TRAINING MANUAL

- PLANTS HEALTH -

CONTROL ORGANISATION AND PHYTOSANITARY INSPECTION

COLEACP

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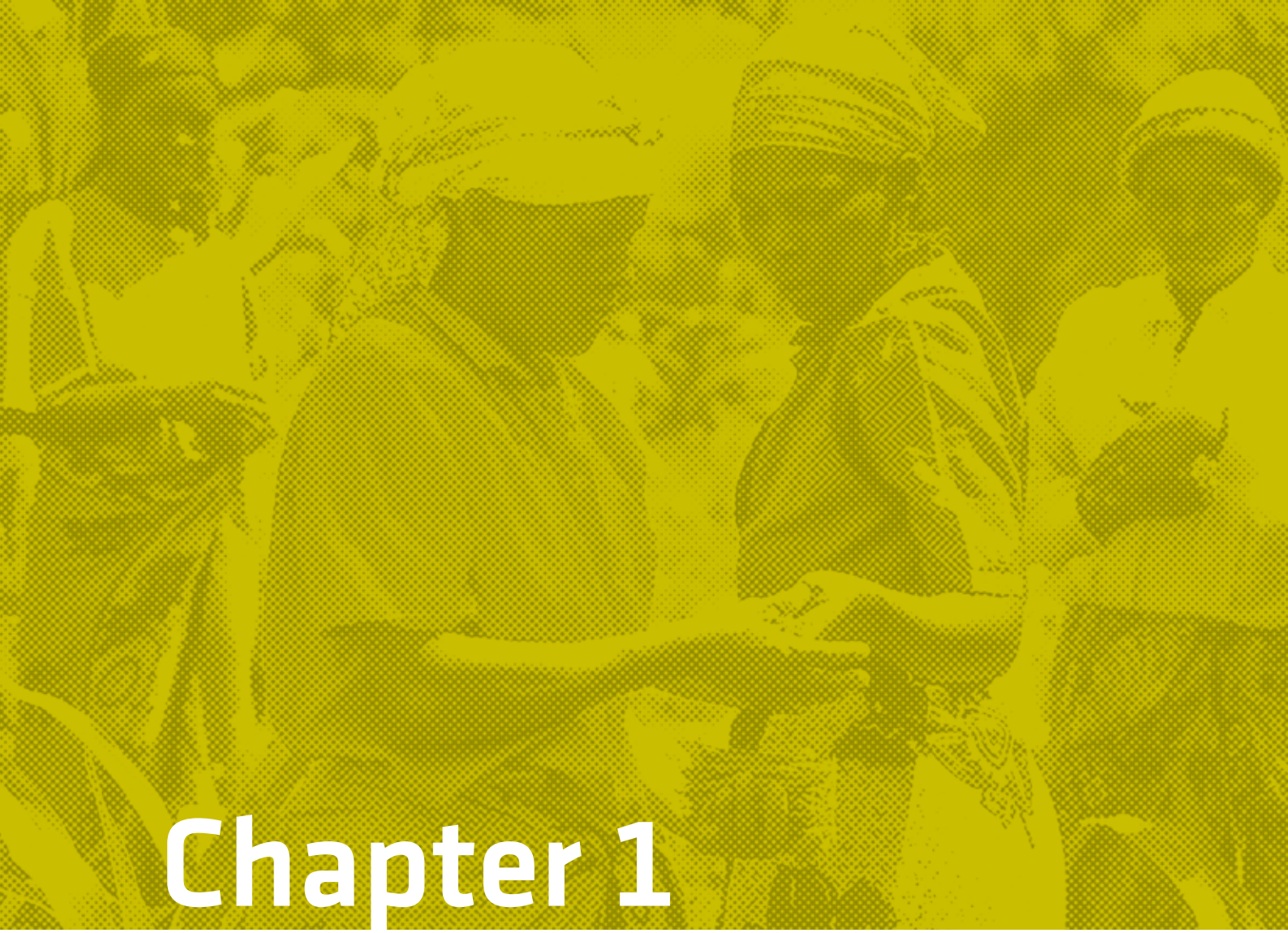

Chapter 1

Principles of official controls and certification systems (public/private)

1.1. HISTORICAL NEED FOR FOOD CONTROL

1.1.1. Introduction

In the old days it was commonplace for relationships between buyer and seller to be based largely on the buyer's trust of the seller and the seller's expectations for future. Unfortunately this trust was often let down. At the rise of the industrial revolution knowledge of physics and chemistry of food and food ingredients strongly improved. As a result both positive and negative manipulation of food increased. Delivered food didn't meet buyers' expectations.

Counterfeiting of food became a way to produce inexpensive food and long distance food transport often resulted in damaged, deteriorated or perished food. Foodborne diseases became a growing public health problem and food supervision developed at local level, based on local food laws.

Even in the Middle Ages some local authorities issued rules on the quality of meat, fish, wine and bread. As time went by it became obvious that the independence of the local authorities was a barrier for traders, because the local authorities developed their own legislations which different requirements on products.

At the beginning of the 20th Century this local supervision and legislation and food legislation increasingly became a recognized task of central authorities. In many developed countries it let to the development of official control institutions, based on national food laws.

After World War II, in Europe, national institutions started to cooperate together, and economic organizations were established (e.g. European Steel and Coal Community, ECSC, European Economic Community, EEC).

European institutions were created to overcome protectionism, practiced by importing countries. There were different reasons for this protection:

- protection for unsafe food;
- protection of national food production.

It was a complex problem to be solved, in spite of the fact that most countries were in favour of the import and especially the export of food. The global governance infrastructure for food is far advanced in comparison to many other areas. All countries in the world are food producers; all participate in the international trade in food, both as importers and as exporters.

All trade-related questions apply to food: how to ensure free and fair trade and how to ensure the life and health of people. At the global level, different institutions and their Member States deal with these questions and from their efforts emerge the contours of a truly global system of food governance.

At the global level, food law is embedded in the general international law structures dominated by the United Nations and the World Trade Organization. Some other organizations specifically address food and food-related issues. This paragraph introduces the most important organizations and Figure 1[1] provides a graphic presentation of their interrelationships. All these organizations play an important role in the development of rules, standards and guidelines for the production and trade of safe food and fair trade.

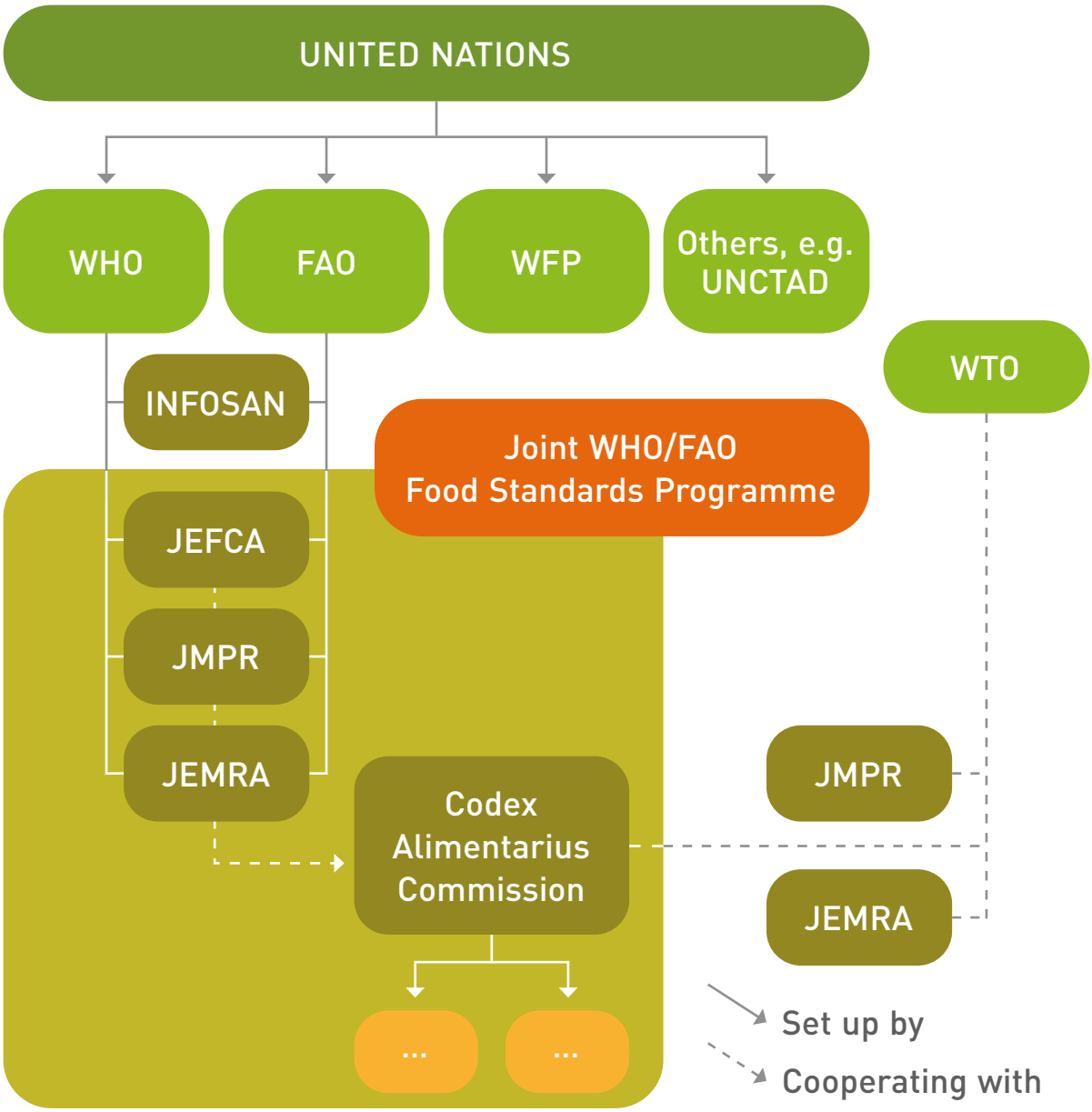

Figure 1 - Global food institutions

1 By courtesy of B. van der Meulen, *Roadmap to EU food law*, ISBN 978-94-90947-26-2, The Hague, Eleven International Publ., 2011.

WHO	World Health Organization
FAO	Food and Agriculture Organization
WFP	World food programme
UNCTAD	United Nations Conference on trade and Development
INFOSAN	International Food Safety Authorities Network
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
CAC	*Codex Alimentarius* Commission
WTO	World Trade Organization

1.1.2. World Health Organization (WHO)

World Health Organization

WHO[2] is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

WHO was constituted on 7 April 1948, after an initiative of diplomats forming the United Nations in 1945. Now 7 April is celebrated as World Health day. Nearly 8000 people from more than 150 countries work for the Organization. In addition to medical doctors, public health specialists, researchers and epidemiologists, WHO staff include administrative, financial, and information systems specialists, as well as experts in the fields of health statistics, economics and emergency relief.

2 www.who.int/about/brochure_en.pdf.

1.1.3. Food and Agriculture Organization

The FAO's objective is to eradicate hunger and to make high quality food accessible to all. It focuses on both developed and developing countries. The FAO supports the elaboration of agreements and policies by providing a neutral platform for negotiation and information. It aims to improve nutrition, raise agricultural production and contribute to the world economy.

The FAO was set up on 16 October 1945,[3] a date commemorated every year as 'World Food Day'.

The FAO is governed by a Conference of the Member States that meets every second year to evaluate the work done and approve the budget. Forty-nine Member States are chosen from the Conference to act as temporary Council. The FAO consists of eight departments that focus on specific topics such as Agriculture and Consumer Protection, Economic and Social Development and Technical Cooperation.

The FAO's headquarters are in Rome. It has a considerable number of regional, sub-regional and national offices around the world, with total staff of about 3,600 employees.

3 www.fao.org.

1.1.4. World Food Programme (WFP)

The WFP[4] is the food aid branch of the United Nations, and the world's largest humanitarian organization addressing hunger worldwide. WFP provides food, on average, to 90 million people per year, 58 million of whom are children. From its headquarters in Rome and more than 80 country offices around the world, WFP works to help people who are unable to produce or obtain enough food for themselves and their families. It is a member of the United Nations Development Group and part of its Executive Committee.

The WFP was first established in 1961 after the 1960 FAO Conference. WFP was formally established in 1963 by the FAO and the United Nations General Assembly on a three-year experimental basis. In 1965, the programme was extended to a continuing basis. The WFP is governed by an Executive Board which consists of representatives from 36 Member States. WFP has a staff of 9,000 people (2007) with 90 % operating in the field.

1.1.5. United Nations Conference on trade and Development (UNCTAD)

UNCTAD[5] promotes the development-friendly integration of developing countries into the world economy. UNCTAD has progressively evolved into an authoritative knowledge-based institution whose work aims to help shape current policy

4 en.wikipedia.org/wiki/World_Food_Programme.
5 www.unctad.org/en/Pages/AboutUs.aspx.

debates and thinking on development, with a particular focus on ensuring that domestic policies and international action are mutually supportive in bringing about sustainable development.

The organization works to fulfil this mandate by carrying out three key functions:

- It functions as a forum for intergovernmental deliberations, supported by discussions with experts and exchanges of experience, aimed at consensus building.
- It undertakes research, policy analysis and data collection for the debates of government representatives and experts.
- It provides technical assistance tailored to the specific requirements of developing countries, with special attention to the needs of the least developed countries and of economies in transition. When appropriate, UNCTAD cooperates with other organizations and donor countries in the delivery of technical assistance.

The first United Nations Conference on Trade and Development (UNCTAD) was held in Geneva in 1964. Given the magnitude of the problems at stake and the need to address them, the conference was institutionalized to meet every four years, with intergovernmental bodies meeting between sessions and a permanent secretariat providing the necessary substantive and logistical support. Simultaneously, the developing countries established the Group of 77 to voice their concerns. (Today, the G77 has 131 members).

1.1.6. International Food Safety Authorities Network (INFOSAN)

INFOSAN[6] has been developed by WHO and FAO to provide rapid access to information during food safety emergencies. An important issue for INFOSAN is the improvement of the safety of street vended food.

In 2006 already 151 countries were member of INFOSAN. The European Rapid Alert System for Food and Feed (RASFF) was established in 2005 as an INFOSAN emergency contact point for the transition of INFOSAN food safety information. All Member States of the EU and European Free Trade Association (EFTA) agreed that the RASFF should be the single point of information exchange to INFOSAN.

6 www.who.int/foodsafety/areas_work/infosan/en.

1.1.7. Joint FAO/WHO Expert Committee on Food Additives (JECFA)

JECFA

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

The Joint FAO/WHO Expert Committee on Food Additives (JECFA)[7] is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

The area of work of JECFA concerns assessments of chemical risks.

While not officially part of the *Codex Alimentarius* Commission structure, the Joint FAO/WHO Expert Committee on Food Additives provides independent scientific expert advice to the Commission and its specialist Committees. FAO and WHO maintain separate websites highlighting the work of the Committee from the points of view of the two parent Organizations.

1.1.8. Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

The current JMPR[8] comprises the WHO Core Assessment Group and the FAO Panel of Experts on Pesticide Residues in Food and the Environment. It is recognized as a successful model on the collaboration with WHO. The JMPR consists of experts drawn from governments and academic circles, who attend as independent internationally-recognized specialists who act in a personal capacity and not as representatives of national governments.

The WHO Core Assessment Group is responsible for reviewing pesticide toxicological and related data and estimating no-observed-adverse-effect-levels (NOAELs) of pesticides and Acceptable Daily Intakes (ADI) of their residues in food for humans. In addition, as data and circumstances dictate, the Group estimates acute reference doses (ARfDs) and characterizes other toxicological criteria such as non-dietary exposures.

The FAO Panel is responsible for reviewing pesticide use patterns (GAPs), data on the chemistry and composition of pesticides, environmental fate, metabolism in farm animals and crops, methods of analysis for pesticide residues and processing studies and for estimating maximum residue levels, supervised trials median residue values (STMRs) and highest residues (HRs) in food and feed commodities. The toxicity of the active ingredient and its metabolites, evaluated by the WHO Core Assessment Group, is taken into consideration in deciding if residues may

7 www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en.

8 www.fao.org/fao-who-codexalimentarius/scientific-basis/jmpr/en.

or may not give rise to problems of public health. The maximum residue levels are recommended to the *Codex* Committee on Pesticide Residues (CCPR) as suitable for consideration as *Codex* Maximum Residue Limits (*Codex* MRLs) to be adopted by the *Codex Alimentarius* Commission (CAC).

The JMPR has evaluated pesticides more than 40 years with the aim of estimating the maximum residue levels in food and feed which are likely to result from legally permitted uses of pesticides. Up to now, there are 42 sessions (meetings) been conducted, and about 250 compounds with more than 2000 MRLs been discussed and recommended by JMPR.

1.1.9. Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA)

JEMRA[9] aims to develop and optimize the utility of Microbiological Risk Assessment (MRA) as a tool to inform actions and decisions aimed at improving food safety and to make it equally available to both developing and developed countries.

The Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) began in 2000 in response to requests from the *Codex Alimentarius* Commission and FAO and WHO Member Countries and the increasing need for risk based scientific advice on microbiological food safety issues.

1.1.10. *Codex Alimentarius* Commission (CAC)

The *Codex Alimentarius* Commission[10] was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

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.

9 www.fao.org/food/food-safety-quality/scientific-advice/jemra/en.

10 ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf.

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.

At present the *Codex* comprises more than 200 standards for specific foods (so-called vertical standards), close to 50 food hygiene and technological codes of practice, some 60 guidelines, over 1,000 food additives and contaminants evaluations and over 3,200 maximum residue limits for pesticides and veterinary drugs. Finally, the *Codex Alimentarius* includes requirements of a horizontal nature on labelling and presentation and on methods of analysis and sampling.

1.1.11. World Trade Organisation (WTO)

The World Trade Organization came into being in 1995. One of the youngest of the international organizations, the WTO is the successor to the General Agreement on Tariffs and Trade (GATT) established in the wake of the World War II.

Where countries have faced trade barriers and wanted them lowered, the negotiations have helped to open markets for trade. But the WTO[11] is not just about opening markets, and in some circumstances its rules support maintaining trade barriers – for example, to protect consumers or prevent the spread of disease.

At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations. The bulk of the WTO's current work comes from the 1986-94 negotiations called the Uruguay Round and earlier negotiations under the General Agreement on Tariffs and Trade (GATT).

These documents provide the legal ground rules for international commerce. They are essentially contracts, binding governments to keep their trade policies within agreed limits. Although negotiated and signed by governments, the goal is to help producers of goods and services, exporters, and importers conduct their business, while allowing governments to meet social and environmental objectives (see Figure 2[12]).

11 www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm.

12 By courtesy of B. van der Meulen, *Roadmap to EU food law*, aforesaid.

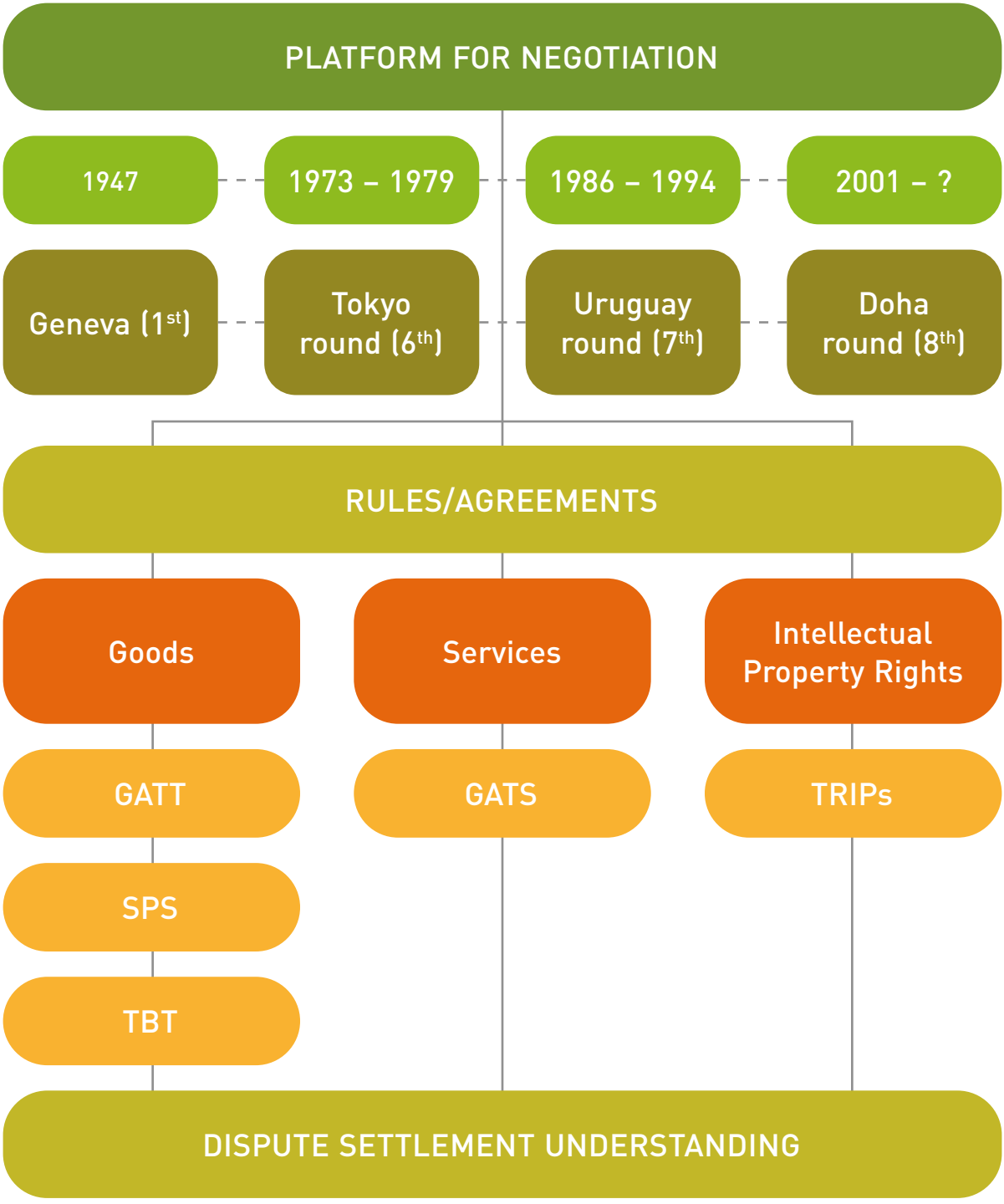

Figure 2

WTO agreement are binding in character. As regards to food, the GATT, SPS and TBT agreements are the most important.

1.1.11.1. General Agreement on Tariffs and Trade (GATT)

The GATT,[13] which predates the WTO, entered into force in 1947. By means of GATT 1994, GATT 1947 was included as an annex to the WHO Agreement. The GATT aims to liberalize international trade by establishing equal treatment of all trading partners as the norm. However it also recognizes the need to make exceptions.

As the food law aims to protect consumer's health, the most important exception to international free trade from the point of view of food law is the protection of health, an exception found in article XX (b) of the GATT Agreement. Another issue is the U.S.'s bioterrorism laws.

1.1.11.2. Sanitary and Phytosanitary Measures Agreement (SPS)

The Sanitary and Phytosanitary Agreement (SPS[14]) allows members to take scientifically based measures to protect public health. It lays down the conditions under which a State may adapt and implement sanitary (animal health, food safety) or phytosanitary (plant health) measures). The agreement commits members to base these measures on internationally established guidelines and risk assessment procedures.

In the case of particularly stringent measures, countries must present scientific justification. When existing scientific evidence is insufficient to determine risk, members may adopt measures on the basis of available information, but must obtain additional information to objectively ground their assessment of risk within a reasonable period of time.

Generally speaking, the SPS Agreement is a compromise that permits countries to take measures to protect public health within their borders so long as they do so in a manner that restricts trade as little as possible.

The most important international standards regarding SPS are set by the so-called "three sisters" of the SPS Agreement:

- the *Codex Alimentarius* Commission;
- the International Office of Epizootics (OIE[15]) ;
- Secretariat of the International Plant Protection Convention (IPPC).[16]

Standards on food are mainly found in the *Codex Alimentarius*.

1.1.11.3. Technical Barriers to Trade Agreement (TBT)

Likewise, the Technical Barriers to Trade Agreement (TBT) strikes a delicate balance between the policy goals of trade facilitation and national autonomy in technical regulations. The agreement attempts to extricate the trade-facilitating aspects of standards from their trade-distorting potential by obligating countries to ensure that technical regulations and product standards do not unnecessarily restrict international trade.

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13 en.wikipedia.org/wiki/General_Agreement_on_Tariffs_and_Trade.

14 www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

15 World Organisation of Animal Health, http://www.oie.int/en.

16 www.ippc.int.

The TBT Agreement works toward this end in three ways:

- The agreement encourages 'standard equivalence' between countries, in other words, the formal acceptance of the standards of other countries through explicit agreements.
- It also promotes the use of international standards.
- Lastly, it mandates that countries establish enquiry points and national notification authorities (the two may be the same body) in order to answer questions about SPS regulations and notify other nations of new regulations respectively. Enquiry points compile all available information in that country on product standards and trade regulations and provide it to other members upon request. The national notification authorities report changes in trade policy to the WTO and receive and take comments on these measures.

1.1.12. The International Organisation for Standardisation (ISO)

The main international organization that develops food safety standards aside from the *Codex Alimentarius* Commission is ISO. Standards prepared by *Codex* or ISO are mainly voluntary.

Differences between the *Codex* and ISO are:

a. The *Codex* was established to define international standards, guidelines and recommendations that guide and establish rules for the elaboration of national regulations in the area of food safety and quality, while ISO's scope of the field of activities extend across a wide range of products, services and management system for food and commodities.

b. The way standards are initiated: *Codex* by members of international commissions, mostly represented by a public servant and ISO from a requirement of an industry sector or other stakeholder group for a standard to one of ISO's national members.

The membership of ISO consists of 160 national standards organizations, and its mission is to promote the development of standardization throughout the world in order to facilitate the exchange of goods, services, as well as to develop cooperation in intellectual, scientific, technological and economic activities.

ISO standards:

- make the development, manufacturing and supply of products and services more efficient, safer and cleaner;
- facilitate trade between countries and make it fairer;
- provide governments with a technical base for health, safety and environmental legislation, and conformity assessment;
- share technological advances and good management practice;
- disseminate innovation;
- safeguard consumers, and users in general, of products and services;
- make life simpler by providing solutions to common problems.

The development of a standard is started by ISO, in response to sectors and stakeholders that express a clearly established need for them. An industry sector or other stakeholder group typically communicates its requirement for a standard to one of ISO's national members. ISO standards are developed by technical committees (subcommittees or project committees) comprising experts from the industrial, technical and business sectors which have asked for the standards, and which subsequently put them to use. These experts may be joined by representatives of government agencies, testing laboratories, consumer associations, non-governmental organizations and academic circles.

1.1.13. Conclusions

The story of public and private standards in food law follows different patterns in development but also shows many aspects of interrelation. In the last ten years, at European level, public food safety standards have been considerably enforced through legislation (the milestone of European Food Law is Reg. No. 178/2002, known as the General Food Law), both at European and at national level. This has been made possible thanks to the desire of European politicians to concentrate power on food legislation increasingly at the European Commission.

The WTO has no authority to force decisions taken in these procedures. However if the party found at fault fails to comply with the decision reached, the WHO can condone the implementation of economic sanctions by the winning party. These sanctions usually take the form of punitive import levies on goods from the state found at fault.

At the same time, stakeholders at different levels of the supply chain have developed different typologies of private standards, enlarging possibilities of fair trade of safe food between countries in all parts of the world.

As mentioned in the introduction there are 2 main reasons for national protection:

- protection against unsafe food;
- protection of national food production.

International standards on safe and reliable food helps to overcome the first reason. The technical barriers to Trade Agreement successfully combats the second reason.

The development of general public law principles in food law has caused profound changes in regulations at national, regional and multilateral levels. Legislations adopted to improve food safety include standards regarding the characteristics of the final product, production practices in the food supply chain, traceability within the supply chain and the liability for the actors of the supply chain. At the international level, formal and informal discussions have primarily focused on the legitimacy and harmonization of standards. The creation of regulatory frameworks in food law has been accompanied by a progressively increased use of private standards.

These standards, which may include rules on infrastructure, equipment, modalities of production, processing and quality management, are often based on more stringent requirements than the ones set up by law.

1.2. PRINCIPLES OF OFFICIAL CONTROLS

1.2.1. Introduction

Principles of food control are based on experience in the past, scientific knowledge and, not to forget, a lot of common sense. This means principles of food control do not really differ from one country to another. Food control in the United States of America looks about the same as in Europe.

Looking at specific regulations (example given food additives or food supplements) the lines are the same. Only additives and supplements that have been proven save may be used in food or sold to consumers. Of course there are some slight differences, some additives from FDA's[17] list of accepted Food ingredients are not allowed in Europe and vice versa. These differences are more based on judgement of scientific data by individuals than on differences in ideas. But sometimes political ideas also may influence these decisions. In Asia and other parts of the world, countries use the FDA list or EU's list of approved additives and other countries (e.g. Australia) use the list of additives approved by the *Codex Alimentarius*.

In the next part of this chapter we will concentrate on the European General Food Law, keeping in mind this is just an example of how principles for official controls work out.

1.2.2. General Food Law

After the publication of the Green Paper on the general principles of food law in 1997[18] and the White Paper on food safety in 2000,[19] in January 2002 the European Commission published the 'General Food Law' (Regul. [EC] No. 178/2002). The GFL provides a framework laying down the general principles and requirements of food

17 www.fda.gov/Food/default.htm.

18 Commission Green Paper on the General Principles of Food Law in the European Union, COM (1997) 176 final, Brussels, 30 April 1997, eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1997:0176:FIN:EN:PDF.

19 Commission White Paper on Food Safety COM (1999) 719 final, Brussels, 12 January 2000, ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf.

and feed law.[20] These principles are laid down in detail in the many other Community- and national rules and regulations.

Besides laying down the general principles and governing food and feed in general, and food and feed safety in particular, the regulation establishes the European Food Safety Authority and procedures for matters regarding food safety. The difference between principles or definitions or objectives is not always easy to point, but the significance from food control is of the same importance.

1.2.2.1. Aims of food legislation

Food laws are developed to serve three main goals:

- a high level of consumer's health protection;
- free movement of goods;
- fair trade between seller and buyer.

Since the publication of the green paper governments has been developing food laws keeping in mind that legislation shall consider general principles to achieve this three aims.

This principles seem very logical, but not always so easy to apply, as we will see looking at the development of European food laws.

Principles regarding public food law

1. Clear definitions of conceptions
2. Equal food legislation in all Member States
3. Internal market
4. Risk analysis
5. Precautionary principle
6. Independent supervision and enforcement
7. Control from stable to table, including feed
8. Traceability of food and food ingredients
9. Crisis management
10. Rapid Alert System Food and feed (RASFF)
11. Risk communication
12. Transparency
13. Training
14. Consumer's interests
15. Food business operators duty's and interest

20 ec.europa.eu/food/food/foodlaw/index_en.htm.

The order of the principles in this figure is meant to indicate an order of importance. As the principles are all van equal importance there is no such order.

1. Clear definitions of conceptions

The GFL provides us with definitions for the most important notions in food law. It is noteworthy that these definitions are 'for the purpose of this regulation' only. The legislator did thus not provide definitions that can be applied automatically in other community or Member States' legislation. By consequence, in each new legislation, the legislator will have to ensure that all definitions are provided (again) or reference to previously laid down definitions is made.

For the first time, a definition of 'Food' is introduced in the regulation. The regulation also defines the notion of 'food law'. Other important definitions provided in the GFL are those of 'food business' and 'food business operator', risk analysis and traceability. The GFL does not provide a definition for 'food safety' but article 14 states that 'unsafe food' shall not be placed on the market. Food shall be deemed to be unsafe if it is considered to be:

a. injurious to health;
b. unfit for human consumption.

2. Equal food legislation for all Member States

Here we see an example of how difficult it is to follow principles. If we completely followed this principle, only EU regulations and decisions should be operative within the EU. But this is looking at the historical grow of the EU no true. A lot of legislation is laid down in directives, leaving possibilities for Member States to add some requirements which are desired form a national point of view.

When the EU food law started its development, all Member State had its own food law. It was very complicated to compromise on international legislation as every member state had his own experience and points of view hoe to protect consumer's interests. Member States also tried to protect national trade interests.

So in the beginning most EU food laws were directives, only showing the headlines of the purpose and most important principles and decisions. Member States can implement this directives and adapt the content to national interests as long as the principles of the directive are not violated. The national implementations of directives still do hinder international trade and causes a lot of (unnecessary?) work. This problem is increasingly recognized by all stakeholders and directives more and more are replaced by regulations, limiting the discretionary powers of the Member States.

Regulations replace directives

Directives	Regulations
No. 2000/13, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. No. 94/35, on sweeteners for use in foodstuffs. No. 94/36, on colours for use in foodstuffs. No. 95/2, on food additives other than colours and sweeteners.	No. 1169/2011, on the provision of food information to consumers, repealing Directive 2000/13/EC, etc. No. 1333/2008, on food additives

3. Internal market

Originally the establishment and the maintaining of an internal market was the most important objectives of European food law. The free movement of goods is one of the fundaments of the internal European market; it forbids quantitative restrictions, or measures having an equivalent effect, on the import of products.

In the 1990s, as a result of a series of food scandals (mad cow illness BSE, dioxin, claw and mouth disease, pigs' bubonic plague etc.) politicians' attention was directed towards food safety. In the white paper is stated that a comprehensive and integrated approach to food is needed to establish a system of safe food production.

Nonetheless, food law still aimed at the free movement of foodstuffs, compliant with the requirements, within the Community. The European legislator therefore tried to harmonize the requirements of individual Member States, as much as possible. As a method the legislator enacted regulations on several aspects of food production that influenced national legislation in each Member State.

To support free movement of goods the EU published Decision No. 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community. This decision stated that where Member State takes steps to prevent the free movement of goods, lawfully produced or marketed in any other Member State, it shall notify the Commission on the effect of the step. The meaning of this decision was to get clearness about national measures banning products and to deal quickly. In 2008 this decision was followed by Regulation (EC) No. 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No. 3052/95/EC.

This Regulation lays down the rules and procedures to be followed by the competent authorities of a Member State when taking or intending to take a decision, where the direct or indirect effect of that decision is any of the following:

- the prohibition of the placing on the market of that product or type of product;
- the modification or additional testing of that product or type of product before it can be placed or kept on the market;
- the withdrawal of that product or type of product from the market.

The regulation concern products which are not or only partly harmonized by EU laws.

Effect of that decision is hinder the free movement of a product lawfully marketed in another Member State and subject to Article 28 of the Treaty.

Foodstuffs imported into the Community to be placed on the market shall have to comply with the relevant requirements of EU food law. Foodstuffs that are exported from the Community shall also comply, unless the authorities of the importing country request otherwise (GFL article 11 and 12). If these requests are met, the import of unsafe foodstuffs shall be radically diminished.

4. Risk analysis

Whether or not a food must be considered unsafe, depends mainly on the likeliness of potential food hazards to occur. In order to secure a high level of protection of human life and health, food law is based on risk analysis, unless this does not apply given the circumstances and character of the measure. The idea is that by performing a risk analysis before applying measurements, invalid restrictions to the free movement of food products can be avoided. Measures shall be appropriate to the food hazard.

Risk analysis, and therefore food law, is based on scientific grounds.

The European Food Safety Authority (EFSA)[21] plays a key role in the European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.

Risk analysis is a process that consists of three interconnected components: risk assessment, risk communication and risk management. As food law needs to be based on science, risk assessments need to be independent, objective and transparent, and based on all available scientific information and data. Risk assessors provide the policy makers with important information in order for them to decide whether or not risks are acceptable or measurements are required to limit the risks.

HAZARD

A biological, chemical or physical agent in, or condition of food or feed with the potential to cause an adverse health effect.

RISK ASSESSMENT

Consists first of all of an identification and characterization of all hazards. Next the exposure of humans to these hazards should be estimated. Finally the risk is characterized, taking into account the likeliness of harmful effects on health to occur and the severity thereof, following the hazard.

21 www.efsa.europa.eu/en/aboutefsa.htm.

RISK COMMUNICATION

Means the interactive exchange of information and opinions throughout the risk analysis process. This regards hazards and risks, risk-related factors and risk perceptions. Assessors, managers, consumers, food and feed businesses, the academic community and other interested parties are involved.

RISK MANAGEMENT

Is the weighing of policy alternatives in consultation with interested stakeholders. In the process risk assessments (especially the opinions expressed by the EFSA) and other legitimate factors are considered. If considered necessary, appropriate prevention and control measures can be chosen (legislation, enforcement and everything in between). The European Commission and national authorities of the Member States play an important role in the process.

5. Precautionary principle

There are specific situations, following an assessment of available information, in which the possibility of harmful effects on health is identified but scientific uncertainty persists. These situations must call for provisional risk management measures in order to ensure the high level of consumer's protection, pending further scientific information for a more comprehensive risk assessment.

The measurements must be of a temporary nature (until satisfactory scientific proof has been provided), proportionate and no more restrictive of trade than is required to ensure the high level of health protection.

The precautionary principle shows clearly how both goals of the GFL are achieved.

On one hand measures have to be taken to protect consumers from hazards if there is any doubt on the safety of food. On the other hand measures shall not needless disturb or harm trade.

THE DIOXIN CRISIS

The dioxin crisis break out in Belgium in spring 1999. The poisonous dioxin had spoiled feed because transformer oil was dumped with edible fats and oils. During some weeks feed, contaminated with PCB's[22] was delivered at chicken and pig farms.

Unexpected illness and dead was detected at chickens. Investigation results showed high doses of dioxins in the chicken meat. The trade in chickens and eggs was forbidden by the Belgian Minister of Health. Member states of the EU were informed about this scandal. Trade of Belgian chickens and eggs was stopped in all Member States and other countries in the world. Because it was not clear where exactly the spooled feed was delivered, 7 million chickens and 60.000 pigs were destroyed. Though the total amount of dioxins deposed in the food chain was very low (less than 100 mg.) the reactions of the press and politicians were extreme heavy (an election campaign used the scandal for political advantage). In reaction not only chickens and eggs were recalled from the market, but also every product for which Belgian chickens or eggs were used as an ingredient. No matter how little; just to protect consumer's health. The economic damage of the scandal was enormous.

This is an example of the precautionary principle that was incorrect applied.

It was quite clear that the amount of dioxins in products with less than 1% chicken or egg would not harm consumer's health. So the measure (recall of every product containing Belgian chicken or egg) was not proportional to the hazard. A few years ago professor van Larebeke stated that the scandal's impact on human health was much extensive, because investigations did not account for the dangerous PBC's which were present in much higher quantities than the dioxins. Legislators and food scientist learned a lot from this scandal. At new outbreaks, risk analysis will be a prominent tool to take the right decisions.

Recently a new outbreak of dioxins in chicken has been detected in Germany. Again the poison was detected in feed (vegetable fats). Because of the good traceability of the feed only 3 pig stables had to be closed. So the measures to solve the problems and the effect on consumer's trust seemed to remain small. But as a result of the publicity in Germany trade in pig meat decreased with 30% because people did not trust the pollution to be so limited. China closed his borders for German pig meat and eggs.

This leads to the conclusion that even if precautionary measures are taken correctly, an important task remains for risk communication.

22 PCB's: polychlorinated biphenyls. PCB's are used as a cooling agent in transformer. As a result of the fact that the PCB's are heated, dioxins will be formed.

6. Independent supervision and enforcement

The GFL states that all food business operator are responsible for the safety of the food they produce.

Member States shall supervise, by verifying and monitoring, that the requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall establish a competent authority to maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

This competent authority shall be independent and free of conflicts of interest.

The activities of the competent authority shall be based on monitoring programmes and multi-year plans that have been approved by the EU.

Member States shall enforce the food law if supervision shows that companies are not compliant with the legal requirements. They can demand from the food business operator to comply with the requirements, or they can impose measures and/or penalties.

Member States shall lay down the rules on measures and penalties applicable to infringements of food and feed law. The Member States can decide if these measures are administrative or criminal sanctions. The authorities have to ensure the offender is informed and safeguarded of his/her legal rights.

The European Commission shall carry out general and specific audits in order to supervise that the Member States' competent authorities perform official controls in compliance with Community law. National competent authorities are obliged to cooperate fully and provide all information requested by the FVO.

The FVO must also carry out official controls in third countries that export products to the EU. The FVO does not have authority in these countries; the controls can thus only be executed if the national authorities of those countries agree to do so. To enable controls on products from third countries, Member States have Border Inspection Posts with access to adequate control facilities for different types of food and feed and require information from business operators on the arrival and nature of each shipment. The inverse situation of third countries carrying out inspections on products that are exported to third countries also exists.

7. Control from stable to table, including feed

The need for control from stable to table (or from farm to fork) is clearly explained in GFL's consideration N^{os} 12, 13 and 14:

In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.

Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.

For the same reason, it is necessary to consider other practices and agricultural inputs at the level of primary production and their potential effect on the overall safety of food.

Though the European food law is applicable to the whole food and feed production chain and all stages of food production, processing and distribution are included, the law does not apply to the primary production for private domestic use and/or to the domestic preparation, handling or storage of food for private domestic consumption.

8. Traceability of food and food ingredients

In GFL's consideration No. 28 and 29 the legislator explains why traceability must be an incorporated principle of modern food law:

It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.

A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas this is either not explicit or else responsibility is assumed by the competent authorities of the Member State through the control activities they carry out.

Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.

The traceability of foodstuffs must be established at all stages of production, processing and distribution. Food business operators should be able to identify any person from whom they have been supplied with a food (or any substance that can be expected to be incorporated into a food). They are required to be able to identify these persons 'one step up' or 'one step down' the food chain. They shall therefore have systems and procedures in place which allow for this information to be made available on demand of the competent authority. Food which is placed on the market in the Community shall be adequately labelled in order to facilitate its traceability.

9. Crisis management

Recent food crises have also shown the benefits of having properly adapted, quick procedures for crisis management. These organizational procedures make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information.

The Commission uses a 'general plan', in close cooperation with the Member States and EFSA, for crisis management. The general plan specifies the types of situations involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by procedures and provisions already in place.

The general plan specifies the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.

In case such a situation emerges, the Commission shall set up a crisis unit immediately, in which at least the EFSA shall participate. The crisis unit shall be responsible for collecting and evaluating all relevant information and for identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible. The crisis unit may request the assistance of any public or private person whose expertise appears necessary to manage the crisis effectively. The crisis unit shall keep the public informed of the risks involved and the measures that have been taken.

10. Rapid Alert System Food and Feed

A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety. The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed.

This revised system is managed by the European Commission and include as members of the network the Member States. The system does not cover the EU arrangements for the early exchange of information in the event of a radiological emergency as defined in Council Decision 87/600/Euratom. As already mentioned in paragraph 1.6., RASFF is also the single point of information exchange to INFOSAN.

Member States shall immediately inform the Commission through the RASFF system of any measurements they have taken, relating risks to human health and requiring rapid action. These can be measurements restricting the placing on the market or forcing withdrawal from the market or the recall of food or feed. It can also include any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed. Finally it could involve any rejection, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State.

The Member States shall immediately inform the Commission on the action implemented or measures taken following receipt of the notifications under the RASFF.

11. Risk communication

Risk communication is one of the main tasks of the competent authorities of the Member States and of course of the European Commission. As stated in consideration 35:

The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; [...]

Daily new incident concerning food safety are reported by newspapers and media to consumers, which get easily worried by the news often negatively reported.

The information from these sources is not always very exact and sometimes even wrong. The competent authority has a role in providing the right, science-based information.

Not only to consumers but especially to food and feed operator's.

This information may deal with:

- Information about the arrest of a mala-fide entrepreneur trading in cheese products;
- Information about avian flu, encountered at a turkey farm;
- Safety warning for consumers, suffering from gluten allergy, not to eat particular chocolate eggs produced by the producer X, because the product's label did not mention it contained gluten.

Risk communication can also consists of inspections' reports and audits in a particular food production sectors or surveys on labelling control.

12. Transparency

The importance of transparency is best expressed by GFL's consideration No. 40:

The confidence of the Community institutions, the general public and interested parties in the Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, ***transparency*** *and efficiency. Cooperation with Member States is also indispensable.*

So transparency, independency, scientific quality and efficiency are of equal importance for confidence of consumers, politicians, business operators and other interested parties in the Authority.[23]

For the same reason transparency is very important for crisis management and communication. This principle is specified in the 'General plan', developed by the European Commission to manage a crisis.

Official controls should cover the whole food chain and are mostly carried out without prior warning. Nevertheless the national competent authorities must ensure that they carry out their activities with a high level of transparency. The Member States are required to prepare multi-annual control plans, which are subject to criticism of the Commission and other Member States. They also have to show how the year

23 Authority is the abbreviation used in the GFL for: European Food Safety Authority (EFSA).

plans have been carried out. At request of the FVO[24] competent authorities have to explain how they perform audits and inspections and sample analyses. Data on inspections and analyses only are at main levels accessible to food business operators and consumers. Specific information only is available to the particular company that is involved.

13. Training

Training of staff is not mentioned in the GFL, but Regulation (EC) No. 852/2004, on the hygiene of foodstuffs states (consideration No. 13):

Successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. To this end, employees should undergo training. The HACCP system is an instrument to help food business operators attain a higher standard of food safety. The HACCP system should not be regarded as a method of self-regulation and should not replace official controls.

In Annex II, chapter 12, is stated that food business operators are required to receive adequate training.

In section IV of annex III of Regulation (EC) No. 853/2004, laying down specific hygiene rules for food of animal origin, training is prescribed for hunters on large and small wild game.

In Regulation (EC) No. 854/2004, laying down specific rules for the organization of official controls on products of animal origin intended for human consumption, one of the points of interests for auditors is checking hygiene training of staff.

Also the national competent authorities have to train their staff for the activities they perform, as stated in article 6 of Regulation (EC) No. 882/2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules:

The competent authority shall ensure that all of its staff performing official controls:

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. This training shall cover as appropriate the areas referred to in Annex II, Chapter I;

(b) keep up to date in their area of competence and receive regular additional training as necessary; and

(c) have aptitude for multidisciplinary cooperation.

24 FVO: the Food and Veterinary Office, is the European supervisor on the work of competent authorities.

14. Consumer's interests

The legislator has laid down rules on the marketing of foodstuffs (or categories thereof). These rules are partly based on the precautionary principle and their aim is to protect consumers against products that are potentially harmful to health, pretend to be something they are not, or be – from a nutrition point of view – of a lesser nutritional quality than conventional products they try to replace. This conviction is stated in consideration No. 22:

Food safety and the protection of consumer's interests is of increasing concern to the general public, non-governmental organizations, professional associations, international trading partners and trade organizations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.

This intention follows the requirements on:

- processing hygiene;
- food additives;
- processing aids;
- novel foods;
- organic food;
- nutritional and health claims;
- microbiological spoilage;
- chemical contamination;
- labelling: allergens and composition.

Food additives, processing aids and health claims only may be used if they are approved by EFSA. Results of EFSA's investigations are free accessible for anyone (except for certain patent secrets).

But there are more aspects regarding consumer's interests. Legislation is also aimed on fair trade to prevent counterfeiting, adulteration and other fraudulent practices.

Another aim is to communicate reliable information with consumers about food and legislation and help consumers to make an informed choice.

15. Food business operator's duties and interests

Last, but certainly not least, the EU legislation states that food business operator are the first responsible for the safety and quality of their products. The competent authority has the role to check whether the food business operators comply with the food legislation, but this does not mean that the competent authority takes over the food business operators' responsibility. Food business operators and competent authority shall work together to protect consumer's interests.

a. ***Registration requirements***[25]

Food business operators must cooperate with the competent authorities. The food business operator shall notify the appropriate competent authority of each establishment under its control that carries out any of the stages of production, processing and distribution of food. Food business operators shall also ensure that the competent authority always has up-to-date information on the establishments. This includes any significant change in activities and any closure of an existing establishment.

The competent authorities lay down the procedures the food business operators need to follow to complete the registration process for their establishment(s). Establishments preparing foodstuffs must be registered in each Member State.

Establishments where products of animal origin are being produced have to be approved, with the exception of establishments carrying out only primary production; transport operations; the storage of products not requiring temperature-controlled storage conditions; retail operations –except if supply to other retail operations is involved-. Approval can follow after at least one on-site visit. An approval can only be given if the establishment meets all requirements. If an approval is withdrawn the establishment shall cease all operations. There are also requirements for the listing of establishments and plants in third countries from which imports into the EU have been authorized.

Furthermore, establishments manufacturing and/or placing on the market certain feed additives, pre-mixtures and compound feeding stuffs must be approved by the competent authority of each Member State.

Member States must update the lists of the mentioned establishments and plants available to other Member States and to the public. A list of all approved EU businesses is available online on the European Community[26] Website.

b. ***Requirements for premises***

Food business operators need to comply with the general hygiene requirements as laid down in the European legislation. The legislation lays down requirements on different types of production rooms, utensils and equipment, waste handling and water supply. There are also requirements on personal hygiene, raw materials and ingredients, packaging, transportation, heat treatment of foodstuffs and the training of employees of food businesses. Special requirements apply to food businesses operating in primary production making distinction between general, animal and plant products. Surfaces and other materials that come into contact with foodstuffs have to comply with the requirements laid down in the legislation on food contact materials.

25 Regulation (EC) 852/2004 (art. 6), Regulation (EC) 853/2004 (article 4), Regulation (EC) 854/2004 (art. 3), Regulation 882/2004 (art. 31).

26 ec.europa.eu/food/food/biosafety/establishments/list_en.htm.

c. ***Food safety plan***

Food businesses are required to develop a food safety plan.[27] To fulfil all legal obligations food business operators have to put in place, implement and maintain several standard operating procedures (SOP's), based on the HACCP[28] principles. They shall ensure that all document describing the developed procedures are up-to-date at all times and retain any other documents and records for an appropriate period.

Some food business operators of small and medium premises can comply with these requirements by using standard procedures, including the HACCP principles, for branches (e.g. butcher, baker) laid down in so called Hygiene Guides.

d. ***Recall***

If a food business operator has reason to believe that a food has been imported, produced, processed, manufactured or distributed does not comply with the food safety requirements, he shall immediately inform the competent authorities, initiate procedures to withdraw the food in question, and if necessary, recall from consumer products already supplied to them when other measures are not sufficient. The company shall work together closely with the competent authorities. This is required from each food business operator in the food production chain; these requirements therefore are not limited to the person(s) causing the non-compliance with food safety regulations.

Retail outlets shall also participate in the event of a recall; they shall pass on all information necessary to trace the foodstuff and cooperate by all means with measures taken by the producers or the authorities.

A food business operator shall immediately inform the competent authorities if he considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities on the action taken to prevent risks for the final consumer and shall not prevent or discourage any action where this may prevent, reduce or eliminate a risk arising from a food.

The European Commission not only laid down rules to steer cooperation between food business operators and competent authorities. Development of private standards is initiated by the food industry. This however does not exclude the ambition of the authorities to influence the process. The authorities actively stimulate the food industry and cooperate in the development of e.g. hygiene guides.

In the next chapter we will see how private food standards are drawn up and how they complement the public food law.

27 Regulation (EC) 852/2004 (art. 5).

28 HACCP: Hazard Analysis and Critical Control points, developed by the *Codex Alimentarius*.

1.3. PRINCIPLES OF PRIVATE FOOD LAW

1.3.1. Introduction

The label private food law is meant to cover all applications of the food sector of rules and instruments generally labelled as 'private' or 'civil' and may include topics such as (product) liability. Here however we focus on the elaborate structure of rules known as, self-regulation, private (voluntary) standards, codes of conduct and certification schemes.

Private standards draw up rules that food businesses operators voluntarily choose to comply with (from a strategic business point). The requirements of private standards are not laid down in legislation by the authorities (it is therefore self-regulation). Many standards do refer to legislative requirements that have to be complied with within the scope of the standard. Some standards set food safety and quality requirement higher than those set by law.

Since the 15th century, Lady Justice has often been depicted wearing a blindfold. The blindfold represents objectivity, meaning that justice shall be objective, without fear or favour, regardless of identity, money, power, or weakness; blind justice and impartiality. Lady Justice[29] is depicted with a set of scales upon which she measures the strengths of a case's support and opposition. She is also carrying a double-edged sword in her left hand, symbolizing the power of Reason and Justice, which may be exercised either for or against any party.

Private law is often represented by a hand shake,[30] which symbolizes that private relations are self-made on the basis of equality and mutual interests.

Private standards are sets of rules how to grow, breed, produce, transport or sell raw materials and foodstuffs. Private standards are developed by private companies who take advantage of safe food and reliable trade.

The evolution of standards was influenced by different factors:

- EU's new approach of 1980;[31]
- International trade;
- Requirements of the General Food law.

29 en.wikipedia.org/wiki/Lady_Justice.

30 www.wpclipart.com/office/handshake.png.html.

31 N. Coutrelis, *Private Food Law*, Chap. 18, ISBN 978-90-8686-176-7, Wageningen Academic Publ., 2011.

1.3.1.1. The new approach

The 'new approach' is a legislative technique put in place in the EU in the 80's to harmonize the legislations of the Member States regarding products to achieve one of the fundamentals of the Common Market: free movement of goods.

Products in various Member States are defined and regulated in different ways. In order to achieve an internal market where products circulate freely two avenues can be taken:

- Harmonize the regulations to have them equal in all Member States;
- Decide that products can circulate despite their differences.

Until the 70's (with only 6 EU Members) the main tool was harmonization. The birth of the so-called 'recipe laws', which resulted in directives for chocolate, fruit juice and the like. The harmonization took a long way of hard labour and difficult consultations. This problem was emphasized by the 'Cassis de Dijon' case, which strongly diminished possibilities for Member states to forbid marketing of products from other Member States that comply with legislation of that country. This resulted in the European Commission' opinion that free movement of goods best could be better realized by limiting harmonization of laws as little as strictly necessary. This idea brought essential developments in view of the complete achievement of a single market and ended in the Commission's 'white paper' of 1992.[32]

The 'new approach' is based on the following principles:

- EU legislation should be limited to the adoption of essential requirements, regarding safety or other special interests;
- The task of drawing up technical specifications of products should be entrusted to organizations that are competent in the standardization area;
- These technical standards are not mandatory;
- However products conform to the standards are presumed to conform to the essential requirements.

This legal technique has become quite common in a lot of industrial sectors (toys, electricity, vehicles). For food however it has been considered the approach should be slightly different. The main reason for this is that for foodstuffs there is no reference to standardization. Specifications of products which benefit from Geographic Indications are mostly derived from professional rules. However compliance with this rules is not optional but compulsory.

The best example of 'the new approach' principle in the food sector is practiced at international level in WTO, where SPS and TBT agreements refer to *Codex* standards. *Codex* standards are not compulsory but conformity to *Codex* standards provides a presumption of conformity tot SPS/TBT principles. However *Codex* rules are set up by representatives of Governments and not by private bodies.

32 aei.pitt.edu/1006/.

1.3.1.2. International trade

Besides this multinational organizations many private food standards have been drawn up. The driving force always is the wish for safe food and reliable trade. Of course standards of the *Codex Alimentarius* do provide enough rules to fulfil this wish, but the international trade uses private laws to regulate more aspects of cultivating, breeding and production of food and feed. For instance food retailers like to add additional rules regarding quality, sustainability or environment, resulting in specific standards.

In the UK in the 1990's a number of supermarket chains (including Tesco, Sainsbury, Somerfield, and Safeway) united themselves on the area of quality and founded the British Retail Consortium (BRC).[33] They developed a standard (the BRC Global Standard for Food Safety) and then made compliance with this standard a requirement for all suppliers (food businesses). The BRC Global Standard requires that a quality system is used, that HACCP is applied and that the establishment, the product, process and personnel are included into this system.

The BRC-scheme consists of an inspection protocol and a technical standard. The inspection protocol was developed for inspecting bodies. The technical standard, an extensive checklist, is relevant to the suppliers of food. The technical standard was set up in 1998 and celebrated its 6th version on 28 July 2011. The BRC code was approved in 2008 by the Global Food Safety Initiative.

With a BRC-certificate a producer complies in principle at once with all the requirements of the British (and also other) international supermarkets. Because this is cost-saving for both the producers and users the BRC certificate is wide appreciated. Most British and many other European large supermarkets and brand owners only do business with suppliers certified for to BRC Global Standard for Food Safety.

Besides this BRC standards a lot of food standards on cultivation, breeding, production, depot and transport of food and have been developed.

1.3.1.3. Requirements of the General Food law[34]

In Regulation 178/2002, the responsibilities on food safety of both authorities and food business are laid down. In Article 13, on international standards, the Union and Member States are stimulated among others to:

"(a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;

[...]

(e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced".

33 www.brc.org.uk.

34 T. Appelhof and R. van den Heuvel, *Roadmap to EU foodlaw*, ISBN 978-94-90947-26-2, The Hague, Eleven International Publ., 2011.

Article 17, in section 1, lays down the responsibilities of food businesses on food safety as follows:

"Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met".

In Article 18 is laid down that food businesses operators must be able to trace their products in all stages of the production chain so that in case of incidents unsafe products can be removed from the market (recall).

All food businesses operators are required to execute a risk analysis on their production (methods), implement control measures and document the results. This is laid down in detail in Article 5 of Regulation (EC) No. 852/2004.

Hygiene Guides

Small and medium sized companies can choose to follow the rules laid down in an appropriate hygiene guide to comply with food law. The use of a hygiene guide is not mandatory though and companies are allowed to develop their own food safety plan. Hygiene guides are usually developed by trade organizations but need to receive final approval by the minister responsible for food safety policy. In some countries food business operators may be certificated against particular hygiene guides by Certification bodies.

A hygiene guide provides instructions on how a food business can comply with all relevant legislation regarding food production, storage, transport and distribution. A risk analysis on the standard activities within the particular branch is included in each hygiene guide. Often, next to legal requirements, some additional branch specific requirements are included. The addition of specific requirements aims at improving the quality and by this improving public opinion on companies that form a part of the branch.

