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Biosecurity in Food and Agriculture

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I. BACKGROUND

1. National regulatory and export certification systems are being challenged by large increases in the volume of food and agricultural products being traded internationally, by the expanding variety of imported products and by the growing number of countries from which these imports are originating. Increased travel is also creating more pathways to spread pests, diseases and other hazards that are moving faster and further than ever before. Improved coordination is being sought among national bodies responsible for enforcing sanitary, phytosanitary and zoosanitary measures to better protect human, animal and plant life and health without creating unnecessary technical barriers to trade.

2. FAO uses the term, *Biosecurity*, in relation to sanitary, phytosanitary and zoosanitary measures applied in food and agricultural regulatory systems. FAO uses the term synonymously with “*Biosecurity* in food and agriculture”. *Biosecurity* is a relatively new concept and a term that is evolving as usage varies among countries with different specialist groups using it in different ways. For FAO, *Biosecurity* broadly describes the process and objective of managing biological risks associated with food and agriculture in a holistic manner.¹

3. *Biosecurity* measures in agriculture are needed:

- i) To protect agricultural production systems, and those dependent on these systems: Producers and others dependent on agriculture can see their livelihood destroyed by animal and plant pests and disease or damage to the environment such as impacts resulting from invasive alien species;
- ii) To protect human health and consumer confidence in agricultural products: *Biosecurity* measures are essential to protect consumers—particularly vulnerable groups—that can be exposed to severe health risks, which *Biosecurity* attempts to prevent;
- iii) To protect the environment and promote sustainable production: Public awareness of environmental issues and human dependency on biodiversity has resulted in numerous commitments to achieving sustainable development, and achieving these will require an effective approach to *Biosecurity*.

4. *Biosecurity* is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the sectors of food safety, animal life and health, and plant life and health, including associated environmental risk. *Biosecurity* covers the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their products, and the introduction and management of invasive alien species and genotypes. *Biosecurity* is a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity.

5. The issues encompassed in *Biosecurity* have traditionally been dealt with in a sectorial manner by means of food safety laws, and animal and plant quarantine and pesticide regulations. Implementation of such laws and regulations has also traditionally been sectorial. Emerging issues of Biosafety² and to control the introduction and management of invasive alien species into the environment means that a growing number of issues need to be addressed. This results in

¹ With “agriculture” used in its broadest sense to include agronomy, livestock, forestry, fisheries and related environmental aspects.

² The term, “biosafety” refers to the introduction, release and use of genetically modified organisms. The Cartagena Protocol on Biosafety to the CBD applies to “the transboundary movements, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health”.

costly regulatory systems that require high investment and recurrent costs (infrastructure and human resources).

6. In recent years, there has been greater recognition of the importance of *Biosecurity* in relation to protection of the environment. In some countries, *Biosecurity* programmes are expanding to include natural ecosystems, including forest and marine ecosystems. The role of traditional *Biosecurity*-related institutions is expanding beyond agricultural production to public health and the environment. Although some of these issues may be outside the core competencies of FAO, they must be addressed in the establishment of sustainable national *Biosecurity* systems. An important factor, which is within FAO's competence, is the heightened attention paid to the environmental impacts of agricultural practices, including increased scrutiny of animal and plant pest and disease control methods.

7. Countries with small economies and limited capacity cannot afford traditional sector-oriented approaches, which are often ill-adapted to their means and circumstances. There is a growing recognition that *Biosecurity* will profit from a more integrated approach. Closer cooperation among institutions responsible for implementing *Biosecurity* and the rationalisation of infrastructures, where appropriate, will benefit, in particular, developing countries and countries with economies in transition. Models to rationalise regulatory functions among sectors in the quest for improved effectiveness and efficiency have appeared in a number of countries. For example, New Zealand has had a *Biosecurity* Act since 1993 and a *Biosecurity* Minister and Council since 1999. In Belize, food safety, and animal and plant quarantine and environmental issues, are dealt with by a single authority, the Belize Agricultural and Health Authority.

8. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization, disciplines SPS measures in relation to international trade. The Codex Alimentarius Commission (Codex), the International Plant Protection Convention (IPPC) and the Office international des epizooties (OIE) provide international standards for food safety, plant health, and animal health, respectively.

9. A further relevant instrument (not yet entered into force) is the Cartagena Protocol, which applies to the transboundary movement, transit, handling and use of Living Genetically Modified Organisms (LMOs). Guidelines on the management of invasive alien species have been developed under the Convention on Biological Diversity (CBD).

10. This group of international agreements, organizations and programmes are part of a loose international framework for *Biosecurity*, and reflect the historically sectorial approach to regulation in this area.

11. FAO has recognized the growing importance of *Biosecurity*, and therefore made it one of the Organization's sixteen Priority Areas for Inter-disciplinary Action (PAIAs). *Biosecurity* was included in the Medium Term Plan to address corporate strategy B, which aims at "*promoting, developing and reinforcing policy and regulatory frameworks for food, agriculture, fisheries and forestry.*"³

12. *Biosecurity* in Food and Agriculture was discussed by COAG in March 2001, in document COAG/01/8. The Committee appreciated the proactive nature of the document and welcomed the recommendation to convene a consultation to explore *Biosecurity* further. The Committee also appreciated the scope for in-house coordination through the PAIA on *Biosecurity*, in particular to identify possibilities to harmonize, where appropriate, methods of risk analysis, to coordinate capacity building, and to establish a system for the exchange of official information on *Biosecurity*. With the aid of external assistance⁴, FAO, through the *Biosecurity* PAIA, undertook

³ The Strategic Framework for FAO 2000-2015, Food and Agriculture Organization of the United Nations, Rome, 1999.

⁴ Financial support from the FAO/Government of the Netherlands partnership programme for international consultation, and financial and in-kind assistance from the USA Government for the information exchange system.

to examine and advance *Biosecurity* in food and agriculture in order to explore possible synergies in relation to standard setting, information exchange and capacity-building.

13. In September 2002, an Inter-agency Meeting on *Biosecurity* in Food and Agriculture⁵ discussed the concept and possible mechanisms for cooperation among relevant international organizations. The Inter-agency meeting was followed by an Expert Consultation⁶, with the participation of nineteen international experts and resource persons from twelve countries, to explore the relevance of *Biosecurity* in Food and Agriculture, and to advise FAO on modalities for its implementation, particularly in developing countries.

14. In order to broaden awareness of *Biosecurity* and to debate its relevance and practicality more widely, particularly in relation to the needs of developing countries and countries with economies in transition, FAO convened an international Technical Consultation⁷ in Bangkok, 13-17 January 2003, with the participation of 38 countries and eight international organizations, including *Codex Alimentarius*, the IPPC, OIE, and the CBD.

15. As information exchange is a common core component of *Biosecurity* sectors, FAO has initiated a project to develop an International Portal for Food Safety and Animal and Plant Health, for the exchange of official *Biosecurity*-related information. This takes the form of a project, implemented in cooperation with other relevant organizations, so as to seek complementarities and synergies, and to avoid duplication.

16. Capacity-building in developing countries and countries with economies in transition has mostly been approached on a sectorial basis. Requests for such assistance have increased substantially over recent years. At the same time, multi-sectorial awareness building has started, through programmes like the FAO Uruguay Round training programme, and various initiatives of WTO and the World Bank, to which the standard-setting organizations have contributed. At the WTO Ministerial meeting in Doha, the Executive Heads of FAO, OIE, WHO, the World Bank and WTO issued a joint communiqué committing their institutions to explore new modes of collaboration to improve the efficiency of their technical assistance programmes on matters related to the SPS Agreement, and to enhance the level and quality of the participation of these countries in international standard setting bodies. The five agencies, including Codex and IPPC, have agreed to establish a Standards and Trade Development Facility.

17. Collaborative efforts to assist developing countries may, in future, also benefit from the participation of international institutions that address biosafety and the introduction and management of invasive alien species.

18. FAO has also developed a programme proposal to address capacity-building in relation to biotechnology, food safety and animal and plant life and health.

