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## Regulation, Standards and Risk Management in the Context of Globalization

John Humphrey

### 2.1 Introduction

Increased interactions between national economies resulting from globalization create new regulatory challenges. Some of these challenges relate to removing obstacles to globalization, and in the area of trade in goods the World Trade Organization (WTO) has been successful in creating a framework for limiting barriers to trade. However, nation-states may also wish to manage globalization by developing rules that place restrictions on trade. Jacoby and Meunier suggest that the management of globalization has been a key element of EU policy over the past two decades:

the concept of “managed globalisation,” articulated explicitly as the central doctrine of EU trade policy since 1999 suggests that order and control should be restored to the process of globalization by framing it

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J. Humphrey (✉)  
University of Sussex, Brighton, UK  
e-mail: Humphrey041@gmail.com

with rules, obeying these rules, and empowering international organisations to make and implement these rules (Jacoby & Meunier, 2010: 304).

The mechanisms through which such rules are developed and enforced vary considerably. In their analysis of transnational regulatory arrangements, Keohane and Victor argue that transnational regulations run the gamut from “fully integrated institutions that impose regulation through comprehensive hierarchical rules” (which would be a description of WTO) to “highly fragmented collections of institutions with no identifiable core and weak or non-existent linkages between regime elements,” with many variants in between (Keohane & Victor, 2011: 8). Specifically, they argue that regulatory arrangements that emerge out of interactions between a multiplicity of interdependent states and interests that change over time result in “regime complexes,” which have been defined as “an array of partially overlapping and nonhierarchical institutions governing a particular issue-area” (Raustiala & Victor, 2004: 279).<sup>1</sup> These arrangements include both public regulations and private standards.<sup>2</sup>

This chapter is particularly concerned with how risk management has been incorporated into the regulation of trade. This chapter considers regulation in three sectors: forest protection, food safety and chemicals. In each of these areas, the management of globalization involves multilevel and multi-actor systems that lack comprehensive hierarchical rules. Alongside transnational public governance through a variety of institutions, transnational private governance also plays an important role in developing risk-management approaches to trade regulation. In addition, nation-states use bilateral arrangements to regulate trade—particularly restraints on market access and treaties that influence risk management in exporting countries. In the construction of these governance mechanisms, economic and political power matters. More powerful nations impose or negotiate rules and regulations, as do powerful businesses.

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<sup>1</sup> Quoted in de Burca et al. (2013: 735).

<sup>2</sup> In this paper regulation is an activity will be applied to both public and private initiatives. When considering particular instruments, there will be reference to private standards (which do not have the force of law) and public regulations (which do).

Market access is an important weapon, for both governments and businesses. As a result, weaker agents—governments and businesses—are standards takers.

A lot of attention has been given in recent years to the impact of private standards on the economies of developing countries, in part because of the importance of private standards in agricultural and food exports and the importance of these sectors for the livelihoods of the poorest. In particular, the development of risk-based approaches in private standards has been seen to have particularly onerous consequences for poor producers (Fuchs et al. 2011; Graffham et al. 2007). However, public regulation, including the development of risk-based strategies, continues to develop, and understanding recent developments in this area will clarify the challenges facing developing countries in globalized trade.

## 2.2 Responding to the Challenges of Globalization

The regulatory challenges arising from globalization have received a lot of attention in recent years. Observers have frequently emphasized the growth of transnational private governance—regulatory initiatives that are designed move left, implemented and enforced by largely non-state actors:

An increasing portion of business regulation emanates not from conventional state and inter-state institutions but from an array of private sector, civil society, multi-stakeholder and hybrid public-private institutions operating in a dynamic, transnational regulatory space. Accounting standards, fair trade labels, forestry certification schemes, labor rights monitoring, transparency standards, and many more: *transnational business governance* (TBG) has grown in scope and importance as production, consumption, and their impacts globalize and as states reconsider established modes of regulation (Eberlein et al. 2014: 1–2, stress in original).

In some areas, transnational private governance arises because governments do not wish to act, or are prevented from acting. Nevertheless,

transnational private governance also addresses issues on which governments do have the power to act. Food safety is an area where governments have a long-standing and continuing commitment to regulation, but where private standards schemes have also proliferated. Why do private initiatives emerge in these areas?

Three reasons are commonly put forward to explain this. First, governments may themselves seek private involvement in standards development when they recognize a problem but defer to private sector expertise and outsource the creation and development of regulatory initiatives to private sector actors, as is seen with international financial regulation (Botzem, 2008) and with accounting and electrotechnical standards (Büthe & Mattli, 2011).

Second, the increasing complexity of value chains and the emergence of new risks create regulatory challenges that are beyond the capacity of established public controls. This is very evident in the food industry, which has become increasingly fragmented, not only in terms of geographical locations and trade, but also in terms of longer supply chains with greater numbers of actors involved in the movement of food from farm to fork. The use of established food safety controls such as border inspection is seen to be inadequate to face the new challenges. In this context, governments may seek to place more responsibility on businesses to ensure food safety, with private standards being one of the responses to the new obligations.

Third, it is argued that transnational public regulation is frequently impeded by differences in approaches between powerful global actors that make consensus impossible to achieve, preventing the creation of new hierarchical regimes. There are various instances of private standards arising as a response to public deadlock. The Greenhouse Gas (GHG) Protocol was developed when “Dissent among [developed countries] about the role of emissions trading, and thus, the possible *uses* of GHG emissions accounting standards took the issue of accounting methodologies off the agenda for inter-governmental cooperation” (Green, 2010: 2, emphasis in original). Similarly, Gulbrandsen (2014: 78) argues that the failure of inter-state initiatives accounts for emergence of the Forest Stewardship Council (FSC) and Marine Stewardship Council (MSC) initiatives. Bernstein and Cashore (2007) provide a similar argument in the case of private regimes for forest regulation. For chemicals, the Strategic Approach to International Chemicals

Management (SAICM) emerged in the context of the inability of leading nations to agree to a new binding agreement on chemicals because of their substantial differences in approach. The scope and financing of SAICM itself was also subject to lengthy negotiations and compromises, reflecting these differences (Perrez, 2006: 250–253).

The novelty of private regulation and private standards schemes<sup>3</sup> has created a lot of interest in the role of private actors in global regulation. This may reinforce a tendency to argue that private standards are gaining in importance, while public regulations and regulatory activities are in decline. Such a tendency is frequently linked to analyses of neoliberalism and expressed in ideas such as the privatization of governance and the decline of public regulatory capacity in the face of both globalization and the fragmentation of global power following the emergence of new actors on the global stage. Private regulation is certainly an expanding field, but it does not displace the public. Many public initiatives are being taken to manage globalization and achieve extraterritorial effects. Governments have developed a range of mechanisms that are risk-based and preventive and involve behind-the-border changes in exporting countries. These will be discussed in this paper. In other words, in spite of the extension of transnational private governance, national governments and intergovernmental organizations continue to be actively involved in regulation processes.

