

# Reforming Biosecurity Legislation in Developing Countries: Increasing Market Access or Maintaining Unequal Terms of Trade?

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*This article explores the challenges faced by developing and transitional countries (For the purposes of this article, Former Soviet Union (FSU) countries now mostly in the Commonwealth of Independent States (CIS), with the exception of the Russian Federation itself, are included in the term 'developing countries'.) in international trade in agricultural goods and other natural resource products in compliance with the normative framework of the World Trade Organisation, and in particular of the Agreement on the Application of Sanitary and Phytosanitary Measures ('SPS Agreement'). It details the legislative and administrative measures, as justified by 'scientific evidence' and 'risk assessment', that a WTO member may take to prevent the importation of unsafe food and animal feed, and pests and disease organisms. As well as considering the policy implications and constraints to relevant legislative reform, the article also draws on the author's experience in biosecurity legislative review and drafting in Africa, Caribbean, Eastern Europe and Central Asia using the umbrella concept of 'biosecurity' to reflect on the challenges facing drafting of legislation consistent with the normative international frameworks for biosecurity. Taken into account is the impact of the SPS Agreement on the terms of food trade imposed on developing countries and the connection between international trade and environmental protection.*

## 1 INTRODUCTION

This article examines the extent to which developing countries have been able to meet the challenges of globalization, and have gained access to markets for their agricultural and natural resource products in richer countries and regional trading

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partners, according to the normative framework of the World Trade Organization's (WTO's) *Agreement on the Application of Sanitary and Phytosanitary Measures* ('SPS Agreement').<sup>1</sup>

Most developing countries including the least developed countries joined WTO in 1995 or within a year or two. Although there has been a rise in antiglobalization sentiment in the west coincident with the growth of populist politics, regrets about WTO membership originating in developing countries themselves are hard to identify, with the causes of inequalities and poor infrastructure not to be blamed automatically on globalization.<sup>2</sup> Also to be taken into account are countries of the FSU (now mostly in the Commonwealth of Independent States, CIS), now mostly members of the WTO.

The SPS Agreement provides the normative framework for regulation of international trade where there is a risk of importing elements potentially harmful to people, animals and plants along with the traded goods or as traded goods – food, live animals and plants and those organs or parts of animals and plants used for breeding and propagation. Primarily the SPS Agreement helps each country to protect itself from importing harmful elements in a manner consistent with trade liberalization. Conversely, it helps WTO members achieve access to markets through satisfying the 'SPS' import requirements of importing countries, such as animal and plant health certificates.<sup>3</sup>

This article is structured according to two main components: Scientific and policy background to biosecurity legislation and reflections from drafting biosecurity legislation – helping to remove barriers for further reform. The starting point will be a definition and explanation of biosecurity, followed by a brief overview of WTO in relation to eliminating or reducing barriers to trade and the key points of the SPS Agreement. This will introduce issues arising from the drafting and adoption of biosecurity legislation in developing countries, these then being tackled in detail under three headings: first, the need for reform of biosecurity legislation in developing countries and barriers to reform; second, environmental protection in the context of international trade relations; third lessons

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<sup>1</sup> The WTO Agreement on the Application of Sanitary and Phytosanitary Measures, [https://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm). 'Sanitary' means human and animal health, 'phytosanitary' means plant health. The term *SPS* as used in this article refers to the concepts of sanitary and phytosanitary controls to protect human, animal and plant life and health and their implementation.

<sup>2</sup> J. Roy, *India and the Anti-Globalization Brigade*, Business Standard (7 Feb. 2017), [http://www.business-standard.com/article/opinion/jayanta-roy-india-and-the-anti-globalisation-brigade-117020601210\\_1.html](http://www.business-standard.com/article/opinion/jayanta-roy-india-and-the-anti-globalisation-brigade-117020601210_1.html); A Lukas, *WTO Report Card III. Globalisation and Developing Countries*, Trade briefing paper No. 10 (2000). Centre for Trade Policy Studies, Cato Institute, <https://www.cato.org/publications/trade-briefing-paper/wto-report-card-iii-globalization-developing-countries>.

<sup>3</sup> Sanitary and phytosanitary measures. WTO, [https://www.wto.org/english/tratop\\_e/sps\\_e/sps\\_e.htm](https://www.wto.org/english/tratop_e/sps_e/sps_e.htm).

drawn from the author's drafting experience that may help reduce barriers to reform.

## 2 SCIENTIFIC AND POLICY BACKGROUND TO BIOSECURITY LEGISLATION

### 2.1 WHAT IS BIOSECURITY?

A definition of Biosecurity has been provided by the United Nations Food and Agriculture Organisation (the FAO):

*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.*<sup>4</sup>

Biosecurity as a concept and strategy has been adopted in the UK and widely in the British Commonwealth<sup>5</sup> with gradual adoption in the EU as well.<sup>6</sup>

Biosecurity frameworks, therefore, encompass border controls and supporting measures for managing and regulating risks to human, animal and plant health and also include aspects of environmental protection. These measures are numerous and many of the issues are cross-cutting such as includes issues of pesticide regulation for the management and regulation of food safety. For this reason, the author's academic offerings have included pesticides regulation in biosecurity.<sup>7</sup> The inclusion of some aspects of environmental protection in biosecurity as an umbrella concept on top of the concept of SPS will be discussed later.

### 2.2 BIOSECURITY AND TRADE – RELEVANCE OF WTO

The extent to which, and type of, national biosecurity measures that can be adopted by a country are now heavily influenced by the rules of the WTO. The WTO agreements to which these consequences could apply are the 'covered

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<sup>4</sup> United Nations Food and Agricultural Organisation (FAO), *Committee of Agriculture, Biosecurity in Food and Agriculture*, Seventeenth Session, Document no. COAG 2003//9 (Rome 31 Mar.–4 Apr. 2003).

<sup>5</sup> When the author began work in 2008 in Rwanda on the Plant Health Protection Act the country had already adopted biosecurity as the underlying concept. He jokingly remarked to colleagues that this made Rwanda the first non-Commonwealth country to do so. The reply was 'we're applying to join the Commonwealth'.

