL will provide MATERIAL XY (for example: highly pathogenic avian influenza virus (HPAIV) of subtype H5N1 Asia) recently received from chicken-samples in Nepal (hereinafter referred to as “Material”) to INSTITUTE XY, COUNTRY XY for confirmatory test and research on the following conditions.

2 Transfer of the Material

- (1) The CVL will provide the Beneficiary with xy ml of MATERIAL XY (e.g. swab sample in VTM) containing infectious HPAIV H5N1 virus.
- (2) Upon receipt the material shall become the property of the Beneficiary.

3 Responsibilities of the Beneficiary

- (1) The Material and all mutations and variations thereof may only be used for research purposes.
- (2) The CVL shall not be liable for the safety or fitness for use or for certain features of the material. Especially, the CVL shall not be responsible for the material’s fitness of use for the intended research purposes.
- (3) The CVL shall not be liable for damages caused by the material or its use.
- (4) The Beneficiary agrees to treat strictly confidential all information given, even after expiration of the contract, and especially not to pass them on to third parties.
- (5) The Beneficiary will provide a report on the research results promptly to the CVL.

4 Research Results

- (1) The research results shall be the property of the Beneficiary. The Beneficiary grants the CVL a simple, royalty free right of use for research purposes. This shall also include the right to use the results in research and development cooperation.
- (2) The Beneficiary shall publish the research results. All descriptions of the original Material in the publication require the prior written consent of CVL. Publications will include the co-authorship of key staff of the CVL.

5 Applicable Law, Jurisdiction

- (1) This agreement shall be governed by Nepal law, except for the Private International Law.
- (2) Place of jurisdiction shall be the court competent for the CVL.

Place and date _____

Place and date _____

Director of CVL

Beneficiary

Biosecurity Manual for Commercial Poultry Production

Approved By Department of Livestock Service (DS)-2069/4 /24 Nepal

Purpose of this Manual

The purpose of this manual is to establish a minimum set of biosecurity standards, applicable to all commercial poultry producers (broiler farms, layer farms) including breeder farms and hatcheries. The stringent implementation of biosecurity measures in backyard poultry seems difficult in present context, but the principle of good biosecurity still applies.

To increase awareness among poultry entrepreneurs and workers in adopting effective farm level biosecurity for improved farm productivity through less exposure to diseases and safeguarding public health is the next important purpose of this manual.

Individual producers and companies may develop enhanced biosecurity manuals, which should nevertheless incorporate these minimum standards in addition to any specific company or industry sector requirement.

Definitions

“**Poultry**” implies for any birds raised commercially in captivity principally for the purpose of human food production. This includes chicken, turkey, duck, quail, guinea fowl, pheasants, geese, pigeon and ostrich.

“**Poultry Breeding Farm**” refers to the farm keeping parent or grand parent stocks that are exclusively used for production of hatching eggs for commercial egg or meat production.

“**Broiler farm**” refers to the poultry farm where male or female chicken are reared primarily for meat production.

“**Layer Farm**” refers to the poultry farm where female chicken are exclusively reared for table egg production.

“**Hatchery**” is a facility where eggs are hatched under artificial condition.

“**Biosecurity**” means to take steps to ensure good hygiene practices are in place so that the risk of disease occurrence or spread is minimized.

Implementation

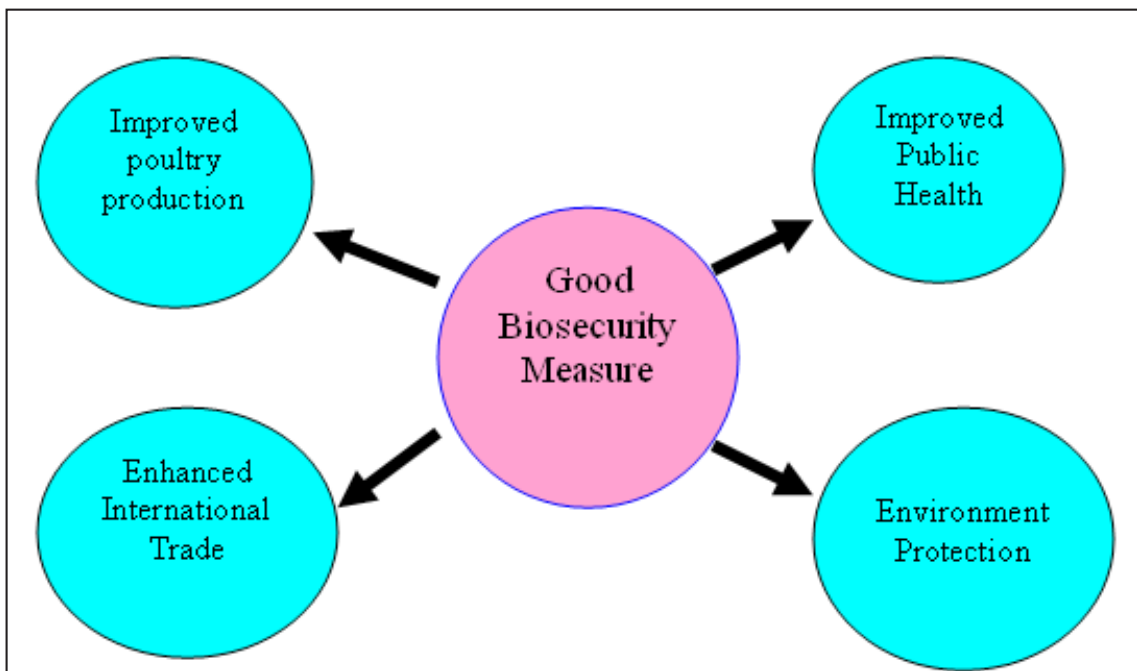
It is in every poultry keeper’s best interest to ensure that they are aware of the risks and do what they can to limit the chances of entering and spreading of diseases in their farm. Therefore, the individual poultry producers/entrepreneurs have the main responsibility to adopt and implement minimum effective biosecurity measures in their production area. People who understand the purpose of biosecurity measure are more likely to adopt the practice as part of their daily routine and ensure that any contractors or visitors coming onto the premises abide by these measures. It is important that the same knowledge is shared with family members, people who are on the

premises but do not work with poultry, and any temporary workers. One should also understand that disease is inevitable if there is frequent breach of biosecurity plan in the farm. In this context, it is hoped that the manual would provide the technical guidelines to the Department of Livestock Services and concerned District Livestock Service Offices to take good biosecurity measures in the poultry farms.

1. General Poultry Biosecurity

1.1 The Meaning of Biosecurity

Biosecurity ('Bio' means 'life' and 'security' refers to some sort of protection) is the measure taken for safety and protection of animals/birds against disease-producing organisms. Biosecurity, therefore, includes all the measures that should be taken to prevent viruses, bacteria, fungi, protozoa, parasites, rodents, and wild birds from coming in contact with birds on the farm. It



is a set of management procedures, which protect the living things from the disease causing organisms by reducing the introduction and spread of pathogens into and between the farms. Biosecurity is the most efficient and cost-effective method of disease prevention.

Biosecurity is:

- Using common sense practices to protect poultry and **birds** from all types of infectious agents—viral, bacterial, fungal, or parasitic;
- Doing everything possible to protect birds from infectious diseases like Newcastle disease (ND) and avian influenza (AI); and
- Preventing disease-causing germs or microbes from entering premises or confining it within the premises and stop spreading in case of exposures.

It is accomplished by maintaining the facility and operation in such a way that there is a minimal

traffic of biological organisms (viruses, bacteria, rodents, parasites etc) across it borders. Biosecurity is about managing risk to avoid diseases in the poultry flock. It is essential that a risk assessment be conducted for each enterprise to establish what level of risk exists in each phase of its operations and to identify and implement control measures appropriate to these levels of risk.

1.2 Why Biosecurity in Poultry Farm?

The biosecurity, combined with sound vaccination schedule is the appropriate measures taken to prevent spread of diseases in the farms. This is an essential component to keep the emerging poultry industries viable which often is badly affected by many diseases. In the present context of spread of Highly Pathogenic Avian Influenza (HPAI) across the globe and its significance in business economics and public health, has made farm bio-security even more important. This is also the component in poultry industries, which is often overlooked and breached due to sheer negligence. Thus creating adequate awareness among all the stakeholder along the poultry value chain and facilitating them to abide by the good biosecurity measures in their parts to save entrepreneurs themselves from economic loss and also to safeguard the public health concerned is of prime importance. Prevention is always better than cure is the basic to be adopted in adopting bio-security measures.

