22. The need for international perspectives to solve global biosecurity challenges

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Abstract

Global biosecurity presents international challenges because the majority of instances of novel organism introductions are due to international movements of goods, food and people and the likelihood of introduced agents crossing political boundaries. The inherent vulnerability of environments to introductions of alien, or non-indigenous, biological agents is due to the greater ecological vulnerability to these exotic entrants in the receiving environment. Agencies and individuals responsible for approving intentional introductions of beneficial organisms recognize this relationship and consider potential impacts in risk assessments prior to release of the organisms. However, some of those responsible for detection and control of novel pathogens and pests, introduced either inadvertently or intentionally, lack extensive training in ecology, environmental biology, and pathology, and may therefore underestimate the risk from such events. The latter is a key factor in the case of food safety. Europe is particularly vulnerable to cross-border movement of introduced agents, and one response to this has been the recent revision of plant health regimes throughout the European Union. Other responses include project-based initiatives, such as PLANTFOODSEC.

Much of the existing framework for biosecurity has evolved over decades due to the need for States to protect the public from unsafe food, and from economic and sociocultural losses to biodiversity and agricultural resources. While malicious intentional releases are rare compared to conventional trade related unintentional introductions of agents, the security paradigm (the possibility of intentional introductions) should be added to more traditional biosecurity approaches that focus on inadvertent and accidental incursions. While there is a need to distinguish the unusual from the ordinary, in both source and receiving areas, security-related risks should be set within that context, in terms of risk assessment (for appropriate scaling) and for management of factors common to conventional plant health risks. This chapter considers the existing international risk frameworks and how to adapt them to include the security paradigm by moving from the traditional concepts (agent-pathway-receptor systems) to also consider motivation.. Motivation for harm may arise from experiences at home or abroad, and the pathway for access, transport and delivery of harmful agents would link a foreign source to the receptor environment in a global system. The adapted processes provide a general framework for analysing malicious biosecurity risks in a consistent and proportionate manner. For food safety in particular, novel agents introduced to the food supply maliciously may not be anticipated or identified initially through the traditional risk assessment. For this and other cases, the formation of networks of experience and technical excellence, such as that accomplished by PLANTFOODSEC, will help to fill the gaps and address the weaknesses of individual national programs. A call is made to create a mechanism and assign a coordination role for a sustainable international cooperation in addressing the full spectrum of global biosecurity concerns.

22.1 Introduction

Biosecurity has been considered within the PLANTFOODSEC (Plant and Food Biosecurity - Network of Excellence: https://www.plantfoodsec.eu/aboutbiosecurity_scenario.php) project as the protection from harm caused by biological agents or, more specific to plant biosecurity, the protection of all plant resources and the food supply from the natural or intentional introduction, establishment and spread of plant pests, pathogens and noxious weeds (Preface). Security is one paradigm of a set of related biosecurity risk approaches that share many common characteristics, analytical processes and outcomes (Fig 1) (Mumford et al, 2013a). The PLANTFOODSEC project has been carried out within a security perspective, consistent with the European Security Research Advisory Board (ESRAB) definition of security research as "'*...research activities that aim at identifying, preventing, deterring, preparing and protecting against unlawful or intentional malicious acts harming European societies; human beings, organisations or structures, material and immaterial goods and infrastructures, including mitigation and operational continuity after such an attack...'*" (EC -European Commission, 2006).

A common concern of these biosecurity risks is the potential introduction of any agent or biological contaminant[1] into a cropping system, natural environment or food supply chain that could cause harm to the public.

An introduced agent would generally have the greatest impact if it is alien or non-indigenous[2] to the affected, or targeted, environment or food. The origin of the agent is important because, in addition to greater biological vulnerability to alien agents, detection and management of these agents would likely be outside the experience of those who must prevent or control them. As novel agents, they may also be more alarming to the public (Suffert et al, 2009; see also Chapter 4). In the case of conventional (not novel) biosecurity risks, the organisms and pathways may be relatively well understood, even if challenging to prevent and control.

The international perspective on the other biosecurity challenges (Fig 1) is essential when considering the security paradigm. Those involved in the trade, importation or production of possible target crops or food are already cooperative partners in the assessment and management of biosecurity risks. The legal and institutional frameworks are well tested and also embedded in each region and country. This makes the international perspective on biosecurity an important starting point, although novel agents may require additional or different partners to respond to and address these new threats.

International legal structure

Protecting domestic agriculture from non-indigenous pests and diseases is generally understood to be a public good, because it promotes both economic and food security. It is a role undertaken by

[1] The Codex Alimentarius Commission (CAC) defines a contaminant as "any substance not intentionally added to food or feed, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination" (CAC, 2015). While this definition does not require that the contaminant be harmful, nor does it refer to intentional introduction of an agent, this chapter includes those possibilities. (Food additives are substances intentionally added to foods.) The project has focussed on living, biological agents, rather than other forms of contaminants such as chemical substances.

[2] A discussion of the meaning of the terms *introduction* and *alien species* appears in the Appendix 1: Terminology of the Convention on Biological Diversity, ISPM 5 Glossary of phytosanitary terms (IPPC, 2015), comparing details of how they are used under the CBD and the IPPC. The IPPC would prefer non-indigenous to describe such a population.

governments, with the cooperation of importers, shippers and travellers (Mumford, 2002). At the international level, the two main instruments that deal with prevention and management of organisms harmful to plants are the International Plant Protection Convention (IPPC) and the Convention on Biological Diversity (CBD).

