Limits of self-regulation in international phytosanitary policy

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1 Introduction

Phytosanitary regulations are important to allow for the smooth movement of goods worldwide as well as within the European Union (EU), protecting plant health as well as the natural environment. In accordance with international agreements, phytosanitary regulations from standard setting to conformity assessment and monitoring have been assigned a public task which is carried out by government authorities. The private sector needs to comply with these phytosanitary requirements, and it is usually the private sector that is actively involved in handling phytosanitary risk within the chain. This report provides insights into possible options to give more responsibilities to the private sector and how such possibilities could be accommodated in the existing International Plant Protection Convention (IPPC) and the EU regulations for plant health. Conceptually, the relationship between self-regulation by the private sector, including firms themselves, and international standards will be elaborated to point out options for engagement of private sector initiatives. The focus is on options for the plant sector from the legal perspective, but examples of initiatives taking place in other sectors and aiming at goals beyond plant health are chosen as case studies. The first case study is on food safety in the EU, which constitutes a particularly interesting example because recent reforms changed the public and private roles in the EU judicial domain of food safety. The second case study is on industry-issued certificates within the US Mill Certification Program.

The report is structured as follows: in Chapter 2 we elaborate on a conceptual framework for the analysis of self-regulation by giving definitions and scoping. The framework was developed by Erik de Bakker and Marie-Luise Rau. Chapter 3 presents the legal analysis of options for self-regulation of plant health and protection from the international and EU perspective. Dutch law is covered to a certain extent. The legal analysis was conducted by Harry Bremmers and Anna Szajkowska. Chapter 4 contains two case studies to demonstrate examples of self-regulation: the example of the private firms' responsibilities for food safety according to EU food law was analysed by Marie-Luise Rau. The example of industry-issued certificates in the US was analysed by Harry Bremmers and Marie-Luise Rau. The report ends with a summary and conclusions on the option of private sector involvement in tasks in plant health protection and control that have traditionally been in the public domain.

2 Analytical framework: definitions and scope

2.1 Regulation between public interests and self-regulation by firms

Regulation is strongly associated with state law and some form of a 'command and control' mechanism. However, regulatory scholars make clear that regulation is increasingly being seen as 'decentred' from the state (Black, 2002). Law is an important regulatory mechanism, but other mechanisms can be considered equally important. More broadly, regulation could be defined as:

> 'The sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome, which may involve mechanisms of standard-setting, information-gathering and behaviour-modification' (Black, 2002: 34).

According to this definition regulation is the intentional activity of attempting to control, order or influence the behaviour of others. Law can be analysed as but one of regulatory mechanisms in terms of its effectiveness, responsiveness and coherence, and in terms of its interaction with other regulatory tools. In this context, also self-regulation can be a regulatory tool. Self-regulation can be described as arrangements whereby private parties are assigned responsibilities for standard setting and compliance control. So self-regulation includes the possibility for economic operators, the social partners, non-government organisations, or associations, to adopt amongst themselves and for themselves common guidelines (particularly formulated in codes of practice or sector agreements).

Regulation deals with public interests that are addressed by some kind of governmental intervention. Public interests relate to societal interests, but societal interests are not necessarily public interests that the government should deal with. Providing sufficient food for society (food security) is a societal interest that can be organised by the market just as the societal interest of a well-functioning civil society can be fulfilled by the citizens themselves. Public interests are societal interests that the government should feel responsible for because it is believed that these societal interests can or will otherwise not be protected by other members of society. The question what constitutes a public interest is a political question that cannot be answered by science (WRR, 2000). However, the question which regulation mechanisms seem most fit to realise and guarantee a public interest has a less political nature. The question about the *how* deals with weighing the pros and cons of certain policy option that can be - to a certain degree - objectified.

Both public and private actors can take operational responsibility to secure a public interest. More generally, the WRR (Scientific Council for Government Policy) argues that what is politically considered as a public interest can be realised through several routes of regulation.

> 'Private organisations do not always function more efficiently than public ones, neither is the handling of public affairs by definition more democratic or meticulous in the hands of public organisation than private ones. [...] Which system of sureties is most suitable, depends on the nature of the public affair and to what extent issues such as effectiveness, efficiency, democratic legitimacy, legal certainty, and equality before the law are considered important.' (WRR, 2000: 10)

According to this view, self-regulatory mechanisms and private arrangements can be in place to secure public interests. With regard to phytosanitary issues, Bremmer and Slobbe (2011) mention that the public interest is served 'privately where possible and publicly where necessary'. They particularly derive a framework for analysing the interests of phytosanitary risks to help choose an appropriate governance approach.

In the Netherlands, self-regulation was a tailpeace of the deregulation policy that made its appearance in the 1980s. The Dutch government was trying to lessen the burden of administrative rules and create better economic opportunities for private enterprise. Firms themselves could decide to fill the gap resulting from the policy approach of deregulation and develop their own private regulation. This deregulation policy changed in the 1990s (Oude Vrielink, 2011). Since then a more pro-active government view came to the fore. Self-regulation was increasingly seen as a policy instrument that the government could develop in coalition with private parties. Hence, a more active policy approach was introduced, leading to various supervisory arrangements whereby private parties were assigned more responsibility for compliance with statutory regulations. Government authorities operated at a greater distance but often retained ultimate responsibility.

Looking at the literature on regulation and self-regulation, a continuum of regulation mechanisms can be identified. On the one end, there are pure governmental regulations, while on the other end there is pure and complete self-regulation. In between there is a range of regulation mechanisms in which vertical (top-down) and horizontal (bottom-up) policy instruments are mixed. Table 2.1 gives an overview of the different regulation mechanisms identified and how the respective mechanisms are developed, implemented, monitored and maintained. In the context of self-regulation, co-regulation is sometimes mentioned as another regulation mechanism. Co-regulation means that a legislative act entrusts the attainment of the objectives defined by the legislative authority to parties that are recognised in the field (such as economic operators, social partners, non-government organisations or associations) (Baldwin and Cave, 1999). On this basis, co-regulation can be defined as self-regulation of industry associations with some oversight and/or ratification by governments, thereby taking the form of covenants or legally conditioned self-regulation (see Table 2.1).

Table 2.1 Regulation mechanisms on a top-down/bottom-up continuum

Regulation form	**Development, implementation, monitoring, and enforcement**
Pure government regulation (top-down)	Government authorities are in charge
Covenants	Different tasks and expectations established in binding agreements with (semi-)public or private parties
Legal conditioned self-regulation	Consigned to (semi-)public or private parties under legal conditions, government supervision on results
Substitutionary self-regulation	Consigned to (semi-)public or private parties, government at the background (fall-back role)
Pure self-regulation (bottom-up)	Private or (semi-)public parties in charge

Source: De Bakker et al. (2007: 13).

Self-regulation is often used as an overarching concept that covers different regulatory schemes in which private parties are involved. However, some scholars have argued that such a general use is questionable. In a strict sense, one could argue that the concept of self-regulation should only be used for regulatory arrangements whereby the development, implementation, monitoring, and enforcement are completely done by private parties or their representatives. One could also argue that 'pure' self-regulation can be seen as the ultimate form of governance because the arrangements are completely 'bottom-up': also the norms for the rules that should be complied with are set by private parties. However, in practice most instances of self-regulation are bound by strict legal frameworks or under some kind of surveillance by government agencies. Moreover, as Havinga (2006) states, there is often the implicit threat of imposed government regulation in case this associational self-regulation becomes derailed.

These forms of restricted self-regulation, often referred to as structured or conditioned self-regulation, illustrate the limits of the widely discussed transition from government to governance (De Bakker et al., 2007). In line with this argument, a conceptual distinction can be made between self-regulation or pure self-regulation and alternative regulation (Witteveen et al., 2007; Oude Vrielink, 2011). The concept of alternative regulation should be applied to all policies that aim to mobilise the self-regulating capacity of the private sector within strict legal boundaries. Although this conceptual distinction is valuable, the term

'alternative regulation' is not very common and might therefore lead to misunderstanding. In this report, we will use the categorisation of self-regulation presented in Table 2.1.

Appendix 2 gives an overview of factors that determine the successful use of self-regulation, for example sector characteristics, firm behaviour and last but not least type of market failure and associated problems that are to be addressed by the regulation mechanism. The list of factors presented has been compiled by Boom et al. (2009), who analyse self-regulation of business to consumers (B2C) marketing, trade practices and advertising of goods and services. Balk-Theuws et al. (2004) look at similar factors in their evaluation of the option of phytosanitary inspections and control by private firms in the agri-food sector, more specifically the bulb sector.

2.2 Framework of regulatory elements

The system to control food safety, animal and plant health issues is rather complex with different types of regulatory elements. For the general framework of the analysis conducted in this report, we distinguish between four broad regulatory elements: 1) requirements and standard-setting; 2) implementation and monitoring at the firm level; 3) conformity assessment and 4) certification.

Table 2.2 gives an overview of the four regulatory elements, including examples. First, there are the requirements that are imposed on products or production processes, such as maximum residue levels (MRLs), the prohibition or bans of products or ingredients used in the production as well as process requirements. This includes the important question about who is involved in the standard setting. The implementation and monitoring at the firm level is considered another category of regulatory elements. Note that there is an overlap with certain process requirements that ensure that product requirements are met, for example the requirement of hazard analysis and critical control point (HACCP) to ensure a certain level of food safety (compare Chapter 4.1). According to the definition of regulatory elements as suggested, conformity assessment refers to testing, controlling and auditing at various stages of the production and supply chain (see Table 2.2). Conformity assessment is generally used to check if certain requirements are met. Those firms that comply are certified. Certification is the process that guarantees conformity and communicates that firms comply with the requirements demanded. In this sense, conformity assessment and certification are interlinked.

Table 2.2 Types of different regulatory elements in agri-food control

Requirements and standard setting	Implementation and monitoring at the firm-level	Conformity assessment	Certification
Maximum residue levels (MRLs) Process requirements (good agricultural practice, fumigation, irradiation, etcetera) Bans Quarantine requirements	Process orientation, process-control systems Reporting and documentation, record-keeping requirement	Controls at the border Controls at the source (firm level) Inspections and testing Auditing	Using information provided by firms, self-declaration Certificates issued for bundles of products, firms, countries Establishment approval, pre-listing

Source: based on Rau et al. (2010).

The public and private sector are more or less involved in the different regulatory elements. The involvement depends on legal provisions, and the principles underlying the control systems. The analysis conducted in this report specifically looks at the options of private involvement in terms of self-regulation in the aforementioned regulatory elements.[1]

[1] The regulatory element of border control was assessed with regard to the options of self-regulation of plant health in Dutch horticulture, more specifically the option of self-regulation of phytosanitary inspections and in consequence a reduction of border inspections by the government; see Balk-Theuws et al. (2004).

2.3 Legal, socio-economic and social-ethical issues of regulation and self-regulation

Looking at regulations in general, we broadly distinguish between legal, socio-economic and social-ethical issues. These three types of issues and questions associated are presented in Table 2.3. The questions associated should be addressed when evaluating whether self-regulation or a certain form of self-regulation makes sense in order to reach certain goals. The issues and questions are elaborated on in the remainder of this section.

