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THE GENERAL PRINCIPLES OF FOOD LAW IN THE EUROPEAN UNION

AND

THE EUROPEAN FOOD SAFETY AUTHORITY

CONFERENCE ROOM DOCUMENT PROPOSED BY THE EUROPEAN COMMUNITY

The General Principles of Food Law in the European Union

On 21st January 2002 the EU Council of Ministers agreed the last steps towards the adoption of a Parliament and Council Regulation setting up the European Food Safety Authority (EFSA) and laying down a new framework for Food Safety in the European Union. The new Regulation, which will be published in the Official Journal of the European Communities in early February also establishes the over-arching principles, definitions and requirements on which all future food law in Europe will be based.

Background

European food legislation has evolved over the last forty years reflecting a blend of scientific, societal, political and economic forces. Over this period, food legislation has had different policy objectives linked to the Common Agricultural Policy or the development of the Internal Market. Although inextricably linked with the establishment and maintenance of a high level of protection of human health, safety and of consumer protection, food law at the European level was characterised with some divergence in approach, some inconsistencies and even some lacunae. One of the key objectives therefore of the new Regulation is to establish common definitions, including a definition of food, and to lay down the overarching guiding principles and legitimate objectives for food law in order to ensure a high level of health protection.

In contrast to the relatively recent development of food law at Community level, national "food acts" have a longer history. The Regulation harmonises at Community level existing national requirements, placing them in the European context.

Definitions

The new Regulation defines the term *'food'* for the first time at the European level and thus removes some differences that exist in its definition between some of the Member States.

In addition it also defines the term *'food law'* which covers a wider range of provisions than those that relate to just food. It includes all measures relating to materials and substances in contact with food for example, and to all measures which may have a direct or indirect impact on food safety.

The objective of defining food and other concepts in this Regulation is to provide legal certainty in relation to future European food law and provide an understanding at Community level for such concepts.

Overarching objectives of food law

The Regulation establishes the rights of consumers to safe food and to accurate and honest information from which they can choose their diet. It complements the EC Treaty requirements in relation to food and the Community's responsibilities to ensure a high level of human health protection in the definition and implementation of Community policies and activities.

Future food law will be based on an integrated approach from the farm to the final consumer, including measures applicable on the farm. This principle will in future be considered in other areas as a general principle. Food law will also pursue the general objectives of the protection of animal or plant health and life and the protection of the environment where this is compatible with the nature of the measure.

Food law, both at the national and Community level not only provides health protection but also protects other consumer interests in relation to the prevention of deceptive practices, including the adulteration of food and ensures consumers are provided with accurate information. This regulation broadens the more specific provisions in Community labelling and advertising legislation by providing an overall principle that consumers must not be misled.

Scientific Basis to food law

The Regulation establishes the principles of risk analysis in relation to food law and establishes the structures and mechanisms in relation to the scientific and technical evaluation which will be, in the main, undertaken by the European Food Safety Authority.

Depending on the nature of the measure, food law, and in particular, measures relating to food safety, shall be underpinned by strong science. The European Community has been at the forefront of the development of the risk analysis principles and their subsequent international acceptance. The new Regulation establishes in EU law that the three inter-related components of risk analysis: risk assessment, risk management and risk communication provide the basis for food law as appropriate to the measures under consideration. Clearly not all food law has a strong scientific basis e.g. food law relating to consumer information or the prevention of misleading practices does not need a scientific foundation.

The new Regulation requires the scientific assessment of risk to be undertaken in an independent objective and transparent manner based on the best available science.

Risk management is the process of weighing policy alternatives in the light of the results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk to ensure the high level of health protection determined as appropriate in the European Community.

In the risk management phase, the decision makers need to consider a range of information in addition to the scientific risk assessment, including for example, the feasibility of controlling a risk, the most effective risk reduction actions depending on the part of the food supply chain where the problem occurs, the practical arrangements needed, the socio-economic effects and environmental impact. The new Regulation establishes the principle that risk management actions are not just based on scientific assessment of risk but also take into consideration a wide range of other factors legitimate to the matter under consideration.

Precautionary Principle

The new Regulation also formally establishes the Precautionary Principle as an option open to risk managers when decisions have to be made to protect health but scientific information concerning the risk is inconclusive or incomplete in some way.

The precautionary principle is relevant in those specific circumstances where risk managers have identified there are reasonable grounds for concern that an unacceptable level of risk to health exists but the supporting information and data may not be sufficiently complete to enable a comprehensive risk assessment to be made. When faced with these specific circumstances, decision makers or risk managers, may take measures or other actions to protect health based on the precautionary principle while seeking more complete scientific and other data. Such measures have to comply with the normal principles of non-discrimination and proportionality and should be considered as provisional until such time that more comprehensive information concerning the risk can be gathered and analysed.