The implementation of hygiene guides has developed itself in quite different ways within the different Member States. In total more than 600 hygiene guides have been developed by the EU Member States.[35] Some countries like Spain and Italy have developed over 100 guides each country, while others like Greece and Ireland did not exceed six or seven per country. Furthermore it should be remarked that the scope of a guide differs from country to country. In some countries the guides describe the complete production process while in others, e.g. Spain, many guides are limited to e.g. the implementation of traceability. The following table shows an overview of the number of hygiene guides per country in 2010.

35 ec.europa.eu/food/food/biosafety/hygienelegislation/register_national_guides_en.pdf.

Country	Quantity	Country	Quantity
Austria	13	Italy	104
Belgium	24	Lithuania	9
Switzerland	2	Latvia	20
Cyprus	6	Luxembourg	9
Czech Republic	27	The Netherlands	40
Germany	47	Poland	8
Denmark	24	Portugal	31
Estonia	1	Romania	17
Greece	6	Sweden	4
Spain	126	Slovenia	6
France	34	Slovakia	9
Hungary	21	United Kingdom	11
Ireland	7		

Major food safety management systems

Multinational corporations often choose to develop their own food safety management system. These systems do not only aim at complying with the (international) law but also cover the requirements and expectations of suppliers and users in the production chain. For the users in the chain it is impossible to check all different management systems of their suppliers.

In the last few decades united retailers and buying associations of agricultural producers therefore have developed 'uniform' food safety management systems (also known as standards or schemes), laying down in detail their requirements for producers and service providers. Every suppliers needs to be able to demonstrate compliance with the quality management system and also to obtain certification. Suppliers are furthermore obliged to let independent audits be performed to verify compliance with the standard(s).

Compliance with legal requirement is one of the pre-requisites of all standards. In 2001 the *Codex Alimentarius* has provided guidelines on the design and use of certificates.[36]

Because of the many different standards and requirements asked for by the customers, suppliers often have to obtain multiple certificates to be able to supply all their customers. This situation can be very burdensome to many suppliers as standards do differ on certain parts; being developed with the same objectives, the principles of the standards are the same and differences are mainly of a bureaucratic nature. The Global Food Safety Initiative (GFSI) aims at merging the different standards as much as possible by accepting only those standards that are of an adequate level.[37]

36 Guidelines for design, production, issuance and use of generic official certificates. CAC/GL 38-2001.

37 www.ciesnet.com.

The GFSI is an initiative started in 2000 by international retailers as a benchmarking instrument for food safety standards. The GFSI is governed by the CIES-the Food Business Forum (a worldwide food business forum that includes as members all major retailers such as Tesco, Marks & Spencer's, Metro, Carrefour, Auchan, Casino and Royal Ahold) and plays an important role in the certification of food safety standards. In 2009 the Consumer Goods Forum was created by the merger of CIES-The Food Business Forum and the Global Commerce Initiative (GCI) and the Global CEO Forum.[38] The mission of the Consumer Goods Forum is formulated in a manifesto.[39] All retailers together, that are members of the CIES, generate an annual turnover of more than EUR 2.1 billion.

One of the main objectives of the GFSI is to improve the efficiency of audits at the suppliers of the different standards. To achieve this, the GFSI has developed a model which standards need to satisfy, before they can receive approval by the CIES members. The GFSI thus focuses on harmonization between countries and achieve efficiency for suppliers. Approval for certification schemes can be applied for at the GFSI. Approval by the GFSI acts as worldwide recognition and acceptance of the certification scheme ('certified once, accepted everywhere').

On the time of writing these were the approved standards by the GFSI:[40]

Manufacturing:

- BRC (British Railway Consortium) Global Standard Version 6
- Dutch HACCP (option B)[41]
- FSSC 22000 (Food Safety System Certification)
- Global Aquaculture Alliance BAP, issue 2 (GAA Seafood Processing Standard)
- Global Red Meat Standard Version 3
- IFS (International Food Standard) Version 6
- SQF (Safe Quality Food) 2000 Level 2
- Synergy 22000[42]
- GlobalG.A.P. IFA Scheme Version 3
- Canada Gap
- SQF (Safe Quality Food) 1000 Level 2
- PrimusGFS

38 www.ciesnet.com/1-wweare/index.asp.
39 Manifesto of the consumer goods forum, 2009.
40 www.mygfsi.com/about-gfsi/gfsi-recognised-schemes.html.
41 Applies only till the end of 2012 for existing certificates. Will not resubmit on GFSI 6th ed.
42 Because of close cooperation with FSSC 22000, Synergy 22000 will not resubmit on GFSI 6th ed.

As mentioned before, national authorities are interested in the role of private standards in ensuring safe food. As an example we can look at the Dutch competent authority (nVWA) that has started a supervision policy where certification by the manufacturers against GFSI standards is taken into account. The same goes for some regional standards drawn up by large food businesses, (examples given: Vion Food Group and IKB-egg) which have been proven transparent and of high quality.

Additional standards

Besides the major internationally accepted food safety management systems many more standards have been developed in the EU that are less known. These standards are more focused on the quality than on the safety of foodstuffs; objectives include among others care for the environment and sustainability. There are standards that are based on existing standards, such as GLOBALG.A.P., or have been developed independently, such as the standard 'Fruitnet' developed in Belgium. These standards have often a local function to protect specific quality aspects of certain products (e.g. 'Gepruefte Qualitæt Thüringen'). Products may carry a logo and/or nomination, indicating that the product complies with the requirements of the standard. In recent years the number of this type of standards has exploded. Most standards are applied for 'business to consumer' (B2C) marketing and only a limited number find their way in 'business to business' (B2B) marketing.

In general the EU has a positive opinion on the development of certification schemes, but it seems that concern has started to be raised over the large number of schemes that have found their way to the market over the last few years in both the EU and the rest of the world. The EU has started a project with the objective to inventory all existing schemes for fruit and vegetables on the European market.[43] In 2010 a report[44] summarizing the results for agricultural products and foodstuffs was published. From Figure 1 follows that the schemes and standards focus on many politically important subjects; it e.g. already includes a standard on climate change.

43 EU, Directorate L. Economic analysis, perspectives and evaluations: L.4. Evaluation of measures applicable to agriculture; studies Subject: Letter of Invitation to Tender – Contract Notice 2009/S 086-123210. Ref: Marketing standards in the fruit and vegetable sector, AGRI-2009-EVAL-07.

44 *Inventory of certification schemes for agricultural products and foodstuffs marketed in the EU Member States*, Areté Research and Consulting in Economics, 2010.

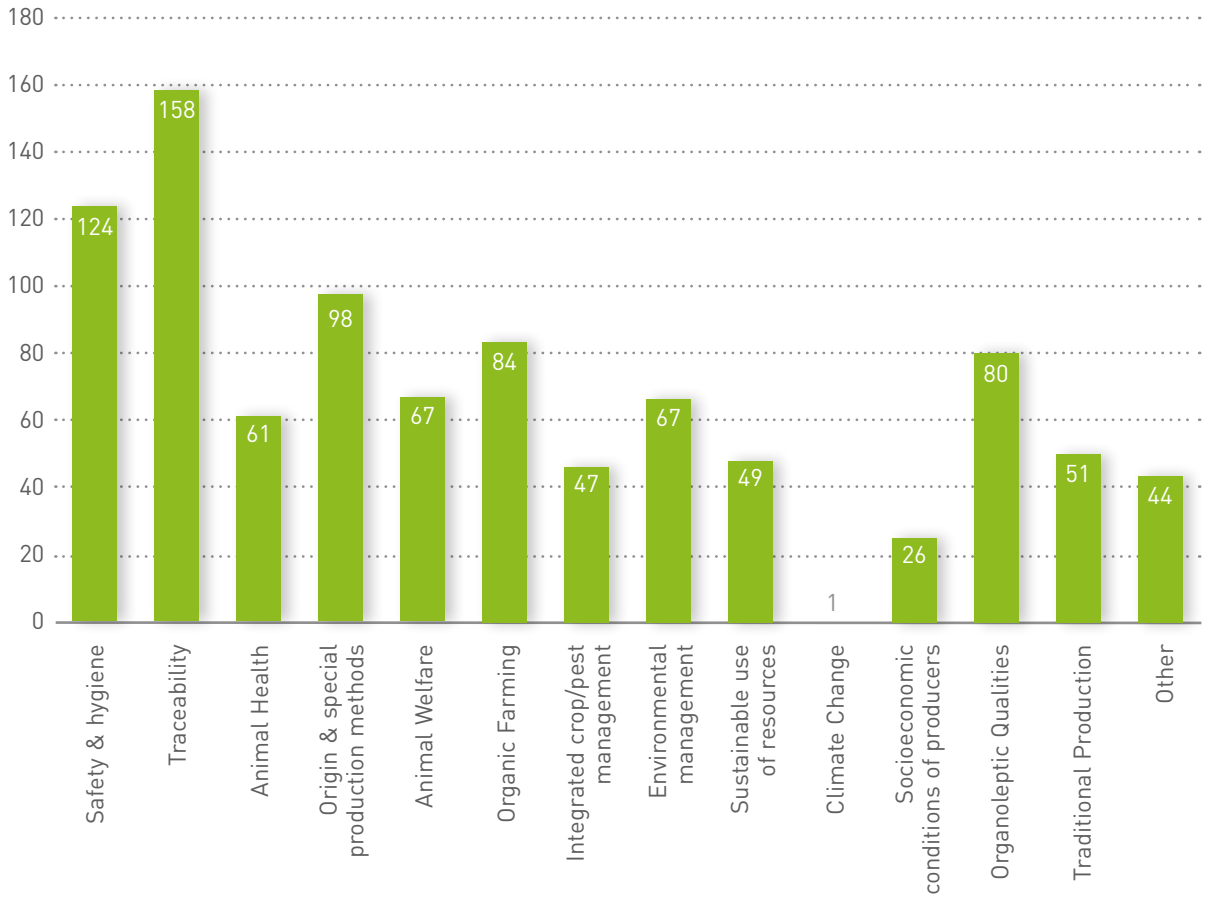


Figure 3 - Number of schemes by policy area covered (EU=27) (aggregation fed by 346 schemes out of a maximum theoretical total of 352). Schemes can cover multiple policy areas

The development of these standards varies greatly over the different Member States (for instance Bulgaria had only a single scheme in 2010, while Germany had as many as 107).

After having carefully assessed the situation, the Commission developed guidelines showing best practice for the operation and implementation of such schemes.[45] These guidelines were drawn up in consultation with stakeholders.

Key factors driving private standards are:

- to provide brand protection
- to meet legislative requirements – encouraged and voluntary
- to promote business improvement and efficiency
- to assist in the response to consumer concerns

In the next section we will look at the principles of food safety systems.

45 Commission Communication, EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs (2010/C 341/04).

1.3.2. Principles of standards

As in public food law we have general food law principles. Private food is based on general starting points.

Principles of private standards

1. Compliance with legal requirements
2. Steady quality of food
3. Certified partners
4. Management commitment
5. Continuous improvement
6. Independent supervision and enforcement
7. Food safety plan based on risk analysis
8. Good Manufacturing Practices
9. System management
10. Clear communication
11. Supplementary principles

The order of the principles in this figure is meant to indicate an order of importance. As the principles are all van equal importance there is no such order.

1. Compliance with legal requirements

Retailers and other business operators have a strong interest in compliance with legal requirements. Food that complies with food safety rules is meant to be safe and will not easily lead to sick or dissatisfied consumers. This helps to decrease consumer's complaints.

There is also another reason why business operators always want to avoid problems with officers in charge of supervision on food safety, environmental pollution or any other territory of legal enforcement. Court cases may result in negative publicity for a product or a company. Therefore compliance with legal rules is the first requirement for private standards.

In the U.K. Food Safety Act of 1990 the 'Due Diligence Defence Principle' is defined:

"...it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control".

All reasonable precautions mean: systems + Good Manufacturing Practice.

Although not specifically mentioned in any other member states legislation the principle of the due diligence is widely understood and practiced by retailers and manufacturers.

Compliance with legal rules in fact also means important principles of public food law, like

- Food supply chain approach,
- Traceability of food and food ingredients,
- Staff training,
- Transparency and,
- Clear communication.

These principles can be considered as essential parts private food standards requirements (see chapter 2).

2. Steady quality of food

Business operators strive by all means for consumer satisfaction. This may be by low prices or a friendly service, but one of the most important parameters is a good and steady quality. So private standards mostly contain specific requirements on food quality. For example: meat from particular certified premises, premium size of apples or the shape of cucumbers.

3. Certified partners

Food standard owners believe the best way to safeguard the quality of raw materials and utensils is demanding that suppliers of these product are certified by independent institutions. This means they should be able to rely on the audits performed by third-parties at the suppliers.

Unfortunately this system does not work to the complete satisfaction of every one. Not every auditor looks as sharp and consequent as may be expected. Some companies incline to set up again their own audits. As criticism from retailers on certification bodies is growing, the owners of food standard promise to set up more strict rules for auditor. British Retail Consortium (BRC) for instance announces important improvements:[46]

- Move to challenging not recording,
- Time spent in the factory, not the office,
- Additional time:
  - for interviews with staff,
  - observing line start and change procedures,
- Vertical audits as part of the traceability,
- Introduction of root cause analysis.

46 D. Brackston, Presentation BRC Global Standards for Food Safety, on VMT meting 27 January 2012.

4. Management commitment

An important issue of standards is the role of management. Quality guru's belief the role and behaviour of managers is essential in setting up a good working quality system.

The management of a company must belief in the benefits of working with a good quality system and show this belief to their staff. The management must be strongly involved with the development of the system and explain why the system is so important for the existence of the company. The involvement also means that the management must choose the best appropriate policy and direction to go. Staff must be involved in developing standard operating procedures (SOP), but managers have to approve these SOP's.

5. Continuous improvement

Food safety standards mostly are based on rules of quality systems. This means that just implementing a standard does not mean the job is over. Working with the system must show continuously improvement. Some food safety systems (e.g. BRC and IFS) use gradations for certification of companies. Companies often start at a low level of compliance with the standard and as they improve the certificate will be upgraded.

This is a principle that auditors also apply in a negative sense when they audit a company from year to year. A small deviation in the beginning will be assessed as minor (commonly coded as C). If at the next audit the situation has not improved, the fact will be assessed as B, demanding more direct action. If the situation still does not improve and there could be any uncertainty regarding food safety the auditor could even decide to call it a major deviation (an A). In that case the situation shall be improved immediately. If the auditee does not obey the auditor, the certificate may be suspended.

6. Independent supervision and enforcement

Food quality systems do not merely express an intention to produce food in accordance with the requirements of the standards. To achieve and keep their certification business operators at first are obliged to audit their system themselves; which is called an 'internal audit'. Results of internal audits are complete and honestly registered and lead to improvement of the system where the audit has shown incorrect behaviour or results.

Besides this internal audits, companies are object of audits by independent auditors of Certification Bodies, with specialized knowledge of the particular standard.

Certification bodies are audit organizations who are fully independent off food standards owners and food operators. Certification bodies exchange their experiences on the certification scheme with a Technical Committee or Board of Experts and the executive board of the standard.

Certification bodies receive their accreditation from accreditation bodies when compliant with their requirements. Accreditations bodies are appointed by national authorities and may governmental institutions or private institutions.

The operational procedures of accreditation bodies in the EU are supervised by international accreditation bodies through peer assessment. Accreditation bodies are accepted into Multilateral Agreements in Europe (EA-MLA) and outside of Europe (IAF-MLA and ILAC-MRA).[47] Regulation 765/2008 lays down the requirements on accreditation and market surveillance relating to the marketing of products. In Article 4 of this Regulation the general principles for accreditation are laid down. Some examples are:

- Each Member State shall appoint a single national accreditation body.
- Where a Member State considers that it is not economically meaningful or sustainable to have a national accreditation body or to provide certain accreditation services, it shall, as far as possible, have recourse to the national accreditation body of another Member State.
- The responsibilities and tasks of the national accreditation body shall be clearly distinguished from those of other national authorities.
- The national accreditation body shall operate on a not-for profit basis.
- The national accreditation body shall not offer or provide any activities or services that conformity assessment bodies provide, nor shall it provide consultancy services, own shares in or otherwise have a financial or managerial interest in a conformity assessment body.
- An accreditation body shall act as an independent organization. In deploying an auditing team it gives much attention to the independence of the auditors.

Certification bodies that carry out audits and issue process/product certificates, are accredited against the standard: ISO/IEC Guide 65 (1996) or ISO/IEC 17021. Certification bodies which carry out audits to certify food management systems are accredited against ISO/IEC 17021.

Certification bodies, that inspect companies on e.g. hygiene guides, are accredited against ISO/IEC 17020. The scope of inspections is more limited compared to audits. During inspections, the emphasis lays more on meeting fixed requirements, while in an audit more attention is paid to how risks are identified and managed. The laboratories, which analyse food and raw materials, are accredited by the AB against ISO/IEC 17025.

With regard to the auditors, with the authority to perform work for a certification body, strict requirements are laid down in the norms mentioned above:

- General: auditors shall have competence in performing technical reviews and have clearly defined instructions, in which tasks and responsibilities are laid down.
- Certification bodies should establish minimum criteria for the qualification of the Auditors.
- Auditors must be contractually obliged to follow established rules and report any kind of previous or on-going cooperation with an auditee.

47 www.european-accreditation.org/the-mla.

- Certification bodies must keep track of information on the right qualifications, training and experience of auditors on the different specialism that are applicable. This information should also indicate the date from which this information is valid.
- Auditors shall not perform other audits than the audits for which they, on the basis of their training and experience, have authority.

Since February 2007, the certification protocol ISO/TS 22003 is available.

ISO/TS 22003:2007 defines the rules applicable for the audit and certification of a food safety management system (FSMS) and provides the necessary information and confidence to customers about the way certification of their suppliers has been granted. It is laying down on among others requirements the auditor and duration of the audit.

7. Food safety plan based on risk analysis

Most food safety management systems contain many rules regarding Risk Analysis (RA), Good Manufacturing Practice (GMP) and System Management SM).

- Examples concerning GMP are: general technical requirements regarding building, machines and tools.
- Examples concerning RA are: requirements on development of apparatus to monitor safe production.
- Examples concerning SM are: requirements on decent registration of processes and production.

The partition of all rules of a standard over this 3 aspects is not a steady fact. Some standards contain a lot of rules regarding risk analyses while in other standards GMP or SM are much more dominant. Though rules regarding RA, GMP or SM may differ a lot in significance, counting the amounts of rules divided over this tree subjects give a nice impression of the nature of a standard.

From the figure below it becomes clear that BRC and IFS have a high content in GMP where Dutch HACCP and ISO 22000 show much more interest in HACCP. Requirements of ISI 22000, combined with PAS 220 are best balanced between the tree aspects.

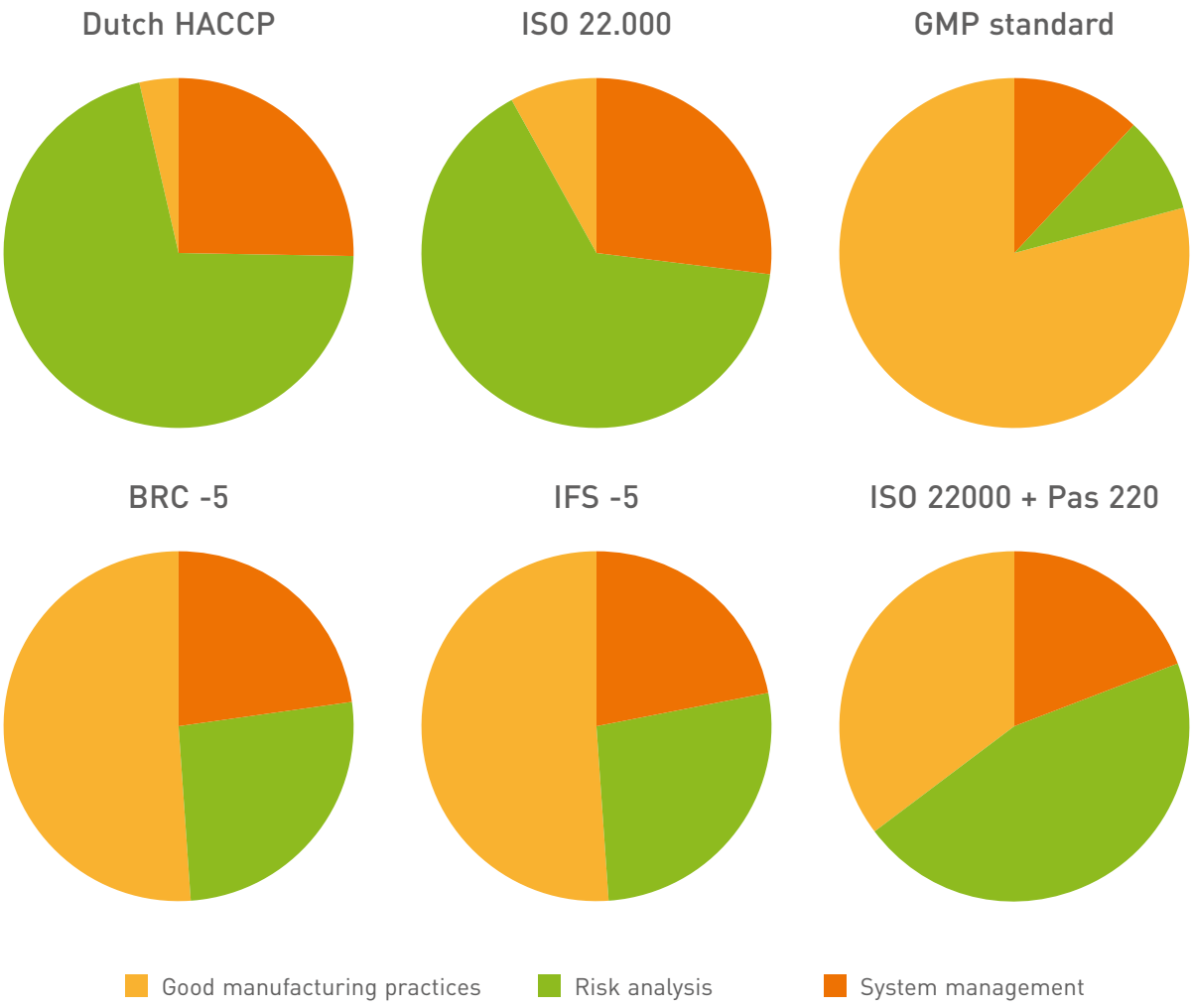


Figure 4 - Comparison of different standards[48]

Set as an obligation in public food law, risk analysis shall be part of a food safety plan. In general there are two ways to establish a food safety plan, based on this principle. If the production process is a common relative simple process hygiene guides can be used as a tools to fulfil the obligation.

More extensive and complicated processes need development of a specific designed food safety plan. A risk analyses of all process steps has to be performed by a team of specialist that indicate the hazards and critical control points. It also develops control measures regarding the critical control points to neutralize the hazards.

Mostly the risk analysis is performed according to the 7 principles of HACCP, as described by the *Codex Alimentarius*.

To check if a company's food safety plan is complete and appropriate the auditor of the CB has to perform an audit.

48 P. Besseling, *Gevaren- en risicoanalyse*, ISBN 978 90 12 38397 4, The Hague, SDU Uitg. b.v., 2010.

8. Good Manufacturing Practices

A good manufacturing practice (GMP) for food production is a production practice that helps to ensure product quality by laying down clear definitions and production rules.

Basic concepts of most GMP requirements for food standards are based on 'The General Principles of Food Hygiene' of the *Codex Alimentarius*[49] or Annex II of EU's Regulation 852/2004. Both are more or less similar and lead to the ultimate goal of safeguarding the health of the consumer as well as producing good quality food products. Complying with GMP is a mandatory aspect in most food quality systems. Food quality management systems.

Common Content of Good Manufacturing Practices contain requirements on

- Facility Environment
- Local Environment
- Facility Layout and Product Flow
- Fabrication
- Equipment
- Maintenance
- Staff Facilities
- Physical & Chemical Product Contamination Risk
- Segregation & cross contamination
- Stock Management (rotation)
- Housekeeping, Cleaning & Hygiene
- Water Quality Management
- Waste Management
- Pest Control
- Personal Hygiene, Protective Clothing & Medical Screening
- Training of staff

Supervision on GMP requirements demands inspection, meaning just check if the situation meets with the prescribed norms.

49 Recommended International Code of Practice, CAC/RCP 1-1969, ref. 4, 2003.

9. System management

System management also is an important aspect of international food quality systems. It controls the way how production, transport and all others aspects of a company are organized and managed. Good management of processes in the whole organization is essential to guard that all intentions and requirements really will lead to the aimed results, including continuous improvement. A full food quality systems contains requirements on the following subjects.

Common Content of a Food Safety Management System

- General Requirements
- Food Safety Policy
- Food Safety Manual
- Management Responsibility
- Management Commitment
- Management Review
- Resource Management
- General Documentation Requirements
- Specifications
- Procedures
- Internal Audit
- Corrective Action
- Control of Non-conformity
- Product Release
- Purchasing
- Supplier Performance Monitoring
- Traceability
- Complaint Handling
- Serious Incident Management
- Control of Measuring & Monitoring Devices
- Product Analysis

10. Clear communication

As seen above the management of food production and a food quality system is a very complex task. Therefore clear communication between all staff is essential. This communication may be verbal or written. Verbal is often given preference when particular things have to be explained to other people, but a lot of communication can

better be written. Written communication often is more exact and thought through. It is also simpler to look at a written instruction for a second time as one does not remember the instruction exactly. For that reason all instruction communication needs to be laid down in Standard Operation Procedures (SOP). A SOP will be developed for every particular task, like handling of goods, storage of raw material and production. In a SOP all essential aspects of a handling, details of reporting, details of production or laboratory specification exactly are described. All SOP's together form the quality handbook.

The SOP's shall be written very clear so that any misunderstanding is avoided.

This handbook is also the guide for auditors of certification bodies and the competent authority to check how requirements are fulfilled and how the results of a risk analysis have been worked out at critical control points.

11. Supplementary principles

In addition to all requirements concerning food safety some standards (also) focus on quite other aspects that are of great interest to consumers who are concerned about particular essential aspects of live. The main aspects are:

- Social responsibility;
- Sustainable development;
- Environmental management;
- Health;
- Religion.

Social responsibility

The most important guide on social responsibility is ISO 26000[50]. Alongside with their conventional business objectives, companies that implement ISO 26000 have a set of specific company objectives, like environment, human rights, labour practices, organizational governance, fair operating practices, consumer issues and community involvement and social development. ISO 26000 provides a guidance on social responsibility. It does not stipulate specific requirements.

Other examples of standards concerning social responsibility are: Fair Trade and Vegetarian food logo.

Sustainable development

An example of sustainable development is UTZ Certified[51]. This system is dedicated to an open and transparent marketplace for agricultural products. It offers coffee, tea and cocoa certification programs and manages traceability for RSPO certified palm oil. UTZ CERTIFIED's vision is to achieve sustainable agricultural supply chains where farmers are professionals implementing good practices which lead to better

50 www.iso.org/iso/iso_catalogue/management_and_leadership_standards/social _responsibility/sr_discovering_iso26000.htm#std-1.

51 www.utzcertified.org/.

business, where the food industry take responsibility by demanding and rewarding sustainable grown products, and where consumers buy products which meet their standard for social and environmental responsibility.

Other examples of sustainable development are: marine Steward Council (MSC), Rainforest Alliance and Organic food logo.

Environmental management

ISO 14000 or ISO 14000:2004 consists of guidelines relating to environmental management systems and supporting standards. Voluntary environmental management refers to how an organization acts to minimize its harmful impact on the environment.

Another example of environmental management is the carbon trust standard.

Religion

Consumers from Muslim of Jewish background only want to eat food that has been prepared at a special way, according to religious requirements set by the Koran or the Torah. These products shall be 'halal' (for Muslims) or 'kosher' (for Jews).

1.3.3. Classification of private standards

According to the FAO/WHO,[52] classification of private agri-food standards can be based on the bodies that have formed the standards:

1.3.3.1. Individual firm standards

These are set by individual firms (large food retailers), and adopted across their supply chains. They can be considered as sub-brands on the private label products (Tesco's, Carrefour's). These standards may have national or international reach.

This individual firm standards are developed and adopted by private food companies, such as major food retailers and food service companies. In case of companies that have technical capabilities, the standards are elaborated in-house, while companies with more little technical capability tend to use external consultants.

Within the category it is also possible to find private standards elaborated by private standards firms or organizations that use internal technical resources and external consultants (AIB international, for example). Advice and consultancy can also be provided, formally or informally, by potential standards adopters. In the US, for instance, where private standards companies are a key element of the private food safety standards, these standards are linked to compliance with regulatory requirements.

52 S. Henson and J. Humphrey, "The impacts of Private Food Safety Standards on the Food Chain and on Public Standard-Setting Processes", Paper prepared for FAO/WHO, 2009, pp. 20 and ff.

1.3.3.2. Collective national standards

These are set by collective organizations that operate within the boundaries of individual countries, including industries associations and Non-Governmental Organizations (NGOs). These organizations represent the interests of commercial entities (food retailers, processors or producers) or be NGOs. These or other entities are free to adopt them.

Within EU these standards serve for compliance with businesses obligation to set up a food safety plan. These hygiene guides play an important role in small and medium companies EU has set up guidelines for the development of these standards.

1.3.3.3. Collective international standards

These are set by organization with international membership. For example, GLOBALG.A.P. was initially created by an international coalition of European retailers.[53] This category of private standards may be set by differing combinations of public, private and NGOs actors. The elements of a GLOBALG.A.P. standard setting process operates as follow:[54]

a. The decision to proceed on a new or revised standard is taken by a board of directors, consisting of elected members with equal numbers from the food retail and production/supply sectors. Decisions are taken by consensus and the terms or reference are drafted and posted on the GLOBALG.A.P. Website, and stakeholders are invited to comments.

b. GLOBALG.A.P. Sector Committees are responsible for technical decision making on elements of the standards that are relevant for the sector. Nevertheless, in practice the Secretariat plays a key role in directing the establishment and the revision of GLOBALG.A.P. standards.

c. Draft standards are publishes on the website at two stages in the standard-setting process.

d. New and revised standards are first agreed by the relevant Sector Committees and then the elected Board of Directors is responsible for final approval of the standard.

The development of GLOBALG.A.P. standards has encouraged the growth of private and/or public codes of good agricultural practices that have been formally recognized as equivalent in a number of countries.

53 See www.globalgap.org/cms/front_content.php?idcat=9.

54 FAO/WHO report cit., p. 22.

1.4. PUBLIC FOOD LAW VERSUS PRIVATE FOOD LAW

In the previous chapters we have seen the principles and characteristics of both public and private food law. In many important aspects they do not really differ. Figure 5 shows with principles both public and private have common and which are specific for public or private food law.

Figure 5

1.4.1. Mutual interest

Figure 5 shows that most principles regard both public and private food law, though some items do not exactly have the same significance for both public and private food law.

PRINCIPLE OF RISK ANALYSIS

In public food law the principle of risk analysis is used for assessment and evaluation of novel foods and food ingredients by EFSA.

Risk analysis is also used to manage a crisis, in order to decide about measures taking in account both consumer's health and trade obstruction.

Competent authorities use risk analysis to set up their year plans concerning audits, inspections and sampling.

In private food law risk analysis is a tool to discover de hazards and critical control points of a production process.

Consumer's interests is of course one of the most important principles for both public and private food law, but the perspective of both parties differ.

Public food law provides legal measures to protect consumer's health interest. In fact most of the public food legislation arises from the wish to protect consumers from hazards like pesticides, heavy metals and PCB's and dioxin. For the same reason food additives and novel foods need approval by EFSA.

Private food law cares for consumer's health and also takes care to quality of food, but that is because consumers are clients needed for trade and sale.

Independent supervision and enforcement in private food has not the same meaning as in public food law. Certification is not an obligation from government. The food business operator does have a choice:

- Do I want to be certificated?
- Which standard will be the right one for me?

Of course his 'freedom' is limited by the demand of his customers, but it is also his own choice to deliver or not. This is not the case regarding public supervision and enforcement.

1.4.2. Public food law

Besides the principles which public and private food law share, there some principles which mainly regard public food law.

Equal legislation in all member is of course important for everyone, but at a different level. The EU and national governments and authorities are working on it for decades to succeed in reaching such a situation. Business operators only can unite themselves in associations which can influence the process of harmonization by lobbying at institutions which can make the difference.

The problem of **free movement of good** within all Member State is an important wish of both European governments as international traders. So interests of both parties are equal, but only public food law has to power to influence the development of free market by setting up.

During a **crisis** both Competent Authorities (including the Commission) and food business operators have to cooperate together to manage the problems and come to solutions where consumer's health is protected in the most effective way in the meantime causing not more trouble to food business operator than strictly necessary.

The authorities take the lead and will build up a crisis team filled with officials and experts from public and private origin.

The **rapid alert system** for food and feed regards only public food law. It is mainly mend to inform all authorities about incidents and crises. Part of the information is also available to food business operators and consumers.

Risk communication especially is a task of the government, but governments should be willing to benefit from scientific insight and advice from EFSA. During crises it often happens that politicians incline to rapidly inform politics and consumer about origin of the crisis and who is to blame. This must be prevented because opportunistic communication may lead to big financial loses.

THE EHEC CRISIS

In May 2011 in Germany there was a lot of fuss about the outbreak of a dangerous EHEC bacteria. At least 1000 people got sick after infection. About 400 people had serious health complaints and at least 14 people died.

The definitive source of the infection was not clear yet, but tomato, lettuce and cucumber were strongly suspected. The German Government therefore warned people not to eat these vegetables, origin from North Germany. This resulted in lots of investigations on these vegetables and consumers were warned to be careful eating these vegetables. As a result consumption of these vegetables dramatically declined.

The next day was communicated that the EHEC bacteria originated from Spanish cucumbers, which were exported to North Germany. Also people in other counties got sick, likely because of visiting in North Germany. 4 Days later the German authorities reported that investigation proved that the Spanish could not be the origin of the infection. Again some days later the authorities communicated that possibly sprout vegetable from a German company could be the origin.

Only 2 weeks after the outbreak the German Koch institute, that was not involved in the crisis before ten days after the outbreak, confirmed that the suspicion of sprout vegetable (Taugé) was the infection' origin.

This resulted again in lots of investigations and warnings to consumers and declining consumption. At the end the most plausible cause of the infection seemed to 2 batches of Fenugreek, imported from Egypt.

Important Lessons to be learned were:

- Don't try to solve big problems by only local knowledge;
- Try to avoid premature uncertain information.

As described above, food business operators are the first responsible for the safety and quality of their products. The competent authority has the role to check whether the food business operators comply with the food legislation, but this does not mean that the competent authority takes over the food business operators' responsibility. Food business operators and competent authority shall work together to protect consumer's interests.

This responsibility is formed by:

- registration requirements;
- requirements for premises;
- establishing of a food safety plan;
- cooperation in case of crises and recalls.

Most of these obligations corresponds to the requirements of the Good Manufacturing Practices in private food law.

1.4.3. Private food law

As shown in Figure 5 private food law has additional principles to these of public food law, because private food law was drawn up for different reasons. Traders and retailers need a quality system to ensure that the delivered food complies with ordered food and also has a **steady quality.** Therefore a chain approach with **certified partners** is needed.

This quality system needs permanent attention of the company's **management** to function as it was mend to function and to bear criticism of auditors of certification bodies. **Good manufacturing practices** are like risk analysis important principles of the standards. GMP rules help to standardize production leading to steady quality.

In public food law all rules on composition and prevention of contamination are to be seen as GMP rules. Nevertheless private food law has more requirements on GMP.

System management is third important principle of private food law, which sets the obligation to draw up standard operating procedures on how process of a company shall be performed.

To achieve **continuous improvements** which not only is a demand of the system, but also favourable for the company, also management's attention is needed.

Because of the importance of steady quality and continuous improvement all information in SOP's must be unequivocal and very **clear communicated** to prevent misunderstanding.

The **additional requirements** in private food law regarding social responsibility, sustainability, environment, and religion probably are the most striking extra requirements.

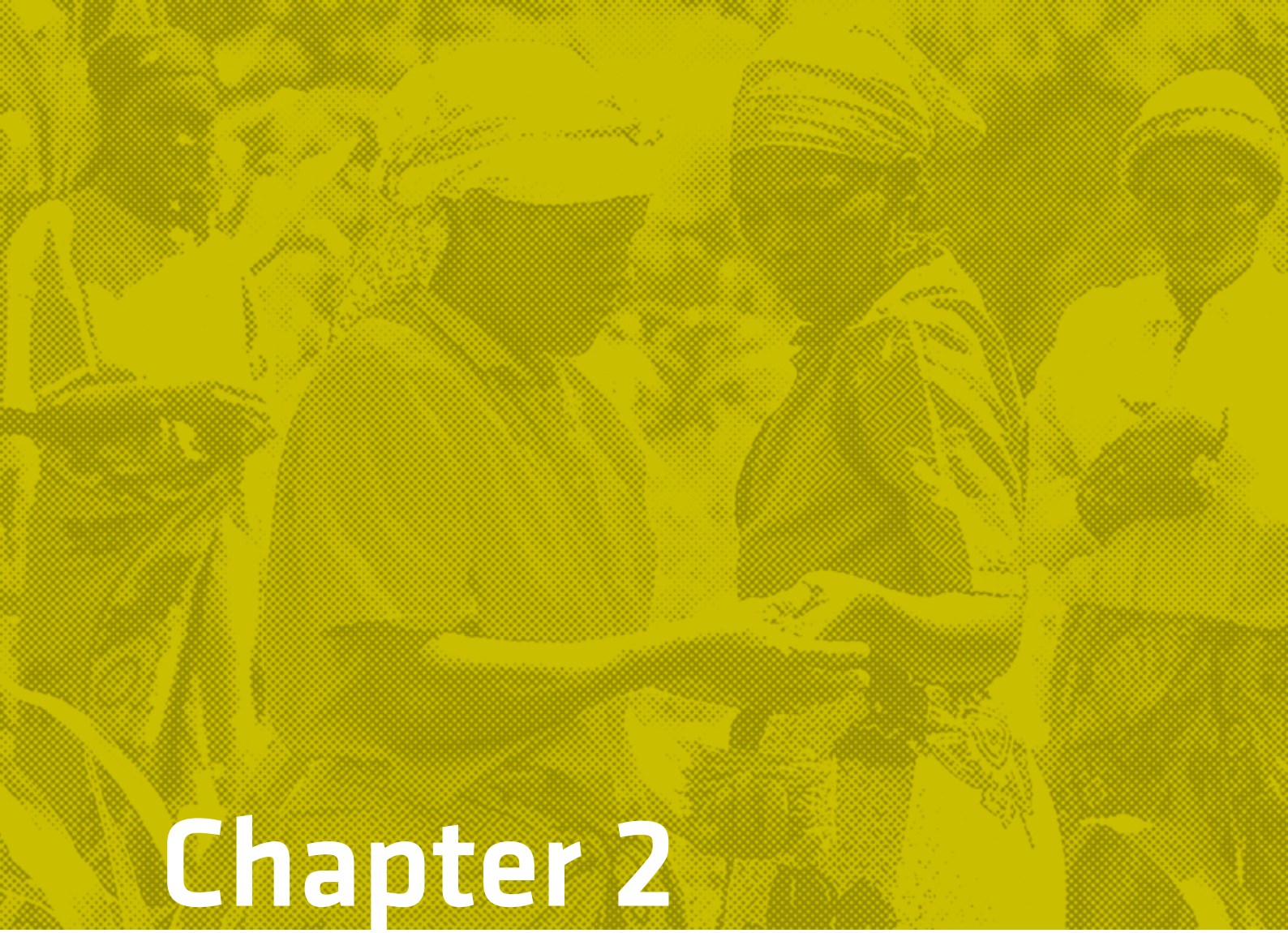
Requirements on social responsibility, sustainability and environment often are some extra requirements on the extensive package of requirements of sizeable international food quality systems. But there are much standards focusing for instance on sustainability, that have a much more limited scope, for instance the standard on sustainable palm oil. Certification on Halal or Kosher food also has a limited scope. Prime attention regards the slaughtering process, and in the case of kosher food certain combinations of food ingredients.

1.4.4. Conclusion

Private food law principles includes most principles of public food law to produce and trade safe food, but food quality standards contain more detailed requirements than public food law. So private food law can be considered to be 'legislation' complementary to official legislation.

In this way the principle of 'the new approach' meaning general public legislation completed with technical standards, more or less is given shape, as intended in 1980.

Guided by the Global Food Safety Initiative all major food standards continuously try to improve food safety management systems to ensure confidence in the delivery of safe food to consumers. GFSI provides a platform for collaboration between some of the world's leading food safety experts from retailer, manufacturer and food service companies to convergent standards in the same direction, always complying with public food law.



Chapter 2

Role of competent authorities in official controls and tasks of official controllers

2.1. INTRODUCTION

2.1.1. Milestones in food law history

The history of food quality and safety is as old as the food trade. The ancient Egyptians, the Greeks and the Romans developed all kinds of monitoring the quality of wine, meat and fish. The marketing of defective products was severely punished.

During the Middle Ages, many European countries kept on developing their monitoring activities over food. Municipalities and local government approved regulations in order to classify foods, especially from the viewpoint of their compositions. Checks and controls were in the hands of municipal judges, who were appointed to monitor food manufacturers and food traders. The expertise in food monitoring became more and more sophisticated, including organoleptic examination and skilful tricks, in order to trace possible adulteration and falsification of foodstuffs. Severe penalties (such as expulsion from the profession, corporal punishment and even death). Often only members of professional associations (in the Netherlands were the guilds) were authorized to sell food. Until the 19th century, the monitoring of food a matter of local cities, counties and small regions. After the industrial revolution in 19th century it emerged the need for better organized supervision. From the late 19th century, the governmental supervision became increasingly centralized, as well as the legislation, which included national rules on hygiene and composition of foodstuffs.

2.1.2. International trade

Already since the late Middle Ages, trade of foodstuffs increased considerably between European countries and progressively between Europe and third countries.

With the advent of the industrial food manufacture and production, in 19th century's second half, the need for broader trades increased. This development caused problems because food quality in the exporting country not always corresponded to the quality expected in the importing country. The first food scandals were detected.

THE BUTTER SCANDAL

In 1862 a Dutch boat with butter arrived to London. At inspection the butter appeared very poor quality and coloured with artificial yellow to mask this fact. The boat was sent back to the Netherlands and for decades Dutch butter could not be traded to England.

In this context, the differences between national legislation became a stumbling stone for the harmonisation of food law principles.

The fragmentation in food legislation and the consequent need for a better organised international legal system were determinant factors for the creation of an international common core of food law principles in the second half of the 20th century.

2.1.3. The Food and Agriculture Organization (FAO)

The Food and Agriculture Organisation (FAO) was set up on 16 October 1945,[55] a date commemorated every year as 'World Food Day'. The FAO's objective is to eradicate hunger and to make high quality food accessible to all. It focuses on both developed and developing countries. The FAO supports the elaboration of agreements and policies by providing a neutral platform for negotiation and information. It aims to improve nutrition, raise agricultural production and contribute to the world economy.

The FAO is governed by a Conference of the member states that meets every second year to evaluate the work done and approve the budget. Forty-nine member states are chosen from the Conference to act as temporary Council. The FAO consists of eight departments that focus on specific topics such as Agriculture and Consumer Protection, Economic and Social Development and Technical Cooperation.

The FAO's headquarters are in Rome. It has a considerable number of regional, sub-regional and national offices around the world, with total staff of about 3,600.

2.1.4. The World Health Organization (WHO)

The UN established the World Health Organization[56] (WHO) in 1948 to monitor global health trends, coordinate health care activities and promote the health of the world's population. The WHO has 193 member states. Its secretariat employs 8,000 people,

55 See generally www.fao.org.

56 See generally www.who.int.

working at the organization's headquarters in Geneva and in regional and country offices. Its most important institution is the 'World Health Assembly', which meets once a year in Geneva to determine the policy and the programme budget of the organization. The Executive Board, which consists of 34 members, implements WHO policy.

The WHO plays a central role in the case of global crises threatening public health, such as large-scale food safety incidents like the melamine crisis. The WHO derives powers vis-à-vis the member states from the International Health Regulation 2005 (IHR). The WHO has set up a global information network for the rapid exchange of information in food safety crises, namely the International Food Safety Authorities Network (INFOSAN).

To promote fair trade in food that makes a positive contribution to consumers' life and health, the FAO and the WHO have joined forces in a common food standards programme. In the context of this programme, three risk assessment bodies provide a scientific basis for international standards formulated by the *Codex Alimentarius* Commission.

In food trade, differences in technical standards like packaging requirements may cause problems, but it is concerns about food safety, human health and animal and plant health that more often prompt national authorities to take measures that may frustrate the free flow of trade.

Measures that are necessary for the protection of public health are accepted as justified barriers to trade. A measure is necessary if it is based on scientific principles, that is to say, on risk assessment, or if it conforms to international standards such as those set by the *Codex Alimentarius* Commission. This presumption that international standards conform to SPS requirements makes it advantageous for WTO members to follow international examples. The logic behind the presumption of the conformity of the *Codex* standards to the GATT/SPS requirements is twofold. On the one hand, the SPS Agreement encourages international harmonization. If measures are in conformance with each other, there is no barrier to trade. On the other hand, the *Codex* standards are themselves science-based through the application of the risk analysis methodology.

2.1.5. The *Codex Alimentarius*

What is this *Codex Alimentarius*[57] that provides such important standards for international trade in food? In 1963, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) established the *Codex Alimentarius* Commission (CAC). Over the years, the CAC established specialized committees hosted by member states all over the world. Some 175 countries, representing about 98% of the world's population, participate in the work of *Codex Alimentarius*. A number of non- governmental organizations and organizations representing private sector interests have observer status.

Food standards are established through an elaborate procedure of international negotiations.

57 See generally www.codexalimentarius.net.

All standards and codes taken together are referred to as the *Codex Alimentarius* (Latin for 'food code'). It can be regarded as a virtual book filled with food standards.

Besides the food standards, the *Codex Alimentarius* includes advisory provisions called codes of practice or guidelines that mainly address food businesses but can also be used by national regulators.

At present the *Codex* comprises more than 200 standards for specific foods (so-called vertical standards), close to 50 food hygiene and technological codes of practice, some 60 guidelines, over 1,000 food additives and contaminants evaluations and over 3,200 maximum residue limits for pesticides and veterinary drugs. Finally, the *Codex Alimentarius* includes requirements of a horizontal nature on labelling and presentation and on methods of analysis and sampling.[58]

The work of the CAC has resulted in a vast collection of internationally agreed food standards that are presented in a uniform format. Most of these standards are of a vertical nature. They address all principal foods, whether processed, semi-processed or raw. Standards of a horizontal nature are often called 'general standards', like the General Standard for the Labelling of Prepackaged Foods.[59]

According to this general standard, the following information must appear on the labelling of prepackaged foods: the name of the food (which must indicate the true nature of the food); a list of ingredients (in particular whether one of a list of eight allergens is present); the net contents; the name and address of the business; the country of origin where omission could mislead the consumer; lot identification; date marking and storage instructions; and instructions for use.

In addition to formally accepted standards, the *Codex* includes recommended provisions called codes of practice or guidelines. These include, for example, a Code of Ethics for International Trade in Food and a set of hygiene codes like the Recommended International Code of Practice – General Principles of Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application.

The *Codex* standards are not legally binding norms. They do bear a slight resemblance to directives in European law in the sense that they present models for national legislation, but without an obligation to implement them. Member states undertake to transform the *Codex* standards into national legislation. No sanctions apply, however, if they do not honour this undertaking.

What is the purpose of such non-binding standards? The answer embraces different elements. Generally speaking, nation states are reluctant to enter into internationally binding agreements because they limit their sovereignty. For this reason, it proves easier to agree to non-binding 'soft law' standards than to binding 'hard law' ones. By agreeing to nonbinding standards, participating States develop a common nomenclature: a 'language of food law'. All States and other subjects of international law will mean the same thing when they meet to negotiate about food – 'food' as defined in the *Codex*. The same holds true for 'milk' and 'honey'

58 See FAO, Understanding The *Codex Alimentarius*, (3rd ed.) Rome 2006, available at: ftp://ftp.fao.org/codex/publications/understanding/understanding_en.pdf.

59 *Codex* Stan 1-1985 (Rev. 1-1991).

and all the standards that have been agreed upon. The notion of HACCP has been developed – and is understood – within the framework of the *Codex Alimentarius*.[60] In this way, the *Codex Alimentarius* provides a common frame of reference.

But there is more.

The mere fact that national specialists on food law enter into discussions on these standards will influence their work at home. A civil servant drafting a piece of legislation will always look for examples. In the case of food, he will find examples in abundance in the *Codex*. In these subtle ways, the *Codex Alimentarius* is likely to have a major impact on the development of food law in many countries, even without a strict legal obligation to implement.

It turns out that soft law has a tendency to solidify. Once agreements are reached, parties tend to attach more weight to them than was initially envisaged or explicitly agreed. The following sections show that this is equally the case for *Codex* standards. Due to several developments, they are well on their way to acquiring at least quasi-binding force.

2.1.6. The European legal framework

After World War II the idea developed European integration is the only way to deal with far-reaching nationalism that had dominated Europe for decades. In 1950 the Schuman design for a European Community was presented.

The European Coal and Steel Community Treaty was signed in Paris in 1951 and entered into force on 24 July 1952, with a validity period limited to 50 years. The Treaty brought France, Germany, Italy and the Benelux countries (Belgium, The Netherlands and Luxembourg) after negotiating a treaty together in a Community with the aim of organising free movement of coal and steel and free access to sources of production. In addition to this, a common High Authority supervised the market, respect for competition rules and price transparency. This treaty is the origin of the institutions as we know them today.

The desired integration of Europe also took shape in food law development. From the beginning of the European Community a cascade of directives, regulations and decisions concerning food production and labelling were produced. Each regulating

60 Recommended International Code of Practice – General Principles of Food Hygiene CAC/PCP 1-1969, Rev. 3-1997, Amd. (1999).

particular aspects, with less consistency between these different pieces of legislation. After the big food crises in the 20th century last decade reforms concerning food production and supervision were announced.

Scientists showed the desired direction in the Green Paper on the general principles of food law in 1997[61] and the White Paper on food safety in 2000.[62] In January 2002 the European Commission presented the 'General Food Law[63] (GFL): Regulation (EC) No. 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 (commonly known as the General Food Law).

2.1.6.1. The general food law

The General Food Law is the first general systematic Regulation on food law, comprising all the general principles in food safety set at international level. By its nature, it's directly applicable and immediately enforceable in any Member State.

It applies to all stages of the production, processing and distribution of food and also feed and other agricultural inputs. The law does not apply however to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

The General Food Law also defines Food Business Operators (FBO) as the establishments responsible for complying with all the requirements established in the Law and the related specific sector legislation.

The GFL provides a framework laying down the general principles and requirements of European food and feed law. These principles are lay down in article 5 to 10:

GENERAL OBJECTIVES

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed.

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law.

61 Commission Green Paper on the General Principles of Food Law in the European Union, COM (1997) 176 final, Brussels, 30 April 1997, eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1997:0176:FIN:EN:PDF.

62 Commission White Paper on Food Safety COM (1999) 719 final, Brussels, 12 January 2000, ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf.

63 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.

RISK ANALYSES

food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

PRECAUTIONARY PRINCIPLE

In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary, proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

PROTECTION OF CONSUMERS' INTERESTS

Food law shall aim at the prevention of:

a. fraudulent or deceptive practices;

b. the adulteration of food; and

c. any other practices which may mislead the consumer.

PUBLIC CONSULTATION

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

PUBLIC INFORMATION

Where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health.

These principles are worked out in detail in the many other Community and national rules and regulations.

The General Food law also states that food imported into the EU must comply with:

1. the relevant requirements of food law; or
2. conditions recognized by the EU to be at least equivalent thereto; or
3. where a specific agreement exists between the EU and the exporting country, with requirements contained therein.

As a result of this obligation, every food business operator from a non EU-country that wishes to export food/food products to the member states has responsibilities related to the following issues:

1. Safety: it is not allowed to place unsafe food on the market. Food is considered unsafe if it is:

   a) injurious to health and/or

   b) unfit for human consumption.

   Only one of these characteristics has to occur for the food to be considered as unsafe.
2. Responsibility: All food business operators are responsible for the safety of the food which they produce, transport, store and sell.
3. Traceability: All food business operators must be able to rapidly identify any supplier.
4. Transparency: All food business operators must immediately inform the competent authorities if they have any reason to believe that their food is not safe
5. Emergency: All food business operators must immediately withdraw food from the market if they have reason to believe that it is unsafe.
6. Prevention: All food business operators must identify and regularly review the critical points in their processes and ensure that controls are applied at these points.
7. Precaution: All food business operators must cooperate with the competent authorities in actions taken to reduce risks.

Under the umbrella of Regulation (EC) No. 178/2002, further regulations and directives have been approved to regulate specific food and feed issues (including the duty to establish a National Competent Authority) and have been implemented at national level.

2.2. EU LEGISLATION AND OFFICIAL FEED AND FOOD CONTROL

2.2.1. Objectives of official controls

The fact that there is a legal system in which rules for food and food producers are laid down, does not automatically entail that consumers get healthy food and have sufficient information to determine a free choice. The fact that there is a tax law does not mean that money flows naturally to the government.

Only a small proportion of entrepreneurs and citizens will exactly follow all the rules in the legislation without coercion. Most entrepreneurs tend to follow what they agree with and what can be achieved without too many problems.

It is therefore necessary, in addition to a legislative body, to have a body that ensures that citizens and entrepreneurs take their legal obligations seriously and comply with them. In general, each national system is therefore provided with a police organization. In line with the rule of law, the concept of police can be defined as a governmental service in charge of:

1. enforcement of public order and safety;
2. detection and investigation of criminal offenses;
3. direct assistance;
4. surveillance and advice.

According to this definition, the police belongs to the executive power most often within the Ministry of Internal Affairs. In case of investigating and detecting crime, then the Public Prosecutor has competence, within the Ministry of Justice.

In detecting and investing crimes, a very wide range of laws is applicable. In principle, the police should have all the necessary expertise. In most countries, governments have however chosen to establish a separate organization for highly specialized activities. Besides the detection of crime (enforcement), these organizations are also responsible for surveillance and monitoring and communication with entrepreneurs and consumers. Examples are: monitoring traffic, monitoring of nuclear installation, monitoring of working conditions, monitoring of environmental aspects and monitoring of foodstuffs. All these organizations have in common that they combine quite different tasks (from communication to enforcement). The public (including the organizations involved) is not always aware that these organizations are an extension of the police unit.

In all European countries, in the last century, organizations have been appointed with the aim to encourage that businesses comply with regulations regarding the cultivation, production and food sale, in order to ensure safe and healthy food for consumers. This aim couldn't be achieved because of the different approaches adopted by European countries in tackling food scandals. During the food scandals the difference in approaches became more and more evident.

As described *supra*, the solution came with approval of the General Food Law where general principles of food law and of official controls have been laid down.

2.2.2. Objectives of official controls in EU legislation

The need of official controls is stated in Regulation (EC) 882/2004 and specific rules on official controls for animal products and on their nature are set up in Regulation (EC) No. 854/2004.

In particular, Article 1 Regulation (EC) No. 882/2004 states that official controls aim at:

1. preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; and
2. guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.

Furthermore, whereas No. 4 of the Regulation (EC) No. 854 states that the ultimate scope of the official controls consists in protecting public health:

> *"(4) Official controls on products of animal origin should cover all aspects that are important for protecting public health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and it should therefore be possible to adapt them as relevant new information becomes available".*

The European regulatory framework of official controls is based on different sources of law, whose common objective aims at improving the consistency and the effectiveness of official food and feed controls and at providing safeguards to the consumers. This common core of principles is in line with the International principles and guidelines set by the *Codex Alimentarius* Commission and in particular with the Working Principles for Risk Analysis for Food Safety for Application by Government.

The *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007) are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health. This first edition includes the text as adopted by the *Codex Alimentarius* Commission in 2007. In this regard, the Working Principles contain a definition of the Risk Analysis, which constitutes the basis for the European legislation on official controls. In particular, the general aspects of the mentioned Working Principles are stated as follows:

1. The overall objective of risk analysis applied to food safety is to ensure human health protection.
2. These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non-discriminatory manner.
3. To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.
4. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.
5. Risk analysis should be:
    - applied consistently;
    - open, transparent and documented; and
    - evaluated and reviewed as appropriate in the light of newly generated scientific data.

In this sense, it is stated that the risk analysis shall follow a "structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the *Codex Alimentarius* Commission, each component being integral to the overall risk analysis".

2.2.3. Duty to establish an official control system

Following the guidelines set by the European White Paper on Food Safety, where the need to establish a Community control system had been clearly stated, the General Food Law (Regulation [EC] No. 178/2002) states the duty of each Member State to enforce food law, maintaining "*a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution*" (Art. 17.2.).

This does not mean only the Competent Authority to be responsible for safe food. Article 17.1. states: "*Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met*".

This means food and feed business operators are prime responsible for safe food and feed and the Competent Authority shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

To ensure the quality of audits by the Competent Authority's inspectors the Commission has set up guidelines laying down criteria for the conduct of the audits on official controls to verify compliance with feed and food law, animal health and animal welfare.

These guidelines are also useful for food and feed business controllers, performing intern-audits.

2.2.4. Nature of Competent Authorities

Fill up regarding risk principle of supervision and enforcement, long-term plans, yearly plan, training of staff, accreditation, transparency, communication with the Commission, etc. Chapter II of Regulation (EC) No. 882/2004 comprises the rules on the designation and tasks of the competent authorities in charge of official controls.

In accordance to the principle of subsidiarity set up in Article 5 of Lisbon Treaty,[64] the competence to establish national competent authority is allocated to each

64 The general aim of the principle of subsidiarity is to guarantee a degree of independence for a lower authority in relation to a higher body or for a local authority in respect of a central authority. It therefore involves the sharing of powers between several levels of authority, a principle which forms the institutional basis for federal States. When applied in a Community context, the principle of subsidiarity serves to regulate the exercise of shared powers between the Community and the Member States. On the one hand, it prohibits Community intervention when an issue can be regulated effectively by Member States at central, regional or local level. On the other, it means that the Community exercises its powers when Member States are unable to achieve the objectives of the Treaties satisfactorily. Under the second paragraph of Article 5 of the EC Treaty there are three preconditions for intervention by Community institutions in accordance with the principle of subsidiarity: a) It must not be an area which comes under the exclusive competence of the Community. b) The objectives of the proposed action cannot be sufficiently achieved by the Member States. c) The action can therefore, by reason of its scale or effects, be implemented more successfully by the Community.
See: circa.europa.eu/irc/opoce/fact_sheets/info/data/how/characteristics/article_7148_en.htm.