The European Union (EU), in particular, has made extensive interventions in areas such as trade in forest products (to be discussed later), the effectiveness of the “competent authorities” responsible for food safety in exporting countries, and the promotion of new transnational regulatory structures (e.g., SAICM for chemicals).<sup>4</sup> All of these initiatives

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<sup>3</sup> The difference between a standard and a standards scheme is that a standard is a series of rules for behavior. A standards scheme also has rules, but they are complemented by monitoring and enforcement mechanisms that are designed to ensure compliance. For a discussion of the activities involved in the creation and operationalization of private standards, see Henson and Humphrey (2010, 2012).

<sup>4</sup> One of the drivers of these tendencies in the EU is the extension of the mechanisms for managing the internal market in the EU to relations with non-EU trading partners. Changes in food safety legislation, for example, were undertaken in response to the crisis in EU food safety and the recognition that variations in practice within the EU were not sustainable in the context of a single market.

seek to manage globalization. Such initiatives may be undertaken by public agents alone, but there are also interactions between public authorities and private agents, with public authorities working with and through private agents, or placing specific demands upon them.

This chapter will consider regulations concerned with controls over production and trade that are designed to impact upon the products imported from other countries and the processes by which they are produced. This section begins by considering two different ways in which the welfare of citizens in one country can be influenced by how products are produced in other countries. It follows by considering regulation as it applies to intrinsic and extrinsic product characteristics, and concludes with a consideration of how globalization impacts with differing levels of severity generate different regulatory strategies and different forms of implementation.

### **2.2.1 Global Impact Pathways**

There are two ways in which production of goods in one country can have effects on citizens in another. The first is through trade. Globalization greatly increases the flow of products across national boundaries. Ideally, the level of safety of imported products should be no less than that of products produced domestically, but regulatory requirements and levels of regulatory capacity (specification, implementation and enforcement) vary from country to country. Therefore, increasing trade may result in increasing risks to citizens that arise from practices outside the jurisdiction of the consuming country. Food safety is an example of the challenges posed by (i) the sourcing of more products from a greater range of countries with different levels of development and food safety capabilities, (ii) the increasing complexity of trade (food products and food inputs may be traded and processed in multiple countries), and (iii) the recognition of new safety challenges (such as mad cow disease and microbial contamination). Governments and businesses have to decide how to keep these risks to acceptable levels by considering what types of

controls might be introduced and the points along the value chain where they would be most effective. While much trade in food has, and continues to be, regulated predominantly through border inspections of products and paperwork, there are serious limitations to this approach.

The second type of regulatory challenges relates to the global impacts of production and trade. These include pollution, resource depletion and loss of biodiversity (e.g., the discussion in the study by van Waarden, 2012). They originate in particular places and at particular times, but their effects, taken in aggregate, have impacts on countries far removed from their origin. Depletion of resources or loss of biodiversity can have global impacts, creating a need for transnational initiatives to address them. Private standards that address, in one way or another, the issue of the management of common resources include the MSC, FSC and the Round table on Sustainable Palm Oil (RSPO). Similarly, chemical pollution, CFCs and GHG emissions have potentially serious consequences for human health and reproduction right across the world. Some, but not all, of these challenges are being addressed through both public regulations and private standards, as well as through intergovernmental agreements.

These issues can be addressed through a broad range of policy instruments. The direct impacts arising from trade can be most directly addressed through trade measures, and these appear increasingly to involve “behind-the-border” measures designed to solve problems at source rather than through border controls. To the extent that poor regulatory capability in exporting countries is a key issue, then the focus may switch to governments and regulation in exporting countries, rather than particular products, and if many exporting countries face the same challenges, then broad-based programs aiming at improving the productive and regulatory capacities of a number of countries might be the most effective response.

With respect to the global (indirect) impacts, one obvious solution would be a global one—global agreements to create collective responses to challenges such as resource depletion and environmental destruction. However, where such agreements are not forthcoming, action by both governments and consumers may try to shape activities in exporting

countries through positive and negative sanctions. In particular, market access to larger economies is one of the major instruments that can be used to shape the behavior of exporting countries.

### 2.2.2 Choice of Regulatory Strategy

One frequent distinction made in relation to the regulation of the characteristics of products and the ways they are produced is that between product and process standards. Product standards lay out rules concerning the intrinsic characteristics of products. They define characteristics that are acceptable or unacceptable—in general or in particular circumstances (e.g., for particular usages). In terms of regulatory strategy, product standards are enforced through performance-based regulation (Coglianese & Lazer, 2003: 694) that is applied after the product has been made. Products that do not meet the standards for the uses for which they are intended may then be excluded from the market and placing them on the market is an illegal act. Enforcing a product standard requires some way of assessing the relevant product characteristics. Border inspection is one way of achieving this, as is approval by the authorities in exporting countries (e.g., through the use of SPS certificates).

Process standards can be used as a substitute for product standards. In this case, the overall objective of the standard is achieved through controlling the way products are made, transported and stored. This approach is most useful when the assessment of product characteristics through inspection is difficult to achieve. The case of microbial contamination in fresh fruit and vegetables is a good example of this strategy. Microbial contamination is difficult to detect through inspection because it can exist in small quantities that are very unevenly distributed within product lots. Random testing may not capture levels of contamination that could subsequently endanger consumers. Therefore, standards that identify the pathways through which products could become contaminated and introduce measures to eliminate these risks can be a more effective means of achieving food safety. The mechanisms for devising these rules are discussed later.



Process standards can also be developed as a means of promoting or enforcing particular ways of producing products that are valued for their own sake. The goal is not to produce a product with certain characteristics, but to implement processes that have desirable impacts. Examples include Fairtrade (for which the process objective is to improve the livelihoods of producers), environmental standards that aim to limit the negative environmental impacts of agricultural production (Rainforest Alliance, etc.), standards aimed at protection of forests (FSC, the PEFC<sup>5</sup> family of standards, RSPO and government initiatives such as the European Union's Voluntary Partnership Agreements for forestry) and standards relating to social impact (SA 8000, Ethical Trade Initiative, etc.).<sup>6</sup> In this case, the characteristics to be controlled are extrinsic to the product.

Such process standards can be managed in two different ways. First, there is what Coglianesi and Lazer refer to as technology-based regulation, which specifies "technologies to be used or steps to be followed" (Coglianesi & Lazer, 2003: 694). These mandate particular technologies or procedures that, if adopted, should lead to particular desirable outcomes. The standard itself identifies the problem and how it should be addressed. Examples would include the requirement for specific testing regimes and purity requirements for water used in agriculture.

