

WORLD HEALTH ORGANIZATION



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ORIGINAL LANGUAGE

# FAO/WHO PAN-EUROPEAN CONFERENCE ON FOOD SAFETY AND QUALITY

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#### CONFERENCE ROOM DOCUMENT

# General Principles of Food Law in the European Union

# **Contribution from the European Community**

On 21<sup>st</sup> 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 <u>rights of consumers to safe food and to accurate and honest information</u> 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 <u>integrated approach from the farm to the final consumer</u>, 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 <u>risk analysis</u> 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 <u>risk analysis</u> principles and their subsequent international acceptance. The new Regulation establishes in EU law that the three inter-related components of risk analysis: <u>risk assessment, risk management and risk communication</u> 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 <u>an independent</u> objective and transparent manner based on the best available science.

<u>Risk management</u> 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 <u>but scientific information concerning the risk is inconclusive or incomplete</u> 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 <u>primary responsibility</u> for ensuring compliance with food law, and in particular the safety of the food, <u>rests with the food business</u>. 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 <u>injurious to health</u> 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 <u>unfit for human consumption</u> 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. <u>Transparency of legislation</u> and <u>effective public consultation</u> 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.