<sup>6</sup> However, the term biosecurity may have a different meaning in other jurisdictions or in other languages. In USA it means 'prevention of bioterrorism'. In French 'biosecrité' means biosafety – biosecurity for GMOs.

<sup>7</sup> O. Outhwaite, R. Black & A. Laycock, *The Pursuit of Grounded Theory in Agricultural and Environmental Regulation: A Suggested Approach to Empirical Legal Study in Biosecurity*, 29(4) L. & Pol'y 493–528 (2007).

agreements' on trade in goods and services, meaning they are covered by the Dispute Settlement Understanding.<sup>8</sup> The potential penalties for an importing country losing a dispute brought to the WTO is in stark contrast to lack of enforcement of the United Nations suite of international conventions

In particular, the SPS Agreement requires Member States to ensure that relevant measures, including laws and regulations related to, for example, quarantine requirements, internal surveillance measures and import requirements, are adopted in a manner that is consistent with the general principles of the General Agreement on Tariffs and Trade (GATT), meaning that the measures must not be protectionist in nature and should be as least trade restrictive as possible.

### 2.3 WTO ELIMINATING BARRIERS TO TRADE

The aim of WTO is to liberalize international trade by removing or minimizing restrictive trade barriers, of which there are two categories as applied to trade in goods: tariff barriers including import taxes and duties, quotas, subsidies and non-tariff barriers.<sup>9</sup> To explain non-tariff barriers in the context of the SPS Agreement as an agreement on trade in goods, it is first necessary to introduce the concept of *non-tariff measures* known as SPS measures with which this agreement deals exclusively. Examples of SPS measures are specific requirements that food meets certain criteria to show it is safe, or that imported meat is free of diseases like foot and mouth disease transmissible to livestock. However, SPS measures include 'all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria'.<sup>10</sup> A non-tariff measure may be viewed as a *non-tariff barrier* by a trading partner denied access to an importing country's markets because it is alleged to be unduly or unfairly restrictive of trade, or discriminatory. The *SPS Committee* was set up to allow WTO members to air their grievances about alleged non-tariff barriers in a semi-formal forum to try to avoid the issue resulting in a full blown dispute under the Dispute Settlement Understanding.<sup>11</sup>

Administrative measures, such as procedures to get an import permit and customs clearance are included as non-tariff measures. WTO is now particularly concerned with *trade facilitation*<sup>12</sup> to speed up the passage of goods through customs

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<sup>8</sup> Introduction to the WTO dispute settlement system, WTO, [https://www.wto.org/english/tratop\\_e/dispu\\_e/disp\\_settlement\\_cbt\\_e/c1s5p1\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c1s5p1_e.htm).

<sup>9</sup> In relation to the current debate about the United Kingdom's withdrawal from the European Union (Brexit), it should be noted that WTO does not abolish tariffs but sets standard levels. Free-trade agreements like the European Union's Customs Union market may abolish tariffs between its members.

<sup>10</sup> Fn. 1. Annex 1.

<sup>11</sup> Fn. 8.

<sup>12</sup> The *Agreement on Trade Facilitation* came into force on 22 Feb. 2017. [https://www.wto.org/english/docs\\_e/legal\\_e/tfa-nov14\\_e.htm](https://www.wto.org/english/docs_e/legal_e/tfa-nov14_e.htm).

and, in the case of SPS, biosecurity inspections by removing or shortening documentary requirements and inspections. Also at issue are fees charged for documentary processing and inspections that, in the case of some regimes, amounts to *rent seeking*.<sup>13</sup>

#### 2.4 SPS AGREEMENT AND SCIENCE AS BASIS FOR SPS MEASURES

The SPS Agreement provides a normative framework to ensure that *SPS measures* are not unduly restrictive of trade because they are not based on scientific evidence/risk assessment (Articles 2, 5) or they are discriminatory (Article 2). The concepts emphasized in this article is that the SPS Agreement promotes *trade by standards* and that SPS measures to be consistent with WTO's normative rules must have a scientific basis or be based on 'scientific evidence'. The three key aspects of the SPS Agreement in these respects are Articles 2 (paragraphs 1, 2), 3 (paragraphs 1, 2, 4) and 5 (paragraphs 1, 2).

The first element in these arguments comes from Article 2 with the provision in Article 5 for *risk assessment* to provide scientific evidence. However, there is an escape from the requirements for risk assessment if, as according to Article 3 – Harmonization – SPS measures are based on *international standards*. Article 3 further refers (paragraph 4) to three international organizations (now referred to as International Standard Setting Bodies (ISSBs)) according to specific SPS sector: Codex Alimentarius Commission ('Codex', administered by World Health Organisation and FAO); the World Organisation for Animal Health (OIE)<sup>14</sup> for animal health and veterinary matters; and the Secretariat of the International Plant Protection Convention (IPPC) (based in FAO).

Before identification of risks there have to be *hazards*. Table 1 indicates some examples of hazards that may pose risks in imported commodities. Further illustration of the use of standards in SPS is best seen with food safety. Examples are maximum permitted levels of contaminants such as pesticides in fruits and vegetables and criteria such as absence of harmful bacteria in specified quantities of milk and other dairy products. Additionally, there are also standards for applying SPS measures such as inspections and monitoring hazards and setting quarantine zones to contain introduced animal diseases or plant pests. Importantly, there is the food hygiene

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<sup>13</sup> Asian Development Bank, *Modernizing Sanitary and Phytosanitary Measures to Facilitate Trade in Agricultural Products. Report on the Development of an SPS Plan for the CAREC Countries* (2013), <http://www.adb.org/publications/modernizing-sps-measures-facilitate-trade-agricultural-and-food-products>.

<sup>14</sup> The SPS Agreement refers to OIE under its original name (International Organisation for Epizootics) but the organization has retained the original French-language acronym, OIE.

