Annexes

1. GLOSSARY

Acceptable daily intake. An estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis that can be ingested daily over a lifetime without appreciable risk.

Animal. For the purposes of this toolkit, animal includes mammals, birds, fish and bees.

Audit. A systematic and functionally independent examination to determine whether control activities and results comply with documented objectives.

Biodiversity. The variability among living organisms from all sources, including diversity within species, between species and of ecosystems.

Biosafety. This term is widely used in biosecurity and a general working description is "the safe use for human, animal and plant health, and the environment, of new biotechnologies." In the Convention on Biological Diversity and Cartagena Protocol, biosafety is defined as the "means to regulate, manage or control the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health (UNEP/CBD. 1992. Article 8(g)).

Biosecurity. Biosecurity is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life and health and associated risks to the environment.

Competent authority. The official authority charged by the government with sector control of biosecurity, including setting and enforcing of regulatory requirements.

Competent body. An officially-recognized body acting under the supervision and control of the competent authority.

Control measure. Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

Emerging zoonosis. A zoonosis that is newly recognized or newly evolved, or that has occurred previously but shows an increase in incidence or expansion in geographic, host or vector range.

Equivalence. The capability of different biosecurity controls to achieve the same health objectives.

Food-borne zoonosis. An infection transmitted through food to humans when the source of the infection is an animal.

Harmonization. The establishment, recognition and application by different countries of biosecurity controls based on common standards.

Hazard-based. Decisions and actions in biosecurity control programmes that are based on objective and verifiable information on hazards.

Input. Any information that is fed into a risk assessment model.

Invasive alien species. An invasive alien species outside its natural past or present distribution whose introduction and/or spread threatens biodiversity.

Maximum residue limit. The maximum concentration of residue resulting from the use of a chemical during primary production that is acceptable in or on a food.

Model. A simplified representation of the real world.

Monitoring. Periodic collection and analysis of data on hazards at relevant steps throughout the exposure pathway.

Performance objective (in relation to food safety)**.** The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to a food safety objective or appropriate level of protection (ALOP), as applicable.

Quality assurance. All the planned and systematic activities implemented within a quality system that provide confidence that an entity will fulfil requirements for quality.

Risk. A function of the probability of an adverse effects on health or life in a biosecurity setting and the severity of those effects.

Risk assessment. A scientifically-based process that is used to identify hazards, characterize their adverse health impacts, evaluate the level of exposure of a given population to those hazards, and estimate the risk.

Risk assessment policy. Guidelines on the availability and choice of default assumptions at scientifically-uncertain decision points in risk assessment.

Risk-based. Decisions and actions in biosecurity control programmes that are based on specific knowledge of risks to health or life.

Risk communication. The interactive exchange of information and opinions on risk, risk management issues and risk perceptions.

Risk management. The process undertaken by the competent authority of weighing risk assessments, policy alternatives and stakeholder views relative to health protection, and selecting any controls needed.

Risk profile. A description of the context and potential risks associated with a biosecurity issue that will help in guiding further action.

Sensitivity analysis. A method used to examine the behaviour of a model by measuring the variation in its outputs resulting from changes to its inputs.

Stakeholder. "Internal" stakeholders are risk assessors, risk managers and risk communicators employed by the competent authority; "external" stakeholders are other branches of government and foreign governments, competent bodies, industry, academic communities and public interest groups.

Surveillance. Active and ongoing collection, analysis and dissemination of data on risks to life and health.

Validation. Objective demonstration that biosecurity controls are effective in achieving stated outcomes.

Verification. Activities that are performed, in addition to monitoring, to determine whether a biosecurity control(s) is or has been operating as intended.

Zoonoses. Infectious diseases that can be transmitted naturally between wild or domestic animals and humans.

2. TYPICAL SECTOR ROLES OF COMPETENT AUTHORITIES IN BIOSECURITY[70]

Agriculture / Forestry

- Formulation and implementation of legislation and policies (e.g. transboundary diseases and pests, zoonoses, food-borne diseases and invasive alien species)
- Development of the agriculture and food sectors including agri-food exports
- Risk analysis
- Inspection, quarantine, diagnosis, surveillance, emergency response and other risk management activities, etc.
- Certification of products
- Participation in international organizations and bodies involved in agriculture (e.g. FAO, OIE, Codex, CPM/IPPC)

Fisheries

- Formulation and implementation of legislation and policies (e.g. transboundary diseases, invasive alien species).
- Development of the fisheries sector including fisheries exports
- Inspection, quarantine, diagnosis, surveillance, emergency response and other risk management activities
- Certification of products
- Participation in international organizations and bodies involved in agriculture (e.g. FAO, OIE, Codex)

Public Health

- Formulation and implementation of public health legislation and policies,
- Prevention and control of illnesses, including food-borne diseases, zoonoses, transboundary diseases
- Prevention of malnutrition
- Participation in international organizations and bodies (e.g. WHO, Codex, WHA)

Environment

- Formulation and implementation of legislation and policies (e.g. invasive alien species, biosafety)
- Inspection, quarantine, diagnosis, surveillance, emergency response and other risk management activities
- Participation in international organizations (e.g. UNEP) and conventions (e.g. CBD)

Trade and Economics

- Regulation of imports and exports including provision of trade permits
- Export promotion and development
- Regulating movement/trade in potential alien invasive species
- Certification of agri-food exports

Justice

- Development and enforcement of laws, rules and regulations

Customs

- Enforcement of government regulations on the import and export of agricultural and related products

Transport

- Safe and documented transportation and storage of food and other agricultural imports, exports, and inputs to agriculture (e.g. chemicals, pharmaceuticals)

Foreign Affairs

- Coordination of international aspects of biosecurity
- Participation in international organizations and bodies (e.g. WTO, Codex, OIE, CPM), international agreements (e.g. GATT, SPS, TBT) and conventions (e.g. IPPC, CBD)

Finance

- Budgetary allocations for biosecurity

Planning and Development

- Formulation of national development strategies and implementation plans

Tourism

- Monitoring effect of tourism on the environment

70 Note that competent bodies, acting under the supervision and control of the competent authority, also implement biosecurity standards.

3. INTERNATIONAL LEGAL INSTRUMENTS, AGREEMENTS, TEXTS, ORGANIZATIONS AND BODIES ASSOCIATED WITH BIOSECURITY[71]

Given the broad scope of biosecurity, several international organizations and bodies are associated with biosecurity and numerous global and regional agreements and soft-law instruments are potentially important. Some of the most relevant are introduced (in alphabetical order) below.

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

The SPS Agreement sets out the basic rules in the WTO on how governments (Members) can apply food safety and animal and plant health measures (sanitary and phytosanitary or SPS measures). Under the SPS Agreement, Members are permitted to set their own standards, but they must be based on science and applied only to the extent necessary to protect human, animal or plant life or health. Members are encouraged to use international standards, guidelines and recommendations where they exist, however, they may use measures which result in higher levels of protection if there is scientific justification. The text of the agreement and other information is available on the WTO web site (www.wto.org/english/tratop_e/ sps_e/sps_e.htm).

Agreement on Technical Barriers to Trade (TBT Agreement)

The TBT Agreement seeks to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade. It states that the procedures used to decide whether a product conforms with relevant standards have to be fair and equitable, and discourages any methods that would give domestically produced goods an unfair advantage. The text of the agreement and other information is available on the WTO web site (www.wto.org/english/tratop_e/tbt_e/tbt_e.htm).

Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety, negotiated under the framework of the Convention on Biological Diversity (CBD) and adopted in January 2000 (entered into force in September 2003), is the first global instrument on biosafety. It sets out a comprehensive regulatory system to ensure the safe transfer, handling and use of living modified organisms (LMOs) resulting from any modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health and specifically focusing on transboundary movements. More information is available on the Internet (www.biodiv.org/biosafety).

Codex Alimentarius Commission and the Codex Alimentarius

The Codex Alimentarius Commission (CAC) was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts. The Codex Alimentarius constitutes a collection of internationally adopted food standards, guidelines and recommendations, developed by the CAC. Although Codex standards and related texts in and of themselves are not binding, they have become international reference points through the SPS Agreement, which adopted them in 1995 as the benchmark for all international food standards. More information is available on the Internet (www.codexalimentarius.net/web/index_en.jsp).

Convention on Biological Diversity (CBD)

Adopted in 1992, under the auspices of the United Nations Environment Programme (UNEP), the Convention on Biological Diversity (CBD) is the first global treaty to provide a comprehensive framework that addresses all aspects of biodiversity (i.e. ecosystems, species and genetic diversity). It explicitly addresses animal and plant life and health as well as the management of risks associated with living modified organisms (LMOs) resulting from biotechnology and the management of risks associated with alien species. There is considerable overlap between the the provisions

[71] Derived from the indicated web sites and the following paper: Ingrassia, A. International and Regional Regulatory Frameworks Relevant to Biosecurity for Food and Agriculture. Background paper commissioned by FAO for the FAO Technical Consultation on Biosecurity in Food and Agriculture, Bangkok, Thailand, 13-17 January 2003.

of the CBD and IPPC. For more information, see the CBD web site (www.biodiv.org/convention/default.shtml).

Food and Agriculture Organization of the United Nations (FAO)

FAO leads international efforts to defeat hunger. Serving both developed and developing countries, FAO acts as a neutral forum where all nations meet as equals to negotiate agreements and debate policy. FAO is also a source of knowledge and information, and provides technical assistance to modernize and improve agriculture, forestry and fisheries practices and ensure good nutrition for all in developing and transition countries. As such, FAO is actively involved in normative work and technical assistance, at the both the national and international levels, to support the effective implementation of biosecurity at the national level. More information is available on the FAO web site (www.fao.org and www.fao.org/biosecurity/).

