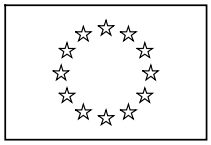

COMMISSION OF THE EUROPEAN COMMUNITIES

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2000/0286 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food

(presented by the Commission)

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EXPLANATORY MEMORANDUM

GENERAL INTRODUCTION

The White Paper on Food Safety[1] outlined the Commission's strategic objectives, priorities and work programme in relation to food safety in particular, and food law in general. It elaborated the Commission's commitment to develop a comprehensive integrated approach to regulating the food supply chain. In particular it proposed the establishment of a European Food Authority and an overarching set of definitions, principles and measures to ensure a high level of protection and the effective functioning of the internal market in food.

This proposal for a European Regulation responds to this commitment by laying down the general principles and requirements of food law, establishes procedures in matters of food safety and establishes a rapid alert system for foods and feeds. It creates a European Food Authority defining its scope, tasks and responsibilities.

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: one has been to harmonise national measures and provide the basis for the internal market, the other, to adopt common measures within the Common Agricultural Policy. Although not always explicit, these objectives have been inextricably linked with the establishment and maintenance of a high level of protection of human health, safety and of consumer protection.

These different objectives have led to some divergence in the approach to food legislation, some inconsistencies and even some lacunae. One of the objectives of this 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 and the effective functioning of the internal market.

In contrast to the relatively recent development of food law at Community level, national "food acts" have a longer history. Therefore, definitions of food and the general principles and requirements of food law have a deep-rooted basis in some Member States' legal history. Although similar in concept and principle, these national measures have some differences in approach and detail, which may cause disruption of the internal market. This Regulation seeks to harmonise at Community level existing national requirements, placing them in the European context.

One objective of this proposal is not only to harmonise national requirements, but also to provide the basic framework of principles and definitions for future European food law. Where measures are revised in the future or where proposals are drafted in new areas, this Regulation will provide the basic principles, definitions and orientation for doing so. Although some specific requirements are proposed in this Regulation, others are more generally applicable and will provide the basis for more specific provisions.

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[1] COM(1999) 719 final, 12 January 2000.

In common with other trading areas, the European Community has had a number of contamination problems in the food supply and other types of food safety emergencies, some of which have arisen as a result of contamination problems in animal feed. This Regulation will establish principles and in some cases responsibilities and obligations on businesses which will address the causes of food safety problems in a broad manner and will include requirements for food businesses at the level of primary production, and, where relevant to food safety, for feed businesses.

The White Paper identified the need to address the issue of securing the confidence of consumers and trading partners in the European food supply. There has been a reduction in the confidence of consumers and trading partners in the public authorities' ability to regulate and control the safety of the food supply, in the system under which European food law is made, and in the European institutions themselves. This has resulted in a significant reappraisal of the existing organisational arrangements at Community level.

The need for rapid, reliable and strong scientific opinions, in what is an increasingly innovative and technological sector, has placed a significant burden on the European system of obtaining scientific opinions through the work of scientific committees. More and more Community legislation requires scientific assessments to be carried out for the European population. This need is currently met by the scientific committees established under Commission Decision 97/579/EC[2] setting up the scientific committees in the field of consumer health and food safety and Decision 97/404/EC[3] setting up the scientific steering committee. This growing need has inevitably stretched the systems both in relation to the ability of the Committees to undertake safety evaluation of scientific dossiers, and in relation to the assessment of broader public health issues.

This proposal addresses the organisational changes needed in relation to the provision of scientific opinions and the increased collaboration with the Member States that must be fostered in order for the best use of expertise to be made.

The White Paper on Food Safety proposed that a European Food Authority be created, in particular in order to consider the scientific issues relevant, either directly or indirectly, to food safety, and to communicate openly on such matters. Public and inter-institutional consultation on the White Paper shows that the creation of a European Food Authority with scientific and technical competencies is widely considered to be the most effective mechanism to address this growing need and to re-establish public confidence. This proposed Regulation responds to the commitment in the White Paper and provides the concrete basis for the functioning of the Authority, detailing its mission, tasks, organisational arrangements and scope.

The proposal also considers the most logical and effective arrangements for the collection and analysis of scientific and other data, the identification of emerging risks to health and the role of the Food Authority in a food safety crisis. It establishes a rapid alert system for foods and feeds, which will integrate and improve the system.

It aligns procedures and responsibilities where a serious risk to health has been identified in the European food supply whether the product originates within the Community or a third country.

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[2] OJ L 237, 28.8.1997.
[3] OJ L 169, 27.6.1997.

The following section refers to Chapters I and II of the Regulation.

SECTION 1

1.1 Overall aims of general Food Law

One of the aims of this proposal is to provide a common comprehensive basis for food law. This proposal establishes the common principles underlying food law, defines common terms and creates a general framework for food law.

It includes the following main provisions:

Food law must provide a high level of health protection;

The effective functioning of the internal market in safe food and feed should be assured;

Clear definitions to increase consistency and legal security including the definition of food;

Food law should be based on high quality, transparent independent scientific advice following the three interconnected components of risk analysis: risk assessment, risk management and risk communication;

The use of the precautionary principle to develop provisional measures where an unacceptable level of risk to health has been identified but further scientific data is required to arrive at a comprehensive assessment of risk to health;

Rights of consumers not to be misled and to have access to accurate information;

Traceability of food, feed, ingredients and food-producing animals;

Primary responsibility for safe food and feed rests with businesses;

Member States are responsible for the enforcement of food law;

An obligation to ensure that only safe food and feed are placed on the market;

Recognition of the Community's international obligations particularly in relation to trade;

Transparency of the development of food law and the access to information in this regard.

Responsibilities of feed businesses where their products or activities may have an adverse impact on food safety.

1.2 Definition of food and other definitions

Although a substantial body of food law exists at the Community level, the term '*food'* has not been defined. The Green Paper on Food Law[4] and the White Paper on Food Safety both propose that in order to increase clarity and legal security the term should be defined and its use adopted in future proposals on food law. Although the term itself has not been defined at the European level, food has generally been accepted to mean substances, ingredients, raw materials, additives and nutrients ingested through the gastro-intestinal tract, including drinks

[4] Green Paper on Food Law, April 1997.

but not medicines, cosmetics or tobacco. It includes residues deriving from the production and processing of foods such as veterinary medicine residues and pesticide residues. Animals that are to be eaten live (e.g. oysters) are generally considered to be food, but live animals which require slaughter prior to consumption are not, until after the slaughter step.

Most Member States have a definition of a food or foodstuff and at the international level a definition exist in Codex Alimentarius.

The proposed definition reflects the general understanding of a food as drafted in Community measures, draws from the definition in Codex Alimentarius and takes into consideration well established definitions in the legislation of the Member States.

The proposed definition includes any substance that is intended to be, or is '*reasonably expected'* to be ingested by humans. The reference to 'reasonably expected' is formulated to ensure that a substance (e.g. palm oil) that may be reasonably expected to find its way into the food supply chain but may find its way into different industry sectors, is handled with the same care as a food until it is clear it will not become a food.

In addition to raw materials and ingredients, the definition includes all water intended for human consumption. This is without prejudice to the standards and requirements for water in Council Directives 80/778/EEC[5] and 98/83/EC [6]on the Quality of Water Intended for Human Consumption.

However, by contrast the term *'food law'* in this proposal 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, to practices on the farm and also animal feed given to food-producing animals, where there may be a direct or indirect impact on food safety.

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

1.3 General objectives of food law

This proposal establishes the overarching principles of food law. It establishes the rights of consumers to safe food and to accurate and honest information from which they can choose their diet. It complements the 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.

The primary objectives of food law established in this proposal will be to ensure the effective functioning of the internal market and in this regard provide a high level of protection of human health, safety and consumer interests. Food law will be based on an integrated approach from the farm to the final consumer, including measures applicable on the farm. In addition, where directly or indirectly relevant to food safety, requirements applicable to feed businesses are established. The 'farm to table' approach has already been followed in the Commission's proposal recasting the Community's hygiene provisions. This principle will in future be considered in other areas as a general principle.

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[5] OJ L 229, 30.8.1980, p. 11.
[6] OJ L 330, 5.12.1998, p. 32.

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 proposal broadens the more specific provisions in Community labelling and advertising legislation by providing an overall principle that consumers must not be misled.

1.4 Scientific basis for food law and the principles of risk analysis

This proposal 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 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. This Regulation proposes 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.

This proposal 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. Therefore, 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.

Risk communication is the third component of the risk analysis process, but should not be considered to be a final phase as, in fact, it encompasses all phases. It is an interactive process of exchange of information and opinions on risk between risk assessors, risk managers and other interested parties. It is required particularly during the risk assessment process between risk assessors and risk managers, to ensure, for example, the relevance of the risk assessment to the problem identified by the risk managers, and also following the risk assessment, the communication of the reasons behind a risk-management decision and the decision itself to all interested parties. This proposal lays the foundation for all elements of risk analysis in relation to matters with a direct and indirect affect on food safety.

