جـهـاز أبـوظـبـي للرقابة الغذائية
ABU DHABI FOOD CONTROL AUTHORITY

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GUIDELINES OF BIOSECURITY GENERAL ASPECTS OF BIOSECURITY VOLUME 1

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GUIDLINES OF BIOSECURITY

I. INTRODUCTION

Abu Dhabi Food Control Authority (ADFCA) mandate is to implement biosecurity by assuring plant and animal Health in the Emirate of Abu Dhabi. Human, animal and plant healthy life in addition to the protection of the environment are inextricably linked and this is the fundamental rationale for an integrated approach to biosecurity

II. PURPOSE

The aim of this guide is to demonstrate the efficient approaches to prevent the exotic pests and diseases from entering, spreading or becoming established in Abu Dhabi and assuring significant pests and diseases are contained, suppressed and managed. An integrated approach to biosecurity can help to minimize potentially adverse health, economic and other impacts such as:

- Incidence and range of food-borne risks to consumers.
- Cross-border spread of new and emerging diseases among humans, domestic and native animals, plants and fish.
- Introduction of alien plant, animal and aquatic species in fish farms.
- Loss of biodiversity and unwanted changes to ecosystems.
- Disruption of the livelihoods and earning potential of rural communities and agricultural industries.
- Loss of consumer trust in food industry.
- Disruptions to trade

Potential benefits are associated with a cross-sectoral approach to biosecurity:

- Improved public health
- Enhanced trade
- Improved agricultural production
- Protection of the environment

III. SCOPE

This guide advocates a general strategic, integrated and harmonized approach to biosecurity as a holistic concept that is of direct relevance in meeting consumer expectations in relation to the safety of their food supply, preventing and controlling zoonotic aspects of public health, ensuring the sustainability of agriculture, safeguarding environments, and protecting biodiversity in the emirate of Abu Dhabi. This guide also provides practical guidance and support for all biosecurity involved parties in Abu Dhabi Food Control Authority to develop and implement biosecurity frameworks as well as agricultural industry.

VI. DEFINITIONS

Biosecurity — It is a set of procedures or preventive measures designed to protect the population against harmful biological or biochemical substances. It is also a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) for analyzing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment.

Foodborne Zoonosis (FBZ) — They are diseases that are caused by consuming food or drinking water contaminated by pathogenic (disease-causing) micro-organisms such as bacteria and their toxins, viruses and parasites. They enter the body through the gastrointestinal tract where the first symptoms often occur. Many of these micro-organisms are commonly found in the intestines of healthy food-producing animals. The risks of contamination are present from farm to fork and require prevention and control throughout the food chain

Zoonosis	Zoonosis or Zoonoses are all diseases and/or all infections naturally transmissible between animal and man. Zoonotic pathogens are bacteria, viruses, parasites or else biological units that can cause a zoonosis. It is any infectious disease that can be transmitted (in some instances, by a vector) from non-human animals, both wild and domestic, to humans or from humans to animals (the latter is sometimes called reverse zoonosis). Many serious diseases fall under this category. It is a disease that can be transmitted from other vertebrate animals to humans. A slightly more technical definition is a disease that normally infects other animals, but can also infect humans. The reverse situation (transmission from human to animal) is known as Anthroponosis.
Alien Plant	Exotic plant which is not native in UAE Ecosystem
Biodiversity	The variety and abundance of different species living on earth like plant and animal life in the world or in a particular habitat, a high level of which is usually considered to be important and desirable.
Competent Authorities	They are federal and local governmental offices and entities that are involved in plant, animal and human health.
Hazard	A biological, chemical or physical agent in, or condition of, climate or air or water or food or feed with the potential to cause an adverse health effect.
Appropriate level of protection (ALOP)	The level of protection deemed appropriate by the country establishing a sanitary or phytosanitary measure to protect human, animal and plant life or health within its territory
Risk Assessment	A scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization.

IV. RELATED DOCUMENTS

- Reg. No. 8 of Year 2012 pertaining to The Technical and Hygienic Requirements of Animal Production Establishments.
- COP No. 15 of Year 2011 pertaining to Good Practices and Welfare for Animal Production Establishments.

1. PART 1: ASPECTS OF BIOSECURITY

1.1 Background

Increasing travel and movement of people across borders, high dependence on food imports, population growth and the increasing demand with diversity and volume of international trade in animals, plants and their products are the key contributors in the spread of recognized diseases from region to region. Changing agricultural practices are resulting in new hazards to health that are readily able to cross borders. Changing human ecology and behavior also contribute to the greater incidence and spread of hazards of public, animal and plant health importance.

1.2 Factors Influencing Biosecurity

The factors influencing biosecurity are:

1.2.1 Globalization and the changed parameters of vaccine development made a double edged sword for advantages and disadvantages.

