

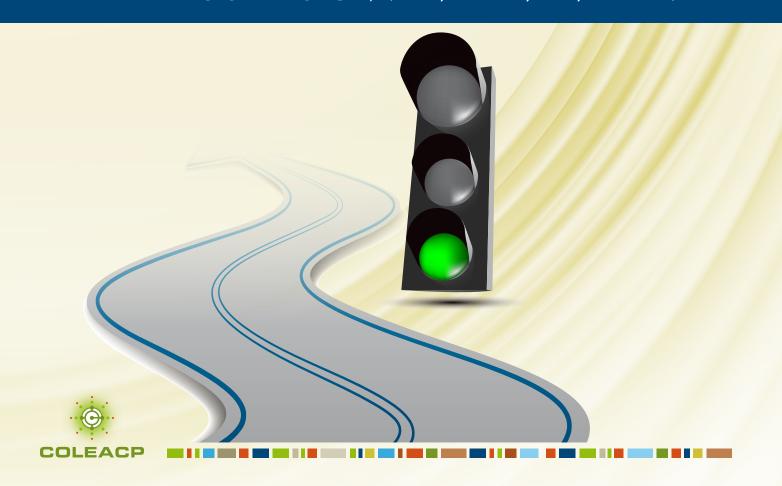
HANDBOOK

12.2

Official Controls

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ROLE OF COMPETENT AUTHORITIES IN OFFICIAL CONTROLS, ACTIVITIES AND TASKS OF OFFICIAL CONTROLLERS (CHECKS, INSPECTIONS, AUDITS, CERTIFICATION)



The handbooks are tools designed for civil servants in charge of restructuring the food safety system, and for all operators involved in drawing up the food safety policy and organising official controls (qualified civil servants, heads of laboratories, heads of departments in official organisations, those in charge of official controls, trainers, technicians, researchers, experts or company executives). They aim to provide an overview of the main points of a specific subject. All of the topics addressed by EDES during the training sessions are covered in separate handbooks.

The handbooks have been designed and drawn up by the EDES Training Unit in cooperation with the Consortium members.



















EDES is a European cooperation programme managed by COLEACP. COLEACP is an international network promoting sustainable horticultural trade. It is funded by the European Union and was implemented at the request of the ACP (African, Caribbean and Pacific) Group of States. EDES aims to promote food safety in African, Caribbean and Pacific countries. EDES operates in all sectors in response to a request filed at national level by any public or private stakeholder involved in the food safety process.



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1. Introduction

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 view-point 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 possibile 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 the 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.

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.

1.3. The Food and Agriculture Organisation (FAO)



The Food and Agriculture Organisation (FAO) was set up on 16 October 1945¹, 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 produc-

tion 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.

1.4. The World Health Organization (WHO)



The UN established the World Health Organisation² (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, working at the organisation'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 organisation. 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 (IN-FOSAN).

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 harmonisation. 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.

¹ See generally www.fao.org

² See generally www.who.int

1.5. The Codex Alimentarius

What is this Codex Alimentarius³ 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 specialised 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 organisations and organisations representing private sector interests have observer status.

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

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.4

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.5

According to this general standard, the following information must appear on the labeling 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 honor 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' and all the standards that have been agreed upon. The notion of HACCP has been developed - and is understood - within

³ See generally www.codexalimentarius.net

⁴ See FAO, Understanding The Codex Alimentarius, (3rd ed.) Rome 2006, available at: ftp://ftp.fao.org/codex/publications/understanding/understanding EN.pdf 5 Codex Stan 1-1985 (Rev. 1-1991).

the framework of the Codex Alimentarius.⁶ 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.

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 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 1997⁷ and the White Paper on food safety in 2000⁸. In January 2002 the European Commission presented the 'General Food Law⁹ (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).

➤ 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, its directly applicable and immediately enforceable in any Member State.

⁶ Recommended International Code of Practice - General Principles of Food Hygiene CAC/PCP 1-1969, Rev. 3-1997, Amd. (1999).

⁷ Commission Green Paper on the General Principles of Food Law in the European Union, COM (1997) 176 final, Brussels, 30 April 1997, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1997:0176:FIN:EN:PDF.

⁸ Commission White Paper on Food Safety COM (1999) 719 final, Brussels, 12 January 2000, http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf.

⁹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 200layingdown the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

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
- 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.

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: 1. injurious to health and/or 2. 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.

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2. EU legislation and official feed and food control

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 in paragraph 1.6, 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. Objectives of official controls in EU legislation

The need of official controls is stated in Regulation (EC) No 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, Art. 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 n°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."

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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. Art. 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.

