

FAO BIOSECURITY
TOOLKIT





FAO BIOSECURITY TOOLKIT



Food and Agriculture Organization of the United Nations
Rome, 2007



The views expressed in this publication are those of the author(s) and do not necessarily reflect the views of the Food and Agriculture Organization of the United Nations (FAO).

The designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of FAO concerning the legal or development status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

ISBN XX-X-XXXXXXX-X

All rights reserved. Reproduction and dissemination of material in this information product for educational or other non-commercial purposes are authorized without any prior written permission from the copyright holders provided the source is fully acknowledged. Reproduction of material in this information product for resale or other commercial purposes is prohibited without written permission of the copyright holders. Applications for such permission should be addressed to the Chief, Electronic Publishing Policy and Support Branch, Communication Division, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy or by e-mail to copyright@fao.org

© FAO 2007

For further information, please contact:

Biosecurity Priority Area for
Interdisciplinary Action (PAIA)
Food and Agriculture Organization of
the United Nations
Viale delle Terme di Caracalla
00153, Rome, Italy
Fax: (+39) 06 57054593
E-mail: biosecurity@fao.org
Web site: www.fao.org/biosecurity/
[www.fao.org/ag/agn/agns/
foodcontrol_biosecurity_en.asp](http://www.fao.org/ag/agn/agns/foodcontrol_biosecurity_en.asp)

CONTENTS

iv	Figures, boxes, tables
vi	Abbreviations
vii	Acknowledgements
viii	Foreword
x	Introduction
1	PART 1. BIOSECURITY PRINCIPLES AND COMPONENTS
3	Introduction
6	Rationale for a harmonized and integrated approach to biosecurity
9	Biosecurity in a modern world
14	Harmonization and integration of approaches to biosecurity
21	PART 2. GUIDE TO ASSESS BIOSECURITY CAPACITY
23	Introduction
25	An integrated biosecurity approach and the assessment of capacity needs
30	Seven steps to assess biosecurity capacity needs
41	PART 3. AN OVERVIEW AND FRAMEWORK MANUAL FOR BIOSECURITY RISK ANALYSIS
43	Introduction
50	Risk analysis: science, policy and values
57	A generic risk management framework for biosecurity
72	Risk assessment
84	Risk communication
90	Conclusions
93	ANNEXES

LIST OF FIGURES, BOXES, TABLES

FIGURES

3	1.1. Sector goals of biosecurity	17	1.12. Components of a national biosecurity strategy
4	1.2. Sector interests that are important to an integrated approach to biosecurity	17	1.13. Improved national biosecurity capability resulting from increasing interdependence of competent authorities and convergence of biosecurity issues
6	1.3. Potential benefits associated with a cross-sectoral approach to biosecurity	18	1.14. Restructuring of competent authorities as expressions of improved biosecurity capability
26	2.1. Levels and dimensions of biosecurity capacity	18	1.15. Improved global biosecurity capability resulting from increasing interdependence of countries and convergence of biosecurity issues
28	2.2. Process to assess biosecurity capacity	19	1.16. Food chain biosecurity – an example of a “complete exposure pathway” legal framework in the European Community
37	2.3. Identification of biosecurity capacity needs	19	1.17. Linkages between international bodies that are enhancing development of international biosecurity standards
48	3.1. Safe and affordable food: an example of the interplay between biosecurity sectors in achieving a common goal	20	1.18. Examples of systems for improving international biosecurity networking
52	3.2. Generic components of risk analysis	23	2.1. Relevant sector-specific capacity assessment tools
58	3.3. Components of a generic RMF	25	2.2. What motivates countries to assess biosecurity capacity needs?
60	3.4. Role of the risk manager in application of the generic RMF process	36	2.3. Our vision – New Zealand’s biosecurity in 2010
73	3.5. A generic representation of steps involved in risk assessment in biosecurity	44	3.1. Risk analysis as a discipline that enhances cross-sectoral biosecurity activities

BOXES

3	1.1. Some factors influencing biosecurity	45	3.2. Measuring the performance of competent authorities
7	1.2. Generic mandate of biosecurity at the national level	45	3.3. Key provisions of the WTO SPS Agreement relating to risk analysis in biosecurity
7	1.3. Moving towards a biosecurity approach to minimize potentially adverse impacts	47	3.4. Examples of the interplay between biosecurity sectors
9	1.4. Definitions of a hazard as applicable to different biosecurity sectors	51	3.5. Prerequisites for effective risk analysis in biosecurity
10	1.5. New influences on food safety biosecurity systems	55	3.6. Working definitions for hazard-based and risk-based control measures
10	1.6. Some new, emerging and “re-emerging” zoonoses of public health importance	55	3.7. General principles of risk analysis in the context of biosecurity
11	1.7. New influences on animal health biosecurity systems	57	3.8. Benefits flowing from application of a generic RMF process at the international and national levels
11	1.8. New influences on plant health biosecurity systems	57	3.9. Additional benefits flowing from application of a generic RMF at the national level
12	1.9. New influences on biosafety aspects of biosecurity systems		
12	1.10. New influences on invasive alien species aspects of biosecurity		
14	1.11. A competent authority structure that facilitates biosecurity as a holistic concept		

