TRAINING MANUAL

- FOOD SAFETY -

REGULATIONS AND PRIVATE STANDARDS

COLEACP

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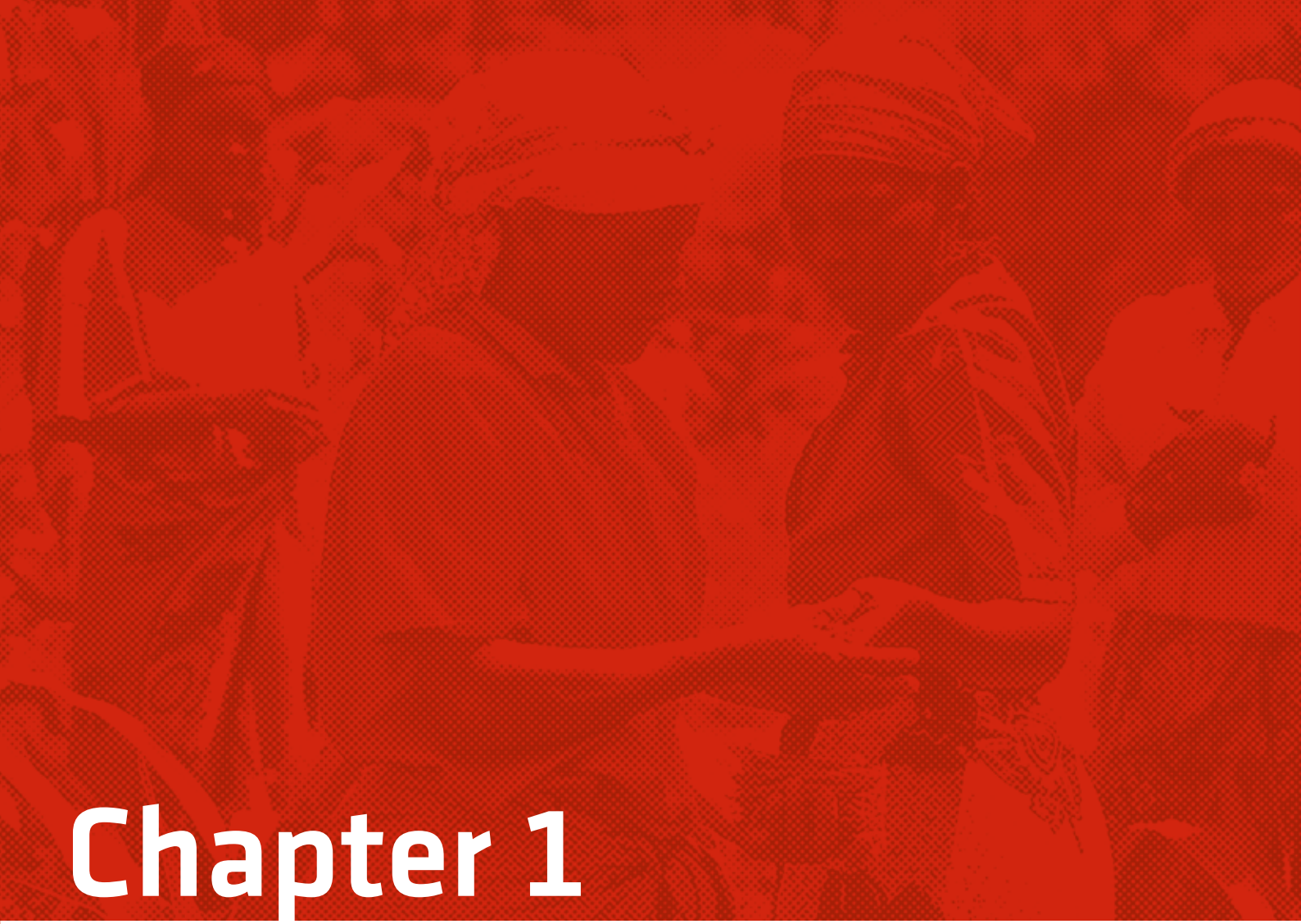

Chapter 1

Specific import requirements for food of plant origin into the EU

1.1. Introduction: EU food trade with third countries

1.1.1. Trade across EU's external borders

This chapter explains the specific food safety-based requirements imposed on food of plant origin imported into the European Union (EU) from outside the territory of the EU (from 'third countries'). Two fundamental issues prevail throughout this chapter:

- Trade in food between EU and third countries, as with other aspects of trade, is based on rules common to all Member States. This creates a high degree of certainty about import requirements for third countries exporting to the EU because these rules are applied whatever the actual place of import and whatever the final destination (apart from a limited number of specific exceptions – see below).

- Secondly the EU and its Member States abide by the **SPS Agreement** of the World Trade Organization (WTO). This means, first, that import controls are risk-based – measures taken against specific hazards to reduce the risk of these hazards actually causing harm; and second, that importing countries must subject imported food and food produced domestically to the same rules and controls – **WTO's Principle of Non-Discrimination**.

There are two consequences of the foregoing observations. First, points of entry for goods into the EU, whether airports, seaports or land border crossings, are effectively external borders for the EU as a whole, irrespective or whether the country of entry has a third country as neighbor or not. Second, the food safety policies of the EU promote a common, high **level of protection** against food-borne hazards. The level of protection is based on food safety standards that usually apply throughout the EU and that feature in import requirements. For example, there is a range of standards that set minimum residue levels for contaminants such as pesticides in foodstuffs. However, there is provision for a Member State to have a different standard in order to maintain the same level of protection as in the EU as a whole.

1.1.2. World trade and risks

This section considers the WTO and rules for the conduct of international trade that have been in place since 1995, in order to understand why WTO members (including the EU) must apply border controls on imported goods that take account of the risks of importing hazardous substances or organisms along with the goods. WTO's principal objective is to liberalize international trade by abolishing unfair or arbitrary barriers to trade. 'Globalization' is the outcome of this strategy whereby, theoretically at least, there is a 'level playing field' giving fair access to export markets based on price and quality. (Whether a level playing field will ever be achieved, so that poorer countries are not at a

disadvantage compared with richer countries, is beyond the scope of this chapter).

The box below indicates the kinds of trade barriers that WTO is designed to eliminate, noting that WTO includes trade in services as well as goods and some fundamental features of production. The principles of fair international trade set out by WTO are accomplished through a series of **Agreements**; these are international legal instruments binding on all members of WTO. There are two Agreements on trade in goods that obviously apply to food trade, the Agreement on the Application of Sanitary and Phytosanitary Measures (**SPS Agreement**) and the Agreement on Technical Barriers to Trade (**TBT Agreement**).

Barriers to Trade and Unfair Competition

Tariff barriers
Duties and imported taxes
Subsidies to domestic production
Quotas for certain exporting countries and other preferential arrangements
Import licensing

Dumping

Non-tariff barriers
Safety and quality restrictions on imports – **trade in goods**
Restrictions on services – **trade in services**
Intellectual property rights (copyright, patents, etc.)

In the *SPS Agreement* 'sanitary' stands for human and animal life and health and 'phytosanitary' stands for plant life and health. The *SPS Agreement* sets rules for application of sanitary and phytosanitary *measures* that may be applied to imported goods – food (fresh and processed of plant and animal origin), live animals (including semen, eggs), live plants and planting materials (including seeds, cuttings, etc.). One is entitled to ask what 'measures' are. The full definition of this term is to be found in Annex A of the *SPS Agreement*[1] but in short *measures* are all legislation, documented rules, requirements, actions and procedures in place for **official controls**.

The most important principle in the *SPS Agreement* is that all SPS Measures must be justified, as set down in Article Two and Article Five; these are in fact the key to the whole Agreement. All SPS measures must be justified by 'scientific evidence' that, without the measures, harm would be done to human, animal or plant life or health of the importing country (Article 2).

The basic means of providing scientific evidence/justification (Article 5) is risk analysis/risk assessment. From these two Articles it is clear that there must be a hazard associated with a particular commodity that poses a risk of harm to human, animal or plant life if there is to be an import measure such as a restriction imposed on the

[1] wto.org/english/docs_e/legal_e/15sps_01_e.htm.

commodity. Import *requirements* or *specifications* are the type of measure that is described in this chapter. Import requirements are usually based on application of *standards.* For example, to avoid the risk of illness from *Listeria* there might be a standard (one kind of 'measure') for cheese such that no *Listeria* bacteria are found in a 25 g sample.

There then could be a regulation (another type of 'measure') prohibiting importation or sale of cheese failing to comply with this standard. Note the distinction between a regulation and a standard. A **standard** is not a regulation but the yardstick by which compliance with **regulation** or rule may be judged. However, both regulations and standards are SPS measures.

The sister of the **SPS Agreement** is the TBT Agreement. This Agreement covers technical specifications about production and performance of goods and their quality. The equivalent of SPS Measures under TBT is 'Technical Regulations'. Provisions under SPS and TBT Agreements are mutually exclusive - an SPS Measure cannot also be a Technical Regulation and *vice versa*.

A short Quiz to help the reader distinguish TBT and SPS issues follows (Table 1.1). The reader is asked to complete the middle column by indicating whether stated action is a TBT or SPS issue. Answers and explanation are given in the Annex.

Table 1: Quiz on SPS/TBT

Requirement or marketing device	**TBT or SPS?**	**Explanation**
Labelling requirement for GMO content		
Restriction on sugar, salt or fat content		
Spraying of passenger aircraft for malaria control		
"Drink this for strength!"		
Packaging requirement for UHT milk		
Pasteurization process for UHT milk		

A key feature of the *SPS Agreement* is the distinction between measures based on/applying international standards and measures derived from national standards or

other sources. International standards are deemed to be justified *per se* as complying with the long-standing and still applicable GATT rules (Article 3.). However, international standards only originate from three International Standards Setting Bodies (ISSBs) recognized in the SPS Agreement: World Organization for Animal Health (OIE), *Codex* Alimentarius Commission (WHO/FAO) and the Secretariat of the International Plant Protection Convention (IPPC). Standards not based on international standards and measures based on these standards must be justified by risk assessment.

1.1.3. Food-borne hazards underlying import requirements

Having set the scene in terms of the constraints imposed by adherence to the *SPS Agreement* it is now appropriate to consider the type of hazards that could be present in food that must be prevented from causing harm. These are listed in **table 2.**

It is important to differentiate the targets at risk from these hazards:

- Animals exposed to animal pathogens transmitted via food and feed;
- Consumers of food exposed to a variety of food-borne hazards;
- Plants exposed to plant pests ('harmful organisms' in EU plant health legislation).

In relation to consumption of food it is noted that the core EU legislation on food safety generally covers animal feed as well. However, animal feed is not considered any further in this chapter.

Table 2: Range of food-borne hazards and their targets

Type of hazard	Target	Examples	Relevant to food of plant origin
Transboundary animal diseases	Livestock, pets, wild animals	Food and mouth disease	No
Zoonotic pathogens	Humans, livestock, pets, wild animals[2]	Avian influenza virus	No
Parasites	Humans, livestock, pets, wild animals	*Trichinella*	Yes – if food exposed to faeces
Food-borne microorganisms	Humans, livestock, pets	*Salmonella*	Yes
Contaminants[3] used in primary production	Humans, livestock, pets	Pesticides/plant protection products Veterinary products (e.g. antibiotics) Nitrates	Yes Yes
Contaminants from the environment	Humans, livestock, pets	Mycotoxins Heavy metals	Yes Yes Yes

[2] Contrary to popular opinion, avian influenza is not transmissible in food.
[3] Definition of contaminant is given below.

		Dioxins and other aromatic chemicals	
Contaminants from processing, packaging	Humans	Cleaning materials, disinfectants Food contact materials	Yes Yes
Food additives	Humans	Sulphites	Yes
Adulterants	Humans	Sudan red	Yes
Physical hazards	Humans (mainly)	Stones, dead insects, rodents Glass fragments	Yes Yes
Radioactivity	Humans, livestock, pets	Ionising radiation	Yes
Plant pests/harmful organisms	Plants, habitats	*Liriomyza sativae*	Yes

1.1.4. The level of protection is fundamental to food safety

❑ **Food safety standards directly applicable to import requirements**

As stated above, most if not all import requirements are based on standards of one sort or another but there are several different types of standards, requiring further enquiry. First of all we shall confine ourselves to hazards to human health and recall that the International Standard Setting Body (ISSB) for food safety recognized in the SPS Agreement is the ***Codex Alimentarius* Commission** administered by FAO and WHO. Food safety standards most directly related to specific import requirements are those setting a limit on the level or severity of hazard in a particular food or food type. International standards of this sort are generally referred to as '*Codex* limits'.

Example of *Codex* limits for some food-borne hazards are given in Table 3. MRL at or near the level of protection' (0.01 mg/kg) applies when in *Codex* tables the permitted level is effectively 'zero' (explained further).

Table 4 gives an example of *Codex* microbiological criteria for ready-to-eat food. It is noted that the criteria have a different numerical basis from that adopted in the EU and by the competent authorities of several countries: the EU's microbiological criteria are based on zero counts of bacteria in a certain sample size, usually 25 g.

Table 3: Examples of* Codex *limits for contaminants and food additives

Hazard category	Specific example	Commodity	*Codex* limit (mg/kg)
Pesticide (Plant Protection Product)[4]	Dimethoate	Lettuce	0.3
Mycotoxin[5]	Aflatoxin	Brazil nuts (shelled, ready-to-eat)	10
Additive/preservative[6]	Sulphites	Spices (e.g. cinnamon)	150

Table 4: Examples of* Codex *microbiological criteria relevant to food of plant origin/composite food

Point of application	Micro-organism	Number or samples conforming	Number of defective samples	Micro-biological limit
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	*Listeria monocytogenes*[7]	5	0	100 cfu/g

Codex limits are achieved by consensus among panels of experts for each type of hazard to which every member country of the *Codex Alimentarius* is entitled to send national representatives. The standard agreed on is based on average or typical level of consumption for a particular food. According to the SPS Agreement, if a country bases its import requirements on compliance with Codex limits, then these SPS measures require no further justification. The combination of standard (limit) and an accepted consumption level together set the **level of protection** to reduce the risk of food poisoning in normal circumstances to a very low probability. Standards for contaminants include a 'safety factor' that ensures that it is extremely unlikely that the consumer would receive a dangerous 'dose' of contaminant. Standards for food-borne microorganisms like *Salmonella* take into account the number of viable bacterial cells needed to cause illness.

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4 www.fao.org/fao-who-codexalimentarius/standards/gsfa/en.

5 www.foodproductiondaily.com/Quality-Safety/Codex-sets-limits-for-melamine-and-aflatoxin-in-food.

6 Codex General Standard for Food Additives (GFSA), www.fao.org/fao-who-codexalimentarius/standards/gsfa/en.

7 CAC/GL 61-2007, www.who.int/foodsafety/areas_work/food-standard/en.

Should a national authority (Competent Authority) find that because for example consumption of a particular food is higher than anticipated by the *Codex* Committee the limit does not give a sufficiently high level of protection, they may adopt a local/national standard that is higher than *Codex*, *i.e.* set a lower maximum limit. To achieve the desired level of protection, the EU usually adopts Codex limits. However, it will adopt a more stringent standard for food if prevailing levels of consumption with the *Codex* limits poses a risk of food poisoning. Occasionally, the EU will adopt a less stringent standard and there is provision for a Member State to set a higher standard because of increased consumption in order to maintain the same level of protection. No cases are known where the latter applies to food of plant origin but some differences between EU and *Codex* limits for pesticides are given in Table 5.

Table 5. Comparison of MRLs for selected pesticides in EU, Russian Federation and Codex MRL (mg/kg)[8]

Pesticide	Commodity	MLR (mg/kg)		
		Russian Federation	EU	*Codex*
Abamectin (acaricide)	Tomato	0.003	0.02	0.02
	Grapes	0.003	0.01	No MLR
Benomyl (fungicide)	Rice	0.5	0.01	No MLR or MRL revoked
	Tomato	Non-authorized	0.50	No MLR or MRL revoked
Metalaxyl (fungicide)	Potato	0.05	0.05	0.05
	Tomato	0.5	0.20	0.5

It is also necessary to consider the situation of 'zero tolerance' that applies to contaminant MRLs, i.e. the acceptable limit is 'zero'. This applies when for example a pesticide, antibiotic or food additive has been banned for use in primary production or has not been submitted for renewal of registration because its use is considered to pose an unacceptable risk. It will also apply to adulterants – substances added fraudulently to alter the food's appearance or other qualities. This begs the question, 'What is zero?' In fact, we should speak of 'effective zero' which in turn means the limit of determination/detection' (LOD). However, different authorities may take a different view of how to record 'zero' MRL, as seen in Table 5 for EU, Codex and Russian Federation. 'Real MRLs' are illustrated by abamectin/tomato in EU and *Codex*, benomyl/rice in RF and metalaxyl/potato or tomato in RF, EU and Codex. 'Very low MRLs' are exemplified by 0.003 for abamectin in RF (applied to all foods for this pesticide). In fact 0.003 is the LOD for abamectin determined by research. The data on which Table 5 is based were taken from Codex in 2009-10 when the approach to 'zero' in Codex was 'No MRL' or 'MRL invoked'. Subsequently, the EU approach of LOD set at 0.01 mg/kg has been taken up by Codex (see Table 3).

[8] Adapted from Kireeva, I., Black R., "Chemical Safety of Food: Setting of maximum residue levels (MRLs) for pesticides and other contaminants in the Russian Federation and in the EU", *European Food and Feed L. Rev.*, vol. 6, No. 3, 2011, pp. 174-186.

❑ Processed standards

There is another category of food-relevant standards that feature prominently in EU food laws and in the food safety legislation of other jurisdictions. These are standards that apply to the post-primary phases of food production, processing, packaging and selling and also to laboratories that test and analyze food for conformity to the product-related standards described above.

These standards have been codified by the International Standards Organization (ISO) as follows:

- ISO 9000 series – Quality Management Systems (QMS);
- ISO14000 series – Environmental Management;
- ISO 17025 - General requirements for the competence of testing and calibration laboratories;
- ISO 222000 – Food Safety Management Systems (FSMS), now incorporating QMS.

The principle behind these standards is safety and quality assurance in the final product by placing responsibility on the producer or processor to ensure hygienic operations or operations that are environmentally sound. Furthermore, the ISO is not an ISSB recognized in the *SPS Agreement*.

What is an international standard *sensu WTO/SPS*? It is **Hazard Analysis Critical Control Points (HACCP)**, which is the specific practical application of FSMS embodied in ISO 22000 developed and codified by Codex. HACCP is the means in EU and other food laws to place primary responsibility on what in EU terms is called the Food Business Operator (FBO) to produce safe food and, most importantly, avoid testing and certifying every batch of every kind of food.

Detailed treatment of HACPP is beyond the scope of this chapter. HACCP or equivalent is mostly required for exports of food of animal origin to the EU but there are some specific hygiene requirements for some foods of plant origin, as discussed below.

❑ Animal pathogens and zoonosis

Passing reference is made to animal pathogens and zoonotic organisms that are not likely to be present as hazards in food of plant origin. The World Organization for Animal Health (OIE) is the ISSB responsible for animal health standards. However, it is noted that the source of the devastating outbreak of food and mouth disease in the UK originated from imported meat products infected with the FMD virus that were fed to pigs as waste (pigswill) without following correct procedures for waste processing. In this connection it is observed that some foods are designated as ‘composite’ meaning that they contain food of animal and non-animal (=plant origin) so there is a possibility that food derived only in part from plants might be infected with animal pathogens or zoonoses. Such foods might be designated as subject to increased levels of control (see section 1.5.1).

1.1.5. Phytosanitary import requirements

Along with food safety-related import requirements imposed by the EU on imports from third countries there are also very numerous and detailed phytosanitary requirements to ensure that food of plant origin, live plants and other plant products do not pose a risk of introducing 'harmful organisms' into the EU. The Secretariat of the International Plant Protection Convention (IPPC) is the International Standard Setting Body (ISSB) designated for plant health standards in the *SPS Agreement*. However, standards in plant health are of a different nature to food safety standards. For a start, there are no internationally recognized pests in the same way that food-borne pathogens such as *Salmonella* or *Listeria* are universally recognized as hazards or in the way that OIE lists transboundary animal pathogens and zoonotic organisms. A comparison of hazards and SPS-consistent measures against them is given in Table 6.

Table 6: A comparison of organisms hazardous for human, animal and plant health

Characteristics	Human health: food-borne micro-organisms	Animal health: OIE listed animal diseases and zoonoses	Plant health: plant pests/harmful organisms
Number of different species	Limited number of species, one species of host - man	Relatively limited number of pathogen species and hosts	Thousands of pests on countless plant host species
Geographical distribution	Present in all countries	Limited distribution	Limited distribution
Justification for import controls	Cause illness in humans	Not present in importing country or declared status	Not present in importing country of under official control and shown to have potential economic impact
Nature of standards as basis for specific import requirements	'Numerical' standards setting limits on levels.	OIE listed diseases	No standards directly applicable. International Standards for Phytosanitary Measures (ISPMs) are standards for developing SPS-consistent measures

The key to understanding the basis of phytosanitary import requirements are the definition of **quarantine pest** in the IPPC. Because there are no standard pests, quarantine pests for each national territory ('area endangered') must be determined by a form of risk analysis peculiar to plant health – **pest risk analysis** (PRA). It must also be demonstrated by PRA that the pest firstly could become established and could multiply and spread and secondly that it would cause economic harm. Further to that, PRA must

be used to justify any measures employed to ensure that quarantine pests are not introduced into the area endangered, including specific phytosanitary requirements.[9]

A final point is that the concept of **quarantine pests** per IPPC include both 'traditional' pests of cultivated plants and commercial forestry but also organisms that pose a threat to the environment by being invasive and potential destroying habitats or reducing biodiversity ('invasive alien species', IAS). Plant health therefore includes an element of environmental protection by controlling IAS that are considered to be 'environmental risks' in the sense described above. The fundamental International Standard for Phytosanitary Measures (ISPM) dealing with pest risk analysis (**ISPM 11**)[10] now includes quarantine pests, environmental risks and Living Modified Organisms (LMOs).[11] However at the moment EU plant health legislation does not formally address invasive species; 'harmful organisms' only includes pests of cultivation. However, there is a proposal for the European Commission to include invasive alien species in its legislative framework.

1.1.6. Food crises and EU food law

The origin of comprehensive import requirements for food imported into the EU is ultimately the '**EU General Food Law'**, **Regulation (EC) 178/2002**. This regulation lays out the principles of EU food law, to be implemented by a series of other regulations introduced in 2004. One major objective was the need for consistency with the SPS Agreement (and it is worth noting that whereas this Regulation covers food and [animal] feed, it only deals with food/feed safety and not quality). However, a major driver for the new law introduced in 2002 and the implementing Regulations was the need to restore consumer confidence after a series of major food crises including dioxins in Belgium, and BSE and food and mouth disease in the United Kingdom.

However, consumers were also becoming concerned about environmentally damaging practices in food production and about animal welfare as well as about food safety. Hence public consultation that began in 1997 with a Green Paper and a White Paper in 2000 ultimately led to the 'Farm-to-Fork' (Farm-to-Table) Strategy, a 'horizontal' strategy starting with primary crop production and animal husbandry (the 'farm') and ending up with consumption of food either in the home or in restaurants and other food outlets (the 'fork'). Hence the inclusion of animal health and plant health as well as core food safety in

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9 Strictly, only 'regulated pests' may be subject of international phytosanitary measures and there are two categories of such pests: 'quarantine pests and 'regulated non-quarantine pests'. The latter are primarily plant pathogens occurring in important planting material ('plants for planting' in EU terminology); these are of no importance in food intended for consumption.

10 www.fao.org/docrep/010/a0785e/a0785e00.htm.

11 LMOs (=GMOs) are only considered within the framework of the IPPC for environmental risks, not the risk to health from the consumption of GMO food.

the strategy, plus controls on agricultural inputs, especially pesticides and veterinary products. The 'vertical' elements of the strategy deal with the differential controls in different sectors: food of animal origin (meat, dairy products, fishery products, etc.), food of plant origin, 'composite foods'.

EU legislation that is relevant to this chapter is listed in Section 1.2.1 while legislation directly relevant to specific import requirements will be referred to in subsequent sections as appropriate.

1.1.7. Other hazard-related controls in food in EU

Some controls on food in EU with accompanying legislation protect the consumer against less specific or well-characterized hazards than have been introduced above. As a consequence there are requirements for:

- food irradiation;
- novel foods;
- product specific requirements for:
  - quick frozen foodstuffs (Directive 89/108/EC);
  - foodstuffs for particular nutritional purposes;
  - genetically modified organisms (GMOs);
- food contact materials.

Generally the obligation is on the manufacturer in the case of EU-produced food or the importer, distributer or retailer in the case of imported food to ensure that the various requirements are met. Relevant legislation is listed in **Section 1.2.1** and considered further in **Section 1.3.1**. In general however, there are no long-standing specific import requirements but there may be some specific alerts.

1.1.8. National laws in Member States and third countries

Regulations in EU legislation have **direct effect** in Member States as they are, but many Member States do transpose Regulations into national legislation. **Directives** on the other hand do not have immediate legal force but must be adopted in appropriate manner by Member States – Directives are **guidelines** (meaning of French word *directif*) for national legislation. There may be some subtle and not so subtle differences in the legal texts in different countries depending on how these guidelines are interpreted. However, specific import requirements as laid down in national legislation will almost always be the same across all Member States. The only exceptions will be where a given country needs to adopt a higher standard than that adopted by the EU as a whole (see Section 1.4). Thus the Annexes to EU Regulations and Directives containing the specific import requirements such as MRLs can be read to apply to the entire EU in nearly every case.

A third type of legislative instrument of general effect is the **Commission Decision**. This may be a response to a food alert laying down some specific rules for importation or it may be a ruling on an alleged breach of EU law.

National laws may still have important contributions, however. There are several instances in the EU food regulations where the manner of implementing official controls rests with the national competent authorities under national law. Secondly, if there are plans for EU-wide legislation on a particular topic but this has not yet been introduced, relevant national laws will apply, as in the case of 'food contact materials'.

A third country exporting to the EU does not have to approximate or harmonize to EU food law. It is not necessary for a third country to have a Competent Authority for food safety. However, a veterinary authority is required if food of animal origin is to be exported and similarly there must be a Competent Authority for plant health established in law to assure compliance with the EU's phytosanitary import requirements.

1.1.9. Food alerts and increased levels of control

Fresh fruit and vegetables exported to the EU are not generally subject to hygiene requirements that apply to food of animal origin. The main exceptions are such products as ready-to-eat salad preparations and pre-cut fruit and vegetables because of potential microbial contamination. Furthermore health certificate of export are generally not required for individual batches of fruit and vegetables. Border inspections and random testing point of entry, distribution or sale in the EU may reveal a problem with certain products from certain countries. For example pesticide residues in fresh fruit and vegetables above the MRL or nuts contaminated with mycotoxins may be detected. When detected, consignments are condemned or destroyed at exporter's cost. In certain cases further exports may not be allowed but in any case an alert will be triggered in the Rapid Alert System for Food and Feed (RASFF) (Section 1.5.4) and if the situation is serious enough it could trigger a number of actions by the European Commission:

- an audit by the FVO of the official controls in place in the third country;
- a ban on certain products until the situation is resolved;
- a requirement for a health certificate and/or certificate of analysis to demonstrate that the contaminants or food-borne bacteria are within acceptable levels.

The first two situations listed above are usually mediated through **Commission Decisions** (Section 1.1.7).

In a few cases, the requirement for a test certificate might become universal. This happened after chill powder exported from India was found adulterated with the carcinogen Sudan Red. A major alert was triggered because food manufacturers or processors all over the world long before the alert had bought the illegal chilli products and mostly remained unaware of the problem. Now all products based on red chilli (dried red chillies, chilli powder, chill sauce, 'hot' tomato sauce, etc.) must bear a test certificate showing there is no Sudan red.

1.1.10. Scope of this chapter

This chapter aims to provide a comprehensive but non-legal guide to specific import requirements for food of plant origin into the EU. In this regard, note that EU legislation (**Regulation (EC) 882/2004**) refers to official controls on food [and feed] of 'animal origin' (Article 14) and on food [and feed] of 'non-animal origin' (Articles 15-16). The useful 'Guidance Document'[12] on food import requirements from DG Sanco interprets these terms as follows:

"The notion 'products of animal origin' covers food that has been derived from animals or coming from animals, whether processed or not. In certain cases this may include live animals (e.g. lobsters or live bivalve mollusks) that are placed on the market for consumption.

*Food of **non-animal origin** includes items such as fruits, vegetables, cereals, tubers, drinks, (apart from drinks prepared from products of animal origin such as milk and certain milk based drinks), food of mineral origin (such as salt), spices, condiments etc.*

*For food hygiene purposes, food containing both products of plant origin and **processed** products of animal origin are called 'composite products'".*

This chapter will also briefly cover special controls (including new ones that came into effect in January 2012) on 'composite products' – such items as meat/seafood in products containing soya, and nuts or fruit in honey, honey being a product of animal origin.

All import requirements applicable to food of plant origin (totally or in composite foods) relating to food safety in the wide sense (Farm-to-Fork Strategy) will be covered including phytosanitary requirements. From the preceding introductory sessions, it should be apparent however that the chapter only deals with relevant SPS measures and not TBT requirements.

Novel foods and food of GMO origin or content are dealt with briefly, realizing that the latter in particular are controversial. However, there are no specific import requirements for imported foods of these kinds but the general EU rules must be complied with, including requirements for authorization and labelling requirements. Contrary to the impression prevalent in many third countries, the EU has not banned GM food, nor will it be banned or subject to food safety restrictions until the European Commission acquires data that suggests that there is any health risk associated with the consumption of any specific GM food.

[12] ec.europa.eu/food/international/trade/interpretation_imports.pdf.

1.2. Legal and other sources of information

1.2.1. EU legislation on food safety

Regulation (EC) 178/2002, the EU General Food Law, is described as "laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety". In addition there are four other principal EC Regulations that implement Regulation (EC) 178/2002. These Regulations and other EU legislative instruments relevant to the subject matter of this chapter are given in Table 7. (Latest versions accessible from the official website of the European Commission15 will be 'as amended' unless amended by another instrument).

The principles of food safety in the EU are set out in just a few articles in Chapter II (Articles 14-21). The basic food safety requirements (Article 14) are simply that 'Food shall not be placed on the market if it is unsafe' and that "Food shall be deemed to be unsafe if it is considered to be: (a) injurious to health; or (b) unfit for human consumption".

Food controls are based on the important principle that the '**food business operator**' is primarily responsible and that the authorities are responsible for monitoring food production, processing and marketing (Article 17-21). There is no general requirement for routine conformity assessment and certification of food but this will be discussed in more detail later in the chapter.

Table 7: EU legislation relevant to imports of food of plant origin into EU

Topic	Instrument type and number	Official title/description
General food law	Regulation (EC) 178/2004	laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Implementing general food law	Regulation (EC) 852/2004	on the hygiene of foodstuffs
	Regulation (EC) 853/2004	laying down specific hygiene rules for food of animal origin
	Regulation (EC) 854/2004	laying down specific rules for the organization of official controls on products of animal origin intended for human consumption

Topic	Instrument type and number	Official title/description
	Regulation (EC) 882/2004	on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Microbiological criteria	Regulation (EC) 2073/2005	on the microbiological criteria for foodstuffs
Pesticides/plant protection products	Regulation (EC) 1107/2009	concerning the placing of plant protection products on the market and repealing Council Directives Nos. 79/117/EEC and 91/414/EEC
	Regulation (EC) 396/2005	amending Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, as regards the implementing powers conferred on the Commission
	Commission Regulation (EU) 600/2010	amending Annex I to Regulation (EC) 396/2005 of the European Parliament and of the Council as regards additions and modification of the examples of related varieties or other products to which the same MRL applies
Contaminants	Council Regulation (EEC) 395/EC	laying down Community procedures for contaminants in food
	Commission Regulation (EC) 1881/2006	setting maximum levels for certain contaminants in foodstuffs
Special conditions for aflatoxins	Commission Decision 2008/47/EC	approving the pre-export checks carried out by the United States of America on peanuts and derived products thereof as regards the presence of aflatoxins
	Commission Regulation (EC) 1152/2009	imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision No. 2006/504/EC
	Commission Implementing Regulation (EU) 274/2012	amending Regulation (EC) 1152/2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins
Additives	Regulation (EC) 1333/2008	on food additives

Topic	Instrument type and number	Official title/description
Food contact materials	Regulation (EC) 1935/2004	on materials and articles intended to come into contact with food and repealing Directives Nos 80/590/EEC and 89/109/EEC
Composite foods	Commission Regulation Commission (EU) 28/12	laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision No. 2007/275/EC and Regulation (EC) 1162/2009
	Commission Implementing Regulation (EU) 468/2012	amending Regulation (EU) 28/2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products
Increased levels of controls	Commission (EC) Regulation 669/2009	implementing Regulation (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision No. 2006/504/EC
	Commission Regulation (EU) 212/2012	1.1.1.1.1.1.1.1.1 amending Regulation (EC) 669/2009 implementing Regulation (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin
	Commission Regulation (EU) 294/2012	1.1.1.1.1.1.1.1.2 amending Annex I to Regulation (EC) 669/2009 implementing Regulation (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin
	Commission Implementing Regulation (EU) 889/2012	1.1.1.1.1.1.1.1.3 amending Annex I to Regulation (EC) 669/2009 implementing Regulation (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin

Topic	Instrument type and number	Official title/description
Food irradiation	Directive 1999/2/EC	**1.1.1.1.1.1.1.1.4** on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation
	Directive 1999/3/EC	**1.1.1.1.1.1.1.1.5** on the establishment of a Community list of foods and food ingredients treated with ionizing radiation
Plant health	Council Directive 2000/29/EC	1.1.1.1.1.1.1.1.6 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community
Wood and wood packaging	Commission Directive 2004/102/EC	1.1.1.1.1.1.1.1.7 amending Annexes II, III, IV and V to Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community
Novel foods	Regulation (EC) 258/97	**1.1.1.1.1.1.1.1.8** concerning novel foods and novel food ingredients
	Regulation (EC) 1829/2003	**1.1.1.1.1.1.1.1.9** on genetically modified food and feed
Miscellaneous	Council Directive 89/108/EEC	On the approximation of law of the Member States relating to quick-frozen foodstuffs for human consumption

1.2.2. *Codex*

Codex standards are available from the Codex Alimentarius website (www.codexalimentarius.org) but some useful publications that can be downloaded are listed in Table 8.

Table 8: Selected Codex documents relevant for imported food of plant origin

Document No.	Title	URL
CAC/GL 61 – 2007	Guidelines on the application of general principles of food hygiene to the control of *Listeria monocytogenes* in foods	www.codexalimentarius.net/input/.../standards/10740/CXG_061e.pdf

CODEX STAN 192-1995	Codex general standard for food additives	www.codexalimentarius.net/gsfaonline/index.html;jsessionid=C5369256A1C7819B42E3292BC9C29AA3

1.2.3. Guidance documents

Finally, some guidance documents and other source of information, both official (European Commission) and private are listed in Table 9.

Table 9. Guidance documents and other sources of information on import requirements

Source	Year	Title	URL
European Commission (DG Sanco)	2006	Guidance Document. Key questions related to import requirements and the new rules on food hygiene and official food control.	ec.europa.eu/food/international/trade/interpretation_imports.pdf
	2008	Factsheet. Food contaminants	http://ec.europa.eu/dgs/health_consumer/press/fs_contaminants_final_web.pdf
	Not given	Factsheet. EU action on pesticides 'Our food has become greener'	ec.europa.eu/food/plant/plant.../eu.../factsheet_pesticides_en.pdf
	Not given	Questions & Answers Paper on the provisions of Commission regulation (EC) No 669/2009 as regards the increased level of official controls on imports of certain feed and food of non-animal origin	ec.europa.eu/food/food/controls/increased.../QandA_paper_en.pdf
	2012	Legislative proposal on invasive alien species	ec.europa.eu/...ia/.../2012_env_011_invasive_alien_species_en.pdf
	Not given	An overview of EU rules on wood packaging materials	ec.europa.eu/food/resources/import_conditions/woodpackaging.pdf
	2009	The Rapid Alert System for Food and Feed. Annual Report 2009	ec.europa.eu/food/food/rapidalert/docs/report2009_en.pdf
European Commission	n/a	Export Helpdesk – webpage. See the Tab 'Requirements and Taxes'	exporthelp.europa.eu/

Source	Year	Title	URL
(External Trade)			
Better Training Safer Food	2011	The new public and animal health import and transit regulations for composite products	animalhealth.defra.gov.uk/about/publications/bip-compendium/guidance/The-new-public-and-animal-health-import-and-transit-regulations-for-composite-products.pdf
INTERREG IVC	Not given	Legislative requirements. European Union	agriexchange.apeda.gov.in/Market%20Profile/MOA/NON_TARIFF_PROTOCOLS/IVC-non_tariffs_EROPEAN_UNION.pdf
Denis de Froidmont	2007 (Sympo-sium)	EU requirements for fresh food and vegetables	aic.ucdavis.edu/research1/de-Froidmont.pdf

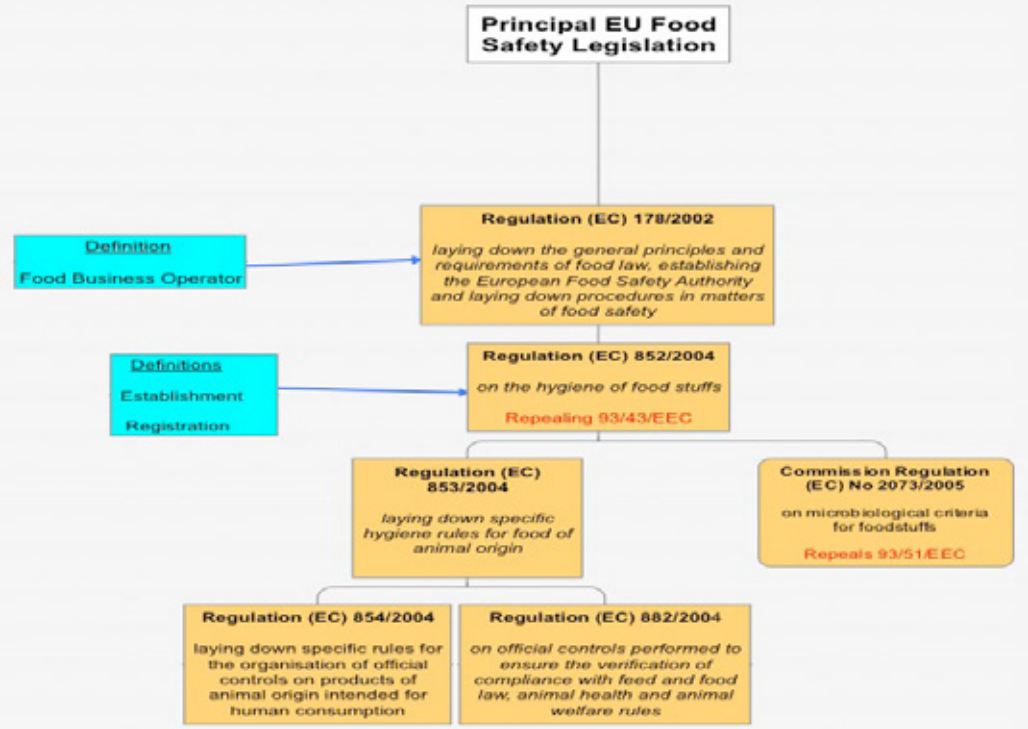
1.3. Food law applicable to food imports – general hygiene

1.3.1. 'After primary production'

How the five principal EC Regulations introduced in the previous section work together is shown in Figure below. This diagram also shows the location of some important legal definitions.

Two of these regulations only apply to food of animal origin but the all-important '**hygiene Regulation**', Regulation (EC) 852/2004, applies to all FBOs '**after primary production**' as does Regulation (EC) 882/2004. For the purposes of this chapter, the key issue in Regulation (EC) 852/2004 is the responsibilities placed on FBOs to ensure that HACCP-based principles are applied at all post-primary production phases of food production and processing. These are general requirements. However, in some cases of foodstuffs of plant origin more specific control plans are required (Section 1.3.2).

Figure 1: Principal EU food safety legislation



Although the hygiene rules and requirements apply to FBOs operating after primary production, there are obligations on FBOs of food of animal and plant origin in the primary production stage (*i.e.* farmers) to ensure that the food they produce is safe and free from contamination for pesticides and other agricultural inputs. These are given in Annex 1 of Regulation (EC) 852/2004 and are described in more detail in Section 1.4 below. Article 10 of the Regulation applies key provisions (Article 3 to 6) on imports of food (see Section 1.3.3.).

It is very clear that, when importing food of non-animal origin, the importer must ensure compliance with the relevant requirements of food law or with conditions recognized equivalent thereto by the EU. This is spelled out in Article 7 of Regulation (EC) 882/2004:

"7. Without prejudice to Article 50(3) of Regulation (EC) 178/2002, when official controls on imports subject to the procedure referred to in paragraph 2 reveal significant non-compliance, Member States shall immediately notify the Commission and other Member States and the operators concerned in accordance with the procedure provided for in Title IV of this Regulation;

Member States shall increase the number of consignments checked and, where necessary to allow a proper analytical examination of the situation, keep an appropriate number of samples under appropriate storage conditions."

1.3.2. Control plans for food of non-animal origin

Food of non-animal origin may be submitted to controls in accordance with a control plan drawn up in the light of potential risks that emerge (see Article 15, paragraph 1 of Regulation (EC) 882/2004). Such controls must take place in accordance with national law in the different Member States. This may be at the point of entry, the point of release for free circulation, the importer's premises, retail outlets, etc. Apart from food hygiene, these import controls may also cover other food safety issues such as additives, materials in contact with food, contaminants, etc., for which specific import requirements of general application may already exist – Section 1.4.

Following the emergence of specific risks or a food alerts, some special conditions or emergency measures may follow, as discussed more fully in Section 1.5. The 'Guidance Document' referred to above lists in Annex III some special conditions in force at the time of publication of that document (2006) but these have generally been consolidated into newer Regulations or superseded entirely.
Generally, however, food of non-animal origin:

- can enter the EU without certification by the competent authorities of the third country of dispatch;
- is not subjected to a pre-notification procedure on arrival.

1.3.3. Microbiological requirements

As stated in Section 1.3.1, Regulation (EC) 852/2004 does apply to food of plant origin and Articles 3 to 6 applies to such food that is imported into the EU. Article 3 places a general obligation on the (post-primary production) FBO to 'ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in the Regulation.' Articles 4, 5 and 6 respectively lay down General and Specific Hygiene Requirements, HACCP requirements and requirements for FBOs to register their **Establishments**.

The specific hygiene requirements listed in Article 4 deserve more detailed attention because among them are included 'Compliance with microbiological criteria for foodstuffs'. These criteria and the rules for compliance are provided in Commission Regulation (EC) 2073/2005 on the microbiological criteria for foodstuffs. This Regulation contains a lot of detail applicable to many different categories of foodstuffs. Relevant to food of plant origin, but recalling also that some salads might be composite foods (e.g. those containing cheese or ham), are the following key features:

- A distinction is made between 'Food safety criteria' (details in Annex 1, Chapter 1) and 'Process Hygiene Criteria' (details in Annex 1, Chapter 2). The former are the key criteria for safety for placing a product on the market; the latter are only indicative of action that might need to be taken by the FBO;
- Food safety criteria reflect concerns about three types of bacteria (*Listeria*, *Salmonella*, *Enterobacter sakazakii* and *Escherichia coli*) and their toxic metabolites (Staphyloccal enterotoxins and histamine);
- *Listeria* might be a problem with certain foods of plant origin if the food is intended for consumption by infants or for special medicinal purposes, has a long shelf-life or is a composite containing cheese for example;
- Otherwise the main concern in this part of the criteria is for *Salmonella* in the following ready-to-eat products:
    - sprouted seeds;
    - pre-cut fruit and vegetables; and
    - unpasteurized fruit and vegetable juices;
    - apart from the possibility of composite foods with meat, egg or cheese content, process hygiene criteria list the following ready-to-eat food categories as applicable for *E. coli* counts:
    - pre-cut fruit and vegetables;
    - unpasteurized fruit and vegetables.

The criteria applicable to food of plant origin together with sampling and testing rules are summarized in Table 10.

Table 10: Microbiological criteria applicable to foods of plant origin

a. Food safety criteria relevant to foods of plant origin

Food category	Micro-organisms/their toxins, metabolites	Sampling (1)		Limits (2)		Analytical reference method (3)	Stage where criterion applies
		n	*c*	*m*	*M*		
1.1 Ready-to-eat foods intended for infants and ready- to-eat foods for special medical purposes (4)	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life
1.2 Ready-to-eat foods able to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g (5)		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
		5	0	Absence in 25 g		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
1.3 Ready-to-eat foods unable to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes (4) (8)	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2 (6)	Products placed on the market during their shelf-life
1.18 Sprouted seeds (ready to eat)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

1.19 Pre-cut fruit and vegetables (ready to eat)	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life
1.20 Unpasteurized fruit and vegetable juices (ready to eat)	*Salmonella*	5	0	Absence in 25 g	EN/ISO 6579	Products placed on the market during their shelf-life

(b) Process hygiene criteria relevant to foods of plant origin

Food category	**Microorganisms/ their toxins, metabolites**	**Sampling** (1)		**Limits** (2)		**Analytical reference method** (3)	**Stage where criterion applies**	**Action in case of unsatisfactory results**
		n	*c*	*m*	*M*			
2.5.1 Pre-cut fruit and vegetables (ready to eat)	*E. coli*	5	2	100 cfu/g	1000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2 Unpasteurized fruit and vegetable juices (ready to eat)	*E. coli*	5	2	100 cfu/g	1000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

(1) n = number of units comprising a sample; c = number of sample units giving values between m and M.
(2) For points 2.1.3-2.1.5 m = M.
(3) The most recent edition of the standard shall be used.
(4) The limits (m and M) shall apply only to samples taken by the destructive method. The daily mean log shall be calculated by first taking a log value of each individual test result and then calculating the mean of these log values.
(5) The 50 samples shall be derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation.
(6) The number of samples where the presence of Salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review.

Adapted from INTERREG IVC 'Non-tariffs European Union' ebookbrowse.com/ivc-non-tariffs-eropean-union-pdf-d146370382.

1.4. Requirements concerning contaminants

1.4.1. Pesticides/plant protection products

❑ **MRLs for plant protection products (PPPs) in food trade**

Council Regulation (EEC) 315/93 defines contaminants:

"'Contaminant' means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Extraneous matter, such as, for example, insect fragments, animal hair, etc., is not covered by this definition".

For food of plant origin, residues of pesticides (plant protection products, PPPs) are globally the most contaminant problems in international trade, arising when residues of found to exceed the MRLs. For the EU, analyzed levels exceeding the MRL are frequently the reason for rejection of fresh fruit and vegetables and the trigger for food alerts. Pesticide residue levels are controversial for several reasons:

- PPPs may be banned from use in importing country; or the manufacturers may decide not to re-register a product under suspicion. The result is an MRL of 'effective zero'.
- The EU's new regulatory regime for plant protection products (Regulation (EC) 1107/2009) came into force in June 2011, replacing the long standing Directive No. 91/414/EC. In this Regulation risks from using PPPs (whether in food or in environment/biodiversity) are paramount in the assessment or re-assessment of an active substance or PPP; previously under Directive No. 91/414/EC risks were balanced against the benefits of the PPP.
- Many third countries, especially ACP countries and other developing countries lack the legislation and regulatory systems to ensure that 'dangerous' PPPs (according to global consensus) are not available for use by farmers and that permitted PPPs are used according to good agricultural practice.
- Middle-income countries with flourishing industries manufacturing PPPs may dispute bans in rich countries and continue to supply PPPs to ACP countries that are banned in say the EU.

❑ **Approval of PPs in EU**

Governing legislation is Regulation (EC) 1107/2009; there is a dual system in place for approval ('registration' in terminology of other systems) of PPPs:

- the European Commission approves the active substances contained in the products;
- EU Member States individually authorize the products on their territory and ensure compliance with EU rules; each MS need only authorize those products that are considered suitable, e.g. the appropriate formulation.

The European Commission has provided more information in its 'Fact Sheet' *EU Action on Pesticides.*[13]

❑ Specific MRLs

Regulation (EC) 396/2005 as amended and available from the official website does not contain the Annexes with specific MRLs (because of frequent amendments as MRLs evolve). The latest version of the specific MRLs may be found at ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN.

However, the information available there is in the form of a database where either the target PPP or the target commodity (confusingly referred to a 'product' in this database) must be inserted. The search may be restricted to specific Annexes but the various Annexes are not explained. A description of the actual Annexes is available from the UK Health and Safety Executive's Web site:[14]

- **Annex 1:** includes a list of all the food and feed commodities for which MRLs are set under Regulation (EC) 396/2005. This includes a number of commodities for which statutory MRLs will be set for the first time. The full list of Annex 1 commodities has been published via Commission Regulation 600/2010.

- **Annex 2:** mostly contains 'definitive' MRLs that were previously set under EC MRL Directives following the review of active substances under Directive 91/414/EEC.

- **Annex 3a:** contains 'temporary' MRLs, mostly for active substances that are awaiting a decision on inclusion under Annex I of Directive 91/414/EEC.

- **Annex 3b:** contains 'temporary' MRLs for the active substances listed in Annex 2 in combination with the new food and feed commodities.

- **Annex 4:** lists active substances for which MRLs are not required, because residues arising from use of the active substance are indistinguishable from natural background levels or other sources.

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13 ec.europa.eu/food/plant/plant_protection_products/eu_policy/docs/factsheet_pesticides_en.pdf.

14 www.hse.gov.uk/aboutus.

Figure 2. EU Pesticides Database Home Page

Active substances not listed in any of the Annexes are no longer in use. In anticipation of these circumstances Regulation (EC) 396/2005 states that a default level of 0.01 mg/kg will apply to any unnamed active substance in combination with any of the food and feed commodities listed under the Regulation.

The UK Web site mentioned above provides access to the same Commission database on MRLs but also provides access to the equivalent database for *Codex* MRLs.

The results of an initial search for all available MRLs applying to tropical roots and tubers ('Products' Tab) are shown in Figure 3. Two specific examples of pesticides and their MRLs in vegetables are now illustrated – dimethoate and methamidophos, the latter no longer approved for use on vegetables but is still permitted on some fruit. Using the 'Pesticide' Tab, the MRL for dimethoate in green beans is shown in Figure 4. The results search for MRLs in vegetables generally is shown in Figure 5.

Figure 3: MRLs for pesticides in tropical roots and tubers

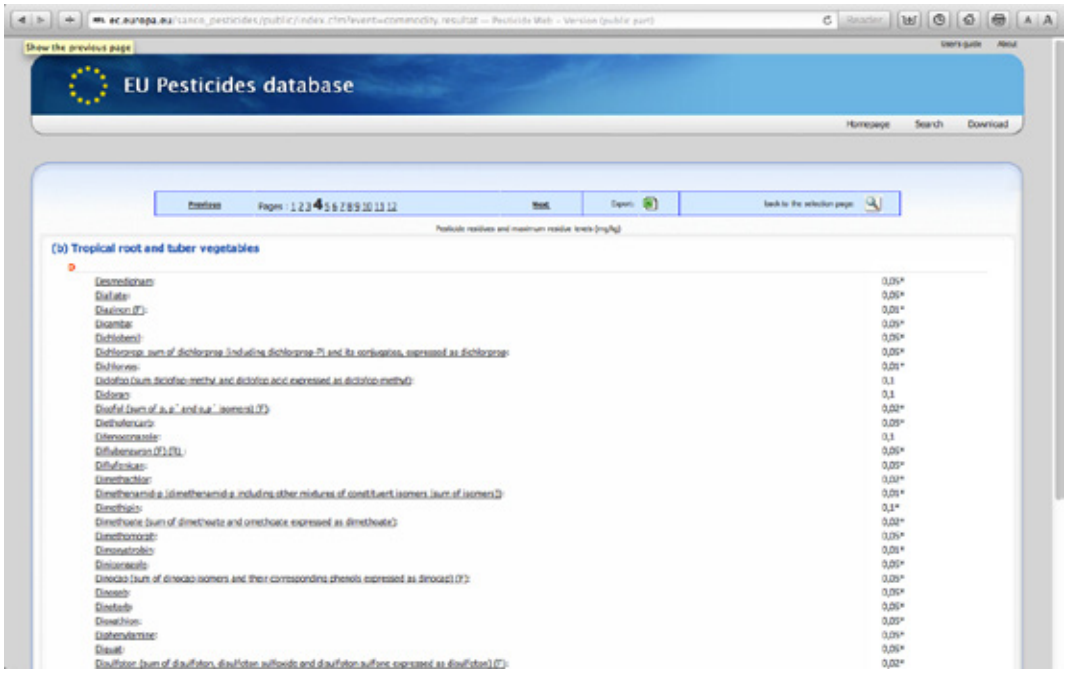


Figure 4: MRL for dimethoate in green beans

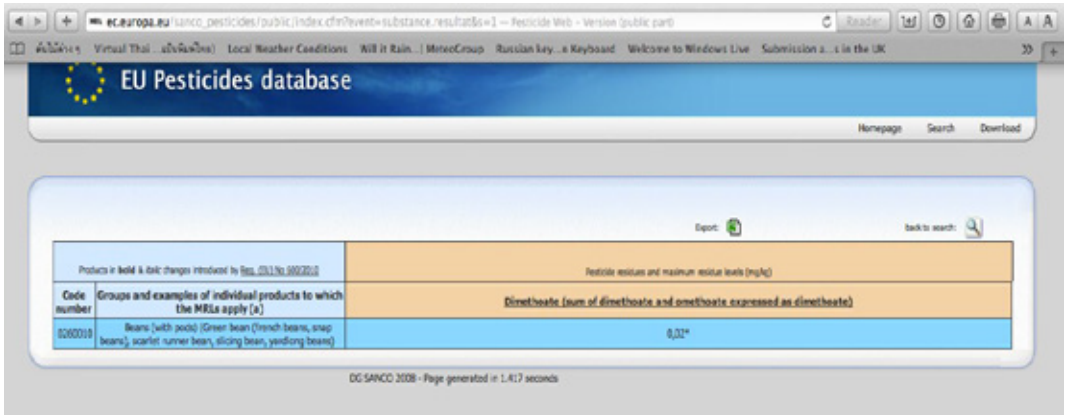


Figure 5: MRLs for dimethoate in vegetables

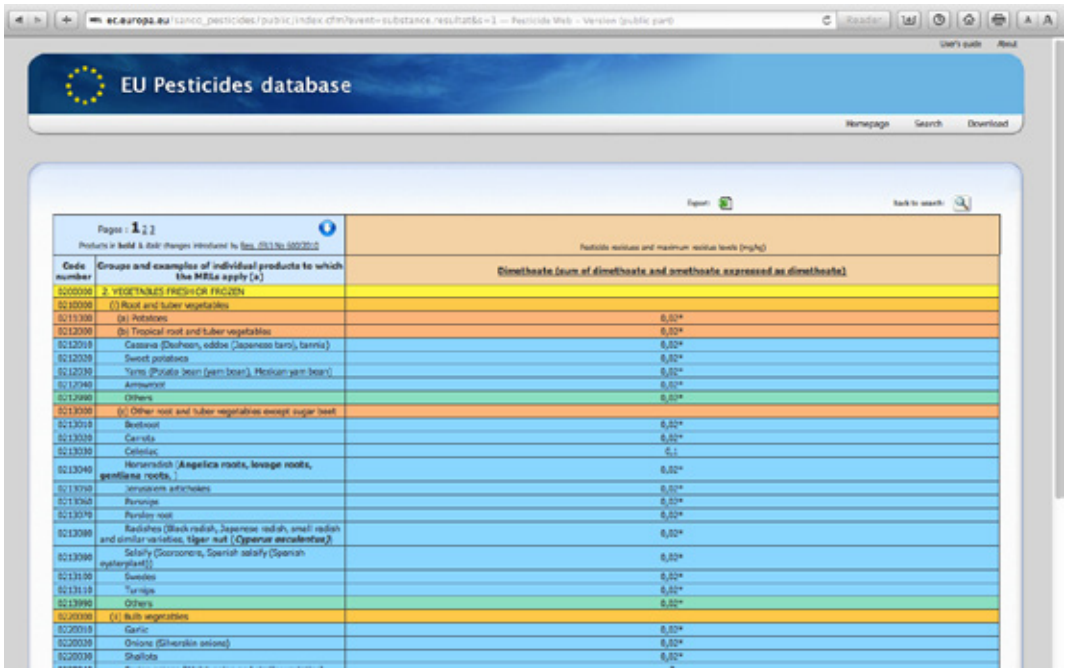


Figure 6 shows the 'effective zero' (standardized LOD of 0.01 mg/kg) set for methamidophos in vegetables generally while Figure 7 shows the 'evolution' of methamidophos MRL in green beans, it originally being approved for use on this crop (MRL of 0.02 mg/kg). The results of the database search may be exported from the screen to an Excel spread sheet as with methamidophos (all products).