Coglianesi and Lazer identify a second approach to regulation, management-based regulation. In this form of process control, there is no attempt to specify a particular way of responding to potential hazards. Instead, businesses are obligated to produce "plans to comply with general criteria designed to promote the targeted social goal" (2003: 694).<sup>7</sup> A requirement for firms to introduce HACCP would be an example of management-based regulation. The requirement is not to introduce a particular

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<sup>5</sup> Programme for the Endorsement of Forest Certification.

<sup>6</sup> Some standards schemes may combine a variety of product and process standards. Standards relating to good agricultural practices, for example, can be aimed simultaneously at impact issues such as protecting the environment and product issues such as food safety.

<sup>7</sup> The term "social goal" indicates that the goal of the regulation is to affect something which has consequences external to the enterprise. If all the costs and benefits of a firm's actions impacted clearly, directly and unambiguously on the firm, there would be no need for regulation.

procedure, but rather to show that risks have been identified and plans for eliminating or controlling them introduced. This approach is useful when the hazards facing enterprises vary considerably. It follows that if two factories have different levels of different hazards, their plans for containing them would be different.

### 2.2.3 The Severity of Risk

It was noted earlier that decisions about the introduction of private standards and public regulations are usually framed by considerations of costs and benefits. One consequence of this is that the way in which regulations are designed and implemented can vary substantially according to the level of risk to be addressed. The higher the perceived risk (and perceptions of risk will vary between agents), the greater the efforts to contain it, and the more likely it is that preventive strategies, often based on a risk management approach, will be employed.

This issue can be approached from the perspective of the presumption of innocence as opposed to the presumption of guilt. Border inspection regimes and tort law work on the basis of a presumption of innocence. In the EU, there is a legal obligation on food business operators not to place unsafe food on the market. However, imported products that are not inspected are assumed to comply with regulations, including the general obligation that food is safe. Many products that have not been inspected at the border are allowed to enter the country. In other words, there is a presumption of innocence. Action will only be taken if at some subsequent point in time a product is found not to be compliant.

The presumption of innocence may change to a “presumption of guilt” when the severity of the risk is higher and/or the risks of non-compliance with regulations are great. This applies to both public regulations and private standards schemes. In the case of private standards for food safety, for example, food processing establishments (and the products coming from them) are not considered compliant until they have shown themselves to be compliant through third-party certification. In this case, the presumption is one of guilt—in the absence of certification by a particular standards scheme, businesses that use that scheme will not accept that the

establishment is compliant and will exclude it from their supply chains. No certification means no purchases.

Similarly, when products have the potential to create serious consequences—for plant or human health, the economy or long-term sustainability—public regulatory strategies will also tend to move toward a more interventionist approach based on the presumption of guilt. Regulatory practices in the case of high-risk foods, such as foods of animal origin, would be an example. In many countries meat processing is considered to be an activity that poses high risks for human health, and consequently food safety regulations focus on the origin of pathogens and contaminants: meat processing plants are required to implement hazard analysis and critical control point (HACCP) controls. HACCP systems are frequently backed up by on-site inspection by public inspectors. Governments may also impose specific controls in response to the identification of specific hazards that are considered both important for health and for which past experience indicates that there is a risk of contamination. The use of risk-based controls for fresh produce in the United States is discussed below.

## **2.3 Regulation in Food, Forestry and Chemicals**

Standards and regulations vary according to the nature of the hazard that is to be controlled, the type of regulatory strategy to be employed and the severity of the risks involved. How do these factors influence the involvement of public and private actors? This question will be explored through the analysis of developments in regulation into three sectors: forest protection, food and food safety, and chemicals.

### **2.3.1 Forestry**

The critical regulation issue in the forestry sector is the sustainable management of forests. In this context, sustainable management can refer to a broad range of issues, including sustainable forest production, protection

of plant and animal life, forest rights for local populations, leisure activities, etc. These issues are seen to have impacts not only on localities and communities, but also more broadly. The destruction of tropical rainforests, in particular, leads to loss of biodiversity and the destruction of valuable habitats. Two private standards are important in forestry—the PEFC family of standards and the FSC. They compete for market share. Both standards work on the basis of certifying forests that are managed according to certain principles and then identify timber that has been sourced from such forests and operate traceability systems that enable this identification to be maintained as timber is processed and incorporated into a wide variety of products. While the two major schemes diverged initially and responded to different groups of stakeholders, there has been a convergence between the two standards in recent years, partly because governments have made clear their own preferences through their purchasing policies (Gulbrandsen, 2014: 79).

These private standards arose partly as a result of failures to reach globally binding agreements on forestry. The inter-governmental option failed to take off in the late 1980s and early 1990s, when proposals for a labeling system for sustainably-produced tropical timber, and later a binding UN Convention both met with resistance from some timber-exporting countries (Auld, 2014: 71–72; Overdevest & Zeitlin, 2014: 29). As Overdevest and Zeitlin note, the simple expedient of imposing unilateral trade restraints based on environmental considerations was also unavailable because of its incompatibility with WTO rules (Overdevest & Zeitlin, 2014: 30). The creation of the FSC in the 1990s was in part as a response of the failure of these initiatives. This process and the factors that led to the FSC are discussed by Auld (2014).

The biggest limitation of both schemes is their limited coverage in developing countries. One recent estimate of global coverage of forest sustainability standards puts the overall figure at 33% of the world's forests (Auld, 2014: 1), but Marx et al. (2012: 85–87) provide data for 2011 showing that coverage of the FSC forest management scheme in Africa, Latin America and Asia was under 10%. Given that protecting tropical rainforests was one of the main motivations for forest standards in the 1980s and 1990s, poor coverage of tropical forests is a major shortcoming.

In response to this challenge, governments have continued to intervene, not only within their own jurisdictions, but also in the management of forests in other countries. Legality Assurance Systems (LAS) or Legality Verification (LV) systems are being promoted by a number of governments, including those in developing countries that were unsympathetic (or hostile) to private certification (as discussed in Cashore & Stone, 2014). The legality assurance approach has also been promoted by the EU. While LAS have been offered by private sector certifiers, the coverage of the LAS approach has been considerably enhanced by the EU, which has negotiated with countries supplying tropical timber to extend the production and trade controlled by such schemes, redefine what is meant by “legal” and strengthen their monitoring and enforcement mechanisms. These schemes are designed to assure that exported timber conforms to the legal requirements of the exporting country. Illegal timber cannot be traded.

The Forest Law Enforcement, Governance and Trade (FLEGT) Action Plan, published by the EU in 2003, resulted in two initiatives. The first is the EU Timber Regulation (EUTR). This established assurance of legality as a requirement for placing timber (sourced from within the EU or elsewhere) on the EU market. This placed an obligation on organizations trading in timber to ensure that the supplies they used were legal (Forest Stewardship Council, 2013).