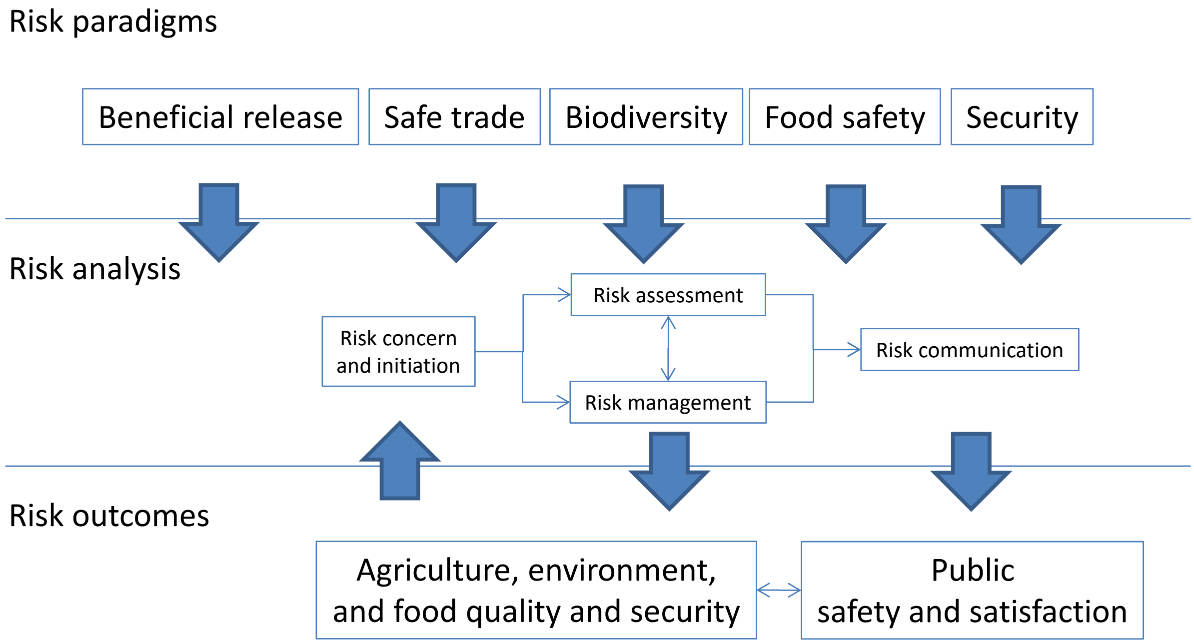

Figure 1. Risk paradigms for global biosecurity (Mumford et al, 2013a).

The earlier instrument is the IPPC (FAO, 1997; IPPC: https://www.ippc.int/en/), which came into force in 1952. The IPPC created an international regime "to secure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control". Its authority regards transboundary movement and the introduction of pests not already established into new areas, rather than general pest control of native or cosmopolitan pests. The IPPC has traditionally focused on safe trade and food security, although its mandate extends to environmental objectives related to natural flora and fauna and aquatic plants. The IPPC became more explicit about how an introduced agent's predicted impact on ecosystems justifies regulation of incoming trade, when its international standards for phytosanitary measures (ISPM) 11 on Pest Risk Analysis was expanded to discuss invasive species (IPPC, 2013; IPPC Secretariat, 2005). This international plant health agreement has 182 signatories and is referenced by the World Trade Organization (WTO: https://www.wto.org/) in relation to phytosanitary rule making under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (WTO, 1994), commonly referred to as SPS.

The CBD (UNEP, 1992, CBD: https://www.cbd.int/) has protection and sustainable use of biodiversity as one of its primary objectives and supports implementation and provides guidance on its principles as part of its ongoing work program. The CBD calls on its parties to "prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats, or species" (Article 8h). It advocates a "three-stage hierarchical approach" of prevention, eradication and containment, with support measures based on identification of challenges and prioritization of objectives, prevention and early detection and control and long-term containment. The CBD is not a standard setting organization, however, and it has collaborated closely with the IPPC on plant biosecurity issues. The CBD has been ratified by 196 of the signatory countries and territories. It also holds a supplementary agreement on biotechnology, the Cartagena Protocol on Biosafety, which has been signed by many (although not all) of the signatories to the CBD.

Both agreements – the IPPC and CBD – consider the intentional release of beneficial organisms into agricultural or unmanaged natural environments. The Food and Agriculture Organization (FAO: http://www.fao.org/home/en/) '*Code of Conduct for the Import and Release of Exotic Biological Control Agents*' (IPPC, 1996) has become one of the ISPMs under the IPPC (ISPM 3: IPPC, 2005). This guidance was revised to cover release of a range of beneficial organisms and is widely followed by national frameworks (Quinlan et al., 2003 and Kairo et al., 2003). Protection of biodiversity and management of intentional release for conservation or reintroduction objectives is also covered by the World Animal Health Organisation (OIE after its original name of Office International des Epizooties: http://www.oie.int/). The OIE is the oldest of the rule making bodies referenced in the WTO SPS, having begun in 1924; it includes 180 member countries.

Food safety is largely governed at an international level by the Codex Alimentarius Commission (CAC: http://www.fao.org/fao-who-codexalimentarius/en/), since its inception in 1963 when it was established by FAO and the World Health Organization (WHO). The CAC (1992), the third rule setting body referenced by the WTO SPS, and its 187 members produce standards, guidelines and codes of conduct on food safety issues. Their procedures for risk assessment are described in general terms in guidelines (e.g. CAC, 2007) as well as specifically for microbiological contamination. Codes of practice to avoid other contaminants are more specific to particular commodities, industries or contaminants. The majority of countries have food laws that reference CAC standards, either implicitly or explicitly. The risk outcomes of food safety and quality are the primary objectives of this body.