Figure 6: MRL for methamidophos in vegetables

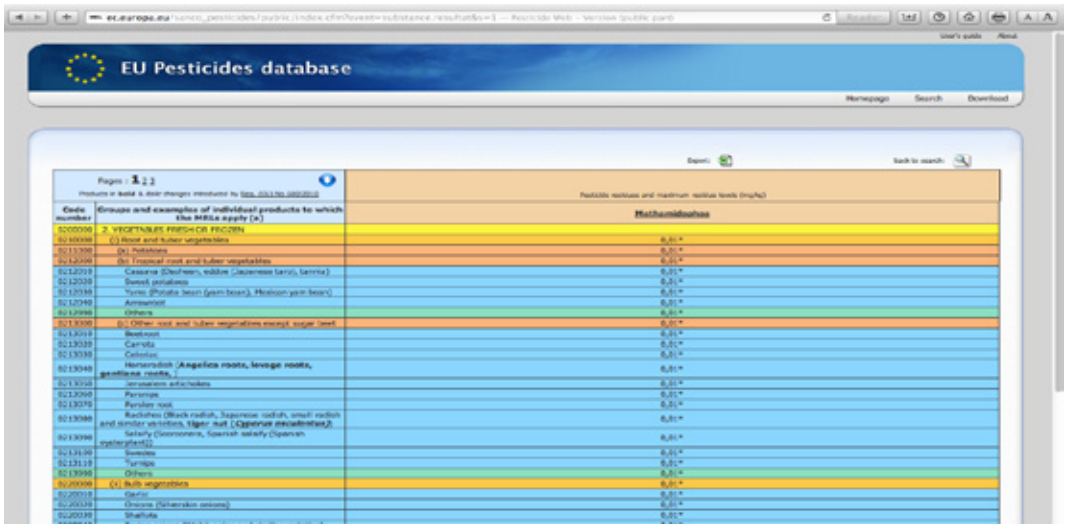


Figure 7: 'Evolution' of MRLs for methamidophos

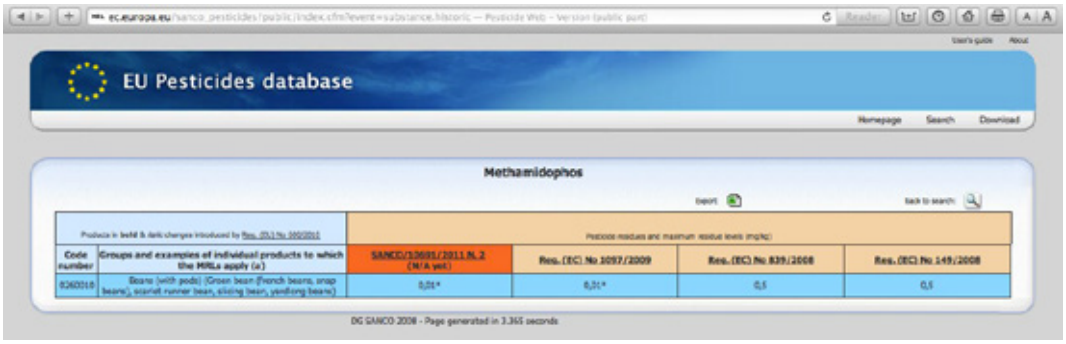
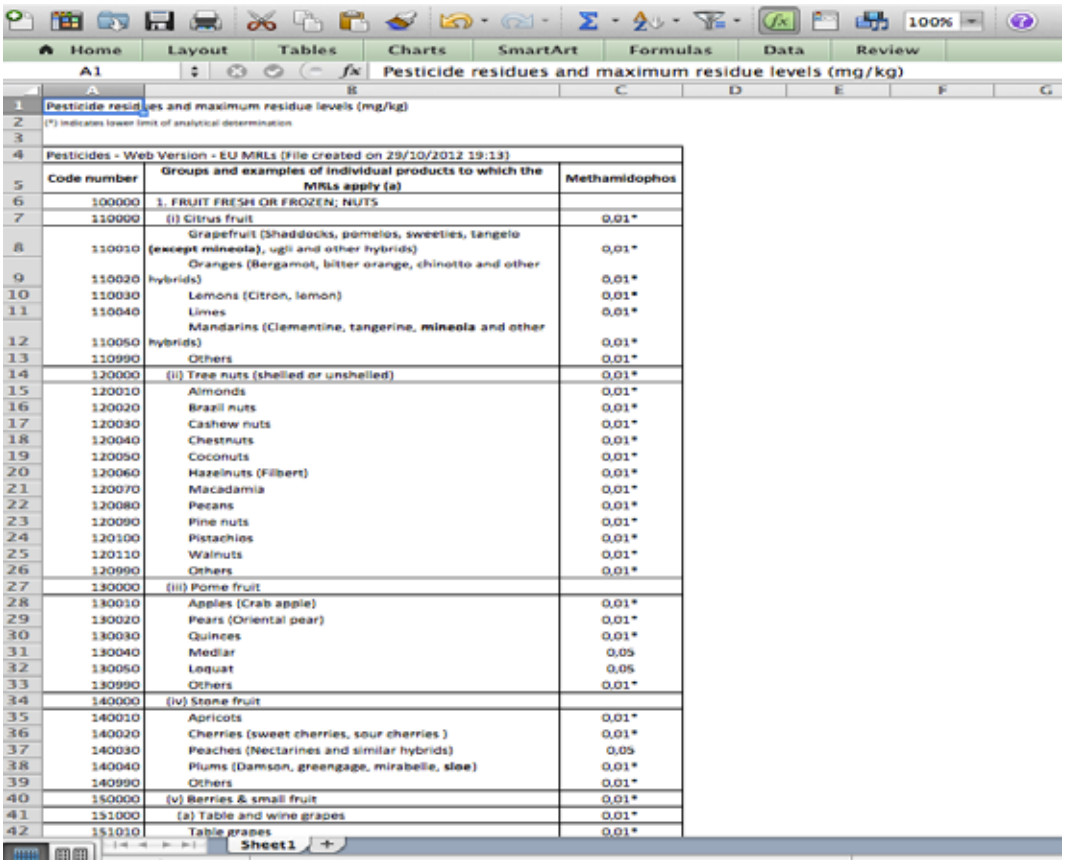


Figure 8: Excel spread sheet exported from pesticide database showing that methamidophos is still in use in some vegetables



Pesticide residues and maximum residue levels (mg/kg)

(*) Indicates lower limit of analytical determination

Pesticides - Web Version - EU MRLs (File created on 29/10/2012 19:13)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Methamidophos
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon)	0,01*
110040	Limes	0,01*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids)	0,01*
110990	Others	0,01*
120000	(ii) Tree nuts (shelled or unshelled)	0,01*
120010	Almonds	0,01*
120020	Brazil nuts	0,01*
120030	Cashew nuts	0,01*
120040	Chestnuts	0,01*
120050	Coconuts	0,01*
120060	Hazelnuts (Filbert)	0,01*
120070	Macadamia	0,01*
120080	Pecans	0,01*
120090	Pine nuts	0,01*
120100	Pistachios	0,01*
120110	Walnuts	0,01*
120990	Others	0,01*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,01*
130020	Pears (Oriental pear)	0,01*
130030	Quinces	0,01*
130040	Medlar	0,05
130050	Loquat	0,05
130990	Others	0,01*
140000	(iv) Stone fruit	
140010	Apricots	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,05
140040	Plums (Damson, greengage, mirabelle, sloe)	0,01*
140990	Others	0,01*
150000	(v) Berries & small fruit	0,01*
151000	(a) Table and wine grapes	0,01*
151010	Table grapes	0,01*

1.4.2. Other contaminants

❑ Types of contaminants other than pesticides

Contaminants for which MRLs are set in *Regulation (EC) 1881/2006* may be categorized for the purposes of the chapter as:

- Nitrates;
- Mycotoxins;
- (Heavy) Metals;
- Organic fumigant/biocide;
- Aromatic compounds including dioxins.

❑ Mycotoxins

Mycotoxins, especially aflatoxins, deserve special consideration because they have potentially very serious implications for human and animal health when present in food and feed; they are regarded as genotoxic carcinogens (*Regulation 1881/2006)*. The problems usually arise because of poor practices in post-harvest handling of a variety of foods, especially tree nuts, groundnuts, pulses and maize.

Special conditions (see Section 1.5.2.) have been imposed by a series of Decisions and Regulations in response to particularly emerging situations (Table 11).

Table 11: Special conditions imposed as a result of aflatoxin contamination

Legislation	Product(s)	Country of origin	Conditions
Commission Decision No. 2008/47/EC	Peanuts (groundnuts)	United States	Pre-export checks
Commission Regulation (EC) 1152/2009	Brazil nuts Groundnuts pistachios Hazelnuts, figs Figs, pistachios, almonds, mixed nuts Peanuts (groundnuts)	Brazil China, Egypt Iran Turkey USA	Health certificates and certificate of analysis; designated points of entry; prior notification of consignments; official controls on arrival
Commission Implementing Regulation (EU) 274/2012 amending Reg. No 1152/2009	As above	As above	Official controls by identity checks and sampling/analysis on arrival.

❑ Nitrates

Excessive nitrates may present respiratory problems in babies and young children. The risks are greatest with fresh vegetables resulting from fertilizer use. Regulation (EC) 1881/2006 sets the following limits for nitrate (Table 12).

Table 12: Limits for nitrate in vegetables, cereal-based food and baby food

Source : USDA-ARS

Foodstuffs	Nitrate limit (mg NO_3/kg)
Fresh spinach	2,500 – 3,000 depending on harvest period[15]
Preserved or frozen spinach	2,000
Fresh lettuce (except iceberg type)	2,500 – depending on growing conditions
Iceberg lettuce	2,000 – 2,500 depending on growing conditions
Processed cereal-based foods and baby foods for infants and young children	200

❑ Heavy metals

Heavy metals are primarily considered to pose a risk to health in food of animal origin, especially fishery products, because they accumulate in fatty tissue. However, there are limits set for some foods of plant origin as seen in Table 13 adapted from the Annex to Regulation (EC) 1881/2009. This type of contamination arises from the soil or from contaminated fertilizer.

Table 13: Limits for heavy metals in foods of plant origin

Metal	Food stuff	Limit (mg/kg wet weight)
Lead (Pb)	Cereals, legumes and pulses	0.20
	Vegetables, excluding brassica vegetables, leaf vegetables, fresh herbs and fungi. For potatoes the maximum level applies to peeled potatoes	0.10
	Brassica vegetables, leaf vegetables and the following fungi: *Agaricus bisporus* (common mushroom), *Pleurotus ostreatus* (Oyster mushroom), *Lentinula edodes* (Shiitake mushroom	0.30
	Fruit, excluding berries and small fruit	0.10
	Berries and small fruit	0.20
	Fruit juices, concentrates and nectars	0.05
	Wines, cocktails, etc.	0.20
Cadmium (Cd)	Cereals excluding bran, germ, wheat and rice	0.10

[15] See Annex to Regulation 1881/2006 for details.

	Bran, germ, wheat and rice	0.20
	Soybean	0.20
	Vegetables and fungi	0.50 – 1.00
Tin (Sn)	Canned beverages, including fruit juices and vegetable juices	100

❑ Acrylamide

Another contaminant that is the focus of current concern is acrylamide, which is known to be present in various foodstuffs as a result of cooking, especially at high temperatures. Products of plant origin being investigated include:

- Products of cereal grain origin (mainly wheat) – bread products, biscuits crackers, crisp bread, breakfast cereals;
- Fried potato products (French fries and crisps).

At the moment there are no specific import requirements because the nature of the contamination and because possible effects on health are very complicated. Currently the Commission and the food industry are cooperating on the way to reduce levels of acrylamide in food.

❑ Hydrocarbons

Three categories of hydrocarbons (organic chemicals) are recognised as contaminants in Regulation (EC) 1881/2006: 3-monochloropropane-1,2-diol (3-MCPD) (a carcinogenic and potentially genotoxic product of protein hydrolysis); dioxins and polychlorinated biphenyls (PCBs); and polycyclic aromatic hydrocarbons (Table 14, adapted from Regulation 1881/2006). It will be seen that the permitted levels of dioxins/PCBs are very low and that the toxicology is complex.

Table 14: Limits on hydrocarbons in foods of plant origin

Contaminant	**Foodstuff**	**Maximum level**	
3- MCPD	Hydrolysed vegetable protein	20 µg/kg	
	Soy sauce	20 µg/kg	
Dioxins and PCBs		Sum of dioxins	Dioxins and PCBs
	Vegetable fats and oils	0.75 pg/g fat	
Polycyclic aromatic hydrocarbons	Oils and fats (excluding cocoa butter) intended for direct human consumption or use as an ingredient in foods	2.0 µg/kg	
	Processed cereal-based foods and baby foods for infants and young children	1.0 µg/kg	

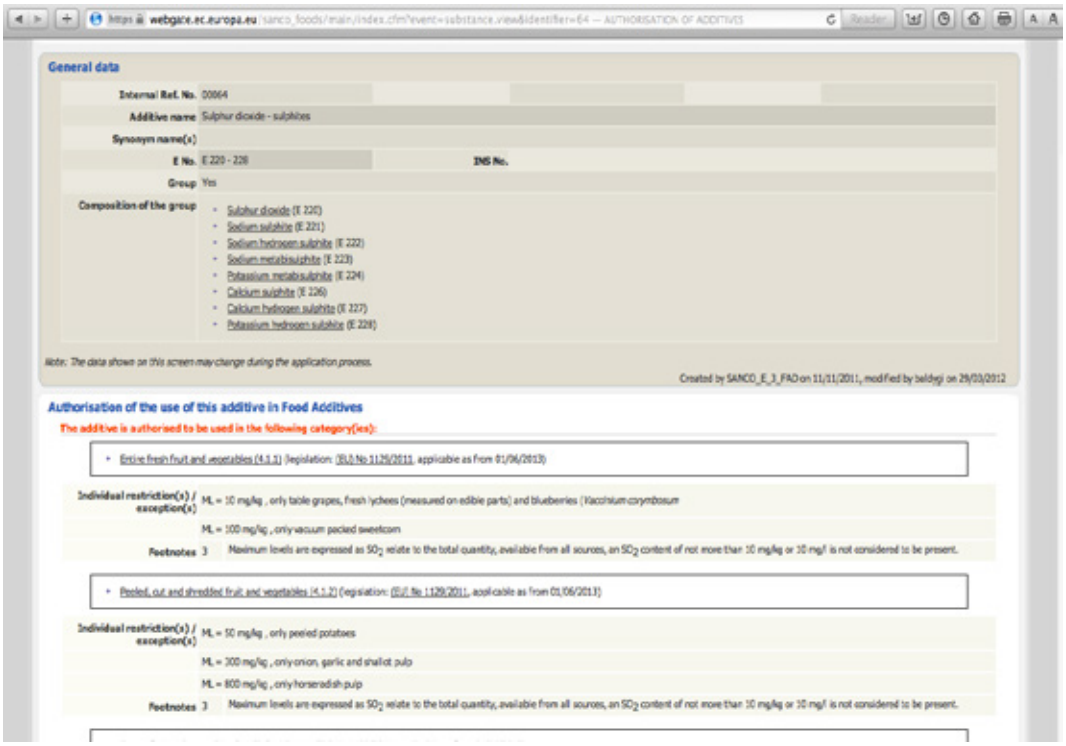
1.4.3. Food additives, food contact materials and fraud

❑ Additives and flavourings

Regulation (EC) 1333/2008 gives the specific additives that are permitted and in addition, because there are very many approved additives for different purposes, there is a **database on food additives**.[16]

Using the Database, one can find the maximum permitted levels for a particular commodity. The result of a search of the database for one example – sulphites – used as a preservative is given in Figure 9.

Figure 9: Limits on sulphites in certain foods



❑ Food contact materials

The rules for food contact materials are given in Regulation (EC) 1935/2004 and the database above also includes food contact materials.

The main issue with food contact materials is substances used in their manufacture or as additives that might migrate into the food from packaging or from pots or crockery in which food cooked or served from. These substances, or which there are very many, are to be found under the 'Substances' Tab of the Database.

[16] www.fao.org/fao-who-codexalimentarius/standards/gsfa/en.

Categories of food packaging materials of most interest for food of plant origin as listed in the Database ('Categories' Tab) are wood, paper and board and plastics. No potential migratory substances are currently covered by legislation for wood and paper/board but plastic packaging materials potentially contain many controlled substances as additives in the manufacturing materials or as raw material ('monomers').

There are two limits set on the **acceptable migration into food** from plastic materials (NOT the content of the material):

- Overall Migration Limit - 10mg of substances/dm² of the food contact surface for all substances that can migrate from food contact materials to foods;
- Specific Migration Limit (SML) for individual authorised substances fixed on the basis of a toxicological evaluation.

SML is set according to the Acceptable Daily Intake or the Tolerable Daily Intake established by the Scientific Committee on Food. The limit is set on the assumption that every day throughout lifetime, a person weighing 60kg eats 1kg of food packed in plastics containing the substance in the maximum permitted quantity.[17]

❑ Fraudulent food

Source : USDA-ARS

Food fraud for good reasons hits the media headlines when it is discovered. There have been high profile cases concerning adulterated milk and milk products produced in China; and cooking oil and wine produced in the EU and elsewhere fraudulently labelled or adulterated.

The most serious case of adulteration of food of plant origin imported into the EU concerned red chilli powder and red chillies adulterated with carcinogenic dyes of the 'Sudan red' type. The original culprits were in India but there is a global food alert at present because adulterated chilli powder was imported into many countries before the crime was detected in the EU. Consequently manufacturers were using the material to manufacture chilli sauce or hot tomato ketchup etc., unaware of the alert.

The Sudan red case has been the major preoccupation of the European Commission as a fraud with potentially serious health consequences that are ongoing. (The Chinese milk fraud has essentially been dealt with).[18]

[17] ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm.

[18] ec.europa.eu/food/food/chemicalsafety/fraudulent/index_en.htm.

1.5. Food of non-animal origin subject to in increased level of controls

1.5.1. Composite food

There are no special requirements for composite food, especially as these are defined as including only **processed** food of animal origin. However, microbiological criteria (Section 1.3.3) may apply to the animal-origin components such as cooked chicken, eggs or cheese in salad. There may also be special conditions applying in the case of such components as honey as well as special conditions for plant-origin components such as chilli (Sudan dyes) or soybean (aflatoxin). HACCP may be required and the establishment producing the composite product in the exporting country may have to be approved following the requirements of Regulation (EC) No 852/2004 and Regulation (EC) No 882/2004.

However, the European Commission has been developing a risk-based approach to composite products with advice from the European Food Safety Authority. In recognition that the veterinary checks required under basic provisions for some foods of animal origin might be overly burdensome, a new regulatory regime for such products was introduced in Commission Regulation (EU) No 28/12 with a new model health certificate for imports. The health certificate was quickly replaced by an amended version in Commission Implementing Regulation (EU) No 468/2012.

1.5.2. Safeguard measures

Normally, food of non-animal origin does not have to be accompanied by a health certificate or equivalent that applies for food of animal origin, nor do individual consignments have to be tested for contaminants (but see microbiological requirements on FBOs, Section 1.3.1). However, in accordance with Article 15, paragraph 5 of Regulation (EC) No 882/2004, the Commission may establish a list of food of non-animal origin (including composite products) that, on the basis of known or emerging risks, should be subjected to an increased level of official controls upon introduction into the EU.

For such food, the following would apply:

- particular points of entry shall be designated;
- food business operators shall give prior notification of the arrival of the goods and of their nature.

Originally there was a series of Commission Decisions imposing special conditions or emergency measures to deal with such cases. These are listed in Annex III of the 'Guidance Document'.[19] Subsequently Commission Regulation No 669/2009 was released consolidating these special measures but this has been subsequently amended by a series of Commission Regulations, which at the time of writing are:

[19] See Footnote 13.

- Commission Regulation (EU) 212/2012;
- Commission Regulation (EU) 294/2012;
- Commission Regulation (EU) 889/2012.

These Annexes in the original regulation and amending legislation should be read together. Most of the special measures concern pesticide residues and aflatoxins in a variety of products from many different countries. The information cannot sensibly be summarised here and so the reader is referred to the above items of legislation.

There have also been special conditions imposed because of aflatoxin contamination. For further information, the reader is referred to the 'Question and Answer' document available from the Commission on Regulation No 669/2009 as amended.[20]

1.5.3. Special measures on radiation

Radiation is a potential hazard in food arising from particular incidents such as the escape of radiation from a nuclear power station or a spill during transport of radioactive materials. In such cases there may be special conditions imposed on certain susceptible food products where there is a risk that primary production may have suffered from contamination, either airborne or in water.

Food deliberately irradiated for purposes of preservation is not considered harmful provided it is carried out in an approved manner (Directive No. 1999/2/EC; Directive No. 1999/3/EC). Authorisations may be given from national laws of the Member States.

Food of plant origin authorised for irradiation includes the following:

- fruits and vegetables including root vegetables;
- cereals, cereal flakes, rice flour;
- spices, condiments ;
- gum Arabic.

For imported food that is irradiated, the main requirement is **labelling** (applying to all irradiated food)[21].

1.5.4. Rapid alerts

Regulation (EC) No. 178/2002 includes a special chapter (Chapter IV – Articles 50-57) on 'Rapid Alert System, Crisis management and Emergencies'. One important pillar of these provisions is the **Rapid Alert System for Food and Feed (RASFF)**, to provide a comprehensive and coordinated information service about food alerts as the basis for special conditions or emergency measures that are deemed necessary. Participation in RASFF is limited to EU Member States (and closely associated countries like Norway and Switzerland), i.e. only those countries may make notifications. However, many alerts arise

[20] ec.europa.eu/food/food/controls/increased_checks/docs/QandA_paper_en.pdf.

[21] ec.europa.eu/food/food/biosafety/irradiation/comm_legisl_fr.htm.

from border controls on imported food and in the past the countries of origin of such food were only formerly made aware of the notification by a cumbersome process involving regular mail. Now however, third countries may participate more directly through the **RASFF Window**, meaning that they will receive rapid notification of alerts that concern their exports. The means of access to the RASFF Window is set out in the *RASFF Report for 2009* (page 44).[22] There is also the RASFF portal database that may be searched by anybody.[23]

[22] ec.europa.eu/food/food/rapidalert/docs/report2009_en.pdf.

[23] ec.europa.eu/food/food/rapidalert/rasff_portal_database_en.htm.

1.6. Phytosanitary requirements

1.6.1. Directive No. 2000/29/EC

The basis for specific phytosanitary requirements for plants and any plant products (whether food or not) imported into the EU is Directive No. 2000/29/EC. The fundamental objective is to prevent the introduction of harmful organisms in to the EU. However, some of these species are already present in parts of the EU rather than being absent from the entire territorial area. Consequently some of the measures prescribed in this Directive concern the prevention of the further spread of harmful organisms within the EU. There are special 'protective zones' established for these organisms. Such measures and others are beyond the scope of this chapter. However, even in such cases, the harmful organisms should be prevented from re-entering the EU across its internal borders because of the free movement of goods across the EU. If there were not such controls, these species would be able to enter areas they are at present absent from. The Annexes to Directive 2000/29/EC listing harmful organisms and phytosanitary requirements for plants and plant products (Sections 1.6.2-1.6.5) take into account whether the pests are present in the EU or not.

1.6.2. Harmful organisms = quarantine pests

Of more immediate relevance is the listing of harmful organisms in Annex I and Annex II of *Directive 2000/29/EC*. **Annex I** includes those harmful organisms that are prohibited from entry into the EU whatever their association with any particular plants, food or other commodity. This means that if they are detected in any imported consignment the goods will be rejected (or destroyed if already imported). This happens frequently with such pests as *Bemisia tabaci* and *Liriomyza sativae* on vegetables and fruit flies on fruit (see Table 15).

Table 15: Selected Annex I pests that could be associated with food imports

Pest type	Scientific name	Common name	Likely pathway relevant to food imports	Geographical distribution/pest status
Insects	*Anoplophora* spp.	Long horn beetles	Wood packaging material	Asia, N. America
	Bemisia tabaci (non-European races)	Whitefly (as virus vector)	Leafy vegetables	Non-European races as vectors of viruses not present in EU
	Diabrotica spp.	Root worms (larval stages)	Maize	North and Central America, Caribbean

Pest type	Scientific name	Common name	Likely pathway relevant to food imports	Geographical distribution/pest status
	Liromyza sativae	Leaf miner	Vegetables	Absent in EU
	Spodoptera spp.	Leafworms, armyworm etc.	Fruit, vegetables	Americas, Asia, Africa, Pacific (depending on species)
	Thrips palmi	Palm thrips[24]	Vegetables	Africa, Asia, Americas, Pacific
	Tephritidae (*Anastrepha, Dacus, Rhagoletis*)	Fruit flies	Fruit	Americas, Africa, Asia
Nematode	*Xiphinema* spp.	Dagger nematodes (as virus vectors)	Soil (on roots and tubers)	Non-European strains vectors of virus not present in EU
Fungus	*Monilinia fructicola*	Brown rot of stone fruit		Absent from Europe

In fact, Annex I covers most of the specific phytosanitary requirements for food imports of plant origin because a great many types of fresh fruit and vegetables would be subject to inspection on arrival and require a phytosanitary certificate issued by the Competent Authority of the exporting country. It can also mean that in the case of *Tilletia indica* (Karnal bunt of wheat), for example, food grain imports could be prohibited from infected areas. According to the regions or countries listed in Annex I where the pest is present, there will be a requirement for the **phytosanitary certificate** to state that the consignment has been inspected and the specified organisms found to be absent. An additional declaration may also be required, e.g. that the consignment has been treated in a specified manner.

Annex II includes those harmful organisms that are banned if found present on particular plants or plant products. This also means those offending consignments will be rejected. The threshold detection for action may be very low for Annex I and II pests – a single live organism in a standard sampling may be sufficient to trigger rejection. In fact, Annex II almost completely concerns plants and seeds for planting, not relevant for food imports. However there is one instance relevant to food. The harmful organism is *Citrus tristeza* virus (European isolates) and the prohibited commodity is Citrus fruit imported into certain protected [citrus growing] zones in southern Europe. However, the material is only prohibited if the fruit has leaves and peduncles attached.

[24] Named after someone called Palm; not a pest of palms.

1.6.3. Prohibited plant material

Annex III lists those 'plants, plant products and other objects' that are prohibited from entry, the reason being the severity of the associated pest risk. Certain pests may be specified but this is not necessary. The prohibition on a particular material may apply globally or only to certain specified countries of origin, depending on pest distribution.

Essentially, there is very little of relevance to food imports, as with Annex II. There is a prohibition on import of potato tubers but this should be understood in the context of **Annex IV.** Soil that might be attached to roots and tubers for consumption is also prohibited.

1.6.4. Special requirements for certain plants and plant products

Annex IV is a lower level of import requirements generally based on the need for certification (phytosanitary certificate) and inspections on arrival, rather than a blanket ban. It might be expected that this is where the majority of food-relevant import requirements will be found. However, when plant products are intended for consumption (even when the food is live 'plants' that could be planted), the pest risk is reduced. Table 16 lists food items likely to be of relevance to ACP exporting countries together with the required statement on the phytosanitary certificate. (Banana fruit is the only major fresh fruit commodity NOT requiring a phytosanitary certificate for import into the EU).

Table 16: Specific requirements for food items from Annex IV of Directive 2000/29/EC

Food types	Official statement and other controls (summarised)
1. Fruits of *Prunus* originating in non-European countries (from 15 February to 30 September,)	Fruits originate in a country known to free from *Monilinia fructicola* or fruits originate in an area recognised as being free from *Monilinia fructicola* or fruits have been subjected to appropriate inspection and treatment procedures prior to harvest and/or export to ensure freedom from *Monilinia* spp.
1. Fruits of *Citrus* and other members of Rutacea, originating in third countries	The fruits shall be free from peduncles and leaves and the packaging shall bear an appropriate origin mark.
	(a) *Xanthomonas campestris* or (b) the fruits originate in an area recognised as being free from *Xanthomonas campestris* or (c) either, in accordance with an official control and examination regime, no symptoms of *Xanthomonas campestris* (all strains pathogenic to *Citrus*) have been observed in the field of production and in its immediate vicinity since the beginning of the last cycle of vegetation and none of the fruits harvested in the field of production has shown

Food types	Official statement and other controls (summarised)
	symptoms of *Xanthomonas campestris* and the fruits have been subjected to treatment such as sodium orthophenylphenate, and the fruits have been packed at premises or dispatching centres registered for this purpose, or any certification system, recognised as equivalent to the above provisions in accordance with the procedure laid down in Article 18, has been complied with.
	(a) the fruits originate in a country recognised as being free from *Cercospora angolensis* or (b) the fruits originate in an area recognised as being free from *Cercospora angolensis* or (c) no symptoms of *Cercospora angolensis* have been observed in the field of production and in its immediate vicinity since the beginning of the last cycle of vegetation, and none of the fruits harvested in the field of production has shown, in appropriate official examination, symptoms of this organism.
	(a) the fruits originate in a country recognised as being free from *Guignardia citricarpa* or (b) the fruits originate in an area recognised as being free from *Guignardia citricarpa* or (c) no symptoms of *Guignardia citricarpa Kiely* have been observed in the field of production and in its immediate vicinity since the beginning of the last cycle of vegetation, and none of the fruits harvested in the field of production has shown, in appropriate official examination, symptoms of this organism, or (d) the fruits originate in a field of production subjected to appropriate treatments against *Guignardia citricarpa* and none of the fruits harvested in the field of production has shown, in appropriate official examination, symptoms of this organism
Tubers of *Solanum tuberosum* (Irish potato)	(a) the tubers originate in countries known to be free from *Clavibacter michiganensis* ssp. sepedonicus or (b) provisions recognised as equivalent to the Community provisions on combating *Clavibacter michiganensis* ssp. *sepedonicus* have been complied with, in the country of origin.
Tubers of *Solanum tuberosum* other than those intended for planting	The tubers originate in areas in which *Pseudomonas solanacearum* is not known to occur.

Annex V lists those plant materials subject to movement controls within the EU, essentially meaning that a **plant passport** is required. This Annex is in two parts, Part A for those materials originating within the EU and Part B for those originating outside the EU. Food materials relevant to ACP countries in Part B consist only of the following tropical and sub-tropical fruit: *Citrus* and Rutaceae, *Annona, Diospyros, Mangifera, Passiflora, Syzygium, Psidium.*

However it is emphasised that the exporter has no responsibility to produce a **plant passport**; this is entirely a matter for people handling the imports inside the EU.

Annex VI provides for 'special arrangements' on certain commodities but as yet these have yet to be developed.

1.6.5. Wood packing material

Annexes III and IV to Directive No. 2000/29/EC make frequent reference to wood and bark. This is of special concern because timber, and especially timber with bark attached, has been the pathway for introduction of many serious pests. More specifically for food imports, the concern is wood used as packing material or as pallets and 'dunnage' (separators, etc.). Directive No. 2004/102/EC (amending Directive No. 200/29/EC) incorporates the provisions of **ISPM 15**[25] requiring wood packaging and dunnage to be treated and marked as follows:

- the wood must be either heat treated or fumigated with methyl bromide, in line with ISPM15 procedures;
- the wood must be officially marked with the ISPM 15 stamp;
- from March 2006, all wood packaging material imported into the EU will have to be debarked.

These requirements do not apply to:

- wood of 6mm thickness or less;
- wood packaging material made entirely from processed wood produced
- using glue, heat and pressure, such as plywood, oriented strand board and veneer;
- wood packaging material used in intra-Community trade.

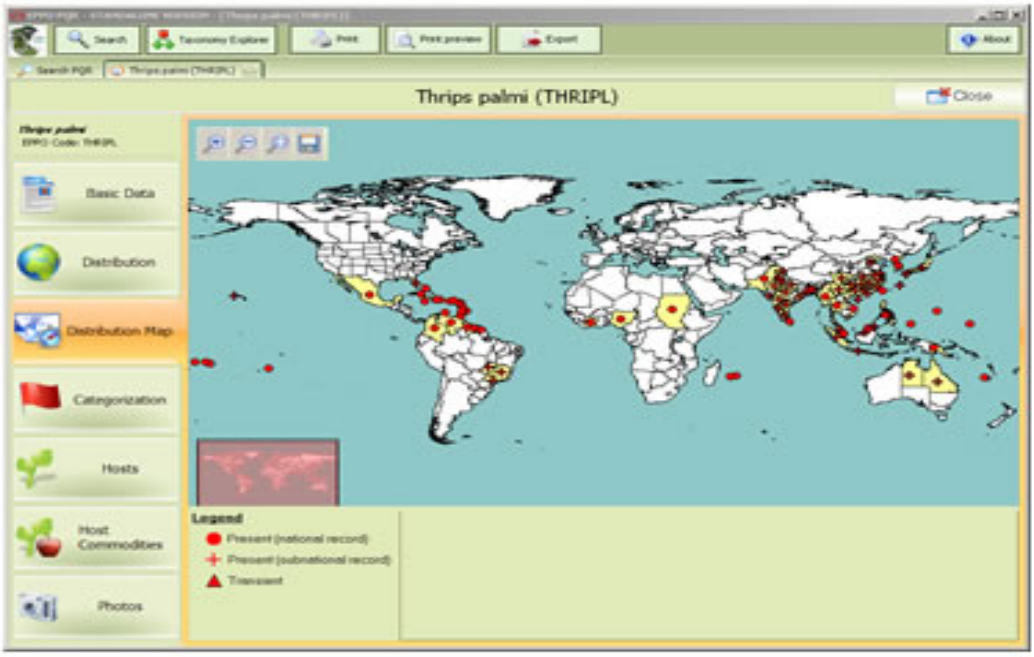
Pallets and dunnage must meet the same criteria as wood packaging material.

1.6.6. How to check phytosanitary requirements

The Annexes to *Directive 2000/29/EC* are very complex with a lot of detail and impossible to reproduce here in their entirety. Apart from going through the Annexes, how may the appropriate phytosanitary requirements for a particular commodity be found? The reader is referred to the following source of information for assistance.

[25] www.ippc.int/file_uploaded/1323945454_ISPM_15_2009_En_2011-11-29_Refor.pdf.

❑ EPPO PQR Database



The European and Mediterranean Plant Protection Organisation (EPPO) has developed and published a free database[26] of pests worldwide that are relevant to the entire EPPO area (much larger than the EU). One of the tools included in the software is a comparison of the pests known to be present in a particular exporting country with the recorded quarantine pests of the importing country/region ('harmful organisms' in the case of the EU). One may also determine the potential pathways for each pest. Knowing the harmful organisms that might pose a risk in exports from a particular country, the Annexes to Directive No. 2000/29/EC can be checked to see what controls might be in place.

[26] www.eppo.int/DATABASES/databases.htm.

1.7. Novel foods and GMOs

1.7.1. Novel foods

Novel foods included in Regulation (EC) 258/97 are:

- foods and food ingredients with a new or intentionally modified primary molecular structure;
- foods and food ingredients consisting of or isolated from microorganisms, fungi or algae;
- foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
- foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

Such foods require authorisation on the basis of a risk assessment that they are safe for consumers and that they are properly labelled. There is a 'fast-track' procedure for notification of novel foods on the basis of 'substantial equivalence'.[27] Regulation (EC) 258/97 applies. New authorisations are provided by Commission (Implementing) *Decisions*. Novel foods imported into the EU must therefore be authorised and must be labelled appropriately.

1.7.2. Food from GMOs

Food derived from genetically modified food is a very controversial subject and whether one believes that such food is inherently dangerous is mostly a matter of ideology rather than originating in any convincing data that consumption of GMO food poses risks to health. Be that as it is, there are regulations and procedures for authorisation of food of GMO origin or content which are derived from the approaches to novel foods described above. Regulation (EC) 1829/2003 applies. This Regulation also contains the labelling requirements (for food with more than 0.9% GMO content).

New authorisations are notified through Commission Decisions but there is also a register of authorised GMO food.[28] Once again, there are no specific import requirements for GMO food of (plant) origin but any such food must be authorised and must be labelled if GMO content exceeds 0.9%.

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27 ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm.

28 ec.europa.eu/food/dyna/gm_register/index_en.cfm.

1.8. Conclusions

The specific requirements for food of plant origin imported into the EU are **SPS measures** according to the WTOs' SPS Agreement. The import requirements described herein are food safety-based requirements or phytosanitary requirements. This chapter has not considered requirements on food quality, composition and other characteristics that are subject to WTO's TBT Agreement nor are animal feed requirements considered (the other subject of the EU's General Food Law). In this respect it is emphasized that EU import requirements are risk-based and therefore meant to be in accordance with the SPS Agreement. However, the primary objective of the EU's Farm-to-Fork strategy is to achieve a high level of protection for consumers and for the environment (through plant health, especially).

It follows that the first stage in developing specific import requirements is to identify and characterise the hazards that might be associated with food of plant origin. There are many different categories of hazards and the methodology to develop risk-based import requirements varies according to the type of hazard. For food safety-based requirements, the simplest approach is to base requirements on limits for microorganisms, contaminants and other substances set by the *Codex Alimentarius* Commission ('international standards'); Codex limits are by definition justified as being risk-based. Any standards set by the EU or an individual Member State that are higher than standard Codex limits must be overtly risk-based to be consistent with the SPS Agreement. Where there is a departure from *Codex*, this is usually because of higher levels of consumption of a particular food so that the limit must be lower to achieve the same level of protection as offered by *Codex*.

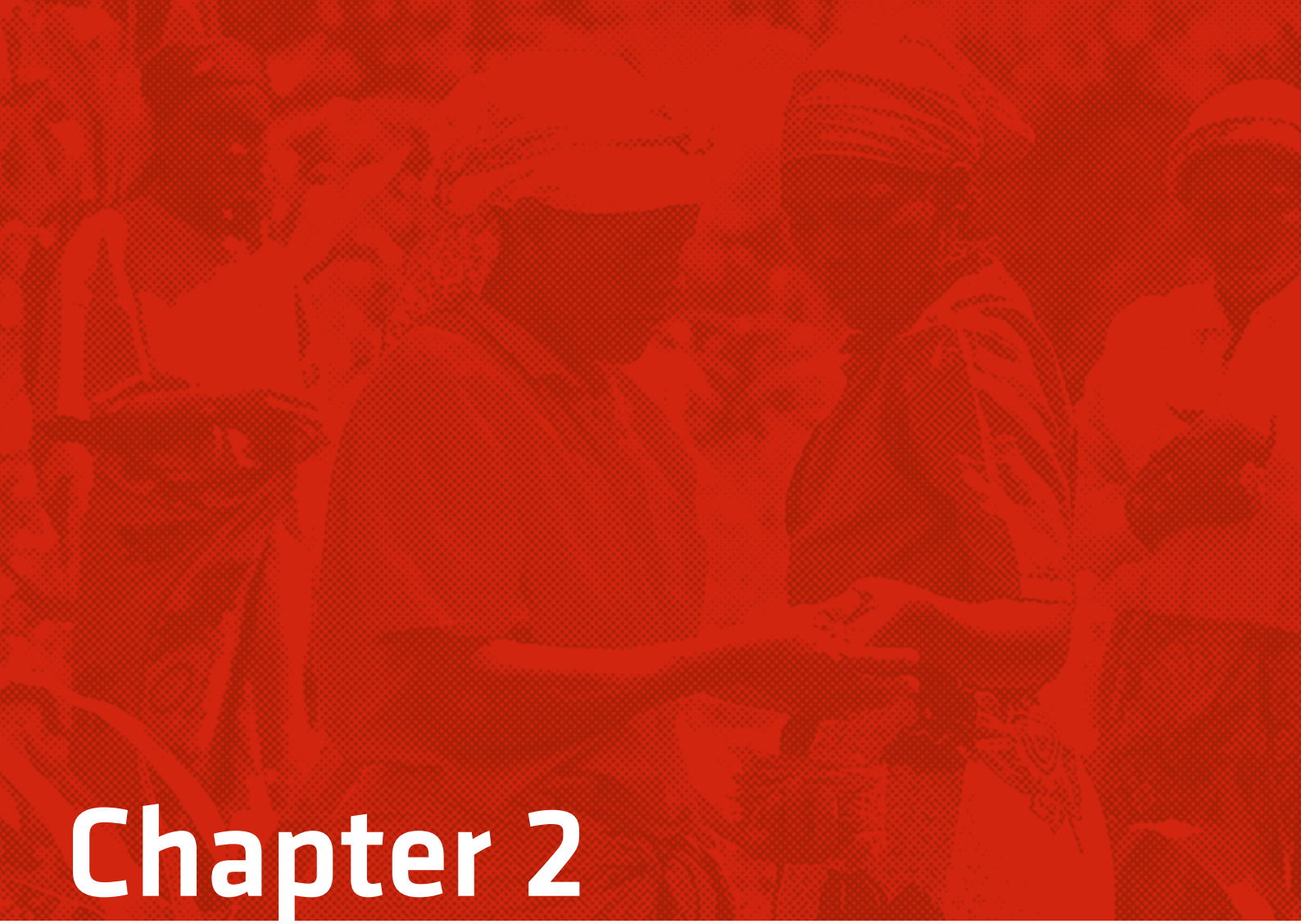
Phytosanitary requirements have a different basis because there are no equivalents of *Codex* standards in terms of specific plant pests and phytosanitary measures that are automatically permissible under the International Plant Protection Convention or the SPS Agreement. In this case the starting point is a risk-based list of 'harmful organisms' that are deemed to pose an actual risk to plant life in the EU. From this specific phytosanitary requirements can be developed.

Associated with these specific import requirements are various documentary requirements, e.g. health certificate for export, phytosanitary certificate. Notwithstanding that the EU attempts to anticipate all possible risks with the very detailed import requirements that have been described in this chapter, there will inevitably new threats identified from monitoring of food imports. This will be seen in food alerts through the RASFF system and the possibility of specific safeguard measures, requiring for example a certificate of chemical analysis not generally required for food of plant origin. There may also be plant pest alerts for organisms that are not yet formally recognized as harmful organisms in the Annexes to Directive 200/29/EC. In this way there is flexibility to respond to emerging situations that is still intended to be consistent with the SPS Agreement.

Appendix

A.1. Answers to Quiz on SPS/TBT and explanation (Table 1)

Requirement or marketing device	TBT or SPS?	Explanation
Labelling requirement for GMO content	TBT	Transparency, consumer choice
Restriction on sugar, salt or fat content	SPS for babies, infants (elderly people?)	Protection of health (e.g. infant formula) – requirement, not labelling.
Spraying of passenger aircraft for malaria control	Public health	Not trade in goods but movement of people
'Drink this for strength!'	TBT	Dubious justification on label Could be allowed as advertising 'puff'
Packaging requirement for UHT milk	TBT	Requirement for shelf-life
Pasteurisation process for UHT milk	TBT	Requirement for shelf-life. Might be SPS for fresh milk



Chapter 2

Regulations governing food safety, animal and plant health

2.1. International food safety policy

The 1990s saw a convergence of two trends. First of all, in developed countries in particular, consumers became increasingly aware of the vulnerability of food supplies and of the international dimension of food risks. Secondly, the pace of economic legislation suddenly picked up speed (in particular in the field of trade).

The ***Codex Alimentarius* Commission** (*Codex*) has always been the main agency responsible for drawing up international regulations on food safety, although the World Organization for Animal Health (the OIE) has also formulated certain rules governing the food safety of products of animal origin in the form of optional standards, i.e. guidelines for use by States and recommendations on the protection of human health.

Since 1995, the World Trade Organization (WTO) has adopted the international regulations laid down by these organizations as part of its own commercial rules, in accordance with **the Agreement on the Application of Sanitary and Phytosanitary Measures (MSP or SPS**).

At international level, **three institutions** have been entrusted with complementary mandates in the field of food safety:

- the United Nations Food and Agriculture Organization (FAO),
- the World Health Organization (WHO),
- the World Organization for Animal Health (OIE).

The joint FAO/WHO programme on food standards is implemented by the ***Codex Alimentarius Commission*** (or '*Codex*').The OIE, for its part, defines the safety rules applicable to the international trade in animals and animal products.

The **World Trade Organization (WTO)** is not directly involved in food safety but the rules adopted within it offer an effective framework for the application of food safety measures to international trade.

Indeed, sanitary and phytosanitary measures,[1] by their very nature, may result in restrictions on trade. A sanitary or phytosanitary restriction that is not actually required for health reasons can be a very effective protectionist device, and because of its technical complexity, a particularly deceptive and difficult barrier to challenge.

Within the framework of the establishment of the World Trade Organization (WTO), which superseded the GATT in April 1994, **two specific agreements** were concluded in Marrakech in order to limit recourse to unjustified barriers to trade using technical rules with a protectionist agenda:

- the **Agreement on the Application of Sanitary and Phytosanitary Measures (the 'SPS' agreement)**;
- the agreement on **Technical Barriers to Trade (the 'TBT' agreement)**. The **TBT measures** usually concern:

[1] Sanitary and phytosanitary measures is an accepted term in English to describe regulatory issues concerned with food safety, animal health and plant health.

- labelling of composition or quality of food, drink and drugs,
- quality requirements for fresh food,
- volume, shape and appearance of fresh food packaging,
- packaging and labelling for dangerous chemicals and toxic substances, pesticides and fertilizer,
- regulations for electrical appliances,
- regulations for cordless phones, radio equipment etc.,
- textiles and garments labelling,
- testing vehicles and accessories,
- regulations for ships and ship equipment,
- safety regulations for toys,
- etc.

The SPS agreement lays down **the conditions under which a State may adopt and implement sanitary** (animal health, food safety) **or phytosanitary** (plant health) measures which have a direct or indirect impact on international trade. The SPS agreement makes explicit reference to three bodies: the *Codex Alimentarius*, the World Organization for Animal Health (OIE) and the International Plant Protection Convention (IPPC). The standards defined by these bodies therefore serve as a reference within the framework of dispute resolution procedures.

The TBT agreement, for its part, concerns, as far as agriculture and food are concerned, the rules that do not come under the SPS agreement. These include the **requirements in the field of composition or labelling**. Contrary to the SPS agreement, the TBT agreement does not require the technical regulation behind the commercial measure to be based on a scientific analysis.

2.2. Regulations governing food safety

2.2.1. A few definitions

❑ What is an SPS measure?

Sanitary and phytosanitary measures are those designed to **protect human, animal and plant life and health** from risks arising from parasites, disease-carrying organisms or pathogens, as well as from food additives, contaminants and toxins (art. 1 of the SPS Agreement).

This naturally includes the entry of animals, plants, food products, drinks or animal feed onto the territory of a Member country.

From a legal point of view, the SPS measures adopted by the governments can take the form of a decree, a regulation, a provision or other legal procedures.

What is the SPS agreement?

The SPS Agreement covers all measures applied:

- to protect human or animal health from food-borne risks,
- to protect human health from animal- or plant-carried diseases,
- to protect animals and plants from pests or diseases.

❑ The difference between SPS measures and TBT measures

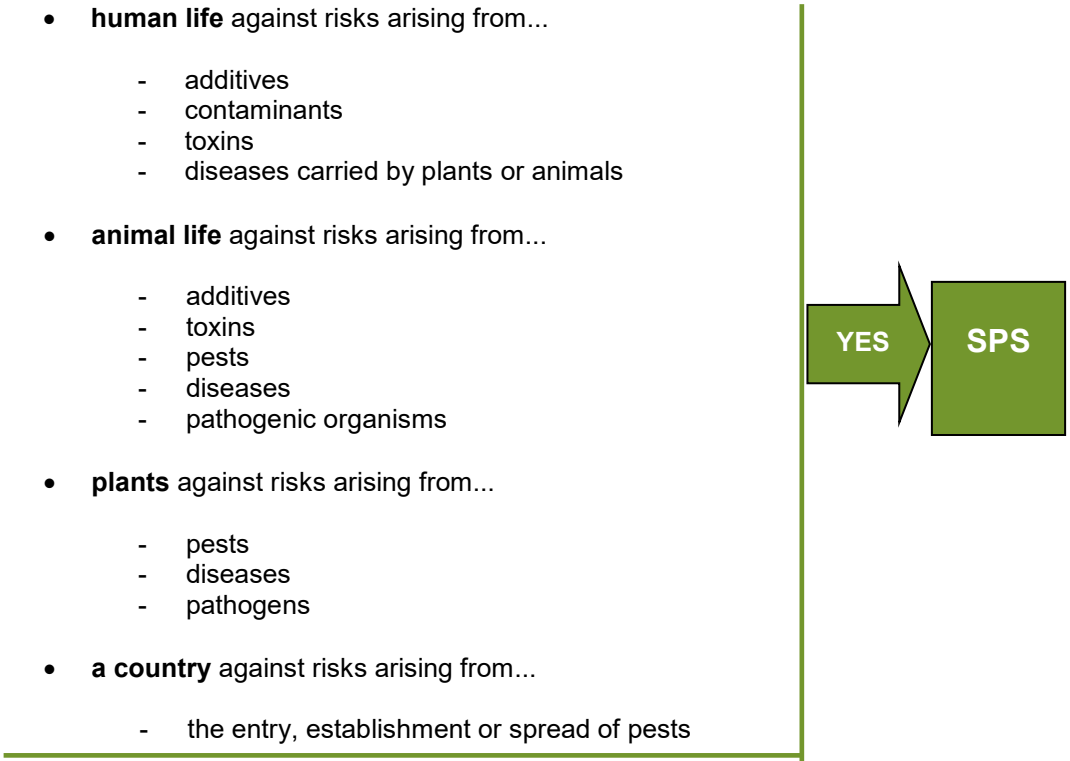
The TBT (Technical Barriers to Trade) Agreement covers **all technical regulations, voluntary standards and the procedures to ensure that these are met, except when these are sanitary or phytosanitary measures as defined by the SPS Agreement**.

It is thus not the type of measure that determines whether it is covered by the TBT Agreement, but the purpose of the measure that is relevant in determining whether a measure is subject to the SPS Agreement.

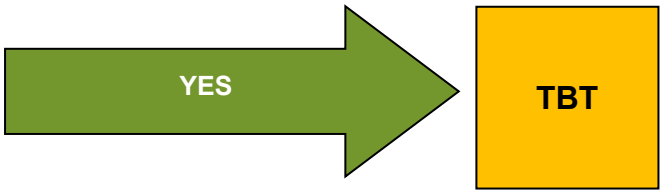
***SPS** or **TBT**?*

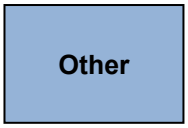
So which agreement governs a particular measure? The first step is to determine whether it concerns a food product, a beverage or animal feed, and **whether it sets out to protect:**

- **human life** against risks arising from...
    - additives
    - contaminants
    - toxins
    - diseases carried by plants or animals
- **animal life** against risks arising from...
    - additives
    - toxins
    - pests
    - diseases
    - pathogenic organisms
- **plants** against risks arising from...
    - pests
    - diseases
    - pathogens
- **a country** against risks arising from...
    - the entry, establishment or spread of pests



Is it a **technical regulation**, a standard or a procedure designed to evaluate whether a product complies with a standard?





2.2.2. The SPS Agreement on the application of sanitary and phytosanitary measures

❑ The background…

The **Agreement on the Application of Sanitary and Phytosanitary Measures** (the "SPS" Agreement) entered into force with the establishment of the World Trade Organization (WTO), on **1 January 1995**. It concerns the application of food safety and animal and plant health regulations.

The decision to start the Uruguay Round trade negotiations was made after years of public debate, including debate in national governments. The decision to negotiate an agreement on the application of sanitary and phytosanitary measures was made in **1986 when the Round was launched.** The SPS negotiations were open to all of the **124 governments** that participated in the Uruguay Round.

Many governments were represented by their food safety or animal and plant health protection officials. The negotiators also drew on the expertise of technical international organizations such as the FAO, the Codex and the OIE. **Developing countries participated in all aspects of the Uruguay Round negotiations** to an unprecedented extent. In the negotiations on sanitary and phytosanitary measures, developing countries were active participants, often represented by their national food safety or animal and plant health experts. Both before and during the Uruguay Round negotiations, the GATT secretariat assisted developing countries to establish effective negotiating positions.

The SPS Agreement calls for assistance to developing countries to enable them to strengthen their food safety and animal and plant health protection systems. FAO and other international organizations already operate programmes for developing countries in these areas.

❑ What is it?

The **Agreement on the Application of Sanitary and Phytosanitary Measures sets out the basic rules for food safety and animal and plant health standards.**

It allows countries to set **their own standards**. But it also says regulations must be **based on science**. They should be applied only to the extent necessary to protect humans, animal or plant life or health. And they should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail. Member countries are encouraged to use international standards, guidelines and recommendation where they exist. The agreement still allows countries to use different standards and different methods of inspecting products.

❑ What are the key features of the SPS Agreement?

➢ *Sanitary and phytosanitary measures*

All countries maintain measures to ensure that food is safe for consumers and to prevent the spread of pests or diseases among animals and plants. These **sanitary and phytosanitary measures** can take many forms. For example, countries may require:

- that the products come from a disease-free area;
- that the products are inspected;

- that the products undergo a specific treatment or processing;
- that the maximum admissible levels are established for pesticide residues or that only certain food additives are used.

Sanitary (human and animal health) **and phytosanitary** (plant health) measures **apply to domestically produced food or local animal and plant diseases**, as well as **to products coming from other countries.**

➢ ***No protectionist measures***

The SPS Agreement builds on previous GATT rules to restrict the use of unjustified sanitary and phytosanitary measures for the purpose of trade protection. The basic aim of the SPS Agreement is to **maintain the sovereign right of any government to provide the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to international trade.**

The SPS Agreement, while permitting governments to maintain appropriate sanitary and phytosanitary protection, reduces possible arbitrariness of decisions and encourages consistent decision-making.

In particular, the agreement clarifies which factors should be taken into account in the **assessment of the risk involved.** Measures to ensure food safety and to protect the health of animals and plants should be based as far as possible on the **analysis and assessment of objective and accurate scientific data.**

➢ ***Assessment of the risk***

Countries must establish sanitary and phytosanitary measures on the basis of an appropriate assessment of the **actual risks** involved, and, if requested, **make known what factors they took into consideration, the assessment procedures they used and the level of risk they determined to be acceptable**. Although many governments already use risk assessment in their management of food safety and animal and plant health, the SPS Agreement encourages the wider use of systematic risk assessment among all WTO member governments and for all relevant products.

➢ ***International standards***

The SPS Agreement encourages governments to establish national sanitary and phytosanitary measures consistent with **international standards, guidelines and recommendations**. This process is often referred to as ‘harmonization’. The WTO itself does not and will not establish such standards. However, most of the WTO’s member governments participate in the development of these standards in other international bodies. The standards are developed by leading scientists in the field and governmental experts on health protection and are subject to international scrutiny and review.

International standards are often higher than the national requirements of many countries, including developed countries, but the SPS Agreement explicitly permits governments to choose not to use the international standards. However, if the national requirement results in a greater restriction of trade, a country may be asked to provide scientific justification, demonstrating that the relevant international standard would not result in the level of health protection the country considered appropriate.

➢ ***Transparency***

The countries are required:

- to **notify other countries of any new or changed** sanitary and phytosanitary requirements which affect trade;
- to set up offices (called '**Enquiry Points**') to respond to requests for more information on new or existing measures;
- to be open to scrutiny on how they apply their food safety and animal and plant health regulations.

The regular and systematic communication of information and exchange of experiences among the WTO's member governments provides a better basis for national standards. Such increased transparency also protects the interests of consumers, as well as of trading partners, from hidden protectionism through unnecessary technical requirements.

A special Committee has been established within the WTO as a forum for the exchange of information among member governments on all aspects related to the implementation of the SPS Agreement. The **SPS Committee** reviews compliance with the agreement, discusses matters with potential trade impacts, and maintains close co-operation with the appropriate technical organizations. In a trade dispute regarding a sanitary or phytosanitary measure, the normal WTO dispute settlement procedures are used, and advice from appropriate scientific experts can be sought.

❑ **What are the benefits of the SPS Agreement?**

Consumers in all countries benefit from the agreement:

- it helps ensure, and in many cases enhances, the **safety of their food**, as it encourages the systematic use of scientific information in this regard, thus reducing the scope for arbitrary and unjustified decisions;
- **more information will increasingly become available** to consumers as a result of greater transparency in governmental procedures and on the basis of their food safety, animal and plant health decisions;
- the elimination of unnecessary trade barriers allows consumers to benefit from a **greater choice of safe foods** and from healthy international competition among producers. Specific sanitary and phytosanitary requirements are most frequently applied on a bilateral basis between trading countries.

Developing countries benefit from the SPS Agreement:

- it provides an international framework for sanitary and phytosanitary arrangements among countries, irrespective of their political and economic strength or technological capacity. Without such an agreement, developing countries could be at a disadvantage when challenging unjustified trade restrictions;
- governments must accept imported products that meet their safety requirements, whether these products are the result of simpler, less sophisticated methods or the most modern technology;
- increased technical assistance to help developing countries in the area of food safety and animal and plant health, whether bilateral or through international organizations, is also an element of the SPS Agreement.

Exporters of agricultural products in all countries **benefit from the elimination of unjustified barriers to their products**. The SPS Agreement reduces uncertainty about the conditions for selling to a specific market. Efforts to produce safe food for another market should not be thwarted by regulations imposed for protectionist purposes under the guise of health measures.

Importers of food products and other agricultural products also benefit from the **greater certainty regarding border measures**. The basis for sanitary and phytosanitary measures which restrict trade are made clearer by the SPS Agreement, as well as the basis for challenging requirements which may be unjustified. This also benefits the many processors and commercial users of imported food, animal or plant products.

A short overview of the scope of application of the SPS measures…

The **SPS** measures usually concern:

- additives in food or drink;
- contaminants in food or drink;
- toxic substances in food or drink;
- residues of veterinary drugs or pesticides in food or drink;
- certification: food safety, animal or plant health;
- processing methods with implications for food safety;
- labelling requirements directly related to food safety;
- plant/animal quarantine;
- declaring areas free from pests or disease;
- preventing disease or pests spreading to or in a country;
- other sanitary requirements for imports (e.g. imported pallets used to transport animals);
- etc.

