RECIEL
Review of European Community & International Environmental Law

RECIEL 19 (2) 2010. ISSN 0962 8797

The International Legal Framework for Biosecurity and the Challenges Ahead

Opi Outhwaite

Effective biosecurity is an important requisite for the conservation of biodiversity. Preventing the introduction and spread of invasive species including pests, diseases and other organisms through biosecurity measures is important, not only for food security and agricultural health, but also links directly with the prevention of biodiversity loss. Although several international instruments are relevant in this regard, legal analysis of biosecurity at both the international and national levels remains limited. In light of the far-reaching implications of biosecurity failures, there is an urgent need to recognize the nature of biosecurity and to understand how effective biosecurity frameworks can be developed. The present article seeks to contribute to this gap, first, by highlighting the nature of biosecurity as a regulatory concept; second, by providing an overview of some of the key international legal provisions and standards applicable to biosecurity; and, finally, by discussing some of the challenges which arise for the application of an international framework to biosecurity and the adoption of domestic biosecurity frameworks, particularly in the context of developing countries.

BIOSECURITY: MEETING THE CHALLENGES FOR FOOD SAFETY, ANIMAL AND PLANT HEALTH AND BIODIVERSITY CONSERVATION

Transport, trade and travel have always carried with them the risk of introducing unwanted pests, weeds and diseases, from one area to another. In the current climate in which these processes are highly globalized, the risks have increased. 'Traditional' risks – the possibility of introducing a plant pest which might damage a particular crop, for instance – have been joined by others, including the introduction into an area of invasive alien species which threaten biodiversity. Not only does the increased volume of trade and the frequency and distance over which people and commodities move increase the possibility of such introductions, but their truly global nature has opened the door to a greater range of risks and risk pathways. The variety and range of transport and packaging methods adopted, as well as the range and quantity of goods themselves increases the number of pathways by which pests (for instance) may enter an area. Technological developments also present potential risks. Genetically modified crops may, for example, have weediness potential and may act as environmental pests or have other impacts on biodiversity. Importantly, it is increasingly recognized that these risks do not occur in convenient sectoral regulatory spaces. The risks associated with zoonoses, for instance, may be relevant to animal health from the perspective of food production and wildlife conservation, as well as to food safety and human health.

In the context of biodiversity specifically, the introduction of invasive alien species (IAS) is now widely recognized as a serious threat and as one of the most significant threats to biodiversity, after habitat loss.[1] IAS include not only large animals such as mammals and reptiles but also weeds, insects, fungi, diseases, parasites and other pathogens. IAS may be introduced intentionally – for example in the case of ornamental plants, such as rhododendrons, which subsequently become established in the wild – or they may be introduced accidentally – for example in the case of zebra mussels which have spread through the movement of ships (as 'hitchhikers' on the ships' hull and in ballast water).[2] The vectors for such introductions are wide ranging and include, for instance, natural packaging materials (such as wooden crates and bamboo), ballast water, vehicles and vessels, fresh food produce, movement of live animals and the sale of live plants through nurseries.[3] Legal and management responses may therefore seek to minimize the risk of IAS entering a particular area (pre-entry controls), to control the

[1] See, e.g., IUCN, *Invasive Species* (IUCN, undated), available at <http://www.iucn.org/about/union/secretariat/offices/iucnmed/iucn_med_programme/species/invasive_species/>; and Convention on Biological Diversity, *Invasive Alien Species* (CBD, undated), available at <http://www.cbd.int/invasive>.

[2] R.P. Keller and D.M. Lodge, 'Prevention: Designing and Implementing National Policy and Management Programs to Reduce the Risks from Invasive Species', in C. Perrings *et al*. (eds), *Bioinvasions and Globalization* (Oxford University Press, 2010), 220, at 220–222 and 228.

[3] These are termed 'plants for planting' within the international standards framework. See International Plant Protection Convention, International Standards for Phytosanitary Measures, *Glossary of Phytosanitary Terms*, ISPM No 5 (IPPC, 2010). The international standards framework for plant health is discussed in greater detail below.

movement and spread of species after they have entered an area, or to eradicate the species after its arrival and establishment (post-entry controls). Jay *et al*. summarize several examples that highlight the direct impacts of IAS on biodiversity loss and environmental damage (in the context of biosecurity):

> Examples abound of the sometimes catastrophic consequences for native biological diversity of invasions by exotic species. American chestnut blight (*Cryphonec-tria parasitica*), introduced into North America from Asia in the late 1890s, spread through 91 million hectares of hardwood forest in eastern USA and caused the virtual extinction of the American chestnut within its natural range . . . the fungus that causes Dutch elm disease (*Ophiostoma ulmi*), thought to have originated in eastern Asia and introduced to Europe in the early 1900s and subsequently to North America, has almost eliminated elms from their natural range. The catastrophic spread of rabbits in the drylands of Australia is a classic example of the detrimental impacts of biological invasion by a mammal . . . More recently, the introduction of Leidy's comb jellyfish (*Mnemiopsis leidyi*) into the Black Sea in 1982 has brought about the collapse of the Black Sea fisheries.[4]

The impacts of climate change and the continued loss of biodiversity may themselves act as drivers for the further spread of IAS and of diseases and pests, which in turn would increase the threat of these to biodiversity, and to human health and food security. A recent accidental introduction in the UK has been the Oak Processionary Moth, which is believed to be becoming more widely distributed as a result of climate change.[5] Increased temperatures will affect the range of diseases, for instance, and changes to ecosystems resulting from biodiversity loss may result in the potential for more species to be categorized as IAS.[6]

Managing these risks is consequently recognized as a serious priority at the domestic, regional and international levels. It is in this context that biosecurity has the potential to play an important role through the more effective and efficient regulation and management of risk.

Traditionally, the regulation of risks in terms of border and movement controls and related regulation has been on a sectoral basis, usually managing plant health, animal health, food safety and environmental protection separately, and assuming separate responses to agriculture and the environment. There are clear limitations to this approach. Sectoral regulation assumes that risks abide by convenient regulatory divisions. It is increasingly understood that this is not the case. Horan *et al*. note, for instance, that livestock epizootics pose a threat not only to agriculture, but also to wildlife resources including endangered species.[7] Bovine tuberculosis is one example of a disease affecting domesticated, agricultural and wild animals (and posing a risk, albeit limited, to human health).[8] IAS are often conceived as an environmental issue but regulation solely on this basis is also too limited to enable adequate management of the risks to the environment, food safety and security and other issues within the remit of biosecurity. As indicated above, the pathways for IAS are diverse and the impacts may be relevant to health and food security as well as biodiversity loss. The Oak Processionary Moth, for instance, is an IAS which poses risks to plant, animal and human health. The UK Forestry Commission states 'This pest has caused serious defoliation and occasional mortality of oak trees on the continent and the hairs of the larvae, which are easily detached and blown on the wind, contain a toxin known to have an impact on human and animal health ranging from severe skin irritation to respiratory problems'.[9] Similarly, focusing too narrowly on the risks of IAS limits the opportunity to address risks associated with species, pests and diseases, which do not fall within the definition of IAS. Adopting regulation within a more systematic framework should provide a more effective risk response in this context.

The demands on quarantine, inspection, surveillance and other services, both within a country or area and at border points, are often subject to increasing demands based on the increased range of pathways and opportunities for risk to arise. The popularity of importing live

[4] M. Jay *et al*., 'Biosecurity, a Policy Dilemma for New Zealand', 20 *Land Use Policy* (2003), 121, at 122.

[5] See, e.g., Forest Research, *Tree Pest Advisory Note; Oak Processionary Moth* (Forest Research, undated), available at <http://www.forestry.gov.uk/fr/infd-5zabpx>. See also S. Denman and J. Webber, 'Oak Declines: New Definitions and New Episodes in Britain', 10:4 *Quarterly Journal of Forestry* (2009), 285; and R. Beckmann *et al*., *Nuisance Insects and Climate Change* (DEFRA, March 2009).

[6] See, e.g., F. Meyerson *et al*., 'Biosecurity from the Ecologist's Perspective: Developing a More Comprehensive Approach', 12:2–4 *International Journal of Risk Assessment and Management* (2009), 147, at 149–154; and, more generally, J. Houghton, *Global Warming: The Complete Briefing* (Cambridge University Press, 2009), chapter 7; and O.E. Sala *et al*. (eds), *Biodiversity Change and Human Health: From Ecosystem Services to Spread of Disease* (Island Press, 2009).

[7] R.D. Horan *et al*., 'Biological Pollution Prevention Strategies Under Ignorance: The Case of Invasive Species', 84:5 *American Journal of Agricultural Economics* (2002), 47. See also P.E. Hulme *et al*., 'Grasping at the Routes of Biological Invasions: A Framework for Integrating Pathways into Policy', 45 *Journal of Applied Ecology* (2008), 403.

[8] See World Organization for Animal Health (OIE), Global Conference on Wildlife: Animal Health and Biodiversity – Preparing for the Future (OIE, undated), available at <http://www.oie.int/eng/A_WILDCONF/Intro.htm>. The conference will be held in Paris, France, 23–25 February 2011.

[9] UK Forestry Commission, The Plant Health (Forestry) (Amendment) Order 2009 (undated), available at <http://www.forestry.gov.uk/forestry/infd-5azlca>; and GB Non-Native Species Secretariat, *Frequently Asked Questions* (GB Non-Native Species Secretariat, undated), available at <https://secure.fera.defra.gov.uk/nonnativespecies/index.cfm?sectionid=25>.

trees to create 'instant' gardens or landscapes, for example, brings with it a significant burden for the inspection of large specimens, which are often accompanied with substantial quantities of soil, both of which may harbour pests. The Oak Processionary Moth, for instance, is believed to have been introduced on semi-mature oak trees to be used for landscaping.[10] In the context of the increased burden which relevant agencies and inspectorates may be under, sectoral regulation also has obvious limitations in terms of costs and efficiency. Since there can be significant sectoral overlap in the impact and corresponding regulation of a particular risk, a sectoral approach poses the risks of, on the one hand, wasted resources through overlapping and doubling-up of efforts and recurrent costs and, conversely, of gaps in regulation and management, on the other.[11] Similarly, demands for notification and reporting within the international standards framework (discussed below) may also be more efficiently implemented within a biosecurity framework, rather than on a sectoral basis.

As an integrated strategy, biosecurity seeks to provide a more efficient and effective response to risks arising from increasingly globalized trade and transport, as well as new and emerging risks such as those associated with the development of novel technologies and the challenges arising from global climate change.[12] Broadly, biosecurity aims to analyse and manage biological risks associated with food, agriculture and the environment in a coordinated or integrated manner and includes the policy and regulatory frameworks to achieve this.[13] An immediate difficulty with this still emerging concept is that the specific applications and aims of biosecurity frameworks may vary (i.e. at the domestic level). Nevertheless, biosecurity, as a concept, seeks to minimize and manage the risks associated with the entry and establishment of pests, diseases, pathogens and species in the broader context of human, animal and plant health and life. Consequently, biosecurity is sometimes used to describe both an integrated approach and the attainment of its objectives ('achieving biosecurity'). Adopting the overarching concept of 'biosecurity' potentially allows for more effective regulation and decision making by placing controls within a context of harmonized and coordinated decision making and of the objectives of biosecurity as a whole, rather than in response to a single specific threat and on an *ad-hoc* basis.