1.2.2 New agricultural production and food processing technologies gave more chances for exposure to hazards.

1.2.3 Increased trade in food and agricultural products.

1.2.4 Legal obligations for signatories of relevant international agreements.

1.2.5 Increasing travel, transportation development and movement of people and animals across borders.

1.2.6 Advances in communications and global access to biosecurity information.

1.2.7 Greater public attention to biodiversity, the environment and the impact of agriculture.

1.2.8 Shift from country independence to country interdependence for effective biosecurity.

1.2.9 Scarcity of technical and operational resources like lack skilled people in diagnostic laboratories.

1.2.10 High dependence of some countries on food imports will open the gate for hazards and pests.

1.3 Involvement of Stakeholders

ADFCA has a primary responsibility for managing Abu Dhabi's biosecurity system in partnership with other government authorities, agencies, industry and the community. The competent authorities associated with biosecurity of food safety, public health, agriculture, fisheries and the environment play the primary role in a contemporary integrated approach to biosecurity to minimize the risk of exotic pests and diseases entering and establishing in Abu Dhabi and harming the natural environment, food security and economy.

On the Federal and International level Responsibilities are shared by the Ministry of Environment and Water (MOEW) among numbers of organizations and bodies.

Biosecurity also involves working offshore to build the capabilities of neighbor countries that UAE import from to reduce risks reaching border. Cooperation and coordination with MOEW is vital to make work in partnership with importers before they bring animal and plant products to Abu Dhabi to ensure they are aware of their responsibilities. In addition it is also vital to work with the emirate's food supply chain including farmers to ensure that plants and animals are free from pests and diseases.

1.4 Priorities

ADFCA's core priorities in managing biosecurity are to assure safe food through good practices in plant and animal health and these could be achieved by :

1.4.1 Safeguard Emirate's animal and plant health status to maintain overseas markets and protect the economy and environment from the impact of exotic pests and diseases, through risk management, inspection and certification, and the implementation of emergency response arrangements for Emirate's agricultural and food industries.

1.4.2 Provide effective biosecurity risk management with the coordination of the concerned sectors of ADFCA work to underpin by sound science. Policy can improve the efficiency and responsiveness of operations and strengthens client relationships.

1.4.3 Manage biosecurity by effectively identifying and targeting risks to focus on the things that matter most.

1.4.4 Partner with other government agencies, industry, clients and stakeholders.

1.4.5 Deliver biosecurity services to support access to overseas markets and protect the economy and the environment from the impacts of unwanted pests and diseases. This could be applied on the plans of exporting local dates and camel milk products.

1.5 Biosecurity Linkages

Biosecurity hazards of various types exist in each sector (Plant and Animal) and have high potential to move between sectors (e.g. many animal pathogens readily infect humans; animal feed may be contaminated with mycotoxins and plant toxins).

Risks from hazardous substances exist in the oil field especially in the western region of the Abu Dhabi Emirate is a threat to the animals rearing in the area. There is possibility to access petrochemical hazards from oil drilling operation and production site. These hazardous materials accumulate in the environment, plants and ingested by animals like sulfide compound derivatives and soil microorganisms and therefore this should be considered for animal protection. Hazards can be introduced to the food chains anywhere from production to consumption and a breakdown in security at any point can result in adverse health consequences to individual or multiple biosecurity sectors. For instance, pesticide residues in plant foods and veterinary drug residues in animal foods can have negative impacts on human health. The size and scope of the global trade in animal feed and animal feed ingredients is one example of the immense potential for biosecurity hazards movements.

Changes in the environment, such as the loss of biological diversity and contamination of food and water sources, sometimes result in significant risks to human and animal health. It has been reported that 10 percent of all preventable human diseases are due to the deterioration of the environment, and the principal causes of these diseases include a lack of sanitary measures, contamination of water sources and unsafe food.

1.6 Mandate of Biosecurity

Biosecurity should stimulate need for individual healthcare mandate. The concluded perception is that the individual mandate for healthcare would be justified by the need for biosecurity by the following:

1.6.1 Protect human health in consumption of agricultural and food products.

1.6.2 Protect the agricultural/animal production systems.

1.6.3 Efficiently utilize limited resources across food safety areas, animal and plant health.

1.6.4 Provide cost-effective and efficient services to private sector.

1.6.5 Building consumer confidence.

Achieving these mandates requires a proactive and dynamic response to ever-changing biosecurity challenges.

1.7 Biosecurity and Food Safety

Biosecurity systems for food safety must control hazards of biological, chemical and physical origin in imported food, food produced domestically and food that is exported. Food controls based on good hygienic practice (GHP) remain the foundation of modern food safety systems. While earlier controls were applied primarily to production and transport of bulk food commodities, the last few decades have seen remarkable changes in the global food supply. Along with the increasing volume of trade, the geographical origins, nature, range, preservation requirements and intended end-uses of foods are now vastly expanded.

New influences on food safety biosecurity systems:

1.7.1 Adoption of HACCP and a risk-based approach.

1.7.2 Documentation of high levels of food-borne disease.

1.7.3 Significant changes in food production and processing.

1.7.4 Shift in primary responsibility for food safety from the competent authority to producers with government assuming an oversight role.