1.3 The Benefits of Good Biosecurity

The adoption of good biosecurity measures in farm

- Helps to keep out poultry diseases such as Avian Influenza, Newcastle Disease and many other economically important diseases;
- Reduces the risk of zoonotic diseases such as salmonellosis;
- Limits the spread of diseases and helps to protect neighbors, public health and the localities;
- Improves overall flock health and productivity;
- Reduces losses (disease treatment cost, reduced productivity and mortality).
- Avoids loss to market access
- Builds consumers confidence

Figure 1: Potential Benefit of Appropriate Biosecurity Measure

One should not think Biosecurity as burden as it is the investment on health insurance.

1.4 Some Factors Influencing Biosecurity

Some factors that influence biosecurity are:

- Globalization,
- New agricultural production and food processing technologies,
- Increased trade in food and agricultural products,
- Legal obligations for signatories of relevant international agreements,
- Increasing travel and movement of people across borders/ countries,

- Advances in communications and global access to biosecurity information,
- Greater public attention to biodiversity, the environment and the impact of agriculture on both,
- Shift from country independence to country interdependence for effective biosecurity,
- High dependence of some countries on food imports.

1.5 Mode of Disease Spread

Broadly, mode of disease spread can be classified into two categories: horizontal and vertical. The knowledge of which is required to plan a good biosecurity measure in the farm. The mode of disease transmission between birds, or between farms differs, depending on the type of infection. For example, respiratory disease viruses replicate in the respiratory tract. Subsequent sneezing and coughing will release virus particles to be spread mostly by aerosol transmission. On the other hand, the causative agents for enteric (gut) diseases causing diarrhea, would mostly spread through droppings, whilst air sac and oviduct infections would mostly be transmitted via eggs.

Microbes or disease causing organisms spread from place to place via animals, vehicles, equipment, and people. Disease is spread through:

- Movement of poultry, people, vehicles and equipment ;
- With the introduction of new birds of low or unknown health status;
- Introduction of healthy birds which have recovered from disease but acting as carriers
- Sharing of equipments and vehicles, which have not been effectively cleaned and disinfected;
- Contact with vermin and wild birds;
- Contaminated water and feed supply;
- Unsatisfactory cleaning and disinfection of vehicles, sheds, feeding troughs and other equipments;
- Not practicing all in and all out programme/ system.
- Contact with inanimate objects (fomites) that are contaminated with disease organisms
- Carcasses of dead birds that have not been disposed of properly
- Contaminated premises through soil or old litter
- Air-borne fomites
- Egg transmission (vertical)

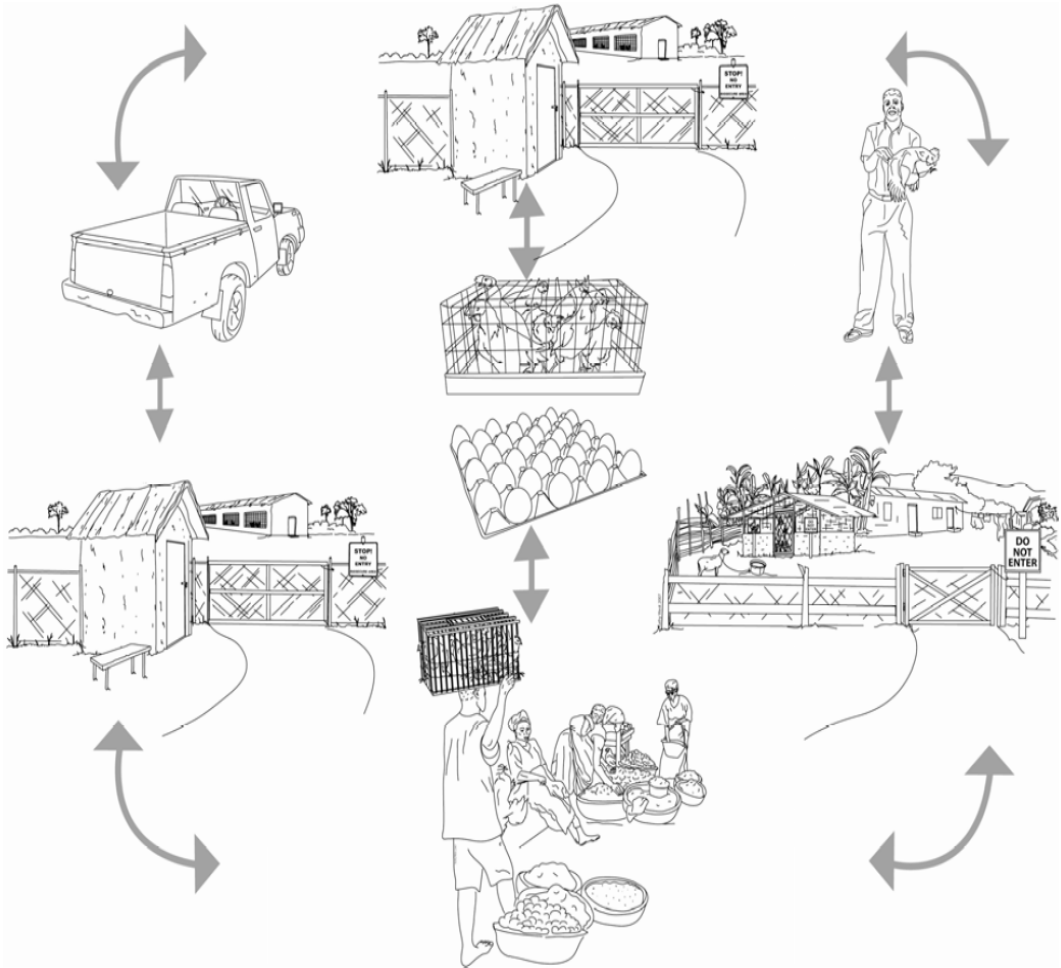


Figure 2: Elements of Disease exposure (source: Practical Manual, Training on Biosecurity for poultry farms and markets, 2009, Nepal)

Many organisms persist outside the host, such as *coccidia*, *Salmonella*, *Aspergillus* and many viruses can survive in this way for a considerable time, especially in organic material. *Pasteurella*, *Mycoplasma* and some bacteria can also live for long time in the beddings. Respiratory viruses tend to be fairly fragile once outside the host, although may be able to travel at least **five miles** in the air if conditions are favorable. Many germs die in two or three days but, under certain conditions (such as cold damp surroundings), they survive much longer. Even with a short, one-day survival, germs can travel several hundred miles when clinging to animals, people and equipment.

When a bird is infected with a pathogenic organism, there may or may not be obvious signs of clinical disease. Nevertheless, this pathogen can reproduce in the bird's body, which then will shed the organisms into the environment through body excretions, including feces, urates from the kidneys, or aerosols from the respiratory system. The organisms contained in these

excretions contaminate the surfaces in the surrounding environment, which then carry the infection to the next bird. If another bird becomes infected and the amount of the pathogen overcomes the bird's immune system, the bird will be clinically ill and the cycle continues. As the pathogenic organism passes through more and more birds, its numbers in the environment multiply rapidly.

Table 1: Longevity of some diseases causing organisms

Diseases	Lifespan away from birds	Mode of transmission
Infectious Bursal Disease	Months	Horizontal (contaminated faeces)
Coccidiosis	Months	Horizontal (feed, water, litter or other material contaminated with Coccidia)
Duck Plague	Days	Vertical
Fowl Cholera	Weeks	Horizontal
Coryza	Hours to days	Horizontal (direct contact, airborne droplets, and contamination of drinking water)
Marek's Disease	Months to years	Vertical/ Horizontal
Newcastle Disease	Days to weeks	Horizontal (direct contact, droppings, secretions from nose, eye and mouth)
Mycoplasmosis (MG, MS)	Hours to days	Vertical (organism in eggs)/ Horizontal (direct contact with infected birds, contaminated equipment)
Salmonellosis (Pullorum)	Weeks	Vertical/ Horizontal
Avian Tuberculosis	Years	Horizontal (by direct contact with infected birds, ingestion of contaminated feed and water, or contact with a contaminated environment)

Source: Gary D Butcher and Salim M Bootwalla (2008). Biosecurity in Commercial Poultry. Technical Bulletin, American Soybean Association.

The knowledge on mode of disease spread is essential so that effective biosecurity plan could be designed and implemented at farm level

1.6 Major Consideration In Biosecurity Plan

In order to assess how much biosecurity is practical for the farm, look at these three factors.