2.2.3. Agreement on the Technical Barriers to Trade (TBT)

Countries often require imported products to comply with compulsory standards adopted to protect the health and safety of their population or to preserve their environment. The Agreement on the Technical Barriers to Trade (TBT) provides that **these compulsory product standards must not be applied by countries in order to create unnecessary obstacles to international trade.** Furthermore, they must be based on **scientific data and facts and on agreements reached at international level.**

The TBT Agreement requires compulsory product standards to be **applied to imported products on a non-discriminatory basis**. However, the sanitary and phytosanitary regulations, in particular those that set out to prevent animal or plant-borne diseases from entering a country, may be linked to the level of prevalence of certain diseases or certain pests and can be applied more rigorously to imports from countries in which these diseases or pests prevail.

❑ **Broad principles and rules of the TBT Agreement**

The main objective of the TBT Agreement is to ensure that the **technical regulations and standards**, including the packaging, marking and labelling requirements and **procedures,** used to assess compliance with these regulations, requirements and standards are not established and applied in such a way as to create unnecessary obstacles to trade.

The Agreement considers that this objective can be achieved if countries use, as far as possible, international standards to set their own technical regulations or develop optional national standards. In the same way, members are invited to build on guidelines and recommendations drawn up by international standardization organizations to define their compliance assessment procedures.

However, the Agreement does not specify which standards, drawn up by which international organizations, must be used to draw up technical regulations.

The main organizations that **develop international standards** covering industrial products are the following:

1. **International Standards Organization** (ISO)
2. ***Codex Alimentarius*** Commission.
3. **International Plant Protection Convention** (IPPC)

2.2.4. General food law in Europe

❑ **Background of food law: the White Paper on Food Safety**

A series of crises concerning human food and animal feed (BSE, dioxin, etc.) has exposed weaknesses in the design and application of food legislation within the European Union. Indeed, European consumers have become increasingly outspoken in response to the growing complexity of the agri-food industry and have challenged science and certain of its implications in terms of regulations. They have growing demands with regard to the quality and safety of foodstuffs. Today, after several headline-grabbing food safety problems, they are calling for more restrictive standards and a stricter application of regulations.

This situation has led the Commission to include the promotion of a high level of food safety among its policy priorities over the next few years. As was stressed at the Helsinki European Council in December 1999, particular attention must be focused on improving quality standards and reinforcing systems of checks throughout the food chain, from farm to table.

In the **White Paper on Food Safety of 12 January 2000** (COM(1999) 719 final), the European Commission proposes a number of measures which will enable food safety to be organized in a more coordinated and integrated manner. These include:

- the establishment of an independent European Food Authority with responsibility for independent scientific advice on all aspects relating to food safety, operation of rapid alert systems and communication of risks;
- an improved legislative framework covering all aspects of food products “from farm to table”;

- greater harmonization of national control systems;
- dialogue with consumers and other stakeholders.

Before looking in more detail at these four areas, the Commission sets out the general principles on which European food safety policy should be based:

- a comprehensive, integrated approach throughout the food chain;
- a clear definition of the roles of all stakeholders in the food chain (feed manufacturers, farmers and food operators, the Member States, the Commission, consumers);
- traceability of feed and food and their ingredients;
- a coherent, effective and dynamic food policy;
- risk analysis (comprising risk assessment, management and communication);
- scientific advice to the highest standards of independence, excellence and transparency;
- application of the precautionary principle in risk management.

Although a broad body of legislation already existed covering both primary production of agricultural products and industrial production of processed food, there was considerable disparity in the means to respond to situations in specific sectors. Another weakness in the system was the lack of a clear commitment from all interested parties to give early warning about a potential risk, which meant that the EU response to food crises was reactive rather than pro-active.

The Commission set out to rectify this situation by proposing **a coherent and transparent set of food safety rules**. These rules aimed to lay down the common principles underlying food legislation, establish food safety as the primary objective of food law, and provide the general framework for those areas not covered by specific harmonized rules.

There are 4 main Regulations relating to food safety in Europe:

1. **Regulation (EC) n° 178/2002 laying down the general principles and requirements of food law**, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
2. **Regulation (EC) n° 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;**
3. **Regulation (EC) n° 669/2009** implementing Regulation (EC) n° 882/2004: as regards the increased level of official controls on imports of certain feed and food of non-animal origin;
4. **Regulation 1099/2010:** updating the list of the products of the reinforced controls.

❑ **Regulation (EC) 178/2002** or regulation on General Food Law

On 28 January 2002, the European Parliament and the Council adopted **Regulation (EC) n° 178/2002** laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters

of food safety, applicable as from 1 January 2005 and to be adopted no later than 1 January 2007.

The different articles of this Regulation concern **foodstuff destined for human consumption as well as animal feed** and apply to all stages of their production and their distribution. They will be applied to **all the types of flows**:

1. intra-European,
2. import/export towards/outside Member States.

The objectives pursued by means of food law are:

- **protection of human life and health, and protection of consumers' interests, with due regard for the protection of animal health and welfare, plant health and the environment;**
- EU-wide free movement of human food and animal feed;
- consideration of existing or planned international standards.

Food law is based mainly on **risk analysis** drawing on the available scientific evidence. Under the precautionary principle[2], the Member States and the Commission may take appropriate provisional risk-management measures when an assessment points to the likelihood of harmful health effects and there is a lack of scientific certainty.
There is a requirement for transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law. When a food or feed product is deemed to constitute a risk, the authorities must inform the general public of the nature of the risk to human or animal health.

The Regulation defines the **responsibilities and obligations in the field of traceability of all stakeholders in the food and feed sector** (operators, producers, processors, distributors). The traceability of food, feed, food-producing animals and all substances incorporated into foodstuffs must be **established at all stages of production, processing and distribution**. To this end, business operators are required to apply appropriate systems and procedures. Food and feed imported with the aim of being placed onto the market or exported to a third country, comply with the requirements applicable to Community food law.

❑ Regulations (EC) 882/2004, (EC) 669/2009 and (EC) 1099/2010

These are the Regulation on the **official checks performed on food and feed**, on the methods of implementation of Regulation (EC) 882/2004 (reinforced checks performed on a series of agricultural products and contaminants) and that on the updating of the list of products concerned by reinforced checks. They will be set out in greater detail below.

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[2] The **precautionary principle** may be invoked where urgent measures are needed in the face of a possible danger to human, animal or plant health, or to protect the environment where scientific data do not permit a complete evaluation of the risk. It may not be used as a pretext for protectionist measures. This principle is applied mainly where there is a danger to public health. For example, it may be used to stop distribution or order withdrawal from the market of products likely to constitute a health hazard.

2.2.5. Legislation on food safety in Africa

❑ Regulation 0007/2007/CM/WAEMU

On 23 March 2007, the Council of Ministers of the West African Economic and Monetary Union adopted Regulation n° 0007/2007/CM/WAEMU on plant and food safety in the WAEMU

This Regulation sets out to establish **the general principles and organizational provisions and procedures** making it possible to ensure healthy plants, animals and food at **Community level** and **domestic level**.

It sets up the cooperation structures and mechanisms in the field of food safety within the Union. It applies to each stage in the production, processing and distribution of plants, animals and food placed on the market. It sets out in particular:

- **to regulate the safety of plants and plant products** and other regulated commodities, including produce obtained from modern biotechnologies such as defined in the Regulation**:**
- **to ensure the safety of animals, animal products, products of animal origin, animal feed and veterinary public health,** including products obtained from modern biotechnologies;
- **to ensure the safety of food,** including products obtained from modern biotechnologies.

It applies to all activities and all aspects touching on the safety of plants, animals and feed, including products obtained from biotechnologies.

❑ The regional conference on food safety (FAO and the WHO) of 2003

Harare, Zimbabwe hosted the FAO/WHO Regional Conference on Food Safety in October 2005. This conference, attended by policy makers and technical experts from throughout the region, was a forum for identifying the challenges facing African countries in developing food safety programmes.
Problems included:

- dumping of sub-standard food in countries emerging from war situations;
- non-functional laboratories;
- lack of reference standards for laboratories;
- no maintenance of equipment;
- lack of collaboration among countries.

Best practices identified for cooperation and coordination of food safety activities included:

- a one source food safety information center (Ghana);
- establishment of a Food Control Authority (Mali, Morocco, Zimbabwe);
- sharing of laboratory facilities (Southern African Development Community, SADC region);
- sharing of information in food safety emergencies (SADC region);
- establishment of pan-African standards based on *Codex Alimentarius* Standards;

- strengthening regional representation at Codex meetings;
- inventory of capabilities of food safety laboratories in the region;
- identifying centers of excellence in aspects of laboratory analysis;
- establishing a food safety desk within the African Union;
- including food-borne disease surveillance in national integrated disease surveillance systems for reporting at the regional level.

An integrated approach to Biosecurity and food safety implementation was suggested and a five-year strategic plan for food safety in Africa was proposed for adoption by the United Nations Food and Health Agencies and the African Union.

❑ Food safety systems in the Caribbean

Food legislation is enforced by different Ministries in each country: Agriculture, Health, Economy, Tourism, Trade and Industry, and others. Multiple agencies, fragmented responsibilities, and limited human and financial resources, make achieving uniform regional standards difficult. Measures are needed throughout the region to improve food safety systems. In 2002, priority was given by Caribbean governments to the establishment of the Caribbean Agricultural Health and Food Safety Agency (CAHFSA) to harmonize regional and national plant and animal health and food safety policies.

A comprehensive plan was proposed to improve food safety and quality for domestic as well as export markets at a regional meeting organized by FAO/WHO in Costa Rica in December 2005. Science-based regulations and the use of risk analysis to identify critical points in the food chain are needed to assist government monitoring programmes.

❑ The food health safety systems in the Pacific

FAO and WHO have worked over the years to provide a forum for policymaking and capacity building in food safety for the region. In 2001, the Regional Committee for the Western Pacific endorsed a Regional Strategy for food safety. In May 2004, experts from 40 countries in Asia and the Pacific met in Malaysia to review threats to public health and international trade posed by potentially unsafe food. Like Africa and the Caribbean, with so many different government agencies, and numerous small producers, harmonizing food safety systems for the region remains a challenge.

Subsequent meetings and workshops proposed the following:

- develop policies, legislation and standards that are relevant and transparent for the region;
- enhance safety and quality of food through more effective import and export control and information networks;
- build regional capacity to assess risk related to food safety;
- build regional capacity in food-safety training and education;
- build regional capacity to assess risk related to food patterns;
- develop a regulatory approach to support national nutrition policies;
- increase the effective participation of Pacific island countries in the work of *Codex Alimentarius*.

The ACP scientific community must show leadership in guiding government policy on national and regional standards and food safety systems and support the food industry in its efforts to conform to international standards. However, this must be done in the context of the level at which ACP food systems operate.
In addition, the following recommendations are proposed:

1. Governments and regulators should take ownership in developing and managing food safety systems to safeguard public health and trade.
2. Scientists, regulators, industry and consumer groups should collaborate with governments in developing and implementing food standards and safety systems and mechanisms for monitoring and evaluating all levels across the various typologies that exist in the food production to consumption chain.
3. Universities and other publicly funded research organizations should embark on research in collaboration with government and industry to identify risks and region-specific food safety challenges.
4. Universities and publicly funded research institutes should develop scientific surveillance methods and response programmes in the unlikely event of a food safety crisis.
5. The public should be educated on food safety and safe food handling. This is a shared responsibility of the science community, government and the agri-food industry.

2.3. Regulations governing plant health

2.3.1. Plant health aspect of the SPS Agreement

The SPS Agreement covers the various measures relating to the control of plant health. Indeed, it applies to all the sanitary **and phytosanitary** measures that can, either directly or indirectly, affect international trade.

The international plant health standards, guidelines and recommendations referred to by the Agreement are those drawn up under the auspices of the secretariat of the **International Plant Protection Convention (IPPC)** in cooperation with the regional organizations operating within the framework of this Convention.

The **International Standards for Phytosanitary Measures (ISPM)** are adopted by the contracting parties to the IPPC via the Interim Commission on Phytosanitary Measures. The **ISPM are standards, guidelines and recommendations recognized as a basis for the phytosanitary measures applied by the members of the World Trade Organization (WTO) within the framework of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)**. The non-contracting parties to the IPPC are encouraged to observe these standards.

The **last edition of these standards was published in 2009** and is available on the IPPC Web site. It sets out in its first pages the terms of the International Plant Protection Convention signed in 1997. This Convention recognizes **the necessity for international cooperation in controlling pests of plants and plant products** and in preventing their international spread and especially their introduction into endangered areas.

The Convention includes the following elements:

- ARTICLE I: Purpose and responsibility
- ARTICLE II: Use of terms
- ARTICLE III: Relationship with other international agreements
- ARTICLE IV: General provisions relating to the organizational arrangements for national plant protection
- ARTICLE V: Phytosanitary certification
- ARTICLE VI: Regulated pests
- ARTICLE VII: Requirements in relation to imports
- ARTICLE VIII: International cooperation
- ARTICLE IX: Regional plant protection organizations
- ARTICLE X: Standards
- ARTICLE XI: Commission on Phytosanitary Measures
- ARTICLE XII: Secretariat
- ARTICLE XIII: Settlement of disputes
- ARTICLE XIV: Substitution of prior agreements
- ARTICLE XV: Territorial application
- ARTICLE XVI: Supplementary agreement

- ARTICLE XVII: Ratification and adherence
- ARTICLE XVIII: Non-contracting parties
- ARTICLE XIX: Languages
- ARTICLE XX: Technical assistance
- ARTICLE XXI: Amendment
- ARTICLE XXII: Entry into force
- ARTICLE XXIII: Denunciation
- Annexes: Model Phytosanitary Certificates

Around **thirty (32) international standards** are listed in the publication:

ISPM n° 1 (2006)	Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade
ISPM n° 2 (2007)	Guidelines for pest risk analysis
ISPM n° 3 (2005)	Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms
ISPM n° 4 (1995)	Requirements for the establishment of pest free areas
ISPM n° 5 (2009)	Glossary of phytosanitary terms
ISPM n° 6 (1997)	Guidelines for surveillance
ISPM n° 7 (1997)	Export certification system
ISPM n° 8 (1998)	Determination of pest status in an area
ISPM n° 9 (1998)	Guidelines for pest eradication programmes
ISPM n° 10 (1999)	Requirements for the establishment of pest free places of production and pest free production sites
ISPM n° 11 (2004)	Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms
ISPM n° 12 (2001)	Guidelines for phytosanitary certificates
ISPM n° 13 (2001)	Guidelines for the notification of non-compliance and emergency action
ISPM n° 14 (2002)	The use of integrated measures in a systems approach for pest risks management
ISPM n° 15 (2009)	Guidelines for regulating wood packaging material in international trade
ISPM n° 16 (2002)	Regulated non-quarantine pests: concept and application
ISPM n° 17 (2002)	Pest reporting
ISPM n° 18 (2003)	Guidelines for the use of irradiation as a phytosanitary measure
ISPM n° 19 (2003)	Guidelines on lists of regulated pests
ISPM n° 20 (2004)	Guidelines for a phytosanitary import regulatory system
ISPM n° 21 (2004)	Pest risk analysis for regulated non-quarantine pests
ISPM n° 22 (2005)	Requirements for the establishment of areas of low pest prevalence
ISPM n° 23 (2005)	Guidelines for inspection

ISPM n° 24 (2005)	Guidelines for the determination and recognition of equivalence of phytosanitary measures
ISPM n° 25 (2006)	Consignments in transit
ISPM n° 26 (2006)	Establishment of pest free areas for fruit flies (Tephritidae)
ISPM n° 27 (2006)	Diagnostic protocols for regulated pests
ISPM n° 28 (2009)	Phytosanitary treatments for regulated pests
ISPM n° 29 (2007)	Recognition of pest free areas and areas of low pest prevalence
ISPM n° 30 (2008)	Establishment of areas of low pest prevalence for fruit flies (Tephritidae).
ISPM n° 31 (2008)	Methodologies for sampling of consignments
ISPM n° 32 (2009)	Categorization of commodities according to their pest risk

1.3.2. European regulations governing the control of plant health

In addition to the existing Directives dating from the 1990s, since 2000, the European Union has adopted measures to protect itself against the introduction of organisms harmful to plants and plant products from other Member States or third countries and their spread within the Community; furthermore, it has provided for checks and the creation of protected zones.

The main Directives or Regulations relating to phytosanitary safety and of interest for exporters from countries outside the EU are:

1. **Council Directive 2000/29/EC** of 8 May 2000 **on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community and its amending acts;**
2. **Commission Directive 2004/105/EC** of 15 October 2004 determining **the models of official phytosanitary certificates or phytosanitary certificates** for re-export accompanying plants, plant products or other objects from third countries and listed in Council Directive **2000/29/EC.**

❑ **Directive 2000/29/EC**

It concerns protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community.

It is based on the principles enshrined at international level, in particular in the International Plant Protection Convention of the Food and Agriculture Organization (FAO) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO).

This Directive establishes:

- measures designed to protect Member States against the **introduction into the Community of organisms harmful to plants or plant products from other Member States or third countries**;

- measures designed to protect Member States against the **spread within the European Union (EU) of harmful organisms**.

➢ ***Scope***

The Directive covers living plants and specified living parts of plants, including seeds.

Living parts of plants are considered to include:

- **fruit and vegetables other than those preserved by deep freezing**;
- tubers, corms, bulbs, rhizomes,
- cut flowers,
- branches with foliage, cut trees retaining foliage,
- leaves, foliage,
- live pollen,
- bud-wood, cuttings, scions, and any other part of plants.

Plant products are considered to mean products of plant origin, unprocessed or having undergone simple preparation, in so far as these are not plants listed above. Wood as such is also covered under certain conditions.

Harmful organisms are considered by the Directive to mean **any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.** This definition covers in particular insects and mites, bacteria, fungi, viruses and parasite plants.

Annexes I and II list the harmful organisms **banned in the EU,** either altogether or when they are on certain plants or plant products.

Moreover, **Annex III** lists **plants and plant products that must not be imported from certain countries.**

The protective measures also relate to the means by which plants, plant products and other related items are moved (packaging, vehicles, etc.).

The protective measures also cover the movements of plants and plant products between the EU and some of its outermost regions, namely the French overseas departments and the Canary Islands.

➢ ***Imports from third countries***

The Directive requires certain plants and plant products from third countries (**Annex V, part B)** to undergo **an inspection upon entry into EU territory**. Plants and plant products that are **potential carriers** of these harmful organisms from third countries may only be imported into the European Union accompanied by a plant passport certifying the absence of these harmful organisms from the exporting country. The inspection includes in particular a documentary check, an identity check and a plant health check:

- the **documentary check** consists in checking certificates and documents accompanying the consignment or batch, in particular the plant-health certificate. **This is issued by the authority responsible in the country of origin** or re-export, using models drawn up by the Commission. It has to certify that the products have undergone appropriate and satisfactory inspections;

- the **identity check** involves checking that the consignment tallies with the plants or plant products covered by the certificate;
- the **plant-health check** involves checking, on the basis of a complete examination or an examination of samples, that the plants or plant products show no signs of contamination by harmful organisms and that they meet the specific requirements defined in this Directive.

The Directive provides for less stringent identity and plant-health checks where certain guarantees are provided.

If the results of the checks are satisfactory, **instead of a phytosanitary certificate a passport and the rules applicable to intra-Community movement apply**. If not, one or more of the following measures may be taken: access to EU territory may be refused, **the consignment may be sent back to a destination outside the EU, the contaminated products may be removed from the consignment, destroyed, placed in quarantine pending further tests**, or treated appropriately (this last measure is possible only in exceptional cases and under very precise circumstances). The Member State concerned must also inform the Commission and the other Member States of the situation and what measures have been taken.

➢ ***Amending acts***

Amending act(s)	**Entry into force**	**Deadline for transposal by the Member States**	***Official Journal***
Directive 2002/89/EC[3]	30 December 2002	1 January 2005	*OJEC*, L 355 of 30 December 2002
Regulation (EC) 882/2004[4]	20 May 2004	-	*OJEU*, L 165 of 30.4.2004
Directive 2009/143/EC[5]	24 December 2009	1 January 2011	*OJEU*, L 318 of 4 December 2009

❑ Directive **2004/105/EC determining the models of official phytosanitary certificates or phytosanitary certificates from third countries**

The main 2 articles of the Directive stipulate that:

- the Member States shall **accept official 'phytosanitary certificates' or 'phytosanitary certificates for re-export'** accompanying plants, plant products or other objects listed in part B of Annex V to Directive 2000/29/EC, **coming from contracting third countries to the International Plant Protection**

[3] Directive 2002/89/EC amending Directive 2000/29/EC on protective measures against the introduction into the Community of Organisms harmful to plants or plant products and against their spread within the Community.

[4] Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

[5] Directive 2009/143/EC amending Directive 2000/29/EC as regards the delegation of the tasks of the laboratory testing.

Convention (IPPC), which are issued in accordance with the models as specified in Annex I of the Directive (model of a phytosanitary certificate);

- Member States shall only accept the certificates … provided that they have been completed **taking into account the FAO International Standard for Phytosanitary Measures No 12 on Guidelines for phytosanitary certificates**.

2.4. Regulations governing biological contaminants

2.4.1. Definitions

Contaminants are substances **that are not intentionally added to food.** These substances can be present in food as a residue of production, packaging, transport or storage, or as a result of environmental contamination.

There are several types of contaminants:

1. **Microbiological contaminants** (*i.e.* bacteria, viruses, parasites, mould and algal toxins). These organisms are often associated with man, animals or simply the environment of the livestock or crop. These can be pathogenic micro-organisms hosted by healthy carriers (human or animal) but also micro-organisms belonging to common flora hosted by humans or animals (digestive flora for example) or present in the environment (telluric flora).
2. **Naturally occurring toxicants in food** (*i.e.* alkaloids, legume toxins, cyanogenic glycosides).
3. **Contaminants in food** (*i.e.* heavy metals, organic chemicals…).

2.4.2. International regulations governing biological contaminants

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) covers biological contaminants and is that which prevails at international level. It recommends the use of international standards in the field, namely those of the ***Codex Alimentarius***.

There is a **Codex General standard for contaminants and toxins in food and feed**: *CODEX STAN 193-1995 (Rev. 1 – 1997).* This standard contains the main principles and procedures used and recommended by the *Codex Alimentarius* in dealing with contaminants and toxins in food and feed and lists the maximum levels of contaminants and natural toxicants in food and feed which are recommended by the *Codex Alimentarius* Commission to be applied to commodities moving in international trade.

The Codex has drawn up a series of standards, guidelines and codes on contaminants and this for different types of foods, one of which is of certain interest for ACP fruit and vegetable exporters, the **Code of Hygienic Practice for Fresh Fruits and Vegetables – CAC/RCP 53-2003.** This Code addresses Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) that will help control microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables, from primary production to packing. Particular attention is given to minimizing microbial hazards.

The Code provides a general framework of recommendations to allow uniform adoption by this sector, rather than providing detailed recommendations for specific agricultural practices, operations or commodities.

The fresh fruit and vegetable industry is very complex. Fresh fruits and vegetables are produced and packed under diverse environmental conditions. It is recognized that some of the provisions in this Code may be difficult to implement in areas where primary production is conducted in smallholdings, in both developed and developing countries and also in areas where traditional farming is practiced. Therefore, the Code is, of necessity, a flexible one to allow for different systems of control and prevention of contamination for different groups of commodities.

There are also codes for:

- **Canned fruit and vegetable products** "Code of hygienic practice for canned fruit and vegetable products" **– CAC/RCP 2-1969**;
- **Dried fruit and vegetables**: "Code of hygienic practice for dried fruit" **- CAC/RCP 3-1969**;
- etc.

2.4.3. European regulations governing biological contaminants

Contaminants and other undesirable substances may enter the food chain at all levels, from the growth and production of raw materials to the distribution and consumption of the final product. Examples include naturally occurring plant toxins, aflatoxins, dioxins and unintentional contamination with heavy metals or other substances.

Microbiological contamination of food is the main cause of food-borne illness and the emergence of new strains of food-borne pathogens such as *E. coli* 0157 and Salmonella enteritidis phage type 4 are of particular concern. There is, however, good evidence that the application of good manufacturing practices have resulted in a decline in microbiological infections resulting from infected foods.

Maximum levels have been set for certain contaminants in food, including a group of mycotoxins known as aflatoxins.

These are naturally-occurring toxicants produced by moulds in improperly stored produce. Maximum levels are set for nuts, cereals, milk, dried fruits (the most commonly affected foods).

Arsenic, lead, cadmium and mercury, the so-called heavy metals, also have maximum limits.

To limit the negative impact of contaminants in food and to prevent the risks they can present for human health, the European Union takes measures to reduce their levels in food.

Council Regulation 315/93/EEC establishes the control procedures of the European Community for food contaminants.

- ❑ **Council Regulation (EC) 315/93 of 8 February 1993** relating to the establishment of **Community procedures regarding contaminating substances in foodstuffs** (and its amending acts)

This Regulation **prohibits the marketing of foodstuffs containing an unacceptable quantity of residual substances**. These substances, so-called contaminants, mean any substance not intentionally added to food, which is present in such food as a result of the production of such food, or as a result of environmental contamination. They are likely to present a public health risk. That is why the European Union is regulating the contaminant levels accepted and keeps them as low as can be reasonably achieved at a toxicological level.

The Regulation shall not apply to contaminants which are the subject of more specific rules nor to extraneous matter such as insect fragments, animal hair etc.

A Member State may take restrictive measures in accordance with this Regulation when it has reason to suspect that the presence of a contaminant constitutes a health risk. In this case, it shall immediately inform the other Member States and the Commission thereof and give reasons for its decision. The Commission shall examine the reasons given by the Member State referred to as soon as possible in the Standing Committee for Foodstuffs and take any necessary measures. This committee helps the Commission on all matters relating to contaminants, including for the setting of the maximum authorized tolerances.

The Member States may not prohibit the placing on the market of foods that comply with this Regulation.

Amending act(s)	**Entry into force**	**Deadline for transposal by the Member States**	***Official Journal***
Regulation (EC) 1882/2003: relating to European administrative and committee aspects	20 November 2003	-	*OJEU*, L 284 of 31 October 2003
Regulation (EC) 596/2009: relating to European decision-making procedures.	7 August 2009	-	*OJEU*, L 188 of 18 July 2009

❑ Commission Regulation (EC) 1881/2006 of 19 December 2006, setting maximum levels for certain contaminants in foodstuffs

The European Union sets maximum levels for certain contaminants in foodstuffs in order to reduce the presence of these contaminants in certain foodstuffs to the lowest levels reasonably achievable by following good manufacturing or agricultural practices, in particular for vulnerable groups in the population such as children, persons with allergies etc.

This Regulation, applied since 1 March 2007, replaces Regulation 466/2001 that has long since served as a basic regulation relating to the maximum levels of contaminants in foodstuffs. However, Regulation 466/2001 has been the subject of several amendments in the form of Regulations in which new maximum contents have been set for certain contaminants.

This Regulation sets the maximum quantities of certain **contaminants**: **nitrates, mycotoxins** (aflatoxin, ochratoxin A, patulin, deoxynivalenol, zearalenone fumonisins, toxins T-2 and HT-2)**, heavy metals** (lead, cadmium, mercury, inorganic tin)**, dioxins and PCB, polycyclic aromatic hydrocarbons:**

- **Nitrates**: These are found mainly in **vegetables (spinach, lettuce**). In order to reduce the levels of nitrates in these vegetables, the Regulation stipulates that growing methods must be modified and codes of good practice applied.
- **Aflatoxins**: these are **genotoxic carcinogenic substances**, which develop at high temperatures and humidity levels. The Regulation sets limits at the lowest possible level. For certain products such as **groundnuts, nuts, dried fruit and maize**, it is acknowledged that the aflatoxin level can be reduced by sorting methods or other physical treatments. In order to minimize the effects on trade, it is therefore advisable to allow higher aflatoxin levels for such products when they are not intended for direct human consumption or for use as an ingredient in foodstuffs. In such cases, they must bear a label showing their intended purpose clearly and marked: "*product that must be subjected to a sorting treatment or other physical treatments aimed at reducing the level of aflatoxin contamination*".
- **Ochratoxin**: Ochratoxin A is a **mycotoxin produced by several fungi** (species 'penicillium' and 'aspergillus'). It **occurs naturally in many plant products from all over the world, such as cereals, coffee beans, cocoa and dried fruit**. It has therefore been detected in products such as **cereal products, coffee, wine, beer and grape juice**, but also in some products of animal origin, specifically pig's kidneys. Studies of the frequency and levels of presence of ochratoxin A in samples of foodstuffs and human blood indicate that foodstuffs are often contaminated. Ochratoxin A is a mycotoxin with carcinogenic, nephrotoxic, teratogenic, immunotoxic and possibly neurotoxic properties. It has also been associated with nephropathy in humans. Ochratoxin A can have a long half-life in humans.
- **Patulin**: Patulin is a **mycotoxin** produced by several types of fungus. It may be found in **fruit juices, particularly apple juice, and in mouldy foods such as bread**, etc.
- **Lead**: lead absorption may constitute a serious risk to public health, since it may induce **reduced cognitive development and intellectual performance in children and increased blood pressure** and cardiovascular diseases in adults. The maximum levels should therefore be as low as reasonably achievable.
- **Cadmium**: cadmium absorption also constitutes a risk to humans, since it may induce **kidney dysfunction, skeletal damage and reproductive deficiencies**. The maximum levels should therefore also be as low as reasonably achievable.
- **Mercury**: this substance may **induce alterations in the normal development of the brain of infants** and at higher levels may induce neurological changes in adults. Mercury contaminates mostly **fish and fishery products**.
- **Dioxins and dioxin-like polychlorinated biphenyls (PCBs): dioxins are chemicals resulting from certain natural phenomena** (volcanic activity, forest fires) or **industrial processes** (e.g. manufactur**ing of pesticides, metals** or paint, paper bleaching, incineration, etc.). **PCBs** are chemicals that are widespread and found in, *inter alia*, **building materials, lubricants, waterproofing agents and inks**. Both types of substance may cause serious health problems, including cancer, immune and nervous system disorders, liver damage and sterility.
- **Inorganic tin**: this type of tin may be **found in food and drink cans**. It may provoke **gastric irritation in certain susceptible groups of the population**. For

canned foods in general other than beverages the maximum levels are set at 200 mg/kg and at 100 mg/kg for canned beverages. For inorganic tin in canned foods and canned beverages for children, the maximum permissible level is 50 mg/kg of wet weight.

➢ ***Conditions of application***

The foodstuff listed under **Annex I** of the Regulation **must not have, at the time of their entry into circulation, contaminant levels that are higher than those set out in this annex**.

➢ ***Targeted products***

The maximum levels set out under Annex I apply to the **edible parts** of the foodstuffs concerned, unless otherwise mentioned in the Annex.

➢ ***General provisions of the Regulation***

- Article 2: Dried, diluted, processed and compound foodstuffs
- Article 3: Prohibitions on use, mixing and detoxification
- Article 4: Specific provisions for groundnuts, nuts, dried fruit and maize
- Article 5: Specific provisions for groundnuts, derived products thereof and cereals
- Article 6: Specific provisions for lettuce
- Article 7: Temporary derogations
- Article 8: Sampling and analysis
- Article 9: Monitoring and reporting
- Article 10: Repeal
- Article 11: Transitional measures
- Article 12: Entry into force and application
- Annex I: Maximum levels for certain contaminants in foodstuffs

2.5. Regulations governing organic production

2.5.1. Definitions and principles of organic agriculture

According to the definition of the *Codex Alimentarius*, "organic agriculture is a holistic production management system which promotes and enhances agro-ecosystem health, including biodiversity, biological cycles and soil biological activity".

On the whole, organic agriculture is a production method governed by a regulation that **bans the use of synthetic materials (fertilizers, pesticides, etc.) and that encourages use of biological and mechanical methods.**

Organic agriculture practices include:

- wide crop rotation as a pre requisite for an efficient use of on-site resources;
- very strict limits on chemical synthetic pesticide and synthetic fertilizer use, livestock antibiotics, food additives and processing aid and other inputs;
- absolute prohibition of the use of genetically modified organisms;
- taking advantage of on-site resources, such as livestock manure for fertilizer or feed produced on the farm;
- choosing plant and animal species that are resistant to disease and adapted to local conditions;
- raising livestock in free-range, open-air systems and providing them with organic feed;
- using animal husbandry practices appropriate to different livestock species.

2.5.2. International regulations governing organic production

Several national governments and a host of private certification organizations and farmers have defined organic agriculture according to specific standards. In general, one of the essential elements distinguishing organic agriculture from other forms of sustainable agriculture is **the existence of production standards and certification procedures.**

In 1999, the Committee on food labelling of the FAO/WHO commission of the *Codex Alimentarius* adopted guidelines on the production, processing, labelling and marketing of food produced organically.

At international level, the body that governs organic agriculture is the *Codex Alimentarius*.

In developing countries, producers and exporters of organic fruits and vegetables looking to sell their products under an organic label in developed countries must obtain an organic certification. This can be performed via the certification bodies of the target

countries for export or via other recognized certification bodies, or again through a partnership agreement between the two types of certification bodies.

❑ The *Codex Alimentarius* guidelines on organic production

The C*odex Alimentarius* Commission adopted **Guidelines for the production, processing, labelling and marketing of organically produced foods in 1999**, with the exception of the provisions for livestock and livestock produce which were adopted in 2001.

The Guidelines for the production, processing, labelling and marketing of organically produced foods have been developed in view of the growing production and international trade in organically produced foods with a view to facilitating trade and preventing misleading claims. The Guidelines are intended to facilitate the harmonization of requirements for organic products at the international level, and may also provide assistance to governments wishing to establish national regulations in this area.
The adopted texts were revised by the *Codex Alimentarius* Commission in 2007 and amendments were made in 2008, 2009 and 2010.

The aims of these guidelines are:

- **to protect consumers** against deception and fraud in the market place and unsubstantiated product claims;
- **to protect producers of organic produce against misrepresentation of other agricultural produce** as being organic;
- **to ensure that all stages** of production, preparation, storage, transport and marketing are subject to inspection and comply with these guidelines;
- **to harmonize provisions** for the production, certification, identification and labelling of organically grown produce;
- **to provide international guidelines for organic food control systems** in order to facilitate recognition of national systems as equivalent for the purposes of imports;
- **to maintain and enhance organic agricultural systems in each country** so as to contribute to local and global preservation.

The Guidelines apply to the following products that carry, or are intended to carry, descriptive labelling referring to organic production methods:

- **unprocessed plants and plant products, livestock and livestock products;**
- **processed agricultural crop and livestock products** intended for human consumption derived from the products mentioned in paragraph a) above.

The Guidelines are available on the *Codex* Web site[6] and cover the following areas:

➢ *Labelling and claims*

General provisions
Labelling of products in transition/conversion to organic

➢ *Rules of production and preparation*

[6] www.fao.org/fao-who-codexalimentarius/codex-home/en.

- ***Requirements for inclusion of substances in annex 2 and criteria for the development of lists of substances by countries***

The open nature of the lists

- ***Inspection and certification systems***
- ***Imports***
- ***Annex 1. Principles of organic production***

A. Plants and plant products
B. Livestock and livestock products
   - General principles
   - Livestock sources/origin
   - Conversion
   - Nutrition
   - Health care
   - Livestock husbandry, transport and slaughter
   - Housing and free-range conditions
   - Mammals
   - Poultry
   - Manure management
   - Record keeping and identification
   - Species-specific requirements
C. Handling, storage, transportation, processing and packaging
   - Pest management
   - Processing and manufacturing
   - Packaging
   - Storage and transport

- ***Annex 2. Permitted substances for the production of organic foods***
- ***Annex 3. Minimum inspection requirements and precautionary measures under the inspection or certification system***

A. Production units
B. Preparation and packaging units
C. Imports

2.5.3. European regulations governing organic production

❑ **Background**

In June 1991, the Council adopted Regulation (EEC) 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and

foodstuffs. This Regulation was completed several times and in particular in 1999 when the Council included organic livestock in its scope. This Regulation was an initiative that entered into the framework of the reform of common agricultural policy, the objective of which was, originally, to increase agricultural productivity, in order to obtain a high degree of food self-sufficiency within the European Community.

Since the entry into force of this Regulation in 1992, tens of thousands of European agricultural operators have turned towards this method of agricultural production and it seems that this trend will continue in years to come. At the same time, the interest of consumers and trade for products derived from organic agriculture has increased considerably.

By adopting Regulation (EEC) n° 2092/91, the Council decided on **the creation of a Community framework defining in detail the requirements to be satisfied for an agricultural product or a foodstuff to be able to carry a reference to the method of organic production.**

This was a rather complex regulation that not only defined a method of agricultural production for plants and animals, but also regulates labelling, processing, inspection and trade in products from organic agriculture within the Community as well as the import of these products from third countries.

❑ The new European regulations

As a reminder, organic production is an overall system of farm management and food production that combines:

1. best environmental practices,
2. a high level of biodiversity, the preservation of natural resources,
3. the application of high animal welfare standards and a production method in line with the preference of certain consumers for products produced using natural substances and processes.

Due to the various developments in the field of organic agriculture, Regulation (EEC) 2092/91 was replaced by a main Regulation and its amendments:

➢ **Regulation (EC) 834/2007** of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EC) 2092/91 which has since been modified by:

- ***Amendment 1***: Council Regulation (EC) 967/2008 of 29 September 2008, amending Regulation (EC) 834/2007 on organic production and labelling of organic products. With this amendment, the Commission postpones the obligatory use of the organic agriculture logo of the European Union on all pre-packaged organic food and the indication of the origin of the organic ingredients, which has to accompany the logo until 1 July 2010.
- ***Amendment 2***: Commission Regulation (EC) 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. This Regulation has since been amended with new rules with regard to the production of organic yeast by:
- ***Amendment 3***: Commission Regulation (EC) 1254/2008 of 15 December 2008, amending Regulation (EC) 889/2008 laying down detailed rules for implementation of Council Regulation (EC) 834/2007 on organic production and

labelling of organic products with regard to organic production, labelling and control.

The new European Regulation on organic agriculture entered into force on **1 January 2009.** This Regulation clearly defines the objectives, the principles and the basic rules for the organic production method in the field of animal production, plant production, animal feed and the production of foodstuffs.

The precise rules of application will subsequently be defined. It also includes a more coherent control system, in particular compared with the current system of European official control of foodstuffs and animal feed. **Finally, it also defines a new import system allowing third countries to export to the Community market in conditions that are equivalent to those of European producers**.

Amendments are made to the reference to the organic method of production on labelling: **only foodstuffs containing 95% and more of organic agricultural ingredients can be labelled as organic**. The reference to the organic method of production can appear in the list of ingredients, and in the same visual field as the sale name, for foodstuffs whose main ingredients are derived from hunting or fishing, when all the other agricultural ingredients are organic and where only the additives or inputs authorized in organic agriculture are used.

- **Regulation (EC) 1235/2008** of 8 December 2008**,** laying down detailed rules for implementation of Council Regulation (EC) n° 834/2007 as regards the arrangements for imports of organic products from third countries.

- **Regulation (EC) 889/2008** lays down more detailed rules on organic production and labelling of organic products with regard to organic production, labelling and control and includes the following parts:

  - **Title I: Introductory provisions**

  - **Title II: Rules on production, processing, packaging, transport and storage of products**
    - Chapter 1 Plant production
    - Chapter 2 Livestock production
      - Section 1 Origin of animals
      - Section 2 Livestock housing and husbandry practices
      - Section 3 Feed
      - Section 4 Disease prevention and veterinary treatment
    - Chapter 3 Processes products
    - Chapter 4 Collection, packaging, transport, storage of products
    - Chapter 5 Conversion rules
    - Chapter 6 Exceptional production rules
      - Section 1 Climatic, geographical or structural constraints
      - Section 2 Non-availability of organic farm input
      - Section 3 Specific management problems in organic livestock
      - Section 4 Catastrophic circumstances
    - Chapter 7 Seed database

- Title III: Labelling

Chapter 1 Organic production logo of the European Union
Chapter 2 Specific labelling requirements for feed
Chapter 3 Other specific labelling requirements

- Title IV: Controls

Chapter 1 Minimum control requirements
Chapter 2 Control requirements for plants and plant products
Chapter 3 Control requirements for livestock and livestock products
Chapter 4 Control requirements for units for preparation of plant, seaweed, livestock and aquaculture animal products and foodstuffs composed thereof
Chapter 5 Control requirements for imports of organic products from third countries
Chapter 6 Control requirements for units using contracts to third parties
Chapter 7 Control requirements for units preparing feed
Chapter 8 Infringements and exchange of information

- Title V: Transmission of information to the Commission, transitional and final provisions

Chapter 1 Transmission of information to the Commission
Chapter 2 Transitional and final provisions

- **Regulation (EC) 1254/2008** of 15 December 2008, amending Regulation (EC) 889/2008 laying down detailed rules for implementation of Council Regulation (EC) 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. This Regulation contains amendments to annex VIII of Regulation (EC) 889/2008 relating to:
  - products and substances for use in production of processed organic food, yeast and yeast products ;
  - processing aids for the production of yeast and yeast products.

- **Regulation (EC) 1235/2008** of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) 834/2007 as regards the arrangements for imports of organic products from third countries.

To be recognized as organic, products from third countries must:

- either come from countries **whose rules are considered to offer equivalent guarantees by the European Commission**: currently 9 countries (Argentina, Australia, Costa Rica, India, Israel, Japan, New Zealand, Switzerland, Tunisia) whose recognized certifying bodies and products concerned feature in Regulation (EC) n° 1235/2008 ;
- or have obtained an **import authorization issued by the competent Ministry of a Member State.**

Products from third countries must therefore be the subject of a recognition of equivalence in terms of production, control and certification rules in order to be recognized as organic at the time of their entry onto the European market (free circulation, customs clearance as an organic product). This recognition can be granted in two ways, depending on which of the two cases set out above apply.

Regulation (EC) 1235/2008 sets out to **extend and harmonize the use of a control certificate (batch certificate) to imported products. A control certificate model** (*cf.* model in Annex I of the Regulation) has been drawn up and must now accompany any batch from any third country.

In practice, this means that, at the time of the customs clearance and inspection of imported batches, the **original** versions of the following documents must be present **at all cost**:

1. the **control certificate;**
2. the **annual import authorization** issued by the competent regional/national ministries.

Consequently, if the first recipient (e.g. a forwarder or a customs agency) is not the actual holder of the import authorization, they will be required to hold the two original documents at the time of customs clearance and inspection. Otherwise, the batch will be blocked by customs or accepted as 'conventional'.

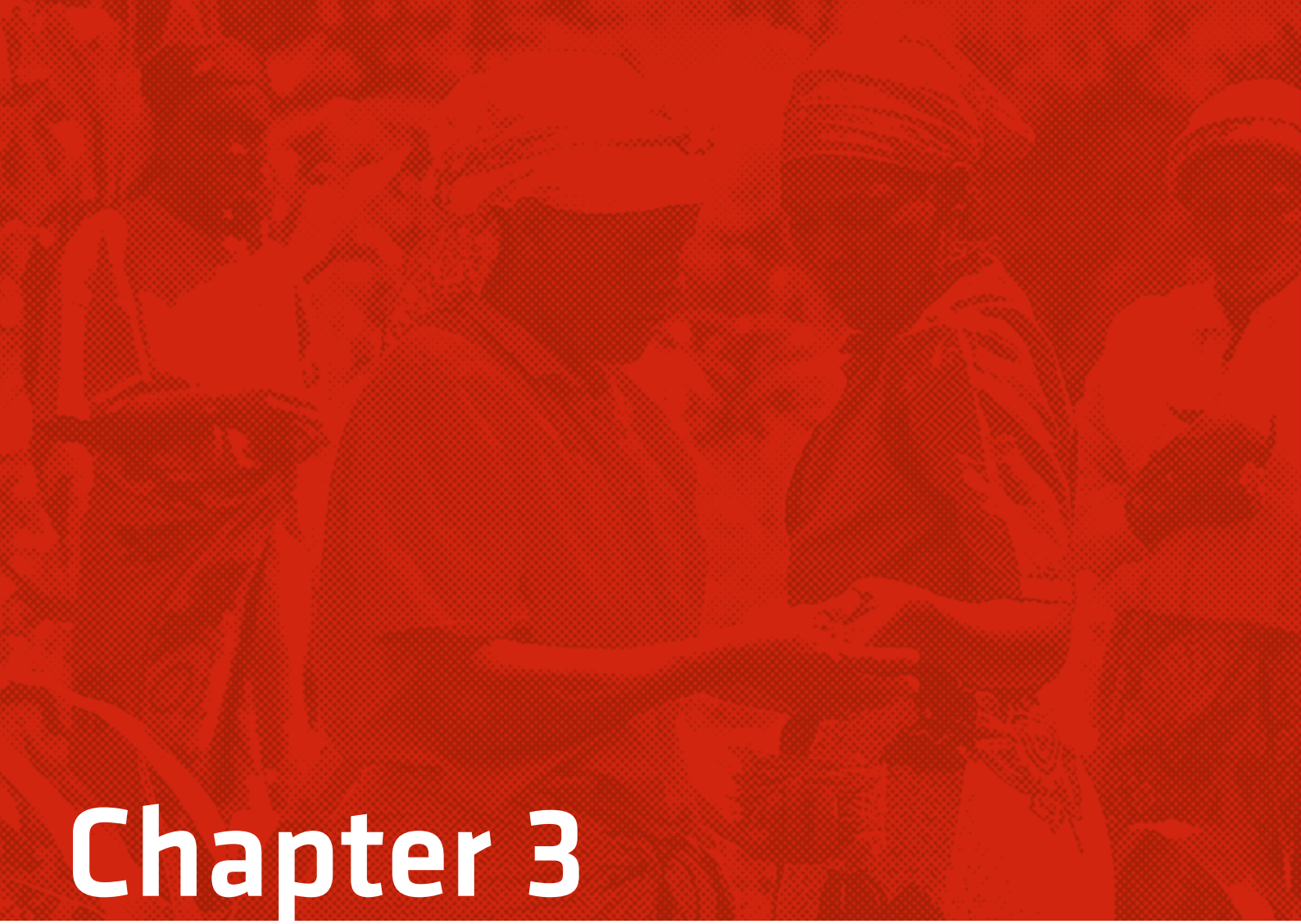
All adapted measures must therefore be taken, in particular with exports, to avoid any blockage. In certain cases, it will be preferable for the batch certificate to accompany the merchandise from the place of export. It goes without saying that the consequences of the impounding of a container of fresh produce, for example, could be catastrophic. Furthermore, in case II, the renewal of import authorizations will have to be established before the expiry date of the existing authorization.

- **Regulation (EC) 1235/2008** was amended by the following regulations:
  - **Commission Regulation (EC) No. 537/2009** of 19 June 2009 amending Regulation (EC) n° 1235/2008 as regards the list of third countries from which certain agricultural products obtained by organic production must originate to be marketed within the Community. The latter simply amends **Annex III** of the Main Regulation (**list of the third countries and specific requirements**).
  - **Commission Regulation (EC) No. 471/2010** of 31 May 2010 amending Regulation (EC) n° 1235/2008 as regards the list of third countries from which certain agricultural products obtained by organic production must originate to be marketed within the Union. The latter once again amends **Annex III** of the Main Regulation (**list of the third countries and specific requirements).**

In short

There are **5 European Regulations** governing organic production within Europe and originating in third countries, 2 of which are main Regulations:

- **Regulation (EC) 834/2007** and its successive amendments:
  - Council Regulation (EC) 967/2008
  - Commission Regulation (EC) 889/2008
  - Commission Regulation (EC) 1254/2008
- **Regulation (EC) 1235/2008** and its amendments:
  - Regulation (EC) 537/2009
  - Regulation (EC) 471/2010



Chapter 3

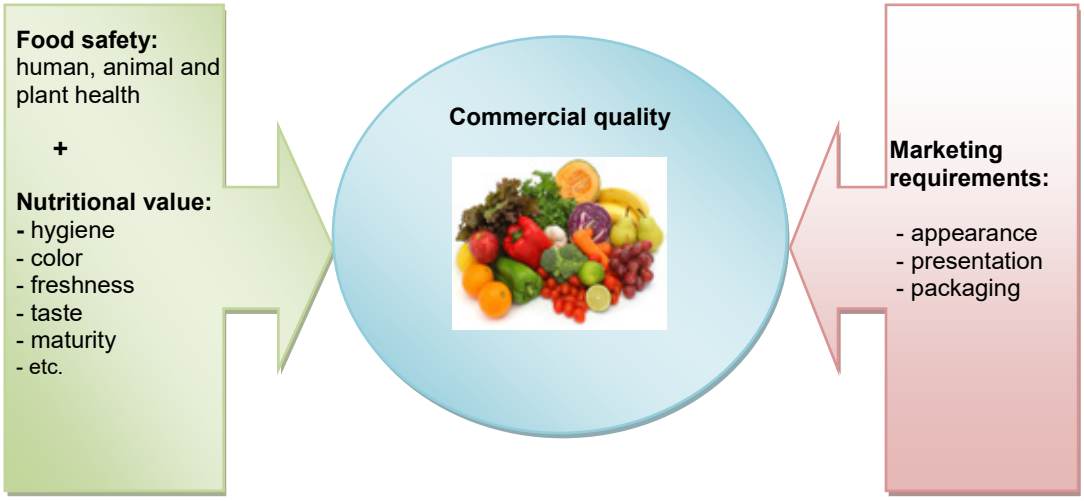
Commercial quality and labelling of fruit and vegetables

3.1. International and European quality standards governing fruit and vegetables

Quality is the key to international markets. Commercial quality standards are used as a common trading language for buyers and sellers and as a reference for quality control. Quality requires the **setting of the necessary quality standards**:

- to build trust and open market opportunities;
- to encourage high quality production;
- to improve the profitability of producers;
- to protect consumer interests.

Commercial quality covers **a range of parameters describing the internal and external characteristics of the product** that are necessary to ensure transparency in trade and obtain good levels of flavor. It lies between essential qualities such as food or nutritional safety and marketing claims.



3.1.1. International standards

❑ **United Nations Economic Commission for Europe (UNECE)**

The UNECE's Committee on Trade (CT) works to develop closer economic relations among Member States, as well as to better integrate their economies into the world economy. It makes policy recommendations, develops standards for use in trade and assists Member countries in implementing them. It also suggests ways and means of creating legal and administrative frameworks for fostering trade, investment and business development.

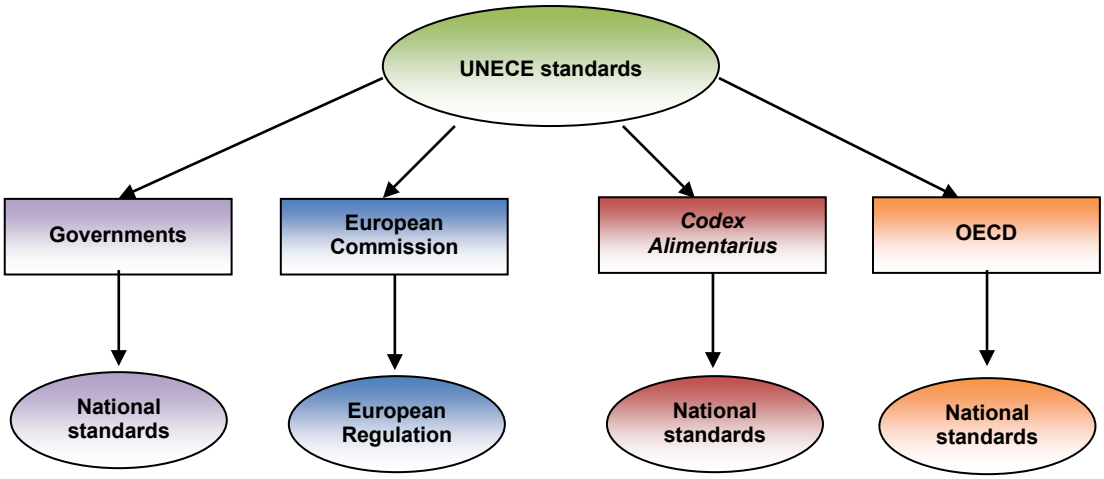
The UNECE has been working for more than 50 years on **commercial quality standards** for a wide range of fresh fruit and vegetables, dry and dried fruit, potatoes, meat products, eggs and egg products and cut flowers. In 1958 it adopted the **Geneva Protocol on Standardization of Fresh Fruit and Vegetables and Dry and Dried Fruit,** which has served since then as a basis for its work. The Geneva Protocol contains the agricultural quality standards according to the following standard layout:

1. **Definition of produce**
2. General provisions concerning quality: these are general requirements relating to healthiness, cleanliness, appearance, moisture, absence of foreign smell and/or taste, development and /or ripeness. The condition of the produce must be such as to enable them to withstand handling and transport and arrive in a satisfactory condition at the place of destination. They also contain requirements on classification in three classes designated 'Extra', 'I' and 'II', and defined according to their quality characteristics and the extent of certain defects.
3. Provisions concerning **sizing**
4. Provisions concerning **tolerances**
5. Provisions concerning **presentation**
6. Provisions concerning **marking (labelling)**
7. Annex I: supplementary provisions
8. Annex II: note on the interpretation to be given to the provisions concerning presentation and packaging of the produce

The **framework standard** for the UNECE standards concerning the marketing and quality control of fresh fruit and vegetables and of dry and dried products (fruit) was **developed on the basis of the Geneva Protocol but enters into more detail on the definition of the quality criteria.**

Since 2007, the UNECE has elaborated **commercial quality standards for fresh fruit and vegetables, dry and dried fruit, potatoes, meat products, eggs, egg products and cut flowers**. These standards are used by governments, producers, importers and exporters as well as other international organizations.

These standards are implemented in accordance with the following diagram:



❑ *Codex Alimentarius* standards

The *Codex Alimentarius*, or the food code, has become the **global reference point for consumers, food producers and processors, national food control agencies and the international food trade**. The code has had an enormous impact on the thinking of food producers and processors as well as on the awareness of the end users - the consumers.

Its influence extends to every continent, and its contribution to the **protection of public health and fair practices in the food trade** is immeasurable.

➢ Codex *and consumer protection*

The *Codex Alimentarius* system presents a unique opportunity for all countries to join the international community in formulating and harmonizing food standards and ensuring their global implementation. It also allows them a role in the development of codes governing hygienic processing practices and recommendations relating to compliance with those standards. The significance of the food code for consumer health protection was underscored in 1985 by the United Nations Resolution 39/248 whereby **guidelines were adopted for use in the elaboration and reinforcement of consumer protection policies.** The guidelines advise, "*When formulating national policies and plans with regard to food, Governments should take into account the need of all consumers for food security and should support and, as far as possible, adopt standards [...] from the Codex Alimentarius or, in their absence, other generally accepted international food standards".*

Since their creation, the *Codex Alimentarius* Commission and its subsidiary committees grant absolute priority to the protection and interests of consumers in the formulation of food standards and related activities.

➢ Codex *and international trade in foodstuffs*

The *Codex Alimentarius* has relevance to the international food trade. With respect to the ever-increasing global market, in particular, the advantages of having universally uniform

food standards for the protection of consumers are self-evident. It is not surprising, therefore, that the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement) both **encourage the international harmonization of food standards**. Products of the Uruguay Round of multinational trade negotiations, these Agreements **cite international standards, guidelines and** recommendations as the preferred measures for facilitating international trade in food. As such, **Codex standards have become the benchmarks** against which national food measures and regulations are evaluated within the legal parameters of the World Trade Organization (WTO) Agreements.

➢ **Food and general standards**

The adopted format for standards reflects the emphasis that *Codex* places on ensuring that consumers receive products that are of **a minimum acceptable quality, are safe and do not present a health hazard**. Format provisions for commodity standards, including the name of "the standard, its scope, description, weights and measures and labelling", are intended to ensure that the consumer is not misled and to induce confidence that the food item purchased is what the label says it is. The provision covering essential composition and quality factors ensures that the consumer will not receive a product below a minimum acceptable standard.

The *Codex Alimentarius* **contains more than 200 standards** (format: **CODEX STAN XXX-year XXX**), for individual foods or groups of foods. In addition, it includes:

- the **General Standard for the Labelling of Prepackaged Foods**;
- the **General Guidelines on Claims**; and
- the **Guidelines on Nutrition Labelling**, aimed at ensuring honest practices in the sale of food while also providing guidance to consumers in their choice of products;
- other **general standards for food hygiene, food additives, contaminants and toxins in food and for irradiated foods**;
- similarly, **maximum residue limits or MRLs for pesticides and veterinary drugs and maximum limits for food additives and contaminants.**

These standards have the same layout as the UNECE standards, namely:

1. The **definition of products**
2. The **quality** provisions: characteristics and classification
3. The **weight** provisions: weight codes according to the diameter of the product
4. The **tolerance** provisions: quality tolerances and size tolerances
5. **Presentation** provisions: homogeneity and packaging
6. The provisions relating to **marking (labelling)**: packaging for the end consumer, not for retail sale.
7. **Contaminants**
8. **Hygiene**

Reference is made to the *Codex Alimentarius* in many bilateral and multilateral commercial agreements in addition to those mentioned above. The Directives of the European Union also frequently refer to the Codex Alimentarius to justify their provisions.

The *Codex Alimentarius*, or the food code, has become the **global reference point for consumers, food producers and processors, national food control agencies and the international food trade**.

There are **Codex standards** (http://www.codexalimentarius.net/web/index_fr.jsp) that guarantee the commercial quality of the product and that it is recommended (not compulsory however) to use for the marketing of fruit and vegetables world-wide.

❑ OECD standards

The OECD (Organization for Economic Cooperation and Development) provides a forum in which governments from 30 countries can work together to meet the economic, social and environmental challenges of globalization. The member Countries of the OECD are: Germany, Australia, Austria, Belgium, Canada, Korea, Denmark, Spain, the United States, Finland, France, Greece, Hungary, Ireland, Iceland, Italy, Japan, Luxembourg, Mexico, Norway, New Zealand, the Netherlands, Poland, Portugal, the Slovak Republic, the Czech Republic, the United Kingdom, Sweden, Switzerland and Turkey. The Commission of the European Union participates in the work of the OECD.