2.4. 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 Art. 5 of Lisbon Treaty,¹⁰ the competence to establish national competent authority is allocated to each 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;

¹⁰ 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: http://circa.europa.eu/irc/opoce/fact_sheets/info/data/how/characteristics/article_7148_en.htm.

- 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.

2.5. 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 200layingdown
 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 183/2005 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).

2.5.1. Regulation (EC) No (EC) 882/2004

Regulation (EC) No (EC) 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 labeling 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, labeling 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.

➤ 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:

- · Living animals (like, cows, horses, one day chickens and decoration fishes);
- · Products of animal origin (like meat, fish, game and feed);
- Foodstuffs (like vegetables, dried fruit, spices, nuts and seeds);
- 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.

Meat products that may be imported:

- Fresh meat, offal and minced meat prepared from domestic cows (including bison and buffalo's) for human consumption;
- Fresh bowel, stomach and bladder are offal, are only allowed to be imported from countries where TSE-BSE risk are negligible;
- Meat preparations, including minced meat to what salt and spices or additives have been added or that have been treated in such that muscle structure has not changed and did not lose the characteristic properties of fresh meat by that way;
- Only deep frozen meat preparations may be imported

All consignments concerning animal food need physical checks. These checks may include the means of transport, the packaging, labeling and temperature and also quality. If needed samples will be taken and analysed.¹¹

Only after the result of laboratory has proven the food to be save, the consignment is released for trade. Despite this checks the duty of feed and food business operators to ensure that feed and food comply with feed and food law from the moment of release for free circulation nor prevent further official controls on the feed or food concerned from being carried out.¹²

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 feed and food;
 - b) the history of compliance with the requirements for the product concerned of the third country and establishment of origin and of the feed or food business operators importing and exporting the product;
 - c) the controls that the feed or food business operator importing the product has carried out;
 - d) the guarantees that the competent authority of the third country of origin has given.

¹¹ Regulation (EC) No 882/2004 shall not affect the requirements for veterinary checks on feed and food of animal origin provided for in Directive 97/78/EC.

¹² Regulation (EC) No 882/2004, Article 14.3.b.

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 feed or food be destroyed in accordance with Article 20;
- Re-dispatched the products outside the Community in accordance with Article 21;
- Intend feed or food for purposes other than those for which they were originally intended;
- Recall in case the products are already on the market;
- verify that feed and food does not give rise to any adverse effects on human or animal health, either directly
 or indirectly;
- If the official controls indicate that a consignment is injurious to human or animal health or unsafe, the competent authority shall place the consignment in question under official detention pending its destruction or any other appropriate measure;
- If feed or 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 feed or 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.¹³

The information of the Competent Authority to the Commission is used for the rapid alert system for food and feed (RASFF¹⁴) or for the rapid alert system for all dangerous consumer products (RAPEX¹⁵).

Decisions on consignments are subject to the right of appeal.

➤ 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 technique's: Inspection, audit and sample taking.

Inspection mostly is a 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 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. ¹⁶ 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 analy-

¹³ In accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002.

¹⁴ http://ec.europa.eu/food/food/rapidalert/index_en.htm.

¹⁵ http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm.

¹⁶ Private Certification Bodies that inspect companies on hygiene guides, shall be accredited against ISI/IEC 17020.

ses 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.

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.¹⁷

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 a of the task 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) most in animal products;
- Dioxin, PCB's, benz(a)pyreen in certain foodstuffs
- · Pathogen micro-organism in perishable raw materials and foodstuffs

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

¹⁷ 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).

production process are effective. For instance: the microbiological examination of milk before and after pasteurisation show the effect of the heating at 80 degrees Celsius at micro-organism.

> 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 aspects¹⁸:

- 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.
- 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.

Criteria for these parameters may be found in:

- Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC;
- Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products;
- Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC;
- Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products;
- Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products.

Where Directive 96/93/EC lays down the rules to be observed in issuing the certificates required by veterinary legislation, the other directives contain criteria for safe food.

¹⁸ http://www3.vwa.nl/werkwijzer/EXA%20VCA/EXA-01.pdf (in Dutch).

It further states the competent authorities shall take all necessary steps to ensure the integrity of certification. In particular they shall ensure that certifying officers designated by them:

- a) have a status which ensures their impartiality and have no direct commercial interest in the animals or products being certified or in the holdings or establishments in which they originate;
- b) are fully aware of the significance of the contents of each certificate which they sign.

2.5.2. Regulation (EC) No 854/2004

Regulation (EC) No 854/2004 on products of animal origin is a good example of analytical regulation over the nature that the controls shall assume, with a differentiation of the different products and the consequent responsibilities for the competent authorities.