Traceability

The identification of the origin of feed, food, ingredients and food sources is of prime importance for the protection of consumers particularly when products are found to be faulty. Traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products. The new Regulation provides for traceability of all food and feeds as they move between businesses, with information on the traceability of the food or feed being made available to the competent authorities if requested. Importers are similarly affected, as they will be required to identify from whom the product was exported in the third country. This measure is limited to ensuring that businesses are at the least able to identify the one step in the food supply ‘above’ them and the one step ‘below’, unless specific provisions exist for further traceability.

Responsibilities

The new Regulation establishes the basic principle that the primary responsibility for ensuring compliance with food law, and in particular the safety of the food, rests with the food business. Similarly this principle is applied to feed businesses. To complement and support this principle, there must be adequate and effective controls organised by the competent authorities of the Member States.

Food safety requirements

The new Regulation establishes a food safety requirement which comprises two elements: i) food should not be injurious to health or ii) unfit for human consumption. Only one of these elements has to be in place for the food to be considered as unsafe. These concepts exist internationally in *Codex Alimentarius* and also exist in the food law of several Member States of the EU. Injurious to health is further defined in this Regulation as this could have a broad interpretation.

In considering whether a food is potentially injurious to health it is important to consider the use of the food, information provided with the food and the processing or subsequent handling to which it is to be subject. Also in terms of the effects on an individual, both long term, cumulative and acute effects are considered as is also the possible impact on subsequent generations.

Food unfit for human consumption is also considered to be unsafe in this Regulation. Food, for example, putrid food, is unacceptable for human consumption and may be injurious to health. It may be almost impossible to prove injury or probable injury to health with such food, so this separate factor is included in relation to the overall food safety requirement.

The new Regulation also makes it obligatory for food businesses to withdraw unsafe foods from the market, and provide accurate information to the consumers when this is done. It requires food safety to be considered at all stages that may have an impact on food safety.

International obligations and trade in foods

The new Regulation acknowledges the Community's commitment to its international obligations particularly in relation to the Sanitary and Phyto-Sanitary (SPS) and the Technical Barriers to Trade Agreements (TBT) under the auspices of the World Trade Organisation (WTO). It underscores the European Community's commitment to the development of international technical standards for foods. It also recognises the Community's obligation to consider international standards within both of these agreements but balances this with the Treaty requirement for a high level of health protection, and with the other objectives of food law established in this proposal. International standards will only be considered where the high level of health protection or the other objectives of food law are not compromised.

The European Community has been active in the development of international trading rules and standards and is committed to free trade in safe and wholesome foods. The new Regulation establishes the general principles upon which the international trade in food shall be based. It establishes the objective that food law will be developed in such a way that it does not arbitrarily or unjustifiably discriminate against any international trading partner and should not present a disguised barrier to trade.

Principle of transparency

The Regulation establishes a framework for the greater involvement of stakeholders at all stages in the development of food law and establishes the mechanisms necessary to increase consumer confidence in food law.

This confidence is an essential outcome of a successful food policy and is therefore a primary goal of Community action related to food. Transparency of legislation and effective public consultation are essential to build this greater confidence. Better communication about food safety and the relevance of potential risks, including full transparency of the scientific opinions given to the Commission by its scientific committees are essential in this respect.

The European Food Safety Authority

On 21st January 2002 the EU Council of Ministers agreed the last steps towards the adoption of a Parliament and Council Regulation setting up the European Food Safety Authority (EFSA) thus paving the way for the Authority to start its operation as early as possible in 2002.

The primary responsibility of the Authority will be to provide independent scientific advice on all matters with a direct or indirect impact on food safety. The Authority has been given a wide brief, so that it can cover all stages of food production and supply, from primary production to the safety of animal feed, right through to the supply of food to consumers. It will gather information from all parts of the globe, keeping an eye on new developments in science. It will share its findings and listen to the views of others through a vast network that will be developed over time. As well as interacting with experts and decision-makers on many levels, EFSA will communicate directly with the public on its areas of responsibility.

Although the Authority's main "customer" will be the Commission, it will be open to respond to scientific questions from the European Parliament and the Member States and it can also initiate scientific investigations on its own behalf. The Authority will carry out assessments of risks to the food chain and indeed can carry out scientific assessment on any matter that may have a direct or indirect effect on the safety of the food supply, including matters relating to animal health, animal welfare and plant health. The Authority will also give scientific advice on non-food and feed GMOs, and on nutrition in relation to Community legislation.

Legal Basis for the European Food Safety Authority

The European Parliament and Council Regulation 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 was adopted by the Council of Ministers on 21 January 2002. In accordance with the provisions of this regulation, it will enter into force twenty days following publication in the Official Journal. Thus the Authority is likely to have a legal base before the end of February.

In January 2000 the Commission issued its White paper on Food Safety in which it announced a comprehensive package of 84 measures the corner stone of which was the Regulation on General Food Law and the establishment of the European Food Safety Authority. The Commission adopted its proposal for the Regulation in November 2000. The rapidity with which this complex and comprehensive Regulation has been adopted reflects the exceptionally high importance attached to food safety in general, and the Authority in particular, by the Community Institutions and the Member States.