The OECD runs a **Scheme for the Application of International Standards for Fruit and Vegetables,** open to any Member country of the United Nations Organization or of its specialized agencies or the World Trade Organization, which desires to participate, in accordance with the participation procedure that is the subject of the Decision of the OECD Council C (2006)95 of 15 June 2006. Twenty-three countries currently participate in the Scheme. Intergovernmental organizations and NGOs also participate as observers in the Scheme's meetings.

The main objectives of this OECD scheme are to:

- facilitate **the adaptation of quality standards to present production, trade and export conditions**;
- promote **uniform quality control procedures** and to disseminate quality assurance guidelines;
- promote and use an **internationally recognized control certificate**;
- improve the conditions for **maintaining the quality of produce during transport and handling**;
- promote **international standardization of packaging and labelling**;
- **improve quality assurance conditions and operations**.

The activities of the Scheme help producers, traders and quality inspectors by developing **new standards** and revising existing standards, in co-operation with the UNECE; developing with **explanatory brochures of standards with photos**; developing tools for **gauging the skin coloring of various products**; providing **guidance** for the application of quality assurance and inspection systems.

The OECD standards are identical to the UNECE standards and have the same layout. There are OECD international standards for at least fifty fruits and vegetables.

3.1.2. European standards

Classifying products according to a single, internationally accepted reference facilitates trade based on fair competition and, consequently, helps improve the fruit and vegetable sector's profitability. These standards ensure that retailers know what they are buying without having to physically check the products at the time of ordering. At the same time, rules on definition, presentation and labelling prevent consumers from being misled. **European marketing standards** are set for the main fresh fruits & vegetables.

They establish **requirements** for:

- **minimum quality –** mainly external quality (appearance, defects) and, for some fruits, maturity (juice content, sugar content, firmness)
- **classification** – Extra, class I and class II, according to external appearance;
- **presentation and labelling –** including country-of-origin labelling.

These **EU marketing standards are aligned with international standards, as established by the United Nations Economic Commission for Europe (UNECE).** They apply to **products marketed within the EU and to import and export.**

Checks on conformity are carried out by Member States; for imported products, checking operations can be performed by approved third countries.

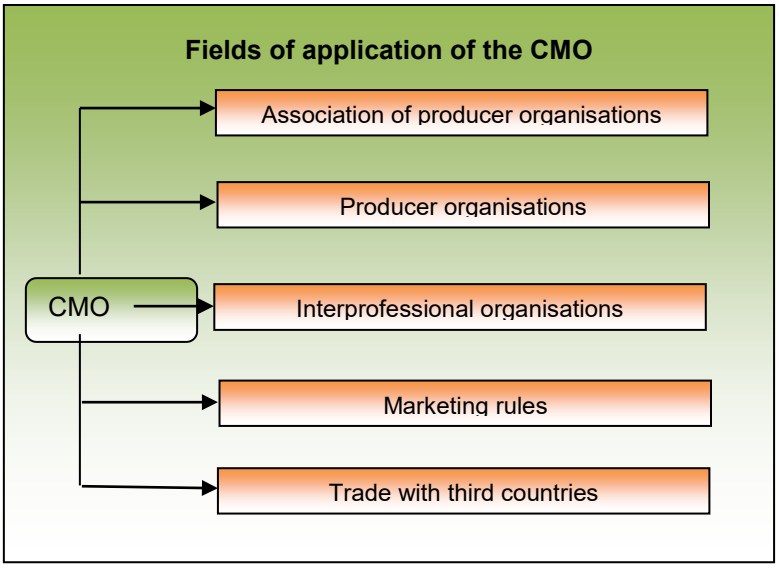
Recognition of checks performed by third countries facilitates the work of importers and national administrations. This approach will be favored in the future.

❑ **Creation of the CMO and standardization**

The 1st of July 2008 marked the creation of a single **Common Market Organization (CMO)** in Europe defined by **Regulation (EC) 1234/2007** of 22/10/2007. It is comprised of a range of provisions at Community level that **govern the production and trade of 21 products or groups of agricultural products from all the Member States of the European Union** (fruits and vegetables, eggs, beef, pork, poultry, cereals, wine, etc.). The Common Market Organization mainly sets out to achieve the objectives of the Common Agricultural Policy (CAP), in particular to stabilize markets and guarantee stable revenues for farmers.

Regulation (EC) 1580/2007 amended lays down the terms and conditions of application of the CMO in the fruit and vegetable sector, it defines the following key concepts:

- **rules on the marketing of fruit and vegetables (including standardization),** that has allowed the setting up of fruit and vegetable standards, has made it possible to identify the products "objectively" (definition of sizes, quality, labelling, presentation criteria) and to establish a common language between public or professional operators;
- **exchanges with third countries;**
- organizations of producers and the associations of producer organizations;
- interprofessional organizations.



❑ **The general marketing standard**

In the wake of the creation of a 'CMO', the European Commission decided to establish a **general marketing standard** applicable to all fresh fruit and vegetables in order to harmonize the many previous Regulations for many products that entered into force on **the 1st of July 2009 Commission Regulation (EC) 1221/2008** of 5 December 2008 amending Regulation (EC) 1580/2007 laying down implementing rules of Council Regulations (EC) 2200/96, (EC) 2201/96 and (EC) 1182/2007 in the fruit and vegetable sector as regards the marketing standards, published in the OJEU L 336 of 13 December 2009).

It nevertheless establishes 'specific' standards for the 10 following products: apples, citrus fruit, kiwis, lettuce, curled-leaved endives and broad-leaved endives, peaches and nectarines, pears, strawberries, sweet peppers, table grapes, tomatoes, which are included in the annex to the Regulation. The **other fruit and vegetables** that do not come under the specific marketing standard must comply with the **general marketing standard that makes the following demands:**

➢ ***Minimum quality criteria:***

The fruit and vegetables must be:

- **intact**;
- **sound**;
- **clean**, practically free from any visible foreign matter;
- practically **free from pests and damage caused by pests**
- practically **free from damage caused by pests affecting the flesh**;
- free of **abnormal external moisture**;
- free of any **foreign taste and/or smell**.

The condition of the products must be such as to enable them:

- to withstand transport and handling;
- to arrive in satisfactory condition at the place of destination.

A 10% tolerance threshold is authorized (not applicable to products affected by rotting or deterioration such as to make them unfit for consumption).

➢ ***Minimum maturity requirements***

The products must be sufficiently developed and display satisfactory ripeness. The development and state of maturity of the products must be such as to enable them to continue their ripening process and to reach a satisfactory degree of ripeness.

➢ ***Marking of origin of produce***

Full name of the country of origin. For products originating in a Member State this shall be in the language of the country of origin or any other language understandable by the consumers of the country of destination.

However it should be stressed

The European Commission stipulates that *"However, where the holder is able to show they are in conformity with any applicable standards adopted by the United Nations Economic Commission for Europe (UNECE), the product shall be considered as conforming to the general marketing standard, it being understood that "holder" shall be any natural or legal person physically in possession of the products concerned".*

UNECE standards:
http://www.unece.org/trade/agr/standard/fresh/FFV-Standards.htm.

Summary table of the products subject and not subject to Regulation (EC) 1221/2008:

Products subject to the general standard and covered by an international UNECE standard	**Classification categories**		
	EXTRA	**I**	**II**
Apricot			
Artichoke			
Asparagus			
Avocado			
Beans			
Blueberry			
Broccoli			
Brussels sprout			
Carrot			
Cauliflower			
Cherry			
Citrus fruit (limes, pomelos…)			
Chicory *witloof* (*endive*)			
Cucumber			
Cultivated mushrooms			
Edible sweet chestnuts			
Eggplant			
Entire date			
Fennel			

Fresh fig			
Garlic			
Hazelnut in shell			
Headed cabbages (Savoy and Chinese)			
Horseradish			
Leek			
Mango			
Melon			
Onion and shallot			
Peas and *mange-tout*			
Pineapple			
Plum			
Radish			
Raspberry			
Ribbed celery			
Spinach			
Truffle			
Walnut in shell			
Watermelon			
Zucchini			

Products not subject to Regulation (EC) 1221/2008, subject to special texts still in force	**Classification categories**			**Reference texts**
	EXTRA	**I**	**II**	
Green unripened banana (Cavendish, Gros Michel, and hybrids)				**R (EC) 2257/94** Amended by R (EC) 228/06

❑ Europe's 'Quality Package' 2010

After a vast three-year consultation and the active participation of stakeholders, the Quality Package puts in place for the first time a **comprehensive policy on certification schemes, value-adding terms for agricultural product qualities, and product standards**, covering the different facets of quality, from the compliance with minimum standards to the production of highly specific products.

The Package comprises:

- a new '**Agricultural Product Quality Schemes Regulation**' bringing coherence and clarity to the EU schemes; reinforcing the flagship scheme for protected designations of origin and geographical indications (PDOs and PGIs); overhauling the traditional specialties guaranteed scheme (TSGs), and laying down a new framework for the development of Optional Quality Terms, such as feeding method and production method;
- a **new general base-line Marketing Standard** for all agricultural products and a specific power to adopt place-of-farming and other sectoral rules for marketing product;
- new **Guidelines of best practices on voluntary certification schemes and on the labelling of products** using PDO-PGI ingredients.

For the future, the Commission has announced its intention to study further the problems faced by small-scale producers in participating in Union quality schemes as well as mountain producers to market their products.

In short…

Guaranteeing quality for consumers and securing fair prices for producers, those are the two objectives of the "Quality Package" adopted by the Commission on the 10th of December 2010. This package is the first step towards an overhaul of the policy governing the quality of agricultural produce and paves the way for a more coherent quality policy.

3.2. Regulations governing the surface treatment of fruit and vegetables

The only treatments generally authorized on fruit and vegetables are surface treatments with substances **classified as food additives**.

3.2.1. General definition of a food additive

Food additives are defined in international and European legislation as "***any substance not normally consumed as a food in itself*** *and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose results in it or its by-products becoming directly or indirectly a component of such foods*".

In the case of fruit and vegetables, these substance additives (mainly **emulsifiers**) which, added in a small quantity to the surface of foods, make it possible to:

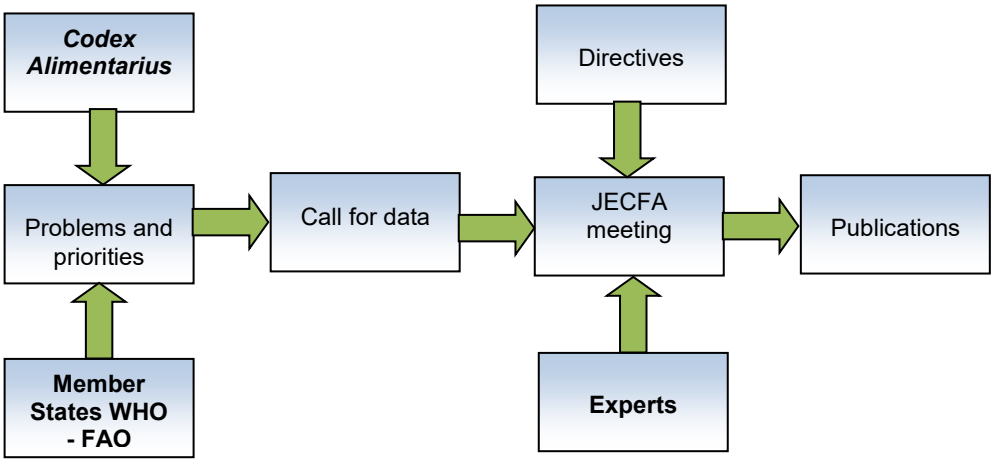
- **avoid the dehydration of fruit and vegetables during their transport and before their consumption**
- improve the presentation or duration.

3.2.2. International regulations

You have the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO). An international committee of scientific experts, the joint FAO/WHO Expert Committee on Food Additives (JECFA) is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The Committee, which has been meeting since 1956, was initially in charge of **evaluating the safety of food additives**. Its work now also includes the evaluation of contaminants, naturally occurring toxicants and residues of veterinary drugs in food.

To date, JECFA has **evaluated more than 1,500 food additives**, approximately 40 contaminants and naturally occurring toxicants, and residues of approximately 90 veterinary drugs. The Committee has also developed principles for the safety assessment of chemicals in food that are consistent with current thinking on risk assessment and take account of recent developments in toxicology and other relevant sciences, such as microbiology, biotechnologies, the evaluation of exposure, food chemistry, including analytical chemistry and the evaluation of the maximum residue limits of drugs.

The work of the JECFA is used by the Codex Alimentarius to develop international food standards and to propose international Directives on food safety.



3.2.3. European regulations

It is governed by **Regulation (EC) 1333/2008 on food additives.** The Regulation has undergone a far-reaching reform launched by the European Commission on 18 July 2006 to modernize the existing legislation on food additives, flavorings and enzymes. This reform has led to the elaboration of a new legislation based on:

- Regulation (EC) 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings;
- Regulation (EC) 1332/2008 on food enzymes;
- **Regulation (EC) 1333/2008** on **food additives;**
- Regulation (EC) 1334/2008 on food flavorings.

Regulation (EC) 133/2008 lays down that food additives, food enzymes and food flavorings must not be placed on the market or used in foodstuffs, unless they are included on a Community list of authorized substances. In this context, a common Community assessment and authorization procedure is established. The additives authorized before 20 January 2009 are the subject of a new evaluation of the risks by the European Food Safety Authority (EFSA). This regulatory text therefore has a broad scope and **enters into force on 20 January 2010**. It defines the additives concerned and supplies the functional categories.

It replaces previous directives and decisions concerning food additives permitted for use in foods. Its aim is to harmonize the use of food additives in foods or in other additives or food enzymes, at Community level. The new Regulation simplifies the approval procedure for food additives and is an opportunity for the Commission to update and supplement the European food additives list.

❑ **The principles**

The Regulation brings together in one single legislative act **all types of food additives, including colors and sweeteners.** Food enzymes are covered by Regulation (EC) 1332/2008.

The Regulation lays down rules on food additives used in foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in the food trade.

A food additive may only be approved if:

- **it does not pose a safety concern to the health of consumers;**
- if there is a **reasonable technological** need that cannot be achieved by other economically and technologically practicable means;
- if its use **does not mislead the consumer**.

This Regulation does not apply to the following substances, unless they are also used as food additives: processing aids, substances used for the protection of plants and plant products, nutrients added to food, substances used for the treatment of water, flavorings and enzymes.

It defines a food additive as: **any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient** of food whether or not it has nutritive value, the intentional addition of which to food **for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage** of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

❑ **Community lists of food additives**

Annex I defines the different **functional classes of food additives**: sweeteners, colors, preservatives, anti-oxidants, carriers, acids, acidity regulators, anti-caking agents, anti-foaming agents, bulking agents, etc.

Additives are included in a list of additives that are authorized at Community level, giving details of their conditions of use **(Annex II).**

Moreover, this Regulation creates a **list of food additives for use in other additives and in food enzymes**, as well as their conditions of use **(Annex III).**

Before incorporating all food additives in the lists in Annexes II and III of this Regulation, the Commission must examine all existing authorizations with regard to criteria such as quantities absorbed, technological need and the potential to mislead the consumer.

Whilst these lists are being drawn up[1], the Annexes of **Directives 94/35/EC, 94/36/EC and 95/2/EC** will be regularly updated and remain in force.

If the production methods or raw materials used in a food additive already included in a Community list are altered considerably, the additive produced in this way shall be considered as a different additive. Before being placed on the market, this new additive

[1] At present, these annexes are drawn up by the European Directorate General for Consumer Health (DG SANCO *Working documents*) but are still at working document stage which need to be circulated to the Member States before being presented as proposals for Regulations to the European Commission between now and the end of 2011. The reassessments of the Community list of food additives (Annex II) and the list of food additives for use in other food additives and food enzymes (Annex III) should be completed by 1 January 2011.

shall be submitted to the European Food Safety Authority (EFSA) for an assessment of health risks.

❑ Labelling

Labelling of food additives must comply with the general labelling conditions defined in **Directive 2000/13/EC**. It must include, in particular, the information necessary for their identification (name, batch, manufacturer, etc.).

❑ Common authorization procedure and risk assessment

Risk assessment and the authorization of food additives are integrated into a common authorization procedure for food additives, enzymes and flavorings established by Regulation (EC) 1331/2008.

❑ Reassessment

The Commission will re-examine all additives that have already been authorized with the assistance of the Standing Committee on the Food Chain and Animal Health.

At the same time, all food additives that were permitted before 20 January 2009 shall be subject to a new assessment carried out by the EFSA. A work programme has been established by the European Commission (see Commission Regulation (EC) 257/2010 of 25 March 2010 establishing a programme for the reassessment of authorized food additives, in accordance with Regulation (EC) 1333/2008 of the European Parliament and of the Council on food additives).

3.3. Regulations governing the labelling of agricultural products

3.3.1. International standards

❑ ***Codex Alimentarius* standards**

Food labelling is the primary means of communication between the producer and seller of food on the one hand and the purchaser and consumer on the other. The standards and guidelines of the *Codex Alimentarius* on food labelling are **included in the standard on the commercial quality of food**. Indeed the latter, specific for each foodstuff, **contain a chapter (VI) on the marking or labelling** of agricultural products for consumption.

This chapter includes the following criteria:

1. CONSUMER PACKAGES

1.1. Nature of produce
Each package should be labelled as to the name and type (bitter) of the produce and may be labelled as to the name of the variety.

1.2. Method of preparation

2. PACKAGING SOLD OTHER THAN BY RETAIL

Each package must bear the following particulars, in letters grouped on the same side, legibly and indelibly marked and visible from the outside, or in the documents accompanying the shipment.

2.1. Identification
Name and address of exporter, packer and/or dispatcher.
Identification code (optional).

2.2. Nature of produce
Name of produce and type (bitter), if the contents are not visible from the outside. Name of variety (optional).

2.3. Origin of produce
Country of origin and optionally, district where grown or national, regional or local place name

2.4. Commercial identification
Class
Size (size code or minimum and maximum diameter in cm)
Net weight
Method of preparation

2.5. Official inspection mark (optional)

There is also a ***Codex* general standard** for the labelling of prepackaged foods. This is the **CODEX STAN 1-1985 (Rev. 2-1999**) standard that applies to the labelling of all **prepackaged foods** sold as such to the consumer or for use by mass caterers and certain aspects relating to their presentation.

However, given that most of the products arrive in their original form without packaging, certain of the list of ingredients are not applicable to these imported foodstuffs.

3.3.2. European standards

The objective of foodstuff labelling is to guarantee that consumers have access to complete information on the content and composition of products, in order to protect their health and their interests. Other information may provide details on a particular aspect of the product, such as its origin or production method. Some foodstuffs, such as genetically modified organisms, allergenic foods, foods intended for infants or even various beverages, are also subject to specific regulations.

Labelling of certain non-food products must also contain particular information, in order to guarantee their safe use and allow consumers to exercise real choice. In addition, the packaging of foodstuffs must adhere to production criteria in order to avoid contaminating food products.

European legislation is based on 3 main legal texts:

- **Directive 2000/13/EC** of the European Parliament and of the Council of 20/03/2000 on the approximation of the laws of the Member States relating to the **labelling, presentation and advertising of foodstuffs**. It was amended by Directives **2001/101/EC** (change of the definition of skeletal muscles in Annex 1 to Directive 200/13) **and 2003/89/EC** (which concerns the indication of the ingredients present in foodstuffs;
- **Regulation (EC) 1924/2006** of the European Parliament and of the Council of 20/12/2006 on nutrition and health claims made on foods;
- **Commission Regulation (EC) 1221/2008** of 5 December 2008 amending Regulation (EC) 1580/2007 laying down implementing rules of Council Regulations (EC) 2200/96, (EC) 2201/96 and (EC) 1182/2007 in the fruit and vegetable sector as regards marketing standards

❑ **Directive 2000/13/EC** amended by Directives **2001/101/EC** and **2003/89/EC**

It applies to **foodstuffs intended to be delivered as such to the consumer or for supply to restaurants, hospitals and other similar mass caterers**. It does not apply to products intended to be exported outside the Community.

It sets out a list of compulsory indications that **must** appear on the label, including two which are only compulsory if necessary (conditions of use) or in the event of confusion (indication of origin):

- the **sales name that** indicates to the consumer the nature of the product. It can be accompanied by an indication of the physical condition in which the foodstuff is found (if confusion possible);
- the **list of ingredients** (barring exceptions) preceded by the term 'ingredients', they must be listed in descending order of weight. Ingredients is understood to be any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the end product, even in a modified form;
- the **net quantity**;
- the **date of minimum durability** (DMD) or **use by date** in the case of foodstuffs which, from the microbiological point of view, are highly perishable;
- the **instructions for use**, for example: "keep refrigerated", "keep in a dry and cool place" etc.;
- the **name or business name and address of the manufacturer or packer, or of a seller established within the Community**;
- **the place of origin or provenance** (in the event of confusion);
- the instructions for use (if necessary);
- the alcoholic strength (for beverages containing more than 1.2% by volume of alcohol).

The **additives** belonging to one of the following functional classes must be mentioned in the list of ingredients by the name of this category, followed by its specific name or its EC number: colors, preservatives, antioxidants, emulsifiers, thickeners, gelling agents, stabilizers, flavor enhancers, acids, acidity regulators, anti-caking agents, modified starch, sweeteners, raising agents, anti-foaming agents, coating agents, emulsifying salts (for melted cheese), flour treatment agents, firming agents, humidifiers, bulking agents, propellants.

❑ **Directive 2003/89/EC**

It concerns **allergens.** This Directive sets out to provide **consumers with more comprehensive information** on the composition of products thanks to a more exhaustive labelling, in particular for those suffering from allergies or food intolerance. This Directive replaces the **25% rule** with the 2% rule: for composed ingredients making up less than 2% of the end product, with the exception of additives, the listing of the ingredients that it contains is not compulsory. This Directive establishes a compulsory list of **allergens** that must appear on the labelling of foodstuffs, namely:

- cereals containing **gluten** (wheat, rye, barley, oats, spelt, kamut or their hybridized strains), and products thereof;
- **crustaceans** and products thereof;
- **eggs** and products thereof;
- **fish** and products thereof;
- **soybeans** and products thereof;
- **milk** and products thereof (including lactose);
- **nuts**: almonds, hazelnuts, walnuts, cashew, pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut and products thereof;
- **celery** and products thereof;
- **mustard** and products thereof;
- **sesame seeds** and products thereof;

- **sulphur dioxide and sulphites at** concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO_2.

❑ **Regulation (EC) 1924/2006** of the European Parliament and of the Council of 20/12/2006

It concerns the nutrition and health claims made on food. The Regulation defines "nutrition claim" as any claim that states, suggests or implies that a food has particular beneficial nutritional properties due to:

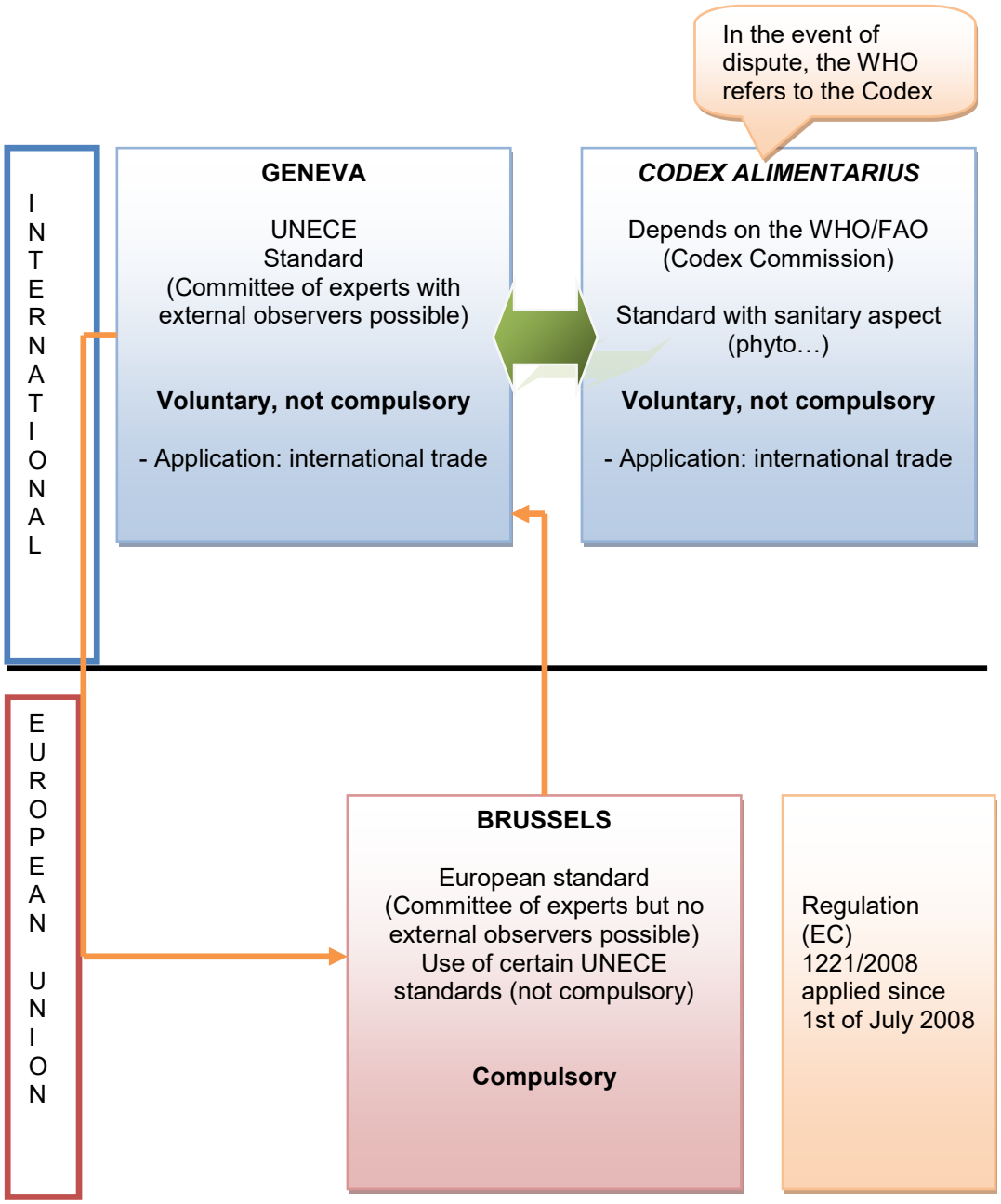
a) the energy (calorific value) it:
- provides,
- provides at a reduced or increased rate, or
- does not provide; and/or

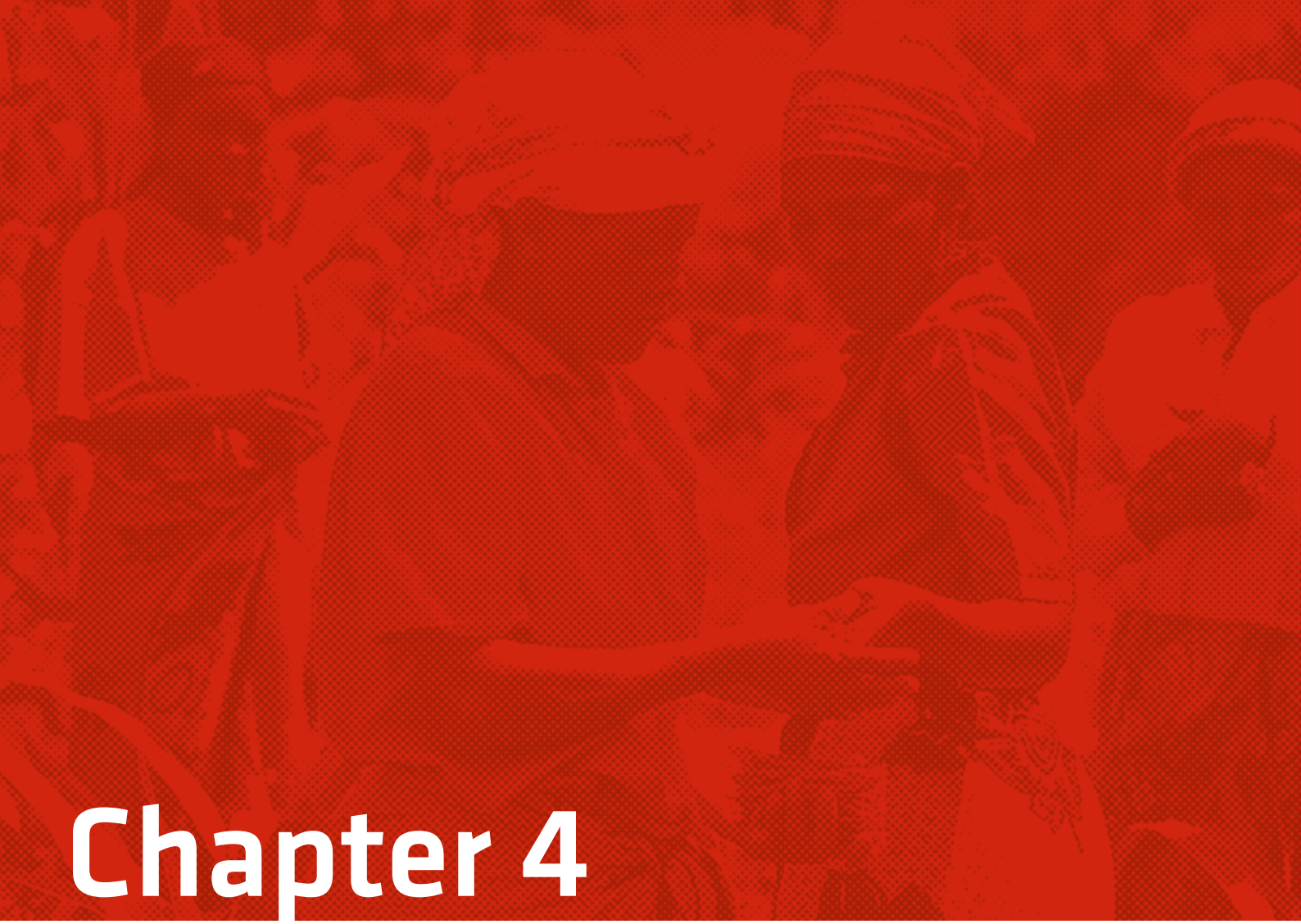
b) the nutrients or other substances it:
- contains,
- contains in reduced or increased proportions, or
- does not contain.

Health claim means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

The Regulations lay down the legal framework and criteria authorizing such claims on packaging of foodstuff destined for human consumption.

Appendix: Summary table on standardization





Chapter 4

Private standards

4.1. Introduction

The purpose of this chapter is to review and describe, in a synoptic manner, the various **private** initiatives relating to the health quality of foods, labor ethics, and environmental stewardship that have arisen from individual or group, national or international actions.

A brief review of the existing literature at the beginning of the chapter summarizes the reasons why these **private voluntary standards** (PVS) came into being and the various categories of standards.

The **main implications** that these private initiatives have for the fruit and vegetable production sector of African, Caribbean, and Pacific countries shall be discussed at the end of the chapter.

4.1.1. Some useful definitions:

❑ **Regulations, norms, standards, certifications, and labels**

In legal terms, **regulations** are:

- an element of a legislative instrument, either national or European;
- a legal obligation which businesses must undertake under penalty of sanctions;
- an element applying to certain business sectors or products.

Example: Regulation (EC) 178/2002 on the traceability of foods.

➢ ***Norms*** refer to a system of reference:

- recommended practice (Good Practice or Best Practice): the best way to proceed for a given subject;
- as a general rule they arise from discussion and debate about businesses led by businesses in standardization bodies (Afnor in France);
- when these norms are not legally binding and when they originate from the private sector and/or civil society, they are referred to as private voluntary standards (PVS).

Example: ISO 9001 "Quality management systems"

➢ ***Standards*** are instruments that are shared:

- among the players of a given sector or involved in a given activity;
- in order to have common operating procedures for facilitating and lending credibility to interactions among these players.

Example: the ETI 8 logistic label in cars.

The term is confusing because in English *standard* and *norm* are used interchangeably. Actually a standard is a reference system for a national or international use published by a private entity other than a national or international standardization body (or other

organization not authorized by one of the latter). **In this chapter, we shall use the term private voluntary standards (PVS) for all of the norms and standards described herein in order to avoid confusing the issue any further.**

- **Certifications** refer to horizontal devices:
  - based on bodies of standards for guaranteeing a level of quality in the operations of a business;
  - validating (by auditing) compliance with standards of practices;
  - certification is a task of quality management (assurance).

Example: ISO 9001, ISO 14001 Certifications, etc.

- **Labels** are an indication that a certification was granted to an organization by a third party.

Labels attest to compliance with standards established out of necessity by a body other than the certification body. In principle, the certification body is itself certified in this capacity by an official agency that ensures that the certification body and the organization establishing the standards are independent and that the evaluation process is reproducible. The standards for certification can be defined by a norm or another standard, but this is not compulsory.

Example: The term 'quality label' is sometimes used when the certification standards relate to a product or a service (e.g., the French 'label rouge' for food products, the French 'NF environment label' for industrial products or services etc.).

4.2. Origin and categories of private voluntary standards

4.2.1. Origin of private voluntary standards

During the 1990s, a series of incidents impacting the safety and integrity of food products dealt a blow to the trust of the European consumer. The European Commission (EC) and the member states reacted by initiating a process of institutional and legislative reforms. In 2000, the EC defined its policies in a white paper. These new policies outlined a programme of changes that would essentially reorient food safety management. Henceforth, integrated management of all steps in the supply chain would be required in order to ensure optimum risk management and in order to be able to initiate preventive and corrective measures.

The introduction of the *Due Diligence* clause in the UK 1990 Food Safety Act constituted another significant change in the regulatory environment. This clause stated: "The accused party may defend itself by proving that it took all precautions that could reasonably have been taken and that it exercised all possible diligence to prevent the infraction from being committed either by itself or by someone working under its orders". The introduction of this clause radically changed the safety management systems of the food industry in the UK by compelling businesses to undertake all necessary checks to prevent adverse effects from their products, or at least to be able to prove that they took all of the mandatory precautions. Businesses were thus made responsible for the safety and the quality of their ingredients, for the actions of their suppliers, and for consumer safety.

This due diligence clause linked to the European legislation concerning the health quality of foods as well as the growing concerns of consumers about what's on their plate had repercussions in the agri-food sector. In order to protect themselves from all risks, the private sector developed **self-regulation systems** or **'private voluntary standards' (PVS)** based on the Good Practices Codes of the food sector.

This process started in the UK with the Good Agricultural Practices (GAP) codes and a good hygiene practices protocol, which later became the food standard of the *British Retail Consortium* (BRC). These standards in turn inspired a diversity of similar private sector initiatives in other European countries (Jaffe, 2005). Traditionally, retailers in the fresh products sector have always insisted that their suppliers respect their requirements concerning volumes, continuous supply, and prices. Now they want these same suppliers to comply with a series of private voluntary standards that apply to their production, manufacturing, and marketing methods.

The private voluntary standards concerning the health quality of foods are frequently described as being more rigorous than the regulations (Henson and Humphrey, 2009). Non-compliance with these private and voluntary standards is not punishable under law. However, they can become *de facto* requirements when they are routinely demanded of suppliers (Henson and Humphrey, 2009).

According to Fulponi *et al.* (2006), businesses that adopt a PVS relating to health quality do so mainly to maintain and improve their reputation through better risk management. In view of the fact that any serious incident can cause tremendous damage to the business in terms of its consumer image, food safety management is considered as one of the most important elements of the PVS.

Private voluntary standards relating to health quality enable the players of the supply chain to **show that they have implemented systems** for taking all necessary precautions (as much as possible) to ensure the quality and safety of their products. The certification of these private voluntary standards by a third party acts as an **insurance policy** in the event of civil or criminal proceedings. Lastly, private voluntary standards make it possible to limit informational asymmetries among the various players of the supply chain and thus to reduce internal monitoring costs through better management of the entire chain (Fulponi, 2007).

There are 2 ways of **checking whether a business is in compliance with a PVS**: via an internal audit and/or an external audit (and most often via a combination of the two).

- The internal, or '**first party**' audit is performed by the business itself, which appoints one of its employees to be in charge of the verification process. The external audit can be either a 'second party' or 'third party' audit. A '**second party**' audit is performed by a party with an interest in the business (e.g. a customer), either directly or indirectly by persons acting in their name.
- The second party audit has become widespread in large-scale retail and agri-food companies (Liu, 2009).
- A '**third party**' audit must be performed by a completely independent organization, usually one officially accredited for doing so. At the end of the verification process, the business is issued a certification or attestation (depending on the PVS) of compliance with said PVS, or not.

Greater demands by consumers and civil societies (along with surveillance by NGOs) are nonetheless urging big name retailers to focus not only on the safety and quality of foods but also where they come from. More and more they are having to deal with labor, environmental, safety, and societal responsibility issues; areas which up until now had been more the responsibility of public and international agencies or NGOs.

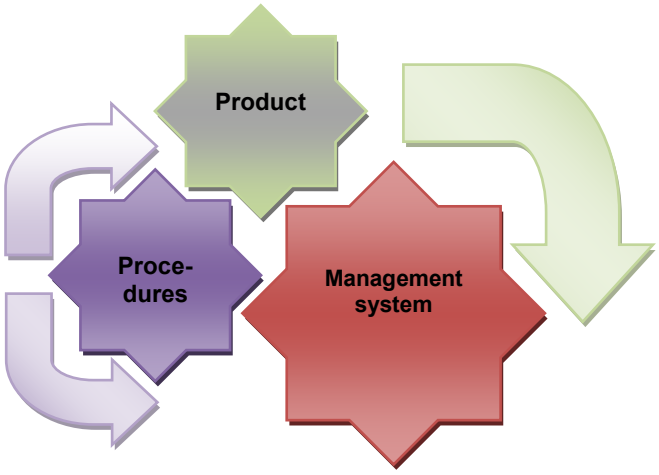
Under pressure from consumers, it seems that big name retailers have addressed these issues as well via specific certification initiatives, which are usually accompanied by labels on the products. Adopting proactive strategies for dealing with these subjects enables businesses to improve their image with their customers, suppliers, and end consumers. In certain cases, doing so also enables them to gain a competitive advantage over other businesses, which in turn may help them win contracts or improve their market share.

Lastly, adopting sustainable development programmes also urges businesses to review their internal management strategies for energy and resource use and waste management, eventually enabling them to lower their energy bills and even improve their productivity.

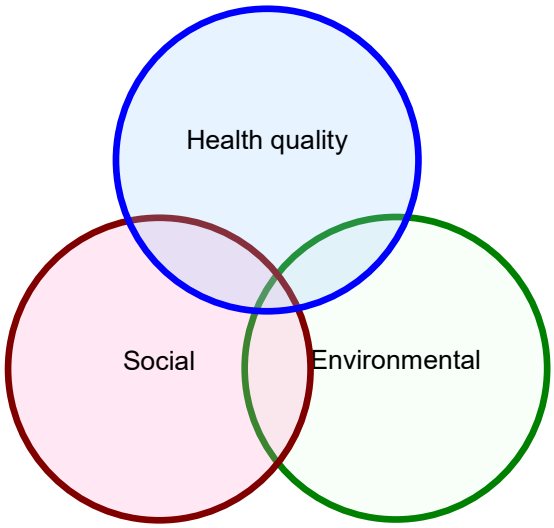
4.2.2. PVS categories

The standards are generally classified in three categories, namely product, process, and management system standards. The first category essentially relates to the characteristics associated with quality. Process standards relate to the conditions under which the products and services must be produced, packaged, or processed. Management system standards help organizations manage their operations. They are often used to create a structure that then enables the organization to satisfy, on a continuous basis, the requirements specified in the product and process standards.

The private voluntary standards described in this chapter on the health quality of foods or compliance with social and/or environmental criteria are standards relating to processes and management systems.



Categorizing the standards within the large PVS family on the basis of subjects covered is conceivable. Nevertheless, such a categorization is generally not feasible due to the fact that the private voluntary standards often cover several subjects simultaneously. This is especially true of certain private voluntary standards relating to the health quality of foods that contain different control points concerning **labor rights** and **environmental stewardship** (GLOBALG.A.P., SQF).



By definition, most private voluntary standards originate with businesses and civil society (Liu, 2009). Among the private voluntary standards concerning the health quality of foods, the WTO distinguishes 3 major categories of standards. This classification is based on the stakeholders who established the standard.

The individual standards (Field-to-Fork of M&S, *Filière Qualité Carrefour*, Tesco's Nurture etc.) of large-scale retail businesses are established by the latter and applied to a series of operators along their supply chains. They are most often accompanied by a label on the final product.

'Field to Fork'[1] is a PVS specific to the British retail chain Marks & Spencer. This PVS relates to the production and processing phases of food products and thus effectively covers not only good agricultural and manufacturing/processing practices but also health quality, environmental stewardship, and decent working conditions.

To guarantee its customers healthy, good quality, and genuine products, **Carrefour** implemented a quality line[2] (*Filière Qualité*) concept for fresh fruits and vegetables in 1999. This quality line relates to apples, pears, carrots, pineapples, melons, figs, leek, and potatoes.

Carrefour implemented a standardization system for its producers, which is based on specific specifications for each product. The requirements relate to each phase of the product's life cycle: from the plants and seed used to the harvesting of the fruits and vegetables. The inspections, which are performed by a third party, focus on the crop protocol, employee working conditions, hygiene on the premises, storage conditions etc.

Nurture[3] is a PVS **reserved exclusively for Tesco** that relates to responsible fruit and vegetable production.

By adhering to the Nurture standard, the producers commit themselves:

- to implementing a traceability system that allows a product to be tracked back to its source;
- to growing and selecting high quality fruits and vegetables;
- to demonstrating their commitment to the protection of animals and the conservation of habitats;
- to adopting sustainable agricultural practices in terms of energy and natural resources use, including recycling;

1 www.agrolibano.com/eng/gpo_montelibano_certified_products.html.
2 www.sgsgroup.fr.
3 www.tesco.com.

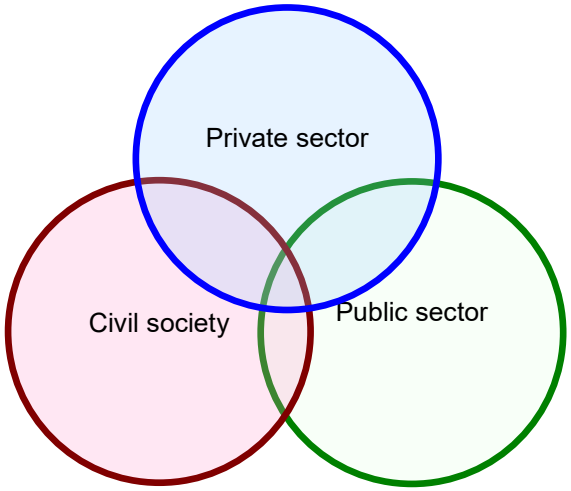
- to using pesticides, fertilizers, and manure in a rational manner; furthermore, the producers shall use natural pest and disease control methods such as solarization of soils as much as possible;
- to ensuring that all of their employees are treated fairly.

National collective private voluntary standards (BRC, Assured Food Standards, Freedom Food etc.) **are established by professional societies and/or NGOs**. Lastly, international collective private voluntary standards (GLOBALG.A.P., IFS, SQF etc.) generally apply to the supply chains established in many regions of the world (Henson and Humphrey, 2009). International collective private voluntary standards are also established by professional societies and/or NGOs (or even public authorities, as is the case with the *International Standardization Organization*).

Individual private voluntary standards of businesses	National collective private voluntary standards	International collective private voluntary standards
• Field to Fork (Marks & Spencer) • Nurture (Tesco) • …	• BRC • …	• GlobalG.A.P. • Fairtrade (FLO) • ISO • …

Source: Henson and Humphrey, 2009

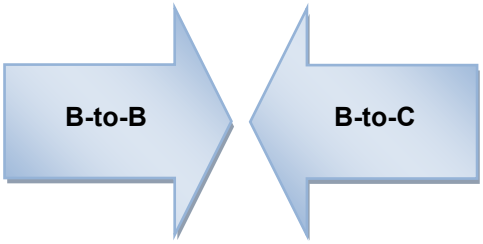
As a general rule, **the private sector has been more active in the development of private voluntary standards relating to the health safety of foods,** whereas civil society has historically played a greater role in establishing private voluntary standards covering the social and environmental aspects of supply chains (Fair trade, organic production, *Sustainable Agriculture Network*, *Social Accountability International*) (Liu, 2009). However, the private sector, civil society, and the public sector also form coalitions (*International Standards Organization* (ISO), *Ethical Trading Initiative*, etc.) in certain cases in order to establish **new standards** or "**codes of conduct**".



Private voluntary standards can also be categorized as '**Business-to-Business'** (B-to-B) or '**Business-to-Consumers**' (B-to-C) standards. The individual standardization initiatives are generally intended to be communicated to consumers (B-to-C). The joint actions relating to health quality are intended to ensure risk management and reduction along the entire supply chain. **Consumers are therefore not notified of them** (B-to-B).

The standards covering social and environmental aspects are generally 'B-to-C' (except for ethics standards such as SA 8000, BSCI, etc.). 'B-to-C' private voluntary standards **usually specify** the product attributes **in the form of a label on the final product,** with the express purpose of distinguishing that product from other similar products.

In contrast to B-to-C private voluntary standards, B-to-B private voluntary standards by definition cannot be funded by the market via a premium paid by the consumer, as the latter is not notified whether or not the product is compliant with one of these private voluntary standards.



Lastly, there may be a final classification of private voluntary standards based on whether they are focused on obligations relating to means (infrastructures, training, systems, inputs, etc.) or results (maximum pesticide residue limits). Examples of private voluntary standards focused on obligations relating to results include the individual standards of large-scale retail businesses relating to lists of active ingredients approved for use on crops (which are often stricter than the official approvals) and maximum residue limits (MRL, tolerances) of pesticides (which are generally lower than the official tolerances set by the EU). The standards related to the intrinsic nature of products (color, size, shape, etc.) are also part of these private voluntary standards focused on obligations relating to results.

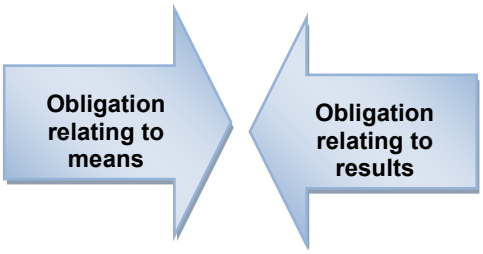
Most of the private voluntary standards described in this chapter that relate to the health quality of foods or to compliance with social and/or environmental criteria are standards focused on obligations relating to means rather than results.[4]

The obligations relating to means stated in these standards concern means and actions that businesses must implement for the production, processing, and marketing phases (AFD, 2010).

The **ways of verifying whether or not a business is in compliance** with a PVS are generally different for **'means' and 'results' private voluntary standards**. Whereas verification is relatively easy (analysis of samples, measurements, visual aspects etc.) for private voluntary standards focused on obligations relating to results, the opposite is true for private voluntary standards focused on obligations relating to means. For a business wishing to comply with one or more of these standards, a systematic documentation of the procedures implemented by the business (Liu, 2009), in other words a suitable

[4] The distinction between obligations relating to means and results is not always obvious. In the literature it is therefore not uncommon to encounter different interpretations of these concepts and consequently, different PVS classifications.

management system, is usually required in order to facilitate the verification process. Hence it is commonly acknowledged that it is generally more difficult to comply with a 'means' PVS than with a 'results' one.



4.3. Identification of the main private voluntary standards

4.3.1. Health quality of foods

There are currently several private voluntary standards relating to the **health quality of foods** that apply to the production and processing of food products, such as BRC, IFS, Dutch HACCP, SQF 2000, FSSC 22000, and Synergy 22000 (all of which are based on the HACCP principles defined in the Codex), SQF 1000 and of course GLOBALG.A.P. All of these private voluntary standards are focused on means-related rather than obligations relating to results and can be classified as procedural private voluntary standards that require businesses to implement internal management systems. Furthermore, in view of the potential repercussions of an adverse incident on the entire sector, these programmes make food safety an issue unrelated to the competitiveness of businesses (B-to-B). In both cases (production and processing), major retailers in the private sector collaborated in order to fill a gap affecting the entire branch, offering a competitive advantage to certified businesses and monitoring their activities ranging from production to distribution. The purpose of this section is to describe, in a synoptic manner and from various angles, the most widespread 'health quality' private voluntary standards in the horticultural sector.

Management of the quality and of the health quality of foods

The organizations involved in the food supply chain must deal with the demands of their customers as well as those of the regulations (*cf. supra*) concerning their aptitude in identifying and controlling the hazards linked to food safety. On the international level, the ISO 9001:2000 standard specifies the requirements for a quality management system. However, this standard relates to quality as a whole and not specifically to the health quality of foods. However, a standard specific to the agri-food sector was created on the basis of ISO 9001:2000, namely ISO 15161:2001: *Guidelines on the application of ISO 9001:2000 in the food industries, which focuses on the quality but not on the safety of foods.*

Hence many countries have created their own private voluntary standards related to health quality management systems. Also, several private standards such as IFS and BRC (described below) have come into being. All of these private standards are based on the HACCP method. However, **HACCP is primarily a process and not normative** (except for the PVS *Dutch HACCP* of the SCV [Dutch foundation for certification of the health quality of foods], which is described below).

It was therefore necessary to create **a standard of international dimensions** based on the ISO 9001:2000 model and **including the HACCP principles, namely**: **ISO 22000:2005** (described in the section on the FSCC 22000 private voluntary standard).[5]

[5] www.norme-iso22000.info/home.htm.

The Global Food Safety Initiative (GFSI) is a non-profit foundation created in 2000 and managed by the Consumers Goods Forum. The main goal of the foundation is to compare and approve (a process known as *benchmarking*) a set of private voluntary standards on the health quality of foods based on their reference document (GFSI Guidance Document).[6] In 2007, 8 major retail chains[7] agreed on this guidance document. The ultimate objective of this approach is to reduce the increasing number of audits that suppliers have to deal with by adopting the philosophy 'once certified, accepted by all'. In practice, an ACP exporter already certified to BRC and wishing to sell products to a customer working with suppliers certified to SQF 2000 or IFS would be able to do so without having to re-certify to one of these standards.

The objectives of the GFSI are as follows:

- to maintain a benchmarking process for health quality management programmes in order to achieve convergence among the various standards;
- to improve cost management throughout the food supply chain through mutual acceptance of GFSI standards recognized by distributors around the world;
- to provide a single international platform for all of the players in order to encourage contacts, exchange of knowledge, and pooling of best practices and information related to health quality.

The GFSI does more than just offer businesses a standardized framework related to the health quality of foods. It is also initiating a three level certification approach for operators. The objective of this action is to enable a business to progressively conform to all of the requirements of the GFSI Guidance Document in 3 years.

One of the consequences of private standards related to the health quality of foods meant that ACP suppliers of fruits and vegetables had to implement a series of consistent organizational, infrastructural, and procedural changes within a very short time interval. Among other things, the widespread implementation and acceptance of this phased approach by European buyers would make it possible to calibrate investments over time, thus facilitating the certification process.

Private Voluntary Standards 'benchmarked' by the GFSI

➢ Private voluntary standards covering processing:
- **BRC Standard Global - Version 5**
- **Dutch HACCP (Option B)**
- **FSSC 22000**
- Global aquaculture Alliance BAP Issue 2 (GAA Seafood Processing Standard)
- Global Red Meat Standard - Version 3
- **International Food Standard - Version 5**
- **SQF 2000 Level 2**
- **Synergy 22000**

[6] www.mygfsi.com.

[7] Carrefour, Tesco, ICA, Metro, Migros, Ahold, Wal-Mart and Delhaize.

- Private voluntary standards covering production:
  - Canada GAP
  - **GlobalG.A.P. Rational crop and livestock production system – Standard V3**
    - **General Regulations: V3.1_Nov09 (all agricultural production)**
    - **Fruits and vegetables: 3.0-2_Sep07**
    - Livestock raising: 3.0-4_Mar10
    - Aquaculture: V1.02_March10
  - **SQF 1000 Level 2**
- Private voluntary standards covering production and processing:
  - Primus GFS

Only the private voluntary standards pertaining to the horticulture industry (in boldface in the table) will be described in detail in this section.

The **British Retail Consortium** (**BRC**) is an umbrella association for a significant number of distributors in Great Britain. In response to the needs of the industry, the BRC developed the *BRC Food Technical Standard* in 1998. This standard is intended to be used for evaluating the food processing plants in order to assist the distributors and owners of food brands in their efforts to comply with the new European regulatory framework concerning the health safety of foods.

As mentioned in the first part of this chapter, in keeping with Regulation (EC) 178/2002, distributors and food brands are obligated to respect the principle of *due diligence.* This means that they must be able to demonstrate that all precautions for preventing non-compliance with health safety have been taken in order not to be held liable under law.

Despite its British origin, this PVS is now used in more than 100 countries throughout the world. The *BRC Food Technical Standard* is a so-called 'B-to-B' (business-to-business) PVS, in other words not accompanied by a label on the final product destined for the consumer. Compliance with this PVS must be verified by a third party accredited as an official certification body and respecting the BRC rules for auditing. Hence the BRC does not audit businesses itself, but is the owner of the PVS and manager of the certification process.[8]

The BRC Food Technical Standard is therefore intended for processors of food products, enabling them to attest to their Good Manufacturing Practices (GMP) and the quality management systems that they have implemented in order to ensure that the products that they sell fulfil the requirements of both their customers and the regulatory framework

[8] A search engine for finding these accredited certification bodies is available at .www.brcdirectory.com.

in effect. This PVS is thus applicable to any plant that processes or packages food products.[9]

The standard has 7 chapters :

1. **Involvement of the company management and continuous improvement:** in order for a food health safety management system to work, it is essential for the company management to support the implementation and encourage the continuous improvement thereof.
2. **The plan for health safety:** the basis for a health quality management system is the implementation of the HACCP process, as defined in the *Codex Alimentarius.*
3. **The quality and health quality management system:** this section lists criteria for quality and health quality management based on the ISO 9000 standard that must be fulfilled. The criteria relate to the product specifications, the choice of suppliers, traceability, and management of incidents and recalls.
4. **The standards for the sites:** this part of the standard defines the constraints for the physical packaging and/or processing environment in terms of layouts, maintenance of the building and the machine fleet, cleaning, disease control and waste management. There is also a section that deals specifically with checking for foreign matter.
5. **Product control:** these are control points relating to the phases of product design and development, management of allergens, and also to product-testing laboratories and test phases.
6. **Process control:** this section relates to the establishment and maintenance of process controls, weight/volume controls, and calibration of the equipment.
7. **Human resources:** lastly, this part defines the criteria for training staff about wearing protective clothing and practicing personal hygiene.

The costs for certification will depend (as is often the case) on the size of the site and on which systems have already been implemented in the business. It may turn out, for example, that the business must invest in order to upgrade its site, or that it may have to resort to outside expertise for documenting its procedures in preparation for an audit. BRC obviously has no control over these costs, nor over the auditing fees charged by the certification bodies.[10]

The first version of Dutch HACCP was launched in 1996 by a national board of HACCP experts in the Netherlands. In 2004 this National Board of Experts (NBE) created a foundation for certifying the health quality of foods (*Stichting Certificatie Voedselveiligheid* – SCV). The SCV is the governing body of the board of experts (and thus the owner of this PVS). Its main tasks consist of updating and improving the Dutch certification system.

[9] The list of businesses certified to BRC Food Standards version 5 can be found at www.brcdirectory.com

[10] There is, however, a fixed price of £125 (included in the cost of the audit) for keeping the PVS up to date. The standard is not available to the public, but can be purchased from the BRC website (www.brcbookshop.com) for a sum of £90.

HACCP (Hazard Analysis and Critical Control Point) is a risk analysis approach that is respected world-wide. As a general rule it is compulsory for businesses that process food products.

The *Codex Alimentarius*[11] recognizes the HACCP as the standard method for hazard identification and risk management in the field of food safety. The criteria of the Dutch system are based on the 7 principles of the HACCP approach, as described in the *Codex Alimentarius* ALINORM. This PVS also relates to the processing of food products and it is a business-to-business (B-to-B) standard. The national board of Dutch HACCP experts published a 4th version of the standard in 2007. This version contains all of the main elements of the ISO 22000 standard.

In actual fact, there are **two kinds of certifications** for a health quality management system based on the HACCP approach:

- option A: certification of the management system;
- option B: certification of the process/product.

The GFSI[12] benchmarked option B of Dutch HACCP. The SCV does not perform any certification audits. Hence various accredited certification bodies pay the SCV for a license to perform these certification audits.[13]

The **steps** for getting certified to a PVS are generally the following:

1. Choosing the standard best adapted to the activity in question.
2. Ordering/downloading the currently valid version of the standard.
3. Diagnosing the level of compliance with the requirements of the standard.
4. Implementing the changes (infrastructures, procedures, documentation etc.) needed to comply with the requirements of the standard.
5. Choosing a certification body (proposal, decision, and signing the contract).
6. Establishing the date, time, and scope of the audit.
7. Optional: performing a pre-audit.
8. Performance of the audit on site on the scheduled date by an auditor qualified for the category of the corresponding product.

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11 The *Codex Alimentarius* is a collection of internationally recognised standards and laws on the processes, directives, and recommendations related to nutrition, food production, and food safety. The standards of the Codex are authoritative in the agri-food sector and most of the recommendations issued by it have been integrated in European and other legislation.