The risk paradigm of security is not as clearly linked to only one particular international agreement (see Chapter 8). The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (more commonly known as the Biological and Toxins Weapons Convention (BTWC, 1976) or simply Biological Weapons Convention (BWC)), entered into force in 1975, presently includes 173 parties and other signatories. The BTWC covers biological weapons, devices that disseminate disease-causing organisms or poisons to kill or harm humans, animals or plants. Historical efforts to produce biological weapons have included, among others, aflatoxin and the rice blast pathogen, *Magnaporthe grisea*. The BTWC also recognises that these agents can be enhanced from their natural state to make them more suitable for use as weapons. The multilateral treaty is aimed at States committing to disarmament and avoiding this category of weapons. It is not written with individual perpetrators in mind. It also does not have close linkage mechanisms with the other conventions relating to biosecurity risks, mentioned above, although some coordination does take place[3]. Therefore, the BTWC is an international framework for security but it does not explicitly address biosecurity.

Overall, however, the biosecurity risks identified in Fig 1 are covered, at least to some extent, by an existing international legal structure and there are shared concerns across the international legal instruments and bodies about the introduction of alien agents that would threaten biosecurity. Furthermore, there are shared principles for analysing risks and planning and communicating their management. The outcomes elaborated in Fig 1 are authorities generally assigned to States, as a public good, albeit less directly in terms of satisfaction of the public. Cross-border cooperation is critical to

[3] https://www.ippc.int/en/liason/organizations/biologicalweaponsconvention/

any effective preparedness and response strategy, for this reason an approach at the European Union (EU)-level is necessary and appropriate.

The European context

Whatever the cause of an introduction of a novel agent or outbreak, a comprehensive biosecurity system is essential to protect domestic agriculture, natural resources and food supplies. Whereas numerous representatives of the United States Administration (Executive branch) and Congress have publicly expressed concern regarding the threat of biological terrorism, in Europe an attack on crop and food biosecurity is not yet discussed as a real threat in the political agenda. Current EU capabilities to detect and respond to agro-terrorism and bio-criminal acts are modest at best, spread amongst many organisations, normally handled by regional or national bodies, and of limited coordination. At the same time, legal regimes concerned with biosecurity, trade, biodiversity and food safety are connected neither at international nor European levels.

Actions related to plant and food biosecurity have a strong transboundary component in most regions. In Europe, a bioterrorist attack or introduced harmful organism could affect several Member States and spread fairly easily across borders. Factors contributing to the vulnerability of European agriculture include the continuing trends of intensive production techniques, the increasing production of genetically uniform crops, a notable amount of imported propagation material, the vertical integration of the production continuum, an increasing industrial dependence on the export market and the limited presence of resistance to disease agents in key crop and livestock species.

Food safety (discussed further in 22.4) and biodiversity have their own European legal and institutional contexts; the former focusing on food hygiene and the latter covering invasive species, habitat preservation and protected areas. The release of beneficial organisms in Europe is regulated through a patchwork of national approaches with links to more than one EC Directive, as discussed in a recent workshop (EPPO/COST SMARTER, 2015). There is not as clear a decision pathway for intentional releases as there is for traditional plant health issues. Security has not been closely coordinated with these sectoral regimes in the past.

Considering plant biosecurity, at a regional level the European and Mediterranean Plant Protection Organization (EPPO) acts, in alignment with FAO, as a recognized regional plant protection organization under the IPPC. EPPO has 50 members, covering almost all countries of the European and Mediterranean region and extending to Russia, the Middle East and North Africa. EPPO advises member governments on the technical, administrative and legislative measures necessary to prevent the introduction and spread of pests and diseases of plants and plant products and provides coordination on risk assessments of alien species of concern. It also works on plant protection products such as pesticides and biological control agents for beneficial release.

For European Member States, all of whom are also members of EPPO, conventional plant health risks are managed by national regulatory authorities, all of which are recognised as competent authorities by the European Commission and the IPPC. The Council Directive 2000/29/EC established the Community Plant Health Regime that aims to protect the EU against the harm caused by the introduction and spread of harmful organisms and thus ensuring food security and plant health protection through sustainable production. Through this framework, all EU Member States are obliged to prohibit the import and internal movement of specified quarantine organisms, to notify the Commission and other Member States of the presence within their territory of these harmful organisms and finally they are obliged to take measures to eradicate or, if this is not possible, contain and prevent their spread. The Commission may also seek scientific advice from the European Food Safety Authority (EFSA), such as from the Scientific Panel on Plant Health.

The Community Plant Health Regime is under revision following an in depth review (EU, 2015; FCEC, 2010). Some of the recommendations for enhancement of the plant biosecurity system appears in Box 1. The results are informative for other international regimes, as well. Some mechanisms have been proposed for better coverage of invasive alien species.

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Box 1 Some recommended enhancements of the European plant biosecurity system.

The European Academies Science Advisory Council (EASAC), in its report "*Risks to plant health: European Union priorities for tackling emerging plant pests and diseases*" (EASAC, 2014), clarified what is needed to achieve EU goals in the analysis and management of plant health risks covering three priority areas:

1. Surveillance systems

EASAC recommends to improve monitoring of pests with establishment of early warning systems; to enhance linkage between databases; to use new forms of monitoring, to extend surveillance to natural habitats and to consider possible new challenges, for example bioterrorism. Meanwhile the EU Biodiversity Strategy to 2020 (EC, 2011) proposes a dedicated EU legislative instrument (Regulation on Invasive Alien Species-IAS) to tackle outstanding challenges relating to Invasive Alien Species pathways (routes of biological invasions and. the mechanisms and vectors that allow the introduction and spread of IAS).

2. Research and training

EASAC also recommended that the research agenda address diagnosis; biology, ecology and epidemiology of plant pests and pathogens and their relationships with hosts and vectors; plant pest resistance; biological and cultural strategies for sustainable pest management; modelling, prediction and extrapolation. In addition, networking among disciplines and sectors should be improved.