Early discussions of biosecurity focused particularly on health, agriculture and (indirectly) international trade. The United Nations Food and Agriculture Organization (FAO) has played a key role in the development of the biosecurity agenda and, in 2001, provided the following definition of the term:

> Biosecurity is composed of three sectors, namely food safety, plant health and life, and animal life and health. These sectors include food production in relation to food safety, 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 safe management of invasive alien species and genotypes.[14]

Since this description was formulated, biosecurity has expanded with respect to both scope and relevance so that it reflects even further the nature of the risks that are faced. The environmental dimensions of biosecurity in particular have gained much wider recognition. Commenting on the position of New Zealand (which, along with Australia, has continued to lead in terms of national legal and policy frameworks for biosecurity) Jay *et al*. note that 'from an earlier biosecurity focus on economically significant pests, weeds and diseases, there has developed a wider concern with threats from bioinvasives for native plants, animals and ecosystems'.[15] The FAO has updated its definition of the term to place much greater emphasis on these aspects of biosecurity and also now expressly recognizes biosecurity as an issue within its work programme on biodiversity and agriculture, reflecting the interconnectedness of these concepts.[16] The FAO also now views biosecurity as 'one of the most pressing issues facing developed, developing and transition countries'.[17]

Both by expressly addressing the issue and by incorporating generally pre- and post-entry measures for the movement of commodities, species and other biosecurity risks, IAS clearly fall within the scope of biosecurity. Biosecurity measures provide an important defence against biodiversity loss in relation to the introduction of IAS but are also broader in scope, including other pests, diseases and pathogens which may have negative impacts but which are not classified as IAS. Measures applied to endemic diseases may be equally important from a biosecurity perspective as those

[10] See UK Forestry Commission, ibid.
[11] FAO Committee on Agriculture, Biosecurity in Food and Agriculture, Seventeenth Session, Rome, 31 March–4 April, Item 9 of the Provisional Agenda (COAG/2003/9, 2003).
[12] See, e.g., R.W. Suthurst, 'The Vulnerability of Animal and Human Health to Parasites under Global Change', 31 *International Journal for Parasitology* (2001), 933.
[13] See, e.g., M.J.W. Cock, *Biosecurity and Forests: An Introduction with Particular Emphasis on Forest Pests* (FAO, 2003).
[14] FAO, Committee on Agriculture, Biosecurity in Food and Agriculture, Item 8 of the Provisional Agenda, Sixteenth Session, Rome, 26–30 March (COAG/01/8, 2001).
[15] See M. Jay *et al*., n. 4 above, at 127.
[16] See FAO, *Biodiversity; Socio-Economic [Issues]* (FAO, undated), available at <http://www.fao.org/biodiversity/socio-economic/en/>.
[17] The FAO Biosecurity Toolkit (discussed below) expressly recognises environmental protection as a component of biosecurity. See FAO, *FAO Biosecurity Toolkit* (FAO, 2007), particularly at 3 and 9–13.

applied to exotic diseases.[18] The use of beneficial insects and other methods of pest control is another area in which biodiversity and biosecurity are linked.[19] Biosecurity is also relevant to biodiversity protection, not only in the obvious sense of protecting one (domestic) species from another (IAS), as, for example, in the much discussed case of red and grey squirrels in the UK, but in less obvious ways through impacts which IAS may have on local habitats and the maintenance of ecosystems and ecosystem services. For instance, the introduction of a particular plant pest might negatively affect native plants and this can have a consequent impact on the insects which visit that plant. If the number of insects declined, for example, this in turn would affect other species such as the plants and birds which rely on those insects for pollination services or as a food source. Discussing the importance of achieving effective biosecurity in the Antarctic region, Hughes notes that:

> invasions by non-indigenous species present one of the greatest threats to global biodiversity . . . causing substantial disruption of communities and, sometimes, local extinction of individual species, which, in turn, affect ecosystem structure and function.[20]

It is also important to remember that discussion of biodiversity loss should not be confined to wildlife. Loss of crop biodiversity and consequent impacts on agricultural production has potentially devastating implications for the economy, food security, and for broader social considerations such as employment. The sectors are not separate, from the point of view of IAS and biosecurity, as illustrated by the Convention on Biological Diversity's (CBD) example of the European bumble bee:

> The European bumble bee was introduced to Tasmania by ships and aircraft from Europe. It competes for nectar with native bees and birds, may disrupt the pollination of native plants and facilitates the spread of some weeds in [the] agricultural field.[21]

It can quickly be seen that the potential impact of biosecurity failures is far reaching, extending to and linking environmental protection, economic development and social issues.[22]

It is worth emphasizing that biosecurity is not simply a conservation tool but is an integrated strategy addressing food safety and aspects of human, animal and plant life and health in a range of contexts, which include IAS and biodiversity loss. Biosecurity measures accordingly are not necessarily presented as environmental measures – they may be taken in response to specific plant or animal health objectives, for example, but in any event are likely to play a role in conservation, whether directly or indirectly. This is the basis on which the discussion below proceeds.

Science and technology have played a strong role in answering the call for effective biosecurity, examining the possible pathways and vectors which would allow these unwanted introductions and investigating and developing approaches to pest and disease surveillance, pest management and food safety controls designed to prevent outbreaks and to control and minimize their impact where they occur.[23] As an approach to risk management, however, biosecurity relies also upon up-to-date and effective legal and regulatory frameworks.

Without effective legal measures associated with the entry into and movement within a country, or area, of articles which may constitute a biosecurity risk and associated regulatory powers for, for instance, the conduct of inspections, movement controls, or orders for quarantine, treatment or destruction of articles, the work of scientific risk analysis can have only a limited impact.[24] However, since biosecurity risks arise largely in the context of increased movement of goods and persons, particularly with respect to international trade, difficulties associated with such controls can soon be identified (see below). In order to improve the effectiveness of biosecurity frameworks, these challenges must be understood and addressed. Like many issues, the consequences of failures in biosecurity could be most significant for developing countries. This is reflected in

[18] J.K. Waage and J.D. Mumford, 'Agricultural Biosecurity', 363 *Philosophical Transactions of the Royal Society* (2008), 863.

[19] See FAO Committee on Agriculture, n. 11 above.

[20] K.A. Hughes and P. Convey, 'The Protection of Antarctic Terrestrial Ecosystems from Inter- and Intra-Continental Transfer of Non-Indigenous Species by Human Activities: A Review of Current Systems and Practices', 20 *Global Environmental Change* (2010), 96, at 96.

[21] See CBD, *National and Thematic Reports* (CBD, undated), available at <http://www.cbd.int/invasive/national-reports.shtml>. See also P.E. Hulme *et al*., n. 7 above.

[22] See, e.g., FAO, *Towards a Food-Secure Asia and Pacific Regional Strategic Framework for Asia and the Pacific*, 2nd edn (FAO of the UN Regional Office for Asia and the Pacific, 2004); G.B Allard *et al*., 'Global Information on Outbreaks and Impact of Major Forest Insect Pests and Diseases', XII *World Forestry Congress* (2003); A. Thompson *et al*., 'Parasites and Biosecurity – the Example of Australia', 19:9 *Trends in Parasitology* (2003), 410; D.B. Morfitt, 'Potential Economic Implications for Regional Tourism of a Foot and Mouth Disease Outbreak in North Queensland', 11:3 *Tourism Economics* (2005), 411; and (discussing the impact of diseases in connection with climate change) United Nations Environment Programme, *Climate Change and Marine Diseases: The Socio-Economic Impact* (UNEP, undated), available at<http://www.unepwcmc.org/oneocean/pdf/Epublication_V3_23092009.pdf>.

[23] This is usually based on the progressive responses of prevention, eradication, or control; see Department for Environment, Food and Rural Affairs (DEFRA), *Ensuring the UK's Food Security in a Changing World*, DEFRA Discussion Paper (July 2008), at 21; and Regulation (EC) No 999/2001, Rules for the Prevention, Control and Eradication of Certain Transmissible Spongiform Encephalopathies, [2001] OJ L147/1.

[24] In addition, risk analysis can only go so far; unpredicted developments are and will remain a problem. In these instances, responsive measures must be adopted.

developments in biosecurity law research (to the limited extent that they have occurred), principally through the 2006 FAO-Norway Programme Cooperation Agreement (PCA) to work on food security and poverty reduction, policy assistance and capacity building in low-income developing countries which included a range of activities in biosecurity.[25] Although overviews such as that set out by FAO-Norway provide a helpful summary of international law related to biosecurity, what is still lacking is an holistic analysis of this framework that directly addresses the particular challenges that it poses to biosecurity regulation, and the implications of these provisions and challenges, particularly for developing countries. The following parts of this article seek to contribute to this identified gap.

THE INTERNATIONAL LEGAL FRAMEWORK FOR BIOSECURITY

States may wish to adopt biosecurity frameworks and measures in order to prevent biodiversity loss and protect natural resources and to maintain health standards and take advantage of trade opportunities. A number of international agreements include provisions which are relevant to biosecurity and, consequently, shape the way that the concept can be adopted and implemented at the domestic level. Following the definitions of biosecurity described in the first section, the international framework for biosecurity includes those agreements and instruments which relate to plant and animal health, food safety, IAS, GMOs and novel technologies, and human health so far as they relate to the management of risks from pests and diseases and to the environment, health and agriculture in the context that has been outlined. These agreements fall mainly into two categories:

1. agreements introduced by the World Trade Organization (WTO Agreements), which together pursue the WTO's objectives of liberalizing trade, and related international standards;
2. multilateral environmental agreements (MEAs), which have the goal of environmental conservation generally, or of specific goals relating to environmental protection, or the protection of plant, animal (and human) health.

AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

International trade is both one of the most significant challenges for biosecurity (because of the risks arising from increased movement of goods) and one of its key outcomes (because achieving a high level of biosecurity facilitates international trade – see discussion of international standards below). The Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement)[26] is the international agreement most directly applicable to biosecurity and was introduced specifically to regulate the application of measures related to plant, animal and human health.[27]

Article 1.1 confirms that the SPS Agreement applies to all such measures, which may, directly or indirectly, affect international trade, while Article 2.1 states that 'Members have the right to take sanitary or phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement'. Clearly these provisions place restrictions on the adoption of legal controls for biosecurity but, in light of the benefits perceived by WTO members of a liberalized trading system, are not particularly controversial since the regulation of risks to life and health are only restricted where that regulation may constitute an unjustified barrier to trade. The general requirements for harmonization and equivalence (under Articles 3 and 4, respectively) are deemed to increase further market access objectives through the equitable use and application of SPS measures.

[25] See K.M. Leresche *et al.*, *Evaluation of the FAO-Norway Programme Cooperation Agreement (PCA) 2005–2007, Final Evaluation Report* (Norwegian Agency for Development Cooperation, August 2008).

[26] World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (Marrakesh, 15 April 1994). The definition of an SPS measure is provided in Annex A: '*Sanitary or phytosanitary measure* – Any measure applied: (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests'. Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety'.

