



Third Laboratory Directors Meeting and Workshop on Biorisk Management in SAARC Countries

*05-06 March 2014
New Delhi, India*



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Acronyms and abbreviations

ASEAN	Association of South East Asian Nations
BLRI	Bangladesh Livestock Research Institute
BSC	Biological Safety Cabinet
CDC	Centre for Disease Control
ECTAD	Emergency Center for Transboundary Animal Disease
EID	Emerging Infectious Disease
EMPRES	Emergency Prevention System for Transboundary Animal, Plant Pests and Diseases
EPT	Emerging Pandemic Threats
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FMD	Foot and Mouth Disease
GLP	Good Laboratory Practice
HPAI	Highly Pathogenic Avian Influenza
HPEDs	Highly Pathogenic Emerging Diseases
LMT	Laboratory Management Tool
LPB-ELISA	Liquid Phase Blocking ELISA
ME-SA	Middle East-South Asia
NARC	National Agricultural Research Centre
NDV	New Castle Disease Virus
OIE	World Organisation for Animal Health
PDFMD	Project Directorate on Foot and Mouth Disease
PPE	Personal Protective Equipment
PPR	<i>Peste des Petits Ruminants</i>
PT	Proficiency testing
QA	Quality Assurance
QM	Quality Management
RAP	FAO Regional Office for Asia and Pacific
RLDL	Regional Leading Diagnostic Laboratory
RLN	Regional Laboratory Network
RSU	Regional Support Unit
SAARC	South Asian Association for Regional Cooperation
SEA	South East Asia

SOPs	Standard Operating Procedure
TADs	Transboundary Animal Diseases
TAG	Technical Advisory Group
WHO	World Health Organization

Summary

The Food and Agriculture Organization of the United Nations (FAO) is implementing a European Union (EU)-funded regional project entitled “Regional Cooperation Programme on Highly Pathogenic and Emerging Diseases (HPED) in South Asia” under the umbrella of the South Asian Association for Regional Cooperation (SAARC) at FAO Sub-regional ECTAD Unit in Kathmandu, Nepal. The overall objective of the project is to strengthen and empower SAARC countries in their ability to prevent, control and eradicate HPED, including HPAI, through improved veterinary and public health services and inter-sectoral collaboration on a regional basis.

To fulfil the mandate of the project, SAARC Regional Leading Diagnostic Laboratories (RLDLs) have been established in Bangladesh (PPR), India (FMD) and Pakistan (HPAI) as agreed by the member countries. These laboratories are co-coordinating and leading a network of national diagnostic laboratories, primarily focusing to maintain uniform diagnostic standards, support training of laboratory scientists/technicians from the member states, and backstop regional surveillance and epidemiological studies. The activities are also being supported by the international OIE and FAO reference laboratories like the Australian Animal Health Laboratory, Geelong, Australia and the High Security Animal Disease Laboratory, Bhopal, India.

The RLDLs implemented a number of laboratory activities including trainings in laboratory diagnostic protocols for regional priority diseases and implementation of proficiency testing (PT) programmes in the region. The proficiency testing of National FMD laboratories is ongoing since September 2012 in Bangladesh, Bhutan, Nepal and Sri Lanka. The RLDLs also supported the standardization of diagnostic technologies and instrumentation besides setting up FMD virus typing facilities in Bhutan and hands-on PCR training on HPAI diagnosis in Bangladesh.

The laboratory networking was initiated in March 2011 followed by the First Laboratory Directors’ Meeting and Workshop on Laboratory Networking and Proficiency Testing for Priority HPEDs in SAARC Countries in January 2012 in Dhaka, Bangladesh. This was followed by the Second Laboratory Directors’ Meeting and Workshop on Enhancing the Laboratory Expertise through Quality Management Systems in March 2013 in Colombo, Sri Lanka.

In the same series the Regional Support Unit, based in the FAO’s Sub-regional ECTAD Unit in Kathmandu, organized the “Third Laboratory Directors’ meeting and workshop on Biorisk Management in SAARC countries” from 5-6 March 2014 in New Delhi, India with support from the European Union.

The frequent outbreaks of emerging and re-emerging diseases in recent years have raised concerns over the preparedness of the animal-health and human-health communities in responding to outbreaks of novel infectious diseases. The biorisk management in laboratories

required to handle infectious agents is presently well recognized as a necessary infrastructure in infectious diseases preparedness and response.

The requirement for biorisk management in microbiology laboratories and animal facilities raises the need to assess the capacity and to identify key areas that require action to enhance laboratory capacity to appropriately and safely handle pathogens.

There is need for emphasis on biorisk management systems, including biorisk assessment, biorisk mitigation, and biorisk management system performance in the SAARC countries.