12 The standards may be downloaded for free at www.foodsafetymanagement.info/net-book.php?op=cms&pageid=2&pageid_up=0&nnl=english.

13 The complete list of certification bodies can be found at www.foodsafetymanagement.info/net-book.php?op=cms&pageid=52&pageid_up=0&nnl=english.

The Food Safety System Certification 22000 is a 'B-to-B' PVS for food safety management systems that is based on the food safety management standard ISO 22000: 2005, "Requirements for all organizations involved in the food supply chain" and on the Publicly Available Specification of the British Standards Institution 220: 2008 'Prerequisite programmes for food safety in food manufacturing (BSI PAS 220: 2008)'.

The Publicly Available Specification 220 of the British Standards Institution (BSI PAS 220) is a document designed as an aid in implementing the ISO 22000 standard. The latter expressly requires the implementation of a prerequisite programme (PRP)[14] and provides a list of headings to consider, but without specifically stating what the PRPs should encompass. The PAS 220 lists these PRPs for food and food ingredient manufacturing processes.

The idea is for all sectors to use ISO 22000 as a generic standard for food safety management systems and for the documents specific to each sector to cover each other's needs.

ISO 22000:2005[15] specifies the requirements for a food safety management system in the food supply chain when an organization needs to attest to its ability to manage the hazards linked to food safety, in order to guarantee that the food is safe for human consumption.

It applies to all organizations involved in some aspect of the food supply chain, regardless of their size, and aims to implement systems for ensuring the provision of safe products at all times. The means for satisfying all of the requirements of this international standard can be implemented with internal and/or external resources.

ISO 22000:2005 defines the requirements for enabling an organization to:

- design, implement, operate, maintain, and update a food safety management system intended to provide products that, when used as approved, are safe for the consumer;
- demonstrate its compliance with the legal and regulatory requirements applicable to food safety;
- evaluate and perceive customer demands, demonstrate compliance with the requirements relative to food safety established in cooperation with customers in order to improve customer satisfaction;
- establish effective communication about issues related to food safety with its suppliers, its customers, and other stakeholders in the food supply chain;
- guarantee compliance with its stated food safety policy;
- demonstrate this compliance to stakeholders;
- have its food safety management system certified by/registered with an

[14] Prerequisite programme (PRP): basic conditions and actions needed to maintain a hygienic, environment throughout the food supply chain that is suitable for the production, handling, and provision of finished products and foods that are safe for human consumption (ISO 22000), www.iso.org/iso-22000-food-safety-management.html.

[15] www.iso.org/standard/35466.html.

external body, or perform a self-evaluation/self-declaration of compliance with ISO 22000:2005.

The **Synergy 22000** private standard is also based on the ISO 22000 standard, to which may be added:

- either the ISO TS 22002-1 technical specification (PRP for food safety) for the manufacture of foods,
- or the PRP 22000 (Synergy) for all steps of the food supply chain.

In contrast to the FSSC 22000 private standard, the combination of the ISO 22000 and PRP 22000 standards is thus applicable to the entire food supply chain and to the activities in connection thereto (from primary production, warehousing, shipping, and processing to distribution). The combination of the ISO 22000 and PRP 22000 standards is solely applicable to the food industry (processing – manufacture).

The FSSC 22000 PVS therefore involves using the existing certification standards (ISO 22000, PAS 220, and ISO 22003), and the certification is then accredited under ISO Guide 17021.[16]

This PVS relates to the food product processing phase, and manufacturers already certified to the ISO 22000 standard will have to undergo an additional inspection in accordance with the BSI PAS 220 specification in order to satisfy the conditions of this certification program.

In actual fact, it was the Confederation of the Food and Drink Industries of the EU (best known by its French acronym CIAA) that took the initiative to develop a technical specification in the food product manufacturing area. The objective of the programme is to harmonize the certification requirements and methods for management systems related to food safety in the food supply chain, as well as to ensure that reliable food safety certificates that are comparable in terms of both contents and scope of application are issued. The SCV Foundation (*Stichting Certificatie Voedselveiligheid*) was commissioned by the CIAA to conduct the programme.[17]

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[16] The complete list of certification bodies can be found at www.foodsafetymanagement.info/en/home. The list of certified businesses can be found at www.fssc22000.com/documents/home.xml?lang=en.

[17] The SCV created the FSSC 22000 private standard and is the legal owner thereof. It must furthermore establish licence agreements for the certification bodies. The ISO 22000 international standard and the PAS 220 are available upon request from the ISO and/or the BSI and they may be used jointly with the additional FSSC 22000 requirements. The latter are part of the FSSC 22000 programme and can be downloaded free of charge from the site www.fssc22000.com. A list of the PAS 220 requirements can be found in the FSSC 22000 programme documents and in other sources, and the auditing and notification of these conditions is required in the scope of each audit.

The members of the German federation of retail distributors – (*Hauptverband des Deutschen Einzelhandels* (HDE) – and those of its French counterpart (*Fédération des Entreprises du Commerce et de la Distribution* (FCD) – have created a safety and quality standard for brand name food products. This standard is known as the International Food Standard (IFS), and its purpose is to provide a uniform approach as a basis for evaluating the quality and safety levels of suppliers of food products. This B-to-B PVS is applicable to all of the food product processing steps subsequent to primary production.

During the course of the years 2005/2006, the Italian federation of distributors also became interested in the International Food Standard. The new version of the IFS Food standard, version 5, was drawn up jointly between three federations of distributors from Germany, France and Italy.[18]

The primary objectives of the IFS are:

1. to establish a common standard with a uniform system of evaluation;
2. to work with accredited certification bodies and qualified auditors;
3. to ensure transparency and the possibility of comparisons along the entire supply chain;
4. to cut back on the costs of audits and the time it takes to perform them for both distributors and suppliers.

IFS Food[19] applies:

- to the processing and/or
- to the handling of unpackaged/bulk products and/or
- to the initial packaging activities.

The following information and options are available on the website www.ifs-online.eu:

- general information about the IFS;
- list of all of the certification bodies accredited for IFS on the European and international level, including the countries in which they have offices;
- online shop for purchasing the various IFS standards;

[18] A list of distributors using the IFS is available at www.ifs-certification.com/index.php?SID=5440440e08f32970144c0ed1e78b40c1&page=home&content=public_content&desc=trader_support&bid=2.

[19] The IFS Food standard consists of the following 4 major parts:

Part 1: Audit protocol (conduct of the audit, length of the audit, the different steps ranging from the audit itself to issuing of the certificate, etc.).

Part 2: Technical requirements. The check list contains 250 requirements relative to the following: responsibilities of the management, quality management system, resource management, manufacturing process, measurements, analyses, improvements.

Part 3: Requirements for accreditation bodies, certification bodies, and auditors.

Part 4: Audit report (sample report, certificate etc.).

Although most of the certificates are issued in Europe, the number of IFS certificates is increasing world-wide owing to the internationalisation of products marketed by European distributors. The IFS (French, English, German) is available on the organisation's website for a price of €39.

- online contact form for contacting the IFS offices in Paris or Berlin.

The secure data base[20] of the audit portal contains:

- the list of audited businesses
- the audit briefs, audit reports, and action plans of the audited businesses.[21]

The Safe Quality Food Institute (SQFI) is part of the Food Marketing Institute (FMI), an American interprofessional society composed of 1500 retail and wholesale distributors that manages various programmes related to regulations, health quality, and research and education on behalf of its members.

SQFI is the only organization within the GFSI to propose B-to-B private standards that not only cover the production (SQF 1000) and processing (SQF 2000) phases but also enable a certification of the intrinsic quality of the product (level 3).

The SQF 1000 and 2000 private standards are divided into three levels of certifications. Each level indicates the progress of the system for managing the health quality (and the intrinsic quality) of the business:

- Level 1: Fundamentals of health quality
- Level 2: HACCP-certified health quality management programmes
- Level 3: Quality and health quality management systems

- **Level 1: Fundamentals of health quality:** Level 1 relates to the general requirements for all health quality management systems. The business must implement prerequisite programmes that include the fundamental procedures of food health quality control. This level is sufficient for low risk products.
- **Level 2: HACCP-certified health quality management programmes:** Level 2 requires the business to document a risk analysis based on the HACCP approach for the products and procedures concerned and to establish an action plan for preventing, reducing, and eliminating these risks. This level is the minimum level

[20] All distributors who recognise and utilise the IFS may access this database. IFS-certified businesses are systematically granted access to this database as soon as their audit data are downloaded in the database by the certification bodies.

[21] All audits that lead to an IFS certification are recorded in the database, but only the names and addresses of the businesses are published. The audited company can then chose, on a selective and individual basis, if it wishes to provide its customers (retail and wholesale distributors, other industries, etc.) with more information. Otherwise this information remains strictly confidential.

of certification required for high risk products. Examples of products considered as high risk include fresh products (fruits and vegetables) and fish.

- **Level 3: Quality and health quality management systems:** Certifications for levels 1 and 2 are compulsory for achieving level 3 certification.

Like the organizations behind the other private voluntary standards benchmarked by GFSI, SQFI does not perform certification audits. That task is delegated to a group of accredited certification bodies. It is highly recommended that businesses wishing to become certified always prepare by performing a series of internal audits.[22]

Ethics module

The SQFI launched an ethics module as a supplement to the SQF 1000 and 2000 standards. The implementation of this module in a business is voluntary. Nevertheless, once a business has undertaken to observe and implement this ethics module, it must observe all of the requirements. The ethics module focuses on requirements relating to providing decent working conditions for employees and environmental stewardship. Observance of the regulatory framework in these two areas is a priority. The goal is not to replace the existing private voluntary 'ethics' standards such as SA8000 or BSCI, but instead to prepare businesses for eventual compliance with these more stringent standards. Besides, the SQFI ethics module is based on a set of 'ethics' standards:

- Social Accountability Standard 8000 (SA 8000)
- The code of conduct of the Business Social Compliance Initiative (BSCI – March 2004)
- The code of conduct for socially responsible sourcing (ethical sourcing code) (SQF, 2nd edition, 2001)
- The environmental module of the Global Social Compliance Program (GSCP – draft)
- The reference code of the Global Social Compliance Program (version 1, June 2007)

EUREPG.A.P. was created in 1997 as the result of an initiative by major retail chains involved in the Euro-Retailer Produce (EUREP) working group. British retailers in conjunction with continental European supermarkets were the driving forces behind this initiative. In response to the growing concerns of consumers about product safety and environmental and labor standards, they decided to harmonize their own, often very different standards.

In order to make the name EUREPG.A.P. synonymous with the project for establishing the international pre-eminence of the GAP standard, and to avoid any confusion with the growing number of players from the public sector and civil society, it was decided to change the EUREPG.A.P. trademark to GLOBALG.A.P.

[22] The standards are available free of charge at www.sqfi.com/documents. The SQFI also provides a set of documents to help businesses become compliant with the standard(s).

GLOBALG.A.P. is thus a private sector [23] organization that defines the certification standards for agricultural products everywhere in the world.[24] **The purpose is to establish a standard for 'Good Agricultural Practice'** with different applications for each product, but nevertheless adaptable to agriculture world-wide.

GLOBALG.A.P. is a so-called *pre-farm gate* standard, meaning that the certificate covers the entire process chain of the certified product **from planting (young plants) and all other agricultural activities to the time that the product leaves the farm**.

GLOBALG.A.P., like the others, is a B-to-B private standard and is therefore not directly visible to the consumers. GLOBALG.A.P. certification is conducted by around a hundred independent certification bodies accredited in more than 80 countries.[25]

GLOBALG.A.P. consists of a set of normative documents encompassing the General GLOBALG.A.P. Regulations, the GLOBALG.A.P. Control Points and Compliance Criteria, and the GLOBALG.A.P. Check List. [26]

❑ Benchmarking

Because numerous other internal quality assurance systems had been in place in agricultural operations for some time prior to the existence of GLOBALG.A.P., it proved necessary to encourage the development of management systems adapted to the regional level and thus spare farmers from having to undergo multiple audits.

Existing national or regional farm assurance schemes that have been successfully benchmarked are recognized as being equivalent to GLOBALG.A.P.

The owners of Good Agricultural Practice (G.A.P.) standards world-wide can try to prove their equivalence to GLOBALG.A.P. by an independent benchmarking procedure. The GLOBALG.A.P. benchmarking procedure can be compared to a filter system that qualifies and harmonizes the different standards in the world. Part of this procedure consists of a peer review among the members, wherein the latter have a six week period to express any objections.

Kenya-GAP®
A standard for safe horticultural produce

Kenya-GAP is a good agricultural practices standard derived from the code of practice of the Fresh Produce Exporters Association of Kenya (FPEAK). It has been in existence since 1995. Kenya-GAP® International was benchmarked to the

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[23] The list of GLOBALG.A.P. members is available at www.globalgap.org/uk_en/who-we-are/members.

[24] It is supported by FoodPLUS GmbH, a non-profit limited liability corporation domiciled in Cologne, Germany.

[25] The list of approved certification bodies is available at www.globalgap.org.

[26] All of these documents are available on the GLOBALG.A.P. website. Version 4.0 of the standard is the most recent one and it shall be compulsory as of January 2012.

GLOBALG.A.P. standard in order to enhance international recognition. Kenya-GAP® National/Regional was adapted so that it would integrate more effectively with local and regional market conditions. The purpose of this PVS is to initiate effective health quality management based on the HACCP approach in packaging/processing plants.

❑ National interpretation guideline and national technical working groups

GLOBALG.A.P. has started linking world-wide implementation activities more closely with the local needs of producers. More and more national technical working groups (NTWG) are being created to achieve this objective. Their role is to develop a set of guidelines for national interpretation and for responding to specific challenges in local adaptation and implementation.

National technical working groups are voluntarily established by GLOBALG.A.P. members in countries where there is a need for clarification of GLOBALG.A.P. implementation on the local level. A number of NTWGs have been established in Africa (Senegal, Ivory Coast, Ghana, Tanzania, Kenya, and Uganda), in some cases with COLEACP-PIP and NRI support.

The guidelines developed by these groups are published on the GLOBALG.A.P. Website.[27] Organizations, businesses, etc. that comply with them are entitled to a conventional GLOBALG.A.P. certification.

These adaptation dynamics could eventually extend beyond the GLOBALG.A.P. standard to include other private standards as well, such as ones covering social and/or environmental issues. Private standards have often been characterized as Eurocentric and not sufficiently adapted to the local realities confronting horticultural businesses in African, Caribbean, and Pacific countries. Officially recognized adaptation efforts could thus be a way to remedy these problems.

There are several ways to get certified to this PVS:

- via the unmodified GLOBALG.A.P. standard;
- via a benchmarked standard;
- via the basic standard, but with certain criteria adapted to local conditions.

❑ Smallholders

For structural reasons, smallholders often face much greater difficulties in complying with the requirements of this VPS. GLOBALG.A.P. has therefore taken three approaches to facilitate market access for smallholders:

1. **Group certification**
   Smallholders can form a group and obtain a joint certification (Option 2). This enables them to lower external certification costs such as inspection and general fees substantially. Moreover, a large number of essential conditions for obtaining GLOBALG.A.P. certification (e.g., pesticide inspections) can be centralized, thus enabling producer groups to benefit to a greater degree. The group structures also make it easier to advise farmers on how to apply the

[27] www.globalgap.org/cms/front_content.php?idcat=21.

standard. The pressure that the group imposes on its members motivates them to comply with the requirements. The use of the Quality Management System forms an integral part of the group, as a global non-compliance according to the QMS will negatively affect the certification result for the group as a whole.

2. **Manual for smallholders**
   GLOBALG.A.P. has developed a manual for smallholders jointly with the German Society for Technical Cooperation – *Deutsche Gesellschaft für Technische Zusammenarbeit* (GTZ) and the Society for Resource Protection – *Gesellschaft für Ressourcenschutz* (GfRS).

3. **Opportunities for input**
   GLOBALG.A.P. wishes to take the needs of smallholders into account in the future application and improvement of the standard. Smallholders thus have several options for systematic input. In May 2007, GLOBALG.A.P. launched the Africa Observer/Smallholder Ambassador Project and Smallholder Task Force, with GTZ and DFID funding. The goal of this project is to convey the input of smallholders to the Sector Committees.

❑ Versions 3.1 and 4.0

Version 4 of the standard on the French sustainable agriculture system (*système raisonné d'agriculture et d'élevage*) was completed after 4 years of work. This version has been usable since January 2011, and starting in January 2012 it will be mandatory. Several parts of the standard underwent substantial modifications, with the underlying goal of simplifying implementation and focusing more on the environmental aspects (particularly management of water resources). A point of interest concerns the reduction of the number of audits for businesses that consistently demonstrate good compliance with this VPS over the years.

GLOBALG.A.P. is a private standard relating to the health quality of foods, and it now covers the social and environmental aspects of agricultural production as well. The 'sustainable' aspects of agricultural production have now been placed on an equal footing with the 'health quality' aspects.

❑ GLOBALG.A.P. Risk Assessment on Social Practice (GRASP)

Like SQF, GLOBALG.A.P. launched an ethics module as a supplement to the standard on the health quality of foods. GRASP, or risk assessment on social practices, is a voluntary standard for businesses. The audit for verifying the compliance of the business with the 11 control points can be performed concurrently with the 'health quality' audit.

Nevertheless, the auditor must have had **specific training** in order to be able to work with the GRASP module. Furthermore, the GRASP module is only applicable in countries that have developed interpretation guidelines adapted to the local conditions. Lastly, the GRASP module obviously only applies to GLOBALG.A.P. certified businesses.

The 11 control points cover the following areas:

- Legal rights of employees
- Communication channels
- Written labor contracts

- Legal status of employees
- Children's rights
- Working hours
- Salaries and wages
- Other social benefits

The main steps for developing a national interpretation guideline are the following:

1. In countries which already have a national technical working group (NTWG), this group will take charge of creating the guideline for the GRASP module. If there is no NTWG, any other organization or group of stakeholders may take charge of developing these interpretations.
2. Preparation of a first version of the guideline.
3. Consultation with the various stakeholders.
4. Official approval of the guideline.

4.3.2. Sustainable development and societal responsibility

Besides the health quality of foods, a set of private voluntary standards covering social and environmental themes have come into being in response to increased demands for sustainability on the part of European consumers. Confronted with these new demands, the major retail chains have adopted a series of initiatives in the form of private voluntary standards, codes of conduct, and multiparty platforms clustered under their societal responsibility policies, with the aim of addressing the concerns of the European consumer.

As a result, an ACP producer/exporter of fruits and vegetables is nowadays confronted with a multitude of terms and concepts associated with and/or defining these initiatives: fair trade, ethical production, social responsibility, sustainable development, carbon footprint, life cycle analysis, etc. The main purpose of this section will be to provide more clarification regarding these different concepts and to describe briefly a set of sustainable development initiatives.

In contrast to the health quality of foods, European authorities have not made any regulations concerning these issues and are therefore leaving it up to the private sector and civil society to make the rules.

❑ **Sustainable development**

According to a commonly accepted definition, sustainable development is "development that responds to the needs of the present generation without compromising the capacity of future generations to respond to their own needs".[28] Sustainable development can also be described as development resulting from the balance of interactions among three pillars:

- **the environment**
- **the economy**

[28] See the Report of the World Commission on Environment and Development*: Our Common Future* (Brundtland Report), Paris, Fleuve, 1987.

- **the social sphere**

This second way of perceiving sustainable development in no way contradicts the first definition. In the business world, it often translates as the adoption of the '3p' philosophy: People, Planet, Profit. The purpose of sustainable development is to ensure sustainability on all levels of society. Consequently, it is not uncommon for the sustainability of an organization (or even an industry) taken individually to be contradictory to the aspirations of society.

For a business, the concept of 'sustainable development' translates to its corporate social responsibility policy (social conscience).

Global Reporting Initiative[29]

The Global Reporting Initiative (GRI) was created in 1997 by the Coalition for Environmentally Responsible Economies (CERES) in the United States. Up until 2002 the GRI was a project under the auspices of the United Nations Environment Program (UNEP). It is now an independent organization.

In actual fact, it is an international, multiparty initiative in which businesses, NGOs, consulting firms, universities, etc. participate.

The GRI is based on guidelines for helping businesses report on their economic, social, and environmental performances. 11 principles and 79 indicators are followed for doing so.

The purpose of the Guidelines is to provide businesses with a 'triple approach' global framework for publishing sustainable development reports. The Guidelines are used in parallel with instruments of societal responsibility such as codes of conduct and management systems, and they provide ways of describing the performances of the latter.

❑ Societal responsibility[30]

The term 'social responsibility' entered everyday language in the early 1970s, although the concept has been in use since the 19th century among various organizations and governments. Social responsibility concerns all types of organizations and not just businesses, and its ultimate objective is to contribute to sustainable development. This explains why diverse stakeholders who participated in the drafting of the ISO 26000 standard (on social responsibility) are now talking about 'societal responsibility' and not just 'corporate social responsibility (CSR)' (which limits the scope of application to the social aspects). Societal responsibility was initially centered around activities of a philanthropic nature (charity). Increased attention to human rights, the environment, consumer protection, and the fight against corruption, however, has resulted in the progressive inclusion of these topics in the social responsibility policies of diverse organizations.

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29 www.globalreporting.org/Information/about-gri/Pages/default.aspx.

30 As defined in ISO 26000.

The ISO 26000:2010 "Guidance on societal responsibility" standard defines the societal responsibility of organizations as an organization assuming responsibility for the impact of its decisions and activities on society and the environment through transparent and ethical conduct that:

- contributes to the sustainable development, health, and well-being of all of society;
- takes the expectations of the stakeholders into account;
- is compliant with the laws in effect and with the international standards of conduct;
- is an integral part of the entire organization and practiced in all of its relationships.

Several underlying reasons are cited in the standard to explain this increased focus on the societal responsibility policies of various types of organizations.

Globalization and the consequences thereof in terms of mobility and access to information enable both individuals and organizations to measure the world-wide impact of certain decisions and activities almost instantaneously. The global nature of certain challenges such as the environment, health, poverty, and economic interdependence often compels organizations to consider certain elements beyond their immediate surroundings.

Moreover, the creation and adoption of a series of instruments/conventions such as the Rio Declaration on Environment and Development, the United Nations Millennium Development Goals, the Johannesburg Declaration on Sustainable Development, and also the international standards of the International Labor Organization (ILO) relating to fundamental principles and rights at work reinforce the global nature of the challenges with which organizations throughout the world are confronted.

In a non-exhaustive manner, these elements explain why society as a whole will only have greater expectations of all types of organizations in terms of societal responsibility.

The **ISO 26000:2010 standard**[31] provides guidelines for organizations of all types, regardless of their size or location. These guidelines relate to:

- the concepts, terms, and definitions related to societal responsibility;
- the origins, orientations, and characteristics of societal responsibility;
- the principles and practices of societal responsibility;
- the key issues and fields of activity of societal responsibility;
- the integration, establishment, and promotion of responsible conduct throughout the organization, and in its sphere of influence via its policies and practices;
- the identification of stakeholders and dialogue with them;
- communication about the commitments, performances, and other information concerning societal responsibility.

[31] www.iso.org/standard/42546.html.

The ISO 26000:2010 standard is about helping organizations contribute to sustainable development. It aims to encourage organizations to go beyond mere observance of the law, all the while realizing that respecting the law is a fundamental duty of every organization and an essential component of its societal responsibility. The standard is about fostering a common understanding in the area of societal responsibility and supplementing, rather than replacing, other societal responsibility instruments and initiatives.

When applying the ISO 26000:2010 standard, it is recommended that the organization give due consideration to the societal, environmental, legal, cultural, and political differences and to the diversity of the organizations, as well as to the differences in economic conditions, in keeping with the international standards of conduct.

An organization cannot get 'certified' to this PVS, but can only follow the recommendations and guidelines mentioned therein.

The Global Compact[32]

Launched in January 2000 on the occasion of the World Economic Forum and proposed by the then Secretary General of the United Nations Kofi Annan, the Global Compact is dedicated to promoting corporate civic responsibility so that the business world can participate in the search for solutions to the problems posed by globalization. Today, hundreds of businesses from all regions of the world as well as international labor and civil society organizations participate in it.

The Global Compact is a voluntary initiative of responsible businesses, with which two complementary objectives are associated:

- integrating the Global Compact and its principles in corporate strategy and corporate activities;
- encouraging cooperation among key interested parties and promoting partnerships to support the goals pursued by the UN.

The Global Compact is not a regulatory instrument. Its purpose is not to sanction, dictate, or assess corporate conduct or actions. Instead the Global Compact relies on responsibility to the public, transparency, and the long term interests of corporations, the world of work, and civil society for launching concrete and joint actions according to the principles set forth therein.

The Global Compact thus asks businesses to adopt, support, and apply a set of fundamental values in their sphere of influence, in the areas of human rights, labor and environmental standards, and the fight against corruption. To put it another way, it is only in the areas that concern them that actual changes are asked of businesses.

[32] www.unglobalcompact.org.

The 10 principles:[33]

➢ ***Human rights***

Businesses are asked to:

1. promote and respect the protection of human rights established by international law in their sphere of influence;
2. make sure that their own companies are not implicated in human rights violations.

➢ ***Rights at work***

Businesses are asked to:

3. respect the freedom of association and recognize the right to collective bargaining;
4. eliminate all forms of forced or compulsory labor;
5. effectively abolish child labor;
6. eliminate discrimination in jobs and employment.

➢ ***Environment***

Businesses are asked to:

7. take a precautionary approach towards problems affecting the environment;
8. undertake initiatives tending to promote more environmental stewardship;
9. encourage the upgrading and widespread adoption of green technologies.

➢ ***Fight against corruption***

Businesses are asked to:

10. take an active stance against all forms of corruption, including extortion and bribery.

One way a business can establish its societal responsibility policy is by adopting private voluntary standards covering various different issues or by participating in an initiative like the Global Compact. These private voluntary standards are B-to-B or B-to-C and hence are sometimes accompanied by a label on the final product. As a general rule they originate from civil society.

❑ **Ethical production or trade**

During the 1990s, a series of media campaigns denounced the deplorable working conditions to which the employees of certain large multinational concerns were subjected, especially in the agri-food and textile industries. **Consumer groups** in many western

[33] The 10 principles of the Compact are derived from the following instruments:
- Universal Declaration of Human Rights;
- ILO Declaration on Fundamental Principles and Rights at Work;
- Rio Declaration on Environment and Development;
- United Nations Convention against Corruption.

countries **then took it upon themselves** to pressure certain large companies, convincing them to adopt codes of conduct compelling them to ensure decent working conditions for their employees everywhere in the world. In order to compel their suppliers to respect these new requirements and to establish the credibility of their initiatives in the eyes of the general public, businesses began organizing first, second, and third party 'social or ethical' audits.

Ethical production (or ethical trade) is oriented towards production conditions and towards corporate operating methods beyond that. In a distributor/producer relationship, it furthermore aims to ensure and to show the customers that the products offered for sale were produced under conditions compliant with the international labor standards set forth by the ILO,[34] the Universal Declaration of Human Rights, and the United Nations Convention on the Rights of the Child (UNCRC). Ethical trade can also include requirements relating to the environmental conditions of production, although most so-called 'ethical' initiatives tend to focus more on labor conditions.

Hence ethical production does not directly relate to production, but instead to corporate operating methods and moral values, for example: employee rights, child labor, fair pay. Ethics certification thus focuses on the production process and not the product itself, hence the term 'ethical production' and the categorization of these private voluntary standards as procedural rather than product standards.

"More than 1.2 million workers are employed by 2100 entities certified to the SA8000 standard in 60 countries and in 67 industrial sectors".[35]

Social Accountability International (SAI) is a multi-stakeholder NGO. Its main objective is to improve working conditions and the conditions of local communities by developing and implementing social responsibility codes for all types of organizations. In 1997, SAI launched 'Social Accountability 8000 (SA 8000)', an auditable PVS serving as a third party verification system and defining workplace requirements. Submission to these requirements by employers is voluntary, and they relate in particular to workers' rights, working conditions, and management systems. The normative elements of this standard are based on national legislation, international human and children's rights standards, and ILO conventions.

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34 The International Labour Organisation (ILO) can be thought of as the only international body whose directives are to be considered as binding by the member states; some believe that the international community grants the authority to establish international labour standards to the International Labour Organisation, which was created with this in mind. In fact it is the triparty structure of the ILO, which involves representatives who are both employers and workers as well as governments and to which is added the technical expertise of the organisation in all of the areas concerning the world of work, that gives the ILO the status of a legitimate and authoritative source for the international labour standards.

35 www.sa-intl.org.

The SA 8000 standard is considered to be the first international reference standard on the rights and respect of the individual at work.

The SA 8000[36] standard comprises requirements relating to 9 categories:

1. Child labor:
2. Forced and compulsory labor
3. Hygiene and safety
4. Freedom of association and the right to collective bargaining
5. Discrimination
6. Disciplinary practices
7. Working hours
8. Remuneration
9. Management systems

An entity wishing to become SA 8000 certified must be audited by an SAAS[37] (Social Accountability Accreditation Services) accredited agency. No label is affixed to the product produced by an SA 8000 certified entity (B-to-B). The certification focuses on the production, processing, and distribution phases.

As with any certification to a PVS, there are 4 major cost items for the business:[38]

- Costs linked to compliance with the standard (preventive and corrective actions);
- Costs of preparing for the audit;
- The costs of the certification audit conducted by an accredited third party;
- Depending on the case, the costs associated with implementing corrective measures to resolve any non-compliances detected during the audit.

The costs generally depend on the number of employees in the entity being certified, the country in which the entity is domiciled, and the auditor's travel time.

In 1998, a group of British businesses, NGOs, and trade unions came up with a new approach to protecting workers' rights across all industrial sectors (from tea to textiles, from horticulture to footballs). The objective back then was to create an alliance of organizations that would work together to define how businesses must implement their labor codes in a manner that is both credible and maximizes the positive impacts on all of their workers.

[36] The standard is available free of charge from http://sa-intl.org/_data/n_0001/resources/live/SA8000%20Standard%202014.pdf.

[37] The list of SAAS accredited agencies is available on www.saasaccreditation.org/accredcertbodies.htm.

[38] www.sa-intl.org/index.cfm?fuseaction=Page.viewPage&pageId=472.

The first businesses to join the Ethical Trading Initiative[39] (ETI) were ASDA, Premier Brands, The Body Shop, Littlewoods, and Sainsbury's.

Today, more than 50 businesses[40] are members of the ETI. These multinational corporations buy from 38,000 suppliers and employ more than 8 million workers throughout the world. The initiative is open to all businesses, although it is understood that the smallest among them will presumably encounter some difficulties in dedicating enough resources to fulfil the obligations that affiliation entails.

All affiliated business must, however, adopt the basic labor practices code of the ETI, which is based on ILO conventions.

The ETI Code of Conduct defines **9 basic principles**:[41]

1. The free choice of employment;
2. Respect of the freedom of association and the right to collective bargaining;
3. Labor conditions must respect health and safety rules;
4. The ban on child labor;
5. Payment of a minimum wage;
6. Reasonable work hours;
7. No discriminatory practices;
8. Provision of regular employment;
9. The ban on resorting to harsh or inhumane treatment.

The principles of the code constitute *minimum* rather than maximum requirements for businesses. Just because a business adopts this code does not mean that it cannot do more than what is stated in the principles set forth above. Businesses are obviously also expected to obey national laws and any other laws in effect. When the laws and the ETI Code of Conduct cover the same subject, businesses must apply the clause that procures the best protection for the workers.

This code is accompanied by a number of principles of implementation[42] for businesses, namely: a true commitment by the business to ethical trade (production), a genuine integration of ethical trade in corporate culture and practices, building the capacities of their suppliers and other stakeholders, the systematic identification of problems along the supply chain, the adoption of measures for improvement and, lastly, transparency in reporting.

The secretariat of the ETI, jointly with the trade union and civil society members, makes random visits every year to at least 20% of the member businesses. The purpose of these visits is to verify that the business has implemented adequate procedures and management systems for gathering the data needed for annual reporting.

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39 www.ethicaltrade.org/about-eti.

40 A complete list of the various categories of members (businesses, NGO, trade unions) is available at www.ethicaltrade.org/about-eti/our-members.

41 The code of conduct is available at www.ethicaltrade.org/sites/default/files/resources/ETI%20Base%20code%20-%20French.pdf.

42 The principles of implementation are available at www.ethicaltrade.org/resources/principles-implementation.

The ETI, as its name indicates, is more of an initiative than a PVS. This multiparty initiative has established a non-certifiable code of conduct that is not accompanied by a label on the final product (B-to-B).

A non-profit organization, the **Business Social Compliance Initiative** (BSCI)[43] is legally dependent on the Foreign Trade Association (FTA) and was created in 2003. The BSCI came into being as a result of the desire of a number of European businesses to harmonize and more coherency among their codes of conduct and verification systems.

The BSCI offers member businesses a common management system for improving working conditions along their supply chains world-wide. Like the ETI, the BSCI created a code of conduct for doing this.[44]

In common with standard conventions, standards, and other international declarations on labor law and human, children's, and women's rights, the objective of the BSCI code of conduct is to enable businesses to become compliant with certain social and environmental standards. By adhering to the BSCI code of conduct, companies undertake to recognize, within their sphere of influence, the social and environmental standards set forth in the code and to take suitable measures in their company policy for ensuring the implementation and observance of these standards.

Furthermore, the suppliers must ensure that the code of conduct is also observed by subcontractors involved in the production processes and final manufacturing phases carried out on behalf of BSCI members.

Depending on their options for action and suitable measures to adopt, these suppliers are obligated to adopt the following criteria for a developmental approach:[45]

1. Observance of laws
2. Rights to freedom of association and collective bargaining
3. Ban on discrimination

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43 www.bsci-intl.org/about-bsci.

44 The code of conduct is available at www.bsci-intl.org/resources/public-resources. There are two ways of joining: either as an ordinary member or as an associate member. Ordinary members are retailers, brand name companies, and also the merchants and manufacturers in non-risk countries actively participating in auditing suppliers and integrating them in the auditing program, and in building the capacities of the BSCI. Associate members are all companies, societies, and parties interested, but not actively involved in the process. They are not part of the logistics chain. In order to be eligible to join, a company must have a minimum business volume of 500,000 euros.

45 The BSCI is cognisant of the fact that many suppliers experience inherent difficulties in implementing the code. Consequently, the BSCI advocates a step-by-step approach and does not require member businesses to cease all dealings with suppliers that may not be in complete compliance with the code. However, the BSCI does insist that these member businesses support their suppliers in their efforts to become compliant through training and capacity building activities.

4. Salaries
5. Work hours
6. Health and safety in the workplace
7. Ban on all abusive forms of child labor
8. Ban on all forms of forced and compulsory labor
9. Problems linked to the environment and safety

The BSCI provides its members with a series of recommendations and auditing tools for implementing this code of conduct. Only SAAS (Social Accountability Accreditation Services)[46] accredited agencies may perform BSCI audits.

Like the ETI, the BSCI encourages businesses to do more than what is required by the code of conduct and to comply with what the BSCI considers to be the best practice in the sector, namely the SA 8000 private voluntary standard. Unlike the SA 8000 and the ETI, the BSCI includes an environmental stewardship principle (No. 9) in its code of conduct. Like the ETI and the SA 8000, however, there is no label on the final product (B-to-B). The BSCI provides businesses with a framework and a harmonized approach for managing their auditing procedures in order to ensure that the results of the audits conducted by different businesses are comparable with each other.

SEDEX[47] (**Supplier Ethical Data Exchange**) is a membership organization for businesses committed to continuous improvement of the ethical performance of their production-distribution chains. SEDEX is a non-profit organization. It was created in 2001 by a group of British retailers and their main suppliers. These businesses all saw the need to collaborate and harmonize their ethical standards and audits. Hence the goals of SEDEX are:

- to reduce the number of ethical audits that big name suppliers must undergo;
- to actually improve the standards relating to working conditions.

SEDEX membership is now open to all companies regardless of their geographic location.[48] In practice, SEDEX provides companies with a database enabling them to store and exchange information and audits of an ethical nature.

SMETA[49] is the acronym for SEDEX Members Ethical Trade Audit. It consists of three elements: a common guideline for the best auditing practices applicable to ethical trade, a common format for corrective action plans, a common format for audit reports.

The SMETA guidelines and report formats were developed by the group of auditors associated with SEDEX in response to demands by members, who wanted an ethics report format that facilitated exchange as well as greater transparency regarding the

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46 A list of these agencies is available at www.bsci-intl.org/resources/links.

47 www.sedex.org.uk/sedex/go.asp?u=/WebSite/Home&pm=6&location=About.

48 The list of members is available at www.sedex.org.uk/sedex/go.asp?u=/WebSite/Home&pm=6&location=List.

49 The SMETA documents are available at www.sedex.org.uk/sedex/go.asp?u=/WebSite/Home&pm=6&location=Smeta.

qualifications and practices of auditors. SMETA spares businesses the unnecessary effort of having to produce redundant ethical auditing reports. SMETA is not a new code of conduct, nor is it a regulatory standard for audits. Instead it is a 0000compilation of best practices in terms of ethics auditing techniques. The results of the audits are then used to build the SEDEX database.

SEDEX differs from the 3 other ethical initiatives studied thus far. It is neither a standard nor a code of conduct, but a tool for businesses and a set of good auditing practices.

The **Occupational Health and Safety Assessment Series (OHSAS) 18001 and 18002** consists of a standard with the objective of establishing a rigorous occupational health and safety management system in a business (safety management).

Globally, this **standard developed by the private sector** aims to unify, on the international level, the various existing standards[50] in this area.

OHSAS 18001 certification ensures that the certified business has implemented an occupational health and safety management system.

It is based on identification and management of risks linked to facilities, products, and manufacturing processes. It requires continuous auditing to verify that constant effort is being made to improve the safety of working conditions.

It consists of **two texts**:[51] **OHSAS 18001** (Occupational health and safety management) and **OHSAS 18002** (Implementation guide, which defines the rules for occupational health and safety management).

00An audit is performed by a licensed body and if the inspection is passed, it issues a certificate attesting to the compliance of the safety system of the business with OHSAS 18001 requirements.

Again, this standard is a business-to-business (B-to-B) standard. Whereas the other initiatives cover several issues, however, this standard focuses on just one: health and safety at work.

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50 BS8800:1996 Guide to occupational health and safety management systems - DNV Standard for Certification of Occupational Health and Safety Management Systems(OHSMS):1997 – Technical Report NPR 5001: 1997 Guide to an occupational health and safety management system – Draft LRQA SMS 8800 Health & safety management systems assessment criteria – SGS & ISMOL ISA 2000:1997 Requirements for Safety and Health Management Systems - BVQI SafetyCert: Occupational Safety and Health Management Standard – Draft AS/NZ 4801 Occupational health and safety management systems Specification with guidance for use – Draft BSI PAS 088 Occupational health and safety management systems – UNE 81900 series of pre-standards on the Prevention of occupational risks – Draft NSAI SR 320 Recommendation for an Occupational Health and Safety (OH and S) Management System.

51 A toolkit containing a set of documents relating to the standard can be purchased online for a price of 395 USD at www.bsigroup.com/en-GB/ohsas-18001-occupational-health-and-safety/.

The ethics initiatives analyzed thus far (and the list is not exhaustive) often cover the same control points and all of them share the ultimate goal of improving working conditions throughout the diverse supply chains of businesses. Nevertheless, their individual specifications result in a divergence of approaches at certain points, which leads to a duplication of efforts to attain a common objective.

In order to initiate a process of harmonization among these initiatives, several businesses have created the Global Social Compliance Program (GSCP).[52] The GSCP is managed by the Consumer Goods Forum, an independent society of retailers and producers of consumer goods.[53] The GSCP encourages and supports the existing systems by helping businesses to identify and exchange the best practices concerning working conditions and good environmental practices. The GSCP is not another monitoring program, nor is it intended to replace the existing initiatives previously described.

The GSCP has created a set of reference tools[54] that describe the best practices concerning ethics and environmental initiatives. This is to ensure that audits performed by businesses among their suppliers are mutually recognized. Businesses can integrate these tools as is (or partially) in their existing systems. They can also serve as standards for businesses wishing to compare their systems to these tools, or even revise them accordingly in order to ensure a certain degree of equivalence relative to the GSCP reference documents.

The GSCP should be seen as an initiative that serves as an 'umbrella' for the other initiatives without replacing them. There are no provisions for auditing businesses for compliance with the various codes, although the GSCP did publish a document specifying the best auditing practices.

The GSCP is a B-to-B initiative and is comparable to a certain degree to the Global Food Safety Initiative (GFSI) (even though there is no formal benchmarking process for the existing private voluntary standards used by the GSCP as a basis for creating its reference documents).

❑ Fair trade

The fair trade initiative[55] came into being in the USA and in Europe during the years 1940 and 1950, respectively, as a result of efforts by religious (the Protestant Church) and non-

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52 www.gscpnet.com/about-the-gscp.html.

53 More than 650 businesses in 70 countries are members of the society.

54 All of these tools can be downloaded from www.gscpnet.com/about-the-gscp/reference-tools-purpose-a-use.html.

55 The term 'Fairtrade' is used to designate the FLO certification and labelling system. The Fairtrade system enables consumers to recognise the products that satisfy the Fairtrade standards. The expression 'fair trade' refers to the fair trade movement in general and may be used to describe both labelled and unlabelled products, the work of alternative trade organisations (ATO) and of fair trade federations and networks such as NEWS, EFTA etc. The expression 'fair trade' is more general. It is often used in the sense of one or the other of the above meanings, and may also refer to commercial justice issues.

governmental (NGO) organizations. On a political level, the concept of fair trade was introduced at the United Nations Conference on Trade & Development (UNCTD) in 1968. The slogan *Trade not Aid* was launched to denounce the inequities of economic relationships between the North and the South. The fair trade of agricultural commodities began with tea and coffee in the 70s, followed by dried fruits, cocoa, sugar, fruit juices, bananas, rice, spices, and nuts. Along with lowering prices for raw materials on international markets, the objective was to ensure small producers in developing countries a decent income by payment of a fair price.

Although the concept spread rapidly throughout Europe in the 70s and 80s, a true coordination among all of these national initiatives was not established until the 90s. Four large organizations were founded in that decade:

- International Fair Trade Association – IFAT – (1989) now the World Fair Trade Organization (WFTO);
- European Fair Trade Association – EFTA – (1990) ;
- Network of European World Shops – NEWS! – (1994) ;
- Fair Trade Labelling Organizations International – FLO – (1997).

FINE (an acronym composed of the initials of these four organizations) is an informal network created in 1997 to enable the members of the four organizations to exchange information and try to coordinate their activities better.

In December 2001, the FINE organizations agreed on the following **common definition and basic principles of fair trade**:

"Fair trade is a trading partnership, based on dialogue, transparency and respect, that seeks greater equity in international trade. It contributes to sustainable development by offering better trading conditions to, and securing the rights of, marginalized producers and workers – especially in the South. Fair trade organizations, backed by consumers, are engaged actively in supporting producers, awareness raising and in campaigning for changes in the rules and practices of conventional international trade."

The basic principles adopted by FINE in 2001 relate to the fair trade organizations themselves (technical, financial, and organizational aid for the producers), trade partnership (respect, transparency, dialogue, market information), the best business conditions for fair trade (fixed price, premium, long-term commitment, prefinancing), the guaranteeing of producers' and workers' rights (compliance with the United Nations human rights and the labor standards established by the International Labor Organization), and the sustainable development process (encouragement of best environmental practices, supporting the organizations of small producers).

The products obtained through fair trade can be sold in two ways, which translates to two lines of certification: the **integrated** and the **labelled line**.

The **integrated line** is the traditional form of fair trade. It encompasses 4 major players: the producer organizations in the South, the importer in the North who buys the products directly from the producer organization, the World Shops (which are generally staffed with volunteers) that sell the products to the consumers, and the National World Shop Federations that organize advertising campaigns to promote fair trade. Each player in the supply chain is a specialized fair trade organization and is generally referred to as an

alternative trade organization (ATO). In this case, each organization is fair trade certified. To obtain the FTO (Fair Trade Organization) trademark launched by the WFTO in 2004, these organizations must respect the 10 WFTO standards, which cover working conditions, transparency, salaries, the environment, gender equality, etc.

The WFTO logo is not a product brand: it is used to distinguish the organizations that are 100% committed to fair trade. It sets them apart from other fair trade businesses and clearly indicates to retailers, stakeholders, governments, and sponsors that their main activity is fair trade. The other two large international fair trade organizations, NEWS! and EFTA, also comprise fair trade organizations (distributors and importers) of the integrated line.

For example, Oxfam World Shops is registered in the integrated line. Crafts are 'the' specialty of Oxfam World Shops. Most of the food products sold by these stores are not fresh products.

The labelled line operates in a totally different way and it came into being much later, with the creation of the Max Havelaar label in the Netherlands in 1989.

The Fair Trade Labelling Organizations International (FLO) came into being eight years later, in 1997. This organization was cofounded by Max Havelaar and comprises 19 national labelling initiatives (e.g. Max Havelaar France, Transfair Italia, Fair Trade Foundation UK etc.) covering 23 pays, 2 Fairtrade marketing organizations, 2 associate members, and 3 producer networks.[56]

The approach complements that of the integrated line. The producer organizations must respect the generic standards of fair trade (which are divided into three: for smallholders, for paid labor, and for contract production) and the specific product standards specifying the minimum price and the premium.

It was the creation of the labelled line that enabled multinational agri-food corporations or big name retailers like Nestlé, Starbucks, Lidl, or Carrefour to offer fair trade products to a large number of consumers.

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[56] Fair trade labelling initiatives: Fairtrade Labelling Australia and New Zealand, Fairtrade Austria, Max Havelaar Belgium, TransFair Canada, Fairtrade Maerket Danmark, Fairtrade Estonia, Fairtrade Finland, Max Havelaar France, TransFair Germany, Fairtrade Mark Ireland, Fairtrade TransFair Italy, Fairtrade Label Japan, Fairtrade Latvia, Fairtrade, Lithuania, TransFair Minka Luxembourg, Stichting Max Havelaar Netherlands, Fairtrade Max Havelaar Norway, Associacion del Sello de Comercio Justo, Fairtrade Sweden, Max Havelaar Stiftung, The Fairtrade Foundation, TransFair USA.

Fair trade marketing organisations: Fairtrade Label South Africa, The Czech Fair Trade Association.

Associate members: Comercio Justo Mexico, Fairtrade Label South Africa.

Producer networks: African Fairtrade Network (AFN), Coordinadora de Latinoamericana y del Caribe de pequeños productores de comercio justo (CLAC), Network of Asian Producers (NAP).

New labelling initiatives besides those under the auspices of the FLO have recently come into being: ECOCERT (ESR) fair trade, Fair for Life (IMO social and fair trade certification programme), and fair trade certification via Naturland.

The Fair Trade Labelling Organizations International (FLO) comprises two entities, FLO e.v., the umbrella organization described above that coordinates the Fairtrade label internationally, and FLO-Cert, a private holding of FLO e.v. that conducts audits and authorizes producers to use the Fairtrade trademark.

FLO e.v. used various internationally recognized standards and conventions, especially those of the International Labor Organization (ILO), as a basis for establishing the criteria of its equitable standards. The standards are organized by product and type of production structure around 3 themes: social, economic, and environmental.

The FAIRTRADE trademark is now one of the mostly widely respected social and development labels in the world. The trademark is held and copyrighted by FLO e.v. in the name of its members. Originally, the Fairtrade labelling initiatives created by FLO e.v. had different labels. The international FAIRTRADE certification trademark was created in 2002 and it gradually replaced the different national labels. Two FLO e.v. members still use their own original labels. In Canada and in the United States, the Fair Trade Certified™ labels indicate compliance with the criteria of the FLO e.v. standards.

ECOCERT is a French inspection and certification service that inspects and certifies organic products. ECOCERT also certifies compliance with certain ISO standards concerning the successful implementation of environmental, food quality, and food health quality management systems.

In 2007, ECOCERT developed specifications defining the principles of fair trade in the form of objective criteria. These specifications[57] were jointly developed with a group of professionals (producers, importers, retailers, consumer groups) from the sector.

The ECOCERT fair trade criteria are based on international sources such as the ILO conventions and the WTO treaties. Moreover, the specifications are in conformity with the FINE consensus and the AFNOR AC X50-340[58] agreement. ECOCERT has been a PFCE (*plateforme française du commerce équitable* [French fair trade platform]) member since October 2007. A fundamental difference from the FLO is the need to be certified 'organic' in order to comply with the equitable standard.

The Institute for Marketecology (IMO) is an international inspection, certification, and quality assurance service for organic products. The IMO is active in the area of organic certification, but also specializes in the sectors of food health quality, sustainable fisheries, natural fabrics, sustainable forestry, and societal responsibility control.

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57 The documents are available at http://www.ecocert.com/en.

58 AFNOR is the French standardisation society. The AFNOR AC X50-340 agreement (January 2006) describes fair trade, the three principles of fair trade, and the criteria that apply to the fair trade approach.

Because the current fair trade certification programs do not cover all of the potentially certifiable products, nor all of the production systems and trade relationships among the players, the IMO and the Swiss Bio-Foundation jointly created and implemented a social and fair trade certification programme in 2006. The IMO is not an organization that establishes standards. For this reason the programme was conceived and is owned and published by the Bio-Foundation.[59]

The term 'programme' rather than standard is explained by the fact that the control points are based on international standards such as those of the International Labor Organization (ILO), SA 8000, FLO, and IFOAM Social Chapter (International Federation of Organic Agriculture Movements). The purpose of the programme is to supplement the existing social and fair trade certification programmes.

Naturland is an organic agriculture society that was founded in Germany in 1982. Naturland is now one of the largest world-wide organizations promoting organic agriculture.

The criteria of Naturland[60] relating to fair trade, as amended, are a logical consequence of the development of Naturland and the inevitable result of a long improvement process. These amended criteria, which are also based on the FINE definition and on the core values of fair trade organizations (such as those described in the "Charter of fair trade principles" (WFTO and FLO 2009), recapitulate the standard criteria of Naturland and broaden them to include equitable partnerships.

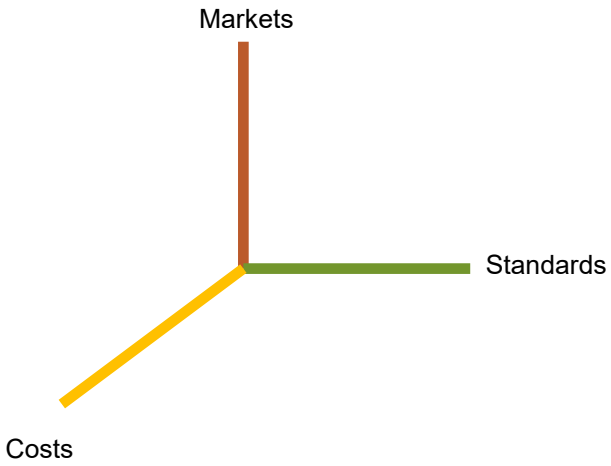
The expression 'Naturland fair trade certification' is used as a generic term not only for the certification of an entire line, but also for the certification of Naturland products in the context of an equitable relationship among partners.

The 'Naturland Fair' logo is used for labelling products in both cases. The additional title of "Naturland Fair Partnership" is reserved exclusively for Naturland producers and processors who are certified along the entire line. Again, this equitable certification only applies to producers who are already certified 'organic'.

These equitable standards entitle certified operators to affix a label to their products (B-to-C PVS). This label generally enables them to get a higher price on the market. There are basically **3 dimensions** to keep in mind when considering a fair trade certification:

[59] The documents are available at www.fairforlife.org.

[60] The documents are available at www.naturland.de.



The markets: there is no point in obtaining a fair trade certificate if the operator does not have a buyer willing to purchase his fair trade-certified products. As a general rule, the initiatives will request proof that there is a buyer interested in fair trade products before going any further with the certification process. This is particularly true for ESR certification, which requires that a supply chain system be in place when submitting a request.[61] As for the other certifications, being fair trade certified does not mean by definition that the product will be sold.

The costs before committing to a fair trade programme: the operator must perform a certification costs-benefits analysis. Besides the costs of the initial request, the costs for auditing/certification and the license rights, if applicable, certain investments may be required in order to ensure compliance with the standards. The price received for the products will definitely be higher that the conventional prices, but it may turn out that the volumes sold are not sufficient to compensate for these investments.

The standards: lastly, the operator must carefully study the different standards and determine which ones are best suited to the products that he wishes to have certified and to the structure of his organization. Also, if the operator fulfils the eligibility criteria for the standard that he has chosen, he should make sure that there is a locally available implementation support system.

Once it has been determined which fair trade standard is appropriate and when a detailed analysis has shown that the certification represents a real business opportunity, the operator must generally follow the following steps:

- Application process: contact the certification company (FLO-CERT, ECOCERT, IMO, or Naturland)
- Start to plan what needs to be accomplished in order to comply with the

[61] Upon request, ECOCERT will send you a set of documents explaining the principles of the approach as well as how to implement it. Subject to fulfilling the eligibility criteria, the first step of your commitment is sending in:

- a questionnaire for establishing an estimate (downloadable document) filled out with as much information as possible for describing your situation;
- a description of the current status of the sectoral project.

standard
- First on-site audit
- Corrective actions (if needed)
- Certification
- Annual inspections

Main differences between ethical trade (production) and fair trade:[62]

Ethical trade	Fair trade
Aims to protect the rights of workers throughout the supply chains	Aims to help underprivileged producers and workers in developing countries
Relates to corporate conduct	Applies specifically to the products
B-to-B	B-to-C

❑ An environmentally friendly production method

Besides the social, economic (fair trade), and health quality of foods aspects, certain private voluntary standards and initiatives focus more on environmental aspects.

A more efficient use of raw materials, better waste management, conservation of water resources, soils, and the world's ecosystems and forests, and reduction of greenhouse gases are some of the challenges that businesses must start tackling in a proactive manner as we enter the 21st century.

On the international level, **the *Codex Alimentarius* committee has compiled a series of recommendations for producing, processing, labelling, and marketing organic products** to serve as a guide to producers and to protect consumers.

The private sector equivalent to the *Codex Alimentarius* recommendations are the international basic standards[63] for producing and processing organic foods created by the International Federation of Organic Agriculture Movements (IFOAM).

These two sets of recommendations constitute the minimum standards for organic agriculture. They serve as guidelines to assist governments and private standardization bodies in establishing their own organic agriculture standards. Specific national standards are often established in order to ensure better adaptation to local conditions. Most national organic agriculture standards (EU, Japan, Argentina, India, Tunisia, USA) are integrated in the legislative frameworks of these countries.

62 www.ethicaltrade.org/faqs#fairtrade.
63 Documents available at www.ifoam.org.

Organic agriculture[64] is based on certain principles and practices for reducing the impact of agriculture on the environment to a minimum, by farming in a manner that is as natural as possible. The practices of organic agriculture mainly include:

- crop rotation, the very foundation for efficient use of soil resources;
- very strict limits on the use of plant protection products, synthetic fertilizers, antibiotics, additives, processing agents, and other inputs;
- ban on genetically modified organisms;
- use of on-farm resources: for example, manure as fertilizer or farm-produced feed for livestock;
- selection of plant and animal species that are resistant to diseases and adapted to the local conditions;
- free range-raised livestock and feeding livestock feeds of organic origin;
- species-appropriate livestock husbandry.

In the European Union, these rules are established by regulations that were presented in the previous chapter.

The East African organic products standards[65] were compiled in order to provide a single organic standard for East Africa that is adapted to the local conditions. The standard is based on organic standards already implemented in the region as well as on the IFOAM standards and the *Codex Alimentarius* recommendations. This standard can obviously serve as a common platform for launching a single organic label on the market. It can also be used as a basis for establishing equivalencies with other organic standards in the world.

There are numerous private organic standards among the various EU member states. Most of these standards have their own organic logo. However, all of them must apply the harmonized organic legislation of the EU at the minimum.

The Soil Association[66] issues the most widely respected organic label in the UK. The organization claims to have some of the strictest (more so than the requirements of the European legislation) yet most straightforward organic standards in the world.

The AB[67] (*Agriculture Biologique*, Organic Agriculture) is a voluntary organic agriculture label in France that enables professionals who desire it and who comply with the rules for its use to identify their products in a unique manner. It serves as a guide for consumers, enabling them to choose easily because it is readily recognizable.

64 ec.europa.eu/agriculture/organic/organic-farming_en.
65 www.organic-standards.info/en/documents/East-African-Organic-Product-standard,25.
66 www.soilassociation.org.
67 www.agencebio.org.

The AB trademark is the exclusive property of the French Ministry of Agriculture, which defines the rules for its use. The AB trademark guarantees:

- a food consisting of at least 95% ingredients from organic production employing agronomic and livestock husbandry practices that respect the balance of nature, the environment, and animal well-being;
- respect of the regulations in effect in France;
- a certification under the control of a government-approved organization fulfilling the criteria of independence, impartiality, competence, and efficiency as defined in European standard EN 45011.

The Rainforest Alliance[68] is an American NGO dedicated to conserving the world's biodiversity and ensuring decent living conditions by modifying agricultural and business practices and consumer behavior. The Sustainable Agriculture Network (SAN)[69] established the standards of the initiative, in compliance with the ISEAL Alliance codes of good practices for establishing social and environmental standards.

The ISEAL[70] (International Social and Environmental Accreditation and Labelling) Alliance is an international umbrella organization for the principal social and environmental standards in the world. The principal objectives of the organization are to reinforce the efficacy and impact of these standards.