TABLES

ABBREVIATIONS

ADI	Acceptable Daily Intake	JECFA	Joint FAO/WHO Expert Committee on Food additives
ALARA	As Low as Reasonably Achievable	JEMRA	Joint Expert Meeting on Microbiological Risk Assessment
ALOP	Appropriate Levels of Protection	JMPR	Joint FAO/WHO Meeting on Pesticide Residues
APFSWG	Animal Production Food Safety Working Group, OIE	LMO	Living Modified Organism
BCH	Biosafety Clearing-House	MDG	Millennium Development Goals
BSE	Bovine Spongiform Encephalopathy	MRL	Maximum Residue Limit
CAC	Codex Alimentarius Commission	NGO	Non-Governmental Organization
CBD	Convention on Biological Diversity	NPPO	National Plant Protection Organization
CPM	Commission on Phytosanitary Measures	NOAEL	No Observed Adverse Effect Level
DALY	Disability Adjusted Life Years	NOEL	No Observed Effects Level
EU	European Union	OECD	Organization for Economic Cooperation and Development
EVIRA	Finnish Food Safety Authority	OIE	World Organisation for Animal Health
FAO	Food and Agriculture Organization of the United Nations	PO	Performance Objective
FSO	Food Safety Objective	PRA	Pest Risk Analysis
FMD	Foot and Mouth Disease	PCE	Phytosanitary Capacity Evaluation Tool
GAINS	Global Avian Influenza Network for Surveillance	QA	Quality Assurance
GAP	Good Agricultural Practice	RIA	Regulatory Impact Analysis
GEF	Global Environment Facility	RMF	Risk Management Framework
GHP	Good Hygienic Practice	RPPO	Regional Plant Protection Organization
GLEWS	Global Early Warning and Response System for Animal Diseases	SPS	Sanitary and Phytosanitary Measures
GM	Genetically Modified	SARS	Severe Acute Respiratory Syndrome
GMO	Genetically Modified Organism	SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice to the Convention on Biological Diversity
GOARN	Global Outreach Alert and Response Network	STDF	Standards and Trade Development Facility
HACCP	Hazard Analysis and Critical Control Point	SWOT	Strengths, weaknesses, opportunities and threats
IICA	Inter-American Institute for Cooperation on Agriculture	TBT	Technical Barriers to Trade
IHR	International Health Regulations	UNDP	United Nations Development Programme
INFOSAN	International Food Safety Authorities Network	UNEP	United National Environment Programme
INGO	International Non-Governmental Organization	WHO	World Health Organization
IPM	Integrated Pest Management	WTO	World Trade Organization
IPPC	International Plant Protection Convention		
IPFSAPH	International Portal on Food Safety, Animal and Plant Health		
ISNAR	International Service for National Agricultural Research		
ISPM	International Standard for Phytosanitary Measures		

ACKNOWLEDGEMENTS

FAO would like to express its appreciation to the many people who provided advice and guidance during the preparation of this toolkit. In particular, FAO would like to recognize the role of Steve Hathaway, New Zealand Food Safety Authority in developing the Overview and Framework Manual for Biosecurity Risk Analysis, and Marlynne Hopper in producing the Guide to Assess Biosecurity Capacity. Thanks are due to Keren Bar-Yaacov, Norwegian Food Safety Authority and Gunnar Hagen, Ministry of Agriculture and Food, Norway for their work on the case study describing implementation of a biosecurity approach in Norway.

A number of experts in various aspects of biosecurity from different parts of the world provided valuable support to the development of the toolkit through a peer review process. This included an expert meeting at FAO Headquarters in Rome from 2 to 4 November 2005, which was attended by the following experts: Michael de Shield, Belize Agricultural Health Authority; Steve Hathaway, New Zealand Food Safety Authority; Chagemu Kadera, Kenya Plant Health Inspectorate Service; Randall Morley, Canadian Food Inspection Agency; Eric Schoonejans, Ministère de l'Ecologie et du Développement Durable, France; and Alfonso Torres, College of Veterinary Medicine, Cornell University, United States of America. In addition, Jörgen Schlundt, World Health Organization and Lee Ann Jackson, World Trade Organization participated in the peer review meeting. Written comments were received from Ruth Frampton, New Zealand on Parts 1 and 2, and from Bill Roberts, Biosecurity Australia on Part 3. FAO is grateful to all these persons for their interest and commitment to participate in the peer review process, and for their valuable contributions to improve the toolkit.