General Agreement on Tariffs and Trade (GATT 1947)

GATT 1947 potentially covers areas not addressed by the SPS Agreement and remains relevant to biosecurity even after the formation of the WTO in 1995. Article XX sets out the General Exceptions to the Agreement as follows:

> *"Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:*
>
> *(*b) *necessary to protect human, animal or plant life or health;"*

More information is available on the WTO web site (http://www.wto.org/english/docs_e/legal_e/legal_e.htm#gatt47).

International Health Regulations (IHR)

A revision of the International Health Regulations was unanimously adopted on 23 May 2005 by the World Health Assembly and these Regulations entered into force in June 2007 for all WHO Member States. The purpose and scope of the IHR (2005) are to "prevent, protect against, control and provide a public health response to the international spread of disease and which avoid unnecessary interference with international traffic and trade". Further information about IHR is available on the WHO web site (http://www.who.int/csr/ihr/en/).

International Plant Protection Convention (IPPC) and the Commission on Phytosanitary Measures (CPM)

The IPPC entered into force in 1952 to regulate plant pests, as well as any organism, object or material capable of harbouring or spreading pests that affect plants or plant products in order to prevent the spread and introduction of these pests and promote measures for their control. It formalizes procedures for standard setting and outlines modern phytosanitary concepts. The New Revised Text of the IPPC was approved in 1997. Revision was undertaken to reflect contemporary phytosanitary concepts and the role of the IPPC in relation to the Uruguay Round Agreements of the World Trade Organization, particularly the SPS Agreement. The New Revised Text provides for the establishment of a Commission on Phytosanitary Measures (CPM) that will serve as the global agreement's new governing body; the members of the CPM are the contracting parties to the Convention. The CPM adopts International Standards for Phytosanitary Measures (ISPMs), which are recognized by the WTO as reference international phytosanitary rules. More information is available on the International Phytosanitary Portal (www.ippc.int).

International Maritime Organization (IMO)

The IMO provides support for national marine biosecurity programmes in several areas (e.g. marine pest surveillance, risk assessment and biofouling management). More information is available on the IMO web site (www.imo.org/).

Organisation for Economic Cooperation and Development (OECD)

OECD contributes to cross-sectoral biosecurity activities in a number of ways. The OECD Environment, Health and Safety Programme fosters international cooperation in the area of chemical safety by harmonizing policies and instruments (e.g. pesticide registration programmes) for use in the protection of health and the environment. It also sponsors economic evaluation of agricultural systems e.g. research into the costs and benefits of private sector standards (G/SPS/GEN/763), works to minimize non-tariff barriers to trade, and develops economic policies and

instruments for use by countries in the management of biodiversity. More information is available on the OECD web site (www.oecd.org).

World Health Organization (WHO)
WHO specializes in human health. Although not directly involved in setting international standards for biosecurity aspects of human health (food safety and zoonoses), it actively contributes to global databases on these topics and assists governments, civil society, industry and consumers in gaining up-to-date scientific information on new and emerging hazards. Regarding food safety, WHO helps in integrating and strengthening surveillance systems for food-borne disease on a world-wide basis and is promoting a multidisciplinary response to emerging food safety issues. WHO is actively involved in normative work and technical assistance, at the both the national and international levels, to support the effective prevention of and response to international spread of zoonotic diseases. WHO hosts the joint WHO/FAO International Food Safety Authorities Network (INFOSAN), which includes a food safety emergency component. The International Health Regulations (2005), which entered into force in June 2007 for all WHO Member States, cover international public health events related to animal and food transport over borders (see above). Further information is available on the WHO web site (www.who.org).

World Organisation for Animal Health (OIE)
The OIE develops normative documents relating to rules that Member Countries can use to protect themselves from animal (including fish and bees) diseases and zoonoses, without setting up unjustified sanitary barriers. These texts include the International Animal Health Code, the Manual of Standards for Diagnostic Test and Vaccines, the International Aquatic Animal Health Code and the Diagnostic Manual for Aquatic Animal Diseases. OIE standards are recognized by the WTO as reference international sanitary rules. More information is available on the OIE web site (www.oie.int/eng/en_index.htm).

World Trade Organization (WTO)
The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business. More information is available on the WTO web site (www.wto.org).

4. EXPERIENCES OF BELIZE IN MOVING TOWARDS AN INTEGRATED BIOSECURITY APPROACH

Reasons for adoption of an integrated approach

- Limited resources to perform key functions in agricultural health and food safety
- Funds out of a consolidated government revenue – competition among public ministries / agencies
- Duplication of roles across ministries / agencies
- Outdated legislative support
- International trade requirements (SPS Agreement)
- Scattered focus, poor coordination of agricultural health and food safety

Agencies responsible for components of biosecurity before change

- Ministry of Agriculture and Fisheries (plant and animal health including fish health)
- Ministry of Health (meat and food inspection, public health functions, zoonoses (rabies programme)
- Ministry of Trade (permits and licences for imported goods including agricultural goods and commodities)
- Bureau of Standards (consumer protection, food standards)
- Ministry of Natural Resources (forestry, environmental functions including biosafety)
- Customs department (ports inspection)

Agencies responsible for biosecurity after change

- Belize Agricultural Health Authority (BAHA) – agricultural health and food safety including aquatic animal health and biosafety
- Ministry of Health – human health and food safety at retail level (through memorandum of understanding)
- Bureau of Standards (food standards, consumer protection)
- Ministry of Natural Resources, Dept. of Environment (environmental impact assessments, environmental monitoring)
- Fisheries Department (aquaculture production)

Responsibilities of agencies involved in biosecurity after change

- Belize Agricultural Health Authority (BAHA) responsible for agricultural health and food safety (animal health, plant health, food safety, quarantine, sanitary and phytosanitary measures, regulation of imports sand exports) based on a risk analysis approach
  - Hosts the focal point for OIE, IPPC, SPS enquiry point and the Biosafety Focal Point (including the Biosafety Clearing House)
  - Codex Contact Point located in the Bureau of Standards under the Government appointed Standards Advisory Council (chaired by BAHA)
- Ministry of Health responsible for human health including food safety at the retail level (restaurants, retail outlets, meat shops, hotels, etc.)
- Ministry of Natural Resources (Dept. of Environment) responsible for environmental programmes and serves as the CBD contact point
- Pesticide Control Board responsible for regulation of pesticides (BAHA on Board of Directors)

Challenges

- Status of staff (including conditions of employment) in BAHA: new staff employed on contract basis while original staff retained their status as civil servants
- Maintaining competency with shrinking resources (human and financial)
- Legal support for BAHA's wide (and expanding) mandate
- Cost recovery for public good programmes (a government function)
- Wide, porous borders – difficult to provide full coverage
- Position under and relationship to parent ministry and weak inputs from other ministries and agencies
- Private sector involvement (raises questions of influence)
- Local recognition as a money generator (raises questions related to sustainability and need for government funds)
- Seen as mainly providing support for the export market and less for local production
- International certification capabilities (recognition of BAHA certification in HACCP, GAP, etc.)

Start-up and other costs associated

- Inter-American Development Bank project (US$3.6 million) covered start-up costs of infrastructure (buildings), equipment, training, etc. and Government of Belize provided US$1.2 million for operational costs
- Resources required to finance vehicles, laboratory buildings, recurrent costs (e.g. reagents and laboratory supplies), insurance, pension funds, etc.

Benefits

- Agricultural health and food safety under one authority provide synergies for effective administration of agricultural health and food safety in Belize
- Increase in agricultural health standards
- One stop shop for processors exporting food and agricultural products and importers (permits)
- Shared resources between the various departments (e.g. quarantine, inspection, internal quarantine for medfly outbreaks, farm quarantine, food safety assessments, surveillance programmes, etc.) – food safety inspectors in slaughter plants perform dual role of food safety and animal health surveillance
- Cost recovery increases sustainability of services provided

Examples of biosecurity capacity building provided to other countries

- Quarantine manual shared with Dominica
- Some parasitoids (biological control) produced in Pink Hisbiscus Mealybug laboratory in BAHA shipped to Mexico and Central America
- Technical cooperation activities with Costa Rica to share experiences in agricultural health and food safety frameworks
- Attachment with BAHA quarantine services (Suriname)
- Consultancies of BAHA technical officers with Caribbean Poultry Association (animal health and food safety programmes and codes of practices) to be shared with CARICOM countries

5. IMPLEMENTING A BIOSECURITY CONCEPT: REFORMING THE FOOD SAFETY, ANIMAL AND PLANT HEALTH ADMINISTRATION IN NORWAY[72]

Background

Until 2004, Norway had separate national control bodies for feed and plant health, animal health and animal welfare and food control, respectively. The central food control authority was a state body, while local food control was performed by municipal authorities. Control of seafood for export was performed by the Directorate of Fisheries. Control of animal health and welfare was performed by district veterinary officers reporting to regional units and the central unit of the Animal Health Authority and control of plant health and feed was performed by plant health inspectors in four regional units and one central unit of the Agricultural Inspection Services.

During the 1990s there was a growing political consensus that the organization of public food administration was not appropriate. Both the structure of the legislation (13 different laws) and the tasks and responsibilities of the different control bodies were fragmented. The industries were also not satisfied with the organization of the control bodies or the control they performed, emphasizing the need to make sure that controls were following a common policy, both between geographical regions and between different sectors along the farm to fork axis.

A process, which went through several phases, encompassed a rather long phase from the political agreement for the need for simplified legislation (a White Paper in 1994) to a preliminary preparation of a reorganized control authority and simplification of legislation in 2002 within the involved ministries. In 2003 an interim authority was established alongside the existing authorities to prepare the practicalities for a physical reorganization of the national and municipal responsibilities and culminated in 2004 in a new control authority and revised and simplified legislation.

The process represented a realization of several overlapping and complementary political signals, both nationally and internationally. These may briefly be summarized as a need to have a clear chain of command and clear constitutional responsibilities along the entire food chain, a need to have a clear separation of tasks between the scientists performing risk assessment and the managers considering risk management, a need to bring regulators closer to the public and operators, and a requirement to simplify regulations in general.