3. Innovation

The translation of knowledge from research to practical applications is recommended by EASAC, in particular to develop durable control approaches to overcome current limitations of pesticides and to breed improved plants, durably resistant to biotic stresses.

EASAC also pointed out that protection and promotion of plant health cannot be tackled successfully without raising political and public awareness of the importance of plant health and resilience for sustainable agriculture, food security and environmental protection.

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A Consortium of European researchers has been exploring the topic of crop biosecurity since 2004, taking into account the risks that the deliberate introduction of plant pathogens poses to European agriculture and forestry. This work has been carried out through several EU and NATO-funded research projects, such as the following:

- FP[4]6 CROPBIOTERROR – "Crop and food biosecurity, and provisions of the means to anticipate and tackle crop bioterrorism" (2004–2007);
- NATO[5] Security through Science – "Tools for Crop Biosecurity" (2005–2006);
- NATO Science for Peace and Security (2008); and
- EuropAid[6] – "Tackling BIOSECurity between Europe and Asia: Innovative detection, containment and control tools of Invasive Alien Species potentially affecting food production and trade" (2007–2010).

The EU Network of Excellence PLANTFOODSEC (2011–2016) renewed and reinforced the established partnership by enlarging it to include new countries, institutions and topics, with the ambition of contributing, through a multidisciplinary mission-oriented research, to building up the capabilities to address food and crop biosecurity threats.

Making reference to the Commission green paper on bio-preparedness (EC, 2007) the PLANTFOODSEC Joint Programme of Activities aimed to enhance European preparedness for deliberate or accidental introduction of the most threatening organisms harmful to plants, thus covering prevention, protection, response and recovery capacities (eradication and containment). The project has been designed to combine and functionally integrate in a durable way a substantial amount of partners' activities in the field, including:

- Actions to identify and update the biology, epidemiology and impacts of high priority pathogens, as well as through the optimization of detection and diagnostic tools;
- Actions to develop effective responder strategies by defining specific protocols on emergent pest and disease management;
- A comprehensive strategy to enhance knowledge of target groups and to inform relevant stakeholders; actions aimed to enhance networking, to overcome the fragmentation of partners' research, and to facilitate and coordinate cooperation within and among the working groups.

These projects have been changing the biosecurity context for Europe. Their experiences demonstrate the need for collaborative or coordinated approaches across national boundaries. Lessons learned could be valuable for solving both current and future global-scale challenges in biosecurity.

22.2 Trade and other sources of unintentional introductions

The risks of unintentional introductions of alien pest organisms through trade or natural spread are assessed at a national level by the competent authority in each receiving (importing) country. For plant health, this is carried out through a risk assessment process in line with the pest risk analysis standard established by the IPPC, ISPM 11 (IPPC, 2013). These risk assessments[7] are often available publicly and document the significant threats that particular organisms pose to agricultural production. The risk assessments are required to identify specific vulnerable crops, defined locations and other conditions (sometimes including time frames) that make preventative action against the organisms essential. These

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[4] EU Framework Programme for Research and Technological Development (FP), numbered by round of funding.
[5] North Atlantic Treaty Organization (NATO) http://www.nato.int/
6 EuropeAid (also shown as EuropAid in many websites) is a new Directorate General (DG) responsible for designing EU development policies and delivering aid through programmes and projects across the world. Its formation is described at: http://ec.europa.eu/europeaid/historical-overview-eu-cooperation-and-aid_en
[7] Risk assessments are discussed, although the documents might be entire Pest Risk Analyses. The difference is whether the possible management options are included in the document, or appear separately. For this chapter, when referring to a risk assessment it may be included in an overarching analysis document, or be standalone.

factors do not need to be defined if the risk is acceptable to the receiving country, and no further steps would need to be taken.

An example of an innovation for conventional risk planning is the UK National Plant Health Risk Register (DEFRA, 2016; Mumford et al., 2013b), which covers over 700 agents from around the world, describes their potential origins, pathways, impacts and management. Any plant health risk agent that warrants consideration through conventional pathways (i.e. trade of commodities associated with the pest) is also worthy of attention as a potential agent to be used in an intentional introduction.

Conventional trade-related pest risk assessment involves an **Agent-Pathway-Receptor** system, although using other terminology such as pest (defined in the categorization phase)-pathway-endangered area and susceptible crops, as shown in Table 1. When considering pest risk from trade pathways, these are always specific to both the pathway (commodity or other pathway, e.g. dunnage, shipping containers, waste) and the origin, since the pest status of the various countries or regions of origin for trade can vary. The final calculation of the level of risk depends, then, on the receiving environment or Receptor. All of these factors taken together define the pest risk from trade.

Table 1. Similar, though not equivalent, terms used in various biosecurity risk paradigms

	Trade/ Plant Health	**Beneficial Release/ Biodiversity**	**Food Safety**	**Security**
Instigator of the event (knowingly or unknowingly)	Exporter Handler/shipper Broker/Importer Smuggler Agroterrorist	Introducer Applicant (when done with permit) Polluter Ecoterrorist	Source Disgruntled (i.e., angry or vengeful employee) Poisoner	**Motivation** (-ed person) Perpetrator Terrorist Criminal
Introduced organism or agent (generally harmful)	Pest Regulated pest Quarantine pest Disease Weed (plants that are pests)	Agent (beneficial or not) Invasive species Weed	Hazard Contaminant Pathogen Food poisoning Toxin Human	**Agent** Pathogen Hazard Toxin Biological weapon
Relationship to location where introduced	Exotic Non-indigenous	Exotic Non-native Alien (e.g. species)	Foreign matter Non-food material	Alien (e.g. substance)
Means or mechanism for introduction	Pathway Diversion from intended use Introduction	Pathway Mechanism Causal pathway Introduction (re-)	Exposure Vector	**Pathway** Means (for introduction)
Environment including conditions into which the agent is introduced	Endangered area Containment area (when spread is being limited through official control measures)	Receiving environment Impacted area Non-target organisms Keystone species Ecosystems Habitat	Food Feed Processing plant	**Receptor** Target

Assessments may be focussed on particular pest agents already known to cause impact in areas where they have been introduced through trade. In that case, the focus is on the likelihood of the agent being introduced, as well as options for mitigation, containment or eradication after the fact. Alternatively, assessments may change to reflect growing concern about the protection of the receiving environment. For example, expansion of production of vulnerable crops, increase of volume of the pathway (trade) or newly imposed limitations on control options are all legitimate reasons to reconsider assessments of risk.