Member State, that shall designate it in accordance to the purposes set up for the official controls.

The competent authorities shall ensure:

1. the effectiveness and appropriateness of official controls on live animals, feed and food at all stages of production, processing and distribution, and on the use of feed;
2. that staff carrying out official controls are free from any conflict of interest;
3. that they have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively;
4. that they have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;
5. that they have the legal powers to carry out official controls and to take the measures provided for in this Regulation;
6. that they have contingency plans in place, and are prepared to operate such plans in the event of an emergency;
7. that the feed and food business operators are obliged to undergo any inspection carried out in accordance with this Regulation and to assist staff of the competent authority in the accomplishment of their tasks.

It's in the power of each Member State to allocate the competence of official controls decentralised competent authorities: in this case, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection.

The designated competent authorities shall ensure the impartiality, quality and consistency of official controls at all levels. In case of different units within the same competent authority efficient and effective coordination and cooperation shall be ensured between the different units.

Competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

2.2.5. The legislative package on official controls

In line with the guidelines set up at international level, and in conformity with the general principles set up in Regulation (EC) No. 178/2002, the European Union has stated the need to establish a legislative framework to support the functioning of national food control systems, under the umbrella of common principles.

In particular, the legislative packet on official controls comprises the following sources of law:

- Regulation (EC) No. 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.
- Regulation (EC) No. 852/2004 of the European parliament and of the council of 29 April 2004 on the hygiene of foodstuffs.
- Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
- Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
- Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EC) No. 83/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene.
- Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules (notified under document number C[2006] 4026).

2.2.5.1. Regulation (EC) No. 882/2004

Regulation (EC) No. 882/2004 of the European Parliament and of the Council of the 29 April 2004 can be considered the foundation stone of the official control regulatory framework. It sets up rules for official controls in order to ensure the verification of compliance with feed and food law, animal health and animal welfare.

In particular, Art. 2 contains the definition of official control, as well as the definition of official controllers and of the activities and tasks performed by the official controllers.

Official controls

- **Official controls:** comprises any form of control on compliance with food and feed law performed by the competent authority in each Member State and by the Community as well.

Official controllers

- **Competent Authority:** corresponds to the central authority of a Member State competent for the organization of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country;

- **Control body:** corresponds to an independent third party to which the competent authority has delegated certain control tasks.

Activities of the Competent Authority

- **Registration:** means registration of data like name, address, process activities, branch of trade of all companies growing, breeding, processing, trading, storing or transporting food or feed;
- **Monitoring:** means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules;
- **Surveillance:** means a careful observation of one or more feed or food businesses, feed or food business operators or their activities;
- **Control plan:** means a description established by the competent authority containing general information on the structure and organization of its official control systems.
- **Official certification:** means the procedure by which the competent authority or control bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance;
- **Official detention:** means the procedure by which the competent authority ensures that feed or food is not moved or tampered with pending a decision on its destination; it includes storage by feed and food business operators in accordance with instructions from the competent authority.

Activities and task of the official controllers

- **Documentary check:** means the examination of commercial documents and, where appropriate, of documents required under feed or food law that are accompanying the consignment;
- **Identity check:** means a visual inspection to ensure that certificates or other documents accompanying the consignment tally with the labelling and the content of the consignment;
- **Physical check:** means a check on the feed or food itself which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law;
- **Verification:** means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;
- **Inspection:** means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect comply with the legal requirements of feed and food law and animal health and animal welfare rules;
- **Audit:** means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

- **Sampling for analysis:** means taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules.

The mentioned activities are brought into action depending the aim of the controllers visit.

2.2.5.2. Border control

Documentary checks mostly are performed were food or feed enters the EE border's.

It the legal duty of all member states to monitor if food and feed comply with EU's legal rules. This might be at harbours, airports or border crossing points where heavy trucks bring their cargo in the EU.

Documentary checks usually are combined with identity checks. For these activities controllers of Competent Authorities often cooperate with custom officers.

The following merchandise shall be checked:

- Foodstuffs (like vegetables, dried fruit, spices, nuts and seeds);
- Living animals (like, cows, horses, one day chickens and decoration fishes);
- Consumer products (like toys, Christmas lightening and electric apparatus);
- Some rare non-animal products (like hay and straw), which may be imported for only few countries.

The EU has set very complex and extensive rules on import of these products, with special rules for each product.

The specific rules for feeding stuffs or foodstuffs of animal origin will not be mentioned here, but the same principles apply to these two categories.

Concerning non-animal food and feed article 16 states:

1. The official controls shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.
2. Physical checks shall be carried out at a frequency depending on:
    a. the risks associated with different types of food;
    b. the history of compliance with the requirements for the product concerned of the third country and establishment of origin and of the food business operators importing and exporting the product;
    c. the controls that the food business operator importing the product has carried out;
    d. the guarantees that the competent authority of the third country of origin has given.

So the need for laboratory checks partly is determined by risk analysis, partly by history of compliance, the controls of the importing food business operator and guarantees given by the Competent Authority of the third country.

In case of suspicion of non-compliance or if there is doubt as to the identity or the actual destination of the consignment or the control activities show food

or feed having serious shortages the competent authority shall place under official detention.

It shall take the following measures in respect of such feed or food:

- Order that such food be destroyed in accordance with Article 20;
- Re-dispatched the products outside the Community in accordance with Article 21;
- Intend food for purposes other than those for which they were originally intended;
- Recall in case the products are already on the market;
- Verify that food does not give rise to any adverse effects on human or plant health, either directly or indirectly;
- If the official controls indicate that a consignment is injurious to human or plant health or unsafe, the competent authority shall place the consignment in question under official detention pending its destruction or any other appropriate measure;
- If food of non-animal origin for which an increased level of controls has been laid down is not presented for official controls, the competent authority shall order that it be recalled and placed under official detention without delay and that it be then either destroyed or re-dispatched;
- When it does not permit the introduction of food, the competent authority shall notify the Commission and other Member States of its findings and of the identification of the products concerned and shall notify its decisions to the customs services, together with information as regards the final destination of the consignment.[65]

The information of the Competent Authority to the Commission is used for the rapid alert system for food and feed (RASFF[66]) or for the rapid alert system for all dangerous consumer products (RAPEX[67]).

Decisions on consignments are subject to the right of appeal.

2.2.5.3. Verification

Verification means: confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. Verification now is part of the 7 principles of HACCP of the *Codex Alimentarius*. It is the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended. To verify if a production process is under control the official controller uses three different techniques: Inspection, audit and sample taking.

Inspection mostly is an unexpected visit at a production place, where the official controller uses his eyes and simple tools like a thermometer to verify if what he sees

65 In accordance with the procedure provided for in Article 50(3) of Regulation (EC) No. 178/2002.

66 ec.europa.eu/food/food/rapidalert/index_en.htm.

67 ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm.

is compliant to legal norms. Inspection is just checking if facts agree to legal norms. Inspections are most effective for checking small enterprises having a food safety plan based on a suitable hygiene guide. For small enterprises using a hygiene guide is advantageous because often all critical control points (CCP's) for his activities have been determined. Sometimes, when the scope of his activities is more extensive than for a standard enterprise he shall determine one of more specific extra CCP's.

The scope of an inspected is limited compared to that of audits.[68] Inspections may verify the total process, but mostly only a very small part of all possible inspection points is checked. Member states should use risk analyses as a tool to make choices which inspection points needs most checks. Examples of risk are: temperature control and cross contamination.

Inspection probable is the most executed action by official controllers. Some examples of verification are: checking temperature of raw materials like chicken meat, checking hygiene aspects of the processing, checking registration papers. Food inspectors have broad knowledge of particular branches of food production.

At bigger and medium sized companies not only inspections, but also more systematic examinations (audits) are needed. Audits take place in deliberation with the entrepreneur and/or his quality officer. This is needed because the auditor not only wants to know how products are produced, but also with measures haven been determined to prevent production of unsafe food and also how this parameters have been developed using risk analyses and what criteria have been used to point out the critical control points. He wants to know all principles of the companies' food safety plan.

He also wants to see how this theoretical description is used in practise.

He checks if procedures described in the food safety plan are logical and effective to prevent production of unsafe food. For instance he looks how and under which conditions raw materials are ordered, stored, checked and used for production.

That means processing people have to take time for him, including the general director to explain the food safety policy of the company. An audit usually takes more than one day. Frequent the official controllers is accompanied by specialist on particular subjects.

All examinations results of the audit must be set down in a report in such a way that other people reading the report get a clear impression of the companies' food safety plan and also of the work performed by the auditor. In many countries this reporting is performed using standard formats. This helps increase transparency of supervision and communication with premises and other stakeholders.

Auditors not only must have specialised knowledge, they also must act completely independent from the audited company and from their principal, the Competent Authority.

68 Private Certification Bodies that inspect companies on hygiene guides, shall be accredited against ISI/IEC 17020.

Other fact is that all auditors of the member states auditing should come to the same conclusions. That is why the Commission decided to lay down guidelines for auditing.[69]

Sampling is a tool for verification too. There are quite different reasons for sampling. Sampling and analysis are useful were the official controller has some doubt concerning the quality of food and feed which he comes across at premises. Analyses can proof if products comply with EU and/or National norms. In cases the result shows the products do not comply measures will be taken to improve the production process and, if possible and necessary, a recall will be organised to prevent dangerous product to be sold at retailers causing sick consumers.

Another reason for official sampling is monitoring food safety. Monitoring is one of the tasks of Competent Authorities. Yearly National Authorities plans for monitoring are decided in consultation with the Commission. These monitoring plans concern among other things:

- Residues of pesticides in vegetables, fruit and other food;
- Heavy metals (like lead, cadmium, mercury);
- Mycotoxins;
- Dioxin, PCB's, benz(a)pyreen in certain foodstuffs;
- Pathogen micro-organism and harmful organisms.

Obvious premises use sampling and analyses of their raw materials, and end-products to check the microbiological and chemical quality. Semi-manufactured products are examined to check whether stages in the production process are effective.

2.2.5.4. Certification

A veterinary health certificate means guarantees the certificated batch complies with certain criteria. The certifying officer shall convince himself the batch meets the certification rules. This means he can determine the declaration of the certificate is valid, based on information from the instruction on countries, other data, knowledge, observations and checks.

Therefore the certifying officer has to attend following aspects:

- He has to know actual instructions on export to the concerning country. He has to convince himself there are no objections.
- He shall know and understand the meaning of all certificates he will sign.
- He has checked animals and/or products being certified.
- He is aware of the general animal diseases situation. If the certificate guarantees requires on this subject he searches for the most recent outbreaks.
- If he uses data of other certificates or other documents, he checks the authenticity. This includes accepted foreign documents.

69 Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules (notified under document No. C[2006] 4026).

- He only signs for the fact he observes himself or fact that his been verified by a official of the Competent Authority.
- He signs no blank or incomplete filled up document.
- He does not sign for fact that take place after delivery of the document and not before delivery at the destination address.
- He only signs at national territory.
- Every deviation from the standard way of working is laid down on paper.

As a consequence of national legislation, EU legislation and rules in export certificates companies shall examine or have others examine their product for microbiological and chemical parameters before export.

Article 15 of Regulation (EC) No. 882/2004 provides rules for official controls on feed and food of non-animal origins, stating that the competent authority shall carry out official controls on the basis of multi-annual national control plan and in the light of potential risks. These controls shall be carried out at an appropriate place, including the point of entry of the goods into one territory, the point of release for free circulation, warehouses, the premises of the importing feed and food business operator, or other points of the feed and food chain.

A list of feed and food of non-animal origin that is to be subject to an increased level of official controls at the point of entry shall be drawn up and updated. The frequency, nature, and fees for these controls may be established in accordance with the same procedure.

2.2.6. The role of the Food and Veterinary Office (FVO)

The main task of the Food Veterinary Office is to ensure effective control systems and to evaluate compliance with EU standards within the EU, and in third countries in relation to their exports to the EU. The FVO does this mainly by carrying out inspections in Member States and in third countries exporting to the EU.

Each year the FVO develops an inspection programme, identifying priority areas and countries for inspection. In order to ensure that the programme remains up to date and relevant, it is reviewed mid-year.

The findings, conclusions and recommendations shall be recorded in an inspection report.

The FVO also publishes an annual report on its activities, which reviews the progress of its inspection programme and presents the global results.

2.2.7. Risk based approach

As above said, the national competent authorities in carrying out official controls are bound by Regulation (EC) No. 882/2004 on official controls. Compliance with the general requirements of the regulations calls for a risk-based approach. The risks related to food in the enterprises usually vary depending on the extent and type of the activities of the enterprise.

A risk-based approach include controls carried out on both large and small scale activities does not mean that small scale activities and measures may always have to be taken in order to manage them.

The controls have to be performed in accordance with the principle of impartiality, which implies all enterprises would be monitored in the same way, as the extent of the controls and the steps taken may vary based on the assessment of the risks.[70]

2.2.8. Integrated multi-annual national plans

Moreover, Reg. 882/2004 requires each Member State to prepare a single integrated multiannual national control plan. This plan shall contain general information on the structure and organization of the systems of feed and food control, and of animal health and animal welfare control in the Member State concerned, in particular on:

1. the strategic objectives of the plan and on how the prioritization of controls and allocation of resources reflect these objectives;
2. the risk categorization of the activities concerned;
3. the designation of competent authorities and their tasks at central, regional and local level, and on resources available to these authorities;
4. the general organization and management of official controls at national, regional and local level, including official controls in individual establishments;
5. control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in these sectors
6. where appropriate, the delegation of tasks to control bodies;
7. methods to ensure compliance with the operational criteria;
8. the training of staff performing official controls;
9. the organization and operation of contingency plans for animal or food borne disease emergencies, feed and food contamination incidents and other human health risks;
10. the organization of cooperation and mutual assistance.[71]

2.2.9. Communication with EU Authorities

Besides, in order to comply with the principles set up in Reulation (EC) No. 882/2004, each EU-Member State has to present an annual report to the European Commission covering information on the implementation of the national control plans. This report is meant to provide:

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70 For further details on the risk-based approach see for instance the website of the Finnish Food Safety Authority: www.evira.fi/portal/en/evira.

71 For further details on the multi-annual national plan, see for instance the Website of the Irish Food Safety Authority: www.fsai.ie/legislation/food_legislation/official_control_of_foodstuffs/integrated_multiannual.html.

1. the results of the official controls and audits carried out during the previous year and,
2. where necessary, an update of the initial control plan in response to these results.

The national control plans and the yearly reports will establish a solid basis for the European Commission Food and Veterinary Office to carry out controls in the EU Member States. The control plans will enable the Food and Veterinary Office to verify whether the official controls in the EU Member State are organized in conformity with the criteria laid down in these Regulations. If appropriate and in particular if the audit of an EU Member State against the national control plans shows weaknesses or non-compliances, detailed inspections and audits will be carried out.[72]

2.3. OFFICIAL CONTROLS AND THIRD COUNTRIES

2.3.1. Rules

Since the adoption of the new rules on the hygiene of foodstuffs (Regulations [EC] Nos 852/2004, 853/2004 and 854/2004), and of the rules on officials controls (Regulation [EC] No. 882/2004, the European Commission has been requested to clarify a number of aspects related to food imports covered by these Regulations. Therefore the European Commission has set up general guidance on EU imports.[73]

The food hygiene conditions for food imports, including the role of the Competent Authority, are laid down in several parts of Community law. The main elements are included in the following:

- Regulation (EC) No. 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 (*OJEC*, No. L 31 of 1 February 2002, p.1)
- Regulation (EC) No. 882/2002 of the European Parliament and of the Council of 29 April 2004 on official controls to be performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*OJEU*, No. L 191 of 28 May 2004, p. 1)
- Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (*OJEU,* No. L 226 of 25 June 2004, p. 3)
- Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (*OJEU,* No. L 226 of 25 June 2004, p. 22)

72 See www.fao.org/docrep/meeting/008/y5871e/y5871e0l.htm.

73 General guidance on EU import and transit rules for live animals and animal products from third countries, European Commission, Health and Consumers Directorate-General, Directorate D – Animal health and welfare, SANCO/7166/2010.

- Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (*OJEU*, No. L 226 of 25 June 2004, p. 83)
- Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries.
- Other legislation concerning animal health, animal welfare, plant health and several food standards. In particular: food additives and maximum residue levels contaminants: residues pesticides, heavy metals, MCPD, benzo(a) pyrenes, PCB's and dioxins.

2.3.2. Competent authority – Duty of establishment

Regulation (EC) No. 882/2004 does not require third countries to have competent authorities in place. However, more specific veterinary and phytosanitary legislation requires that competent authorities must have been established.

It is essential that competent authority (the national authority) is able to deliver the level of veterinary controls required. Any shortfall would mean that approval could not be considered, or that an existing approval might have to be revoked.

As part of the approval process, a detailed questionnaire, relating to the sector for which approval is sought, is sent to the national authority. Amongst the various issues raised, the following are of particular importance in evaluating the authority's performance:[74]

1. *Management structure*. The central authorities, who are answerable for standards, must have good communication between central, regional and local service offices and be able to exercise control over regional and local services.
2. *Independence*. The official services must be independent of outside pressures, and be able to carry out their duties without undue restrictions. Individual officials must enjoy a status that ensures no conflict of interest and high ethical standards.
3. *Resources*. All levels of the official services, including border controls and laboratories, must have sufficient personnel, financial and equipment resources to allow them to carry out their control functions.
4. *Personnel*. All staff must enjoy an independent status within the official services. Where external staff is used, arrangements must be in place to ensure that they have the same degree of independence and accountability as full-time officials.

74 General guidance on EU import and transit rules for live animals and animal products from third countries: ec.europa.eu/food/international/trade/guide_thirdcountries2009_en.pdf.

5. *Recruitment and training*. The competent authority must be able to show that vacancies are promptly filled, and that the operation of the official services is not damaged by shortages of suitably qualified personnel. Training programmes, so that staff can carry out their duties properly, should be in place, and properly recorded.
6. *Legal/enforcement powers.* These must be available to, and used by, the official services. The powers must be enshrined in national legislation and allow these services to carry out their control functions in an effective manner.
7. *Prioritisation and documentation of controls.* Official services should have in place written systems to prioritise their control activities, reflecting the risks posed by the different stages of the production chain. The planning, performance and outcome of these controls at central, regional and local levels should be recorded so that compliance with EU standards can be demonstrated. Ideally, internal audit systems should be in place to monitor the operation of these controls.
8. Laboratory services. There should be a properly resourced laboratory network, including a central reference laboratory, enjoying a status independent from producers/processors, and covering the whole country. It might, however, be acceptable to use laboratory facilities in other countries where these can be shown to offer the same level of service. Specific EU rules governing the operation and capabilities of these laboratories for particular production sectors must be respected. The duties of the laboratory network should be clearly established, as should reporting procedures when non-compliant results are detected. Links with international or EU reference laboratories should be established. The central competent authority must be able to direct the activities of the laboratory service which are relevant to the production sector concerned, even where it is not part of the same management structure.
9. *Import controls.* There must be effective import controls in place at the points of entry to the third country to safeguard the health status of the country. These must be properly staffed and resourced, and provided with the necessary legal powers to take control and enforcement action. In particular, the reception, handling, storage and onward transmission of animals and products intended for despatch to the EU, or for use in the production of EU-status products, must meet EU requirements and avoid risk of cross-contamination by non-eligible animals and products. The import policy of the country will also be assessed to ensure that the health status of the country is not jeopardised.
10. *Animal health controls.* There must be an effective system for the detection and notification of animal diseases relevant to the animals/products for export. This should include surveillance measures, farm registration, animal identification and movement controls, so that the eligibility of animals used in the manufacture of EU status products can be demonstrated (traceability). It may also require disease monitoring and control or eradication programmes to be in place. The prompt notification of confirmation of diseases must also be demonstrated.

11. *Food safety controls.* Details of the zoonoses covered by national legislation, and the control action taken, should be provided. Co-ordination procedures between animal and public health authorities should be in place. Systems should be in place to record the actions taken, and their outcome, when zoonotic pathogens are identified. Traceability must be assured throughout the whole process of food of animal origin production.

2.3.3. Approval by the EU

With regard to food of animal origin only a third country that appears on list established by the Community can export to the EU.[75]

With regard to food of non-animal origin, third countries do not need to appear on a list for being eligible for export.

2.3.4. Submission of a control plan

Regulation (EC) No. 882/2004 authorises the Commission to request third countries to provide accurate and up-to-date information on their sanitary and phytosanitary regulations, control procedures and risk assessment procedures with regard to products exported to the EU.

This is fully in line with Article 7 and Annex B of the World Trade Organisation's Agreement on the Application of Sanitary and Phytosanitary Measures (15 April 1994).

2.3.5. Registration of food establishments

With regard to food of non-animal origin, it is in many cases sufficient that exporting establishments in third countries are known to and accepted as suppliers by importers of food into the Community. Exports of food of non- animal origin towards the EU can therefore continue to be organised as before 1 January 2006.

For **consignments containing plants or plant products** which are covered by the EU plant health acquis, the exporter must obtain a **phytosanitary certificate** issued by his competent national authorities. This will normally involve **registration**.

2.3.6. Implementation of procedures based on the HACCP principles

In this case, the duty to implement procedures based on HACCP lays upon the competent authorities in the Member States, that have to guarantee that foodstuffs imported into the Community have been submitted to official controls for the purpose of ensuring that the relevant provisions of the food hygiene rules, including the requirement of putting in place, implementing and maintaining HACCP-based procedures were observed (see Article 8, paragraph 3 of Directive 93/43/EEC on food hygiene).

75 Commission Regulation (EU) No. 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements.

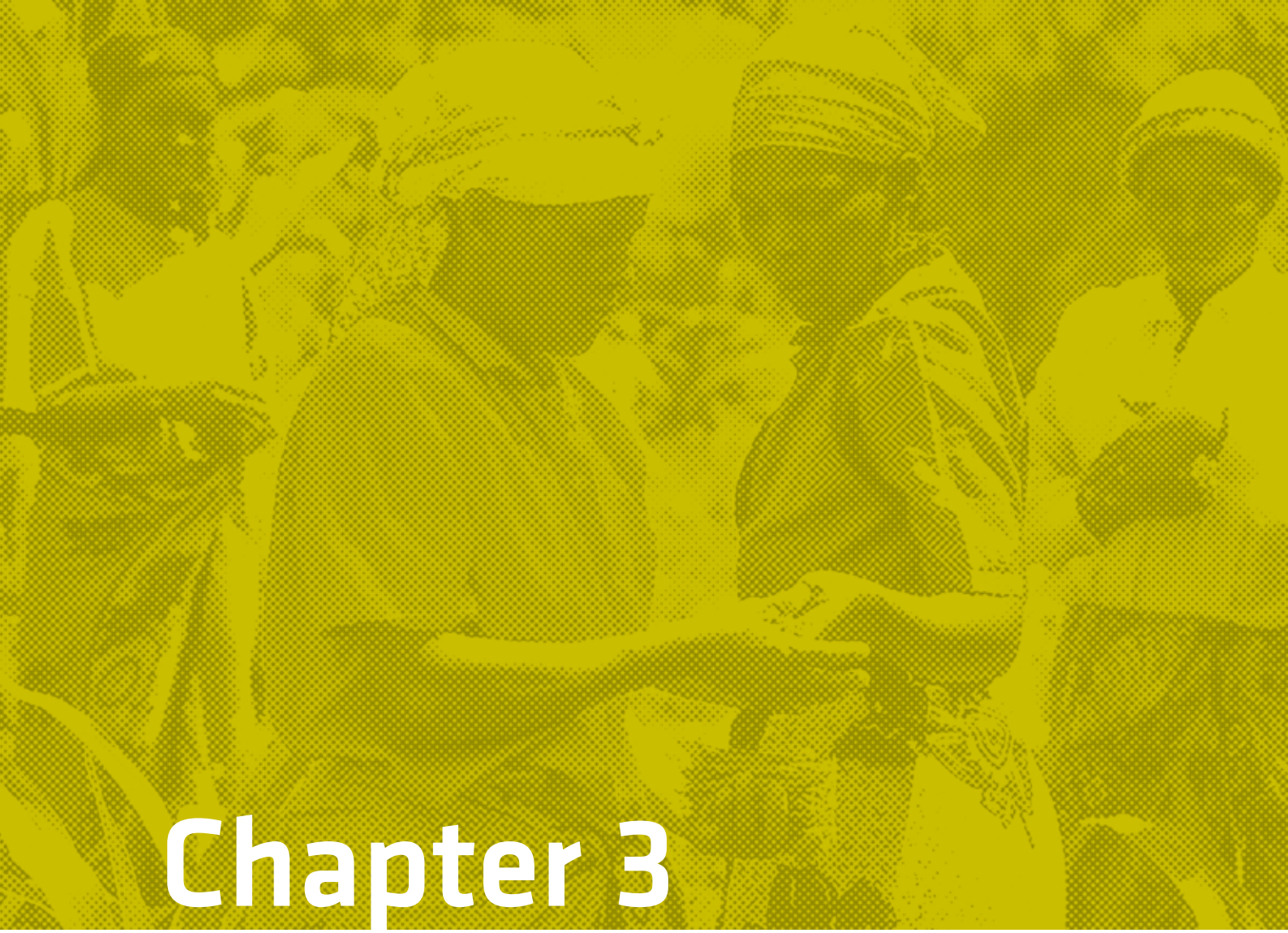
The new EU rules on food hygiene confirm that all food businesses after primary production must put in place, implement and maintain a procedure based on the HACCP principles. These rules are however more flexible than the old system, as the HACCP based procedures can be adapted to all situations.

2.3.7. Reference laboratories

There is no requirement for third countries to have reference laboratories. However, Regulation (EC) No. 882/2004 requires laboratories that are engaged in verifying compliance with EU food standards to be accredited. Such laboratories may be private laboratories that have been designated for the purpose of verifying compliance with EU food standards by the body in charge of official controls.

2.3.8. The role of Food Veterinary Office in third countries

The Food and Veterinary Office (FVO) shall carry out inspection missions in both Member States and third countries. However, the Commission is responsible under Regulation (EC) No. 882/2004 for requesting third countries intending to export food to the Community to provide accurate and up-to-date information on the general organisation and management of sanitary control systems.



Chapter 3

General principles of national surveillance and official control programmes for of plant origin

3.1. INTRODUCTION

3.1.1. Context

This chapter sets out the general principles of national surveillance and official control programmers in processing of food of plant origin. It is aimed at helping inspectors and their managers to design and implement official controls on plant products during their processing and distribution.

This document does not specifically address controls during primary production, which are the subject of another Guide. However, it does recognize that there are important linkages along the supply chain, in line with the farm to fork principle. Therefore, whilst the official controls described focused mostly of food safety hazards, it also recognizes that inspectors also have a responsibility to be vigilant for plant pests and diseases which may be spread through the processing and distribution of products of plant origin.

The Guide is divided into sections. Key terms are defined and explained. The guide provides then provides a brief description of some of the important food safety hazards which may occur in foods of plant origin, and which must be addressed in a risk-based system of official controls. The main sections of the guide describe the official controls to be established, from two main angles.

Firstly, the guide describes the organizational and management of official controls as a system. This section will help managers to decide put in place an effective and efficient system of controls, and how best to direct the staff and financial resources available. It sets out some of the best current practices in applying principles of risk management to the decisions made by Competent Authorities regarding the implementation of the official control functions.

Secondly the guide sets out specific guidance for inspectors, regarding the assessment of compliance of food business operators and their establishments, in terms of what and how to inspect establishments and products to assess their compliance with typical food safety requirements.

Finally the guide considers the important function of surveillance programmes intended to assess the effectiveness of the official control system in preventing non-compliant products from reaching the consumer.

The guide is therefore intended to provide practical advice for the operation of official controls. It is written on the premise that it is impossible for a Competent Authority to control everything within its remit, all of the time. Competent Authorities therefore make choices (whether expressed or implicitly by default, for example due to lack of resource) regarding what is controlled. The best we can hope is that it will control some of the things most of the time, and that in making such choices, those things will be the most important from the point of view of protecting the health of consumers. This essentially is the concept of risk management, where the managers and inspectors within the official control system focus their efforts on the most severe hazards which represent the greatest likelihood of harming consumer health. It is concept which is expressed at different levels throughout this chapter.

3.2. DEFINITIONS

3.2.1. Foods of plant origin

There is no specific definition of foods of plant origin. They are usually defined in comparison to foods of animal origin, but other non-animal foods such as minerals (salt), synthetic additives and water need also to be considered if this approach is to be adopted.

This guide has been prepared taking into account a wide range of foods of plant origin. It is applicable to the processing and packing of:

- fresh fruit and vegetables, including cut products;
- fruit and vegetable juices;
- herbs and spices;
- animal feeds of plant origin (e.g. soymeal);
- oils;
- non-alcoholic beverages (tea and coffee);
- grains and pulses (especially tropical e.g. rice, millet, sorghum, quinoa);
- fermented foods and drinks;
- bakery goods;
- alcoholic beverages (beer);
- plant-based food enzymes;
- algæ/fungi;
- novel foods.

Note that honey, whilst being based on material of plant origin, is usually regarded in official control terms as a product of animal origin. It is therefore not considered in this document.

3.2.2. Official controls

Official control can generally be regarded as the series of actions taken by a Competent Authority to protect its consumers and farmers from risks of non-compliance with sanitary and phytosanitary measures. It is thus a system of regulatory controls designed to ensure compliance with food safety, plant health and animal health regulations.

However in the context of the EU, official control has a specific meaning set out in Regulation (EC) No.882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. This defines 'official control' as "any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules". The regulation sets out more details as to what is to be included as shown in the box below.

Regulation (EC) No. 882/2004, Article 10, defines:

Official controls on feed and food shall include, *inter alia*, the following activities:

a. examination of any control systems that feed and food business operators have put in place and the results obtained;

b. inspection of:

- **i.** primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;
- **ii.** raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;
- **iii.** semi-finished products;
- **iv.** materials and articles intended to come into contact with food;
- **v.** cleaning and maintenance products and processes, and pesticides;
- **vi.** labelling, presentation and advertising;

c. checks on the hygiene conditions in feed and food businesses;

d. assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices (GFP) and HACCP, taking into account the use of guides established in accordance with Community legislation;

e. examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;

f. interviews with feed and food business operators and with their staff;

g. the reading of values recorded by feed or food business measuring instruments;

h. controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;

i. any other activity required to ensure that the objectives of this Regulation are met

3.2.3. Surveillance

Surveillance is a series of activities undertaken by competent authorities to gather data which is used to assess the extent of compliance of different foods with the national safety requirements. The data so collected forms an important element of the risk assessment activities undertaken by Competent Authorities, and therefore complements official controls.

3.3. HAZARDS IN FOODS OF PLANT ORIGIN

There are a plethora of different hazards associated with foods and feeds of plant origin this section outlines the major hazards specifically associated with foods of plant origin ranging from a selection of naturally occurring issues to a variety of manmade issues.

3.3.1. Microbial pathogens

Pathogens are an ever present issue when dealing with any type of food or feed. However there are some organisms that are particularly associated with products of non-animal origin.

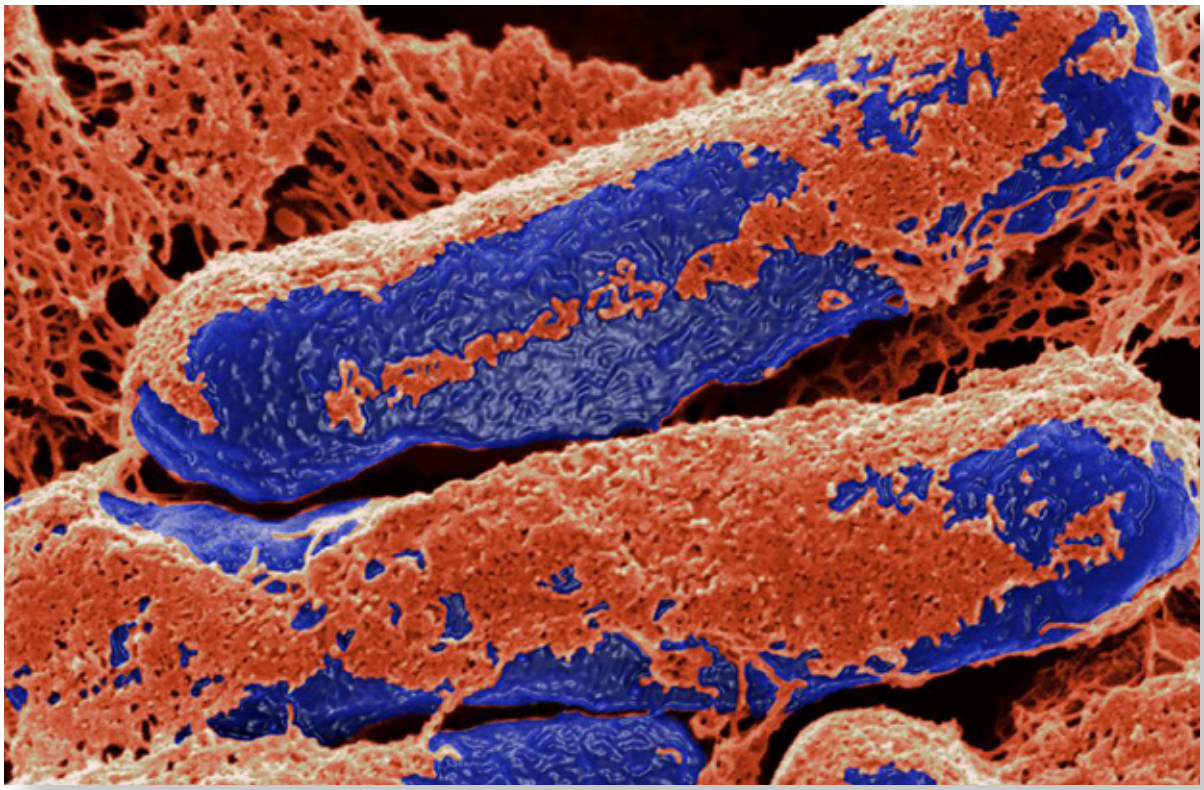
These pathogens can be roughly divided in to four separate groups; environmental-based, fecal-based pathogenic bacteria, pathogenic parasites and pathogenic viruses:[76]

- environmental-based including soil and air borne (e.g. *Clostridium perfringens*, *Clostridium botulinum*, *staphylococcus aurous* and *Listeria monocytogenes*)
- fecal-based (e.g. *Salmonella* spp., *Shigella* spp. and *Escherichia coli*)
- viruses (e.g. Hepatitis A and Entero virus)
- parasites (e.g. *Cryptosporidium* and *Cyclospora*)

All of these pathogens are associated with a wide range of negative health effects which can range from relatively minor symptoms such as nausea up to paralysis and death. The specific pathology of the different organisms can be found in more detail elsewhere. However official control of many of these pathogenic organisms share similar methods and practices.

76 FDA, "Bad Bug Book – Foodborne Pathogenic Microorganisms and Natural Toxins", 2nd ed., www.fda.gov/food/foodsafety/foodborneillness/foodborneillnessfoodbornepathogensnaturaltoxins/badbugbook/default.htm.

3.3.2. Clostridium botulinum in low acid canned foods



(Source: Microbe Wiki)

Clostridium botulinum although a pathogenic organism is considered separately because of the very specific risk it poses in low-acid canned foods.[77]

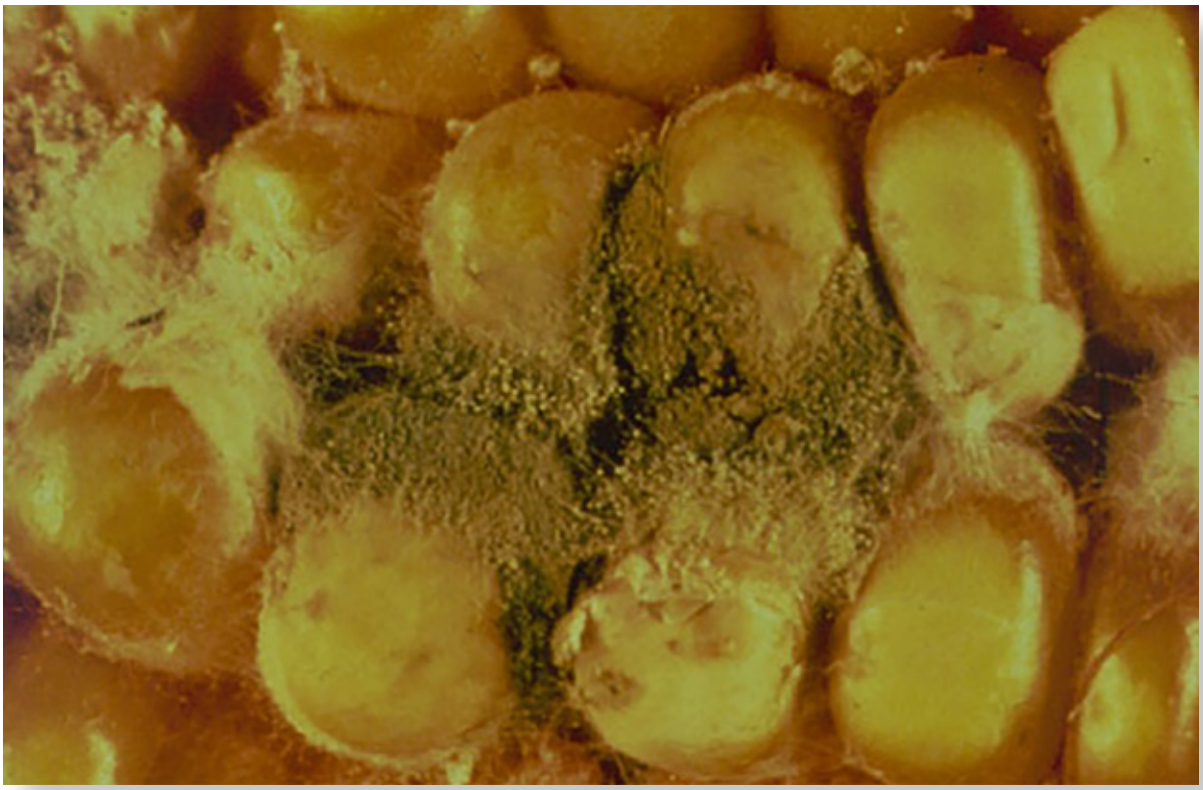
Clostridium botulinum is a heat resistant, anærobic and spore forming bacteria. These characteristics make it of particular significance in low-acid canned foods (foods with pH values above 4.6) as if they are incorrectly processed *Clostridium botulinum*, if present, may proliferate producing a dangerous neurotoxin that if ingested can cause symptoms including vomiting, diarrhea, paralysis and potentially death.[78]

Heat treatment is a particularly key in controlling this hazard but other controls are also important such as can seam integrity and safety of cooling water.

77 *Codex Alimentarius*, "Code of hygienic practice for low and acidified low acid canned foods", 2011, www.codexalimentarius.net/input/download/.../24/CXP_023e.pdf.

78 FDA, "Bad Bug Book – Foodborne Pathogenic Microorganisms and Natural Toxins", 2nd ed., www.fda.gov/food/foodsafety/foodborneillness/foodborneillnessfoodbornepathogensnaturaltoxins/badbugbook/default.htm.

3.3.3. Mycotoxins



(Source: College of Agriculture and Life Sciences – North Carolina State University)

Mycotoxins are a form of toxic chemical produced by a wide variety of fungi. They are considered to be one of the most significant food contaminates because of their negative impact on public health, food security and in turn the economy. Mycotoxins effects can be carcinogenic, mutagenic, teratogenic and immunosuppressive.

Aflatoxins are mycotoxins produced by two species of fungi of the genus Aspergillus. They are well known to be genotoxic and carcinogenic, and as such present a major concern especially because of the hugely diverse range of plant products that they can potentially impact, these include maize, rice, groundnuts, tree nuts, vegetable oils and a wide variety of other dried products. Mycotoxins come in many different forms dependent upon the causative agent and product type.

Although *Aspergillus* spp. are widespread they require specific conditions for growth namely warmth and moisture. If these factors are correctly controlled then levels of mycotoxin should not reach potentially harmful amounts. Specific consideration needs to be given in official controls to the processing and storage of any product considered to be at risk from aflatoxins. Good Agricultural Practices immediately post-harvest represent the primary defense against mycotoxin contamination. National or international bodies often set limits to aflatoxin content to protect consumers.[79]

79 FAO, "Manual on the Application of the HACCP System in Mycotoxin Prevention and Control", 2001, www.fao.org/docrep/005/y1390e/y1390e00.htm.

3.3.4. Residues of pesticides/agro-chemicals

Today a wide variety of different agro-chemicals or plant protection products including pesticides, herbicides, fungicides, insecticides, growth hormones and fertilizers all used to protect and promote the growth of both agricultural and horticultural crops. These plant protection products however may, if not correctly controlled, have deleterious impact on both human health and the environment. These effects vary depending upon the type of chemical used.

These chemicals are generally controlled by setting Maximum Residue Limits (MRL in the product. These limits are set to reflect the levels of the product expected if the chemical applied has been used correctly if the product exceeds the MRL than the product is considered to present an unacceptable risk to human health.[80] Certain toxic substances are often banned.

3.3.5. Heavy metals

Heavy metal is a term that describes a number of metals that if present in food or feed may present a significant hazard to human health. Some heavy metals are essential to life in small quantities and are present in all food stuffs. However some heavy metals present a serious risk to human health and should be carefully controlled.[81]

Examples of heavy metals of note include cadmium, lead and mercury. These are not easily metabolized and are all highly toxic causing a range of symptoms depending upon the substance and exposure levels. For example lead causes tissue damage to a variety of organs and systems and can in extreme cases cause death. Lead can occur naturally in foods but contamination is more likely from industrial contamination.

3.3.6. Additives

Additives is a term that describes a variety of different substances that are not normally consumed as food but are added intentionally to food for a specific purpose. Common examples of additives include sweeteners, colorants, preservatives, antioxidants stabilizers and emulsifiers. The EU recognizes 26 separate types of additive.

Additives should be free from appreciable risk if used in accordance with recommended levels. If this level is exceeded than the additive many become hazardous with wide ranging health effects depending on the nature of the substance.

Some additives that are widely used in one region may be considered dangerous by another an example of this is Sudan 1 a widely used colorant that in the past has been frequently used to color spices but in recent years has been banned by many countries because of its carcinogenic properties.

Additives are general controlled by restricting their use to certain justifiable products.

80 EC, Plant protection pesticide residues, 2009, ec.europa.eu/food/plant/protection/pesticides/index_en.htm.

81 EFSA, Metals as contaminants in food, 2011, www.efsa.europa.eu/en/topics/topic/metals.htm.

3.3.7. Dioxins and PCBs

(Source: ChromaBLOGraphy)

Dioxins are a group of polychlorinated aromatic compounds related by structural properties. They are not produced intentionally but are the by-products of a variety of chemical processes (both manmade and natural).

PCBs, or polychlorinated biphenyls are a separate group of chlorinated aromatic hydrocarbons. PCBs are often grouped in with dioxins because of similar toxicological processes and as such are described as 'dioxin like'.

These chemicals are fat soluble and bind easily with organic matter and sediment which and is endemic in air water soil and food. Dioxins and dioxin like chemicals are not biodegradable and will easily bio-accumulate in animal and human fat tissues when exposure occurs. Although most commonly found in products of animal origin they can be an issue in products of plant origin, most notably in vegetable oils.

These chemicals have a range of toxic effects some are known carcinogens while other have been linked with reproductive conditions, developmental impairment and a variety of immunotoxic effects.[82]

3.3.8. Phytotoxins

Phytotoxin is a broad term used to describe toxic metabolites produced by plants. There are many different types with significant variation depending upon plant species, strain and environmental conditions.

There are various example of this issue. One common phytotoxin is solanine, a glycoalkaloid that naturally occurs within potatoes. This toxin is not destroyed by the cooking process and can cause gastrointestinal and neurological issues, but is easily avoided as its presence is indicated by green discoloration. Some other important phytotoxins are cyanogenic glucosides in cassava, or hemagglutinin in kidney beans, where soaking and cooking is an essential step undertaken by the consumer in making the product safe.[83]

Given the wide variety of different phytotoxins, they should be dealt with on a case by case basis. Inspectors should be aware of products that may potentially present this issue, and their associated controls. The official controls applied need to take into account common end uses, as well as any storage or usage information provided by the producer to the consumer (for example in the labelling).

3.4. OFFICIAL CONTROL SYSTEM

This section sets out some of the main requirements for the management of a system of official controls. It describes the main components of such a system, and the typical management tools which can be applied by the Competent Authority for implementation of an effective and efficient system of controls.

3.4.1. Objectives of official controls

Whilst the responsibility for delivering safe food is that of the producer, the objective of the official control system is to use regulatory controls to ensure that the food is safe for the consumer to eat.

82 EC, "Fact Sheet on dioxin in feed and food", 2001, ec.europa.eu/dgs/health_consumer/library/press/press170_en.pdf.

83 R. Sprenger, *Supervising food safety (level 3)*, 11th ed., Doncaster, Highfeld Ltd, 2008.

All major sources of hazards must be addressed by the system of official controls, and all possible means of information should be used by the inspector to ensure that the risks to consumers from unsafe food are minimized.

In terms of the production system for foods of plant origin, controls should be applied throughout the supply chain, from input supplier through the producer and to the consumer. The activities of the inspectors from the Competent Authority must be programmed to cover the entire chain, placing emphasis and priority on those points which are known to present the most risk.

However, in practice, one of the main means of control, particularly for exports, is at the processing and packing establishment. This is because as the final point of dispatch to market, it is the most visible and easily controllable point in the distribution chain.

The central approach to official control set out in this guide is that such controls are best achieved by the presence of a well-informed inspector at the point of production.

3.4.2. Legal basis and principles official control

In relation to processing food of plant origin, official controls will primarily be concerned with checks undertaken by inspectors to ensure compliance with food safety considerations. Inspectors should therefore be fully informed of the precise requirements as set out in the national legislation.

In the EU, for example, the legal basis for food safety requirements of foods of plant origin is set out in Regulation (EC) No. 852/2004 on the hygiene of foodstuffs. Annex 2 specifically sets out the application general hygiene requirements for all food business operators (except for primary producers, where the requirements are set out in Annex 1).

The controls set out in this document describe the controls that are typically required to control the food safety hazards described in section 3 above. They are based on requirements set out in EU Regulations and CAC Codes of practice.

Plant health controls on the other hand, are mostly concerned with the conditions of primary production and concern surveillance and control measures for pests and plant diseases, ensuring application of good agricultural practices, and proper management of plant protection products. Inspection of products of plant origin later in the supply chain (for example during processing or packing) provides additional checks and guarantees that the plant health controls at primary producers are operating effectively. Therefore, as well as food safety concerns, inspectors concerned with controls on products of plant origin should also be aware of the need to ensure compliance with any relevant plant health measures.

3.4.3. Registration and approval systems

A pre-condition for official controls is that the Competent Authority is aware of the existence of food business operators. It should therefore be mandatory for all food business operators who are to be subject to official control to register with the Competent Authority. It should be noted that there is a fundamental difference between registration and the licensing (also known as approval).

Registration	Should be conditional only on the submission of the required information (not subject to any food safety conditions). The CA cannot refuse to register a food business operator providing that the required information is supplied. Since the objective is to register all relevant businesses, registration should be made as easy and cheap as possible. Online registration, or registration at the business operators premises are ways of making the process easy. A registration period should be specified, after which operators should be required to renew registration. Failure to register should be a criminal offence.
Licensing / Approval	Should be limited to higher-risk premises with licenses issues subject to compliance with a set of technical food safety conditions. The CA may wish, for example to apply licensing conditions to establishments processing for sensitive markets (for example export) or for especially high risk products (low acid canned foods). Determining which establishments should be subject to approval is a matter of control policy, which should be expressed by the CA. An approval period should be specified, after which operators should be subject to additional inspection and approval. Approval periods can be adjusted depending on risk and compliance conditions (e.g. low risk, fully compliant establishments could be subject to longer approval periods).

The registration process should collect information to allow risk profiling, considering all of the above, as well as other relevant data (for example size of business as evidenced by number of employees). The process should aim to collect the address and contact details. Consideration should also be given to obtaining GPS coordinates (and equipping inspectors with GPS to identify specific locations). Contact details should include key-holder contacts for out of hours control activities.

The registration system also should collect information regarding the raw materials, ingredients used, the processing technology, type of specialized equipment and the final products. An indication of markets is also required. This information is necessary to be able to perform risk profiling.

One of the most powerful tools for official control is the approval (or licensing) of establishments. This means that as well as being required to comply with regulatory conditions, establishments must have been through an explicit process to confirm that they comply with the regulatory requirements.

Approval or licensing is a higher requirement, and should therefore be used as a tool for official controls applied to higher risk product categories or establishments.

3.4.4. Annual control plan

The official activities should be set out in annual control plan which guides the routine activities of the Competent Authority. The annual control plan provides the mechanism by which control policy is implemented in practice. The objective of the plan is to guide the decisions of inspectors in terms of what to inspect, how often, and the nature of the controls in each case.

The annual control plan should therefore set out a programme of inspections. It should list all of the inspection points. For products of plant origin, these could include:

- wholesale markets;
- distribution/storage establishments;
- processing and packing establishments;
- transport vehicles;
- import and export establishments (including port facilities).

The plan should also define the different types of inspections that may be applied to each. Generally there are four types of inspection which may be applied, although this can be adapted according to requirements.

Type of inspection	Activity/Purpose
Preliminary	Initial inspection of establishments/facilities to confirm degree of compliance with conditions, identify works to be undertaken. Often conducted by a team, possibly before commissioning of an establishment.
Formal/Approval	Formal inspection Conducted by a team, with an in depth inspection during operation of the establishment covering all issues in detail often applied to establishments requiring approval or licensing, to establish whether approval should be granted or not.
Interim routine	Interim detailed inspection conducted to check compliance, follow up on compliance, or on progress with works requested.
Spot check	*Ad hoc* inspection of short duration to observe whether there is any obvious defect/malpractice. It could be a follow up to check compliance with previous instructions.

Each type of inspection will be likely to have different team compositions and undertake different activities, and use different checklists. For example a formal in depth inspection will confirm details which do not change very regularly, such as the nature of the processes and products, address, ownership, names of management and key holders. This information would not normally need to be checked again in a spot checks or interim inspections.

Similarly, an in-depth inspection would be expected to undertake a full audit of the HACCP plan and its implementation. A spot check might just check that the relevant forms regarding monitoring of critical variables are being completed.

The plan should seek to reflect the food safety risks of different hazards associated with the different inspection points. It should use this information to establish the approximate numbers and types of inspections in each category of inspection points (establishments/vehicles) to be undertaken during the period. This can be broken down geographically, and by sub-sector if required. This then sets the target for the inspection department. This information can be further broken down to provide work plans to individual inspectors or groups of inspectors.

The annual plan should be published by the Competent Authority. Variances from this plan should also be foreseen by the preparation of appropriate emergency or crisis management plans, which set out foreseeable circumstances requiring actions additional to the annual plan, and describe those actions, responsibilities and procedures.

3.4.5. Risk-based approach to official controls

It is important to remember that official control is always a matter of risk management. It is not possible to eliminate all risk from the food supply chain, since food and its associated health hazards are products of a biological system which is naturally variable. Combined with human decisions which vary the sources of raw materials and the processes to which they are subject, this means that official controls will never be able to control everything all of the time. This is the essential difference between the approaches of "official control" of sanitary and phytosanitary hazards, and the "conformity assessment" of industrial products subject to technical standards.

The advantage of a risk-based approach to official control is that it improves efficiency in the allocation of control resources, allowing them to be focused where they are most likely to have the maximum effect on food safety and public health.

A typical approach is to classify the establishments according to high, low and medium risk.[84] This should be undertaken by the Competent Authority, based on scientific knowledge of the hazards in the situation in which they are located. An example follows.

84 E.g., Food Safety Authority of Ireland, *Code of practice on the risk categorisation of businesses to determine the priorities for inspection, Code of practice No. 1/2000*, www.fsai.ie/resources_and_publications/codes_of_practice.html.

Table 1: *Examples of risk categorization of establishments processing products of plant origin*

Risk category	Extent of risk	Examples (products of plant origin)	
		Process	Hazard
High risk	Significant potential to put at risk vulnerable groups (elderly, infants, immuno-suppressed) or large numbers of consumers.	Ready to eat prepared cut fruit pieces in modified atmosphere	Pathogenic bacteria e.g. *E.coli, Listeria*
		Low acid canned foods pH>4.5 (e.g. canned moambe)	*Cl. Botulinum*
		Nuts susceptible to growth of *Aspergillus* moulds	Aflatoxins
		Packing of seeds and production of salad sprouts e.g. bean sprouts, cress)	Pathogenic bacteria e.g. *E.coli, Listeria*
Medium risk	Reduced potential to put vulnerable groups at risk, where the distribution may be limited or where the product is to be cooked before consumption;	Dried ground spices	Pathogenic bacteria e.g. *Salmonella*
		Canned fruits with pH<4.5 (e.g. pineapples, grapefruit)	Tin
Low risk	Only a minimal potential to harm consumers	Pre-packed whole fresh fruits and vegetables;	Minimal
		Bread and other (non-confectionery) bakery goods	Minimal
		Fried plantain chips	Minimal

Note that risk classification of an establishment should be related to the highest risk activity undertaken, and needs to take into account the hazards and risks in the territory covered by the Competent Authority. It should also be remembered that a product may present more than one hazard with different risks. There is no global approach.

The risk categorization would then be used to establish a number of operational parameters applied by the inspector:

- requirements for the design and layout of the establishment;
- frequency of formal approval (and whether required);
- frequency of interim and spot check inspections;
- nature, and depth of checks made during official controls.

In addition, at the level of the establishment the assessment of risk may be factored to take into account the compliance record of the individual establishment. Thus, establishments with a good compliance record could be subject to a less vigilant regime of official controls than those which were not compliant. This allows the inspectors to focus additional control resources on the problem establishments.

Similarly, very small establishments (with limited production) or those which sell only to limited markets (for example sales within the locality of production) may also be considered as presenting a reduced risk.

3.4.6. Approval system for establishments

Where an establishment is required to be approved (e.g. in the case of high risk establishments) the requirement and the technical conditions for approval should be set out in the relevant legislation.

The approval process should be clearly defined in the procedures of the Competent Authority. The applicant should also be provided with information setting out the actions available in case the applicant disagrees with the decision of the Competent Authority or is dissatisfied with the service rendered.

The approval process will formally start with the reception of the application form, in which the applicant requests the approval.

The form should set out the basic information required for the approval conditions. This should include:

- the name and address of the establishment;
- sources and species of raw material;
- processes to be undertaken;
- products to be produced;
- specific markets of destination;
- the number of employees;
- the production and storage capacities.

The Competent Authority may wish to specify the documents which should be submitted with the application. These may include:

- plans of the establishment setting out:
  - the establishment facilities and their respective utilization;
  - the flow of products fit for human consumption and that of products non fit for human consumption;
  - the equipment lay-out and its respective utilization;
  - the sanitary facilities (shower rooms, changing rooms and toilets), wash basins and taps;
  - the air, smoke and moisture exhaust systems;
  - the waste water disposal system;
- water reticulation plan (water outlets or taps serially numbered on the map and in the plant);
- list of suppliers;
- specification of process conditions;
- HACCP and quality documentation and record;
- technical staff CVs;
- the system for handling, storage and disposal of by-products;
- the pest control system;
- the product(s) flow diagram(s);
- the traceability system;
- any other formal information (company deeds, land title, lease etc.).

For new establishments it is essential that the operator discusses the hygiene conditions with the Competent Authority at the design stage. Otherwise there is a risk that costly alterations will be required to a newly constructed establishment before it can be approved.

The Competent Authority may consider awarding a provisional approval for new establishments which are in the phase of construction, based on a review of the documents submitted. Final and full approval may only be awarded on the basis of a full inspection of the establishment once it is in operation. This is because the approval should take into account the implementation of the hygiene requirements, including the HACCP system.

The Competent Authority should always issue an approval document where an establishment is approved. The approval document should specify details of the establishment and the conditions of the approval follows:

- name of establishment;
- location;
- approval number;
- date and period of approval;

- species (or groups of species) and sources of raw material;
- processes to be applied;
- markets (or groups of markets).

The approval should apply to these circumstances only. Should the establishment wish to undertake any activities which are not within the terms of the approval, then a request for a variation of approval conditions should be made to the Competent Authority. This procedure is necessary to prevent an establishment from trying to market high risk products (e.g. bean sprouts) when it has received approval only for low risk products (e.g. packing tree fruits).

The approval period should be finite. It should be subject to periodic renewal. One year is frequently chosen for the validity period. However this is arbitrary and a more effective approach would be to choose validity periods based on relative risk in relation to control resources available.

As noted above, higher risk establishments or establishments with a record of compliance difficulties would be subject to a more frequent renewal (and interim inspections). Low risk establishments and establishments with good compliance records, and well implemented HACCP systems could be subject to approval periods with longer validity.

Since approval renewal will be associated with a cost incurred by the enterprise, this approach could be used to create an additional financial incentive for compliance.

3.4.7. Use of checklists

Inspections of establishments (and the processes which take place within them) are a central element of official control. Inspectors often use inspection checklists as a guide for the things to be checked under each type of inspection, with different checklists for each type of inspection in different sectors.

The main advantage of checklists is to ensure that the inspector does not omit to consider an important element of the controls. They also allow for comparison and benchmarking of the inspection system. The main disadvantage is that there may be risks present in the establishment which are not expressed in the checklist categories, which are thus not identified by the inspector.

To address this disadvantage the inspector must be adequately informed. He/she must be capable of conducting inspections without checklists, using the checklist simply as an aide memoire. The use of a checklist can never compensate for a less than well informed inspector.

The checklist should be designed to reflect the objectives and type of inspection being conducted. It should also reflect a logical approach to the inspection procedure and its progress through the establishment. For example, it may be logical to follow the process flow from reception of raw material to final product. Alternatively, a counter-flow inspection may be indicated where there is a need to avoid contamination from dirty to clean processing areas (unless the inspector wishes to change protective clothing).