1.5 The precautionary principle

This proposal reflects the Commission's recent position expressed in its Communication on the precautionary principle in relation to its application in food law[7]. The precautionary principle is recognised as an option open to risk managers when decisions have to be made to protect health or the environment 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. This proposal places the precautionary principle in the context of its application in the area of food law. It is also in step with the growing international acceptance of this principle as it applies in the field of food safety.

1.6 Traceability

Recent food scares (BSE and dioxin crises) have demonstrated that the identification of the origin of feed, food, including ingredients and food sources is of prime importance for the protection of consumers. In particular traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products. Recent proposals from the Commission in relation to the recast of the hygiene legislation provide the general requirements in relation to hygiene problems. This proposal broadens this. This Regulation also enables derogation from the requirements for traceability in those sectors where this is impracticable, and on the other hand provides for more specific requirements where necessary.

This proposal requires all feed and food businesses to have in place systems so that they can identify the supplier of foods, feeds and food-producing animals to their businesses and also to whom they have supplied such products. This information should be 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.

1.7 Responsibilities

In some areas of European food law, notably in hygiene legislation, the primary responsibility for ensuring compliance with food law, and in particular the safety of the food, rests with the food business. To complement and support this principle there must be adequate and effective controls organised by the competent authorities of the Member States. In other areas of food law this principle is not so widely applicable. This proposal will extend this principle to all food law, and lead to a general review of food law to establish if this principle is respected or whether there are rules where Community legislation has unnecessarily taken responsibility

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[7] COM(2000) 1 final. Communication on the precautionary principle.

away from the feed or food business by prescribing how a given objective has to be achieved instead of fixing the objective.

1.8 Food and feed safety requirements

This proposal seeks to define a food safety requirement. One of the lacunae identified in European food law is that there is no overarching principle for only safe food to be placed on the market. However, this principle exists in the food law of several Member States. This proposal seeks to fill this gap by establishing a food safety requirement which comprises two elements: food should not be potentially injurious to health or unfit for human consumption or contaminated in such a manner that it would not be reasonable to expect it to be used for human consumption according to its intended use.

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 in the provisions of some Member States.

Potentially injurious to health is further defined in this proposal as this could have a broad interpretation. In considering whether a food is potentially injurious to health it is important to consider the likely, and reasonably foreseeable use of the food and the processing or subsequent handling to which it is to be subject. For example, raw foods which are to be consumed after cooking or other processing, and have been produced in line with good hygiene practices may nevertheless contain low levels of harmful bacteria which will be destroyed by normal processing, including novel processes, irradiation or cooking. The same levels of bacteria in a food, which is to be eaten raw, would not be acceptable. However, the fact that processing may eliminate certain types of hazards, does not abrogate a business from its responsibility to ensure that food safety is considered all along the food supply and that practices are consistent with good practice and, where these exist, in line with the requirements of specific provisions.

The requirement applies to acute effects but can also apply to longer term effects where one exposure may have an adverse effect in the future, as in the case of prions or micro-organisms with a long incubation period. The cumulative effects on the health of the consumer must also be considered in relation to the term potentially injurious to health.

Certain foods are marketed for particularly sensitive consumers, and the concept of potentially injurious to health for these consumers has also to be taken into consideration when determining whether a food is unsafe. Consumers have the right to choose the types and amounts of foods they eat, and otherwise have the freedom to choose their diet. Where information is provided either on a label or otherwise, or information is generally available, and yet the consumer ignores this information in his choice of diet, or for example, consumes food at abnormal levels which may ultimately lead to detrimental health effects, this Regulation does not consider these foods to be unsafe where other requirements of food law are met.

Food unfit for human consumption or contaminated food is also considered to be unsafe in this Regulation. Food, for example, putrid food, may or may not be potentially injurious to health but it 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 proposed in relation to safety within this Regulation.

Similarly, food which is contaminated with, for example, insect parts, or beef which may be contaminated with the hairs from cattle, may not be injurious to health but it is still not reasonable to expect this to be used for human consumption, and proving that it may be potentially injurious to health should not be required to declare that it is unsafe.

Provided that a food business ensures that foods are in compliance with the specific provisions applicable to that food, then the food business shall be deemed to have met his responsibilities in relation to the food safety requirement. However, where a food complies with the relevant specific provisions for that food, but is still deemed to be unsafe by the Competent Authorities, the food may still be withdrawn by the Competent Authorities or other measures taken to impose restriction on that food.

To reinforce the primary responsibility of operators in the food sector, this proposal contains a general obligation for all food businesses to ensure within their respective sphere of influence, that food put on the market complies with the principles of safety. This proposal also makes a general requirement for food businesses to inform the Competent Authorities where a food is suspected to be unsafe and to provide the authorities with all assistance to ensure that consumer health is protected. Where a serious risk to health is identified the competent authorities shall inform the European Food Authority via the rapid alert system.

The proposal requires food businesses to withdraw food if other means of safeguarding the consumer are not sufficient, and to inform consumers of the needs for this withdrawal.

Recent experience has clearly implicated animal feed as a root cause of food safety problems. This Regulation seeks to ensure that food safety is considered at all stages that may have an impact on food safety. Therefore a feed business must ensure that feeds for which they are responsible do not have the potential to cause a food safety problem, and should ensure that practices are carried out in such a manner that food safety is not compromised. It establishes a requirement for only safe feed to be placed on the market and establishes a link with the need to ensure that food from animals fed on such feed is safe. The responsibilities of feed businesses also extend to a duty to withdraw products and to inform the Competent Authorities where they become aware that a feed may affect food safety.

1.9 International obligations and trade in foods

The proposal acknowledges the Community's commitment to its international obligations particularly in relation to the Sanitary and Phyto-Sanitary and the Technical Barriers to Trade Agreements under the auspices of the World Trade Organisation. It underscores the European Community's commitment to the development of international technical standards for foods.

It is proposed that the Community will contribute to the development of international standards and also take them into consideration in the adoption of food law. The texts of Codex Alimentarius and the Office International des Epizooties have gained particular importance under the World Trade Organisation Agreements in the context of food law.

Under the Sanitary and Phyto-Sanitary Agreement, compliance with these standards is considered as conforming to the obligations of the Agreement. Members may require a higher level of health protection, and apply measures which are based on a risk assessment. The Technical Barriers to Trade Agreement similarly acknowledges the need for member countries to use international standards on which to base their regulatory measures unless using such a standard would be an ineffective or inappropriate means for the fulfilment

of its legitimate objectives. This proposal 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 agro-food sector of the European Community is a major player in the global market place being an active producer, exporter and importer of foods. The Community therefore has a vital interest in ensuring that the high standards of Community food law are widely accepted internationally and consumers are protected both within the Community and in third countries. Through the building of consumer and trading partners' confidence, food safety contributes to the competitiveness of the European food industry. The Community will also take into consideration standards which are at the final steps of adoption procedures in line with the rules of the governing international bodies.

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. This 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. It underlines the Community's commitment to developing equivalency and other trade agreements in appropriate circumstances.

1.10 Principle of transparency

This proposal 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 following section refers to Chapter III of the Regulation.

SECTION 2

2.1 The European Food Authority (EFA)

The White Paper on Food Safety presented an analysis of the scientific elements that underpin food safety policy and, on that basis, set out proposals for a European Food Authority that would meet the needs of the Community in the new millennium. It concluded that a European Food Authority (EFA) would not only contribute to a high level of consumer health protection in the area of food safety but also to the restoration and maintenance of consumer confidence in food safety. Earning consumer confidence would however require the Authority to function at the highest levels of scientific excellence, independence and transparency. The European Food Authority will give effect to the General principles and requirements of Food Law and will be a key component to improve human health protection and consumer confidence.

The White Paper considered that EFA's essential role would be to provide the Community with the independent scientific and technical advice that it requires to underpin policy and legislation in the areas of food safety, nutrition, animal health and animal welfare, plant health at both the European and international level.

It stressed that such an Authority would have to respect the principle of separation of risk assessment and risk management and should respect the existing policy and legal responsibilities of the Commission, European Parliament and Council.

In addition to its core task of providing the Community with first class, independent scientific opinions, it is proposed that the EFA will be responsible for the day-to-day operation of the rapid alert system (covering both food and feed) and that it will have a key role in the management of crisis situations under the Commission's responsibility. Central to the restoration of consumer confidence, it will give clear and publicly accessible information on all matters that fall within its mandate. Its right to communicate on its own initiative on any such matter provides an important additional safeguard to ensure consumer concerns related to food safety are not overlooked during the Community decision-making process.

The Commission also proposed that the EFA would be entrusted with the fundamentally important task of the collection and analysis of data that would allow characterisation and monitoring of food related safety issues in the Community. No such mechanism exists at present even though this information is vital for the early identification of emerging risks, for the identification of weaknesses in Community legislation and for comprehensive risk assessments in many areas.