Useful comments were provided by FAO staff in different technical units and their inputs are gratefully acknowledged. FAO would also like to recognize the contribution of Niek Van Der Graaff, former Chief of the Plant Protection Service in the Plant Production and Protection Division, in chairing the FAO inter-departmental biosecurity working group during the initial stage of development of this toolkit. Last, but not least, FAO would like to thank the Government of Norway, which provided financial support for the development and publication of this toolkit under the FAO Norway Partnership Programme.

FOREWORD

Biosecurity is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life¹ and health and associated risks to the environment. Interest in biosecurity has risen considerably over the last decade in parallel with increasing trade in food, plant and animal products, more international travel, new outbreaks of transboundary disease affecting animals, plants and people, heightened awareness of biological diversity and greater attention to the environment and the impact of agriculture on environmental sustainability. Growing membership of the World Trade Organization (WTO) and the need to comply with global agreements governing the trade in agricultural and food products – particularly the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and, to some extent, the Agreement on Technical Barriers to Trade (TBT Agreement) – have heightened the focus on biosecurity. At the same time, changes in the way food, plants and animals are produced, processed and distributed, and the use of new technologies, have introduced new concerns about the health of plants and animals, as well as food safety and agricultural and environmental sustainability. Improved coordination is being sought among national bodies responsible for setting and enforcing sanitary² and phytosanitary measures to better protect human, animal and plant life and health without creating unnecessary technical barriers to trade.

During the past decade, some governments have moved towards an integrated approach to biosecurity that harmonizes and rationalizes policy, legislation and core roles and responsibilities as a means to better manage relevant risks in food and agriculture. However, most countries continue to manage biosecurity along traditional, sector-oriented lines, resulting in a lack of strategic focus, inefficient use of scarce resources and less than optimal results.

The Technical Consultation on Biological Risk Management in Food and Agriculture, organized by FAO in Bangkok, Thailand in January 2003, acknowledged the advantages of a more integrated approach to biosecurity to take advantage of synergies across sectors at the national and international levels, and recognized the efforts under way in some countries to adopt such an approach. It noted that several countries, including developing and transition countries, were revising their biosecurity arrangements and stressed the importance of external support in this context. It noted, in particular, the need for FAO to provide the necessary guidance and tools to assist developing countries in their efforts to move towards a more coherent and holistic approach to biosecurity.

This toolkit, which comprises three parts, has been developed by FAO in this context with support from the Government of Norway. The first document in the set, *Biosecurity Principles and Components*, is an introductory text providing a contemporary context for the development and implementation of a harmonized and integrated biosecurity approach across all sectors. The second part is a *Guide to Assess Biosecurity Capacity*, which offers a process for assessing dimensions of

biosecurity capacity across all sectors and sector organizations. The third part of the toolkit, *An Overview and Framework Manual for Biosecurity Risk Analysis*, presents a generic framework to structure and guide the application of risk analysis principles in biosecurity.

¹ For the purpose of this toolkit, “life” is used as a generic term to cover impacts of biosecurity activities that are not easily categorized as health impacts.

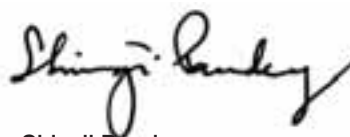
² For the purpose of this toolkit, “sanitary” refers to humans and animals (zoosanitary).

Respectful of variations in conditions across countries, biosecurity sectors and sector organizations, the toolkit fully acknowledges that there is no universally acceptable or standard policy or infrastructure that should govern national biosecurity systems. It offers countries guidance to develop and implement national biosecurity systems in accordance with their international obligations and based on their particular needs. It seeks to increase knowledge on the broader development and implementation of biosecurity policies and frameworks at the national level. This includes enhancement of biosecurity capacity through the assessment of needs and the generic application of risk analysis principles as an essential element of biosecurity. Indeed, the toolkit develops the thesis that risk analysis provides a common foundation for biosecurity.

We welcome comments and feedback on this toolkit as part of our ongoing commitment to support member countries to better manage biosecurity as a means to protect public health, agricultural production and the environment, and promote economic development through enhanced compliance with international agreements focused on sanitary and phytosanitary measures.



Ezzeddine Boutrif
Director
Nutrition and Consumer
Protection Division



Shivaji Pandey
Director
Plant Production
and Protection Division



INTRODUCTION

Biosecurity is emerging as one of the most pressing issues facing developed, developing and transition countries. Globalization, the increased movement of people, agricultural and food products across borders, greater attention to biodiversity and the environment, the emergence and spread of transboundary diseases, changes in the way food, plants and animals are produced, processed and distributed, uncertainties surrounding new technologies, as well as international legal obligations are some of the trends driving this growing interest, and highlighting the importance of adequate biosecurity capacity.