1. Economics (cost involved and potential benefits)
2. Common sense and
3. Relative risk

Analyze disease risk at your farm periodically; think of economics (possible cost involved and potential benefits) and use common sense to implement effective biosecurity measures.

A biosecurity program should be applied with the same intensity to all sectors of poultry operation. It must be practical and easily understood by everyone within the poultry operation. Complicated biosecurity programs, which are not easy to implement, will fail. Consistency in following biosecurity rules throughout the year (i.e. production cycle) is very important. Biosecurity program implementation comes at little cost when compared to the costs associated with disease outbreak. Biosecurity is necessary expense and can make a difference between success and failure in a poultry operation.

It really does not matter how comprehensive your biosecurity measures are on paper but rather whether the programme is implemented correctly in farms.

1.7 Principal Components of Biosecurity

An effective biosecurity program is based on two main concepts: exclusion (keeping the disease out of the flock) and containment (if it has been introduced, preventing its spread within the premises or to other uninfected flocks). Because the risks are different for each poultry operation, consult veterinarian to customize the biosecurity program to the specific situation. However, there are certain key components, addressing both exclusion and containment, which should be included in any biosecurity program. These are isolation, traffic control, and cleaning and disinfection.

These biosecurity components could be applied through proper selection of:

Location: Farms should be located so that they are isolated from other poultry and livestock. Single-age sites are preferable so that recycling of pathogens and live vaccine strains is limited.

Farm Design: A barrier (fence) is necessary to prevent unauthorized access. Housing should be designed to minimize traffic flow, to facilitate cleaning and disinfection, and constructed to be bird and rodent proof and

Operational Procedures: Procedures must control movement of people, feed, equipment and animals on the farm to prevent introduction and spread of disease. Routine procedures may need to be modified in the event of a change in disease status.

1.7.1 Isolation: Preventing exposure of poultry to viruses and other disease agents is the first step. The following recommendations are barriers designed to keep birds isolated from sources of disease introduction.

- Maintain a buffer distance from other poultry establishment and possible source of infection as given in Table 2. However, it is also influenced by the terrain of sites where poultry farms are being established, e.g. natural barriers of hills.

Table 2: Isolation requirement for different types of poultry farms

	Grand Parents	Parent Stock	Layers	Broilers
1. Minimum distance between a poultry farm to the next poultry farm	5 km	2 km	200 m	200 m
2. Minimum distance allowed of backyard poultry to poultry farm	5 km	2 km	200 m	200 m
3. Minimum distance between a poultry farm and processing plant	5 km	2 km	1 km	1 km
4. Minimum distance between poultry farm to live bird markets	5 km	2 km	1 km	1 km
5. Minimum distance between poultry farm and residential area	5 km	2 km	500 m	500 m
6. Minimum distance between a poultry farm to the nearest village waste disposal facilities	5 km	2 km	1 km	1 km
7. Minimum distance between a poultry farm to the nearest standing body of water (pond, lake, dam)	2 km	1 km	200 m	200 m
8. Minimum distance between a poultry farm to nearest river with possibility of flooding	1 km	1 km	1 km	1 km
9. Minimum distance between a farm fence and poultry house	15 m	15 m	2 m	2 m
10. Minimum distance between a poultry house to large trees that host wild birds	100 m	100 m	100 m	100 m
11. Minimum distance between shower/ washer/toilet for the farm worker and the poultry house	10 m	10 m	10 m	10 m

Source: Biosecurity guidelines for the commercial poultry industries in Bangladesh,

Department of Livestock Services, Ministry of Fisheries and Livestock, Government of the People Republic of Bangladesh.

- Properly fence the poultry complex from all four sides to avoid unwanted encroachment.
- Install a sign at the farm gate and at the entrance of each poultry house to instruct unauthorized people not to enter the premises/houses. Lock all doors to the poultry houses at all times in order to restrict access.
- Minimize contact with other poultry, including neighboring backyard flocks. Do not share any farm equipment. Do not allow any farm employees, including manager/owner, to keep backyard or pet birds, nor attend any live bird shows or markets.
- Apply a strict rodent and insect control program and monitor its efficacy regularly. Keep vegetation and debris cleared around poultry houses, as these will attract rodents and wild birds.

- Avoid establishing poultry houses near ponds. These will attract wild birds and waterfowl that can carry diseases.
- Ensure all poultry houses are wild bird proof. Screen all inlets and fans and plug or repair any gaps and holes in the structure. Monitor buildings regularly and repair immediately.
- Immediately clean feed and water spills in the farm environment, especially outside poultry houses.
- Do not allow dogs and cats inside poultry houses at any time.
- **Have a separate sick bird room.**
- Collect dead bird from poultry houses as soon as they are seen and dispose off appropriately. It is important to prevent access to dead birds by wild birds and other animals. In consultation with veterinarian, **establish a proper carcass disposal protocol.** Clean and disinfect all used equipment (such as barrels) at the end of carcass pick up.
- When burial methods are used, the excavation trench or pit should be a minimum of 3 meters above the water table and not closure than 100 m from any flowing water source. A final cover for all trenches and pits should be 0.5 meters of compacted soil. The carcasses must be buried so that seepage will not issue from the pit, either surface or sub-surface, to cause spread of disease and/or pollution. When a burial pit is in use, care should be exercised to ensure that scavengers do not have access to the carcasses and that fly breeding cannot occur.
- Litter and manure disposal/ storage pit should be at least 50 m away from poultry houses, 500 m from urban residential area, 100 m from rural residential area and 50 m from water sources. Piled up litter/ manure should covered with the plastic all the times.

1.7.2 Traffic and Visitor Control

Since it is not possible to completely isolate the flock and the farm, it is essential to follow proper protocols for movement onto and within the operation.

- Park all vehicles in a designated area far from poultry houses and away from farm vehicle traffic areas.
- Allow only certain authorized and necessary personnel to enter poultry houses. It is important that visitors wear clean coveralls, mask, cap and disposable footwear. Use disposable gloves and wash hands with appropriate hand soap or sanitizer before and after each visit. Regular necessary visitors such as meter readers, fuel and feed delivery drivers and service personnel, must also use all necessary clothing and footwear as mentioned.
- **Use separate designated clothing and footwear for each poultry house and for each person or attendants.**
- Keep a record of all visits in a designated logbook (Annex 2). Record names of the individuals, the nature of their business and their contact information.
- If using a footbath, follow label instructions for the disinfectant to ensure appropriate concentration and refill as necessary. A dirty footbath increases the risk of infection.
- Catchers must use separate clothing, footwear, mask and cap for each farm. Clean and disinfect catching equipment after each loading and before entering the next farm. This is extremely important if only part of the flock is shipped to the processing plant (thinning out or partial pick up).

- It is preferred to have an all-in, all-out system (single age flock at any given time). If this is not possible, always visit from youngest to oldest and from healthy to sick flocks.

Identify low risk, moderate risk and high risk visitors to the farm and take biosecurity measure accordingly

Low-Risk Visitors- Visitors from urban areas or others who have no contact with livestock present very little risk of carrying diseases.

Moderate-Risk Visitors- People who routinely visit farms but have little or no contact with animals such as salesmen, delivery people, and mechanics present only a moderate risk of introducing disease.

High-Risk Visitors- High-risk visitors include **Vet Technicians**, livestock haulers, livestock-owning neighbors, and anyone else who has close contact with animals and their bodily discharges.

1.7.3 Cleaning and Disinfection

Proper cleaning and disinfection are important component of biosecurity. While isolation and hygiene practices are very effective, it is inevitable that some contamination of the farm environment will occur. These recommendations will limit the spread of the contamination within the premises, and to other premises.

- A minimum gap of two weeks between successive restocking of poultry house is recommended during which the poultry house could be properly cleaned and disinfected.
- After disposal of every batch of birds the dirty litter material and manure should be removed, walls and floors should be cleaned, white washed with lime and disinfected with effective disinfectants.