The White Paper recognised that the current scientific advisory system is hampered by a lack of capacity which has led to serious delays in the delivery of the opinions required for both the management of important matters of consumer health and for the authorisation of products, substances and process under the Community regime. It identified the need to establish in-house scientific support that would undertake much of the preparatory work that is currently done by the scientific committees in order that their members could focus on the core problems of risk assessment.

Central to the establishment of a modern structure that will provide the Community with timely scientific and technical support in EFA's areas of competence, is the deep integration of the expertise and resources of the Member States through various networks. This support will touch all aspects of the Authority’s work including preparatory work for the scientific committees, information gathering and emerging risks. An essential facet of the EFA will be to add value to what can be achieved within the existing system through the coordination and collaboration of the Member States.

Finally, and fundamental to the overall success of the EFA, the White Paper recognised that consumer confidence can only be regained if the Authority acts independently of outside pressures and is accepted as doing so by all parties concerned. Its statute must therefore provide for assurances in respect of independence, transparency, representativity and accountability.

2.2 Mission and tasks

A broad mandate is essential if the EFA is to take a comprehensive view of the food chain and to provide a coherent scientific basis for the Community's policy and legislation in this area. In addition to food safety and certain aspects of nutrition it therefore also embraces plant health, animal health and animal welfare. Its competence extends to all matters having a direct or indirect impact on the safety and health of consumers arising from the consumption of food. It thus covers all stages from primary production of food and feed, processing, storage and distribution to the final consumer.

The Commission's proposal recognises that the safety assessment of products of importance for the food and feed areas cannot be made without regard to important non-food aspects. It is essential to ensure that risk assessments are both comprehensive, consistent between related industrial sectors and maintain the "one-door one-key principle" for authorisation of industrial products which fall under the Community regime. Therefore, the EFA will ensure that, where the legislation relating to the authorisation of a product or process of primary relevance to food or animal safety also requires an assessment of environmental risk and/or worker safety (notably for GM plants and seeds, pesticides and feed additives), this will continue to be dealt with by a single scientific committee or panel. For reasons of scientific coherence and administrative efficiency, it is proposed that the EFA will also provide scientific opinions on genetically modified organisms even if they are not intended for food or feed use. However as concerns Community legislation and policy relating to genetically modified organisms that are not intended for human or animal consumption, the mission of the Authority will be limited to the provision of scientific opinions in order to avoid confusion in relation to responsibilities for environmental matters in the Community. In practice this means that the Authority cannot undertake its others tasks such as the collection of data or identification of emerging risks in relation to genetically modified organisms except if these organisms are food or feed. However according to point n) of Article 22 the Commission remains free to require more scientific support in relation to all genetically modified organisms from the Authority.

The EFA will address consumer health aspects of water intended for human consumption.

It is also important to avoid risk of confusion between the role of the Authority and the European Medicinal Evaluation Agency (EMEA). The proposal therefore makes clear that its scope is without prejudice to the competences attributed to EMEA.

It is to be noted that the scope of the rapid alert system which will be operated by the Authority, and the management of crises are limited to food and feed safety.

In the area of nutrition the EFA must take account of the need to ensure that nutritional advice is only given within the framework of broad public health policy. The EFA must ensure continuity of scientific opinions in relation to the nutritional requirements of foods for particular nutritional purposes (dietetic foods marketed under Community rules such as foods for infants and young children and for sports people), the expanding area of nutritional claims and nutritional aspects of novel foods. However, it is essential that advice on nutrition and health is carefully coordinated by the Commission and Member States to avoid confusing or incomplete messages to the public.

2.3 Organisation

The proposed organisational structures will facilitate the involvement of EFA's many and diverse stakeholders, independence from external pressures, transparency and accountability to the democratic institutions. It is therefore proposed that the EFA's board includes four representatives appointed by the Council of Ministers, four by the Commission, four by the European Parliament and four representatives of consumers and industry designated by the Commission. The Commission also believes that, as a Community body, the EFA should ensure the best use of the expertise and resources of the Member States in pursuit of its mission whilst respecting the principle of separation of risk assessment and risk management and the overarching requirement for independence. It is therefore proposed that the EFA includes an Advisory Forum comprising representatives of the analogous Member States bodies to ensure the effective operation of the various information gathering networks and supporting mechanisms. It is evident that individual Member States will need to consider how they will interface with the EFA in such a Committee given that not all Member States have established "food agencies" and, even where they have, their scope is unlikely to reflect the broad remit proposed for the Authority.

The proposal foresees transfer and radical restructuring of the 6 independent scientific committees which currently advise the Commission on matters to be covered by EFA: the Scientific Steering Committee (SSC) and its sub-group as concerns BSE and TSE, the Scientific Committee on Food (SCF), the Scientific Committee on Animal Nutrition (SCAN), the Scientific Committee on Plants (SCP), the Scientific Committee on Veterinary measures relating to Public Health (SCVPH) and the Scientific Committee on Animal Health and Welfare (SCAHAW). The restructuring is necessary to both streamline the scientific advisory process and to reflect current rationales in Community policy and legislation as typified by the farm-to-table approach to the safety of the food chain. The proposed structure, which consists of 8 permanent independent panels and a scientific committee, responsible for providing scientific opinions, each within their own sphere of competence, on all matters falling within the Authority's mission. This system is also designed to ensure greater scientific coherence in related areas such as in GM products, food and feed contaminants and microbiological risk, and to anticipate future needs for example, in the area of nutritional claims and novel feed. The system also has the flexibility to handle questions not covered by the panels. For example, problems connected with natural mineral waters, food irradiation or plant health, can be managed by the scientific committee which includes the chairpersons of the permanent panels and will thereby allow maximum flexibility and best use of available scientific expertise.

The excellence of scientific opinions will continue to be ensured on the basis of the procedures introduced by the Commission in 1997 which allow individual scientists to propose themselves for consideration for membership of a committee or a panel. The executive director will be responsible for the management and for ensuring the transparency of the selection process but the decision on Membership will reside with the Management Board.

The lack of capacity of the existing scientific committees to address the increasing number and urgency of questions was highlighted in the White Paper. In addition to providing the Committee secretariat, EFA will need to have the means necessary to ensure that the Committee members enjoy sufficient administrative and scientific support to allow them to concentrate their limited time on the core issues of risk assessment. This implies substantial in-house scientific expertise which, together with the support of the Member States in the preparatory work, will allow the scientific committee and the independent panels to work

primarily by peer review. Members of the scientific committee and panels will thus be very largely liberated from the detailed and time-consuming dossier preparation and evaluation that characterises the present, overloaded system.

2.4 Scientific opinions

Currently, the scientific committees are constituted under Community legislation to advise the Commission. It is proposed that the EP, the Member States or their competent bodies will also be able to address requests for scientific opinion to the EFA with the important exception of questions in areas where consultation of the EFA is obligatory under Community law. In such cases, the Commission, in accordance with its right of initiative, is solely responsible for addressing a question to the EFA. The right of EFA to initiate its own questions reflects the Authority's independence and is an additional and important safeguard that consumer safety is given pride of place in Community policy and rule making.

The extension of the right to the EP, Member States or their competent bodies to make direct requests to the EFA for scientific opinions brings with it the need to avoid overload, needless duplication, loss of coherence and distraction from priority tasks. It is also important that the right of Member States to pose questions does not lead to a reduction of the already limited national resources on which the long-term success of the EFA will depend.

These considerations imply the need to establish clear and transparent rules covering the treatment of questions including criteria by which EFA will assess the acceptability and management of questions from different sources and the guidelines governing the submission of dossiers in support of a request to include products or processes in a Community positive list. It is proposed that the Commission, after consultation of the EFA, brings forwards a proposal to define these modalities.

2.5 Conflicting scientific opinions

Differences between the scientific opinions of the Commission's scientific committees and those of other Community bodies can complicate both risk management and risk communication, especially where the issues touch on matters which are sensitive for the public or for our trading partners.

The Commission does not consider that it is practical or appropriate to empower the EFA to act as a final, scientific, arbitrator in the case of conflicting scientific opinions in a manner which is binding on the parties concerned. However, the draft Regulation foresees an important role for EFA to anticipate conflicts, to bring the parties together and to identify and agree the basis of the difference of opinion. Even if the EFA is unable to resolve the conflict, the procedure will provide the Commission with a transparent basis on which to develop its proposals for risk management with a clear understanding of the underlying scientific issues.

Where the conflicting opinions involves a Community body or one of the Commission's scientific committees, the Authority and the body or committee concerned shall be obliged to work together to resolve the conflict, or, if this is not possible, to submit a joint document to the Commission clarifying the contentious issues.

Where the conflict involves differences in scientific opinion between the Authority and a national body, a similar procedure will be followed but in consultation with the Advisory Forum. The procedure does not imply the supremacy of the Authority in the case of scientific conflict. Indeed, it is envisaged that an analogous provision will be considered for the European Medicines Evaluation Agency during its forthcoming review.

Conflicts arising from national measures are addressed in mediation procedures established under Chapter V of this proposal.