Table 1 Examples of Hazards to Be Encountered in Food and Other Natural Resource Products Traded Internationally

<i>Sector</i>	<i>Commodity</i>	<i>Hazard</i>
Human health/food safety	Food – fresh and processed	(Chemical) contaminant: pesticides, antibiotics, heavy metals, nitrates, food additives and adulterants  Food-borne pathogens – bacteria ( <i>Salmonella</i> , <i>E. coli</i> , etc.) Zoonoses (e.g. brucellosis), viruses, parasites  Physical hazards – glass, stones, metal fragments, etc.
Animal health/veterinary	Meat and animal products	Contaminants, feed-borne pathogens and physical hazards as above in animal feed  Animal diseases
	Eggs, semen for breeding	Animal diseases
Plant health	Fresh fruit and vegetables	Plant pests – bacteria, fungi, viruses, phytoplasmas, insects, molluscs, mites, rodents, etc.
	Packing material	
	Planting material for propagation – seeds, bulbs, tubers, roots, cuttings	
Plant health, habitats and biodiversity	Potentially invasive plants and animals deliberately imported	Invasive, predatory

system/standard Hazard Analysis and Critical Control Points (HACCP) which is to be found in the Codex.<sup>15</sup>

However, SPS standards are unique in that they are themselves measures and different from quality standards and specifications for food composition and packaging. The latter feature in another WTO instrument, the *Agreement on Technical Barriers to Trade* ('TBT Agreement')<sup>16</sup> where one finds that 'standards' are 'voluntary' while Technical Regulations that use them are 'mandatory'. Such definitions may be found in national standards legislation throughout the world but the National Standards Institutions (NSI) in some developing countries have attempted to apply these concepts to SPS standards. For one thing, Technical Regulations and SPS measures are mutually exclusive but more importantly SPS standards such as those emanating from Codex Alimentarius are *official standards* and the concept of voluntary nature is completely irrelevant. SPS standards should be enforced by the appropriate SPS agency acting as competent authority such as Ministry of Agriculture or Ministry of Health and not the NSI.<sup>17</sup>

The other important issue very relevant to the article's themes is the argument that SPS Standards are 'Western Standards' that are too high or not affordable in developing countries that don't have sufficient resources for food safety and public health. There are various arguments for and against this proposition but two positions may be advanced in opposition: First, the SPS standards themselves provide basic assurances of a right to safe food and that poor food hygiene in many developing countries is due to lack of resources and perhaps most importantly lack of political will to implement better domestic provisions in favour of ensuring exports to meet western countries' standards. Second, in this connection private standards, including environmental safeguards and ethical supply chain and labour standards have more impact on restricting access to export markets than the SPS standards themselves.

Concerns relevant to developing countries' participation in international trade have been touched on already, albeit tangentially. Drawing on the author's legislative drafting experience in food safety, plant health and pesticides regulation, the article will now turn to barriers for reform of biosecurity legislation in these countries that need to be addressed to broaden participation in international trade.

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<sup>15</sup> Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application, FAO, <http://www.fao.org/docrep/005/y1579e/y1579e03.htm>.

<sup>16</sup> Agreement on Technical barriers to Trade, WTO, [https://www.wto.org/english/docs\\_e/legal\\_e/17-tbt\\_e.htm](https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm).

<sup>17</sup> In Ethiopia and some CIS countries justification for SPS standards being voluntary was found in an assertion to the effect that *the Standards Institution did not adopt these standards; they were adopted by a community-based committee, being owned by the public and merely published by us.*

## 2.5 BASIC LEGISLATIVE REQUIREMENT FOR SAFE FOOD

The basic legislative principles for food safety following Codex guidelines that *food should be safe and fit for human consumption*<sup>18</sup> provide that food that is not safe should not be placed on the market or withdrawn from the market if necessary. The criteria for unsafe food are:

- Injurious to health, or
- Unfit for human consumption because spoiled, damaged packaging, illegal labelling, passed sell by date, etc.

Following these principal provisions, the law should affirm that whether food *is* injurious to health must be determined by risk assessment of the potential hazards causing food poisoning or physical injury. This requires knowing what the hazards are for each type of food – food-borne bacteria, pesticides, etc., usually requiring schedules or annexes in secondary legislation listing the hazards and the ‘physical’ standards such as maximum residue limits for contaminants that define the boundaries of safe food.<sup>19</sup>

Unreformed food law in developing countries typically lacks these basic provisions. Furthermore, one may find ‘safety’ and ‘quality’ in the same phrase or bundled together in a definition. This is very important because quality aspects such as nutritional composition are not food safety matters apart from when some vulnerable consumers like babies and diabetics are concerned, and quality/composition is not subject to risk assessment. Instead, these matters are dealt with through ‘mandatory’ Technical Regulations under the TBT Agreement and the corresponding ‘voluntary’ standards. A good example of intentional conflation of quality and safety is the standards system of the FSU, now the CIS.

In this region there was, and still is to some extent, a dual system of food controls operating: conventional import criteria (SanPin)<sup>20</sup> more or less linked with food safety but with some obsolescence such as inclusion of pesticides no longer presenting significant risks in food (e.g. DDT); and the GOST (*государственный стандарт* – State Standards) regime for internal market access. GOST standards primarily regulated quality/composition as Technical

<sup>18</sup> FAO, *Food Hygiene*, Basic texts (4th ed. 2009), <http://www.fao.org/docrep/012/a1552e/a1552e00.pdf>.

<sup>19</sup> Table 1.

<sup>20</sup> I. Kireeva & R. Black, *Sanitary and Veterinary Hygiene Requirements for Imports of Fish and Fishery Products into Russia – Tensions Between Regional Integration and Globalization*, 15(4) ERA Forum 495–418; R. Black & I. Kireeva, *General Overview of the Russian Federation Sanitary and Phytosanitary Legislation in Light of the WTO SPS Agreement and EU Principles of Food Safety*, 35(3) Rev. Cent. & East Eur. L. 225–55 (2010).