Table 2.3 Legal, socio-economic and social-ethical issues and questions

Dimension	Issues	Questions
Legal	National regulations International and EU regulations Legal institutions	Questions concerning law and regulation, developments, tensions between different legal systems and institutions
Socio-economic	Costs and benefits for government Costs and benefits for firms Costs and benefits for society	Questions concerning costs and benefits for different stakeholders are for example: - Who wins, who loses? - Can costs and benefits be made transparent? - Which financial incentives are most efficient and effective? - What is the balance between economic costs and specific degrees of food safety?
Social-ethical	Public support and legitimacy Impact on other food values (sustainability, fair trade et cetera)	What about social and environmental effects, national and international? What about democratic values, looking at the criteria of participation, transparency and accountability (see Fuchs et al., 2011)

Legal issues and questions

Legal issues concern the opportunities and barriers in international and regional law or EU law on the involvement of private parties in the process of plant protection. The question is whether there are opportunities for private involvement in the requirements to prevent issues of plant health and risks. If yes, what are the opportunities and barriers to private involvement? The following three aspects, which are interrelated, seem to determine the legal possibilities for private sector involvement in plant health and should therefore be considered in the subsequent analysis:

- The effect of prevention of plant pests on international trade: this falls within the scope of WTO/GATT, FAO and IPPC.
- The relationship with the production of high quality plants (which is a matter of Common Market Organisation as well as activities of producer associations).
- The relationship between EU law and the IPPC.

Socio-economic issues and questions

In the presence of information problems and externalities, market mechanisms fail to ensure the desired level of phytosanitary protection, food safety and quality of products, leading to a sub-optimal market outcome. A sub-optimal market outcome refers to an undersupply of products that consumers desire and are willing to pay for.[1] As far as information problems are concerned, providing information to consumers would in theory solve the sub-optimal market outcome, with producers supplying the range of quality products buyers are willing to pay for. However, this may not be true for the case of externalities where

[1] For example, in the case of information problems, Akerlof (1970) described the so-called lemon problem as follows: If consumers do not have information about products, producers tend to produce lower quality levels such that high quality products are undersupplied or may even disappear from being offered.

negative external effects occur and the resulting costs of pollution, food scare or disease are not accounted for in the production decision.

Externalities stand in close relation to public goods, and public-good arguments have often been used to justify governmental regulations. For example, health and food safety is generally considered to be a public good, while other quality-related aspects may not clearly exhibit the properties of public goods (non-rivalry and non-excludability). Plant health is another important example and shall be looked at in detail in the legal analysis below. For a general concept of a market for plant health using public good arguments, see Lansink (2011).

In the context of public goods, the collective action is often mentioned as an issue as individual producers fail to effectively co-ordinate and control activities along the supply chain. That is, individual producers' efforts for example tend to be insufficient to control animal and plant diseases. While being costly for consumers and society as a whole, the consequences also negatively affect the entire sector, and those causing the problems are difficult to be tracked and identified. From the economic point of view, there are costs and benefits of self-regulation. The methodological problems measuring associated costs and benefits are well-known and have been widely discussed; see for example De Bakker et al. (2007): 20-21; Oude Vrielink (2011): 11-13; Baarsma et al. (2004).

In general, the question arises whether self-regulation is really cheaper than interventions such as policy measures by governments. A comparison is generally challenging, partly due to the measurement issues. Self-regulation may be successful because of other benefits such as the better use of expertise on the spot, which allows for considerable flexibility in comparison to rigid rules and regulations. Furthermore, self-regulation could create more private commitment because of involvement, but when applying the principles of good policy-making, governmental regulations are of course also developed with the involvement of the private sector. In general, the frustration of 'command and control at a distance' can be tackled by direct personal contacts on a regular basis. More examples are provided in Appendix 1, where the costs and benefits are summarised as advantages and disadvantages of self-regulation in comparison to governmental regulations.

Social-ethical issues

The policy debate on self-regulation should not be restricted to economic efficiency. In this context, it should not be assumed that more effective control systems would guarantee a higher level of societal support (a policy strategy that is also known as 'output legitimacy'). Self-regulation could provide more legitimacy and public support when it contributes to a more effective and efficient dealing with food safety, but the evidence seems to be problematic. There may be cases where leaving regulatory matters to the private sector and firms can lead to effects on environmental and social values, which are undesired by society as a whole. This also relates to the issues of externalities described above. Moreover, the concept of output legitimacy is frequently used as justification for the democratic legitimacy of features of private governance by sweeping and superficial terms. The issue of economic efficiency in the context of self-regulation is also complicated by the fact that the costs of regulation and (cultural) risk perceptions are interconnected. The higher the level of safety that will be considered socially acceptable, the more costs it will take to create a system to control this risk satisfactorily. Therefore, societal expectations and the demands concerning food safety can be considered to have great influence on monitoring and control (De Bakker et al., 2007: 19-20).

The effect on power relations in the sector is another important issue. For example, small farmers and firms tend to be confronted with demands and requirements that are hard for them to fulfil, often leading to considerable compliance cost that cannot be reduced by economies of scale or facilitated by investment options. The resulting issue of market access has been widely analysed in the literature, in particular in the context of firms in developing countries' access to markets of industrialised countries (see e.g. Jaffee and Henson, 2001). Concerning social-ethical issues, another important question refers to the influence of different stakeholders in the process of setting standards; see for example Fuchs et al. (2011). Specifically for food-safety standards, see Henson and Humphrey (2009). Next to stakeholder involvement or participation, transparency and accountability are other important social-ethical issues.

2.4 Approach of legal perspective: International and EU plant health

This report addresses the legal environment for plant health and protection at different institutional levels as follows:

- International: World Trade Organisation (WTO), in particular the TBT and SPS Agreement, Food and Agriculture Organisation (FAO), International Plant Protection Convention (IPPC); the EU as member implements the Convention in EU law. However, the IPPC guidelines (ISPMs) are optional to follow.
- EU level, including implementation of EU legislation into national Dutch legislation. National legislation of the EU member states implements EU directives and regulations as well as ensuring compliance with the EU rules.

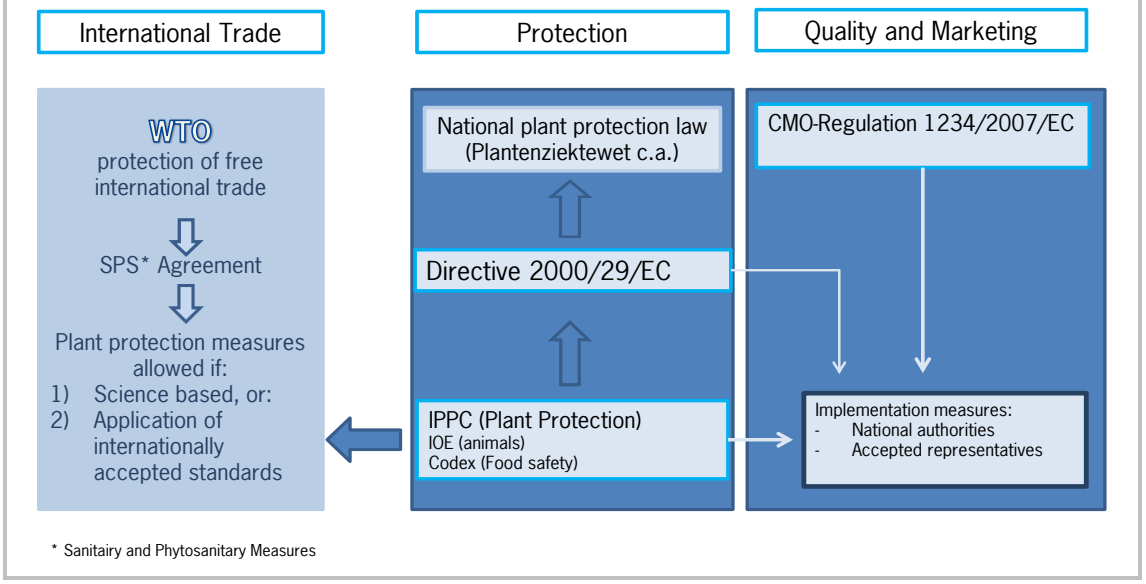
The following three areas of regulation are discerned according to the aims for which standards and controls are designed:

- The protection against plant pests[1] and improvement of productivity by protecting plant health - designated as plant protection.
- The smooth functioning of markets at the international, EU and national level trade objective.
- The protection of the quality of plants - marketing standards relating to trade and quality of plant and plant products in the context of common market organisation (CMO), which provides quality standards to promote the smooth exchange of products in the EU, including plant products.

These key areas of free trade, plant health and plant quality are interrelated, as illustrated in Figure 2.1. The aim of the legal analysis is to assess the structure of laws governing the prevention of the spread of plant pests; to consider the effects of measures on free international trade and plant quality and to analyse whether the involvement of private players in the process can be increased without violation of the international legal requirements. The three key areas will be addressed in Chapters 3 and 4, respectively from the international and EU perspective.

[1] A pest is any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products (International Standards for Phytosanitary Measures - hereinafter referred to as ISPM No. 5). Interestingly, the interpretation applied with reference to the SPS Agreement seems to be broader: 'pest' under the SPS Agreement is understood as 'an animal or plant which is destructive, or causes harm to the health or other animals, plants or humans, or other harm, or a troublesome or annoying animal or plant' (Panel Report, EC - Measures Affecting the Approval and Marketing of Biotech Products, WT/DS/291/R, WT/DS292/R, WT/DS293/R, adopted 21 Nov. 2006, par. 7.240)

Figure 2.1 **Legal fields affecting outsourcing possibilities**



3 International institutional and legal environment for plant health protection

We will first address the international trade environment for the protection of plant health: the SPS Agreement governed by the World Trade Organisation (WTO). As shown in the first column of Figure 2.1 (presented in Section 2.4), standards, guidelines and recommendations developed in the context of the International Plant Protection Convention (IPPC) can form a base for exemptions to the general principle of free trade with the aim of preventing plant pests to spread. Next, we address the contents of the International Plant Protection Convention and the space it provides for private party involvement in standard setting and implementation. We then will show that the EU Directive 2000/29/EC has adopted the principles of the IPPC.

3.1 WTO: GATT 1994 and the SPS Agreement

The World Trade Organisation was established in 1995 to ensure that trade between nations flows 'as smoothly, predictably and freely as possible'. The WTO agreements are the result of the 1986-94 Uruguay Round of negotiations, signed at the Marrakesh ministerial meeting in 1995. The WTO regime is the successor of the system created in 1947 by the General Agreement on Tariffs and Trade (GATT). The WTO promotes free trade worldwide and provides a meeting place and dispute settlement function to mitigate the effects of international trade barriers. Under the WTO a new set of rules, especially concerning the problem of non-tariff barriers to trade, was introduced, in addition to the 1994 GATT.

Because WTO Agreements bind its members, the WTO plays a role in the application of plant health standards in trade and in dispute resolution. The Dispute Settlement Understanding provides a procedure to resolve conflicts. If a party so requires, the Dispute Settlement Body (DSB) forms a panel to deal with the issue. Panel decisions can be appealed to the Appellate Body (AB). The WTO cannot enforce decisions taken in this procedure. It can, however, allow the winning party to implement economic sanctions if the party found at fault does not comply. These sanctions are usually additional import levies on goods from the member found at fault.