2.6 Scientific and technical support

In addition to the need for independent scientific opinions from the scientific committees in relation to various kinds of risks, the Commission needs substantial, on-line assistance on a wide range of scientific and technical matters that do not fall within the scope of the scientific committee and permanent scientific panels. Examples include the gathering and interpretation of scientific information to assist with policy matters, the drafting of specifications in relation to the purity criteria of food and feed additives, assistance with the technical evaluation of third country residue programmes, support to assessment of technical notifications under WTO rules, the development of technical guidelines and guides to good practice in food hygiene. It is proposed that the EFA will facilitate this support by various means including use of its in-house expertise, external contracts with industry and research bodies and Member State networks. Such support cannot however be unlimited and it will be essential to agree an annual work programme with sufficient flexibility to manage ad hoc and urgent problems. Full account must also be taken of the contribution of Joint Research Centre (JRC) expertise in specific areas of scientific and technical support to the Commission. This support should continue with appropriate coordination to ensure best use of existing expertise and resources.

2.7 Scientific studies

The White Paper identified the need for the EFA to have its own budget to undertake scientific studies where necessary in order to fill gaps in knowledge which prevent it from fulfilling its mission or to respond to crises. This ensures that the EFA has the necessary independence to investigate problems which are not examined elsewhere.

It is essential however to make best use of existing resources and to develop synergies through appropriate coordination with the JRC and with Community and national research activities. EFA scientific studies would be characterised by their relatively high degree of focus and short-term duration as necessary to ensure that it is able to react with due urgency to well defined problems which arise in its work.

2.8 Information and data collection

The absence of a centralised mechanism for gathering and analysing intelligence at Community level on matters relating to the health and safety of consumers and animals in respect to food and feed is recognised as a major weakness in current procedures. The availability of reliable, comparable and up-to-date information will provide the Community at large with an objective overview of food safety, allow the legislator to identify gaps in Community legislation concerning public health objectives and the EFA itself to identify emerging risks. Information relating to food consumption, composition and the levels of potentially harmful substances and biological agents are essential if the Authority is to evaluate nutrient intake and dietary exposure for the general population of the Community, and more importantly, for vulnerable sub-groups such as infants, children and the elderly. The

lack of such information frequently prevents completion of risk assessments and is an additional weakness in the current situation which will be remedied by this task. Relevant information will be collected from all accessible sources including data-bases, scientific literature and Member State networks. Collection of data from third countries will be necessary where relevant to the health and safety of the European consumer.

The draft Regulation takes account of the many existing information gathering networks of Member States that have been established under Community legislation. In general, these networks address sectoral problems with little cross fertilisation and often lack the infrastructure and support to ensure that the data generated are comparable, fully exploited or published in a timely manner.

In those cases where the subjects are of indirect interest to the work of the Authority, the most appropriate approach will be to arrange for exchange of information of mutual interest. This is likely to be the case, for example, for the network for the epidemiological surveillance and control of communicable diseases in the Community established by European and Council Decision No 2119/98/EC.

In view of the number and complexity of the existing networks it is proposed that the Commission publishes an inventory of the Community networks that are relevant to the EFA's mission together with recommendations concerning their transfer to the EFA and an analysis of weaknesses which need to be corrected.

2.9 Identification of emerging risks

Although it is obviously not possible to prevent all problems and crises, early warning of emerging risks or newly identified concerns will allow the risk manager to take preventive rather than curative measures. In response to the broad consensus that a European Food Authority should be pro-active and not simply reacting passively to food scares and crises, it is proposed that the EFA undertakes prospective actions to identify and monitor emerging risks that are of potential concern for the Community. In addition to the use of its own intelligence gathering and analysis procedures and Member State networks to identify potentially worrying trends, it will also need to establish close contacts with international agencies and third countries. Communication of EFA's conclusions in relation to emerging risks are an inherent component of this activity. The Authority will also need to make best use of relevant information sources established at Community level, notably in the JRC and the European Environmental Agency.

2.10 The rapid alert system

It is proposed that the EFA is charged with the day-to-day operation of the enlarged rapid alert system for food and feed. Experience with a wide range and large number of alerts over the past years has shown the need for considerable scientific and technical judgment in assessing the health importance and urgency of certain notifications. The Commission considers that this can best be done within the multi-disciplinary environment of a European Authority having immediate access to food related safety data. The provisions for the operation of the rapid alert system are set out in Chapter IV.

2.11 Networks of organisations operating in the same fields as the Authority

The establishment of effective networks of organisations operating in the same fields as the Authority will provide the mechanism by which the Member States can combine their expertise in the common interests of the Community. This will give the proposed Authority an overall capacity which is comparable to much bigger national organisations such as the US FDA. The Commission's proposal in this area takes account of experience of the operation of the system of scientific cooperation with the Member States on food related issues under Directive 93/5/EEC (SCOOP). Although SCOOP has demonstrated the tremendous potential to focus Member State resources on a wide range of Community problems, it also highlighted the limitations arising from a system which depends on the voluntary support of the Member States. This has meant that important tasks that underpin Community policy and legislative development could not always be managed with the rigour necessary to ensure their adequate completion within the necessary time-limits.

The Authority will work in direct cooperation with the competent organisations in the Member States in order to closely associate them with its work in a manner which not only draws on their scientific potential but also conserves and even reinforces the capacity of their scientific institutes. It is particularly here that the Advisory Forum comprising representatives of the analogous Member States' bodies will be key to ensuring the effective operation of the various networks.

The draft Regulation provides for the Authority to draw up a list of organisations designated by the Member States (governmental bodies, university department or private institutes) that have the scientific competence in the domains covered by the EFA and which could undertake various tasks on its behalf. This procedure will be particularly important for the evaluation of industry dossiers submitted in the context of requests for Community level authorisation of products and processes. It is proposed that the Authority will enlist the expertise of the Member States for the drafting of an initial assessment report on the basis of the authorisation dossier in preparation for final evaluation by one of the specific scientific panels. This procedure draws on the successful experience of the EMEA which is able to meet strict time-limits for the evaluation of dossiers for the authorisation of medicinal products in the Community. It is therefore intended that, where appropriate, the EFA may remunerate such competent organisations for their assistance with authorisation dossiers in order to ensure time delays and common quality standards are met. Detailed procedures will need to be established by means of a subsequent Commission decision covering the criteria for inclusion of organisations on the Authority's list and the rules governing any financial support.

Community level authorisation places a clear responsibility on the legislator to ensure that the granting of an authorisation to use a process or to place a product or substance on the market does not lead to risks to human or animal health, or to the environment. It is important to note that, in the areas of concern for EFA, there are wide variations in the nature and extent of the preparatory work undertaken by the Member State Authorities in relation to dossiers submitted as part of the Community authorisation processes. For food additives, flavourings, materials in contact with food, technological aids, nutritional substances, the scientific committee undertakes the entire work apart from limited assistance through SCOOP. In the case of pesticides, novel foods, feed additives and GM plants the petitioner selects the Member State to act as Rapporteur in accordance with procedures which are specific to the sector. This has resulted in wide differences in the nature and level of involvement of the scientific committees in the risk assessment work related to Community authorisations.

To take maximum benefit from the resources of the Authority and the system of Member State support, the establishment of the EFA will need to be accompanied by a revision of existing procedures relating to the scientific support by Member States to the preparatory work particularly as concern dossiers related to requests for authorisation. It will be essential to ensure that all scientific evaluations undertaken by EFA meet the expectations of consumers and industry in terms of scientific quality and independence.

In view of the practical and legislative complexity of advancing harmonisation within the current proposal, it is proposed that, within 12 months of the Regulation entering into force, the Commission will publish an inventory of the various systems of scientific support of relevance to the work of EFA, particularly as concern Community authorisation dossiers. The report will be accompanied by appropriate proposals.

The scope of the SCOOP as currently defined will be reviewed at the same time.

2.12 Independence, transparency, confidentiality and communication

Acceptance of the advice and the objectivity of the EFA by the public and the scientific world will depend crucially on establishing a culture of independence and transparency at all levels of its operation. The proposed Regulation therefore foresees a series of obligations on the Management Board, the members of the scientific committee, scientific panels and their working groups and the Advisory Forum of Member States. These are designed to ensure that EFA's advice is both truly and visibly independent.

Provision is made for the Management Board to hold some of its meetings in public or to allow stakeholders to observe some of the Authority’s activities.

The EFA will adopt the internal rules, which govern the practical and detailed application of these requirements.

2.13 Communication

The White Paper highlighted the importance of direct and open Communication with consumers relating to scientific opinions and to its monitoring and surveillance tasks. It recognised that consumer confidence would be greatly enhanced by readily accessible and easily understood information. The proposal to give the EFA a right of initiative to communicate on subjects within its competence provides an important, additional safeguard for the consumer. In line with the White Paper, the Commission will remain responsible for communication on risk-management decisions, however, it is important that there is appropriate exchange of information between EFA and the Commission to ensure that coherence of the overall message.

The work of the EFA in the area of public information campaigns on matters of food safety or nutrition will need to be carefully orchestrated with the Member States and other interested parties to take account of broader public health considerations, regional factors and the need to avoid conflicting or incomplete advice.