Table 3: Efficacy of disinfecting agents to different pathogen

Disinfecting agents	Bacteria	Mycoplasma	Viruses	Fungal spores	Nematode eggs	Coccidia	Sensitivity to organic material
Sodium chloride	++	+++	+	++	+	-	Not sensitive
Chlorine Sol	++	+++	+	+	-	-	Not sensitive
Quaternary Ammonium Sol	+	++	+/-	+	-	-	Little sensitive
Phenol Sol	++	+++	+/-	+	-	+	Little sensitive
Formaldehyde	++	+++	+	++	-	-	Little sensitive
Peroxide	++	+	++	+	-	-	Sensitive
Ammonia	-	+	-	-	+	+	?
Combined products	++	?	++	++	?	-	Little sensitive

Note: +++ Excellent Efficacy; ++ Very good efficacy; + Good efficacy; - not effective; +/- works against certain viruses and, ? Efficacy unknown

Source: General protocol for C & D in www.virocid.com

- It is important to apply disinfection only after barns are completely cleaned from litter/debris, pressure washed with warm water and detergent and allowed to dry.
- If there is a history of an infectious disease in the previous flock, it is strongly recommended to perform a complete cleaning and disinfection and evacuation for at least 35 days.
- Avoid borrowing or lending farm equipment. If equipment is shared, clean and disinfect before and after use. Complete removal of any organic material before disinfection is very important.
- Proper sanitation of drinking water is a must. There are different methods of water sanitation. If using pond water, proper sanitation of the water is extremely important as waterfowl and wild bird excretions can contaminate it.

1.8 Level of Biosecurity

The level of the biosecurity one has to consider primarily depends on the appraisal of risk associated with it. In general two levels of biosecurity are recommended

Level 1: Routine Biosecurity Procedure

These procedures should be implemented and followed on a daily basis. They give a high degree of assurance that diseases and pathogens will not be carried into poultry production areas and will reduce the risk of transmission between production areas. These should be seen as a minimum requirement.

Level 2: High Risk Biosecurity Procedure

In the event of an outbreak of an emergency disease or serious endemic disease, high risk biosecurity procedures need to be implemented to increase biosecurity protection by minimizing movements on and off the property, and to protect the property from the increased threat of a disease being introduced in a suspected outbreak of an emergency disease or serious endemic disease.

Action Plan for Suspected Emergency Poultry Disease

Each owner must establish and document clear guidelines regarding the circumstances when an emergency **poultry disease** alert should be raised (e.g. an unusual increase in mortality or drop in production), and who must be informed. The action plan must also clearly state that, if an alert is raised, movement of birds must cease immediately, other movements on and off the production area and the property must be limited to the absolute minimum.

During this period

- Gates must be kept locked.
- Shed doors must be locked at night.
- No visitors are allowed enter the production area unless absolutely essential. Company personnel will discontinue routine visits except on suspicion of problems.
- Essential visits – head-to-toe shower before and after visit. A complete change of clothes, footwear, hair covering and breathing protection is required. Used clothing and all used

personal protection equipment must remain on the property.

- Repairs and maintenance – no routine work, only emergency work to be carried out.
- Any vehicle which must enter the property must be washed and disinfected at the wash pad before and after going onto the property (e.g. feed trucks). Vehicle driver cabins must also be sanitized inside.
- No birds or litter to be moved on or off farm until disease status is clarified.

2. Biosecurity in Poultry Breeding Farm

The poultry breeding farm refers to the farm keeping parent or grand parent stocks that are exclusively used for production of hatching eggs for commercial egg or meat production. As the whole poultry industries relies on healthy chicks produced from the egg from healthy parent stock, the biosecurity measures in the breeder farms should be more stringent than that are taken in commercial egg or meat production farms/units. Breach in any biosecurity measures in poultry breeding farm should be non tolerable.

2.1 Breeder Farm Location

The breeder farm should ideally be located away from other poultry establishment and human settlement. The farm should be at least 2 km away for parent stock and 5 km away for grand parent stock from other commercial poultry to avoid aerosol spread of diseases. The direction of prevailing wind should be taken in to account to facilitate hygiene and disease control in the breeder farm. The poultry house should be sufficiently away from main road that handles high volume of poultry vehicles.

2.2 Site Characteristics

Building sites near waterways, ponds or lakes utilized by migratory water fowl should be avoided and should be 1km (parent stock) to 2 km (grand parent stock) away. Well drained areas avoiding standing water should be chosen.

2.3 Fencing

The farm/establishment should be surrounded by a **security fence** and a gateway to control traffic and access to the site. A sign indicating restricted entry should be posted at the entrance. Farm gate should be closed and locked most of time. The standard fence height of 2m is recommended that should also be able to control entry of unwanted small animals (eg. cat, stray dogs etc.)

2.4 Poultry House Construction:

Poultry houses should be constructed so that all surfaces inside the buildings are of an impervious smooth material so that cleaning and disinfection can be carried out adequately. The orientation of house should also take account of prevailing climate of the location.

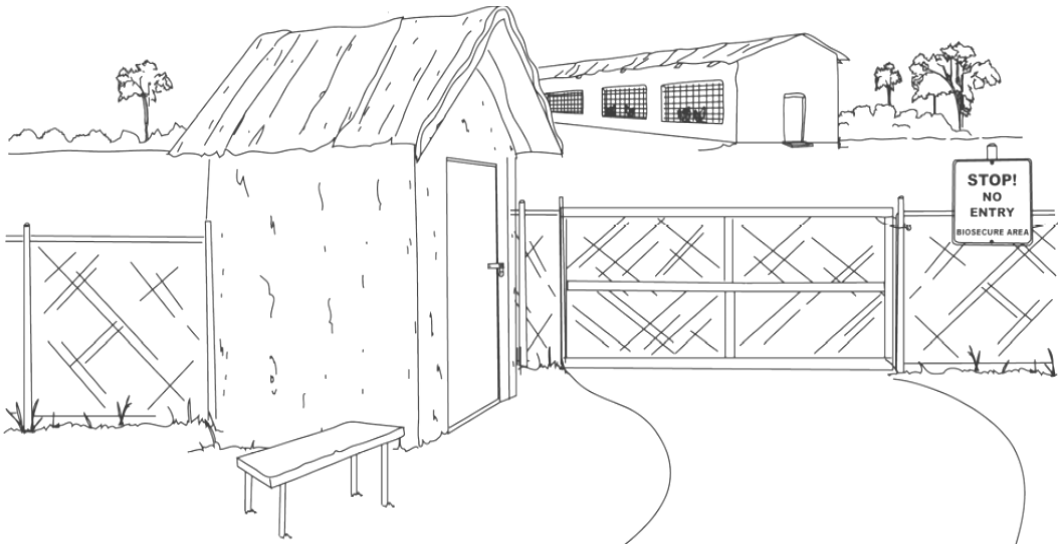


Figure 3: Fencing around the establishment showing prohibition to unwanted access

2.5 Single Purpose Establishment:

Poultry breeding establishments should be single purpose - single species enterprises, and ideally an all-in, all-out single age group principle should be adopted whenever possible. Where several *flocks* are maintained on one establishment, the individual flocks should be managed as separate entities.

2.6 Buildings for housing poultry or those used to store feed or eggs should be free of vermin, rodents and not accessible to wild birds.

2.7 The area immediately surrounding the poultry houses should be free from vegetation and debris and ideally this should consist of an area of concrete or other similar material. An exception to this would be trees for heat control, with the exception of fruit trees which could be attractive to birds.

2.8 Domestic animals including pets (dogs and cats) should not be permitted access to poultry houses.

2.9 The entry into poultry house should be absolutely limited to necessity only.

2.10 Showering/spraying and changing facilities should be adopted for all visitors to the establishment and for all staff entering individual poultry houses. A shower-in, shower-out policy for all visitors and employees is the most efficient approach in poultry breeding farm.

2.11 All site visitors should be provided with adequate protective clothing, and should wash their hands prior to visiting birds. An effective hand hygiene system should be followed. Clean coveralls or overalls, hats and footwear must be provided for all personnel and visitors entering the establishment

2.12 Personnel and visitors should have no direct contact with other poultry or poultry products.

2.13 Entrance of vehicle must be restricted to absolute necessary. Thorough cleaning and disinfection of the vehicle is required to enter. Procedure for vehicle cleaning is given in Annex 5.