The main objective of this meeting is to keep the Directors' of Regional Leading Diagnostic Laboratories and key national laboratories updated on the ongoing activities related to laboratory capacity building and laboratory networking in South Asia. The ultimate goal of this meeting is to provide a platform to discuss problems and issues related to the national veterinary diagnostic laboratories and the Laboratory Networks within the member states in the SAARC region. The meeting discussed the following issues:

- i. The Directors' forum will take the lead to organize annual coordination meetings to review, assess and plan network activities on sharing of information and enhancing the laboratory expertise;
- ii. Advocacy for support to sustain regional laboratory networks;
- iii. The current status/activities and expectations of the national veterinary diagnostic laboratories, problems and challenges for collaborating among laboratories; and
- iv. Support of biorisk management implementation/strengthening in the national laboratories.

The meeting and workshop was attended by 15 participants from the SAARC countries including Afghanistan, Bangladesh, Bhutan, India, Nepal, Pakistan and Sri Lanka with technical support from the Mahidol Oxford Tropical Medicine Research Unit (MORU), Thailand, Bangkok and FAO ECTAD, Kathmandu, Nepal.

The expected outcomes of the meeting were:

1. To prepare and agree on a Regional Framework for laboratory capacity building and networking in South Asia and on the ways to strengthen the in-country / national laboratory networks in addition to regional laboratory networks
2. To agree on implementation and support for biorisk management strengthening in the national laboratories

The laboratory Directors made presentation on the mandate, facilities available, constraints and challenges in implementation of biorisk management.

Based on the deliberations of the Third Laboratory Directors' meeting and workshop on Biorisk Management Systems, the following main recommendations were drawn;

Recognising that;

1. National Animal Disease Diagnostic Laboratories are responsible for supporting the disease surveillance programmes in their respective countries, towards early detection and response in a timely manner.
2. Regional Laboratory Networks have enhanced laboratory capacity for the diagnosis of priority diseases, and promote sharing of reagents, biological materials and information.
3. The Laboratory Directors' Meeting can provide a platform to discuss regionally relevant problems of mutual interest and issues among national and leading laboratories of SAARC Region.

The Meeting recommended;

1. Institutionalise the SAARC Laboratory Directors' Forum with commitment to organise annual meetings with participation from the National and Regional Leading Diagnostic Laboratories.
2. The meeting recommends that towards institutionalisation of the Directors' forum a Chair of the forum be established with host country chairing the forum/network until the next annual meeting.
3. There is need to constitute a technical advisory group (TAG) to guide and monitor the activities in the region.
4. Regional Leading Diagnostic Laboratories (RLDLs) should take initiative to ensure full ownership of the network and support capacity building and laboratory networking activities on a long term basis.
5. Guidelines and programmes may be developed to address the deficiencies in implementing quality assurance (QA), quality management (QM), biosafety and undertake trainings as a priority activity.
6. The RLDLs/Regional FAO/OIE Reference Laboratories should make efforts to get their laboratories accredited as per ISO guidelines (ISO 9001/ ISO/IEC 17025).
7. The Laboratory Directors' forum recognised the need for in country hands-on trainings provided by RLDLs/OIE Reference Laboratory experts.
8. Assess specific needs on biosafety management and constraints, through consultation with laboratory staff, using international standard biosafety regulations.

Background

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The requirement for biorisk management in microbiology laboratories and animal facilities raises the need to assess the capacity and to identify key areas that require action to enhance laboratory capacity to appropriately and safely handle pathogens.

There is need to emphasise on biorisk management systems, including biorisk assessment, biorisk mitigation, and biorisk management system performance in the SAARC countries.

Objectives of the meeting/workshop

The main objective of this meeting was to keep the Directors' of Regional Leading Diagnostic Laboratories and key national laboratories updated on the ongoing activities related to laboratory capacity building and laboratory networking in South Asia. The ultimate goal of this meeting was to provide a platform to discuss problems and issues related to the national veterinary diagnostic laboratories and the Laboratory Networks within the member states in the SAARC region. The meeting discussed the following issues:

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The meeting expected the following outcomes

The Laboratory Directors' agreement:

1. To prepare and agree on a Regional Framework for laboratory capacity building and networking in South Asia and on the ways to strengthen the in-country / national laboratory networks in addition to regional laboratory networks
2. To agree on implementation and support for biorisk management strengthening in the national laboratories

DAY ONE

Inaugural session

The inaugural session started with the welcome by Dr Mohinder Oberoi, ECTAD Sub-regional Manager, Kathmandu, Nepal. He introduced the participants about the purpose, background and expected outputs of this meeting. He informed that the Regional Cooperation Programme on Highly Pathogenic Emerging Diseases (HPEDs) in South Asia was funded by

European Union with the help of SAARC Secretariat and implemented by FAO. He highlighted that under this project several activities were conducted for last several years in the areas of policy, laboratory diagnosis and epidemiology. He narrated that in 2005 it was agreed by the SAARC member states to control transboundary animal diseases (TADs) with regional cooperation. He informed that Asian Development Bank has agreed to provide two million USD to support this important programme for another 2 years from mid 2014. Under this regional cooperation programme laboratories for HPED like FMD, PPR and HPAI have been established and recognized in three Member States, and in a limited manner strengthening of epidemiology unit and supply of equipment to RLDLs has been done. He informed that several gaps have been identified in Reference as well as National Laboratories which needs to be filled up. He emphasized to develop strong regional coordination.