2.14 Access to information

Although the policy of transparency demands easy public access to information held by the EFA, there are inevitable constraints arising from legitimate commercial confidentiality and from legislation governing the protection of personal information. The Management Board will adopt any additional internal rules that it considers appropriate to respect confidentiality where it considers it justified.

2.15 Contact with consumers and other interested parties

The Commission's proposal recognises the need for the Authority to have contact with consumer representatives and other interested parties. This would serve to increase confidence in its work and would be consistent with its broad communication mandate.

2.16 Fees

Unlike the EMEA system, it is not intended to levy fees for the work of the EFA, at least, not in its initial period of operation. It is to be noted however that Community legislation relating to the Community approval of plant protection products and on the authorisation of feed additives provides for the charging of fees by the Member State that undertakes the initial assessments. The Commission proposes that the possibility of charging fees, particularly in regard to the work relating to Community authorisation of commercial products, should be the subject of a reflection. It therefore proposes to review the situation within 3 years of operation of EFA and to issue a report on the matter.

2.17 Participation of third countries

Appropriate provisions will be established in relation to the participation of EEA and candidate countries.

The following section refers to Chapter IV.

SECTION 3

3. Rapid alert system, management of crises and emergency situations

The Authority will be responsible for ensuring the operation of a broadened rapid alert system for food and feed. A system for rapid alert already exists in the framework of the General Product Safety Directive under which the Member States must notify the Commission of measures taken which restrict the placing on the market, or require the withdrawal of a product or a product batch. In the case of products posing a serious and immediate risk, the information on such measures taken or decided by a Member State must be rapidly transmitted by the Commission to all Member States including EEA and EFTA countries through the Community rapid alert system. The scope of the existing rapid alert system is limited to consumer products (food and industrial products) and does not cover animal feed. However, in the food sector the rapid alert system has evolved on a voluntary basis to cover other circumstances where it is useful for Member States to be informed about risks to health, in particular, in relation to the rejections of consignments of product at the external borders of the European Union.

The Commission considers that there is an urgent need to separate food from other consumer goods and to set up an improved and broadened rapid alert system which covers the entire food chain. The new system will therefore specifically address products intended for human consumption and for animal feed in a network that will include the Commission, the Member States and the Authority. The Authority will ensure the operation of the network, namely, the immediate transmission of the notifications received through the rapid alert system to all the members of the network and the analysis of the data generated by the system, the Commission and Member States remaining responsible for management measures in their own domains of competence. The revised system provides for the following types of mandatory notifications in relation to food and feed: notification of a serious direct or indirect risk for health, notification of measures taken in relation to food or feed and notification of rejections at the EU borders. In case of notification of a serious direct or indirect risk for health, the Authority can assess the risk and complement the notification with scientific or technical information thereby facilitating rapid and appropriate action by the Member States.

This new system takes into account the improvements made in proposal for amendment of the General Product Safety Directive. In particular, the measures or actions to be notified by the Member States are those related to a serious direct and indirect risk to human health which require rapid intervention including the notification of voluntary action initiated by business operators or agreed with the authorities. The proposal foresees the possibility to open the rapid alert system to non-EU countries or international organisations on the basis of reciprocity, under appropriate conditions.

3.2 Crisis management

Recent events have demonstrated the importance of establishing clearly defined operational procedures which allow the Commission to manage food crises efficiently especially where there are specific needs for coordination and/or close interaction with scientists. New modalities are envisaged by this proposal to ensure optimum coordination and to strengthen the Community's overall capacity to identify the most effective measures to prevent, reduce or eliminate a risk for human health. These modalities are consistent with a global approach of the safety of the food chain, encompassing products for both human consumption and for animal feed.

These new tools include the definition of a crisis management plan and provide for the Commission to establish, where necessary, a crisis unit in which the Authority will participate. The Authority will give scientific and technical support to the crisis unit, the Commission remaining responsible for the management measures. The crisis unit will be responsible for communication during the time of crisis.

3.3 Emergency situations

Under current Community legislation, measures to be taken in the event of emergencies differ according to the type and origin of the product. This source of confusion and inefficiency is addressed by this Chapter in relation to all foods. These emergency measures do not cover products intended for animal feed because analogous provisions to deal with emergencies in this area are in the process of adoption by Parliament and Council.

This Section refers to Chapter V.

SECTION 4

4.1 Establishment of the Committee

This Chapter provides for the introduction of a Committee for Food Safety and Animal Health covering all relevant regulatory activities with a direct or indirect impact on the food chain. The establishment of a single, overarching Committee, will foster greater harmony of approach and provide flexibility to manage problems which affect several sectors, for example dioxin contamination of food and feed.

4.2 Mediation

This Chapter establishes a mediation procedure enabling the Commission, without prejudice of other applicable procedures, to ask for the opinion of the Authority on contentious scientific issues if a Member State considers that another Member State has taken measures which are either incompatible with the proposed Regulation or likely to affect the operation of the internal market. This mediation procedure will be of particular value in case of a conflict involving differences of scientific opinions.

4.3 Commencement of the Authority

It is proposed that the Authority takes up its responsibilities after entry into force of the Regulation, at a date to be decided, so as to ensure continuity of existing functions, in particular, as concerns the provision of scientific opinions. The existing scientific committees will continue to exercise their functions until the nomination of the scientific committee and 8 panels by the administrative board. This process requires the establishment of the management board, appointment of the Executive Director and completion of a call for expressions of interests from scientists who wish to be considered for membership of a scientific committee or panels.

This Section refers to miscellaneous matters.

SECTION 5

5.1 Personnel

For carrying out the tasks described above, the Authority needs to have a sufficient number of high-quality and specialised staff. The staff will provide extensive, scientific and organisational support to ensure the efficient work of the independent scientific committee and the eight panels and manage the various Member State networks that underpin the Authority's work, prepare the communication strategy for a food safety crisis. Personnel are also required for information gathering networks, technical support to the Commission, communication and the administrative support necessary for a stand-alone body.

The analysis leads to an estimated number of staff for the Authority of around 339 when fully functional in the year n + 5 (n being the year of adoption of the regulation). However the current personnel estimates attached to this Regulation cover the period n + 3 where it is estimated that 255 persons will be required.This will be reviewed during the third year to ensure that there are sufficient personnel to enable the EFA to function effectively in subsequent years. By way of comparison, the newly established United Kingdom Food Standards Agency has 570 staff to carry out tasks relevant to food safety only. The most

comparable organisation to the EFA in terms of the population it covers is the CFSAN part of the United States Food and Drug Administration which employs approximately 850 people. The European Medicines Evaluation Agency, which operates in the field of human and animal medicine evaluation, and has a more limited remit than is envisaged for EFA, has 210 staff.

The personnel of the Authority will be subject to the Staff Regulations applicable to Officials of the European Communities and the Conditions of Employment of Other Servants. It is envisaged that a relatively small number of these will be seconded from the Commission in order to ensure efficient transfer of expertise and continuity of the work concerning the secretariats of the independent scientific advisory system, the operation of the rapid alert system, the management of certain existing Member State information collection networks and to set up the administrative and informatics systems. It is envisaged that staffing will be primarily on the basis of temporary renewable contracts and will take account of the need to ensure that the personnel keep abreast of scientific developments.

5.2 Budget

The Authority needs a budget allocation large enough to hire its personnel as described above; to organise and host the meetings of the scientific committees; to refund the Member States for evaluation work on authorisation dossiers and to commission scientific studies. For the first year this budget can be valued at roughly EUR 9 000 000. When fully operational it is estimated that the Authority will need a budget of circa EUR 67 200 000 in year n + 5 (n being the year of the adoption of the Regulation). However, the present financial assessment attached to this Regulation covers the period from n until year n + 3 when it is estimated that EUR 44 400 000 will be required. In the third year and in light of the experience gained this will be reviewed to ensure the continued effective functioning of EFA.

By way of comparison the United Kingdom Food Standards Agency has a budget of EUR 136 500 000 for the year April 1999 to April 2000. The European Medicines Evaluation Agency which has a more limited scope and remit than EFA has a budget of approximately EUR 50 000 000 for the year 2000, a proportion of which it is able to retrieve from charges it levies in relation to its main work of evaluation of dossiers for proprietary medicines.

The Authority's budget will be financed by a subsidy from the Community. It is not generally accepted to levy fees on petitioners, however, the Commission will review this area. Consequently, the Community contribution will be EUR 9 000 000 the first year and increase progressively to EUR 44 400 000 in the third year and reviewed for subsequent years.

The Authority must put in place an appropriate set of rules and controls assuring the highest level of financial control. The Management Board will be entitled to adopt, after having achieved the approval of the European Commission, the necessary measures and rules, but the Authority will ultimately be subject to the supervision of the Court of Auditors. The Authority will make use of existing Commissions expertise and resources when it carries out or commands audits and evaluations.

2000/0286 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95, 133 and 152(4)(b) thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(3) The free movement of food within the Community can be achieved only if food safety requirements do not differ significantly from Member State to Member State.