1.7.5 Development of controls based on "production-to-consumption" considerations.

1.7.6 Consumer perceptions and fears reflected in more stringent regulatory requirements.

1.8 Biosecurity and Plant Health

Application of regulatory controls to protect plant health is an important biosecurity domain, one of the major challenges for biosecurity system is protecting the vast range of date palms based industries present in Abu Dhabi. Plant health can be adversely affected by different types of factors (e.g. pests or pathogenic organisms which are injurious to plants or plant products). Management of pathways and vectors is an important aspect of plant health biosecurity. Establishment and spread of a pest often depends directly on biological factors such as availability of suitable plant hosts and vectors, crop cultivation practices, suitability of the environment and natural enemies. With an increasing interest in environmental issues, competent authorities that are responsible for plant health must also manage environmental pests that primarily affect other organisms, thereby causing harmful effects on plants and plant ecosystems. Competent authorities can be proactive in preventing import of pests, risk management programs are needed to control pests that have become established within the borders of a country.
New influences on plant health biosecurity systems:

1.8.1 Adoption of a risk-based approach.

1.8.2 Improvements in taxonomic knowledge and diagnostics.

1.8.3 More attention to non-agricultural pests and safeguarding the environment.

1.8.4 Adoption of "systems approaches" which integrate controls in a defined manner throughout the complete hazard exposure pathway.

1.8.5 Higher levels of public participation needed in implementation of controls.

1.8.6 Greater urbanization resulting in less public empathy with controls.

1.8.7 Plant health needs farm biosecurity. This is a set of measures designed to protect a property from the entry and spread of pests, diseases and weeds.

1.8.8 Best practice biosecurity procedures relating to plant production at the farm level include:

1.8.8.1 Regular monitoring for pests.

1.8.8.2 Use of warning and information signs for biosecurity awareness.

1.8.8.3 Limiting visitor entry to production areas.

1.8.8.4 Cleaning of equipment, vehicles and footwear between properties.

1.8.8.5 Sourcing certified pest free propagation material.

1.8.8.6 Isolating and inspecting newly purchased plant material.

1.8.8.7 Controlling volunteer or neglected plants that could harbour pests.

1.8.8.8 Use of chemical control measures to control pest vectors and alternative hosts.

1.8.8.9 Controlled disposal of crop residues.

1.8.8.10 Integration of biosecurity awareness into staff training, postharvest handling and transport procedures.

1.8.8.11 Use of dedicated equipment in high risk areas.

1.8.8.12 Restriction of people and vehicle movement in production areas.

1.8.8.13 Record keeping monitoring movement of people and equipment.

1.8.8.14 Reporting suspect pests to appropriate local & federal authorities.

1.8.8.15 Including farm biosecurity in industry best management practice and quality assurance schemes.

1.8.8.16 Encouraging good hive biosecurity practices by pollination service providers.

1.9 Biosecurity and Animal Health

Animal health biosecurity is a series of management practices designed to protect farm animals from any type of harmful or infectious agent by preventing the introduction of disease and pests and to minimize their spread. Animal health biosecurity is concerned with import, domestic and export health controls. Animal's related Divisions within ADFCA have generally been the sole authority responsible for animal health and, in many cases, have also been responsible for food safety aspects of the slaughter of animals up until the end of primary processing. Import controls are primarily designed

to prevent the introduction of hazards pathogenic to animals during trade in animals, animal genetic material, animal products, feedstuffs and biological products. Competent local and federal authorities in the domestic setting, besides being responsible for control and eradication of animal diseases, are often responsible for implementing controls that prevent the introduction of unacceptable levels of chemical hazards to the food chain (e.g. residues of veterinary drugs and pesticides). Recently, concern has arisen over antibiotic resistant bacteria being conveyed by animals and animal products to humans via food.

Influences on animal health biosecurity systems:

1.9.1 Adoption of a risk-based approach.

1.9.2 Increasing number of new and emerging pathogens.

1.9.3 Increasing attention to oil field biosecurity.

1.9.4 Increasing availability of sophisticated diagnostic tools for epidemiological surveillance.

1.9.5 Changing epidemiology of disease due to confluence of animals and people in intensive farming situations.

1.9.6 More attention to traceability systems.

1.9.7 Greater focus on emergency preparedness and response.

1.9.8 Increasing attention to marine and freshwater biosecurity.

1.9.9 More attention to zoonoses associated with asymptomatic animal carriage of enteric pathogens.

1.10 Biosecurity and Zoonosis

Many factors contribute to the expression of emerging food-borne zoonoses in human populations. Emerging zoonoses illustrate the recent convergence of biosecurity aspects of animal and human health and this is likely to lead to marked changes in the roles, partnerships and regulatory activities of competent authorities collectively involved in their control.
The Zoonotics include Foodborne Zoonosis (FBZ) and other Zoonotics:

1.10.1 Enterohaemorrhagic E. coli from mammals (FBZ)

1.10.2 BSE from cattle(FBZ)

1.10.3 Norovirus from seafood(FBZ)

1.10.4 Campylobacter from poultry(FBZ)

1.10.5 Salmonella from poultry and eggs(FBZ)
1.10.6 Cryptosporidium from ruminants(FBZ)
1.10.7 Q Fever(FBZ)
1.10.8 Brucellosis(FBZ)
1.10.9 Avian influenza from poultry
1.10.10 Bovine tuberculosis from mammals
1.10.11 Monkeypoxvirus from pets
1.10.12 West Nile virus from birds
1.10.13 Rift Valley Fever from ruminants
1.10.14 Rabies and related Lyssavirus infections from mammals
1.10.15 Lyme borreliosis from small mammals and birds
1.10.16 Ornithosis from birds