This process overlapped in time with some key issues for Norway on the international scene, namely an European Economic Area (EEA) Agreement between the European Free Trade Association (EFTA) States and the EU encompassing much of the veterinary and food legislation in 1994 and later also encompassing a common veterinary border control in 1998, the WTO agreement in 1995 removing custom barriers to international trade and the fact that the EFTA States Sweden, Finland and Austria chose to join the EU in 1995, while Norway chose to retain the EEA agreement and thereby become one of the only remaining EEA States. These international agreements all had, and continue to have, a major impact on the structure and material content of Norwegian veterinary and food legislation.

Elements and aims of the reorganization

The reorganization of public food, animal and plant health control in Norway consisted of four main elements:

- modernization of the legislation;
- restructuring of responsibility between ministries;
- establishment of a new, national authority for all food and feed production including animal and plant health; and
- reorganization of the scientific support for the new authority.

The aims of the process were:

- to ensure that food (including drinking water) that is produced or sold is safe for consumers;
- to avoid fraudulent practices;
- to ensure that the quality of food complies with national and international standards;

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[72] Case study prepared by Keren Bar-Yaacov, Chief Veterinary Officer, Norwegian Food Safety Authority and Gunnar Hagen, Senior Adviser, Ministry of Agriculture and Food. For further information, contact kebay@mattilsynet.no.

- to ensure good animal health, plant health and animal welfare in Norway; and
- to ensure a more cost-efficient administration.

Modernization of the legislation

Before 2004, Norwegian legislation for feed and food production was fragmented and consisted of 13 different laws. A new food law replacing these 13 laws was enforced from 1 January 2004. The law aims at ensuring food safety, animal and plant health and improving quality and other consumer interests, commercial and environmental aspects. The new law has contributed to simplification of the legislation and also enforces a new system of control fees and taxes. Animal welfare is still regulated in a separate law.

A new law represented the first step in a major restructuring of the regulations in the field of food safety, plant health and animal health. Regulations under all the old laws were updated to take into account the new organizational structure and competence, but two years on there is still much left to be done with regard to realizing the political signal pertaining to a simplified regulatory framework.

The new food law strengthened the official legal powers, giving the authority power to demand action by an operator, act on the operators' behalf and at their expense should they themselves not comply with the authorities demands, impose fines, close business until action is taken, impose a quarantine on businesses for up to six months, and actively inform the public. In addition, the courts may impose penalties.

A major challenge for the new authority is to harmonize actions, so that operators throughout the country can expect both proportionate and consistent reactions to similar situations and conditions. A new organization is only part of the solution, and this is a theme that the authority will have to focus on during the early years.

Restructuring of constitutional responsibility between ministries

Three different ministries are responsible for regulations under the new Food Law. These are the Ministry of Agriculture and Food, Ministry of Fisheries and Costal Affairs and Ministry of Health and Care Services. The constitutional responsibility between the ministries has been reorganized. The ministries have been through a process of clarifying their responsibilities, defined both between primary production and end product and between animal, fish, plant and human health.

All responsibility related to primary production and plant and animal health is placed in the Ministry of Agriculture and Food for terrestrial production and Ministry of Fisheries and Costal Affairs for aquatic production. The Ministry of Health and Care Services is responsible for measures related to human health and also for a majority of rules intended to avoid fraudulent practices.

The Ministry of Agriculture and Food is administratively responsible for the new control authority, while the Ministry of Health and Care Services is administratively responsible for the new risk assessment body.

Establishment of a new, national food control authority for all food production, animal and plant health

In April 2002, the Government proposed an organization with two different control bodies, one for terrestrial production and one for aquatic production. When this matter was discussed in Parliament (Stortinget), the majority of representatives agreed that it would be better to establish one food control authority with responsibility for both terrestrial and aquatic production. The main argument for establishing one control body was to ensure that the needs of industry would be met by an efficient and coordinated body. Many business operators would otherwise be subject to inspection from different control authorities. This conclusion was also in line with the outcome of a broad hearing of the proposed reorganization.

A revised proposal of one food control authority for all food production from farm to fork got broad support from Parliament after being presented in November 2002. In essence this meant that the authorities responsible for seafood controls were given a much shorter time to prepare for the proposed reorganization than the other authorities.

It was decided that the new authority should be operative from 1 January 2004. The authority should have three organizational levels (central, regional and local) and inspections and decisions concerning the food businesses and primary production should be performed primarily by the local level. As responsibility for the tasks performed by the food control authority is divided between three different ministries, a special coordinating group has been set up headed by the administrative leaders in the three ministries.

Much of the practical preparation was performed by working groups with profound knowledge of the matters to be handled. To ensure involvement of different stakeholders (industry, consumers and other NGOs), a reference group was also set up.

An interim organization was set up one year before the new control authority was to be operative. This organization was headed by the already appointed Director General of the new authority who had the necessary power to direct work during an interim period. Employees from all of the former authorities that were to merge into the new authority were involved in the interim organization. Employee organizations were quickly contacted to form a representative reference group (see addendum with comments on the process from this reference group).

For the ministries it was important that the reform also resulted in a more efficient control body (i.e. reduced cost). An objective of at least 10 percent cost reduction was established. This objective should be met by 2008 and, so far, a cost reduction of seven percent has been imposed in the yearly budgets of the new control authority.

The new authority represents a merger of four government authorities and 89 municipal authorities, which in total covered the responsibility for controls along the entire food chain, from the farm to the fork, but in a fragmented organizational and constitutional system. The reorganization involved approximately 1,600 employees, both at central level and throughout the country.

The merging authorities were:

- The Norwegian Food Control Authority
- The Norwegian Animal Health Authority
- The Norwegian Agriculture Inspection Service
- The Directorate of Fisheries, Seafood inspectorate
- The Municipal Food Control Authorities

The new authority is a governmental body responsible for controls along the entire food chain, from primary production to product delivery. The new authority also covers animal welfare and health not related to the food chain, plant health also not related to the food chain, drinking and production water and cosmetics.

The role of the new authority is to:

- prepare draft legislation;
- inform and guide on legislation;
- perform risk-based inspections;
- monitor food safety, plant and animal health; and
- plan for contingencies.

The new authority does not have its own diagnostic services; such services are procured by the authority either on the basis of tenders or through separate agreements with government reference laboratories. This solution was adopted due to political signals to make a clear distinction between government controls and service delivery (see next section).

As required during the political process, a three-level organization has been set up. There is a head office, with approximately 130 employees, eight regional offices with approximately 240 employees and 63 district offices with approximately 950 employees. Most first instance decisions have been delegated to the district level.

Among the eight regional offices, three offices have been designated as national centres for specific productions (terrestrial animal production, aquatic animal production and plant production) and two have been designated specific administrative support functions (data support and archive, book keeping and payments). These are intended to support the entire organization within their specified competence areas so as to boost a small head office. The reasoning behind this organizational choice is partly based on historical factors such as where some of the authorities were based before the reorganization and the desire to maintain competence. However, is was also a major compensation for the political decision to limit the size of the head office in Oslo due to a general political aim to reduce government offices in the capital and decentralize them to rural areas.

During the one year preceding the actual reorganization, the preparations were project based. Some of these projects focused on preparing a set of administrative tools, such as one central electronic archive, electronic document handling and electronic budget planning and control. Other projects focused on preparing major thematic issues such as export certification and seafood controls and finally there were also projects aimed at building a common “brand” including a name for the new authority, a logo and agreed aims and responsibilities. The meetings where such issues were discussed around the whole country were also used as an introduction to cultural fusion between the old authorities.

The most difficult aspect of the reorganization was the process of assigning personnel to new offices. All top management positions (director general and regional directors) were advertised and were open for external candidates. All other management positions

were only open for candidates from the former authorities (including the municipal food control authorities). Once these positions were filled, personnel were given the opportunity to state where they believed they belonged in the new organizational chart and the new managers made a round of interviews to clarify who was to work where.

In this complicated process there was a further complication due to two very difficult issues. One was the decision to sever the contact between the local authority and existing local laboratories. This meant there had to be a clarification concerning which personnel primarily belonged to the new authority and which personnel had to stay behind with the laboratory units. The other was a decision to limit the possibility for local official veterinarians to take part in private practice. In many rural areas of Norway this mix of official work and private practice was historically the only possibility to recruit practitioners to these areas. These employees were, in the process of the reorganization, given the choice to join the new authority as full-time officials or leave and become full-time practitioners. This was a very difficult decision for many, and their choice could also leave the authority very vulnerable in some regions, since very experienced employees often preferred private practice to full-time official work. The consequences of these two very difficult issues are still felt two years on.

The process of identifying which office one was to work from was rather simpler at local and regional level than head office. The background for this was the decision to limit the size of the head office. This limit meant that many employees working at central level in the old authorities would not be given a slot at this level in the new authority. These employees were then offered positions at the national centres at regional level. For many this meant a geographical move. Employees were given leeway to prepare their move over 18 months (i.e. no one was forced to physically move before July 2005 and compensation was provided to cover moving expenses as well as to those who decided to resign). Still, this was a very traumatic experience for many employees who had worked for many years in the same position.

Reorganization of scientific support for the new authority

An important element in the reorganization was to ensure that the risk management performed by the authority was scientifically based. Many international food and animal health crisis during recent years have focused on the need to have a clear separation of tasks between risk assessors and risk managers. In order to ensure independent scientific risk analyses for the authority and ministries, a new scientific committee with an independent budget was created.

The scientific committee shall provide a scientifically based risk assessment covering the remit of the new authority. In addition to serving the new authority, the committee may also themselves initiate and perform risk assessments. The structure of the scientific committee mirrors the structure chosen by the European Union in the establishment of the European Food Safety Agency (EFSA), a small secretariat serving eight independent scientific panels. The participants on the panels are chosen based on their scientific merits in the appropriate field covered by the panel.

A challenge in relation to utilizing this asset is to have clear routines and understanding on communication between the authority and the committee secretariat. During the two first years a document describing the interaction between authority and scientific committee has been developed and refined.