(4) There are important differences in relation to concepts, principles and definitions of food in the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.

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1 OJ C
2 OJ C
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4 OJ C

(5) Accordingly, it is necessary to approximate these concepts, principles and definitions of food in the Member States so that they form a common basis for measures governing food taken in the Member States and at Community level.

(6) In this regard, water is ingested as other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. It should therefore be considered to be food, without prejudice to the requirements established in Council Directives 80/778/EEC[5] and 98/83/EC[6] on the quality of water intended for human consumption.

(7) The Community has chosen a high level of health protection as appropriate in the development of food law which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.

(8) It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.

(9) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that only safe food is placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health.

(10) In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.

(11) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum because each element may have a potential impact on food safety.

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

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

(14) Measures adopted by the Member States and the Community governing food safety should not be based on the yardstick of general conjecture but on the basis

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[5] OJ L 229, 30.8.1980, p. 11; Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

[6] OJ L 330, 5.12.1998, p. 32.

of a risk analysis. Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.

(15) Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected principles of risk analysis: risk assessment, risk management, and risk communication, provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.

(16) In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.

(17) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk-management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, ethical and environmental factors and the feasibility of controls.

(18) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food. By adopting a uniform basis throughout the Community, the possibility of an improper use of this principle is diminished.

(19) In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.

(20) Experience has shown that the functioning of the internal market in food can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within feed and food businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.

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

(22) A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, he should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas, this is either not explicit or else responsibility is assumed by the competent authorities of the Member State, through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.

(23) Similar requirements should apply to feed and feed business operators.

(24) Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, such Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise.

(25) It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.

(26) The safety and confidence of consumers within the Community, and in third countries, are of paramount importance. The Community is a major global trader in food and in this context, it has entered into international trade agreements, it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe and wholesome foods in a non-discriminatory manner, following fair and ethical trading practices.

(27) It is necessary to establish the general principles upon which food may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.

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

(29) The scientific and technical basis of Community legislation relating to the safety of food should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.

(30) The scientific and technical issues in relation to food safety are becoming increasingly important and complex. The establishment of a European Food Authority, hereinafter referred to as "the Authority", should reinforce the present system of scientific and technical support which is no longer able to respond to increasing demands on it.

(31) It is therefore necessary to establish the Authority to serve as a mechanism for applying the general principles of food law, in particular by carrying out the risk assessments necessary for the adoption of Community measures governing food safety, in an independent, objective and transparent manner.

(32) The Authority should take on the role of an independent scientific point of reference and in so doing should assist in ensuring the smooth functioning of the internal market. It may be called upon to give opinions on contentious scientific issues, thereby enabling Member States to take informed risk-management decisions necessary to ensure food safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food.

(33) The Authority's role as an independent scientific point of reference means that a scientific opinion may be requested not only by the Commission, but also by the European Parliament and the Member States or a competent national body. Steps should also be taken to help avoid conflicting scientific opinions and, in the event of conflicting scientific opinions between several scientific bodies, procedures should be in place to solve the conflict or provide the risk managers with a transparent basis of scientific information.

(34) The Authority should be an independent source of information and risk communication in order to improve consumer confidence.

(35) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992[7] on general product safety. The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed. This revised system should be operated by the Authority. The system should not cover the early exchange of information in the event of a radiological emergency established in Council Decision 87/600/Euratom[8].

(36) The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food supply chain, which implies wide-ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food supply chain, animal health and welfare, plant health and nutrition.

(37) Since some products authorised under food legislation such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should be covered by the Authority.

(38) The Authority should provide scientific opinions concerning all genetically modified organisms within the meaning of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms[9] whether or not intended for human of animal consumption, including the scientific assessment of their environmental impact in order to avoid duplicated scientific assessments and related scientific opinions on these

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7 OJ L 228, 11.8.1992, p. 24.
8 OJ L 371, 30.12.1987, p. 76.
9 OJ L 117, 8.5.1990, p. 15; Directive as last amended by Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

organisms. However, it is necessary to avoid confusion of competence with the environmental fields as concerns genetically modified organisms that are not food or feed. therefore the Authority should be restricted in its mission in relation to genetically modified organisms that are not food or feed to scientific opinions.

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

(40) The Authority should have the means to perform all the tasks required to enable it to carry out its role.

(41) It is necessary to ensure that there is effective monitoring of the Authority by the various Community institutions involved, and for this purpose its Management Board should include four representatives appointed by the European Parliament, four by the Council, and four by the Commission. The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations, appoint members of the Scientific Committee and Scientific Panels and appoint the Executive Director.

(42) It is necessary to build up a relationship of confidence and transparency with the general public, and therefore the Management Board should include four representatives of consumers and industry.

(43) The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively, in particular with regard to the networking system, and an Advisory Forum should be created for this purpose.

(44) The Authority should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence. It is necessary to reorganise these Committees to ensure greater scientific consistency in relation to the food supply chain and to enable them to work more effectively. A Scientific Committee and Permanent Scientific Panels should therefore be set up within the Authority to provide these opinions.

(45) In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure.

(46) The Authority should also be able to commission scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States prevent duplication of effort. The Authority should take into account existing Community expertise and structures notably as concerns networks of scientific experts established under Community programmes for research and technological development (RTD) and by the Joint Research Centre. In addition, the Authority when planning its work should take due note of relevant actions undertaken by the Joint Research Centre and under Community RTD programmes.

(47) The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. a system for the collection and analysis of relevant data in the fields covered by the Authority should therefore be set up, in the form of a network coordinated by the Authority. Specific provisions for the adaptation of Community data collection networks already existing in the fields covered by the Authority are called for.

(48) Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in the exercise of its policies. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance.

(49) The establishment of the Authority should enable Member States to become more closely involved in scientific procedures; there should therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.

(50) It is necessary to ensure that a balance is struck between the use of national organisations carrying out tasks for the Authority and the need to ensure for the purposes of overall consistency that such tasks are carried out in line with the criteria established for such tasks for the Authority. Existing procedures for the allocation of scientific tasks to the Member States, in particular with regard to the evaluation of dossiers presented by industry for the authorisation of certain substances, products or procedures, should be re-examined within a year to take into account the establishment of the Authority and the new facilities it offers.

(51) The independence of the Authority and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information. However, the Commission remains fully responsible for communicating risk management measures; the appropriate information should therefore be exchanged between the Authority and the Commission.

(52) Appropriate cooperation with the Member States is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.

(53) In addition to its operating principles based on independence and transparency, the Authority should be an organisation open to contacts with consumers and other interested groups and should be able to arrange their involvement in some of its work, in accordance with its own rules.

(54) The Authority should be financed by the Community budget. however, in the light of experience acquired, in particular with regard to the processing of authorisation dossiers presented by industry, the possibility of fees should be examined within three years after the entry into force of the Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the Communities are concerned; moreover, the auditing of accounts should be undertaken by the Court of Auditors.

(55) It is necessary to allow for the participation by European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.

(56) Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, should be subject to common measures in the event of a serious risk to human health. such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of food representing a serious risk to human health.

(57) Recent food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crises management. These organisational procedures should make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information; therefore, revised procedures should take into account the Authority's responsibilities and should provide for its scientific and technical assistance in the event of a food crisis.

(58) In order to ensure a more effective, comprehensive approach to the food chain, a Committee on Food Safety and Animal Health should be established to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs, the Standing Committee for Feedingstuffs and the Standing Committee on Plant Health. Accordingly, Council Decisions 68/361/EEC[10], 69/414/EEC[11], 70/372/EEC[12] and 76/894/EEC[13], should be repealed.

(59) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[14], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

(60) Without prejudice to the obligation of the Member States to ensure compliance with the requirements laid down in this Regulation, a provision should be established to avoid creating legal uncertainty as to existing Community and national measures governing food.

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10 OJ L 255, 18.10.1968, p. 23.
11 OJ L 291, 19.11.1969, p. 9.
12 OJ L 170, 3.8.1970, p. 1.
13 OJ L 340, 9.12.1976, p. 25.
14 OJ L 184, 17.7.1999, p. 23.

(61) It is important to avoid confusion between the missions of the Authority and the European Medicinal Evaluation Agency (EMEA) established by Council Regulation (EEC) No 2309/93[15]. Consequently, it is necessary to establish that this Regulation is without prejudice to the competence conferred on the EMEA by Community legislation, including powers conferred by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[16].

(62) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objectives of this Regulation to provide for definitions, principles and measures for food legislation in the Community and to establish a European Food Authority. This Regulation confines itself to what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty,

HAVE ADOPTED THIS REGULATION**:**

CHAPTER I

SCOPE AND DEFINITIONS

Article 1
Aim and scope

1. This Regulation provides the basis for the assurance of a high level of protection of human life and health and consumers' interest in relation to food, whilst ensuring the effective functioning of the internal market. It establishes common principles, definitions and responsibilities, a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food safety.

2. For the purposes of pararaph 1, this Regulation lays down the general definitions and principles governing food and feed in general, and food and feed safety in particular, in the Community.