Dr Suresh S Honnappagol, Animal Husbandry Commissioner to Government of India and Chief Veterinary Officer, Department of Animal Husbandry, Dairying and Fisheries, Ministry of Agriculture, India in his remarks extended warm welcome to all the participants. He narrated the importance of biosafety and biosecurity to combat and control TADs. He highlighted the importance of regional collaboration in eliminating HPEDs from the region. He appreciated the RLDLs for performing diagnosis and regional backstopping. He showed concern for important disease like HPAI where unprecedented outbreaks, stamping out policy, emergence of subtype are a matter of discussion. He suggested rethinking for development of a more potent vaccine. He informed that in recent past southern India encountered several FMD incidences and death due to secondary complications. He was of the opinion that focus of research need to be changed to develop strains and varieties of animals that have disease resistance gene to improve food hunger and protein requirement.

Dr Mohinder Oberoi, ECTAD Sub-regional Manager, Kathmandu, Nepal provided a background of the Laboratory Directors' meeting and update on SAARC regional network activities. He narrated key mandates of Regional Support Unit, Regional Epidemiology Centre and Laboratory Coordination Mechanism. He also informed about the functioning of RLDLs and Reference Laboratories in the SAARC region. He discussed the key mandates of laboratory coordination and emphasized that Reference Laboratories have to play the key role in strengthening the RLDLs for reliable diagnosis and surveillance of priority HPEDs. He discussed initiation of Laboratory Networks in South Asia where diagnostic laboratory and surveillance network coordination for control and prevention of avian influenza was launched in 2005 and that was followed up by a regional workshop on laboratory networking in 2010 funded by European Union. Subsequently three laboratory directors' meetings were held. He also reminded about the recommendations of the second meeting to take in to consideration for developing recommendations of the present meeting.

Technical Session 1: Organize Laboratory Networks on Sharing of information

Dr Venkatasubbarao Mandava, former Laboratory Coordinator, Regional Support Unit/Sub Regional ECTAD, FAO, Nepal presented 'Role of laboratory networks in epidemiology and disease surveillance'. He explained the objective of laboratory network to upgrade and

maintain national and regional laboratory capacity for reliable diagnosis and surveillance of priority TADs and zoonoses. He discussed the core functions of this network at various levels and how to build the networks. He narrated about the organization of the laboratory networks to respond to the demands of epidemiological and surveillance networks at national level and also the regional networks. He was of the opinion that building a well-organized diagnostic laboratory network forms the basis of successful surveillance of HPEDs and their control. He discussed about the organization of laboratory networks and institutional position in surveillance network. He discussed the role and challenges of regional laboratory networks. He emphasised the role of laboratories in disease surveillance prior to outbreak, at the time of the outbreak and inter outbreak period and also the importance of establishing links between laboratory and surveillance networks.

Dr Aparna Singh Shah, Regional Adviser, Blood Safety and Laboratory Technology, World Health Organization (WHO) Regional Office for South-East Asia, New Delhi, India presented 'Cross-sectoral collaboration to develop harmonized laboratory procedures and protocols for zoonotic diseases'. She introduced that WHO works with a goal of attainment of health of highest possible level by all peoples. She informed that WHO is providing leadership on matters critical to health and engaging in partnerships where joint action is needed in addition to monitoring the health situation and assessing health trends. She discussed about the pre-requisites of control of infectious diseases and reliable laboratory health capacity. She discussed the international health regulations where laboratory plays a key role in detection, verification and risk assessment to respond to public health emergency events of international concern. She informed about the WHO Collaborating Centres for Zoonosis/ EIDs in South East Asia (SEA) and WHO informal Regional Network of Laboratories for various diseases. She informed that WHO has been promoting international/intersectoral collaborations to prevent and control zoonosis mainly for the priority diseases like avian influenza, rabies, leptospirosis, brucellosis and anthrax.

Technical Session 2: Overview of activities of SAARC laboratory Network Members in 2012

Dr B Pattnaik, Project Director, PD-FMD and RLDL (FMD), Mukteswar, India presented the over view of the activities undertaken at FMD RLDL during 2013. He informed about the trainings organized on diagnosis and surveillance of FMD and also the reagents supplied to the SAARC countries. He informed that round 1 of proficiency test has already been completed and round 2 samples are provided during this meeting. He explained in detail about the clinical samples diagnosed, isolated in cell culture and characterized at RLDL-FMD, Mukteswar during 2013. He presented the FMD virus serotype distribution during 2012-13 which revealed isolation of serotype O from all over the country. Molecular characterization revealed complete dominance of Ind2001 lineage of Middle East-South Asia (ME-SA) topotype in serotype O, genotype 18 in serotype A and lineage C in serotype Asia1.