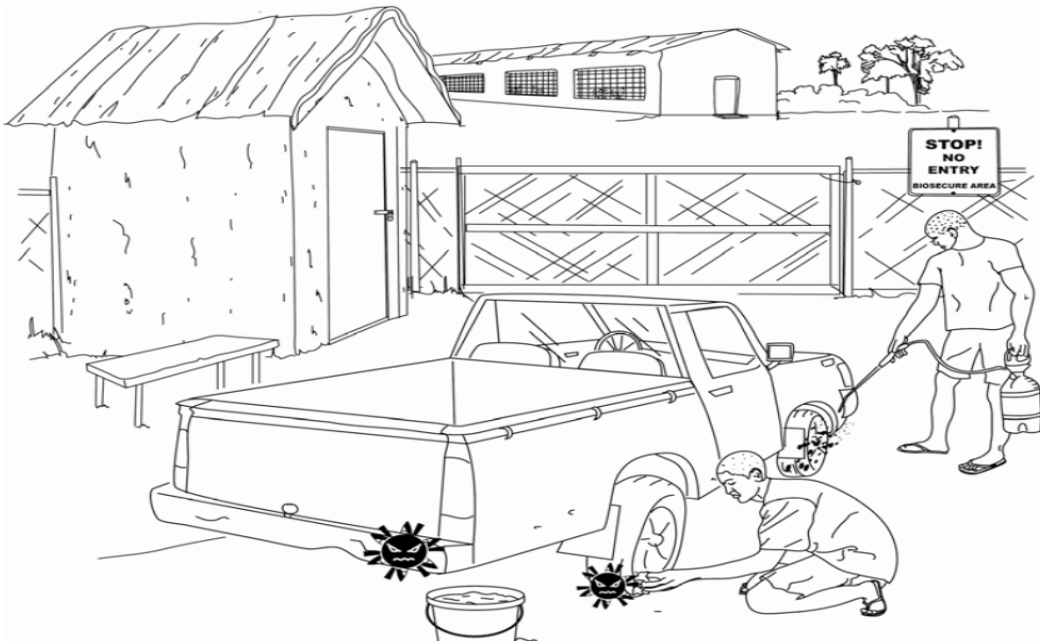


Figure 4: Cleaning of vehicle before entry into poultry premises

2.14 When a poultry house or establishment is depopulated, all manure should be removed from the houses and effective cleaning and disinfection procedures applied. Bacteriological monitoring of the efficacy of disinfection procedures is recommended. When necessary, rodent and insect control procedures should also be carried out. The poultry house disinfection method is given in (Annex 6).

2.15 Stocking of poultry houses or establishments should only be made from poultry flocks of known high health status and which are regularly monitored for salmonella and other poultry pathogens.

2.16 All feed used in poultry houses and establishments should be monitored for *Salmonella* prior to use. The use of pelleted feeds or feeds subjected to other *Salmonella* decontamination procedures is recommended. Feed should be stored in clean, closed and dry containers or places.

2.17 The water supply to poultry houses should be of a satisfactory potable standard (Annex 7).

2.18 Sick and dead birds should be removed from poultry houses as soon as possible and effective and safe disposal procedures implemented. Dead birds from one house should not be brought inside another house in the due course of collecting dead birds. While disposing dead birds, consider the following:

2.18.1 All dead birds need to be stored in fly tight containers or screened houses or refrigerated boxes until removed from the farm.

2.18.2 When a burial pit is in use, care should be taken to ensure that scavengers do not have access to carcass, and seepage does not occur to cause spread of diseases.

2.18.3 Pits shall be sized to accommodate catastrophic mortality using appropriate weight to volume conversions. The burial pit should be a minimum of 4 feet wide with length necessary to accommodate mortality. Depth should accommodate a minimum of 2 feet of cover over the mortality. Pit bottoms should be relatively leveled. If more than one pit is required, they shall be separated by a minimum of three feet of undisturbed or compacted soil. The burial site should be finish graded to slightly above natural ground elevation to accommodate settling.

2.19 Daily records relating to mortality, sample collection, treatments and vaccinations should be maintained on an individual flock basis within the establishment. Such records should be readily available for inspection.

2.20 Disinfectant foot-bath for footwear is necessary and the disinfectant solution should be changed at least once in a week or more frequently if disinfectants become heavily soiled. Washing the hands in disinfectant solution or with soap and water should be required.

2.21 Farm workers should not keep other poultry in their houses and should not make any visit at other poultry farm without prior consent and without taking proper biosecurity measures.

2.22 The litter in the laying house should be kept dry and in good condition.

2.23 The nest box litter should be clean and adequate in quantity.

2.24 The hand of farm worker should be properly sanitized before every collection of hatching eggs from the shed. Eggs should be collected at least twice a day, cracked, odd size and misshaped eggs should be separated and should not be used for hatching.

2.25 The collected hatching eggs should be properly sanitized as soon as possible after collection and be stored in appropriate condition (clean, dust free room kept at temperature of 13-15°C and a relative humidity of 70- 80 %.)

2.26 The eggs should be transported to the hatchery in new or clean cases which have been fumigated or sanitized with a liquid disinfectant.

2.27 The birds in the breeding farm should be periodically monitored for Salmonellosis. Sample of fresh faeces (each sample at least one gram) or dead or culled birds on the premises in which

birds are housed are taken.

2.27.1 All samples should be selected at random to represent the house or in the case of samples taken at the hatchery to represent the hatching eggs from that poultry flock.

2.27.2 The following minimum frequency of sampling is recommended:

a. Rearing flocks

At day-old and 3 weeks before moving to laying accommodation

Where birds are moved from the rearing premises other than direct to laying accommodation, a further sample should be taken 3 weeks before such movement.

b. Breeding flocks in lay

The laying flocks should be sampled at least at monthly intervals during the laying period.

2.27.3 Following number of samples need to be taken on each occasion of sampling.

Number of birds in the flock	Number of samples to be taken on each occasion
25-29	20
30-39	25
40-49	30
50-59	35
60-89	40
90-199	50
200-499	55
500 or more	60

2.27.4 All samples should be fully marked and identified as to the date of sampling and the flock to which the samples relate. The samples should be stored in a refrigerator at between 1-4°C until they are dispatched to the laboratory (not more than 3 days).

2.27.5 All samples should be examined in a laboratory authorized for that purpose by the DLS

3. Biosecurity in Hatchery

Once adequate biosecurity measures are maintained at breeder farms, additional measures need to be taken in hatcheries so that healthy chicks can be delivered to the farmers.

Hatchery set up

1.1 The design of the hatchery should be based on suitable work flow and air circulation principles. It should be constructed so that there is a one way flow for the movement of eggs and chicks, and the air flow also follows this same one way direction.

1.2 The hatchery buildings should include physical separation of all work areas. If possible,

separate ventilation should be provided for these work areas, namely, the rooms for:

- Egg receiving and egg storage;
- Egg traying, egg grading;
- Fumigation;
- Setting or initial incubation;
- Hatching;
- Sorting, sexing and placing chicks in boxes;
- Material storage, including egg and chick boxes, egg flats, box pads, chemicals and other items;
- Facilities for washing equipment and disposal of waste;
- Room for employees to have meals;
- Offices and
- Personnel changing, showering and sanitary facilities.

Hatchery building hygiene

- 1.3** Openable windows, ventilators and other open areas should be screened against insects and vermin.
- 1.4** Wild birds, domestic and wild animals must be excluded from the hatchery area. When necessary, a specific programme for fly control should be implemented.
- 1.5** The area adjacent to the hatchery buildings should be surrounded by a security fence and a gateway to control all traffic.
- 1.6** The hatchery area should be maintained free from all hatchery waste, garbage of all kinds and discarded equipment.
- 1.7** Approved disposal methods and adequate drainage must be available.
- 1.8** All hatchery equipment, tables and horizontal surfaces in rooms must be promptly and thoroughly vacuumed, cleaned, washed, scrubbed, rinsed with clean water and finally disinfected with an approved disinfectant by DLS after each batch of operation.
- 3.9** Hatching eggs and day old chicks from different breeder flocks should be kept separate during incubation, hatching, sorting and transportation.
- 3.10** Clean coveralls, hats and footwear must be provided for all working personnel and visitors entering the hatchery.

Hygiene measures during the handling of eggs and day-old birds

- 3.11** Egg handlers in the hatchery should wash their hands with soap and water and change to clean outer garments before handling hatching eggs received from the poultry farm.
- 3.12** Chick sexers and chick handlers must wash and disinfect their hands and change into clean protective clothing and boots before commencing work and between different lots of chicks.
- 3.13** Day-old chicks must be delivered or distributed in new chick boxes.
- 3.14** The chicks should be delivered directly from the hatchery by personnel wearing clean, disinfected outer clothing. Outer clothing should be changed or disinfected between each delivery.
- 3.15** The outlet must be separate or away from the sheds.

Sanitization of hatching eggs and hatchery equipment

- 3.16** Sanitization refers a) Fumigation with formaldehyde, or (b) Spraying with or immersion in an egg shell disinfectant in accordance with the manufacturers instructions, or (c) Made hygienic by another method approved by the DLS. Fumigation procedure is given in Annex 8.
- 3.17** Monitoring for *Salmonella*: The samples to be taken are dead in shell and culled chicks. Additionally, it is recommended that environmental samples such as drag swabs, litter, feather, down and dust, are also taken in both the premises and the hatchery at a similar frequency. Where the laying flock is sampled only on the premises, environmental sampling of the hatchery is required.