Making the European Food Safety Authority operational

The adoption of the legal basis is a major milestone, opening the door to a series of practical measures that will need to be undertaken to make the Authority operational. Most importantly, it allows the Commission to initiate the procedures leading to the nomination of the Management Board and the Executive Director, which will give the Authority its legal personality.

Central to the tasks of the Authority is the provision of scientific advice by its Scientific Committee and Panels. The important steps of selecting and appointing members of the Scientific Committee and Panels can be made only after the Management Board and Executive Director are in place.

Once the Executive Director is in place the Authority will also be able to recruit suitable scientific, technical, communications and administrative staff to ensure that it is able to meet the demands placed upon it.

Legal Status of the European Food Safety Authority

The European Food Safety Authority will be a Community body with its own legal identity, funded from the Community budget but operating independently of the Community institutions. It will not therefore be managed by the Commission but by an Executive Director who in turn will be answerable to a Management Board.

The tasks of the European Food Safety Authority

The Authority will be responsible for:

- the scientific evaluation of risks,
- the collection and analysis of scientific data,
- safety evaluations of dossiers put forward by industry for Community level approval of substances or processes,
- identification of emerging risks,
- scientific support to the Commission particularly in the case of a food safety crisis,
- direct communication to the public and other interested parties of information concerning matters within its remit.

The Authority will primarily be a scientific risk assessment body; the responsibility for risk management or decision making remaining with the EU's political institutions: the European Commission, the Council of EU Ministers and the EU Parliament.

The Authority will develop and issue scientific and technical information on a wide range of matters affecting the safety of the food chain. It will also have extensive responsibilities for communicating scientific and technical information directly to the public in a coherent and consistent manner, working with other key food safety bodies in the Member States and the European Commission.

The objective is to ensure that its independence, scientific excellence and openness will make the Authority the automatic first port of call on matters relating to food safety.

Scope of the European Food Safety Authority

The European Food Safety Authority will have a broad remit, allowing it to make scientific assessments of any matter which may have a direct of indirect effect on the safety of the food supply including matters in relation to animal health, animal welfare and plant health.

This is essential so as to avoid repeating the failures of the past to identify emerging risks in one field that may have an impact on another as was the case with BSE which emerged initially only as an animal health problem.

The Authority will also give scientific advice on non-food/feed GMOs and on nutrition in relation to Community legislation. It will therefore cover all stages of production and supply, from primary production, animal feed, right through to the supply of food to consumers.

The primary components of the European Food Safety Authority

The Authority comprises 4 separate components:

i) Management Board

A Management Board shall have responsibility for ensuring that the Authority functions effectively and efficiently. The Board will be composed of 14 members appointed by the Council in consultation with the European Parliament. The Commission will be responsible for drawing up a list of candidates from which the selection is made. There will also be a representative from the Commission on the Board. Four of the members shall have their background in organisations representing consumers and other interests in the food chain.

The members of the Management Board will be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.

ii) The Executive Director

An executive director will responsible for the day to day management of the Authority and will be answerable to the Management Board.

The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication of a call for an expression of interest in the Official Journal of the European Communities and elsewhere. The appointment will be for a period of five years, which may be renewable.

iii) Advisory Forum

The Executive Director will be assisted by an Advisory Forum composed of representatives from the competent bodies in the Member States, which undertake tasks similar to those of the Authority, on the basis of one representative per Member State.

These bodies will most probably be national agencies performing risk assessments in the food sector where they exist in a Member State. Their close involvement is essential, for example, to ensure efficient networking with national scientific organisations as a mechanism for exchanging information on potential risks and for pooling knowledge. This will also encourage broad understanding and acceptance of the scientific advice of the Authority in Europe.

iv) Scientific Committee and Panels

A Scientific Committee and several Scientific Panels will be responsible for the scientific opinions of the Authority.

The **Scientific Committee** will be responsible for the general co-ordination necessary to ensure the consistency in the scientific opinions of the different panels. This Committee will be composed of the chairpersons of the scientific panels and six independent experts who do not belong to any panel.

The **Scientific Panels** will be composed of independent scientific experts selected following an open call for expressions of interest and appointed by the Management Board. They will be selected on the basis of criteria of competence, knowledge, independence and experience. Members of the Scientific Committee and Panels will not be employees of the EFSA. The following 8 panels will be established:

- Panel on food additives, flavourings, processing aids and materials in contact with food;
- Panel on additives and products or substances used in animal feed;
- Panel on plant health, plant protection products and their residues;
- Panel on genetically modified organisms;
- Panel on dietetic products, nutrition and allergies;
- Panel on biological hazards (including TSE/BSE issues);
- Panel on contaminants in the food chain;
- Panel on animal health and welfare.

For further background see:

www.efsa.eu.int

http://europa.eu.int/comm/food/fs/efa/index_en.html

http://europa.eu.int/comm/dgs/health_consumer/library/press/press135_en.pdf