This uses market access as a means of enforcing regulations relating to forest management. It also puts part of the burden of ensuring legality on the private sector and foresees a role for private certification schemes. The European Commission’s own guidance notes refer to “laying down the obligations of operators who place timber and timber products on the market” (The European Commission, 2013: 1), and operators are required to work with a due diligence system (DDS) to prevent illegal timber being placed on the market. Importers have a number of ways of meeting this due diligence requirement. The EUTR refers to “voluntary forest certification and timber legality verification schemes” in the context of the requirement for a DDS, but still puts the onus on private sector operators to “determine whether the scheme incorporates a standard that includes all the applicable legislation” (The European Commission, 2013: 15). An FSC document on the EUTR (Forest

Stewardship Council, 2013) provides an extensive discussion about the interaction between certification schemes and EUTR obligations.

This regulation is designed to have a considerable effect on the way exporting countries manage their own resources, and its impact is greatly increased through a second measure adopted by the EU, the FLEGT VPA. The VPAs are agreements that the EU has signed with a number of important timber exporting countries.<sup>8</sup> These address the legality issue from the supply side, focusing very directly on the challenges of extending the scope and effectiveness of controls over forestry in developing countries. In effect, the VPAs are designed to promote the development of national-level legality assurance schemes in timber exporting countries. Such schemes, if effective, would demonstrate that timber has been legally produced and acquired. As described by the Commission:

“[VPAs] are bilateral agreements between the European Union (EU) and timber exporting countries, which aimed to improve forest sector governance and which ensure that the timber and timber products imported into the EU are produced in compliance with the laws and regulations of the partner countries. Under VPAs partner countries develop control systems to verify the legality of their timber exports to the EU. The EU provides support to establish or improve these control systems. Once ratified and implemented the VPA is legally binding on both parties, committing them to trading only in verified legal timber products” (The European Union and the Republic of Indonesia, 2011).

One of the incentives for agreeing to a partnership is that imports from a country with which the EU has signed a voluntary partnership agreements (VPA) are assumed to be compliant with the EUTR, and importers are under no further obligation to prove legality (Fishman & Obidzinski, n.d.).

The implementation of legality assurance requires a range of actions to make it operational and effective. In one of the FLEGT briefing notes produced by the European Union and the Republic of Indonesia five

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<sup>8</sup>By the end of 2011, these included Ghana, the Republic of Congo, the Central African Republic, Indonesia and Liberia (Overdevest & Zeitlin, 2014: 36).

different elements of a timber LAS are identified. These are summarized in [Table 2.1](#), together with indications of the ways in which negotiations around VPAs can affect how an LAS is defined.

This approach offers some advantages compared with private standards schemes. Private schemes only apply to exports that are covered by the scheme. The VPAs go much further. As well as applying to all timber exported to the European Union, the goal of the VPAs is to subject *all* timber exports from partner countries to legality assurance. In the case of the EU Cameroon VPA, the treaty summary provided by the EU states: “The Agreement goes beyond the limited product coverage proposed in . . . ‘the FLEGT Regulation’ . . . to cover trade in all timber products and, in doing so, commits Cameroon to building a system that will provide assurance to the EU that all forest products from Cameroon are legally harvested and produced and contributing positively and sustainably to Cameroon’s growth.”<sup>9</sup> Similarly, the briefing note on the EU Indonesia VPA states that “Indonesia has committed to using its Indonesian TLAS control systems to verify the legality of all exports of timber and timber products, regardless of the destination” (The European Union and the Republic of Indonesia, 2011: 12). Given that one of the weaknesses of both import control schemes and private certification is the relatively rapid growth of demand in emerging markets where government and consumer pressures for standards are lower, this extension of export controls is significant. The EU is using a combination of its market power as a major buyer of tropical timber products—in conjunction with concerns on the part of some exporting governments about sustainable forest management—to both extend the scope of its agreements beyond bilateral trade and play a part in the design of LAS in other countries. This is WTO compliant because the exporting countries are defining what they consider to be legal.

As with all process standards, the effectiveness of this approach depends on whether the controls in place would achieve the desired outcomes if functioning correctly, and the effectiveness of implementation of the controls. On the

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<sup>9</sup> <http://ec.europa.eu/world/agreements/prepareCreateTreatiesWorkspace/treatiesGeneralData.do?step=0&redirect=true&treatyId=8986&back=9341>.

**Table 2.1** Using Voluntary Partnership Agreements to define what legal and how legality is to be enforced

| Legality assurance system requirements  | How VPAs try to meet these requirements  |
|---|--|
| A clear definition of what constitutes legally produced timber. This means specifying the legal framework and which laws apply. | The negotiation of the VPAs includes processes to define and strengthen the legal framework in the partner countries. Improvements in governance, law enforcement and transparency are part of the process (The European Union and the Republic of Indonesia 2011: 3). The definition of what is “legal” may include community rights, sustainable harvesting, protection of biodiversity, etc.    |
| Compliance with the LAS and traceability system has to be verified through some system of audit/ inspection.                    | VPAs develop or reinforce licensing systems based on audit and certification. Conformity Assessment Bodies are responsible for verifying compliance and issuing licenses for operators (The European Union and the Republic of Indonesia 2011: 13).  |
| A traceability system that tracks timber products through the supply chain from origin to export.                               | The VPAs support the development of traceability systems. A FLEGT briefing note outlines what is required. The VPAs provide detailed agreements on traceability procedures, and traceability is verified by the Conformity Assessment Bodies.  |
| Licenses have to be issued by some specified organization. This is an enforcement role.   | VPAs are meant to strengthen governance and to provide mechanisms for enforcement.   |
| Independent monitoring of the system is required in order to ensure its credibility.  | VPAs include provisions for independent monitoring of the system. In the case of Indonesia, this includes giving civil society bodies the right to raise objections to certification or to make complaints about how forest businesses are operating. Comprehensive monitoring and periodic evaluation are built into the agreement (European Forest Institute n.d.; Fishman and Obidzinski n.d.). |

Sources: Legality Assurance Scheme requirements, taken from European Commission (2007: 1)



first point, concerns have been raised about Indonesia's definition of legality, pointing to the fact that the definition of legality varies across four different types of forests, with controls for state-owned forests greater than for privately owned ones (European Forest Institute, [n.d.](#): 1). On the second point, the overall goal of the VPA is clear:

“The core of the VPA process is to define the set of laws and regulations that apply to the Indonesian forest sector (‘the legality definition’), and to develop the control systems and verification procedures that ensure that all timber and timber products exported from Indonesia to the European Union are legal. This means that those products have been acquired, harvested, transported and exported in line with Indonesian laws and regulations” (The European Union and the Republic of Indonesia, [2011](#): 3).