Record keeping

- 3.18** Records on fertility and hatchability should be maintained in the hatchery.

4. Biosecurity in Broiler Farms

Broiler refers to the male or female chicken primarily kept for meat production. Following biosecurity measures in broiler farm are recommended:

- 4.1 Location:** Broiler farms should be ideally located in an isolated place at least at a distance of 200m from other poultry farms (Annex 1). Poultry houses within same farm should be at least 30 feet apart.
- 4.2 Site Set Up:** All farms are to have a sign at the entrance to the site, stating that this site is a biosecurity area and that all visitors are to contact the poultry broiler company or site manager before entry. All sites need to be clearly marked to prevent unauthorized entry. There should be secure fence with lockable gate.
- 4.3 Exclusion of Animals:** Other livestock species including domestic pets should be completely restricted from entry to the poultry sites with a physical barrier between poultry site and other livestock.
- 4.4 Drainage Requirement:** Drainage systems are required on the site to prevent pooling of water, as well as overflow onto defined pathways. Drains should be regularly maintained so water can flow freely through them and does not accumulate. Drains should be kept clean, free-flowing and free of vegetation.
- 4.5 Foot Bath Requirement:** There should be provision of foot bath in the main entrance and on doorstep of every broiler house. The use of foot bath should be ensured with
- Cleanliness of footwear prior to entering the foot bath
 - Cleanliness of the foot bath itself
 - **The frequency of changing the bath contents**
 - Approved chemicals are to be used

- 4.6 Clothing Requirement:** All visitors (including contractors) who go into the shed need to wear overalls, head cover and boots. Operations that are not all-in, all-out should provide clothing that is shed-specific. Clothing should be stored in a clean area and laundered or replaced after each use or on a daily basis. Clean and dirty clothing should be kept separately to prevent cross contamination.
- 4.7 Hand Hygiene:** All people should wash their hands with water and soap, or hand sanitizer, immediately prior to entering the shed and coming out from the shed. Hands should also be washed or sanitized:
- Before starting work, and before and after breaks
 - Before handling food, eating, drinking or smoking
 - After handling rubbish, birds or any litter
 - Before and after using the toilet
- 4.8 Vehicles:** Vehicle entry to sites will be kept to a minimum. Any vehicles not associated with essential services (e.g. delivery of feed, clean litter, or chicks etc.) should be parked in a defined parking area. The vehicle personnel for essential services should limit their activities to necessity only.
- 4.9 Equipment Sanitation:** Burrowing poultry equipment from other farm should be discouraged. All equipment used in transferring and/or spreading clean litter into sheds should be physically cleaned and sanitized. The standard is removal of all dirt, mud, feathers, manure, litter etc. and the thorough wetting of all surfaces with sanitizer. Equipment used in sheds should not be stored outside of sheds, unless there is a program to clean and sanitize prior to taking it into the shed.
- 4.10 Water Supply:** The water supplied to the broiler should be of potable quality. If using water from unsecured source or contaminated, need to be properly sanitized (e.g. chlorination).
- 4.11 Vermin and wild bird control:** A vermin and wild bird control program should be in place which could be achieved through:
- 4.11.1** Proper shed construction with no chance for the entrance of wild birds and vermin. Sheds should also be constructed in such a way to minimize roosting and nesting sites.
- 4.11.2 Exclusion of vegetation:** Site and shed surrounds will be kept clean, tidy and free of weeds and debris. Around the immediate vicinity of the shed, vegetation is to be kept short or cleared with herbicide where it is not possible to be kept short.
- 4.11.3 Storage shed exclusion:** Sheds and areas used for storing equipment and supplies (e.g. brooders, brooder paper etc) should be constructed to exclude wild birds and vermin to the best possible extent.
- 4.11.4 Wild bird discouragement:** Wild birds should be discouraged from gathering in and around sheds by ensuring the following measures are met:
- any feed spills from feed deliveries are immediately cleaned up and disposed of
 - any potential nesting sites on and around sheds and feed sites should be prevented, and where found, eliminated

- During clean-out, shed end doors are not to be left open, allowing the entry of wild birds.

4.11.5 Rodent Control Programme consists of

- Provision of bets and traps in possible sites to kill or avoid rodents.
- Keeping the premises and environment clean and tidy, and keeping vegetation from around sheds.
- Construction of shed not permeable to rodents.

4.12 Dead Bird Disposal: Dead bird disposal methods should not attract rodents, cats and/or dogs, or insects, and should comply with environmental requirements. Dead birds are to be removed from sheds whenever they are seen. Containers used for dead bird collection and transfer to disposal site should be thoroughly disinfected before re-entry into the shed and should be separate for each shed.

4.13 Harvest of Birds: Care should also be taken during the harvest of birds:

4.13.1 Vehicle and equipments: All equipment used during harvest - trucks, other vehicles, crates, forklifts and modules – should be physically cleaned and sanitized between sites to a visibly clean standard. Trucks, crates, modules and forklifts should be washed to a standard then completely wetted with sanitizer.

4.13.2 Catching crew clothing requirements: Catching crews should change into clean clothes, including hats, boots, and, gloves prior to each site visit, or between sheds on multi-age farms.

4.14 Clean-out: All repairs, maintenance and building should be done at intercrop, before cleaning and sanitation. All dirty litter should be removed from the site before sanitation of the sheds commences. All equipment brought on to any broiler site to clean out dirty litter should be thoroughly cleaned and disinfected before entering the site. The standard is washing off of all manure, dirt, feathers and dirty litter, and the complete wetting of all areas with sanitizer. Dirty litter will be removed in a covered container and taken from the site. Dirty litter should not be spread on the farm closer than **100m to sheds**.

All poultry broiler companies should have a detailed clean-out procedure, which should cover the following elements:

1. Dirty litter removal and containment of dirty litter, as well as procedures to clean up any areas of dirty litter spilled during removal.
2. Cleaning and sanitation of all shed equipment
 - Feeders and removal of feed
 - Drinkers
 - Equipment taken out of sheds (e.g. brooding curtain)
 - Brooders and heaters
 - Shed dividers
3. Cleaning and sanitation of internal shed surfaces.
4. Cleaning and sanitation of air intakes and vents.
5. Sheds should be dry prior to the introduction of clean litter.

6. Maintenance of integrity of shed floor and walls.
7. Prevention of site contamination from wet cleaning

4.15 Operation: All in all out operational procedure is recommended for broiler production. At least two week off period between batches in the shed is recommended for proper cleaning and disinfection.

4.16 Monitoring for (*salmonella*): Broiler flocks should be screened for *Salmonella* regularly.

4.17 Recording: Records on feeding, disease, mortality on the broiler flock, vaccination and medication should be maintained. Any unusual mortality in the flocks should be immediately reported.

5. Biosecurity in Layer Farms

Layers in this manual refer to female chicken kept exclusively for commercial table egg production. Following biosecurity measures in layer farm is recommended:

5.1 Location: Layer farms should be ideally located in an isolated place at least at a distance of 200m from other poultry farms. Poultry houses within same farm should be at least 30 feet apart.

5.2 Site set up: All farms should have a sign at the entrance to the site, stating that this site is a biosecurity area and that all visitors are to contact the site manager before entry. All sites need to be clearly marked to prevent unauthorized entry. There should be securely fenced with lockable gate.

5.3 Restrict entrance to other livestock including pets into the farm

5.4 Pullet rearing: Consider the following measures

5.4.1 Always purchase the day old chicks from trusted source with known health status

5.4.2 Clean/ disinfect houses and equipments between broods

5.4.3 Restrict and minimize traffic into farms and poultry houses

5.4.4 Follow personnel and vehicle sanitation procedures

5.4.5 Minimize exposure of flock to wild animals (Bird, rodents etc.)

5.4.6 Provide routine health monitoring of flock

5.5 Layer house biosecurity: Consider the following measures

5.5.1 Clean and disinfect house and equipment between flocks

5.5.2 Remove all manure and litter between flocks

5.5.3 Restrict wild animals

5.5.4 Restrict and minimize traffic onto the farm, into the houses and between flock

5.5.5 Strictly follow personnel and vehicle sanitation procedures

5.5.6 Minimize exposure of equipment, feed and flock to wild animals (bird, rodents)

5.5.7 Minimize bird contact with their faces, keep litter dry.

5.5.8 Maintain feed storage and delivery system clean and in good operating condition.

5.5.9 Provide fresh water to the birds that meets human consumption standard

- 5.5.10 Block access to stored feed by rodents and other animals
- 5.5.11 Maintain a routine flock health monitoring programme which incorporates the veterinary diagnostic support
- 5.5.12 Provide employees with easy and nearby access to clean restroom and hand washing facilities during work hours, instruct employees to wash hand before collecting eggs.
- 5.5.13 Maintain dead bird disposal area far from production facilities
- 5.5.14 **Minimize exposure of eggs to poultry faces**
- 5.6 **Record Keeping:** Records on feed consumption, egg lay performance, diseases and mortality should be maintained on the daily basis. Any unusual mortality should be immediately reported.
- 5.7 Avoid adding birds from other farm to compensate heavy mortality

Annex 1. Checklist to Implement an Effective Poultry Biosecurity Plan

Implementing any of these measures will reduce the risk of disease entry.

