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**EUROPEAN FOOD SAFETY CONTROLS SYSTEMS:
NEW PERSPECTIVES ON A HARMONIZED LEGAL BASIS**

*(Paper prepared by the Ministry of Agriculture, Nature and Food Quality and
the Food and Consumer Product Safety Authority of the Netherlands)*

1) Introduction

Effective food control systems are essential to protect the health of consumers. They are also vital in enabling countries to assure safety and quality of food products for international trade and to verify that imported food products meet national requirements. The legal framework for food safety in the European Union Member States is currently in process. Serious food safety incidents during the nineties urged the European Union and other countries across the world to review their food safety systems and to look for better ways to protect consumers against unsafe food. In 2000 the European Union launched its **White Paper on Food Safety** as a start for a new legal basis for appropriate food and animal feed production and food safety control. The **Codex Alimentarius Commission** continues to develop international standards, guidelines and recommendations to reduce food safety risks. The Codex Alimentarius developed risk analysis, the integrated food chain approach and HACCP. The **risk analysis paradigm**, including risk assessment, risk management and risk communication have been incorporated as general principles in EU law and form the legal basis of the food safety systems in the Member States.

In the White Paper of the EU the entire food production chain (including animal feed) is held responsible for the safety of food. The Governments of the Member States verify that this responsibility is adequately met by the producers to protect the health and well-being of consumers. The document contains 84 action points that have to be processed into community law to strengthen the food safety systems of the Member States. Within this framework, the EU introduced the **General Food Law** in 2002, defining general food safety principles and food safety procedures. Once this Regulation was in place, the **European Food Safety Authority** was set up. This organization started its activities in 2003, by focusing on risk assessment and scientific advice in the field of food safety questions. The White Paper has helped to strengthen and synchronize hygienic conditions and practices throughout all the EU Member States. This year an integrated **EU Hygiene Package** was completed in which the existing rules on hygiene were incorporated.

The European Union has established a specific legislation to harmonize official control procedures in the Member States. It also regulates the provisions that countries outside the EU should fulfil for entering the EU markets with their food products. Although control procedures are largely harmonized, the structure and set-up of control organizations is quite different across the European Union. The variety in national political and economical conditions have led to differences in the way Community legislation was transposed in national law and in operational systems for food production and inspection. Therefore, there is a large variety of food safety **control systems** throughout the Member States. In certain countries the responsibility of food control is decentralized and mandated to regions or provinces, whereas in other countries food safety control is in the hands of just one central

organization. In recent years many countries in the European Union have established a **National Food Safety Authority**. Again, the responsibilities and tasks of this organization may vary from one country to another. The main task is usually enforcement of food control regulations, but **risk assessment** and scientific advice, and **risk communication** are also often included.

Risk management remains basically a prime responsibility of governments to protect consumers against food safety hazards. Risk management is based on risk assessment and scientific evidence, but also other aspects of food production could be taken into consideration like environmental protection and animal welfare. An effective food safety management system may be a combination of direct governmental supervision based on food safety requirements prescribed by law and private food safety control systems. **Certification** of production processes by accredited organizations may help producers to reduce risk levels and to convince Governments and consumers of the safety and quality of their produce. The confidence of consumers strongly depends on the quality of the certification body. In many western countries the private sectors have established their own additional quality requirements and certification schemes for specific product groups. These non-official requirements may improve certain quality aspects of products, but such higher demands may also hinder the access of businesses to markets. All European Union legislation and other related information can be found at website: <http://europa.eu.int/eur-lex/>.

2) **The EU White Paper on Food and Feed, principles of food control**

White papers are documents containing proposals for Community action in a specific area. They sometimes follow a green paper published to launch a consultation process at European level. While green papers set out a range of ideas presented for public discussion and debate, white papers contain an official set of proposals in specific policy areas and are used as vehicles for their development.

Assuring that the EU has the highest standards of food safety is a key policy priority for the European Union. The White Paper on Food Safety reflects this priority. A radical new approach has been proposed. This process is driven by the need to guarantee a high level of food safety. Greater transparency at all levels of food safety policy is the thread running through the whole White Paper and will contribute fundamentally to enhancing consumer confidence in EU Food Safety policy.

The writing of a white paper on food safety was mainly driven by events and developments during the 1990s. The well-known dioxin and BSE crises have led to a whole new approach of risk management. The risks associated with the contamination of foods were brought into sharp focus by the dioxin crisis. Steps will be taken to address those areas where existing legislation needs to be improved to provide adequate protection. But also developments in the rulemaking process have led to new ways of dealing with food safety control. The experience of the Commission's own Food and Veterinary Office, which visits Member States on a regular basis, has shown that there are wide variations in the manner in which Community legislation is being implemented and enforced. This means that consumers cannot be sure of receiving the same level of protection across the Community, which makes it difficult to evaluate the effectiveness of national measures.