But reservations have been raised about the complexity of the systems, the will and capacity of enforcement bodies and the politics of regulation. Fishman and Obidzinski note that there are many forests and many companies involved in forestry and timber, but in 2013 there were only 11 evaluators qualified to conduct legality verification (Fishman & Obidzinski, [n.d.](#): 5–6). Further, these authors observe that the closeness and complexity of the relationships between the Conformity Assessment Bodies, the industry they are regulating and the government provides scope for regulatory capture. It remains to be seen whether these challenges will be mitigated through the monitoring processes provided within the VPA. In Indonesia, the VPA recognizes the role of civil society groups and individuals in pointing to problems, and there is also provision for “multi-stakeholder monitoring and evaluation working group,” a periodic evaluation of the whole scheme and independent monitoring of licensed timber in the EU market (European Forest Institute, [n.d.](#): 3).

### 2.3.2 Food Safety

This section considers the development of risk-based approaches to food safety, with a particular focus on the development of food regulations for fresh fruit and vegetables in the United States and the European Union.

The types of controls exercised over both domestic food production and imported food depend in part on the perceived risks arising from different types of food. The major focus of legislation in both regions has been on food processing establishments and food of animal origin. These are where the greatest risks occur and where food hygiene regulations are strictest.<sup>10</sup> In the United States all meat and poultry processing plants have had to develop pathogen reduction programs based on HACCP principles following the introduction by the USDA of the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulation in 1996 (Ollinger et al. 2004). With such products, there is a “presumption of guilt,” with producers and food processors having to demonstrate compliance with safety regulations.<sup>11</sup>

At the same time, there have been significant shifts in perceptions of the hazards that might arise from fresh fruit and vegetables, both in the USA and in the EU, leading to changes in both public regulations and private standards. The shift has been particularly marked in the United States. For a long time, the United States government was reluctant to impose controls on the production, harvesting and packing of fresh produce (fruit and vegetables). Rather than issuing mandatory rules and enforcing them, government agencies preferred to issue guidelines and provide tools that farmers could use voluntarily to check the safety of their farming systems (US Food and Drug Administration, 1998; USDA, 2009). Among the reasons put forward for taking this hands-off approach, two are highlighted by Calvin (2003). The first is the diversity of farming systems in the United States, which makes any country-wide system of good agricultural practices inefficient—standards applicable for one type of farming systems might be under- or over-specified for another. The second is that the scientific basis for strict controls was

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<sup>10</sup> For food of animal origin, registration of processing plants, assessments of the competence of food safety authorities in exporting countries and the importer obligations create a much more stringent regime.

<sup>11</sup> These safety regulations for food of animal origin have been tightened in recent years, partly in response to food safety crises such as BSE (mad cow disease), which has led to greatly increased controls on live cattle and abattoirs.

lacking. According to Calvin, “guidelines do not outline specific testing and monitoring regimes because scientific data is lacking for establishing more specific guidelines” (2003: 77).<sup>12</sup>

Nevertheless, repeated outbreaks of foodborne illness arising from microbial contamination of domestically produced leafy greens (lettuce, spinach, etc.) and other fruits and vegetables did eventually change attitudes. In particular, a food illness outbreak in California in 2006 associated with *E. coli* O157:H7 in spinach led to over 100 people being hospitalized and 31 suffered from a serious complication associated with *E. coli*, haemolytic-uremic syndrome. It also led to a very substantial and prolonged decline in domestic spinach sales and the threat of import bans in Canada and elsewhere. In the EU, changing perceptions about the long-term threats to human health from excessive pesticide residues in fruit and vegetables led to a tightening of regulations in 2000 (The Commission of the European Communities, 2000), and repeated food safety scares in the EU in the 1990s (see Knowles et al. 2007: 46) led to the EU White Paper on food safety in 2000 and the subsequent establishment of the European Food Safety Authority (Caduff & Bernauer, 2006: 153–157).<sup>13</sup>

In neither area did the authorities respond to these challenges by immediately introducing preventive controls. But pressures on business did lead to the development of standards that achieved precisely this outcome. In the United States, the damage caused by the 2006 *E. coli* outbreak led shippers (the companies that processed and distributed products, but did not necessarily grow them) in the leafy greens sector, in collaboration with the California State government, to introduce the California Leafy Green Products Handler Marketing Agreement (LGMA) (LGMA, 2010). This introduced technology-based regulation as a strategy for minimizing the risks of microbial contamination. Good agricultural practices in areas such as water quality, water testing, worker hygiene and animal intrusion were prescribed and backed up by audit and certification by the California

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<sup>12</sup> As will be seen subsequently, this approach to information requirements bears parallels with the requirements on the US Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) to prove that chemicals are harmful before imposing restrictions.

<sup>13</sup> See also, Vincent (2004) and Vogel (2003).

Department of Agriculture. The adoption of the LGMA by shippers responsible for distributing 99% of California-produced leafy greens made compliance with its practices effectively mandatory for Californian farmers growing leafy greens.

In the EU, the most widely adopted standard for certification of farms growing fresh fruit and vegetables, GlobalGAP (known as EurepGAP until 2008) established preventive controls for food hygiene and pesticide residues.<sup>14</sup> This scheme was developed and adopted by large food retailers. While the initial motive was to secure compliance with the law rather than reassure consumers, it is noteworthy that its adoption was spurred in some countries by food scares that undermined consumer confidence in the safety of fresh fruit and vegetables, as was the case in Germany (Rodman, 2008). One initial driver for the development of this standard was the 1990 Food Safety Act in the UK. This introduced *strict liability* for food business operators. This means that they could not claim a warranty defense—in other words, a defense that they purchased the food in good faith with a warranty from the supplier, with the result that the supplier is responsible for any consequences of selling unsafe product. The Act allowed one line of defense for food business operators: they would not be found to have committed an offence if they could show that they had exercised “due diligence” in ensuring that the supply chain was delivering safe food (UK Government, 1990: Section 21, para. 1). GlobalGAP and other private standards relating to food, such as the British Retail Consortium’s Global Standards (see <http://www.brcglobalstandards.com/>), are believed to provide a due diligence defense.

In both the United States and the EU, food safety challenges have led businesses to lead the way in establishing preventive controls through the use of private standards backed up by audit and certification schemes. GlobalGAP, like the LGMA, originally adopted an approach using technology-based regulation, with early versions of the standard (which is revised every 4–5 years) dictating very specific procedures to be adopted at farm level to eliminate food safety risks. More recent

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<sup>14</sup>The scheme was later extended to a range of other agriculture and aquaculture products.

revisions have adopted a more management-based approach, requiring farms to develop credible assessments of risks to food safety, to implement plans to control for them and to take corrective action where necessary.