Regulations but also incorporated some safety factors (as with SanPin criteria, often redundant, like DDT in bread). The GOST food standards were linked with an elaborate system certification of conformity that presented another major problem in addition to the merging of food safety and quality – authorities were and still are to a varying extent using this system for rent seeking with all the accompanying problems of corruption. In several FSU countries and Mongolia, the NSIs have resisted reform and tried to maintain a dominant role in the regulation of food safety whereas the competent authorities should be either the Ministries responsible for Agriculture or Health or an independent agency. In the West, quality/composition is a matter for the private sector and food industry. This recalls previous observations about ‘voluntary’ standards under the TBT agreement and their incompatibility with SPS measures.<sup>21</sup>

According to Codex what should replace the dual system of *official food controls* is HACCP or a HACCP like system, with responsibility placed on food producers or processors to ensure safe and hygienic production by ensuring reliable and safe inputs and identification and elimination of hazards during the processes. With HACCP, there is no routine certification and instead monitoring of e.g. pesticide residues, and primary producers are required to observe Good Agricultural Practice. Russia took steps for partial conformity with the internationally recognized/SPS consistent approach to food law and regulation when it negotiated membership of WTO but insisted on applying *Technical Regulations for SPS Measures* instead of SPS measures.<sup>22</sup> Overall, there has been a move from the GOST/SanPin towards a unified Technical Regulation system that includes SPS measures but there is still opposition to adopting a strictly risk-based approach to food safety including HACCP.

## 2.6 RISK IN PLANT HEALTH LEGISLATION

The need for attention to risk is made here by reference to plant health legislation. The IPPC in the 1997 version<sup>23</sup> provides the normative framework for plant health legislation consistent with the SPS Agreement. Conceptually plant health measures consistent with IPPC/SPS Agreement are all based on the form of risk analysis developed for the sector called *pest risk analysis* (PRA).

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<sup>21</sup> Public health measures are a third category of measures to protect human health. Examples are quarantine for infectious diseases and spraying aircraft cabins against mosquitoes. These do not involve either the TBT or SPS Agreements because trade in goods is not involved.

<sup>22</sup> Fn. 13, at 6.

<sup>23</sup> <https://www.ippc.int/en/core-activities/governance/convention-text/>.

The key principles are:

- Plant health measures can only be taken against ‘regulated pests’ (‘mainly quarantine pests’)
- PRA is necessary determine regulated/quarantine pests and each country or harmonized region will have its own unique list of quarantine pests
- PRA is needed to determine the risks of importing each type of commodity from each country of origin and the consequent *phytosanitary import requirements* (restrictions, need for inspections, treatments, etc.)
- PRA is needed whenever a new type of commodity appears at the borders for potential import

Politically adoption of the principles of the IPPC into national plant health legislation is not so difficult as food safety legislation, although plant health is invariably the most poorly resourced of all agricultural sectors in developing countries. However, because PRA is very resource intensive, formally documenting quarantine pests is a lengthy and elaborate process without which detailed import requirements cannot be laid down. Many developing countries may have up-to-date primary legislation but lack regulations with detailed lists of quarantine pests, import requirements, and detailed rules for risk-based commodity inspections (or Parliament may refuse to consider bills for new legislation if there is no delegated legislation). The question of ‘missing’ regulations will be addressed later.

Consequently, many developing countries rely on import permits for each consignment, even for commodities like canned vegetables that bear no plant health risk. The import permit application and approval process is likely to be excessively lengthy and therefore a non-tariff barrier in itself, and consequently feature in trade facilitation projects.

In countries of the former Yugoslavia, there were difficulties in convincing the authorities to transform controls that were a legacy from the authoritarian era into risk-based measures. For example, *plant passports* in the EU Plant Health Directive<sup>24</sup> are not internal movement controls applied to all commodities; and registration of farms is only required for establishments producing sensitive propagation material.

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<sup>24</sup> Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. *Official Journal L 169, 10/07/2000 P. 0001 – 0112*. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32000L0029>.

## 2.7 LEGISLATION FOR PESTICIDES REGISTRATION AND CONTROL

For pesticides regulation, core legislation that is particularly relevant to ensuring that food crops are grown safely without the risk of harmful pesticide residues and to avoid environmental pollution should provide for:

- **Approval** of *active substances*/active ingredients that are actually toxic to pests. Risk assessment is necessary to ensure that they are safe to use (operators, consumers, environment) as well as being effective for specified pests in particular crops
- **Registration** of formulated **products** actually available on the market for farmers to use<sup>25</sup>

It is normal practice to designate an independent agency or statutory body to implement the legislation and regulate trade and use of pesticides, rather than a government department. It is also preferable to have this agency under the Ministry of Agriculture or reporting to the Minister for Agriculture because most pesticide use is in agriculture. However, in three countries in which the author worked (Ethiopia, Macedonia, Mauritius) there was a power struggle between the Ministries of Agriculture and Health, the latter taking the view that pesticides came under the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals and therefore within their mandate. This is inappropriate – GHS was primarily intended for the transport, handling and storage of industrial chemicals whereas pesticides are generally traded and used in small quantities and agricultural experts are the people likely to have most experience of their field use and the adverse consequences of their use. Nevertheless, risk assessment of pesticides requires a multidisciplinary team with agriculturalists, toxicologists, clinicians and ecotoxicologists. This then becomes a resource issue and the political will to share expertise for a common purpose.<sup>26</sup>

Underlying risk analysis of pesticides is the need for data requirements in legislation. Where a country lacks the expertise for risk analysis for approval of active substances, even when the required data are available, and lacks the scientific infrastructure such as analytical laboratories to monitor pesticide use, it is possible to resort to a simplified registration system according to various internationally approved models such as *registration by analogy*<sup>27</sup> while prohibiting dangerous

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<sup>25</sup> FAO, *International Code of Conduct on Pesticide Management. Guidelines on Pesticide Legislation* (2015), <http://apps.who.int/iris/handle/10665/195648>.