1 Keep equipment and poultry yard clean

- Remove litter, sand and grit from the poultry house between batches of birds, and every few months for resident birds
- Thoroughly clean concrete floors, walls and aviary wire with soapy water, and disinfect as needed
- Clean and disinfect feed and water containers regularly
- Don't share equipment with other bird keepers, unless it has been thoroughly cleaned and disinfected
- Remove dead bird immediately when found. Take appropriate measures while disposing dead birds, so that they are out of reach from dogs or wild animals.

2 Limit Visitors

- Allow entry to essential personnel only and avoid unnecessary access to bird area
- Provide visitors to put on clean protective clothing and use foot-baths containing appropriate disinfectants at the entrance to bird areas or sheds
- Keep records of visitors

3 Avoid contact between your birds and wild birds and maintain strong vector control programme

- Prevent contact with wild birds by restricting access to open ponds, lakes and creeks - protective netting can also help prevent wild birds from entering domestic bird areas
- Clean up surrounding areas to reduce shelter and hiding places for wild birds
- Avoid fruit trees in the poultry farm that attracts wild birds
- Maintain a strong vector control program for insect, mammalian and avian vectors. Maintain bait stations, clean up feed spills, prevent entry by wild animals (rats, birds, insects) or pets (cats, dogs). Use screens in windows, air inlets, doors, feed bin exhausts etc.
- Maintain minimal vegetation and no debris around poultry facilities to lessen food and shelter opportunities for vector

4 Create regular awareness among farm workers and adopt secured operational practices

- Ensure staff and visitors are aware of dangers of raising or visiting other avian species and their contact to your flock
- Staff should change into dedicated/ disposable boots and coverall upon entering each different shed. Clean footbaths may be appropriate within a shed if changed regularly
- Minimize entry of equipment, supplies etc. and take appropriate precautions such as disinfection, removal from shipping boxes etc.
- Ensure that feed, water and bedding sources are free from infectious agents

5 Quarantine new birds

- Avoid mixing new birds into existing flocks unless extremely necessary. In such circumstance, separate and monitor new birds for at least 30 days before introducing them to your existing flock
- Always source your birds from a reputable producer or breeder whose bird health status is known
- Always buy healthy looking birds and avoid buying them from markets
- Feed and clean quarantined birds **after** you have tended to other birds
- Encourage all-in all-out practices

6 Know the signs of illness/diseases

- swollen heads
- dullness
- drop in egg production
- respiratory distress
- diarrhoea
- loss of appetite
- sudden death of several or more birds

Other potential signs include:

- reluctance to move, eat or drink
- droopy appearance
- inability to walk or stand
- unusual head and neck posture.

7 Immediately report any unusual sick or dead birds (Mandatory)

- If any unusual symptoms have seen in birds or find that a number of them have died within a short period of time, be on the safe side and report it immediately to your local veterinarian or at authority at District Livestock Service Office.

8 Health and hygiene of farm workers

- Encourage farm workers to properly adhere on hygiene practices, regular monitor it and maintain good health of farm worker.

Review your biosecurity plan and flock health program, including vaccination protocol with your veterinarian on a regular basis. Self evaluation checklist of your farm and effective vaccination protocol are presented in Annex 3 and Annex 4 respectively.

Annex 2: Visitors' Log Book

Keep this Log Book in the Farm Entry Gate and ensure that it is filled each time visitors other than regular farm workers enter the farm

SN	Visitors' Name and address	Date and time	Purpose of visit	Last date of other farm visit	Poultry Shed entered	Visitor's Signature

Annex 3: Checklist for Level of Biosecurity Adopted in the Farm

A.Score 5 points for each “Yes” answer	Score
1. My poultry farm has only one age flock (all-in all-out)	
2. My farm is isolated from other poultry farm	
3. My replacement birds are raised in isolation at separate location	
4. My vaccination and disease prevention program are the result of the veterinary consultation and are continually updated	
B. Score 4 points for each “Yes” answer	
1. I routinely meet with neighbors who own poultry and other birds to discuss health problems and to plan area disease prevention	
2. My birds have been effectively vaccinated for each of the diseases prevalent in my area	
3. I check source of my replacement stock for disease problems	
4. I do not purchase hens as a part of my replacement program	
5. I have someone observe each flock every day for abnormal symptoms and maintain a dairy diary of flock health	
6. I routinely analyze my poultry production, feed consumption and mortality records for sign of problems	
7. Vehicles or people cannot enter my farm complex without the manager’s permission or knowledge	
C. Score 3 points for each “Yes” answer	
1. My poultry housing is animals and wild bird proof	
2. Houses are thoroughly cleaned and disinfected between flocks	
3. When vaccine are used, I record the brand name, serial numbers, expiration dates and how they were used and by whom	
4. I routinely have birds examined to monitor the health of my flocks	
5. Trucks for dead birds do not enter my farm gate	
6. Dead birds are picked up daily from the houses and stored in tightly closed container	
7. I have the farm communication system to minimize the movement of people on the farm	
8. Service crew members working on my farm bathe, put on clean clothing and disinfect all equipment before they enter the farm	
9. For necessary visitors, I provide clean, disinfected coveralls and boots that do not puncture or tear	
10. I never place more than one age group in a single house	
11. My employers do not travel to other poultry premises not under my control	
12. Egg crates and racks are cleaned and sanitized before they are brought on to my farm	
D. Score 2 points for each “yes” answer	
1. All service vehicles entering my farm are properly sanitized before entry and the drivers do not enter the poultry houses	
2. All manure equipment is cleaned before coming on my farm	

3. Farm employees work only in assigned areas, they do not go to other areas of the farm	
4. Dead birds are not carried out from house to house	
5. I have introduced my employees and service crews about poultry disease and about vaccination and treatment methods	
E. Score 1 point for each “yes” answer	
1. My employees do not poultry in the house	
2. Poultry waste from other farm is never spread on fields adjacent to my farm	
3. I have a continuous program to control rodents in the poultry houses and farm	
4. I have an effective fly control programme	
5. All visitors to my farm must sign a log book	
6. I regularly attend educational programs to keep abreast of new developments in disease control	
Total Score	

Guideline:

- If you score less than 60, you should take a hard look at your operation. The higher the score, the better is your farm biosecurity status. However, this checklist is just a start, add to or change it to make it most useful to you.
- Regardless of how well or how poor you scored, list your weaknesses and after consultation, establish your own priorities for improvement

Annex 4: Factors for Successful Vaccination Programme

Programme(s) Design	Administration	Effectiveness
Programme must be based on veterinary advice tailored to specific local and regional challenge based on health surveys and laboratory analysis	Follow manufacturer recommendations for product handling and method of administration	Seek veterinary advice prior to vaccinating sick or stressed birds
Single or combined vaccine must be carefully selected according to the health status of the flocks	Properly train vaccine administrators to handle, and administer vaccines	Periodic and efficient house cleaning followed by placement of new litter materials reduces the concentration of pathogens in the environment
Vaccination must result in the development of consistent levels of immunity while minimizing potential adverse effect	Maintain vaccination records	Adequate down time (2 weeks) between flocks helps to reduce the build up of normal house pathogens that can affect flock performance when reusing litter
Breeder programme should provide adequate and uniform levels of maternal antibodies to protect chicks against several viral diseases during the first week of life	When live vaccine are given in chlorinated water, use a vaccine stabilizer (such as non fat powder of liquid milk) added to the water prior to the vaccine to neutralize the chlorine, chlorine can reduce vaccine titre of cause inactivation	Regular audits of vaccine handling, administration techniques and post vaccinal responses are critical to control challenges and improve performances
Maternal antibodies may interfere with the chicks' response to some vaccine strains. Level of maternal antibodies in broilers will decline as the breeder source flock ages		Ventilation and management should be optimized post vaccination, especially during times of vaccine induced reaction

Annex 5: Vehicle Cleaning and Disinfection Procedures

Step-by-Step Practical Guide to Vehicle Cleaning and Disinfection

To help prevent the spread of disease via transportation, adopt the following procedures for vehicle cleansing and disinfection.