   It establishes the European Food Authority.

   It lays down procedures for matters with a direct or indirect impact on food safety.

3. This Regulation shall apply to all stages of production and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for domestic consumption.

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[15] OJ L 214, 24.8.1993, p. 1; Regulation as amended by Regulation (EC) No 649/1998 (OJ L 88, 24.3.1998, p. 7).

[16] OJ L 224, 18.8.1990, p. 1; Regulation as last amended by Commission Regulation (EC) No 2391/2000 (OJ L 276, 28.10.2000, p. 5).

Article 2
Definition of "food"

'Food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or expected to be ingested by humans.

It includes drink, chewing gum and any substance intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water, without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

It shall not include:

(a) feed;

(b) live animals unless they are prepared, packaged and/or served for human consumption;

(c) plants prior to harvesting;

(d) medicinal products within the meaning of Council Directive 65/65/EEC[17];

(e) cosmetics within the meaning of Council Directive 76/768/EEC[18];

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC[19];

(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961 and the United Nations Convention on Psychotropic Substances, 1971.

Article 3
Other definitions

For the purposes of this Regulation:

(1) 'food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, in the Community; it covers all stages of production and distribution of food, and also feed where feed may have an adverse effect on food safety;

(2) 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to the stages of production and distribution of food;

(3) 'food business operator' means the person or persons responsible for ensuring that the requirements of food law are met within the food business under their control;

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17 OJ 22, 9.2.1965, p. 369/65.
18 OJ L 262, 27.9.1976, p. 169.
19 OJ L 359, 8.12.1989, p. 1.

(4) ‘feed’ or ‘feedingstuff’ means products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from industrial preparation thereof, intended for oral feeding to food-producing animals;

(5) ‘feed business’ means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage or distribution of feed including any agricultural producer producing, processing or storing feed for feeding to food animals on his own holding;

(6) ‘feed business operator’ means the person or persons responsible for ensuring that the requirements of food law are met within the feed business under their control;

(7) ‘retail trade’ means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes mass catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;

(8) ‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, to third parties, and the sale and other forms of transfer themselves;

(9) ‘official control’ means any inspection, verification audit, sampling, laboratory examination or analysis or other means of performing controls by the competent authority of the Member States or their agents or by the services of the Commission with a view to ensuring compliance with food law and to protecting human health and consumer interests;

(10) ‘risk’ means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

(11) ‘risk analysis’ means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

(12) ‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

(13) ‘risk management’ means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

(14) ‘risk communication’ means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk-assessment findings and the basis of risk-management decisions;

(15) ‘hazard’ means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;

(16) ‘traceability’ means the ability to trace a food, feed, food-producing animal or ingredient, through all stages of production and distribution;

(17) ‘all stages of production and distribution’ means all stages from and including the primary production of a food, up to and including its sale or supply to the final consumer and, where relevant to food safety, the production, manufacture and distribution of feed;

(18) ‘unfit for human consumption or contaminated’ means that the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay;

(19) ‘primary production’ means the production, rearing or growing of primary products up to and including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing.

CHAPTER II

GENERAL FOOD LAW

Article 4
Scope

This Chapter shall relate to all stages of the production and distribution of food and to feed produced for, or fed to, food-producing animals.

The general principles laid down in Articles 5 to 8 shall form a general framework of a horizontal nature to be followed when new measures are established.

SECTION 1

PRINCIPLES OF AND REQUIREMENTS OF FOOD LAW

Article 5
General objectives

1. Food law shall pursue one or more of the general objectives of the protection of human life, health or safety, the protection of consumers’ interests, and other objectives, including, where appropriate, the protection of the environment, the protection of animal health, life and welfare and the protection of plant health and life.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or there is a scientific justification, or where they would result in a different level of protection than the one determined as appropriate in the Community.

Article 6
Protection of health

1. Food law shall aim to achieve a high level of health protection, and shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the European Food Authority established in Article 21, and other factors as legitimate to the matter under consideration.

Article 7
Precautionary principle

1. In those specific circumstances where, following an assessment of available pertinent information, a risk to health is identified but scientific uncertainty persists, provisional risk management measures necessary 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.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Article 8
Protection of consumers' interests

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It 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.

2. Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of foods, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

Article 9
Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be incorporated into a food or feed shall be established at all stages of production and distribution, where necessary under the conditions laid down pursuant to paragraph 5.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

   To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify other businesses to whom their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors shall be adopted in accordance with the procedures laid down in Article 57(2).

Article 10
Responsibilities

1. Food and feed business operators at all stages of production and distribution within the businesses under their control shall ensure that foods or feeds satisfy the relevant requirements of food law and shall put in place systems and procedures to verify and monitor that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production and distribution.

   For that purpose, they 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 and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

Article 11
Liability

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC[20] concerning liability for defective products.

SECTION 2

REQUIREMENTS OF FOOD SAFETY

Article 12
Food safety requirements

1. Only food that is safe under normal and reasonably foreseeable conditions of use shall be placed on the market.

2. Food shall be considered as unsafe if it is:

   (a) potentially injurious to health;

   (b) unfit for human consumption or contaminated.

3. The safety of food shall be considered at all stages of production and distribution, taking into account, at each stage, its normal and reasonably foreseeable conditions of use.

4. In determining whether any food is potentially injurious to health, regard shall be had:

   (a) to the normal and reasonably foreseeable conditions of use of the food so that the food does not present a risk which is unacceptable or which is inconsistent with the high level of protection for the health of a person consuming the food;

   (b) not only to the possible immediate or short term effect of that food on the health of a person consuming it, but also to the potential cumulative toxic effects of a food on the health of a person, or on subsequent generations of a person consuming that food in ordinary quantities;

   (c) to the particular sensitivities of a specific category of consumers where the food is intended for that category of consumers.

[20] OJ L 210, 7.8.1985, p. 29.

5. In determining whether the food is safe, consideration shall also be given to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods, and whether, despite such information, the consumer has chosen to ignore such instructions or other information concerning that food or categories of foods.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all of the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions of food law shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, and in particular Articles 28 and 30 thereof.

Article 13
Feed safety requirements

1. No feed shall be place on the market or fed to any food-producing animal unless it satisfies the feed safety requirements.

2. A feed does not satisfy the feed safety requirement if it:

   – has a detrimental effect on human or animal health;

   – makes the food derived from the food-producing animal to which it is fed or to which it may be expected to be fed, unsafe for human consumption;

   – harms the consumer by impairing the distinctive features of the animal products.

3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

5. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law of the Member State governing feed safety in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, and in particular Articles 28 and 30 thereof.

Article 14
Responsibilities for food safety: food businesses

1. Food business operators shall ensure that all stages of production and distribution under their control are carried out in such a manner that food complies with the relevant provisions of food law, and in particular, food safety.

2. A food business operator shall immediately inform the competent authorities if he considers or suspects that a food which it has placed on the market may be potentially injurious to human health. The operators shall inform the competent authorities of the action taken to prevent risks to the final consumer.

   In cases where the food business operator considers or suspects that a food may present a serious risk to human health he shall notify the competent authority thereof.

3. Food business operators shall collaborate with the competent authorities according to the requests of the latter, on action taken to avoid risks posed by a food which they supply or have supplied.

4. If a food business operator considers or suspects that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall initiate procedures to withdraw the food in question from the market. The operator shall adequately and effectively inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

5. A food business operator responsible for import, retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall act with due care to help ensure compliance with the food safety requirements.

   Within the limits of their respective activities, such food business operators shall initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

Article 15
Responsibilities for food safety: feed businesses

1. Feed business operators shall ensure that all stages of production and distribution under their control are carried out in such a manner that the feed they produce or handle complies with the relevant provisions of food law, and in particular that the feed satisfies the feed safety requirements.

2. A feed business operator shall immediately inform the competent authorities if it considers or suspects that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed.

   In cases where the feed business operator considers or suspects that the use of the feed would present a serious risk to human health he shall notify the competent authority thereof.

3. Feed business operators shall collaborate with the competent authorities according to the requests of the latter, on action taken to avoid risks posed by a feed which they supply or have supplied.

4. If a feed business operator considers or suspects that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall initiate procedures to withdraw the feed in question from the market. The operator shall adequately and effectively inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

5. A feed business operator responsible for import, retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed, shall act with due care to help ensure compliance with the feed safety requirements.

   Within the limits of their respective activities, such operators shall initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

SECTION 3

PRINCIPLES OF FOOD TRADE

Article 16
Food imported into the Community

1. Food imported into the Community shall comply with the relevant requirements of food law or, where specific agreements exist, with requirements which are at least equivalent.

2. By way of derogation from paragraph 1, food which is not intended to be placed on the market in the Community by reason of its being in transit from one third country to another, or intended to be processed for immediate exportation, may be allowed on to the territory of the Community provided that such food or its derivatives do not enter the Community market.

3. Feed imported into the Community shall comply with the relevant requirements of food law, or, where specific agreements exist, with requirements which are at least equivalent. Paragraph 2 shall apply to feed similarly.