Another central element in the reorganized scientific support was the question of laboratory support. In order to have a clear separation between service providers and public administration, laboratory services were not included in the new authority. Before the reorganization, the municipal food control units had integrated laboratory services as part of their remit. This in effect meant that the local food control units had to be split into elements that joined the new authority and elements that were not included in the authority, and therefore had to find other solutions for personnel and equipment. This was a very traumatic and difficult process for all involved.

The new authority was also given the task of solving their laboratory needs through official tenders. There was in this matter in many ways a steep learning curve both for the buyers and for the sellers. A political requirement to be both cost efficient and to support rural development was also a very difficult balance to keep.

Conclusions and lessons learned

The reform of the food safety administration in Norway represents one of the larger administrative reforms in Norway in recent years. The reform included many

elements, which all are interdependent in achieving a successful conclusion to such a radical process. The reform required clarification of the constitutional responsibilities, strengthening and simplification of legal powers, a clear division of risk assessment and risk management, and a coherent and effective operational body in close contact with operators and the public.

Some immediate lessons learned are:

- Make sure the political signals are clarified early on.
- Ensure that operational capacity is maintained in the existing authorities while preparing for the new one.
- Ensure that legislation gives the new authority sufficient legal powers.
- Political and organizational decisions concerning changes to personnel requires time. It is wise to try and limit the number of different processes to be handled at once. Consider if some decisions may be better delayed. Avoid "brain drain".
- Do not overestimate the readiness to learn and understand new administrative solutions in a very turbulent, and for many, personally difficult situation. New and technically advanced solutions require time if they are to become efficient. Non-essential revolutions are probably best planned for a stage where things have begun to settle down.
- Do not expect success from day one. Do not underestimate the cost-effectiveness of local solutions, and how much new solutions really cost, both in relation to budget and in relation to human resources to change a system.
- Cultural differences in the merging organizations need special focus. In the aftermath of the first wave of inspiration, there is often a sense of personal loss.
- Estimate that there will often be a gap between expected time and actual time spent on solving different tasks. Organizational theory implies that it might take two to four years to finally settle down. In the meantime, efforts need to be taken to minimize energy loss.

ADDENDUM: PARTICIPATION OF EMPLOYEES' ORGANIZATIONS IN THE FOUNDING OF THE NORWEGIAN FOOD SAFETY AUTHORITY[73]

The employees' organizations were included in the work involved in establishing one single food safety authority in the autumn of 2001. Two working groups, which were functional throughout 2002, were set up:

- One was supposed to assess the new Norwegian Food Safety Authority's professional areas of focus, which names and terms should be used within the organization and whether there should be two or three administrative levels
- The second was supposed to appraise the ramifications of moving the local food control authorities' functions to the State, look at personnel matters related to founding the Norwegian Food Safety Authority and the transferral of personnel from municipal to state activities

Part of the reason the process involved in establishing the Norwegian Food Safety Authority has been deemed a success, as opposed to many other attempts at reorganization of government authorities, was that the employees' organizations were included in the process very early on.

The Norwegian Food Safety Authority was solely responsible for building up an organization to prepare for the founding of the new Norwegian Food Safety Authority. The director soon brought in the employees' organizations. The principles guiding the organizations' participation in the founding of the Norwegian Food Safety Authority were regulated by a special agreement between the Ministry of Modernization and the main employer organizations.

Political decisions

Parliament made important political decisions on the establishment of the Norwegian Food Safety Authority. These political decisions had wide-ranging repercussions on employees. The decision to have a "slimmed down" head office entailed reducing the number of employees in relation to the total labour force at two of the three original authorities (the Agricultural Inspection Service had its main office in Ås) which had their main office in Oslo. A great many employees' jobs were transferred to other parts of the

[73] Written by Ingunn Bråthen, Senior Adviser, Confederation of Vocational Unions (YS) and Odd Jenvin, Senior Adviser, Federation of Norwegian Professional Associations.

country. However, many people could not imagine moving with their jobs. Some were offered other jobs, but there is reason to believe that the decision to have a "slimmed down" head office led to the Norwegian Food Safety Authority losing employees and thus important skills during the reorganization process.

Parliament decided that laboratory services would not be a part of the new Food Safety Authority. The laboratories in the remit of the municipal food safety authorities were expected to become independent units. Not all these units could survive; some were closed down and some employees lost their jobs.

Excluding laboratory services made it difficult to match municipal workers to jobs in the Norwegian Food Safety Authority. Some employees' jobs were connected to laboratory services only in part. Some employees worked at the laboratory and for the municipal administration, or for the municipal food safety authority. This made gaining an overview difficult, i.e. whether the person concerned should stay in the municipality, be placed in a new job in the Norwegian Food Safety Authority or carry on working at a newly independent laboratory.

Parliament's decision in November 2002 that the Norwegian Food Safety Authority should be operative from 1 January 2004 meant that reorganization would have to take place over an extremely short period of time. A lack of time was a real obstacle to cooperation between the Norwegian Food Safety Authority's management and the employees' organizations. On a number of matters, it was impossible to have thorough and inclusive discussion. Many employees have thus been left with the impression that decisions were made without their involvement. This posed a dilemma for the organizations: either to participate in a process with very short deadlines and thus only have limited chances to scrutinize matters thoroughly and inclusively or to be mere onlookers.

Transferral of employees from municipalities

It was most problematic that there was a great deal of insecurity among the employees of the 89 municipal food control authorities, who were supposed to be integrated into the new, state-administrated Norwegian Food Safety Authority, as it was not known how many employees would be transferred in total.

Negotiations were conducted between the Ministry of Agriculture and the municipalities on transferring approximately 800 people. These negotiations were only completed in August 2003. Only jobs in which more than 50 percent of the tasks came under the remit of the Norwegian Food Safety Authority were transferred. The organizations were not involved in these negotiations.

Municipal employees were thus placed in new jobs, but a uniform system for salaries and job structure had not yet been fully worked out. One important challenge for the Norwegian Food Safety Authority in the time ahead will thus be how to respond to the differences in salaries which have arisen within the same job code. The same applies to variations in and between the regions concerning use of job codes within the same skills field.

Employees' skills went unused

Establishing the Norwegian Food Safety Authority did not just entail merging five existing authorities, but also extensive restructuring of the way these authorities operate. The farm-to-fork principle entailed a new and more uniform inspection philosophy. This meant that employees had to develop new methods of working. When assigning tasks between head office and the regional centres was decided, this process did not sufficiently involve the employees who had the relevant skills. Skilled employees were not consulted when the management was deciding to move tasks and transfer methods of working.

Summary

From the point of view of the employees' organizations, some aspects of the process facilitated the extensive reorganization during a short period of time. First, a completely new authority was to be established. There is broad agreement that merging will be beneficial from the point of view of efficiency in a number of areas. In addition, the Norwegian Food Safety Authority is not regarded as being just an organizational continuation of one of the earlier authorities. It is a brand new organization with a new inspection philosophy. Second, a director was employed at the Norwegian Food Safety Authority whose background was not from one of the merged authorities. The director appeared to be independent, unbiased towards any one authority and could thus think in new ways. Third, it is important to emphasize that the Norwegian Food Safety Authority's management had an open and inclusive attitude towards the employees' organizations in most areas. The Norwegian Food Safety Authority's

management was interested in finding solutions. Solutions to problems which appeared along the way were found mainly thanks to cooperation and dialogue with the employees' organizations. The form of cooperation which was established between the management of the Norwegian Food Safety Authority's interim organization and the employees' organizations is still in place today, even after the formal founding of the Norwegian Food Safety Authority has been completed.

6. BROAD QUESTIONS TO TAKE STOCK OF EXISTING CAPACITY AND PERFORMANCE OF CORE BIOSECURITY FUNCTIONS

Scientific research and advice

- Are there established policies, procedures and regulations governing the provision of scientific advice?
- What is the scope of scientific research and advice (outputs) provided?
- Which stakeholders are responsible for the provision of scientific advice? What are their respective roles and responsibilities? How do they work together?
- What operational principles (scientific integrity, honesty, impartiality, etc.) and procedures (e.g. risk analysis) guide the provision of scientific advice?
- What is the capacity for risk assessment?
- What human, financial and other resources are available for the provision of scientific advice? How are they allocated?
- What linkages exist between those responsible for the provision of scientific advice and other stakeholders (e.g. public health and academic institutions, inspection services, national / international laboratories, etc.)?

Risk profiling and priority setting

- Is there an established policy governing risk profiling and priority setting?
- What is the scope and nature of risk profiling activities carried out? How are priorities set?
- Which government agencies and other stakeholders are involved in risk profiling and priority setting? What are their respective roles?
- What operational principles and procedures guide risk profiling and priority setting activities?
- What resources (e.g. human, financial, information) are available for risk profiling and priority setting? How are they allocated?
- What linkages exist between those responsible for risk profiling (a scientific activity) and those responsible for priority setting (a risk management activity)?
- Are there linkages between biosecurity sectors that facilitate cross-sectoral priority setting where appropriate?

Setting and implementing biosecurity regulatory activities

- Are there established policies, procedures and regulations governing biosecurity regulatory activities?
- What is the scope of biosecurity regulatory activities including standard setting and implementation?
- What operational principles and procedures guide biosecurity regulatory activities and their implementation?
- Which stakeholders are involved in standard setting and other biosecurity regulatory activities? What are their respective roles?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for implementation of biosecurity regulatory activities? How are they allocated?
- What linkages exist between those responsible for biosecurity regulatory activities and other concerned groups (e.g. industry)?

Diagnostic services

- Are there established policies, procedures and regulations governing diagnostic services?
- What is the scope and type of diagnostic services (outputs) provided?
- Which stakeholders are responsible for diagnostic services? What are their respective roles and responsibilities? How do they work together?
- What operational principles (e.g. independent, unbiased, etc.) and procedures (e.g. sampling protocols, analytical procedures, quality assurance, reporting and documentation, etc.) guide the provision of diagnostic services?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for the provision of diagnostic services? How are they allocated?
- What linkages exist between those responsible for the provision of diagnostic services and other stakeholders (e.g. public health and academic institutions, inspection services, national/international laboratories, etc.)?