Dr Md Rafiqul Islam, Director (In charge) from RLDL PPR, Bangladesh Livestock Research Institute, Dhaka, Bangladesh presented an overview of the activities of SAARC

RLDL for PPR. He informed that quality assurance document have been prepared and implemented at the laboratory that includes standard operating procedures on laboratory biosafety, biosecurity, laboratory tests and general housekeeping. He informed that several diagnostic facilities are available at RLDL for PPR diagnosis and surveillance. He discussed the present activities of PPR-RLDL including diagnostic services provided. He informed that several outbreaks were investigated by RLDL in 2013, and sequencing and phylogenetic analysis revealed prevalence of lineage IV PPR virus. He also highlighted the future plan of work for 2014 at National and Regional level.

Dr Naila Siddique, Programme Leader, SAARC RLDL for HPAI, National Agricultural Research Centre (NARC), Islamabad, Pakistan, gave an overview of activities of RLDL during 2013. She discussed about the network of national avian disease surveillance programme in Pakistan. She mentioned that a large number of clinical and serum samples were tested under this project for virus/bacteria isolation and detection. She also presented the trend chart for referral identification of major poultry pathogens during 2013 where throughout the year H9N2 influenza virus, Newcastle disease virus (NDV) and *E. coli* could be isolated. She told that the laboratory organized a regional training on differential diagnosis of avian influenza (AI) and Newcastle disease (ND) for the participants from five SAARC countries. She discussed harmonisation of protocols and capacity building including other allied activities. She informed that the laboratory received ISO 17025 accreditation. She shared that phylogenetic analysis of fusion protein of Pakistani virulent NDVs and H14 HA of AI revealed emergence of a new sub genotype (VII-F) of NDV and re-emergence of rare AIV subtypes in Asia.

Dr Harshad V Murugkar Principal Scientist and Biosafety Officer, High Security Animal Disease Laboratory, OIE Reference Laboratory for Avian Influenza, Bhopal, India presented OIE reference laboratory activities during 2013. He informed that the laboratory performed diagnosis including pathotyping on large number of clinical and serum samples from India. Samples received from Nepal and Bhutan was also confirmed by this laboratory. Hands-on- training was organized to personnel from OIE member countries of Nepal, Bhutan, Bangladesh and Sri Lanka. Under ASEAN-India cooperation Fund, two training programmes on laboratory diagnosis of TADS were also organized for 14 participants from 8 Nations in two batches. The laboratory participated in OIE reference laboratories in proficiency testing network. The laboratory provided comments on Chapter 2.3.4 of the OIE terrestrial manual of diagnostic tests and vaccines and disseminating avian influenza information.

Dr Harshad V Murugkar, Bhopal, India informed about the biorisk training for laboratory and engineering personnel and equipment maintenance. He informed that the laboratory is providing education and training on biosafety measures for handling high risk animal pathogens, transboundary animal diseases and genetically modified organisms. He described about the biosecurity practices in place at the laboratory including use of personal protective equipment.

Dr Aniket Sanyal, FAO National Consultant RLDL FMD, Mukteswar presented the progress of proficiency testing of four FMD laboratories conducted in the SAARC region. The analysis of results indicated that all laboratories performed well with most results reported within one dilution of the median for all the serum samples of PT panel. Results analysed for all the three serotypes using Youden plots and Z-score indicated that all laboratories fall within the ellipse with no outliers which indicate lack of random errors. He informed that the laboratory is providing the second round of PT samples for testing in four FMD gene pool-2 countries.

Technical Session 3: Expectations of National Diagnostic Laboratories from the OIE Reference and Regional Leading Diagnostic laboratories

The participants were divided in two working groups to discuss the issue. The groups came out with the following inputs.

Input from Group 1

Country	Expectations from FMD laboratory
Common comment	<ul style="list-style-type: none"> • Institutionalization of laboratory directors meeting annually • Initiate the formal network for data sharing • Provision for frequent trainings • Training of personnel for PCR and sequencing • Establishment of database for gene sequences for each country
Sri Lanka	<ul style="list-style-type: none"> • Initiate the development of formal network for data sharing • Communication to be made through teleconferencing or social network (Skype) • Help in vaccine production • Once in three months to meet/ talk on phone • Sharing expertise
Nepal	<ul style="list-style-type: none"> • Sending of samples to the reference centre • To work out the mechanism of samples submission including the courier facility • Mechanism for continuity of kit supply after completion of the project • Visit of scientist/ staff from the regional laboratory or mechanism of technical backstopping visit
Bangladesh	<ul style="list-style-type: none"> • Support for indigenous diagnostic kit development (validation) •
India	Support for inter-laboratory validation for newer kits