[27] Although the rules of the General Agreement on Tariffs and Trade 1994 (GATT) permitted national measures 'necessary to protect human, animal or plant health or life', or relating to the conservation of exhaustible natural resources, where such measures did not create unjustified trade barriers (Article XX), the SPS Agreement addressed the possibility that measures which were ostensibly for the purpose of protecting health and life might be used to disguise protectionist measures and could therefore be a powerful barrier to free trade under the multilateral trading system: General Agreement on Tariffs and Trade (Marrakesh 15 April 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, the Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations.

The requirements related to the extent to and circumstances under which SPS measures can be adopted have proved more controversial. Article 2.2 states that:

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

Article 5 provides further information on how this will be determined, providing that the required 'assessment and determination of the appropriate level of sanitary or phytosanitary protection' must be appropriate to the circumstances (Article 5.1) and shall take into account, *inter alia*, 'available scientific evidence'. Importantly, Article 5.7 provides that, in cases in which available scientific information is insufficient:

> . . . a member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary and phytosanitary measures applied by other members. In such circumstances, members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

As can be seen, these rules go further than simply requiring a non-discriminatory approach. The SPS Agreement requires that relevant measures are 'necessary' and are based on risk assessment with due account given to scientific evidence.[28] Consequently, the SPS Agreement has far-reaching effects on the choices that can be made with respect to the regulation and management of identified risks.[29]

AGREEMENT ON TECHNICAL BARRIERS TO TRADE

The Agreement on Technical Barriers to Trade (the TBT Agreement) aims to ensure that all 'like' products are treated equally and that no 'technical regulation' is used to create an unnecessary trade barrier.[30] Where pursuing a 'legitimate objective' – which includes the protection of human health or safety, animal or plant health, and environmental protection[31] – measures must create the minimum restrictions to trade possible.[32]

It is important to note that the provisions of the TBT Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the SPS Agreement.[33] Nevertheless, the provisions of the TBT Agreement have an important impact on regulation in this area since they apply to some other forms of health and environmental protection. WTO members may wish to impose certain standards on products or processes in order to meet domestic economic, environmental or health objectives. The use of standards can however impact on trade:

> They can facilitate exchange by clearly defining product characteristics and improving compatibility and usability. They also advance domestic social goals like public health by establishing minimum standards or prescribing safety requirements. Finally, they can be used as hidden trade barriers, as protectionism in disguise.[34]

Of particular relevance to biosecurity is the extent to which the TBT Agreement allows countries to treat products differently in pursuing national health and environmental objectives. The TBT Agreement applies to measures concerning the process and production methods related to the characteristics of a product.[35] This area of the TBT Agreement has caused much discussion but there is still little clarity as to how the provisions apply to certain measures. The Centre for International Development states that:

> nations disagree, for example, over the extent to which the TBT Agreement allows nations to differentiate between identical products that were produced in different ways. Can a country treat products differently because the production methods used have different environmental impacts?[36]

To put this in the present context, can a country treat products differently because they entail or result in different biosecurity risks? In such situations, the

[28] The term 'risk analysis' refers to the overall regulatory process, comprising risk identification, risk assessment, risk management and (debatably) risk communication. 'Risk assessment' refers to the technical and scientific processes used to evaluate the probable impacts of the subject of the assessment. See IPPC, ISPM No 11: Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms (IPPC, 2004).

[29] See nn. 107–116 below with respect to the application of these articles and their relationship with MEA provisions.

[30] A discussion of the complex subject of 'like' products is beyond the scope of this article but see, e.g., I.E. Grant and W.A. Kerr, 'Genetically Modified Organisms and Trade Rules: Identifying Important Challenges for the WTO', 26:1 *The World Economy* (2003), 29; G. Winter, 'The GATT and Environmental Protection: Problems of Construction', 15:2 *Journal of Environmental Law* (2003), 113.

[31] Article 2.2 expressly confirms that these are recognized as 'legitimate objectives'. See I. Carreno, 'TBT and Agriculture: Some Examples', in B. O'Conner, *Agriculture in WTO Law* (Cameron May, 2005), 319.

[32] World Trade Organization Agreement on Technical Barriers to Trade (Marrakesh, 15 April 1994). See Annex 1 for terms and definitions.

[33] Ibid., Article 1.5.

[34] Center for International Development at Harvard University, *Sanitary and Phytosanitary Measures and Technical Barriers to Trade Summary* (Center for International Development at Harvard University, 2004), available at <http://www.cid.harvard.edu/cidtrade/issues/spstbt.html>.

[35] See Agreement on Technical Barriers to Trade, n. 32 above, Annex 1. Process and production methods fall within the definition of 'Technical Regulation'.

[36] See Center for International Development, n. 34 above.

measures adopted by a State might be open to challenge. The TBT Agreement might therefore also have an impact on the adoption of domestic biosecurity measures.[37]

In the brief analysis of the SPS and TBT Agreements above, it can be seen that WTO members are not entirely free to regulate the different areas of biosecurity. Of course, the purpose of these WTO requirements is to ensure that WTO members are able to benefit from a fair and open international trading system and that all members are able to compete on an equitable basis. However, in pursuing these objectives, WTO members must be aware of the potential restrictions that are imposed on the regulation and management of environmental protection and the protection of human, animal and plant health and life.

MULTILATERAL ENVIRONMENTAL AGREEMENTS

MEAs also impose certain obligations on contracting parties that may affect the biosecurity measures that a party could adopt. A large number of MEAs have some degree of relevance to biosecurity. FAO-Norway cites the following non-exhaustive list of 'sectoral instruments' related to biosecurity, which includes several MEAs: the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade;[38] the Convention on Persistent Organic Pollutants;[39] the FAO International Code of Conduct on the Use and Distribution of Pesticides;[40] the Biological and Toxin Weapons Convention;[41] the FAO International Code of Conduct on Responsible Fisheries;[42] the Ramsar Convention on Wetlands;[43] the Protocol to the Antarctic Treaty on Environmental Protection;[44] the Convention on the Conservation of Migratory Species of Wild Animals;[45] the Global Programme of Action for the Protection of the Marine Environment from Land-Based Activities;[46] the United Nations Framework Convention on Climate Change;[47] and the United Nations Convention on the Law of the Sea.[48]

The CBD[49] is discussed in more detail below because it is the most relevant to biosecurity in an overall sense. Measures necessary to achieve a high level of biosecurity will also be impacted by provisions in these various other MEAs that tend to address specific biosecurity issues, such as the use of pesticides and hazardous chemicals (from the perspective of human health and environmental protection) and the control of IAS, often within the context of other objectives such as the protection of particular habitats. The objective of the Ramsar Convention on Wetlands, for instance, is 'the conservation and wise use of all wetlands through local and national actions and international cooperation, as a contribution towards achieving sustainable development throughout the world'.[50] Resolution VIII.18 (invasive species and wetlands) urges parties to take decisive action to address the problem of IAS in wetland ecosystems, including to undertake risk assessments of alien species which may pose a threat to wetlands, cooperation for the prevention, eradication and control of invasive species in shared wetland ecosystems, and to ensure that relevant policies are incorporated into domestic legislation and that work is undertaken closely with national counterpoints of relevant international bodies such as the CBD.

The Cartagena Protocol[51] applies to living modified organisms (LMOs) and requires Advance Informed Agreement for the movement of LMOs intended for release into the environment between exporting and importing States and makes it clear that the precautionary approach should be adopted. The stated objective of the Protocol is:

> to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.[52]

[37] See FAO, n.17 above, at 98.
[38] Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam, 10 September 1998).
[39] Convention on Persistent Organic Pollutants (Stockholm, 22 May 2001).
[40] FAO International Code of Conduct on the Use and Distribution of Pesticides (Rome, November 2002), as revised.
[41] Biological and Toxin Weapons Convention (London, Moscow and Washington, 10 April 1972).
[42] FAO International Code of Conduct on Responsible Fisheries (Rome, 31 October 1995).
[43] Ramsar Convention on Wetlands of International Importance especially as Waterfowl Habitat (Iran, 2 February 1971).
[44] Protocol to the Antarctic Treaty on Environmental Protection (Madrid, 4 October 1991).
[45] Convention on the Conservation of Migratory Species of Wild Animals (Bonn, 23 June 1979).
[46] Global Programme of Action for the Protection of the Marine Environment from Land-Based Activities (Washington, 3 November 1995).
[47] United Nations Framework Convention on Climate Change (New York, 9 May 1992).
[48] United Nations Convention on the Law of the Sea (Montego Bay, 10 December 1982). See also Biosecurity Resources from Norway PCA, *Legal Frameworks for Biosecurity* (FAO, undated), available at <http://km.fao.org/biosecwiki/index.php/Biosecurity_Resources_from_Norway_PCA#Legal_frameworks_for_Biosecurity>.
[49] Convention on Biological Diversity (Rio de Janeiro, 5 June 1992).
[50] See Ramsar Convention on Wetlands, *The Ramsar Convention and its Mission* (Ramsar Secretariat, undated), available at <http://www.ramsar.org/cda/en/ramsar-about-mission/main/ramsar/1-36-53_4000_0__>.
[51] Cartagena Protocol on Biosafety (Montreal, 29 January 2000).
[52] Ibid., Article 1.

This is clearly relevant to the adoption of biosecurity measures to minimize risks associated with the entry, establishment or spread of LMOs.

CONVENTION ON BIOLOGICAL DIVERSITY

The CBD provides a further clear link between biosecurity generally and biodiversity. The goals of the CBD, particularly those concerned with the conservation of biodiversity and sustainable use of the components of biodiversity, are directly relevant to the principles of biosecurity. The CBD applies not only to general conservation measures but also to the specific components of biodiversity and to processes and activities, regardless of where the effects occur.[53] In addition, Article 8 sets out obligations for *in situ* conservation including:

- the establishment or maintenance of means to regulate and manage the risks associated with LMOs and 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' (paragraph g);
- preventing the introduction of, controlling or eradicating, alien species 'which threaten ecosystems, habitats or species' (paragraph h); and
- develop and/or maintain legislation and regulatory provisions for the protection of threatened species and populations (paragraph k).

Obligations imposed by the CBD will therefore have some impact on the way in which the CBD's contracting parties can regulate and manage biosecurity frameworks at the national level.[54] In implementing the CBD, contracting parties must consequently consider the wider context in which their policies may affect biodiversity. This requirement may have important consequences in terms of biosecurity regulation by shaping the way in which certain risks should be managed and the factors that must be taken into account when certain biosecurity decisions are taken.

The CBD also expressly recognizes the importance of biosecurity in preserving biodiversity through the control of IAS[55] and has provided specific guidance to national, regional and international institutions on IAS.[56] Principle 1 of the Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threaten Ecosystems, Habitats or Species specifically requires the adoption of the precautionary approach, providing that '[t]he precautionary approach should also be applied when considering eradication, containment and control measures in relation to alien species that have become established'.[57] For the purpose of preventing the entry of IAS, parties should implement appropriate border controls and quarantine measures (Principle 7). Other requirements are set out for authorization, identification of pathways and appropriate regulatory measures for both intentional and unintentional introductions in domestic frameworks. Decision VIII/27 emphasizes the need for consistency in action to address IAS, including at the international level.[58] The Decision addresses issues such as, *inter alia*, conveyances (such as vessels, floating timber, equipment and machinery, household goods, packaging and containers, waste materials, air transport vessels and tourist vessels), aquaculture/mariculture, ballast water, marine biofouling and civil air transport as pathways for IAS, and encourages further communication, harmonization and action among the relevant international bodies and agreements.