The White Paper proposes that, as a general principle, all parts of the food production chain must be subject to official controls. Responsibility for safe food production and control is shared between operators, national authorities and the European Commission. Operators are responsible for compliance with legislative provisions, and for minimizing risk on their own initiative. National authorities are responsible for ensuring that operators respect food safety standards. They need to establish control systems to make sure that Community rules are being respected and, if required, enforced. To ensure that these control systems are effective, the Commission, through the Food and Veterinary Office (FVO), carries out a programme of audits and inspections. These controls evaluate the performance of national authorities against their ability to deliver and operate effective control systems, and are supported by visits to individual premises to verify that acceptable standards are actually being met.

One of the action points in the White paper is to develop a regulation on official food and feed safety controls. Earlier this year Regulation 882/2004/EC (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) was published. This Regulation sets a Community framework of national control systems, which will improve the quality of controls at Community level, and consequently raise food safety levels across the European Union. The operation of such control systems remains a responsibility of the individual Member States.

3) **The EU General Food Law, the legal basis of European Union food control**

An important need mentioned in the White Paper was to create a coherent and transparent set of food safety rules. With the publication of the General Food Law (GFL), the European Union has made a new legal framework laying down the principles to ensure a coherent approach and to fix the principles, obligations and definitions that apply in the field of food safety. It defines the common principles underlying food legislation and the establishment of a food safety policy as a primary objective of EU food law. This Regulation also provides the general frame for those areas not covered by specific harmonized rules but where the functioning of the Internal Market is ensured by mutual recognition. Under this principle, in the absence of Community harmonization, Member States may only restrict the placing on the market of products lawfully marketed in another Member State when and to the extent that this can be justified by a legitimate interest such as the protection of public health and only when the measures taken are proportionate.

The General Food Law consists of three parts. The first part lays down the general principles and requirements of food legislation, the second part defines the establishment of the European Food Safety Authority and the last part lays down procedures in matters of food safety. Let us focus on the first part.

A general principle of food law is that operators in the feed and food business have the **primary responsibility** for food safety. Competent authorities monitor, enforce and verify this responsibility through the operation of national surveillance and control systems at all stages of production, processing and distribution. Member States are also obliged to lay down rules on measures and penalties applicable to infringements of food and feed law. They shall be effective, proportionate and dissuasive. The Commission concentrates on evaluating the ability of competent authorities to deliver these systems through audits and inspections at the national level.

A successful food policy demands the **traceability** of feed and food and their ingredients. This is an important requirement of the GFL. It includes the obligation for feed and food businesses to ensure that adequate procedures are in place to recall products that might pose a possible health risk. Operators should also keep adequate records of suppliers of raw materials and ingredients so that the source of a problem can be identified.

4) **National implementation of the General Food Law**

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. For instance, in the national implementation of the General Food Law the penalties must be laid down to be applied if an operator does not have an adequate traceability system and the competent authorities for inspections and controls.

National implementation of EU law must fit into national structures, such as centralized and decentralized control structures. Therefore most EU food safety legislation focuses on criteria and procedures rather than on detailed regulations for control.

In addition to the legal implementation of EU legislation it is also necessary to put a national performance policy in place and to explain the meaning of this policy to the public. This process may give rise to questions that must be checked with other EU Member States and the European Commission.

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. These authorities comply with the requirements of the General Food Law but their establishment has never been obligatory. The responsibilities and tasks of these organizations may be quite different per Member State. 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. Risk management tasks are usually kept in the hands of the responsible ministries.

5) Food safety control policies in the EU and its Member States

5a) General framework and coverage

Feed and food should be safe and wholesome. European Community legislation comprises a set of rules to ensure that this objective is attained. These rules on hygiene and safety extend to the production, processing and the introduction of food products on consumer markets.

The basic rules with regard to feed and food law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, often referred to as the “General Food Law”. This law lays down the general principles and requirements of food legislation, the establishment of the European Food Safety Authority, and procedures in matters of food safety.

In addition to these basic rules, more specific feed and food laws cover different areas such as animal nutrition including medicated feeding stuffs, feed and food hygiene, zoonoses, animal by-products, residues and contaminants, control and eradication of animal diseases with a public health impact, feed and food labelling, pesticides, feed and food additives, vitamins, mineral salts, trace elements and other additives, materials in contact with food, quality and compositional requirements, drinking water, ionization, novel foods or genetically modified organisms (GMOs).