Although the WTO consists of about 60 different agreements, only two are of direct relevance to the area of plant protection. These agreements are GATT 1994 and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The next sections will briefly describe the content of these agreements and how to navigate between them.

General Agreement on Tariffs and Trade (GATT) 1994

GATT 1994 is a basic act concerning trade in goods, with the purpose of the 'substantial reduction of tariffs and other trade barriers and the elimination of preferences, on a reciprocal and mutually advantageous basis' (preamble). ArticleXXb of the Agreement allows WTO Members to introduce trade restrictions on grounds of the protection of human or animal life or health (sanitary measures) or plant life or health (phytosanitary measures). Members have the right to take these measures as long as they are not applied in a manner that is arbitrary or leads to unjustifiable discrimination between countries, or constitutes a disguised restriction on international trade in goods.

With the progress in negotiating tariff reduction, the risk that countries use non-tariff barriers to trade to protect domestic industries increasingly became a problem. Among these non-tariff barriers, a wide range of measures aimed at the protection of human, animal or plant life or health were of special concern, as these measures mostly related to agricultural products. Under the WTO agriculture has been - up till now - one of the biggest challenges to liberalisation efforts. Therefore, the Uruguay Round established a separate Agreement on the Application of Sanitary and Phytosanitary Measures, laying down conditions for the application of these measures, extending and giving precision to the exceptions of GATT Article XX.

Text box 3.1	GATT: General Exceptions

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
(a) necessary to protect public morals;
(b) necessary to protect human, animal or plant life or health

Agreement on Sanitary and Phytosanitary Measures (SPS Agreement)

The SPS Agreement established conditions under which WTO Members can take sanitary and phytosanitary measures, with a view to reduce the negative consequences of such measures to trade. The Agreement allows taking sanitary and phytosanitary measures which are necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the Agreement (Article 2 SPS). Measures taken in concordance with the SPS Agreement are presumed to be in line with Article XXb GATT. SPS measures broadly include all relevant national laws, decrees, regulations, requirements, as well as procedures.

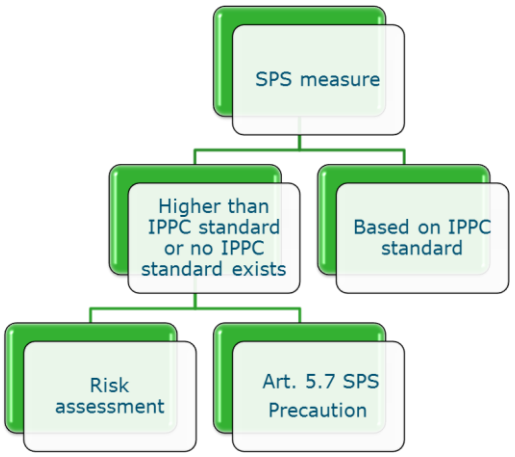
The SPS Agreement introduces a science-based regime governing international trade in agricultural products and foodstuffs. Article 2.2 of the Agreement states that WTO members shall ensure that any SPS measure is 'based on scientific principles and not maintained without sufficient scientific evidence'. Article 5 SPS introduces risk assessment as a method for determining the appropriate level of health protection, carried out according to the internationally developed techniques.

As we already mentioned above, the SPS Agreement sets the requirement that sanitary or phytosanitary measures are based on scientific evidence. The standards concerning food safety, animal and plant health that serve as a benchmark are developed outside the WTO. The SPS Agreement strongly encourages the adoption of international standards by its Members because SPS measures which are taken in line with these international guidelines, standards and recommendations are presumed to be necessary for the protection of human, animal or plant life or health (Article 3.2 SPS). In other words, in so far as measures are based on these internationally accepted standards, no separate scientific evidence is needed. Annex A states that the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organisations operating within the framework of the International Plant Protection Convention are recognised as relevant standards for plant health.[1]

In all other cases, Members have to provide scientific substantiation that their measure is necessary to protect plant health. Members may take measures that result in a higher level of protection than an international standard if human, animal or plant health are threatened. In doing so, they must provide scientific risk assessment. The same requirement of providing scientific risk assessment to justify national phytosanitary measures hindering international trade will exist for measures for which no international standard exists (Figure 3.1).The only exception to the obligation of providing scientific evidence is Article 5.7 SPS, which allows Members to take provisional measures in situations where relevant scientific information is insufficient. Such measures, however, have to be reviewed within a reasonable period of time and the Member must seek to obtain additional information enabling to carry out a more objective risk assessment. In all these cases, economic consequences have to be taken into account and only measures that are reasonable have to be selected, given the possible negative consequences of pests and diseases, for instance in the implementation of ISPM11.

[1] For food safety standards the relevant organisation is the Codex Alimentarius Commission, and for animal health and zoonosis the standards developed under the auspices of the World Organisation for Animal Health (formerly: Office International des Epizooties - the name changed in 2003, but the Organisation has kept its historical acronym OIE).

Figure 3.1 **SPS Agreement and IPPC standards**



Annex C of the SPS Agreement addresses the organisation of control, inspection and approval procedures, including procedures for sampling, testing and certification. Main principles concerning the organisation of control, inspection and approval procedures are as follows: they should not discriminate between imported products and domestic products; requirements should be limited as much as possible, not to unnecessarily obstruct international trade; the confidentiality of information on imported products is respected. The SPS Agreement does not 'appoint' or specify 'competent bodies' for executing inspection or certification tasks. It only sets boundaries to such activities and requires that there should be no discrimination and minimised effects on trade.

It has to be noted that the scope of the SPS Agreement is confined to sanitary and phytosanitary measures, defined in Annex A of this Agreement as measures applied:

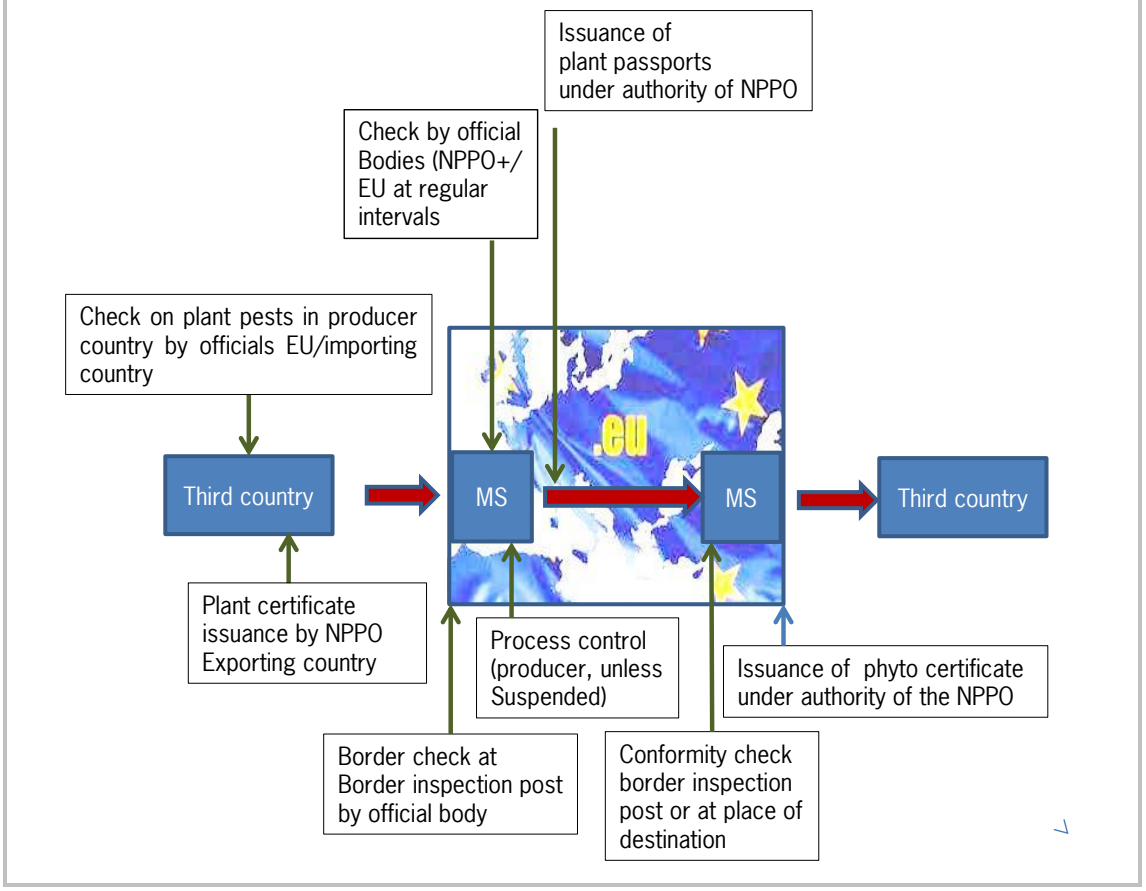
(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or diseases causing organisms in foods, beverages or feedstuffs;
(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Therefore, if the purpose of a measure is to protect human, animal or plant health from specific risks listed in Annex A SPS, a measure will be an SPS measure. For example, measures concerning animals or plants, but primarily aimed at the protection of the environment, animal welfare (other than animal health through for instance contaminants or residues) or consumer preferences are not covered by the SPS Agreement. They may be regulated by the TBT Agreement. To conclude, national measures introduced by importing countries that follow standards of the IPPC are presumed to comply with the SPS Agreement; in other instances scientific justification for a phytosanitary measure is required. The SPS Agreement does not provide information on how phytosanitary control at a national level should be organised.

3.2 International Plant Protection Convention (IPPC)

The International Plant Protection Convention (IPPC) provides a set of standards which are not only instruments to prevent plant pests from spreading, but also a benchmark for standard setting and the instalment of legitimate obstructions of trade within the ambit of the WTO (compare Figure 2.1). The Convention resorts under the FAO; it intends amongst others to formulate standards and recommendations on which regulatory action of the Members can be based. It provides the foundation for European and national protection against plant pests. The system of plant health from the international EU perspective is illustrated in Figure 3.2.

Figure 3.2 **System of plant health**



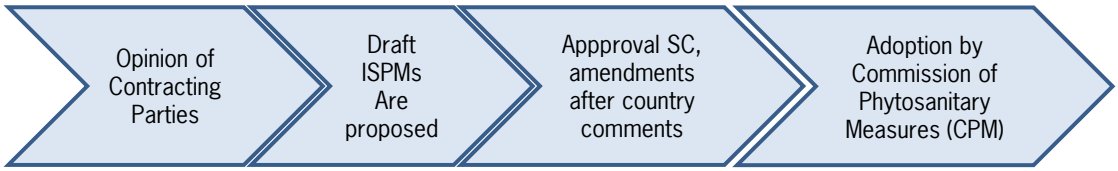
Article 1 of the IPPC states:

> 'With the purpose of securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control, the contracting parties undertake to adopt the legislative, technical and administrative measures specified in this Convention [...]'