The role of government in this process is not straightforward. In the United States, continuing concerns about food safety eventually led to the FDA Food Safety Modernization Act (FSMA) being passed by Congress in 2010. The Act instructed the FDA to develop and introduce provisions for both increased use of preventive controls in food processing establishments and new, mandatory standards for the production and harvesting of “those types of fruits and vegetables that are raw agricultural commodities for which the Secretary [of Health And Human Services] has determined that such standards *minimize the risk of serious adverse health consequences or death*” (United States Congress, 2010: Section 105 (a)(1)(A), emphasis added). In other words, controls were needed because of unacceptable risks to human health arising from certain categories of fresh fruit and vegetables.

The rules subsequently introduced did mandate the introduction of a HACCP-based approach, with written food safety plans, monitoring, corrective actions and verification for food processing establishments. However, these establishments are not required to show compliance through certification. They are only required to provide documentation to the FDA showing that they have the required plans and processes in place, and it is far from clear how closely this documentation will be examined. Similarly, the extensive new rules proposed for regulating farm-level practices have explicitly ruled out the use of audit and certification for verifying compliance. The rules provide clear instructions and a legal obligation for farm to assess risks in their activities (e.g., through water testing and identification of animal intrusion) and take action when evidence of microbial contamination, or the risk of such contamination, is revealed. In spite of this, there still appears to be a presumption of innocence—no proof of compliance is required in advance of any inspection or identified contamination. The FDA does, however, expect that business pressures would lead to adoption of the rules. The 2013 proposed rule suggests that a combination of awareness raising and adoption by retailers of standards that will provide equivalent controls

at farm level, such as the LGMA and existing USDA certification programs (US Food and Drug Administration, 2013: 391–392) will promote adoption, while simultaneously suggesting that inspections by public authorities will not be the primary basis for securing compliance.

In Europe, Regulation 178/2002, also known as the General Food Law, introduced an EU-wide approach to food safety incorporating a risk-based approach. The guiding principles, which were subsequently incorporated into subsequent regulations on food hygiene, put risk management at the center of this approach. It specified that the elimination or avoidance of risks to health requires risk assessment, risk management and risk communication (paragraph 17), and emphasized the centrality of the HACCP methodology for achieving this goal. At the same time, the General Food Law put food business operators at the heart of the food safety regime. Paragraph 30 of the preamble to the General Food Law legislation states that: “A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety” (The European Parliament and the Council of the European Union, 2002). Furthermore, “feed and food business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that feed and food satisfy the requirements of feed and food law which are relevant to their activities” (The European Parliament and the Council of the European Union, 2004: preamble, para. 4).

How did these changes, which were primarily driven by concerns with tackling regulatory failures in domestic food industries, impact upon imports of food into the United States and the EU? In the United States, the new legislation did introduce specific obligations on food importers. The FDA Deputy Commissioner for Food, Michael Taylor, emphasized that importers would be made accountable for food imported into the United States, being obliged to verify that it was produced in accordance with US standards, or at an equivalent level of safety (Taylor, 2012). The proposed rule for importers issued by the FDA requires them to “develop, maintain, and follow an FSVP [Foreign Supplier Verification Program] that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and

procedures that provide at least the same level of public health protection as those required [for food establishments and for fresh produce safety in the United States]" (US Food and Drug Administration, 2014: 9). The proposed rule sets out three options for meeting this obligation: (1) for the importer to arrange for on-site audit and documentation of the foreign supplier by a "qualified auditor," as defined by the FDA; (2) to rely on FDA inspection of the foreign establishment; (3) for inspection by an officially recognized food safety authority in those countries whose food safety systems have been approved by the FDA. In this last case, the importer is still obliged to verify that the operation complies with the rules of the local food safety authority.

This is a significant increase in the obligations placed on importers, particularly with respect to food processing establishments. A presumption of innocence remains (as it does for the UK Food Safety Act), because it is not clear that importers have to provide proof of the effectiveness of the measures they are taking.<sup>15</sup> However, there would be severe penalties for not having a FSVP, and risk-averse importers would adopt one of the three options in order to meet their legal obligations. Given that the rules for food processing establishments appear to indicate that third-party certification provided by private standards-setting organizations may provide evidence of compliance with FDA requirements, importers might regard such certification as a convenient means of meeting their obligations.<sup>16</sup>

In the case of the EU, a literal reading of the regulations on food hygiene introduced in 2004 would suggest that with respect to food of non-animal origin (including fresh fruit and vegetables) food business operators in third countries are expected to comply with food hygiene

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<sup>15</sup> As Coglianese and Lazer (2003: 699) point out, there are varying degrees of oversight associated with management-based regulation. This can range from no examination of the systems put into place up to detailed analysis of the steps taken to ensure conformance to legislation.

<sup>16</sup> The rule for food processing establishments does not endorse third-party certification, but it does state that "to the extent that scientific and technical information available from GFSI or another standard setting organization provides evidence that a control measure, combination of control measures, or the food safety plan as a whole is capable of effectively controlling the identified hazards, a facility may use such information to satisfy the validation requirements of the rule" (U.S. Food and Drug Administration, 2015: 56054).

regulations (European Commission, 2006: 14–15), and as a corollary, importers have a responsibility to ensure that there are sufficient food safety controls in place in the country of origin. The legislation states that: “Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognized by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein” (The European Parliament and the Council of the European Union, 2002: Article 11).

But how difficult is this? There is the possibility that products imported from countries that have food safety controls validated by the EU would generally be accepted as being safe, with no obligations on businesses, but obligations on governments to show that the competent authorities for food safety are in fact competent. In fact, controls appear even less stringent than this. The EU guidance notes on food imports and hygiene regulations state that “with regard to food of non-animal origin, it is in many cases sufficient that exporting establishments in third countries are known to and accepted as suppliers by importers of food into the community” (European Commission, 2006: 10). A study by Neeliah et al. (2013) of exports of shrimp and fresh vegetables from Mauritius suggests that the controls facing fresh vegetable exporters are substantially less demanding than for those exporting fishery products. The exceptions to the presumption of innocence are products with known risks (such as nuts from countries with previous records of aflatoxin contamination), for which intensified border inspections are required, and for which improved access to the EU market is dependent upon preventive controls being introduced by governments and the exporting countries. A discussion of exporting country responses to aflatoxin restrictions and the types of preventive controls that might be adopted can be found in the study by Diaz Rios and Jaffee (2008).

Controls over fresh produce imports only increase after non-compliant products have been detected. In spite of this, the use of preventive controls by large food retail companies in some European countries has increased. As was noted previously, one reason for this is the overall legal requirement to place safe food on the market and the adoption of



standards as a strategy for containing the risks from possible food safety lapses—risks to food retail businesses as much as to consumers. This can also be seen as a brand protection strategy by large retailers. In the UK, brand protection issues would have been exacerbated by the issue of due diligence.