1.11 Hazards of Petroleum Industry and Biosecurity

In oil-producing region of Abu Dhabi, the proximity of livestock (particularly camels in the western region) to the drilling operations and production sites often results in poisoning of animals from ingestion of crude oil, condensate, salt water, heavy metals, and caustic chemicals. The heavy metals encountered most frequently are lead from pipe joint compound, and arsenicals and chromates used as corrosion inhibitors. Numerous toxic and caustic chemicals are used in drilling mud's fluids. Crude oil and salt water spills are commonly found around production sites. Pipeline breaks may result in exposure of livestock to crude oil or refined petroleum hydrocarbons. Ingestion of petroleum hydrocarbons may result in sudden death. The most common cause of illness or death following exposure to petroleum hydrocarbons is aspiration pneumonia, which may cause a chronic progressive deterioration of health, with death after several days or weeks. Cases in which livestock are exposed to limited levels of oil, salt water, or caustic chemicals may not cause sudden death but it may end by toxic metal in the food chain. Camels rearing near the oil field may let loose for grazing have a chance to accidental ingestion of petroleum hydrocarbons. Cases in which livestock are exposed to oil, salt water, or caustic chemicals, but do not die acutely or from aspiration pneumonia are more frustrating to diagnose. The more volatile petroleum hydrocarbons also are more irritating to skin and mucous membranes and appear to be more damaging to rumen flora.

1.12 Fundamental Principles of Animal Farms Biosecurity

There are three main principles:

1.12.1 Segregation

The creation and maintenance of barriers to limit the potential opportunities for infected animals and contaminated materials to enter an uninfected site. This step, properly applied, will prevent most infection.

1.12.2 Cleaning

Materials (e.g. vehicles, equipment) that have to enter (or leave) a site must be thoroughly cleaned to remove visible dirt. This will remove most of the microorganisms that is contaminating the materials.

1.12.3 Disinfection

Properly applied, disinfection will inactivate any microorganism that is present on materials that have already been thoroughly cleaned.

1.13 Biosecurity Capacity

Without efficient and effective capacity it is difficult to fulfill the requirements of biosecurity. This can be achieved by following seven steps to assess biosecurity capacity needs:

- Step 1: Obtain high-level support
- Step 2: Agree on the purpose, scope and process
- Step 3: Profile the biosecurity context at the country level
- Step 4: Assess existing biosecurity capacity and performance
- Step 5: Describe the desired future situation (goals and objectives) of biosecurity
- Step 6: Identify capacity needed to reach the desired future situation
- Step 7: Generate options to address the identified capacity needs

2. BIOSECURITY RISK ANALYSIS

Risk analysis encompasses three main components (risk assessment, risk management and risk communication). Effective application of risk analysis in biosecurity is fully dependent on an appropriate legislative base, infrastructure and regulatory system, as well as equitable stakeholder engagement. Risk analysis capability also is a key component of biosecurity capacity, and

enhances cross-sectoral biosecurity activities, risk analysis approach is essential to address some cross-sectoral biosecurity concerns. Risk assessment involves a scientific process to estimate risks to health and life that may be associated with a particular food, animal and plant. Prevention, reduction or elimination of those risks by risk management actions can take many forms.

Both risk assessment and risk management should be wrapped in a "sea of communication" in multi rounds that includes all stakeholders as appropriate, and facilitates the iterative and ongoing nature of risk analysis, See Figure (1).

Good science is essential to conduct proper risk assessment; risk management incorporates considerably different processes. Core decisions involve balancing scientific findings against questions of health and life expectations, likely economic, political and social impacts, and technical feasibility and cost effectiveness of potential control measures.

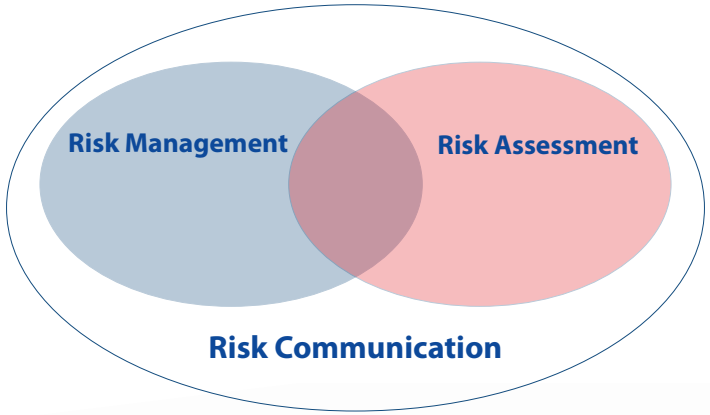

Figure (1)
Relation between components of Risk Analysis

2.1 Prerequisites for risk analysis in biosecurity

Risk analysis cannot be undertaken in a vacuum. It needs high level support. It should include:

- 2.1.1 Policy and legislation
- 2.1.2 Biosecurity strategy
- 2.1.3 Infrastructure, Scientific and research capability
- 2.1.4 Development of standards and guidelines
- 2.1.5 Implementation of standards
- 2.1.6 Verification, audit and enforcement
- 2.1.7 Emergency preparedness and response
- 2.1.8 Monitoring and surveillance
- 2.1.9 Certification & Performance measurement
- 2.1.10 Communication systems
- 2.1.11 Training