In particular, Regulation (EC) No 854 states that the official controls shall include audits of good hygiene practices and HACCP principles (Hazard Analysis and Critical Control Points), as well as specific controls whose requirements are determined by sector (fresh meat, bivalve molluscs, fishery products, milk and dairy products, food of non animal origins). These controls are:

- a) Official controls on fresh meat
- b) Official controls on bivalve molluscs
- c) Official controls on fishery products
- d) Official controls on milk and diary products
- e) Official controls on animal products from third countries
- f) Official controls on food of non animal origins.

a) Official controls on fresh meat19

An appointed and authorised official veterinarian shall audit:

- the permanent application of good hygiene practices (maintenance of plant structure and equipment, plant hygiene, staff hygiene, training, processing of animal by-products not intended for human consumption);
- the procedures based on the HACCP in the following areas: compliance of products of animal origin with microbiological criteria, absence of excessive quantities of prohibited substances, contaminants or chemical residues, absence of physical hazards, such as foreign bodies, absence of patho-physiological abnormalities or changes, absence of contamination.

The inspection tasks of the official veterinarian shall cover:

- food chain information giving health data concerning animals which have been sent or will be sent for slaughter.
- ante-mortem inspections. Within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter, all animals must undergo ante-mortem inspections. The official veterinarian verifies the existence of any sign indicating that the welfare of the animals has been compromised or signs of any condition which might adversely affect human or animal health
- animal welfare during transport and during slaughter
- post-mortem inspections
- · specified risk material and other animal by-products
- · laboratory testing.

After carrying out the controls mentioned, the official veterinarian shall take appropriate measures, in particular as regards:

1. the communication of inspection results;

¹⁹ For further details, see http://ec.europa.eu/food/food/controls/index_en.htm

- 2. decisions concerning food chain information;
- 3. decisions concerning live animals;
- 4. decisions concerning animal welfare; and
- 5. decisions concerning meat.

Member States may allow slaughterhouse staff to assist with official controls by carrying out certain specific tasks, under the supervision of the official veterinarian, in relation to the production of meat from poultry and lagomorphs. If they do so, they shall ensure that staff carrying out such tasks:

- (i) are qualified and undergo training in accordance with those provisions;
- (ii) act independently from production staff; and
- (iii) report any deficiency to the official veterinarian.

A risk-based approach shall be followed to assess the number of official staff that need to be present on the slaughter line in any given slaughterhouse. The number of official staff involved shall be decided by the competent authority and shall be such that all the requirements of Regulation (EC) No 854/2004 can be met.

b) Official controls on bivalve molluscs

The competent authority shall determine the location and the extension of production areas for bivalve molluscs. The production areas from which harvesting of bivalve molluscs is authorised are divided into three classes:

Class A areas: areas from which molluscs may be collected for direct human consumption;

Class B areas: areas from which molluscs may be collected but may be placed on the market for human consumption only after treatment in a purification centre or after relaying;

Class C areas: areas from which molluscs may be collected but may be placed on the market only after relaying over a long period (at least two months), whether or not combined with purification.

In this regard, the competent authority shall make an inventory of the sources of pollution from human or animal origin and examine the quantities of organic pollutants released during the different periods of the year and their circulation characteristics. It shall establish a sampling programme to verify the microbiological quality of the bivalve molluscs, based on sampling plans that determine the frequency of these controls.

Where the results of sampling reveal non-compliance with the essential health standards, the harvesting of molluscs shall be prohibited within the production area concerned.

In addition to the monitoring of relaying and production zones, a control system including laboratory tests must be set up in order to verify compliance with the requirements applicable to the end products.

c) Official controls on fishery products

In addition to the common control requirements, specific official controls on fishery products shall be carried out and namely:

- · organoleptic surveillance testing;
- total volatile basic nitrogen tests;
- histamine testing;
- surveillance testing for contaminants;
- microbiological checks;
- · parasite screening tests;
- checks for the possible presence of poisonous fish species or fish containing bio toxins.

In case of excessive quantities of substances dangerous to human health, the competent authority shall declare the fishery products unfit for human consumption.

d) Official controls on milk and diary products

In addition to the common control requirements, specific official controls shall include:

- Inspection of holdings. Animals must undergo regular veterinary inspections to ensure compliance with the health requirements for raw milk production (health status of the animals, use of veterinary medicinal products).
- Control of raw milk upon collection. The competent authority shall organise control schemes in order to
 ensure compliance with the standards that apply to raw milk. When the raw milk fails to meet mandatory
 food safety criteria the competent authority may suspend the delivering of the milk in question and ask the
 farmer to take the necessary measures.

e) Official controls on animal products from third countries²⁰

The Commission draws up lists of third countries or parts of third countries from which the importation of products of animal origin is authorised. A third country may only be listed if the country in question provides the appropriate guarantees and after a Community inspection has been carried out in the country.