<sup>26</sup> In Ethiopia the health ministry in 2005 withdrew its experts from the pesticides safety panel when responsibility for pesticides regulation was allocated to the agriculture ministry.

<sup>27</sup> <http://www.fao.org/pesticide-registration-toolkit/tool/page/pret/quick-start-guide>.

chemicals under international conventions including the *Stockholm Convention on Persistent Organic Pollutants (POPS)*<sup>28</sup> and the *Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade*.<sup>29</sup> In Rwanda the approach of *Equivalence* as ‘the capability of registration systems in different countries to meet the same standards and objectives’ (not to be confused with ‘pesticide equivalence’ as discussed below) was adopted in the *Law on Governing of Agrochemicals*<sup>30</sup> with a requirement to source pesticides from a country where there was already a ‘link’. In the Republic of Georgia the intention was to allow pesticides approved in OECD countries to be imported and used. However, one has to be conscious that the primary risk considerations apply to the active substance and that different formulated products are available in different countries according to the marketing arrangements of the manufacturers. In the Republic of Georgia the original law covering pesticides did not make adequate distinction between active substances and formulated products with consequent confusion about the application of the intended approach.

Another related difficulty faced by developing countries is the desired use of cheaper ‘generic’ pesticides as alternatives to patent-expired trade names. Whereas some generics are fraudulent or substandard, generics can be used successfully. In the first place, manufacturers of the original patented pesticide will generally not release the required data unless their products are being officially considered. Second, in order to protect innovator rights, the major agrochemical companies launched a series of legal initiatives to try to block the marketing of generics and their use in developing countries, most notably by interpreting *pesticide equivalence* to their advantage.<sup>31</sup> However, international guidelines have been developed to allow generic pesticides to be used at least for public health purposes.<sup>32</sup> The EU uses the concept of ‘parallel trade’ in the regulation on plant protection products.<sup>33</sup> That generic pesticides and pesticide equivalence provoked controversy in drafting the Law on Plant Protection Products to approximate to EU Acquis in the Former Yugoslavian Republic of Macedonia became apparent at the compulsory public

<sup>28</sup> <http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx>.

<sup>29</sup> <http://www.pic.int/TheConvention/Overview/TextoftheConvention/tabid/1048/language/en-US/Default.aspx>.

<sup>30</sup> Law No, 30/2012 of 1 Aug. 2012 on Governing of Agrochemicals. Official Gazette No. 37 of 10 Sept. 2012, at 59–100.

<sup>31</sup> E. Rosenthal, *Who's Afraid of National Laws?: Pesticide Corporations Use Trade Negotiations to Avoid Bans and Undercut Public Health Protections in Central America*, 11(4) *Int'l J. Occ. & Env'tl. Health* 437–43 (2005).

<sup>32</sup> World Health Organisation, *Determination of Equivalence for Public Health Pesticides and Pesticide Products* (2017), <http://apps.who.int/iris/bitstream/10665/254751/1/WHO-HTM-NTD-WHOPES-2017.1-eng.pdf>.

<sup>33</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 Oct. 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. *Off. J. Eur. Union* 24 Nov. 2009 L 309/1.

hearing to announce the newly drafted Law on Plant Protection Products in 2005.<sup>34</sup>

## 2.8 RISK AS A TRADE BARRIER

After reviewing legislative issues matters specific to the various sectors of biosecurity, the appropriate background has been provided for a discussion of more general issues. First it is necessary to take a serious look at risk assessment and evaluate whether it is a trade barrier in itself.

The view that the United States was highly influential in drafting the SPS Agreement is given credence because in the biological/agricultural fields nobody outside of USA knew anything about risk assessment.<sup>35</sup> Even the EU, let alone the developing world had to play catch-up after WTO came into existence. It can be argued that the requirement for SPS measures to be risk-based (when international standards are not available or not appropriate) is the most important and possibly most blatant trade barrier of all. This is because risk assessment is very resource intensive and has become more so with increasing sophistication since 1995:

- Requires personal trained in risk assessment not just in professional expertise like food safety, plant health, and other recognized disciplines.
- Frameworks and guidelines for risk assessment do not provide methodology so understanding the frameworks is no help in actually doing assessments.
- Requires information resources that are often/usually beyond the budgets of many developing countries
- Requires sophisticated information technology linked with information resources

Risk analysis is not about absolutes but about making informed judgments and predictions based on scientific evidence so each risk assessment made is open to evaluation on the soundness of these predictions and the quality of the data used in the assessments. In the SPS/biosecurity area each country needs a capacity to

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<sup>34</sup> The provisions for generics were attacked by a member of the audience who it turned out ran a very lucrative business importing generics from China, and who it seemed had the support of the media. The Law on Plant Protection Products incorporating provisions for 'parallel products' was eventually enacted in 2008, <http://extwprlegs1.fao.org/docs/pdf/mac137214.pdf>.

<sup>35</sup> Risk assessment first came into the public domain from engineering and construction activities (e.g. how many years could a nuclear power plant operate before undergoing Chernobyl-like meltdown) and possibly public health and finance.

evaluate importing countries risk assessments as well as the capacity to apply risk assessments to their own imports.<sup>36</sup>

Additionally, the author believes that legal professionals and others involved in trade decisions who have not had scientific education probably have the layman's view of science as giving absolute certainty about 'facts'. Unfortunately, the expression of doubt or *uncertainty* (formally part of risk assessment) has been used by politicians to ignore warnings provided in risk assessments, sometimes with disastrous consequences (e.g. BSE crisis).<sup>37</sup> The problem of uncertainty has been touched on in works on the economics and politics of risk,<sup>38</sup> features in commentary on the SPS Agreement,<sup>39</sup> and is central to arguments about the precautionary principle.<sup>40</sup> However, it is doubtful whether the simplistic view of science and scientific evidence preferred by politicians has been properly exposed.<sup>41</sup>

There is a related legal concept that has been intriguing the author for several years. When WTO/SPS Agreement came into being in 1995, the terms *risk assessment* and *risk analysis* were used interchangeably. However, risk assessment is the scientific/technical core of **risk analysis**, the latter also including risk management (means to mitigate the risk) and risk communication (reporting). The question raised here is whether Article 5 should have had the term risk analysis instead of risk assessment. This would mean that the administrative economic and political reasoning that may go into risk management should be taken into account in the justification of SPS measures, including standards. This might have had an impact on various disputes at WTO because of allegedly unfair or discriminatory standards.