2.2 Basics of Risk Analysis

When we are not sure, for any reason, we are uncertain. The future is uncertain. We make decisions in the present based on information from the past that are intended to affect the future. We can't be sure how those decisions will turn out in an uncertain future. Risk analysis is a framework developed to aid decision-making under such conditions of uncertainty. Risk analysis is a way of approaching problems that integrates science and social values. Traditional standards based approaches are no longer enough to solve problems. We have to identify uncertainties to be monitored and managed. Risk analysis should determine the following:

- 2.2.1 The extent of expected wrong things (What can go wrong?)
- 2.2.2 The likelihood or the probability of wrong events (How likely is it to go wrong?
- 2.2.3 The impact of the wrong event. (How serious would it be if it went wrong?)
- 2.2.4 Options to reduce the likelihood or the impact of wrong event (What can be done to reduce the likelihood and/or seriousness of it going wrong?) See Figure (2).

2.3 Generic Aspects of Biosecurity Risk Analysis

Many aspects of biosecurity risk analysis are generic in nature. There is a need to determine the risks that are faced in a given situation, decide on the required outcomes or level of acceptability of risk, and ensure that there is ongoing management to keep risks within acceptable levels. Whatever the biosecurity issue, there should be (A strategic, organizational and operational context for risk analysis, a systematic and structured process for applying the components of risk analysis).

There are various descriptions in the different biosecurity sectors as to what constitutes a potential threat to health or life of human, animal in addition to the plant and these have been presented. A clear understanding of the difference between the terms "hazard" and "risk" is fundamental to an Understanding of biosecurity risk analysis.

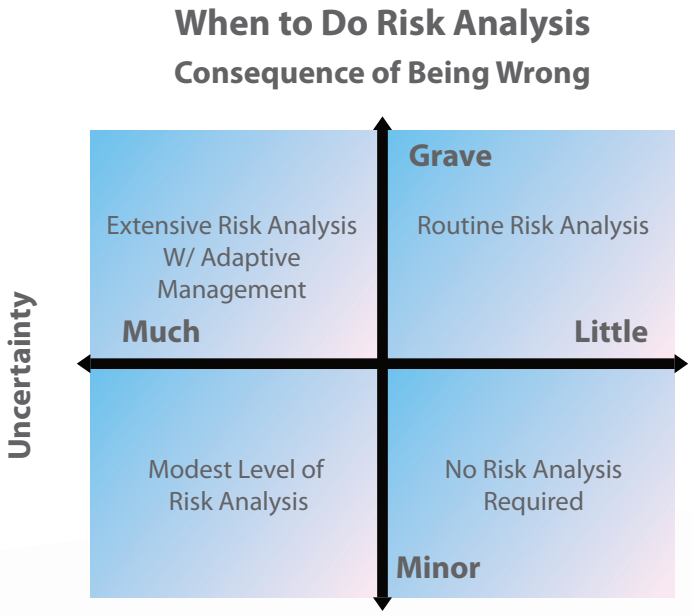

Figure (2)
Risk Analysis Decision Levels

2.4 Risk Assessment

Risk assessment in biosecurity can be described in general terms as characterization of the likely adverse effects to health and life resulting from exposure to hazards over a specified time period. Characterization of risks will include quantitative estimation of the probability and severity of adverse effects to health and life that result from exposure to a hazard in a particular circumstance. Risk assessment methodologies are subject to variation, both within and between biosecurity sectors.

A risk assessment should be fit for its intended purpose. Risk assessment should be based on sound science and take into account the whole hazard exposure pathway. Four general sets of activities are common across risk assessment in the sectors of biosecurity.

2.4.1 Hazard identification and categorization

2.4.2 Characterization of exposure

2.4.3 Evaluation of likely adverse effects

2.4.4 Estimation of risk

In animal health and plant health, risk assessment can be qualitative or quantitative with potential economic impact estimated as the primary adverse effect.

A qualitative risk estimate is one where the likelihood and/or the magnitude of the consequences are expressed in qualitative terms such as high, medium or low.

A quantitative risk estimate is one where the likelihood and/or the magnitude of the consequences are expressed numerically and this should include a numerical description of uncertainty.

2.4.5 Transparency

The risk assessment process must be transparent, Characteristics of documentation that ensure transparency:

2.4.5.1 Scientific rationale and model structure is clearly presented.

2.4.5.2 Any factors that impact on the risk assessment (e.g. resource constraints, non-representativeness of data inputs, data gaps) are identified.

2.4.5.3 All scientific inputs are clearly and systematically described.

2.4.5.4 Assumptions and uncertainties are identified and explained.

2.4.5.5 An interpretive summary is provided for lay readers.

2.4.5.6 Draft assessments are discussed with the public before finalization

2.4.6 Dealing with uncertainty

When data is lacking, uncertainty about the available scientific information can be represented in a risk assessment by using a range of possible data values. Uncertainty also arises from various conceptualizations of limitations imposed when modeling a biosecurity system. The risk assessment should describe how assumptions made in the face of uncertainty affect the results of the assessment. This should be distinguishable from the impact of biological variation that is inherent to any system. Risk assessment will often raise levels of uncertainty that can only be mitigated by further research. After a core risk assessment has been completed, risk assessors may identify that they cannot properly answer the questions asked by risk managers until they have more scientific information.