The IPPC delineates a phytosanitary measure as any legislation, regulation or official procedure which has the purpose to prevent the introduction or spread of pests (Article 2 IPPC). The standards set by the IPPC provide a basis for compliance within the SPS Agreement. For an illustration of the steps of the standard-setting procedure, see Figure 3.3. International Standards for Phytosanitary Measures (ISPMs)

are put forward through the Commission on Phytosanitary Measures,[1] after intense coordination and collaboration with representatives of national authorities. The accepted principles that have to be applied are included in ISPM no. 1 and are as follows: sovereignty,[2] necessity, managed risk, minimal impact, transparency, harmonisation, non-discrimination, technical justification, cooperation, equivalence of phytosanitary measures, and modification.[3] These principles are in line with the requirements set out by GATT-WTO and the SPS Agreement.

Figure 3.3 Standard-setting procedure



Note: SC = standards committee of the IPPC.

The formulated international standards[4] do not have direct legal effect in the Member or EU legal environment. They need to be implemented into national or regional (EU) legal systems. The IPPC sets obligations to the contracting parties to take legislative, technical and administrative measures to adopt the agreements made in the Convention and in supplementary ISPMs (Article 1 IPPC).

The IPPC plays an important role in the European regulatory context. While the SPS Agreement, to which the European states are members, refers directly to the IPPC with respect to standard setting, controls and inspections, Directive 2000/29/EC refers to the structure of phytosanitary certificates, or 'phytosanitary certificates for re-export' that have to be granted in accordance with the format provided by the IPPC. ISPM No. 12 provides a guideline for the issuance of exporting plants by the National Plant Protection Organisation (NPPO). It refers explicitly to Article V.3 of the IPPC, which states that contracting parties may not require from importers into its territory phytosanitary certificates which are inconsistent with the models designed for this; the models are Annexes to the Convention and therefore obligatory; ISPM is a guideline and therefore not binding, however, the use of other procedures may have consequences for international trade in the ambit of the WTO (see Section 3.1.1) The EU and its Member States are members of the IPPC, EU legislation should thus generally avoid to come into conflict with agreements made in the ambit of the Convention.

International standards for phytosanitary measures have to be set in accordance with Article X, paragraphs 1 and 2. The Members of the IPPC are obliged to install an official national plant protection organisation (Article IV and ISPM No. 1). The responsibilities of this national plant protection organisation (NPPO) are included in the text box below. The NPPO in the Netherlands is the Plant Protection Service (Plantenziektenkundige Dienst) which is part of the Nederlandse Voedsel- en Warenauthoriteit (NVWA), and as such forms an integral part of the Dutch Ministry of Economic Affairs, Agriculture and Innovation. Text box 3.2 summarises the responsibilities of the NPPOs, as defined by the IPPC.

[1] This text is based on the IPPC website information (www.ippc.int).The standards can be viewed at the International Phytosanitary Portal of the IPPC.

[2] ISPM No. 1: 'Contracting parties have sovereign authority, in accordance with applicable international agreements, to prescribe and adopt phytosanitary measures to protect plant health within their territories and to determine their appropriate level of protection for plant health'.

[3] Modifications of phytosanitary measures are based on pest risk analysis. This instrument builds on scientific data evidence to whether an organism constitutes a pest. It includes Initiation, Pest Risk Assessment and Pest Risk Management as stages. It is necessary because measures to rule out pests have to be science-based (ISPM No. 2). However, agreed upon changes or removals should be made promptly.

[4] An international standard for phytosanitary measures is ´an international standard adopted by the Conference of FAO, the Interim Commission on phytosanitary measures or the Commission on phytosanitary measures, established under the IPPC' (ISPM No. 5). A phytosanitary measure is any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of risks.

Phytosanitary certification involves checks of certificates and conformity with phytosanitary requirements at import and the issuance of phytosanitary certificates before export. According to Article V paragraph 2(a), the issuance of export certificates has to be carried out by 'public officers, who are technically qualified, and duly authorized by the official plant protection organization to act on its behalf and under its control [...]' According to ISPM No. 12, Guidelines for phytosanitary certificates, 'public' means employed by a level of government, not by a private company.

Article V paragraph 2 IPPC limits the possibilities to outsource inspections for certification. It states that 'inspection and other related activities leading to issuance of phytosanitary certificates shall be carried out only by or under the authority of the official national plant protection organization' (see ISPM 7, below). The use of the IPPC certificate model(s) (see Appendix 1) is mandatory and the certificate information should take into account 'relevant international standards'. ISPM No. 7 ascertains that the NPPO should have the sole responsibility for issuing certificates for export. It has to bear the legal responsibility for what it does and 'implement safeguards against potential problems such as conflicts of interest and fraudulent use of certificates'.

Although issuing phytosanitary certificates should stay in the hands of the NPPO and can be executed by public personnel, personnel that do not resort under the NPPO can be accredited under specific conditions to perform adjacent tasks (see Text box 3.3).

Text box 3.2 Article IV IPPC

The responsibilities of an official national plant protection organization shall include the following:

(a) the issuance of certificates relating to the phytosanitary regulations of the importing contracting party for consignments of plants, plant products and other regulated articles;

(b) the surveillance of growing plants, including both areas under cultivation (*inter alia* fields, plantations, nurseries, gardens, greenhouses and laboratories) and wild flora, and of plants and plant products in storage or in transportation, particularly with the object of reporting the occurrence, outbreak and spread of pests, and of controlling those pests, including the reporting referred to under Article VIII paragraph 1(a);

(c) the inspection of consignments of plants and plant products moving in international traffic and, where appropriate, the inspection of other regulated articles, particularly with the object of preventing the introduction and/or spread of pests;

(d) the disinfestation or disinfection of consignments of plants, plant products and other regulated articles moving in international traffic, to meet phytosanitary requirements;

(e) the protection of endangered areas and the designation, maintenance and surveillance of pest free areas and areas of low pest prevalence;

(f) the conduct of pest risk analyses;

(g) to ensure through appropriate procedures that the phytosanitary security of consignments after certification regarding composition, substitution and re-infestation is maintained prior to export; and

(h) training and development of staff.

Inspection tasks

Inspection is defined in the IPPC as the official visual examination of plants, plant products or other regulated articles to determine if pests are present and/or to determine compliance with phytosanitary regulations. The inspector is a person authorised by an NPPO. The responsibility for inspection is located at the NPPO. It has to inspect itself via its public servants, or can delegate the task to another person under its authority (ISPM No. 23, see Section 1.3). IPPC does not specify what 'under its authority' exactly means. However, the European Directive is very specific in this respect (see Section 3.3).

Documentation
Activities related to data management[1] can be delegated to an 'institution designated by the NPPO acting as the national repository for plant pest records' (ISPM No. 6). On the basis of the IPPC release of certificates for export cannot be delegated to other institutions. With respect to all other tasks delegation is possible. Ultimately, the Minister/NPPO stays responsible. The Contracting Parties under the IPPC have some specific tasks that are assigned to them in Article IV (3):

- The distribution of information within the territory of the contracting party.
- Research and investigation in the field of plant protection.
- Issuance of phytosanitary regulations.[2]
- The performance of other functions as required by the Convention.

As to research, pest risk analysis may use relevant scientific publications and/or expert judgment. However, risk communication with stakeholders has to take place via the NPPO (ISPM No. 2, Paragraph 3.4).

Text box 3.3 International Phytosanitary Measure (ISPM) No. 7

Section 3.1: *The NPPO should have personnel with a level of expertise appropriate for the duties and responsibilities of the positions being occupied. NPPOs should have or have access to personnel with training and experience in:*

- *performing inspections of plants, plant products and other regulated articles for purposes related to the issuance of phytosanitary certificates*
- *identification of plants and plant products*
- *detection and identification of pests*
- *performing or supervising phytosanitary treatments required for the certification in question*
- *survey, monitoring and control activities related to phytosanitary certification*
- *constructing appropriate certification systems and formulating instructions from importing country phytosanitary requirements*
- *auditing of accredited personnel and certification systems, where appropriate.*

Section 3.1 states further:

Except for the issuance of phytosanitary certificates, non-governmental personnel may be accredited by the NPPO to carry out specified certification functions. To be accredited, such personnel should be qualified and skilled, and responsible to the NPPO. To ensure independence in their exercise of official functions, they should be subject to restrictions equivalent to those for government officials and have no financial interest in the outcome.

Note: Italics by the authors.

3.3 European legal context

The EU competences in the area of plant health are delineated by the Treaty on the Functioning of the European Union (TFEU) provisions referring to the Common Agricultural Policy (CAP). Harmonisation of laws at EU level is mostly based on Article 43 TFEU. Harmonised legislation referring to plant health will be discussed in more detail below.

Apart from the protection against plant pests, the improvement of productivity and harmonisation of rules and regulations are also the goals of the European legislator. Plant health and quality assurance, laid down in standards for the quality and marketing of plants, are interrelated with respect to control requirements, but serve different goals. Both benefit from a ban on the introduction of harmful organisms and of certain plants and plant products into the European Union. The Directive provides the standards for

[1] i.e. the collection, verification and compilation of data concerning specific pests.
[2] These constitute a subgroup under 'phytosanitary measures' and, according to Article VII, include the prescription of legislation for entry of plants into their territory, border controls and possible prohibitions, for instance on transport through their country/region, amongst other. This relates to the sovereignty principle as accorded in the IPPC.

such bans and it is a matter of public policy to do so. However, quality standards can be set by public as well as private parties. Private parties can define brands that they can legally protect and make known to the public by means of a logo, specific name, a sign or pictorial representation. In the European context, public common marketing standards (CMOs) have been defined, with the primary aim to facilitate the functioning of the internal market. They include therefore not only minimum product standards, but also, for instance, definitions of products and production methods and labelling requirements. For as far as such standards exist at EU level, national standardisation is not possible anymore. However, private producers can organise themselves to establish a standardised quality with respect to plants and plant products.

EU common market organisation (CMO)

Product quality is ensured by public as well as private regulation. Private standards may, just like the public standards, act as a technical barrier to trade. While the public standards have to meet the scrutiny of the WTO regime, the private standards escape from the standards the WTO adheres to in protecting the free competition in international markets. In many cases, private standards do not take the protection against diseases as a primary goal, but the guarantee of a certain quality level, which can be expressed by means of a trademark with a logo, symbol or sign on the package.

Next to private quality schemes, European marketing standards exist which also address quality of plants to improve the functioning of the internal market. The difference between quality and plant health protection is subtle and in practice often no distinction is made. In the Netherlands, public quality inspection bodies have been merged with plant health inspection bodies.

Council Regulation (EC) No 1234/2007[1], which establishes a common organisation of agricultural markets and on specific provisions for certain agricultural products (single CMO Regulation), aims at the smooth functioning of EU agricultural markets and serves a basis for market intervention and pricing policies. It includes marketing standards for live plants and plant products. Recital 49 of the Regulation states that 'the application of standards for the marketing of agricultural products can contribute to improving the economic conditions for the production and marketing as well as the quality of such products'. The application of such standards is therefore in the interest of producers, traders and consumers. Accordingly, within the CMOs for bananas, olive oil and table olives, live plants, eggs and poultry meat, marketing standards were put in place which relate, in particular, to quality, grading, weight, sizing, packaging, wrapping, storage, transport, presentation, origin and labelling.'