1. Before commencing, ensure you are wearing clean and disinfected personal protective gears consisting of waterproof coveralls, boots, gloves and goggles.
2. Once all modules are removed scrape and brush soiling/litter from the transporter deck.
3. Enclosed trailer only, scrape and brush the sidewalls, floor and tail lift of the vehicle
4. Remove any deposits of mud, straw etc from the wheels, wheel arches, mudguards and exposed chassis.

Cleansing and Rinsing

Using an appropriate detergent solution, soak all surfaces of the vehicle allowing at least 10 minutes contact time for it to penetrate and loosen dirt.

1. Clean the outside of the vehicle, start at the top and work down each side, wash the transporter deck thoroughly and pay particular attention to the wheels, wheel arches & mudguards.
2. Inside (if applicable), soak the ceiling, sidewalls and floor of the vehicle.
3. Wash the tail lift thoroughly (where applicable).
4. Wash all vehicle equipment, tools and the belly box
5. After washing is complete high pressure rinse all surfaces with clean water and check that they are clean of any muck or debris.

Disinfection

Apply a suitable broad spectrum viricidal disinfectant solution to all vehicle surfaces.

1. Outside, start at the top and work down each side and over the transporter decking, paying particular attention to the wheels, wheel arches mudguards and underside of vehicle.
2. Inside (if applicable), ensure that the ceiling, sidewalls and floor of the vehicle are disinfected thoroughly finishing the procedure on the tailgate (if applicable).
3. Disinfect all vehicle equipment and belly box.
4. Remove all removable items e.g. mats and boots from the vehicle cab and brush any debris or mud into a bucket or dustpan. Dispose of the cab waste into a refuse sack.
5. Wash the cab floor, mats and vehicle pedals with heavy-duty detergent and leave for 10 minutes allowing for the solution to penetrate and loosen dirt, then rinse with clean water.

Annex 6: Cleaning and Disinfection of Poultry Houses

First, clean

1. Remove all bedding, feed, and manure.
2. Sweep out loose dirt, cobwebs, etc.
3. Scrub all surfaces with a detergent/disinfectant. A high-power sprayer may be helpful
4. Rinse all detergent and organic matter from surfaces.

Next, disinfect.

5. Apply the disinfectant.
6. Allow the disinfectant to dry completely.
7. Reapply the disinfectant and allow it to dry a second time (optional).
8. Bed the area with fresh materials and clean, disinfect, rinse, and dry all water and feeding equipment before refilling them.

Choosing a disinfectant: The lethal action of disinfectants for various pathogens (viruses, bacteria, fungi, protozoa) depends on the chemical composition of the disinfectant and the make-up of the organism. When choosing a disinfectant, consider these characteristics:

- Cost
- Efficacy (killing efficiency against viruses, bacteria, fungi)
- Activity with organic matter
- Toxicity (relative safety to animals)
- Residual Activity
- Effect on fabric and metals
- Activity with soap
- Solubility (acidity, alkalinity, pH)
- Contact time
- Temperature
- Concentration.

No disinfectant works instantaneously. All require a certain amount of contact time to be effective. Temperature and concentration of disinfectant influence the rate of killing of microorganisms. Using the recommended concentration of disinfectants is important. The activity of many disinfectants improves markedly if the temperature is increased.

Annex 7: Drinking Water Quality for Poultry

Quality parameter	Level considered average	Maximum tolerable limit	Desirable
1. Bacterial			
Total bacterial count	0/ml	100/ml	0/ml
Coliform bacteria	0/ml	50/ml	0/ml
2. Nitrogen compound			
Nitrate	10mg/l	25mg/l	
Nitrite	0.4mg/l	4mg/l	
3. Acidity and hardness			
pH	6.8-7.5	Not less than 6.0	
Total hardness	60-180		
4. Naturally occurring chemicals			
Calcium	60mg/l		
Chlorine	14mg/l	250mg/l	
Copper	0.002mg/l	0.6mg/l	
Iron	0.2mg/l	0.3mg/l	
Lead		0.02mg/l	
Magnesium	14mg/l	125mg/l	
Sodium	32mg/l		
Sulphate	125mg/l	250mg/l	
Zinc	1.5mg/l		

Source: Schwartz, D. L., "Water Quality," VSE, 81c., Penn. State Univ. (mimeographed); and R. Waggoner, R. Good, and R. Good, "Water Quality and Poultry Performance," in Proceedings AVMA Annual/ Conference, July, 1984.

Annex 8: Fumigation Procedure

For fumigation, three levels of concentration have been used. Also, two methods of use have been adopted.

1. Method 1
 - a. Concentration A: 53 ml formalin (37.5%) and 35 g potassium permanganate per m³ of space
 - b. Concentration B: 43 ml formalin (37.5%) and 21 g potassium permanganate per m³ of space
 - c. Concentration C: 45 ml formalin (40%) and 30 g potassium permanganate per m³ of space
 - d. Procedure

Fumigation of hatching eggs and equipment should be carried out in a special chamber or in a room or building constructed of impermeable material which can be made as airtight as possible. A fan is necessary to circulate the gas during fumigation and to expel it after fumigation is completed.

The total volume of the room is determined accurately from the internal measurements. The space occupied by trays, or eggs, or articles to be fumigated, is to be disregarded. The quantities of materials required are based on the total volume.

Place in the centre of the floor, one or preferably several large metal basins, metal trays or containers of earthenware, enamelware, asbestos or other non-inflammable material. Fumigation procedures at the hatchery

1. Fumigation of eggs in setting machines

Eggs should be fumigated within 12 hours after setting and after the temperature and humidity has returned to normal operating levels. The temperature of the machines must remain at the operating level.

The setting machine doors and ventilators should be closed, but the circulation fan should be kept operating.

After fumigation for 20 minutes, the ventilators should be opened to the normal operating position in order to release the gas.

Warning

Do not fumigate eggs that have been incubated for 24 to 96 hours, as this can result in embryo mortality.

2. Fumigation of eggs in hatching machines

This is a common practice in certain areas and under certain conditions. The eggs should be fumigated after being transferred from the setting machine to the hatching machine and before **10% of the chicks have begun to break the shell**. After transfer of the eggs, the hatching machines are permitted to return to normal operating temperatures and

humidity. The ventilators are closed and fumigation is conducted with the fans running. The standard amounts of formalin (53 ml) and potassium permanganate (35 g) per m³ are used. Fumigation time is 20 minutes.

3. Fumigation of empty setting and hatching machines

Following removal of all the eggs or the chicks and the subsequent cleaning and disinfection of the empty machine, the disinfected egg trays are replaced and the machine prepared for the next batch of incubating eggs.

The doors and ventilators should be closed and the temperature and humidity returned to normal operating levels. Fumigation time should be at least 3 hours or preferably overnight, using the standard amounts of formalin and potassium permanganate (Concentration A).

The machines should be well ventilated before use to remove any residual fumigant.

Warning

The above fumigation procedure applies to a machine in which there are no hatching eggs. Eggs and chicks cannot be fumigated using the above fumigation time.

4. Neutralization of formaldehyde gas

This can be achieved with a 25% solution of ammonium hydroxide using an amount not more than one half the volume of formalin used. The ammonia can be spread on the floor of the machine and the doors closed quickly.

Annex 9: Effective and Available Disinfectants

Disinfectants	Preventive Spray Rate	Spray rate during disease outbreak
TH4+ liq. (<i>Solvay</i>)	5 ml./liter of water	10 ml./liter of water
Khorsolin TH liq. (<i>Virbac</i>)	25 ml./5 liters of water	200 ml./5 liters of water
Omnicide liq. (<i>Vetcare</i>)	7 ml./ liter of water	10 ml./ liter of water
Virkon – S pv. (<i>Pfizer</i>)	5 gm./ liter of water	5 gm./ liter of water
Qualitrol liq. (<i>Ranbaxy</i>)	100 ml./ 25 liters of water	100 ml./ 25 liters of water
B 904 liq. (<i>Venky's</i>)	4 ml./ liter of water	10 ml./ liter of water