The Rainforest Alliance standards for agriculture comprise **10 principles**:

1. Environmental and social management system
2. Conservation of ecosystems
3. Protection of the flora and fauna
4. Water conservation
5. Fair treatment and good working conditions for employees
6. Health and safety at work
7. Relationships with the local communities
8. Integrated pest management (IPM)
9. Soil management and conservation
10. Integrated waste management

In order to become certified, the farm must be audited by one of the Sustainable Farm Certification, Intl[71] associates. Once certified, the business may market its products under the Rainforest Alliance label. This B-to-C private standard applies mainly to the production of bananas, mangoes, and pineapples.

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[68] www.rainforest-alliance.org/about.
[69] san.ag/web.
[70] www.isealalliance.org/content/about-us.
[71] The list of organisations is available at sustainablefarmcert.com.

The purpose of the LEAF Marque label[72] is to ensure consumers that care has been taken by farmers in the production of foods and other products. This standard attests that the product was produced in an environmentally responsible manner. In order to be entitled to use the LEAF Marque label, the farm must be fully compliant with the conformity criteria defined in this standard.[73]

The currently authorized certification bodies and the countries in which they have authority are listed on the www.leafmarque.com website. This standard is mainly used by the British supermarket chain Waitrose.

The evaluation points of the standard are as follows:

- Organization and planning
- Management of soils and crop nutrition
- Crop protection
- Fight against pollution and waste management
- Efficient use of energy and water resources
- Wildlife and landscapes
- Livestock raising and environment
- Involvement with local communities.

This B-to-C private standard is based on the principle of Integrated Farm Management (IFM). This principle consists of combining traditional and modern techniques in order to increase productivity and minimize the impact on the environment. Producers who apply the principles of the LEAF standard can generally reduce their costs thanks to better soil management, minimal use of pesticides, and reduced tillage. Moreover, such practices often result in lowered CO_2 emissions and increased animal species diversity.

International Standard Organisation

"The ISO 14001: 2004 standard is applied by around 200,000 organizations in 155 countries".

The **ISO 14000**[74] family relates to '**Environmental Management**'. This term covers what an organization does to:

- minimize the harmful effects of its activities on the environment,
- continuously improve its environmental permanence.

The first two standards, ISO 14001:2004 and ISO 14004:2004, relate to environmental management systems (EMS). ISO 14001:2004 defines the requirements for an EMS and ISO 14004:2004 gives general guidelines for an EMS. The other standards and

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[72] Available at www.leafuk.org/leaf/consumers/theLEAFmarquecons.eb.

[73] An authorised certification body will first check these criteria and then issue the farm a certificate in the event of compliance. The products may then be marketed under the LEAF label.

[74] www.iso.org/iso/fr/iso_catalogue/management_and_leadership_standards/environmental_management.htm.

guidelines in this family relate to specific environmental aspects, namely: labelling, performance evaluation, life cycle analysis, communication, and auditing.

'Certification' in the context of ISO 9001:2000 (and ISO 9001:2008) or ISO 14001:2004 refers to the issuing of a written attestation (the certificate) by an independent, outside organization that audits a management system and verifies its compliance with the requirements specified in the standard.

'Registration' means that the auditing body subsequently records the certification in its client file. Hence the management system is both certified and registered. Consequently, in the context of ISO 9001:2000 (and ISO 9001:2008) or ISO 14001:2004, the difference between the two terms is not significant and both are acceptable in general use. 'Certification', however, is more widely used in the world, although registration is often preferred in North America and the two terms are interchangeable.

Using the term 'accreditation' as a synonym for certification or registration, however, is incorrect, because the former has a different meaning. In the context of ISO 9001:2000 (and ISO 9001:2008) or ISO 14001:2004, accreditation refers to the formal recognition by a specialized organization (accreditation body) that a certification body is competent to certify to the ISO 9001:2000 (and ISO 9001:2008) or ISO 14001:2004 standards in the specified sectors of activity. To put it simply, accreditation can be thought of as certification of the certification body. The certificates issued by accredited certification bodies may be perceived on the market as having greater credibility

The ISO has numerous other standards relating to specific environmental issues. The purpose of ISO 14001:2004 is to provide a **framework for a holistic and strategic approach** to the policies, plans, and actions of the body with regard to the environment.

ISO 14001:2004 gives the **generic requirements** for an environmental management system. The underlying philosophy is that, regardless of the activity of the body, the requirements for an effective EMS are the same. The end result is the establishment of a **common standard** of communication about environmental management issues among the bodies, their clientele, regulatory agencies, the public, and other stakeholders. ISO 14001:2004 does not define environmental performance levels; the standard can be implemented by **very diverse organizations** regardless of their mastery of issues linked to the environment. Nevertheless, a **commitment towards compliance** with the applicable environmental legislation and regulations is required, as is a commitment to **continuous improvement.** The EMS provides the necessary framework to this end.

ISO 14001:2004 is a tool for achieving **internal objectives**:

- assuring company management that they are in control of the organizational processes and activities that have an impact on the environment;
- assuring employees that they are working for an environmentally responsible organization.

ISO 14001:2004 also helps in achieving **external objectives**:

- providing external stakeholders such as clientele, the community, and regulatory agencies with assurance about environmental issues;
- complying with environmental regulations;

- verifying the organization's statements and reporting about its own environmental policies, plans, and actions;
- providing a framework for demonstrating compliance through declarations of compliance from suppliers and the assessment of compliance by an outside stakeholder (e.g. a customer), and for certification of compliance by an independent certification body.

This B-to-B[75] private voluntary standard not only relates to the environmental aspects of the processes of the organization, but also relates to those of its products and services. Life cycle analysis (LCA) is a tool for identifying and evaluating the environmental aspects of products and services 'from the cradle to the grave' (ranging from input resources to the scrapping of the product and the disposal of any resulting wastes). **ISO 14040** gives guidelines on the principles and conduct of the life cycle analysis, which enables the business to discern how to reduce the overall impact of its products and services on the environment.

Parts 1, 2, and 3 of the ISO 14064 standard relate to the quantification and verification of greenhouse gases (GHG). The standard defines a clear and verifiable set of requirements designed to help businesses and project authors lower GHG emissions. ISO 14065 supplements this standard by establishing the requirements for the accreditation (or other forms of official recognition) of bodies involved in GHG validation and verification according to ISO 14064 or other relevant standards or specifications. ISO 14063 gives guidelines and examples concerning reporting on environmental management and helps businesses establish important links with outside stakeholders.

The ISO 64 Guide explains how to handle the environmental issues in the product standards. Although primarily intended for those who draft standards, the recommendations of ISO 64 are also useful for designers and manufacturers. ISO 14067 on the carbon footprint of products gives requirements for the quantification and reporting of the GES associated with the products. This two part standard deals with the quantification of the carbon footprint (Part 1) and with the harmonization of the methodologies for reporting information about the carbon footprint, and gives recommendations for this reporting (Part 2).

A set of standards and initiatives relating to the measurement of the carbon footprint of products has been developed. It is too soon to talk about a true harmonization among all of these initiatives, even though the ISO 14067 standard and that of the Greenhouse Gas Protocol Scope 3&4 of the World Resource Institute are headed in this direction. In the UK, the PAS 2050 of the British Standards Institute is the first standard created for measuring the carbon footprint of goods and services and already it is undergoing a first revision. In France, the planning law for implementing the Environment Round Table (law No. 2009-967 of 3August 2009, the so-called 'Grenelle 1 law') established the right of the consumer to "have access to sincere, objective and comprehensive environmental information, on the global characteristics of the pair product/packaging" and "access to environmentally friendly products at reasonable prices" (article 54).

As for the development of a new system for displaying the environmental characteristics of products, the national bill for commitment to the environment (the so-called 'Grenelle 2 law'), which the French Senate voted on 8 October 2009 and which

[75] www.iso.org/iso/en/theiso14000family_2009.pdf.

is being debated in the French Parliament, states that “as of January 1, 2011, the consumer must be informed, by marking, labelling, displaying, or by any other appropriate method, of the equivalent carbon content of products and their packaging, as well as the consumption of natural resources or the impact on natural environments which are attributable to these products during their lifecycle” (article 85).

An ADEME-AFNOR platform has been created for producing a general methodology document, BP X30-323 (General principles for the displaying of environmental information on mass market products). This document is supplemented by a detailed methodological annex. There are currently supplements to this annex, by product category, in ten sectoral groups (food products, household products, furniture, textiles, etc.). Pilot projects provide food for thought on these different groups. These four standards merely reflect part of the dynamism in the sector.

The ISO 14000 standards were designed to supplement one another, but they can also be used individually to achieve specific objectives relative to the environment. The ISO 14000 family provides management tools enabling organizations to manage their environmental aspects and assess their environmental performances. As a whole, these tools offer some very real economic advantages:

- reduced use of raw materials and resources;
- reduced energy consumption;
- improved process efficiency;
- less waste and lower costs for disposal;
- use of renewable resources.

These economic advantages go hand in hand with specific environmental advantages. Such is the interest of the ISO 14000 family in dealing with the environmental and economic components of the triple bottom line (economic, social, environmental) of sustainable development.

4.4. Implications of private voluntary standards for the ACP fruit and vegetable sector

The emergence and adoption of these private voluntary standards by many players along agri-food supply chains has had several consequences for the ACP fruit and vegetable sector, particularly in terms of market access and above all for the small and medium-sized businesses of the sector. In short, ACP producers wishing to export must now not only observe the new EU regulations, but also satisfy the requirements of importers and big name retailers that often turn out to be more complicated and stricter than the regulations. Although they are voluntary (in the sense that they are not compulsory under law), the standards are nevertheless becoming indispensable to be able to 'operate' and therefore, in fact, mandatory. The lack of a PVS certification can exclude producers from certain key market sectors.

Certification requires certain non-negotiable technical and financial means. In the case of private voluntary standards relating to the health quality of foods, this certification is not financed by the market, given that there is no direct reporting regarding the compliance of the business to consumers. Moreover, the synchronization of these private voluntary standards on the European market means that an ACP producer operating on several markets with several customers has to juggle several certifications that generally intersect on several levels. The producers thus find themselves confronted with a plethora of private voluntary standards, each one of which involves compliance and certification fees.

However, the private voluntary standards can also offer ACP producers considerable advantages. GLOBALG.A.P., for example, has translated the regulatory obligations into a document that enables the practical application thereof. Compliance with the standards can also increase productivity and competitiveness by reducing the costs of inputs (pesticides, fertilizers) and by helping farmers adopt Good Agricultural Practices (GAP), improve hygiene, and use modern management methods. Compliance is also accompanied by social advantages in terms of, e.g., food safety, worker health and safety (Okello, 2005), and better wages for qualified staff. However, even though they may increase the capacity of the supply chain to produce products with the required characteristics, the effect of private voluntary standards is also the exclusion of those who are incapable of complying with them, notably small and medium-size businesses and small farmers. As a general rule, the ability to comply with the standards varies among countries and players, in accordance with their size, status, and resources.

In this new 21st century, world agriculture remains the human activity that has the greatest impact on our environment. Although greenhouse gas emissions may nowadays be considered as the major environmental concern in the world, other ecological impacts, especially on soils and water resources, are also sources of increasing concern to society and must also be taken into consideration by the horticultural industry in African, Caribbean, and Pacific nations.

New types of initiatives are coming into being in response to the social, economic, and environmental challenges in our world. Certification to certain private standards described

in the ‘societal responsibility’ section can in some cases enable businesses to gain access to more interesting markets (fair trade and organic niche markets, for example), to broaden their clientele, and thus increase the demand for ACP horticultural exports.

The concept of sustainability is not the exclusive domain of western societies. ACP businesses also need to adopt this concept in order to limit the counter-productive effects and maximize the positive effects on their communities. The challenge now facing ACP businesses exporting fruits and vegetables to Europe is to transform these new requirements into opportunities for developing and improving their competitiveness. The objective of COLEACP is to enable them to identify these opportunities, to make informed choices and, once they have made these choices, to be guided by them in their endeavors. It is necessary to progress from the concept of ‘good agricultural practices’ to that of ‘sustainable agricultural practices’ in order for the horticultural sector to continue to be a driving force for sustainable economic development in ACP nations.
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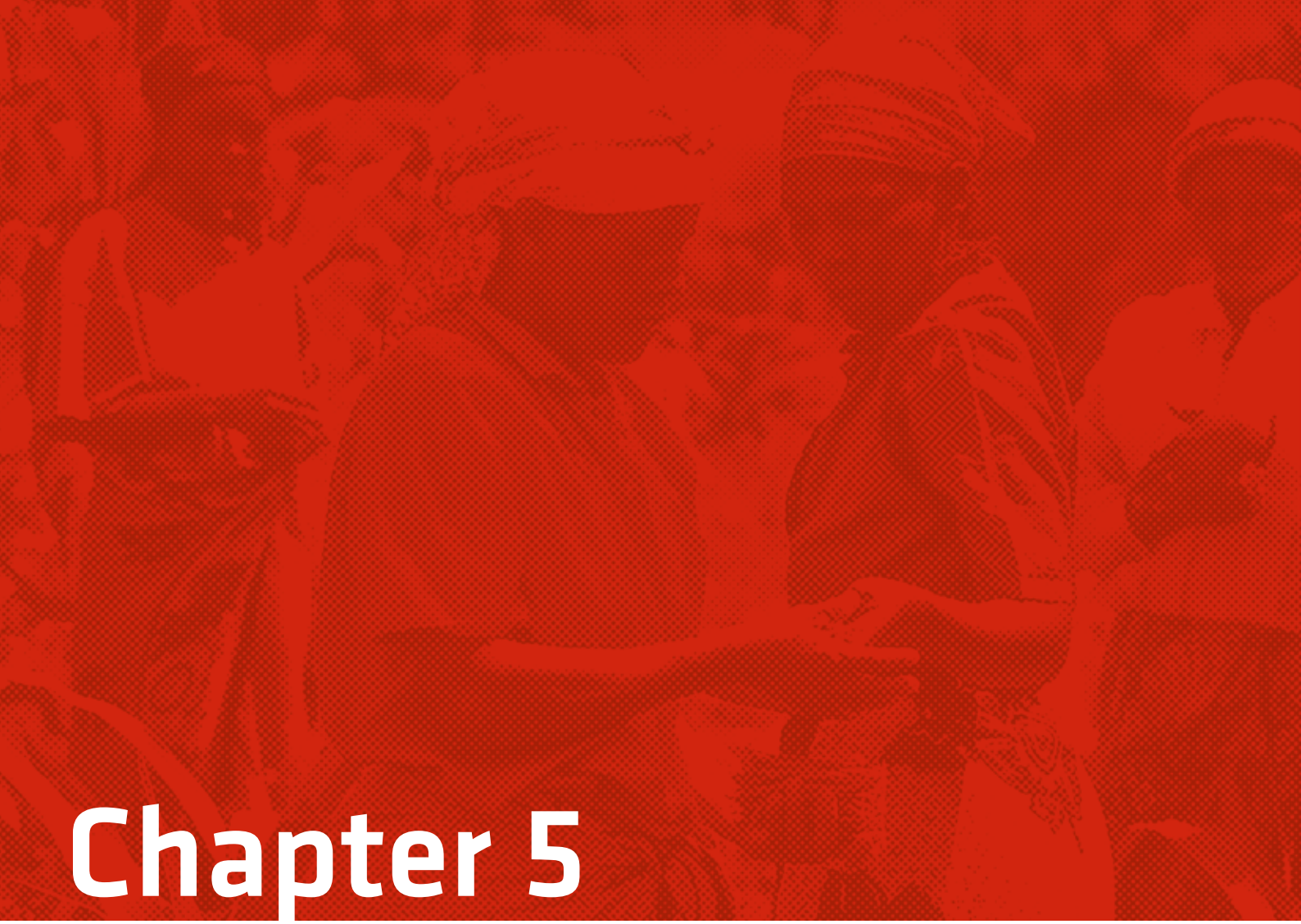


Chapter 5

Pesticides and biocides regulations

5.1. Background

5.1.1. Some definitions

The word '**pesticide'** is the generic term used to designate all **natural or synthetic substances capable of controlling, attracting, repelling, destroying, or inhibiting the development of living organisms** (microbes, animals or plants) considered as **harmful or detrimental to agriculture, publc hygiene** (e.g., cockroaches in houses), **public health** (insect parasites such as lice and fleas or insect vectors of diseases such as malaria, and pathogenic aquatic bacteria destroyed by chlorination), **veterinary health** or **non-agricultural surfaces** (roads, airports, railroads, power networks etc.).

Plant protection products are also considered as pesticides and are defined **as products consisting of active substances,** safeners, or synergists intended for any of the following uses:

- protecting plants or plant products from all harmful organisms, or inhibiting the activity of such organisms;
- exerting an effect on the life processes of plants (e.g. exerting a growth regulatory effect);
- preserving plant products;
- destroying undesirable plants or plant parts, slowing or inhibiting undesirable growth of plants, except algae.

5.1.2. The 1991 legislative framework today

The legislative framework is based on Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.

❑ **What does this Directive contain?**

The regulation of plant protection products in the European Union (EU) was first harmonized in **Council Directive 91/414/EEC**, which took effect on **26 July 1993**. This Directive is the basis for all market authorizations of plant protection products in the European Union and it **shall remain in effect until 14 June 2011, the date on which it will be repealed by Regulation 1107/2009**.

This Directive establishes **criteria to consider relative to the safety of active substances**, as well as the safety and efficacy of formulated products. The Directive establishes a two-phase evaluation system:

- a **Community evaluation of active substances;**
- a **national** authorization of **plant protection products** derived from active substances**.**

This Directive has 24 articles, and 6 appendices (Annexes) in the form of Directives:

- **Annex I** or 'positive list' is the list of active substances not posing unacceptable risks to human health and the environment and which are therefore approved in the Community for use in manufacturing plant protection products.

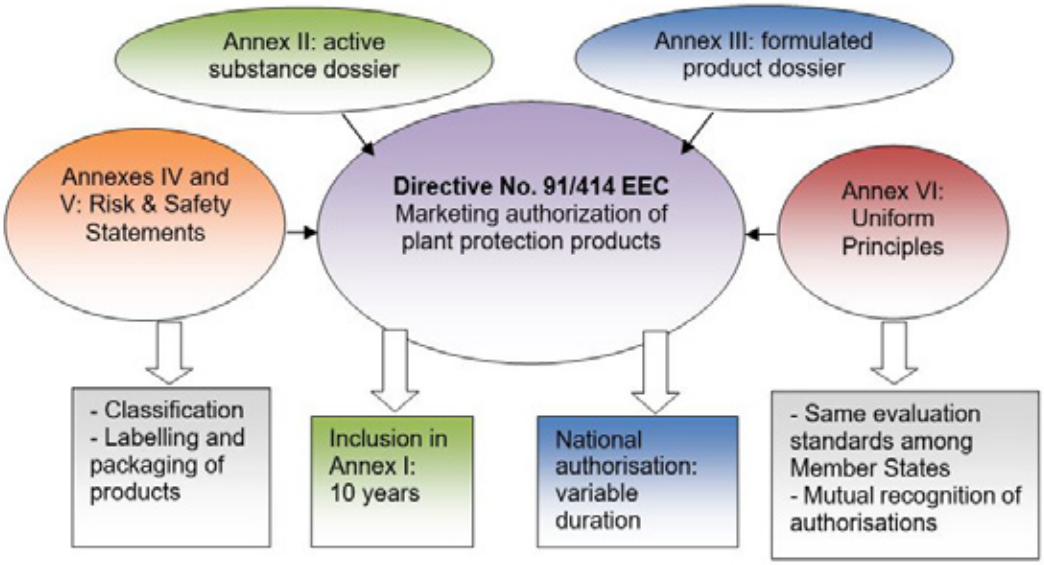
- **Annex II** is the list of required tests and studies for any active substance for which inclusion in Annex I is requested. It is divided into a Part A for chemical substances and a Part B for microorganisms.

- **Annex III** is the list of required tests and studies for any plant protection product for which a dossier was submitted on the national level after inclusion in Annex 1, or presented as representative usage in the dossier for inclusion in Annex 1. These conditions concern, specifically, the identification of the substance or the product, the identity of the manufacturer and of the applicant for the authorization, the performance of tests and analyses by official or officially recognized testing services or agencies, etc. The information held by the applicant or the manufacturer may be protected under a confidentiality clause when such information consists of an industry or business secret.

- **Annexes IV and V**, respectively, contain the standard statements relating to specific risks and the standard statements relating to the precautions that must be taken. This information must be printed on the packaging of the plant protection product. The Directives representing these annexes are gradually being replaced by the European Regulation on the classification and packaging of substances and mixtures (Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 concerning the classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006 (*OJEU*, L 353 of 31 December 2008).

- **Annex VI** contains the uniform principles for the evaluation and authorization of plant protection products by the Member States. By applying these uniform principles, the Member States ensure that authorizations are granted according to the same standards.

Summary outline of the various components of EU Directive 91/414:



❑ **What is the process and what is the duration of inclusion in Annex I?**

Prior to 1991, there were many active substances on the market that were used in manufacturing numerous plant protection products. These were approved by diverse national systems, and the requirements for authorization were heterogeneous. Directive 91/414 has been the basis of the harmonized European system for approving plant protection products since 1993. As a result, all old active substances had to undergo a 10 year reevaluation in parallel with the requests for the registration of new active substances. An evaluation timetable was established by the European Commission, and the evaluation of old active substances was completed in 2009.

Under the harmonized system, a plant protection products manufacturer must submit a complete Annex I registration dossier on the **active substance** for Community evaluation in a chosen Member State (the Rapporteur member state), according to the requirements described in Annex II of the Directive. These requirements range from data on the identity of the active substance to data for assessing the risk to human health and the environment.

The evaluating parties are a **Rapporteur Member State, the European Food Safety Authority** (**EFSA**), **and the experts from other Member States**. Based on the evaluation report by the Rapporteur Member State and the experts from the other Member States, the EFSA draws up its conclusions on the risks linked to the use of the active ingredient, which it forwards to the European Commission. The recommendation for inclusion/non-inclusion given by the Rapporteur Member State as well as the conclusions of the EFSA are submitted to all of the Member States and to the European Commission, the latter being the risk manager for European citizens. A final decision, by qualified majority voting, is made on the inclusion/non-inclusion Directive by the Member States, and published 3 months later in the *Official Journal of the European Community*.

Directive 91/414 per se did not establish any deadlines for evaluating the inclusion dossiers for active substances that were already on the market (*i.e.* prior to 1993), in spite of the classification and evaluation timetable published in Directive form. The evaluations

took an average of 4 to 5 years for each class of active ingredients, hence the length of the reevaluation process for old active substances. The European Commission declared the **review officially complete in March 2009**. Of ca. 900 active substances on the market prior to 1993, **500 had to be evaluated** following an initial screening based on the requirements of Directive 91/414. The evaluation took place in several phases from 1992 to 2009. As a result, 67% of the active ingredients were withdrawn from the market because they were unsubstantiated, 7% were not registered after review, and **26% were**.

The inclusion of an active substance in Annex I is **valid for 10 years** and can be renewed. It can be cancelled if the required conditions are no longer fulfilled, and it can be amended if the development of new scientific or technical knowledge permits.

5.1.3. Regulation (EC) 33/2008

This Regulation concerns resubmission in the event of non-inclusion in Annex I of Directive 94/414/EC. The European Commission made this Regulation in order to establish new procedures and, more generally, clearer rules concerning the resubmission dossier in the event of non-inclusion in Annex I during the Directive 91/414/EC review programme. This Regulation therefore allows the possibility of resubmitting a dossier requesting inclusion in Annex I of Directive 91/414/EC. It went **into effect on 25 January 2008** and it explains the regular and accelerated procedures that a manufacturer of an active ingredient used in the formulation of a plant protection product must follow for filing a resubmission dossier.

The evaluation procedure can be regular or accelerated, depending on whether the active ingredient was part of the first list (or phase) or part of the second, third, and fourth phases of substances to be evaluated under Directive 91/414.

- The **regular procedure applies to the active substances of the first phase** and requires a complete dossier. From the receipt of the dossier and the declaration of the completeness thereof by the Rapporteur Member State to the issuing of an evaluation report by the European Commission, followed by a vote, the entire evaluation process can be expected **to take 18 to 24 months.**

- The **accelerated procedure applies to the active substances of the second, third, and fourth review phases** if the dossier was resubmitted within 6 months after the publication of the non-inclusion decision (substances of lists 3 and 4) or in the month after the taking effect of Regulation 33/2008 (list 2 substances). The dossier is abridged and consists of the submission of additional data specific to certain points that were not resolved during the first evaluation. The procedure is termed accelerated in the sense that the EFSA is only consulted upon request by the European Commission, which has between 3 and 6 months to issue its evaluation. The procedure takes 12 to 18 months.

Eighty active substances have been resubmitted since this Regulation went into effect. The complete list is available in the *SANCO 01896/2008* Rev. document of 21 January 2011**.**

5.2. The new European legislative framework

The new legislative framework concerns **Regulation (EC) 1107/2009** of the European Parliament and of the Council of 21 October 2009 on the placing of plant protection products on the market, and repealing Council Directives 79/117/EEC and 91/414/EEC.

5.2.1. Why replace Directive 91/414/EEC?

In July of 2002 the European Commission, the European Parliament, and the Economic and Social Committee jointly published a Communication in which they established the groundwork for a **thematic strategy** for **reducing the impact of pesticides on human health and the environment** and, more generally, for achieving a more sustainable usage of pesticides as well as a significant global reduction of the risks and usage of pesticides, but nevertheless one that is consistent with crop protection needs. Five principal objectives were set forth:

1. Minimizing the dangers and risks to human health and the environment posed by pesticide use.
2. Better monitoring of pesticide use and marketing.
3. Cutting back on the use of highly toxic active substances by replacing them with less toxic alternative active ingredients.
4. Encouraging the use of low risk pesticides or integrated agriculture by raising awareness among users, by publicizing the good practice codes, and by considering the possibility of applying financial instruments.

In order to achieve these objectives and reflect the advancement of scientific knowledge and the lessons learned from the review of the existing active substances, an update of the existing legislation (i.e. Directive 91/414/EEC) turned out to be necessary. The result was a group of 4 legislative texts:

- Regulation 1107/2009/EEC to replace Directive 91/414/EEC ;
- Directive 2009/128/EEC of 21 October 2009 on sustainable pesticide use;
- Regulation 1185/2009 of 25 November 2009 on pesticide statistics;
- an amendment (Directive 2009/127 of 21 October 2009) to Directive 2006/42/EEC on agricultural machinery for applying pesticides.

5.2.2. What is in Regulation (EC) 1107/2009?

Regulation (EC) 1107/2009 was published on 24 November 2009 and it replaces Directive 91/414/EEC. It took **effect on 14 June 2011** in all Member States, and did so immediately (in contrast to a Directive with a deadline for implementation in national legislation). The Regulation shall continue to harmonize the evaluation of plant protection substances and products throughout Europe, and it introduces some **new requirements** for the approval of active substances, such as:

- **hazard criteria** which take the chemical properties of a pesticide into account but not the risk. This approach differs markedly from the approval procedures in Directive 91/414/EEC, which not only took into account the dangers (toxicity) but also the risks (evaluation of potential risks linked to exposure to the product according to the manner, time, place, and frequency of use, etc.);
- **evaluation of cumulative and synergistic effects** of pesticides;
- **comparative evaluation** of pesticides;
- **disruption of the endocrine system** by the pesticides that were only indirectly evaluated under Directive 91/414.

According to the criteria set forth in the new Regulation, the use of a substance shall not be approved (shall be prohibited) if this substance is classified in any of the following categories:

- category 1 or 2 mutagenic substances;
- category 1 or 2 carcinogens or substances toxic to reproduction, unless exposure is 'negligible';
- endocrine disruptors capable of exerting harmful effects, unless exposure is 'negligible';
- persistent organic pollutants (POP);
- persistent, bioaccumulable, and toxic (PBT) substances;
- very persistent and very bioaccumulable (vPvB) substances.

The Regulation has 9 chapters and 5 appendices (annexes) covering the following points:

➢ **Chapter I: General provisions**

➢ **Chapter II : Active substances, safeners, synergists, and co-formulants, for which are set forth**:

- for active ingredients:
  - the criteria and conditions for approval of active ingredients;
  - the period of the initial approval, which is generally for 10 years, but which can be adapted according to the characteristics of the substance;
  - the approval restrictions;
  - the approval process (contents of the submission dossier, admissibility, evaluation report, and rules for approval);
  - the renewal of the approval and the 10-year review;
  - the exemptions for low-risk active substances;
  - compounds (molecules) that are candidates for replacement;

- for plant protectants and co-formulants:
  - the approval thereof;
  - the review of the ones already on the market, starting in December of 2014;
  - unacceptable compounds.

➢ **Chapter III : Plant protection products**
  - the marketing authorization thereof;
  - the temporary (no more than 3 years) authorizations thereof;

- the duration of the placement on the market;
- the procedure for obtaining marketing approval;
- the principle of mutual recognition of authorizations among Member States in the same zone;
- the renewal, cancellation, or amendment of an authorization (and the grace period in the case of cancellation);
- special cases (low-risk products, products containing GMOs, treated seed, etc.);
- the comparative evaluation of products containing active ingredients that are candidates for replacement;
- the extension of minor uses;
- parallel importation;
- research and development;
- pesticide usage (according to GAP);
- information on unacceptable effects.

- **Chapter IV: Adjuvants**
- **Chapter V: The protection and sharing of data**
- **Chapter VI: Public access to information**
- **Chapter VII: Packaging, labelling, and advertising of plant protection products and adjuvants**
- **Chapter VIII: Surveillance and controls** (responsibility of the Member States and the Commission)
- **Chapter IX: Emergency situations** (in case of risks to human and animal health, and to the environment)
- **Chapter X: Administrative and financial provisions**
- **Chapter XI: Temporary measures,** particularly concerning the applicability of Directive 91/414/EEC for active substances included prior to 14 June 2011
- **Annex I** lists the **different agro-climatic zones** (Northern, Central, and Southern Europe) for mutual recognition.
- **Annex II** gives **the procedure and the criteria for approval of active substances, safeners, and synergists** cited in Chapter II of the Regulation. These conditions are similar to those of Annex II of Directive 91/414/EEC, but with new requirements concerning the carcinogenic or mutagenic nature of the active substance or its effect on human reproduction, endocrine disruption, and the criteria of persistence, bioaccumulation, and environmental toxicity, which are also **criteria for exclusion**. The endocrine disruption criteria have yet to be defined, and the European Commission has set the date of 14 December 2014 for doing so.
- **Annex III** contains **the list of unauthorized co-formulants** added to plant protection products.

- **Annex IV** is dedicated to **the comparative evaluation of plant protection products**.

- **Annex V** contains **the list of repealed Directives** and their successive amendments.

5.2.3. What is the impact of Regulation (EC) 1107/2009 on exports from ACP countries?

This new Regulation will inevitably have an impact on **the availability of pesticides** used on horticultural crops destined for sale on European markets.

Although many pesticides currently used on crops intended for export may be withdrawn from European markets, the new Regulation should **not** have any **significant short-term effects** in ACP countries. Firstly, when a pesticide is banned in Europe, **it may still be used on crops grown in ACP countries and destined for export as long as it is registered for local use and it satisfies the European requirements on maximum pesticide residue levels and importation tolerances.**

In addition, the substances shall remain approved until their review upon expiry of their approval by virtue of their inclusion in Annex I (and as a consequence, their maximum residue levels (MRL) shall not change until the expiry date). Thereafter, the possibility of granting exemptions should allow sufficient time to develop replacement substances.

As a whole, the effects may be felt **in the long term**, particularly by small farmers, owing to **the possible exclusion** (or lowering of the MRLs) **of certain cheaper broad spectrum pesticides.** The replacement pesticides could be more expensive and in turn result in increased production costs. Furthermore, there may be problems concerning the **availability of these replacement products**. Other than citrus and bananas, fruits and vegetables, especially in the ACP countries, are minor markets for the plant protection industry; hence there is less interest on the part of manufacturers to invest in the development of new products and in labelling new products in ACP countries.

Certain elements of the new regulation still need to be clarified. For example, the criteria concerning endocrine disruptors have yet to be defined, which is a considerable source of uncertainty. Nor is it known whether the import tolerances for the substances that will be banned under the exclusion criteria linked to public health will be set at the limit of quantification (LOQ).

It is essential to **start developing replacement strategies for managing crop pests** in order to limit the negative effects once the substances are banned. In view of the general trend towards reduction of pesticides on the European market, these strategies should focus on minimum residue levels in foods.

Firstly, research and development should focus ***(i)*** on the cases where **important active substances may be lost faster than anticipated** (i.e. active ingredients that are still under review for inclusion in Annex I of Directive 91/414 and where the outcome of the review is still unknown); and ***(ii)*** on the situations where there are no effective and affordable alternative methods at the present time.

It is also essential to continue working closely with manufacturers in order to urge them to develop new products and to introduce the existing products in the ACP countries.

5.3. Directive 2009/128/EC

This Directive of 21 October 2009 set up a **Community action framework for promoting the use of pesticides that are compatible with sustainable development**.[1] It was published the same time as Regulation (EC) 1107/2009 (**November 2009)**.

It went into effect the day after its publication and it must be **implemented or incorporated in the legislation of the Member States by 14 December 2011.**

It applies only to plant protection products and biocides, and it establishes a legal framework for promoting good and best practices regarding the storage, use, and disposal of pesticides. This includes:

- **training for** pesticide **users/applicators**;
- **inspection of spray equipment;**
- **aerial applications** (prohibited in the European Area, except for certain exemptions);
- **protection of the aquatic environment, public areas, and natural conservation;**
- **minimization of the risk of pollution** from the handling, storage, and disposal of pesticides;
- **promotion of low input systems**.

The Directive has provisions for Member States to implement **national action plans** consisting of objectives, timetables, and deadlines to observe, with the aim of reducing the risks and impacts of pesticide use on human health and the environment, and developing and introducing integrated pest management or alternative approaches/techniques. The latter shall become mandatory for all professional operators as of 1 **January 2014, in order to reduce the dependency on pesticide use.**

[1] Population growth and the improved standard of living in many countries have led to increased consumption and greater demands for the world's natural resources. By definition, sustainable nature relates to the **long-term viability of a system**. The goal of sustainable agriculture is **to grow food products in a productive and efficient manner while conserving and improving the environment and the life of local communities.** The concept of sustainable agriculture includes activities such as maintaining the use of pesticides and fertilisers at a level as low as possible in order to ensure that adverse effects on the environment are reduced to a minimum. It also presupposes improvement of the living conditions in local communities by providing employment and ensuring the protection of the environment.

5.4. Regulation (EC) 1185/2009

This Regulation on pesticide statistics was published on **10 December 2009** and it went into effect 20 days after its publication. It establishes a legal framework for the systematic compilation of Community statistics on the marketing and use of plant protection products. These statistics must concern:

- the **amounts of pesticides marketed annually;**
- the **amounts of pesticides used annually.**

The key elements of this regulation concern:

- the **collection of data on annual sales by the Member States** and the forwarding of this data to the European Commission ;
- the **reports of the European Commission to the Parliament and to the Council every 5 years** on the quality of the data, the data collection methods, the market restrictions, the agricultural companies, national administrations, and the usefulness of these statistics for the thematic strategy.

5.5. Regulation (EC) 396/2005

Regulation (EC) 396/2005 relates to **the maximum pesticide residue levels** in foods and feeds. It amends Council Directive 91/414/EEC.

5.5.1. Pesticide residue levels in foods

The use of plant protection products can lead to the presence of residues in the treated products. **Maximum residue levels (MRL)** were established in order to protect consumers from exposure to unacceptable levels of residues in foods and feeds. The pesticide residues present in foodstuffs must pose **no danger to consumers and their level must be as low as possible**, *i.e.* correspond to the minimum quantity of pesticide for obtaining the desired treatment effect.

A maximum residue level (MRL) is **the maximum legally allowable concentration of a pesticide (active ingredient) residue in foods or feeds.** The pre-harvest interval (PHI) is the shortest period of time that must be left between the pesticide application and harvest in order to ensure that residues do not exceed MRLs.

In the EU, the legislation on pesticide MRLs has been harmonized among the Member States. This legislation applies to foods and feeds produced in the EU as well as to those imported from other countries (including the ACP countries).

5.5.2. Background of the European legislation on maximum residue levels of pesticides

Until September 2008, **the European Commission and the Member States were jointly responsible** for legislation on pesticide residues. Since 1976, more than 45,000 Community MRLs (published in **Directive** form) have been established for various crops, specifically for 245 pesticides on fruits and vegetables, grains, and foods of animal origin. For the tens of thousands of pesticide/crop combinations for which there were no Community MRLs, **the Member States were allowed to establish national MRLs** to protect their consumers. The Member States could also have national MRLs that were higher than the European ones, in order to adapt to new uses in the respective Member State.

Since September 2008, all statutory MRLs are now established for the EU as a whole on the basis of Regulation 396/2005.

5.5.3. What is in Regulation (EC) 396/2005 about maximum residue levels of pesticides?

Regulation (EC) 396/2005, instituting harmonized MRLs for all EU Member States, **went into effect** on 1 September 2008. The previous MRL scheme was too complex because it **combined rules harmonized on the European level and divergent national**

legislation. This situation was a source of confusion in terms of the applicable MRL and complicated things for distributors and importers, particularly in cases where foodstuffs that exceeded the MRLs set in one Member State were acceptable in another one.

The Regulation has **10 chapters** and **7** very important **annexes**:

- Chapter I: Subject, application, and definitions
- Chapter II: Procedure for MRL dossiers
- Chapter III: MRLs for foods of plant and animal origin
- Chapter IV: Special provisions concerning the introduction of existing MRLs into this Regulation
- Chapter V: Official monitoring, reports, and penalties
- Chapter VI: Emergency measures
- Chapter VII: Support measures concerning the harmonized MRLs
- Chapter VIII: Coordination of submissions of MRL dossiers
- Chapter IX: Implementation
- Chapter X: Final provisions

The structure of Regulation 396/2005 is outlined below.

Diagram of the structure of Regulation (EC) 396/2005

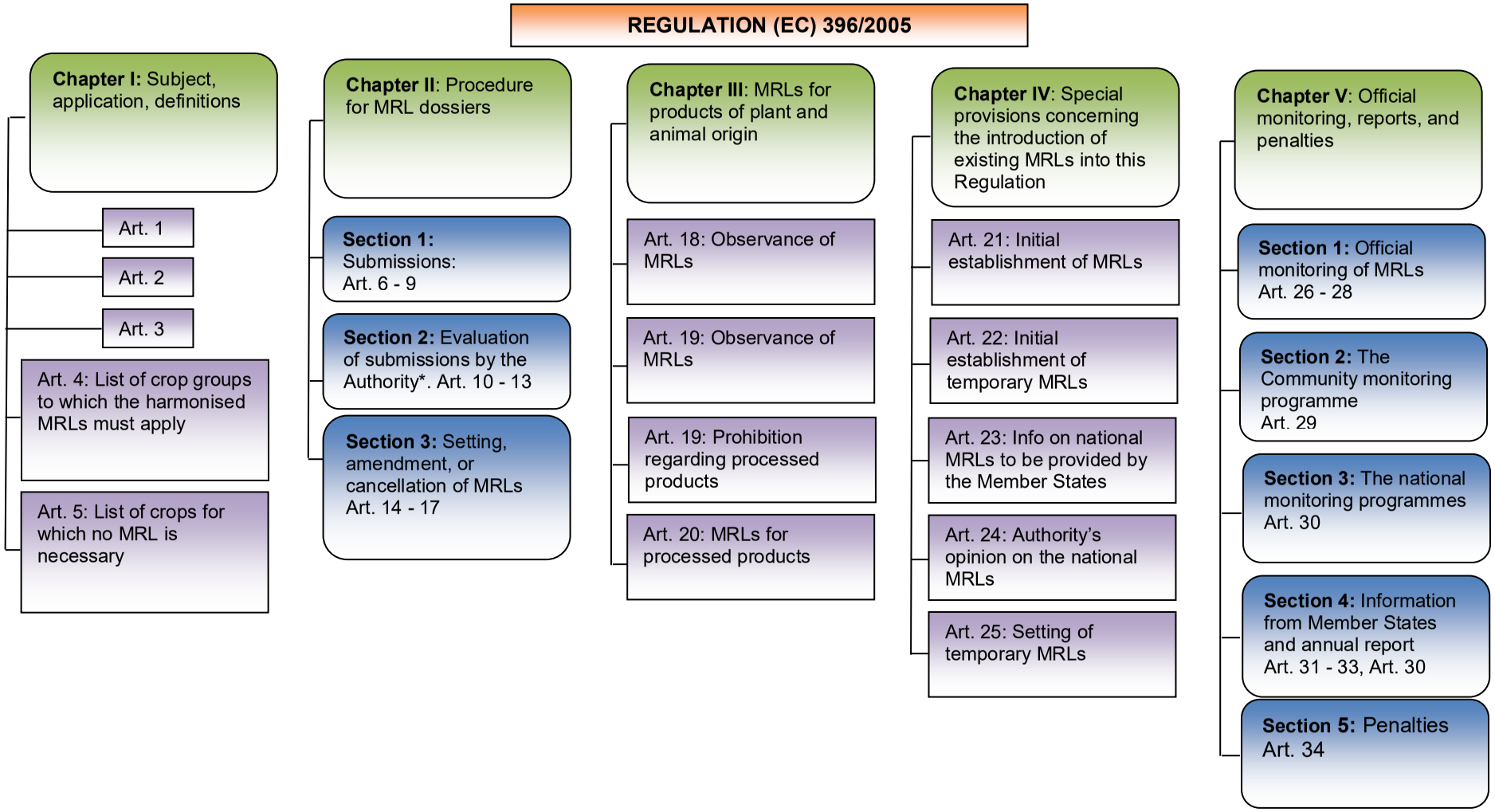
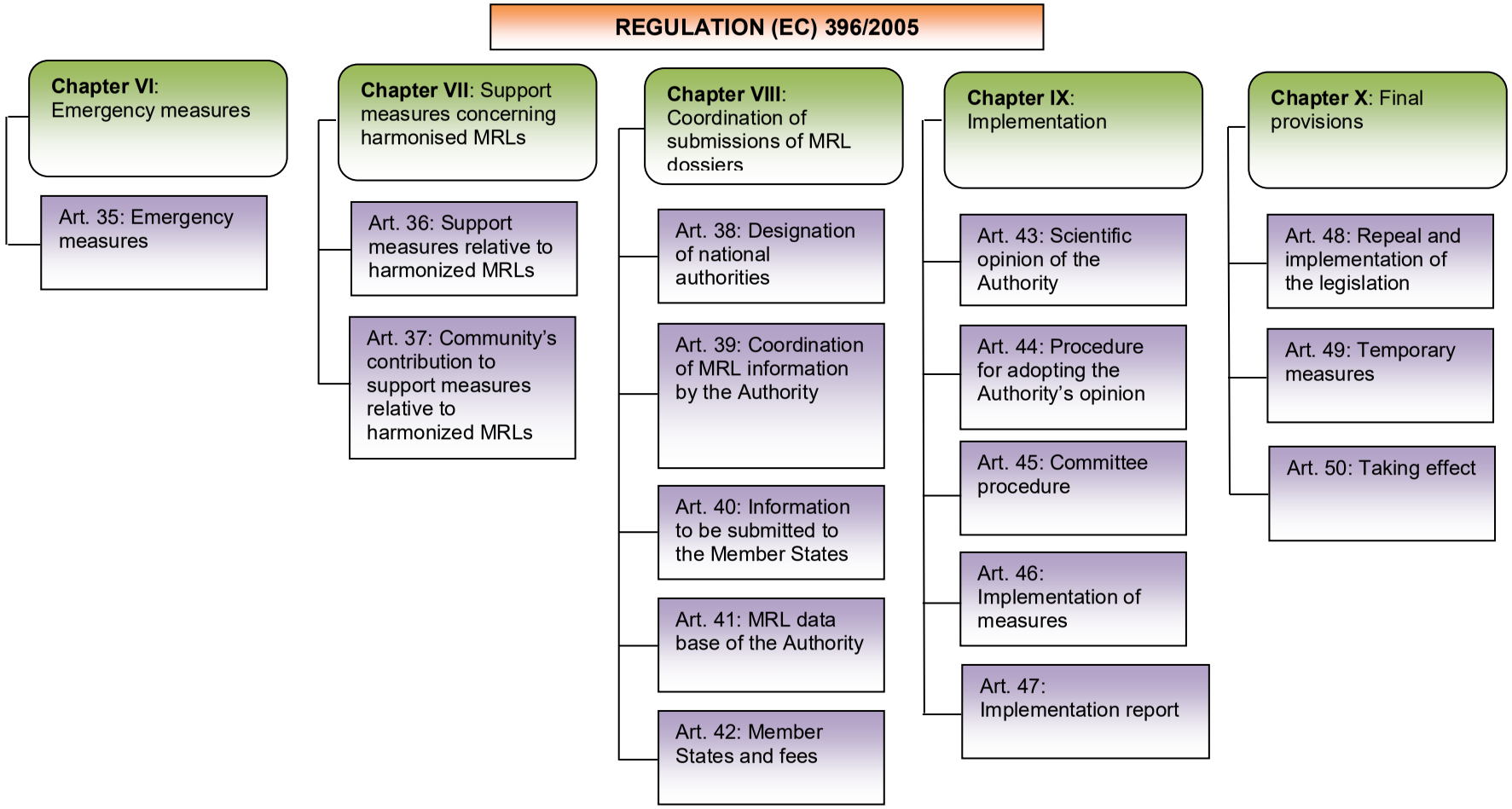


Diagram of the structure of Regulation (EC) 396/2005 – continued



The **Annexes** to Regulation (EC) 396/2005 specify the MRLs and the products to which they apply:

- **Annex I** lists the **products/foods** to which the MRLs apply. This annex was established by Commission **Regulation (EC) 178/2006**. It contains 315 products, including fruits, vegetables, spices, grains, and products of animal origin.

- **Annex II** lists the **definitive MRLs that apply in the EU** and consolidates the European legislation that existed prior to 1 September 2008. It also specifies the MRLs for 245 pesticides, and the import tolerances established by the new Regulation will also be indexed.

- **Annex III** lists the **so-called 'preliminary' MRLs**. It is the result of the harmonization process, as it lists the active substances for which MRLs had been set on the national level only prior to 1 September 2008. It specifies the MRLs for 471 pesticides. These MRLs will be progressively reviewed and they will become definitive MRLs.

- **Annex IV** lists the active substances (52) for which **MRLs are not needed** owing to the low risk that they pose.

- **Annex V** will list the active substances to which a **limit value other than 0.01 mg/kg** will be applied **by default**. This annex has not yet been published.

- **Annex VI** will index the **conversion factors for MRLs for processed products.** This annex has not yet been published.

- **Annex VII** indexes the active ingredients used as **fumigants** to which the Member States may apply special exemptions before these products are placed on the market.

If an active ingredient is not listed in any of the aforementioned annexes, the **MRL** of **0.01 mg/kg** applies **by default** (chap. II, art. 18, paragraph 1, point b, of Regulation (EC) 396/2005).

5.5.4. What are the implications of Regulation (EC) no. 396/2005 for products from ACP countries?

❑ Duty of importers

Food safety is the responsibility of farmers, distributors, and **importers**, meaning that they must observe the European MRLs or ITs (import tolerances), the latter being MRLs that satisfy the European standards of food safety established for an active substance used on a product (or foodstuff) imported to the EU. These MRLs/ITs were established on a scientific basis, and the establishment of a MRL presupposes the Rapporteur Member State and the EFSA performing an evaluation of the risk posed by the residue if ingested by consumers. This evaluation is based on a dossier submitted by all parties desiring a review or the establishment of a MRL. These evaluations are based on the properties of the pesticide, on the maximum levels anticipated in nutritional products, and on the different dietary habits of European consumers, and they take the safety of all consumer groups (e.g. babies, children, vegetarians) into account.

❑ **Where can the European MRL values for the active substances used in crop protection be found?**

There is a database specifying the MRLs that apply to each crop and to each pesticide on the European Commission website. In order to ensure the availability of transparent and up-to-date information on European pesticide residue legislation, this database can be accessed free of charge at: http://ec.europa.eu/sanco_pesticides/public/index.cfm.

❑ **What happens if there are no European MRL values for a crop(s)/active substance combination?**

In the case where ***(i)*** there is no EU MRL for an active substance used on a foodstuff imported to Europe and ***(ii)*** the residue content exceeds the default value (0.01 mg/kg), an **import tolerance dossier may be forwarded to the European authorities**. A request for an import tolerance must contain information about the residues, the toxicology and the risks to consumers, as well as a certificate of authorization in the producing country and a proposed MRL. A Rapporteur Member State will perform the preliminary evaluation and forward it to the EFSA. The process **can take 18 months,** according to the deadlines set forth in Regulation (EC) 396/2005. In the event that there is a Codex MRL value, the import tolerance shall preferably be based on it.

An MRL (or IT) can also be set for a group of crops, and in this case it would apply to each crop in the group. Depending upon the characteristics of a crop, it may also be possible to extrapolate an existing MRL on a representative crop to another crop in the same group (e.g., from green beans to sugar snap peas).

❑ **How are imported products monitored under Regulation 396/2005?**

The **authorities of the Member States** are in charge of monitoring the observance of MRLs and ensuring that they are applied to foodstuffs produced within the territory of Europe as well as those that are imported. The **Commission performs inspections in the Member States** in order to evaluate and test their monitoring activities. Chapter V of the Regulation distinguishes:

- **official monitoring of MRLs**: which must be performed by sampling and analysis with methods that have been validated on the Community level;
- **Community monitoring programme:** which must be multi-yearly, wherein the European Commission shall issue a report for the attention of the European Committee 6 months before the end of each year;
- **national monitoring programmes:** these checks must also be performed several times a year and must be based on the risk to the consumer. The Member States must publish the results of their residue monitoring online each year. In the event that MRLs are exceeded, the States may publish the names of the distributors, sellers, and producers. The EFSA must also publish an annual report on pesticide residues.

❑ **How will the EU react in the event that MRLs are exceeded and a serious risk to human or animal health is posed?**

There is a ***European Rapid Alert System for Food and Feed*** **(RASFF)** based on **Regulation (EC) 178/2002,** which establishes this system as a network involving the EU Member States, the European Commission as both a manager and a member, and the European Food Safety Agency (EFSA). Certain member countries of the EEA (European

Environmental Agency) such as Norway, Liechtenstein, and Iceland are also part of the RASFF.

A new Regulation (**Commission Regulation (EU) 16/2011** of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed) has just been published. It clarifies certain points of the previous Regulation.

The Rapid Alert System was set up in order to provide the authorities in charge of foods and feeds with an effective tool for exchanging information on the measures taken for dealing with serious risks relative to foods and feeds. The system consists of clearly identified **contact points** within the EU, the EEA, the EFSA, and, on the national level, within the Member States.

The Member States must immediately notify the Commission via the rapid alert system of:

- **any measures that they adopt concerning the restriction of marketing approval**, the withdrawal, or recall of foods and feeds from the market intended to protect human health;
- **any recommendations or arrangements made with professional operators relative to the prevention, limitation, or imposition of conditions for market access or use of foods or feeds due to a serious risk to human health;**
- **any rejections owing to a direct or indirect risk to human health** by a responsible authority at a European border.

Mainly there are **market notifications** and **border rejection notifications**.

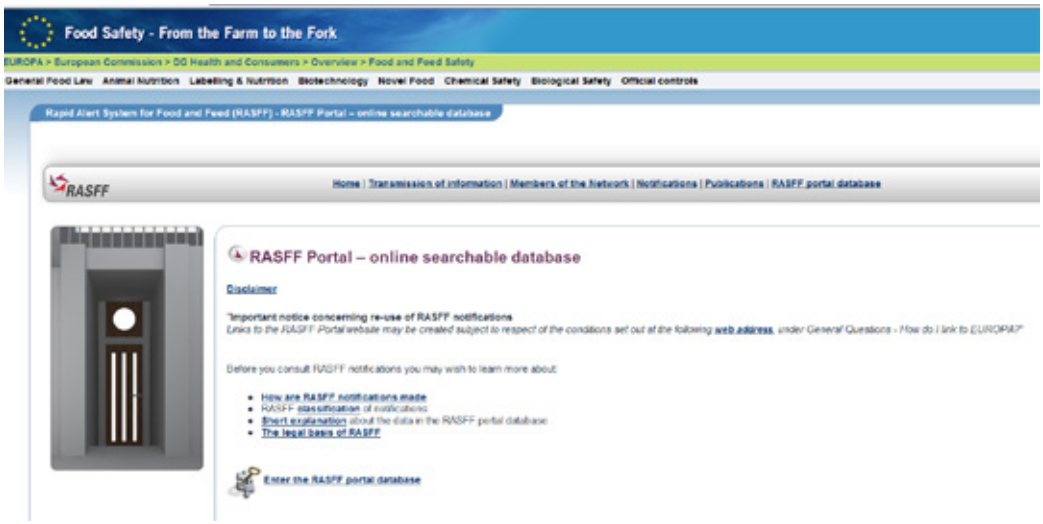
Of the various market notifications, an **alert notification** is sent within 48 hours to the Commission's contact point when the food or feed poses serious risks to the market and when rapid action is required. Within 24 hours, the Commission must notify the other members of the network. The products for which an alert notification was issued must be withdrawn from the market in each member state, according to their own mechanisms.

An **information notification** is issued by a notifying country when a risk is identified for a certain food or feed without requiring rapid action (for example, a product that has not yet reached the market or that is no longer on the market of other Member States). An information notification is addressed to the RASFF contact point of the Commission, which directs it within 24 hours to all of the member states of the network.

A **border rejection notification** signifies that the European Community refused a food or feed posing a risk to human or animal health.

An original notification may be rejected and not transmitted through the RASFF after evaluation by the Commission. Furthermore, an alert or information notification may be rejected by the Commission upon request by the notifying country if it was made on the basis of incorrect or insufficient information.

All of these notifications can be looked up on the RASFF Portal: ec.europa.eu/food/food/rapidalert/rasff_portal_database_en.htm


Food Safety - From the Farm to the Fork
EUROPA > European Commission > DG Health and Consumers > Overview > Food and Feed Safety
General Food Law Animal Nutrition Labelling & Nutrition Biotechnology Novel Food Chemical Safety Biological Safety Official controls
Rapid Alert System for Food and Feed (RASFF) - RASFF Portal – online searchable database
RASFF
Home | Transmission of information | Members of the Network | Notifications | Publications | RASFF portal database
RASFF Portal – online searchable database
Disclaimer
Important notice concerning re-use of RASFF notifications
Links to the RASFF Portal website may be created subject to respect of the conditions set out at the following web address, under General Questions - How do I link to EUROPA?
Before you consult RASFF notifications you may wish to learn more about:
How are RASFF notifications made
RASFF classification of notifications
Short explanation about the data in the RASFF portal database
The legal basis of RASFF
Enter the RASFF portal database

5.6. Regulation (EC) 1907/2006

This Regulation concerns the **R**egistration, **E**valuation, **Authorization**, and Restriction of **Ch**emical substances**, and also the restrictions that apply to these substances (REACH)**. It set up a European agency for chemical products, amended Directive 1999/45/EC, and repealed Council Regulation (EEC) 793/93 and Commission Regulation (EC) 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC, and 2000/21/EC.

5.6.1. General principles

The REACH Regulation was adopted on 18 December 2006 and published in the Official Journal on 29 May 2007, and is directly applicable in the Member States. The new Regulation aims to progressively **phase out the most hazardous chemical substances in the European Union**. To this end, the burden of the proof of harmlessness of the chemical substances currently in use has been reversed: it is up to the **manufacturer (and the importer) to demonstrate the harmlessness of these substance to human beings and the environment,** by means of studies on the risks to human health and to the environment, prior to placing them on the market or using them.

Article 1

It is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

REACH applies to all chemical substances, produced or imported, existing or new, in quantities greater than one ton per year. This translates to 30,000 substances (among the more than 100,000 used in Europe).

REACH does not apply:

- to radioactive substances,
- to substances subject to customs control, in temporary storage, in a free zone or free warehouse for reexportation, or in transit,
- to the transport (all modes) of hazardous substances as is or contained in hazardous preparations,
- wastes are not considered as substances, formulations, or articles.

The essential point of this Regulation is for any manufacturer or importer of a substance, either as is or in one or more formulations, **in quantities of 1 ton or more per year, to submit a request for registration to the European Chemicals Agency (ECHA).** The latter will register the molecules (compounds), have them evaluated and register them in a data base which businesses, private individuals, and NGOs can access.

The regulation defines 3 different statuses as far as obligations to the European Chemicals Agency are concerned.

- **Importer**: any natural or legal person established within the Community who is responsible for importing (physical introduction in the customs territory of the European Community).

- **Downstream user**: any natural or legal person established within the Community who uses a substance, either as is or formulated, in the performance of their industrial or professional activities. Distributors and consumers are not downstream users.

- **Manufacturer**: any natural or legal person established within the Community who manufactures a substance (product or extract of natural substances) within the Community.

The Regulation stipulates that the secretariat of the European Chemicals Agency shall create and keep updated a database (accessible free of charge on the internet for some of the information, except in cases where a request for confidentiality has been granted) on the substances registered, the classifications and labellings, and the harmonized list thereof.

5.6.2. Implementation and deadlines

The goal of the EU was to pre-register around two million substances by the end of 2008.

Article 15 (1) of the Regulation, however, stipulates that **active substances and co-formulants manufactured or imported solely for use in plant protection products** and included either in Annex I of Council Directive 91/414/EEC (2) or in Commission Regulation (EEC) 3600/92 "(3), [...] and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC **shall be regarded as being registered and the registration as completed for manufacture or import for use as a plant protection product and therefore as fulfilling** the requirements of Chapters 1 and 5 of the Regulation".