Whereas the WTO agreements discussed above are concerned primarily with the restriction of measures relating to biosecurity, that is, they prevent measures which might form an unjustified barrier to trade, it can be seen that the objectives of the CBD and the guidance in respect of IAS specifically are pursued by a distinctly different approach. The primary function of the CBD in achieving its goals is to impose on the contracting parties positive obligations for the conservation of biological diversity and its components. In pursuing these obligations, contracting parties must take into account the way in which risks to human, plant and animal

[53] See CBD, n. 49 above, Article 4.

[54] A number of other relevant obligations exist in the convention: Article 6 requires contracting parties to develop national strategies and programmes for the conservation and sustainable use of biological diversity and to integrate, '*as far as possible and appropriate*' the conservation and sustainable use of biological diversity into relevant cross-sectoral plans and programmes; Article 7 provides obligations concerning identification and monitoring; Article 9 provides obligations for *ex-situ* conservation and Article 10 for the sustainable use of components of biological diversity.

[55] See, e.g., *Strategic Plan, National Reporting and Operations of the Convention: Multi-Year Programme of Work for the Conference of the Parties up to 2010: Note by the Executive Secretary* (UNEP/CBD/COP/6/5/Add.2/Rev.1, 6 March 2002), paras 5(c) and 21

[56] Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threaten Ecosystems, Habitats or Species, found in CBD Decision VI/23, Alien Species that Threaten Ecosystems, Habitats or Species, Annex I, printed in *Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, The Hague 7–19 April 2002* (UNEP/CBD/COP/6/20, 27 May 2002), Annex I.

[57] Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threaten Ecosystems, Habitats or Species, ibid., Principle 1.

[58] CBD Decision VIII/27, Alien Species that Threaten Ecosystems, Habitats or Species (Article 8 (h)): Further Consideration of Gaps and Inconsistencies in the International Regulatory Framework, printed in *Report of the Conference of the Parties to the Convention on Biological Diversity, Eighth Meeting, Curitiba, Brazil, 20–31 March 2006* (UNEP/CBD/COP/8/31, 15 June 2006,) Annex I.

health are regulated with regard to meeting the objectives of the CBD. As has been seen, the control of IAS in particular is an important area of regulation for the purpose of biosecurity (though it is only one area). Domestic governments must therefore be mindful of these requirements when developing and implementing legal frameworks for biosecurity.[59]

INTERNATIONAL STANDARDS FOR BIOSECURITY MEASURES

International agreements relevant to biosecurity have been reviewed because they provide the overarching principles and obligations that must inform the development of national biosecurity frameworks. There are, however, international standard-setting agencies that directly influence the content and approach of national biosecurity frameworks and which are widely recognized as the most relevant bodies with respect to biosecurity.[60] These bodies are: for plant health, the International Plant Protection Convention (IPPC),[61] through the IPPC Secretariat; for animal health, the World Animal Health Organization (OIE); and for food safety, the Codex Alimentarius Commission (Codex).

These standards and texts are significant also because they are recognized by the WTO as internationally acceptable standards for WTO members.[62] Indeed, under the relevant WTO agreements, members must base national measures on these international standards or otherwise justify them on the basis of risk analysis, as described.[63] This is important because it means that national measures based on the adoption of, and compliance with, these standards will be recognized as based on risk analysis and as being compliant with WTO General Agreement on Tariffs and Trade (GATT) principles.[64] These three bodies identify their roles as protecting the level of health in their respective areas, whilst ensuring that sanitary or phytosanitary measures (as applicable) are not used as unjustified trade barriers.[65] In the case of the IPPC, the scope of work is not limited to traded commodities only, but includes also the protection of wild flora.[66]

The IPPC framework is based on the associated convention, the present version of which was revised in 1997, and on the more specific International Standards for Phytosanitary Measures (ISPMs).[67] In the case of the OIE, the main documents are the Terrestrial Animal Health Code (TAHC),[68] which sets out principles and standards generally as well as for specific diseases, and the accompanying *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*[69] (the *Terrestrial Manual*), which provides relevant standards, and the equivalent documents for aquatic animal health. The Codex Alimentarius is a collection of standards, codes of practice, guidelines and other recommendations setting out both more general principles, for example the Codex General Principles of Food Hygiene,[70] and specific standards, for example maximum residue limits (MRLs) or commodity-based standards.[71] Draft standards may be submitted by Member States and are usually prepared by the respective commissions. These should then be adopted by the members. Although there is a vast range of standards, many of which are extremely specific, there are also a number of principles and standards developed by all of three of the institutions which are relevant to the development of national biosecurity frameworks. The measures most relevant for the present purposes and which provide common characteristics of national biosecurity frameworks are summarized below.

COMPETENT AUTHORITIES

One important feature is the need for a competent authority or authorities, with responsibility for plant

[59] A related issue is that of 'perverse incentives' defined by the CBD as 'a policy or practice that encourages, either directly or indirectly, resource uses leading to the degradation of biological diversity'; see CBD, *Economics, Trade and Incentives: Information on Perverse Incentives* (CBD, undated), available at <http://www.biodiv.org/programmes/socio-eco/incentives/perverse.asp>.

[60] See FAO Committee on Agriculture Discussion Paper, n. 11 above.

[61] UN FAO International Plant Protection Convention (Rome, 6 December 1951). Revised text was approved at the FAO Conference Twenty-Ninth Session (Rome, 7–18 November 1997); entered into force 2 October 2005.

[62] See IPPC, *Guide to the International Plant Protection Convention* (IPPC, 2000), available at <https://www.ippc.int/servlet/BinaryDownloaderServlet/26227_Guide2002_English.pdf?filename=1063264041495_IppcGuide02eb.pdf&refID=26227>; FAO, *Understanding the Codex Alimentarius* (WHO-FAO, 2006), available at <http://www.who.int/foodsafety/publications/codex/understanding_codex/en/index.html>; OIE, *What is the OIE?* (OIE, undated), available at <http://www.oie.int/eng/oie/en_oie.htm>; B. Vallat, 'Role of the International Organization for Animal Health (Office des Epizooties: OIE) in the Control of Foot and Mouth Disease', 2:5–6 *Comparative Immunology, Microbiology and Infectious Diseases* (2002), 383; and R. Black, 'The Legal Basis for Control of Imports of Animal and Plant Material into the United Kingdom', 5 *Environmental Law Review* (2003), 179, at 181.

[63] For further discussion, see R. Black, ibid.

[64] See SPS Agreement, n. 26 above, Article 3. See also J. McMahon, 'Food Safety and the SPS Agreement', in B. O'Conner, n. 31 above.

[65] See, e.g., IPPC, n. 62 above; FAO, n. 62 above; and OIE n. 62 above.

[66] See IPPC, ibid., at 3; and IPPC, *Summary of the IPPC* (IPPC, 2001), available at <https://www.ippc.int/servlet/CDSServlet?status=ND0zNzk1OSY2PWVuJjMzPSomMzc9a29z.>.

[67] See IPPC, International Standards for Phytosanitary Measures (ISPMs) (IPPC, undated), available at <https://www.ippc.int/index.php?id=13399&L=0> for the complete list of standards.

[68] OIE, The Terrestrial Animal Health Code (TAHC), 18th edn (OIE, 2009).

[69] OIE, *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (OIE, 2009).

[70] Codex Alimentarius, Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4 (2003)).

[71] See FAO, n. 62 above.

health, animal health, food safety, or a combination of these. This is necessary to ensure that there is a contact point, which can act as a link between the Member State and the relevant institution.[72] In all cases, the official contact point is usually the relevant regulatory authority in the Member State (for example the IPPC requires a National Plant Protection Organization (NPPO) which may be the Plant Health Authority). Similarly, there must be a relevant authority or authorities in-country, which is/are able to administer and enforce the relevant national measures. The IPPC 1997 (Article IV) sets out the responsibilities of NPPOs which include:

- the issuance of phytosanitary certificates;
- surveillance with the object of reporting the occurrence, outbreak and spread of pests, and controlling those pests;
- inspection of consignments of plants and plant products and regulated articles with the object of preventing the introduction and/or spread of pests;
- disinfection or disinfestation of consignments to meet phytosanitary requirements;
- protection of endangered areas and the designation, maintenance and surveillance of pest free areas and areas of low pest prevalence;
- the conduct of pest risk analysis to ensure phytosanitary security of consignments after certification, prior to export; and
- training and development of staff.

These responsibilities, with respect to import systems, are reiterated in ISPM 20.[73] Similar activities are identified as necessary components of control systems in the relevant Codex and OIE texts. In all cases, the relevant standards recognize the need for the competent authorities to employ or designate personnel (i.e. an inspectorate) who have been appropriately authorized and who have the appropriate skills and/or qualifications to discharge their responsibilities (such as carrying out inspections, issuing certificates and taking action in cases of non-compliance).[74]

'REGULATED ARTICLES'

For the purpose of maintaining adequate levels of protection, it may be necessary to regulate a wide range of articles, not only plant and animal species and food products. IAS, pests, diseases and pathogens may, as noted in the first section, enter a country or area via a wide range of pathways. Vallat notes, for example, that there are risks for the entry of foot and mouth disease associated not only with animals and their meat products, but also with straw and fodder.[75] These, in turn, may represent higher or lower levels of risk and for this reason there may be a need to distinguish between different types of regulated article. The IPPC 1997 recognizes two types of regulated pest: quarantine pests (pests of economic importance which are not yet present or are not widely distributed and which are being officially controlled); and regulated non-quarantine pests (pests whose presence in plants for planting has an unacceptable economic impact and which are regulated within the importing territory).[76] In order to prevent the entry of regulated pests, a range of articles may be subject to phytosanitary restrictions and measures. These include any plants, plant products, storage places, packaging, container, conveyance, soil and any other organism, object or material capable of harbouring or spreading pests deemed to require phytosanitary measures.[77] According to ISPM 20, all articles may be regulated for quarantine pests but, in the case of regulated non-quarantine pests, regulations may only be applied with respect to plants for planting.[78]

The OIE provides for the control of 'listed diseases', which means any disease included in the list of transmissible diseases agreed by the OIE Commission (and set out in Chapter 2 of the TAHC), and 'notifiable diseases', which are those listed by the Veterinary Administration (the governmental authority having responsibility for animal health, for the purpose of the OIE) that, as soon as detected or suspected, must be brought to the attention of the Veterinary Authority, in accordance with national regulations.[79] 'Regulated articles' are not provided for but definitions are given for various commodities that may be disease vectors such as meat and meat products, milk and milk

[72] This is provided for in the Codex Alimentarius Commission Procedural Manual, 19th edn (Codex Alimentarius, 2010), Section VI. (The nineteenth edition was prepared following the Thirty-Second Session of the Codex Alimentarius Commission (Rome, 29 June–4 July 2009).) The TAHC, n. 68 above, provides that communication between the OIE and the Member State should be through the Veterinary Administration of that State (Article 1.1.1.1). The IPPC, n. 61 above, requires contracting parties to make provision for a National Plant Protection Organization (NPPO) (Article IV(1)).