## 2.9 OTHER ASPECTS OF THE SPS AGREEMENT

Two further Articles of the SPS Agreement now deserve consideration because of their importance in developing countries, *viz.* Article 7 (with Annex B) and Article 8 (with Annex C) of the SPS Agreement.

<sup>36</sup> In providing guidance and formal training on certain aspects of risk assessment and risk analysis, the author has frequently encountered statements from developing country to the effect that 'We've been to several seminars and courses where the international guidelines have been explained but we came away without knowing how to do risk assessments in our area of specialisation'.

<sup>37</sup> E. Fisher, *Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Public Accountability*, 20(1) Oxford J. Legal Stud. 109–30 (2000).

<sup>38</sup> For example, E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart Publishing 2007).

<sup>39</sup> For example, J. Peel, *Risk Regulation Under the WTO SPS Agreement: Science as an International Normative Yardstick?* (2004), <http://www.jeanmonnetprogram.org/archive/papers/04/040201.pdf>.

<sup>40</sup> For example, European Commission, *Commission Adopts Communication on Precautionary Principle*, Press Release Database IP/00/96 (2 Feb. 2000), [http://europa.eu/rapid/press-release\\_IP-00-96\\_en.htm](http://europa.eu/rapid/press-release_IP-00-96_en.htm).

<sup>41</sup> Quotation from Francis Bacon seems appropriate: 'If a man will begin with certainties, he shall end in doubts; but if he will be content to begin with doubts, he shall end in certainties.' *The Advancement of Learning* (1605), Book I, v, 8.

2.9[a] *Transparency in SPS Agreement (Article 7)*

Article 7 is about Transparency with two key provisions:

- SPS National Notification Authority (NNA) to collect all relevant legislation and administrative acts to transmit to WTO and trading partners
- SPS Enquiry Point to receive all enquiries about the country's SPS measures, particularly import requirements, from both trading partners and prospective traders and importers within the country and then forward to the designated specialist authority.

Neither of these provisions necessarily require legislation and mostly it is a question of designating personnel, providing training and IT support. However, of all the provisions of the SPS Agreement these are the least implemented in developing countries. There may be unnecessary obstructive rivalry being competing agencies because, according to the *SPS Agreement*, the NNA and the Enquiry Points need only be mailboxes without any interpretative or regulatory function.

2.9[b] *Article 8 and Trade Facilitation*

The purpose of Article 8 (Control, Inspection and Approval Procedures) is to ensure that the procedures to implement SPS measures (permit application and approval, sampling, inspection and laboratory testing, etc.) are not unduly lengthy and any fees are 'reasonable'. The implementation of Annex C requirements is linked with Trade Facilitation, basically streamlining clearance of goods at ports of entry or borders. These principles have been incorporated into the new *WTO Agreement on Trade Facilitation*.<sup>42</sup>

One consequence of international development programmes and national projects on trade facilitation (World Bank, etc.) is handing over SPS inspection responsibilities to either a single SPS inspection agency or to Customs. Having a unified inspection force is a sensible measure but questions have to be asked when this agency is appropriately Customs, as has happened with some countries in FSU. This may be more power broking rather than logistics. In the first place, there can be a vacuum of technical expertise on which to make risk-based decisions. More importantly, Customs are known to be secretive and corrupt in many developing countries.<sup>43</sup>

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<sup>42</sup> Fn. 12.

<sup>43</sup> R. Black & I. Kireeva, *Sanitary and Phytosanitary Issues for the Customs Union of Russian Federation, Belarus and Kazakhstan in Relation to Trade with Other Countries and CIS, with Special Reference to Food of Non-Animal Origin and Phytosanitary Controls*, 49(5) *J. World Trade* 802–36 (2015); trader in one CIS country: 'Customs are in the Premier League of corruption'.

## 2.10 EQUITABILITY, DEMOCRACY AND TERMS OF TRADE

First, amid all the protests against globalization, what perhaps is a simplistic question about the SPS Agreement is asked: does it promote ‘democracy’?

The author’s view is that the agreement itself provides an important component of democracy if adopted into national biosecurity legislation. However, the prevailing lack of resources to implement it has created an inequitable division between rich and poor countries.

On the plus side:

- Risk assessment or adoption of international standards removes the opportunity for unjustified restrictive measures to go unchallenged.
- Transparency provision means that all measures must be communicated to trading partners, with ‘measures’ embracing procedures and administrative provisions as well as legislation.
- Before WTO, importing authorities did not have to reveal the sampling procedures so they would not say how many positive results would lead to rejection of a consignment. Now they do.

On the negative side:

- Risk assessment is about information and information is power. Risk assessment can be used to erect trade barriers if the exporting country does not have sufficient capacity in this area.
- Very poor implementation of Article 7/Annex B in many developing countries.
- Lack of infrastructure for implementation:
  - Scientists across the various disciplines
  - Poorly trained inspectors
  - Inadequate laboratory facilities
  - Antiquated administrative arrangements (Annex C)

Inequalities in human and physical resources are perhaps best illustrated by the poor conditions for pesticides regulation prevailing in developing countries, affecting not only capacity for pesticide approval and registration but the capacity for laboratory analysis to ensure that pesticide use does not lead to unsafe food.<sup>44</sup>

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<sup>44</sup> See s. 2.7, *infra*.