2.4.7 Sensitivity analysis

Where a quantitative risk assessment is available, sensitivity analysis helps risk managers select those control measures that best achieve risk management objectives. Probabilistic software programmes can perform sensitivity analysis by producing graphs or rank correlation statistics between input parameters and output parameters. "What if" scenarios can be used to evaluate the impact of different assumptions and different ranges of input data on model outcomes. The results for each new "what if" scenario are compared to the baseline outcome to determine the degree of change.

2.4.8 Risk Assessment in Animal Health

Animal health risk assessment incorporates 4 steps as described by OIE:

2.4.8.1 Release assessment.

2.4.8.2 Exposure assessment.

2.4.8.3 Consequence assessment.

2.4.8.4 Risk estimation.

Hazard identification includes identification of the pathogenic agents which could be present in the exporting country and that could potentially produce adverse animal health consequences in the importing country. It also includes identifying whether the hazard is already present in the importing country, and whether it is a notifiable disease or is subject to official control or eradication. Evaluation of the veterinary services and their systems in the exporting country is an important input to assessing the likely presence of the hazard.

Risk assessments under the OIE process are designed to answer the question "What is the likelihood of specified adverse consequences occurring as a result of exposure to a particular commodity or pathogen that came from a defined release source?" No single method of import risk assessment is recommended for all situations and special reference is drawn to the fact that risk increases with increasing volume of the animal commodity imported.

2.4.8.1 Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to "release" hazards into a particular environment, and estimating the probability of that complete process occurring, either qualitatively or quantitatively. It includes a description of how the probability of "release" in terms of amount and timing may change as a result of various actions, events or measures (i.e. biological factors, country factors and commodity factors). Biological factors include species, age and breed of animal, agent predilection sites, and vaccination, testing, treatment and quarantine. Country factors include incidence/prevalence of the hazard, evaluation of veterinary services, and surveillance and control programmes in the exporting country.

2.4.8.2 Exposure assessment

This activity details the probability of animal (and/or human) exposure to the hazard via the identified biological pathway(s). Outputs of exposure assessment can be described in quantitative (e.g. numbers of herds or animals likely to experience adverse health consequences over time) or qualitative terms.

2.4.8.3 Consequence assessment

Consequence assessment is the probability of specific exposures causing adverse impacts in terms of direct consequences (e.g. animal production losses and human health impacts) and indirect consequences (e.g. surveillance, control and compensation costs, potential trade losses, adverse environmental

effects). Economic impacts include those from lost production, mortality, disease control and lost sales. The extent of each of these can change markedly in each biosecurity environment, depending on how the disease behaves epidemiologically and how national and international markets react.

2.4.8.4 Risk estimation

Exposure assessment and consequence assessment are combined to estimate risk. Quantification of the risk estimate itself is attempted in only a small proportion of import risk analyses and is inherently difficult for many of the same reasons found in food safety microbiological risk assessment. Risk management is almost exclusively focused on selecting control measures that will reduce the likelihood of introduction of exotic diseases and organisms to a level that is considered acceptable.

2.4.9 Zoning, Regionalization and Compartmentalization

While these concepts are a shared concept in biosecurity risk assessment, they are especially important in animal (and plant) health. They allow definition of geographical areas of different animal health status within the territory of a country for the purposes of risk assessment and international trade.

2.5 Risk communication

Risk communication can be described as the interactive exchange of information and opinions throughout the risk analysis process, with explicit consideration given to communicating the decision criteria applied in risk management. Full documentation and transparency are important contributors to effective risk communication. Communication and consultation needs must be planned as early as possible in the risk analysis process and should be continually re-evaluated. The effectiveness of risk communication with external stakeholder groups will depend on the transparency, inclusiveness, accuracy and timeliness with which they are informed.

2.5.1 Risk managers and risk assessors should engage in clear and iterative communication throughout the risk analysis process.

2.5.2 There should be effective communication and consultation with all relevant stakeholder groups throughout the risk analysis process, with all information and opinion required for effective risk management being incorporated into the decision-making process.

2.5.3 Risk managers should clearly communicate the purpose, scope and form of the outputs when commissioning a risk assessment.

The risk communication component has generally received much less attention than risk assessment and risk management. This has been to the detriment of risk analysis in some recent high profile biosecurity events that have had global impacts (e.g. BSE and FMD outbreaks in Europe). Ideally; a risk communication team should be deployed for all risk management projects that involve a significant risk assessment to identify relevant stakeholders develops key messages, engage with stakeholder groups and monitor the effectiveness of communication. Information flows associated with biosecurity regulatory actions have been no participatory and "one-way" in respect of stakeholders external to government. Adoption of risk analysis as a discipline central to biosecurity has meant that "two-way" communication and consultation is now becoming the norm.

2.5.4 Principles of risk communication in biosecurity:

2.5.4.1 Risk communication strategies and programmes should actively promote the understanding and involvement of all stakeholders in the risk analysis process.

2.5.4.2 Risk communication should facilitate an open and interactive exchange of information, facts and opinions about risks amongst risk managers, risk assessors and other stakeholders.

2.5.4.3 Management of each biosecurity issue involving a significant risk assessment should include a risk communication strategy and implementation plan.

2.5.4.4 Variability, uncertainty and assumptions in risk models should be communicated to risk managers and external stakeholders in a user-friendly and understandable manner.