Furthermore, the Commission draws up a list of establishments from which products of animal origin may be imported or dispatched. An establishment may only be listed if the competent authority in the third country of origin guarantees that the said establishment complies with the relevant Community requirements. Regular Community inspections are carried out in order to check these guarantees.

f) Official controls on food of non-animal origins

Art. 15 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.

2.6. 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.

2.7. 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.²¹

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.²²

2.9. Communication with EU Authorities

Besides, in order to comply with the principles set up in reg. 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:

- 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 a EU Member State against the national control plans shows weaknesses or non-compliances, detailed inspections and audits will be carried out.²³

²¹ For further details on the risk-based approach see for instance the website of the Finnish Food Safety Authority: http://www.evira.fi/portal/en/evira/.

²² For further details on the multi-annual national plan, see for instance the website of the Irish Food Safety Authority: http://www.fsai.ie/legislation/food_legislation/official_control_of_foodstuffs/integrated_multiannual.html

²³ See http://www.fao.org/docrep/meeting/008/y5871e/y5871e0l.htm

3. Official controls and third countries

3.1. Rules

Since the adoption of the new rules on the hygiene of foodstuffs (Regulations (EC) No 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.²⁴

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 (Official Journal L 31 of 1.2.2002, 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 (Official Journal 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 (Official Journal 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 (Official Journal L 226 of 25 June 2004, p. 22);
- 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 (Official Journal 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 dioxines).

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 performance²⁵:

²⁴ 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.

²⁵ General guidance on EU import and transit rules for live animals and animal products from third countries: http://ec.europa.eu/food/international/trade/guide_third-countries2009_en.pdf

- (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.
- (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.

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.²⁶

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

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).

On the contrary, the EU food law requires mandatory submission of information with respect to:

- Residues of veterinary medicinal products and other pharmacological active substances used to treat animals
- · Zoonotic diseases.

3.5. Registration of food establishments

With regard to food of animal origin, in most cases only products from establishments (including factory and freezer vessels) that appear on a list approved by the Community can export to the EU. That system has not been changed and exports of food of animal origin may therefore continue to be organised as before 1 January 2006.

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.

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).

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.

²⁶ Commission Regulation (EU) 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.

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.

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.

4. National implementation and establishment of competent authorities within the EU

4.1. Introduction

Regulations and directives in the framework of the General Food Law have to be transposed into national legislation of individual EU Member States regarding enforcement, sanctioning and the designation of the competent authority. Regulations are imposed directly on countries and need no further interpretation, while directives may be implemented according to national policies.

In recent years many countries in the European Union have chosen to establish a National Food Safety Authority to contribute to higher food safety standards and more effective food safety control. The responsibilities and tasks of the national competent authorities are quite different in any Member State, provided that any Member State complies with the common general principles. In some countries their mandate is limited to risk assessment and scientific advice to the Government. In other cases their mandate includes risk communication and enforcement of food control regulations.

To show how different member states may work out the common general principles, the situation in two member states (Italy and The Netherlands) is described in the following paragraphs.

4.2. Examples of national competent authorities in Europe

4.2.1. Italy

National legal framework

Italy has set up rules on official controls and established the competent authority by D.lgs. 6 Novembre 2007, n. 193 (Attuazione della direttiva 2004/41/CE relativa ai controlli in materia di sicurezza alimentare e applicazione dei regolamenti comunitari nel medesimo settore), enhancing Directive 2004/41/CE on controls in food safety and applying the CE regulations in the same sector.

Competent Authority

According to Art. 2 of the above mentioned D. lgs. 193/2007, the competent authorities in carrying out official controls are organized according to the principle of delegation of powers and in line with the constitutional principle of subsidiarity, and namely:

- 1. Ministry of Health
- 2. Regions and Provinces
- 3. Local health units, within their respective competences

The same authorities are also competent in the general area of veterinary public health and of veterinary police for "ordinary measures" in the field of veterinary public health and veterinary police, In case of emergency, specific competence is also attributed to the municipal statutory authority.

At the central level the Ministry of Health (MoH) is the central competent authority (CCA) which has overall responsibility for official controls.²⁷ At the regional level the Regional Public Health Services (RPHS) co-ordinates and undertakes detailed planning of the instructions received from the central level. The operational work is carried out by the Local Health Units (AUSL).²⁸

²⁷ In the official publication on food offices for Italy 'Istituto Superiore di Sanit" has been mentioned as the Competent Authority. But the institute is a part of the Ministry of Health.