Checklists may adopt a scoring system, which provides a numerical score for different food safety attributes. Typically these apply the concept of negative demerit points (where points are awarded for the presence of a non-compliance). Thus low overall scores represent better compliance. This approach has the advantage that where a factor is not present in an establishment it is simply ignored and not scored, and does not affect the overall score. This avoids having to adjust the scoring system to account for differences in establishments and processes.

The advantage of having a scoring system is that it permits benchmarking of:

- the inspection system (by comparing scores of different inspectors for the same establishment); and
- the establishments (by comparing the score of a different establishments or groups, for example different processing segments, or of a single establishment over time).

A typical generic inspection checklist for an establishment processing products of plant origin is shown in Annex 2.

3.4.8. Categories of compliance

Overall categories of compliance may be allocated to the establishment which reflects the overall score or rating. This is often useful since in practice, it is often difficult to categorize a plant as simply compliant/non-compliant. For example, although plants must be clean, vegetable washing and preparation is a dirty process and the plant cannot be kept clean all the time during normal operations. In practice the inspector accepts this and allows a lack of cleanliness to a certain degree during normal operations, subject to limitations. There are therefore issues of judgement and degree introduced, which can be reflected in grades of compliance. Another example is a plant which has no major non-compliances, but several non-critical non-compliances.

The allocation of grades of compliance is also desirable since it provides an incentive for compliant establishments to improve their standards. The category assigned may be used to determine the frequency of the follow-up inspections, and/or the cost of approval (if charges are made). In this way the Competent Authority can introduce financial incentives for compliance.

The allocation of grades of compliance also allows for a quantifiable assessment of the overall standards of the sector (broken down by different variables such as product, size, ownership etc.). This allows the Competent Authority to monitor development of compliance standards over time, and in response to specific actions or campaigns.

The approach is to allocate the establishment with a category of compliance. One example is shown below, where the classification ranges from 'Very good', through 'Good' to 'Acceptable' if it meets the minimum standards, and 'Deficient' if it does not. The categories can be adapted by the Competent Authority to suit their specific purposes.

CATEGORY	STATUS	INSPECTION FREQUENCY
A	Very Good	Every three months
B	Good	Once to twice a month
C	Acceptable	Every week (depends on risk)
D	Deficient	Continuous inspection to up-grade, once the critical deficiencies are corrected

For new premises or systems the frequency of official control could be fixed for the initial period. Thereafter the above schedule may be applied, depending on the on-going performance and compliance record.

3.4.9. Sampling for official controls

Sampling for official control should only be undertaken by inspectors responsible for official control. This is to ensure that the sample is drawn from the batch which is subject to control. Otherwise sampling may be biased. Under no circumstances should samples for official control be supplied by the establishment.

An inspector may wish to take a sample as part of the official control activities. Circumstances in which a sample may be taken include:

- following evidence of practices or conditions which give rise to the risk of a hazard being present, to confirm or otherwise its existence in fact (e.g., on observing observe mouldy groundnuts, the inspector may wish to take samples to establish compliance with aflatoxin limits);
- checks on efficacy on internal controls applied by the business operator (for example validation of HACCP plan);
- check on effectiveness of standard operating procedures (cleaning and sanitation systems, handwashing, water sanitizing systems such as chlorination or UV sterilizers).

There is no fixed approach to sampling and testing for compliance. The inspector is expected to use his/her experience and technical knowledge to identify potential risks and a scientifically rigorous approach to acquiring the data required to make decisions to protect consumer health.

Note that sampling for official controls does not need to consider only finished products. Depending on the decisions of the inspector, samples may include raw materials or semi-processed products, water, swabs of hands or equipment or chemicals used in the establishment etc.

The inspector should consider whether it is strictly necessary to take a sample to establish a breach of regulations. This can only be decided on the basis of the observed facts and knowledge of the legislation. For example if the inspector observes failure in hand washing practices, this may in itself be a contravention of food safety legislation, and it may not be necessary to take samples from the product or swabs from hands to establish that the hand washing failure results in contamination and risk to health.

However, where samples are taken and the results are likely to be used in evidence of a contravention, then it is important that the sampling and sample treatment is undertaken in strict accordance with written sampling procedures. Important principles expressed in the sampling procedure may be set out in legislation.

Sampling procedures should set out:

- technical procedure for sampling (specifically to ensure sample integrity such as avoidance of bacterial contamination during selection and taking a sample for microbiological testing). Handling and storage procedures should also be specified;
- recording of relevant information regarding the sample and its selection, to include:
  - name and address of provider of sample;
  - nature of sample and state (fresh/frozen/dried etc.);
  - tests to be conducted;
  - date of sampling;
  - treatment applied to preserve the sample such as freezing, addition of stabilizers;
- ensuring fair opportunity for analysis by the provider of the sample (typically a sample may be divided into three parts, and one part selected by the provider to keep for his/her own analysis a seen fit);
- requirements for sample integrity during storage transport and dispatch to the laboratory (to avoid the possibility that it may be tampered with, or otherwise adulterated). This may include sealing the sample container, and recording transference of possession from one person to another, so as to establish the 'chain of custody'.

It should be noted that monitoring and surveillance programmes (described in Section 6) are used to help the Competent Authority assess whether the control system is working to prevent contaminated products from the market. These activities are distinct from official control and sampling and testing for surveillance purposes requires a different approach, not least of which is that samples are taken at the point of sale to the consumer (although this may also be the case in official controls undertaken at retailers). The differences in sampling approach therefore depend on the testing objective. Since official control may result in prosecution, rules of evidence must be upheld. As described in Section 6, Surveillance does not usually result in prosecution.

3.4.10. Management of laboratory testing for official controls

3.4.10.1. Organization of laboratory testing

The availability of accredited laboratory services is an essential tool which should be available to the Competent Authority for testing official controls.

An important task of the Competent Authority is therefore to manage the laboratory testing for official controls. The CA will often nominate a person to responsible for this task, since it demands technical knowledge of laboratory practices and analytical methods. The role of this position is to manage the technical aspects of the relationship between the Competent Authority and the laboratories performing tests.

Laboratory testing for official controls should be conducted in a laboratory which is approved by the Competent Authority for the tests to be undertaken. However it should be noted that there is no requirement for the Competent Authority to operate a testing laboratory. It is acceptable for a Competent Authority to purchase testing services from any laboratory, providing that it is technically competent to provide them.

The testing capacity of the laboratory will be dependent on the nature of the hazards encountered within the territory of the third country, the types of controls and the official control and testing requirements.

Note that it is not a requirement that there is capacity for all tests within the national territory of the Competent Authority. Some tests with relatively low demand may require high capital expenditure with costly operating costs to maintain the capacity. In such cases it is cheaper for the Competent Authority to make arrangements for the samples to be transported for the test to be undertaken at a laboratory in another country. The Competent Authority must be able to demonstrate that it has made the arrangements for all of the tests it requires for official control.

Laboratory functions should be organizationally independent from the Competent Authority. If the Competent Authority does operate a testing laboratory, then there should be a clear separation of laboratory functions and control functions. Tasks of laboratory staff should be limited to laboratory testing functions; they should not perform as inspectors, and should never take samples, since this compromises their impartiality as analysts and is in direct contravention of the accreditation standard. Analytical staff should not be aware of the provenance of the samples which they analyse.

The Competent Authority must designate the official laboratories which may undertake the analysis of samples for official controls. These laboratories must be assessed and accredited in accordance with EN ISO/IEC 17025:2005 standard on "General requirements for the competence of testing and calibration laboratories". The testing services may be provided by any such laboratory, whether private or public sector.

Accreditation of a laboratory goes some way to assuring that when a sample is submitted:

- the laboratory will be using appropriate and validated methods;
- that the laboratory will have applied its own quality assurance and quality controls to ensure that the test results will be valid (measuring what it says) and reliable (reproducible).

By specifying an agreed standard method, a true comparison of results is possible.

Accreditation is an independent process undertaken by an established accreditation agency. The agency must be clearly established and must comply with the general criteria for accreditation bodies laid down in ISO/IEC 17040:2005 "Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies". Evidence of this is membership of International Laboratory Accreditation Cooperation (ILAC).[85]

The Competent Authority cannot accredit the laboratory. It may only nominate accredited laboratories as official testing laboratories.

It is recognized that particularly in less developed countries, a lack of technical and financial resources limit the ability of many laboratories to achieve accredited status. In the best of cases establishing systems in line with ISO/IEC 17025:2005 can take several years. Nevertheless, these difficulties should never be an excuse to avoid implementation of feasible quality assurance procedures, many of which, such as calibration and record keeping, can be undertaken through a diligent approach to good laboratory practices and quality assurance methodologies.

Often the Competent Authority will negotiate standard test fees as part of an annual contract with the designated laboratories (or a protocol in the case of state owned laboratories).

Note that it is often desirable that several laboratories are designated as official laboratories by the Competent Authority (to cover different needs and regions). A laboratory may be designated in respect of only some of the tests it undertakes. For example a laboratory may be designated for certain microbiological tests, but not for heavy metal testing.

3.4.10.2. Standard analytical methodologies

There is no single source of standard testing methodologies used for official controls for fishery products. Harmonized methodologies should be applied where there is an official method specified in the legislation. Where this is not the case, but there is an appropriate ISO or EN standard method then this should be used.

Otherwise the choice of method is not standardized. Some laboratories may choose to use national standards, others to adopt methods from other organizations (e.g. AOAC). The Competent Authority should maintain an updated list of standard laboratory testing methods and source documentation required for official control, with alternatives where available.

3.4.10.3. Delivery of samples and receiving results

The inspector should deliver samples to the laboratory, identifiable only by a code. The following information should also be supplied:

- nature of sample and state (fresh/frozen/dried etc.);
- tests to be conducted and method (if appropriate);
- date of sampling;

85 More information available at www.ilac.org/.

- treatment applied to preserve the sample such as freezing, addition of stabilizers;
- name/contact details of person/authority delivering the sample;
- reporting instructions.

Note that it is the responsibility of the inspector to specify the test parameters to be analyzed. This decision should not be left to the laboratory since a single sample could be analyzed for several different parameters, some of which are not relevant to the hazards being considered by the inspector.

The laboratory applies the required tests and should deliver test results to the inspector only, showing in a test certificate the value of the parameter tested. The certificate should not consider compliance or otherwise with a standard (unless specifically requested).

Judgment regarding compliance and non-compliance should therefore be made by the inspector based on the results and the circumstance of the sampling.

3.4.10.4. Reference laboratories

The Competent Authority should consider the nomination of reference laboratories for different parameters. The function of the reference laboratory is to co-ordinate the activities of laboratories whose task it is to conduct analyses for official controls. It is therefore a vitally important element of ensuring the quality of service of the national testing laboratories.

The reference laboratory should advise the Competent Authority on the organization of the laboratory testing system. It should periodically organize comparative tests of standardized samples, and ensuring that all laboratories maintain internal systems of quality assurance (method validation, record keeping, reagent storage, safety, routine calibration of equipment and introduction of intra-calibration activity). The other main task is the dissemination of information to the Competent Authority and other laboratories carrying out analyses.

A reference laboratory should therefore develop and maintain the capacity to test for a parameter using more than one method. It will be the national center of expertise on the analytical methods being applied and will promote research to develop new analytical methods and compare them with the existing ones.

It will have a training role and will offer training courses in the different tests to staff from other laboratories (including industry laboratories). At a minimum the reference laboratory will be accredited and it will provide examples of the GLP approach and maintain a Quality Assurance system.

It should also participate in international inter-calibration tests and will maintain and supply standard reference materials and organize the national level tests. It should keep a network of contacts with laboratories in the region and in the main export market countries and will research and divulge up-to-date technical information and documentation. A reference laboratory will also promote inter-calibration both to governmental and private laboratories and provide a forum for discussions on laboratory problems between the Competent Authority, industry and testing laboratories.

As can be seen the role of reference laboratory is one of great responsibility, and is costly to sustain. The nomination of a laboratory as a reference laboratory should be accompanied by the allocation of an appropriate budget by the Competent Authority to allow it to function adequately in these tasks.

Also, it should be noted that the level of expertise required cannot be developed in the short term. The reference laboratory and the Competent Authority will need to work together closely over a period of years to develop the level of analytical expertise required.

3.4.11. Non-compliance procedures

To ensure that official controls are implemented, there is a vital need for a procedure to be set out and followed when non-compliances are identified. Without a formal, defined and verifiable non-compliance procedure there is a risk that negative findings from inspections will not be corrected.

The outcome of the non-compliance procedure should be that either corrective actions are undertaken by the non-compliant fishery business operator, or that sanctions are applied by the Competent Authority.

The Competent Authority should ensure that the following are in place:

- clear written procedures which indicate how the Competent Authority will deal with non-compliances detected during inspections, including how the non-compliance is to be notified to the food business operator, and crucially, procedures for follow-up inspections; all inspectors should be trained in the procedures;
- classification of non-compliances according to the severity of the health risk; severe non-compliances should be treated more urgently and with stronger sanctions than less severe ones. For example:
    - critical non-compliance could be a non-compliance which presents a severe and/or immediate risk to public health; critical non-compliances may only occur in establishments in operation;
    - non-critical non-compliance could be a non-compliance which presents only limited or minimal risk to public health;
- inspectors should periodically conduct joint inspections to ensure that there is a consensus on the classification of non-compliances;
- non-compliances for each establishment should be recorded on a non-compliance record form, which is a key part of the file on each establishment;
- when a non-compliance is detected, preparation of a non-compliance summary record sheet for each establishment, which records the following information in relation to each non-compliance:
    1. non-compliance number;
    2. date of inspection;
    3. details of non-compliance;

4. severity of non-compliance;
5. date of notification for correction;
6. deadline for correction;
7. date of follow-up;
8. finding of follow-up;
9. date of notification for correction;
10. deadline for correction;
11. date of follow-up;
12. finding of follow up;
13. decision on sanction;
14. sanction.

Record keeping on non-compliances and follow up actions is very important; it should be possible to see at a glance the record of a particular operator in terms of non-compliances identified, corrective actions implemented, and outstanding non-compliances. Key data about the non-compliances are therefore transferred from the inspection record sheet to an establishment non-compliance record sheet.

A follow-up check is required to establish whether the non-compliance has been corrected in line with the notification. If it has not been corrected then there may be additional steps taken, leading to launch of the sanctions procedure.

Over time such a record (especially if computerized) provides a powerful tool, for example in risk assessment in relation to establishments, or in terms of benchmarking the sector and strata within it. The data may also form part of an annual report, showing the number of non-compliances addressed and providing a verifiable basis for monitoring developments in sanitary compliance and conditions within the sector being controlled.

3.4.12. Sanctions

Ultimately the official control system should deliver safe food to consumers. This requires the availability of sanction procedures, which aim to remove unfit food from the market, close down unsafe establishments or cause the cessation of unsafe processes.

The sanction procedure must be set out in the legislation and be in line with the relevant Criminal and Civil Code. Competent Authorities have several tools available. The choice of tools provided by the law is a key element of official control policy. Some typical approaches are:

Suspension/revocation of approval	Removals license/approval to operate
Improvement notice	Requires changes to premises, plant, equipment or personnel hygiene
Prohibition notice	Prohibits certain acts or practices from taking place (for example high risk processes)
Emergency notice	For short term actions in case of imminent risk to health where above procedures would not protect consumers
Withdrawal order	Requires food business operator to issue a product recall/withdrawal to remove suspected non-compliant products from distribution
Seizure of food	Removes a specific item of food from sale
Prosecution	Criminal/administrative penalty for contravention (prison or fine)

Note that the use of prosecution as the only tool for official control is regarded as ineffective, since it allows the establishment to continue operator pending the legal process, and does not prevent others (for example managers or new owners) from continuing the operation of non-compliant businesses at the same premises.

3.4.13. Reporting and record keeping

3.4.13.1. Documentary record keeping

Proper records should be kept of all inspections made, along with completed checklists.

In the longer term, this is best kept on a computer database, with the inspector inputting data directly from inspection forms. The database will retain information for each food establishment/food business operator, regarding:

- basic identification data;
- licensing information;
- risk classification;
- inspection records (completed checklists);
- samples taken;
- results of tests;
- non-compliance records (classification, follow-up and outcome).

The system of record keeping creates the basis for monitoring and audit of the food safety control system. It also permits the creation of an annual report on the activities of the CA.

3.4.13.2. Monitoring indicators

The data system should to allow the generation of monitoring indicators from inspection and control records. This allows the performance of the CA to be monitored.

Examples of key performance indicators for official controls may include:

- average number of inspections/establishment during one year;
- average number of critical non-compliances detected/premises;
- % of food establishments inspected which are compliant;
- % of non-compliant establishments which become fully compliant;
- number of notices issued (improvement, prohibition, emergency prohibition and withdrawal orders) and outcomes.

3.4.13.3. Annual reports

Competent Authorities should seek to publish an annual report on the official controls undertaken in the previous period. In its simplest form this reflects the extent to which the annual control plan was implemented. Typical sections in the annual report will consider:

- Competent authority resources:
  - Staff;
  - Vehicles;
  - operating budget;
  - sampling and testing budget;
- reporting on some of the monitoring indicators (above);
- reporting on food poisoning outbreaks/crises;
- plans for the next period.

3.4.14. Official border controls for imported and exported products

3.4.14.1. Organization of border control system

In general, the Competent Authority should endeavor to avoid creating parallel control systems for domestic and export markets. Food safety should be a fundamental requirement for products destined to all markets. Imported products should of course comply with national requirements. Exported products should comply with national requirements, but may have additional requirements set by the regulations of the importing country.

Therefore when dealing with exports there is often a need to ensure compliance with the relevant regulations applicable in the export market. These may differ in the detail from the national system. Furthermore export markets may require different ways of establishing evidence of safety. Therefore the inspectors must be fully conversant with the regulatory framework of the importing country so as to ensure that certification statements are factually correct.

It is also important to note that there are essentially two different kinds of certification:

a. Certification which states something about the nature of the product (for example its composition or a process to which is it has been subject). One example might be that it has been analyzed and found to comply with a certain standard (e.g. a *Codex* Standard). Another may be that it has been processed in a certain way (e.g. that fresh mangoes have been hot water treated to kill fruit fly larvæ).

b. Certification which states something about the control system under which the product was produced; one example would be to certify that groundnuts have been produced and harvested in conditions which were subject to routine inspection by the Competent Authority and packed in an approved establishment under HACCP conditions.

The key points to be established in the integrity of any certification system established by the CA are:

- that there is in place a system of traceability which can be used by the inspector to prove that the consignment which is presented for certification has been subject to the relevant conditions or process (and that it is not for example derived from a supply chain which is outside the official control system);
- that once a sample is taken, or a certificate is issued, that there is in place a system which guarantees the integrity of the consignment subject to certification. This eliminates the risk that non-compliant products are added or exchanged with those which are subject to the certification. For example, containers may be placed under seal of the CA, with a final check on seal integrity by port authorities.

3.4.14.2. Implementation of food safety border controls

Typically border control checks for export and import apply three levels of checks:

- documentary checks;
- integrity checks;
- physical checks.

The documentary check will establish the consistency of the paper records, invoices etc., to ensure that provenance and traceability conditions are met. For example, for exports, the inspector may check the HACCP records for the batch code numbers indicated on the request for certification to ensure that a) HACCP monitoring was carried out correctly and b) process parameters were within critical limits for that batch. For imports the inspector may cross check invoice and health certificates from the exporting country, or check that the signature on the export certificate corresponds with the list of authorized signatories for that country. Increasingly CAs place their export certificates online, to allow import authorities to check validity directly.

(Source: University of Tennessee, Institute of Agriculture)

The integrity check will establish that the products listed in the documentation are physically consistent with those present in the consignment, in terms of both nature and quantity of products.

The physical check will undertake some measurements of critical parameters deemed important for the food safety condition of the consignment. This may include checks on cross contamination risks from previous cargoes, pest control measures, temperature of the cargo. In some cases, the inspector may decide to take a sample for analysis in a laboratory.

The Competent Authority should prepare an export certification protocol which sets out the required documentary, integrity and physical checks for each kind of product for each destination market.

Sampling of export consignments should be subject to the requirements of the importing country. Unless it is a specified requirement, the sampling protocol should be based on risk. Most low risk consignments can be certified on the basis of documentary and integrity checks, and basic physical checks without sampling and testing. The certification protocol would normally require the specified physical checks to be applied on the basis of frequent sampling of export consignments (thus one consignment in every 100 of ground nut oil may be sampled for dioxins, but one consignment in every 3 of groundnuts for aflatoxins).

As well as establishing sampling frequency on the basis of consignments, the protocol should also set out the sampling procedures and sampling rates within consignments.

In view of these requirements it is clear that in order to perform an effective official control the inspector must be presented with the full consignment, so as to allow for example, a proper sample to be drawn and to check important information (such as temperature of consignment). For these reasons, official controls for export certification must be performed on the export consignment and at the moment of consignment (e.g. during loading of a container/vessel). They cannot be performed remotely.

Special considerations may be required for inspection and certification of processed products consigned in bulk (such as flour, soy meal etc.).

3.5. OFFICIAL CONTROL OF INDIVIDUAL ESTABLISHMENTS

This section sets out some of the issues that should be addressed by Competent Authorities when performing official controls on processed foods of plant origin and establishments in which they are handled, processed and stored.

3.5.1. Raw material checks

3.5.1.1. Checks on raw material

Inspectors should check that raw materials of plant origin (both materials directly from the farm, as well as imported raw materials) are safe and free from potential hazards. If there are any relevant national or international criteria required, the inspector should be aware of these and ensure that they are complied with. One example is in the case of maize (see box).

OFFICIAL CONTROLS ON MAIZE USED IN FOOD PROCESSING

Maize is one of a number of grains that is susceptible to mycotoxic contamination, a common hazard in products of plant origin. Inspectors need to ensure that checks are in place to ensure that the product has been grown and harvested in conditions designed to minimize these risks, that any contaminated grain has been removed from the supply chain and that the product has been stored and transported in a manner suitable for minimizing the risk of this hazard.[86]

In the case of imported raw materials, the inspector should at a minimum check that import documentation, which should include a health certification by port authorities responsible for sanitary and phytosanitary border inspections and controls. The certification provides the guarantee that food meets relevant standards and the goods imported are accurately described.

86 FAO, "Manual on the Application of the HACCP System in Mycotoxin Prevention and Control", 2001, www.fao.org/docrep/005/y1390e/y1390e00.htm.

3.5.1.2. Supplier audits and third party certification

An important tool available to inspectors in ensuring that raw materials used in processing meet food safety requirements is to check whether the establishment has in place a system of supplier audit. This provides a guarantee that the suppliers have complied with specific standards which include parameters for food safety.

In general for such systems to perform their intended function, the supplier should be audited on a regular basis to ensure they are meeting the specified requirements.

There are different approaches which can be adopted. One the one hand the purchaser can perform the audit directly according to an internal standard. However, this requires a significant investment, and most operators now engage third party certifying bodies to certify compliance against a standard promoted by private operators, in many cases collective groups of food industry operators.

Third party certification therefore provides is a clear indication that products are manufactured and handled to a specified standard. This form of certification is neither mandatory nor a legal requirement, but indicates good practice and may be a requirement of the intended final customer for the product.

There are numerous such schemes available. However for processing of products of plant origin, the most relevant requirement is to show that good agricultural practices have been employed during production. The GlobalG.A.P. standard is one of the most common standards used by the food industry to demonstrate this. Certification of farms is undertaken by accredited certification bodies, which act as independent auditing companies.[87]

Inspectors should have a good knowledge of the different certification schemes applied in the sector for which they are responsible. In official control of establishments, they should check whether such a certification scheme is in place covering the raw material inputs to processing. The inspector should also check that the certification is real and not forged, and from an approved third party certification body with relevant experience and qualifications to provide a third party audit. The presence of a valid and reliable third party certification of supplies may also allow the inspector to apply a more limited level of checks on raw material origins.

3.5.1.3. Plant health checks

Whilst most of the official controls undertaken regarding processing of products of plant origin will concern sanitary measures (*i.e.* related to food safety) inspectors should be aware of the need to observe that any requirements applying to phytosanitary (*i.e.* plant health) conditions are met.

Plant health checks are undertaken to ensure that plants are not likely to transmit important plant diseases or pests. A plant health check may include:

- documentary evidence of plant heath most notably a phytosanitary certificate. These certificates should conform to the International Plant Protection Convention (IPPC). This is especially relevant in the case of imported products,

87 GLOBALG.A.P., System Integrity via Certification Body Administration, 2012, www.globalgap.org/cms/front_content.php?idcat=30.

where such certificates may be mandatory for certain products from certain regions;

- checks that the product corresponds with associated documentation;
- verification that plant material is free from harmful organisms.

In some cases there may be a requirement for 'plant passports', for example under the EU's new plant health regime.[88] These are essentially plant health certificates which can be issued by growers for a given period following and official inspection. They are required for some products of plant origin which host the most serious 'quarantine' pests and diseases. The passport facilitates its movement across international borders and between zones with different plant health status. The inspector should be aware of the kinds of products subject to such controls and apply checks during official controls.

3.5.1.4. Transportation

(Source: psmag.com)

Food may easily become contaminated during the transportation phase if not handled correctly. This is especially important for raw materials, where product is often transported in bulk, without the benefit of packaging to protect it from contamination. It is therefore important that vehicles used in transport are under official control. It should be noted that sanitary requirement apply to all forms of transportation including motor vehicles, rail transport, vessels or and other form of vehicle used in the transportation of foods.

88 EC, "Harmful Organisms – Third Country Imports – Inspection of Imported Products", 2012, ec.europa.eu/food/plant/organisms/imports/inspection_en.htm30.

Inspectors should be aware of regulations laying down any specific requirements for the transportation of feed and foodstuffs including those of plant origin. Some of the key requirements to be checked are that:

- conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition; they should be designed and constructed to permit adequate cleaning and/or disinfection;
- vehicles and/or containers should not to be used for transporting anything other than foodstuffs especially in the case of bulk foodstuffs in liquid, granulate or powder form;
- where necessary, conveyances and/or containers used for transporting foodstuffs should be capable of maintaining foodstuffs at appropriate temperatures and have a means of monitoring temperatures.

An inspector should also examine transportation practices to ensure that these cannot potentially damage or compromise the product in such a way as to present a hazard. An inspector may wish to view the loading or unloading of goods to ensure that all relevant procedures and practices required are being implemented.[89]

The inspector may also check records surrounding transportation to confirm:

- compliance with specific transporting conditions, *i.e.* temperature records or moisture/CO_2 levels;
- vehicle cleaning records;
- records of previous good carried.

Certain products of plant origin may require special transportation considerations for example fresh and leafy vegetables may require refrigeration and atmosphere controls to prevent deterioration and some products of plant origin may require transportation that minimizes the risk of water activity such as herbs, spices, legumes, groundnuts and a variety of grains as these products are susceptible to toxigenic moulds growth.

3.5.2. Checks on processing establishments

3.5.2.1. Establishment location and layout

The design and construction of the establishment is important to the hygienic handling of produce and inspectors should ensure that requirements are met in terms of:[90]

- **location**: the general nature and conditions of the area surrounding a food processing establishment may significantly impact the hygiene of the product. For example factors such as the proximity of rivers and other water courses, proximity to sources of airborne pollution or dust should be examined;

89 [FDA, "Investigations Operations Manual (Establishment inspections)", 2012, www.fda.gov/ICECI/Inspections/IOM/default.htm.

90 *Codex Alimentarius*, "General principles of food hygiene", 1969, revised 2003, www.codexalimentarius.org/input/download/.../23/CXP_001e.pdf.

- **size and layout**: Size must be appropriate to the dimensions of the production, without overcrowding. Layout should consider hygiene product flows, without crossing of lines and with separation of raw from ready to eat or cooked products. The positioning of equipment should be position to allow for easy access for operators, any necessary maintenance and that the equipment and surrounding areas may be cleaned and sanitized in a suitable manner.

3.5.2.2. Storage facilities

Subject to the specific process requirements, in general the processing establishment should possess adequate facilities for storage of:

- raw materials;
- other food ingredients storage for additives and other ingredients;
- chemicals which may potentially be considered contaminants (cleaning and sanitizing materials, lubricants, hydraulic fluids etc.);
- packaging materials;
- final products.

The storage of both the raw materials and the final products can significantly impact on the safety and the quality of a product, and some foods of plant origin present particular hazards from poor storage conditions. An inspector should take in to consideration storage conditions ensuring they are suitable for the product and note storage patterns, general stock rotation and the housekeeping of the storage areas. All raw materials and final products should be easily assessable for inspection and there should be no evidence of adverse conditions present such as rodent or insect infestation.

3.5.2.3. Plant construction

Construction of the establishment is another critical area to be checked during official controls. Some of the main factors to be considered are:

- hygienic design and materials; the establishment's walls, floor, ceiling, windows, wiring, piping etc. should all be designed hygienically to avoid dirt traps, and be constructed of materials which are smooth, impermeable and easy to clean. Inspectors need a good level of technical knowledge to be able to identify deficiencies in these elements;
- lighting should be sufficient, with higher levels of illumination over key areas. Inspectors may check lighting levels with a light meter;
- ventilation: should be adequate, especially in areas where the process generates significant heat and water vapor (for example steaming/cooking). Checks should be made on the functionality of extraction systems. Inspectors should check to ensure that water vapor does not condense on surfaces, and present a risk of contamination of food. Attention also needs to be paid to proper ventilation of storage facilities, where excessive moisture may lead to the growth of pathogenic organisms and mycotoxins. Inspectors should check that air can circulate around the products (*i.e.* stored on pallets, with gaps between them for air circulation;

- maintenance: when viewing a plant or production facility and inspector will wish to check the plant for any form of defect such broken windows, lack of insect screening, damage to walls, floors and ceilings or any other defect that may potentially lead to hygiene failure. It is important to establish who is responsible for repairs and maintenance.[91]

3.5.2.4. Provisions of sanitary facilities

Sanitary facilities should always be checked against requirements since they are key to ensuring the basic hygiene of the establishment. Checks should be undertaken to ensure that:

- there are adequate numbers and types of toilets and hand washing facilities, and that there is adequate separation between toilets and food handling areas;
- hand washing facilities are located in places where they must be used (toilets, staff entrances, work areas);
- there is an adequate water supply of both hot and cold water, soap and hand drying facilities;
- there is adequate provision for the disposal of both liquid and solid waste;
- adequate changing facilities are provided;
- that suitable measures are undertaken for the correct cleaning and sanitization of any protective clothing worn which may include the provision of laundry facilities or the use of a suitable contractor;[92]
- the facilities are clean.

3.5.2.5. Hygiene of equipment and utensils

The hygiene of equipment and utensils should be checked during official controls, to ensure that their design and construction meets requirements and that they are kept in good condition. The inspector should therefore check:

- that equipment is designed, constructed, and installed in such a way as to allow for correct maintenance and sanitation;
- that equipment is appropriately cleaned, maintained and stored to ensure sanitary conditions;
- that records are kept of sanitization and maintenance of equipment and utensils;
- where products of plant origin are processed using corrosive substances (such as pickling brine and vinegar) that process equipment and materials are non-corrosive.[93]

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91 *Ibid.*

92 FDA, "Investigations Operations Manual (Establishment inspections)", 2012, www.fda.gov/ICECI/Inspections/IOM/default.htm.

93 *Codex Alimentarius*, "General principles of food hygiene", 1969, revised 2003, www.codexalimentarius.org/input/download/.../23/CXP_001e.pdf.

3.5.2.6. Hygiene of personnel

Poor personal hygiene practices can render even the best establishments dangerous, so inspectors should take special steps to check that all personnel working at any stage of food processing should maintain a high standard of personal hygiene while on duty.

(Source: humani-corporis.blogspot.be)

Good personal hygiene practices that should be observed include:

- clothing including headgear and footwear should be suitable for the operation being undertaken and be kept clean.
- hands should be washed as often as required to maintain sanitary condition.
- unsanitary practices such as chewing, smoking, spiting, eating and drinking in the food production area should be prohibited.
- adequate first aid procedures should be in place to deal with minor injuries such as cuts and abrasions.
- food handlers should be free from communicable disease gastro-enteric and skin and should not be involved in food processing until they have been declared medically fit or have been free of symptoms for a sufficient period.[94]

94 *Ibid.*

An inspector will wish to observe staff carefully noting the state of their attitudes and actions throughout the inspection process ensuring compliance with the conditions stated above. The inspector should also therefore determine the type duration and adequacy of the establishment's training programs and any documentation associated with the training and the facilities personal hygiene policies.

Additional focus should be placed by the inspector on these checks when ready to eat products are being processed, as these may not be subject to further processing that could remove any hazards that might be introduced during the process. The inspector should give careful thought to the potential end uses of the product, to consider whether product will be consumed without further processing. Examples are beans and spices which are traditionally consumed after cooking by the consumer. However beans may also be used for salad sprouts, and spices which may be used as table condiments. A case study of such an outbreak is described in the box below.

E.COLI OUTBREAK IN EUROPE TRACED TO SPROUTED FENUGREEK SEEDS

In 2011 a sudden increase in the number of cases of severe hemolytic food poisoning outbreaks in France and Germany were associated with a shiga toxin producing *E. coli* 0104:H5. This is a rare serotype of *E.coli* associated with fresh salad vegetables. Initially the outbreak was blamed on cucumbers produced in Spain but the outbreak was later traced to a sprouted seed producer based in Germany. When examined this plant met the hygiene prerequisites required for the hygienic production of food. The suspected source of the outbreak when traced back to the producer was freshly sprouted fenugreek seeds that had been imported for Egypt and were likely contaminated with fecal bacteria prior to their growth in Germany. This outbreak lead to over 50 deaths and 4000 others suffering from a range of symptom ranging from the relatively minor up to long term kidney damage. Any producer or manufacture of sprouting seeds needs to be aware of the risks associated with this product and take appropriate actions to minimize them and ensure that hygiene conditions are appropriate to ready to eat foods. There is also a need for a robust traceability system to allow for fast identification of the source of an issue.[95]

3.5.3. Checks on water supply

Water quality is a key issue in the processing of products of plant origin. Water can present a variety of hazards and can carry chemical, physical or microbiological contamination. Test should be undertaken to ensure the water used in processing meets the national or international requirements for water quality (such as *Codex Alimentarius* or WHO standards). These set limits for heavy metals, chemical contaminates like pesticides and herbicides and for a wide variety of pathogenic organisms associated with water. Inspectors should be aware of the innate quality of the water in the areas they are responsible for.

95 EFSA, "Shiga toxin-producing E. coli (STEC) O104:H4 2011 outbreaks in Europe: Taking Stock", 2011, www.fao.org/docrep/005/y1390e/y1390e00.htm.

Water may be used for a variety of different post-harvest processing activities including washing, rinsing, blanching, cooling, chilling or a means of transportation. Generally water used in processing should be potable, although clean fresh water may also be used for primary processing (such as washing, removal of gross contamination, soil etc.). Water used in secondary and tertiary processes should be potable. This is particularly key in the production of ready to eat foods.

There are various official controls that should be undertaken to ensure the quality of the water meets requirements:

- water sampling of water sources to assess microbial quality of water used;
- proper application of any necessary procedures to ensure or prevent contamination of the water supply, *i.e.* proper arrangement and routine cleaning of storage tanks, separation of waste and potable water, backflow devices to prevent contamination;
- checks to ensure that water treatment functions correctly to maintain or improve water quality (such as UV treatment, chemical treatment, filtration or any other suitable safety procedures). This should include checks on maintenance and inspection records for any equipment used in the treatment of water used as part of the production process. More details are provided below.

Chlorination and UV treatment are the two common treatments applied to water to ensure that it is potable. It must be noted that it is better to prevent a water source from becoming contaminated in the first place, than to actively rely on any form of treatment. In this case treatment provides the safeguard.

The active element in chlorination is the hypochlorite ion (OCl). This can be typically applied by the use of gaseous chlorine, or by addition of a solution of sodium or calcium hypochlorite (the principal component of household bleach). The use of hypochlorite is highly effective and a relatively inexpensive and common form of water treatment. However, it is easily inactivated by organic material in the water, and requires at least 30 minutes of contact time to be effective. As a result, checks should be made to ensure that there is a residual free chlorine at the point of use. Municipal water supplies are often chlorinated, however the establishment should check and undertaken additional treatment if necessary. The monitoring of chlorine levels should be carefully documented and recorded by the establishment to ensure safety and allow for corrections if an issue develops. Records, processes and corrective actions should be checked during official controls to ensure that all relevant safety procedures are being complied with. Additional checks on chlorination may be undertaken by the inspector with relatively cheap and easy to use colorimetric test kits.[96]

Ultraviolet irradiation treatment is a common method of treatment for water in which the water passes through a treatment chamber where it is passes in front of a UV fluorescent lamp. The UV radiation kills bacteria and viruses. However the UV lamps have a finite life, and the key factors in official control of such systems is to ensure that bulb usage is monitored and that it is regularly replaced in accordance with

96 J.A. Sciortino and R. Ravikumar, "Fishery Harbour Manual on the Prevention of Pollution – Bay of Bengal Programme", 1999, www.fao.org/docrep/X5624E/x5624e00.htm#Contents.

manufacturers recommendations. Water flows should also be checked to ensure that the correct exposure levels are being reached. In regions where power supply is not reliable the inspector should check that the power source remains uninterrupted.

Both of these systems should be supported by maintenance records and sampling of water for microbiological testing to provide evidence that the systems are operating effectively. If a treatment fails or the water does not meet the criteria needed for the production process the production should not continue until an appropriate substitute has been found or the issue corrected.

3.5.4. Checks on additives

There are a wide variety of additives available to food processors which perform various functions in the product (such as preservatives, anti-oxidants, emulsifiers and stabilizers, colors etc.). In general additives are generally strictly regulated by national or international regulations. Regulations may express non-permitted substances (in which case certain substances are banned). Regulations may also provide permitted lists, with some additives allowed to be applied subject to certain limitations (for example in specific products and within maximum limits in the final product). Some additives may be used relatively freely in a wide range of products, subject to principles of good manufacturing practice. The regulations on additives may be regularly revised. Whilst detailed knowledge of all additives is a specialized subject, inspectors should be aware of the key elements of the control of additives, and be able to locate information regarding compliance.

The key point for official control is to check to that that any additives applied to products are permitted to be used, and that they are applied in accordance with the legal requirements.

A particular problem in some countries is the use of unauthorized additives. Typically certain unauthorized chemicals are commonly used as functional ingredients because they are cheap, widely available, effective and/or easy to apply. Some common examples are the use of hypochlorite solution to reduce bacteriological loads on foods, the application of illegal dyes such as Sudan Red to color species and sauces or the addition of melamine to boost nitrogen levels and apparent compliance with minimum protein specifications. The problem is that these additives present health risks to consumers and these applications are therefore banned. The inspector should be aware of the most common malpractices in the sectors in which he or she is performing official controls.

However, it should be considered that it is not simply a matter of ensuring that illegal additives are not used, or that maximum levels of legal additives are not exceeded. In some products, the correct use of additives can be also regarded as a critical point in the process and provide an essential protection against potential food safety risks. One example would be acidifiers and acidity regulators in fruit drinks, which helps to maintain the correct pH to prevent the risk of growth of *Cl. botulinum*. Inadequate control of food additives may therefore lead to an imbalance with in the final product that may present a serious microbiological or chemical hazard.

The inspector should therefore ensure that:

- no unauthorized additives are used in the process.
- a written formula is available for any additive used and additional information required for its safe usage for example the concentration of an additive and specific ingredients;[97]
- the additives used in the production process meet the requirements of any relevant food safety legislation;
- relevant documentation is available such as additive specifications, data sheets, dose levels, and certification from additive manufacturer confirming quality of product;
- calculations have been performed to ensure that the correct dose of the required additive is being used and is within the maximum levels specified by food legislation;
- relevant controls are in place to ensure the correct amounts of additive are added to the product, that they are correctly distributed throughout the product and that any other procedures relevant to the product are in place and being followed correctly;
- the storage of additives is appropriate and in line with basic hygiene requirements and ay specifications lay down by the manufacturer.

If it is suspected that an additive is being used incorrectly, inappropriately or against national legislation then action must be taken as the misuse can potentially lead to serious health issues.

Finally, if the inspector suspects that additives are being misused by the establishment, then he/she should consider taking a sample for subsequent laboratory analysis to confirm the suspicion.

3.5.5. Checks on internal control systems

3.5.5.1. Checks on pest controls

Food processing establishments should be free from pests including rodents, birds, and flying and crawling insects due to the risk of contaminating or damaging the product. To ensure that this is the case they should possess a written pest control plan. The role of the inspector in official controls is generally to check that the plan is adequate and that it is implemented effectively.

Products entering the facility should be carefully checked to ensure that no form of pest contamination is present in incoming goods as this is a common source. Food should be stored in such a way as to discourage pests and allow for easy inspection.[98]

97 FAO, "Food quality and safety systems. A training manual on food hygiene and the Hazard Analysis and Critical Control Point (HACCP) system", 1998, www.fao.org/docrep/W8088E /W8088E00.htm.

98 FDA, "Investigations Operations Manual: establishment inspections", 2012, www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf.

An inspector should be able to see records of regular pest checks and the routine and *ad hoc* pest control actions undertaken. The inspector should also check the establishment's capacity to correctly store any pest control equipment or chemicals used. In general such items should be kept in a separate storage area which should be kept clean and in good order.

In particular an inspector should check that:

- facility is free from signs of pests such as excrement, larval cases, dead pests, pest damage to produce or structure;
- the product is stored and produce in a way that minimizes risk or pests and allows for easy inspection for pests;
- any pest control measures taken are effective an appropriate to the problem;
- any records relating to pest control measures such as contractors' reports, maintenance schedules, product checks and inspection records are up to date and have been checked by the responsible party;
- any pesticides that are being used are appropriately stored and used in such a manner as to prevent contaminating the product.

If any evidence of pests is found by an inspector then appropriate action should be taken, including a review of the pest control plan.

3.5.5.2. Checks on cleaning and sanitization systems

The cleaning and sanitation of a processing establishment is one of the basic hygienic operating requirements and potentially impacts every stage of production.

The establishment should have detailed written procedures set out for the cleaning of the facility, equipment and utensils with the main objective of removing any form of contamination present that might present a potential hazard to the product.

Cleaning generally consists of the use of some form of appropriate detergent and physical means to remove residues or odors.

Sanitization is the disinfection of an object used in the production process, and is generally achieved either through chemical or thermal treatment.[99]

An inspector will wish to see a clearly documented regime for the cleaning and sanitation of all parts of the establishment, its facilities and equipment. A documented system may include any key factors like cleaning methods, frequency of cleaning, cleaning chemicals used, safety data sheets, staff training records, specific cleaning instructions for more complicated equipment and inspection sheets.

All documentation should be up to date and have been checked and updated frequently. Theoretically it should be possible for an outsider to view the system and be able to follow the cleaning procedure.

99 R.H. Schmidt, "Basic Elements of Equipment Cleaning and Sanitizing in Food Processing and Handling Operations", 2012, edis.ifas.ufl.edu/fs077.

The inspector will wish to confirm during official controls that the procedures are being appropriately applied. This may be done through:

- visual inspection of equipment (it should be free of obvious contamination or residue);
- visual observation of practice and staff to ensure procedures are undertaken fully and correctly;
- taking hygiene swabs from relevant surfaces to check whether cleaning and sanitation is effective.

Any cleaning and sanitation products should comply with national or international regulations.

3.5.5.3. Checks on Hazard Analysis Critical Control Points (HACCP) systems

An essential element of the official control in the processing of products of plant origin is the check that the operators has in place an effective system for managing food safety hazards. The typical requirement is for a system which employs the principles of the Hazard Analysis and Critical Control Points system, known as HACCP.

HACCP is food safety management system based on 7 separate principles. The wording varies depending on who is defining the system, but the core principle remains the same. EC regulation 852/2004 offers a good official definition of HACCP principles as follows:

a. Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;

b. Identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

c. Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

d. Establishing and implementing effective monitoring procedures at critical control points;

e. Establishing corrective actions when monitoring indicates that a critical control point is not under control;

f. Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;

g. Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

These steps should create a strong well documented preventative system that should be easily applicable to any form of food business or producer. The important point for official control is that the system is auditable.

HACCP plans are specific documents which apply only to the process and establishment in which they are implemented. Because of the huge flexibility of the HACCP system, the plans will vary hugely between manufacturers and producers

depending upon the nature and type of the product produced. However there are elements in common that an inspector should assess. In general the inspector should be able to check that:

- the development of the HACCP plan has followed established procedures (which may be set down in the regulations);
- the HACCP plan as documented is scientifically valid, and that this has been confirmed and periodically re-confirmed;
- the HACCP plan is implemented correctly and in line with the documentation.

However before auditing the system, the inspector should be satisfied that all of the pre-requisite controls are in place. This means that there should be compliance with hygienic and sanitation requirements (such as Good Manufacturing Practices), along with proper maintenance, pest controls, training, sanitation and traceability systems, many of which are discussed in further detail elsewhere in this document.

An inspector should expect to see a fully documented HACCP plan for each product/ plant species concerned, which should contain at a minimum:

- description of the raw material, origins, product and process, composition, packaging, distribution, validity, storage conditions etc.;
- adequate nomination of HACCP team and allocation of responsibilities;
- document describing critical points and controls;
- other potentially pertinent documentation relaying to the process, including charts showing the plant layout / products, materials and personnel flow;
- description of batch identification codes providing suitable traceability;
- description of end users and potentially sensitive consumers with adequate instructions provided for the distribution, storage and utilization of the product.

In terms of the content of the plan the inspector should check that the HACCP Principles have been correctly applied in a manner consistent with scientific evidence. The inspector should therefore consider whether:

- all relevant hazards which present a realistic risk to consumer health have been considered at each step;
- preventive measures are correctly identified to ensure control of each relevant hazard;
- critical control points (CCPs) and preventive measures are correctly identified;
- critical limits are established taking into account published or experimental evidence;
- a monitoring procedure is established for each critical parameter which specifies what to check, where, when, how, who, frequency of monitoring and data recording system;
- corrective measures are established for each critical parameter and that these are realistic and effective (including appropriate treatment of non-suitable products).

In addition to ensuring the validity of the plan, the inspector should also check to see that the plan is implemented. This means checking that the required critical process variables are in fact monitored, that data is recorded, and specified corrective actions taken when critical limits are reached, and that the plan is periodically re-validated.

In general, checking the validity of the plan is only undertaken during in-depth inspections, and periodically thereafter when for example there is a change in the product or process. The inspector should check the implementation of the plan on a more frequent basis, with the most frequent checks being that adequate records are kept. If the operator cannot provide relevant documentation, then the system is not correctly implemented and this could result in a risk to consumer health.

To verify that the HACCP system is being implemented correctly the inspector may wish to make some measurements of his/her own. In HACCP plans for the processing products of plant origin, many of the critical variables applied by the food industry relate to time and temperature, acidity, water activity, and salt and sugar content. Most of these process variables can be checked with relatively simple equipment (either on the spot or in a basic laboratory). Inspectors should be familiar with the use of equipment such as probe or infra-red thermometers, refractometers, pH meters or colorimetric comparators, and conductivity meters etc. Simple and cheap equipment (and especially thermometers) can greatly assist both in the evaluation of the HACCP plan, and allow the inspector to cross check the calibration of the establishments' own instrumentation systems.

The inspector may also wish to review the results of the food business operators own sampling and testing regime to ensure that HACCP system is performing effectively. If at any stage, the inspector identifies a problem in the HACCP system which gives rise to doubts regarding its efficacy, the inspector may wish to take an official sample for testing.

Official control of HACCP is perhaps one of the most technically challenging elements of the work of the inspector. It demands a scientific knowledge of the hazards which may arise in a particular product or process, and the conditions under which they may be controlled. It also requires knowledge of the capacities of the process technology and engineering systems employed. It also requires that the inspector has full awareness of the implementation of GAP, GMP and HACCP controls systems along the supply chain.

An example which illustrates the system level checks to be addressed in official controls throughout the supply chain is provided in Figure 1.

Figure 1 - GAP, HACCP and GMP controls for production peanut butter
Source: Manual on the Application of the HACCP System in Mycotoxin Prevention and Control, *FAO/IAEA Training and Reference Centre for Food and Pesticide Control Rome, 2001 Reprinted 2003.*[100]

100 Can be downloaded from www.fao.org/docrep/005/y1390e/y1390e00.htm#Contents.

3.5.5.4. Checks on traceability

Traceability is defined by the EU in Regulation (EC) No. 178/2002 as "the ability to trace and follow food feed and ingredient through the production, processing and distribution".

Traceability is critical for consumer protection since it allows tracing back to the beginning of the supply chain. It thus provides a mechanism for identification of the origin of unsafe foods and correction of the circumstances which gave rise to the problem. Through tracing forward from this point traceability also provides the ability for food business and Competent Authorities to ensure the withdrawal from the market of potentially harmful products affected by the same circumstances.

A good traceability system will comprise several elements of data record keeping regarding transfer of ownership (purchase and sell) and product flows within the establishment The official controls should check documents that include the following information in relation to a specific batch:

- names and addresses of the supplier and customers;
- origin of product;
- volume and quantity of product;
- nature of product (*i.e.* raw or Processed);
- delivery dates and records;
- batch numbers and sort codes;
- detailed description of product.

The traceability system should also contain a detailed recall plan, to allow the food business operator to trace and physically recall from the distribution chain any batch product in which food safety hazards may potentially be present. This system should be tested on a regular basis to ensure that the system is effective throughout the supply chain and official controls should check that this is done.

There may also be some national or international system in place to help Competent Authorities implement this process across international boundaries. In the EU the Rapid Alert System for Food and Feed (RASFF) is a system that facilitates and coordinates the transfer of information that is key to tracing non-compliant consignments of food products through the food chain.[101]

3.5.6. Special considerations for official controls on some specific products/ processing operations

Some products of plant origin present more specific and higher risk of food safety hazards than other products. As such, special consideration must be given to these products where official controls seek to manage the risk through specific checks.

101 More information on this is available at: ec.europa.eu/food/food/rapidalert/index_en.htm.

3.5.6.1. Herbs and spices

Herbs and spices like most products of plant origin can potential present a number of different hazards including pesticide or herbicide contamination, infestation with insects, foreign objects, contamination with plant or mineral material, poor microbial quality and a susceptibility to moulds, including mycotoxic varieties.[102]

Also some herbs and spices are ether used directly on foods, either in a raw or in a dried form, which means that after initial processing little or nothing will be done to reduce the potential microbial hazards. Even if dried, they may only undergo minimal heat treatment during the drying process, as higher forms of treatment may alter the flavor and nature of the final product. Official controls may therefore need to consider such products as ready to eat foods (see below).

If the product is not adequately dried after harvest, or is subject to adverse storage conditions at any stage during the supply chain, there is potential for the growth of moulds associated with aflatoxins. The only way to check is by sampling and analysis, and the official controls should regard this kind of inspection as a high priority. Since such products may also be susceptible to heavy metal contamination and application of banned additives import control authorities will usually require sampling and testing of herbs and spices upon importation.

3.5.6.2. Ready-to-eat foods

Food that is considered as ready to eat will receive no further processing or cooking which might normally be expected to eliminate heat sensitive hazards before consumption. In all cases the inspector undertaking the official controls should consider all possible end uses of the product concerned. Some ready to eat products include:

- fried or roasted snacks (plantain or cassava chips, roasted nuts);
- dried fruits (of all kinds);
- herbs and species;
- seeds produced for salad sprouts.

Some products of plant origin that are considered as ready to eat may undergo some other form of processing by the consumer such as hulling peeling or washing which removes potentially harmful agents. Some ready to eat foods may be considered potentially hazardous and as such require controls such as low temperatures or low moisture contents to ensure there continued safety. Many countries operate comprehensive sampling regimes on products they consider to be hazardous and this is a key part of any national control system dealing with ready to eat foods when considering there microbiological safety.[103]

102 M. Matthews and M. Jack (FAO), "Herbs and spices for a home market", 2011, www.fao.org/docrep/015/i2476e/i2476e00.pdf.

103 HPA, "Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods", 2009, www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1259151921557.

A key example of a ready to eat food that has a demonstrable history of presenting a health hazard is sprouted seeds often used in salads these have been associated with a variety of pathogens including E coli, salmonella and listeria. The box on page 35 illustrates the importance of such controls.

Where ready to eat foods are minimally processed (for example cut fruit, or salad sprouts) special considerations need to be given to both to:

a. minimize the risk of pathogenic organisms contaminating the product (the application of GAP in production, special post-harvest treatments and aseptic packing techniques for example); and

b. the application of treatments which may reduce or eliminate the hazards (e.g. the application of potassium permanganate treatment for salads, or the use of sodium metabisulphite in cut or peeled fruits).

These are specialized areas and require the inspector to possess the scientific and technological expertise to assess the efficacy of controls applied by the establishment and to apply the necessary official controls, including sampling and testing where required.

3.5.6.3. Low acid canned foods

Low acidity canned foods (with a pH of 4.6 or below) present the ideal environment for the growth of Clostridium botulinum an obligate spore forming anærobe which produces a potent neurotoxin. The toxin has no odor or flavor, and *C. Botulinum* itself does not produce gas, so cans and the product in them may appear normal.[104]

There are various factors and considerations that should be undertaken to prevent the occurrence of this hazard. The official controls should check that:

- can seam dimensions are within proper tolerances;
- heat processing is sufficient to eliminate practical risk of survival of heat resistant spores of *Cl. Botulinum*; and that proper heat processing records are kept;
- cooling water is treated to prevent micro-organisms from entering the can via the double seam during its cooling phase

Given the potentially direct lethal consequences of failure of internal and official controls, this is a vitally important task. More detailed information of how to dealing with this type of product can be found in the *Codex Alimentarius* Code of hygienic practice for low and acidified low acid canned goods (CAC/RCP 23-1979).[105]

It is important to remember that the heat treatment and the acidification of the product are the key controlling factors for this type of product and any disruption in these processes may cause a potential serious health hazard.[106]

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104 FDA, "Guidance for Industry: Acidified Foods", 2012, www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/Guidance. Documents/AcidifiedandLow-AcidCannedFoods/UCM227099.pdf.

105 Available at the following site: www.codexalimentarius.org/codex-home/en/.

106 *Codex Alimentarius*, "Code of hygienic practice for low and acidified low acid canned foods", 2011, www.codexalimentarius.net/input/download/.../24/CXP_023e.pdf.

3.6. NATIONAL SURVEILLANCE OF PROCESSED PLANT PRODUCTS

3.6.1. Reasons for surveillance

National surveillance is a research programme used to assess the degree of compliance of foods with the national safety requirements. It forms an important element of the risk assessment activities undertaken by Competent Authorities, and therefore complements official controls. As a part of the monitoring system it allows the Competent Authority to improve the effectiveness and efficiency of the official control system by providing data which allows control resources to be focused on areas of weakness in the system, and where significant risks to consumer health are most likely arise.

The output of the surveillance system is therefore an adjustment of the official control actions of the Competent Authority. It may result in a change in procedures or in the re-allocation of inspectors to areas identified with emerging hazards. Normally, non-compliant product identified in surveillance programmes do not lead to a launch of legal procedure, but result in a follow up investigation to identify the origin and reasons for the non-compliance. This leads to a risk assessment and a subsequent risk management decision regarding what, if anything, should be done to address the problem in future.

In products of plant origin, the surveillance programme will address the common hazards which arise during the production. It is important that they consider all stages of production and processing, including possible hazards arising from agricultural inputs such as pesticides and fertilizers. They will also seek to identify common hazards such as mycotoxins, illegal additives, residues of heavy metals and microbiological contaminants.

3.6.2. Sampling approach

Typically sampling for surveillance purposes is undertaken at the level of the market (*i.e.* final products). This means that samples are usually taken from retail or catering outlets. However, it may also be necessary to take samples during the production and processing stages (usually when seeking to identify the use of unlawful substances, such as a prohibited pesticide).

The supplier of the sample is therefore not necessarily the person responsible for anyfood safety non-compliances in the product. Many legal system approaches to food safety provide defenses related to non-compliances which are the fault of another, or where the operator exerts due diligence, or otherwise takes steps to guarantee product safety such as warranty clauses in the contract terms. This is one of the reasons why surveillance results cannot be used as the basis for legal action against non-compliance.

Sampling is usually stratified by product, process, region and sometimes origin (for example import/national products). This means that the design of the sampling frame (number of samples and the parameters to be assessed in each case) will be focused on certain areas at the expense of others. This is essentially a policy decision and should reflect other risk assessment information (such as previous studies, health indicators, consumption trends, concerns arising from official control, international trends etc.).

Sampling procedures should follow the technical requirements for preserving the conditions of the sample. Normal protocols regarding recording of data and preservation of sample identity and integrity should be followed. However, since the process is not one of official control, sampling does not have to be undertaken by an authorized inspector (surveillance sampling is often contracted to external bodies), nor does it require that sampling procedures set out in laws governing official controls be followed (such as division of sample).

Surveillance is frequently limited by resource availability, and this is expressed in the number of samples and the types of tests to be undertaken. The Competent Authority should set out the relative priorities (in terms of expenditure proportionate of the different products/hazard combinations, according to the prevailing interest and demand for information), and these priorities are then applied to the budget available.

It should also be considered that a single sample may be used for testing for several parameters. For example a single sample of ground chili pepper may be submitted for tests for heavy metals, mycotoxins, illegal colors and microbiological contamination. In this way sampling costs may be reduced.

3.6.3. Testing methods

It is not always necessary to apply the official testing method to the analysis of all samples for the surveillance programme. Such tests may be more time consuming, and demand a higher level of analytical inputs, and are therefore often more expensive. Testing in surveillance programmes often therefore applies an analytical cascade, which employs one or more screening tests. These tests are usually quicker and cheaper than the official test method, but lack the level of validity and reliability required for official testing. The screening test is used to select which samples go forward for testing by the official test. They therefore provide an indication of compliance, and by a judicious choice of protocol (for example selecting non-compliant and border line samples, plus a proportion of compliant ones at screening) the impact of false negative results can be minimized. False positive results of screening will be identified in most cases by the subsequent official test.

The results, even from screening tests must be as reliable as possible, since they inform national risk management decisions. Therefore all testing in laboratories for surveillance programmes should take place in laboratories which are accredited to ISO 17025.