According to Latxague et al. (2007), pest risk analysis schemes aligned with the related international standard for plant health in trade should be amended for security risks to account for at least five further criteria: (1) the ease of use of the agent, (2) the epidemic potential of the agent, (3) the importance of the target crop in relation to the motivation (may be economic or social), (4) potential obstacles to swift and effective response, and (5) potential regional or global consequences of a planned attack. Despite aspects which are missing, these trade related risk assessments provide a baseline against which intentional malicious introductions of pest organisms should be assessed. There is substantial experience in assessing and managing such accidental introductions and this expertise should be brought to bear on intentional introductions. In conclusion, existing pest risk assessments may reveal a large set of possible threats for malicious, intentional introductions. The agents of concern in the security paradigm, however, extend further to include some that would not normally be associated with trade pathways.

22.3 A framework for assessing intentional introductions

The **Motivation-Agent-Pathway-Receptor** paradigm for biosecurity risks extends the conventional Agent-Pathway-Receptor concept of plant health risk to include the possibility of intentional agent introduction (Fig 2, and see Chapter 10). The motives, agents and pathways all have potential global aspects.

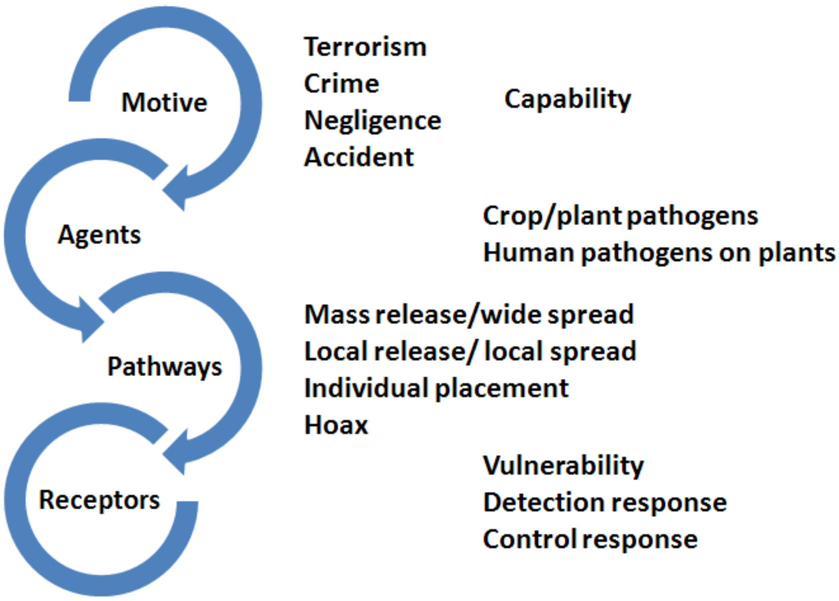

Figure 2. A paradigm for biosecurity risk assessment, involving a risk chain.

The PLANTFOODSEC project has developed an extensive set of risk scenarios for assessment and management based on this risk chain approach.

Vulnerability is a key concept related to impacts (Kareiva and Quinlan, 2002; see also Chapter 3). In terms of ecological vulnerability, agricultural systems are generally more vulnerable to alien organisms than are more diverse natural systems. In terms of management vulnerability, prevention, detection and control are likely to be less effective for agents that are unfamiliar and unexpected than for known or endemic threats. Those sourced from abroad are more likely to be unfamiliar and unexpected. And for social and institutional vulnerability, unfamiliar risks are likely to have greater impact when they occur than do normal, local problems.

Within the PLANTFOODEC project (see Chapter 4) plant disease epidemiology has been applied to crop biosecurity to develop a list of 555 target plants and crop products relevant to Europe, which includes field crops, vineyards, orchards, vegetable crops, nursery and ornamental horticulture, medicinal and aromatic plants, forest products, beverage crops, straw, tree sap and seeds. In addition, 570 pests were identified, updating the list of candidate pathogens established under the EU project CROPBIOTERROR, including harmful organisms likely to threaten crop biosecurity. Criteria for prioritisation were also identified, leading to a short list of 21 crops strategic for Europe and to a short list of pests including 63 pathogens.

Increasing preparedness against biosecurity threats requires authorities to increase the knowledge of the disease initiation and spread, because the earlier a disease is detected, the quicker counter-measures will be implemented. To mimic the early dynamics of an epidemic following a deliberate introduction, the course of epidemics occurring naturally in crops has been investigated: the scientific knowledge framework and appraisal tools developed may be applied to important crop systems across Europe.

A tool was developed to enable rapid assessments of agro-terrorism scenarios. The tool is based on pest risk assessment schemes, but includes agro-terrorism threats. The usefulness of the tool has been demonstrated on almost 100 scenarios covering a wide range of potential motivations, biological agents, pathways and receptor systems in order to provide a comparative measure of risk. By re-evaluating the ratings of appropriate criteria to reflect a managed situation, the tool makes it possible to assess the effects of potential prevention and mitigation measures. The results indicate how the threat posed by different scenarios might be reduced and how responses might be improved. PLANTFOODSEC contributed to the effectiveness and efficiency of surveillance and response programmes by allowing models of management systems to be tested against representative bio-terrorism threats.