²⁸ Final report of a specific audit carried out in Italy, from 04 to 12 October 2010: http://ec.europa.eu/food/fvo/last5_en.cfm?reptoshow=4&co_id=IT

Within the Directorate General for Food Safety and Nutrition (DGFSN) several offices carry out different actions. Office II is responsible for General Food Hygiene which includes official controls in the area of food of non animal origin.

Although Air and Sea Health Offices are under the supervision of Office III of the Directorate General for Sanitary Prevention, for activities related to food additives and food contact materials instructions are provided by Office II.

Office VI is responsible for Food Technology and Hygiene which includes activities in the field of food contact materials and food additives.

Office VIII is responsible for food chain control systems plans and management of Rapid Alert system Food and Feed (RASFF).

Within the Directorate General for Animal Health & Veterinary Medical Products (DGAHVM) Office IX deals with audit.

At the regional level the Region Public Health Services (RPHS) co-ordinates and undertakes detailed planning of the instructions received from the central level. The 19 regions and two autonomous Provinces have responsibility within their territories, for planning, co-ordination, guidance, authorisation and verification of controls.

The operational work is carried out by the Local Health Units (AUSL) which are public bodies responsible for the organisation and management of all public health services at the local level. They have a high degree of managerial, administrative, financial and technical autonomy. There are 195 AUSL in total in Italy.

There are two units dealing with Food Safety: the Hygiene and Nutrition Services (SIAN) which is responsible for food of non animal origin and the Local Veterinary Service (LVS) which is responsible for food of animal origin.

The Police for Health (NAS) are a special branch of the Carabinieri which operate under the supervision and direction of the MoH. The NAS are responsible for investigations and controls on tainting of foodstuffs, fraud and illegal trafficking of medicines. Their food safety inspection activities are generally triggered by a suspicion of fraud or other criminal activity and account for 50% of their work.

There are twelve Air and Sea Health Offices along with 37 territorial units which are located at the main ports and airports. They are responsible for controls on imported food of non animal origin and food contact materials.

Relations between the State and Regions are managed through the State-Region Conference. The State-Region conference is composed of the Presidents of all Regions and deals with the political, technical and co-ordination aspects of food safety. It meets 15-20 times per year.

In addition there is an Inter-Regional committee on Food Safety in which MoH's DGFSN takes part by invitation. This committee is assisted by technical working groups. These meetings occur approximately ten times per year. The outcome of the Inter Regional Committee is formally adopted by the State / Region Conference.

The IZS is a network which covers the whole national territory and is composed of 10 head offices located in the cities of Brescia, Foggia, Padua, Palermo, Perugia, Portici (Naples), Rome, Sassari, Teramo and Turin and over 90 diagnostic sections present in almost all Italian provinces.

The network of IZS laboratories has generic accreditation since 1998 by SINAL (now merged into one accreditation body for Italy, ACCREDIA). The MT visited the IZS in Piemonte which is the designated official laboratory for chemical analysis of FAO and the microbiological analysis for all types of food.

The ARPA is a network of regional laboratories coordinated by the regions and by 'Istituto Superiore per la Protezione e la Ricerca Ambientale' (the National Institute for Environmental Protection and Research). It belongs to a network system known as the Environmental Agency System. In Italy, there are currently 21 ARPAs.

The laboratory is also accredited to EN ISO 17025 since 1998.

➤ Istituto Superiore di Sanità

ANALYS OF STATES

The Istituto Superiore di Sanità²⁹ (National Institute of Health) in Rome is the leading technical and scientific public body of the Italian National Health Service. Its activities include research, control, training and consultation in the interest of public health protection.

An important activity of the Institute, which is mandated by the Minister of Health or the Regions, is certification of the chemical and biological purity of drugs and vaccines, as well as inspection and quality control of medical and diagnostic devices and equipment, food products and packaging. It also supervises the laboratories engaged in the testing of prohibited substances in sport and the national veterinary institutes.

The institutes includes various departments, including the department of Food Safety and Veterinary Public Health.

The mission of the Department of Food Safety and Veterinary Public Health is to protect human health and welfare through the development of knowledge, tools and strategies for preventing and controlling animal diseases and improving food safety.