Inspection, verification and enforcement

- Are there established policies, procedures and regulations governing inspection and enforcement?
- What is the scope and type of inspection, verification and enforcement?
- Is inspection and verification risk-based?
- Which stakeholders (government and others) are involved? What are their respective roles and responsibilities? How do they work together?
- What operational principles and procedures guide inspection, verification and enforcement?
- What human, financial and other (infrastructure, equipment, etc.) resources are available? How are they allocated?
- How are competencies for personnel other than government established and maintained (e.g. accredited training programmes)?
- What linkages exist between those responsible for inspection, verification and enforcement and other stakeholders (e.g. laboratories, industry, general public)?

Quarantine and certification

- Are there established policies, procedures and regulations governing quarantine and certification?
- What is the scope and type of quarantine services (e.g. border control, animal quarantine, plant quarantine, human quarantine, government and/or third party certification)?
- Which stakeholders are responsible for quarantine and certification? What are their respective roles and responsibilities? How do they work together?
- What operational principles (e.g. independent, unbiased, etc.) and procedures (e.g. sampling protocols, analytical procedures, quality assurance, reporting and documentation, etc.) guide quarantine and certification?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for the provision of quarantine services? How are they allocated?
- What linkages exist between those responsible for the provision of quarantine services and certification and other stakeholders (e.g. inspection services, laboratories, etc.)?

Emergency preparedness and response (including contingency planning)

- Are there established policies, procedures and regulations for biosecurity emergency preparedness and response?
- What type of work is carried out under emergency preparedness and response?
- Which stakeholders are responsible for biosecurity emergency preparedness and response? What are their respective roles and responsibilities? How do they work together?
- What operational principles and procedures guide biosecurity emergency preparedness and response?
- Are risk analysis principles applied with ranking of risks as appropriate?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for emergency preparedness and response? How are they allocated?
- What linkages exist between the organizations responsible for biosecurity emergency preparedness and response, organizations responsible for preparing for and responding to other types of emergencies, and other concerned stakeholders (e.g. consumers, industry, general public)?

Risk communication

- Are there established policies, procedures and regulations governing risk communication?
- What is the scope of work carried out as part of risk communication? Does it cover both “outgoing” communication to inform stakeholders about biosecurity risk(s) and measures to manage it (them), and “incoming” communication to obtain information, data, opinions and feedback from them?
- Which agencies are responsible for biosecurity risk communication? What are their respective roles and responsibilities? How do they work together?
- What operational principles and procedures guide biosecurity risk communication?
- What human, financial and other (infrastructure, equipment, etc.) resources are available for biosecurity risk communication? How are they allocated?
- What linkages exist between the organizations responsible for biosecurity risk communication and other stakeholders?

Monitoring and surveillance

- Are there established policies, procedures and regulations governing monitoring and surveillance?
- What is the scope of monitoring and surveillance activities?
- Which stakeholders are responsible for monitoring and surveillance? What are their respective roles and responsibilities? How do they work together?
- What operational principles and procedures guide monitoring and surveillance?
- What human, financial and other resources are available for monitoring and surveillance? How are they allocated?
- What linkages or communication procedures exist between those responsible for monitoring and surveillance and emergency response? What linkages exist with other stakeholders (e.g. inspection services, general public, industry, etc.)?
- Are biosecurity outcomes subject to regular evaluation with review of risk management options if appropriate?

7. STAKEHOLDER ANALYSIS FOR BIOSECURITY

The following template can be used to identify the stakeholders responsible for different aspects of biosecurity.

Task	Ministry / department / group responsible
Formulation and implementation of policies addressing: • public health • food safety • animal health • plant health / forestry • biosafety / biotechnology • environment • fisheries • invasive alien species	
Formulation, implementation and enforcement of legislation addressing: • public health • food safety • animal health • plant health / forestry • biosafety / biotechnology • environment • fisheries • invasive alien species	
Regulatory activities including: • provision of scientific advice • risk profiling and ranking • setting of hazard-based and risk-based regulatory standards • inspection, verification and enforcement • quarantine • certification • diagnostic services • emergency preparedness and response • information exchange and risk communication • monitoring and surveillance	
Competent body / third party activities including: • inspection • verification • certification and /or trade permits • diagnostic services • emergency preparedness and response • monitoring	

(continued)

Task	Ministry / department / group responsible
Coordination and participation in the work of international and/or regional organizations and bodies related to biosecurity: • CAC • FAO • WHO • OIE • WTO • CPM/IPPC • UNEP • Regional bodies	
Implementation and oversight of relevant international agreements, conventions and codes of practice: • GATT • SPS Agreement • TBT Agreement • CBD • IPPC, ISPMs and other international standards • Code of Conduct for Responsible Fisheries	
• Major finance and budgetary decisions related to food and agriculture	
• Formulation of national development plans, strategies, etc.	
• Export promotion and development	

8. SWOT ANALYSIS SCENARIO FOR BIOSECURITY

SWOT analysis is a strategic planning tool that can be used to identify and assess strengths and weaknesses of biosecurity, as well as the opportunities and threats. The process of conducting a SWOT helps to facilitate a common understanding of "reality" among a group of people. This makes it easier to understand and identify key capacity goals and needs, as well as possible solutions. An example SWOT analysis scenario for biosecurity is presented below.

	Positive	***Negative***
Internal	**Strengths:** internal assets that enable those concerned to perform their mandate effectively. • Good animal health status inside the country – effective control and eradication programmes in place for endemic animal and zoonotic diseases and import controls to exclude exotic diseases • Central food analysis laboratory accredited by an international agency • Plant protection border control inspectors in place • Increased interest in biosecurity among government agencies • Adequate risk analysis capacity	**Weaknesses:** internal deficits that constrain those concerned from effectively carrying out their mandate. • Limited understanding and knowledge about biosecurity in some competent authorities • Inconsistent approaches and systems • Fragmented accountabilities • Lack of overall leadership for biosecurity • Inefficient use of human resources available • Poor inter-agency coordination • Resources not allocated on the basis of major risks faced • Weaknesses in monitoring and evaluation • Overall lack of preparedness to cope in the event of a major biosecurity emergency – no strategy or plan for control or containment • Budgetary constraints within government • Competition for government funds among ministries involved in different aspects of biosecurity
External	**Opportunities:** any external circumstance or trend that could positively affect operations. • Recent membership of the WTO and increasing opportunities for international trade • Recent membership of the OIE • Increased attention to biosecurity risks at the regional level following animal disease outbreak in a neighbouring country • Increased availability of international standards • Scientific and technological advances • Availability of risk assessments carried out by international bodies or other national governments • Increased availability of donor financing for biosecurity	**Threats:** any external circumstance or trend that could negatively affects operations. • Other issues competing for high level national attention and resources • Weak capacity of some neighbouring countries to identify and adequately respond to biosecurity risks • Migratory birds • Transboundary animal and plant disease • Pressure to permit entry of certain commodities (imports) • Dumping of inferior quality food products • Civil unrest

9. KEY QUESTIONS TO SUPPORT THE IDENTIFICATION OF BIOSECURITY CAPACITY NEEDS

Existing capacity and performance ***(Step 4)***	**Desired future** ***(Step 5)***	**Capacity needs and options to address them** ***(Steps 6 and 7)***
• How is biosecurity handled at present? • What is the nature and effectiveness of the existing: - policy framework? - legal and regulatory framework? - organizational arrangements (including coordination)? - mechanisms for communication? • What is the scope of biosecurity functions (scientific research and advice, diagnostic services, risk profiling and priority setting, standard setting and implementation, quarantine and certification, inspection, verification and enforcement, emergency preparedness and response, monitoring and surveillance, etc.)? • Which competent authorities and competent bodies are responsible for these functions? What are their respective roles and responsibilities? Is there any duplication or gaps? • What operational principles and procedures guide the delivery of core biosecurity functions? • What resources are available for the delivery of core biosecurity functions? How are they allocated? • What linkages exist between competent authorities and competent bodies responsible for core biosecurity functions and other stakeholders? • What are the main strengths and weaknesses of the existing arrangements for biosecurity?	Describe the desired future of biosecurity in terms of the outcomes and results achieved • What outcomes should be expected of the biosecurity system? • How should biosecurity outcomes be enhanced in the future? • What would the biosecurity system achieve as a whole if it worked effectively and maximized potential cross-sector gains?	• What is required to move from the existing situation to the desired future situation? • What minimum level of capacity is necessary to perform core biosecurity functions, ensure cross-cutting aspects of biosecurity are addressed effectively, and achieve the goals identified? • What maximum level of capacity could be properly utilized? • What are the critical capacity needs (i.e. those that should be addressed first)? • What options are available to address the identified needs? • What are the expected biosecurity impact, costs and benefits, feasibility, affordability, legitimacy and timeliness of these options? • What are the obstacles to achieving the goals identified and what is required to overcome them? • Which actions and activities would be most effective?

10. OPTIONS TO ADDRESS BIOSECURITY CAPACITY NEEDS

This annex presents a variety of options to address biosecurity capacity needs. These options are offered as guidance and are not definitive. As discussed under Step 7 in the Guide to Assess Biosecurity Capacity (Part 2), several options exist and different courses of action will suit different countries, based on their national needs and priorities as well as their access to external support (for instance through technical advice, financial support, mentoring or twinning). Some of the options presented below can be pursued simultaneously and they are not therefore mutually exclusive. There is no inherent "best" set of options. Consequently, the specific type, combination and sequence of options pursued by countries may differ widely.

I. OPTIONS TO STRENGTHEN THE BIOSECURITY POLICY FRAMEWORK

A biosecurity policy framework sets out a broad course of action to address biological risks in food and agriculture based on appropriate public goals and a set of beliefs about the best way of achieving those goals. It provides a common framework for assessing biosecurity risks and priorities, and gives direction and guidance to all the parties concerned.