In the fresh fruit and vegetables sector, then, governments have created legal frameworks that make businesses responsible for the safety of imported food that they might place on the market. Preventive measures are not obligatory and an assumption of innocence still prevails. Nevertheless, there are two ways in which the new food safety measures have impacts on exporting countries. The first is that governments may promote the adoption of new food safety standards in exporting countries because of the reduced controls placed on exports from countries that can demonstrate that their food safety systems are effective. Second, the responsibilities placed on businesses by the new regulations introduced in the past two decades, combined with the strategic role of large businesses for whom brand reputation is a significant and valuable commodity, have been sufficient to promote the development and adoption of controls, including private standards, that make the use of preventive methods into the production and processing of fresh fruit and vegetables a requirement for entry into some significant segments of export markets. As will be seen in subsequent papers in this volume, GlobalGAP has knock-on effects in other countries, and its relevance for producers in the ASEAN region is discussed in this book by Nabeshima and Michida.

### 2.3.3 Chemicals

The chemical industry is a global industry. Global trade in chemicals has expanded very rapidly in recent years, and there has been a considerable growth in chemical production and export by developing countries. The chemicals sector is also global in terms of its impacts, which have transboundary effects. These arise from trade in chemical substances and mixtures and from trade in products which incorporate chemicals, as well as from the release of chemicals into the environment and their

spread around the world. With respect to the second effect, there are tens of thousands of chemical substances that are considered as dangerous for health or for the environment, and many substances are found in humans (including newborn infants) and in the oceans and uninhabited parts of the planet (Bengtsson, 2010: 183–184). Persistent, toxic chemicals that bioaccumulate are a particular concern because of the risks to the environment and to human and animal health.

Reflecting these risks, a large number of transnational agreements on chemicals management have been implemented. Some specific international conventions have been created to address some of these issues. As described by Selin (2013: 111–116), the global chemicals regime consists of a number of binding conventions (Basel on trade in international waste, Rotterdam on informed consent prior to trade and the Stockholm Convention on persistent organic pollutants).<sup>17</sup> Alongside these conventions, there are also many other transnational initiatives—“with upwards of 100 international agreements, programs and initiatives on chemical safety” (Bengtsson, 2010: 204). This is why Selin refers to a global chemicals regime: “Rather than organizing cooperation under an overarching framework convention, as in for example the cases of climate change, ozone depletion, and biodiversity, international legal and political efforts to address problems of hazardous chemicals are structured around a diverse set of legally independent treaties and programs” (Selin, 2013: 107).

In part, this diversity reflects divisions between the major powers about how to approach chemical safety (Bengtsson, 2010: 205). These divisions came out very clearly in the difficulties that arose in the negotiations that led to the creation of the SAICM. This pursues the goals set out by the World Summit on Sustainable Development in 2002—that “by the year 2020 chemical should be produced and used in ways that minimise significant adverse impacts on the environment and on human health” (Bengtsson, 2010: 188). However, the approach to be adopted by SAICM was the subject of intense negotiation, with disagreements about whether it should incorporate a legally binding

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<sup>17</sup> See also the account by Simon (2012: 20–21) of these Conventions.

agreement and the use of the precautionary principle (Perrez, 2006: 250–252). As was noted in the case of forestry, the failure to achieve inter-governmental responses to global problems was a factor in creating transnational private governance initiatives. In the case of chemicals, the initiatives have been public and transnational, with the EU REACH program particularly important.

The main conventions on control of chemicals are targeted at particular substances and mixtures that have been identified as particularly hazardous for humans, animals and the environment. However, one of the challenges of chemical regulation is that among the many thousands of chemicals that are produced and used, information about their toxicity is lacking and also quite hard to establish. Here, national regulations on production, storage, use and recycling are more relevant. The traditional approach to chemical regulation worked on the basis of “acting only against proven effects” (Hansson & Rudén, 2010: 73), even though minimal information was available on the toxicity of many chemicals.<sup>18</sup> In other words, there was a presumption of innocence.

The shortcomings of this approach have been highlighted by critiques of the 1976 Toxic Substances Control Act (TSCA) in the United States. It has been characterized as ineffective in either “assessing the hazards of the great majority of chemicals” or “controlling those of greatest concern,” or “motivating investment in . . . cleaner chemical technologies” (Schwarzman & Wilson, 2011: 103). The TSCA puts the emphasis on government (the Environmental Protection Agency) to provide scientific proof through a quantitative risk assessment that chemicals are dangerous before their production or use can be restricted, but it places no obligation on chemical companies to create or provide the information that might support a proper assessment. As has been argued forcefully by Sachs, “The default presumption of TSCA, therefore, is that the vast majority of chemicals can be freely marketed, even absent any toxicity testing, unless and until EPA can prove that they pose unreasonable risks” (Sachs, 2009: 1827).

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<sup>18</sup> According to Hansson and Rudén, this lack of information extends even to the chemicals produced in the largest volumes (Hansson & Rudén, 2010: 72).

In the EU, the “presumption of innocence” stance held until the 1990s. Then, a series of chemical disasters pointed to the weakness of EU legislation. Just as food safety crises led to the White Paper on food safety in 2000, a review of EU chemicals regulation was launched in 1998 and a White Paper on chemical safety produced in 2001 (Hansen & Blainey, 2006: 270–271; Heyvaert, 2010: 219–220). This process culminated in the REACH Regulation in 2006. This legislation represented a paradigm shift in chemical regulation:

“With the enactment of REACH in 2006, the EU launched a second generation of chemical regulation. The legislation is, in many respects, the ‘anti-TSCA’—the transatlantic converse of the American regulatory regime. It fundamentally reshapes the €537 billion European chemical market and embodies a new paradigm in global chemicals management in which the burden of proof on chemical safety is shifted from government to industry for the most hazardous classes of chemicals” (Sachs, 2009: 1833).<sup>19</sup>

The presumption of innocence is replaced by a presumption of guilt. In order to gain access to the EU market, chemical companies need to provide data to show that products are safe. REACH places the onus on producers and importers of chemicals to provide the relevant data. The data required covers both hazards and risks. Hazards are the result of the intrinsic characteristics of a chemical, while data on risk “combines laboratory findings of hazard with analysis of actual human exposure to the compound. Risk, therefore, is the product of hazard and exposure” (Sachs, 2009: 1835–1863). This hazard and risk analysis requirement is usually summed up in the expression “no data, no market.”

The data requirement is a fundamental element of chemicals risk management, as discussed by Bucht (2010).<sup>20</sup> It provides information about the hazardous properties of chemicals. This information is also transmitted along the value chain so that users of chemicals are properly informed about their properties. Chemical use information is also central to risk analysis, as this is

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<sup>19</sup> Similar arguments are made by Schwarzman and Wilson (2011: 103–104).