Article 54 of the Regulation refers to measures that can be taken by the Commission to encourage trade and joint trade organisations to facilitate to adjust supply to market requirements. The standards address - among other things - the specificities of the product (weight, size, package, presentation, labelling) the Commission can require import licences for certain live plants and set minimum export prices. According to Article 194, the Commission is authorised to provide the rules concerning the implementation of controls and their results.

Directive 2000/29/EC on plant health[2]

Council Directive 2000/29/EC concerns protective measures against the introduction into the EU of organisms harmful to plants or plant products and against their spread within the EU.[3] Its scope is exports from third countries to the EU as well as trade within the EU and within the individual Member States. Plant health checks, preferably carried out at the place of production, may lead to the issuance of a

[1]OJ 2007 L 299/1.

[2]The European Commission is currently carrying out a review of the EU plant health regime. A draft legal text of a new plant health law is expected to be proposed by the Commission in 2012. Integration of the future plant health regime in the scope of the Official Controls Regulation (EC) 882/2004 is foreseen. The initiative fits in the comprehensive EU approach of controls in the sectors of food and feed safety, animal health, plant health and plant reproductive material.

[3]OJ 2000 L 169/1.

phytosanitary certificate, which joins the plants for export, or a plant passport for intra-EU trade. Certificates of third countries may upon import be replaced by a plant passport also.
The legal requirements are largely included in the Annexes to the Directive. These come up to the requirements set out in the International Plant Protection Convention,[1] but do not necessarily have to be the same. However, if international standards are applied, then a country or region is less likely to be accused of discriminatory or protective trade measures within the WTO. Thus, the IPPC plays a double role: in the field of guaranteeing free trade, within the ambit of the SPS Agreement, and as a source for standards which are agreed upon by international members.

The requirements regarding plant health, the protection against imported pests and diseases and their implementation are included in the Directive. The requirements in Directives - in general - have to be implemented into national laws by the national legislators. Practice shows that this is done in many different ways.[2] See Text box 3.4 for the implementation of plant protection in Dutch law.

The Directive concerns phytosanitary control (i.e. regulation, inspection and certification). It is the successor of Council Directive 77/93/EEC. The intention of the Directive is to increase productivity and plant health by reducing the negative impact of harmful organisms connected to plants. The Directive addresses the spread of diseases in the internal market, as well as the import of plant diseases from abroad.

The Directive makes a distinction between three plant health scopes that can be applicable: in the internal market, products being imported from third countries, as well as a regime that is applicable to 'protected zones' which are designated vulnerable areas. The Directive lists the suspected harmful organisms and substances on plants that should not be spread throughout the European Union. It bans the introduction of certain plants carrying organisms at the border completely or sets minimum levels. Checks are made upon introduction in the internal market and certificates will be checked for plants coming from outside the European Union. For trade inside the European market, a plant passport may be sufficient.

Text box 3.4 Plant protection in Dutch law

The basis for plant protection in the Dutch law is the 'Plantenziektewet' of 1951 (Plant Disease Law) and implementing ministerial regulations ('Regelinginvoer, uitvoer en verkeer van planten', 'Regeling Tarieven Plantenziektekundige Dienst en de Keuringsdiensten', etcetera). It attributes to the Minister (of EL&I) the legal authority to prohibit or govern exports and/or imports of plants and plant material, packaging, etcetera. The Minister is competent with respect to regulations, research, information on planned import or export, quarantine, transport to place of research, cleaning, decontamination and other tasks to be accomplished (Article 2).

The director of the Plant Protection Service is competent to prohibit the importation or transport of plants which are infected. Governmental decrees can be issued with respect to plant production requirements, plant hygiene measures, or also decontamination and disinfection (Article 3, 1). These tasks can be carried out also by institutions that are: non-profit, and governed by a management that is composed to represent all parties concerned. Conformity assessment and inspection tasks have to be carried out by public servants (Article 10), but can be delegated. In its implementation, the Dutch law follows the Plant Heath Directive.

Directive 2000/29/EC leaves no space with respect to public standard setting on a national level, for instance the application of more stringent norms than required by the European Union, or alleviate the norms for plant protection. More stringent norms cannot be used to protect national markets. However, the organisation of control and enforcement with requirements is a national matter. The directive requires the implementation of measures to protect plants at a firm level, as well as conformity assessment, which is the responsibility of public authorities.

[1] See in this context: http://ec.europa.eu/food/plant/organisms/index_en.htm, accessed 17-11-11.
[2] Due to differences in knowledge, training, traditions, et cetera. See: Evaluation of the Community Plant Health Regime: Final Report. Food Chain Evaluation Consortium, 2010, on behalf of DG Sanco, p. IV.

The annexes to Directive 2000/29/EC refer to bans in the entire Union and/or in Protected Zones (a region for instance Isle of Man, and/or entire country):

- The ban of harmful organisms whose introduction into, and spread within, all Member States are banned, even those which are not known to occur in (any part of) the European Union (Annex 1).
- Harmful organisms which are detected to be present on certain plants and the spread of which is banned (Annex II).
- The ban of plants, plant products and other objects which are prohibited to be introduced (Annex III).

The next two Annexes do not impose restrictive bans on organisms or plants but prescribe organisation and control by Member States: for instance the provision of de information, the guarantee that plants are in a specified condition prior or during marketing, or that the plants are or will be handled in a specified way:

- Special requirements to be laid down by all Member States for the movement of plants, plant products and other objects into the Union and over its borders (Annex IV).
- The requirement of plant health inspection: At the place of production, if origination in the European Union, before being moved**,** and in the country of origin or consigner country, before admittance to the Union.

Implementation tasks of the Member States are checked upon by the Food and Veterinary Office (FVO), which resorts under the European Directorate General for Health and Consumer Protection (DG SANCO). Plant health inspection and tasks to be performed before certificates can be issued, eventually carried out by appointed private parties, have to come up to strict requirements.

For intra-EU movement of plants, a plant passport system is set up. Plant passports are issued to imports or domestic production for intra-EU trade. For certain seeds (Annex IV, Part A/Article 10) the documents issued for the marketing of officially certified seed may be considered to be plant passports. The issuance of plant passports can be delegated to private parties, under the responsibility and supervision of the NPPO. This delegation option has been implemented massively in the European Union, but the reliability of the system meets concerns, since it is not applied uniformly over Europe.[1]

The possibly unfamiliar[2]- at least for outside parties such as the FVO, which inspects the inspection systems - situation exists that autonomous public authorities ('zelfstandige bestuursorganen') may be structured as legal persons under private law (as is the case with a foundation, such as SKAL, which inspects the conformity of biological production with the respective norms and standards. This however is allowed under the conditions described earlier. If the authorities to whom such inspection tasks are delegated also execute related commercial activities, a conflict with Article 2(g) of Directive 2000/29/EC is immanent. While the private legal structure may in the end not be a problem, the execution of commercial activities may violate the principles of independence and objectivity.

In Article 1(4), the Directive obliges the Member States to install a *single responsible authority* (in the Netherlands that is the 'Plantenziektenkundige Dienst', a legal body which nowadays is part of the NVWA) as well as *responsible official bodies* in a Member State. This does not only include the single responsible authority but also state authorities at a national or regional level (like the official body of point of entry[3] and the official body of destination).

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[1] Evaluation of the European Plant Health Regime: Final Report, FCEC, 2010, p. VIII. While the certificates, in line with the IPPC, have a uniform format, every country as its own standard for the passport.

[2] This Section is based on P. Zwaan, *Struggling with Europe: How initiators of horizontal forms of governance respond to EU formal rules*. PhD thesis, Wageningen University, 2012, but includes own interpretations. See also: DG(SANCO)/2010/8363 - Final Country Profile - Current Status of progress made by the Netherlands in the implementation of FVO recommendations; DG(SANCO)/2007-8006 Final report of a general audit of official controls in the Netherlands, 2007; TRCDL/2006/918 (Conclusies en bevindingenuit het rapport Plantkeur), 13 April 2006; DG(SANCO)/7681/2005 - MR Final: Final report of a follow-up mission carried out in the Netherlands from 3 to 7 October 2005 in order to audit the plant health system in the potato sector.

[3] Points of entry in the Netherlands include for instance the harbour of Rotterdam and the airport region of Schiphol, Amsterdam. 'Point of entry' does not refer to transfer of plants from one Member State to another.

The single authority, which according to the Directive preferably is the 'official plant protection organisation set up under IPPC', has as a special task to provide for cooperation and communication between Member States and the Commission. As to Article 2 of the Directive, the official bodies have the possibility (1) to *delegate tasks,* (2) to be carried *out under their authority and supervision,* (3) to a *legal person, public or private*, (4) provided that that person has no personal interest in the outcome of the measure. The person should be (5) *exclusively charged with specific public function* (with the exception of laboratory testing). The requirement of specificity and impartiality rules out the carrying out of any commercial activities in the same legal person. Uncertainties about impartiality may be induced if the staff of a private person also has other tasks than those that have been delegated to him, or equipment is used for other purposes than those that have been assigned to the legal person that carries out delegated tasks (as was the case in the Dutch 'Plantkeur' construction in the tasks carried out by NAK and NAK Agro[1]).

The delegation opportunity refers to the exercise of tasks, under the supervision and responsibility of the official legal body. This implicates that the *preparation* of decisions can be delegated to private parties, but the ultimate decision has to be confirmed by the responsible authority/body. Recital 27 of the Directive states that

> '[to] ensure more effective application of the Community plant health regime in the internal market, it must be possible to use, for the purpose of plant-health checks, available official manpower other than that of Member States' official plant protection services, whose training should be coordinated and supported financially by the Community.'

This opens the door to delegate public tasks, such as plant health checks, to non-governmental legal entities performing public tasks.[2]

[1] A recent description from a European perspective of the inspection system for import controls is contained in DG (SANCO) 2011-8977 - MR Final - Final report of an audit carried out in the Netherlands 09 - 13 May 2011.

[2] Notably, plant health checks can be granted to be carried out at reduced frequencies (see Commission Regulation (EC) 1756/2004; accessed on 17/11/11:http://ec.europa.eu/food/plant/organisms/imports/inspection_en.htm

4 Examples of self-regulation: two case studies

In the case study, we aim to shed light on self-regulation in the EU food safety regulations and the US plant health protection. The detailed evaluation of options for self-regulation should ideally cover the three aspects of legal, socio-economic and social-ethical issues and questions, as outlined in Chapter 2. In our case study, we focus on the legal perspective.

4.1 Example of firms' responsibility in EU food safety regulations

In the example of the self-regulation in the EU food safety, we look at the following questions: How does self-regulation fit into the EU food safety law, and which provisions specifically allow for self-regulation of which regulatory elements? After an introduction about the principles of EU food safety regulations, we analyse the firms' responsibility that seems to trigger self-regulation.