The options available to strengthen the biosecurity policy framework in a particular country will depend on the nature of relevant existing policies and the policy process. Some countries may already have formulated a policy or policies related to biosecurity or particular sectors of biosecurity. In other countries, the policy framework for biosecurity may be incomplete or outdated. Depending on the needs identified and the future goals of biosecurity, changes may focus on the scope and substance of biosecurity policy and/or the policy process (formulation, implementation to monitoring and evaluation, etc.).

Option 1: Align and harmonize existing sectoral policies related to biosecurity

Advantages

- Policy integration: provides an opportunity to simultaneously a) revisit existing but outdated policies and associated strategies and programmes in light of new and anticipated realities, and b) create a forward-looking system of policies geared towards current biosecurity goals and requirements.
- Continuity: builds on what already exists, providing an opportunity to maintain institutional memory and use local capacities.

Challenges

- Complexity: the traditional definition of roles and responsibilities on a sectoral basis tends to create barriers and conflicts. As a result, harmonization of existing policies, strategies and programmes may be overly ambitious.
- Resources required: reviewing and updating existing sectoral policies may require significant time and resources.

Option 2: Formulate a new national biosecurity policy

Advantages

- Raise awareness: provides a means to increase awareness about biosecurity.
- Clean start: incorporates the latest scientific knowledge and may provide a more effective way to overcome organizational resistance.

Challenges

- High-level support: will require high-level government endorsement.
- Adequately representing all interests: need to avoid domination by particular sector interests.

Option 3: Involve stakeholders in the policy process to reflect the multi-sectoral nature of biosecurity

Advantages

- Legitimacy: reflects the multidimensional nature of biosecurity and diversity of the stakeholders involved in managing biosecurity.
- Feasibility and acceptability: involving concerned stakeholders from the outset can help to build awareness of biosecurity, increase acceptance of the need for coordinated action, and enhance the ownership and sustainability of future biosecurity related programmes and activities.

Challenges

- Resource intensive: consulting stakeholders on policy formulation in a meaningful way often requires significant inputs in terms of time and financial and human resources.
- Diverging views: different types of stakeholders have different views, increasing the possibility of conflict if the process is not well managed.

Option 4: Develop / adopt a regional approach to policy formulation

Advantages

- Holistic: recognizes the knock-on effects of issues (e.g. species distribution, ecological boundaries, communicable diseases, etc.) that are not confined by national borders.
- Sharing experiences: provides a wider database from which to share knowledge and experiences.
- Improved outcomes: regional collaboration to implement international agreements related to biosecurity can generate concrete benefits such as improved protection, increased competitiveness, economic growth, regional consensus at international forums, etc.

Challenges

- Country diversity: different national characteristics (e.g. population, income, agricultural production, trade patterns, etc.) mean that needs are not uniform, increasing the difficulties of developing a common policy.
- Balancing costs and benefits: costs and benefits will not be shared equally among countries and sub-regions.
- Absence of supranational institutions: regional action works only if the national and regional agendas are aligned, and may be easier to achieve in regions where there are supranational institutions with the power to mandate regional-based action.

Other options, or a combination of the above, are possible. Regardless of the course of action selected, biosecurity policy should be based on sound, independent science and clearly defined goals and objectives for biosecurity to provide a clear rationale for decisions related to investment and resource allocation.

II. OPTIONS TO STRENGTHEN BIOSECURITY LEGISLATION

Sound biosecurity legislation (encompassing laws, regulations and standards) is necessary to create an enabling environment of predictability and certainty through good governance and respect for the rule of law. Legislation clarifies the roles, responsibilities and rights of stakeholders, including those parts of government with policy and delivery roles for biosecurity outcomes and programmes. However, most countries have a variety of laws and regulations in place related to different aspects of biosecurity. These normally cover public health, food safety, animal and plant health, and associated aspects of the environment. In many cases, other legislation that focuses on newer aspects of biosecurity such as products of modern biotechnology, invasive alien species, protection of fish and aquatic environments, etc. may be in force or under development, and is also relevant for biosecurity. Often, these laws and regulations may have developed over time in response to specific needs and requirements and different facets of biosecurity may be directly or indirectly regulated by many, often inconsistent and/or incompatible, Acts.

Countries can address capacity needs in biosecurity legislation in different ways. One option is to review and improve existing biosecurity legislation by removing inconsistencies, addressing gaps and better meeting international obligations. A second option is to create a new biosecurity law and supporting regulations to cover all the relevant subject areas. However, regardless of which option is selected, it is important to ensure that legislation, *inter alia*:

- states overarching biosecurity goals and objectives;
- includes a clear definition of biosecurity to ensure consistency and legal security;
- clearly identifies the mandates and responsibilities of government agencies and other stakeholders responsible for different aspects of biosecurity;
- includes provisions to ensure transparency and access to accurate information
- ensures that standards will be set based on scientific advice and risk analysis; and
- captures the country's regional and international obligations related to biosecurity.

Option 1: Review and improve existing laws and regulations related to biosecurity

Review and amend relevant parts of existing sectoral legislation as a means to remove inconsistencies, address gaps and meet current national and international needs and requirements related to biosecurity.

Advantages

- Enhances existing legislation: provides a way to address overlaps, gaps and inconsistencies in existing legislation.
- Less controversial: modifying existing legislation is often less controversial than developing new legislation.

Challenges

- Challenging, meticulous work: requires substantial technical and legal expertise and needs to draw on operational experience.
- Group effort: requires significant inter-agency coordination and collaboration.
- Potential delays: whenever existing legislation is reexamined, government and other stakeholders can raise other unrelated issues and stall the process.

Option 2: Create a new biosecurity law and supporting regulations

Draft a new biosecurity Act encompassing all aspects of biosecurity and prepare supporting regulations to clarify the relationship of this law to existing sectoral legislation and creation of cross-sectoral linkages.

Advantages

- Clean start: easier to capture the new concepts and structures.
- Time required: in some cases, it may be faster to create a new law than to harmonize existing legislation.

Challenges

- Complexity: many existing laws may be directly and indirectly related to biosecurity so it will be necessary to carefully determine whether and to what extent to consolidate relevant provisions of these laws by enfolding them into a new act.
- Delay: it can often take several years to get a new law passed.

Norway's approach to strengthen the legislative framework for biosecurity

As part of the efforts to reform the Food Safety Administration in Norway and move towards an integrated approach to biosecurity, the Norwegian authorities decided on the need for a major restructuring of legislation related to food safety, plant health and animal health. The following actions were taken:

- 13 acts related to food safety, plant health and animal health were merged into a new Food Law, which was given royal assent in December 2003.
- Other acts focused on animal welfare, animal breeding, cosmetics, plant breeders rights and animal health personnel are also being modernized.
- Regulations under all the old laws were updated to reflect the new institutional arrangements and competencies ■

III. OPTIONS TO STREAMLINE ORGANIZATIONAL ARRANGEMENTS FOR BIOSECURITY

Experiences from countries that have moved towards an integrated approach to biosecurity illustrate that the shape and scope of the organizational arrangements can vary. Different models and options will suit different countries depending on various factors such as: i) the political, socio-economic and physical environment; ii) the number and nature of government organizations responsible for biosecurity; iii) readiness to streamline existing government organizations responsible for different functions of biosecurity; and iv) available resources.

Three main options to streamline organizational arrangements for biosecurity are presented below. These options differ in the extent to which the resulting structure is organizationally independent and able to make independent decisions regarding biosecurity planning, implementation, resource allocation, etc. No one option is inherently better than another. Ultimately, the organizational arrangement selected should: i) reflect the goals of biosecurity; ii) ensure focus, accountability and efficiency in the planning and delivery of core biosecurity functions; and iii) facilitate an appropriate level of coordination and consistency of approach across the sectors of biosecurity. As such, they will promote a risk-based approach that enables those involved to plan and implement biosecurity decisions and allocate resources based on the risks faced.

Option 1: Coordinated multi-agency system

A coordinated multi-agency system relies on the infrastructure and capacity of its member agencies. Its power to make biosecurity decisions and allocate resources depends on the ability and willingness of sector competent authorities (normally involved on an equal basis) to work together. Under this model, concerned agencies would regularly share information and seek to harmonize their respective processes and systems for priority setting, programming, monitoring and review. However, each competent authority would retain responsibility for its core sectoral functions.

A coordinated multi-agency system requires the establishment of some sort of mechanism - such as a biosecurity coordinating committee or task force - to discuss biosecurity strategies, priorities and other relevant issues, and make recommendations for consideration by the competent authorities concerned. This mechanism could be established outside the authority of the main agencies involved (for instance under the prime minister's office) or implemented through an existing structure (such as a national SPS committee). It may include the participation of national Codex and OIE contact points and possibly committees if they exist, and National Plant Protection Organizations (NPPOs). A coordinated multi-agency system is likely to be selected where few resources are available, and it works best when the competent authorities concerned have both the desire and the determination to work together effectively.

Advantages

- Straightforward approach: often the fastest and most straightforward way to institutionalize an integrated approach to biosecurity as it does not require substantial reorganization or rationalization of roles and responsibilities.
- Acceptability: likely to be more acceptable bureaucratically and to encounter less resistance from competent authorities and staff involved in various aspects of biosecurity as it does not require large-scale organizational restructuring.
- Enhanced use of existing resources: can contribute to more effective use of existing resources and technical expertise if there is genuine commitment and collaboration.
- Potential for stakeholder involvement: provides a mechanism to bring together diverse stakeholders including representatives of competent authorities, government regulators, academics, scientists, NGO representatives, etc.
- Flexibility: often has the power to appoint sub-groups and co-opt individuals with technical expertise to provide specific inputs as needed.