5b) Food safety responsibilities

Community feed and food law is based on the principle that feed and food business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that products and manufacturing processes satisfy the requirements of feed and food law which are relevant to their activities.

This principle of placing the main responsibility on producers can only work adequately, when effective and efficient government controls are in place. As a consequence all relevant information on the application of process controls, essential for safe food production, should be fully available for government control purposes. The same applies to information that is of importance for proper traceability.

The EU-Members enforce feed and food law and monitor and verify that the relevant requirements of law are fulfilled by business operators at all stages of production, processing and distribution. Official controls should be organized for that purpose.

The organization of the official controls differs to a large extent throughout the European Union, as a result of different historical backgrounds and traditions. The differences vary from a completely centralized system (the Netherlands, Denmark, Belgium) to decentralized systems where the competent

authorities are working according to a regional (Spain, Germany) or local system (United Kingdom, Ireland).

5c) Harmonization and coherence

To achieve equivalent official feed and food control systems across Member States, the European Commission has chosen to establish a harmonized framework of general rules at Community level for carrying out such controls. For this reason Regulation No. 882/2004/EC on the official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and Regulation No. 854/2004/EC laying down specific rules for the organization of official controls on products of animal origin intended for human consumption have recently been adopted.

5d) National implementation and Community verification

In order to have a global and uniform approach with regard to official feed and food controls, EU Member States must establish and implement national control plans in accordance with broad guidelines elaborated at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. After developing these guidelines a Community strategy for a comprehensive, integrated approach to the operation of controls can be reached. Moreover, 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:

- the results of the official controls and audits carried out during the previous year and,
- 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.

Eventually Community controls in the EU-Member should allow the Food and Veterinary Office to verify whether feed and food law, and the legislation on animal health and animal welfare are implemented in a uniform and correct way throughout the European Union.

5e) Imported goods

Regulation 882/2004/EC gives rules for the official control on the import of products from third countries. For this reason, Community controls in third countries are required in order to verify compliance or equivalence with Community feed and food law. Third countries may also be requested to establish control plans similar to those intended for Member States, in respect of the feed and food exported by them. These plans, which must be established on the basis of Community guidelines, should form the basis for subsequent Commission controls, which should be carried out within a multidisciplinary framework covering the main sectors exporting to the Member States. This development should allow a simplification of the current control regime, enhancing effective control co-operation, and consequently facilitating trade flows.

To help developing countries in setting up official feed and food control systems equivalent to the control systems in the European Union, it is appropriate to identify and consider the special needs of those countries. The EU is committed under Regulation 882/2004 to support developing countries with regard to feed and food safety, which is an important element of human health and trade development.

Besides this Regulation, there is a specific Regulation No. 854/2004/EC for the organization of official controls on products of animal origin intended for human consumption. The purpose for a specific official control procedure for these products is that specific sanitary rules must be complied with here (Regulation No. 853/2004/EC).

The Member States are aware of the need to harmonize control procedures of imported goods across the European Union. There is a need for setting detection limits of certain residues in food products in order to facilitate uniformity of procedures and sanctioning at all European border posts.

6. Organization of official feed and food control according to European legislation

6a) General requirements

A EU Member State must designate competent authorities to carry out official controls. If a Member State has different competent authorities, it must ensure efficient and effective coordination between these authorities. To harmonize the verification of compliance with legislation, specific operational criteria are prescribed. Thus competent authorities must:

- ensure their impartiality and effectiveness;
- have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly;
- carry out the official controls using appropriate techniques developed for that purpose, including routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples;
- establish regular frequency of official controls proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or Quality Assurance Programmes, where these are designed to meet requirements of feed and food law;
- carry out ad hoc controls where businesses are suspected of non-compliance with feed and food law;
- carry out official controls on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of consistent high quality;
- ensure that laboratories involved in the analysis of official samples work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have as far as possible been validated;
- ensure that adequate financial resources are available for organizing official controls. Where for that purpose fees are imposed on feed and food business operators, common principles should apply;
- with regard to fees applicable for import controls, establish directly the rates for main import items with a view to ensuring their uniform application and to avoid trade distortions;
- Breaches of feed and food law may constitute a threat to human health, animal health, and animal welfare. Such breaches should therefore be subject to effective, dissuasive and proportionate measures at national level throughout the Community and must include administrative action by the competent authorities in the Member States who should have procedures in place for that purpose;
- Legal persons/corporations should also be subject to effective, dissuasive and proportionate penalties, because breaches of Community law to a large extent are committed in the interest of legal persons/corporations or for their benefit;

- Feed and food business operators must have a right to appeal against the decisions taken by the competent authority as a result of the official controls, and be informed about such right.