22.4 A framework for consistent response

Whatever the cause of an introduction of a novel agent or outbreak, a comprehensive biosecurity system is essential to protect domestic agriculture, natural resources and food supplies. The management of both conventional and malicious biosecurity risks requires responses to be proportionate to risks in order to prevent and limit damage to legitimate activities (Mumford, 2013). It is important that both sources of risk (generally unintentional, and intended and probably malicious) are consistently managed on any shared components to ensure that this proportionate response is achieved. Schrader et al, (2012) considered the issue of consistency in assessment and response in relation to conventional plant health risks. Authentic consistency, however, recognises real differences.

While some dimensions of risk are quite different in intentional introductions there remain common elements in the analysis. The ISPM 11 (IPPC, 2004) describes a framework for pest risk analysis that provides a basis for addressing concerns, assessment, management and communication of biosecurity risks. The PLANTFOODSEC project has adapted this framework (see Chapter 10) to conduct malicious biosecurity risk assessments in a similar way. So, risk components related to motivation of perpetrators, handling of agents, and public susceptibility and reaction are added to the basic trade biosecurity analysis. While other components of trade related risks, such as volume, seasonality and distribution of trade, are removed because they are less relevant to an intentional introduction.

After the risk is assessed, management actions should address the factors that contribute to risk. The measures to be taken in order to prevent the establishment and spread of harmful crop pathogens or pests have been established by identifying activities and responsibilities following pathogen introduction (see Chapter 9). In particular, PLANTFOODSEC identified international expertise for setting up contingency plans; listed resistant cultivars and alternative crops for a given pathogen; and developed containment and eradication protocols for selected pathogens to increase convergence of responder networks. Agencies and individuals have similar responsibilities to prevent and control an introduction of agents that pose a threat, although additional security agents would also be involved to deal with perpetrators and public reactions. Communication about security threats and responses to incidents needs to be culturally appropriate and allay fear rather than exacerbate it.

As biosecurity risks transcend national and regional boundaries, we must monitor, assess and manage these risks in a coordinated way across the EU, as well as other regions. Strong plant biosecurity programs should integrate elements of penalties and incentives, prevention and detection measures, and response and recovery planning by including the following: early detection and diagnostic systems; epidemiological models for predicting pathogen spread; reasonable but effective strategies and policies for crop biosecurity; distributed physical and administrative infrastructures; a national response coordination plan; and strategies for forensic investigation and attribution in cases of intentional or criminal activity. Most of these recommendations hold true for biodiversity and food safety biosecurity programs as well.

22.5 Enhanced preparedness for foodborne introductions

In today's global economy, a head of lettuce produced in summer on a farm in the southern hemisphere can be harvested, packed, and shipped to a winter-bound country in the northern hemisphere on the other side of the world in a time frame equivalent to a small fraction of its shelf life. Consumers in developed nations now expect to find fresh, high quality fruits, vegetables and grains of all types in their grocery stores year-round, and rely upon sanitary standards at all points along the food distribution chain, as well as at border inspections, to safeguard these critical commodities. Their trust is generally well placed. However, although serious outbreaks of foodborne illnesses due to contamination by either human enteric bacteria or fungus-produced mycotoxins continue to be relatively infrequent in first world nations they are on the increase, in part due to vulnerabilities of the global marketplace. Furthermore, consumers in developing nations cannot be as confident of consistency in either food safety or food security.

Food biosecurity specialists (see Chapters 6 and 7) have examined and identified the most critical food safety issues/vulnerabilities for the EU partners and associated countries and provided a baseline assessment of forensic capability within the EU to trace the sources of foodborne pathogens and toxins. The sheer volume and diversity of critical food-associated issues was addressed by the development of a prioritization strategy based on the political, economic, social, technological, legal and environmental (PESTLE) factors of a threat scenario. Currently available methods for the detection of human pathogens in foods were reviewed, and areas for improvement identified. Practical tools for applications in the food safety arena were also developed. PLANTFOODSEC partners developed a decision tool, intended to aid case investigators to discriminate, in the early stages of an investigation, between deliberately caused and accidental incidents. A new molecular detection assay capable of fine discrimination among strains of pathogenic, foodborne *E. coli* was developed to support forensic trace back efforts. Finally, PLANTFOODSEC project partners reviewed technologies available for detection and identification of mycotoxins in food items, with a focus on applications and gaps in biosecurity related investigations.

In addition to producing the specific deliverables noted above, the interactions and collaborations among PLANTFOODSEC partners and others has led to the realization of the larger goal of creating a network of excellence that crossed national, continental and hemispheric lines in a manner that allowed for the incorporation of global perspectives and examples, international training and exchange experiences for students, postdocs, and mature scientists, and lasting collaborative partnerships among the partners. However, to minimize foodborne illnesses caused by microbial contamination of foods in the future, larger and more comprehensive international networks will be needed for continuing progress in addressing challenging vulnerabilities and gaps in food safety and biosecurity associated with food production, processing, shipping, trade and marketing, and consumption. Targeted research is needed to generate new knowledge related to the biology and genetic variability of foodborne pathogens, over time and in diverse plant hosts and geographical location. We need to know more, also, about fundamental interactions between human pathogens, plant associated microbes, the host, and the environment. Furthermore, we need to better understand how on-farm production and harvesting standards impact food safety.