## 2.11 BOTTLENECKS IN LEGISLATIVE INITIATIVES

Another issue preventing legislative reform in developing countries is the lengthy, sometimes indeterminate process of enacting new legislation or amendments. It can take years for new bills to actually reach the legislature with the possibility of further delays once there. This is partly because of drafting bottlenecks as considered below but mostly because of lack of political will for reform. One reason is that the agriculture ministry responsible for plant health and animal health legislation has low status in terms of cabinet influence. The author finished drafting the new Law on Agrochemicals and the Law on Plant Health Protection for Rwanda in 2011. The Agrochemicals Law was enacted in 2012 but the Plant Health Protection Law only enacted in February 2016. There may be other reasons, however. For example, in Tanzania it was apparently a case of political dogma overriding consistency with international norms, in spite of various reports and advisories from influential donors and consultants, as it still does not have primary plant health legislation consistent with IPPC. The country remains reliant on the Plant Protection Act that subsumes plant quarantine with agriculture as a farming-led activity with pest control based on minimizing pesticides and maximizing use of biological control.

The situation in CIS/Central Asia may be even worse. Although most if not all countries have elected parliaments, there may not be an opposition and MPs do not really have constituencies as understood in the West, merely being there to serve the interests of the President. Resistance to adopting a modern approach to food controls has already been discussed. For plant health in many CIS countries there is resistance to moving on from the legacy of the FSU with a typical split between a law covering 'plant quarantine' and a law covering 'plant protection' with 'plant protection' officials primarily concerned with distributing pesticides to major crops such as grain and cotton that were formerly on state-owned collective farms. On the other hand, billions of dollars are being invested by the US in diagnostic laboratories for the Threat Reduction Programmes in many countries in CIS, a response to the perceived biosecurity (US sense) risks in these mostly authoritarian countries.<sup>45</sup> It is not clear to what extent these hi-tech facilities will be available for civilian use.

## 2.12 INTERNATIONAL TRADE AND ENVIRONMENTAL PROTECTION

Traditionally, the SPS Agreement covers human, animal and plant health sectors but it is now generally accepted that certain aspects of environmental protection

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<sup>45</sup> Fn. 6.

are also included implicitly, i.e. SPS measures could legitimately be taken to reduce the risk of importing harmful agents that could degrade the environment. The primary reason is that plants are major components and indeed architects of most natural habitats and so anything harming plants may damage habitats and the homes of other creatures, plant and animal. So, one is no longer talking only about agriculture and commercial forestry but protecting ‘natural’ vegetation as well. Additionally, exotic diseases and pests can be very damaging to wild animals as well as livestock. The normative framework for PRA under IPPC now includes ‘environmental risk’ – essentially organisms, plant or animal, that might be ‘**invasive**’ and Genetically Modified Organisms (GMOs). This is in concordance with the Convention on Biological Diversity (CBD) partly to avoid risk analysis having to be done twice for protecting agriculture and the environment.<sup>46</sup> This is another reason for adopting a biosecurity approach which can be explicitly concerned with environmental protection, as seen in FAO’s definition with reference to *invasive alien species*.<sup>47,48</sup>

However, one should not forget that there are a number of other factors that might influence the type of measure adopted and the success of national biosecurity frameworks. One of these is the extent to which countries which are members of the WTO are also signatories to relevant Multilateral Environmental Agreements (MEAs) such as the CBD. There are a number of actual and potential conflicts between these trade and environment agreements that lead to conflicting or confusing obligations for implementing member countries. The existence of trade-related measures in MEAs is considered to be an area in need of further attention by the WTO. A number of further conflicts existing in the trade-environment field, such as the extent to which a precautionary approach can be adopted, are relevant to biosecurity law. This is in marked contrast to the EU, which applies the precautionary approach.<sup>49</sup> And there have been several rulings in disputes in GATT/WTO that originally outlawed extraterritorial measures – tuna dolphin, shrimp-turtle, etc.<sup>50</sup>

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<sup>46</sup> Secretariat of the International Plant Protection Convention, *International Standards for Phytosanitary Measures. ISPM 11 Pest Risk Analysis for Quarantine Pests* (2016), [http://www.acfs.go.th/sps/downloads/34163\\_ISPM\\_11\\_E.pdf](http://www.acfs.go.th/sps/downloads/34163_ISPM_11_E.pdf).

<sup>47</sup> Fn. 4.

<sup>48</sup> R. Black & I. Kireeva, *International Biosecurity Frameworks to Protect Biodiversity with Emphasis on Science and Risk Assessment*, in *Agriculture Biodiversity and Markets* Ch. 5. (S. Lockie & D. Carpenter eds, Earthscan 2015).

<sup>49</sup> Art. 191 of the Lisbon Treaty. See also fn. 37.

<sup>50</sup> Environmental disputes in GATT/WTO, [https://www.wto.org/english/tratop\\_e/envir\\_e/edis00\\_e.htm](https://www.wto.org/english/tratop_e/envir_e/edis00_e.htm).

### 3 REFLECTIONS FROM DRAFTING BIOSECURITY LEGISLATION – HELPING TO REMOVE BARRIERS FOR FURTHER REFORM

#### 3.1 WHO INSTRUCTS AND WHO DRAFTS SPS LEGISLATION?

One of the problems with implementing the SPS Agreement is that some fundamentally important principles are embedded in terms of scientific concepts like risk, standards and contaminants, and proper understanding of these concepts is necessary for drafters of national legislation.

