

Biosafety in the broader context of biosecurity

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Masami Takeuchi, Ph.D.¹ Food Quality and Standard (Food Safety) unit of FAO



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What is biosecurity?

Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks for analyzing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment.² Biosecurity covers food safety, zoonoses, the introduction of animal and plant diseases and pests, the introduction and release of living modified organisms (LMOs) and their products (e.g., genetically modified organisms or GMOs), and the introduction and management of invasive alien species. Thus biosecurity is a holistic concept of direct relevance to the sustainability of agriculture, and wide-ranging aspects of public health and protection of the environment, including biological diversity.

Biosecurity linkages

Human, animal and plant life and health and protection of the environment are inextricably linked and this is the fundamental rationale for an integrated approach to biosecurity at the national level. Biosecurity hazards of various types exist in each sector and have high potential to move between sectors. While transfer of problems between biosecurity sectors may occur on a lesser scale, inadequate control can have impacts well beyond one sector.

In respect of food chains, hazards can be introduced anywhere from production to consumption and a breakdown in security at any point can result in adverse health consequences to individual or multiple biosecurity sectors. Changes in the environment, such as the loss of biological diversity and contamination of food and water sources, sometimes result in significant risks to human and animal health.

Biosafety within the biosecurity framework

In the context of biosecurity, biosafety has been 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.”³ As such, biosafety does not represent an individual biosecurity sector as it is cross-cutting in scope. See box 1 for new influences on biosafety aspects of biosecurity systems.

¹ Masami Takeuchi, Food Safety officer of Food and Agriculture Organization of the United Nations. Phone: +39 06 570 53076. Email: Masami.Takeuchi@fao.org

² FAO Biosecurity Toolkit. FAO. 2007. ISBN 978-92-5-105729-2.

³ UNEP/CBD. 1992. Convention on Biological Diversity: Article 8(g).

Box 1. New influences on biosafety aspects of biosecurity systems

- Adoption of a risk-based approach
- Rapid proliferation of new gene technologies
- Emphasis on rapid establishment of credible and effective controls so as to maximize the benefits of biotechnology while minimizing associated risks
- Development of detailed national strategies for conservation and protection of the environment
- Increasing “public good” regulation for sustainable use of biological resources
- Greater inclusion of indigenous and local communities in decision making

LMOs are increasingly being released on a world-wide basis. While they may have potential benefits for human well-being and achieving sustainable economic development, their proliferation could have unintended adverse effects on the environment, including destruction of native flora and fauna, as well as adverse effects on human health. This could be especially significant in developing countries that do not have the capacity to track releases of these organisms and therefore cannot adequately safeguard national interests.

Regulatory requirements covering the safe transfer, handling and use of LMOs resulting from modern biotechnology are a new focus point in biosecurity and are triggering strong cross-sectoral interest in more holistic approaches to their management. However controls on trans-boundary movements currently vary considerably between countries in terms of their development, importation, field testing or release. Food may also be derived from (or traits introduced) by modern biotechnology. Although international guidelines on assessment of the safety of foods derived from GMOs are being developed, the adequacy of current processes is a continuing issue of public concern.

As with plant biotechnology in the early 1990's, animal biotechnology has reached a point where developers are beginning to market products derived in this manner. This may, in the near future, include agri-food applications. As an example, transgenic animals derived from recombinant DNA technology or by cloning (somatic cell nuclear transfer) is a means to generate animals with preferred traits. These animals and/or their products are likely to trigger regulatory requirements in most countries but guidance on safety assessment is still at the developmental stage.

Biosafety, biosecurity and environmental protection

Environmental protection in a broad sense is also a biosecurity activity. While not excluding any aspects of the above sectors, specific biosecurity cross-sectoral environmental initiatives may be undertaken by competent authorities, especially in the management of biological resources to ensure sustainable agriculture while maintaining full biological diversity of genetic resources.

Changing approaches to biosecurity

Biosecurity at the national level can be approached on a continuum that progresses from complete separation (and fragmentation) of sectors to high levels of harmonization and integration. In a traditional system, biosecurity is managed on a sector basis through the development and implementation of separate policy and legislative frameworks. Sector

agencies organize their work without much attention to the other sectors. Moreover, in some cases, roles and responsibilities within a biosecurity sector may not be under the same legislative jurisdiction and this further creates fragmented biosecurity.