Principles of EU food safety regulations and private sector involvement

The EU food safety standards are public standards and thus formulated in legal texts. They define minimum requirements as a regulatory floor for possible own regulations of the member states. While the regulations in the individual member states have to fulfil the EU minimum standards and must not compromise their objectives, member states can target standards and regulations towards specific objectives relevant to them. The member states may introduce further reaching requirements than the EU minimum standards prescribed but cannot impose stricter standards on foreign products in the EU common market so that the common EU market is not obstructed.

Regulation (EC) 178/2002 (the General Food Law) provides a general framework of principles for food safety in EU agri-food processing, together with effective instruments to manage food safety and possible food crises (RASFF) as well as the scientific support for food legislation (EFSA). Complementary to this framework legislation, more detailed regulations on food and feed hygiene are found in Regulation (EC) 852/2004, Regulation (EC) 853/2004 for animal health and Regulation (EC) 854/2004 for official controls on products of animal origin intended for human consumption. This is called the 'EU hygiene package'. Note that, for implementing the EU framework at the national level, some member states have adopted horizontal legislation on food safety imposing a general obligation on economic operators to market only food that is safe.

The EU regulations clearly assign the responsibility for food and feed safety to food business operators. The private sector's responsibilities are defined by the EU food law. Regulation (EC) 178/2002, Article 17 (1) states that feed and food firms at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that the relevant food satisfy requirements laid down by the food and feed law are met. In addition, other regulations of the 'EU hygiene package' also formulate the responsibility of the private sector for food safety. Text box 4.1 gives an example where the German supermarket chain Lidl was held liable for selling alcohol bottles and cans, whose alcohol content was not appropriately declared.

In general, the liability for damage arising from defective products is regulated in Directive 85/374/EC. Articles 1 to 12 of the directive specifically create a scheme of strict product liability, and this liability is in addition to any existing rights that consumers enjoy under domestic law; see Article 13. Product liability for agri-food products has become increasingly important in the wake of food scares such as incidences where unsafe food was sold or disease outbreaks, for example the outbreak of BSE that was considered a threat to human health. Directive 99/34/EC adopted an extension of product liability to agri-food products.

Text box 4.1	Case: Retailers' liability for selling alcohol bottles and cans, which mis-declare the alcohol content according to EU food safety law
The European Court of Justice ruled that retailers could be held liable for selling alcohol bottles and cans mis-declaring their alcohol content, even when they are pre-packed and labelled in another EU member state. The precedent comes in a case involving supermarket giant Lidl selling a German spirit called 'AmaroalleErbe' in Italy. National health authorities took action against Lidl after it was revealed that bottles declaring 35% alcohol content actually contained 33.91%. Lidl claimed 'the distributor cannot know whether or not the label contains true information'. The ruling by the European Court of Justice however held Lidl responsible. Note that the legal situation was amended such that for branded articles the responsibility remains with the brand holder according to Regulation (EU) 1169/2011.	
Source: EU Food Law Weekly EU Food Law nº 288, February 2007.	

According to EU food law, the ultimate responsibility for food safety does not lie with the regulator (or with the consumer) but with food business processors (including farmers, producers and retailers). Whereas any individual or firm produces, processes, prepares, imports and exports food, these activities are only possible with the inseparable responsibility to ensure that such food is wholesome and safe and that the business activities are within the applicable laws (European Commission, 2000). Public authorities or rather the governments of the member states are responsible for law enforcement and verification, for example via official controls or other activities including public communication on food and feed safety and risk, surveillance and other monitoring activities; see Regulation (EC) 178/2002, Articles 17 (2) and (3).The public responsibility also comprises measures and penalties applicable in case of infringements of food and feed law.

After the general introduction into the EU food safety case, the remainder of this section elaborates on the private sector involvement and responsibilities, respectively considering the regulatory elements as defined in section 2.2. Appendix 4 provides a summary overview of the public and private involvement in the different regulatory elements with regard to EU food safety.

Regulatory element: Requirements and standard setting

The EU food safety standards are set at the international EU level by the member states resorting under the EU treaties. The private sector is thus not directly involved in the standard-setting procedure, but given good practise of policy-making, firms or rather private sector representatives in general have the possibility of some influence on suggestions and even the decision about requirements. On the one hand, the private sector is consulted in the policy-making process, and on the other hand, there are specific private sector activities aiming to influence policy-making.

While the private sector is involved in the standard setting to a limited extent only, some standards were actually developed by the firms and have been taken over as governmental requirements. With regard to food safety, the system of Hazard Analysis and Critical Control Points (HACCP), for example, has become a mandatory requirement for agri-food processing firms to monitor food safety and hygiene matters across member states.[1] The private sector developed and applied the HACCP system because traditional 'end-of-pipe' testing was not efficient to ensure the level of product quality (and safety) as desired. The WHO-FAO Codex Alimentarius Commission has brought forward guidelines for the general principles of the HACCP system, and the EU HACCP requirement refers to these internationally agreed principles. The HACCP system is fully adapted from a private sector initiative to a mandatory governmental requirement in agri-food production.

In Regulation EC/852/2004, Articles (7)-(9) give provisions about the HACCP system for food processing firms. The HACCP system provides general guidelines, to be filed in at a company level. The HACCP system is process-oriented in terms of controlling production processes in order to achieve

[1]HACCP is a systematic preventive approach to ensure food and pharmaceutical safety that addresses physical, chemical, and biological hazards as a means of prevention rather than investing finished products. HACCP is used in the food industry to identify potential food safety hazards, so that key actions can be taken to reduce or eliminate the risk of the hazards being realised.

the desired level of product quality, which are formulated in product requirements such as MRLs. Note that primary producers (for example farmers) do not have to apply the HACCP system. However, guides to good agricultural practice aim to encourage the use of appropriate hygiene practices at the farm level. It can be argued that the mandatory procedures based on the HACCP principles, together with the application of good hygiene practice, reinforce the responsibility of food business operators.

Regulatory element: Implementation and monitoring

The implementation and monitoring takes place at the firm-level, and thus firms are obviously directly involved. However, it can be argued that provisions in the EU food law reinforce the firms' responsibly for the implementation and monitoring of food safety. First, the EU regulations stipulate the 'farm to table' approach such that food safety (and quality) is guaranteed along the entire supply chain. Following the White Paper on food safety(see European Commission, 2000), and the General Food Law, Regulation (EC) 852/2004 adopts this approach by stating that food and feed business operators shall ensure that the desired level of food safety is achieved at all stages of production and distribution under their control. In this regard, traceability constitutes an important aspect. The private sector is responsible for providing the relevant information, thereby ensuring traceability (one-step up, one-step down the production chain). According to Article 18 of Regulation (EC) 852/2004, food and feed business operators should be able:

- to identify their suppliers of food, food-producing animals and any other substance intended or expected to be incorporated into food;
- to identify the businesses to which they have supplied products;
- to produce this information to the competent authorities on demand.

The purpose of the traceability is to assist in targeted and accurate withdrawals as well as to give information to control officials in the event of food safety issues. As stated in the regulation, traceability applies to any business that trades in food at all stages of the food and feed chain, including primary producers, manufacturers, wholesalers, retailers, transporters, distributors, those dealing in the purchase and sale of bulk commodities, caterers and food brokers. The private sector takes a front role in monitoring, and according to EU food law, firms are obliged to report to immediately inform the competent authorities if they have a reason to believe that their food or feed is not safe and withdraw unsafe food or feed from the market (Regulation (EC) 178/2002, Article 19 and 20). The private sector is also asked to co-operate with the competent authorities in actions taken to reduce risks.

The combination of ensuring food safety along the supply chain and the liability for safe food products in the end means that those processors that trade and sell food products to consumers play a particularly important role. It could be argued that this combination has motivated producers, retailers and supermarkets to make sure that food safety requirements are met. Retailer and supermarket standards particularly proliferated during the last years, and there is a number of private sector initiatives in the EU that aim to ensure food safety but also the quality of food products, which goes beyond the public standards demanded by governments.

Supermarket standards have widely been discussed at the international floor. Text box 4.2 briefly introduces GlobalGAP (previously EurepGAP) as an important private standard initiative. Many of private sector initiatives, such as GlobalGAP, make public requirements practical for the direct application by producers. GlobalGAP for example translates requirements into control points that serve as criteria for GlobalGAP certification, thereby prescribing requirements to be implemented in considerable details. It can be argued that GlobalGAP ensures compliance via implementation and monitoring requirements, but this has implications for the power relation in the supply chain.[1]

[1] Fuchs et al. (2011) elaborate on the democratic and social-ethical issues arising due to food retailer standards that are mainly about food safety.

Private standards have often been criticised in the trade context as obstructing market access, in particular developing countries' access to the market of high-income industrialised countries. Van de Port (2009) describes the negative effect of GlobalGAP or other retail standards on producers in developing countries, which have difficulties to comply and thus cannot supply the respective markets. For example, standard requirements can constitute a greater burden for small-scale producers than for large ones, potentially leading to their exclusion from markets. The GlobalGAP standards have received much criticism in this regard. For example, Graffham and Cooper (2008) suggest how the current GlobalGAP-version should be changed in order to help small-scale producers in Africa to comply with the respective requirements.

Text box 4.2 Case: GlobalGAP (previously EurepGAP)

Starting as a private standards initiative of European retailers and supermarket chains, GlobalGAP was formerly EurepGAP. The change of the name indicates that EurepGAP is now established in the global market place, serving as a key reference for retailers/supermarket chains worldwide and not only in the EU. For detailed information about GlobalGAP see http//www.globalgap.org. GlobalGAP is a business-to-business standard that retailers or supermarket chains impose on primary agri-food producers (pre-farm gate standards). GlobalGAP is not communicated to consumers (e.g. via labels) and hence consumers do not pay higher prices for the quality aspects addressed. Usually, GlobalGAP does not set its own food safety standards but directly refers to the public requirements by importing countries, in particular the EU import requirements. With regard to aspects beyond food safety, for example environmental issues and workers' welfare, GlobalGAP however goes further than governmental and international public standards (Henson and Humphrey, 2009). Most importantly, GlobalGAP relies on strict proses requirements and management of food safety risks, underlining the producers' responsibility to provide products of the desired safety and quality level. Furthermore, GlobalGAP emphasises the need of written documentation and record-keeping for producers to provide proof and to ensure credibility. Next to credibility, comprehensive and detailed documentation also helps retailers to protect themselves in cases of liability issues. Producers undertake internal audits in order to prove compliance to get GlobalGAP certified.

Regulatory element: Conformity assessment and certification

Regulation (EC) 882/2004 describes how official controls should be implemented in the EU member states. The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control or quality assurance programmes. In general, there seems to be a change of focus from the simple verification of compliance of a product or premises to an evaluation of the controls that have been put in place to address food-borne disease risk factors.

The private sector is not mentioned in the aforementioned regulation and thus do not assume a responsibility for controls. However, it is stated that the performance of official controls shall be without prejudice to feed and food business operators' primary legal responsibility for ensuring feed and food safety, as laid down in Regulation (EC) 178/2002, and any civil or criminal liability arising from the breach of their obligations (Regulation (EC) 882/2004, Article 1). Furthermore, the EU food law stipulates that food processors have to: (a) provide the competent authority with evidence of their compliance; (b) ensure that any documents describing the procedures developed in accordance with the requirements are up-to-date at all times; and (c) retain any other documents and records for an appropriate period(Regulation (EC) 178/2002, Article 5). In this way, the private sector responsibility is to make available the information necessary for the controls.