Certain substance **require a specific authorization**:

- those in categories **CMR 1 or 2**: carcinogenic, mutagenic, toxic to reproduction (i.e. endocrine disruptors);
- those that are extremely hazardous to the environment, i.e.:
  - Persistent, Bioaccumulable, Toxic to the environment **('PBT')**,
  - or very Persistent, very Bioaccumulable **('vPvB')**,
- and those that the Agency feels pose a very high risk (the Agency reserves the right to define which substances shall be subject to authorization).

These substances subject to authorization are considered as a source of concern and they must be regularized within a period of 3 1/2 years counting from 1 June 2007. As they are regularized, these substances are added to a list placed in Annex XIV of the regulation.

The Regulation stipulates deadlines according to specified tonnage bands. The greater the volume of production, the tighter the regulatory requirements.

Dates	**Production >1 000 t/yr CMR 1 or 2 > 1 t/yr R50/53 >100 t/yr**	**100 < Production < 1000 t/yr**	**1 < Production < 100 t/yr**
June 2007	Date REACH went into effect		
June to December 2008	Pre-registration		
December 2010	Registration		
June 2010		Registration	
June 2018			Registration

t/yr = tons per year

5.6.3. Registration dossier

The registration dossier consists of 2 parts:

- **The technical dossier** covers the following points:
  - identity of the manufacturer/importer applying for registration;
  - identity of the substance;
  - information on the manufacturing, the identified uses (incl. the non-recommended uses); optionally: the use and exposure categories;
  - classification/labelling;
  - recommendations for use;
  - study summaries (Annexes VII-X);
  - Robust study summaries (Annexes VII-X if prescribed by Annex I);
  - certain information checked by an evaluator (with relevant experience) chosen by the manufacturer/importer;
  - proposed test(s), if the latter are specified in Annexes IX-X (S > 100 t/yr);
  - for S < 10 t/yr: information on exposure (Annex VI section 6);
  - request that certain data be kept confidential (art 118) when publishing online (+ justification).

- A **Chemical Safety Report** (CSR) for certain substances. It concerns substances produced in quantities greater than ten tons a year. It is an evaluation of the chemical safety, which rates:
  - the hazards to human health;
  - the physicochemical hazards to human health;
  - the hazards to the environment;

- the PBT and vPvB evaluation.

For substances fulfilling the criteria for CMR category 1 and 2 and PBT/vPvB classification, the dossier also consists of an evaluation of exposure (Exposure Scenario) as well as a risk characterization for all identified uses.

5.6.4. Consequences for fruit and vegetable producers in the ACP countries

The REACH Regulation mainly concerns the registration of chemical substances in Europe and therefore has little direct impact on imports of foods from the ACP countries. Given that the European Chemicals Agency also rules on hazardous chemical substances (CMR 1 & 2, PBT, vBvT), it is possible that certain substances, co-formulants or adjuvants may no longer be available on the market.

5.7. Regulation (EC) 1272/2008

European Parliament and Council Regulation (EC) 272/2008 of 16 December 2008 on the **classification, labelling, and packaging of substances and mixtures**, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) 1907/2006, was **published** in the European Official Journal of **31 December 2008**. The Regulation is mandatory in all of its elements and **directly applicable in each Member State**, without transposition into national law.

This Regulation is known as the '**CLP Regulation**' (Classification, Labelling and Packaging) and it implements the General Harmonized System (GHS) in Europe and will lead to **new labels on all hazardous chemical products**.

The Regulation went into effect on the 20th day following its publication in the Official Journal of the European Union. Titles II, III and IV became **applicable to substances as of 1 December 2010** and shall become applicable to **mixtures as of 1 June 2015**.

The transition period shall end on 1 June 2015, when the CLP Regulation shall take full effect. On 1 June 2015, the CLP Regulation shall replace in their entirety:

- the Directive on hazardous substances (67/548/EEC)
- the Directive on hazardous formulations (1999/45/EC)

The table below summarizes the obligations of chemical product suppliers during the transition period:

➢ **For substances**

20 January 2009 – 1 December 2010	Suppliers must classify substances according to the 4 Regulations of 2009 concerning chemical hazard information and packaging for supply (CHIP), which went into effect on 6 April 2009. However, they may also choose the alternative of classifying, labelling, and packaging substances in accordance with the CLP Regulation.
1 December 2010 – 1 June 2015	Suppliers must classify substances according to the CHIP regulations and the CLP Regulation. They must label and package in accordance with the CLP Regulation.
As of 1 June 2015	Suppliers must classify, label and package in accordance with the CLP Regulation.

➢ **For preparations (mixtures)**

20 January 2009 – 1 June 2015	Suppliers must classify substances according to the 4 Regulations of 2009 concerning chemical hazard information and packaging for supply (CHIP), which went into effect on 6 April 2009. However, they may also choose the alternative of classifying, labelling, and packaging substances in accordance with the CLP Regulation.
As of 1 June 2015	Suppliers must classify, label and package in accordance with the CLP Regulation.

There are certain limited cases where these temporary provisions for substances and preparations may be extended. The relabelling and packaging of substances and mixtures that are already in the supply chain on the above-mentioned compliance dates may be postponed until 1 December 2012 and 1 June 2017.

The principal classification criteria as well as the changes in classification, labelling, and packaging are given in the **7 annexes** of the CLP Regulation. These annexes underwent amendments in the form of **adaptations to technical progress** (**ATP**), which were published as Regulations:

➢ The **first ATP** was published on 5 September 2010 (**Regulation (EC) 790/2009**) and it revised the 30th and 31st ATPs (Directives 2008/58/EC and 2009/2/EC respectively) already reflected in Annexes (I, II, III, IV and V) of the CLP Regulation.

➢ The **second ATP** was approved on 18 October 2010 and should soon be published as a Regulation. Among other things, it contains new respiratory and skin sensitization subcategories, the revision of the classification criteria for long-term risks (chronic toxicity) to the aquatic environment, a new hazard class for substances and mixtures hazardous to the ozone layer, and labelling with provisions for protecting persons already sensitized to a specific chemical product that could therefore trigger an allergic reaction at very low levels of exposure.

5.8. Directive 2009/127/EC

Directive 2009/127/EC on pesticide application equipment introduced **environmental protection measures applicable to the design and construction of new equipment** for applying plant protection products into Directive 2006/42/CE (the old 'Machinery' Directive) of 17 May 2006. The equipment will have to fulfil these requirements **before it is placed on the market**. Furthermore, as maintenance of pesticide application equipment plays an important role in reducing the effects of pesticides on human health and on the environment, the Framework Directive introduced requirements for inspection and maintenance to be performed on this type of equipment. These new provisions will **become applicable on 15 December 2011** and **must be transposed into national law no later than 15 June 2011.**

5.8.1. A broad outline of the Directive

The "Machinery" Directive of 2006 took effect on 29 December 2009. This Directive defines measures for protecting the health and safety of human beings, domestic animals, and goods, but generally without addressing the essential requirements for protecting the environment. The situation is changing today, mainly owing to the publication of Directive 2009/127/EC of 21 October 2009 (OJ of 25 November 2009). This Directive 2009/127/EEC amends the "Machinery" Directive as far as pesticide application equipment is concerned.

Environmental protection was explicitly covered in the essential health and safety requirements in article 2 of the old Directive and is therefore already valid in principle. By introducing **precise rules for the design and construction of pesticide application equipment** in the "Machinery" Directive, however, Directive 2009/127/EC goes beyond this "statement of principle". Manufacturers must henceforth perform a risk analysis to evaluate the (involuntary) environmental pollution risks linked to the use of this equipment. They must take the risk analysis results into account in constructing their equipment and make sure that all leaks are prevented.

5.8.2. What equipment do the new rules apply to?

The new rules (Directive 2009/127/EEC) apply to **equipment designed to apply pesticides** that are plant protection products. **Machinery for pesticide application includes self-propelled machinery, towed, vehicle-mounted and semi-mounted machinery, airborne machinery, as well as stationary machinery intended for pesticide application, both for professional and non-professional use.** It also includes **motorized or manually-operated, portable and hand-held equipment equipped with a pressure tank.**

The old rules in the 2006 Directive likewise apply to foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and materials, with the same rules of inspection.

5.8.3. Principal requirements for new sprayers sold after December 15, 2011

- ***Precise application rate***

Ensure means for easily, precisely, and reliably regulating the application rate (*i.e.* the volume of spray mix applied per hectare).

- ***Pesticide distribution, coverage, and drift***

  Pesticides must be applied to the target zones and any offsite movement must be prevented. If applicable, even pesticide distribution and uniform pesticide coverage must be ensured. To address these first two points, the manufacturer or its representative must perform, or have performed, appropriate tests for each type of machine concerned.

- ***Maintenance and cleaning***

  Easy and thorough cleaning, and easy replacement of worn parts without contaminating the environment.

- ***Checks***

  Easy connection of measuring instruments to check the equipment for correct operation must be possible.

- ***Identification markings on nozzles, sieves, and filters***

  The type and size of these elements must be clearly identified.

- ***Indication of the pesticide being used***

  A specific piece of equipment must have a way for the operator to indicate the name of the pesticide being used.

- ***Information in the instructions for use***

  As a supplement to all of the key points for using the sprayer set forth above, indication of when the equipment must be periodically inspected by a designated body pursuant to Directive 2009/128/EC (Directive on environmentally compatible use).

5.8.4. Impact of the Directive on ACP farmers and producers

From a legal standpoint, this Directive does not apply to the ACP countries. However, it illustrates the European desire to manage the use of pesticides and their impact on human health and the environment at the source, as well as the more stringent legislation regarding improper usage of agricultural equipment that could have a detrimental effect on European consumers. This Directive underscores the significance of a major factor in the management of pesticide residues: agricultural equipment that is in good condition and checked. Although most agricultural operations in ACP zones are small operations with essentially manual agricultural equipment, even backpack sprayers must be checked for correct calibration in order to avoid excessive pesticide residues in fruits and vegetables grown for export to the European market.

5.9. Directive 98/8/EC

5.9.1. General definition of the term 'biocide'

In Europe, Directive **98/8/EC** of the European Parliament and of the Council **of 16 February 1998** concerning the placing of biocidal products on the market (*OJEC*, L 123 of 24 April 1998) defines biocides as follows: *"Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to* ***destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means****".*

Biocides are commonly designated as **pesticides for non-agricultural use**. A distinction is made between biocidal active substances and biocidal products:

- ***Biocidal active substance***
  Substances or microorganisms, including viruses or fungi, having a general or specific action on or against harmful organisms. Around 270 biocidal active substances representing thousands of products subject to marketing authorization are undergoing evaluation in the EU by the Member States.

- ***Biocidal products***
  Active substances and preparations containing one or more active substances put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

5.9.2. Scope of application of Directive 98/8

Act	**Date of taking effect**	**Deadline for transposition in the member states**	***Official Journal***
Directive 98/8/EC	14 May 1998	13 May 2000	*OJEC*, L 123 of 24 April 1998

The Directive concerns:

- **the authorization and the placing on the market of biocidal products in the Member States**;
- the **mutual recognition of authorizations** within the European Community;
- **the establishment of a list of active ingredients** approved for use in biocidal products **in the European Community**.

In its **Annex V,** the Directive presents an "exhaustive list of **twenty three product types** with an indicative set of descriptions for each type."

The Directive **does not apply** to products within the scope of application of the following legislative acts:

- Directive 2001/83/EC (medications for human use);
- Directive 2001/82/EC (veterinary medications);
- Regulation (EC) 726/2004 (European Medicines Evaluation Agency) ;
- Directive 90/385/EEC (active implantable medical devices);
- Directive 93/42/EEC (medical devices) ;
- Directive 98/79/EC (in-vitro diagnostic medical devices);
- Regulation (EC) 1333/2008 (food additives);
- Directive 88/388/EEC (food flavorings);
- Regulation (EC) 1935/2004 (materials and objects in contact with foods);
- Directive 90/167/EEC (medicated feeds);
- Regulation (EC) 767/2009 (feeds);
- Regulation (EC) 1831/2003 (feed additives);
- Regulation (EC) 1223/2009 (cosmetic products);
- Regulation (EC) 1107/2009 (plant protection products).

The Directive contains 6 important annexes designed for both active substances and biocidal products:

- ***Annex I***: list of **active substances** with requirements **agreed at** Community level for inclusion in **biocidal products**
- ***Annex IA***: list of **active substances** with requirements **agreed at** Community level for inclusion in **low-risk biocidal products**
- ***Annex IB***: list of **active substances** with requirements **agreed at** Community level
- ***Annex IIA***: common **core data set for active substances**
- ***Annex IIB:*** common **core data set for biocidal products**
- ***Annex IIIA:*** additional data set for active substances/chemical substances
- ***Annex IIIB***: additional data set for biocidal products/chemical products
- ***Annex IVA***: data set for active substances/fungi, microorganisms, viruses
- ***Annex IVB***: data set for biocidal products/fungi, microorganisms, viruses
- ***Annex V***: **biocidal product-types and their descriptions** as referred to in article 2(1)(a) of this Directive
- ***Annex VI:*** **common principles for the evaluation of dossiers** for biocidal products

5.9.3. Key points of Directive 98/8

❑ **Obligations of Member States**

Authorization, classification, labelling, packaging, and proper use of biocidal products in compliance with this Directive is the responsibility of the Member States. Proper use encompasses measures for restricting the use of biocidal products to a minimum, as well as the obligation to ensure that use in the workplace is in compliance with the worker protection directives. The Member States designate one or more competent authorities

responsible for fulfilling the obligations imposed upon them by this Directive, including the granting of authorizations and the receipt of information on biocidal products in order to be able to respond to any medical requests.

Each quarter, each Member State shall notify the other Member states and the Commission of all biocidal products registered and authorized in its territory or for which authorization or registration was denied, amended, renewed, or cancelled.
Every three years since 2003, the Member States have been submitting a report to the Commission, in which they indicate any cases of poisoning due to biocidal products.

❑ Principle of mutual recognition of authorizations

The authorization system is based on the principle of mutual recognition of authorizations. According to this principle, a biocidal product already authorized or registered in a Member State is authorized within a period of 120 days or registered within a period of 60 days in another Member State, counting from the date on which the request was received by the other Member State.

❑ Conditions for granting authorizations

Marketing authorization for a product is mandatory, except for certain exemptions for low-risk products. The Member States will only authorize a biocidal product:

- if its active substances are listed in annex to this Directive and if the requirements set forth in the annexes are satisfied;
- if it is established that:
  - the **biocidal product is sufficiently effective**,
  - has **no unacceptable effect on target organisms**,
  - has **no unacceptable effect on human or animal health,** nor **on surface water or groundwater,**
  - has **no unacceptable effect on the environment**;
- if the nature and the quantity of the active substances can be determined under the requirements listed in annex to the Directive;
- if **its physical and chemical properties have been judged acceptable** for ensuring appropriate use, storage, and transport of the product.

A biocidal product **classified as toxic, carcinogenic, mutagenic, or toxic to reproduction shall not be authorized for sale to the general public.**
Authorizations are subject to reexamination at any time during the period for which they were granted.

❑ Marketing approval for active substances

An active substance intended for use in biocidal products may be placed on the market if:

- a **dossier**, accompanied with an attestation that the active substance must be incorporated in a biocidal product, **was submitted to a Member State**. This condition applies to active substances that were not covered by marketing authorizations prior to 14 May 2000;
- the active substance is classified, packaged, and labelled according to Directive 67/548/EEC and is approved for use until 1 June 2015.

All active substances approved for inclusion in biocidal products are listed in **Annex I or IA of the Directive**. A substance will be registered in the annex for a maximum period of **ten years**.

❑ Inclusion of a new active substance in the annex

To register a new active substance in Annex I, IA or IB of the Directive, the Commission must submit a proposal to the standing committee. The proposal is based on an evaluation of the substance, which is performed using the data furnished by the applicant.

❑ Cancellation of an authorization

An authorization will be cancelled if:

- the active substance is no longer listed in Annex I or IA of this Directive;
- the conditions for obtaining the authorization are no longer fulfilled;
- false statements were submitted with the authorization request;
- the holder of the authorization requests it.

❑ Amendment of an authorization

An authorization may be amended:

- by a Member State, when it feels that doing so is necessary in order to protect health and the environment;
- upon request by its holder.

It is the responsibility of the holder of an authorization for a biocidal product to notify the competent authority immediately of any information concerning an active substance or a biocidal product containing this substance of which it has knowledge and which may influence the continuation of the authorization.

❑ Procedure for requesting an authorization

An authorization request comes from the person primarily responsible for placing a biocidal product on the market in a Member State, and it is addressed to the competent authority **in that Member State**. To obtain the authorization, the applicant must submit:

- a **dossier or a letter of access concerning the biocidal product** and providing the information specified in **Annexes IIB, IIIB, IVB** according to the type of biocidal product. Examples of the type of information requested are the applicant's name and address, the name and the composition of the product, the envisioned uses, the protective measures to be taken, etc. Dossiers for low-risk biocidal products are less detailed;
- a **dossier or a letter of access for each active substance** in the biocidal product and providing the information required by Annexes IIA, IIIA, IVA.

Like the registration of substances in Annex I, IA, or IB, there is also a fee for the marketing authorization for biocidal products.

The Member States may only use the information in the authorization request dossier for the benefit of another applicant under certain conditions, including the written consent of the first applicant.

❑ Provisions for an already authorized biocide

The applicant for a marketing authorization may use the information provided by a previous applicant provided that it can **demonstrate that the product is similar and that the active substances are identical to those of the previously approved product.**

Before performing experiments on vertebrates, the applicant for an authorization must ask the competent authority of the country in which it intends to submit its request:

- if the product in question is similar to an already approved biocidal product;
- for the contact information of the holder of the authorization.

The applicant and the holder or holders of prior authorizations are encouraged to come to an agreement on sharing information in order to avoid having to repeat experiments on vertebrates.

❑ Exemptions

The Directive provides the possibility for exemptions to the requirements for placing biocidal products on the market. A Member State may grant a temporary marketing approval, for a limited and controlled use, of biocidal products that do not comply with the provisions of the Directive, if such a measure appears necessary because of an unanticipated danger that cannot be controlled by any other means.

❑ The European Commission's role

After adopting the Directive, the Commission initiated a work program for the methodical investigation of risks associated with all active substances authorized for inclusion in biocidal products. The programme was established by a Regulation adopted by the standing committee for biocidal products, and it shall run for ten years. Its purpose is to investigate all substances being used as active ingredients in a biocidal product that were already on the market as of 14 May 2000, except for products being used for scientific and process-oriented research and development. No later than two years before the end of the work programme, the Commission shall forward a progress report on it to the European Parliament and to the Council.

In order to facilitate the implementation of the Directive, the Commission must draw up technical notes for guidance and publish them in the *Official Journal of the European Union*.

❑ Classification, packaging, labelling

Biocidal products are classified, packaged and labelled according to **Directive 1999/45/EC relating to the classification, packaging, and labelling of dangerous preparations**, effective until 1 June 2015. In order to avoid any misunderstandings (such as confusion with foodstuffs or beverages), however, the directive establishes additional requirements relative to the packaging and labelling of such products.

❑ Safety measures

A specific information system was set up in order to enable professional and industrial users of biocidal products to take the necessary measures for protecting the environment and health. This system consists of safety data sheets provided by the person(s) responsible for placing the product on the market.

❑ Confidentiality

The Directive provides the opportunity for the applicant to request that certain sensitive information not be disclosed to any parties other than the responsible authorities and the Commission. This confidentiality clause, however, does not apply to certain elements (such as the applicant's name and address, the physical and chemical properties of the biocidal product, etc.).

❑ Safeguard clause

A Member State may restrict or temporarily ban the use or sale of an approved biocidal product provided that it has grounds for believing that said product poses unacceptable risks to human or animal health or to the environment. It must notify the Commission and the other Member States accordingly without delay, specifying its reasons for doing so.

❑ Comitology

The Commission is assisted a standing committee for biocidal products. The committee follows a regulatory procedure for performing certain tasks such as the decision to consent to or deny a ban (safeguard clause), or a management procedure for performing others such as the registration of an active substance in the annex and the granting of confidentiality.

❑ Various amendments and legislative texts

Directive 98/8/EEC has been amended by several legislative texts, which are listed below:

Amending act(s)	Date of taking effect	Deadline for transposition in the Member States	Official Journal
Regulation (EC) 1882/2003	20 November 2003	-	*OJEU*, L 284 of 31 October 2003
Directive 2007/47/EC	11 October 2007	21 December 2008	*OJEU*, L 247 of 21 September 2007
Directive 2008/31/EC	21 March 2008	-	*OJEU*, L 81 of 20 March 2008
Directive 2009/107/EC	26 October 2009	14 May 2010	*OJEU*, L 262 of 6 October 2009

5.9.4. The draft of Regulation replacing Directive 98/8

In June of 2009, the European Commission proposed a draft of a new regulation for safer biocidal products, but also for a simplified procedure. It was adopted and supplemented on **20 December 2010** by the Ministers of the Environment (after voting by the European

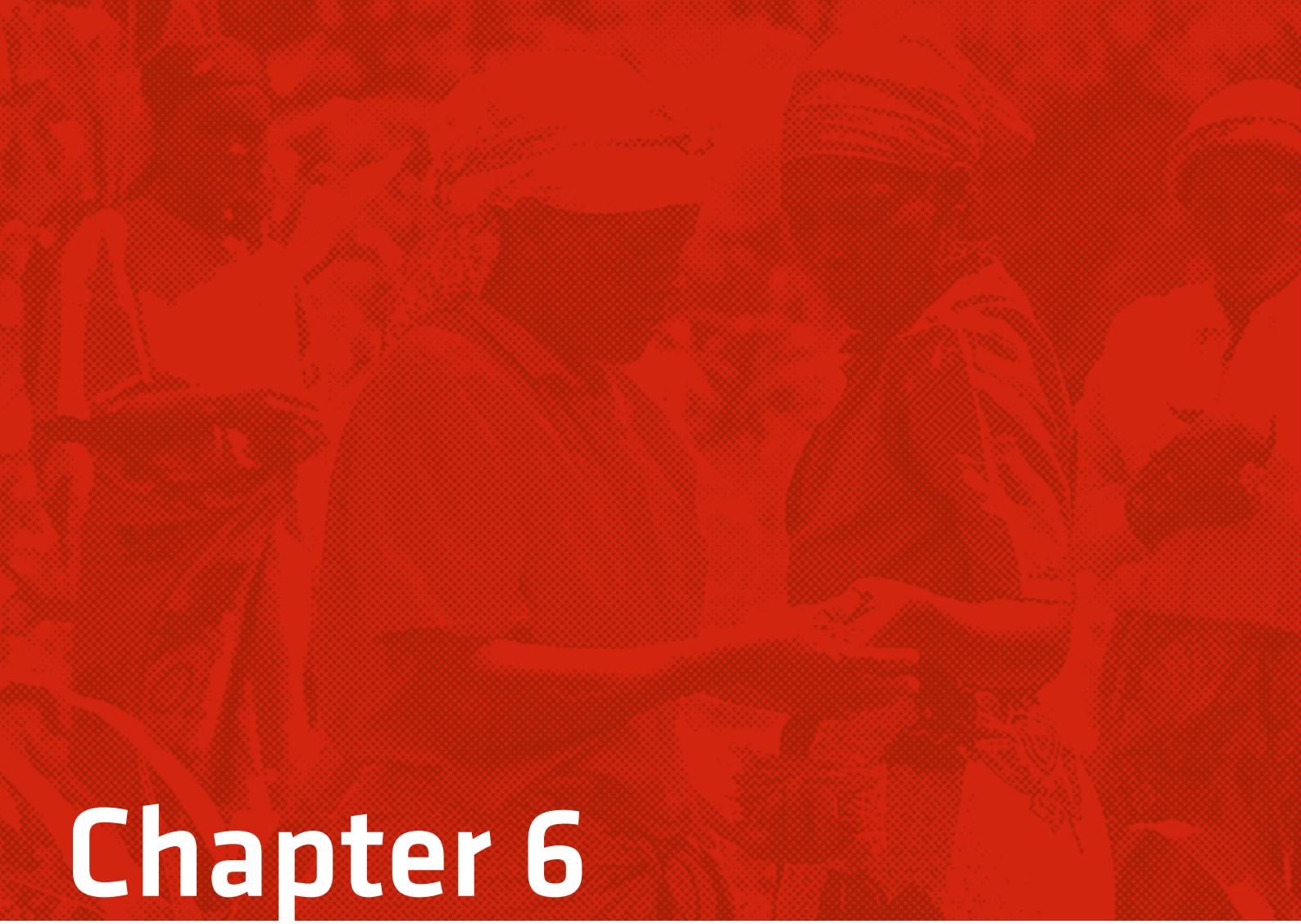
Parliament). It shall replace the 1998 Biocide Directive. The ban on unauthorized biocides concerns the usage thereof in Europe, and is now extended to include **imported goods** as well. EU authorization shall first be made mandatory for certain products starting in 2013, (in-can preservatives, antifungals, biocides for textiles and fibers, leather, rubber, and polymers, biocides used in the metal processing industry or in embalming and taxidermy fluids), and then it shall be extended to include most biocides before 2020.

Certain extremely toxic substances (confirmed carcinogens or substances toxic to reproduction), *as well as* **chemical products acting as endocrine disruptors** and certain persistent, bioaccumulable, and toxic (PBT) or very persistent and very bioaccumulable (vPvB) materials shall be banned henceforth, and around 270 biocides (corresponding to several thousand products subject to authorization in the European market) are currently undergoing toxicological evaluation. Agricultural antibiotics and pesticides, however, are excluded from this regulation and subject to other Directives.

Requests for temporary authorization shall be simplified, and the field of application of the Directive was expanded to include certain articles (e.g. furniture or clothing impregnated with biocides such as nanosilver in anti-odor socks, sleeping bags, or certain couches) which may no longer be treated with unapproved chemical products and which must now be labelled.

The European Chemicals Agency (ECHA) has been asked to issue authorizations for both substances and products (optional process supplementing the existing national authorization system).

Exemptions may still be granted for certain toxic products **under certain conditions,** for instance when such products appear to be needed for "**preventing a serious risk to public health or to the environment**".



Chapter 6

Regulations on the control of agricultural products

6.1. International regulations

The main objective of the **OECD Scheme** for fruits and vegetables is to facilitate international trade by harmonizing the implementation and interpretation of marketing standards. Another objective is **to encourage the participating countries to mutually recognize each other's inspections.**

The scheme is known for its brochures explaining the standards. It also strives to **define the inspection procedures that are recognized in numerous countries**, and it sponsors trainings.

There are currently 25 member countries[1] in the OECD Scheme, certain ones of which are the main exporting countries for all or a portion of the products covered by the scheme.

The OECD Scheme for fruits and vegetables **provides a comprehensive and internationally harmonized quality inspection system.** The mutual recognition of inspections is reinforced by peer reviews of national quality inspection systems and also by the organization of meetings of the heads of the national inspection services and workshops for the inspectors. Frequent meetings are also an opportunity for the various partners to engage in intensive dialogue for reviewing and drafting the OECD standards, for interpreting them, and for defining the inspection procedures. The 69th plenary session on the fruit and vegetable scheme was held in December of 2010, with the 25 member countries in attendance.

The intergovernmental standardization of fruit and vegetable quality is essential for reducing the technical barriers to international trade and for offering more transparency to the consumers. The interpretation of the standards is indispensable for putting them into practice, which is why the OECD Scheme, its explanatory brochures on the standards, and its inspection guidelines will continue to play a decisive role.

As numerous African and Asian countries specialize in fruit and vegetable production, it would benefit them to implement the scheme in order to reinforce their export capacities. Only 3 countries (South Africa, Kenya, and Morocco) are members of this scheme at the present time.

Since the 70s, the OECD has published a guidance document (*Guidance on objective tests to determine quality of fruits and vegetables and dry and dried produce* - http://www.oecd.org/dataoecd/32/47/19515719.pdf) on the application of quality assurance and inspection systems, in which the various types and means of quality measurement of fruits and vegetables (sugar content, water content, etc.) are described.

[1] Austria, Bulgaria, Greece, Ireland, Italy, Luxembourg, Netherlands, Poland, Serbia, South Africa, Spain, Sweden, Switzerland, Turkey, Slovakia, Romania, New Zealand, Morocco, Kenya, Israel, Hungary, Germany, Finland, Belgium.

6.2. European regulations

There are essentially 2 types of controls of agricultural products at border posts:

- **health quality** checks;
- **checks for pesticide residues.**

In the wake of globalization and health crises, the health quality of fresh fruits and vegetables has become a major source of concern to European consumers and one of the principal issues in this line of products. This issue is of paramount concern to governments, which traditionally assume the task of defining and controlling health standards. It is their job to deal with and reduce the risk to human health that is on the rise with the intensification of agriculture and the internationalization of trade, while reassuring misinformed consumers who are easily influenced by the media.

5.2.1. Health quality control

The rules for implementing the Sanitary and Phytosanitary Measures Agreement (SPS) were established by the EU, and they determine to what extent the latter can maintain an open and scientific approach regarding animal and plant health and food safety in general.

The controls (checks) established by the EU are **compliant with the standards** defined by the international standardization bodies competent in food safety and animal and plant health, namely the ***Codex Alimentarius* Commission**, **the World Organization for Animal Health (OIE),** and **the International Plant Protection Convention (IPPC)**, as established by the agreement on the application of sanitary and phytosanitary measures (SPS Agreement) of the World Trade Organization (WTO).

Although national governments may enact **supplementary sanitary and phytosanitary measures** to protect human, animal, and plant life or health, the latter are only admissible when it can be proven that they are **scientifically based, proportionate, and non-discriminatory**.

The EU is one of the main players in the world trade of food and feed, and in this capacity it is resolute in fulfilling its international obligations. It is also conscious of the fact that the requirements that it lays down often serve as standards for international trade and have a considerable impact on developing countries, many of which are highly dependent on access to European markets.

The requirements for food safety and checks are laid down by the following Regulations:

1. **Regulation (EC) 178/2002** of the European Parliament and of the Council of 28 January 2002, laying down the **general principles and requirements of food law**, establishing the European Food Safety Authority and laying down procedures in matters of food safety, better known as the '**General Food Law**'**.**

2. **Regulation (EC) 882/2004 of the European Parliament and of the Council** of 29 April 2004**,** commonly referred to as the Official Feed and Food Controls

Regulation.

3. **Commission Regulation (EC) 669/2009** of 24 July 2009 **implementing Regulation (EC) no. 882/2004** of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC. Regulation 669/2009 had its Annex I (list of agricultural products) amended by **Commission Regulation 1099/2010** of 26 November 2010

❑ **Regulation (EC) 178/2002 or General Food Law**

According to this Regulation, the EU policy on food safety must:

- ensure free movement on the internal market;
- ensure a high level of protection of human health, serve the interests of the consumers;
- ensure that food and feed imported to the European Union comply with requirements ensuring safety levels equivalent to those established by the EU (in other words, taking existing international standards or ones in preparation into account).

This Regulation lays down the general obligations of the food trade, which are**:**

- the compliance of the food and feed imported for placing on the market with Community food law requirements;
- the contribution of the Community and the Member States to the drafting of international technical standards relative to food and feed and to the drafting of international sanitary and phytosanitary standards.

The European Food Safety Authority (EFSA) was established and a **standing committee for the food supply chain and animal health** was created. The mission of the EFSA ('the Authority') is to provide opinions and scientific and technical support in all areas that have an impact on food safety. It constitutes an independent source of information on all issues pertaining to these areas and ensures that the general public is informed of the risks. The Standing Committee is composed of representatives from the Member States and chaired by the Commission representative. It is organized in sections for dealing with all relevant matters.

The existing **food safety procedures** were supplemented and reinforced by this Regulation:

➢ ***Rapid alert system***

The rapid alert system (RASFF) was expanded to include all food and feed. This network links the Member States and the Commission, which is responsible for managing it, and, what is new, the Authority as a member of the network.

The Member States use this rapid alert system to notify the Commission, which immediately transmits information of the following nature through the network:

- any measure aiming to restrict the placing of food or feed on the market or to recall food or feed;

- any action undertaken with the professionals with the aim of preventing or regulating the use of food or feed;
- any case of rejection of a batch of food or feed by a European Union border post.

If it concerns a food risk, the information transmitted through the alert network must be made available to the general public.

➢ ***Emergency situations***

When food or feed, whether produced in the Community or imported from a third country, are capable of posing a serious risk to human health, animal health, or the environment and when the risk in question cannot be adequately dealt with by measures taken by the Member State(s) concerned, the Commission will immediately take, either on its own initiative or upon request by a Member State, one or more of the following measures, depending upon the seriousness of the situation: for **products imported from a third country, suspension of the imports, laying down of special conditions, implementation of any necessary interim measures**.

➢ ***General crisis management plan***

In close cooperation with the Authority and the Member States, the Commission draws up a general crisis management plan. This plan specifies the situations implying direct or indirect risks to human health and for which no provision is made by this Regulation, and further specifies the practical measures to take for handling the crisis that would result from such situations. When a situation implying a serious risk cannot be dealt with under the existing provisions, the Commission immediately sets up a crisis unit in which the Authority participates by providing scientific and technical support. This crisis unit collects and evaluates all relevant data and identifies the available options for preventing, eliminating or reducing the risk to human health.

❑ **Regulation (EC) 882/2004: official controls for food and feed**

The General Food Law is supplemented by **Regulation (EC) 882/2004,** commonly referred to as the Official Feed and Food Controls Regulation. The latter establishes the basic framework for **official controls (checks) performed by the competent authorities of the Member States and by the Commission** for ensuring compliance with the food and feed laws, with the Regulation on animal health and well-being, and, to a certain extent, with the phytosanitary rules.

More precisely, as far as **imported products** are concerned, the Official Feed and Food Controls Regulation defines the **general principles** underlying:

- the establishment of import conditions;
- the recognition of equivalence;
- the approval of controls performed prior to export by the competent authorities of third countries;
- the recognition of the need to subject certain goods to specific controls before they are brought into the territory of the European Union.

Imports of **living plants or plant products** are also considered as posing significant risks linked to the introduction of new plant pests and diseases into European Union territory, which could have disastrous consequences for crops and the environment. Before they may be brought into the European Union, all living plants and certain plant products **must**

have a phytosanitary certificate issued by the competent authority of the third country concerned, according to the model established by the international plant protection convention.

Phytosanitary controls, which include documentary checks, identity checks, and physical checks, are **performed at a designated entry point on all batches of regulated plants and plant products**. An exemption, under which the physical checks may be performed at the destination site, may be granted by the national authorities under certain conditions, such as the movement of goods under the supervision of customs authorities. The latter will not authorize imports of plants and plant products without proof that the required phytosanitary checks have been performed and that the results thereof were satisfactory.

❑ **Who performs the official controls of the European Commission?**

➢ ***The Food and Veterinary Office*** **(FVO),** which is the **inspection service of the Directorate General for Health and Consumers (European Commission):**
- annual inspections based on an annual schedule in the Member States and in the third countries (compliance with EU laws);
- routine missions for on-site verification of compliance with the import conditions established for third countries.

➢ ***The European Food Safety Authority*** **(EFSA),** an autonomous regulatory agency unaffiliated with any EU institutions:
- provides the Commission with unbiased scientific opinions on all issues having a direct or indirect impact on the safety of the food supply chain;
- evaluates the risk linked to a given commodity relative to the hazards that it poses.

❑ **Multilateral and bilateral agreements**

The EU plays an active role in the World Trade Organization and in the international standardization bodies. It is thus able to promote its own regulatory model and consequently influence the development of international standards with which it too must comply.

The EU also maintains a standing dialogue on sanitary and phytosanitary (SPS) issues with third countries and **negotiates bilateral trade agreements that contain SPS provisions concerning the agricultural product trade.** In certain cases, these agreements make provision for equivalence recognition, which can lead to an exemption from certain veterinary checks.

The Official Feed and Food Controls Regulation also provides the opportunity for **unilateral recognition of equivalence by the EU throughout the food supply chain.** In keeping with the SPS agreement, each WTO member may ask its trade partners to examine the issue of equivalence recognition. A third country may also request the relaxing of import checks performed at entry in the EU if the checks performed prior to export are reinforced. The latter must be verified by the FVO.

❑ **Perspectives**

The General Food Law and the Official Feed and Food Controls Regulation **shall continue to provide the framework for the checks of food and other products relevant to the food supply chain.**

However, several innovative measures for determining ways for the present system to evolve into a more effective mechanism for coordinating import checks at EU borders are planned.

Most of these changes will result in the anticipated amendment of the Official Feed and Food Controls Regulation; however, **new veterinary and phytosanitary provisions are also under examination.**

Another goal is to ensure coherence with the provisions of the **new modernized customs code, which shall take effect in 2013.**

Also, the **EU phytosanitary regulation shall be revised** to:

- take new realities into account;
- **protect the EU from the introduction and propagation of harmful organisms**, promote sustainable production;
- ensure the competitiveness of the agricultural sector;
- contribute to the protection of forests and landscapes and to food safety. There have been many changes since the present regulations were developed in the 70s, thus justifying the thorough evaluation thereof. These changes in particular include the expansion of the EU, globalization, climate change, as well as an appreciable advancement of the scientific knowledge on which the original phytosanitary regulations are based.

5.2.2. Control of residue levels

The problems of microbial contamination confronting fresh products such as meat, fish, and cold cuts, which can have serious and immediate consequences for human health, are relatively rarely encountered in fruits and vegetables. The main problems encountered in the latter commodities are **pesticide residues.** More and more epidemiology studies are showing an increase in certain diseases among professional pesticide users.

Chromatographic analysis of residues

These effects on consumer health are more difficult to test for, but many scientists suspect that there may be longer term impacts of the same nature and recommend taking the precautionary approach.

The EU pesticide laws are probably the strictest in the world, and the EU has undertaken numerous major reforms. The result thereof is an increased level of consumer protection in the European Union, due in part to **the withdrawal of harmful pesticides from the market and the reinforcement of controls at the EU borders.**

The EU rules on controls were implemented in January of 2010. They are based on Regulation (EC) 669/2009 of 24 July 2009 **implementing Regulation (EC) 882/2004** of

the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC, OJ L 194 of 25 July 2009.

The rules laid down require **reinforced controls at the borders for a certain number of imported fruits and vegetables (Annex I)**. The checks are performed **by the competent authorities of the Member States,** and they focus on a list of products of plant origin originating from certain third counties and requiring reinforced monitoring. Products such as vegetables from Thailand and tropical fruits from the Dominican Republic are on this list, which is reviewed and revised on a quarterly basis.

Among other things, the new scheme makes provision for documentary checks and **pesticide analysis for a wide range of fruits and vegetables such as mangoes, bananas, eggplants, squash, and pears imported from certain third countries.**

Several levels of checks for pesticide residues are implemented before fruits and vegetables reach the tables of EU citizens. These controls are mandatory under EU law and go hand in hand with the strict EU rules on pesticides.

These controls thus apply to all levels of the food supply chain, and to domestic as well as imported products.

The EU primarily established **one common border post for certain fruits and vegetables** since January 2011. **A new scheme** was implemented for **these imported products,** under which **batches are checked at the border before entering the European Union**.

2010 News

Around 13,600 batches of imported fruits and vegetables have been inspected since this scheme was implemented in January of 2010. 10% of these products were tested, and 10% of those tested were found to be non-compliant with the EU safety requirements.

A second Regulation made some changes to Regulation (EC) 669/2009, namely: **Commission Regulation (EC) 915/2010** of 12 October 2010 concerning a **coordinated multiannual control programme of the Union for 2011, 2012 and 2013 to ensure compliance with maximum levels of and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin**.

This Regulation went into effect on 1 January 2011 and it establishes the **procedures for taking and analyzing** samples for combinations of products and pesticide residues from 2011 to 2013. It applies to samples taken in 2010.

Annex I of this Regulation is the list of food/pesticide combinations. The foods are:

- beans with pod (fresh or frozen), carrots, cucumbers, oranges or mandarins, pears, potatoes, rice, spinach (fresh or frozen), and wheat flour;
- eggplants, bananas, cauliflower, table grapes, orange juice (concentrates or fresh fruits), peas without pod (fresh/frozen), peppers (sweet), wheat, and olive oil;

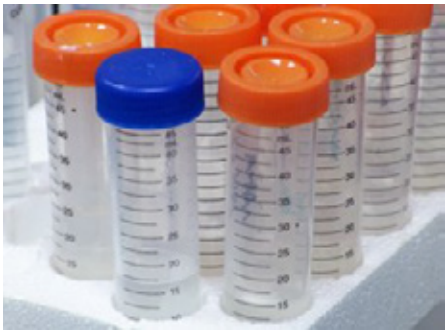
- apples, head cabbage, leek, lettuce, tomatoes, peaches, including nectarines and similar hybrids, rye or oats, strawberries and (red or white) wine grapes;
- butter, chicken eggs;
- cow's milk, pork;
- poultry meat, liver (bovine and other ruminants, swine and poultry);
- cereals (excluding rice), table grapes, and pears.

Article 2 of this Regulation also stipulates that:

- the batch to be sampled shall be chosen **randomly**,
- the sampling procedure, including the number of units, must comply with the provisions of **Directive 2002/63/EC**;[2]
- the samples shall undergo analyses in accordance with the residue definitions set forth in Regulation **(EC) 396/2005**.[3]

Lastly, article 3 makes the following provisions:

- The Member States shall disclose the results of the sample analyses performed in 2011, 2012, and 2013 on **31 August 2012, 2013, and 2014,** respectively.
- In addition to these results, the Member States shall provide the **following information**:
  - the methods of analysis used and the notification thresholds attained, in keeping with the document on the validation of the methods and the quality control procedures for analyses of pesticide residues in food and feed. When qualitative detection methods are used, results below the detection notification threshold can be listed as "not detected";
  - the determination limit used in the national control programmes and in the European Union control programmes;
  - the details of enforcement measures taken, when permitted by national laws;
  - in cases where maximum residue levels (MRL) were exceeded, a statement of the reasons that could explain this excess, together with all relevant observations regarding possible risk management solutions.
- When the definition of a pesticide residue comprises active ingredients, metabolites, and/or degradation or reaction products, the Member States shall disclose the analysis results corresponding to the legal definition of the residue. Where appropriate, separate analysis results for each of the main isomers or metabolites mentioned in the residue definition shall be provided.



[2] Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC.

[3] Regulation (EC) 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

6.3. How the controls are organized

6.3.1. A reminder of the legal framework

Internationally, the OECD (Organization for Economic Cooperation and Development) has implemented a scheme for fruits and vegetables. This scheme provides a **comprehensive and internationally harmonized quality inspection system,** the purpose of which is to **encourage the participating countries to mutually recognize each other's inspections.**

There are two levels of control ***in the European Union***: checks for the **health quality** of agricultural products and **checks for residues** in those products intended for human and animal consumption. These two controls are performed by the **European Union Member States,** as well as by the **European Commission** itself in the Member States in order to ensure compliance with the Regulations in effect in European territory.

Control by the Member States is regulated by (3) main Regulations: **Regulation (EC) 178/2002**, **Regulation (EC) 882/2004**, and **Regulation (EC) 669/2009**.

Each Member State has **its own agency(ies) and laboratory(ies) for inspecting foods** entering its territory.

The Commission, in its role as guardian of the European Community Treaties, is responsible for ensuring that Community legislation on food safety, animal health, plant health, and animal welfare is properly implemented and enforced. As a Commission service, the **Food and Veterinary Office (FVO)** plays an important role in fulfilling this task.

The FVO is responsible for issuing inspection reports:

- Veterinary inspections
- Phytosanitary inspections
- Inspections concerning the contamination of food and feed
- Food hygiene inspections
- Inspections concerning the irradiation of food
- Genetically modified food inspections
- Pesticide inspections
- Inspections relative to the controls on the trade and the use of plant protection products and pesticide residues in food on the national scale
- Annual reports on pesticide residue monitoring in the European Union
- Organic agriculture inspections
- Special reports *(the reports published under this heading contain an overview of a specific topic relating to a series of inspections performed in Member States or in third countries).*

6.3.2. How the controls are organized on the international level

The control of agricultural products is the **responsibility of the exporting country or of the exporter itself,** which must provide assurance that the products that they export comply with the health quality standards and residue limits. It is also the **responsibility of the importing country to ensure** that the food imported in its territory complies with the international standards.

Developing countries that mainly export their products to Europe and Asia, however, are better off adopting the ***Codex Alimentarius* standards** rather than undertaking the laborious and expensive process of elaborating their own standards.

However, **Europe** also **has strict regulations concerning the quality of foods imported from third countries**, and agricultural products being shipped to a European Union Member State must comply with these regulations.

As a reminder, the *Codex Alimentarius* is a harmonized set of internationally adopted food standards. The purpose of these standards is to protect consumer health and interests and to ensure the fairness of the practices followed in the food trade. The nature of the Codex standards is such that adopting them supports an inspection system based on solid grounds.

The documents produced by the Codex in the form of standards, reports, notes, codes of practice, etc. can be enormously valuable to national agencies in charge of the inspection of foods, as they **enable** these agencies to **strengthen the capacity of their own programmes, to review their priorities, and to train their inspection office staff.** Besides the Codex standards, there are **codes of practice,** two of which are particularly important: *General principles of food hygiene* and the *Code of ethics for international trade in food.*

6.3.3. How the controls are organized in Europe

The organization of the control entities in the EU Member States is essentially regulated by **Regulation (EC) 882/2004,** which aims to fill the gaps in the existing laws on the official control of food and feed by means of a harmonized Community approach to designing and implementing national control systems.

Within the meaning of this Regulation, "official control" is understood to mean: **any form of control implemented by the competent authority or by the Community for verifying compliance with the feed and food laws** as well as provisions concerning animal health and well-being.

❑ **Frequency, items to control**

Official controls are performed:

- **routinely**;
- in principle **without advance notice;**
- at **any phase of the production**, processing, or distribution of feed or food;
- according to the **identified risks**, the experience and knowledge acquired from past controls, the reliability of the controls already performed by the producers in the sectors concerned, and upon suspicion of any shortcomings.

❑ Competent authorities in the Member States

The Member States designate the authorities that are competent to carry out official controls (often the **Ministries of Agriculture, Health, Industry, and Trade**). These authorities must:

- satisfy **operational criteria** ensuring their efficacy and impartiality;
- have **suitable equipment, duly qualified staff,** and emergency action plans in place. Internal or external audits may be performed to ensure that the competent authorities are achieving the objectives laid down in the Regulation.

In cases where some of the controls are delegated to regional or local entities, effective collaboration between the central authority and these different entities is a must.

The competent authority may delegate specific control tasks to **non-governmental organizations (laboratories, research centers)** if the latter fulfil the strict conditions outlined in the Regulation. These organizations must be audited or inspected.

❑ Sampling and analysis

The sampling and analysis methods employed in official controls must be validated in accordance with Community laws or internationally recognized protocols (*Codex*, OECD etc.). These analysis methods must take the criteria set forth in Annex III of the Regulation into account and must be implemented by laboratories certified for this purpose, in accordance with the standards developed by the European Committee for Standardization (*Comité européen de normalisation* – CEN).

For more information on the analysis methods
(Annex III, Regulation (EC) 882/2004):

1. The analysis methods must be characterised by the following criteria:
   a) accuracy
   b) applicability (concentration matrix and range)
   c) limit of detection
   d) limit of determination
   e) precision
   f) repeatability
   g) reproducibility
   h) recovery
   i) selectivity
   j) sensitivity
   k) linearity
   l) margin of error
   m) other criteria may be retained according to needs.

2. The values characterising precision referred to in point 1 e) are:
   - either obtained from a **collaborative trial conducted in accordance with an internationally recognised protocol** for this type of trial (e.g. ISO 5725:1994 or the IUPAC international harmonised protocol),
   - or, when performance criteria for **analytical methods have been established, based** on criteria compliance tests. The values for repeatability and reproducibility, respectively, shall be expressed in an internationally recognised form (e.g. 95% confidence intervals, as defined in ISO 5725:1994 or by the IUPAC). The results of the collaborative trial shall be published or made accessible without restriction.

3. Preference shall be given to **methods of analysis uniformly applicable to diverse groups of products** over methods solely applicable to specific products.

4. In situations where the methods of analysis can **only** be validated **in one laboratory,** they must be **validated according to the IUPAC harmonised guidelines**, or when performance criteria for the analytical methods have been established, be based on criteria compliance tests.

5. **Methods of analysis** adopted under this Regulation **must be edited in the standard layout for methods of analysis recommended by the ISO.**

❑ National official laboratories

National official laboratories are designated by the competent authority in the Member State and are authorized to analyze samples taken during official controls.

However, the competent authority may only designate laboratories that perform their activities and that have been evaluated and accredited in accordance with the following European standards (official certification)[4]:

- **EN ISO/IEC 17025** "General requirements for the competence of testing and calibration laboratories";
- **EN 45002** "General criteria for the assessment of testing laboratories";
- **EN 45003** "Accreditation system for testing and calibration laboratories – General requirements for management and recognition"; taking into account the criteria applying to the various testing methods laid down by the Community laws on feed and food.

The competent authority may cancel the designation when the conditions set forth above are no longer fulfilled.

❑ Community reference laboratories

Several Community Reference Laboratories (CRL) have been established (Annex VII of the Regulation) in the scope of the Community legislation in effect. They may receive financial support from the EU and their duties are to:

- **supply the national reference laboratories with detailed information on the methods of analysis;**
- **set up comparative trials** and coordinate, within their areas of competence, the necessary practical and scientific activities for obtaining new analytical methods;
- **coordinate training;**
- provide **technical support to the Commission**.

The Member States shall ensure that one or more national reference laboratories are designated for each CRL. The latter function as the point of communication between the CRL and all the official laboratories in the Member States.

❑ Control of products originating from third countries

These aforementioned controls consist of at least a document check, an identity check, and where appropriate, a physical check. In cases of confirmed non-compliance with the laws, the products concerned may be **seized or confiscated and destroyed,** subjected to a special treatment, **or shipped out of the Community at the expense of the producer responsible for the non-compliant batch**.

❑ Controls performed in third countries

Third countries wishing to export goods to the EU must provide the Commission with information on the general organization and management of their health control systems. If this information is not satisfactory, the Commission may take provisional measures after consultation with the country concerned.

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[4] The procedure by which the competent authority or the control bodies authorised to act in this capacity attest to compliance, either in writing, by electronic means, or by other equivalent means.

❑ **Funding for the official controls**

Funding is the responsibility of the Member States, which must ensure that adequate financial resources are available for the organization of official controls. However, the minimum fees or charges linked to the official controls of Community establishments, which are the fees received by the Member States for inspection visits to (mainly livestock) production sites, can be found in the Regulation (Annexes IV to VI).

6.3.4. How the control bodies and the official laboratories operate

❑ **The control bodies**

'Control body' is understood to mean an independent third party **to which the competent authority (**Ministries of Health, Agriculture, Industry, or Trade etc.) has **delegated certain control tasks** related to animal products, living animals, and foods.

In the European area, the control bodies that inspect imports of food are often a **division or a national directorate of a ministry** (competent authority), such as the **Ministry of Health** where health inspections of imports of food of non-animal origin are concerned, or the **Ministry of Agriculture** where phytosanitary inspections of imports of food of plant origin are concerned.

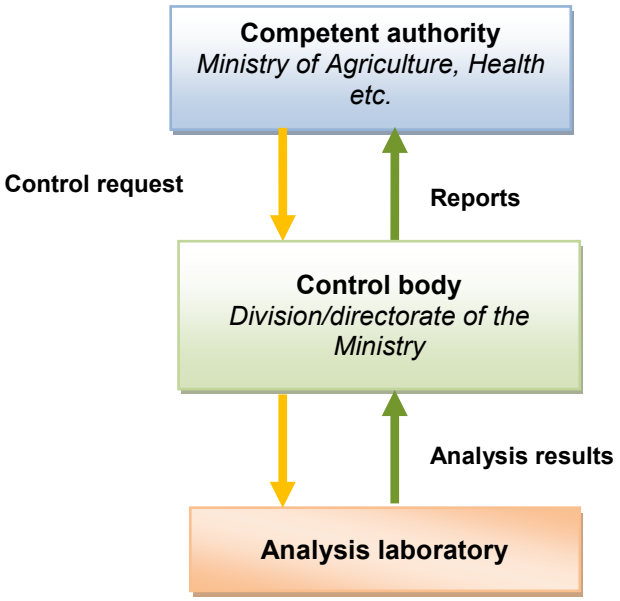
The national control body handles the formalities involved in the application of European Regulations.[5] The foods in the list of Annex 1 of the aforementioned main Regulation (669/2009) mentioned above are integrated in the list of products subject to an analytical control handled by the division and provided to the **Customs and Excise Administration**.

This administration has integrated the foods in question in its risk analysis system.

When a food in the list of Annex 1 of Regulation (EC) 669/2009 is presented for import, the importer informs the control body accordingly (using the common entry document: CED). The latter then decides, on a case by case basis, which checks to perform on the products in question.

The control body then has the required laboratory analyses performed and receives the analysis reports. It then drafts an evaluation report, which specifies the final destination of the inspected food.

[5] Regulation (EC) 669/2009 of 24 July 2009 implementing Regulation (EC) 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC.



❑ **The national control laboratories**

These laboratories operate in accordance with the **ISO and IUPAC standards** as well as the **European EN** standards, as required by the European Regulations. Most of these laboratories operate under the **GLP principles** or Good Laboratory Practices established by the OECD.

➢ ***ISO/IEC 17025:2005***

It is an international standard implemented by the International Organization of Standardization (ISO), which lays down the **general competence requirements for performing trials and/or calibrations, including sampling**. It covers the trials and calibrations performed by standardized methods, non-standardized methods, and methods developed by the laboratories.

It applies to all organizations that perform trials and/or calibrations; for example, first, second, and third party laboratories, as well as laboratories where trials and/or calibrations are part of product control and certification.

ISO/IEC 17025:2005 applies to all laboratories regardless of their personnel and the scope of their testing and/or calibration activities. ISO/IEC 17025:2005 is intended **to be used by laboratories that develop their own management systems for quality and administrative and technical activities.** It can also be used by laboratory clients, regulatory authorities, and accreditation bodies engaged in the activities of confirming or recognizing the competence of laboratories. ISO/IEC 17025:2005 is not intended to be used as a standard for laboratory certification.

➢ ***The EN 45000 series of European standards***

It comprises three standards:

- **EN 45001**: the purpose of this standard is to establish **quality criteria for recognizing a testing laboratory as competent and reliable**, in order to facilitate the accreditation[6] thereof and to benefit international trade. The laboratory **must apply the EN 45001 standard in order to be accredited.**
- **EN 45002**: this standard lays down the **quality criteria enabling the evaluation of testing laboratories** for accreditation, in order to facilitate international trade. The evaluation procedure must comply with the EN 45002 standard.
- **EN 45003**: this standard lays down **quality criteria for acknowledging the competence and reliability of a testing laboratory accreditation body**, in order to facilitate international trade. The organization and operation of the accreditation body must comply with the EN 45003 standard.

The criteria defining the EN 45001 standard relate to the various operational aspects of a laboratory, mainly:

- management and organization;
- staff;
- sites and equipment;
- work processes;
- analysis results in the case of a medical analysis laboratory;
- record keeping (archiving of activities performed or of results obtained);
- confidentiality and security;
- cooperation with clients and with other laboratories.

To become accredited, the laboratory must submit an official application to the accreditation body, in which it specifies/states:

- the scope of the desired accreditation, i.e. the tests or measurements for which the accreditation was requested;
- the commitment to comply with the accreditation procedure, notably to welcome the auditing team, to pay any duties owed, and to pay the fees incurred from the subsequent monitoring of the accredited laboratory;
- all required information for evaluating the laboratory, notably the general characteristics of the laboratory, human and technical resources, description of the quality control system, list of tests for which accreditation is being requested, the names and titles of the persons in charge of technical validity, test report templates etc.

The accreditation body shall designate an auditing team with the necessary qualifications for evaluating the laboratory. This auditing team shall be composed of experts who are industrial and health professionals commissioned by the accreditation body and bound to professional secrecy in the conduct of their audit.

Accreditation is issued for a period of 3 years to the requesting laboratories that have satisfied the conditions. At the end of this period the accreditation must be renewed. The validity period of renewed accreditations is then set at 4 years. Accreditation may be revoked or suspended, totally or partially, at any time should it be ascertained that the laboratory is no longer in compliance with the requirements of the accreditation body or fails to fulfil its commitments.

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[6] Accreditation: Procedure by which an authoritative body formally recognises that another body or person is competent to perform specific tasks (Source: ISO/IEC Guide 2:1996).