Country	Expectations from PPR laboratory
Sri Lanka	<ul style="list-style-type: none"> • Help required to acquire PPR free status
Nepal	<ul style="list-style-type: none"> • Support in Quality Assurance of vaccine • Supply of diagnostic kits • Funding mechanism to be established for planning of eradication of PPR in SAARC countries
Bangladesh	<ul style="list-style-type: none"> • Follow/ development of SOP for sample submission to the regional laboratory •
India	Support for inter-laboratory validation for newer kits

Country	Expectations from HPAI laboratory
Sri Lanka	<ul style="list-style-type: none"> • Help required in sero-monitoring • To develop surveillance plan to acquire free status
Nepal	<ul style="list-style-type: none"> • Support to national laboratory in accreditations • Support in Quality Assurance of laboratory protocols • Supply of kits
Bangladesh	<ul style="list-style-type: none"> • Establishment of control strategy

Input from Group 2: The inputs from the group on expectations from Reference laboratories and RLDLs are summarised below

FAO/OIE Laboratory	RLDL
<ul style="list-style-type: none"> • Certified reference material for test validation • Onsite Capacity building of Specific technique considering time constraints according to the laboratory resources • Regular review meeting of key/resource persons from national laboratories • Sharing of information regarding new variants/new SOPs developed and its 	<ul style="list-style-type: none"> • Continuous supply of diagnostic kits on regular and on requirement basis • Provision of Reference antigens/biologicals/ test kits (with sufficient shelf-life) for diagnostics validation • Guidance on shipment of samples should be provided considering logistics of specific country • Training programme offered should be based on the knowledge level of the trainee • Onsite capacity building of specific technique considering time constraints according to lab resources • Regular visit for onsite training and capacity/ competence assessment of particular laboratory

further application	<ul style="list-style-type: none"> • Regular PT provision • Regular review meeting of key/resource persons from national laboratories • Sharing of information regarding new variants in the region/new SOPs developed and further application
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DAY TWO Workshop on Biorisk Management Systems

Session 4: Quality Management system: Why Quality Systems are essential for good laboratory practices:

Dr Stuart D Blacksell, the FAO Regional Biosafety Coordinator, Bangkok, Thailand presented the outline of FAO Regional Biosecurity programme. He informed that biosafety is about managing infectious disease risk in laboratories and must be driven by management. He told that fundamental of biosafety and biorisk management lies in planning, doing, checking and acting. He discussed about biosafety documentation and management including hazard and risk assessment. He discussed about FAO regional biosafety programme, on-site laboratory assessment protocol and training. He informed about the biological safety cabinet (BSC) testing at various laboratories as per the standard. He also discussed about the FAO laboratory mapping tool (LMT) which was developed as a standardised matrix to assess laboratory capacity and infrastructure. He was of the opinion that it is better to have BSL2 facility with BSL3 practices to minimize the cost of running the facility. He concluded that continuing biosafety development is not possible without commitment, ongoing support and dedicated budgets from national governments, donors, laboratory management and staff.

This was followed by the presentations from RLDLs on challenges in implementation of biorisk management system.

Dr B Pattnaik, Project Director, PD-FMD and RLDL (FMD), Mukteswar, India informed that management of the risks concerning laboratory biosafety and biosecurity should be handled as per the SOP. He discussed the challenges of handling FMDV and stressed that bio-security should be implemented at the farm/ village level to prevent the spread of virus. Policy makers need to be sensitized about what facility is required for which virus. He was of the opinion that entire BSL laboratory must be covered under surveillance and SOP must be validated for decontamination of materials/ biologicals/ carcass free from the live agent/ infectious genome.

Dr Naila Siddique, Programme Leader, RLDL for HPAI, Islamabad, Pakistan, gave an overview of challenges in implementation of biorisk management systems at RLDL-HPAI. She informed that handling of HPAI requires high level biosafety and laboratory bio-security during transportation of material and in-field investigations. She discussed expectations from laboratory personnel's and challenges despite advances in technology, the availability of more and more sophisticated instruments, increasingly effective techniques and the availability of personal protective equipment. The key issues and constraints like

mobilization of human and financial resources, lack of awareness at highest level of policy makers, lack of policy / regulatory standards, inadequate resources and infrastructure and lack of sufficient technical expertise were highlighted for improvement.

Dr Md Rafiqul Islam, Director (In charge), RLDL PPR, Bangladesh presented the challenges in implementation of biorisk management systems at RLDL-PPR. He discussed about the waste management of the laboratory and accountability to important biological materials. While narrating the challenges in implementation of biorisk management systems in RLDL-PPR, he informed that there is a need of making biosafety and biosecurity an organisational culture. There is lack of trained manpower and resources, institutional plan for bio-risk management and continuous risk assessment and plan for improvement.