It is the competent authorities that perform official controls in the EU. Independent third parties could generally be involved in official controls, but it needs to be notified. The competent authorities are only allowed to delegate specific tasks related to official controls to one or more third party if certain criteria, such as independence, competence, qualification of staff, are fulfilled (see Regulation (EC) 882/2004, Art. 5).

4.2 Example of US industry-issued certificates within the Mill Certification Program

In the US plant health protection and quarantine fall under the auspice of the United Sates Department of Agriculture (USDA), and within USDA the Animal and Plant Health Inspection Service (APHIS) aims to safeguard agriculture and natural resources from the entry, establishment and spread of animal and plant pests and noxious weeds into the US as well as aims to supports trade and exports of US agri-food products. The legal basis is given by the Plant Protection Act, more specifically Title IV Plant Protection Act, Public Law 106-224-June 20, 2000, with complementary acts covering specific topics. Being a member of IPPC, the US follows the IPPC in its plant health legislation (also within the North American Free Trade Agreement, NAFTA).

In the case study, we focus on export certificates and here in particular the US industry-issued certificates for wood products as an interesting option for some kind of self-regulation. In general, Section 7 Agriculture, part 353 of the US Code of Federal Regulations (7 CFR 353.7) covers certificates for exporting plants and/or plant products. Four types of certificates are described: phytosanitary certificates, which are issued to attest that consignments of plants and/or plant products satisfy the phytosanitary import requirements and are in conformity with the certifying statement of the respective model certificate. Phytosanitary certificates for exporting contain a standard wording and format so that the essential information is reported and easily found, including information about the validity of the documents. The IPPC model certificate is presented in Appendix 3.

According to APHIS, importing countries require phytosanitary certificates for plants, bulbs and tubers, or seeds for propagation, fruits and vegetables, cut flowers and branches, grain, and growing medium. Importing countries should not require phytosanitary certificates for plant products that have been processed in such a way that there is no potential for introducing regulated pests.

In the US, the option of industry-issued certificates is used for forestry products (lumber) under the Mill Certification Program, which aims to facilitate exports of coniferous sawn wood and to address the export concerns of the importing country (US Mill Certification Program, 2012-2014). Coniferous sawn wood is an important export from the US and highly regulated due to various pests, including the pine wood nematode, *Bursaphelenchusxylophilus*. The Mill Certification Program defines how wood products will be inspected and treated at the mill, and with this information, contains agreements of understanding (Memorandum of Understanding, MOU) between firms, more specifically lumber mills, and APHIS. The agreement document states that two of the MOUs eliminate the need to issue a phytosanitary export certificate (Plant Protection and Quarantine Form 577) for coniferous sawn wood and allow participating lumber mills to issue their own certification for kiln dried coniferous lumber. This covers the following treatments:

- Heat treatment of coniferous sawn wood going to EU member states (HT).[1]
- Kiln-Dried coniferous sawn wood going to non-EU member states (KD).[2]

Note that most companies join both the HT and the KD programmes. If products qualify for the KD programme, then they can usually also be exported under the HT programme. In the past, APHIS did not request that the EU accepted the industry-issued certificates under the KD programme, but recently there has been a hardwood KD derogation request submitted to the EU Commission. The EU Commission has not yet replied yet.

APHIS controls the Mill Certification Program in the state where the accredited inspection companies are located. Inspection companies perform monthly record reviews and spot inspections. Thus, while firms issue the certificates to verify their compliance with requirements, APHIS remains in control via accredited inspection, which APHIS reviews biannually. MOUs with APHIS and the inspection companies are signed

[1] Heat treatment (HT) - lumber or used, previously assembled or repaired wood packaging material which has been placed in a closed chamber and artificial heat added until the lumber or packing achieves a minimum core temperature of 56 °C for 30 minutes.

[2] Kiln dried (KD) - lumber or used, previously assembled or repaired wood packaging material seasoned in a closed chamber by means of artificial heat to a maximum moisture content of 19% or less. The KD programme requires 71.1 °C for 75 minutes.

every five years, but there is the option to revoked or denied recertification if any improper activity is found.

The Mill Certification Program for heat treatment of coniferous sawn wood going to the EU member states is the most widespread of the Mill Certification Programs. This programme provides an industry certification system that is officially approved to meet the EU phytosanitary requirements for coniferous wood from the US. The US use the industry-issued certificates based on derogation between the US and the EU. The softwood derogation involved a USD5 million joint study by the US and Canada, which verified that certain heat treatments (see footnote 22 and 23) effectively kill pinewood nematode, thereby eliminating the risk of infestation and spread if US wood is exported to the EU (and other countries).

The acceptance of the industry-issued certificates in lieu of phytosanitary certificates issued by public authorities needs to be agreed upon between the US and partner countries. For example, as the US and Canada apply heat treatment (as described in footnote 23 and 24) there has been an agreement between the respective NPPOs to use industry-issued certificates in lieu of phytosanitary certificates. According to US Aphis, very few countries accept industry-issued certificates. Those countries that do not accept industry-issued certificates base their objection on the fact that for IPPC members a phytosanitary certificate endorsed by the respective NPPO should accompany the shipment. The general practise is that IPPC members prefer to continue to have the NPPO endorsement of the shipments.

For APHIS, industry-issued certificates are an efficient solution to facilitate trade. The private sector appreciates the industry-issued certificates within the US Mill programme because they offer faster shipping than the usual phytosanitary system. However, the industry-issued certificates are granted only in case of wood packaging material, given the space that is provided in ISPM 15, which provides a label for treated and thus safe wood packaging. It can be argued that the ISPM 15 somewhat paves the way for the industry-issued certificates with trust and some sort of guarantee being established through ISPM 15 certification.

In order to apply industry-issued certificates more, US Aphis must first verify for each country and product that the proposed programme will mitigate all pests of concern for the respective country. Currently, industry-issued certificates have not been successfully established for products other than lumber, which can be treated under more rigorous conditions than most other products.

To conclude, the industry-issued certificates give firms the option to issue their own certificates in lieu of the governmental phytosanitary certificates for exports. US Aphis however remains in control of the industry-issued certificates via the third party inspections accredited by US Aphis and the MOU between US Aphis and lumber/milling firms. The industry-issued certificates thus fall within the category of conditioned self-regulation. They are a specific case of the Mill Certification Program for coniferous sawn wood used for packaging, and it can be argued that specific conditions have facilitated the option of industry-issued certificates applied. In fact, they can be considered as prerequisite for establishing the industry-issued certificates, as follows:

- A good relationship with trust between trade partners, authorities and firms as well as amongst firms selling and buying the respective product. For coniferous sawn wood, the relationship between buyers and sellers appears to be well-established in the specific (and small) sector. The good trading relation of the US and Canada seems to have facilitated the introduction and acceptance of the industry-issued certificates.
- The existence of business standards and norms such as the label for treated and thus safe wood packaging, seems to have helped the acceptance of the industry-issued certificates.
- Trade partners have to agree on the measure, in the case of the Mill Certification Program the treatment for coniferous sawn wood, and that the measures lead to the appropriate level of protection. The heat treating for coniferous sawn wood entirely removes the risk of diseases and pests.

5 Summary and conclusions

Looking at different regulatory elements, this chapter summarises findings on options of self-regulation in the field of plant health, given international, the EU and national Dutch legislation and practises. Table 5.1 provides an overview of the division of tasks in plant health between public and private parties, including the legal references. In the remainder of this chapter, conclusions are presented according to the different regulatory elements looked at as well as the case studies.

Table 5.1 Overview of public and private involvement in plant health

Standard setting	References	Public/Private
Bans on plants/plant products	Reg. 2000/29/EC, Annexes	Strictly public
MRLs	Reg. 2000/29/EC; Annexes	Public: EU (cooperation MS)
Procedures for checks	IPPC-guidelines (not mandatory), EU official procedures for monitoring MSs	Public
Official measures: quarantine for imports	EU + MS; Art. 13c (7) of 2000/29/EC	Public: official body of point of entry
Official measures: EU internal	Members States; 2000/20/EC, Art. 11 (3)	Public: NPPOs and delegation to qualified agents possible
Quality standards for end product	CMO, producers associations	Public & private
Standardisation of production processes	Private associations of producers	Private
Standard of certificates	IPPC/Art. 13a Reg. 2000/29/EC	Public
Standard of plant passports	EU / MS	Public
Implementation	References	Public/Private
Quality of product	CMO	Public & Private
Testing/Research	Reg. 2000/29/EC	Public & Private, under strict conditions
Process control	PZW + Ministerial directives + producer activity (may be suspended temporarily), Art. 11 (4) 2000/29/EC	Public/Private (producer)
End product control	Reg. 2000/29/EC (plant passport/certificate)	Public (NPPO & official bodies)
Conformity assessment	References	Public/Private
Border checks for third-country imports	Reg. 2000/29/EC, Art. 13/13a	Public (NPPO & official bodies)
Controls at the source	Reg. 2000/29/EC, Art. 12	Public (NPPO+)
Auditing	Reg. 2000/29/EC, Art. 21 (2)	Public; EU, cooperation with NPPO; involvement of expert under strict conditions
Certification	References	Public/Private
Phytosanitary certificate	IPPC/Reg. 2000/20/EC	Strictly under the direct authority of the NPPO
Plant Passports	Reg. 2000/29/EC	Public (prepared by the NPPO or responsible official body)

Note: + means that delegating to the private sector is possible under strict conditions, MS means EU member states.

Standard setting

In line with the EU Treaty principles regarding free trade and the common agricultural policy, standard setting with respect to phytosanitary control is a public task, which is taken on at the EU level. It is also logic to leave it at that level, since the issuance of national standards not only may come into conflict with EU law but also with requirements in international trade.

The WTO uses the reference of IPPC standards, guidelines and procedures. These may not prevent that national authorities, or the EU, will deviate under circumstances from the ISPMs, as these are formulated as guidelines. If standard setting was heavily influenced by private entities with potentially commercial interests, a protectionist purpose or vested commercial interest could be suspected behind the measures. It should however be noted that the private sector is generally involved in standard setting both at the international (IPPC, EU) level and at the national government level, as required for good practise in policy making.

Conformity assessment

According to international and EU legal provisions, conformity assessment tasks can be delegated by the NPPO or other responsible official bodies to legal persons, which are exclusively charged with a certain public function (except for laboratory testing). Such a legal entity can have a private structure, but its constitution should be officially approved. The final responsibility remains at the level of the NPPO. Those involved may not have commercial activities or interests, directly or by means of their associates or sub-units, and this may not be desirable. It is crucial to ensure independence and impartiality, since ultimately plant as well as human health can be affected seriously.

Controls on imports are conducted at the border since new diseases or pests may occur during transport. For domestic production, products are checked at the production facility, but products to be exported can also be checked in the country of origin (on-spot inspections). Even if a certificate by the NPPO of the trade partner country ensures plant health, border inspections of the end-product take place.