Finally, new information and understanding gleaned from both fundamental and applied research must be translated into practical recommendations for implementation by food producers, distributers, and marketers. Training opportunities targeted to each of these specific groups, as well as to consumers, should be developed. Access by food producers and handlers to assistance and incentives for on-site implementation would likely boost rates of acceptance and adoption of new regulations or recommendations. Each nation, in the EU or elsewhere in the global food arena, has unique farming practices and governmental requirements addressing both consumer protection and environmental impacts, but coordination and communication across borders, within and outside of the EU, will be needed for consistent and reliable outcomes.

22.6 Detection and diagnostics

Few nations have effective customs and border inspection practices that eliminate the risk of inadvertent introductions from external sources, for example trade. This is due, in part, to the limits on resources and sustained support for trained border agents and the massive flow of people and goods. In addition, adequate detection technologies are not available, although some are emerging as discussed below. To rely on border control for detecting malicious introductions from outside of a country or region is not wise.

The PLANTFOODSEC project developed a web-based diagnostic network (see Chapter 15) as one approach to strengthening detection and diagnostic systems. The virtual diagnostic network allows information to be gathered, searched and reported, and also makes possible information flow between experts and field workers. The primary components are a database of diagnostic laboratories and expertise in the EU Member States; a community resource detailing plant pathogen news, updates on diagnostic techniques, and training and workshop information; and a structure to allow the uploading of diagnostic records and their interrogation. The network thus provides a unique tool and allows Member States to access summary information on plant pest and food safety outbreaks in Europe. While its uptake will depend on adoption of recommended practices in all Member States, and a promotion of the concepts beyond EU members, the durability of the tool will be ensured in the framework of new

EU-funded initiatives for plant health, such as the Horizon2020[8] Project "EMPHASIS". In addition, techniques for mycotoxin analysis have been reviewed (see Chapter 11).

Recent advances in the technologies that underpin detection and diagnostics of pests and pathogens (see Chapters 11 and 14) offer both opportunities and challenges for international cooperation. These technologies have dramatically lowered the detection limits for many pathogens and pests while at the same time increasing the accuracy of identification. The use of partial gene sequencing for pest and pathogen identification has become routine in many diagnostic laboratories. Recent developments in transitioning these technologies into point-of-care applications will make it easier to support biosecurity surveillance in the field and at ports of entry. One such portable technology under development is a disposable gene sequencing system the size of a thumb drive that plugs into a laptop computer (Benowitz, https://www.genome.gov/27555651). Clearly, this type of system will revolutionize our approaches to surveillance and in-field detection, although challenges also remain as considered in Box 2.

Box 2 Challenges and opportunities from emerging diagnostics technologies

As such technologies develop, users must also choose the best software systems to analyse the data generated by these technologies and determine the dependability of the databases necessary to interpret the data. Both the software systems and the databases have been steadily improving and in time they will have been vetted to a level to support regulatory decisions. Calls for sequencing all organisms (plants, pests, and pathogens) detected at points of entry may be premature (Roberts, 2013). Although that may be technologically feasible, it is uncertain as to whether the requisite databases to support data interpretation are ready for the legal scrutiny of regulatory actions. If the resources are available to support such sequencing, the data acquired could be very useful to support the generation of the requisite databases and the validation and verification of those databases.

We are now able to detect organisms at population levels far below what traditional detection methods have allowed. This should reduce the risk of inadvertent introductions associated with trade and travel. But do we have the knowledge base in place to interpret the results that we generate with increased sensitivity and specificity in detection and diagnostic tools? What level of confidence can be applied to a "new" detection? Government agencies will be asked if the newly detected organism really is new to an area or has always been present but below the detection limit of traditional methods. How reliable are the existing geographic distribution maps of pests and pathogens? Historical boundaries may not be relevant due to the changing demographics of plants, pest, and pathogens as a consequence of climate change, trade, and travel; not to mention possible intentional introductions. Geographical boundaries (e.g., oceans, mountains) are not congruent with phylogeographic boundaries used for more ecologically based analyses.

Will these new, more sensitive detection technologies encourage a shift to tolerance-based phytosanitary and sanitary decisions? Will they generate a need for revisiting international standards that are based on presence/absence? This is a worthy discussion to promote. Some of these were raised already by the International Barcode for Life project (iBOL, 2011), and answers were not yet available.

[8] EU Framework Programme for Research and Technological Development (FP), funding from 2014 to 2020 is now in the Horizon 2020 program.

22.7 International cooperation in a broader context

Alien pest organisms or novel food contaminants can be among the most significant threats to domestic plant and public health due both to the novelty of the agents, whether introduced by accident, such as through trade, or intentionally and to the lack of preparation for identifying and managing them. The motivation for intentional release may have a basis in international terrorism or bio-crime, adding a global dimension not considered in the current international legal structures for plant biosecurity. The pathways for delivery of harmful agents to a targeted area may involve foreign actors and origins, and handling and transport not identified in traditional pest risk analysis, for example, as a pathway for risks. While some intentional releases of harmful organisms may involve local actors using local agents, these cases are likely to result in lower levels of impact and will be less disruptive than those with foreign elements.

Risk analysis processes for unintentional introductions of pests are well established for international trade and environmental conservation. The same is true for accidental, but anticipated, introduction of pathogens to food supplies. Release of organisms into the environment has always been more complicated in terms of agreement on risk analysis criteria and conclusions, but global protocols and standards do exist to guide this analysis. Although the international convention most related to security, the BTWC, is not designed for similar pathway and receptor analysis, the infrastructure exists for notification and information sharing.