Challenges

- Agreeing on operational rules and procedures: requires the establishment of effective mechanisms for administration, coordination and decision-making in areas of common concern.
- Inter-agency collaboration: effectiveness depends to a large extent on the readiness of those involved (leaders and staff) to think beyond the traditional boundaries of their organization, share information and engage in genuine collaboration. Overlaps, inconsistencies and incompatibilities in the roles, responsibilities, procedures and culture of the competent authorities involved may give rise to difficulties and conflicts, and permit only small changes in existing policies or procedures as opposed to major innovations that may be required.
- Temporary nature of national committees: national committees are often seen as temporary structures – to be seen as a legitimate part of the government, they may need to be institutionalized as a permanent office within government. The work of a national biosecurity committee can be held back when members are appointees or volunteers with limited time to devote to biosecurity activities.

Option 2: Lead Agency Approach

Another option to institutionalize an integrated approach to biosecurity is to place overall responsibility for biosecurity with one ministry or government department, which will take the lead while working with other concerned parts of government. This approach builds on the existing roles of government ministries and departments, and seeks to establish clear lines of accountability. The designated

Organizational arrangements for an integrated biosecurity approach in New Zealand

Biosecurity New Zealand is the new lead agency in New Zealand's biosecurity system. Established in November 2004, it is tasked with a "whole of system" leadership role, encompassing economic, environmental, social and cultural outcomes. It also has international trade and animal welfare responsibilities. In particular, Biosecurity New Zealand is responsible for biosecurity protection encompassing economic interests, health, natural environment, native flora and fauna, biodiversity, marine areas and a range of resources uniquely important to Maori.

Biosecurity New Zealand replaces the former Biosecurity Authority in MAF. It was created as a new division of the Ministry of Agriculture and Forestry (MAF) and reports to the MAF Assistant Director-General.

Biosecurity New Zealand's structure is based on a "points of intervention" model. It consists of six structural units - Pre-clearance, Post-clearance, Policy & Business Development, Animal Welfare, Compliance & Enforcement, and Incursion Investigation & Reference Laboratories.

Source: Extracted from Biosecurity New Zealand web site (available at: http://www.biosecurity.govt.nz/about/overview.htm)

lead competent authority normally already plays a major role in one or more components of biosecurity. It may be charged with developing biosecurity policies and overseeing the process of planning and implementing activities in collaboration with other concerned organizations. These activities would be additional to its regular work as a line ministry.

Advantages

- Builds on existing resources: can build on existing infrastructure for staffing, budgeting, coordination, etc.
- Requires fewer resources: may be faster and less resource intensive to implement than the establishment of a new biosecurity agency.

Challenges

- Willingness and ability of partners: effectiveness depends to a large extent on the capacity of the lead competent authority, as well as the commitment and readiness of other concerned organizations to work with it.
- Strain on lead competent authority: unless additional resources are available to help meet the new responsibilities, there is a risk of overburdening the staff and budget of the lead agency.
- Reaching agreement on lead competent authority: there may be competition among government ministries and departments to be designated as lead agency.
- Lack of influence: lead competent authority may have limited ability to influence the functions carried out by other competent authorities responsible for biosecurity functions.
- Open mind: Lead competent authority must be ready and willing to appropriately accommodate, prioritize and coordinate responses to risks previously dealt with by another competent authority.

Option 3: Independent Biosecurity Agency

Some countries may decide to create a biosecurity agency as an autonomous entity with its own budget (see following example of Belize). This competent authority may have responsibility for all aspects of biosecurity policy and regulatory functions, planning, programming and implementation. Alternatively, it may be responsible for normative functions (such as policy formulation, regulatory development, risk analysis, coordination, monitoring and evaluation, etc.) leaving responsibility for technical functions and operations (such as inspection and enforcement activities, diagnosis) to existing competent authorities and competent bodies.

Advantages

- Demonstrates importance: establishing an independent biosecurity competent authority provides a clear sign of the importance and high priority that the government gives to biosecurity.
- Innovation: presents an opportunity to overcome some of the institutional obstacles associated with a coordinated multi-agency system or lead competent authority approach (see above).

Challenges

- Agreeing on roles and responsibilities: may be difficult to determine the responsibilities to be transferred to the new competent authority and those to remain in sector competent authorities.
- Institutional rivalry: disinclination of some competent authorities to see their influence or mandate reduced and some of their roles or responsibilities transferred to a new biosecurity competent authority.
- Institutional constraints: the existing institutional context may not be conducive to enable a new competent authority to be effective.
- Start-up costs: significant leadership, facilitation, time and resources may be required to address start-up costs associated with organizational reorganization or establishment of a new competent authority.
- Financial sustainability: if the new competent authority is autonomous, gets support from external funders and charges fees for its services, the government may seek to reduce its contribution over time, which may affect long-term financial sustainability.
- Start-up difficulties: during the start-up period there may be a temporary reduction in the performance of activities due to disruptions to processes related to the reorganization and establishment of the new competent authority, confusion with respect to roles, responsibilities and accountability, assimilation of employees into a organizational culture, etc.

IV. OPTIONS TO FACILITATE BIOSECURITY COMMUNICATION

The complexity inherent in identifying, managing and preventing biosecurity risks in food and agriculture requires communication among a wide range of

Establishment of a semi-autonomous biosecurity agency in Belize

During the 1990s, the reduced availability of resources in the public sector in Belize, competition between and within ministries for available resources, and the new challenges posed by international trade pointed to the need to reorganize agricultural health services then provided by the Ministry of Agriculture, Fisheries and Cooperatives (MAFC). The Belize Agricultural Health Authority (BAHA) was established in response to these organizational problems and challenges. It was intended to provide a new and economically viable organizational model to meet the challenges of ensuring safe agricultural products for domestic use and fulfilling the requirements of international trade.

In 1999 the Government of Belize adopted legislation (BAHA Act No.47) to establish the Belize Agricultural Health Authority (BAHA) as a semi-autonomous, statutory body under the MAFC. Initially, the Authority included three departments with responsibilities for animal health, plant health and quarantine. However, in response to the impact of a number of animal health activities on human health and the need to demonstrate the compliance of shrimp exports with international food safety standards, a food safety department was subsequently created.

In establishing the Belize Agricultural Health Authority, Belize was the first country in the Caribbean and Central America to adopt an integrated approach to biosecurity. In practice, this means that animal health, plant health, quarantine and food safety are all managed by one institution. Therefore staff, supplies and equipment can be used across departments as necessary. For instance, food safety inspectors combine the inspection of slaughter and processing establishments with animal health surveillance activities. Technicians in the Mediterranean fruit fly surveillance programme visit livestock farms along their surveillance routes to assist with vesicular disease surveillance.

Other innovative aspects and achievements of the model adopted in Belize include:

i) **a private sector approach** which permits the collection of fees on a cost-recovery basis and faster decision-making in response to market demands;
ii) **the establishment of user groups** (including representatives of farming and processing industries, and related government departments) to discuss issues affecting services provided by BAHA;
iii) **high-level political support** from relevant ministers to ensure an effective environment for the enactment of laws and regulations, cost-recovery of services and cooperation with relevant agencies such as the Ministries of Health and Natural Resources.
iv) **collaboration and partnerships** with relevant government and non-governmental organizations, national associations and client representatives;
v) **public awareness programmes** and consultation to build support for BAHA among the general public who are seen as the primary users and beneficiaries of BAHA's activities and services
vi) **human resource development** to create a highly-trained, dedicated and motivated group of employees who are recognized as leaders in the application of disease control and phytosanitary measures in Central America and the Caribbean.

Source: Góngora, V. 2003. Veterinary Services in Belize: adapting organizational models to the needs of small economies. *Rev. sci. tech. Off. Int. Epiz.*, 22 (2), 463-471 (available at: http://www.oie.int/eng/publicat/RT/2202/10_GONGORAang.pdf)

stakeholders including government agencies, the private sector (agricultural producers, processors, enterprises, importers/exporters, etc.), the scientific and research community and the general public. Communication helps to provide timely, relevant and accurate information to, and obtain information from, concerned stakeholders. Effective communication is an essential part of biosecurity capacity.

The nature of the organizational arrangements for biosecurity, the extent to which roles and responsibilities are defined in legislation and the existence of a policy framework that sets out an overall course of action for biosecurity will all have an important effect on the feasibility and potential success of communication options. Such options may include the following.

Option 1: Regulate risk communication through legislation

Regulating risk communication through legislation provides a clear basis for systematic consultation and dialogue with interested parties on matters related to biosecurity.

Advantages

- Enhances legitimacy and trust: stakeholder interests and responsibilities may be significantly affected by the regulatory decisions taken as a result of risk analysis. Transparent and systematic communication on these decisions therefore promotes public confidence in the decision-making process, enhances the legitimacy of resulting government policies and action and fosters trust in the regulatory system in general.
- Improved outcomes: the information and knowledge obtained through systematic communication on biosecurity-related matters will inform the decision-making process, clarify the feasibility of different courses of action and improve overall results.

Challenges

- Resources required: effective communication will require significant human resources and financial resources.

- Number and diversity of interested stakeholders: the existence of many different consumer groups, interest groups, industry associations, etc. and absence of national federations or networks may make it more difficult to identify the main players and will make two-way communication more complex.
- Political tradition: the general political ideology in some countries may discourage real dialogue, or make it more difficult to achieve.

Option 2: The creation of memoranda of understanding defining roles and mechanisms for multi-stakeholder communication

Another option to facilitate biosecurity communication is to create memoranda of understanding (MOU) defining the specific roles, responsibilities and accountabilities of the competent authorities and other organizations involved in core biosecurity tasks, and specifying the mechanism for communication and information exchange between them and with other concerned groups.

Advantages

- Flexibility: MOUs can be generated on the basis of inter-agency agreement rather than imposed from above or through lengthier legislative or legal procedures; hence they can be more easily updated to reflect changing needs.
- Cost-effectiveness: Due to this flexibility and their ability to be targeted at particular activities, MOUs are normally cost-effective to develop and implement.