Biosecurity is a strategic and integrated approach to analysing and managing relevant risks to human, animal and plant life³ and health, and associated risks to the environment. It is based on recognition of the critical linkages between sectors. Biosecurity hazards⁴ of various types exist in each sector and have high potential to move between sectors. For that reason, inadequate controls in one sector can have far-reaching consequences for other sectors.

Harmonizing and integrating national biosecurity systems and controls whenever possible provides a means to take advantage of the synergies that exist across sectors. This will considerably enhance the capability of countries to protect human health, agricultural production systems, and the people and industries that depend on them. In addition, there are likely to be other benefits. A harmonized and integrated approach to biosecurity will help to safeguard the environment and protect against the uncertainties associated with new technologies. It will further enhance the capacity of countries to meet obligations under relevant international agreements and to take full advantage of opportunities associated with the global trade in food and other agricultural products.

PURPOSE AND SCOPE

This toolkit provides practical guidance and support to develop and implement national biosecurity frameworks at the country level. It presents the benefits of a harmonized and integrated approach to biosecurity and illustrates the experiences of countries, including Belize, Norway and New Zealand, which have adopted such an approach in recent times.

By providing a framework to identify cross-cutting biosecurity capacity needs based on an integrated approach, this toolkit addresses the gaps inherent in a purely

sectoral approach to biosecurity. The purpose is to support governments to better manage biosecurity as a means to protect public health, agricultural production and the environment. At the same time, this will enhance the ability of countries to comply with international agreements, regulations and requirements focused on sanitary and phytosanitary measures, contributing to economic development and trade.

The toolkit comprises three separate but linked documents. All three documents are developed on the premise that biosecurity concerns different parts of

³ As indicated in footnote 1, above, “life” is used as a generic term to cover impacts of biosecurity activities that are not easily categorized as health impacts. These can be diverse and often remain unquantified. For instance, in servicing the Convention on Biological Diversity (CBD), the Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA) has noted that current means to determine the “value” of biological diversity and its components are inadequate. In ecological risk assessment, stakeholder involvement is essential to identifying and prioritizing valued ecological attributes so that appropriate risk assessment can proceed.

⁴ The term “hazard” is used in this document in relation to all biosecurity sectors, however, the International Plant Protection Convention (IPPC) generally uses the term “pest” rather than the term “hazard”.

government, that biosecurity risks are interrelated, and that the best way to manage the risks faced is through coordinated action across the relevant sectors, contributing to improved outcomes and efficiencies.

PART 1: BIOSECURITY PRINCIPLES AND COMPONENTS

The first part of the toolkit provides a broad introduction to biosecurity and outlines the contemporary context for development and implementation of a harmonized and integrated biosecurity approach across all sectors. It shows how such an approach can enhance the protection of human, animal and plant life and health and the environment by taking advantage of synergies across sectors, as well as generating a number of other tangible benefits.

PART 2: GUIDE TO ASSESS BIOSECURITY CAPACITY

The second part of the toolkit provides guidance on how to assess dimensions of biosecurity capacity across all sectors and sector organizations in accordance with the requirements of an integrated biosecurity approach as presented in Part 1. Use of this guide will enable governments to increase awareness of the synergies and interdependencies that exist across biosecurity sectors. It will further help to generate an understanding of existing biosecurity capacity and performance, a medium-term vision for national biosecurity, and a strategy and action plan to enhance biosecurity capacity based on an identification of capacity needs.

PART 3: AN OVERVIEW AND FRAMEWORK MANUAL FOR BIOSECURITY RISK ANALYSIS

The third part of the toolkit presents a generic framework to structure and guide the application of risk analysis principles in biosecurity. Risk analysis is at the heart of modern approaches and is rapidly emerging as a unifying discipline across all biosecurity sectors. International standard-setting organizations and bodies have embraced risk assessment as an essential tool to achieve their goals and national competent authorities are obliged by international agreements to similarly utilize risk assessment wherever possible and practical. Part 3 of the toolkit explores the processes and methods common to cross-sectoral risk analysis and illustrates the role of this discipline in forging better linkages and promoting more efficient use of technical resources.

TARGET AUDIENCE

Government officials involved in biosecurity or a particular biosecurity sector are the main target audience. This group will include officials involved in food safety and public health, animal and plant life and health, and protection of the environment, at both the policy and/or operational level. In addition, development agencies, consultants and trainers supporting biosecurity activities and programmes will find the toolkit useful.