II. OUTCOME OF THE CONSULTATION PROCESS

19. The present document is based on the outcome of a broad consultation process on *Biosecurity*, which included the Inter-agency Meeting, the Expert Consultation, specialized studies and bilateral interaction with interested bodies. The process culminated in the inter-

⁵ Delegates from eleven organizations participated in the meeting: the Convention on Biological Diversity (CBD), the World Trade Organisation (WTO), the United Nations Environment Programme (UNEP), the United Nations Industrial Development Organisation (UNIDO), the Organisation for European Economic Cooperation and Development (OECD), *Office internationale des épizooties* (OIE), the International Plant Protection Convention (IPPC), *Codex Alimentarius*, FAO, the International Plant Genetic Resource Institute (IPGRI), the International Centre for Genetic Engineering (ICGEB).

⁶ Report of the Expert Consultation on *Biosecurity* in Food and Agriculture, 10-13 September 2002, FAO, Rome, Italy.

⁷ Report of the Technical Consultation on Biological Risk Management in Food and Agriculture, 13-17 January 2003, Bangkok, Thailand.

governmental Technical Consultation, and the following section contains its conclusions and recommendations.

20. The Consultation recognized the advantages of a more coherent, holistic approach to *Biosecurity* that sought synergies between the sectors at national and international levels, without necessarily creating new or unified structures. It further recognized that the integration of various aspects of *Biosecurity* and the institutions involved was occurring in a number of countries. The traditional focus on regulating individual production systems was shifting to one of ensuring confidence in the overall regulatory framework. It noted that many countries, including developing countries and countries with economies in transition, were revising their *Biosecurity* arrangements to take into account the SPS Agreement, at the same time seeking greater efficiencies. The Consultation recognized the valuable contribution of the development of international standards⁸, which provided countries, particularly small countries, with a means to achieve *Biosecurity* objectives, while reducing the burden of having to implement national risk assessment and management procedures in each individual case. However, external support for capacity-building in developing countries and countries with economies in transition, to enable them to effect such improvements, including facilitating the development of trade partnerships, was crucial for many countries. It stressed the need to further incorporate developing country perspectives in the development of international standards, in ways that took into account local conditions, and in ways that facilitated their economic development. These included economies characterized by the existence of large numbers of small farmer communities.

21. The Consultation recognized the central role of risk analysis as a framework for *Biosecurity*, including across sectors. There was therefore an opportunity to harmonize terminology and methodology, while respecting the need for individual sectors to tailor risk analysis procedures to the characteristics of the risks involved. It recognized that risk analysis procedures should provide an appropriate basis for *Biosecurity*, while not creating unnecessary barriers to trade. Increased trade was increasing the need for effective risk analysis capacities, including in developing countries and countries with economies in transition, and for bilaterally and multilaterally agreed standards. In this context, many developing countries and countries with economies in transition have insufficient risk analysis capacities to support *Biosecurity* frameworks for both imports and exports. The Consultation recognized that biological risk analysis across sectors necessarily involves the consideration of complex risks and uncertainties associated with them.

22. The Consultation supported the need for a variety of economic analyses in relation to *Biosecurity*. It was suggested that examples be compiled and analysed of where pest eradication campaigns, or the implementation of improved food standards, had resulted in quantifiable export increases. One possible methodology could be developed around an analysis of the values of goods transiting through control and inspection systems, in relation to the costs of such systems. Examples of effective, pooled regional *Biosecurity* standards and procedures were needed. Methodologies were required to document the economic advantages flowing from cross-sectorial cooperation, and of documenting and analysing the costs and the benefits of public-private sector cooperation, as well as where investments in *Biosecurity* measures had been most successful. A further methodology could consider market opportunities in relation to the *Biosecurity* investments that would be required to realize them.