The author's experience with legislation began in Belize when problems became apparent with the Plant Protection Act and the Pesticides Control Act that prevented implementation (the author's responsibility). There were also problems with legislation dealing with bananas in relation to disease control. The Solicitor General asked the author to help resolve the issues as the technical person in charge of pesticides and plant disease control but also as the regulator. Following that, with his regulatory experience becoming known to his clients, the author was frequently asked to review biosecurity legislation during his assignments for the British Government in Africa and elsewhere, culminating in specific drafting assignments. The first of these assignments was back in Belize where the first two lessons learnt in drafting new primary legislation for plant protection were<sup>51</sup>:

*Style and structure are very local and that model laws (in this case the Model Plant Protection Law of the Caribbean Plant Protection Commission) and that normative frameworks like IPPC are a guide to the content but not the structure and the wording of provisions.*

*Drafting primary legislation in several jurisdictions, one needs to be a chameleon in drafting style because, official language of legislation apart, structure and drafting style of legislation follows uniquely national norms.*<sup>52</sup>

The next lesson learned was that with the exception of Belize and Rwanda it has been very difficult or impossible to work with local legal drafters. Generally, they are practising attorneys in the AG's office rather than dedicated drafting counsel. Consequently, they are very busy, creating drafting bottlenecks, but may also be resentful of outsiders, particularly perceived 'technocrats'. What lawyers there may be in the relevant ministry might not have drafting experience but be devoted to contract matters and litigation.<sup>53</sup> The bottlenecks and the technical nature of the

<sup>51</sup> Eventually incorporated in to the Belize Agricultural Health Authority Act, Revised edition 2000, C. 211, encompassing plant and animal health and food safety.

<sup>52</sup> Sir Geoffrey Bowman, former UK First Parliamentary Counsel, referred to squirrels and chickens in terms of drafting methods. Perhaps another species has been added to the Field Guide to Drafting Animals.

<sup>53</sup> The worst case was one Caribbean territory. The legal team engaged in a EU-funded project to review all agricultural legislation were denied any meaningful dialogue with AG Department's counsel and even refused access to the consolidated volumes of the Laws of the country. Fortunately, one of the

legislation is why consultants are brought in but without the support from the AG's office, and with lack of political pressure from the sponsoring Ministry, it is quite possible that anything drafted will never reach Cabinet.

*Lesson learned: The author as drafter had to instruct himself and needed high level legal and political support.*

### 3.2 WHERE ARE THE REGULATIONS?

Another reason that a Bill may not proceed through Parliament is because there are no regulations and other secondary legislation to implement primary legislation, considered necessary in some legislatures before review of the Bill. One reason for this is that consultants tasked to prepare draft Acts or Laws may not be contracted to prepare the implementing legislation. Where local lawyers are involved they may not relish drafting regulations on highly scientific matters. There is a paradox here: whereas Acts of Parliament or Laws may be very different from one country to another, regulations could be very similar as the business end may be Schedules or Annexes of such things as lists of pests, lists of food contaminants and lists of food subject to regulation.

*Lesson learned: regulations could be adapted from other countries or normative frameworks (in contrast with primary legislation).*

### 3.3 TAKING ACCOUNT OF THE OFFICIAL LANGUAGE OF LEGISLATION

Finally, before concluding this part of the article, the author recalls experience of drafting in a trilingual legal culture – Rwanda. On arrival in 2009 to begin drafting Law on Agrochemicals and continuing Law on Plant Health Protection, Rwanda was transforming from a francophone Central African country into an Eastern African/Commonwealth country with English becoming more important. Laws are enacted in three languages, Kinyarwanda (akin to Swahili), French and English. The author proceeded on the assurances given by the Assistant Attorney General that a new Law provided that Bills would be considered in parliament in the language of original drafting, and in spite of some linguistic obstacles along the way, the drafting in English work was completed in 2010 with an opportunity to correct the French translation before the draft was adopted by the Ministry of Agriculture. Quite quickly the

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librarians in the city library took pity on the legal team who were allowed to borrow for photocopying the necessary volumes from the Reference collection.

Ministry must have submitted the draft bill for Agrochemicals Law **in three languages** to cabinet who approved draft in March 2010 but then the author had to return to the country in 2011 to draft secondary legislation to inform parliament of the Ministry's plan for implementation. This law was enacted in 2012.<sup>54</sup> On reading through the published law in the Gazette it quickly became apparent that the bill had been debated in Kinyarwanda and then translated back into English and French. Several key definitions had been misunderstood in the re-translations into English and French, with other definitions missed out altogether but the terms appeared undefined in the text, and details of data requirements drastically abridged. For example, in relation to the discussion above on pesticide registration, there is no further reference in the text to the definition in Article 2.12 of 'equivalence [of registration systems]' and the provision for the adoption of pesticides already registered elsewhere was omitted apart from the reference to countries with a link (Article 13).

In fact Article 35 of this law reads:

Article 35: Drafting, consideration and adoption of this Law

This Law was drafted in English, considered and adopted in Kinyarwanda.

Fortunately there was a much better outcome with the Law on Plant Health Protection enacted in 2016,<sup>55</sup> with some grammatical errors but mainly following the text approved by Ministry (2008!) based on normative guidelines. The article equivalent to Article 35 in the Agrochemicals Law has been retained but the outcome with this Law suggests that the legislature and other authorities had become much comfortable with the original language of drafting:

*Lesson learned: not to expect much if any iteration between even official drafters and instructors or when the original drafter and instructor are one and the same person.*

### 3.4 CONCLUDING REMARKS

The SPS Agreement provides the normative framework for 'trade with standards' but also provides a basis for broader application of biosecurity to protect habitats and biodiversity from invasive alien species (non-native species in UK terminology). The first thing that has to be considered in improving developing countries' access to export markets are the generally inadequate resources to implement a trade regime based on science and risk. Also, however, the processes of drafting national law in consistency require understanding of the underlying science.

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<sup>54</sup> Fn. 30.

<sup>55</sup> Law no 16/2016 of 10 May 2016 on Plant Health Protection in Rwanda. *Official Gazette* no 22 of 30 May 2016, at 52–92.

Typically, the normal process of ministry experts instructing official drafters is lacking, a situation unlikely to provide much opportunity for iteration to check that the instructions were followed in terms of science. There are some particular problems in drafting legislation on pesticides control, a field that the author considers to be part of biosecurity provisions. This is compounded by drafting instructions or original legal drafting not being in a different language from the language in which the legislation is adopted.

In conclusion, it may be necessary to reflect that there may be confusion between food safety and quality among the general public in both developed and developing countries. One receives what one pays for in terms of quality but food safety is essentially a binary matter. If food meets the standards set it is safe. If not, food is legally unsafe.