3.6.4. Follow-up on surveillance results

When non-compliance is identified through the surveillance programme, the Competent Authority should follow up with a view to investigating the circumstances which gave rise to the non-compliance. This will invariably mean returning to the business operator who provided the sample, conducting an interview and examining any relevant records. In many cases, if the sample was taken at retail or wholesale level, the Competent Authority may need to trace back through the supply chain and conduct the investigation at each transaction level, sometimes

at the processor/packer or at the farm level. This may also involve investigations which cross international boundaries where the corresponding Competent Authority is requested to conduct the follow-up.

The objective in all cases is to identify the circumstances which gave rise with regard to the non-compliance, describe them fully and consider what changes to the official control system could be applied to prevent a recurrence in future. Finally the CA should consider whether such changes should be applied, this being a risk management policy decision determined by practicality, best use of resources or other considerations. It should always be borne in mind that no control system can guarantee that all risks are controlled all of the time, and that random events can intervene to cause non-compliances. Sometimes it is not possible to identify the cause of the non-compliance due to lack of evidence.

3.6.5. Reporting and use of results

The Competent Authority should always publish the results of the surveillance programme, since it can provide a useful guide to the implementation of internal controls by food business operators in the supply chain, as well as valuable information for consumers, health professionals and others concerned about the health status of the national diet and associated risk assessment data.

The data base of findings provides scientific basis for formal risk assessment activities since it provides scientifically valid data regarding the presence and level of hazardous agents in different categories of foods. Combined with consumption data, this allows risk assessors to compute the exposure of different groups of consumers to the hazard concerned. Once exposure is known, this can be assessed in combination with toxicological data regarding the hazard to allow the risk assessment to be made.

3.7. ANNEXES

A.1. Example of an inspection record form for establishments processing products of plant origin

The following form is for illustrative purposes only. It focuses on hygiene conditions of the establishment, staff and operations. However it excludes inspection of pest control, HACCP, traceability etc., which may be recorded on additional forms.

Generic inspection form for food establishments	
Criteria	**Demerit points**
1. Location	
Establishment exposed to contamination or pollution which could contaminate the product	C
2. Establishment exterior	
Surrounding area not of concrete or in poor condition	3
3. Raw material transport	
Insulated vehicles not used for transport of chilled/frozen foods	2
Product in vehicle exposed to sun, dust rain or contamination	5
Product in contact with the wood of vehicle construction	3
Vehicle not washed and disinfected after unloading	4
4. Reception and storage of raw material	
Precautions not taken to prevent entry of insects to establishment	3
Insufficient facilities for the storage of raw material	2
Storage facility for raw materials inappropriate materials or in poor condition	3
5. Establishment construction	
Floors not impermeable, not hard, not easy to clean or in poor condition	4
Inadequate system of drains and traps	C
Walls not impermeable, not easy to clean, not of a light color, or in poor condition	2
Windows not covered by adequate mesh against entry of insects birds etc.	C
Doors not smooth, or not impermeable or in poor condition	1
Ceilings and lights not free from dust, flaking paint or condensation	4
Accumulation of odors, condensation or heat in processing areas (inadequate ventilation)	3
Ventilation ducts and fans not meshed against entry of insects, birds etc.	C
Inadequate illumination	2

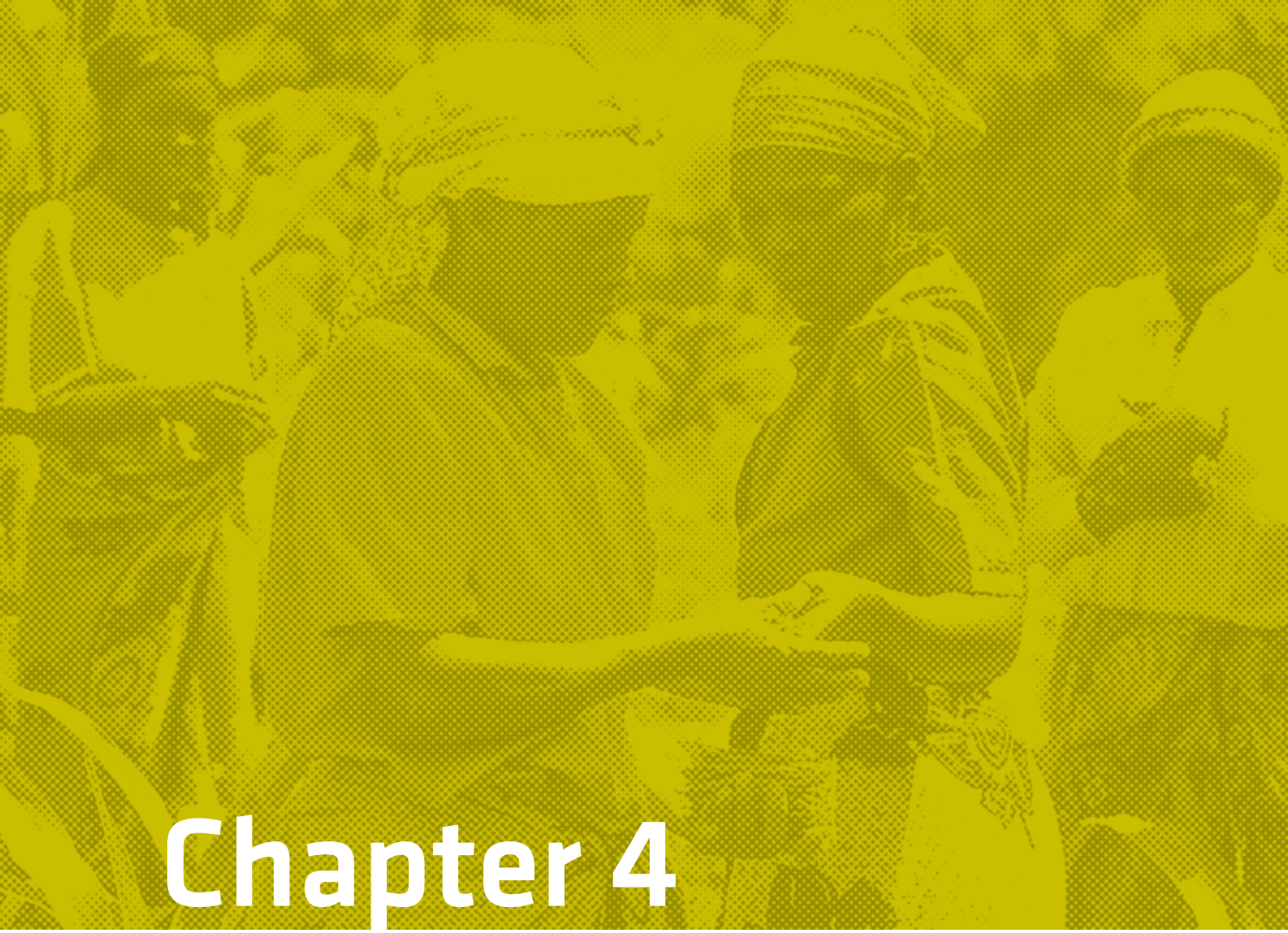
Generic inspection form for food establishments	
Criteria	**Demerit points**
6. Hygiene facilities in processing areas	
Insufficient number of wash-hand basins	4
No permanent provision of hot and cold water to wash-hand basins or lack of soap	3
Insufficient number of taps, sinks and hoses for washing of establishment and equipment	4
7. Contamination and decontamination	
Deposits of dirt, grease etc. on floor or walls	5
Equipment, tools, tables of wood or other permeable or corrodible material	3
Equipment, tools, or tables in contact with food in dirty condition	3
Evidence of insect or rodent pests in the establishment	C
Inadequate method of cleaning and sanitizing	4
10. Personnel	
Food handlers have open or infected wounds	C
First aid box not provided, or with inadequate contents	5
16. Cold stores (- 18 ºC) and chill stores (0 ºC)	
Refrigeration stores not provided with thermometer	2
Temperature of cold store > - 18 ºC	3
Accumulation of ice or dirt in cold stores	4
Poor air circulation (product in contact with floor or walls)	2
17. Transport of finished product	
Transport of chilled/frozen products in unrefrigerated vehicles	3
Transport of products in dirty vehicles	4
19. Sanitary facilities	
Sanitary facilities not readily accessible to establishment staff	C
Direct access between processing area and sanitary facilities	C
Inadequate number or types of sanitary facilities	C
Inadequate number or types of wash-hand basins in toilet area	C
No permanent hot and cold running water for hand washing	C
Inadequate ventilation to exterior	2
Inadequate illumination	2
Sanitary facilities in poor condition or dirty	C

Generic inspection form for food establishments	
Criteria	**Demerit points**
20. Water	
Water supply inadequate to satisfy the demands of the process	C
Water not treated with chlorine or UV sterilization	C
Organoleptic quality of water inadequate	1
Water tanks and cisterns of inadequate capacity or inappropriate construction	4.
Tanks and cisterns not protected against entry of rain and flood water, birds, insects or rodents	C
Cisterns not provided with inspection hatch	3
Area surrounding cistern is dirty	3

At the end of the inspection the inspector may sum the demerit points and calculate the percentage score of the establishments as a proportion of the total demerit points available.

The inspector may sum the critical points.

Criteria may then be applied to the results to classify the establishment and determine the desired course of action.



Chapter 4

Guidelines for inspection according to FAO standard

4.1. INTRODUCTION

This chapter is based on the text of ISPM No. 23.

This standard was endorsed by the Interim Commission on Phytosanitary Measures in April 2005.

4.1.1. Introduction scope

This standard describes procedures for the inspection of consignments of plants, plant products and other regulated articles at import and export. It is focused on the determination of compliance with phytosanitary requirements, based on visual examination, documentary checks, and identity and integrity checks.

4.1.2. References

Export certification system, 1997. ISPM No. 7, FAO, Rome.

Glossary of phytosanitary terms, 2004. ISPM No. 5, FAO, Rome.

Guidelines for a phytosanitary import regulatory system, 2004. ISPM No. 20, FAO, Rome.

Guidelines for pest eradication programmes, 1998. ISPM No. 9, FAO, Rome.

Guidelines for the notification of non-compliance and emergency action, 2001. ISPM No. 13, FAO, Rome.

Guidelines on lists of regulated pests, 2003. ISPM No. 19, FAO, Rome.

Guidelines on phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.

International Plant Protection Convention, 1997. FAO, Rome.

Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

Pest risk analysis for regulated non-quarantine pests, 2004. ISPM No. 21, FAO, Rome.

Principles of plant quarantine as related to international trade, 1995. ISPM No. 1, FAO, Rome.

Regulated non-quarantine pests: concept and application, 2002. ISPM No. 16, FAO, Rome.

The use of integrated measures in a systems approach for pest risk management, 2002. ISPM No. 14, FAO, Rome.

4.1.3. Definitions

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (Glossary of phytosanitary terms).

4.1.4. Outline of requirements

National Plant Protection Organizations (NPPOs) have the responsibility for "the inspection of consignments of plants and plant products moving in international traffic and, where appropriate, the inspection of other regulated articles, particularly with the object of preventing the introduction and/or spread of pests." (Article IV.2c of the IPPC, 1997).

Inspectors determine compliance of consignments with phytosanitary requirements, based on visual examination for detection of pests and regulated articles, and documentary checks, and identity and integrity checks. The result of inspection should allow an inspector to decide whether to accept, detain or reject the consignment, or whether further analysis is required.

NPPOs may determine that consignments should be sampled during inspection. The sampling methodology used should depend on the specific inspection objectives.

4.2. REQUIREMENTS

4.2.1. General requirements

The responsibilities of a National Plant Protection Organization (NPPO) include "the inspection of consignments of plants and plant products moving in international traffic and, where appropriate, the inspection of other regulated articles, particularly with the object of preventing the introduction and/or spread of pests" (Article IV.2c of the IPPC, 1997).

Consignments may consist of one or more commodities or lots. Where a consignment is comprised of more than one commodity or lot, the inspection to determine compliance may have to consist of several separate visual examinations. Throughout this standard, the term 'consignment' is used, but it should be recognized that the guidance provided for consignments may apply equally to individual lots within a consignment.

4.2.1.1. Inspection objectives

The objective of inspection of consignments is to confirm compliance with import or export requirements relating to quarantine pests or regulated non-quarantine pests. It often serves to verify the effectiveness of other phytosanitary measures taken at a previous stage in time.

An export inspection is used to ensure that the consignment meets specified phytosanitary requirements of the importing country at the time of inspection. An export inspection of a consignment may result in the issuance of a phytosanitary certificate for the consignment in question.

Inspection at import is used to verify compliance with phytosanitary import requirements. Inspection may also be carried out generally for the detection of organisms for which the phytosanitary risk has not yet been determined.

The collection of samples for laboratory testing or the verification of pest identity may be combined with the inspection procedure.

Inspection can be used as a risk management procedure.

4.2.1.2. Assumptions involved in the application of inspections

As inspection of entire consignments is often not feasible, phytosanitary inspection is consequently often based on sampling.[107]

The use of inspection as a means to detect the presence of pests in, or to determine or verify the pest level of, a consignment is based on the following assumptions:

- the pests of concern, or the signs or symptoms they cause, are visually detectable;
- inspection is operationally practical;
- some probability of pests being undetected is recognized.

There is some probability of pests being undetected when inspection is used. This is because inspection is usually based on sampling, which may not involve visual examination of 100% of the lot or consignment, and also because inspection is not 100% effective for detecting a specified pest on the consignment or samples examined. When inspection is used as a risk management procedure, there is also a certain probability that a pest which is present in a consignment or lot may not be detected.

The size of a sample for inspection purposes is normally determined on the basis of a specified regulated pest associated with a specific commodity. It may be more difficult to determine the sample size in cases where inspection of consignments is targeted at several or all regulated pests.

4.2.1.3. Responsibility for inspection

Inspections are carried out by NPPOs or under their authority (see also section 3.1 of ISPM No. 7: Export certification system; and section 5.1.5.2 of ISPM No. 20: Guidelines for a phytosanitary import regulatory system; Articles IV.2a, IV.2c and V.2a of the IPPC, 1997).

4.2.1.4. Requirements for inspectors

As authorized officers or agents by the NPPO, inspectors should have:

- authority to discharge their duties and accountability for their actions;
- technical qualifications and competencies, especially in pest detection;
- knowledge of, or access to capability in, identification of pests, plants and plant products and other regulated articles;

107 Guidance on sampling will be provided in the ISPM under development.

- access to appropriate inspection facilities, tools and equipment;
- written guidelines (such as regulations, manuals, pest data sheets);
- knowledge of the operation of other regulatory agencies where appropriate;
- objectivity and impartiality.

The inspector may be required to inspect consignments for:

- compliance with specified import or export requirements;
- specified regulated pests;
- organisms for which the phytosanitary risk has not yet been determined.

4.2.1.5. Other considerations for inspection

The decision to use inspection as a phytosanitary measure involves consideration of many factors, including in particular the phytosanitary requirements of the importing country and the pests of concern. Other factors that require consideration may include:

- the mitigation measures taken by the exporting country;
- whether inspection is the only measure or combined with other measures;
- commodity type and intended use;
- place/area of production – consignment size and configuration;
- volume, frequency and timing of shipments;
- experience with origin/shipper;
- means of conveyance and packaging;
- available financial and technical resources (including pest diagnostic capabilities);
- previous handling and processing;
- sampling design characteristics necessary to achieve the inspection objectives;
- difficulty of pest detection on a specific commodity;
- experience and the results of previous inspections;
- perishability of the commodity (see also Article VII.2[e] of the IPPC, 1997);
- effectiveness of the inspection procedure.

4.2.1.6. Inspection in relation to Pest risk analysis

Pest risk analysis (PRA) provides the basis for technical justification for phytosanitary import requirements. PRA also provides the means for developing lists of regulated pests requiring phytosanitary measures, and identifies those for which inspection is appropriate and/or identifies commodities that are subject to inspection. If new pests are reported during inspection, emergency actions may be undertaken, as appropriate. Where emergency actions are taken, a PRA should be used for evaluating these pests and developing recommendations for appropriate further actions when necessary.

When considering inspection as an option for risk management and the basis for phytosanitary decision making, it is important to consider both technical and operational factors associated with a particular type and level of inspection. Such an inspection may be required to detect specified regulated pests at the desired level and confidence depending on the risk associated with them (see also ISPM No. 11: Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, 2004, and ISPM No. 21: Pest risk analysis for regulated non-quarantine pests).

4.2.2. Specific requirements

The technical requirements for inspection involve three distinct procedures that should be designed with a view to ensuring technical correctness while also considering operational practicality.

These procedures are:

- examination of documents associated with a consignment;
- verification of consignment identity and integrity;
- visual examination for pests and other phytosanitary requirements (such as freedom from soil).

Certain aspects of inspection may differ depending on the purpose, such as for import/export purposes, or verification/risk management purposes.

4.2.2.1. Examination of documents associated with a consignment

Import and export documents are examined to ensure that they are: – complete – consistent – accurate – valid and not fraudulent (see section 1.4 of ISPM No. 12: Guidelines for phytosanitary certificates).

Examples of documents that may be associated with import and/or export certification include:

- phytosanitary certificate/re-export phytosanitary certificates;
- manifest (including bills of lading, invoice);
- import permit – treatment documents/certificates, marks (such as provided for in ISPM No. 15: Guidelines on regulating wood packaging material in international trade) or other indicators of treatment;
- certificate of origin;
- field inspection certificates/reports;
- producer/packing records;
- certification programme documents (e.g. seed potato certification programmes, pest free area documentation);
- inspection reports;
- commercial invoices;
- laboratory reports.

Problems encountered with either import or export documents should, where appropriate, be investigated first with the parties providing the documents before further action is taken.

Verification of consignment identity and integrity

The inspection for identity and integrity involves checking to ensure that the consignment is accurately described by its documents. The identity check verifies whether the type of plant or plant product or species is in accordance with the phytosanitary certificate received or to be issued. The integrity check verifies if the consignment is clearly identifiable and the quantity and status is as declared in the phytosanitary certificate received or to be issued. This may require a physical examination of the consignment to confirm the identity and integrity, including checking for seals, safety conditions and other relevant physical aspects of the shipment that may be of phytosanitary concern. Actions taken based on the result will depend on the extent and nature of the problem encountered.

Visual examination

Related aspects of visual examination include its use for pest detection and for verifying compliance with phytosanitary requirements.

- **Pests**

  A sample is taken from consignments/lots to determine if a pest is present, or if it exceeds a specified level. The ability to detect in a consistent manner the presence of a regulated pest with the desired confidence level requires practical and statistical considerations, such as the probability of detecting the pest, the size of the lot, the desired level of confidence, the sample size and the intensity of the inspection (see ISPM on sampling -under development).

  If the objective of inspection is the detection of specified regulated pests to meet phytosanitary import requirements, then the sampling method should be based on a probability of detecting the pest that satisfies the corresponding phytosanitary requirements.

  If the objective of the inspection is the verification of the general phytosanitary condition of a consignment/lot, such as when:

  - no specified regulated pests have been identified;
  - no specified pest level has been identified for regulated pests;
  - the aim is to detect pests when there has been a failure of a phytosanitary measure;
  - then sampling methodology should reflect this.

  The sampling method adopted should be based on transparent technical and operational criteria, and should be consistently applied (see also ISPM No. 20: Guidelines for a phytosanitary import regulatory system).

- **Compliance of phytosanitary requirements**

  Inspection can be used to verify the compliance with some phytosanitary requirements.

  Examples include:

  - treatment 2 degree of processing;
  - freedom from contaminants (e.g. leaves, soil);
  - required growth stage, variety, colour, age, degree of maturity etc.;
  - absence of unauthorized plants, plant products or other regulated articles;
  - consignment packaging and shipping requirements;
  - origin of consignment/lots – point of entry.

Inspection methods

The inspection method should be designed either to detect the specified regulated pests on or in the commodity being examined, or to be used for a general inspection for organisms for which the phytosanitary risk has not yet been determined. The inspector visually examines units in the sample until the target or other pest has been detected or all sample units have been examined. At that point, the inspection may cease. However, additional sample units may be examined if the NPPO needs to gather additional information concerning the pest and the commodity, for example if the pest is not observed, but signs or symptoms are. The inspector may also have access to other non-visual tools that may be used in conjunction with the inspection process.

It is important that:

- examination of the sample be undertaken as soon as reasonably possible after the sample has been drawn and that the sample is as representative of the consignment/lot as possible;
- techniques are reviewed to take account of experience gained with the technique and of new technical developments;
- procedures are put in place to ensure the independence, integrity, traceability and security of samples for each consignment/lot;
- results of the inspection are documented.

  Inspection procedures should be in accordance with the PRA where appropriate, and should be consistently applied.

Inspection outcome

The result of the inspection contributes to the decision to be made as to whether the consignment meets phytosanitary requirements. If phytosanitary requirements are met, consignments for exports may be provided with appropriate certification, e.g. phytosanitary certificates, and consignments for import will be released.

If phytosanitary requirements are not met, further actions can be taken. These actions may be determined by the nature of the findings, considering the regulated pest or other inspection objectives, and the circumstances. Actions for noncompliance are

described in detail in ISPM No. 20 (Guidelines for a phytosanitary import regulatory system), section 5.1.6.

In many cases, pests or signs of pests that have been detected may require identification or a specialized analysis in a laboratory or by a specialist before a determination can be made on the phytosanitary status of the consignment. It may be decided that emergency measures are needed where new or previously unknown pests are found. A system for properly documenting and maintaining samples and/or specimens should be in place to ensure trace-back to the relevant consignment and to facilitate later review of the results if necessary.

In cases of repeated non-compliance, amongst other actions, the intensity and frequency of inspections for certain consignments may be increased.

Where a pest is detected in an import, the inspection report should be sufficiently detailed to allow for notifications of non-compliance (in accordance with ISPM No. 13: Guidelines for the notification of non-compliance and emergency action). Certain other record-keeping requirements may also rely on the availability of adequately completed inspection reports (e.g. as described in Articles VII and VIII of the IPPC, ISPM No. 8: Determination of pest status in an area, and ISPM No. 20: Guidelines for a phytosanitary import regulatory system).

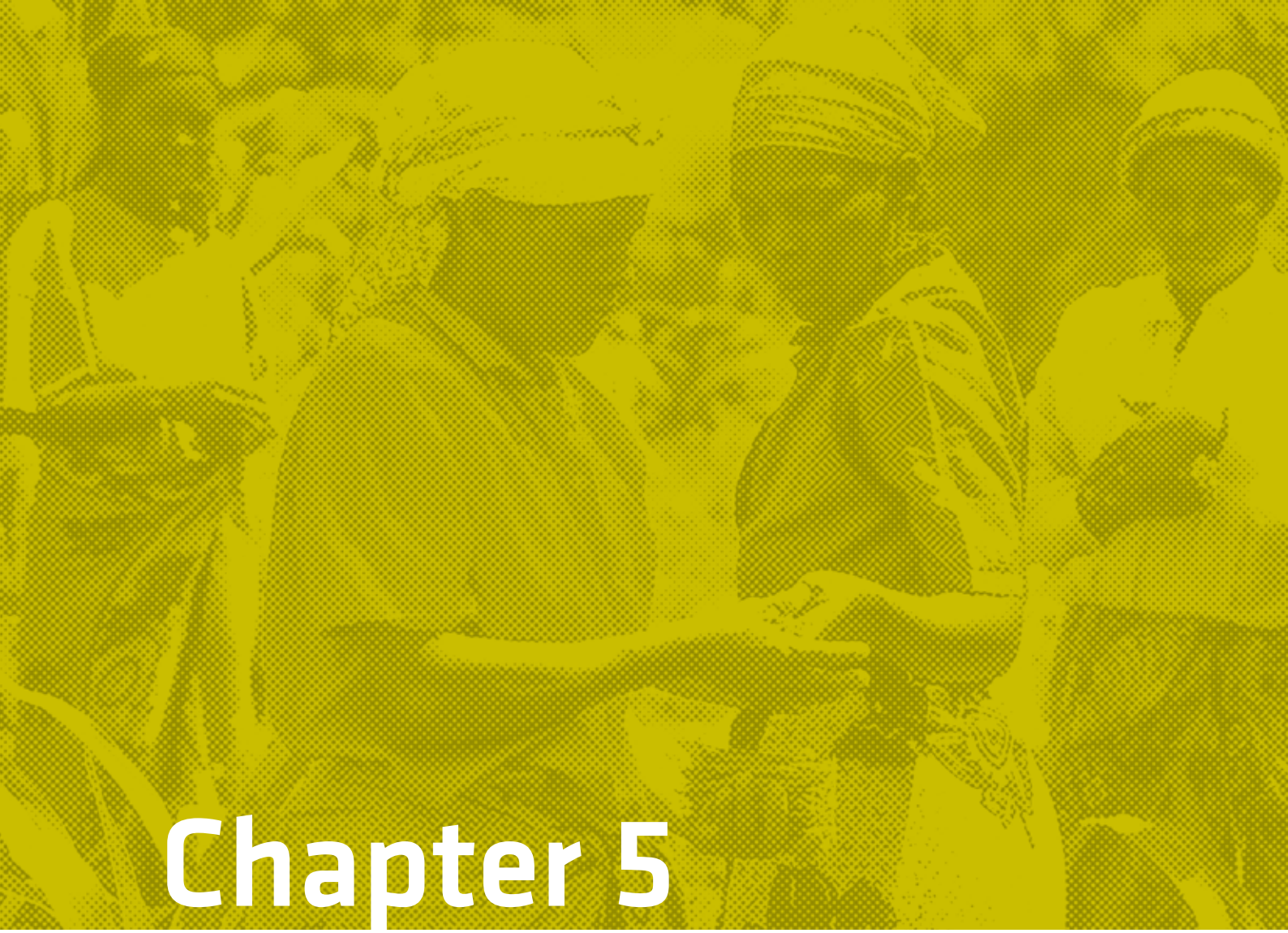
Review of inspection systems

NPPOs should conduct periodic reviews of import and export inspection systems to validate the appropriateness of their design and to determine any course of adjustments needed to ensure that they are technically sound.

Audits should be conducted in order to review the validity of the inspection systems. An additional inspection may be a component of the audit.

Transparency

As part of the inspection process, information concerning inspection procedures for a commodity should be documented and made available on request to the parties concerned in application of the transparency principle (ISPM No. 1: Principles of plant quarantine as related to international trade). This information may be part of bilateral arrangements covering the phytosanitary aspects of a commodity trade.



Chapter 5

Planning controls, inspections and audits

5.1. INTRODUCTION

5.1.1. Preamble

(Source: wikipedia.org)

The organization, sequence and code of ethics of controls are the same when verifying foodstuffs, be they of animal or plant origin.

The same scheme always covers the planning of controls or foodstuffs of animal or plant origin:

- a level one control (verification that products and services comply with the regulatory requirements);
- one or several samplings for microbiological analysis

The aim of these controls is to ensure compliance with food safety laws of food products of animal or plant origin offered to the consumers.

5.1.2. Definitions

A **control**, like a **verification**, is an operation intended to determine, using suitable methods, whether or not the controlled product complies with the regulations and its pre-established specifications and requirements.

The administrative difference between the two terms results, above all, from the nature of the operation:

- control is understood to mean the unannounced nature, *i.e.* the investigation that takes place in the field in consideration of the experience of the agent;
- verification is understood to be the notion of preparation, study of a corporate file.

An **audit** is a control and consultancy activity involving an assessment by a competent and impartial agent and a judgement on the organisation, the procedure or any operation whatsoever of the entity.

The audit is above all an on-going improvement tool, as it allows to review the current situation (inventory) in order to reveal the weak and/or non-compliant points (based on the audit baselines). Suitable actions can then be performed subsequently which will correct the noted discrepancies and dysfunctions.

Given changes in the regulations and case law, it is nowadays recommended that an investigator does not perform an audit.

Regardless of what conclusions he may draw, he could at any moment and on any occasion be reminded of them and they could serve as an argument against him acting as an investigator.

5.2. LEGAL BASIS OF THE CONTROL

The hygiene control reference texts are basically European.

5.2.1. Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002

It lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

This regulation[108] ensures the quality of foodstuffs intended for human consumption and of animal feed. It thus guarantees the free circulation of safe, healthy food in the European market.

In addition, the food legislation protects consumers against unfair trade practices. The legislation is also intended to protect animal health and welfare, plant health and the environment.

5.2.1.1. Safety standards

No **foodstuff that is hazardous** for health and/or unfit for consumption may be placed on the market. The following are considered to determine whether a foodstuff is hazardous:

- normal conditions of use;
- information provided by the consumer;
- the probable immediate or delayed effect on health;
- cumulative toxic effects;
- the specific sensitivity of certain consumers.

When a hazardous foodstuff is included in a batch or load, the entire batch is presumed to be hazardous.

108 eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:FR:NOT

5.2.1.2. Duty of operators

The operators apply the food legislation at all stages in the food chain, during production, processing, transport, distribution and supply of foods.

Similarly, the operators are responsible for ensuring the traceability of products at all production, processing and distribution stages, including the substances incorporated in the foodstuffs.

If an operator believes that a food is harmful to human or animal health, he immediately embarks on the procedures to withdraw it from the market and advises the competent authorities accordingly. When the product may have reached the consumer, the operator advises the consumers and recalls the products already supplied.

5.2.1.3. Food risk analysis

The health risk analysis is broken down into several phases: assessment, management and communication to the general public. This is an independent, objective and transparent process. It is based on available scientific proof.

When the analysis reveals the presence of a risk, the Member States and the Commission can apply the principle of precaution[109] and adopt temporary, balanced measures.

5.2.1.4. International market

The legislation is applied to exported or re-exported foodstuffs before being launched onto the market in a third country, unless the importing country decides otherwise.

The legislation helps to develop international technical standards for foodstuffs and to the international sanitary and phytosanitary standards.

5.2.1.5. Creation of a Food Safety Agency (EFSA)

efsa
European Food Safety Authority

The agency's mission 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 and ensures that the general public is informed of the risks.

It is also in charge of:

- coordinating the risk assessment and identifying the emerging risks;
- providing the Commission with scientific and technical advice, including under crisis management procedures;

109 europa.eu/legislation_summaries/food_safety/general_provisions/l32042_en.htm.

- gathering and publishing scientific and technical data in the fields of food safety;
- establishing networks of bodies active in food safety.

5.2.1.6. Rapid alert system

A rapid alert system brings the Member States together. Information can be exchanged on:

- measures to restrict the circulation in or withdraw foods from the market;
- actions undertaken with the professionals to regulate the use of foods;
- the rejection of a batch of foods by a border post.

In the event of a food risk, the information transmitted through the alert network must be made available to the general public.

5.2.1.7. Emergency situations

When foodstuffs, including those imported from a third country, pose a serious, uncontrollable risk to human health, animal health or the environment, the Commission introduces protection measures and:

- suspends the marketing or use of products;
- suspends the imports of products from a third country.

However, if the Commission does not act after being advised that a serious risk exists, the Member State concerned can take protection measures. Within ten working days, the Commission instructs the Standing Committee on the Food Chain and Animal Health[110] to extend, modify or repeal the national measures.

5.2.1.8. Crisis management plan

In a situation involving direct or indirect risks for human health not provided for under this regulation, the Agency and the Member States can draw up a general crisis management plan.

Similarly, where there is a serious risk that cannot be controlled under existing arrangements, a crisis cell is set up immediately to which the Authority provides scientific and technical support. This crisis cell collects and evaluates all relevant data and identifies the available options for preventing, eliminating or reducing the risk to human health.

110 europa.eu/legislation_summaries/food_safety/general_provisions/f80502_en.htm.

5.2.2. Regulation (CE) No. 852/2004[111] of the European Parliament and the Council of 29 April 2004 on the hygiene of foodstuffs

Under the revision of the legislation on the hygiene of foodstuffs ("hygiene package"), this regulation emphasizes the definition of objectives to be reached in terms of food safety, leaving it to the food sector operators to adopt safety measures to be implemented to guarantee the harmlessness of foods.

This regulation introduces an integrated global policy applying to all foodstuffs from the farm to the consumer point of sale.

5.2.2.1. Scope

This regulation is designed to ensure food hygiene through all stages in the production process, from primary production until the sale to the end consumer. It does not cover issues relating to nutrition nor the composition and quality of foodstuffs.

This regulation applies to firms in the food sector, not to primary production and domestic preparation of foodstuffs for private use.

5.2.2.2. General and specific provisions

All food sector operators make sure that all the stages for which they are responsible, from primary production to the sale or availability of foodstuffs to the end consumer, are carried out hygienically, in accordance with the provisions of this regulation.

The food sector operators exercising primary production and certain related activities must comply with the general hygiene provisions. Dispensations may be granted to small operators, as long as this does not compromise the objectives of the Regulation.

The related activities in question are:

- the transport, handling and warehousing of primary products on the production site when their nature has not been altered significantly;
- the transport of live animals if necessary;
- the transport, from the production site to an establishment of products of plant origin, fishery or wild game products, when their nature has not been altered significantly.

In addition, food sector operators who are exercising activities other than primary production must also comply with the general hygiene provisions detailed below:

- premises, including outdoor sites;
- transport conditions;
- facilities;
- food waste;
- water supply;
- personal hygiene of people in contact with the foodstuffs;

111 eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0852:FR:NOT.

- foodstuffs themselves;
- conditioning and packaging;
- heat treatment used to process some foodstuffs;
- training of professionals in the sector.

The Member States can adapt these requirements to take account of the needs of food sector farms in regions subjected to special geographical constraints or experiencing supply problems, which serve the local market, or to consider the traditional production methods and the size of farms. The food safety objectives must not, however, be compromised.

In addition, all food sector operators must comply with the provisions of Regulation (EC) No. 853/2004[112] on the rules specific to foodstuffs of animal origin and, where appropriate, certain specific rules pertaining, mainly, to the microbiological criteria applicable to the foodstuffs, temperature control and compliance with the cold chain, sample taking and analyses.

5.2.2.3. HACCP system

Food sector operators (apart from those involved in primary production) apply the principles of the HACCP system (Hazard Analysis and Critical Control Points) introduced by the *Codex Alimentarius* (compilation of international food standards under the work of the Food and Agriculture Organization of the United Nations).

These principles stipulate a certain number of requirements that must be respected during the entire production, processing and distribution cycle so that, using a hazard analysis, critical points can be identified that must be controlled to ensure food safety:

- identifying any hazard that must be avoided, eliminated or brought back to an acceptable level;
- identifying critical points where a control is essential;
- introducing critical limits beyond which intervention is necessary;
- introducing and applying effective monitoring procedures for critical points;
- introducing corrective actions when the monitoring process reveals that a critical point is not controlled;
- establishing self-assessment procedures to check the effectiveness of measures taken;
- establishing registers intended to prove the effective application of these measures and facilitate the official controls by the competent authority.

5.2.2.4. Good practices guides and guidelines for applying the HACCP system

The Member States encourage the preparation of national good practices guides by food sector operators, including advice on compliance with general hygiene rules and HACCP principles. The Member States assess these national guides to ensure

112 europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f84002_en.htm.

that their content can be put into practice, that they have been prepared taking account of the *Codex Alimentarius* general food hygiene principles and that all interested parties have been consulted. The national guides considered to comply are sent to the Commission for inclusion in a register.

The Commission will investigate the opportunities when a member State or the Commission sees a need to provide for uniform EU guides. The Member States assess these national guides to ensure that their content can be put into practice, that they have been prepared taking account of the *Codex Alimentarius* general food hygiene principles and that all interested parties have been consulted.

Food sector operators may refer to either national or EU guides.

5.2.2.5. Registration or approval of food sector companies

Food sector operators must cooperate with the competent authorities and, especially, make sure that all the establishments under their responsibility are registered with the appropriate authority and that it is advised of changes in situation (e.g., closure of an establishment).

When so required under national or EU legislation, the food sector companies must be approved by the competent authority and may not operate without such approval.

5.2.2.6. Traceability and withdrawal of foodstuffs

In accordance with Regulation (EC) No. 178/2002,[113] the food sector operators set up systems and procedures to trace ingredients and foodstuffs and, if appropriate, animals used to produce foodstuffs.

Similarly, when a food sector operator notes that a foodstuff presents a serious health risk, he withdraws it immediately from the market and advises the competent authority and the end users.

5.2.2.7. Official controls

The application of HACCP principles by the food sector operators does not replace the official controls by the competent authority. The operators are normally required to collaborate with the competent authorities, in accordance with the provisions of the EU, or failing that, national legislation.

5.2.2.8. External dimension

The foodstuffs imported into the EU must comply with EU hygiene or equivalent standards.

Products of animal origin exported to third countries must meet at least the same requirements as those applicable to their marketing within the European Union, in addition to any requirements imposed by the third country in question.

113 europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f80501_en.htm.

5.2.3. Regulation (EC) No. 882/2004[114]

It re-organizes the official controls of foodstuffs and animal feeds in order to incorporate the controls at all production stages and in all sectors.

The official controls must ensure the compliance with the legislation on animal feeds and foodstuffs and include, among other things, the following activities:

- examination of any control systems that feed and food business operators have put in place and the results obtained;
- inspection of:
  - primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;
  - raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;
  - semi-finished products;
  - materials and articles intended to come into contact with food;
  - cleaning and maintenance products and processes, and pesticides;
  - labelling, presentation and advertising;
- checks on the hygiene conditions in feed and food businesses;
- assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with EU legislation;
- examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;
- interviews with feed and food business operators and with their staff;
- the reading of values recorded by feed or food business measuring instruments;
- controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;
- any other activity required to ensure that the objectives of this regulation are met.

5.2.4. Regulation (EC) No. 2073-2005 on microbiological criteria for foodstuffs

The safety criteria define the acceptability of a product or a batch of foodstuffs. They apply to the products placed on the market until the end of their shelf life.

The process hygiene criteria indicate the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value which, if exceeded, requires corrective measures to maintain the hygiene of the process, in accordance with the legislation on foodstuffs, but does not pronounce on whether or not a product is compliant.

114 europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f84005_fr.htm.

5.3. CONTROL OF FOOD HYGIENE AND MICROBIOLOGICAL SAFETY

5.3.1. Purpose

Establish a framework for carrying out inspections into food hygiene, including the microbiological quality, and their follow-up.

As such, the investigators retain the margin of initiative specific to the inspection activity. In particular, during an enquiry, it may not be possible to monitor all the phases described in this document and the order in which they are listed.

5.3.2. Scope

All food hygiene controls, including the microbiological quality, are covered. The hygiene control checks that all the necessary measures are implemented to control the hazards from microbiological, chemical or physical contamination.

It takes place at all stages in a product's life: preparation, storage, transport, selling, etc. It therefore examines the premises, their environment and their influence on the contamination of products, good hygiene practices, setting up a hazard control system by controlling critical points, the temperatures and storage times, cleaning and disinfecting, etc.

The microbiological quality control is a sub-assembly of the hygiene control that checks the health quality of a foodstuff through microbiological analysis.

5.3.3. Specific vocabulary

- ***Best-before date*:** date until which a foodstuff keeps its specific properties in appropriate conditions.
- ***Contaminant (Codex Alimentarius)*:** any biological or chemical agent, any foreign matter or any other substance not added intentionally to the food product which may compromise safety or health.
- ***Contamination*:** accidental introduction of contaminants in a raw material or during the processing or distribution of a foodstuff or in a food environment. There can be direct or cross contamination.
- ***Control*:** situation in which the procedures are followed and the criteria satisfied.
- ***(To) control*:** take the required steps to guarantee and maintain compliance with the defined criteria, especially in the HACCP plan; lay out the conditions to control, contain and execute an operation or process safely.
- ***Corrective action (or measure)*:** action undertaken to eliminate the causes of a non-conformity, defect or any other existing undesirable event, to prevent them from being repeated.
- ***Criterion*:** parameter or requirement relating to one or more physical, chemical or microbiological characteristic of the operation or the product.
- ***FBI (foodborne illness)*:** appearance of at least two similar grouped cases with symptoms, normally gastrointestinal, where the cause can be related to the same food origin.
- ***FoAO*:** food of animal origin.
- ***Food hygiene*:** all necessary conditions and measures to ensure the safety and health of food at all stages in the food chain.
- ***Food*:** see 'foodstuff'.
- ***Foodstuff (or 'food')*:** any substance or product that is processed, partially processed or unprocessed intended to be swallowed or reasonably likely to be swallowed by a human being. The term covers drinks, chewing gum and any substance including water that is incorporated intentionally in foodstuffs during their manufacture, preparation or processing.
- ***FPO*:** food of plant origin.
- ***Growth test*:** study intended to find out the growth capacity of a micro-organism (phase 1 growth test) or intended to measure the quantitative changes in a microbial population (phase 2 growth test), in various samples of a same foodstuff, inoculated artificially with a known culture of micro-organisms.
- ***HACCP*:** *Hazard Analysis Critical Control Points* System that identifies, assesses and controls the significant hazards for food safety.
- ***Hazard*:** biological, chemical or physical hazard found in a food or state of this food that may have a harmful effect on health.

- ***Hazard analysis*:** approach to collect and assess the data relating to the hazards and the conditions that cause them to decide which of them are significant for food safety, based on the likelihood of them appearing and the severity of their consequences and, therefore, which should be considered in the HACCP plan.
- ***Health*:** assurance that the foods, when consumed in accordance with their intended use, are acceptable for human consumption.
- ***Instruction*:** document that states how an operation should be executed.
- ***Likelihood of a hazard appearing:*** estimation, preferably quantitative, of the possibility of a hazard appearing.
- ***Micro-organism (or microbe)*:** any living organism that is only visible under a microscope. Micro-organisms include viruses, bacteria, moulds and yeasts (plant kingdom) and protozoa (animal kingdom).
- ***Microbiological*:** relating to micro-organisms;
- ***Microbiological ageing study or test:*** see "microbiological ageing test".
- ***Microbiological ageing test*:** study of changes in a food of populations of micro-organisms normally found it in, whether or not they can be detected.
- ***mixed foodstuff*:** foodstuffs made of a mix of foodstuffs of animal origin and foodstuffs of plant origin which is not subjected to a specific text in veterinary law.
- ***Pathogen*:** can cause a complaint or disease (pathogenic bacterium, pathogenic power).
- ***Prevention*:** all preventive measures.
- ***Preventive measure*:** action undertaken to eliminate the causes of a potential non-conformity, potential defect or any other potential undesirable event, to prevent them occurring.
- ***Procedure*:** specific manner of accomplishing an activity.
- ***Processing*:** all operations that culminate in the preparation of a finished product.
- ***Recontamination*:** contamination of a food following an operation to control identified hazards. There can be direct or cross recontamination.
- ***Safety*:** assurance that the foods will not cause any damage to the consumer when prepared and/or consumed in accordance with their intended use.
- ***Shelf life*:** maximum planned period between preparation and consumption.
- ***Use-by date*:** date beyond which a foodstuff may not be marketed or consumed. The use-by date covers microbiologically highly-perishable foodstuffs and which are therefore likely, after a short time, to present an immediate hazard for human health.

5.3.4. Types of controls

The control of the health and microbiological quality of food is one aspect of the quality and safety control of products. It aims to make sure with a sufficient degree of confidence that food contamination is restricted to acceptable levels of safety and health.

It is specific as prevention is the dominant characteristic in convincing professionals to control the safety and health of food they prepare and market and thus protect the health of consumers.

The preventive approach towards hygiene and microbiological control does not exclude criminal proceedings. These are applied when prevention has failed or in the event of serious findings or ill will or obvious negligence by operators.

This control now favours a global hygiene control, *i.e.* reasoning on the control of hygienic risks and on the means implemented to achieve this rather more than a simple observation of anomalies mainly on the microbiological quality of the finished product.

It incorporates the microbiological control of food that aims to ensure that the food has no microbial contamination at levels that could alter the product or be hazardous for the consumer. This microbiological quality control is therefore an integral part of the hygiene control, except for special cases (monitoring plans, seeing the food origin of a foodborne or food illness, listeriosis, etc.).

The control therefore involves checking:

- the ability of the professional to control the hazards relating to his activity (training, preparing relevant control plans according to an HACCP-type system);
- the actual control of the hazards (compliance of premises and equipment, application of good hygiene practices, effective application of HACCP plans, including the corrective actions);
- the conformity of products to the regulatory obligations through analysis.

The control covers all stages in the sector: production, manufacture, storage, packaging, transport and distribution.

For foods of animal origin, in the area of microbiological safety, the control is applied to the foodstuffs sold, put on sale or held for sale or transferred free of charge and preferably at the storage, transport and distribution stages.

5.3.5. Means and methods

Regulations are one way of managing health risks.

Three major principles underline these regulations that highlight the accountability of professionals in the health quality of foods they offer to the consumer.

5.3.5.1. Regulations

1. The regulations lay down general food hygiene principles, with the aim of limiting:
   - food contamination;
   - its recontamination;
   - the development of micro-organisms or the production of toxic substances from their metabolism to avoid reaching hazardous health levels or altering the food;
   - the survival of micro-organisms.
2. They make it mandatory to control the risks by the use of procedures founded on the principles of the HACCP approach, which is one hazard management method.
3. They make it mandatory to limit the presence of microorganisms or toxic substances from their metabolism to avoid reaching hazardous health levels, combined with setting thresholds for certain of these microorganisms.

The health regulations therefore publish stipulations regarding:

- the structures (layout of premises and equipment);
- the operation (use and maintenance of premises and equipment, staff hygiene and training, organization of risk control and self-assessment);
- the products (processing, storage, presentation, criteria).

To achieve the objectives set by the regulations, the professionals must therefore:

- be trained in hygiene;
- have suitable premises and equipment to prevent food contamination and the development of hazards and maintained with this in mind;
- define and implement good hygiene practices to prevent food contamination and the development of hazards;
- have established and apply a control plan on the principles of the HACCP system (identifying steps and stages of their activities which are of particular importance in controlling these hazards – critical control points, defining control measures at these points, with limits that can be measured, if possible, and monitoring the control, laying down corrective measures in the event of a failure, records, etc.);
- have established and apply self-assessment measures (including the monitoring measures provided for in the HACCP plan).

In addition, it is also stated that:

- the HACCP plan aims to control, at certain locations or specific operations, one or more identified risks and through the obligation of fixing limits at critical points, to monitor their compliance and record the results of this monitoring process;

- the use-by and best-before dates are covered by a general measure which is set under the responsibility of the packer. The professional must therefore exercise this responsibility and determine these dates according to appropriate procedures: the use-by date must be justified by convincing elements (ageing study, microbiological assessment, etc.).

5.3.6. The hygiene control

5.3.6.1. The hygiene control logic

The hygiene control checks that the objectives set by the regulations, recalled above, are achieved and that the specific means that they stipulate in certain cases are applied.

For every objective and obligation set by the regulations, the control must firstly attempt to identify the means introduced by the profession to achieve it, in terms of training, premises or equipment, good hygiene practices, analysis and the HACCP plan, self-assessment, *i.e.*:

- which means is used, including procedures, whether or not written down?
- how was it chosen (by an in-house study, in which case by whom and using which system or by reference to a good hygiene practices guide)?

The means then has to be assessed for compliance with the obligation or an ability to achieve the objective, *i.e.* to control the related risk. A judgment is then made following this assessment; this must be justified and may be marked:

- totally satisfactory;
- acceptable;
- unsatisfactory;
- hazardous to health.

When the objective is not reached, the professional must introduce modifications within the timescales that must be set in consideration, if necessary, of the level of risk from the anomaly.

5.3.6.2. The assessment of the control system based on the HACCP approach implemented

As stated above, professionals must have suitable premises and equipment and use them in accordance with good hygiene practices by staff trained in hygiene to comply with objectives set by the regulations.

The regulations also require the operators to apply an approach based on the HACCP principles to control and monitor in particular the most critical points of their activity.

The control of this particular aspect of the food hygiene regulations should be based on the following principles:

1. Has the professional identified clearly the critical control points in his activity?
2. Who identified them (skills, training, means)?

3. How were they identified (internally, via a report, method used: life cycle, list of hazards)?
4. What are the control and monitoring measures adopted (means, limit, monitoring procedures, recordings, corrective measures on the control measure, on the products)?
5. What is the capacity of the adopted measures to carry out the control?
6. Do written or verbal instructions exist?
7. How far can control measures defined in the HACCP plan be applied in reality (who is in charge of applying them, how are they applied, when are they applied, where are they applied)?
8. Do records of monitoring operations exist?
9. Do records of corrective actions (on the processes, on the products) exist?

5.3.6.3. Assessing the validation of product shelf lives

Food hygiene control also includes assessing the choice of expiry dates (use-by and best-before dates) allocated to the products by the professional. He must endeavour firstly to assess the relevance of choosing between use-by and best-before and secondly, to assess the time himself.

5.3.6.4. Microbiological control: supplementing the hygiene control

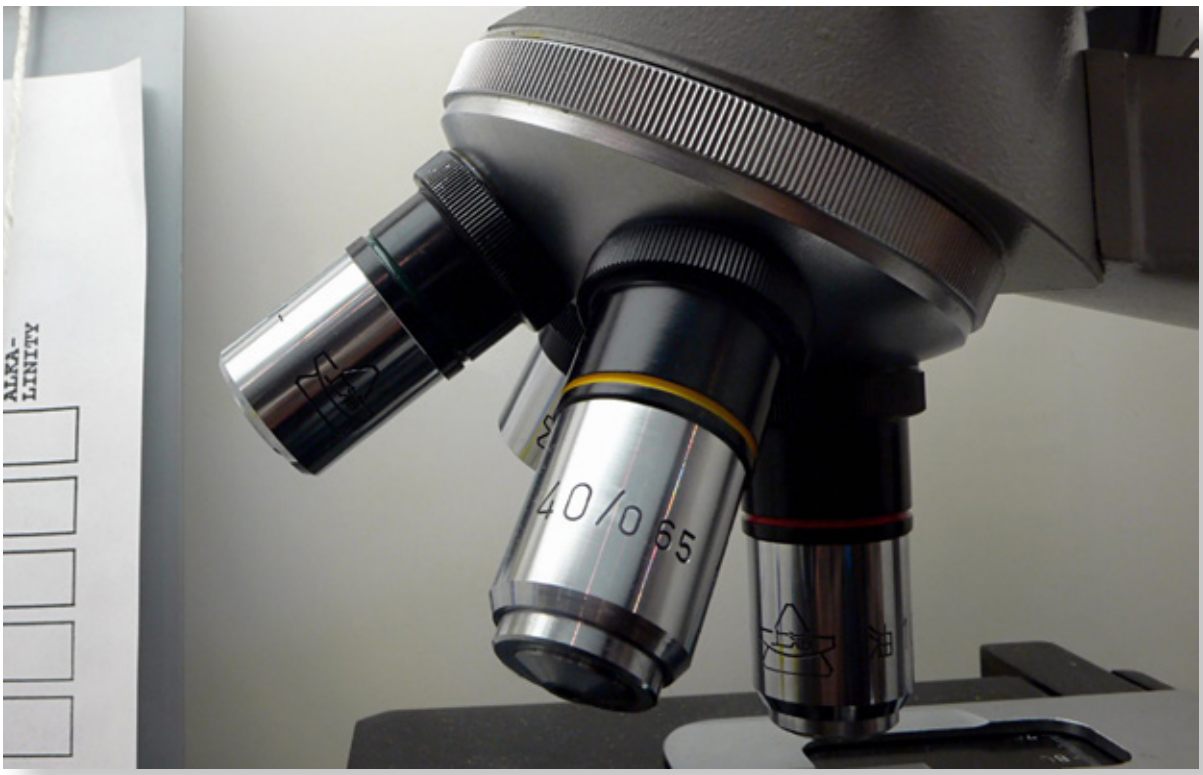
1. ***Why microbiological control (the context)?***

Microbiological control provides a time 't' through a determined food sample or a so-called "surface" sampling, a photograph of the product's health quality (health and safety) and hygiene conditions during its manufacture and storage. It is therefore an additional assessment to the observation of the hygiene of the foodstuffs' environment (state of premises and equipment, handling etc.) and their preparation, warehousing and storage conditions.

It also helps to assess the relevance of the choice of shelf life of products and is a factor in assessing the effectiveness of the company's health quality control system.

Microbiological control is therefore justified as supplementing the hygiene control. Apart from very special cases, for example an FBI, disease or intoxication, even a monitoring plan, its findings may be meaningless in terms of those of the hygiene control. It is understood below with this in mind.

Samples are taken, whenever possible, during the control. Remember in this respect that certain samples may be frozen whilst waiting to be transferred to the laboratory.



The investigator may decide to leave time between the control and the sampling to take account of the scheduling constraints affecting laboratory analyses. The types of product to be sampled are then identified during the control and the same investigator takes the samples on the scheduled date.

2. ***Microbiological control: when?***

The sampling for microbiological analysis normally occurs when the hygiene control reveals dubious situations. It can then clarify the effects of a situation that is difficult to assess based on observations only (e.g., assessment of a slightly low pasteurization scale or mediocre state of premises etc.).

It is therefore important to sample the products for which firstly, the visual examination allows direct intervention – this is particularly true of spoiled foodstuffs whose state is described in the seizure report and foodstuffs with an expired use-by date (exceeding this date is alone sufficient to warrant action) – and secondly, the products from establishments where good manufacturing practices have quite clearly not been followed.

3. ***Microbiological control: where?***

These are the normal intervention locations. In the special case of foodstuffs of animal origin, the processing plants for these products do not undergo specific investigations in this area. Remember, nevertheless, that if hygiene anomalies are noted during controls covering the areas of expertise of the department, they must be signalled to the competent administrative departments.

4. *Which food should be sampled?*

The samplings must cover products sensitive to microbial development, *i.e.* with characteristics favourable to microbial development: composition, pH, water activity and temperature.

The analysis aims to check the microbiological quality of a foodstuff by highlighting the contamination microbial flora. In some products, especially fermented products, the 'technological' flora (lactic flora) can interfere with this revelation.

5. *What research?*

Microbiological sampling must always be justified. Lack of justification is thus likely to render any analysis useless.

The tests requested can cover:

- compliance of a product with regulatory microbiological criteria, mainly after 'to be monitored' or 'non-conforming' samplings;
- highlighting a pathogen following a foodborne illness or an identified food disease (examples: salmonellosis, listeriosis etc.);
- specific research:
  - the search for a pathogen to make sure that there are no hazards attached to a product where the production, storage or distribution conditions are suspect or to confirm or invalidate information on the potential degree of danger of a food (*Listeria monocytogenes*, *Salmonella spp.*, *Bacillus cereus*, *Clostridium perfringens* etc.);
  - the search for toxins (e.g. staphylococcus toxin);
  - the search for fecal contamination indicators: *E. coli*, fecal streptococcus (old contamination).

For the laboratory to conduct its analysis in the best possible conditions, precise information is essential on the nature and composition of the product, its storage method at the time of sampling and the sampling stage (production or distribution).

6. *How?*

Samplings must be carried out carefully to avoid the laboratory refusing to analyse them.

The most frequent causes rendering a laboratory analysis impossible are:

- incorrect sampling: pierced bag, defective bag closure etc.;
- sampling not reaching temperature, failure to provide the minimum quantity required (in some cases, the analysis will only cover certain determinations, mainly the pathogenic bacteria).

In addition, as already stated above, the lack of justification for the sample is likely to render the analysis useless.

7. *The nature of sampling*

There are two possibilities:

- taking a sample from one unit;
- taking a sample from three units of a same product, *i.e.* normally, three consumer sales units or three commercial packagings relating to a same manufacture or batch number.

The number of samplings is determined either by the administrative authority or by the approved laboratory depending on the type of control.

Essential precautions and information:

The usual precautions must be taken during the sampling operation; each unit is packaged in a sterile sampling bag, including the samples in commercial packaging.

The laboratory must have certain information for the analysis or test report:

- a precise description of the product that is essential to identify relevant analytical criteria, for example:
  - raw, cooked or fried product;
  - deep-frozen or fresh product, frozen in the department;
  - cheese made of unpasteurized, pasteurized or heat-treated milk;
  - product category when the name is unreliable;
  - composition of a complex dish;
  - unpacked product or not;

  - packaged product;
  - vacuum-packed product;
  - etc.;
- the temperature when the sampling takes place;
- the sampling stage: production or distribution.

A sampling report is produced on the sampling operation.

8. ***Transporting the sampling to the laboratory***

Transporting samples is a major stage that conditions the laboratory analyses. This operation must be organized, prepared and carried out with care. Poor transport conditions can in fact result in the laboratory rejecting the samples, especially when the sample temperature conditions were not met.

9. ***Conclusions of the analysis report***

It sets out the test conclusions based on their results and according to whether or not there are regulatory microbiological criteria.

10. ***Technical expertise of agents***

The hygiene control and monitoring of microbiological safety of foods are essentially based on assessing the suitability of means chosen by the professionals to achieve the objectives laid down by the regulations.

The responsible agents must therefore be trained in the following areas:

- microbiology: knowledge of different micro-organisms encountered in the food;
- food technology: knowledge of foods (composition, physico-chemical characteristics, intrinsic food contamination), effect of technologies on the development, survival and destruction of micro-organisms;
- microbiological hazard control system (HACCP): system implementation and assessment.

In line with the role assigned above to the microbiological analyses, the samplings should also only be entrusted to agents who have acquired these same skills.