The Department's research objective is the development of tools and strategies to prevent and control animal diseases - with special reference to zoonoses - in order to reduce the risks to humans and improve the safety of food of animal origin. Specific fields of investigation are:

- The pathogenesis and epidemiology of zoonoses (with special reference to food-transmitted diseases): the study of virulence in micro-organisms and the hosts' immune response; the development of standard and molecular diagnostic methods; the monitoring of antibiotic-resistance.
- Transmissible Spongiform Encephalopathies (TSEs): studies of their pathogenesis and characterisation of strains; investigations into the molecular bases of the species barrier and the zoonotic potential of animal TSEs; the genetic factors involved in susceptibility/resistance to TSEs and the development of strategies for control and eradication.
- The collection of epidemiological information related to food safety and animal health: the collection and analysis of data on pathogens responsible for food-transmitted diseases; the development of tests for the assessment of animal welfare as an epidemiological marker of food safety and animal health; studies of the safety of food of animal origin and of chemical residues; metabolic studies of animals exposed to xenobiotics and drugs; by-products of the food industry. Development of analytical methods for the identification of chemicals in food.
- Nutritional pathologies: studies of the prenatal role of nutritional factors in neurodegenerative processes; obesity-inducing factors; food disorders caused by genetic factors, with special reference to coeliac disease.

Furthermore, long-term national plans on official controls have been approved and updated. The national plan for 2011-2014 identifies the following strategic objectives, in line with the European legislation on official controls:

- 1. Protection of consumer health
- 2. Contrast of environmental contamination, in relation to agro-livestock
- 3. Defense of national production
- 4. Protection of human health and animal welfare

The strategic goals shall be implemented by the respective public administrations, within their respective jurisdiction, in accordance with the following operational objectives:

- 1. Strengthening of controls in key productive sectors (Made in Italy): cheese, wine, oil, meats, etc., aimed at verifying compliance with the requirements of food safety and quality;
- 2. Control of foods marketing through non conventional channels (such as e-commerce);

29 See general: http://www.iss.it/chis/?lang=2

- 3. Intensification of the coordination between the competent administrations in order to optimize the planning and programming of research activities of contaminants in food with the environmental monitoring, comparative analysis of the results and identification of possible interconnections;
- 4. Creation of a single integrated system of epidemiological surveillance networks that allows to provide useful governmental information and to adequately support policies of risk assessment and risk management;
- 5. Improvement of animal welfare controls
- 6. Training activities that promote the objectives of improving the quality of the production processes of health activities and health systems.
- 7. System information improvements for intra-Community trade in veterinary goods to encourage the simplification of administrative activities

In this regard, the competent authorities, including the offices of the Ministry of Health, shall cooperate in specific joint plans of action, that will be included in the Annual National Program document and reported in an Annual Report in order to monitor the level of achievement of objectives.

The ISS also hosts the European Union Reference Laboratory for Chemical Elements in Food of Animal Origin, the reference laboratory for parasites and the reference laboratory for Escherichia coli.

Organization and management of a national audit system

The national audit is a cascade system between the Competent Authorities (Ministry of Health, Regional and Local Health Authority) appointed by Decree 193/2007. The Department of Veterinary Public Health, Nutrition and Food Safety (DSVET) of the Ministry of Health carries out audits on regional food safety and prevention. The Regions carry out local audits on Local Health Units (ASL). The audits are considered internal within the National Health System and they are conducted by auditors with an extensive knowledge of the competent authorities and specific experience in the field of food safety and veterinary public health. The audits are designed specifically to verify that the objectives of Regulation n.882/2004 have been achieved, ensuring in particular:

- a) whether the activities and their related results comply with the planned arrangements;
- b) whether the standards are effectively implemented;
- c) whether the "plan arrangements" (Art. 4 (6) are adequate to achieve the objectives of official controls.

4.2.2. The Netherlands

➤ National Legal framework

In the Netherlands most legislation concerning food has been laid down in "de Warenwet". Furthermore rules for hygiene and supervision, including sample taking at farms and breeding stations are stated by the Product Boards, like the Boards on cattle and meat, fishery, poultry and eggs, farming (including wine) and animal feed.

Competent Authority

The Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel en Waren Authoriteit) has been appointed Competent Authority for food, feed and commodities.

The domestic statutory framework for the NVWA is:

- the Health Act/Inspectorate Act
- the Independent Risk Assessment (NVWA) Act
- the Commodities Act
- the Rendering Act
- · the Agriculture Act
- the Experiments on Animals Act
- the Pesticides Act 1962
- · the Hazardous Substances Act
- · the Licensing and Catering Act
- the Tobacco Act
- the Veterinary Medicines Act
- the Animal Health and Welfare Act
- the Agricultural Food Choice and Quality Act
- the Nuclear Energy Act

The Dutch NVWA is a single organisations that performs all task's as required by the EU legislation in the whole country: Inspection, sample taking, microbiological and chemical analysis, administration, communication, registration and often even punishment (warnings and administrative fines) in case of non compliance of inspection or sample results. Headquarters is domiciled in Utrecht, the centre of the Netherlands. Most laboratory activities on microbiology and chemistry will been centralized in the near future in Wageningen. In many places in the country, annexes have been established for inspector's administration and certification.