Dr Harshad V Murugkar Principal Scientist and Biosafety Officer, High Security Animal Disease Laboratory, Bhopal, India presented challenges for the laboratory biosafety in India where biosafety laboratory construction and commissioning, availability of financial resources on a sustainable basis and availability of biosafety specialists are of concern.

Group discussion on biorisk systems suitable for Veterinary Diagnostic laboratories in SAARC region.

The two groups came out with the following outputs:

Biorisk need for Laboratory

1. Development of policy frame work for the protection of lab workers
2. Biosafety cabinet testing and validation
3. Onsite training on SOPs and risk assessment for important pathogens in the laboratory
4. Road map for biosafety in the field (training on biosafety precautions during field sample collection)
5. Training and support for implementation of biosafety measures especially to personnel given the responsibilities of maintaining laboratory biosafety
6. Technical assistance on infrastructure development for implementation of biosafety programme in the laboratory
7. Technical assistance on installation and operation on solid waste disposal plant
8. Periodic review of biorisk management standards by competent authority.
9. Formation of TAG on biorisk management according to local conditions in SAARC regions

10. Onsite training with baseline material of LMT for biorisk assessment tools to validate laboratory, gap analysis and their solution
11. Onsite training for TOTs in respect of laboratory and field staff
12. Support to the National Biosafety Association in terms of training materials

**Proposed Road map for development of biorisk management systems in RLDLs –
Dr. Stuart Blacksell**

Background

Recent expansion of the human population, international trade and travel has enhanced the risk of being exposed to virulent pathogens in humans and animals. The frequent outbreaks of emerging and re-emerging diseases in recent years have raised concerns over the preparedness of the animal-health and human-health communities in responding to outbreaks of novel infectious diseases. The biosafety and biocontainment in laboratories required to handle infectious agents is presently well recognized as a necessary infrastructure in infectious diseases preparedness and response.

The ASEAN Regional Laboratory Network and Biorisk activities experience

Strengthening national laboratory capacities, collaboration as well as information sharing among the laboratories within the region through the “Regional Laboratory Network (RLN)” is essential for the effective surveillance and control programme against transboundary animal diseases in the Southeast Asia (SEA). In Southeast Asia and selected South Asian countries (Bangladesh, Nepal, Bhutan), the requirement on biosafety and biocontainment in microbiology laboratories and animal facilities raised the need to assess the capacity and to identify key areas that require action to enhance laboratory capacity to appropriately and safely handle pathogens. In 2013, there are 29 national veterinary diagnostic and network laboratories from 11 countries from Southeast and South Asia enrolled in and benefitting from the programme. In 2014, FAORAP has continued the activities of the Regional Biosafety Programme with the focus on provisions of technical support, biosafety resources, and annual biosafety cabinet certification. In addition, as 2014 marks the final year of EPT IDENTIFY programme, all national diagnostic laboratories will be reassessed, using the Laboratory Mapping Tool (LMT) and the 5th Edition of the US Centre for Disease Control and US National Institutes of Health publication, “Biosafety in Microbiological and Biomedical Laboratories” (BMBL 5th ed.). The results obtained from the assessment activities will be used as one of the key performance indicators for the project implementation.

ASEAN Regional Animal Health Laboratory Technical Advisory Group (Lab-TAG) experience

The ASEAN Regional Animal Health Laboratory Technical Advisory Group (Lab-TAG) was established to provide technical advice to the member countries on strategic planning and

laboratory capacity building activities related to emerging, re-emerging and priority animal diseases of the region. The Lab-TAG members include experts from key technical partners in particular the leading laboratories for the region, international reference centres, key donor agencies supporting laboratory activities in the region and the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE). The role and responsibilities of the Lab-TAG include 1) Provision of advice on strengthening laboratory capacity, improving quality of laboratory diagnostic services, and laboratory biosafety and biosecurity; 2) Advocacy for the relevant policy level and development partners to gain sustainable support for the implementation of the “Regional Strategic Framework for Laboratory Capacity Building and Networking in Southeast Asia”; and 3) Facilitation and coordination among relevant partners in implementing the activities related to laboratory capacity buildings to minimize the duplication and maximize the outputs.

Objectives from a Regional Biosafety Programme

A Regional Biosafety Programme should on provisions of technical support, biosafety resources, and annual biosafety cabinet certification with objectives as follows,

A. To enhance the quality biosafety management and practices and good laboratory practices (GLP) at the participating laboratories through;

- Provision of laboratory biosafety baseline assessment, consultation, and backstop trainings on biosafety management to the target laboratory within the Regional Laboratories Network (RLN)
- Advocacy for biosafety awareness, improvement of the laboratory biosafety and coordination with other implementation partners to ensure the quality laboratory practices and biosafety management at the targeted laboratories in a sustainable manner

B. To ensure the well maintenance of the biosafety equipment and access to essential biosafety supplies through;

- Provision of annual Biosafety Cabinet (BSC) Testing and Certification to the participating laboratories
- Provision of regional resources, biosafety equipment and supplies, where necessary