Link between certain anomalies and the general hygiene objectives

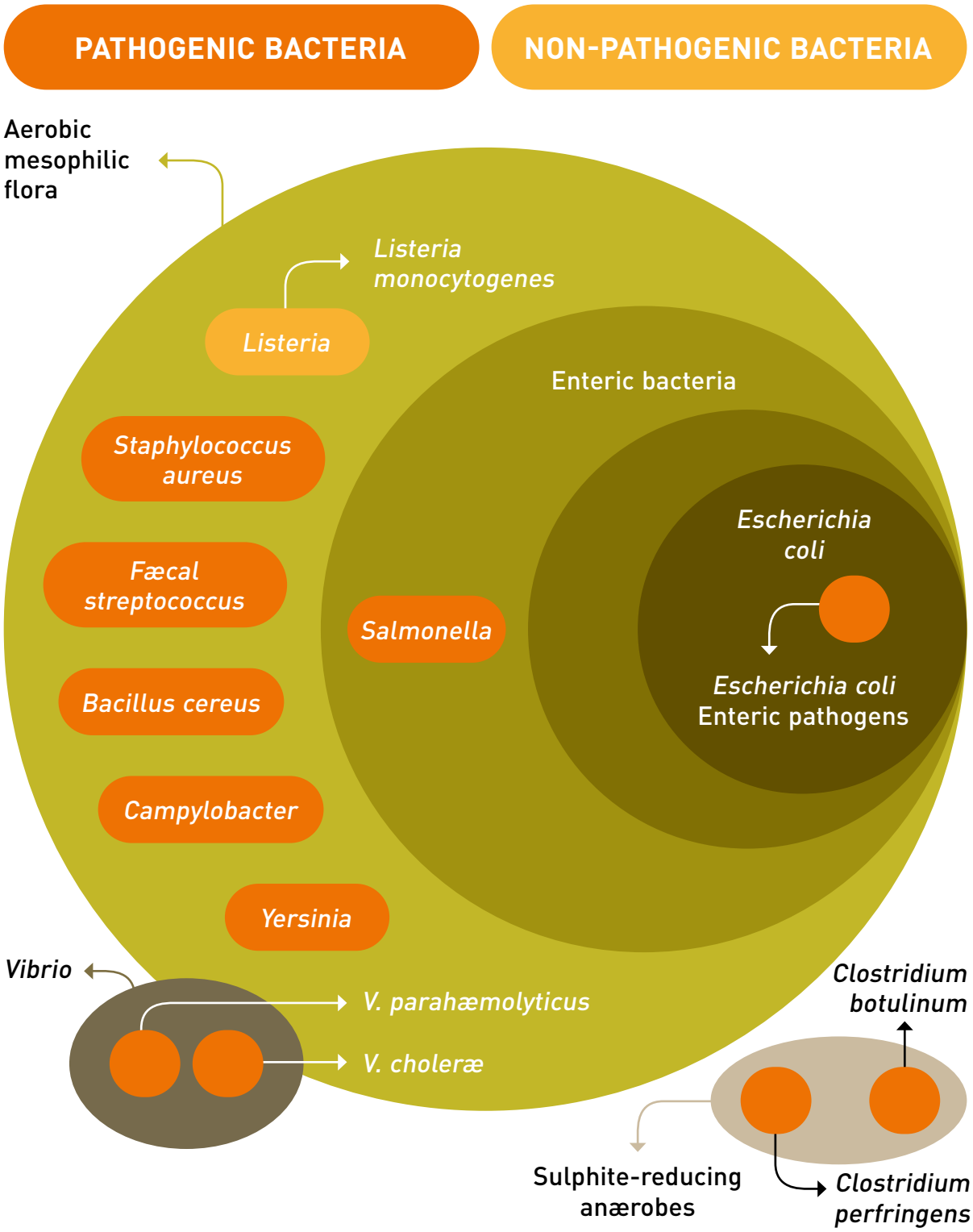
Anomalies concerning:	Related objectives:
Premises (design, product flow etc.)	• avoid cross contamination between products; • avoid contamination through the work environment;
Organizing the manufacture	• avoid contaminations and waiting times, source of microbial development to potentially hazardous levels;
Stacking and storage (warehousing on the ground)	• avoid contaminations via the ground; • avoid contaminations from draughts, the state of shelves, dirty crockery etc.;
Staff (general hygiene such as no headgear, dirty work clothes, no adequate hygienic hand-washing facilities; lack of training)	• make the staff understand the precautions to be taken to comply with the good practices; • limit the input of microbes from people or handling; • limit the input of foreign bodies (hair etc.);
Maintenance, cleaning-disinfecting	• limit the contamination by the premises or the equipment and utensils;
Pest and insect control	• limit food contamination by **preventive** action against rodents and flying insects by preventing them from entering and propagating;

Cold stage	• avoid unacceptable microbial propagation for consumer health by:
	  • complying with the stipulated temperatures;
	  • keeping the cold rooms in good working order;

Rapid cooling	• prevent the rapid propagation of microbes that have not been destroyed (spores) during cooking by lowering the product temperature rapidly; the hazardous temperature range is between +10 °C and +63 °C;
Freezing	• stop the development of microbes, respect the product texture and ensure long-term storage by lowering the temperature rapidly (at least – 18 °C) in the heart of the product;
Defrosting	• limit microbial propagation when raising the temperature of the product by controlling the time (limit the duration) and the temperature (+4 °C maximum or cooking); • limit product contamination during this operation (protection of foodstuffs);

Controls and checks	• check the hygiene quality of products available for sale:
	  • for consumer health;
	  • to ensure that the manufacturing, storage and/or distribution conditions comply with good hygiene practices.

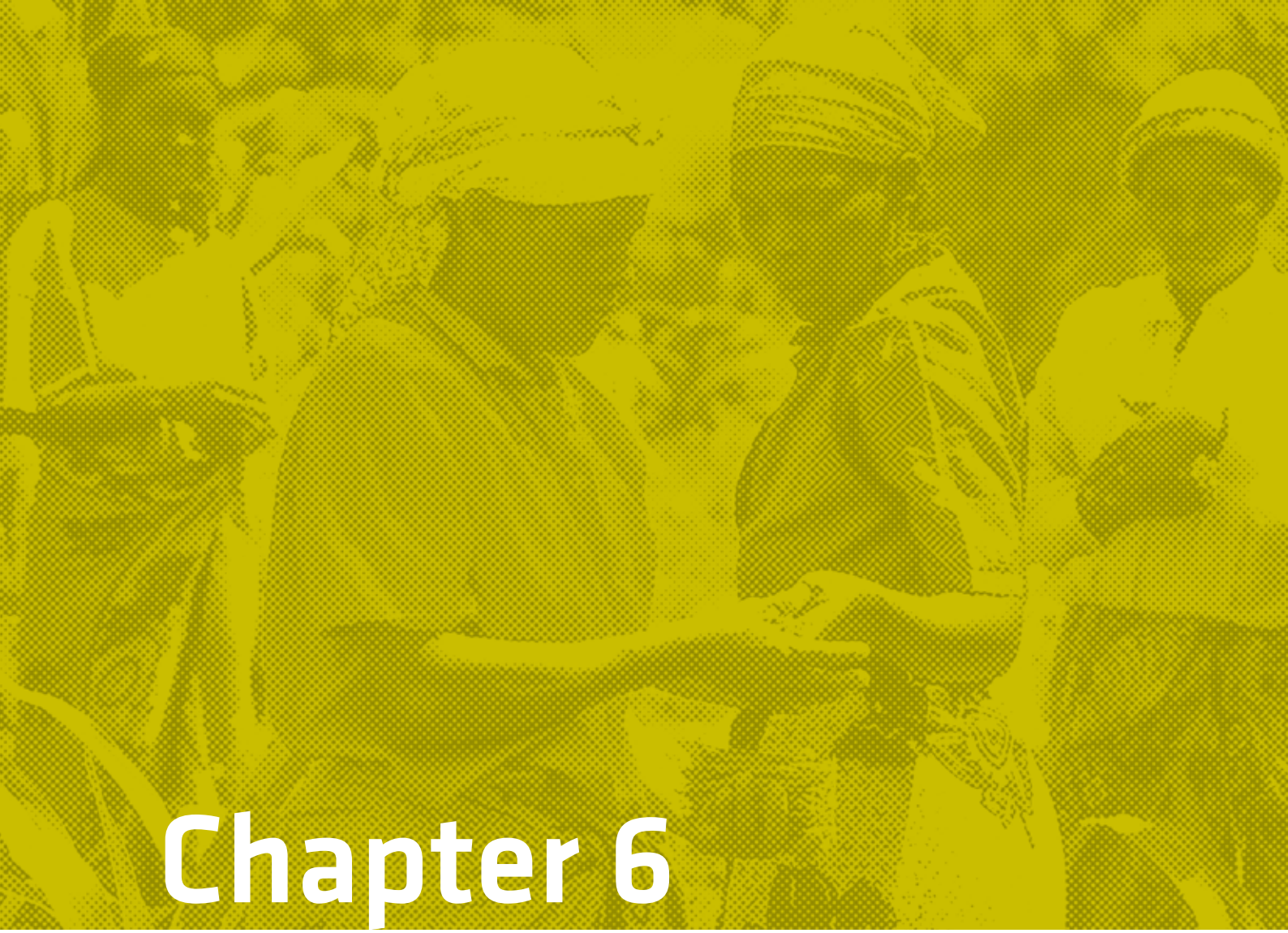
Microbiological criteria: the various bacteria



5.4. REGULATORY MICROBIOLOGICAL CRITERIA AND APPLICATION LEVEL

APPLICATION LEVEL	CRITERIA TYPOLOGY
Production	Imperative standards (LM, *Salmonella*)
Manufacture	Imperative standards (LM, *Salmonella*) Indicative standards (*E. coli*, *Staphylococcus aureus*) Guidelines (AMF, *E. coli*)
Up to the consumer	Raw vegetable products and their preparations, preserved vegetable products: • Imperative standards (pathogens) • Indicative standards (*E. coli*)

Key:
Imperative standard: regulatory criterion; failure to observe it makes it unfit for consumption
Indicative standard: regulatory criterion; failure to observe it does not result in direct action on the product
Guideline: warning criterion characterizing the application of good hygiene practices
AMF: Mesophilic ærobic flora (at 30 °C).
LM: Listeria monocytogenes.



Chapter 6

Planning border controls

6.1. PREAMBLE

Border controls of food and industrial products depend on the economic situation of the country in question.

This economic situation can be as follows:

- the State does not have an economic partnership with other countries: it therefore controls and checks all products imported into its territory;
- the State has a trade agreement with one or more neighbouring countries: this trade agreement is normally based on trading surplus products in one, and products in short supply in the other. These products are defined by a commercial contract and also their composition and conditioning. In this case, these products circulate freely via an import-export network defined by the States;
- the State is part of a political and commercial organisation of States: the agreements governing this organisation provide for free circulation of people and goods.

In the two latter cases, a State has a duty to watch over the health and physical safety of its citizens and organise post-import controls in its territory.

Two import control planning scenarios will therefore be examined, depending on whether or not the country has a trade agreement with one or several more States.

The legal bases will be expanded in the second part, as the first scenario is limited to systematic controls of products entering the territory in question.

(Source : fotolia.com)

6.2. PLANNING IMPORT CONTROLS IN A COUNTRY WITH NO TRADE AGREEMENT WITH ANOTHER COUNTRY

As a rule, for imported products, the importing country sets up an "Authorised for entry" type regime for products on a specific list, which is updated regularly.

Checks are made by agents at entry posts for goods into the national territory.

There can be three types of controls:

- documentary control, which involves checking the reality of goods through accompanying documents submitted by the importer (bill of lading, pro-forma invoice, certificate of conformity, original packing list, declaration of origin etc.);
- visual inspection: the agent has the container opened and checks product conformity, mainly the inclusion of essential information in the language of the country in question (importer details, country of origin) and, for some industrial products, the translated instruction manual.

  The agent has a duty to go inside the container to examine the load:

  - either he can easily achieve this given the space taken up by the goods;
  - or, in the case of a completely full container, he asks the employees of port handling companies to create a 'corridor' so that he can reach the end opposite the opening.

  For so-called hazardous goods, such as ærosols, and goods lacking secure premises in the inspection areas, the examination takes place on the vessel in the presence of an officer.
- analytical control, which allows the agent to make sure, after sampling and analysis, that the goods are harmless and compliant with regulations.

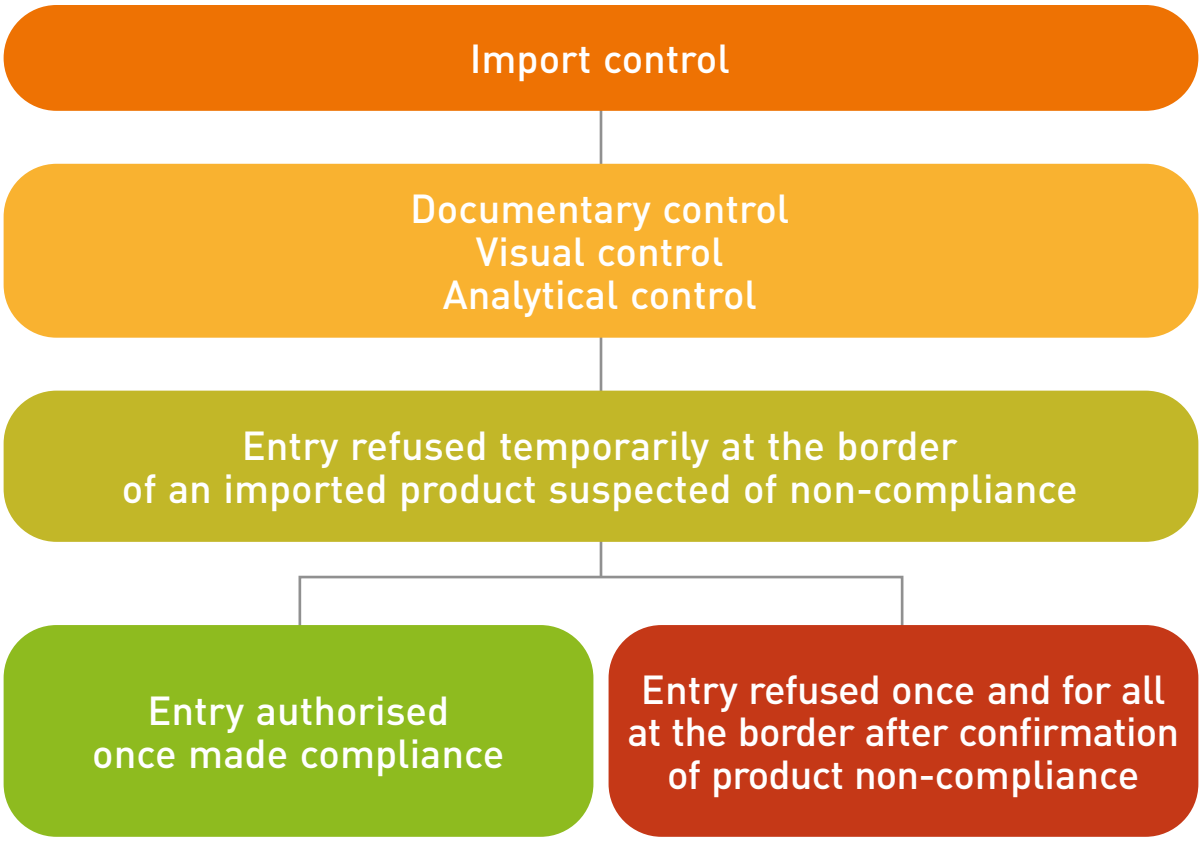
Following these controls, there can be two possibilities:

1. the product complies with the country's regulations and can therefore be marketed in it;
2. the product is not compliant: a temporary entry refusal is issued until it is made compliant.

The product is re-presented to the department in charge of importing goods once the required modifications have been made. Two cases are again possible:

1. compliance is noted and the product is authorised for entry;
2. compliance is not noted and the product is denied entry through the border once and for all.

The diagram below summarizes the sequence of an import control under the conditions described above.



6.3. EXPORTING GOODS

As a rule, any natural person or corporate body can export goods, except for goods that require an export authorisation: endangered species of fauna and flora, State-regulated products of the soil and sub-soil, etc.

However, each country has specific rules and obligations that can generally be summarised as follows:

- registration with the Trade Register or acquisition of the trader's permit;
- acquisition of the exporter/importer permit.

6.3.1. Steps to be taken before exporting

- Obtain a company number issued by the official body in charge of exports (ministry, local offices etc.).
- Identify the goods you wish to export. You must have an accurate description of the goods that you plan to export before you export them.
- You must also investigate the requirements of other ministries, to determine whether the goods you wish to export are controlled, banned or regulated or whether they require a permit, a licence or a special certificate before being exported.
- Make sure that the goods can be exported, according to the regulations applicable to each country.

6.3.2. Export process

It varies from country to country but, as a rule, Customs is in charge of imports and exports.

This department will therefore supply all the official documents required and will be able to redirect you to the correct department, if necessary.

Given its strategic position in the administrative organisation of a country, the main task of Customs is to:

- gather, in a timely manner, precise statistical data on the exports;
- control the export of strategic, hazardous, embargoed and other controlled and regulated goods;
- control the movement of goods in transit.

This department also has a fiscal role, as it is mandatory to submit packing lists in order to check the products and quantities exported.

This department also has a fiscal role, as it is mandatory to submit packing lists in order to check the products and quantities exported.

6.3.3. Export controls

Some countries (including the European Union, the United States and Canada) require that products imported into their territory, and therefore exported from a third country, undergo a technical control by a competent State laboratory or approved private laboratory.

This mainly applies to foodstuffs of animal origin, but also to any product intended for this market.

In principle, the exported product is analysed against standards or rules laid down by the importing countries; the lack of this technical control is a reason for not accepting the product in question.

6.4. PLANNING IMPORT CONTROLS IN A COUNTRY WITH A TRADE AGREEMENT WITH A THIRD COUNTRY OR PART OF A POLITICAL AND TRADE ORGANISATION OF STATES

To explain clearly the difference between these two types of cooperation, the following organisation models can be quoted as examples:

- **The North American Free Trade Agreement (NAFTA)** which creates a freetrade area between the United States, Canada and Mexico. ALENA, which started by establishing a common market, has no intention of creating supranational institutions with legislative powers, like the European Union. This agreement is closer to an international economic and financial treaty. Since its entry into force, most mass retail products from the North American continent are delivered with information in three languages: English, French and Spanish.
- **The Treaty on European Union** is the constituting treaty of the European Union. It sets out the objectives of the Union, defines the pillars of its action and provides the European Council and the reinforced cooperation procedure with an institutional framework.

The Treaty has been signed by all Member States of the European Economic Community

There follows a broad outline:

- the elimination, between Member States, of customs' duties and quantitative restrictions of goods on entry and exit;
- a common trade policy;
- an internal market, characterised by the abolition, between Member States, of obstacles to the free circulation of goods, people, services and capital;
- measures relating to the entry and circulation of people within the internal market;
- common agricultural and fishery policies;
- common transport policy;
- a regime ensuring that competition in the internal market is not distorted;
- the aligning of national legislations to the extent necessary for the functioning of the internal market;
- a social policy.

6.4.1. Legal bases

- **Articles 34 to 36 of the Treaty instituting the European Economic Community of 25 March 1957**

  Free circulation of goods and people.

- **Regulation (EC) No. 764/20081[115] of the European Parliament and the Council of 9 July 2008**

  The aim of this regulation is to improve the free circulation of goods within the Community. It lays down rules and procedures that must be followed by the authorities of Member States when they take or intend to take a decision that could hinder the free circulation of a legally-marketed product in another Member State and that is not covered by harmonised community rules. It is applicable with effect from 13 May 2009.

  The regulation applies to the administrative decisions based on a technical rule which has the direct or indirect effect of:

  - banning a product from being placed on the market;
  - modifying the product or carrying out additional tests on it before it is placed on the market;
  - withdrawing the product from the market.

115 eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R0764:EN:NOT.

- **Regulation (EC) No. 765/2008[116] setting out the requirements for accreditation and market surveillance relating to the marketing of products**

  This regulation envisages establishing clear rules covering the organisation and process of accreditation, in the Member States, of bodies responsible for assessing a substance, preparation or other product, processed or not, intended for the EU market.

  It is important to ensure a high level of market surveillance in order to meet the requirements for the protection of public interests, such as health and safety in general, health and safety in the work place, consumer protection, and environmental protection and security.

- **Regulation (EC) No. 1152/2009[117] amended, imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins**
- **Regulation (EC) No. 669/2009[118] amended by Regulation (EU) No. 514/2012[119] as regards the increased level of official controls on imports of certain feed and food products of non-animal origin**

6.4.2. The control of the first placing on the market of an imported product

Under the principle of free circulation of goods, any product legally placed on the market in a country can be freely marketed in the other Member States, unless it endangers imperative requirements of public interest (especially, the health and safety of people).

When introducing any kind of goods into a State in the European Union, regulations state that the article must have all the safety guarantees in the meaning of community regulations.

The importer must make sure that the imported product is compliant before it is marketed, that the general obligation of safety is met and that it contains no banned ingredient or component.

Once all these obligations are met, the product can circulate freely within the Community trading area.

The fact remains that each State can, and even sometimes must, make sure that the product introduced into its national space complies with the community regulations. Examples include compliance with standards on toys, controlling counterfeiting and the presence of aflatoxins or traces of genetically modified organisms in certain foodstuffs.

116 eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R0765:EN:NOT.
117 eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:313:0040:0049:EN:PDF.
118 eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:194:0011:0021:EN:PDF.
119 eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:158:0002:0008:EN:PDF.

The monitoring process is intended to ensure compliance with provisions of regulations regardless of product origin, especially in terms of consumer health and safety, and thus to guarantee a high level of consumer protection throughout the Union market.

When the controls carried out under marketing monitoring reveal that a product does not comply with the regulations applicable to it and that it is hazardous for health or safety, it may be banned from entering the market.

If it is already on the market, its withdrawal from points of sale and, eventually, its recall from consumers may be ordered. The economic operators involved may be sanctioned.

Official controls consist of:

- a systematic documentary control;
- an identity control and a physical control (sampling and analysis), at intervals defined in principle by the regulations.

The control of the first placing on the market of a foodstuff or an imported product follows the same administrative steps as the control of a product manufactured by the company.

6.4.2.1. Purpose

The control methodology for the first placing on the market by companies of an imported product is identical to the control methodology of the control of the first placing on the market of a product.

6.4.2.2. Scope

1. ***Definition***

The control of the first placing on the market, based on a methodical, in-depth inspection, comprises:

- checking, in the exact location of a business activity, the correct application of regulatory stipulations in terms of safety, fairness of transactions and consumer protection;
- assessing the means used by the professional to ensure compliance with his obligations.

In all cases, the intervention by investigators must aim to ensure compliance of products with the regulations.

It does not mean it is a substitute for the choice of companies in the execution of their self-assessments, nor for consultancy or audit companies.

This methodology can, theoretically, be used in all the companies justifying regular monitoring over time. The choice of intervention is determined by criteria linked to the risks and economic importance.

2. ***Challenges***

The control of the first placing on the market is an appropriate response to the need for fairness and safety expressed by consumers with respect to domestic, or imported, products and the requirements of fair competition between operators.

It gives an overview of all the company's activities falling under the field of expertise of investigators.

It is the preferred method for understanding economic and technological changes and for acquiring knowledge of companies and their activity; which is why it is necessary to carry out controls.

3. ***Objectives***

The control takes place as far in advance of the market launch as possible, with the following objectives:

- identifying compliance or non-compliance and hazardous goods and preventing their dispersion in the territory; it therefore takes place in all premises where production or importing activities take place and where goods are assembled before bursting onto the market (production companies, importers, storage warehouses, distribution purchasing group hubs when the latter are involved in import activities);
- detecting unauthorised technologies and practices;
- assessing the means used by the professional to ensure that his activity is executed correctly with respect to his regulatory obligations and remedying the anomalies detected during his self-assessments;
- reminding professionals of their obligations and advising them of changes in regulations;
- sanctioning unfair practices.

4. ***Exclusions***

The control of the first placing on the market of a product is different from an isolated random control such as sampling a precise product, impounding or seizures in a crisis, scheduled tasks providing for a selective investigation etc.

6.4.2.3. Administrative organisation

Implementing this type of control implies an appropriate organisation of the structures and close cooperation with the laboratories.

1. ***Specific vocabulary***

- **Direct control:** verification that products and services comply with the regulatory requirements;
- **Evaluation of the self-assessment:** inventory and assessment of the relevance, effectiveness and reliability of methods implemented by the company to ensure that its products comply with the regulatory requirements;

- **FMECA:** the FMECA method (Failure Modes, Effects and Criticality Analysis) is an inductive analysis method of failure modes and their effects. This tool is more particularly suited to non-food products;
- **HACCP:** the HACCP method (Hazard Analysis Critical Control Point) is an approach used to define, evaluate and control hazards threatening food safety. This tool is the most suitable to control chemical or microbiological risks;
- **Importing/importer:** any physical introduction of goods onto the territory;
- **Introducing/introducer:** any physical introduction of goods from a Member State onto the territory of another State;
- **Production company:** includes companies that have items manufactured under their own responsibility;
- **Quality approach:** action by a company or an entity that decides to monitor a predefined procedure or baseline (internal procedures, standards, regulations, specifications, good practices guide) to improve the quality of its products or services;
- **Regulatory sensitive point:** any stage in a process that can generate a regulatory non-conformity and which therefore must receive special attention from the professional and the control services. The regulatory sensitive points must be included in the wider set of sensitive points identified by the company to manage the quality of its products;
- **Self-assessment:** set of measures taken by operators, whether carried out themselves or by a third party, to ensure that the products they manage at all production, processing and distribution stages meet food safety legal requirements and product quality and traceability requirements; and that there is effective control of these requirements;
- **The person responsible for the first placing on the domestic market:** this is the person who manufactures or imports a product into the territory, regardless of the product's origin;
- **Traceability:** ability to track the history, implementation or location of a product (e.g. origin of materials and components, execution history, location of the product after delivery).

2. ***Type of controls***

All controls as defined above.

6.4.2.4. Means and methods

1. ***Organisation of controls***

- *Selecting companies and programming*

  The 'listing companies', 'selection' and 'programming' phases must have written records kept by the unit.

- *The skills*

  Both managerial staff and agents are concerned.

- *The skills of agents*

  These skills are acquired during initial and on-going training and through experience and personal efforts.

  The investigators must master the "know-how to control", which is based on regulatory knowledge, application of the control methodology and practising different enquiry techniques.

  It is recommended to set up a tutor system for beginner agents.

  Diverse levels are required for these controls, resulting from basic knowledge supplemented by in-house training.

- *The skills of managerial staff*

  They cover:

  - total understanding of all procedures, to ensure that the interventions of investigators are legally sound;
  - the methodological approach and the issues of the control of the first placing on the market, including the quality approach;
  - coordinating the control of the first placing on the market: listing, selecting companies with the agents, programming, coordinating actions, involvement in assistance and information for agents, monitoring training, checking the updating and filing of corporate files;
  - communication: internal and external;
  - evaluation and validation of controls: this evaluation covers the number of controls and their quality.

  The managerial staff must ensure that the agents have the necessary skills and abilities to carry out the enquiries and the controls.

- *Setting up a company file*

  A company file must be held systematically within the department. It must contain all the information on the company (legal, organisational, economic) and on the controls made and all the elements collected during controls (labelling, manufacturing flow charts, self-assessments, import or introduction documents, etc.) and correspondence with the company.

- *Composition of a standard company file*

  Two of the documents listed must without fail be included in this file:

  - the company fact sheet, with headings that may be changed to suit the context. Among other things, it contains all the elements for crisis management, especially the managers' contact details, product/distribution circuits, self-assessments and recall plans introduced by the company;
  - the control report drawn up by the investigator.

  The managerial staff must update files and ensure the traceability of interventions.

6.4.2.5. The control of the first placing on the market

1. ***Preparation***

The life cycle of the product identifies the regulatory sensitive points that the company must understand fully in terms of safety and fairness.

The analysis of the company file, when this is not the initial control, assesses the "degree of confidence" in the company based on the results of previous controls and the guidelines that were defined for the subsequent controls.

This preparation phase is shorter for an initial control, as the corporate elements will be compiled during the opening meeting. First and foremost, it is important to understand fully the regulations applicable to the sector, highlight the regulatory sensitive points and have sufficient knowledge of the technology and of good manufacturing practices.

In the preparation phase, the context analysis and the corporate file (where it exists) are used to put together an intervention framework that will serve as a guide during the control. It will focus especially on the list of contacts to be met, the workshops to visit, the points to be addressed, the life cycle of the product, when it has one, and the import or introduction circuit.

Prior compilation of the following data can be useful in the control:

- general economic data on the sector to be controlled (competition, supply and distribution circuits, import...);
- and export flows in particular etc.);
- technological data;
- legal structure of the company by consulting existing databases;
- other regulatory constraints weighing on the company (classified establishment, health approval etc.);
- assessment of the role of the company in relation to its activity and its place in the sector;
- knowledge of the company's internal self-assessments or quality approach (quality assurance, certification, HACCP, FMECA etc.).

Identifying skills useful for carrying out the control must lead the investigator to seek, where appropriate, the assistance of different internal structures.

The scientific and technical laboratory staff can also be consulted for guidance on the intervention (sampling guidelines, analytical capacity) and, if needed, associated with certain controls.

Other control services can also be called on.

2. ***Execution***

The intervention normally takes place unannounced, except for the initial meeting to make contact. It obviously varies it length, based on its purpose, the practical circumstances, the elements noted, the size of the company etc. It can involve one or more of the stages defined below, be conducted in depth or with respect to one of the identified sensitive points and give rise to several interventions.

This phase has three stages: the opening meeting, the control itself and the debriefing meeting.

- ***Opening meeting***

  It is intended, especially during a first contact, to open the corporate file, in addition to presenting the service and compiling the main economic and technological data. This meeting is not mandatory and may be delayed if necessary (e.g. suspicion of fraud).

  The fact sheet is handed over during the first meeting.

  The record will be filled in completely, updated regularly and added to the corporate file.

  Special attention will be paid to the elements relating to the crisis management system, such as:

  - the contact details to be used in an emergency (names, telephone and fax numbers, and e-mail addresses of managers to be contacted);
  - production technologies;
  - distribution circuits (internal market, imports, exports, sub-contracting);
  - the corporate crisis management system: self-assessments, withdrawal and recall plan, product traceability.

  When the initial contact is made, the fact sheet will be handed over with the maximum number of elements, but may not be filled in fully and completed during subsequent controls. It is in any case updated when controls take place. This sheet is part of the corporate file.

- ***Intervention***

  The intervention is based, firstly, on the assessment of control means used by the professionals (evaluation of self-assessment) and, secondly, on the product compliance control (direct controls).

  Agents can use the evaluation of the self-assessment to assess the relevance and reliability of the controls implemented by the company. These controls also have the advantage of directing the direct controls more effectively.

- *Evaluation of the self-assessment*

  It features in particular:

  - the inventory of methods to control regulatory requirements implemented by the company, for each regulatory sensitive point identified in the life cycle;
  - the listing of sensitive points defined by the company and matching them with the actual regulatory sensitive points;
  - the documentary study of the application of the internal traceability study described in the importer's technical documents.

  The identification of weak points or shortcomings in the system can guide the direct controls.

  Liaising with laboratories can also prove useful with a view to verifying the relevance of analysis or test documents obtained in the company (reliability of analyses conducted by internal or external laboratories and more especially those supplied to the importer by the foreign manufacturer).

- *Direct control*

  It ensures product conformity with the regulatory requirements and assesses the effectiveness of the selfassessment systems used by the company.

  Faced with an inadequate self-assessment, or none at all, the direct control is the fundamental, even the only constituent of the control.

  The direct control takes the form of:

  - an inspection of premises, equipment, manufacturing technologies, products and their raw materials;
  - book controls (purchase invoices for miscellaneous inputs mainly, labelling controls, metrological controls, analyses of documents provided by the foreign manufacturer etc.);
  - samplings to ensure the quality and compliance of imported products.

  The direct control can be expanded to all the stages:

  - at reception;
  - on the imported products;
  - during storage, conservation, transport up to distribution.

- *Debriefing meeting*

  The intention is to assess the control, to advise the envisaged follow-up and ask what actions the company intends to implement and their timescales to rectify any anomalies noted.

6.4.2.6. Follow-up

1. ***Internal follow-up***

The elements compiled during controls are stored in the corporate file.

The agent must write the control report systematically after each control and as quickly as possible.

The control report must detail the scope of the intervention; this clarification is essential to set the range of the control carried out as well as certify that it is legally sound and useful for monitoring the company over time.

The control report may be split into two parts:

- one part that may be communicated to the company with the control elements and conclusions;
- an internal part with the specific company monitoring elements and the guidelines for the next controls.

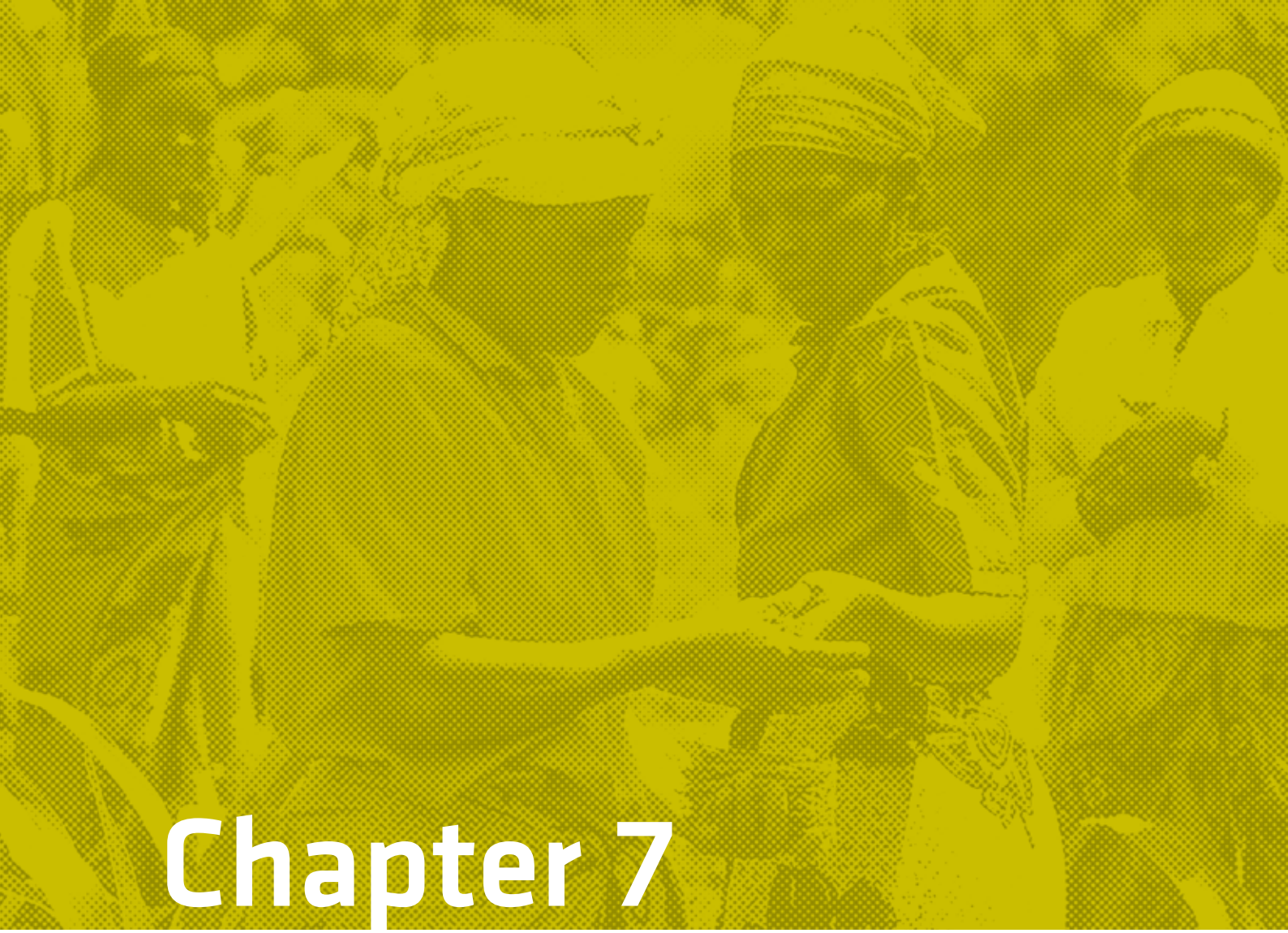
This phase also includes the exploitation of data compiled through the laboratories (analysis results, information on analysis methods, etc.).

This phase must end, in the case of anomalies, with a decision on whether it is appropriate to withdraw the imported goods.

2. ***External follow-up***

In the event of anomalies, the company should introduce the essential corrections, mainly the withdrawal of the incriminated product by all possible means available to it (telephone calls, e-mails, audio or televised messages etc.).

It may also be required to arrange for the return of goods sold.



Chapter 7

Early pest detection and emergency intervention

7.1. INTRODUCTION

7.1.1. Context

Based on risk management, official controls and self-assessments within food-processing industries are not a total guarantee of food safety. Incidents with a potential impact on consumer health can occur and they must be detected and dealt with as quickly as possible so that an emergency response can be provided. It therefore has to be decided whether or not these products should be withdrawn from consumption if they are at the distribution stage, be it regional, national or international. Globalization encourages trade in foodstuffs between the countries in a same economic area or different continents. A product recall system is therefore a fundamental tool in risk management in responding to potential incidents requiring an urgent response.

Some countries have already introduced such a system with the adequate infrastructures and a solid legal basis. Guides for developing product recall systems have been prepared by international institutions or organizations like the FAO:

- FAO/WHO guide for developing and improving national food recall systems, www.fao.org/docrep/017/i3006e/i3006e.pdf
- FAO/WHO framework for developing national food safety emergency response plans, www.fao.org/docrep/013/i1686e/i1686e00.pdf

International crises like Bovine spongiform encephalopathy (mad cow disease) in Europe (1986-2000) and more recently the Fukushima accident in Japan in March 2011 prove the need for such a system and the introduction of communication networks to withdraw the foodstuffs in question from the market.

7.1.2. Document objective and scope

The aim of this document is to help the ACP countries to improve or set up an emergency food safety response system in line with the principle of risk analysis.

The document is intended for the competent authorities in ACP countries responsible for managing food crises and professionals in the food-processing sector. It describes the principles of an emergency food safety response plan, including the process to trigger a rapid alert and the recall and withdrawal of products from the market.

7.2. TERMINOLOGY

7.2.1. Definitions

Batch:

Shipment or partial shipment of foodstuffs, produced in the same way and by the same producer, on the same date or within a short period, packaged in receptacles of the same size and bearing the same name.

Competent authority:

Central authority in a country, competent to carry out controls covering food safety or any authority to which it has delegated this competence. National named authority authorized by law to carry out inspections, evaluate production and control equipment and systems, record, approve and supply, depending on circumstances, approval certificates to the establishments and other installations and issue health certificates authorizing the placing of foodstuffs on the market.

HACCP (method):

Methodology for the risk analysis and critical points control and product safety management intended to identify the hazards, assess the associated risks and establish critical parameters of processes to control hazards.

High-risk products:

Products that can be associated with serious risks for health and safety if they are not prepared or processed correctly.

Hygiene:

All necessary conditions and measures to ensure the safety and wholesomeness of food at all stages in the food chain.

Inspection:

Official examination of establishments, foods and their processing, of companies in the food sector and their management and production systems, including documents, tests on finished products and supply practices, and of the origin and destination of incoming and outgoing products, in order to check compliance with the legal standards.

Inspector:

Official agent authorized by the competent authority who carries out inspection duties to guarantee food safety.

Monitoring:

Planned observation or evaluation of a parameter, at a point or at an established time, which is then compared with a reference (*i.e.* a standard, an operational limit or a critical limit).

Official control:

Describes any form of control undertaken by the competent authority to verify compliance with the regulations.

Risk analysis:

The risk analysis is a method with three components: risk assessment, risk management and communication on the risks (FAO/WHO, 2005. *Codex Alimentarius* Commission Procedure manual, 15th edition). For further information, please refer to: FAO/WHO, 2006. Food safety risk analysis: A guide for national food safety authorities – ftp.fao.org/docrep/fao/009/a0822e/a0822e00.pdf.

7.3. DEFINITION OF AN INCIDENT THAT MAY TRIGGER AN EMERGENCY SITUATION

7.3.1. Definition

Codex Alimentarius[120] defines an emergency situation as follows: a situation whether accidental or intentional, that is identified, by a competent authority, as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.

The aim of any response to food safety emergencies is to withdraw contaminated foods from the market as quickly as possible in order to protect consumer health. Before any emergency food safety response, it is vital that the competent authority determines the criteria used to define a genuine emergency and the necessary strategy to compile the information required to evaluate the severity of the incident triggering an emergency situation.

Countries describe the emergency situation with reference to their own food control systems. The definition of an emergency can therefore vary from one country to the next, as can the triggering threshold for the emergency situation.

Emergencies can be events that occur suddenly (Fukushima accident in Japan) or can evolve from an incident that did not initially look like a health crisis. One such example is the Bovine spongiform encephalopathy, which from an epidemiology in 1986 in Great Britain became over time a European food crisis affecting the entire beef sector. The intervention level varies according to the seriousness of the incident; thus, the more serious the event, the more resources are needed along with the centralizing of decisions at the highest level.

7.3.2. Collecting information

Setting up a process to develop an emergency food safety response plan is normally entrusted to an authority designated by law as having the skills to collect the information and manage the incident for all regional or national fields or for each sector. However, given that food safety incidents can come from several sectors (plant production, animal production, animal feed etc.), consultation with other official organizations is necessary to centralize the information and manage the incident. The key to success of an emergency response plan is to get all the governmental and administrative institutions with responsibility in this area involved; these are the competent authorities designated as risk managers. Here are a few examples:

- Ministry of Agriculture and Fisheries, veterinary services, phytosanitary services, fishery product inspection services, feed inspection services etc.;
- customs, border inspection posts;
- food hygiene laboratories, veterinary surgeons, environment;

120 In "Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations" (CAC/GL 19-1995, Rev. 1-2004).

- Ministry of Health;
- Ministry of Environment.

Standardized documents or reports must be used to collect the information and send it to the services involved.

7.3.3. Hazard identification

When a competent authority receives the first reports of an incident that is widespread and/or with serious consequences for health, it is necessary to determine:

- the likely magnitude of the event;
- the need to inform and involve the senior authorities;
- the need to activate the emergency intervention plan.

In this context, the hazards can be identified from the following factors:

- reports of official controls in the food sector;
- reports of analyses from official controls;
- reports of analyses from controls by the food-processing industry;
- consumer complaints;
- health alerts from other partner countries in terms of food exchanges (example: RASFF).

Hazards with pathogenesis can vary in type:

- biological, including organisms harmful to plant health and regulated (quarantine pests);
- microbiological (*Salmonella*, *Listeria monocytogenes*, *Escherichia Coli* 0157:H7, *Vibrio choleræ* etc.);
- chemical (contaminants from the environment such as heavy metals, toxic substances, pesticides, growth accelerators, antibiotics etc.);
- physical (foreign bodies).

Ideally, the competent authority has a database on the pathogenesis of hazards built up from known and published scientific data. The hazard pathogenesis can sometimes be regulated.

EXAMPLE

In European legislation, Regulation (EC) No. 1441/2007 amending Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs indicates the food safety criteria implying withdrawal from the market of the batch in question in the event of non-compliance.

In some situations where the hazard has not been fully identified, or where the existing data are incomplete, the competent authority can ask for additional analyses from reference laboratories in the field in other countries, or request the assistance of international bodies such as the regional or international laboratories. Where no validated test method is available, existing publications should be perused rapidly or the international scientific community should be contacted for scientific opinions or, as a last resort, a suitable method should be prepared as quickly as possible. However, it can sometimes take a long time to generate new data. In this case, existing data can be used as substitution data to answer the scientific question, following expert opinions. It can also be decided to wait for additional information to become available. However, in the absence of sufficient available data within a set time and taking account of uncertainties that may affect the robustness of the risk assessment, a careful approach based on the precautionary principle 2 should be applied and the entire population may then be considered as sensitive to the hazard identified.

7.3.4. Evaluating the seriousness of the event according to the risk analysis principle

Evaluating the information collected determines whether or not the prevailing situation requires an emergency response. Many parameters must be considered and the risk analysis (PRA) is therefore essential.

When risks are assessed to decide whether an emergency response is necessary, the available information must be examined initially within time constraints and availability of information.

Decision trees can be useful in accelerating the identification and quantification of the risk level of a particular product. They can also make it easier to explain the different risk levels to the competent authority and communicators.

It is important to document the results of the risk analysis. The documentation must include all data on the incident in chronological order (analysis reports, e-mails exchanged between the various departments involved and the operators in the industrial sector), meeting reports or minutes covering the risk analysis and decision made. This documentation must then be archived as it may be used subsequently to identify gaps and needs for improvement.

7.4. DESIGNATION OF RESPONSIBILITIES

To develop a national emergency response plan/recall of foodstuffs, it must be understood that the responsibilities are shared between the government bodies (competent authority) and the food-processing industry. The operators in the food-processing industry are initially responsible for withdrawing their product from the market in conjunction with the competent authority.

7.4.1. Legal bases

The priority for the legislator is to appoint the competent authority in charge of the emergency food safety response and of withdrawing and recalling these foodstuffs. This appointment can be made at different levels, among the services with food safety responsibilities (veterinary services, phytosanitary services, fishery product inspection service etc.). An interdepartmental group can be formed and contact points named to encourage the exchanges between these various authorities.

As for any institution with legal status, the legislation must set out the powers of the competent authority to manage emergency food safety responses and indicate the sanctions to be applied if there are breaches in requirements or obstacles to its powers.

Legal requirements can also apply to operators in the food-processing sector, namely:

- introducing a product withdrawal and recall plan at the request of the competent authority;
- having an upstream/downstream product traceability system and keeping the traceability records;
- having regularly-tested procedures for product withdrawal and recall;
- informing the competent authority when a detected batch presents a hazard that may have an impact on consumer health and communicate all the information necessary on the product withdrawal.

EXAMPLE

Regulation (EC) No. 178/2002 sets up a rapid alert system for food and feed (RASFF). This is managed by the Commission and associates of the EU member States, the Commission and the European Food Safety Authority (EFSA) with the goal of making available to control authorities an efficient notification instrument for risks posed by food or feed on human health. Article 50 of the said regulation defines the RASFF scope and operating rules. Commission Regulation (EC) No. 16/2011 supplements this first regulation and covers the application methods for the rapid alert system for food and feed. It mainly indicates the notification modalities and states the exchange modalities with third countries in Article 10.

7.4.2. Powers of the competent authority

The need to respond rapidly to an incident must urge the legislator to give the competent authority sufficient power in an emergency situation to manage the crisis and the recall/withdrawal of food products from the market successfully. The competent authority must especially have the powers to undertake the following actions:

- review of product withdrawal and recall procedures during routine official controls of food-processing operators;
- launch a food recall plan and oblige an operator in the food-processing sector to recall a batch of foodstuffs presenting a risk for consumer health;
- supervise the recall;
- intervene day or night in any establishment where food products are handled and held;
- detain foodstuffs when their safety is in doubt and whilst awaiting results of additional examinations;
- detain products deemed unfit for human consumption or fraudulent for seizure;
- take samples for examination or additional analyses;
- require any document or record that may contain useful information for the risk analysis, seeking causes of the incident and product withdrawal;
- decide on what becomes of the product withdrawn from the market.

7.4.3. Roles and responsibilities of all operators

7.4.3.1. Competent authority

To make a success of all these tasks, the competent authority must receive appropriate training and have the necessary resources. Its main responsibility is to protect the consumer from any potential risk to his health. As such, it is responsible for supervising and coordinating the emergency response plan and product withdrawal and recall. It must organize itself and appoint people in charge so that it can deal urgently with any incident with a potential risk for the consumer.

7.4.3.2. Private operators in the food-processing sector

Given that the operators in the food-processing sector are responsible for the safety of foodstuffs that they place on the market, they are also responsible for withdrawing them rapidly from the market if there is a proven risk of an impact on consumer health or on plants health.

To achieve this, they must have efficient procedures for product withdrawal and recall that ensure rapid broadcasting of information. These procedures can include a clear definition of responsibilities for this within the company: name people and circulate their contact details. They are sent to the competent authority for information and validation accompanied by the product traceability procedure. Regular testing of the feasibility, efficiency and speed of such procedures is recommended.

When a product withdrawal and recall plan is launched, they must communicate urgently with the competent authority to which they report and send it everything they possess on the incident.

7.4.4. International standards

The international food safety management standards (QMS: Quality Management System) have all incorporated the notion of incident management, product withdrawal/recall for the companies, the need to have the required procedures and to perform simulations to guarantee consumer health. These standards may be viewed at the following addresses:

- IFS (International Food Standard) version 6, www.ifs-certification.com/index.php/en/;
- BRC (British Retail Consortium) Global Standards, brcglobalstandards.com;
- ISO 22000, www.iso.org/standard/35466.html.

EXAMPLE

Extract of Chapter 5.9 of the IFS standard version 6:

"A documented procedure shall be defined for management of incidents and of potential emergency situations that impact food safety, legality and quality. This includes as a minimum: the nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information, and a communication plan, including information to consumers".

7.5. WITHDRAWAL AND RECALL

Withdrawing foodstuffs from the market is frequently the obvious response to the emergency situation. This action can be initiated by the operators in the food-processing sector or by the competent authority if the incident has been detected during official controls or from information from competent authorities in other countries or from any other incident. There are three potential scenarios for product recall and withdrawal:

- Scenario 1: withdrawal/recall initiated by the operators in the food-processing sector.
- Scenario 2: withdrawal/recall initiated by the competent authority and professional assigned to set up the withdrawal/recall of products from the market.
- Scenario 3: withdrawal/recall initiated by the competent authority of another country.

It is recommended that the emergency response plan for product withdrawal and recall describes the procedures to follow for each of the steps described below and indicates the specific responsibilities of the personnel depending on the organization set up.

Scenario 1

Where the professional detects an incident in a foodstuff for which he is responsible and which may have serious consequences for consumer safety or plants health, he can decide to withdraw it from the market and therefore launch a withdrawal and recall plan according to the pre-established procedure. In this case, the professional can use his traceability system to find the batch in question and identify all the distribution points so that he can advise them of the withdrawal and recall of the batch. He also arranges for the information to be broadcast to the consumer in the form of posters, letters or messages via the media. The competent authority must be advised of the withdrawal and recall of the batch and can ask to receive all the documents held by the professional relating to the cause of the incident (e.g. analysis bulletins) and product traceability (examples: traceability sheets, acceptance sheet, production sheet, raw material purchase invoices, sales invoices with list of customers involved). It makes sure that it has all the information needed to evaluate the situation and that the scope of the withdrawal and recall plan is sufficient. The professional decides in conjunction with the competent authority what should become of products (destruction, controlled processing or destination to another market). The competent authority can then verify how the information is communicated to the customers and the end consumer. It also communicates with the other designated points of contact.

Scenario 2

The competent authority can carry out the following actions when it initiates the withdrawal and recall:

- compiling and processing information relating to an incident;
- forwarding information to other contact points;
- risk analysis and decision making;
- making decisions on what should become of the offending batch of foodstuffs;
- assigning the professional to the launch of the product withdrawal and recall and supervising actions carried out;
- identifying batches involved;
- ensuring that the information is communicated to the customers and ultimately to the consumer.

If necessary, the competent authority can use a standard notification template to give the professional the order to launch the withdrawal and recall of the offending product. This notification must repeat all the information useful to the professional for the launch of his product withdrawal and recall plan.

Scenario 3

When the withdrawal and recall is initiated by the competent authority of another country, be it for a product it has imported or a product which has been exported to this country, the competent authority triggers its emergency response plan for withdrawal and recall of products involved, according to Scenario 2. The competent authority must then communicate to the competent authority of the other country the results obtained according to the procedures requested by the other country using the required documents; this is the case, for example, of the EU for the RASFF.

The competent authority can include in its procedures one that is intended for the professionals, mainly comprising all documents and records to be provided in a crisis. Document templates are suggested in Chapter 8 of this document. The competent authority can nevertheless prepare a guide for professionals to assist them in managing a withdrawal and recall plan and require them to be trained in this field.

7.6. PRODUCT TRACEABILITY: SYSTEM SUPPORT

7.6.1. Definition: upstream/downstream traceability

The European Committee for Standardization (CEN) defines traceability as "the ability to retrace the history, application or localization of a product". The history of a product can include its origin, its elements and the detail of their routing.

The traceability systems set up by the food-processing professionals must allow a product or an ingredient contained in a foodstuff to be traced throughout the entire food chain. The aim of a traceability system is to be able to find the products incriminated by a health alert and to withdraw them from consumption as quickly as possible. To achieve this, it must be possible to identify and monitor them until they are handed over to the consumer. The most efficient way of achieving this objective is a unique batch code. The product is thus traced from its entry in the company and throughout the process until shipment. Any ingredient entering into the composition of a product is traced by allocating a batch number on entry; its traceability is then taken up at the production stage when it is incorporated into the composition of the finished product. Its inclusion is then registered on a production sheet or another document with a link to the batch code allocated to the finished product. Thus, all the batches of ingredients can be found using the finished product batch code and the product into which the ingredient has been incorporated can be found via the ingredient batch.

Batches are most frequently given codes, but the production or expiry date is occasionally repeated for batch numbering. For greater transparency, the operator must define the batch encoding in his traceability procedure. Traceability records are increasingly computerized, which makes searches faster in an alert.

The obligation of traceability can be considered as a fundamental part of the HACCP system, as the system is meaningless unless the data are registered against a batch number that states not only the day of production and the acceptance or shipment period, but also the origin of the raw material used.

7.6.2. Traceability requirements to produce the food withdrawal plan

The traceability system must be able to find the offending products quickly in a health alert for a withdrawal or recall. This system must be reliable as it is unacceptable for products constituting an offending batch being withdrawn or recalled to be missed because they are poorly identified and monitored.

The following diagram describes this process. However, it is up to the professional to define his own traceability system and to prove his efficiency.

7.6.2.1. Classic diagram of a traceability system

The batch code is marked on the product label and recorded on the documents throughout the process (production/storage) and on the documents accompanying the products like invoices. All records including the traceability elements and a duplicate invoice are stored once the product is placed on the market. In case of a food safety alert, in the absence of products already placed on the market, the food business operator will search in the documents. The batch numbers shown on the invoices will also be used to find the customers that have received the offending batch. They will therefore be archived for a set period mainly based on product shelf life, as products will be recalled at least on the batch shelf life, even beyond. The hypothesis can be put forward for a product distributed fresh that it was frozen by the consumer and that it has therefore been preserved even beyond the original expiry date.

7.6.3. Legislation

To be consistent with the legal requirements on the withdrawal and recall of foodstuffs, the competent authority must have the legal power to impose traceability requirements and to validate the traceability system set up by the food business operator. The legislation can thus impose a documented traceability system on food processing professionals. This regularly updated and tested system feeds the information on products both upstream and downstream in the food chain. These requirements can also include the obligation to show the traceability on product labelling.

EXAMPLE

Article 18 of Regulation (EC) No. 178/2002 of the Council of 18 January 2002 "laying down the general principles and requirements of food law..." requires that the traceability of "food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution". The regulation also requires that the suppliers and customers of each batch may be identified and that operators in the industrial sector set up systems to facilitate the access by inspectors to this information. The food products circulating in the markets must also be labelled to facilitate their traceability.

7.7. COMMUNICATION AND NOTIFICATION SYSTEM

7.7.1. Communication between the competent authority and the other agencies

The emergency food safety response plan must firstly refer to the national legislation in force which forms the legal basis for its implementation. The plan can describe the roles and responsibilities of different national authorities involved in the emergency food safety response and contact points can be designated and communicated in each of these organizations. Responsibilities must also be defined for decentralized services in contact with food-processing operators, as they are responsible for official controls in these establishments or the control posts that carry out border food safety controls. These decentralized services are frequently in the front line in detecting incidents and feed the information to the competent authority's centralized services. Contact points can be designated for local services and communicated to the food-processing professionals that depend on them.

The communication can be organized under procedures that will include:

- identifying roles and responsibilities for communication and information within the competent authority;
- identifying contact points: partners in other ministries, local administrations, international partners (national contact points for these partners: partner country embassies, European delegation, INFOSAN, WTO etc.).

It is important to indicate the telephone number and e-mail address of each contact point in the procedures.

Where the competent authority initiates the withdrawal or recall plan, it is responsible for communicating to the professionals involved the reasons for this decision and the information whereby they can find the offending product to withdraw it from the market, namely:

- product name and brand;
- nature of product (fresh, frozen);
- reason for recall;
- safety approval number of the establishment involved only for food of animal origin;
- production date;
- expiry date;
- batch number;
- what is to become of the product.

Templates to standardize the notifications can be created for circulation to the miscellaneous organizations and operators in the food-processing industry (see Chapter 8). It is also recommended to use terminology standardized by the industry and understood by all operators in writing these notifications.

7.7.2. Communication between food business operators and the competent authority

In the withdrawal and recall procedures of operators in the food-processing sector, contact points within the company can be designated: name of the person in charge of the recall plan and his replacement along with their telephone numbers. This information and its updates is communicated to the competent authority and may be used to create a database.

Under the product withdrawal and recall plan, it is essential that the professional communicates the key elements about the product as quickly as possible as they will identify it and justify its withdrawal or recall, namely:

- product name;
- nature of product;
- brand name;
- type of packaging and conditioning;
- base weight/size;
- production date;
- expiry date;
- batch number;
- summary of the incident: description of the hazard, origin, symptoms;
- quantity in stock in the company, quantity sold;
- distribution details: sales outlets, list of customers, countries to which the products have been exported;
- what is to become of the product.

The professional communicates on the actions carried out throughout the product withdrawal and recall operation.

It is advisable to keep records of all communications made. The quantities of foodstuffs returned and, if appropriate, destroyed must be recorded in order to prove what became of them.

7.7.3. Communication with the competent authority of other countries (e.g. RASFF system)

Where a notification relates to a product from another country or distributed by another country, the country advises the competent authority quickly who will then apply the necessary measures described in the national emergency food safety response plan.

Where this involves an exported product, many countries with a rapid alert management system, like the European Union's RASFF system, require a contact point to be designated and communicated to the country in question. In this case, the competent authority may have to deal with two types of notifications:

- ***Information notification:*** relates to a foodstuff that has been notified in the country where the product has been exported and for which the competent authority must take measures regarding future exports: exports suspended, strengthened controls and information transmitted on the corrective actions undertaken.
- ***Alert notification:*** send when a food is found on the market in the country involved and requires immediate measures.

The following, non-restrictive information in an alert notification can be communicated to the competent authorities of the other country:

- nature of product;
- product description and brand;
- production date, expiry date, batch No.;
- reason for recall;
- name and address of establishment concerned by the recall;
- quantity, volume;
- border post where the product entered;
- container No. for frozen products;
- name and address of the importer;
- what is to become of the product.

It is recognized that the recall process is dynamic, with potentially changing information throughout the event, for the information communicated at the initial recall can be incomplete. The competent authority should communicate rapidly any new or additional information to all foreign countries involved as soon as it is available.

Some countries request that the health alert be notified on their notification form template which can be downloaded from their electronic portal.

The INFOSAN secretariat holds a list of national contact points for countries with a rapid alert management agency: www.who.int/foodsafety/areas_work/infosan/en.