2.5.4.5 Competent authorities should take into account knowledge, attitudes, values, practices and perceptions of stakeholders when communicating risk management options and decisions.

2.5.4.6 A risk communication programme should ensure openness and transparency when arriving at and implementing risk management decisions.

2.5.4.7 Risk communication should respect the legitimate concern to preserve confidentiality of scientific data where appropriate.

2.5.4.8 Risk communication should improve the overall effectiveness and efficiency of the risk analysis process and strengthen the working relationship among participants.

2.5.4.9 Risk communication should be carried out in a way that fosters public trust and confidence in regulatory decisions and control measures.

2.5.4.10 Selection of risk management options that are nonregulatory in nature should be subject to a tailor-made risk communication program.

2.5.4.11 Competent authorities should develop specific risk communication strategies and implementation plans for emergency situations.

2.5.4.12 Risk communication should include stakeholders in other countries and should service international reporting obligations.

Risk communication encompasses a continuous and interactive exchange of information between all parties throughout the risk analysis process. The risk communication strategies and implementation plans of competent authorities should effectively service:

2.5.4.13 Provision of general information and advice on hazards and their management.

2.5.4.14 Standard-setting processes.

2.5.4.15 Emergencies as they arise.

2.5.4.16 International reporting obligations.

2.5.4.17 Monitor and evaluate effectiveness of risk communication

2.6 Risk management

Policies and values in risk management include legal, economic, social and environmental concerns. Criteria for their application are likely to be considerably different in different local settings. Where possible and practical, risk management will include a decision on an appropriate level of protection (ALOP).

Simple risk management tasks needs to identify risk then to assess the risk and control it. Review of controls is to keep safe situation and to develop it (see figure 3).

Risk managers ideally should know the degree of health and life protection they are aiming to achieve when deciding on risk management actions.

Preliminary risk management activities in the RMF process consist of:

2.6.1 Identification of biosecurity issues.

2.6.2 Risk profiling.

2.6.3 Establishing broad risk management goals.

2.6.4 Setting risk assessment policy.

2.6.5 Commissioning of a risk assessment.

2.6.6 Considering the results of a risk assessment.

2.6.7 Ranking and prioritization

2.6.8 Constraints, uncertainties and assumptions in risk assessment processes should be explicitly considered by risk managers making decisions.

Where appropriate, risk managers should ask risk assessors to evaluate potential changes in risk resulting from different risk management options.

Risk management should be a continuing process that takes into account newly generated data in the periodic re-evaluation and review of decisions.

Microbiological Risk Management (MRM) should take into account the whole food or feed chain.MRM should follow a structured approach-uniform procedures and practices to be used in the development and implementation of MRM.

Risk managers should take account of risks resulting from regional differences in hazards in the food chain and regional differences in available risk management options

Figure 3
Simple Risk Management

2.7 General Principles of Risk Analysis

In the context of biosecurity the application of risk analysis in different biosecurity sectors allows a number of general principles to be identified:

2.7.1 The primary goal of risk analysis should be protection of health and life.

2.7.2 All aspects of risk analysis applied in a particular context should be documented and transparent.

2.7.3 Risk management should follow a structured and systematic process.

2.7.4 Risk managers and risk assessors should engage in clear and iterative communication throughout the risk analysis process.

2.7.5 There should be effective communication and consultation with all relevant stakeholder groups throughout the risk analysis process, with all information and opinion required for effective risk management being incorporated into the decision-making process.

2.7.6 There should be functional separation of risk assessment and risk management to the extent practicable so as to preserve the scientific integrity of the risk assessment and avoid confusion over the roles of risk assessors and risk managers.

2.7.7 Risk managers should clearly communicate the purpose, scope and form of the outputs when commissioning a risk assessment.

2.7.8 A risk assessment should be fit for its intended purpose.

2.7.9 Risk assessment should be based on sound science and take into account the whole hazard exposure pathway.

2.7.10 Constraints, uncertainties and assumptions in risk assessment processes should be explicitly considered by risk managers making decisions.

Where appropriate, risk managers should ask risk assessors to evaluate potential changes in risk resulting from different risk management options.

Risk management should be a continuing process that takes into account newly generated data in the periodic re-evaluation and review of decisions.

Risk analysis should be used where relevant to prioritize biosecurity issues for management.

2.8 Steps of Risk Management Framework (RMF)

There is a simple four-step process to work through biosecurity issues.

The first step in the RMF is preliminary risk management activities, consists of a number of interconnected tasks including the commissioning of a risk assessment if deemed necessary by risk managers.

The second step is identification and selection of risk management option in the RMF process whereby potential control measures are identified and selected according to appropriate decision-making criteria.

The third step is implementation of control measures and this involves actions carried out by the competent authority, industry and other stakeholder groups.

The last step is monitoring and review and this is the gathering and analysing of data so as to give an overview of the level of protection achieved, with review of risk management decisions where necessary.