Challenges

- Complexity: bilateral MOUs between two agencies can quickly proliferate in light of the cross-cutting nature of biosecurity, resulting in overlaps, inconsistencies or conflicts. On the other hand, multilateral MOUs are more difficult to negotiate in the absence of crises or high-level demands, especially when the organizations involved have very different institutional histories and cultures as well as diverging perceptions of biosecurity.
- Informality: without commitment from the leadership of the competent authorities involved or strong incentives for implementation, the responsibilities enshrined in MOUs, as well as the requisite accountabilities, are difficult to guarantee.

Option 3: Establish stakeholder advisory groups

The establishment of stakeholder advisory groups provides a mechanism for regular and systematic dialogue between particular stakeholder groups (e.g. scientific institutions, industry, environment, consumers, etc.) with a role to play in the identification, management and/or prevention of biosecurity risks, or to provide independent advice to the government on the performance of biosecurity. Such groups could possibly be implemented through or in coordination with an existing structure (such as a national SPS, CAC and/ or OIE committee or NPPO).

Advantages

- Knowledge generation: opinions and knowledge from different stakeholders can inform biosecurity policy and decision making and management.
- Legitimacy: provides a forum for concerned public, private and non-governmental sectors to interact and communicate with the government on issues related to biosecurity, thereby enhancing legitimacy.

Challenges

- Conflict: given the divergent perspectives of stakeholders, conflict may be inevitable and skilled moderation will be imperative to channel the constructive dimensions of such conflict.
- Incentives: some stakeholders may not want to engage in dialogue with government and may seek more confrontational ways of influencing biosecurity outcomes.

Option 4: Develop biosecurity information systems

The development of biosecurity information systems facilitates the collection, analysis and reporting of relevant data and information to support a more integrated decision-making process. These systems could use existing biosecurity-related information systems, such as the International Portal on Food Safety, Animal and Plant Health (www.ipfsaph.org).

Advantages

- Comprehensive: facilitates risk-based decision making across the entire biosecurity arena.
- Efficiency: enables competent authorities responsible for biosecurity management to identify and respond to gaps and overlaps in the availability of required data and information.
- Transparency: strengthens ability of national notification authorities and SPS enquiry points to provide required information to the WTO and other member countries.

Challenges

- Compatibility: existing data sets or information systems developed and used by competent

authorities responsible for different aspects of biosecurity may be incompatible with each other, requiring new biosecurity information systems to be developed from scratch.
- Content and maintenance: adequate resources (human, financial, information) and sound procedures are essential for content development and maintenance.
- Analysis and reporting: regardless of the contents, human resources are required to ensure that any information systems can effectively generate the necessary outputs.
- Quality versus quantity: the quality and/or quantity of the data and information necessary to develop such systems may be problematic.

V. OPTIONS TO IMPROVE BIOSECURITY FUNCTIONS

Some options to improve the delivery and performance of biosecurity functions are presented below. These options are not mutually exclusive and one or more may be pursued at the same time. The range of possible options will be linked to the organizational arrangements for biosecurity (see section III above on options to streamline organizational arrangements for biosecurity) including the way in which roles and responsibilities are allocated.

Option 1: Involve competent bodies and/or other third parties in the provision of some biosecurity functions

Involving competent bodies and/or other third parties in the provision of some biosecurity functions, such as inspection or diagnostic services, can provide a way to enhance delivery and results. This can be achieved in different ways from sub-contracting some services to the private sector or academic or research institutes (while maintaining overall responsibility) to complete privatization. The best mechanism will depend on the function(s) in question and the particular country situation.

Advantages
- Improved efficiency and performance: involving competent bodies and/or other third parties can increase efficiency and improve the quality of services.
- Access to new resources: the private sector often has new sources of capital and resources, knowledge of new technologies, etc.
- Likelihood for success: may be simpler and more effective to involve competent bodies and/or other third parties in the delivery of specific services than to overcome vested interests and patronage networks to render public services more competitive.

Challenges
- Prerequisites necessary: involving competent bodies and/or other third parties requires the government to have clear specifications/standards for this purpose in place, and also requires the existence of capable service providers.
- Inadequate capacity: private sector involvement does not provide an automatic solution when the private sector itself has inadequate technical capacity, resources, etc.

Option 2: Apply a cost-recovery model for services provided

The application of a cost-recovery model can generate additional revenues, which can help to improve the quality, quantity and sustainability of services. Introducing a fee for services provided is often associated with the involvement of the private sector, however, under certain circumstances and in some legal systems, government agencies can also charge for particular services.

Advantages
- Access to additional resources: resources generated through fees charged for services can be used to improve the quality of services delivered (e.g. by upgrading technology or skills).
- Cost effective: increased cost-effectiveness and efficiency due to scrutiny of costs by industry.
- Sustainability: applying a cost recovery model can enhance the sustainability of service delivery particularly during times of budgetary constraints.

Challenges
- Unexpected outcomes: when cost-recovery models are seen as being successful, this may lead to a reduction in the availability of funding from central government.
- Stakeholders' ability to pay: not all users may have the capacity to pay, which may bias the delivery of such services towards certain groups (e.g. export-oriented firms) but fees can be designed differently for different groups (based on the size or value of consignment, for example).
- Need for new rules and regulations: in some cases, government agencies may be unable to charge fees

for services without legal action to amend the rules and regulations governing their work

Option 3: Use shared infrastructure and technical expertise

Sharing infrastructure (such as laboratories or import inspection facilities) and technical expertise across competent authorities can generate efficiencies and improve service delivery. For instance, competent authorities in some countries have decided to share laboratory facilities (especially for microbiological analysis).

Advantages

- Increased efficiency: more effective and faster service for users including streamlined procedure and reduced time to obtain necessary import permits and permissions, which will be especially valuable for importers of fresh and perishable products.
- Cost savings: saving may result from a reduction in duplication of services rendered by different competent authorities.

Challenges

- Obtaining agreement from the agencies involved: it may be difficult for competent authorities to agree on operational rules and procedures and financing including respective contributions to the budget and technical expertise, the allocation of technical and financial resources, the rights of contributing agencies to use the shared infrastructure and the amount to be contributed for use of services. There may also be competition from competent authorities to head the "shared" unit.
- Uneven use of facilities: difficulties may arise if one competent authority uses the shared infrastructure much more than the other agencies participating unless there is clear agreement on rules, rights and obligations for different types of access and use.
- Inter-agency collaboration: effectiveness depends to a large degree on the ability of individuals from different competent authorities and technical areas to work together effectively as a team.

Option 4: Develop shared information systems for specific technical areas

Shared information systems may be developed and operated for particular technical areas such as diagnostic services, inspection, verification and enforcement, and/or monitoring and surveillance.

Advantages

- Function-based: presents an opportunity to pursue collaboration in specific areas (e.g. inspection, verification and enforcement, monitoring and surveillance), which may be more likely to be successful than efforts to integrate all information systems related to biosecurity.
- Enhanced resource allocation: will support the delivery of services based on risk so that resources can be allocated to areas for which there is greatest need.

Challenges

- Incompatible data: may be more difficult or require additional resources if existing data sets developed and used by competent authorities are not compatible.
- Inter-agency collaboration: requires agreement from the competent authorities involved on what information will be shared, what resources will be contributed, operational rules and procedures, user rights, etc.

Option 5: Utilize risk analysis to prioritise risks and guide biosecurity decision-making

Risk analysis (comprising risk management, risk assessment and risk communication) provides a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to biosecurity problems. It can be used to support and improve the identification and prioritization of risks, to develop biosecurity standards and inform other regulatory activities, as well as to address biosecurity issues that result from emerging hazards or breakdowns in the application of controls.

Advantages

- Improved decision-making and outcomes: the process of conducting a risk analysis enables competent authorities to identify the various points of control at which measures could be applied, to weigh up the costs and benefits of these different options, and to determine the most effective one(s)
- Focuses resources on hazards of greatest risk: using risk analysis to prioritize risks helps to ensure that attention and resources are focused on the issues and areas of greatest importance to life and health.
- Enhanced trade access: the use of risk analysis enables governments to meet their obligations under the SPS Agreement and to strengthen their basis for trading foods internationally.

- Take advantage of resources available internationally: risk assessments carried out by international bodies can be partially or fully applied at the national level (depending on particular circumstances), which can reduce the technical resources required in the country.
- Ensuring transparency: Full documentation of risk assessment and risk management inputs allows all interested stakeholders to understand risk-based decisions.

Challenges

- Prerequisites necessary: the successful use of risk analysis for biosecurity requires countries to have certain essential conditions in place including sound legislation, efficient institutions, effective inspection and laboratory services, infrastructure and equipment, and officials who understand risk analysis and the value it adds to biosecurity sectors.
- Scientific capability required: the use of risk analysis in biosecurity requires specialized scientific knowledge and skills, which may be unavailable or in short supply in some countries.
- Availability of scientific inputs for risk assessment: scientific data gaps are often a significant limitation.
- Stakeholder support and participation: the effective use of risk analysis is dependent on transparent and open processes and the support and participation of key interested stakeholders such as consumers, academic and industry.

Option 6: Develop shared training materials and programmes

Common biosecurity concerns and methodologies (including risk analysis) are often shared between sectors and this means that there is much to be gained from the alignment of training materials and programmes focused on core functions of biosecurity.

Advantages

- Cross-fertilization: taking advantage of common biosecurity concerns and methodologies to develop joint shared training resources can enrich the content of training materials and learning outcomes achieved.
- Food chain biosecurity: developing shared training materials and programmes enables a consideration of complete hazard exposure pathways, which supports the implementation of controls at those points where they will be most effective.
- Cost sharing and efficiencies: the development and delivery of shared training materials and programmes can contribute to savings and efficiencies in the use of available resources.

Challenges

- Inter-agency collaboration: developing joint training materials and programmes requires competent authorities to work together effectively and success depends on the willingness and ability of those involved to effectively collaborate and liaise on work programmes and roles.

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