7.7.4. Communication with the general public under the principle of transparency

Consumer information is essential in a recall plan, especially when the product presents a major hazard and therefore a serious risk to consumer health. The competent authority initiates the communication with the general public. It is recommended to target the population concerned by the consumption of the product and to broadcast clear, sensible advice, namely:

- give a precise description of the product, add a photograph if possible;
- why the product is being recalled;
- a short description of the hazard, symptoms and incubation time;
- what the consumer must do if he has consumed the offending product;

- what the consumer must do if he has the offending product in his possession;
- give a telephone number or a website where the consumer can find other information and ask questions.

The alert message can be broadcast to the consumer in a variety of ways:

- posters in sales outlets;
- letters sent to customers;
- message on the Web site of the competent authority;
- message on the Web site of the company involved by the health alert;
- press release: newspaper, radio and television.

7.8. TOOLS TO BE USED FOR THE COMMUNICATION

7.8.1. Reports, records and existing templates

To achieve a methodical and harmonized approach, all information compiled and transmitted should preferably be recorded in established templates adapted to the situation, for each stage in the emergency food safety response plan. Recording data constitutes a written trace.

Numerous templates are given in the FAO/WHO Guide for developing and improving national food recall systems: www.fao.org/docrep/017/i3006e/i3006e.pdf, namely pages 51-56: notification template for a foodstuff recall issued by the competent authority.

7.8.1.1. Form template for compiling information on a health alert by the competent authority

MINISTRY … – FORM TO BE USED FOR AN EMERGENCY RESPONSE

Document created on: .....

DESCRIPTION OF THE INCIDENT

Date information received	
Service receiving the information	
Person in this service receiving the information	
Type of document transmitted for information	
Origin of information	
Reason of alert	
Non-compliant values	
Number of victims	
Country concerned	
Product concerned	
Batch No.	
Establishment concerned	
Health approval No.	
Means of transport	
Incriminated country	

1. Actions carried out

Actions	People of the CA
TRACEABILITY search	
Search for related documents	
REINFORCED CONTROLS	

2. Conclusions on the state of products and what is to become of them

Actions	Quantities	Detention certificate No.
Detention of offending batches		
Seizure of offending batches		
Recall/withdrawal of marketed batches		

7.8.1.2. Template for notification issued by an operator in the food-processing sector to withdraw and recall one of his products

ISSUED BY: .....

INTENDED RECIPIENT: .....

Date of alert: .....

Product name:		
Size:		
BRAND NAME:		
Approval No.:		
Date packed:		
Use-by and best-before dates:		
Batch No. indicated on the product label:		
Quantity delivered:		
Reason for alert:		
Origin of information:		
WHAT IS TO BECOME OF THE PRODUCT:		
Do you still have this product in stock?	Yes	No
If yes, quantity:		
Place where product may be collected:		

*Please pass the information on to your customers and advise us of any withdrawals made.

Please fax this document to…

If you have a question, please contact Mr. DUPONT

FAX: XX XX XX XX – TEL.: XX XX XX XX

7.8.1.3. RASFF rapid alert notification

GENERAL INFORMATION

1	NOTIFICATION TYPE		
2	CONTROL TYPE		
3	NOTIFYING COUNTRY		
	Contact ref. No.		
4	NOTIFICATION DATE		

HAZARD

5	HAZARD NATURE		
6	TESTS/ANALYSES RESULTS		
7*	COUNTER-ANALYSES		
8*	SAMPLING	Dates	
		No. of samples	
		Method	
		Place	
9*	LABORATORY		
10*	ANALYSES	Sample processing/ analysis matrix	
		Analyses Methods	
11*	PERSONS AFFECTED		
12*	SYMPTOMS/DIAGNOSIS		

PRODUCT

13	PRODUCT CATEGORY		
14	PRODUCT NAME		
15*	PRODUCT DESCRIPTION	BRAND NAME	
	PHOTOGRAPHIES	PRODUCT PRESENTATION (e.g. package)	
		WEIGHT	

RESULTS OF INVESTIGATION AND MEASURES ADOPTED

16	DISTRIBUTION	
17*	VOLUNTARY MEASURES	
18*	IMPOSED MEASURES	
	Date of application	
	Length	
	Public announcement	
19	LEGISLATION	
	Scope	
	Maximum permitted level	

BATCH IDENTIFICATION

20*	CONSIGNMENT/BATCH		
21*	HEALTH CERTIFICATE	No.	
		Date	
		CVED No.	
22	VALIDITY	Use-by date*	
		Best-before date*	
		Sell-by limit	
23	BATCH DESCRIPTION	Number of units*	
		Total net batch*	

ORIGIN

24	COUNTRY OF ORIGIN		
25	PRODUCER	Name	
		Address	
		Vet. App-No	
26*	EXPORTER	Name	
		Address	

DISTRIBUTION

27*	DISTRIBUTED BY	Importer	
		Wholesaler	
		Retailer	
28*	DISTRIBUTION IN MEMBER STATES		
	DISTRIBUTION LIST ATTACHED		
29*	EXPORTED TO THIRD COUNTRIES		
	DISTRIBUTION LIST ATTACHED		

WHEN SEIZED AT THE BORDER

30*	POINT OF ENTRY		
31*	TYPE OF VERIFICATION		
32*	COUNTRY OF SHIPMENT		
33*	COUNTRY OF SHIPMENT		
34*	CONSIGNEE	Name	
		Address	
35*	NUMBER OF CONTAINERS		
36*	MEANS OF TRANSPORT		

OTHER INFORMATION

37	ORGANISATION/MINISTRY:	
38*	CONTACT PERSON:	
39	OTHER INFORMATION:	
41*	ATTACHED DOCUMENTS: (compressed format)	• Health certificate • CVED • Phytosanitary certificate • Analytical report • Invoices/delivery documents • Press release/information public recall • Other
42*	CONFIDENTIAL:	
43*	If yes, which boxes (Nos):	
44*	If yes, reason:	

Numbers underlined: mandatory information

Numbers with*: information required, if applicable

7.8.1.4. Poster template designed to inform the consumer

Date: .....

CONSUMER INFORMATION

PRODUCT RECALL

'Company XXX' is today withdrawing 'Product name' from sale due to ...

This involves products with the following characteristics:

Nature of product: .....

Brand: .....

Presentation: .....

Date marketed: .....

All products (name, nature, product presentation and reason for withdrawal) are withdrawn from consumption.

Some of these products were however available on the market before the withdrawal measure.

The product (name, nature and presentation of the product) was sold in aisle ... between [date] and [date] in our 'store name' stores.

Any person in possession of products belonging to the batch described above is advised not to consume them and to destroy them or get them reimbursed.

Company 'XXX' is at the disposal: .....

7.8.2. Computer network and databases

7.8.2.1. Alert notification portals

Some agencies in charge of emergency food safety response management have an Internet portal with a database where all notifications involving them can be found. This is the case of the RASFF portal for the European

Union:

- RASFF portal:

  www.ec.europa.eu/rasff-window/portal/index.cfm?event=notificationsList

  www.ec.europa.eu/food/food/rapidalert/index_en.htm
- Canadian Agency portal:

  www.inspection.gc.ca/francais/fssa/recarapp/rap/mggunidf.shtml
- Australian Agency portal:

  www.foodstandards.gov.au/scienceandeducation/factsheets/foodsafetyfactsheets/foodrecallsystemsfor104.cfm
- United States Agency portal:

  www.fda.gov/safety/recalls/default.htm

These portals give access to all the notifications and where they originate. It is also possible to monitor their management online.

7.8.2.2. RASFF portal

The RASFF notifications cover the risks identified in food, feed or materials in contact with the foodstuffs placed on the market in the notifying country, or held at an entry point on the border with a neighbouring country. The country that has notified the risks must identify the product, its traceability and the measures it has taken. Depending on the severity of risks identified and the distribution of the product in the market, the RASFF notification is classified in different categories by the Commission's point of contact as an alert, information or border rejection before being sent to all the network members.

a. ‘RASFF ALERT’ alert notification

An alert is sent when a food, feed or a material in contact with the foodstuffs presents a serious risk for the market or when rapid action is required in a country other than the one that submitted the notification. The alerts are launched by the network member who has detected the problem and initiated the procedures to be followed like the product withdrawal and recall. The notification aims to give all network members the information to verify whether the offending product is present in their market and so that they can take the necessary action. The products subject to an alert notification have been withdrawn or are being withdrawn from the market. The member States have their own mechanism for performing such actions, including broadcasting information via the media, if necessary.

b. ‘RASFF INFORMATION’ alert notification

A notification of information covers a food, feed or material in contact with foodstuffs where a risk has been identified but does not require rapid action, for it is not viewed as serious and the product is not on the market at the time of notification.

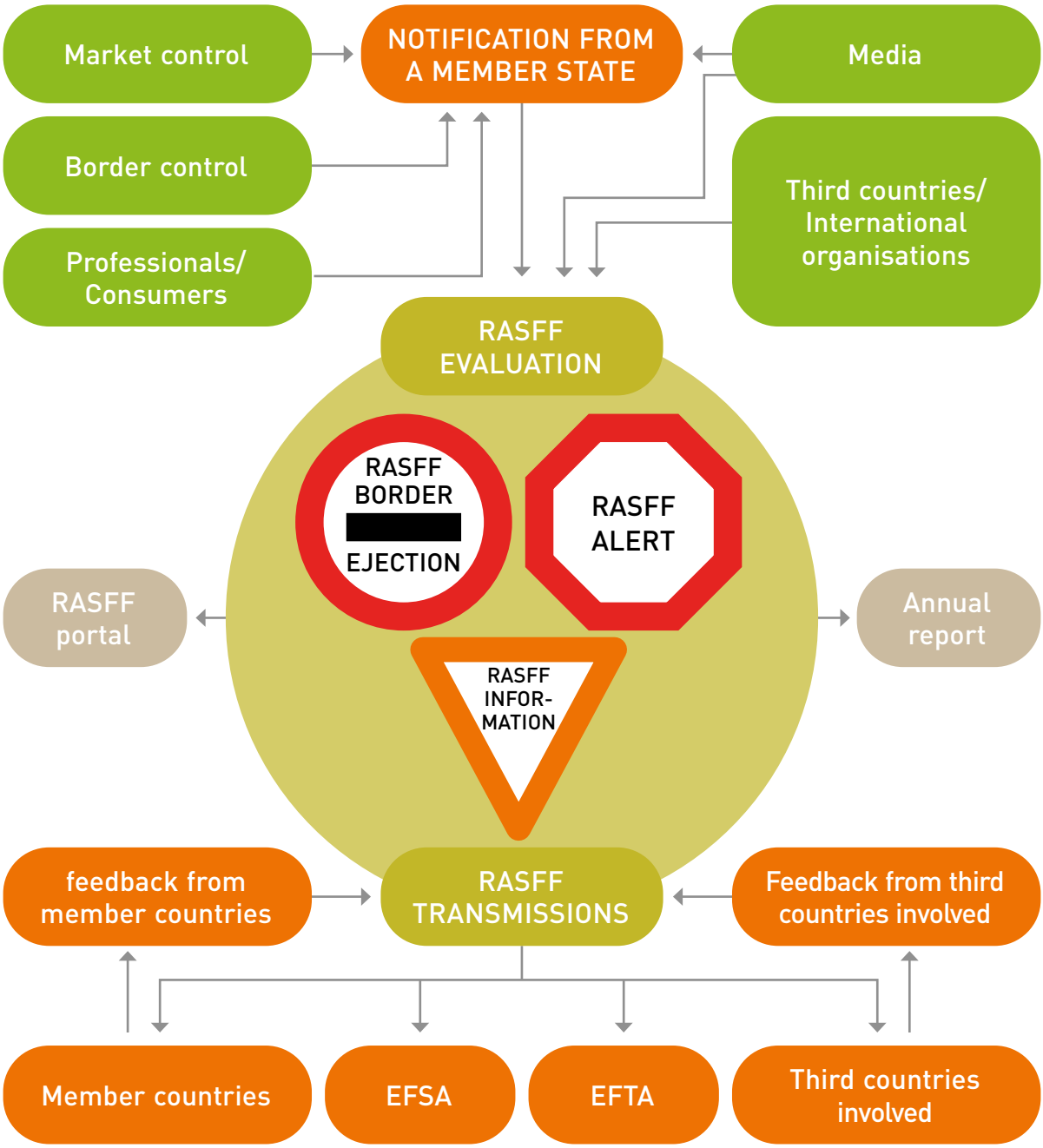
Regulation (EU) No. 16/2011 has added two types of information notification:

- “information notification for follow-up”: this relates to a product that is or may be placed on the market in another member country;
- “information notification for attention”: this relates to a product that is present only in the notifying member country or has not been placed on the market or is no longer on the marke.

c. ‘RASFF BORDER REJECTION’ notification

A border rejection notification covers the detention of a food, feed or material in contact with foodstuffs which has been refused entry into the European Union as it is hazardous for consumer or animal health or for the environment if that concerns animal feed.

Example: RASFF notification representation diagram



7.8.2.3. Databases

To facilitate the management of emergency food safety responses, the competent authority can have a variety of databases at his disposal.

They provide rapid access to the information. Therefore, a database of food-processing businesses per sector is an easy way to find businesses involved and the notification of a product withdrawal or recall can therefore be sent very quickly. The obligation for companies to make themselves known to the competent authority can help constitute this base. This is true of certain food-processing companies that must seek approval for their activity. Fact sheets can be prepared to identify companies.

Scientific and technical information can be grouped in databases accessible to the competent authority and used in developing the risk assessment:

- scientific journals;
- risk assessments available online;
- survey data on food consumption and statistics;
- international data on consumption habits like those in the WHO's GEMS/Food Programme.

7.9. SCENARIO OF A FOOD WITHDRAWAL/RECALL PLAN

7.9.1. The different steps in a food recall plan

Step 1: Compiling information

Step 2: Initial communication with the partners involved (government and industry)

Step 3: Risk evaluation

Step 4: Search for the batch(es) involved and identifying their distribution

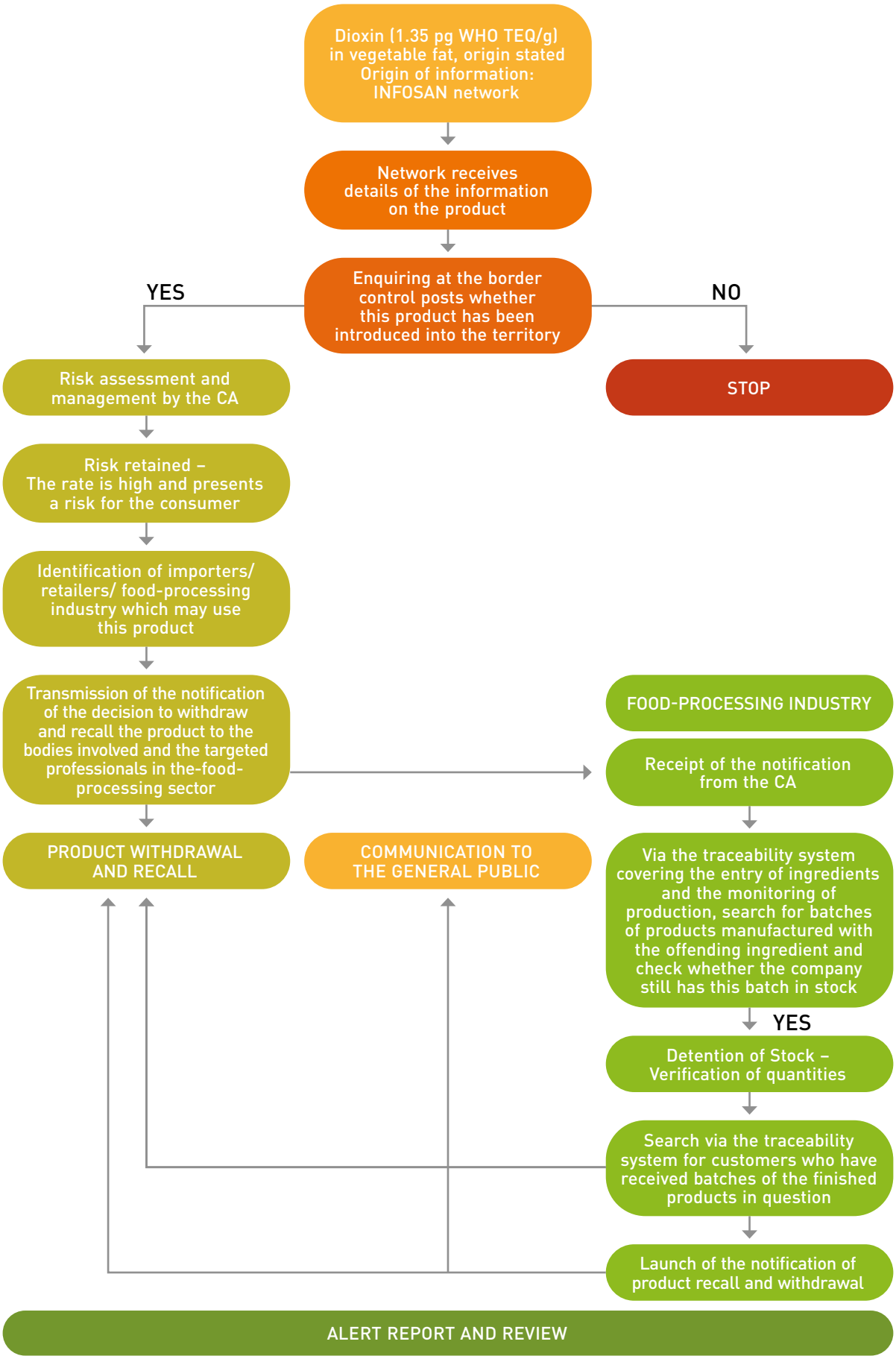
Step 5: Implementation of the recall plan: using communication circuits and appropriate documents

Step 6: Monitoring feedback

Step 7: Monitoring corrective actions

Step 8: General evaluation of the recall

7.9.2. Scenario of an incident with an international information source



7.10. SUBSEQUENT EVALUATION AND IMPROVEMENT ACTIONS

7.10.1. By the competent authority

Before closing the file on the management of the emergency food safety response, when a product has been withdrawn from the market, the competent authority can make sure that all the products from the offending batch have indeed been withdrawn from the market. Documentary control is ideal for this (return slips, receipts, invoices), supplemented if necessary by physical control of products, the company and distribution points. The competent authority can also ask to be present when products are destroyed.

The food business operator must introduce corrective actions to prevent the event from recurring. The competent authority can ask that these actions are communicated to him and also inspect the establishment in question to make sure that the corrective actions have been implemented and produce the anticipated effect.

When an incident is closed, it is often interesting to evaluate how it was managed, to identify the elements that functioned well and those with the potential for improvement so that future incidents are managed better.

The examination may cover the activities carried out under the response to protect public health and on the different means of communication, the regulations, the procedures available to inspectors to prevent the production and distribution of harmful foodstuffs, the capacity of laboratories and inspection services, the quality of their reports and the effectiveness of product withdrawals and recalls.

An analysis of the emergency response management process can lead to recommendations to improve the emergency food safety response plan, namely:

- improving agent training;
- building up laboratory capacities;
- reviewing certain procedures of the emergency response plan, especially adding new contacts;
- supplementing the regulations in force;
- reinforcing the official controls: audits, inspections, sampling programme.

Incident simulations can be scheduled to ensure that the established procedures are effective and to modify them if necessary. These simulations can also be used to train the competent authority's agents and test their efficiency.

7.10.2. By the food business operators

The information obtained during the enquiry into the causes of the incident can reveal processes or practices to be corrected to prevent a recurrence of a similar incident. The professional will have to introduce all the necessary corrective actions and mainly improve his safety control plan:

- reinforcing the evaluation and monitoring of his suppliers;
- improving controls of raw materials;
- reviewing and improving good hygiene practices;
- reinforcing monitoring procedures;
- updating product withdrawal and recall procedures;
- reinforcing the finished product sampling plan, setting up 'discharging' analyses.

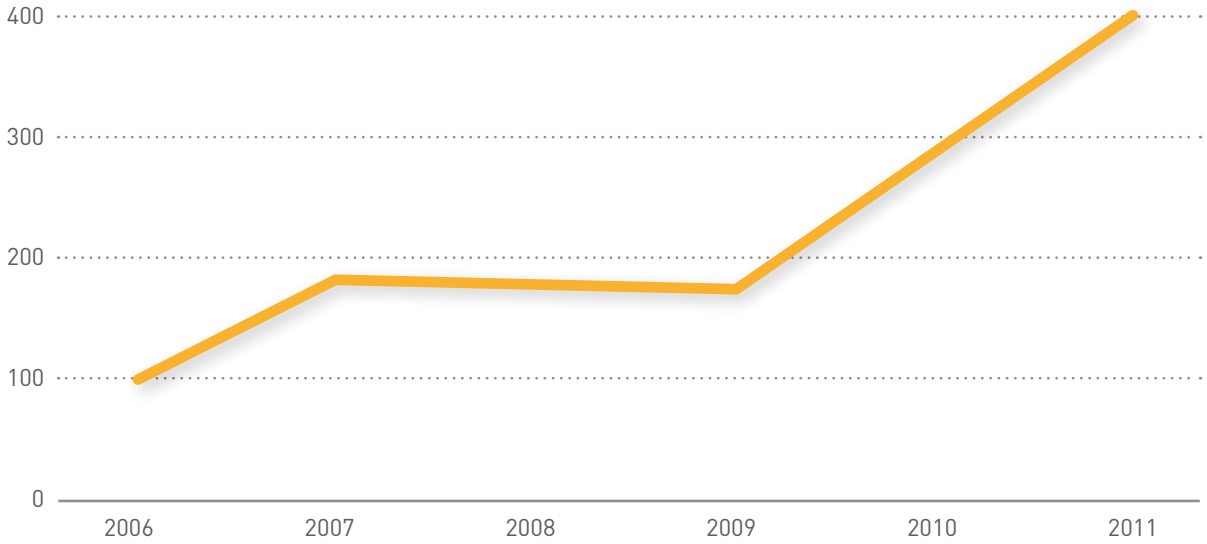
7.11. STATISTICAL STUDIES AND EXPLOITATION OF DATA

The incidents involving an emergency response can be studied statistically by product, hazard or origin. These studies can form sources of information that can be used especially in improving the national emergency response plan. Statistics can be used to monitor the evolution of various notifications and thus anticipate the means to reinforce, supplement or direct certain research and at the same time reinforce laboratory capacity and agent training. The increase in notifications relating to a particular hazard can result in the competent authority legislating on controls and values to be respected for this hazard.

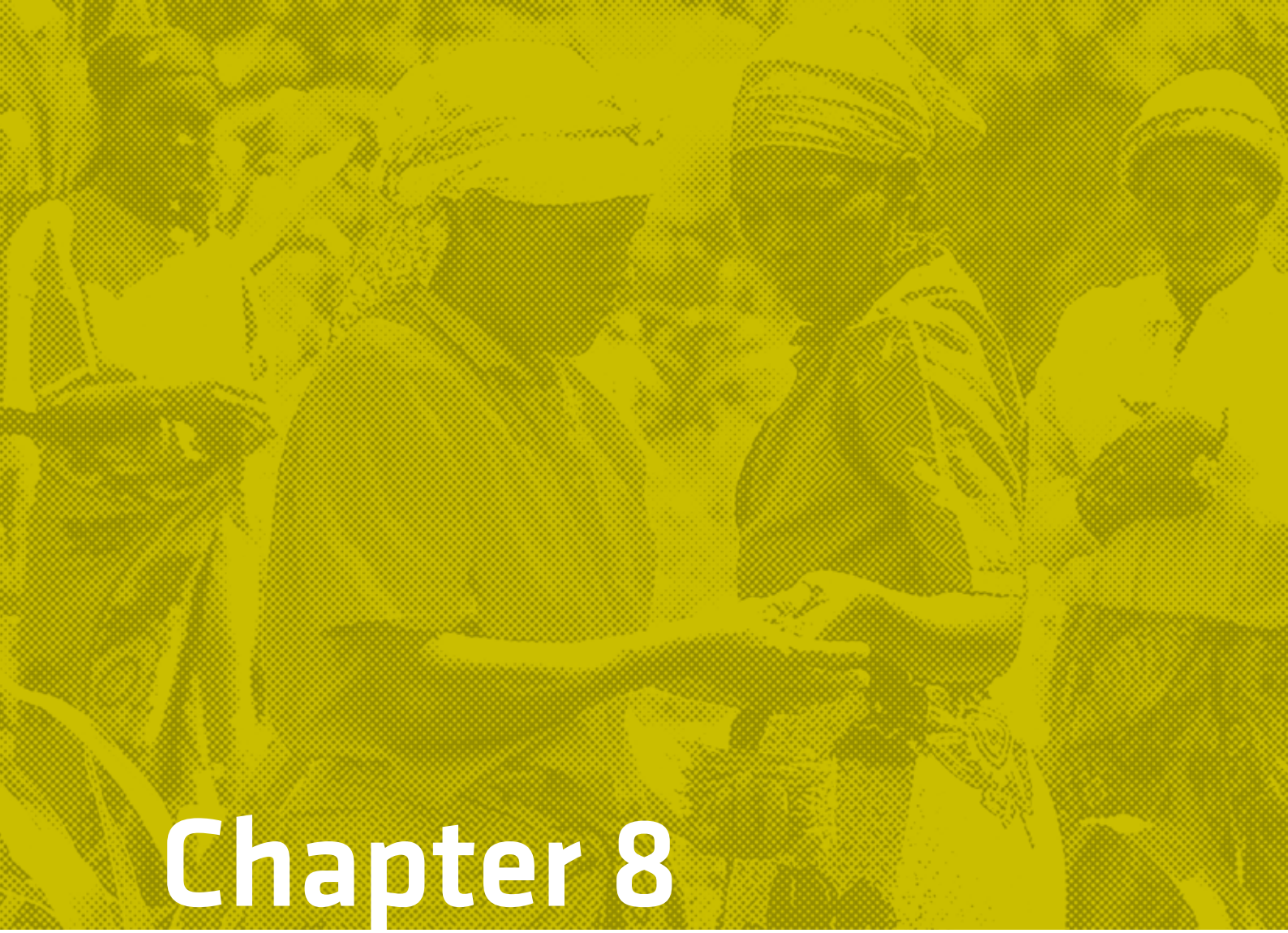
More advanced analyses of statistical data can back up the risks analysis and the evaluation per product of the recurrence of the hazard. These studies can therefore serve as a database for the food-processing professionals when setting up the HACCP approach to evaluate food safety-related hazards, depending on their seriousness in terms of harmful effects on health and the likelihood of them appearing.

The statistical studies can be repeated in reports which are then published. This is the case of the RASFF annual reports. The RASFF 2011 annual report is available on the site: ec.europa.eu/food/food/rapidalert/docs/rasff_annual_report_2011_en.pdf.

Example: Notifications on pesticide residues (extract of RASFF 2011 report)



The published reports are thus a source of information for the general public on the questions of food safety and public health protection. If the reports are not consulted by the consumer himself, they can however be used by consumer associations which then produce publications that are more accessible to the general public.



Chapter 8

Principles for conducting a control, inspection or audit – Code of ethics

8.1. INTRODUCTION

8.1.1. Purpose

The purpose of this chapter is to assemble the control, inspection and audit doctrine to reply to those questions most asked of investigators.

8.1.2. Scope

It covers all controls by the general management or department involved.

8.1.3. Legislative and regulatory texts or other references

This designates the Consumer Code and application texts.

8.1.4. Specific vocabulary

Vocabulary relating to ***quality***.

Vocabulary relating to the ***quality means***: see especially the notion of quality control and corporate control.

Vocabulary relating to ***certification*** and ***accreditation***.

Vocabulary relating to the ***audit***.

8.1.5. Type of controls

This involves all types of research conducted in the context of controls, inspections and audits.

8.1.6. Means and methods

7.1.6.1. Organisation

The body of the chapter is broken down into three parts:

- Legal bases, objectives and scope of the corporate control (points 8.2.1. and ff.).
- Control methodology (points 8.3.1. and ff.).
- Control monitoring (points 8.4.1. and ff.).

7.1.6.2. Sensitive points

It is useful to refer to the points listed below:

- **Corporate controls certified by a system certifying body** (points 8.3.8., 8.3.9., 8.3.10.). See point 8.3.9., especially: the agent must only check the documents pertaining to the control of the regulations involved.
- **Connection between the level 1 and level 2 controls** (point 8.3.14.): it is essential to conduct level 1 controls, in order to be able to apply sound judgment to the self-assessment system implemented by the businesses.

- **Content of diagnoses communicated to the businesses** (point 8.4.1.): the written diagnoses sent to the businesses must only include the list of noted anomalies and shortcomings.
- **Limit of the administrative support in setting up self-assessments**: it is normal to provide support to businesses, but our information action is limited.
- **Choice of means to be implemented by the business** (point 8.4.1.): the means are chosen freely by businesses.

8.2. LEGAL BASES, OBJECTIVES AND CONTROL SCOPE

8.2.1. Obligation of sector operators

Question	The regulations lay down that the person responsible for marketing a product for the first time is required to check that it complies with the stipulations in force. He is required to justify any checks and controls performed. Does this mean that other operators are not required to perform checks?
Answers	• General obligation of conformity Immediately after the market launch, the regulations impose an *obligation of product conformity* to the stipulations in force (*i.e.* all the quality and safety regulations). This is a results-based obligation that involves all stages in the chain (import, manufacture, distribution, transport etc.). • Obligations of those responsible for the first marketing The provisions detailed above define explicitly, also, for those responsible for the first marketing (manufacturers, importers), an *obligation of self-assessment*, *i.e.* the introduction of a set of means for compliance with the obligation of conformity. The professional is responsible for choosing the means. He thus defines, for these operators, an *obligation to provide supporting documentation* to the accredited agents, who are then able to detect any shortcomings in the self-assessment. • Obligations of other operators This arrangement does not, however, exempt the other professionals (simple retail distributors especially) from any obligation. All operators in the chain contribute, each in their own respect, to the *obligation of product conformity*. In addition, these operators have a responsibility for the *obligations arising from their activity* (compliance with foodstuff conservation, product advertising etc.). • Operator responsibility When a noted non-conformity justifies legal action, the *responsibility of the professional is assessed by the courts*, according to the present case and the circumstances, mainly based on his quality and the means he had, given his skills, speciality and the extent of his activities, to prevent the offence. It will therefore be necessary sometimes to target both a simple retail distributor and an importer or a manufacturer.

Answers	• Consequences for the operators Those responsible for the first marketing must introduce a self-assessment system adapted to the obligation of product conformity. On the other hand, the simple retail distributors have no formal obligation to introduce a self-assessment system. But it is in their own legal interest – less risk of being liable for either civil or criminal action – to do everything necessary, in line with their own situation, so that they respond definitely and without wavering to the regulatory requirements. Operators are responsible specifically for choosing their means, under all circumstances.

8.2.2. Production control, corporate control

Question	Why instigate corporate control?
Answer	Controls were exclusively repressive in the past, carried out mainly on finished products at the distribution stage. To make controls more effective before bulk distribution, the notion of *control at source* was mooted, meaning at the production stage. This is what was meant by *production control*. In addition, this type of control only applied to certain business sectors and was essentially seen as preventive. Today, the control at source is applied to all premises where goods are assembled before bulk distribution (import companies, storage warehouses, bulk distribution platforms etc.). The notion of *corporate control* was therefore introduced, which could apply to production, import, distribution, etc. depending on circumstances. A *control methodology* was also introduced (see point 8.3.4.). Corporate control is a tool that can be adapted to the context (control stage, preventive or repressive control) and to the new initiatives being introduced into businesses (quality assurance etc.).

8.2.3. Powers of seizure (quality/safety procedures)

Question	The regulations give agents powers of seizure. Is it appropriate to implement them in a corporate control?
Answer	Yes, if the controls justify it.

8.2.4. Spot check and corporate control, intervention modalities

Question	When can a quality-safety spot check be considered as a corporate control?
Answers	• Definition of a spot check Regardless of the reason for intervening in a business (complaint, survey request, scheduled task): 1. either the inspector restricts himself to the reason for the intervention (sampling, labelling etc.) without having the time to analyse the firm's records, and in that case, it is a *spot check*; 2. or the inspector uses the stipulated corporate control methodology, and in that case, it is a *corporate control.* • Corporate control intervention modalities Corporate control conducted according to the stipulated methodology gives a **global approach** of businesses and enables **monitoring over time.** But a business cannot always be seen in its entirety at the first intervention. Interventions taking several days in a row in businesses can sometimes be somewhat incompatible with the organisational constraints of the department's activity (unlike private audits). Nor are they inevitably more efficient and may be poorly perceived by the businesses. They can therefore be **broken up over time**, provided intervention coherence is maintained: • control designed to **understand the business**, update knowledge or conduct an assessment; • **control of a product sector** or a family of products (vertical approach), designed to assess full or partial compliance with regulatory requirements (composition, hygiene, labelling etc.); • **control by 'module(s)'** (horizontal approach), designed to assess compliance with one (or more) requirement(s) for all the business' products (hygiene, safety, labelling, metrology etc.). Combinations are possible depending on circumstances. The aim is to understand the business in depth within a reasonable timescale (depending on the context, three months, six months, one year or more). This knowledge is updated regularly. These corporate controls are therefore scheduled over time. This coherence over time makes the interventions – each one may only take half a day – stand out from spot checks, which have a more restricted objective.

8.2.5. Initiative control, scheduled survey and corporate control

Question	Should initiative controls conducted within the businesses, mainly as scheduled tasks, be considered as corporate controls?
Answer	Definition Any initiative control using the stipulated control methodology can be considered as a corporate control. Otherwise it is a spot check. *Corporate control included in the scheduled task* This involves surveys of the national activity programme that calls **explicitly** on the corporate control methodology stipulated by the texts. *Initiative corporate control under a scheduled task* This involves controls carried out, according to the corporate control methodology, at the same time as a scheduled task which did not explicitly state the use of this method. These are definitely two sets of actions, as more time is spent (preparation, intervention, particularly when planned under the scheduled task, follow-up).

8.2.6. Number of employees

Question	Is it essential to only include businesses with more than ten employees?
Answer	The quality-safety corporate control theoretically involves all businesses in the sector, regardless of size. In practice, it is neither possible nor rational to control everything, and control priorities therefore have to be set. Choice criteria have been defined for this purpose. Their goal is to determine the risk from the business and therefore the level of confidence that can be allocated to it. The application of this grid will normally mean controlling large businesses carrying out their activity in regulated product sectors. However, a business with less than ten employees can prove to be reliant on the national or international market, or present special risks (some importers, for example) and it should therefore be included for control. Similarly, craft businesses must not be systematically excluded from controls, especially in regions with little industry.

8.2.7. Choice of businesses, criteria

Question	Does the choice of businesses to be controlled only depend on their economic importance or the existence of specific regulations to be applied?
Answer	No. The choice of businesses to be controlled does not largely depend on the abundance of regulations. The general provisions apply, even if there are no specific regulations (product safety, advertising etc.). It is all therefore a question of appraisal. Thus, the control is theoretically not justified in certain businesses. On the other hand, it can become necessary if the business falls under suspicion or an incident is reported. This will involve a corporate control, not a spot check, if the corporate control methodology is used for this intervention (see point 8.3.4.). The example of a spectacle frame manufacturer can illustrate this question. This is a production with no special risk and which is not governed by qualitative regulations that we are called on to apply. Nevertheless, the business could advertise qualitative guarantees, fail to comply with its customer contracts, produce frames unfit for use or arms with a composition that could trigger epidermal reactions, etc.

8.2.8. Role of control agents

Question	What is the exact role of control agents during corporate verifications?
Answer	The investigators carry out a control, in order to ensure the compliance of products with the quality-safety regulations. They are not there to promote a particular quality or to usurp the freedom of choice of businesses or service companies. It is also useful for them to assess the technical and economic difficulties faced by the business, in order to *pinpoint the technical (control of sensitive points) and legal (criminal liability) responsibilities.* They have a *duty of information and explanation concerning the regulations.* They must also urge the businesses to implement relevant, reliable and efficient means to ensure product compliance (identification of regulatory sensitive points, **external guarantees** for their customers, suppliers or other service providers and **internal guarantees**). In addition, they can evoke existing means (HACCP, quality assurance etc.) but **it is not up to them to decide on suitable means.**

8.2.9. Allocation of agents

Question	Must corporate control agents be allocated only to this task?
Answer	According to the instructions, the managers must give themselves the means of exercising this action priority in the department. The 'quality-safety' corporate control by the management is a specialist control that requires the agents performing it to have both the technical skills to understand the product technology and an investigation methodology. These specific qualities are acquired as much from initial and on-going training as through experience and personal efforts.

8.2.10. Role of samplings

Question	Must a corporate control be ended with samplings?
Answer	Sampling is not mandatory, but it remains a preferred method for noting product non-conformity. The knowledge of the business acquired during the level 2 control and the experience of the agents combine to orientate the level 1 control usefully (including samplings, if appropriate). This is used to determine the effectiveness of the means employed by the business in relation to compliance with the quality-safety regulations. Sampling must be used wisely and in sufficient fashion: it should be used when fraud is suspected following the control of the manufacturing process or if it is the only way of making sure that the product is compliant. Remember that sampling is not restricted to finished products only. It can increase an understanding of the quality of raw materials, for example. This is constructive for both the professional who may query the validity of his controls and for the control department in the knowledge of the quality of suppliers' products (networking: information sent to the department at headquarters).

8.2.11. Know-how and knowing how to control

Question	How can agents really get to grips with the skill of professionals and assess their practices?
Answer	The professionals have the know-how. The inspectors must know how to control, based on regulatory knowledge, the application of a control methodology, the gradual knowledge of the professional environment, an external viewpoint on the business and the possibility of comparing them. If everyone sticks to their role, there is no fundamental need to get to grips with the know-how, even if acquiring a minimum of technological knowledge can prove very useful. In this respect, theoretical training, however necessary, cannot supplant personal effort and time spent in the manufacturing premises. The agents will be able to use the **experience acquired** to refer to patterns of life of products or processes seen in another context, in order to identify the regulatory sensitive points and assess the extent to which the business has them under control. For example, the production of dry animal feed and the manufacture of paint are both technologies involving mixing. In both cases, component dosing is a sensitive point that must be grasped clearly to comply with the stated composition. Sharing experiences at regional level and networking are also factors in enhancing skills.

8.2.12. Obligations of distributors

Question	Do distributors have a general obligation of self-assessment?

Answer	No, it depends on their role in the marketing chain.
	But it is to their advantage, in all circumstances, to set one up.
	Distributors operate in the marketing chains, depending on circumstances, as processors, importers or simple retailers.
	They therefore play an essential role in the quality of food and manufactured products offered at the retail stage.
	
	Self-assessments are necessary for distributors:
	• First and foremost, because it can be an obligation defined expressly by the regulations. The distributors are involved:
	  ◦ as *responsible for the first product marketing*, when they are processors or importers;
	  ◦ as *holders of goods*, for certain product-related conditions: for example, the obligation to withdraw the products beyond their use-by date, obligation to sort and withdraw from sale preserves showing outward signs of alteration, ban of all untrue or misleading advertising;
	  ◦ lastly, they will be concerned for the hygiene of foodstuffs, like *all operators*, in accordance with the order regulating the hygiene of foodstuffs delivered directly to the consumer, transposing Directive 93/43/EEC, which mainly makes it mandatory to introduce self-assessment procedures inspired by the HACCP system (hazard analysis and critical control points).
	• Secondly, because nothing is free of all liability within a sector. Even when distributors are not expressly governed by any rule, they participate in the *general obligation of product conformity* with the rules of quality and safety. Case law assesses the liability of each operator based on his professional quality and the means he possesses to prevent breaches of regulatory obligations.
	• Lastly, because beyond that, the very brand image of the distributor can be called into question.

8.3. CONTROL METHODOLOGY

8.3.1. Unannounced control or not

Question	During a corporate control, should the professional be warned in advance of our visit to his business or not? Should an appointment be made with him?
Answer	The general principle is to arrive without an appointment. Nevertheless, it can prove useful to make an appointment to be able to meet the appropriate contacts or others than those normally encountered during controls, or to compile certain information, for example, during a first visit, an information visit or certain follow-up visits such as an assessment meeting. The investigator will inform his contacts during his first visit that subsequent visits normally take place unannounced.

8.3.2. Intervention purpose

Question	Should the professional be told the purpose of the intervention right from the start?
Answer	It is better to give a general overview of the intervention goal, excluding nothing, rather than its purpose. State only that you are going to carry out a corporate control. If the professional persists, remind him of the objectives of the corporate control.

8.3.3. Control or audit

Question	Is corporate control comparable to an audit?
Answer	No. An **audit** assesses the gap between what actually takes place and a pre-set standard (specifications, good practices guide, quality assurance system etc.) chosen by the business. It is a voluntary approach. A consensual relationship also exists between the business audited and the auditor. Depending on circumstances, the audit can be external or internal, and focus on a product, a process, a procedure or the corporate quality system. The **control** is mandatory for the business. It is coercive: repression is not excluded, although it includes preventive aspects. The standard is also mandatory: it is public; it involves the **quality-safety regulations**.

8.3.4. Corporate control methodology

Question	What is understood by audit methodology in a corporate control?
Answer	Corporate control is not an audit, but the stipulated methodology takes its inspiration from quality systems audits: 1. Preparatory phase starting from the analysis of the firm's records and culminating in the preparation of an intervention framework. 2. The intervention, which identifies the regulatory sensitive points, and level 2 and level 1 controls. 3. Follow-up including mainly exploiting the observations and analysing the means used by the business, determining the level of confidence that can be allocated to the business and the business records service The stipulated control methodology involves three phases in succession: • Preparatory phase This includes an analysis of the firm's records (knowledge of the business, its products, technological elements, regulatory or normative standards etc.) and leads to the preparation of an intervention framework (choice of contacts, products to be controlled, workshops to visit etc.). • Intervention phase It has three stages: • an opening meeting mainly intended to supplement or update the information on the business. This stage can be delayed if appropriate (suspicion of fraud etc.); • the intervention itself intended to identify the regulatory sensitive points in the life pattern of the product, to make an inventory of means used by the business to control these sensitive points, to assess their relevance and their reliability (level 2 controls) and to check product conformity with level 1 controls (taking samples, for example); • a closing meeting intended mainly to review with the business the observations made and the planned follow-up, if there are any anomalies. • Follow-up This phase *exploits the observations* made and *analyses the means* used by the business (products, processes and organisation). It *draws conclusions on the effectiveness* of these means in relation to the quality-safety regulations and *deduces the level of confidence* to be granted to the business. It also *orientates the subsequent controls*, mainly by determining the intervention intervals and the intensity of level 1 controls to be performed. Possible legal action may also be envisaged during this phase, if appropriate. Finally it leads to serving the business records. Corporate control conducted according to this methodology gives a global approach of businesses and enables monitoring over time (see point 8.2.6.).

8.3.5. Notions of self-assessment

Question	What should be considered as self-assessment, and how is its value measured?
Answer	'Self-assessment' is understood to mean all the means used by the business to satisfy the obligation of conformity imposed on all operators in the sector (see point 8.2.1.). The extent of this obligation varies according to the role of the operator in product conformity: • anyone responsible for the initial launch onto the market has an explicit obligation of self-assessment and is required to justify it to the accredited agents; • the other operators in the sector, particularly the distributors, work in their own individual activity to comply with the obligation of conformity (see point 8.2.1.). This obligation means, for all professionals, taking out advance guarantees and performing controls themselves. The control will involve assessing the relevance and reliability of the means used by the business with respect to the quality-safety regulations (level 2 controls) and checking their effectiveness (level 1 controls).

8.3.6. Businesses with no self-assessment

Question	In corporate control, is there a provision for carrying out a level 2 control (self-assessment control) before performing our so-called level 1 checks. What is the procedure where a business has no self-assessment?
Answer	In most cases, there are always the beginnings of a self-assessment, at least (written formula or operating instructions and verification of their implementation, for example) and therefore a level 2 control can be performed. Otherwise, the level 2 control is limited to noting the lack of self-assessment, a reminder of the legal obligations and urging that it is set up by underlining its advantage for the quality control. The interested party is also told that the lack of self-assessment can be a constituent part of an intentional element in the event of a noted offence. The intensity of the level 1 control in corporate control is proportional to the level of confidence in the business. Where there is no self-assessment, and for an activity that is difficult to control in relation to the quality-safety regulations, the risk of non-conformity justifies a major level 1 control.

8.3.7. Businesses with a quality approach

Question	What is the point of talking about corporate certification, quality systems, the HACCP system, FMECA, quality audit etc. to address the corporate control?
Answer	• Understand the means used by the businesses The inspectors cannot be unaware of the private approaches used by the businesses when performing controls. They must have heard of and be familiar with the most common approach principles (HACCP, FMECA, quality assurance etc.) to be in a position to discuss them with the professional and to assess their use. In-house training can see to this. But this may not be sufficient, given the large number of potential approaches. Faced with an unfamiliar approach, the inspector must therefore try to understand its principle and, if necessary, liaise with the administration. • Be able to assess these means The investigator cannot trust these approaches at face value. He must check: • during the level 2 control, the relevance and reliability of the means used by the business in relation to regulatory requirements. The means used by the business can be analysed more critically and the level 1 controls can be directed more effectively with a good understanding of quality approaches. • through the level 1 controls, the regulatory conformity of products leaving the business and therefore the effectiveness of the approach (good application of means without deviation). Of course, the number and frequency of level 1 controls depends on the level of confidence set for the business. • Be able to transpose them in our controls The fundamental difference between the two approaches is the type of standard: 1. The business reasons in terms of the standard it has chosen, often in agreement with its customers. 2. The control service only has the regulations as its standard and must ensure that the firm's standard incorporates the regulatory aspect.

8.3.8. Establishments preparing feed or food of animal origin

Question	What attitude should be taken when controlling establishments preparing feed or food of animal origin?
Answer	As in any food-processing business, the control investigates a variety of areas: food and feed composition and labelling, quality, aspects relating to safety (additives, processing aids, contact materials, cleaning and disinfecting products etc.) and hygiene (microbial contamination of foods, preservation, shelf life etc.) Nevertheless, if serious shortfalls in hygiene (e.g. holding of spoiled or toxic foodstuffs, disguising the use-by date etc.) are noted when controlling other regulatory aspects of the quality, including those relating to safety, any action must be according to the regulatory powers. Any other hygiene anomalies noted must be pointed out to the professional during the control.

8.3.9. Industrial product businesses

Question	Could it not be thought that the corporate control methodology is less suited to industrial and manufactured products?
Answer	It follows different guidelines depending on the type of product, mainly based on regulatory and normative standards, the technologies used and the sensitive points generated. Thus, regardless of the type of product (food-processing or industrial products), there are always three stipulated stages: • preparatory phase with analysis of the firm's records and preparation of the intervention phase; • intervention, which identifies the regulatory sensitive points, and level 2 and level 1 controls; • follow-up and service of the corporate records. At the production stage (for all products), the control covers both the guarantees taken upstream by the business (qualification of suppliers, finished product and raw material specifications etc.), the internal guarantees and in particular the controls at reception and during the process. At the distribution or import stage, the control of industrial products mainly covers the upstream guarantees (qualification of the supplier or importer, specifications, fitness for use etc.), the reception control (visual conformity) and the after-sales service. The control of evolving food-processing products also covers the elements controlled by the distributor (maintaining the cold chain, for example).

8.3.10. Non-regulated sectors (see point 8.2.9.)

Question	How do you intervene in a business in a given sector where there are no particular regulations or only 'private standards'?
Answer	Provided no special problem has been reported, the control in this type of sector is not priority. However, in principle these firms should not be distanced from the corporate control (see point 8.2.9.). The control is necessary to understand the business, identify, if appropriate, the sensitive points likely to be of interest to the control (loyalty, safety), look at the means used and assess them.

8.3.11. Contractual requirements extending beyond the regulations

Question	What can be done when faced with a 'crunchy toast' type advertisement?
Answer	This is a specific feature that is neither banned nor regulated. Theoretically, the investigator has no need to worry about it, except if this characteristic is advertised to the consumers, in which case he should check compliance with the regulations. But under any circumstances where an innovative characteristic is underlined by the business, questions must be asked about the means used to obtain it (additive etc.).

8.3.12. Value of supporting documents (see also points 8.2.1. and 8.2.5.)

Question	What attitude should be taken towards someone responsible for the first launch onto the domestic market of foreign food or industrial products, who vouches for regulatory conformity by producing self-certification-type supporting documents from his supplier?
Answer	These products must carry markings that vouch for their conformity with the essential requirements through compliance with a conformity assessment procedure that varies according to the sector and the product in question (self-certification, certification by a third-party body, quality assurance etc.). When the self-certification procedure alone is required, the foreign supplier must provide documentary evidence of this self-certification to the person responsible for introducing it into the territory. The national operator cannot hide behind this document to claim exemption from his liability. He must at least assess its validity. Thus, for example, he must not be content with inaccurate or partial certificates that do not cover all of the marketed products. He must carry out additional controls, when he considers – or should have considered as a professional – based on documents in his possession, that the elements provided by the manufacturer are insufficient to ensure the conformity of goods. Similarly, when he receives written notification of non-conformity from the control services, the operator must reinforce his controls. For other products with no marking requirement, the self-certification by a foreign supplier in no way exempts the national operator from his obligation to check the product.

8.3.13. Sampling

Question	Do the provisions planned for sampling have to be respected?
Answer	These provisions remain today the reference to be recommended.

8.3.14. Level 2 controls and level 1 controls

Question	How are the level 2 and level 1 controls connected?
Answer	The first goal of an official control service is to **make sure that the products or services comply with the regulations.** As a preventive measure, he urges all operators to implement self-assessments that take account of regulatory requirements. At the same time, a two-level control methodology has been developed that allows him to consider the quality of self-assessments implemented by the professionals more effectively. This methodology is based firstly, on the assessment of the means used by the professionals (**level 2 controls**) and secondly, the direct control of the finished products and their environment (**level 1 controls**). • Level 2 controls Agents can use these controls to assess the relevance and reliability of the firm's self-assessment system. These controls also have the advantage of directing the level 1 controls more effectively. The analysis of the results can lead to suspected shortfalls and has sometimes revealed the lack of a temperature control when products are received into the stores, for example, which could prove detrimental to maintaining correct temperatures in the chain. **But it is impossible to go further with the diagnosis.** • Level 1 controls **Level 2 controls are always accompanied by level 1 controls** They involve a direct control of products and their environment on site (production line etc.). Only this type of control (for example, product temperature check, sampling) and an analysis of the results can provide control agents with a basis for judging whether or not products are indeed compliant and therefore whether the self-assessment system introduced by the businesses to deal with the regulatory requirements actually works. The detection of regulatory shortfalls (for example, noting non-compliant product temperature in the stores) would reveal either a failure to take regulatory requirements into account in the self-assessment system or a self-assessment system not up to the task of managing them, or a deviation in the system.

8.4. CONTROL MONITORING

8.4.1. Diagnoses sent to the businesses

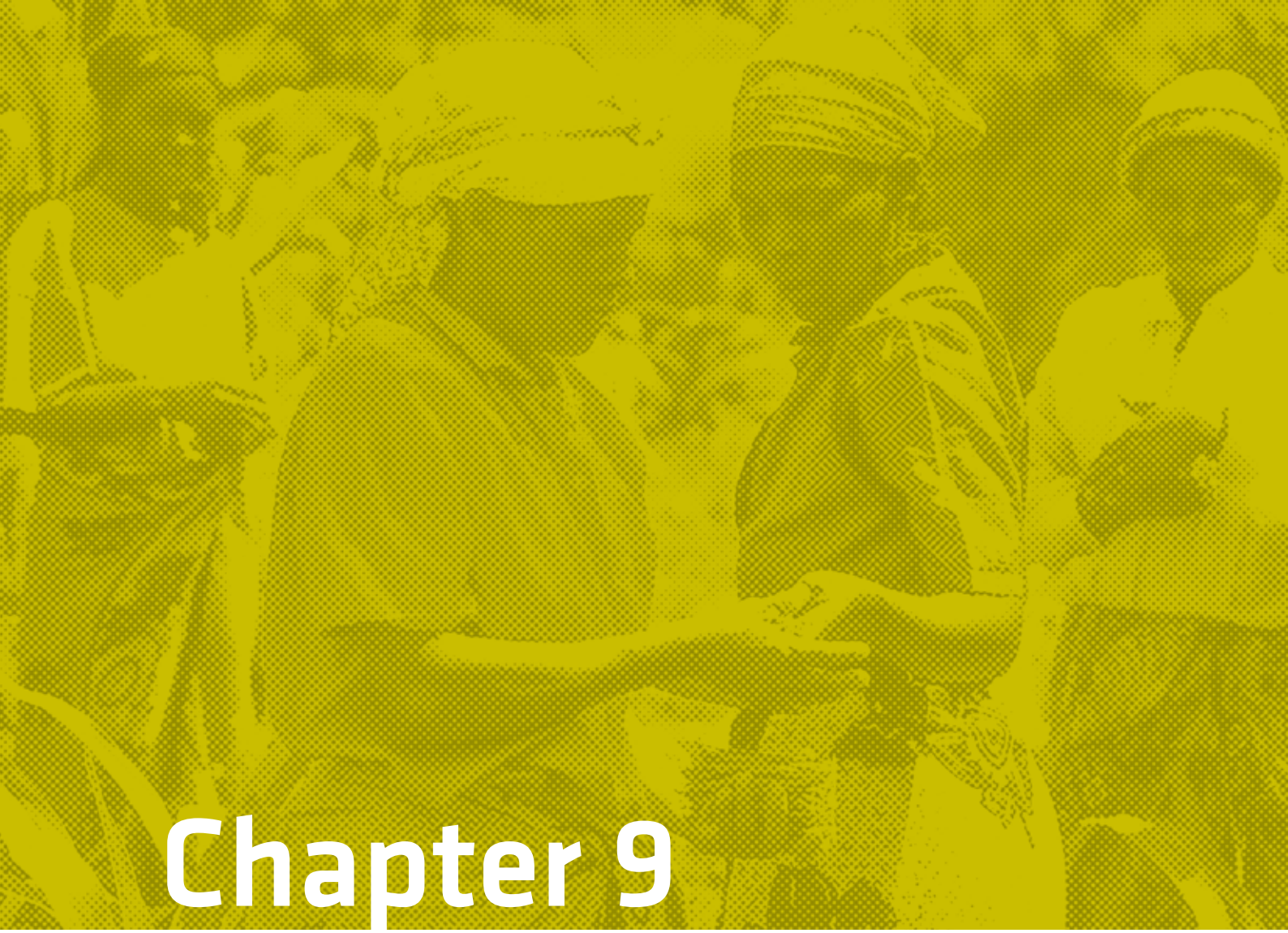
Question	What can firms be told at the end of a corporate control?
Answer	It is advisable to restrict the communication of results to listing breaches of the regulations (for example, detected additive or non-conforming temperature of cold units) and the anomalies or risks of shortfalls (for example, risk of a break in the cold chain when products are received). Any advice that may have been given during the control must not be communicated in writing. It is then up to the business to propose corrective actions to remedy the situation. The control service must not usurp the freedom of choice of the businesses or the consultancy firms.

8.5. STARTING THE SURVEY: QUALITY CONTROL

8.5.1. Reminder of a few basic principles

Question	What is the purpose of quality control?
Answer	The purpose of quality control is to protect the consumer by monitoring product quality and safety from manufacture and/or importing to marketing. The agents control PRODUCTS, not individuals or corporate bodies.
Question	Who has the power to trigger a survey of product quality?
Answer	The Government, the governing Minister, his departments through scheduling or investigation, the jurisdictions, the civil (consumers) or merchant (businesses) sphere.
Question	Is a control legal, if based on an anonymous tip-off?
Answer	Yes, as long as the control complies with the right of defence and the procedures.
Question	Can an investigator be required to know the extent of a quality control?
Answer	No, but when preparing his intervention, the investigator must make sure that he has all the information required for the control to proceed smoothly.
Question	Duration of a quality control
Answer	This can vary. Started during normal working hours, it can continue into the night.
Question	Can the agents conduct controls at night?
Answer	Yes, if the premises are open to the public or activities relating to the products are in progress.

Question	Which operations are carried out by agents from the Ministry?
Answer	• The agents conduct seven operations in a business: • The basic control • Consulting documents • Taking samples • Seizing business-related documents • Impounding goods • Seizing goods • Final withdrawal



Chapter 9

Control activity report

9.1. INTRODUCTION

The control activities include four parts:

- results of a control,
- setting up a verification and a survey in the control unit,
- the control sequence,
- the follow-up planned for the control.

During the survey, verification or control, the investigator(s) will be the sole judge of his actions and decisions, naturally in compliance with the texts and regulations he is responsible for enforcing.

Once he has terminated his control, his firm conviction will dictate his decision on the follow-up required.

No account should be taken of comments by intervening parties who have not taken part in the verification, as only the opinion of the person present on day D at time T during the control counts.

This situation implies that his survey report must reflect faithfully the reality noted, and that it must be precise, impartial and concise, and also that anyone reading it must be able to understand the situation encountered and the reason for the decisions taken.

The entire significance of the control report is thus justified.

9.2. SETTING-UP A SURVEY

9.2.1. Reminder of a few basic principles

Question	What is the purpose of quality control?
Answer	The purpose of quality control is to protect the consumer by monitoring product quality and safety from its manufacture and/or importing to its marketing. The inspectors control PRODUCTS, not individuals or corporate bodies.
Question	**Who has the power to trigger a survey of product quality?**
Answer	The Government, the competent Minister, his departments through scheduling or investigation, the jurisdictions, the civil (consumers) or merchant (businesses) sphere.
Question	**Is a control legal, if based on an anonymous tip-off?**
Answer	Yes, as long as the control complies with the right of defence and the procedures.
Question	**Can an investigator be required to know the extent of a quality control?**
Answer	No, but when preparing his intervention, the investigator must make sure that he has all the information required for the control to proceed smoothly.