23. The Consultation recognized the central importance of capacity-building, in particular to assist developing countries and countries with economies in transition to establish and sustain their *Biosecurity* systems, to meet international *Biosecurity* standards for food and agriculture, and take advantage of trade opportunities. It welcomed the various initiatives under way. The Consultation stressed that institutional sustainability should be a guiding priority in capacity-building. It was agreed that the IPPC's Phytosanitary Capacity Evaluation model and similar tools

⁸ The term "standards" used in this document includes agreed guidelines, recommendations and procedures.

would be useful in the development of *Biosecurity*-wide capacity-building tools, and that relevant international organizations should be associated in such an initiative. The Consultation noted that case studies on institutional development for *Biosecurity* would be valuable, and that governments should take measures to ensure lasting support for their *Biosecurity* organizations.

24. The Consultation supported the development of the International Portal for Food Safety and Animal and Plant Health as a valuable database and information tool for *Biosecurity*, which could help bring together the various sectors involved, nationally and internationally. It should be coordinated with other relevant organizations, so as to add value, avoid duplication, and achieve inter-operability. The Consultation noted that countries needed to improve their internal system for communication and information exchange.

A. GENERAL RECOMMENDATIONS

25. The Consultation considered the use of the English term, *Biosecurity*, bearing in mind the need for translation and to harmonize terminology. Delegates noted that the term *Biosecurity* is used widely, and that usage varies among countries. They also noted that the term presents translation challenges, particularly for Spanish and French translation⁹. Following considerable discussion on terminology, delegates agreed that the term *Biosecurity* in food and agriculture best describes the concept as used by FAO, and recommended that for the purposes of the Consultation and this report, the English term, *Biosecurity* be used in all languages, and that it be italicized and capitalized, and not be translated.

26. The Consultation considered that *Biosecurity* involves the management of biological risks in a comprehensive manner to achieve food safety, protect animal and plant life and health, protect the environment and contribute to its sustainable use. Achieving *Biosecurity* requires an understanding of, and the ability to analyse diverse and complex risks, and determine and apply measures in a coherent manner while respecting differences among sectors and organizations. Risk analysis¹⁰ is the most important unifying concept across different *Biosecurity* sectors¹¹. *Biosecurity* frameworks should not create unjustified barriers to international trade.

27. The Consultation recommended that:

- i) Countries should determine the potential for synergies and harmonization within their national and sub-national regulatory frameworks that would result from a holistic and coordinated approach to *Biosecurity*. Policy-makers should recognize the importance of *Biosecurity* as a key element of sustainable development, and the benefits, including in trade that can be gained from comprehensive approaches to *Biosecurity*.
- ii) Recognizing the efficiencies that may emanate from regional and sub-regional approaches to risk analysis, particularly in relation to animal and plant life and health, and living modified organisms, countries should also cooperate to address *Biosecurity* issues at regional and sub-regional levels.
- iii) Risk analysis and management frameworks are essential to achieve *Biosecurity*. In the past, such frameworks have been mostly sectorial or used to address specific technical issues. In future, such frameworks should seek to improve collaboration among diverse interests and institutions (particularly agriculture, public health, environment, trade, and their associated stakeholders) to achieve *Biosecurity* in a mutually supportive manner, thus avoiding duplication and possible inconsistencies.

⁹ The terms "Bioseguridad" and "Biosécurité" have been used in the Cartagena Protocol on Biosafety for the translation of the word "Biosafety" (see footnote 2).

¹⁰ Risk analysis as used in this document includes risk assessment, risk management and risk communication, unless otherwise indicated.

¹¹ These include, *inter alia*, food safety, plant and animal health and life, and the environment.