In a modern national system, there is a more harmonized and integrated approach, with competent authorities responsible for different sectors and components of biosecurity working together towards common goals. Sector policies, laws and regulations can be harmonized to avoid contradictions, overlaps and/or gaps. Sector agencies can better coordinate their work and actively seek to take advantage of the synergies and complementarities in their roles and responsibilities. This encompasses the joint setting of biosecurity priorities and allocation of resources, joint planning and implementation of activities, and integrated systems for monitoring and review of outcomes.

Developing countries and biosecurity

Further technical advances and cost reductions are easing the adoption process for developing countries. It is possible that biotechnologies play one of the key roles in agriculture and safeguarding food supply in the future. However, the evolution of biotechnologies needs to go hand in hand with regulation. Biosecurity encourages a risk-based approach to regulatory programmes – that is, decisions and actions based on specific knowledge of risks to health or life.

Better risk analysis through a harmonized and integrated approach

There are considerable advantages from a harmonized and integrated approach to risk analysis at the national level. While international risk assessment processes differ in part between sectors, many aspects are common (e.g. recognition of the benefits of probabilistic modeling of hazard pathways to better represent and describe the complexity of real-world situations). Utilization of the expertise and experience gained in all biosecurity situations has the potential to improve risk analysis both within and between sectors, provide for consistency in approaches and outputs, and facilitate better uptake and understanding by competent authorities and other stakeholders. A more integrated and holistic approach will help in ensuring public confidence in overarching regulatory frameworks and assist in optimization of scarce biosecurity resources in developing countries.

Expanded uptake of risk assessment methodologies by competent authorities and more systematic risk management processes will result in enhanced implementation of integrated national biosecurity goals. If a national biosecurity strategy has been developed, an integrated risk management approach enables the overall use of government resources to be prioritized according to a broad ranking of biosecurity issues.

Risk assessment of food products derived from various biotechnologies

Biotechnologies may broaden the scope of various changes that are introduced into food products derived from them, with different parameters for safety assessment requirements. However, it does not necessarily mean that food products derived from biotechnologies are less safe than those produced by more conventional techniques.⁴ While some biotechnologies would introduce very clear limited changes in food, others may require applying risk assessment principles to “whole” foods, which by nature are very complex

⁴ OECD, 1993; US NAS, 2004

compounds and not single chemicals that can be investigated individually. Safety assessment is in essence the first step in identifying any hazards that may be associated with the food, after which the risks to human health are evaluated.

Conclusions

Improved health and well-being of human populations are the ultimate outcomes of well-functioning biosecurity systems. These outcomes are strongly influenced by society and the environment and, in this context; agriculture and health are linked in many ways. Agriculture produces the world's food, fibre and materials for shelter, and is an important source of livelihoods.

The benefits of a more harmonized and integrated approach to biosecurity are already apparent in specific national situations. While the multi-sectoral character of biosecurity and the diverse range of interest involved make each national situation different, there are likely to be significant improvements in biosecurity systems and outputs if more coherent national and international approaches are applied. Benefits include improved regulatory and policy frameworks for human health, food safety, improved animal and plant health, greater efficiencies in the use of human and financial resources, better understanding of potential risks and appropriate measures to manage them, and improved protection and sustainable use of the environment. Moreover, a more holistic approach to biosecurity will enable these benefits to be achieved in a manner that avoids inconsistencies, fills gaps, and prevents the creation of unnecessary barriers to trade.

Invitation to a Parallel Session on Cross-sectoral issues entitled “Biosafety in the broader context of biosecurity”

This session will highlight success stories in developing countries in utilizing biotechnologies for food and environmental safety. It will relate national and regional efforts at drawing up biosecurity frameworks and the actions to implement biosafety related measures. The process of holding stakeholder consultations, framing appropriate legislations and setting up institutional frameworks to implement a biosecurity strategy will be underscored. At the multilateral level, these experiences can be utilized by developing countries as a source of sound and unbiased advice. Any conference participants are invited to the session. The session starts at 16.45 pm on March 3, 2010.