In many places in the country, annexes have been established for inspector's administration and certification. A wide system of education, standard procedures and checks care for high standing and equal quality of staff and labour.

> Task of the Competent Authority

The task of the NVWA is to protect human and animal health. It monitors food and consumer products to safeguard public health and animal health and welfare. The Authority controls the whole production chain, from raw materials and processing aids to end products and consumption.

The Netherlands Food and Consumer Product Safety Authority is an independent agency in the Ministry of Economic Affairs, Agriculture and Innovation and a delivery agency for the Ministry of Health, Welfare and Sport.

The three main tasks of the Netherlands Food and Consumer Product Safety Authority are: supervision, risk assessment and risk communication. Other important activities are incident and crisis management and policy advice for the Minister of Agriculture, Nature and Food Quality. A significant part of its work involves liaising with other ministries. Maintaining international contacts (EU's rapid alert systems: RASFF and RAPEX) is also of vital importance.

More in detail the NVWA deals with the following subjects:

- · Registration of production plants,
- · Animal health (prevention),
- Animal health (combating diseases),
- · Animal welfare,
- · Residues of animal drugs and antibiotics,
- · Food safety in slaughterhouses and meat processing industries,
- · Manure procedures,
- · Plant protection,
- · Nature reserve,
- Phytosanitary safeguarding,
- · Food safety industrial processing of foodstuff's,
- · Particular nutrition,
- Animal feed.
- · Animal by-products,
- · Fishery and trade,
- Food safety small enterprises, retail and institutions,
- · E-commerce,
- · Alcohol and tobacco,
- · Safe non-food products,
- Import of food and food products and non-food products,
- Export of food and food products and non-food products.

Supervision and enforcement

The enforcement's strategy follows the idea of voluntary compliance with legislation by premises, institutions and consumers. The NVWA's attitude with regard to premises and consumers is characterized by the principle of trust, unless... The NVWA uses risk approach, based on knowledge, collaboration with the different food sectors and affecting of conduct of enterprisers.

The used enforcement methods are:

- · Community services,
- Enforcement communication,
- · Horizontal supervision,
- Repressive supervision,
- · Track tracing or hunting down.

The choice for one or more methods depends on the sector or the company that must be supervised.

The NVWA elaborates on a variable approach on target groups. Depending on the risk's, compliance behaviour and developments in the sector, a suitable enforcement method will be selected.

Plans for development of supervision and enforcement are laid down in a long-range plan (4 years). From this long-range plan a yearly plan is set up for supervision, based on risk analysis and results in former years.

Based on this condition the NVWA classify all premises in 3 categories:

- Good reliable premises that hardly need supervision (green)
- Good willing premises that need regular supervision (orange)
- · Unwilling premises that need intensive supervision (red)

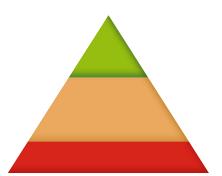


Figure 1. Pyramid of supervision

Premises are classified green if all relevant inspection subjects are judged positive. This inspection subjects are: hygiene, temperature control, constructional conditions of processing rooms, pest control, quality of raw materials, storage and cooling conditions, heating and cooling processes, cross contamination, storage and transport conditions.

The supervision pyramid is a bonus/malus system. Premises in the red sector that get a positive score at the coming inspection will move to the orange sector.

Premises in the orange sector that deserve 3 fine's in 2 years automatically drop to sector red.

A lot of premises are part of large companies. This premises all have to obey the quality system of this company (for example: a retailer sometimes encloses hundreds of almost identical shops). If the quality system ensures that all shops comply with legal requirements, it is not necessary the inspect all these shops. For this kind of enterprises the NVWA start with an theoretical investigation at headquarters to judge the quality of the company's system. After that a random check is performed in the arbitrary selected shops, to check if the quality system is working in practise. Results of these inspections are published on the website of the NVWA.

Also private food systems play a role in judging the "green status" of a company. The NVWA has decided premises adopting self control private food systems that have been proven to perform very reliable audits and are willing to cooperate with the NVWA (being transparent on data information) automatically get the "green status", unless there are circumstances that prove the company has problems in spite of the quality system.