C. To perform the laboratory capacity and biosafety risk re-assessment at the national veterinary laboratories

Deliverables from a regional Biorisk network

A. Provide a safe working environment for infectious disease manipulations for diagnostic and research purposes,

- For the staff and support staff
- For the community
- For the environment and surrounding livestock and wildlife

B. Training in Biosafety practises management

- Training in Biosafety practices for staff at SAARC laboratories
- Training in Biosafety management and Training of Trainers for SAARC laboratories
- FAO Biosafety management manual translated into local language

C. Assessment of biosafety practices and management capacity at all SAARC laboratories

- Report of biosafety practices and management capacity at all laboratories using US CDC BMBL 5th ed. regulation checklists
- Risk assessments of infectious diseases procedures and development of critical SOPs
- Assessment and remediation of infectious waste procedures
- Biosafety cabinet assessments to determine if they meet the international standards (NSF49) – recommendations on repair and replacement as required

C. Regional biosafety laboratory certification

- A strategic plan for the implementation of a regional biosafety certification for national level veterinary laboratories including a mentoring programme to Biosafety Level 2 (enhanced) certification of “Champion” laboratories where possible.

“Road map” to establish a Biorisk management network in SAARC

- Given the success of the ASEAN RLN it is recommended that the “road map” to establish a Biorisk management network in SAARC member countries should use the principles established in the ASEAN RLN.
- The starting point is to determine the common biorisk deficiencies throughout the SAARC region and provide recommendations on how to address the needs using a regional approach. Institute a framework, similar to that implemented in SEA/ASEAN at the SAARC RLDLs for the assessment the biosafety and quality assurance capacities of each of the laboratories in the participating countries. Assessments would be performed by an independent biosafety professional to investigate containment levels, risk assessments, personal protective equipment (PPE), infectious waste disposal and emergency procedures and clear recommendations be made to rectify areas of non-compliance. Laboratory assessments be performed bi-annually.
- Implement biosafety management action plan programmes at all participating RLDLs which includes the appointment of a biosafety manager, biosafety documentation and verification of procedures (i.e., infectious waste disposal).
- A biosafety and quality assurance training programme be implemented for biosafety managers and laboratory staff. This is accomplished by hands on and didactic training in country and regionally.
- SAARC establish a TAG with similar objectives to those of the ASEAN TAG that meets annually.
- A SAARC regional BSC testing programme that identifies deficient BSCs and recommends repair or replacement.

Conclusions and recommendations:

Based on the deliberations of the Third Laboratory Directors' meeting and workshop on Biorisk Management Systems, the following main recommendations were drawn;

Recognising that;

1. National animal disease diagnostic laboratories are responsible for supporting the disease surveillance programmes in their respective countries, towards early detection and response in a timely manner.
2. Regional Laboratory Networks have enhanced laboratory capacity for the diagnosis of priority diseases, and promote sharing of reagents, biological materials and information.
3. The Laboratory Directors' Meeting can provide a platform to discuss regionally relevant problems of mutual interest and issues among national and leading laboratories of SAARC Region.

The Meeting recommends;

1. Institutionalise the SAARC Laboratory Directors' Forum with commitment to organise annual meetings with participation from the National and Regional Leading Diagnostic Laboratories.
2. The meeting recommends that towards institutionalisation of the Directors' forum a Chair of the forum be established with host country chairing the forum/network until the next annual meeting.
3. There is need to constitute a technical advisory group (TAG) to guide and monitor the activities in the region.
4. Regional Leading Diagnostic Laboratories (RLDLs) should take initiative to ensure full ownership of the network and support capacity building and laboratory networking activities on a long term basis.
5. Guidelines and programmes may be developed to address the deficiencies in implementing quality assurance (QA), quality management (QM), biosafety and undertake trainings as a priority activity.
6. The RLDLs/Regional FAO/OIE Reference Laboratories should make efforts to get their laboratories accredited as per ISO guidelines (ISO 9001/ ISO/IEC 17025).
7. The Laboratory Directors' forum recognised the need for in country hands-on trainings provided by RLDLs/OIE Reference Laboratory experts.
8. Assess specific needs on biosafety management and constraints, through consultation with laboratory staff, using international standard biosafety regulations.

Closing remarks

Dr Mohinder Oberoi, ECTAD Sub-regional Manager, Kathmandu, Nepal thanked WHO and SAARC Member States for deputing delegates to the workshop. He emphasised that Biosafety and Biosecurity is an important part of the biorisk management system and the implementation of the biorisk management system and biosafety and biosecurity should go hand in hand. There is a need to identify the important issues to develop laboratory biorisk management systems within national laboratory plans. There is a need to constitute a technical advisory group (TAG) to guide and monitor the activities in the region.