[73] IPPC, Guidelines for a Phytosanitary Import Regulatory System, ISPM No 20 (IPPC, 2004).

[74] See TAHC, n. 68 above, Articles 1.2.1.3 and 1.2.2.3; ISPM No 20, ibid., Articles 4.6 and 5.2; Codex Alimentarius Commission, Guidelines for Food Import Control Systems (CAC/GL 47-2003), Sections 3.6–3.8, 3.10 and 4.41–4.43 and Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997), Sections 6. 19, 6.23 and 6.43. Both documents are found in Codex Alimentarius Commission, *Food Import and Export Inspection and Certification Systems, Combined Texts*, 3rd edn (Codex Alimentarius, 2007).

[75] See B. Vallat, n. 62 above, at 389.

[76] See IPPC, n. 61 above, Article II (Use of Terms). Definitions are also set out in IPPC, *Glossary of Phytosanitary Terms*, ISPM No 5 (IPPC, 2005).

[77] See IPPC, n. 61 above, Article 2 (Use of Terms), 'Regulated article'.

[78] See ISPM No 20, n. 73 above, Article 4.1.

[79] The TAHC, n. 68 above, glossary, provides the following definition: 'Veterinary Authority means the Governmental Authority of an OIE Member, comprising veterinarians, other professionals and paraprofessionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code in the whole territory'.

products. A similar approach is taken by Codex, which provides definitions such as 'food', 'contaminant' and 'pesticide residue'.[80] In the case of food safety, food products and their components including ingredients and artificial additives as well as contaminants may be the subject of regulation.

CERTIFICATION AND DOCUMENTATION

The operation of phytosanitary and sanitary measures, such as those described below, will often be based on the need for documentary evidence of compliance, for instance affirmation that required procedures or conditions have been met. Exporting authorities may be required to issue certificates confirming conformity of commodities with import requirements. In recognition of the potential difficulties arising from the use of such certificates by different Member States, and the potential for these to be used as unjustified trade restrictions, the key international institutions have provided standards concerning the use of certificates. In the case of the OIE, Model International Veterinary Certificates are provided in Part 4 of the TAHC. Principles for the drawing up of certificates are set out in Article 1.2.2.2. The equivalent for plant health is the International Phytosanitary Certificate, models of which are provided in the IPPC 1997.[81] Principles for the preparation and use of these certificates are provided in ISPM 12.[82] For food safety, Codex provides Guidelines for Design, Production, Issuance and Use of Generic Official Certificates, which provide detailed guidance on the design and use of official and officially recognized certificates.[83]

IMPORT CONTROLS

One of the most important ways of maintaining desired levels of biodiversity, plant and animal health and food safety is to prevent the entry of relevant species, pests and diseases, etc.[84] This point was highlighted recently by Piero Genovesi, Chair of the International Union for the Conservation of Nature (IUCN)/SSC Invasive Species Specialist Group:

> [M]anagement [i.e. control and eradication] of invasive species is not the only tool we have in our hands. The experiences gathered in several areas of the world have also shown that stringent biosecurity policies can prevent a large part of invasions, protecting not only the environment, but also economies. For example, if Australia remains free of the varroa mite – a pest that has caused the collapse of the honey industry in many countries of the world – this is likely due to the strict biosecurity policy adopted in that country. A large proportion of the economic losses to the European economy caused by invasive species could be prevented with stricter import regulations.[85]

Similarly, Black comments that the foot and mouth disease outbreak in the UK in 2001 'demonstrated in the most dramatic way for a generation the extent to which the health of livestock is threatened by harmful agents introduced from abroad in the form of pests such as insects and ticks and diseases'.[86]

Import-based measures may prohibit the entry of an article (including the commodities or species themselves, the materials which accompany them and the means by which they are moved into a country) or may allow its entry subject to conditions.[87] For example, importing countries may require fresh food commodities to have been inspected prior to export to ensure that they are free from specified pests, or have been subject to testing or analyses confirming freedom from certain contaminants or compliance with specified levels for these. Imported commodities and articles may be subject to documentation checks, inspections and requirements for quarantine or treatment.[88] As has been seen, controls may be applied to a variety of articles. The use of wood packaging material, for instance, has been a major pathway for the introduction of IAS (and plant pests, for IPPC purposes) including insects which may feed off untreated wood including bark, if it is present, and remain concealed here. In such cases, identification through inspection may be difficult. Wood packaging is consequently an important target for regulation; importing States may seek to ensure that wood has been processed or treated in a way which will prevent such introductions. In this specific case, the IPPC has developed a standard for the regulation of wood packaging, requiring that it be treated in one of the ways specified and be made of debarked wood.[89]

[80] See Codex Alimentarius Commission, n. 72, above, Definitions for the Purposes of the Codex Alimentarius.
[81] See IPPC, n. 61 above, Annex.
[82] IPPC, Guidelines for Phytosanitary Certificates, ISPM No 12 (IPPC, 2001).
[83] Codex Alimentarius Commission, Guidelines for Design, Production, Issuance and Use of Generic Official Certificates (previously Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates) (CAC/GL38, 2001), printed in Codex Alimentarius Commission, n. 74 above.
[84] Preventing entry is recognized as the best form of control; see M. Doelle, 'The Quiet Invasion: Legal and Policy Responses to Aquatic Invasive Species in North America', 18:2 *The International Journal of Marine and Coastal Law* (2003), 261.
[85] P. Genovesi, 'Editorial', 29 *Aliens: The Invasive Species Bulletin* (2010), 1.
[86] See R. Black, n. 62 above, at 179.
[87] See TAHC, n. 68 above, Article 1.4.4.3; IPPC, n. 61 above, Article VII(1); and ISPM No 20, n. 73 above, Article 4.2.
[88] See ISPM No 20, ibid.; IPPC, ibid., Article VII; TAHC, ibid., Articles 1.4.4.3 and 1.4.4.1; and Codex Alimentarius Commission, Principles for Food Import and Export Inspection and Certification (CAC/GL20, 1995), printed in Codex Alimentarius Commission, n. 74 above.
[89] IPPC, Regulation of Wood Packaging Material in International Trade, ISPM No 15 (IPPC, 2009), as revised.

In compliance with the requirements of the SPS Agreement and general GATT/WTO principles, a common feature of standards is the requirement that measures, including those applicable to imports, are both necessary (for the protection of health) and technically justified. Measures should be no more stringent than those applied within the importing country.[90] Under the TAHC and the IPPC 1997, measures should not be applied to pests or pathogens which are not subject to official control within the country.

Following these point-of-entry controls, the international texts provide that procedures should be in place for the decision making and action that will be taken in the event of non-compliance. This may arise in cases in which certification is invalid or incomplete or where other import conditions are not met. The OIE provides that, in cases of non-compliance with certification, the importing authority should notify the exporting authority immediately in order to provide an opportunity for correction.[91] Codex and the IPPC also require members to provide timely advice to exporters regarding the basis of decisions with respect to compliance.[92] In cases in which the certificate cannot be corrected, or in which a regulated pest or disease is confirmed, there are a number of options available to the importing authorities. The commodity may be refused entry and may be returned to the exporter under certain conditions. Alternatively, the commodity may be destroyed in circumstances in which it is too dangerous or impractical to re-export it. In other cases, the commodity may be permitted entry under certain further conditions.[93] Based on risk assessment, import controls may also be applied to goods in transit through a country.[94]

EXPORT CONTROLS

To ensure that access to markets is maintained and to prevent exporters incurring the costs associated with non-compliance with import controls (such action will normally be taken at the exporter's expense), States may need to implement measures related to exports. The competent authorities of exporting WTO Member States may need to undertake inspections, audits, sampling and analyses to verify that consignments conform to the requirements of the importing country. In this context, it is important that export systems and measures are reliable and provide valid assurances.

The TAHC provides that countries should only authorize exportation from their territory of animals that meet the requirements of the importing country (Article 1.4.1.1). Biological tests or vaccinations should be carried out in accordance with the TAHC and the *Terrestrial Manual* (which provides a number of specific standards for these). Similarly, authorization for meat or products of animal origin intended for human consumption should only be granted if the products are fit for human consumption and are accompanied by an International Veterinary Certificate.

ISPM 7 sets out an export certification system to produce valid and credible phytosanitary certificates.[95] This includes provision that the NPPO should have sole authority for the issuance and control of phytosanitary certificates, that staff with appropriate expertise should be available and that the model certificates should be used.[96] The Codex Principles for Food Import and Export Inspection and Certification also provide that countries which certify the export of food should take steps to ensure confidence in official inspection systems.[97]

INTERNAL CONTROLS

As well as controls applicable at points of entry, internal measures are also important in maintaining levels of health and protection within a given country or area (for instance by ensuring continuation of point-of-entry controls or restricting the spread of a pest or disease). Such measures include the collection of data which can form the basis of risk analysis and sanitary or phytosanitary measures.[98] Measures imposed internally may also provide the basis for compliance with export requirements.

One such measure, related both to import controls and to internal controls, is the establishment and maintenance of pest free areas (PFAs) (as defined under the IPPC) or their equivalents (zones or compartments under the TAHC, Article 1.3.5). The TAHC provides that, given the difficulty of establishing and maintaining disease-free status for an entire country, there may be benefits for member countries in establishing and

[90] See TAHC, n. 68 above, Article 1.2.1.2; IPPC, n. 61 above, Article VI(1); Codex Alimentarius Commission, n. 74 above, Sections 3.2–3.6.
[91] See TAHC, ibid., Article 1.4.4.3.
[92] See Codex Alimentarius Commission, n. 88 above, Section 3.15; IPPC, n. 61 above, Article VII(2)(f); and ISPM No 20, n. 73 above, Article 5.1.6.3.
[93] See TAHC, ibid., Article 1.4.4.3; IPPC, ibid., Article VII(1); ISPM No 20, ibid., Article 5.1.6.1; Codex Alimentarius Commission, Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL26, 1997), Section 6.35; Codex Alimentarius Commission, n. 74 above, Section 4.27.
[94] See ISPM No 20, ibid., Article 4.3; IPPC, ibid., Article VII(4); and TAHC, ibid., Article 1.4.4.4.
[95] IPPC, Export Certification System, ISPM No 7 (IPPC, 1997).
[96] See also IPPC, n. 61 above, Article V.
[97] See Codex Alimentarius Commission, n. 88 above, Section 3.19.
[98] Accurate monitoring of this nature was one of the important biosecurity objectives in surveillance measures for foot and mouth disease in *R (Swami Suryanda) v. Welsh Ministers*, [2007] EWCA Civ 893.

maintaining a sub-population with a different animal health status within national boundaries. The TAHC provides principles and procedures for defining a zone or compartment. ISPM 1 (Principle 13) provides that countries shall recognize the status of areas in which a specific pest does not occur.[99] ISPM 4 sets out the requirements for the establishment of PFAs.[100] The establishment and use of PFAs is therefore an important biosecurity mechanism within the context of international trade, since they provide an opportunity for export without the need for the application of additional measures (when certain conditions are met). The absence of the specific pest must be officially maintained (ISPM 4, Article 1.2.1). This again is consistent with the requirements for non-discrimination in international trade. ISPM 4 provides that phytosanitary measures can be used to maintain PFAs: for example (i) regulatory action such as adding pests to lists of quarantine pests, specification of import requirements, and restricting the movement of certain products within the country; (ii) routine monitoring; and (iii) extension advice to producers.[101] Similar principles will apply to the maintenance of disease-free zones.