Question	Which premises are the agents allowed to enter?
Answer	The agents can enter commercial or production premises including means of transport. More generally any location where trading takes place, except residential premises.
Question	**What is the duration of a quality control?**
Answer	This can vary. Started during normal working hours, it can continue into the night.
Question	**Can the agents conduct controls at night?**
Answer	Yes, if the premises are open to the public or activities relating to the products are in progress.
Question	**Which operations are carried out by the inspecting agents?**
Answer	The agents conduct seven operations in a business: • the basic control, • consulting documents, • taking samples, • seizing business-related documents, • impounding goods, • seizing goods, • final withdrawal, if appropriate.
Question	**Are there specific procedures for the import of goods?**
Answer	Provided there are no trade agreements with one or more third countries, for imported goods, an entry regime is set up for products on a specific list that is regularly updated. Checks are made by agents at entry posts for goods coming into the national territory. There can be three types of control: • Documentary control that involves checking the reality of goods through the accompanying documents submitted by the importer (bill of lading, pro-forma invoice, certificate of conformity, original packing list, declaration of origin etc.). • Visual inspection: the agent has the container opened and checks product conformity, in particular the essential inclusion of information in Arabic (importer details, country of origin) and, for some industrial products, the user manual translated into the language of the country. The agent has to go inside the container to examine the load: • either he can easily achieve this, given the space taken up by the goods; • or, in the case of a completely full container, he asks the employees of cargo-handling companies to create a 'corridor' so that he can reach the end opposite the opening. For the so-called hazardous goods like ærosols, and in the absence of secure premises in the inspection areas, the examination takes place on the vessel in the presence of an officer. • The analytical control which allows the agent to make sure after sampling and analyse the harmlessness and conformity of the goods.

9.3. THE SURVEY: PREPARATION – SEQUENCE – INCIDENTS

Prior to any survey, remember that all investigators represent the State and the Public Authorities in the field.

This situation gives them **rights:** right of inspection, to communicate documents, to take samples etc.

But also **obligations:** politeness, respect for other people, impeccable turnout and above all an image of representing the State etc.

The oath taken by officials confirms this commitment by making them accountable.

9.3.1. Preparing the survey

Question	How is a survey file created?
Answer	Following a complaint, concerted action at any administrative level whatsoever, personal initiative by one or more agents, a situation encountered during unscheduled controls etc. This file is normally opened by the head of the control unit and submitted by name to the investigator.
Question	Must there be a survey file for each control?
Answer	It is absolutely essential for the traceability of interventions in the businesses and to inform the hierarchy; a survey file can be drawn up at a later date, following a day of controls, if it was not scheduled.

Question	What should a survey file contain?
Answer	• Initially the complaint or action sheet drawn up by the administration or the control service. • The records of the offending business (which will be put back in their initial place once the survey has been completed with the elements gathered during this intervention). • The most complete regulations possible of the professional sector. • Any other element known to the investigators such as press articles, advertising etc.
Question	**Should you study a survey file before going to the firm**
Answer	It is absolutely essential, as you must understand all the ins and outs of this project (regulations, business etc.). On the other hand, it is clear that knowledge of the regulations is enough under scheduled intensive controls such as the control of restaurants or the control of price displays, for example.

9.3.2. Survey sequence

Question	Should the reasons for the control be presented and announced?
Answer	This is mandatory. You must state your function and present your official identification; each official taking part in the verification process is obliged to execute this process. The professional must know the reasons for the control, even succinctly if, for the needs of the survey, you do not wish to reveal all the reasons for the intervention.
Question	**Does the absence of the legally-responsible person mean that the verification cannot be performed?**
Answer	No, if the business is operating in his absence, he is assumed to have made the necessary arrangements to compensate for this. However, it is advisable to request his presence, if possible, to obtain documents that he perhaps has not passed on to his stand-in. If he is unable to attend, the control must go on, and the missing elements and documents required by the survey should be requested in writing.
Question	**Should you restrict yourself to the regulatory domain covered by the verification and not take into account economic breaches noted in the business?**
Answer	The survey, the purpose of the visit, should take priority, but it is the duty of any investigator to list the anomalies and breaches noted elsewhere in the business visited. The officials would otherwise be liable for any shortcomings in their duties and obligations, above all if consumer health and safety is threatened.

Question	Can a survey be broken down over several occasions?
Answer	Only where there is a physical or administrative impossibility. It is always important to intervene under the same conditions; delaying the verification by one or more days distorts the conditions of the visit, and essential proof or information may well disappear, all the more so that all controls must be unscheduled whenever possible.

9.3.3. Incidents

Question	Can a professional refuse to accept a control?
Answer	There are texts in every country that reinforce the protection of investigating agents. They can, frequently, request support from law enforcement officers to help them continue with their mission.
Question	**What attitude should you take if the professional persists in trying to disturb the investigator during the survey?**
Answer	The survey must always be directed by the official. Should the professional try to distract him from his work, it is both important and necessary for the investigator to get the initiative back using simple phrases such as “May I remind you, Sir (or Madam), that I am here following a complaint from one of your customers and I should be grateful if you would only give me elements relating to this matter” or “Sir (or Madam), would you mind only answering the questions I am asking you?”.
Question	**What must you do if the investigators are assaulted?**
Answer	You must leave the place of the control as quickly as possible and go to the Management offices to advise the hierarchy, who will decide on what action is to be taken in this matter. The physical integrity of officials must always be protected.
Question	**Can a professional refuse to hand documents over to the investigators?**
Answer	No, in principle, the documents requested must be handed over to the officials. Failure to hand them over is assimilated with obstructing duties.

9.4. RESULTS OF THE CONTROLS

Question	What is the definition of the role of an investigating agent?
Answer	The basic mission of an investigating agent, be he assigned to controlling the domestic market or in a border control post, is to note and list FACTS (for example, the lack of legal notices on a product in the language of the country) or after analysis or not, the conformity or non-conformity of a PRODUCT with a regulatory text or a national or international standard.
Question	**How can these observations be followed up?**
Answer	• Either by the administration, for breaches that have no effect on consumer health or safety, which can be in the form of a formal notice (see § Possible follow-up to a control), warning, reminder of regulations etc. • Or if the offence is characterised by establishing a contentious act. The various follow-up options will be examined in point 5 “Follow-up to the controls”.
Question	**What is the legal value of observations made by an official during his assignment?**
Answer	The reports written by the investigating agents are believed until proof of the contrary; it is therefore easy to dispute them. It is possible that some legislations qualify the reports “believed until proven otherwise”; in this very special case, the statements by the investigator provide weight of evidence and it is very difficult for the offender to demonstrate the contrary. It is important to make clear that this notion tends to disappear from texts in order to provide for remedies for the defending party.
Question	**What must a control report include?**
Answer	The control report must normally include the following mandatory information: • place and date of the control, • the facts noted, • if appropriate, any other fact likely to be brought to the attention of the hierarchical or judicial authority (insults, assaults, control conditions, external intervening parties, etc.), • the offences and their related sanctions, • the identity and quality of the agents, • the identity, relationship, activity and address of the intervening party controlled, • the signature of the investigator. There is no specific template for writing a control report. Some administrations can provide a formal framework for writing reports, but only the facts indicated, reported and recorded by the investigator count.

Question	What must a contentious act include, *i.e.* an official report?
Answer	An official report is a legal act which refers to an observation made by a commissioned and accredited agent. This act takes the form of a legal syllogism which will include: • ***The foreword*** As stipulated by the law or local texts, it must state: • the full identity of the agent: name, first name, rank; • that he introduced himself to the contact stating his identity and that he showed him his official identification (never leave this document with the intervening party); • that the agent is authorised to carry out controls (*N.B.*: All agents who have taken part in the control must be mentioned in the contentious act with the same information as stated above). It states the place, date and time of the start of the intervention and repeats the identity of the intervening party, with his relationship, his status in the business, the number and title of the Trade Register, the tax identification number, the trading name, which may be different from the company name listed in the Trade Register, the precise activity of the establishment and its place in the production/import-distribution chain. If the control takes place during transport, this must of course be noted in the foreword. • ***The observations*** The agent relates the facts that he has noted and that he will describe in detail. He will be precise and perfectly clear, so as to leave no room for possible interpretation. When the investigations took place after legal opening hours, the agent will note that the establishment was open to the public or that an activity under any form whatsoever was taking place there. The agent must not record any personal impressions, even elliptically. The report must be objective, neutral and cold (it is a photograph of a fact at a given moment). The agent will attach all documents backing up his report (if documents have been seized, he will write a separate document seizure report). To persuade magistrates (prosecution or bench), the agent may illustrate the contentious act with photographs that he was able to take during his investigations, particularly in terms of hygiene. • ***Pronouncement of the law*** With respect to the observations made, the agent will list the legislative or regulatory tests breached by the intervening party. Even if the jurisdiction can always re-qualify an offence, the agent will endeavour here also to be as precise as possible by quoting the bill of indictment. If he has any doubts over the text to be applied, he may of course ask advice from the other investigating agents, his hierarchy or the disputes bureau before finally writing the report (a contentious act cannot be altered once it has been finalised).

Answer

- ***Act of accusation***

This is the part of legal syllogism that incriminates an offender during a survey.

The agent will state that the intervening party is rendered guilty of an offence against a regulatory or legislative text.

- ***Position of the agent as to legal proceedings***

The agent will indicate that for the type of offence noted, the file should either merit a transactional fine or legal proceedings *de plano*.

- ***Closure of the contentious act***

The agent will indicate that the offender has been advised of the date and time of the writing of the report, whether or not he has responded to this summons.

The officer reporting the offence will note the observations of the intervening party or take a copy of his written statements (a short delay could nevertheless be granted to him to present his defence).

The agent will close the act by indicating the place, date and time of writing. Mention will be made of the refusal by the offender to sign the report.

Lastly, he will carefully count the words that are crossed out or invalid and will draw a line through spaces left blank to cancel them.

- ***Special statements of offence***

This involves the case of statements of offence recorded when the following take place:

- insults,
- threats or attempted threats (death threats with or without an instrument, involvement of the agent's family, etc.),
- obstructing duties with or without violence.

As was the case for the acts governed by observations, the special statements of offence shall be written extremely carefully. They will relate scrupulously all the details of the incident, so that justice may take its course with all speed.

REMINDER: contentious acts in both form and content are scrutinised by the courts and also by lawyers, who will search out the least flaw to discredit the action of agents by invoking procedural irregularities, fundamental errors or flaws that ultimately bring the contentious act down before the court.

The agents will be required to demonstrate the utmost rigour in accomplishing their assignment.

9.5. POSSIBLE FOLLOW-UP TO THE CONTROLS

9.5.1. The classification

There is no follow-up to the control if no anomaly has been noted.

9.5.2. Administrative follow-up

9.5.2.1. Notification of regulatory information

For minor breaches or for general information of professionals, a notification of regulatory information is sent to the professional. In this case, no reference is made to the breaches noted.

9.5.2.2. Written warning

A warning is sent to the professional for minor breaches. In this, reference is made to the breaches noted.

9.5.2.3. Reminder of regulation

When more substantial regularities have been noted, but no litigation is required, a letter is written setting out the facts noted, the regulatory base and the associated offences. The restaurant owner is asked to acknowledge receipt of this letter within two weeks, indicating the corrective actions he wishes to apply. Information is given as to the possibility of a new control.

These corrective actions can be required when the establishment has been seen to represent or is likely to represent a threat to public health due to a breach of regulations. These regulations can cover the establishments and also the products.

In any case, this must be in writing, referring in all circumstances to the breaches to regulatory provisions. Its aim is to advise the professional as comprehensively as possible on the type of anomaly and how this constitutes a failure to observe the regulatory stipulations, especially when these stipulations are expressed as hygiene objectives.

These requests cannot include advice or solutions. It is up to the professionals to choose the relevant means, except when the regulations have set an obligation of means.

9.5.3. Criminal prosecution

9.5.3.1. Report

When major anomalies have been detected, a report is written levelling charges against the professional, and is sent to the Public Prosecutor.

The report is the legal act whereby the verifying agent reports the facts he has noted, in the strict order in which they took place and describing the premises faithfully.

9.5.3.2. Administrative policing measures

When an establishment's operating conditions are such that the physical elements (premises, equipment and foodstuffs) are liable to be a hazard for public health or consumer safety, all corrective measures can be ordered:

- injunction to carry out work and cleaning or disinfecting operations;
- injunction to comply with the basic food safety provisions (compliance with the cold chain, quality of the ingredients used etc.);
- if appropriate, injunction to reinforce the self-assessments and staff training.

9.5.3.3. Impounding

This involves suspending the marketing of a product recognised as non-compliant by direct observation.

The impounding is lifted once the product is noted as compliant.

The product is seized if there is no possibility of making it compliant.

9.5.3.4. Temporary withdrawal

This involves suspending the marketing of a product that is suspected to be non-compliant whilst awaiting the results of analyses or additional verifications.

If the verifications are not made within seven working days or if they do not confirm that the product is non-compliant, the temporary withdrawal is lifted.

The product is seized and the jurisdiction is so advised if the product is proven to be non-compliant.

9.5.3.5. Seizure

This procedure involves the products impounded or temporarily withdrawn that have not been made compliant.

The seizure gives rise to a report and the incriminated products are placed under seal and in the custody of the intervening party involved.

9.5.3.6. Definitive withdrawal

Operated by investigating agents without prior authorisation from the competent judicial authority in the following cases:

- products recognised as falsified, spoiled, toxic or expired,
- products recognised as unfit for consumption,
- products held without legitimate reason and liable to be used for falsification purposes,
- counterfeit products,
- objects or apparatus likely to be used for producing falsifications.

Destruction costs are payable by the intervening party and the jurisdiction is advised.

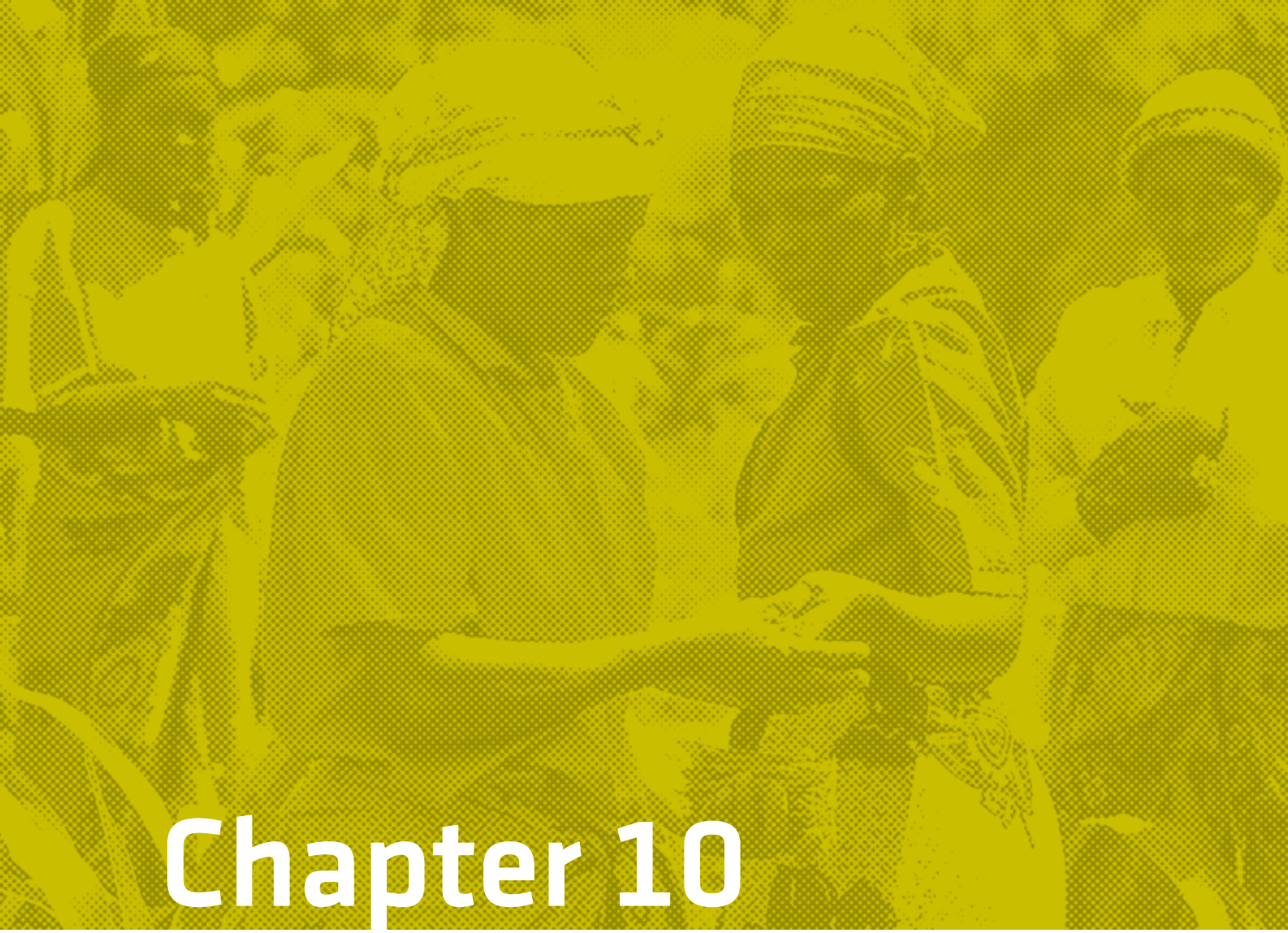
A destruction report is drawn up.

9.5.3.7. Temporary suspension of activity

The activity of an establishment is suspended when the non-conformity has been established, and remains so until the causes behind the suspension have been totally eliminated.

This decision is taken either by the judicial authority or by the competent administrative authority as proposed by the investigators and on the basis of the duly-explained survey report.

Criminal sanctions can also accompany this notification.



Chapter 10

Implementing an inspection system

10.1. SCOPE

9.1.1. Definition

Inspection, based on a methodical and in-depth inspection of the company, involves:

- checking regularly, in the exact location of a business activity, the correct application of regulatory stipulations in terms of safety, fairness of transactions and consumer protection;
- assess the means used by the professional to ensure compliance with his obligations.

In all cases, the purpose of the verification is to ensure compliance of food products, non-food products and services with the regulations. It does not mean it is a substitute for the choice of companies in the execution of their self-assessments nor for consultancy or audit companies.

Implementing the inspection method is only conceivable if the controlled company has an activity covered by 'quality' (fairness, safety) or consumer protection texts for which the service is approved.

It can in theory be used in all the companies proving regular monitoring over time, regardless of their size or their activity stage in the sector. The choice of intervention is determined by criteria linked to the risks and economic importance.

10.1.2. Challenges

Inspection is an appropriate response to the need for honesty, fairness and safety expressed by consumers with respect to domestic or imported products and the requirements of fair competition between operators.

In a context of globalisation of trade, it must be performed on the products intended for the domestic or international market using the same modalities.

Formalising an inspection method as set out in this specification meets this objective and boosts the credibility of the official control with respect to foreign partners. Issuing an export certificate, for example, can be based on such controls.

Inspection gives an overview of all the company's activities falling under the control service's field of expertise.

It is the preferred method for understanding the economic and technological changes and for acquiring knowledge of companies and their activity that is necessary to carry out controls.

10.1.3. Objectives

Inspection takes place as far in advance of the market launch as possible, with the following objectives:

- identifying non-conforming and/or hazardous goods and preventing their dispersion in the territory; it therefore takes place in all premises where goods are assembled before bursting onto the market (production companies, importers, storage warehouses, distribution purchasing group hubs etc.);
- detecting at each stage unauthorised technologies and practices;
- ensuring the conformity of the service offered;
- assessing the means used by the professional to ensure that his activity is executed correctly with respect to his regulatory obligations and to remedy the anomalies detected during his self-assessments;
- remind professionals of their obligations and advise them of changes in regulations;
- sanction unfair practices.

10.1.4. Exclusions

Inspection as defined in § 10.2.1 is different from an isolated random control such as sampling a precise product, impounding or seizures in a crisis, scheduled task providing for a selective investigation etc.

Inspection is not a quality audit in the sense of quality assurance standards. As indicated in § 1.1, inspection does not involve becoming a substitute for the choices of the company in its self-assessments or the consultancy or audit companies.

If during an inspection, the manager of the company notes abnormal practices by other operators such as competitors, suppliers etc., it is important to note this for subsequent intervention.

10.1.5. Administrative organisation

Implementing this type of control implies an appropriate organisation of the administrative structures and sufficiently developed cooperation between them (*cf.* § 10.5.1).

Cooperation with the laboratories is also a requirement when preparing and carrying out controls.

10.2. SPECIFIC VOCABULARY

FEMCA

The FMECA method (Failure mode, effects and criticality analysis) is an inductive analysis method of failure modes and their effects. This tool is more particularly suited to non-food industrial products.

HACCP

The HACCP method (Hazard Analysis Critical Control Point) is an approach used to define, evaluate and control hazards threatening food safety. This tool is the most suitable to control chemical or microbiological risks.

Importing/importer

Any physical introduction of goods into a foreign country.

Introducing/introducer

Any physical introduction of goods into a State with which there is a trade agreement.

Level 1 control

Verification that products and services comply with the regulatory requirements.

Level 2 control

Inventory and assessment of the relevance, effectiveness and reliability of methods implemented by the company to ensure that its products and services comply with the regulatory requirements.

Product

Result of a process. Distinction is made between two large product families: the tangible products (goods) and the intangible products (services, software programs). Numerous products combine the two.

Quality approach

Action by a company or an entity that decides to monitor a predefined procedure or baseline (internal procedures, standards, regulations, specifications, good practices guide) to improve the quality of its products or services.

Quality audit

Methodical, independent and documented examination to determine whether the quality policies, procedures or requirements used comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Regulatory sensitive point

Any stage in a process that can generate a regulatory non-conformity and which therefore must be paid special attention by the professional and the control services. The regulatory sensitive points must be included in the wider set of sensitive points identified by the company to manage the quality of its products.

Self-assessment

Set of measures taken by operators, whether carried out themselves or by a third party, to ensure that the products they manage at all production, processing and distribution stages meet food safety legal requirements and product quality and traceability requirements; and that there is effective control of these requirements.

The person responsible for the first marketing

This is the person who manufactures or introduces into the territory a product regardless of its origin.

Traceability

Ability to find the history of a product through all the stages of production, distribution and processing (e.g. origin of materials and components, execution history, location of the product after delivery).

10.3. MEANS AND METHODS

10.3.1. Administrative organisation of inspections

9.3.1.1. Organisation by local control administrative unit

Selecting companies and programming

The phases described below – 'company listing', 'selection' and 'programming' – must be covered by written traces stored by the local unit and updated, mainly based on changes in the economic environment or the regulations, at intervals set by the local authorities.

- ***Listing of companies involved***

All companies whose activity is covered by 'quality (fairness-safety)' regulations and which are important for the national or provincial economy.

The listing may benefit from consulting certain databases (see Annex 1). This listing forms the index of companies to be controlled under the corporate control

For distribution companies, their manufacturing, import and introduction activities are taken into account at this stage.

- ***Selection and programming***

Where the number of listed companies exceeds the work capacity of the investigators in charge of inspections, a selection is made taking into account the 'risk/confidence' ratio.

Intervals between controls will be more spaced out when there is high confidence and low risks.

This involves taking account of the risk linked to the type of product (goods or services) of the company, the stage when the control will be most effective and the ability of the company to face up to its regulatory obligations.

The choice criteria must be formalised and a trace must be kept.

Liaise with laboratories if appropriate to assist in selecting sectors to be controlled as they can direct the investigators towards the sectors at risk of fraud.

The programming must consider the time required to implement the inspection method. This period that varies according to the company's activity, the investigator's knowledge of it, the type, complexity and magnitude of operations to be conducted also includes preparation time and monitoring time.

If samplings are planned, the programming must also take account of the availability of laboratories to conduct the analyses.

The selection and programming can be modified if warranted by development.

Skills

Both managerial staff and agents are concerned.

The quality corporate control (fairness-safety) requires the agents who perform it to have technical skills so that they can grasp the technology of products (goods or services), regulatory knowledge and mastery of the investigation methodology.

These specific skills are acquired during initial and on-going training and through experience and personal efforts.

The technical level of agents is a major issue.

The investigators must master the 'know-how to control' which is based on regulatory knowledge, application of the control methodology, practising different enquiry techniques, knowledge of the economic and professional environments and the companies that have the 'know-how'.

In this respect, theoretical training, however necessary, cannot supplant personal effort and time spent on the manufacturing premises.

The agents will be able to use the experience acquired to refer to life cycles of products or processes seen in another context, in order to identify the regulatory sensitive points and assess the extent to which the business has them under control.

In terms of the technical expertise required to control certain sectors of activity and their diversity, specialists can assist "junior" agents by acting as their tutors.

The managerial staff, made aware of the issues resulting from the effectiveness and credibility of administration controls and understanding the particularities (or constraints) of inspections, must ensure that the agents possess the skills and ability to undertake the investigations and inspections.

However, if it is impossible to build up the necessary skills for one or more economic sectors, interventions should be limited to selective controls whilst awaiting a solution.

Various levels are required for these controls, resulting from basic knowledge supplemented by in-house training.

- *The skills of agents*

The corporate controls frequently require the intervention of two agents and the skills required may be complementary.

- *Economic and legal skills*

  - Investigative powers and procedure rules (seizure, impounding, sampling etc.);
  - Community rules and mechanisms;
  - Knowledge of the company's legal (corporate law) and economic environment (situation of the market in question);
  - Legal and regulatory knowledge.

- *Technical skills*

  - Physics and chemistry bases and/or biology and agronomy and/or food-processing and/or mechanics and/or IT;
  - Total understanding of investigation and sampling techniques;
  - Product quality (fairness: economic interest in fraud; safety: risk);

- Specific technological and regulatory knowledge about certain products (specialised modules);
- Book and documentary controls (accounts balance sheets, materials accounting etc.);
- Metrological controls.

- ***Special skills***

  - Inspection methodology;
  - Quality control approaches:
    - Quality assurance system;
    - Certification;
    - Risk analysis method (HACCP, FMECA etc.);
  - Identification signs.

- ***The skills of managerial staff***
  - Understanding of all procedures with a view to securing the interventions of investigators;
  - Methodological approach, mechanism and issues of inspection including the quality approach;
  - Coordinating inspection: listing, selecting companies with the agents, programming, coordinating actions, involvement in assistance and information for agents, monitoring training, checking the updating and filing of company's files;
  - Communication: internal and external;
  - Assessing and validating controls: traceability, quantitative assessment, qualitative assessment.

Setting-up a corporate file

A corporate file must be held systematically within the local unit. It must include:

- all the corporate elements (legal, organisational, economic);
- all the elements relating to the controls made and the elements collected during controls (labelling, manufacturing flow charts, self-assessments, etc.);
- correspondence exchanged with the company;
- a copy correspondence exchanged with the company.

The managerial staff must update files and ensure the traceability of interventions.

10.4. INSPECTION

The inspection is broken down into three phases: preparation, execution and follow-up.

10.4.1. Preparation

First and foremost, it is important to understand fully the regulations applicable to the sector, highlight the regulatory sensitive issues and have sufficient knowledge of the technology and good manufacturing practices.

In the preparation phase, the context analysis and the company's file (where it exists) are used to put together an intervention framework that will serve as a guide during the control. It will focus especially on the list of contacts to be met, the workshops

to visit, the points to be addressed, the equipment required for the intervention and the life cycle

of the product when it exists.

The life cycle of the product identifies the regulatory sensitive points that the company must understand fully in terms of safety and fairness.

The analysis of the corporate file, when this is not the initial control, assesses the 'degree of confidence' in the company based on the results of previous controls and guidelines that were defined for the subsequent controls.

This preparation phase is shorter for an initial control as the corporate elements will be compiled during the opening meeting (see § "Opening meeting").

Prior compilation of the following data can be useful to the control:

- general economic data on the sector to be controlled (competition, supply and distribution circuits, import and export flows in particular, etc.);
- technological data;
- legal structure of the company by consulting company databases if they exist;
- other regulatory constraints weighing on the company (classified establishment, health approval, etc.);
- assessment of the role of the company in relation to its activity and its place in the sector;
- knowledge of the company's internal self-assessments or quality approach (quality assurance, certification, HACCP, FMECA etc.).

These data can be mentioned in internal files within the department but held under other activities.

Identifying skills useful for carrying out the control must lead the investigator to seek, where appropriate, the assistance of different internal structures, if they exist (central level, specialised investigation structure, other departments, control networks).

The scientific and technical laboratory personnel can also be consulted for guidance on the intervention (sampling guidelines, analytical capacity) and if needed associated with certain controls.

Other control services can also be called on.

10.4.2. Execution

The intervention normally takes place unannounced, except for the initial meeting to make contact. It obviously varies in length, based on its purpose, the practical circumstances, the elements noted, the size of the company etc.

It can cover one or more stages defined below, be conducted in depth on one of the identified sensitive issues, be repeated if necessary or start through temporary necessity with a level 1 control.

This phase has three stages: the opening meeting, the control itself and the debriefing meeting.

10.4.2.1. Opening meeting

It is intended, especially during a first contact, to open the corporate file in addition to presenting the service and compiling the main economic and technological data. This meeting is not mandatory and may be delayed if necessary (e.g. suspicion of fraud).

It hands over the fact sheet comprising the following elements: legal and organisational (legal structure, flow chart, adherence to a group, subsidiaries, etc.), economic (turnover, company's position in the domestic and international market, production units, suppliers, customers, competitors), technological, self-assessments and full understanding of the quality and regulatory requirements.

Under the crisis management system, the elements listed below must without fail figure in the fact sheet, namely:

- the contact details to be used in an emergency (names of managers to be contacted, telephone and fax numbers);
- production technologies;
- distribution circuits (internal market, exports, sub-contracting);
- the corporate crisis management system: self-assessments, withdrawal and recall plan, product traceability.

When the initial contact is made, the fact sheet will be handed over with the maximum number of elements, but may not be filled in fully and completed during subsequent controls. It is in any case updated at each control.

This sheet is part of the corporate file.

10.4.2.2. Intervention

The intervention is conducted according to the two-level control methodology. This methodology is based firstly, on the assessment of control means used by the professionals (level 2 controls) and secondly, the direct control of raw materials, finished products and their manufacturing and storage methods (level 1 controls).

Agents can use the level 2 controls to assess the relevance and reliability of the company's self-assessment system. These controls also have the advantage of directing the level 1 controls more effectively.

10.4.2.3. Level 2 control

It features in particular:

- the inventory of methods to control regulatory requirements implemented by the company, for each regulatory sensitive issues identified in the life cycle:
  - external guarantees: specifications, supplier audits, etc.;
  - internal guarantees: internal control plans, analysis reports, internal logs, quality approach (quality assurance, quality management, etc.);
- the listing of sensitive issues defined by the company and matching them with the regulatory sensitive points;
- the documentary study of the application of the internal traceability study described in the documents (acceptance approval sheet, records of self-assessment control results, operational instructions, manufacturing sheets, monitoring sheets, return and recall logs).

The critical examination of control methods introduced by the company, the results of its self-assessments and its ability to implement corrective actions are used to assess the relevance and reliability of self-assessment systems.

The identification of weak points or shortcomings in the system can guide the level 1 controls.

Liaising with approved laboratories can also prove useful with a view to verifying the relevance of analysis or test documents obtained in the company (reliability of analyses, of internal or external laboratories).

10.4.2.4. Level 1 control

It is mandatory for all interventions.

It ensures product conformity with the regulatory requirements and assesses the effectiveness of self-assessment systems used by the company.

Faced with an inadequate self-assessment, or none at all**, it is the fundamental, even the only constituent of the control**.

The level 1 control takes the form of:

- an inspection of premises, equipment, manufacturing technologies, products and their raw materials;
- book controls, labelling controls, metrological controls, etc.;
- samplings and analyses. Regardless of the company's situation, justified and suitable samplings may be taken from raw materials, materials, components, additives and finished products. They are mandatory when fraud is suspected following the control of the manufacturing process or when they are the only means of ensuring product conformity (verification of physico-chemical thresholds). Samplings are taken so that they can be interpreted reliably and taking the laboratory's analytical possibilities into account.

The level 1 control can be expanded to all the stages:

- acceptance (raw materials, ingredients, materials, etc.);
- manufacture (processes, manufacturing sheets, etc.);
- finished products (composition, advertising, labelling, etc.);
- storage, conservation, transport up to distribution.

10.4.2.5. Debriefing meeting

The intention is to assess the control with the company manager, to advise him of the envisaged follow-up and ask him what actions he intends to implement and their timescales to rectify any anomalies noted.

It is also a chance to widen the intervention of concern to the manager on any question relating to the intervention of the department.

10.4.3. Follow-up

10.4.3.1. Internal follow-up

The elements compiled during controls are stored in the company file.

The agent must write the control report systematically after each control and as quickly as possible (see annex 10.7.4).

The control report is:

- a precise definition of the field of intervention; this is essential for monitoring the company over time and for delimiting the range of the control carried out;
- a summary of verifications and observations made during the investigation of the raw materials, manufacturing processes and sheets, labels, finished products, internal controls, etc. It describes the operations carried out, quotes the people met etc.;
- a statement of samplings made;
- an inventory of determined regulatory sensitive issues and anomalies in controlling these sensitive points by the company;
- a description of the envisaged follow-up (corrective actions implemented by the company, regulatory reminders, disputes) and guidance for future controls and their implementation timescales;
- a list of questions without response and for which prolonging the investigation seems unavoidable;
- support for the degree of confidence shown in the company.

The company file is updated or created if it does not exist.

This phase also includes the exploitation of data compiled through the approved laboratories (analysis results, information on analysis methods, etc.).

It also guides the subsequent controls, by determining the intervention intervals and the intensity of level 1 controls to be performed.

This phase must end, in the case of anomalies, with a decision on the opportunity to embark on contentious follow-up or to send a reminder of regulations.

10.4.3.2. External follow-up

The investigator advises the company's management of the intended follow-up to the control, reminder of regulations or report, and the analysis results given to the samplings taken from their products.

The written communication in relation to the company is limited to observations of the application of the quality regulations (fairness-safety) and the risks of shortfalls.

10.5. ANNEXES

A.1. Databases for listing companies

Web sites

Searches to be made on existing sites in the country in question (legal, commercial, administrative sites etc.).

Other sources

- Press,
- Technical or professional journals.

A.2. Composition of a company file

Most documents in the company file are paper documents, but some may be replaced by computerised documents.

Log book

This summarises the interventions made in the company (control, correspondence, selective control, scheduled task etc.)

Fact sheet

Its contents are given in Annex 7.3. It groups the information required for crisis management.

Control documents

- Control report (its contents are given in Annex 4.);
- Sampling report;
- Analyses report;
- Life cycles;
- Manufacturing sheets.

Labels, advertising

Document affixed to or included in the finished product.

Self-assessment documents

Reports of analyses or tests conducted by the company, elements from the conformity file etc.

Documentation

Any element that may be useful to comprehensive knowledge of the company for a quality control (technical documents, press articles, catalogues etc.).

Correspondence

All correspondence exchanged with the company.

Disputes

Copy of reports and judgements.

Other elements

Tariffs, general terms and conditions of sale.

A.3. Fact sheet

GENERAL INFORMATION

Company activity:

☐ Manufacturer ☐ Importer ☐ Introducer ☐ Other (state)

Legal form: .....

Address of the controlled establishment: .....

Address of the head office: .....

Other units: .....

Site where the accounts are held: .....

Fax number of the company controlled: .....

E-mail: .....

CRISIS MANAGEMENT – direct contacts in an emergency: .....

The company must designate three contacts: .....

Name – First name – Telephone numbers (private, work, mobile):

.....

Company creation date: .....

Turnover (last two years): .....

Year N-2	Year N-1

Annual closure: .....

Opening times and manufacturing timetable: .....

Membership of professional organisation: .....

1- FLOW CHART:

Senior Legal Officer:

	Name	First name
Chairman and Managing Director		
Managing Director		
Manager		

Manager of the controlled unit: .....

Head of manufacturing: .....

Sales and Marketing Manager: .....

Quality Manager: .....

Total workforce: .....

Permanent productive workforce: .....

Seasonal productive workforce: .....

Special comments: .....

(Attach all administrative documents and the group's presentation leaflet, etc.)

2- COMPANY ACTIVITY

Main products, product families or services (1)	Introduced or imported (2)	FManufactured F(2)	Subcontracting by third parties (2)	Sub-contracting for third parties (2)	Brands	Quant. (tonnes or %)

(1) Attach the sales tariff and the general terms and conditions of sale
(2) State the country

Address of third parties if appropriate: .....

Existence of products under identification signs: labels, organic agriculture, product or service certifications, ecolabels, etc.

3- PROCUREMENT

Main raw materials or components used	Suppliers	Technical files	Specifications

Special comments: .....

.....

.....

4- MANUFACTURE – TECHNIQUES – TECHNOLOGIES:

- Production surface area (attach a plan of premises if appropriate): .....
- Storage capacity (m^2, m^3 and days of use: .....
  - Raw materials: .....
  - Finished products: .....
- Cold storage capacity (m^3): .....
  - Positive temperature: .....
  - Negative temperature: .....
- Basic materials and technologies (mainly those with a potential impact on regulatory requirements): .....
- Packaging (origin, type, contact material etc.): .....
- Delivery methods: .....
- Special comments: .....

5- QUALITY AND REGULATORY REQUIREMENT CONTROL ELEMENTS:

- External guarantees
  - Service providers: .....
  - Supplier or service provider contracts: .....
  - External laboratories (accreditations): .....
- Internal guarantees
  - Understanding of the regulations (documentation available): .....
  - Self-assessment procedures: .....
  - Risk analyses (HACCP, FMECA etc.): .....
  - Validation procedures for use-by dates and best-before dates: .....
  - Corrective measures for discrepancies or non-conformities (procedures, effectiveness, dealing with nonconforming raw materials and finished products): .....
  - Dealing with customer claims and returns: .....
- Internal laboratory
  - Workforce: .....
  - Type of analyses performed and products controlled: .....
- Quality management where appropriate (state internal audits, external audits, ISO 9000 company certification, laboratory accreditation, other): .....

.....

- Environmental management where appropriate (stated standard ISO 14000 or other environmental management system): .....

  .....

- Crisis management (describe or attach copies of procedures): .....
  - Batch number formation: .....
  - Traceability: .....
  - Product recall procedure: .....

6 – PRODUCT MARKETING:

- Geographical selling area: .....
- Market share: .....

Export share of turnover: .....

Main products exported	Countries	Quantities

Main customers:

Names of main customers	% of turnover

Advertising: .....

Existence of consumer service?: (if yes, contact details) .....

Existence of Web site?: (if yes, which one) .....

A.4. Control report

Establishment: .....

Control date:	Agents:

Main people met: .....

Name, First name	Functions

Field of intervention

Activity sector (manufacturing, assembly or packaging workshops, laboratory, storage areas, administrative areas, transport vehicles, other): .....

.....

.....

Products or product categories controlled (raw materials or components, products on the production or assembly line, finished products): .....

.....

.....

Verifications performed and inventory of sensitive points:

- Level 2 control (inventory of company's control methods, listing sensitive issues defined by the company and matching them with the regulatory sensitive issues, verifying their relevance and reliability, examining the results of the company's self-assessments and its ability to implement corrective actions, etc.): .....

  .....

  .....

- Level 1 control (inspecting premises, equipment, manufacturing technologies, manufacturing chains, products and their raw materials and components, controlling manufacturing or assembly sheets, book controls, controlling labels, metrological controls, taking samples, etc.): .....

  .....

  .....

Noted anomalies:

- Internal follow-up (request for investigation, programming new controls, points to be verified at the next control, etc.): .....

  .....

  .....

- External follow-up (reminder of regulations, contentious procedure): .....

  .....

  .....

TECHNICAL SHEET

Intended follow-up to the investigation (non-contentious follow-up, contentious follow-up)

Question	What is the definition of the role of an investigating agent?
Answer	The basic mission of an investigating agent, be he assigned to controlling the domestic market or in a border control post, is to note and list FACTS or after analysis or otherwise, the conformity or non-conformity of a PRODUCT with a regulatory text or a national or international standard.
Question	How can these observations be followed up?
Answer	Either by the administration, for breaches that have no effect on consumer health or safety, which can be in the form of a formal notice, or if the infringement is characterised by establishing a contentious act.
Question	What is the legal value of observations made by an agent?
Answer	The reports written by the agents are believed until proof of the contrary (it is therefore easy to dispute them).
Question	What must a contentious act include, *i.e.* a report?
Answer	The report must include the following mandatory information: control dates and places, the facts noted, the infringements and related sanctions, the identity and position of agents and the identity, relationship, activity and address of the intervening party controlled. The law makes no stipulation as to the form of the report.
Question	What is an observations report?
Answer	A report is a legal act which refers to an observation made by a commissioned and accredited agent. This act takes the form of a legal syllogism which will include: **The foreword** As stipulated by the texts, it must state: • the full identity of the agent: name, first name, rank; • that he is introduced to the contact stating his identity and that he showed him his official identification (never leave this document with the intervening party); • that the agent is accredited to carry out controls. (*N.B.*: all agents who have taken part in the control must be mentioned in the contentious act with the same information as stated above). It states the place, date and time of the start of the intervention and repeats the identity of the intervening party with his relationship, his status in the business, the legal information on the company, the trading name that can be different from the company name, the precise activity of the establishment and its place in the production/import-distribution chain. If the control takes place during transport, this must of course be noted in the foreword.

Answer

The observations

The agent relates the facts that he has noted and that he will describe in detail. He will be precise and clear so as to leave no room for possible interpretation.

When the investigations take place after legal opening hours, the agent will note that the establishment was open to the public or that an activity under any form whatsoever was taking place there.

The agent must show no personal feeling even elliptically. The report has a duty to be objective, neutral and cold (it is a photograph of a fact at a given moment).

The agent will attach all documents backing up his report (if documents have been seized, he will write a separate document seizure report).

To persuade magistrates, the agent may illustrate the contentious act with photographs that he was able to take during his investigations, mainly in terms of hygiene.

Pronouncement of the law

With respect to observations made, the agent is going to list the legislative or regulatory tests breached by the intervening party.

Even if the judges can always requalify an offence, the agent will endeavour here also to be as precise as possible by quoting the bill of indictment.

If he has any doubts over the text to be applied, he may of course ask advice from other investigating agents or his supervisors before the final writing of the report (a contentious act cannot be altered once it has been finalised).

Act of incrimination

This is the third part of the legal syllogism that incriminates an offender during an investigation.

The agent is going to state that the intervening party is rendered guilty of an offence against a regulatory or legislative text.

Position of the agent as to legal proceedings

The agent will indicate that for the type of offence noted, the file should either merit a transactional fine or legal proceedings without argument.

Closure of the contentious act

The agent will indicate that the offender has been advised of the date and time of the writing of the report, whether or not he has responded to this convocation.

The officer reporting the offence will note the observations of the intervening party or take a copy of his written statements (a short delay could nevertheless be granted to him to present his defence).

Lastly, the agent is going to close the act by indicating the place, date and time of writing.

Mention will be made of the refusal by the offender to sign the report.

He will carefully count the words that are crossed out or invalid and will draw a line through spaces left blank to cancel them.

Answer

Special reports

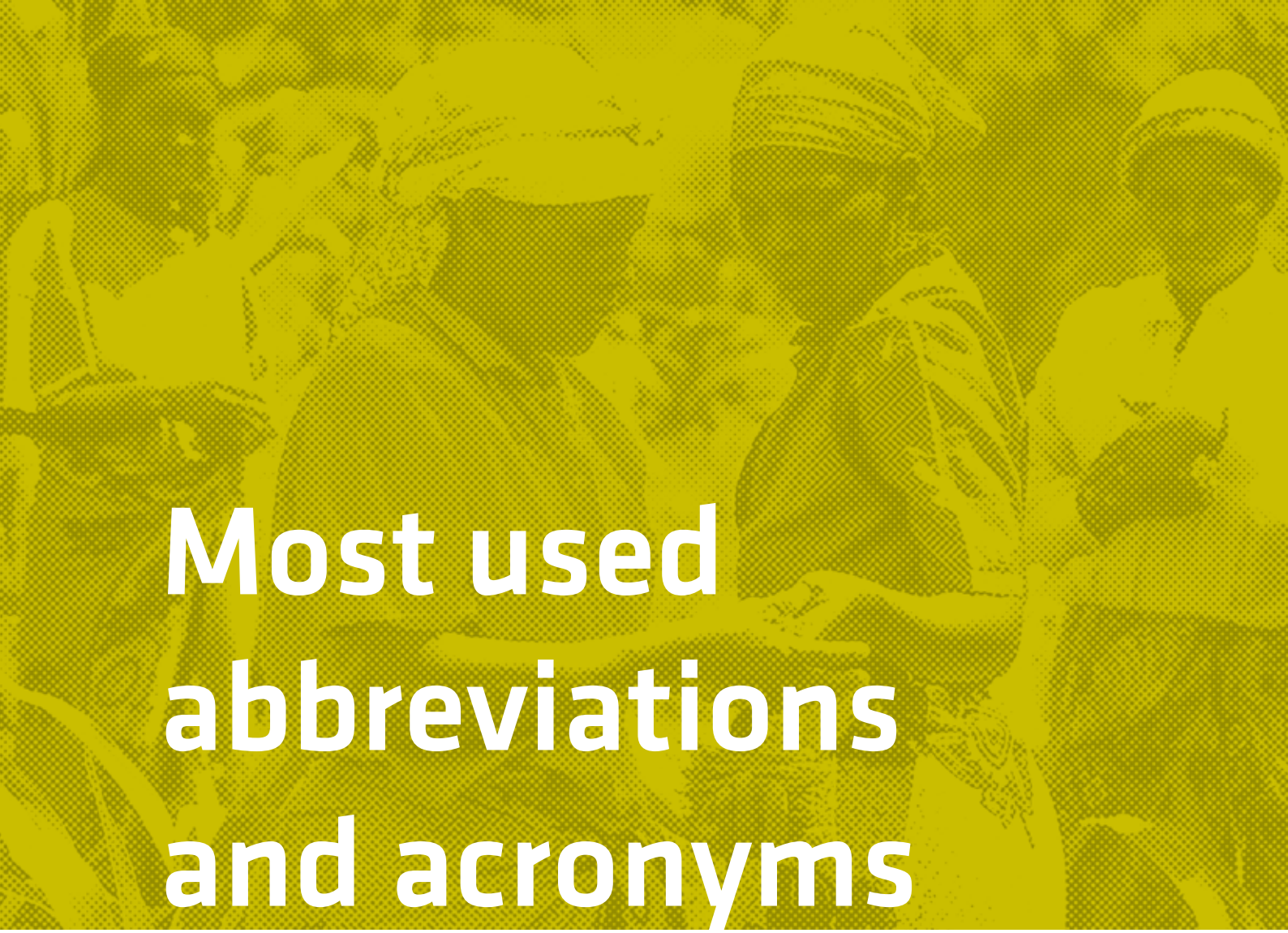
This involves the case of statements of offence recorded when the following take place:

- insults;
- threats or attempted threats (death threats with or without an instrument, involvement of the agent's family, etc.);
- obstructing duties with or without violence.

As for acts governed by observations, the special statements of offence will be written extremely carefully. They will relate scrupulously all the details of the incident so that justice may take its course with all speed.

REMINDER: *contentious acts in both form and content are scrutinised by the courts and also by lawyers who will search out the least flaw to discredit the action of agents by invoking procedural errors, substantive errors, defects of form that ultimately bring the contentious act down before the court.*

The agents should therefore show tremendous rigour in accomplishing their assignment.



Most used abbreviations and acronyms

MOST USEFUL ABBREVIATIONS AND ACRONYMS

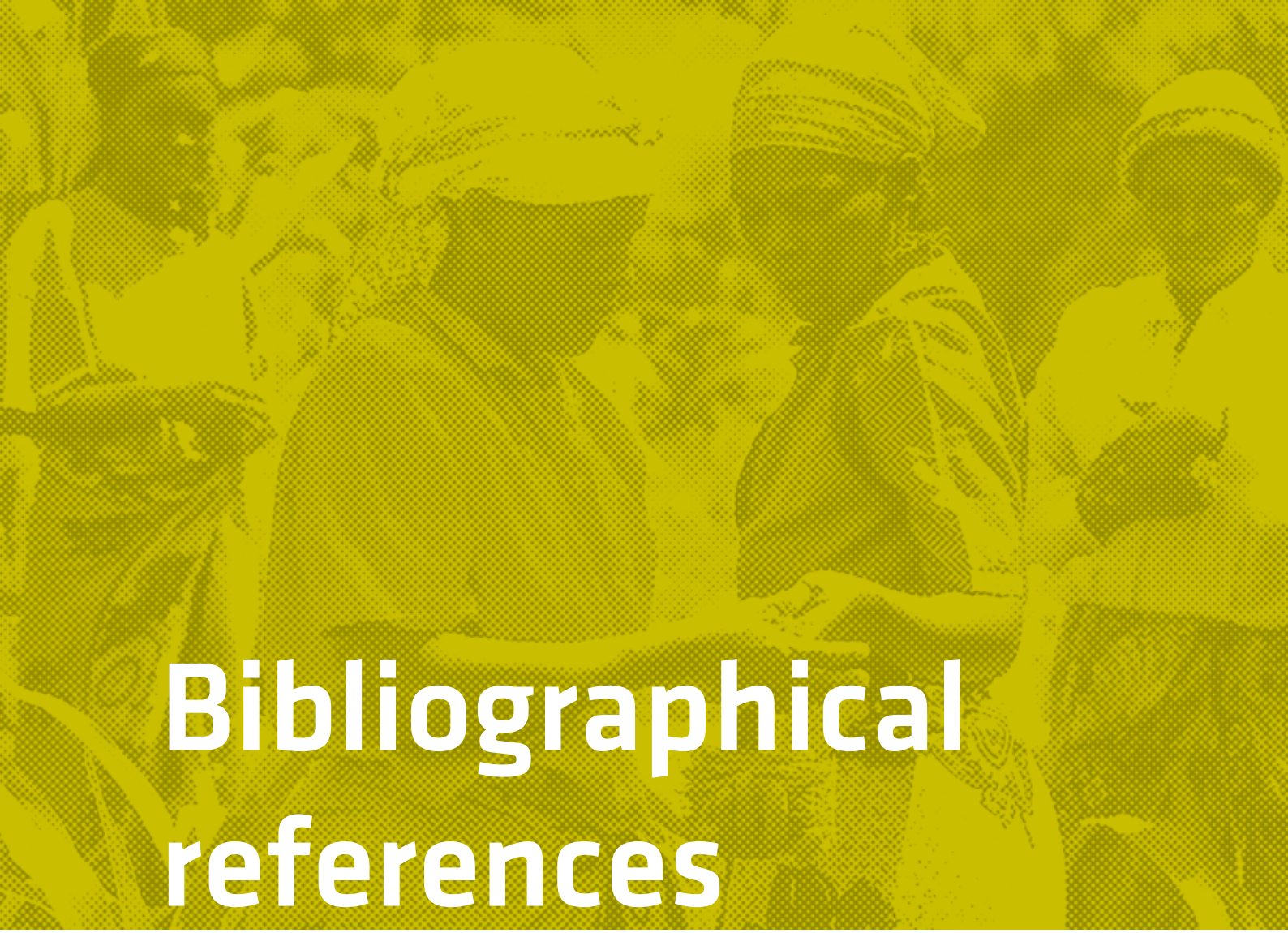
AAC	Association of analytical communities
ACP	Africa – Caribbean – Pacific (countries of the ACP Group, having signatories of a series of specific agreements with the EU called the "Cotonou agreements")
ADI	Acceptable Daily Intake
AIDCO	EuropebAid Office of Cooperation
AOAC	Association of Analytical Communities
ArfD	Acute Reference Dose
ARPA	*Agenzia regionale per la protezione dell'ambiente* (Regional agency for the protection of the environment)
ASL	*Azienda sanitaria locale* (Local Health Unit)
AUSL	Local Health Unit (*Azienda Unità Sanitaria Locale*)
Aw	Water Activity
BRC	British Retail Consortium
CA	Competent Authority
CAC	*Codex Alimentarius* Committee
CCA	Central Competent Authority
CCP	Critical Control Points
CCPR	*Codex* Committee on Pesticide Residues
CEN	European Committee for Standardisation
COKZ	*Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel* (Dutch Control Authority for Milk and Milk Products)
DEVCO	European Commission DG Development and Cooperation
DGAHVM	Directorate General for Animal Health & Veterinary Medical Products
DGFSN	Directorate General for Food Safety and Nutrition

DSVET	*Dipartimento di sanità veterinaria* (Department of Veterinary Public Health and Food Safety)
EC	European Community
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EHEC	Enterohemorrhagic E. coli
EL&I	*Economische Zaken, Landbouw en Innovatie* (Dutch Ministry of Economic Affairs, Agriculture and Innovation)
EPPO	European and Mediterranean Plant Protection Organization
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FBO	Food Business Operators
FIO	Foodborne illness outbreaks
FoAO	Food of animal origin
FMECA	Failure mode, effects and criticality analysis
FSSC	Food Safety System Certification
FVO	Food and Veterinary Office
GAA	Global Aquaculture Alliance
GAP	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GCI	Global Commerce Initiative
GFL	General Food Law
GFSI	Global Food Safety Initiative
GHP	Good Hygiene Practices
GLP	Good laboratory practices
GMP	Good Manufacturing Practices
GPS	Global Positioning System
HACCP	Hazard Analysis and Critical Control Points

HR	High Residue
IFS	International Food Standard
ILAC	International Laboratory Accreditation Cooperation
INFOSAN	International Food Safety Network
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
IT	Information Technology
IZS	*Istituto Zooprofilattico Sperimentale* (Experimental Zooprophilactic Institute)
JEFCA	Joint FAO/WHO Expert Committee on Food Additives
JEMRA	Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meetings on Pesticide Residues
LNV	*Landbouw, Natuur en Voedselkwaliteit* (Dutch Ministry of Agriculture, Nature and Food Quality)
MLA	Multilateral Agreement
MRA	Microbiological Risks Assessments
MRL	Maximum Residue Limit
MSC	Marine Stewart Council
NAFTA	North American Free Trade Agreement
NGO	Non-governmental Organisation
NOAEL	No observed adverse effect level or DWE (Dose without effect)
NAS	*Nucleo Antisofisticazioni Sanità* (Health Police)
NRL	National Reference Laboratory
NVWA	*Nederlandse Voedsel- en Warenautoriteit* (Dutch Authority for Food and Consumer Goods)
OCl	Hypochlorite ion

OIE	World Organisation for Animal Health (*Office international des épizooties*)
OJEU	*Official Journal of the European Union*
PAH	Polycyclic aromatic hydrocarbons
PCB	Polychlorinated biphenyl
PEQ	Post Entry Quarantine
pH	Power of hydrogen
PMU	Project Management Unit
PRA	Pest Risk Analysis
RA	Risk analysis
RAPEX	Rapid Alert System for non-food dangerous products
RASFF	Rapid Alert System for Food and Feed
RIVM	*Rijksinstituut voor Volksgezondheid en Milieu* (Dutch Royal Institute for Public Health and the Environment)
RPHS	Regional Public Health Service
RPPO	Regional Plant Protection Organization
RSPO	Roundtable on Sustainable Palm Oil
SANCO	DG Health and Food Safety
SIAN	Hygiene and Nutrition Services
SM	System Management
SOP	Standard operating procedures
SPS (Agreement)	Sanitary and phytosanitary System
SQF	Safe Quality Food
STMR	Supervised Trials Median Residue Values
TBT (Agreement)	Technical Barriers to Trade
TSE	Transmissible spongiform encephalopathies

UNCTAD	United Nations Conference on Trade and Development
WFP	World Food program
WHO	World Health Organisation
WTO	World Trade Organisation



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USEFUL WEB SITES

British Retail Consortium
www.brc.org.uk

Clipart
www.wpclipart.com

Codex Alimentarius
www.fao.org/fao-who-codexalimentarius/codex-home/en

COLEACP
www.coleacp.org/en

EFSA
www.efsa.europa.eu

EUR-Lex
eur-lex.europa.eu/homepage.html?locale=en

European Accreditation
www.european-accreditation.org

European Commission
ec.europa.eu/index_en.htm

Evira (Finnish Food Safety Authority)
www.evira.fi/portal/en/evira

FAO
www.fao.org/home/en

Food and Drug Administration
www.fda.gov

Food and Veterinary Office
ec.europa.eu/food/fvo/how_en.print.htm

French Department of Economy and Finances
www.economie.gouv.fr

FSAI (Food Safety Authority in Ireland)
www.fsai.ie

General Food Law
ec.europa.eu/food/safety/general_food_law/index_en.htm

Global Food Safety Initiative
www.mygfsi.com

GLOBALG.A.P.
www.globalgap.org/uk_en

Global Trade Negociations
www.cid.harvard.edu/cidtrade

ILAC
ilac.org

International Plant Protection Convention
www.ippc.int/en

ISO 26000
www.iso.org/iso/en/discovering_iso_26000.pdf

Istituto Superiore di Sanità
www.iss.it

Michigan Food & Farming Systems
www.miffs.org

National Institute for Public Health and the Environment
www.rivm.nl/en

Nederlandse Voedsel- en Warenautoriteit
www.nvwa.nl

RIKILT
www.wur.nl/en/Expertise-Services/Research-Institutes/rikilt.htm

The Consumer Goods Forum
www.theconsumergoodsforum.com

United Nations Conference on Trade and development
unctad.org/en/pages/Home.aspx

UTZ
www.utz.org

Voeding Centrum
www.voedingscentrum.nl/nl.aspx

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en.wikipedia.org/wiki/Main_Page

World Health Organization
www.who.int/en

World Organisation for Animal Health
www.oie.int/en

World Trade Organization
www.wto.org/index.htm

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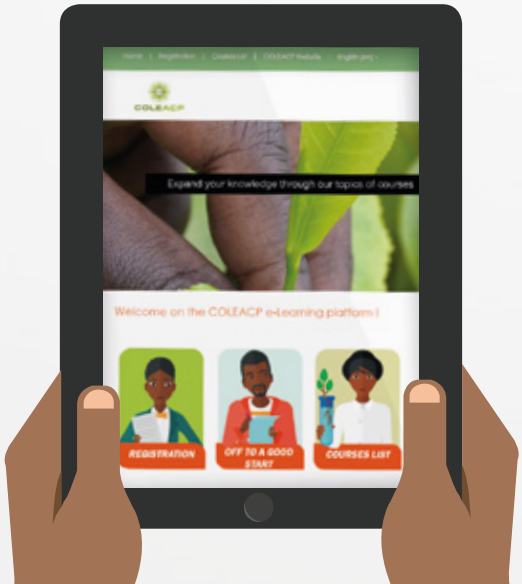

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