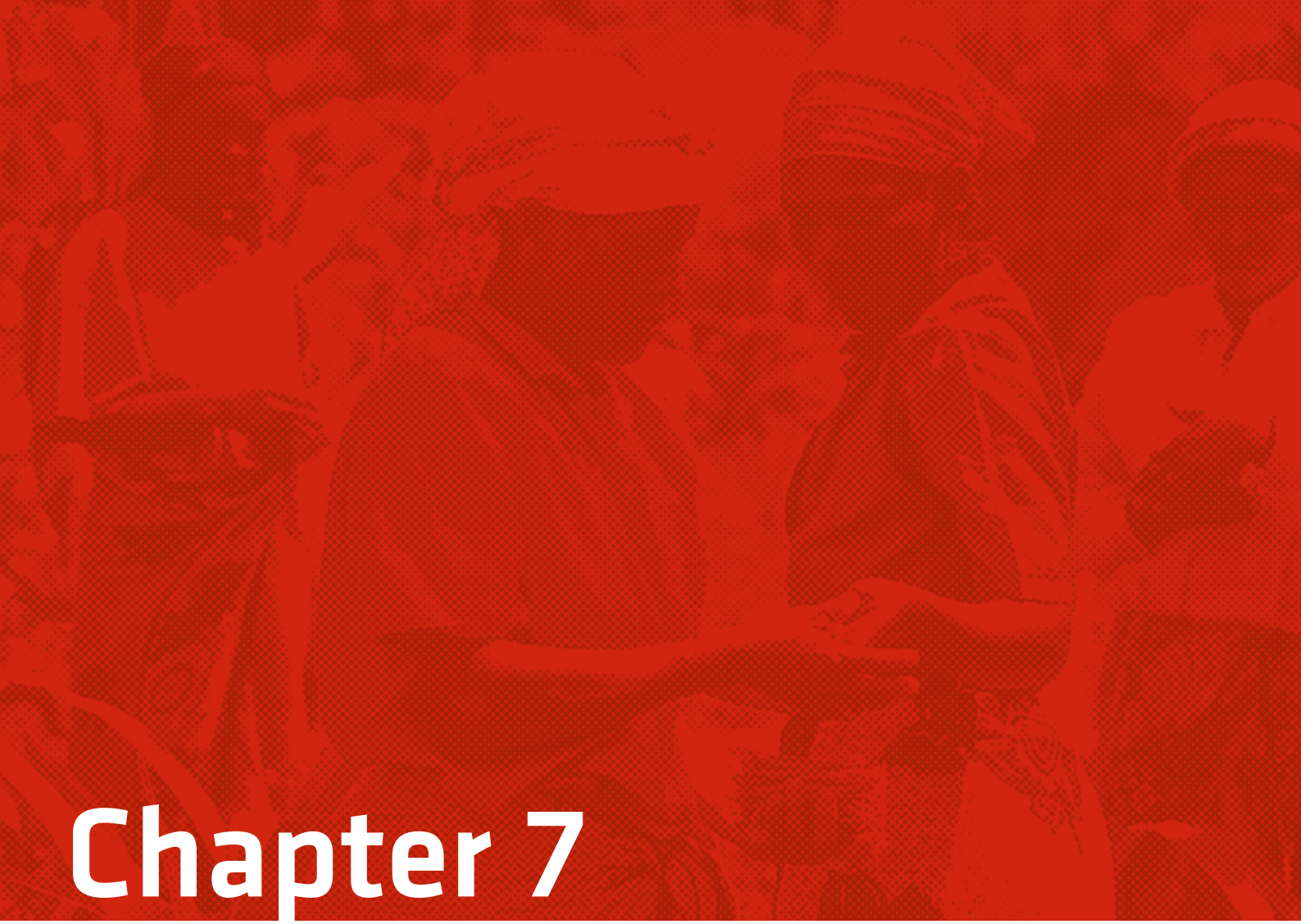
➢ ***The OECD (Organization for Economic Cooperation and Development)***

It has set forth a certain number of **Good Laboratory Practices** and means for verifying compliance with these principles.

Good laboratory practices are closely linked to this concept of total quality. They are a **quality assurance tool, and established for ensuring the validity of the results provided by the laboratory.**

This concept has been in use in industry for several decades. The interest of GLPs is a much broader integration of all laboratory components that goes beyond mere quality control.

The first thing that needs to be done when a laboratory wants to make itself GLP compliant is to draft a *Quality Manual*. The objectives set for each of the methods used and the procedures describing each operating method precisely must be stated in this manual. In truth these GLPs are very demanding on the organization, the staff, and the installation of a laboratory, the equipment, the materials, the reagents, and the operating methods. Checks in the form of inspections and study audits are performed in order to verify the correct application of Good Laboratory Practices.



Chapter 7

Registration and control of plant protection products and biocides

7.1. Introduction

This document sets out the objectives and general principles of registration and control of plant protection products and biocides. It is important therefore to begin by specifying what is meant by those terms.

7.1.1. What is a plant protection product?

There are different definitions of plant protection products (PPPs), also referred to as phytosanitary products or pesticides (a term used less and less because of its negative connotations, in particular in the French language). The definition can vary from country or group of countries to another and therefore the field of application of plant protection legislation may also vary on the basis of the definition.

More generally, a 'plant protection product' is a product with the purpose of protecting a plant against disease, pests or weeds, also called adventitious plants.

There are several **categories of plant protection products**, determined on the basis of their purpose:

- fungicides to control fungal plant diseases, those caused by pathogenic fungi;
- bactericides to control diseases of a bacterial origin;
- insecticides to control insects (arthropods with three pairs of legs);
- aphicides, which are insecticides to control aphids;
- acaricides to control acarids (arthropods with four pairs of legs);
- molluscicides to control molluscs (such as slugs);
- Plant-growth regulators: these products affect the life cycle and development of plants to change their size or appearance, the quantity of flowers and fruits etc.;
- adjuvants: these are products that do have a direct effect on a disease, pest or weed but which improve efficacy by their ability to act as wetting, sticking, penetrative agents etc.

7.1.2. What is a biocide?

Here too there are different definitions. One of them summarizes the situation well by indicating, in particular, that biocides “are products which are intended to destroy, deter or render harmless, to prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means”.[1]

Note: if the target treated is a cultivated plant, we are dealing with a plant protection product.

[1] Federal Public Health Department, Belgium.

The above definition could also apply to plant protection products if it did not exclude from its field of application the treatment of cultivated plants.

There are many uses for biocides; for example, European legislation has identified **4 groups**, each subdivided into a total of **23 types**:

- ***Group 1:*** Disinfectants and general biocidal products, including disinfectants
- ***Group 2:*** Preservatives, for example wood preservatives
- ***Group 3:*** Pest control products, for example rodenticides used to control rodents
- ***Group 4:*** Other biocidal products, for example products used for the preservation of food or feeds through the control of harmful organisms

For example, and to make a clear distinction between biocides and plant protection products, an insecticide used to control insects on a crop such as potatoes or tomatoes is considered to be a **plant protection product**; the same product used to eliminate cockroaches in industrial premises or in kitchens is classified as a **biocide**.

7.1.3. What does registration of plant protection products (PPPs) and biocides involve?

This is the set of procedures covering an application to the authorities and their approval (or rejection) to place on the market a PPP or biocide.

Since these products are not without potential harm for human health and for the environment, they cannot be freely sold but are, on the contrary, subject to approval (*i.e.* **authorization for placing on the market** or **approval** of the product by the authorities).

An application is generally made by a company that markets such products. But it may also come from farmers faced with a particular plant protection problem, or public bodies wishing to provide farmers with a solution to their problem. The latter cases occur notably when no company submits an application because the market is too small (i.e. minor uses, for example to control diseases in crops grown on small land parcels at country level, such as aromatic plants or berries).

The application is accompanied by a very detailed file presenting the characteristics of the product, the conditions for their use (uses, corresponding doses, etc.) and the risk assessment that all lead the applicant to propose the use, being that it is acceptable from a human health and environmental view point.

The definition is given below, together with examples of this acceptability criterion.

❑ **Who handles it?**

In the past, the authority responsible for registering PPPs and biocides often reported to the Ministry of Agriculture. The growing recognition of the risks to health and the environment linked to their use had led to them being attached to the government agencies responsible for public health and the environment. Experts coming from the

different authorities concerned (public health, environment, agriculture, economic affairs, etc.) and university circles take part in assessments under the aegis of the agency.

7.1.4. What is control?

It is all the procedures and actions making it possible for the authorities to ensure that the products are properly used in accordance with the legislation and regulations and do not present an unacceptable risk to the public and the environment.

In certain cases, the authorities, which cannot be present everywhere and at all times, delegate part of the appraisal to farming networks/supply chains, for them to ensure that all their practices abide by the law. This is referred to as self-assessment. This must, of course, be documented (to ensure **traceability**: **which** includes holding registers in which treatments with PPPs or biocides are recorded) so that the authorities can check compliance at their convenience.

❑ **Who is responsible for the control?**

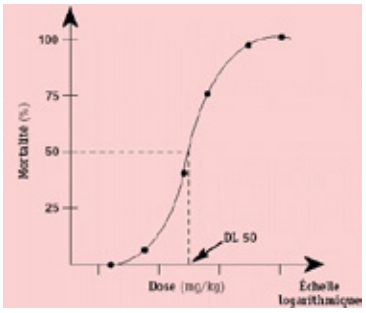
To ensure that it is systematic and to prevent conflicts of interest, it must be entrusted to an agency separate from that responsible for registration. Often this agency is responsible for monitoring the safety of the entire food chain. The checks are conducted at their critical points (manufacturers, distributors, farmers, storage agencies, processing industries, wholesale sector, etc.) and relate to product conformity (packaging, labels, storage conditions, residues, proper operation of spraying equipment, etc.)

7.2. General principles

In accordance with generally recognized risk management principles (risk analysis, risk management and communication measures), the general principle of registration is based on risk assessment, that is to say, comparison of the intrinsic danger of the product with the hazard presented by exposure to persons and other living bodies to be protected.

7.2.1. The hazard

The hazard represented by an active plant control or biocidal substance (the substance which, within the commercial preparation, gives the effect sought) is generally qualified and quantified using measurable criteria, such as:



- the **lethal dose 50%** (or **LD_{50}**) or dose which if administered all at once, would result in the death of half of the animals tested (generally laboratory rats). It is a measurement of the acute toxicity of substances, that is to say, their immediate toxic effect follow the ingestion of that substance alone but in a massive quantity;
- the **No observable effect level** (NOEL) that is to say the dose which administered regularly to rats throughout their life, for example orally through a feed bowl, has no observable effect of any kind whatsoever on their health. The NOEL is a measurement of the chronic toxicity of substances, i.e. their toxicity in the long term following repeated exposures to low doses for a lifetime.

Such criteria determine the intrinsic danger of the substance; they are linked to its nature. However, a product, even if it is very dangerous, will only have a toxic effect if its target is exposed to it (involuntarily or accidentally in the case here).

7.2.2. Exposure

Exposure to a toxic substance corresponds to its actual absorption by a person, non-target organism or the environment. It can be measured, or in contrast estimated, on the basis of mathematical models simulating what happens in a real scenario where a field, premises, etc., are treated.

To full understand the difference between hazard and exposure, let's take the example of a visitor to the Masai Mara national park in Kenya: the lions that live there are dangerous animals, particularly when they are hungry, but visitors who abide by the safety instructions and do not leave their vehicle and keep the doors closed are not exposed to the lions' bite. The risk assessment we have just done based on this example shows us that the visit to the park under those conditions is acceptable since visitors who abide by the instructions do not take any real risk with their lives.

7.2.3. Risk assessment

It is therefore the combination of hazard and exposure in order to ensure that the dose of the toxic substance to which a living body organism is exposed is below the hazard threshold, that is to say, the dose at which the substance gives its initial adverse effects.

Assess the risk to health and to the environment, both of which are exposed

7.3. Registration of plant protection products and biocides

7.3.1. General objectives

As indicated in the introduction, these products are not without danger for man nor for the environment. This is why their use is regulated.

❑ **Protection of humans**

The aim of the legislation and regulations is to ensure that the exposure of people to PPPs or biocides does not have adverse consequences for their health, neither in the short term (following an ad hoc exposure during a treatment, for example) nor in the long term (for example, when, as a consumer, we regularly ingest small quantities of residue from those products present on fruit, vegetables or in the water supply that we consume each day).

❑ **Protection of other living beings**

Since PPPs and biocides are intended to control living organisms considered to be harmful (in relation to farming, industrial processing activities, disinfection of premises, etc.), they have the potential to also affect other living organisms. For example:

- The cloud from spraying an herbicide that drifts beyond the confines of the field could destroy adjacent flora found in a neighboring field or aquatic flora in an adjacent stream!

Illustration of the phenomenon of drift due to the wind

- The residue of a biocide product poured down the drain, for example when the spray equipment is inappropriately rinsed, may also contaminate surface water or underground waters, and therefore affect aquatic organisms (such as fish, water plants) and man (through drinking water).

Emptying surplus quantities and inappropriate rinsing of the packaging

The object of the legislation and regulations is to protect living beings that are not the target from the adverse effects of treatment.

❑ **Environmental protection**

Water, ground and air must also be protected from potential pollution. For this reason, the legislation and regulations require a study to be conducted on the behavior and outcome of active substances in the environment: how do they degrade and at what speed? Under what conditions? What products (metabolites) arise from the degrading?…

7.3.2. Specific objectives

In this section, we will discuss the specific protection objectives of each of the categories concerned and defined above: humans, organisms not targeted and the environment.

❑ **Protection of humans**

➢ ***Means of exposure***

As humans, we may be exposed to plant protection products and biocides by various means:

- **Orally:** if we accidentally swallow a product, but also by consuming every day food that may carry product **residues**: fruit, vegetables, meat, milk, water, etc. This exposure route is therefore very relevant for the food **consumers** we are.

Food is a source of oral contamination for consumers.

- **Through the skin and mucous membranes:** this corresponds to penetration of the product through the skin or the mucous membranes (eyes). This is especially relevant for product users if they not adequately protected (burns, irritation, allergic reactions etc.).

This operator is not wearing gloves, nor a suit or a mask; he is therefore exposed to the product he is applying, not only through the skin but also through inhalation (respiration).

Source: B. Schiffers

- **Inhalation:** this is when you breathe in the mist from a sprayer. This contamination route is relevant to those applying products but also for **spectators**, people who are present while treatment is going on but are not taking part in that treatment.

The spectators (here, children) are present on the site when the treatment is applied (here, ornamental trees).

Source: B. Schiffers

❑ Consumer protection

As suggested above, we are all consumers since we all ingest foodstuffs; If the residue content of foodstuffs does not exceed the legal ceiling (MRL: maximum residue limit), the consumer runs no risk to health, in the short term (acute poisoning) or in the long term (chronic poisoning).

MRLs are, indeed, set so that the quantities ingested in a lifetime are below a toxic ceiling (combined with an adequate safety factor). This safety factor takes into account differing degrees of sensitivity to toxic substances (infants, pregnant women and the elderly are deemed to be categories particularly at risk), and the fact that toxicity trials are conducted on laboratory animals (such as rats) which may be less sensitive to the toxic substances than man.

❑ User protection

This means the operator, the person who handles and applies the product. For this category, the main routes of exposure are inhalation and more particularly through the skin. Effective protection can only be ensured through the systematic use of **personal protection equipment (PPE)** such as masks, protective goggles, gloves and overalls. Prior to registration the regulatory authorities check that the exposure of the user (also referred to as the operator), under the conditions for the use of the product given on the label, is below the **no observable effect level (NOEL), again accompanied by a safety factor (generally 100)**.

If the PPE is not used correctly, unfortunately often the case, the doses to which the operator is exposed may increase rapidly and exceed the no-observable-effect level.

❑ Protection of other population categories

As indicated above, this primarily relates to spectators, that is to say people to be found on the treatment site or in its immediate vicinity who are not directly involved in the work underway (walkers, people in gardens bordering fields, people entering premises that have been treated with a biocide etc.).

For this category too, the primary means of exposure are inhalation and through the skin. The risk is assessed in a way similar to that for users indicated above. The exposure is less high, but the risk is by no means negligible since spectators, by their very nature, are not wearing any PPE. Again, the conditions for the use of the product given on the label must be such that exposure to the product is below the no observable effect level, accompanied by a safety factor - generally equal to or above 100.

❑ Protection of other living beings

In this case, like that for humans, the risk is generally assessed by comparing the NOEL against the toxic concentrations (the active substance of the product trialed) to be found in the environment. These are determined by taking measurements *in situ* (for example, in the water of a river), or in an experimental set-up that simulates, as far as possible, the real circumstances in practice (for example, a small parcel of land on which a maximum number of parameters are monitored, such as temperature, rainfall etc.). Another method, often adopted, is to use predictive mathematical models based on what has occurred in reality when, for example, a product used to protect wood against pests is found in surface water after the treated wood is exposed to bad weather.

It is then for the authorities to ensure that the concentrations of the toxic substances to be found in the environment (for example, water in rivers) are well below the no observable effect level for fish in the river. Here too these concentrations are calculated with a safety factor to allow for the differing degrees of sensitivity of species and people and for the fact that the conditions in practice sometimes differ from those prevailing during trials.

This process is repeated for the other categories of non-target organisms (NTOs), such as crustaceans, aquatic plants, birds, arthropods present in the soil or sediments, bees and other useful types of fauna etc.

❑ Environmental protection

In addition to the living organisms not targeted by the treatment and/or present outside the area to be treated, it is also necessary to protect the environment – the water, soil and air – we share with the animal, vegetable and microbial species that ensure biodiversity.

The legislation and regulations on product registration plays an important role in this regard since these rules establish acceptable usages and prohibit those that pose a genuine threat to the environment.

It should be noted, however, that legislation and regulations alone do not suffice. To protect the environment (water, air, soil, non-target organisms), the use of products must be accompanied by measures either voluntary or mandatory (through other laws and regulations), in the following areas, in particular:

- training for stakeholders (users, sellers, advisers);
- inspection of spraying equipment;
- promotion of alternative pest control methods (as part of a holistic approach that combines all direct and indirect methods of control of a physical, chemical and biological nature). For example:
  - to control fruit and vegetable diseases, use less sensitive varieties, products of a natural origin, practice crop rotation, limit use of fertilizers, maximize the number of plants per hectare, etc.;

  - or in the case of pest control within buildings, eliminate the sources, use traps and equipment for physical destruction, improve site cleanliness and hygiene, etc.;
- monitoring the quality of the environment, and in particular water;
- statistical tools for measuring changes in the quantities of products used over time.

In these areas, an important role is played by stakeholders in the sectors concerned, and in particular research institutes and rural extension institutes, trade associations (such as farmers' unions or agrochemical industry), international institutions, but also national and/or supra-national authorities (such as the European Union through **Framework Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides**, transposed at national level by specific plans aimed at reducing the impact of plant protection practices on man and the environment).

Voluntary and mandatory programmes are therefore putting in place **agri-environmental measures** to provide greater protection for the surrounding environment: Grass buffer strips designed to trap and degrade contaminants, flower strips for fauna, anti-erosion techniques, hedgerow planting etc.

The presence of grassland to the left of the stream and of a grass buffer strip to its right is an efficient method to reduce transfers of pollutants (PPPs, fertilizers) to the brook visible in the middle of the photo.

Source: B. Bodson, Gembloux Agro-Bio Tech

Perennial flower strip (5 years); after three years, apiaceae prevail over poppies and cornflowers.

Source: T. Nuytten

'Hunting-style' grass buffer strip with a drying surface, nesting area and feeding area for birds and small mammals.

Source: T. Nuytten

Furrow-diking of potatoes in order to limit run-off and erosion.

Source: A. Maugnard

❑ Protection of water

The earth has a constant quantity of water that circulates between the land surface, the oceans and the atmosphere as part of what is referred to as the 'water cycle'. More than 9/10th of this water is salty and therefore unsuitable for human consumption. The remainder consists of fresh water, be it on the surface (watercourses and stretches of water) or at a depth (underground water, including water tables). The water we drink has therefore already been used in centuries past. It is therefore a rare resource that is essential for life and the quality of which must be ensured.

Fresh water (rivers, lakes, ponds, etc.) and salt water must be protected.

Specific legislation has been written to protect water quality. For those aspects linked to its use, legislation on plant protection products and biocides also lays down a number of provisions aimed at assessing the risks of contamination and at limiting them quantitatively.

Water generally falls into the following categories:

- surface waters (ditches supplied constantly or intermittently with water, watercourses and stretches of water);
- deep and underground waters, including water tables.

Agriculture is a major source of water pollution, in particular pollution of fresh underground and surface waters from which pollutants can flow to the sea.

Work around a well in Burkina Faso

Source: B. Schiffers

Indeed, in contrast to industry where the growing trend is to discharge effluents after treatment (decontamination), agriculture spreads PPPs and fertilizers over large areas of farmland with a percentage being transferred directly to the water. However, due to legislation and regulations and the fact that PPPs are captured by ground vegetation then broken down, particularly in the soil, it is clear that in the vast majority of cases pollutants

have an ad hoc and sometimes accidental nature: Leaks from containers that are not properly closed, starting or rinsing spraying equipment on surfaces that are not water tight, etc.

Although domestic usage of PPPs and biocides represents a small proportion of the total products used, the non-professional public is much less aware of protection issues and thus account for the vast majority of cases of pollution (inappropriate rinsing of packaging and sprayers, overdosing, etc.).

It is for this reason that many countries are now distinguishing between professional and domestic registration. This ensures that the products used each segment are different and are identified as such administratively, so that they can be monitored more closely and their risk can be managed more effectively (the authorities may, for example, limit or prohibit certain uses on the amateur market, monitor the quantities of the products which are sold etc.).

The FAO (Food and Agriculture Organization) establishes guideline values for the concentration of numerous pesticides in waters intended for human consumption. These standards are less stringent than certain regional or local standards. For example, European legislation (Directive 98/83) states that water intended for human consumption must not contain more than 0.1 microgram/l of the active substance of any given plant protection product (and its metabolites and degradation products) and no more than 0.5 microgram/l for the total substances measured.

❑ Soil protection

The active substances in PPPs and biocides, once applied, may also migrate to the soil. This is relatively obvious for active substances present in plant protection products since once applied to the crop they will be broken down in part on site or absorbed by the plant, the residue being transferred to the soil or the residue will be affected by the following physic-chemical and biological phenomena:

- the extent to which it is soluble in water, which will reduce the length of time the substance is present in the sub-surfaces (layers) of the soil but increases the risks of contamination of subterranean waters;
    - Adsorption (adhesion, bonding) on soil particles and on organic matter deriving from the decomposition of vegetation and on clay particles. This phenomenon is reversible given that under the effect of other mechanisms the active substances end up detaching themselves and being transferred to the water in the soil, but it increases the length of time they are present in the soil (its 'persistence'), measured in half-life or 'DT50', that is to say the number of days necessary to reduce by half the quantity initially present in the soil);
    - degradation (also referred to as metabolization) of the active substance, under the combined effect of temperature, oxygenation, humidity, acidity (measured by the pH of the water in the soil) and the macro-organisms (such as worms) and micro-organisms (such as fungi and bacteria) living in the soil. The speed of degradation varies depending on the chemical composition of the molecules concerned.

The intermediary products produced by this degradation are called metabolites. The end products are water, carbon dioxide, other simple molecules, and sometimes also a proportion that does not degrade or is less degradable which may combine with more or less stability with soil particles (the clay-humus complex).

All these phenomena must be carefully analyzed and quantified in order to determine precisely the behavior of the pollutants and their outcome in the environment, as well as the environmental risks linked to their use in order to be able to identify appropriate measures for managing those risks.

Soil erosion following the application of herbicide to a bank: collapse of the bank because its cohesion is no longer ensured by the root system of living grasses, the consequences being the risk of drains being blocked, the need to dredge the stream more quickly, etc. If the product is persistent, the adverse effect will persist for longer.

Source: Comité régional phyto, Belgium

❑ **Air quality protection**

If they are volatile (that is to say, capable of being changed into its gaseous phase in the atmosphere), active substances and their metabolites may contaminate the atmosphere and therefore affect air quality, particularly if they decompose slowly. When there is a real possibility of this occurring, the authorities use an appropriate and validated calculation model to assess as accurately as possible the concentration of the active substance, the metabolites and the degradation products, as well as the reaction likely to be produced in the air after application of the PPP under the requisite conditions. Furthermore, they ensure that the concentrations measured are below the toxic ceiling after application of a safety factor (in general 100).[2]

7.3.3. Verification of biological efficacy and selectivity

This involves ensuring that the product is sufficiently active against the harmful organisms, diseases, pests and weeds it claims to control (efficacy), while being harmless for the plant (PPPs) or sundry materials (biocides) it claims to protect.

In this area, there are **two principal approaches**:

- The American-style ***'self-regulatory approach'***: the authorities perform a perfunctory biological efficacy evaluation of the product. They do not ask for many data. The underlying idea is that the best guarantee of efficacy is the interest the firms marketing the products have in seeing that these products give satisfaction to the users, as they do not want to lose sales or see their markets disappear due to a lack of demand, nor do they wish to expose themselves to proceedings if the efficacy observed by the user does not correspond to that claimed by the firm. There is thus a degree of market 'self-regulation'.

- ***The 'regulated' or 'European' approach*****:** the authorities require a greater quantity of efficacy and selectivity data in the form of a report on trials performed in

[2] European Union Directive 97/57 – Uniform principles for evaluation, set out in previous legislation.

accordance with GEP (Good Experimental Practices) standards, in order to guarantee their quality and comparability.

For example, in line with the practices in the European Union, to support an application to register a fungicide against odium mould on greenhouse tomatoes, the applicant firm must present a sufficient number (at least 8) of conclusive biological efficacy trials obtained over a period of at least two years.

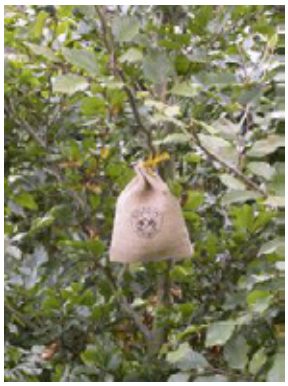
If it wishes to register the product for the same usage but for another crop, such as zucchinis, the firm will again need to present a similar number of conclusive trials conducted on this crop. There are standard protocols for such trials, for example those produced by EPPO (*European and Mediterranean Plant Protection Organization* – a member of the *International Plant Protection Convention*) with protocols for tropical crops in overseas territories and for crops under glass. The approach is similar for verifying the biological efficacy of rodenticides, insecticides, mosquito control products, etc.

By applying this approach, the authorities claim to protect users against claims by manufacturers about the efficacy of their products that may be exaggerated, misleading or simply lacking sufficient evidence.

Applicant firms also voluntarily present their findings in relation to the inadvertent effects of products on beneficial insects introduced to crops (in general, under glass) to improve pollonisation (bumblebees) or to control pest populations (parasites and predators such as the ladybird that control greenfly). This makes it possible for the user to check in advance the compatibility of his treatment programme with the use of such beneficial insects.

Ladybirds are carnivorous and happily consume greenfly. It is therefore appropriate to check the effect of insecticides on the natural enemies of pests. Many countries include this requirement in the registration file.

Source: www.lanature.fr



Like other insect species, ladybirds are raised by specialist companies for introduction into greenhouses, orchards and gardens to control pests such as greenfly. The canvas bag contains ladybird larva which will escape to feed on greenfly in the neighbourhood.

Source: commerce.sage.com/biobest

7.4. Registration

Registration is required for both active substances and the formulation. It should be noted that countries signing international treaties must ensure that their national legislation and regulations comply with those treaties. Stakeholders in the supply chain must also comply with the obligations in this regard.

For example:

- ***The Rotterdam Convention*** on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, which includes pesticides such as organo-mercury compounds, aldicarb and heptachlor.

- ***The Stockholm Convention*** on persistent organic pollutants (POPs) provides for the gradual elimination of certain pollutants, including pesticides and biocides such as DDT and heptachlor.

The provisions of these international treaties must be complied with, in particular when they relate to the restriction or prohibition of products.

7.4.1. Registration of active substances

Insofar as many of the risks these products pose to human health and the environment arise from the properties of the active substance, this must be indicated in the risk assessment required for registration of a commercial preparation (formulation).

In most countries, registration of active substances and formulations occurs at national level using a single procedure covering both active substances and formulations.

But active plant-protection products and biocides may also be assessed and registered (referred to more frequently by the terms 'approved' or 'authorized') at the community of States level; there is, for instance a European list of approved substances: echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/list-of-approved-active-substances.

Commercial preparations (formulations) containing these active substances may then be the subject of applications for registration (approval) in the different member states of the community in question.

In contrast, commercial preparations containing active substances not registered at Community level cannot be registered at national level (except in the case of derogations explicitly established to deal, for example, with an imminent danger to food safety which cannot be controlled by any other means).

This way of proceeding is specific to the European Union. However, many States neighboring the European Union or linked to it through major commercial trade in

agricultural commodities, and in particular in Africa, recognize European standards and/or take them as their starting point.

7.4.2. Registration of formulations

Commercial preparations of plant protection products and biocides not only contain one or more active substances for controlling harmful organisms, diseases, pests, weed and microbes; they also include thinners and other formulation adjuvants, also referred to as 'co-formulants' (solvents, wetting agents, adhesives, repellents, colorants, etc.) to make the product easier to use and improve its efficacy. While these are not pesticides or biocides, they may affect (increase or decrease) the toxicity of the preparations. For example, organic solvents, such as xylene, used to dissolve active substances in liquid formulations have toxic properties themselves and may also make it easier for active substances to penetrate through the skin. It is therefore important to assess the toxicity of the formulations and not just the active substances.

National requirements to be met in drawing up a file for registration can often be consulted over the Internet.[3]

The OECD also publishes standard structure and content for approval files as well as recommendations relating to trial protocols for obtaining and assessing the data themselves. These recommendations also cover aspects linked to residues, risk reduction, minor uses (plant protection problems which are significant for the sector concerned but which relate to a small surface area), biopesticides (plant protection products of natural origin) etc.

It should be noted that a growing number of countries are taking part in coordinated registration systems making mutual recognition possible: When a product is registered for a given usage in a given country, it can be automatically registered after an expedited procedure in the other participating countries; this is the case of Inter-African Pesticide Authorization (several western African countries), the Common Pesticide Committee of Central Africa and the Sahelian Pesticides Committee.

Certain countries include a principle of subsidiarity giving regional bodies the discretion to authorize or reject on their territory a product registered at national level (the case of the USA).

7.4.3. File content

The application file must contain the following information.

- **Physico-chemical characteristics of the active substance and of the formulation**

The active substance must be described in terms of its composition and chemical structure. An ISO (*International Organization for Standardization*) name is assigned, as is

[3] For example, the following requirements and procedures can consulted: for Belgium: fytoweb.be/en. For France: www.formulaires.modernisation.gouv.fr/gf/cerfa_11906_02.do. For the United Kingdom: the approval and authorization guidance at www.pesticides.gov.uk/guidance/industries/pesticides. For the USA: the Pesticide Registration Manual (Blue book) at www.epa.gov/pesticide-registration/pesticide-registration-manual.

an IUPAC (*International Union of Pure and Applied Chemistry)* name, based more explicitly on the chemical formula, and a CAS (*Chemical Abstract Service*) code.

The properties, such as solubility (in water and in solvents), volatility, fusion point, boiling point, degradation by light etc., of the active substances must also be determined, as well as the granulometry, suspensibility, viscosity, shelf life, etc. properties of the formulations.

The FAO has published standards relating to the minimum specifications for active substances ('technical grade', that is to say the active substance partially purified in the form it leaves the synthesis facility) for agricultural pesticides and the WHO does the same for those used for public health.

Analysis methods must be developed to quantify the active substance and its principal degradation products (metabolites) in formulations, foodstuffs, water, air, the soil and the plant.

The Collaborative International Pesticides Analytical Council (CIPAC) publishes such analysis methods.

Under the FAO standard, applicants must also present a ***five-batch analysis*** representing the technical grade and its impurities profile (which could also be toxic for man and the environment). All this is useful for risk assessment and post-registration checks.

❑ Toxicology

A distinction must be made between acute toxicity, chronic toxicity and, if appropriate, toxicity to the nervous system (the case of many insects which act in modes that can be toxic to the nervous system).

The trials are costly; they involve a large quantity of data, in particular for chronic toxicity studies, which are generally conducted on rats and take two years. They must be conducted in accordance with the generally accepted international procedural standard, the '*Good Experimental Practice'* (GEP) standard; this standard *guarantees the quality of the trials and their recognition in a large number of countries.* The OECD (Organization for Economic Cooperation and Development) publishes guidelines on protocols for such trials.

❑ Eco-toxicity

This involves short and long-term (acute and chronic-toxicity) trials on *non-target organisms*, such as aquatic flora (higher plants and algae), aquatic microfauna (crustaceans, molluscs, fauna inhabiting aquatic sediments such as mud), fish, microfauna (notably earthworms and other animals living in and turning over the soil), fauna (in particular birds), bees, and soil and sediment micro-organisms.

For these trials too, there are OECD guidelines for protocols and the Good Experimental Practice standard applies for the same reasons as set out above.

❑ Environmental fate

This involves understanding (qualitative and quantitative determinations) by which routes and at what speed active substances degrade into metabolites then into simple

molecules, such as carbon dioxide and water; this relates to different environments such as (surface and deep) water, soil (different types relevant for the crops concerned), air and plant. Relevant metabolites (that is to say those that are quantitatively dominant or that are toxic to man or the environment) are the subject of detailed toxicological and eco-toxicological evaluations in the same way as the parent substance.

Here too, there are OECD guidelines for protocols and the GEP certification standard applies for the same reasons as set out above.

❑ **Efficacity and selectivity trials**

Efficacy and selectivity trials are conducted as described above in point 3.3. It should be noted that applicants are increasingly required to present recommendations on the prevention of resistance (partial or total loss of efficacy arising from a genetic mutation of the target as a result of intensive use of the product: for example, mildew resistance to fungicides in the phenylamide family). These anti-resistance strategies may have an impact on the dose and number of applications per year or per crop cycle authorized, which will, in turn, affect their efficacy.

❑ **Label proposal**

This includes the trade name of the product, the type of formulation and the concentration, the name and address of the holder of the approval, the GAP specifications proposed (dose, period and number of applications, period before harvesting etc.), the risk and safety phases proposed, the indications for first-aid and for the doctor etc.

This information will be validated and completed by the authorities when the evaluation is completed.

❑ **Packaging specifications**

Packaging is relevant in protecting human health and the environment (risks linked to packaging that is not water tight or cannot be resealed; exposure of the operator depending on the format and size of the opening etc.).

These parameters must therefore be incorporated in the risk assessment. There are United Nations (UN) standards for the approval of packaging.
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7.5. Inspection

Inspections aim to verify that PPPs and biocides on the market comply with legislation. This makes it possible to ensure there is no compromise to the protection of people and the environment and that there has been no fraud.

For the purposes of good governance, registration (authorization for placing on the market and approval) and inspections must be kept entirely separate in order to avoid conflicts of interest. Registration and inspections are therefore performed by two separate agencies.

7.5.1. Active substances compliance checks

The checks relate in particular to impurities accompanying active substances. Active substances are virtually never entirely pure. Their synthesis generates secondary products, called impurities, which cannot be entirely eliminated at a reasonable cost.

The Technical Grade (TG) used to manufacture the formulations, that is to say the sum of the active substances and residual impurities which could not be eliminated during the purification phase, generally grades (has a concentration, purity) at 95-97%. If the grade or impurities profile of the active substance deviates significantly from what was submitted by the applicant filing for registration, the biological, chemical and toxicological properties may be altered, invalidating *de facto* the assessment conducted and resulting authorization.

7.5.2. Formulation compliance checks

This relates in particular to:

- the active substance concentration: a 5% tolerance upwards or downwards is generally accepted. It is generally held that a more stringent standard would unnecessarily complicate work on formulations and would significantly increase the cost without any additional benefit in terms of protection of people and the environment.
- compliance of co-formulants (nature and concentration);
- compliance of physic-chemical properties (viscosity and sedimentation of liquid formulations, granulometry of solid formulations such as powders etc.);
- labelling compliance; when the authorities grant marketing authorization, they fix the terms and conditions and procedures in a document, the approval certificate, the content of which is often published, in full or in part, including through the corresponding Internet site.[4]

[4] For example: www.fytoweb.be for Belgium; e-phy.agriculture.gouv.fr for France; www.pesticides.gov.uk/guidance for the UK.

The product labelling must comply rigorously with the terms of the registration certificate, in particular all indications relating to use (dose, period of application, number of treatments, compliance with the buffer area bordering the treated area, etc.), indications for first-aid and for the doctor, hazard pictograms, risk phases ('r' phases) and safety phases ('s' phases) etc.

For example, readers can find an exhaustive list of the risk and safety phases applicable within the European Union at the site: www.inrs.fr/accueil/produits/mediatheque/doc/publications.html.

In Annex 3 there is a list of the pictograms most commonly used on labels to warn of the types of hazard associated with the formation concerned.

It should be noted that the new international classification, the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS), provides for new pictograms. These pictograms and the corresponding new alert phrases, must appear on all plant protection product and biocide labels in the medium term. They can be consulted on the Web site: eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF.

7.5.3. Active substances residue checks in food

The authorities take samples at farms, but also across the food chain (from the farmer to the consumer's plate, going through agri-food industry processors and supermarkets). These samples are taken to check that the quantity of residues found in agricultural commodities do not exceed the standards authorized locally (the Maximum Residue Level or MRL).

It is expressed in mg of active substance per kg. The MRLs applicable in a given country are fixed at local, regional and global level.

❑ **Global level**

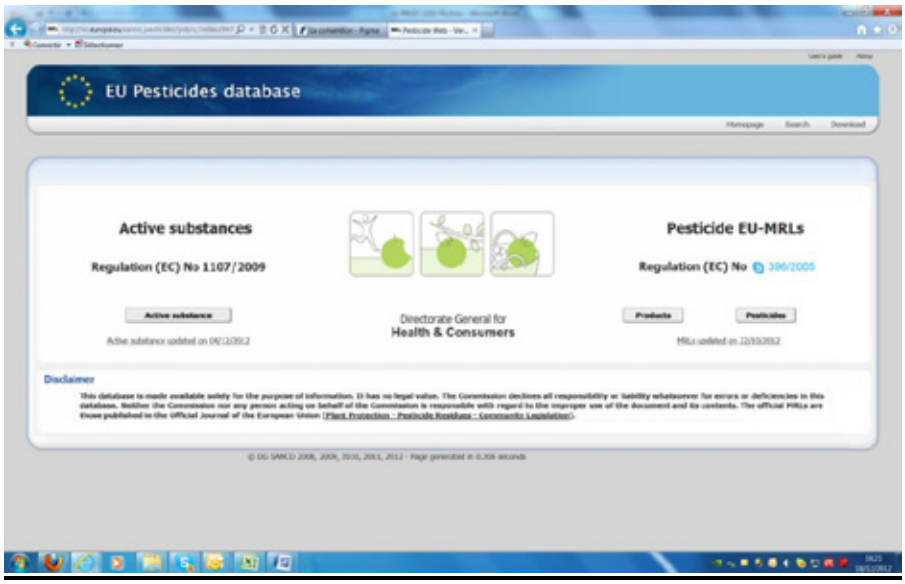
The FAO and WHO are working together within a consultative committee called the '*Codex Alimentarius*', which has the task of defining international food standards, and in particular MRLs, which are fixed on proposal by the JMPR (Joint Meeting on Pesticides Residues), its consultative body on this matter. Updates are regularly published on the *Codex Alimentarius* Web site: www.fao.org/fao-who-codexalimentarius/standards/pestres/en.

MLR for tomato				
Pesticide	**MRL**	**Year adopted**	**Symbol**	**Grade**
Ethoprophos	0.01 mg/kg	2005	(*)	
Quintozene	0.02 mg/kg	2003		
Abamectin	0.02 mg/kg	2001		
Pyrethrins	0.05 mg/kg	2003	(*)	
Spinetoram	0.06 mg/kg	2009		
Hexythiazox	0.1 mg/kg	2010		
Methidathion	0.1 mg/kg			
Triadimefon	0.2 mg/kg	1997		Withdrawal recommended (JMPR 2007)
Penconazole	0,2 mg/kg	1997		

Excerpt on MRLs for tomatoes from the Codex Alimentarius database www.fao.org/fao-who-codexalimentarius/standards/pestres/en.

❑ **Regional level**

In the European Union, pre-existing national MRLs (generally based on FAO standards) have been replaced, under Regulation (EC) NO 396/2005, by MRLs that apply across EU territory and even apply to imported foods. They can be consulted on the Web site: ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN.



Pesticide residues and maximum residue limits in mg/kg for tomatoes	
1,1-dichloro-2,2-bis(4-ethylphenyl)ethane (F)	0.01*
1,2-dibromoethane (ethylene dibromide) (F)	0.01*
1,2-dichloroethane (ethylene dichloride) (F)	0.01*
1,3-Dichloropropene	0.05*
1-Naphthylacetamide	0.05*
1-Naphthylacetic acid	0.05*
1-methylcyclopropene	0.01*
2,4,5-T (F)	0.05*
2,4-D (sum of 2,4-D and its esters expressed as 2,4-D)	0.05*
2,4-DB	0.05*
2-phenylphenol	0.05*
Abamectin (sum of avermectin B1a, avermectinB1b and delta-8,9 isomer of avermectin B1a) (F)	0.02

* Indicates the lower limit of analytical determination
Excerpt from the European Union residues database
Source: ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

❑ National level

Many countries continue to use MRLs fixed nationally, often derived from FAO standards.

MRLs are always set per combination of active substance-agricultural commodity (wheat, tomatoes, dessert grapes) or processed product (wine, apple juice etc.).

MRLs are also fixed for animal products (meat, milk, eggs) including processed products (butter). Active substance residues can pass into animal products through their feed, recipients containing that feed, treated surfaces with which animals come into contact, etc.

Each MRL is fixed on the basis of the quantities of residue actually found in samples taken from food following treatment to growing crops, by ensuring that at the concentration found there is no observable effect on human health, in the short or long term, even if the food is regularly consumed over a lifetime.

As indicated above, there are also MRLs for tap water (for human consumption). The FAO has established a reference value for various pesticides.

There are more restrictive standards, such as in the European Union (0.1 microgram of active substance per liter for each active substance considered individually, and 0.5 microgram of active substance per liter for the total substances measured). It is interesting to note that these European MRLs for water are set independently of any risk assessment; these standard levels are identical for all active substances. Furthermore, the European authorities have established a standard for the total active substances. This is not the case for other foods, for which there is no ceiling of this type, just individual MRLs for each active substance (and its relevant metabolites) likely to be found on the food. This different approach is undoubtedly explained by the need to harmonize the

different European legislations on water, firstly, but also, and secondly, due to the particularly sensitive nature of issues relating to the quality of water and its impact on the health of populations.

Criticism can legitimately be levelled at the approaches set out above.

- With the exception of the European Union water standard, MRLs and other benchmark values (including those of the FAO) take no account of the fact that consumers are exposed through their meals to a cocktail of active and non-active substances, and not just one substance. This criticism is justified, even if evaluation of the potential effects of combining two or more active substances is hampered by a methodological impossibility due, notably, the exponential number of combinations to be tested.
- With regard to the European Union 'water' standard, it takes no account of the intrinsic toxicity of active substances, since it applies equally to both those that are intrinsically toxic and those that are less so.

Finally, it should be noted that in many countries certain stakeholders in the agri-food sector, like supermarkets, put in place secondary standards that often go beyond what is required under legislation:

- agricultural commodities, such as fruit and vegetables which they buy from farmers must not contain traces of more than 'x' active substances; or,
- each active substance that can be detected must not have a concentration of more than 'y'% (for example, 25%) of the MRL.

Consequently, farmers must adopt treatment programmes compatible with these different standards, both for crops destined for local markets and those for export.

7.5.4. Self-assessment and traceability

Since it is impossible for authorities to be present everywhere and at all times, certain countries have put in place a ‘self-assessment’ arrangement requiring compliance with food safety… and traceability requirements.

Indeed, foodstuffs must sometimes be withdrawn from the market. This can occur, for example, when a pesticide used incorrectly results in the MRLs for this pesticide being exceeded and constituting a hazard for consumers. Where this is the case, the foodstuffs must be intercepted before they reach the market and sometimes even called back from consumers. This is only possible if the operator keeps up to date records identifying the products that enter and leave the farm or business.

Details (date, quantity, surface area, crop etc.) of the application of pesticides for agricultural use and biocides must also be kept in a register.

For the farmer, this traceability makes it possible to limit loss: any measures taken will only be applied to foodstuffs that exceed the MRL (a batch). The measures would otherwise cover the entire crop, since it would be impossible to distinguish healthy foodstuffs from contaminated food.

7.5.5. Placing on the market

Any person or company wishing to place a PPP or biocide on the market in a given country, for example through a network of distributors, must ensure in advance that the product is registered in the country concerned or, failing this, that it is not subject to registration requirements. The latter case is rare but does exist: certain products, such as 'phyto-fortifiers' (products that strengthen plant growth), adjuvants (added to the product in the spray mixture to improve efficacy) or beneficial insects (pollinizer, parasites or pest predators) are subject in certain countries to different, and often simpler, legislation or regulations.

7.5.6. Distribution

Businesses and cooperatives that sell plant protection products and biocides must also ensure that the products they sell to users are registered in accordance with the rules applying in the countries concerned and that they are labelled correctly. They must not hold outdated stock, but dispose of them through the proper channels for the destruction of dangerous chemical products/substances. They must keep the products in their original sealed packaging.

7.5.7. Labelling

The final user (farmer, biocides applier) must also ensure that the product he uses is registered and correctly labelled. He must comply scrupulously with the indications on the label (which means that he must first have read them), and in particular those relating to the terms and conditions of use: compliance with the dosage, the interval, the number of applications, the re-entry time (the period of time which elapses, for safety reasons, before staff are authorized to re-enter a parcel of land which has been treated), time periods before harvesting, compliance with untreated buffer zone along the edges of the field, etc. In this way the user is able to guard against MRLs being exceeded, health implications and environmental impact.

Most used abbreviations and acronyms

Most used abbreviations and acronyms

3P	*People, Planet, Profit*
ACP	Africa – Caribbean – Pacific (the ACP Group of States that signed a series of special treaties with the EU known as the 'Cotonou Agreement')
ASDA	Acronym of ***As****quith* and ***Da****iries*
ATO	Alternative Trade Organizations
ATP	Adaptations to Technical Progress
BRC	British Retail Consortium
BSCI	Business Social Compliance Initiative
BSE	Bovine spongiform encephalopathy ("mad cow disease")
BSI	British Standards Institution
B-to-B	Business-to-Business
B-to-C	Business-to-Consumer
CAHFSA	Caribbean Agricultural Health and Food Safety Agency
CAP	Common Agricultural Policy
CAS	Chemical Abstract Service

CCP	Critical Control Points (in the HACCP method)
CED	Common entry document
CERES	Coalition for Environmentally Responsible Economies
cfu	Colony-forming units
CIAA	*Confédération des industries agro-alimentaires de l'Union européenne* (Confederation of the Food and Drink Industries of the EU)
CIPAC	Collaborative International Pesticides Analytical Council
CLP	Classification, Labelling and Packaging
CMO	Common Market Organization
CO_2	Chemical symbol for carbon dioxide
CSR	Chemical Safety Report
CSR	Corporate social responsibility
CT	Committee on Trade
DMD	Date of minimum durability
EC	European Community (for legislation) – legal authority before Treaty of Lisbon)
ECHA	European Chemicals Agency
EEA	European Environment Agency

EEC	European Economic Community (for legislation) – original legal authority
EFSA	European Food Safety Authority
EFTA	European Fair Trade Association
EMS	Environmental management systems
EPPO	European and Mediterranean Plant Protection Organization
ETI	Ethical Trading Initiative
EU	European Union
EUREP	Euro-Retailer Produce
FAO	Food and Agriculture Organization: the United Nations' World Food Organization
FBO	Food Business Operator
FCD	*Fédération des entreprises du commerce et de la distribution* (French Federation of Businesses in Trade and Distribution)
FINE	Acronym formed from the name of its members: **F** for Fairtrade Labelling Organizations (FLO) **I** for International Federation of Alternative Trade (IFAT), today WFTO, World Fair Trade Organization **N** for Network of European World shops (NEWS) **E** for European Fair Trade Association (EFTA)
FLO	Fairtrade Labelling Organization
FMD	Food and mouth disease
FMI	Food Marketing Institute

FPEAK	Fresh Produce Exporters Association of Kenya
FSMS	Food Safety Management System
FSSC	Food Safety System Certification
FTA	Foreign Trade Association
FTO	Fair Trade Organization
FVO	Food and Veterinary Office
GAP	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GEP	Good Experimental Practices
GFSI	Global Food Safety Initiative
GHS	Global Standards Harmonized
GLP	Good Laboratory Practices
GMO	Genetically modified organism
GMP	Good Manufacturing Practices
GPP	Good Phytosanitary Practices
GRASP	Risk Assessment on Social Practice

GRI	Global reporting initiative
GSH	General Harmonized System
GSCP	Global Social Compliance Programme
ha	Hectare
HACCP	Hazards analysis and critical control points
HDE	*Hauptverband des Deutschen Einzelhandels* (Main association of German retailers)
IAS	Invasive alien species
IFAT	International Fair Trade Association
IFOAM	International Federation of Organic Agriculture Movements
IFS	International Food Standard
ILO	International Labor Organization
IPPC	International Plant Protection Convention
ISEAL	International Social and Environmental Accreditation and Labelling
ISO	International Standard Organization. ISO brings together national standards bodies from 149 countries and develops international standards.
ISPM	International Standard for Phytosanitary Measures
ISSB	International Standard Setting Body (SPS Agreement)

IT	Import tolerances
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint Meeting on Pesticides Residues
LD	Limit of detection
LOQ	Limit of quantification
LMO	Living Modified Organism (= GMO)
MRL	Maximum residue level
NBE	National Board of Experts
NEWS!	Network of European World Shops
NGO	Non-Governmental Organizations
NOAEL	No Observable Effect Level
NRI	Natural Resources Institute
NTO	Non Target Organism
NTWG	National Technical Working Group
OECD	Organization for Economic Co-operation and Development

OHSAS	Occupational Health and Safety Assessment Series
OHSMS	Occupational Health and Safety Management Systems
OIE	*Office international des épizooties* (World Organization for Animal Health)
OJEC	*Official Journal of the European Communities*
OJEU	*Official Journal of the European Union*
PAS	Publicly Available Specification
PBT	Persistent, Bioaccumulable, Toxic for the environment
PCB	Polychlorobiphenyl
PDO	Protected designations of origin
PGI	Protected geographical indications
PIP	Pesticide Initiative Programme, a European cooperation programme managed by COLEACP for sustainable development of the ACP horticultural industry
POP	Persistent organic pollutants
PPE	Personal protective equipment
PPP	Plant protection product (pesticide used on crops)
PRA	Pest Risk Analysis (IPPC)
PRP	Pre-requisite Programmes

PVS	Private Voluntary Standards
QMS	Quality Management Systems (ISO 9000 Series)
RASFF	Rapid Alert System for Food and Feed
SAAS	Social Accountability Accreditation Services
SAI	Social Accountability International
SAN	Sustainable Agriculture Network
SCV	*Stichting Certificatie Voedselveiligheid* (Foundation for the certification of food safety, The Netherlands)
SEDEX	Supplier Ethical Data Exchange
SO_2	Chemical symbol for sulphur dioxide
SPS (Agreement)	Agreement on the Application of Sanitary and Phytosanitary Measures (WTO)
SQF	Safe Quality Food
SQFI	Safe Quality Food Institute
TBT	Technical Barriers to Trade
TG	Technical Grade
TSG	Traditional specialties guaranteed
UHT	Ultra-High Temperature

UN	United Nations
UNECE	The United Nations Economic Commission for Europe
vPvB	very Persistent, very Bioaccumulable
WFTO	World Fair Trade Organization
WHO	World Health Organization
WTO	World Trade Organization

Bibliographical references

Bibliographical references

BLANDIN, B., “Normes, standards, labels, chartes et démarches qualité pour l’e-formation”, in CEDEFOP / Centre Info, *Pratiques innovantes en formation et enjeux pour la professionnalisation des acteurs*, Luxembourg, Office for Official Publications of the European Communities, 2005, pp. 52-57.

BRC (British Retail Consortium Technical Standard), Executive summary, 2001.

BRUNTLANDT, G.H., *Our common future*, Paris, Fleuve, 1987.

EC, *Guidance Document: Key Questions Related to Import Requirements and the New Rules on Food Hygiene and Official Food Controls*, 2006, ec.europa.eu/food/international/trade/interpretation_imports.pdf.

FSA, Food Standards Agency’s international workshop on food incident prevention and horizon scanning to identify emerging food safety risks, organized in cooperation with European, Food Safety Authority, London, 5-6 March 2007.

FULPONI, L., *Final Report on Private Standards and the Shaping of the Agro-Food System*, OECD, AGR/CA/APM, 9, 2006.

FULPONI, L., *Private Standard Schemes and Developing Country Access To Global Value Chains: Challenges And Opportunities Emerging From Four Case Studies*, OECD, AGR/CA/APM, 20, b, 2006.

FULPONI, L., *Private standard schemes and developing country access to global value chains: challenges and opportunities emerging from four case studies*, OECD, 3 August 2007.

GFSI, Press Release of the Global Food Security Initiative: Presentation.

HAMMOUDI, A., GRAZIA, C., GIRAUD-HÉRAUD, É. and HAMZA, O., “Hétérogénéité internationale des standards de sécurité sanitaire des aliments : Quelles stratégies pour les filières d’exportation des PED ?”, Work document, 101, Agence française de développement, October 2010.

HENSON, S. and HUMPHREY, J., “The impacts of private food safety standards on the food chain and on public standard-setting process”, FAO/WHO, May 2009.

JAFFEE, S., *From challenge to opportunity: the transformation of the Kenyan fresh vegetable trade in the context of emerging food safety and other standards*, 2003.

KIREEVA, I. and BLACK, R., “Chemical safety of food: setting of maximum residue levels (MRLs) for pesticides and other contaminants in the Russian Federation and in the EU”, *European Food and Feed Law Review*, 6(3), 2011, pp. 174-186

LIU, P., “Private standards in international trade: issues and opportunities”, WTO’s workshop on environment-related private standards, certification and labeling requirements, Genève, 9 July 2009.

NUTRINOV, “GFSI and food safety management’’, 2003.

WTO, “WTO Negotiations on Agriculture: Issues Taken and Status”, 2002.

Useful Websites

Useful Websites

Agence Bio: www.agencebio.org

Agrolibano: www.agrolibano.com

BRC Global Standards: www.brcglobalstandards.com

British Retail Consortium (BRC): www.brcdirectory.co.uk

Business Social Compliance Initiative: www.bsci-intl.org

Information Center ISO/IEC: www.standardsinfo.net/info/index.html

Codex Alimentarius: www.fao.org/fao-who-codexalimentarius/codex-home/en

ECOCERT : www.ecocert.com

e-Phy: e-phy.agriculture.gouv.fr/

Ethical Trading Initiative: www.ethicaltrade.org

EUR-Lex : eur-lex.europa.eu/homepage.html?locale=en

European Commission: ec.europa.eu

Fair for life: www.fairforlife.net

Fairtrade Labelling Organization: www.fairtrade.net

FAO: www.fao.org/home/en

Food navigator: www.foodnavigator.com

Food Safety Management: www.foodsafetymanagement.info/en/home

Food Safety System Certification 22000: www.fssc22000.com

FSS (Food Surveillance System): www.food.gov.uk

Global Food Safety Initiative (GFSI): www.mygfsi.com

GLOBALG.A.P: www.globalgap.org

Global Reporting Initiative (GRI): www.globalreporting.org

Global Social Compliance Programme: www.gscpnet.com

Health and Safety Executive: www.hse.gov.uk

IFOAM: www.ifoam.org

INFOSAN (XHO): www.who.int/foodsafety/areas_work/infosan/en

International Food Safety: www.ifsqn.com

International Federation of Organic Agriculture Movements (IFOAM): www.ifoam.org

ISEAL Alliance: www.isealalliance.org

International Organisation for Standardization (ISO): www.iso.org

Linking Environment and Farming (LEAF) : www.leafuk.org

Naturland: www.naturland.de/en

NORME-ISO22000.INFO: www.norme-iso22000.info/home.htm

NURTURE: www.tesco.com/nurture

OECD: www.oecd.org

Occupational Health and Safety Zone (OHSAS): www.bsigroup.com/en-GB/ohsas-18001-occupational-health-and-safety

OIE, World Organization for Animal Health: www.oie.int/en

Overseas Development Institute: www.odi.org.uk

OXFAM Magasins du Monde: www.oxfammagasinsdumonde.be

OXFAM FAIR TRADE: www.oft.be/fra-produits

Phytoweb: fytoweb.be/en

Rainforest Alliance: www.rainforest-alliance.org

RASFF(EC): ec.europa.eu/food/safety/rasff_en

Safe Quality Food Institute: www.sqfi.com

SAN: san.ag/web

SCENHIR (Scientific Committee on Emerging and Newly Identified Health Risks) : ec.europa.eu/health/scientific_committees/emerging_en

SEDEX: www.sedex.org.uk

SFQI: www.sqfi.com

SGS: www.sgsgroup.fr

Social Accountability Accreditation Services (SAAS): www.saasaccreditation.org

Social Accountability International (SAI): www.sa-intl.org

Soil Association: www.soilassociation.org

Supplier Ethical Data Exchange (SEDEX): www.sedex.org.uk

TESCO: www.tesco.com

United Nations Global Compact: www.unglobalcompact.org

USDA-APHIS Center for Emerging Issues (USA): www.aphis.usda.gov

WHO – Global outbreak Alert and Response Network and global Public Heath Intelligence Network (GOARN): who.int/en

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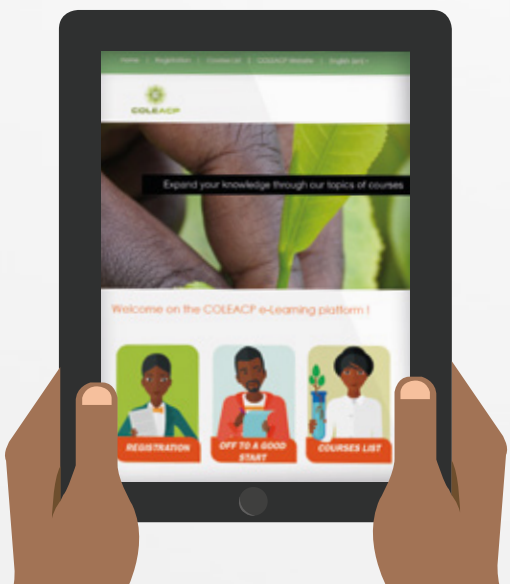

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