Surveillance is an important internal measure. The TAHC notes that information collected through surveillance is essential to support the risk-analysis process and to provide a clear rationale for the application of sanitary measures.[102] These aims are also identified, with respect to plant health, in ISPM 20. The TAHC sets out specific surveillance methods and provides that surveillance can be based on (i) structured population surveys (sampling at point of slaughter or random surveys); or (ii) structured non-random activities such as reporting and notification requirements, ante-mortem and post-mortem inspections, and field observations.[103] The IPPC 1997 requires its contracting parties to conduct surveillance for pests and ISPM 6 describes the components of survey and monitoring systems.[104] The use of systems of registration and licensing, and of inspection and testing, are similarly important internal measures for diagnosing and monitoring the presence of species and pests that are being controlled. Internal measures should play an important role in minimizing the impact of introductions by enabling early detection and response and also provide baseline information on the presence and establishment of IAS and other regulated risks.

[99] IPPC, Principles of Plant Quarantine as related to International Trade, ISPM No 1 (IPPC, 1995).
[100] IPPC, Requirements for the Establishment of Pest Free Areas, ISPM No 4 (IPPC, 1996).
[101] See ibid., Article 1.2.2.
[102] See TAHC, n. 68 above, Appendix 3.8.1.
[103] Ibid., Annex, 3.8.1.
[104] IPPC, Guidelines for Surveillance, ISPM No 6 (IPPC, 1997).

THE CHALLENGES AHEAD

It has been argued above that biosecurity is a potentially necessary and effective regulatory response to the developing risks to health, security and biodiversity including those posed by the movement of diseases, pests, and IAS, and by related technological developments such as those in agricultural biotechnology. There are a number of international instruments, spanning both hard and soft law, whose obligations, requirements and guidelines will affect the shape of domestic biosecurity choices, as well as cooperation between States in this field. However, this framework leaves unaddressed a number of challenges, both conceptual and practical, which could undermine biosecurity efforts.

LACK OF COHERENCE AND CLARITY IN THE INTERNATIONAL FRAMEWORK

Although there are a number of relevant international instruments they do not collectively form a robust and cohesive framework or one that sufficiently reflects the potential of biosecurity regulation.

Most obviously, the instruments do not employ the term 'biosecurity' and there is no agreed definition or application of the term for the purpose of implementation of these agreements. Where the term is used it is not used consistently in different contexts. The FAO, as noted, adopts a relatively broad definition of the term and this is mirrored in the institutional adoption of biosecurity in New Zealand, Australia and other jurisdictions. The CBD sometimes appears to use biosecurity as synonymous with IAS or the control of IAS, which is arguably an overly restrictive approach.[105] In the majority of instruments the term is not used or defined at all.

Similarly, the concept of biosecurity is generally not reflected in the international framework. Whilst international instruments set out guidelines and obligations for specific concerns, they do not facilitate the coordinated and integrated approach which is a key benefit of biosecurity. Internal divisions within the international framework remain, reflecting traditional divisions – environment from agriculture, animal health from food safety, and so on.[106] The IAS agenda is principally aligned with environmental objectives and strategies, whilst the more traditional focus on pests and diseases prevails in the agricultural context. Although the trade-focused SPS Agreement applies to many biosecurity

[105] See, e.g., CBD, *Report of the Sixth Meeting of the Conference of the Parties*, n. 56 above, Item IV(24): Strategic Plan, National Reporting and Operations of the Convention.
[106] See J.K. Waage and J.D. Mumford, n. 18 above.

measures, it also reflects traditional sectoral classifications in terms of plant and animal health and food safety. Further, it does not make express reference to regulatory areas that are more difficult to classify, including IAS and the regulation of GMOs. MEAs also do not specifically incorporate biosecurity. Although many address IAS, this is only one aspect of biosecurity, albeit an important one.

Without adopting biosecurity as a concept, it may be difficult to make progress on achieving the objectives of biosecurity. The standards produced by the OIE, IPPC and Codex, for instance, often apply different terms to their respective equivalent concepts. This is an obstacle to the integration and harmonization of such measures, which could be addressed if such terms were placed in an overarching biosecurity framework.

Leaving aside the difficulties arising from the fact that the term biosecurity is not included in any of the relevant international legal instruments, it may be observed that the international legal framework is problematic due to potential conflicts in the principles and rules which are applicable. The difficulties associated with the status of WTO agreements and MEAs has been addressed widely and need not be rehearsed in detail here.[107] However, these difficulties do have implications for biosecurity. Frequently, action taken to achieve biosecurity objectives will engage both WTO and MEA provisions. For example, several agreements outline guidance or requirements to minimize the risks posed by IAS but, in instances where these involve trade restrictions, the provisions of the SPS Agreement will also be relevant if the IAS are characterized as, say, a pest (other WTO provisions may be relevant where the measures have more general environmental objectives).

One of the key issues for biosecurity is the extent to which measures are influenced by science and/or precaution in their response to identified risks. The SPS Agreement requires measures to be based on 'sound science' and to be no more trade restrictive than necessary. This approach is reflected in the relevant international (WTO recognized) standards that apply risk assessment in line with the WTO concept of 'sound science' to identify and list pests and diseases which will be subject to control. This approach does not directly address broader objectives of minimizing the risk of entry overall.[108] Article 5.7 of the SPS Agreement appears to provide some scope for the application of precaution but in fact this provision has been one of the most controversial in terms of determining the extent to which the precautionary principle can be applied. In its document *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures*, the WTO states that 'the SPS Agreement clearly permits the precautionary taking of measures when a government considers that sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process' and that the SPS Agreement does not 'require countries to give priority to trade over food safety or animal and plant health'.[109] However, in a subsequent publication, the WTO applied a more qualified interpretation and considered that '[Members] can *to some extent* apply the "precautionary principle", a kind of "safety first" approach to deal with scientific uncertainty'.[110] WTO jurisprudence and academic analysis has suggested that the opportunity for precaution-based decision making is significantly limited under the WTO provisions. Conversely, many MEAs clearly advocate or require a precautionary approach. The lack of clarity over the application of Article 5.7 and related provisions and the apparent conflict between WTO and MEA provisions has been addressed extensively in the literature,[111] but it remains unresolved despite consideration by the WTO Appellate Body in cases such as the *Beef Hormones* case, *Australian Salmon*,[112] *Japanese*

[107] For a summary, see M. Lee, *Environmental Protection, Law and Policy* (Cambridge University Press, 2007), at 270–316; and see H. Nordström and S. Vaughan, *WTO Special Studies 4: Trade and Environment* (WTO, 1999); United Nations Environment Programme and the International Institute for Sustainable Development, *Trade and Environment: A Handbook* (IISD, 2000); and R. Schwartz, 'Trade Measures Pursuant to Multilateral Environmental Agreements – Developments from Singapore to Seattle', 9:1 *RECIEL* (2000), 63.

[108] C.M. Brasier, 'The Biosecurity Threat to the UK and Global Environment from International Trade in Plants', 57 *Plant Pathology* (2008), 792.

[109] WTO, *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures* (WTO, 1998), available at <http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm>.

[110] WTO, *Understanding the WTO – the GATT Years: From Havana to Marrakesh* (WTO, undated), available at <http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm> (emphasis added).

[111] See, e.g., M. Stilwell and R. Tarasofsky, *Towards Coherent Environmental and Economic Governance: Legal and Practical Approaches to MEA-WTO Linkages*, WWF–CIEL Discussion Paper (Worldwide Fund for Nature, 2001); P. Hardstaff, *The Precautionary Principle, Trade and the WTO*, Discussion Paper for the European Commission Consultation on Trade and Sustainable Development (Royal Society for the Protection of Birds (RSPB), 2000); S. Shaw and R. Schwartz, *Trading Precaution: The Precautionary Principle and the WTO* (United Nations University-Institute for Advanced Studies, 2005); and N. Huei-Chih, 'Can Article 5.7 of the WTO SPS Agreement be a Model for the Precautionary Principle?', 4:4 *SCRIPTed* (2007), 367. See further C. Weiss, 'Scientific Uncertainty and Science Based Precaution', 3:2 *International Environmental Agreements* (2003), 137; G. Goh, 'Precaution, Science and Sovereignty: Protecting Life and Health Under the WTO Agreements', 6:3 *The Journal of World Intellectual Property* (2005), 441; A. Trouwborst, 'The Precautionary Principle in General International Law: Combating the Babylonian Confusion', 16:2 *RECIEL* (2007), 185; WTO, n. 109 above; and WTO, n. 110 above.

[112] WTO AB 6 November 1998, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R.

Varietals,[113] *Japan – Apples*[114] and *EC – Biotech*[115] and inclusion in Section 6 of the Doha Ministerial Declaration.[116]

As our understanding of the interrelatedness of biosecurity issues in environmental, agricultural, social and trade and economic terms develops, it is questionable how much longer this lack of clarity or the more limited scope for decision making apparently permitted by the WTO can be accommodated. Developments such as the Millennium Ecosystem Assessment have highlighted both the broader economic implications of biodiversity loss (and therefore of biosecurity) and the need for preventative rather than responsive strategies.[117] Increased recognition of the environmental dimensions of biosecurity, along with the parallel developments with respect to the ecosystems approach and ecosystems services, raise concerns about the adequacy of existing concepts in international standards, such as how the concept of 'economic importance' is to be evaluated for the purpose of regulation under the IPPC, and introduces the question of whether economic importance is an appropriate measure at all for responses to biosecurity risks.[118]

Whilst the potentially conflicting approaches required under WTO agreements and MEAs are widely recognized, it is equally clear that this lack of coherence remains a barrier to the adoption of effective biosecurity frameworks at both the international and domestic levels. On the one hand, the importance of WTO compliance continues to be a key priority, and biosecurity choices must therefore be justified accordingly. On the other hand, the greater need for, for instance, plant health controls on horticultural commodities because of the potential impact on native forests, and the clear mandate for precaution in the CBD, suggest that more trade-restrictive measures might be appropriate and desirable.