<sup>20</sup> For an analysis of the content of the REACH legislation and what it is designed to achieve, see Karlsson (2010), Biedenkopf (2015) and Heyvaert (2010).

the basis for calculations of exposure (by workers, by consumers, etc.). This information then provides public institutions with a basis for decisions about how to regulate particular chemicals. The data requirement places new responsibilities on the private sector in the same way that private sector obligations and actions were generated by EU regulations on food safety and forestry. It is businesses that are required to provide information and to conduct risk assessments. At the same time, businesses are obliged to provide information for downstream uses of chemicals (Heyvaert, 2010: 223). This is a major departure compared to the TSCA and to regulatory approaches in Canada and Japan (Naiki, 2010). As Heyvaert notes, however, this does not mean that public authorities abandon their responsibility for chemical safety. REACH involved a strengthening and centralization of EU authority to enforce chemical regulations (2010: 224).

The overall goal of REACH is to achieve the safe production and use of chemicals in the EU. In order to achieve this, the EU has obliged chemical companies from many parts of the world to meet EU requirements with respect to information provision, compliance with restrictions on usage and investigation of possible substitutes. By shifting the burden of proof in one of the largest chemical markets in the world, the legislation promotes sharing of information about chemical hazards across many different countries. It also provides information that can be used by many authorities, public and non-public, and has encouraged harmonization and emulation. It provides a template for governments seeking to raise levels of control over chemicals, and a challenge to governments that do not.

The REACH legislation clearly uses access to the EU market to impose European norms and standards on other countries. Businesses in other countries have to change the way that they obtain and provide data on the safety of chemicals marketed in the EU, as discussed by subsequent chapters in this volume. Biedenkopf (2015: 122) shows that almost one-quarter of chemical dossiers provided by companies were submitted through the representative bodies appointed by foreign companies to make submissions. This figure does not include submissions by European subsidiaries of transnational companies, so the overall level of submissions by foreign companies would be even higher. This is the most direct way in which EU regulations impact on other countries, but just as VPAs in forestry are designed to affect trade with third countries, REACH will have broad impact through its influence on

policy development in other countries. At the most basic level, this might arise through the use of the data generated by REACH to inform domestic decision-making. This is seen clearly in the case of the response in California: “In crafting its new chemicals policy, California is looking to Europe for regulatory models, chemical lists developed under EU directives and for potential hazard data that could become available under REACH” (Schwarzman & Wilson, 2011: 116).<sup>21</sup>

The response of other governments to EU regulations could vary considerably, as has been argued by Sachs (2009: 1847–1854)—ranging from opposition (including through the WTO)—not responding because the costs outweigh the benefits, harmonizing domestic regulations with REACH requirements and seeking transnational regulation as a means of providing an acceptable substitute for REACH.<sup>22</sup> The case of California indicates that government (in this case the State government) responses will partly be determined by their appetite for regulation, with the federal government in the USA taking a more oppositional stance. The choice of response(s) will also be influenced by the costs and benefits of incorporating REACH-like controls in the domestic market—how important is the export market in general and the EU market, how big a change will be required and what will be the costs? Exporting countries may decide to do nothing, leaving the response to private businesses, but even if this is considered to leave too much of a burden on the private sector and to potentially undermine competitiveness, the level to which domestic regulations are harmonized with REACH will vary. This comes out clearly in the analysis of the Japanese response to REACH provided by Naiki (2010). Japanese authorities have not replicated REACH in domestic legislation, although there are controls on production and use of chemicals that are more stringent than in the United States. The responses of other businesses and governments in Asia to REACH and RoHS regulations are discussed in subsequent papers in this volume.

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<sup>21</sup> For further discussion of the use of the data on chemicals generated by REACH, see Biedenkopf (2015: 125–126).

<sup>22</sup> For countries closely tied to the EU market, such as the countries of the European Economic Area, there is no choice but to closely harmonise domestic regulations with those applying within the EU (Heyvaert, 2010: 230–231).

## 2.4 Conclusions

The literature on private standards has pointed to the limitations of government regulations in a globalized world, and there has been increasing recognition of the importance of business actors in regulating production and trade through the use of private standards. However, these trends should not obscure the continuing role of public regulations—not only in placing constraints and requirements on traded products, but also the potential of these regulations to directly impact upon production systems in exporting countries.

The analysis of the regulation of production and trade in the forestry, fresh fruit and vegetables and chemicals sectors shows that, first, preventive controls—controls that introduce obligations on producing and importing businesses that are designed to reduce or eliminate risks—can be developed and adopted by private companies or by a mixture of business and non-business actors. This is seen clearly in the private standards developed in the forestry and fresh produce sectors. Nevertheless, it is also apparent that the growth of private standards has, itself, been shaped by public interventions. In some cases, governments may actively promote private certification schemes when they recognize their role in providing effective preventive controls and offer private certification as one strategy for demonstrating compliance. In forestry and in fresh produce, the use of private standards is one of the options foreseen by legislation concerning import safety. In addition, private standards have also been developed by businesses in response to the legal environment created by national governments. These legal frameworks place obligations on businesses and expose them to certain risks arising from non-compliance, and private standards are then developed as a means of meeting the obligations and reducing risk exposure.

Second, it is clear that some governments—and in this paper the focus has been mostly on the EU—are able to use market access as a means of securing changes in exporting countries. In some cases, as with food safety, the changes may be aimed at improving the safety of products exported to the EU, but in other cases, the goal is much broader. In the case of forestry, one salient feature of the EU's VPAs is their intent to influence forest

management through establishing legality norms that apply to all exports (including third countries) This concern with products that will not be imported into the country originating the regulation is a logical outcome of the recognition of the indirect harm that can arise from practices that, for example, undermine biodiversity or increase GHG emissions.

Third, it is clear that import controls sit alongside intergovernmental treaties, a broad range of global initiatives (such as SAICM) and bilateral agreements. There is a broad arsenal of attempts to manage globalization, and different sectors may benefit from different initiatives. Governments, too, may make different strategic choices about the use of instruments. Across the three sectors, there are marked differences in the nature of public interventions.

Fourth, the precise impact of preventive controls can vary considerably according to the way in which they are implemented. It was argued that the switch from a presumption of innocence to a presumption of guilt has a major impact on the challenges facing exporting countries and exporting businesses. How developing country governments and businesses respond to the challenges created by the increased use of preventive controls is the subject of the papers in this volume.

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**John Humphrey** was a professorial fellow at the Institute of Development Studies at the University of Sussex for many years and is currently a Visiting Professor at the School of Business, Management and Economics at the University of Sussex. He has researched and published extensively on global value chains, contributing both theoretical papers and empirical analysis, with particular attention paid to the global food industry. More recent work has focused on value chains and food standards. He has provided consultancy services to many international organizations on value chain issues.