6b) Specific requirements

With regard to the official controls on products of animal origin more specific requirements have to be met. These requirements concern:

- the approval of production establishments;
- the check of certain aspects and features;
- the role of the official veterinarian and official auxiliaries;
- the introduction of specific requirements for different types of products of animal origin.

The new legislation specific for products of animal origin is mainly based on pre-existing traditional "veterinary" rules, while at the same time new HACCP rules are coming into force. Whether these two quite distinct legislative approaches go well together has not yet been clearly documented. The traditional veterinary approach is labour intensive and relatively costly however, it does not seem to be scientifically based in all cases, nor focused on the most relevant human health risks.

7) The role of private food control systems

7a) General remarks

Private control systems have an important impact on the food safety systems as a whole. They can be divided into two different types:

- Private control on official standards and procedures;
- Private control on private criteria and quality schemes.

The first type may be helpful for governmental control bodies and for companies to meet standards. In this case the government verifies that the private controls and control bodies are reliable. Accreditation of certifying control bodies is a usual method for reliable verification. Internal control systems in production facilities, such as an (obligatory) HACCP system, may play an important role in the reduction of food safety risks.

The private sector may also require criteria and quality standards from their suppliers, not based on official standards. These non-official requirements are meant to further strengthen the confidence of consumers. In responding to the demands of consumers, retailers and their global suppliers have created and implemented a series of sector specific farm certification standards in the EUREPGAP quality schemes. The aim is to ensure integrity, transparency and harmonization of global agricultural standards. This includes the requirements for safe and high quality food, respect for workers' health, safety and welfare, and environmental and animal welfare issues.

7b) The International Standardization Organization (ISO)

Regulation 882/2004 states that the frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or Quality Assurance Programmes, where these are designed to meet requirements of feed and food law. At present ISO is working on a specific standard on food safety management system (ISO 22.000). This international standard specifies requirements for a food safety management system in the food chain where an organization needs to demonstrate its ability to control food safety hazards in order to consistently provide safe final products. These both meet agreed customer and applicable regulatory food safety requirements, and aim to

enhance customer satisfaction through the effective control of food safety hazards, including processes for updating the system. This international standard specifies requirements to enable an organization to:

- plan, design, implement, operate, maintain and update a food safety management system aimed at providing final products that, according to their intended use, will ensure that the food, when eaten, is safe for the consumer;
- evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety;
- demonstrate effective communication with customers and other interested parties across the food chain;
- demonstrate conformity with applicable regulatory requirements as regards food safety;
- assure that it complies with its stated food safety policy;
- demonstrate such compliance to other interested parties;
- seek certification or registration of its food safety management system by an external organization.

All requirements of this international standard are generic and intended to be applicable to all organizations wishing to design and implement an effective food safety management system, regardless of type, size and product provided. This includes organizations directly involved in one or more steps of the food chain (for example, but not limited to feed producers, farmers, producers of ingredients, food producers, retailers, food services, catering services, organizations providing cleaning, transportation, storage and distribution services) and other organizations indirectly involved with the food chain (such as suppliers of equipment, cleaning agents and packaging material and other food contact material). ISO 22000 follows the structure and approach of ISO 9001 on quality management and integrates this with food safety on the basis of HACCP, developed by the Codex Alimentarius Commission.

7c) Verification of delegated control activities

In premises where adequate and effective control systems exist, the frequency of official inspections may be diminished. Private control systems, like certification bodies, may help the competent authorities to perform their control tasks. However, it is important that the competent authorities actively verify the quality of those organizations and their activities. The Regulation gives the possibility that competent authorities delegate tasks to external control bodies under strict conditions. The main restrictions include:

- external control bodies cannot impose sanctions, which means that in case a control body finds non-compliance they should warn the competent authority;
- external control bodies should carry out their tasks in line with the description and conditions laid down;
- external control bodies should have the expertise, equipment and infrastructure required to carry out the tasks delegated to them;
- external control bodies should have sufficient numbers of suitably qualified and experienced staff;
- external control bodies should be impartial and free from any conflict of interest as regards the exercise of the tasks delegated to them;
- external control bodies should work and be accredited in accordance with European Standard EN 45004 “General criteria for the operation of various types of bodies performing inspection”;
- there should be efficient and effective co-ordination between the delegating competent authority and external control bodies.

Competent authorities that delegate tasks to external control bodies are obliged to organize audits. When repeated non-compliance is found and external control bodies fail to take appropriate and timely remedial action their tasks will be withdrawn without delay.