Criteria related to risk assessment

2.8.1 Prevalence of adverse health effects

2.8.2 Severity of adverse health effects

2.8.3 Economic impacts

2.8.4 Environmental impacts

2.8.5 Degree of uncertainty in the risk estimate

2.8.6 Availability of validation data

Additional criteria related to risk management

2.8.7 Regulatory jurisdiction

2.8.8 Contribution to national biosecurity goals

2.8.9 Likely social impact

2.8.10 Feasibility and practicality of control measures

2.8.11 International trade obligations

2.8.12 Cost benefit analysis

2.9 Decisions on Levels

It is a common desire in all biosecurity sectors to quantify levels of protection/ levels of risk, some quantitative expressions of level of protection / level of risk:

2.9.1 Incidence of a disease in an entire population in a country per year.

2.9.2 Public health risk per edible portion of a food.

2.9.3 Animal health risk per import consignment of a commodity or conveyance.

2.9.4 Animal health risk per total imports of a commodity or conveyance per year.

Appropriate Levels of Protection (ALOP)/acceptable level of risk

"Zero risk" is rarely, if ever, attainable in biological systems. Further, attempting to achieve "zero risk" is seldom economically efficient; successive step reductions in risk usually become increasingly costly to achieve and will eventually add more costs than benefits. Risk is generally described in terms of probability and severity of adverse effects. However, problems can arise when attempting to quantify these characteristics to inform a decision on level of protection/level of risk. Where an ALOP cannot be precisely expressed, the ALOP may be determined on the basis of the level of protection reflected in the control measures in place.

General approaches/ Appropriate Levels of Protection (ALOP)

Some general approaches to decision-making on the level of health and life protection in different situations:

2.9.5 Direct comparison of risks (e.g. classification of animal diseases by OIE).

2.9.6 Balancing approaches (e.g. inspection of plant commodities for freedom from a hazard to a specified tolerance).

2.9.7 Procedural approaches where ALOP is determined by legal mandate, precedent or negotiation (e.g. full protection of endangered species or fragile protected areas, legal requirement to address weeds classified as noxious regardless of abundance or spread potential).

2.9.8 Zero-risk determinations (e.g. amount of a food additive that can be ingested daily over a lifetime without appreciable health risk).

2.9.9 Threshold approaches (e.g. no more than one additional case of disease above background per million target population).

2.10 Economic Factors

Economic factors provide a common thread in making decisions on biosecurity control measures. The WTO SPS Agreement states that in selecting measures to protect animal or plant health, governments shall take into account as relevant economic factors: costs of potential losses in production or sales, costs of control or eradication, and the relative cost-effectiveness of alternative measures. Costs of compliance on individual stakeholder groups (e.g. farmers, fishermen, exporters) and society as a whole affect international trade competitiveness, innovation and sector growth. Cost-effectiveness analysis may have wider applicability e.g. determining the least-cost method of achieving a particular health target. Other methods that are narrower in scope can be employed (e.g. compliance cost analysis and economic impact assessment). The latter focuses only on the consequences of risk. When common units for costs and benefits cannot be found, techniques include identification of "significant" risks and risk ranking.

Risk managers should develop an implementation plan that describes how the option will be implemented, by whom, and when after the validation of the option which will be followed by verification to ensure proper and effective implementation.

Collaboration and assistance should be provided by international intergovernmental organizations where necessary, e.g. FAO and WHO, and developed countries in the spirit of the SPS Agreement.

2.11 Monitoring and Review

Monitoring in biosecurity is variously described as either including or excluding "surveillance". For the purposes of this manual, "monitoring" includes activities ascribed elsewhere to both "monitoring" and "surveillance". The aim of monitoring is to gather and analyse data on the level of control of specific hazards throughout the exposure pathway and the level of protection/level of risk in the target population that is attributable to those hazards. For imported agricultural products or conveyances, it is not possible to check every unit or lot in a consignment for the presence of hazards. Official monitoring programmes in the country of origin are often imposed by importing countries as a means to improve the limited assurance that can be gained from sampling plans and procedures imposed at the border. Monitoring may be enhanced by national networks incorporating genotyping of pathogens. As an example, FoodNet in the United States is a surveillance system where specific sites are used to seek out

epidemiological information on food-borne illnesses identified by public health and regulatory laboratories. Data are collected into the PulseNet system that expedites comparison of pathogens to quickly spot related clusters of infections.

Where monitoring of hazards or risks indicates that biosecurity objectives are not being achieved, risk management strategies and/or control measures will need to be reviewed. Review may also be required when new information on hazards and/or risks arises. Some reasons for review of biosecurity strategies and/or control measures:

2.11.1 Changes in monitoring outcomes

2.11.1.1 Changes in risks (prevalence and/or severity) identified.

2.11.1.2 New hazards identified.

2.11.1.3 Inadequate performance against risk reduction goals identified.

2.11.2 Changes in the biosecurity situation

2.11.2.1 Change in type of commodity or conveyance in trade.

2.11.2.2 Change in volume of trade.

2.11.2.3 Change in environmental "stressors" (e.g. climate change).

2.11.2.4 Availability of more effective and/or more efficient control measures.

2.11.2.5 Inability to consistently comply with a control measure

Evaluation of the overall performance of a competent authority will draw heavily on full application of the RMF process. Performance indicators for measuring intermediate and ultimate outcomes will mostly be derived from monitoring data. Monitoring programmes to demonstrate such outcomes depend on appropriate infrastructure and technical capacity and this can be provided by competent authority, competent body and industry resources.

V. REFERENCES

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4. The National Plant Biosecurity Status Report in Australia 2012