Refocusing from end-product control to the control of production process would be an option for enhancing the private sector's involvement in plant health. Such a process orientation could be accomplished by further combining quality control and phytosanitary control during production, which in turn implies that the private sector becomes engaged in the standardisation of production processes and the enhanced application of plant health measures (e.g. plant pest control). If the production process is monitored more intensely, which could be done by private organisations under NPPO supervision, the official inspections at the end of the supply chain could possibly be reduced. This would lead to less regulatory costs for public authorities.

Certificates

Certification is defined as issuing guarantees of conformity, which communicate that firms comply with the requirements demanded. Certificates are particularly important for trade, import and exports with trade partner located in different countries, producing under different production conditions and applying different production processes. For plant products, phytosanitary certificates confirm plant heath, thereby creating trust between buyers and sellers as well as importing and exporting county. Public authorities have traditionally been playing a crucial role in issuing certificates, and this role is also emphasised by IPPC that developed models of phytosanitary certificates.

Main results from the case studies

The case study of the US Aphis Mill Certification Program revealed that industry-issued certificates can signal an opportunity of enhanced self-regulation, but industry-issued certificates appear to function under certain conditions only. Good existing trading relations facilitate the establishment of industry-issued certificates. Business standards or norms, such as the label for treated and thus safe wood packaging, seem to have paved the way towards using industry-issued certificates instead of governmental phytosanitary certificates for exporting. An important prerequisite is that trade partners have to agree on the measure (in the case of the Mill Certification Program: the treatment for coniferous sawn wood) and that

the measures lead to the level of protection that the importing country desires. Such agreement was possible through the heat treatment of coniferous sawn wood. This treatment entirely removes the risk of diseases and pests.

The case study on EU food safety and hygiene looked at the regulatory elements and how the private sector is involved in the process. EU law provides incentives to the private sector to take responsibilities, in fact reinforces the private sector's responsibility by means of liability provisions. However, public controls remain important. Only under specific criteria, public authorities are allowed to assign certain tasks of the public control to third parties. This is achieved by means of a covenant or a conditioned type of self-regulation in the private sector. This could also be implemented for plant health in a more pronounced way.

While EU law for food hygiene ('hygiene package') seems to be a good example of how private sector involvement could work in the case of plant health, it should be noted that there are differences between food safety and plant health. One main difference relates to the public good characteristics of plant health and associated external effects. In case of pest outbreak or importation of plant invasive species, consequences can be detrimental on a large scale and harmful for producers, the entire sector and beyond. Thus, government interventions are warranted to ensure plant health, and other aspects, such as socio-economic consequences, should be considered besides legal options of self-regulation of firms.

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Appendix 1

Costs and benefits of self-regulation

	Description of characteristics of regulation
Advantages over legislation	
Use of specific expertise	Social actors have specific expertise at their disposal which is necessary for effective regulation, or alternatively they can buy in such expertise at lower costs. As the field has or can gain greater insight into the need for rules and conditions that influence the adherence to and enforcement of those rules, the regulation links up better with the situation in practice.
More flexible, with scope for diversity	Procedures and interpretation rules are less rigid, as a result of which rules come into being faster and can be more easily modified in the event of changes in insights and new developments. Regulation by social actors is more effective as there is more scope for diversity. This facilitates a better response to specific resistance against regulations and specific regulation requirements.
Greater willingness to comply	Rules created by social actors are better adhered to. The acceptance of rules is greater due to the involvement in their formulation and the internalisation of them; a certain 'ownership' of the rules is felt.
Less of a burden on the apparatus of government	In the case of self-regulation, social actors bear part or all of the costs associated with creating and enforcing the rules.
Reduction of regulation costs	In the case of regulation by social actors, decision-making procedures are less laborious and the costs of enforcement are lower because mutual trust forms the starting point and there is a greater willingness to comply with the rules.
Disadvantages compared with legislation	
Encroachment on the public interest	In the case of regulation by social actors, private interests may encroach on the public interest. The specific knowledge of the field can be used to transfer regulation costs to third parties or to restrict competition, for instance through excessively high quality standards, through fixing prices or by obstructing access. Intensive communications.
More limited enforcement	Social actors have fewer opportunities to enforce the rules that they have created. The sanctions are not public, as a result of which the mechanism of deterrence is restricted. The arsenal of sanctions is limited (fines, publicity and expulsion of members). Enforcement is also at loggerheads with the interests of a large support base.
Less certainty	Self-regulation offers less certainty as it is not bound to a fixed, formal procedure for the announcement of rules or changes to rules and because regulation, the settlements of disputes and enforcement are all carried out by the same party.
Increase in regulation costs	Continual modification and changes to the rules, resulting in an increase in regulation costs. The government often wants to monitor matters after all, increasing the costs of second-line monitoring.
More limited social legitimacy	The social legitimacy of self-regulation is more limited as a consequence of the lack of democratic procedures and protection through the legal system.

Appendix 2

List of factors determining the successful use of self-regulation

Factor	Expected influence on the use of self-regulation
Societal demands	Substantial public demand for regulation may increase the chances of self-regulation but it is not a sufficient condition for self-regulation. Such a demand may also cause the legislator to intervene with legislation.
Density rate of organisation	The more densely organised a specific branch of trade, service or industry is, the more likely the possibility it will engage in self-regulatory initiatives. Whether this cooperative attitude satisfies the legislator depends on the policy goals it formulates along the way.
Support	The more support there is within a specific branch for taking a certain substantive course, the more likely self-regulation will be instituted and complied with. If free riders are dominant, self-regulation will not be achieved. Moreover, full compliance is never guaranteed.
Clear sanctioning	If a piece of self-regulation encompasses clear sanctions, this may signal that the industry involved is committed to enforcement of the self-imposed rules. Such a signal does not impress policymakers, especially if the sanctions are never applied and cannot be imposed on those parties that did not subscribe voluntarily to the self-regulatory framework.
Practicable	The more easily that standing business practice and design are reconciled with the product of self-regulation, the more likely self-regulation is to succeed. If the stakeholders involved do not have a private interest in the policy goals and expect compliance with self-regulation to influence business results negatively, chances of successful self-regulation are slim.
Extent and size of branch	The influence of the extent and size of the branch is not clear. However, it can be argued that the more sizable a certain branch is, the more difficult it will be to coordinate action and to reach agreement on self-regulation.
Divergence of interest	The more extensively the interests of the various stakeholders within the branch diverge, the less likely will self-regulation be agreed upon and/or complied with.

Source: Van Boom et al. (2009), p.94-95.

Appendix 3

IPPC certificate model

Model Phytosanitary Certificate

No. _____

Plant Protection Organization of _____ (contracting party of re-export)

TO: Plant Protection Organization(s) of _____ (contracting party(ies) of import)

I. Description of Consignment

Name and address of exporter: _____

Declared name and address of consignee: _____

Number and description of packages: _____

Distinguishing marks: _____

Place of origin: _____

Declared means of conveyance: _____

Declared point of entry: _____

Name of produce and quantity declared: _____

Botanical name of plants: _____

This is to certify that the plants, plant products or other regulated articles described above _____ were imported into (contracting party of re-export) _____ from _____ (contracting party of origin) covered by Phytosanitary Certificate No. _____, *original ☐ certified true copy ☐ of which is attached to this certificate; that they are packed ☐ repacked ☐ in original ☐ *new ☐ containers, that based on the original phytosanitary certificate ☐ and additional inspection ☐, they are considered to conform with the current phytosanitary requirements of the importing contracting party, and that during storage in _____ (contracting party of re-export), the consignment has not been subjected to the risk of infestation or infection.

* Insert tick in appropriate ☐ boxes

II. Additional Declaration

III. Disinfestation and/or Disinfection Treatment

Date _____ Treatment _____ Chemical (active ingredient) _____

Duration and temperature _____

Concentration _____

Additional information _____

_____

Place of issue _____

(Stamp of Organization) Name of authorized officer _____

Date _____ _____

(Signature)

_____

No financial liability with respect to this certificate shall attach to _____ (name of Plant Protection Organization) or to any of its officers or representatives.

* Optional clause

Model Phytosanitary Certificate for Re-Export

No. _____

Plant Protection Organization of _____ (contracting party of re-export)

TO: Plant Protection Organization(s) of _____ (contracting party(ies) of import)

I. Description of Consignment

Name and address of exporter: _____

Declared name and address of consignee: _____

Number and description of packages: _____

Distinguishing marks: _____

Place of origin: _____

Declared means of conveyance: _____

Declared point of entry: _____

Name of produce and quantity declared: _____

Botanical name of plants: _____

This is to certify that the plants, plant products or other regulated articles described above _____ were imported into (contracting party of re-export) _____ from _____ (contracting party of origin) covered by Phytosanitary Certificate No. _____, *original ☐ certified true copy ☐ of which is attached to this certificate; that they are packed ☐ repacked ☐ in original ☐ *new ☐ containers, that based on the original phytosanitary certificate ☐ and additional inspection ☐, they are considered to conform with the current phytosanitary requirements of the importing contracting party, and that during storage in _____ (contracting party of re-export), the consignment has not been subjected to the risk of infestation or infection.

* Insert tick in appropriate ☐ boxes

II. Additional Declaration

III. Disinfestation and/or Disinfection Treatment

Date _____ Treatment _____ Chemical (active ingredient) _____

Duration and temperature _____

Concentration _____

Additional information _____

_____

Place of issue _____

(Stamp of Organization) Name of authorized officer _____

Date _____ _____

(Signature)

_____

No financial liability with respect to this certificate shall attach to _____ (name of Plant Protection Organization) or to any of its officers or representatives. **

** Optional clause

Appendix 4

Summary about public and private sector involvement in EU food safety

Requirements and standard setting	**References**	**Public/Private**
Food safety requirements, guidelines for minimum requirements by international organisations, e.g. FAO-WHO Codex Alimentarius (maximum residue levels)	Regulation EC/178/2002, Article (13)-(16), and internationally Codex Alimentarius	Generally public standards, but private sector consulted in policy making process (good practice)
Defining process requirements, e.g. HACCP	Regulation EC/852/2004, Article (7)-(9)	Private but originally private standard can be taken over by public
Traceability requirement, farm-to-table	Regulation EC/178/2002, Article (18)	Public but reinforces private sector responsibility for food safety
Standards that go beyond public, especially food quality issues but in some cases also food safety	n/a	Private sector
Implementation and monitoring	References	Public/Private
Process control		Private
'Farm to table approach' puts pressure on coordinating the supply change and thus gives options to firms upstream, in particular retailers	EC (2000)	Public/private
Conformity assessment, certification	References	Public/Private
Controls at the border	Regulation EC/854/2004, Chapter III on procedures concerning imports	Public, but also third party
Controls at the source (firm-level), controls of the product	Regulation EC/854/2004, Article (4)-(5)	Public, but also third party
Issuing certificates, guarantees for exporting (export certificates)	Regulation EC/854/2004, Annex IV	Public

LEI develops economic expertise for government bodies and industry in the field of food, agriculture and the natural environment. By means of independent research, LEI offers its customers a solid basis for socially and strategically justifiable policy choices.

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