8) The European Food Safety Authority

Following a series of food safety crises in the 1990s (e.g. BSE, dioxins) which undermined consumer confidence, the European Union concluded that it needed to establish a new scientific body charged with providing independent and objective advice on food safety issues associated with the food chain. Its primary objective as set out in the White Paper on Food Safety would be to: "...contribute to a high level of consumer health protection in the area of food safety, through which consumer confidence can be restored and maintained". After the publication of the General Food Law this resulted in the establishment of the European Food Safety Authority (EFSA).

Set up provisionally in Brussels in 2002, EFSA provides independent scientific advice on all matters linked to food and feed safety - including animal health and welfare and plant protection - and provides scientific advice on nutrition in relation to Community legislation. The Authority communicates to the public in an open and transparent way on all matters within its remit. EFSA's risk assessments provide risk managers (consisting of EU institutions with political accountability, i.e. European Commission, European Parliament and Council) with a sound scientific basis for defining policy-driven legislative or regulatory measures required to ensure a high level of consumer protection with regards to food safety.

EFSA was born from Parliament and Council regulation (EC) No 178/2002 of 28 January 2002. The new Authority quickly found its feet, organizing its first Management Board meeting nine months later. Shortly afterwards it nominated its first Executive Director and created the Advisory Forum, made up of representatives from food safety bodies in the EU Member States. Momentum grew in 2003 as EFSA developed into a fully-fledged independent European Union agency. EFSA truly opened for business in May with the establishment of its Scientific Committee and Panels. World-class scientists from all over Europe were appointed to eight Panels, covering everything from food additives to animal health, and to a Scientific Committee with oversight of these panels.

In July 2003 a Chair of the Scientific Committee, a Deputy Director General, a Director of Science and a Director of Communications were appointed; the first scientific opinion related to GMOs was published. By December last year, the Authority employed around 70 people and already had over 120 registered scientific questions with confirmed deadlines to address in its working programme.

Staff numbers are expected to double during 2004, as EFSA continues to expand and prepares to establish itself permanently in Parma, Italy. Overall capacity building will continue, enabling the Authority to meet working programme commitments including the significant expansion of both its scientific and communications activities as well as the development of its institutional, stakeholder and international relations.

EFSA is now dealing principally with requests for risk assessments from the European Commission and plans to take on a wider brief from other European institutions in the near future. Notwithstanding the important needs of its key customers, EFSA is already undertaking its own work in order to look ahead and address broader issues of importance to its mandate. For example, through such "self-tasking", the Authority's Scientific Committee has initiated work in relation to the identification of emerging food safety issues. Website: <http://efsa.eu.int/>

9) Future developments

The European Union will review and further elaborate the legislation mentioned in the White Paper in the field of animal feed, animal health and zoonoses, animal by-products, contaminants and additives, labelling, pesticides, healthy food, plant reproduction materials and international relations.

International agreements, such as SPS and TBT, and standards and guidelines of international organizations, like Codex Alimentarius, the World Organization for Animal Health (OIE) and the International Plant Protection Convention, will continue to have impact on policy processes in the European Union.

The European Union will develop a more harmonized approach to verify the effectiveness of the official controls in the EU as well in third countries.

In special cases, direct controls and inspections of food performed by Governmental bodies, may evolve to Governmental supervision over accredited control bodies. In the further development of food chain control, process control systems will further improve and checks of final products will lose importance, although not entirely.

10) Conclusions

1. Food operators are entirely responsible for the quality and safety of the food they produce and provide to consumer markets. Food safety legislation and control are meant to impose this responsibility and to verify that all policy conditions are adequately met;
2. Food safety legislation in the European Union Member States is largely harmonized under Community law. A new policy approach has been introduced after food scares in the 1990s. It is based on risk analysis and complies with principles of the SPS Agreement of WTO. Therefore it is closely connected to the standards, guidelines and recommendations developed by the Codex Alimentarius Commission;
3. The harmonization process has strongly reduced the former policy differences between individual Member States and contributed to higher transparency of the European Union importation system and consumer markets. Control procedures and sanctions however, have not yet been fully harmonized;
4. Harmonization of food control in the EU is based on specific criteria and not on control structures. There should be one specific template for an official control structure, which takes into account a country's historical backgrounds and economic circumstances. Official controls should be fitted to the national food safety framework;
5. Imported goods have to comply with the internal EU standards. Exporting countries with well-organized official control structures will meet the EU requirements more easily than countries without it;
6. For developing countries and economies-in-transition technical assistance and capacity building in the field of food legislation and control are valuable tools to enhance the international trade of safe and wholesome food products.