Additional risk analyses related to intentional introductions motived by terrorism or other criminal acts should build on currently recognised systems to ensure that security risks involving similar agents, pathways and receptors can take advantage of existing legal and institutional structures and expertise for other risks to crops and food supply chains. The motivation and capabilities of perpetrators and the vulnerability of ecological and social systems to terrorism and criminal acts are particular points that distinguish malicious biosecurity risks from more conventional risks, and these aspects need further development for robust risk analysis to take place. Therefore, rather than focusing solely on the biological agents or pathways, it is appropriate to develop additional components within these conventional risk analysis processes based on scenarios related to perpetrator motivation, feasibility of access, to complement the biological potential for introductions and receptor details. While the specificity of a target or endangered area indicates what information to use regarding the receptor environment, there is likely to be an international dimension to the motivation, agents and pathways related to these biosecurity risks. One component of that is the use of alien organisms.

Risk assessment processes modified to include security components can be used by risk assessors familiar with agricultural trade, biodiversity or food safety risk analysis. These processes, along with security analysis, will be able to cover a broad range of potential agroterrorism and bio-crime scenarios. The process should be compatible with existing international standards or regional regimes as far as possible, to enhance effectiveness of the assessment and management measures. A system is needed to integrate these new components for malicious biosecurity scenarios.

The considerable amount of research promoted by the European Union – which has also involved non-EU countries such as the United States, Israel and Turkey – has made possible the development of a comprehensive set of tools to this end. Project achievements included the identification and regulatory analysis of biosecurity challenges; experimental and modelling approaches applied in plant disease epidemiology; advanced molecular diagnostics; and, more generally, training, dissemination and networking activities to increase awareness of plant biosecurity and food safety among agronomists and food producers and within the scientific, policy and inspection sectors.

PLANTFOODSEC performed the first step needed to set up a virtual Centre of Competence on Biosecurity, the aim of which is to become the backbone for the EU Plant and Food Biosecurity Scientific Community. PLANTFOODSEC acted as a network of research centres, universities and other stakeholders to enhance preparedness and response capabilities to prevent, respond and recover from both intentional and unintentional biosecurity threats to EU agriculture, farming and the agro-food industry. The PLANTFOODSEC Consortium is currently working to make the virtual European Centre of Competence on Plant and Food Biosecurity a sustainable reality by building the capability to ensure the broad implementation of the project results.

The WTO and the IPPC at the FAO have long recognized the many threats to plant health posed by international trade. WTO encourages the harmonization of phytosanitary standards among trading partners to facilitate trade while safeguarding plant health. However, the WTO's primary focus is to promote safe trade. The IPPC provides science-based recommendations for safe trade, but does not have enforcement authority. The WHO and CAC at the FAO have decades of experience in providing guidance for assessing, detecting and managing threats to food safety. For both the CAC and the IPPC, compliance with standards is essentially voluntary unless incorporated into national or regional legal regimes. Thus mechanisms and entities are in place to foster international cooperation to protect biosecurity, two of the primary treaties being deposited at FAO in Rome, and yet FAO itself has reported that inspection and interception systems regularly fail to intercept non-novel and predictable introductions due to a variety of human and material resource shortcomings (FAO, 2007a).

National governments should consider biosecurity in the broadest context to include the potential for intentional introductions (FAO, 2007b; Myerson and Reaser, 2009; Stack et al., 2010). As such, the responsible authorities within each national government should include security experts with the responsibility for identifying threat agents, assessing risks, and developing mitigation and recovery plans for intentional introductions of plant pests and pathogens. By integrating security into the existing plant protection and food safety networks, creating new platforms and networks would be unnecessary and synergies can be achieved. This has already been recognized between human food safety and animal health networks in regard to zoonotic diseases and certain classes of contaminants of food and feed.

Additional funding will be needed to engage countries with emerging market economies. With a few exceptions, they lack the resources necessary to develop and maintain the physical infrastructure, policy framework, and human capital required to support an effective biosecurity system from the sectoral systems that are already strained from traditional threats. One last challenge results from a global food security strategy that is dependent upon emergency food aid. Often, emergency food aid is distributed across large geographic distances and geopolitical boundaries in very short time periods that preclude adequate inspections prior to movement. A possible consequence of such well-intentioned actions is the introduction of pests and pathogens into countries or regions that are already stressed with respect to food production capacity. Although the most likely biosecurity risk from this scenario would be the inadvertent introduction of a pest or pathogen, this scenario also provides a difficult to manage pathway for an intentional introduction.

Our global biosecurity strategy needs more thinking. Much more work is needed to develop phytosanitary strategies that account for the rapid movement of plant-based foods and feeds, plant products, and containers in response to food emergencies should be developed to provide post-shipment monitoring in areas that receive emergency food aid and post detection rapid response capabilities in affected areas. Further thought is needed on adapting food safety practices to be applied at points in the food system chain where hazards could be introduced but are not traditionally present. This will require a more comprehensive biosecurity framework built and sustained on international cooperation.

It may be difficult for some to imagine intentional introductions of pests, pathogens or other agents with the intent to harm plant systems or cause large food safety incidents as a real or significant threat to the public. It is true that there are very few documented cases of intentional introductions of pests or pathogens to harm plant systems, and that most foodborne disease outbreaks have not been traced to intentional introductions but rather to accidental lapses. It is equally true that determining whether an introduction was intentional or accidental is exceedingly difficult. The lack of demonstrated intentional introductions may be due to the inability to identify introductions as intentional, better forensic systems may resolve this dilemma. Meanwhile the absence of evidence is not evidence of absence (Altman and Bland, 1995). It would seem prudent to err on the side of "preparedness with prioritization," recognizing that we cannot protect everything at all times but at the same time enhancing and expanding existing systems to face prioritized novel threats. From a "win-win" perspective, such enhanced systems will provide improved response to the traditional threats even if novel threats never arrive. The most effective way to accomplish these goals is through international cooperation, across sectors and disciplines, with the perspective of global biosecurity showing the way.

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Note: All adopted international standards for phytosanitary measures (ISPMs) should be checked against latest versions and are available at www.ippc.int.