- iv) General principles for risk analysis for biological risk analysis in food and agriculture are the same, although procedures may differ depending on the hazards addressed. The IPPC, the *Codex Alimentarius*, the OIE, the CBD and its Cartagena Protocol (noting that the Protocol has not yet entered into force), where appropriate, should apply coherent risk analysis methodologies in different sectors by jointly analysing differences and commonalities in approaches, and use of terms in risk analysis.
- v) Many developing countries and countries with economies in transition have limited infrastructure and limited capacity to undertake risk analysis, and to enforce risk management decisions. International standards should thus be developed with due consideration of their implications and impacts on developing countries and countries with economies in transition, including the effect on their ability to participate in international trade. The participation of countries in the development of such standards should be supported.
- vi) Countries should implement a more coherent and holistic approach to biological risk management in food and agriculture by respective government authorities to strengthen the achievement of common *Biosecurity* objectives.
- vii) FAO, in collaboration with relevant international and regional organizations should provide guidance and develop guidelines to assist countries to develop and implement national *Biosecurity* frameworks in harmony with their international obligations.
- viii) FAO, in collaboration with other relevant international and regional organizations should consider undertaking further analysis to better understand and advance *Biosecurity*, including:
 - analysis of differences, similarities, duplications and gaps, across the various sectors of *Biosecurity*;
 - the implications for developing countries and countries with economies in transition of *Biosecurity* standards, procedures and technical regulations; and
 - measures required to establish coherent and mutually supportive *Biosecurity* approaches in relation to food safety, animal health and life, plant health and life, and the environment.

B. CAPACITY BUILDING RECOMMENDATIONS

28. The Consultation stressed the importance of capacity-building as the challenges of *Biosecurity* are increasingly placing demands on countries, with urgent needs in particular areas. The Consultation identified the critical need for capacity-building for developing countries and countries with economies in transition, taking into account both the public and private sector.
29. The Consultation recommended that:
- ix) FAO should work with *Codex*, the IPPC, the OIE, the CBD and other relevant international organizations to further develop tools, including tools to extend the Phytosanitary Capacity Evaluation to other sectors, to assist countries analyse their capacity-building needs that take account of the full scope of *Biosecurity*, including the communicational, legal, institutional, scientific and technical aspects.
 - x) Countries should use the tools developed under the above recommendations or other appropriate methodologies to identify, analyse and integrate their *Biosecurity* capacity building needs and determine priorities.
 - xi) Donors should base their support for capacity-building activities on this assessment.
 - xii) In developing capacity-building activities, donors and recipient countries should aim to achieve sustainable improvements in *Biosecurity* systems.
 - xiii) The roles and responsibilities of both the public and private sectors should be considered in planning *Biosecurity* capacity-building initiatives.

- xiv) Appropriate linkages and coordination mechanisms among existing and planned *Biosecurity* capacity-building initiatives should be established to enhance complementarity and avoid duplication of efforts, and to ensure that capacity building is directed at country and regional *Biosecurity* priorities.
- xv) FAO, in collaboration with other relevant international organizations, should compile, analyse and summarize examples or cases studies of *inter alia*: economic analysis of *Biosecurity*; establishment of regional *Biosecurity* approaches; and implementation of *Biosecurity* measures, including risk communications measures, and widely share these examples among Member Nations and relevant organizations.

C. INFORMATION EXCHANGE RECOMMENDATIONS

30. The Consultation stressed the need to share information and to ensure better understanding of the requirements for achieving *Biosecurity*. It endorsed the need for an Internet-based *Biosecurity* Portal to facilitate information exchange on *Biosecurity*. It also recognized the importance of information access and exchange in developing *Biosecurity* capacity.

31. The Consultation recommended that:

- xvi) FAO, in collaboration with relevant organizations, should give further support to the development of a publicly accessible, Internet-based *Biosecurity* Portal mechanism for exchange of official information on food safety, and animal and plant health and the environment, which would facilitate improved communication among countries in these sectors, noting the need for this mechanism to complement but not duplicate other relevant information exchange mechanisms. The Portal should be user friendly, demand-driven and linked to other existing relevant portals.
- xvii) Countries should be encouraged to develop appropriate mechanisms for information exchange in *Biosecurity*, and to participate in the development of the Portal.

D. COMMUNICATION RECOMMENDATION

32. The Consultation recommended that:

- xviii) Countries should ensure adequate opportunities for appropriate participation by all stakeholders, including members of the public, in addressing *Biosecurity*, and enable them to contribute in meaningful ways to the design and implementation of *Biosecurity* risk management frameworks.

III. ISSUES THE COMMITTEE MAY WISH TO CONSIDER

33. The Committee may wish to consider the recommendations of the Technical Consultation, as given above, for possible endorsement, and where appropriate give guidance to the secretariat in the area of *Biosecurity*.