Agenda

Wednesday, 05 March 2014

Time	Topic	Chair
08.30 - 09.00	Registration	
	Inaugural session	
09.00 - 10.00	Welcome address Introduction to workshop and expected outputs <i>Dr. Mohinder Oberoi, Sub Regional Manager – ECTAD, RSU Coordinator, FAO, Nepal</i> Opening Remarks <i>Dr Suresh S Honnappagol, Animal Husbandry Commissioner to Govt of India & CVO, Department of Animal Husbandry, Dairying and Fisheries, Ministry of Agriculture, India</i>	
	Group Photograph	
10.00 - 10.15	Tea Break	
10.15 - 10.25	Introduction of participants	
10.25 - 10.40	Background of the Laboratory Directors' meeting and update on Regional network activities in the region - <i>Dr Mohinder Oberoi, RSU FAO, Nepal</i>	
Session 1	Organize Laboratory Networks on Sharing of Information	
10.40 - 11.00	Role of laboratory networks in strengthening diagnostic capacity- <i>OIE SSR (Bangkok)</i>	
11.00 - 11.20	Cross-sectoral collaboration to develop harmonized laboratory procedures & protocols for zoonotic diseases - <i>Dr , WHO-SEARO New Delhi, India</i>	
Session 2	Overview of Activities of SAARC Laboratory Network Members in 2012	
11.20 - 11.35	FMD Regional Leading Laboratory - <i>Dr B Pattnaik, FMD RLDL, Mukteswar (India)</i>	
11.35 - 11.50	PPR Regional Leading Laboratory- <i>Dr Md Rafiqul Islam, PPR RLDL, Savar (Bangladesh)</i>	
11.50 - 12.05	HPAI Regional Leading Laboratory – <i>Dr Khalid Naeem, HPAI RLDL, Islamabad (Pakistan)</i>	

12.05 - 12.20	OIE Reference Laboratory on Avian Influenza- <i>Dr D D Kulkarni, High Security Animal Diseases laboratory, Bhopal (India)</i>	
12.20 - 13.00	Overall discussion on activities undertaken in 2012 by SAARC Laboratory Network members and progress made since the last meeting <ul style="list-style-type: none"> • Report on Biorisk Training for Laboratory and Engineering and Equipment Maintenance Training workshops at Bhopal (10mins) <ul style="list-style-type: none"> - <i>Dr. D D Kulkarni</i> • Progress of Proficiency testing of FMD Laboratories conducted in the SAARC region <ul style="list-style-type: none"> - <i>Dr Aniket Sanyal, FAO National Consultant (FMD, Mukteswar (India)</i> 	
13.00 - 14.00	Lunch	
Session 3	Expectations of National Diagnostic Laboratories From the OIE Reference and Regional Leading Diagnostic Laboratories	
14.00 - 15.00	Group discussion	
15.00 - 15.30	Tea Break	
15.30 - 16.30	Group discussion (continued) and presentations	

Thursday, 06 March 2014

Session 4	Quality Management Systems: Why Quality Systems Are Essential for Good Laboratory Practices:	
0.900- 09.45	Background and overview of biorisk management system including biorisk assessment, biorisk mitigation, and biorisk management system performance <ul style="list-style-type: none"> - <i>Dr Stuart Blacksell</i> 	
09.45 - 10.45	Challenges in implementation of biorisk management systems Speakers: RLDL – FMD- <i>Dr B Pattnaik</i> RLDL – HPAI- <i>Dr Khalid Naeem</i> RLDL – PPR – <i>Dr Md Rafiqul Islam</i> OIE Reference Laboratory for Avian influenza – <i>Dr D D Kulkarni</i>	
10.45 - 11.00	Tea Break	
11.00 - 12.30	Group discussion	- <i>Dr. Stuart</i>

	<p>Review and discuss the biorisk systems suitable for Veterinary Diagnostic laboratories in SAARC region</p> <p>Biosafety & Biosecurity is a important part of the biorisk management system and the implementation of the biorisk management system and Biosafety & Biosecurity go hand in hand</p> <p>Development of laboratory biorisk management systems within national laboratory plans</p> <p>What are the experiences and challenges of countries that have already made steps towards meeting the objectives?</p> <p>What are the important issues relevant to the development of biorisk management systems on a national basis?</p> <p>What is preventing your laboratory implementing a biorisk management system</p>	<i>Blacksell</i>
12.30 - 13.00	Report on group work	
13.00 - 14.00	Lunch Break	
14.00 - 15.30	Group work: Road map for development of biorisk management systems in RLDLs	- <i>Dr. Stuart Blacksell</i>
	<p>Participants in three working groups to discuss:</p> <ul style="list-style-type: none"> • how to develop national laboratory policies and standards to support biorisk management systems • advocacy for setting and implementing national biorisk management quality standards 	
15.30 - 15.45	Tea Break	
15.45 - 16.30	Report on Group work	
16.30 - 17.30	Conclusions and recommendations - <i>Dr Mohinder Oberoi, FAO</i>	

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