➤ Delegation of tasks

Not all of the tasks are performed by the NVWA themselves:

- Supervision on production of milk and milk product has been delegated to the Netherlands Controlling Authority for milk and milk products (COKZ).
- Supervision on poultry and eggs has been delegated to Stichting Controlebureau voor Pluimvee, Eieren en Eiproducten.
- Supervision on trade norms, quality of fish, shrimps, and crustaceans and the catching areas of bivalve molluscs

These institutions are mandated by the responsible ministries to drawn up special laws on safety and quality of certain product and are also authorized to enforce these laws, under supervision of the NVWA.

> Office for Risk Assessment

The Food and Consumer Product Safety Authority (NVWA) is an agency of the Ministry of Agriculture, Nature and Food Quality (LNV). Its organisation, remit and procedures are laid down in a ministerial decree. In addition to supervision and enforcement the NVWA is responsible for risk assessment and coordinating research.

These two tasks are assigned to the NVWA Office for Risk Assessment. The Office assesses risks and provides independent and scientifically based advise concerning potential threats to food and product safety. It also advises on animal health and welfare where they impinge upon food safety or public health. Pro-active risk assessment, targeting future risks, is a strategically important component of the Office's duties. The 2006 Independent Risk Assessment Act regulates the independent implementation of these tasks and independent position of the Office within the VWA.

The Office provides solicited advise or unsolicited, on its own initiative. Requests for advise may come from government departments, the NVWA, the European Food Safety Authority (EFSA) and sister agencies in other Member States. The Office also provides scientific support to other divisions within the NVWA. The Office also issues advise as it sees fit, or in response to concerns in society.

The advises are classified in accordance with relevant societal developments:

1. Climate change

Impact of (micro and macro) flora and fauna on food safety.

2. Demographic trends and impact of age on risks

Impact of demographic change due to ageing and migration and the special situation of children and elderly.

3. Socio-cultural trends

Impact of changes in lifestyle and behaviour; individualisation and segmentation of society and antisocial behaviour.

4. Globalisation

Decline in transparency in production chains due to increasing movement of goods, people and animals.

5. Changes in production and processing

Impact of production and processing based on new technologies, such as genetic modification, decontamination, nanotechnologies, and, on the other hand, the desire for nostalgic and traditional products.

6. Aiming for sustainability and ethical production

National Reference laboratory

(RIVM) in Bilthoven is a national and international reference laboratory for food is the National Institute for Public Health and Environment.³⁰

As a research institute and centre of expertise, RIVM advises and supports policy-makers and professionals in their respective fields of work.

The institute's results of research, monitoring, modelling and risk assessment are used to underpin policy on public health, food, safety and the environment. The RIVM reports both positive and negative aspects of certain foods to the Ministry of Health, Welfare and Sport in the Netherlands.

The RIVM also supports the Food and Consumer Product Safety Authority (VWA) by taking measures to combat food borne infections. Considerable information has also been collected for the non-professionals in all these areas. RIVM employs over 1500 employees, many of whom work in multidisciplinary fields.

RIKILT - Institute of Food safety³¹ is an independent research organisation in the field of food and feed safety and health. The institute advises the Dutch and foreign governments on standard violation, incidents and critical situations. RIKILT also supports governments with advice on the elaboration of standards and guidelines, and on the authorisation of new agricultural additives and foodstuffs of vegetable and animal origin.

An important part of this research concerns the Statutory Research Tasks carried out for the Dutch Ministry of Economic Affairs, Agriculture and Innovation (EL&I) and the Dutch Food and Consumer Products Safety Authority (NVWA).

RIKILT is a National Reference Laboratory (NRL) responsible for assuring the quality and reliability of the laboratories which carry out the official controls in a country within the framework of the European foodstuffs and animal feeds legislation.

The tasks of RIKILT include: coordinating the activities of the national laboratories, standardisation of analytical methods, developing new methods and organising comparative tests between the national laboratories (proficiency tests).

RIKILT currently has 19 NRL tasks in various areas including dioxins & PCBs, PAH compounds, heavy metals, mycotoxins, marine biotoxins, residues in animal products, animal proteins, feed additives, milk and milk products, GMOs, and water content in poultry meat.



Handbook Topics

- 1 Food Safety System
- 2 Regulations and Standards
- 3 Risk Assessment
- 4 Training Methods
- 5 Risk Communication
- 6 Self-Assessment Systems
- 7 Traceability and Labelling
- 8 Management of Laboratories
- 9 Procedures
- 10 Animal By-Products
- 11 Product Registration
- 12 Official Controls