The difficulties with balancing and reconciling differing commitments arises in the case of standards as well as their broader agreements. Whilst developments such as the International Maritime Organization (IMO) Convention on Ballast Waters (discussed below) might potentially play an important role in minimizing the entry of IAS, currently only those standards developed by the IPPC, OIE and Codex are 'approved' by the WTO and these are frequently identified as the most significant for biosecurity. The IUCN provides a clear summary of the problem with respect to IAS:

> The WTO rules and trade-related controls on alien species introductions is still unclear to many governments. There are currently three organizations recognized under the WTO-SPS Agreement as international standard-setting organizations in the areas of food safety, animal and plant health. From the perspective of biodiversity conservation, however, these do not directly or explicitly address biodiversity or impacts of invasive species on the natural environment as much as may be desired under the Convention on Biological Diversity. There is currently no SPS-recognized source of international standards regarding general environmental and biodiversity protection against alien invasive species, except the IPPC as it relates to plant pests.
>
> There is growing recognition that harmonization and improved linkages need to be promoted between the parallel regimes dealing with phytosanitary, biosafety and biodiversity issues. The expertise vested in different institutions at international and national levels needs to be retained and strengthened, whilst building a basis for systematic consultation and cooperation with regard to new or broader standards and criteria.[119]

One of the more commonly discussed approaches for addressing both the conflict between international agreements and the implementation burden associated with them is harmonization, an approach which is advocated by the FAO.[120] The FAO has observed that a common approach would allow for a more integrated strategy to basic biosecurity issues, while still enabling sectoral application and notes that the international harmonization of regulatory biosecurity measures, including the analysis of gaps and potential overlaps within and across international agreements, 'will provide the basic legal framework for a common approach to Biosecurity'.[121] One output of the FAO-Norway Programme Cooperation Agreement was a

[113] WTO AB 22 February 1999, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R.
[114] WTO AB 26 November 2003, *Japan – Measures Affecting the Importation of Apples*, WT/DS/245/R.
[115] WTO DS 29 September 2006, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291 (*EC – Biotech*)
[116] See J. McMahon, n. 64 above, at 218–219, with respect to uncertainty surrounding the precautionary approach in the case of the Cartagena Protocol. See also C.E. Foster, 'Precaution, Scientific Development and Scientific Uncertainty under the WTO Agreement on Sanitary and Phytosanitary Measures', 18:1 *RECIEL* (2009), 50.
[117] See Millennium Ecosystem Assessment Board, *Living Beyond Our Means: Natural Assets and Human Well-Being* (Millennium Ecosystem Assessment Board, March 2005).
[118] On the ecosystems approach, see, e.g., CBD, *Ecosystem Approach* (CBD, undated), available at <http://www.cbd.int/ecosystem/>; and see A. Trouwborst, 'The Precautionary Principle and the Ecosystem Approach in International Law: Differences, Similarities and Linkages', 18:1 *RECIEL* (2009), 26.
[119] C. Shine *et al.*, *A Guide to Designing Legal and Institutional Frameworks on Alien Invasive Species*, Environmental Policy and Law Paper No 40, (IUCN – Environmental Law Centre, 2000), at 30.
[120] See FAO, n. 14 above. The need for harmonization in the more general trade and environment field is discussed by M. Stilwell and R. Tarasofsky, n. 111 above, and by Toepfer who notes that the international coordination process can aid the '*implementation of the conventions at the national level*'; see K. Toepfer, 'Implementing Multilateral Environmental Agreements at the National Level: The Search for Synergies and Complementaries', in National Councils for Sustainable Development, *NCSD Report 2001: Integrating Global Environmental Conventions at National and Local Levels* (The Councils, 2002).
[121] See FAO, n. 14 above.

legislative study entitled 'Development of an Analytical Tool to Assess National Biosecurity Legislation'.[122] This reviews the international legal framework for biosecurity but fails to respond to the relevant tensions in a meaningful way, as does the FAO Biosecurity Toolkit, which 'provides practical guidance and support to develop and implement national biosecurity frameworks at the country level'.[123]

This is not to suggest that there have not been positive developments. Some steps have been taken which reflect the concept of biosecurity to a limited extent.

In 2004, the IPPC, CBD and the Cartagena Protocol on Biosafety executed a memorandum of cooperation which 'formalized the cooperation between the three conventions and initiated the development of a joint work plan as well as regular tripartite meetings which address IAS issues as they affect plant health in the broadest sense' (i.e. including environmental impacts).[124] Additionally, the IPPC has explicitly recognized the importance of addressing the agricultural and environmental risks together.[125] With respect to food safety, Codex produces 'horizontal' standards – such as those applicable to processes and labelling – rather than only 'vertical' standards, applicable to a specific food product.[126]

Concerning IAS, some measures which focus on the pathways by which pathogens may enter an area have been developed. For instance, the International Maritime Organization's International Convention for the Control and Management of Ships Ballast Water and Sediments (the IMO Convention) aims to 'prevent, minimize and ultimately eliminate the transfer of harmful aquatic organisms and pathogens through the control and management of ships' ballast water and sediments'.[127] The convention sets out specific measures and activities to be taken, provides that parties may take more stringent measures than those set out, where 'consistent with international law', and includes technical guidance and standards. But the convention is not yet in force. The IPPC introduced ISPM 15 on 'Import regulations for packaging containers made from solid wood' based on the need to reduce the risk of introduction or spread of quarantine pests associated with wood packaging material. Such measures provide more specific standards and guidelines for IAS than those set out in many of the broader agreements. This approach provides some opportunity for more proactive and strategic efforts to tackle risks prior to entry, although these measures are similarly fragmented in terms of the instruments in which they are situated.

IMPORTANCE OF BIOSECURITY FOR DEVELOPING COUNTRIES

From a policy perspective, biosecurity is seen as a useful concept for developing countries since, by taking an integrated and strategic approach to the regulation and management of risks within its sphere, biosecurity allows for more efficient use of resources and technical capacity, which may be limited.[128] Whilst biosecurity failures can have serious consequences in any area, the need to maintain effective biosecurity frameworks may be of particular importance for developing countries, to the extent that the FAO recognizes biosecurity as a priority area for interdisciplinary action.[129] With respect to biodiversity, many species and habitats are found only in specific regions of the world and developing countries are of course home to some of these, including many which are seriously threatened with extinction. Importantly, biosecurity is also strongly linked with food security, making its effective regulation a priority.[130]

The problem of IAS is, as noted, an important component of biosecurity, affecting biodiversity and human, animal and plant health and life and the economy more generally.[131] The need to regulate and to manage the risks related to the introduction of IAS may be particularly important for developing countries because of the potential impact on often fragile ecosystems and economies.[132] The CBD notes some of the problems arising from IAS, stating that:

> Alien Water Weeds . . . are a global problem; African nations alone spend an estimated US$60 million annually

[122] See K.M. Leresche *et al*., n. 25 above. For the outputs of this agreement, see Biosecurity Resources from Norway PCA, n. 48 above.
[123] See FAO, n. 14 above.
[124] C. Shine, 'Invasive Species in an International Context: IPPC, CBD, European Strategy on Invasive Alien Species and Other Legal Instruments', 37:1 *EPPO Bulletin* (2007), 103. See also S. Riley, 'Preventing Transboundary Harm from Invasive Alien Species', 18:2 *RECIEL* (2009), 198.
[125] See IPPC, *What We Do* (IPPC, undated), available at <https://www.ippc.int/ippctypo3_test/index.php?id=1110600&L=0>.
[126] See K.M. Leresche *et al*., n. 25 above.
[127] International Convention for the Control and Management of Ships' Ballast Water and Sediments (London, 13 February 2004), Article 2.1.
[128] See FAO, n. 17 above, at 3.
[129] See FAO, *Multidisciplinary Areas; Biosecurity for Food and Agriculture* (FAO, undated), available at <http://www.fao.org/multidisciplinary/priorities-areas/biosecurity-for-agriculture-and-food-production/en/?>.
[130] See R.N. Strange and R.P. Scott, 'Plant Disease: A Threat to Global Food Security', 43 *Annual Review of Phytopathology* (2005), 83; FAO, n. 14 above; FAO, *Priorities for Asia and Pacific Office* (FAO, undated), available at <http://www.fao.org/world/regional/rap/regional_priorities.asp?id=5>; A. Thompson *et al*., n. 22 above; and B. Rodoni, 'The Role of Plant Biosecurity in Preventing and Controlling Emerging Plant Virus Disease Epidemics', 141 *Virus Research* (2009), 150.
[131] On the management of IAS and biosecurity measures, see R.D. Horan *et al*., n. 7 above.
[132] See IUCN, n. 1 above.

> on their control. International trade has introduced the Asian Tiger Mosquito – which carries dengue fever – to the Americas and Africa, and has spread life-threatening [strains of] bacteria Escherichia coli in meat exports.[133]

The impact of animal diseases can be significant since the impact on both animals for food production and on wildlife can have severe consequences for the economy and also on human health.[134]

A further example consists of the problems that may arise in the context of GMOs. It has been argued that the pressure for harmonization and the development of legal frameworks from both internal and external bodies can lead to the introduction of insufficient regulatory programmes in this field. Mackenzie and Glover note, for example, that:

> demands for speedy progress of Biotechnology research and development have led to *ad hoc* responses which, though may be pragmatic in the short term, may obscure the need for clear and comprehensive regulation based on a thorough appraisal of national needs, priorities and capacity . . . [135]

The failure to plan effectively and to regulate biotechnology measures may have serious effects on human, animal and plant health and life and the environment. However, developing countries face a number of pressures in this area, including limited financial and technical capacity, which may make such planning difficult, in addition to the debates about how GM regulation should interact with food aid.[136]

IMPLEMENTATION BURDEN ASSOCIATED WITH INTERNATIONAL AGREEMENTS AND STANDARDS

In addition to overcoming uncertainties associated with international legal obligations, when developing biosecurity law and regulatory measures at the national level, States also face the implementation burden associated with relevant international instruments, as well as with biosecurity specifically. One issue is that the sheer number of requirements places a burden on implementing States.[137] This burden consists of the numerous practical requirements that accompany the implementation of international obligations and corresponding national requirements covering matters such as implementation, reporting and infrastructural capacity to support these. In turn, these place a burden on the State in terms of administrative and financial resources. For developing countries, least developed countries and transition States in particular, financial and technical capacity may be limited and external issues (to biosecurity) such as corruption, instability and lack of political will can increase difficulties with implementation.[138] The adoption of effective frameworks for biosecurity poses a further burden because of the often highly technical and resource-intensive measures needed to demonstrate compliance with international standards and requirements. As discussed, significant scientific and technological capacity may be needed to assess risks, test for the presence of a particular disease and so on. Adequate levels of inspection, monitoring and surveillance are a necessary ongoing commitment for prevention and control. The treatment of ballast water, in accordance with the IMO Convention, or inspection and analysis of soil, to meet IPPC requirements, for instance, carry substantial requirements in terms of availability of suitably trained or qualified personnel, diagnostic equipment and treatment facilities, and effective communication and response mechanisms including bureaucratic and regulatory responses. The burden on developing countries is great and may exceed their capacity.[139] The need to prioritize may mean that some areas are inadequately regulated, leaving these countries in breach of their international obligations, as well as threatening human, animal and plant life and the environment.

The enforcement and implementation of relevant instruments and requirements poses significant challenges, which may be particularly difficult for developing countries too because they do not take into account the actual conditions and capacity of the implementing country.[140] Despite the inclusion in relevant agreements

[133] CBD, *Alien Species; Introduction* (CBD, undated), available at <http://www.biodiv.org/programmes/cross-cutting/alien/>.
[134] See W.Y. Ayele *et al*., 'Bovine Tuberculosis: An Old Disease but a New Threat to Africa', 8:8 *International Journal of Tuberculosis and Lung Disease* (2004), 924.
[135] R. Mackenzie with D. Glover, 'Harmonization, Diversity and Uncertainty in International Biosafety Regulation', in *Democratizing Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series*, Briefing 6 (Institute of Development Studies, 2003), at 1. See also D. Collier and C. Moitui, 'Africa's Regulatory Approach to Biotechnology in Agriculture: An Opportunity to Seize Socio-Economic Concerns', 17:1 *African Journal of International and Comparative Law* (2009), 29.
[136] For examples of some of the views expressed, see N.E. Borlaug, 'Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry', 124 *Plant Physiology* (2000), 487; and N. Zerbe, 'Feeding the Famine? American Food Aid and the GMO Debate in Southern Africa', 29 *Food Policy* (2004), 593.
[137] See K. Toepfer, n. 120 above.
[138] See M.G. Faure, *Enforcement Issues for Environmental Legislation in Developing Countries*, UNU/INTECH Working Paper No 19 (March 1995).
[139] See K. Toepfer, n. 120 above, at 11; and R. Mackenzie and D. Glover, n. 135 above.
[140] See V. Schillhorn, 'International Trade and Food Safety in Developing Countries', 16:6 *Food Control* (2005), 491. Schillhorn notes that the costs of implementing food safety rules will be particularly difficult for small-scale producers and can exclude these producers and therefore limit rural growth. This is also discussed by A. Sawhney,

of provisions that are designed to improve the position of developing countries in this regard, it has frequently been argued that there is a wide discrepancy between the potential benefits of the agreements and the actual benefits achieved at the national level.[141]

DOMESTIC LEGAL AND REGULATORY CAPACITY

The implementation burden associated with biosecurity may be particularly onerous because it incorporates not only the broad challenges related to implementation of international law and the bringing together of several different sectors, but also a substantial level of specialized legal and scientific capacity.

As demonstrated in the preceding sections, the international standards employ detailed technical requirements and regulatory terms. To ensure that trading partners are satisfied with the legal requirements of a particular country, these terms must be properly used both in primary and secondary legislation. In many countries, however, relevant legislation (for instance the equivalent to a Plant Health Act) may not have been revised for several years. Such legislation is unlikely to reflect current requirements – for instance articles may be regulated outside the scope of IPPC standards. This clearly places the country in question in a weak position with respect to trade (and trade disputes), as well as the management of risk.[142] Updating the legislation, however, requires significant technical legal expertise and resources. Added to the fact that drafting, revision and adoption of legislation, even secondary legislation, is often a very lengthy process, the requirements of biosecurity may not be perceived as sufficiently pressing to warrant high priority except where high profile biosecurity failures have occurred.[143] In terms of national legal and policy developments, Australia and New Zealand have traditionally taken the lead in this respect and continue to do so, expressly recognizing the inter-related nature of biosecurity and biodiversity.[144]

With respect to the technical aspects of implementation, some countries may not have the resources to maintain laboratories to carry out testing and analyses or may lack the infrastructure to maintain border controls and import measures.[145] In implementing measures to prevent the entry of a particular pest, for instance, WTO members must take into account the need for these measures to be based on risk analysis. In order to comply, WTO members may undertake their own risk analysis, for which there will be certain technological and infrastructural needs. Alternatively, they may adopt international standards. In either case, there may be a need to adopt import, export and internal measures, which, in turn, will require further resources to enable administration and enforcement. Weaknesses in this regard again have implications not only in terms of effective risk management but also in terms of trade opportunities. As has been observed, whilst the SPS Agreement, for instance, has assisted in establishing measures which protect health, countries lacking the capacity to carry out effective inspection, quarantine, surveillance, inspection and certification will be at a trade disadvantage.[146]

In any country, the way in which legal and regulatory provision for biosecurity is organized might not be the most efficient, both in terms of minimizing risk and in achieving the best use of resources. In most cases, regulation currently remains sectoral and may therefore result in overlaps and gaps in regulation, conflicting or

'Quality Measures in Food Trade: The Indian Experience', 28:3 *The World Economy* (2005), 329. For a summary of GATT/ WTO provisions aimed at developing countries and least developed countries (LDCs) and discussion of the status of those provisions, see G. Olivares, 'The Case for Giving Effectiveness to GATT/ WTO Rules on Developing Countries and LDCs', 35:3 *Journal of World Trade* (2001), 545. With respect to the SPS Agreement specifically, see J. Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures*: *A Commentary* (Oxford University Press, 2007), chapter 8.

[141] See J. Scott, ibid., chapter 8, part B. On the theory and practice of differential obligations under the CBD, see A. Iles, 'Rethinking Differential Obligations: Equity under the Biodiversity Convention', 16 *Leiden Journal of International Law* (2003), 217. In relation to food safety, see P. Athukorala and S. Jayasuriya, 'Food Safety Issues, Trade and WTO Rules: A Developing Country Perspective', 26:9 *World Economy* (2003), 1395; see also V. Schillhorn, ibid. The need also to consider local conditions for the purposes of implementing environmental legislation is discussed by Michael Faure, who notes that both formal and informal legal procedures, as well as social and political attitudes, may operate differently in developing countries than in 'Western' countries and this will lead to specific considerations for the implementing country. See M.G. Faure, n. 138 above.

[142] See, e.g., W.Y. Ayele *et al*., n. 134 above, with respect to obstacles to the control of bovine TB in Africa.

[143] See S. Riley, 'Invasive Alien Species and the Protection of Biodiversity: The Role of Quarantine Laws in Resolving Inadequacies in the International Legal Regime', 17:3 *Journal of Environmental Law* (2005), 323. In the UK, e.g., the government was criticized for not prioritizing honey bees prior to the decline in their numbers, which was followed by the Healthy Bee Plan, incorporating a biosecurity plan. See Public Accounts Committee, *The Health of Livestock and Honeybees in England*, Thirty-Sixth Report (17 June 2009); DEFRA, *Healthy Bees Protecting and Improving the Health of Honey Bees in England and Wales* (OPSI, March 2009); and National Audit Office, *The Health of Livestock and Honeybees in England* (NAO, March 2009).

[144] See, e.g., Australian Department of Environment, Water, Heritage and the Arts, *Invasive Species, What is Environmental Biosecurity?* (Australian Department of Environment, Water, Heritage and the Arts, undated), available at <http://www.environment.gov.au/biodiversity/invasive/index.html>; New Zealand Ministry of Agriculture and Forestry, *Biosecurity* (New Zealand Ministry of Agriculture and Forestry, undated), available at <http://www.biodiversity.govt.nz/land/nzbs/biosecurity/index.html>.

[145] See, e.g., K. Neumann *et al*., *The Central Asia and Mongolia Bioresources and Biosecurity Network Capacity Development on Access to Genetic Resources, Benefit-Sharing, and Biosafety in Central Asia and Mongolia* (United Nations University Institute of Advanced Studies, 2004).

[146] See FAO, n. 17 above, at 45.

clashing mandates across relevant departments and authorities, and, similarly, inadequate communication and reporting provision.[147]

In response to these issues, the FAO has suggested that there may be a particular need for technical assistance to developing countries in adopting coordinated approaches to biosecurity and for the strengthening of relevant national and regional institutions.[148] The need for technical assistance and capacity building is also recognized by the OIE, the IPPC and Codex and by the CBD. At a meeting of the Committee on Agriculture in 2003, the FAO recognized the 'central importance' of capacity building to assist developing countries in establishing and maintaining effective biosecurity frameworks.[149]

PARTICIPATION IN THE DEVELOPMENT OF INTERNATIONAL RULES AND STANDARDS

All of the relevant international frameworks envisage, and indeed require, that their member countries play a role in the development of international standards and other international measures and agreements. In the field of biosecurity, the international standards set by the OIE, IPPC and Codex form a complex foundation on which national biosecurity efforts are likely to be based. Participation in the development of standards to be applied in the areas of food safety and plant and animal health is therefore seen as essential to ensuring that these standards are appropriate and that the needs of developing countries are addressed alongside the need to maintain international trade access and ensure adequate controls are maintained.

The difficulties with, and the need for, developing country participation at the international level have long been discussed. Mukerji notes that, following the first triennial review of the operation of the TBT Agreement, in 1997, a 'major concern expressed by developing countries was that they were not able to play a full part in the preparation by appropriate international standardizing bodies of international standards'.[150] Mukerji also notes that 'a major challenge facing developing countries in this respect is the need to create the necessary domestic infrastructure to deal with the proliferation of national and international standards and measures'.[151] However, the costs of improving the capacity of developing countries to participate can be considerable.[152]

The weight afforded to certain international standards may also be an issue of concern for some members. McMahon comments that although the WTO AB stated in *EC – Hormones* that it was not the intention of members to vest obligatory force and effect in the standards and guidelines produced by the international bodies, the central role which they play in the SPS Agreement suggests that the effect is otherwise.[153]

CONCLUDING REMARKS

The adoption of biosecurity measures is essential in order to meet a range of challenges, including mitigating the loss of biodiversity, the need for a safe and secure food supply and the prevention of heath risks and spread of diseases. Effective legal and regulatory controls are a necessary aspect of this risk management strategy, yet little analysis and research has been undertaken to provide an understanding of how these controls might be developed and implemented in practice. The above analysis highlights, however, how international agreements and standards will influence national decisions regarding biosecurity. This international framework poses a number of challenges concerning the extent to which they adopt or reflect the concept of biosecurity, the interaction of legal rules and principles more generally, and the practicalities of their implementation. Whilst the need to achieve adequate biosecurity has become more widely recognized, the existing frameworks that will enable the underpinning legal and regulatory provision has not necessarily kept pace. Without a greater degree of clarity and coherence at the international level, there may be difficulties in the long term with the adoption of domestic biosecurity frameworks (for instance where these are perceived to be inconsistent with international commitments) or responses may follow a fragmented and sectoral approach to risk management, which, if not effective,

[147] See M. Doelle, n. 84 above.
[148] See FAO, n. 14, above.
[149] See FAO Committee on Agriculture, n. 11 above. See also K. Neumann *et al*., n. 145 above.
[150] A. Mukerji, 'Developing Countries and the WTO: Issues of Implementation', 34:6 *Journal of World Trade* (2000), 33, at 49.
[151] Ibid., at 50–51. Michalopoulos discusses the limited participation of developing countries in the WTO itself, in terms of representation in Geneva, and also notes that the effectiveness of this participation depends on the ability of developing countries to develop adequate infrastructural capacity. See C. Michalopoulos, 'The Developing Countries in the WTO', 22:1 *The World Economy* (1999), 117. See also R. Blackhurst *et al*., 'Options for Improving Africa's Participation in the WTO', 23:4 *The World Economy* (2000), 491; and A. Sawhney, 'Quality Measures in Food Trade: The Indian Experience', 28:3 *The World Economy* (2005), 329.
[152] G. Mayeda, 'Developing Disharmony? The SPS and TBT Agreements and the Impact of Harmonization on Developing Countries', 7:4 *Journal of International Economic Law* (2004), 737.
[153] See J. McMahon, n. 64 above, at 208.

has the potential to undermine policy and regulatory objectives.

Further work is needed to understand how areas of uncertainty can legitimately be interpreted by implementing parties, to achieve further developments in the international framework and, beyond this, to gain a better understanding of what successful legal frameworks for biosecurity look like and how they can be achieved.

Opi Outhwaite is a Lecturer in Law at the University of Greenwich and was previously AHRC Researcher on Corruption in International Business at the University of Surrey. Prior to this, she was involved in research and consultancy in biosecurity and agricultural health. Her current research interests focus on biosecurity, ecosystem services and legal and regulatory issues in the field of agriculture, trade and the environment.