Article 17
Food exported from the Community

1. Food exported from the Community shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or stated by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food exported from the Community to that third country shall comply with the said provisions.

3. Food exported from the Community shall not be unsafe, or labelled or presented in a manner that is false, misleading or deceptive.

4. Food which has been found to be injurious to health, or labelled or presented in a manner that is false, misleading or deceptive in the Community, or has been otherwise denied access to the Community market shall not be exported or re-exported from the Community, unless the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances under which, the concerned food could not be placed on the market in the Community.

5. Paragraphs 1 to 4 shall apply similarly to feed.

Article 18
International food standards

Without prejudice to its rights and obligations, the Community shall:

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

(b) promote the coordination of work on food and feed standards undertaken by international governmental and non governmental organisations;

(c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed related measures;

(d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries.

SECTION 4

PRINCIPLES OF TRANSPARENCY

Article 19
Public consultation

Wherever circumstances allow there shall be effective public consultation, directly or through representative bodies, at an appropriate stage, during the preparation of food law.

Article 20
Public information

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food may present a risk for human, animal or plant 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, identifying to the fullest extent possible the food, or type of food, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

CHAPTER III

EUROPEAN FOOD AUTHORITY

SECTION 1

MISSION AND TASKS

Article 21
Mission of the Authority

1. A European Food Authority is hereby established, hereinafter referred to as the "Authority".

2. The mission of the Authority shall be to contribute to a high level of protection of human life and health, protection of animal health and welfare, protection of plant life, protection of the environment and protection of the health of workers, while facilitating the functioning of the internal market, by setting up an integrated, coherent system of scientific and technical support for the Community's legislation and policies and by the provision of independent information and risk communication.

   That mission shall cover:

   (a) all fields having a direct or indirect impact on the safety of the food;

   (b) animal health and welfare, plant health;

   (c) nutrition;

(d) any matter relating to genetically modified organisms within the meaning of Directive 90/220/EC.

As regards genetically modified organisms that are not food or feed, the mission of the Authority shall be limited to the provision of scientific opinions.

The mission of the Authority shall include the operation of the rapid alert system for food and feed.

3. The Authority shall provide opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.

4. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation and its diligence in performing the tasks assigned to it.

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks.

5. The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.

Article 22
Tasks of the Authority

The tasks of the Authority shall be the following:

(a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;

(b) to promote and coordinate the harmonisation of risk assessment methodologies in the fields falling within its mission;

(c) to provide scientific and technical support to the Commission in the areas within its mission;

(d) to commission scientific studies necessary for the accomplishment of its mission;

(e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;

(f) to undertake action to identify and characterise emerging risks with a view to reducing or preventing them, in the fields within its mission;

(g) to establish a system of networks of organisations operating in the fields within its mission and shall be responsible for their operation;

(h) to be responsible for the operation of the rapid alert system for food and feed established by this Regulation;

(i) to provide scientific and technical assistance when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;

(j) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, European Union applicant countries, international organisations and third countries, in the fields within its mission;

(k) to provide, when requested to do so by the Commission, assistance concerning communication on health-policy related nutritional issues;

(l) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

(m) to express its own conclusions and orientations on matters within its mission;

(n) to undertake any other task assigned to it by the Commission within its mission.

SECTION 2

ORGANISATION

Article 23
Bodies of the Authority

The Authority shall comprise:

(a) a Management Board;

(b) an Executive Director and his staff;

(c) an Advisory Forum;

(d) a Scientific Committee and Scientific Panels.

Article 24
Management Board

1. The Management Board shall be composed of four representatives appointed by the European Parliament, four representatives appointed by the Council, four representatives appointed by the Commission and four representatives of consumers and industry designated by the Commission.

2. Representatives may be replaced by alternates, appointed at the same time. Their term of office shall be four years, and may be renewed once.

3. The Management Board shall elect its Chairperson from among its members for a two-year period, which shall be renewable.

4. The Management Board shall adopt its rules of procedure.

Unless otherwise provided, the Management Board shall act by a majority of its members.

5. The Management Board shall meet at the Chairperson's invitation or at the request of at least a third of its members.

6. The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

7. Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Commission’s legislative and policy priorities in the area of food safety.

Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.

The Executive Director shall forward the programmes and report to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

8. The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director.

9. The Management Board, having received the Commission's approval and the opinion of the Court of Auditors, shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the financial regulation applicable to the European Union's general budget.

10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat.

Article 25
Executive Director

1. The Executive Director shall be appointed by the Management Board, on the basis of a proposal by the Commission, for a period of five years which shall be renewable. He may be removed from office by the Management Board.

2. The Executive Director shall be the legal representative of the Authority. He shall be responsible:

(a) for the day-to-day administration of the Authority;

(b) for drawing up the Authority's work programmes in agreement with the Commission;

(c) for implementing the work programmes and the decisions adopted by the Management Board;

(d) for ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;

(e) for ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;

(f) for the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;

(g) for all staff matters.

3. Each year, the Executive Director shall submit to the Management Board for approval:

(a) a draft report covering all the activities of the Authority in the previous year;

(b) draft programmes of work;

(c) the draft annual accounts for the previous year;

(d) the draft budget for the coming year.

4. The Executive Director shall approve all financial expenditure of the Authority and report on the Authority's activities to the Management Board.

Article 26
Advisory Forum

1. The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State.

2. Members of the Advisory Forum may not be members of the Management Board.

3. The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation and shall ensure close cooperation between the Authority and the competent bodies in the Member States which undertake tasks similar to those of the Authority.

4. The Advisory Forum shall be chaired by the Executive Director, who shall convene its meetings. Its operational procedures shall be specified in the Authority's internal rules.

5. The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the secretariat of its meetings.

6. Representatives of the Commission's departments shall be entitled to take part in the work of the Advisory Forum.

Article 27
Scientific Committee and Scientific Panels

1. The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence.

2. The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on multisectoral issues falling within the competence of several Scientific Panels, and on issues which do not fall within the competence of any of the Scientific Panels.

3. The Scientific Committee shall be composed of the Chairpersons of the Scientific Panels and 6 independent scientific experts who do not belong to any of the Scientific Panels.

4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:

   (a) the Panel on food additives, flavourings, processing aids and materials in contact with food;

   (b) the Panel on additives and products or substances used in animal feed;

   (c) the Panel on plant protection products and their residues;

   (d) the Panel on genetically modified organisms;

   (e) the Panel on dietetic products, nutrition and allergies;

   (f) the Panel on biological hazards;

   (g) the Panel on contaminants in the food chain;

   (h) the Panel on animal health and welfare.

   The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request, in accordance with the procedure referred to in Article 57(2).

5. The members of the Scientific Committee that are not members of Scientific Panel and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, which shall be renewable, following publication in the *Official Journal of the European Communities* of a call for expressions of interest.

6. The Scientific Committee and the Scientific Panels shall each choose a Chairperson and two Vice-Chairpersons from among their members.

7. The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.

8. The representatives of the Commission's services shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.

9. The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules.

   These procedures shall relate in particular to:

   (a) the number of times that a Member can serve consecutively on a Scientific Committee or Scientific Panel;

   (b) the number of members in each Scientific Panel;

   (c) the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;

   (d) the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;

   (e) the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups.

SECTION 3

OPERATION

Article 28
Scientific opinions

1. The Authority shall issue a scientific opinion:

   (a) at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;

(b) at the request of the European Parliament or a Member State or a national competent body as mentioned in Article 21(4) , in respect of any matter within its mission, where Community legislation makes no specific provision for the Authority to be consulted on such a matter;

(c) on its own initiative, on matters falling within its mission.

2. Where Community legislation does not already specify a time-limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time-limit specified in the requests for opinions, except in duly justified circumstances.

3. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure referred to in Article 57(2). These rules shall specify:

(a) the procedure to be applied by the Authority to the requests referred to it, laying down in particular the circumstances in which it may refuse or modify a request for an opinion;

(b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

4. The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

Article 29
Conflicting scientific opinions

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of conflict between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of conflict, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.

3. Where a substantive conflict over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to cooperate with a view to either resolving the conflict or presenting a joint document to the Commission clarifying the contentious scientific issues.

4. Where a substantive conflict over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate, in consultation with the Advisory Forum, with a view to either resolving the conflict or presenting a joint document clarifying the contentious scientific issues.

Article 30
Scientific and technical assistance

1. The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which do not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular the establishment or evaluation of technical criteria, the development of technical guidelines or guides as to good practice.

2. Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time-limit within which the task must be completed.

Article 31
Scientific studies

1. The Authority shall commission scientific studies necessary for the performance of its mission. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

Article 32
Collection of data

1. The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve in particular the collection of data relating to:

   (a) food consumption and the exposure of individuals to risks related to the consumption of food;

   (b) incidence and prevalence of biological risk;

   (c) contaminants in food intended for human and animal consumption, including residues.

2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from European Union applicant countries, third countries or international bodies.

3. The Member States shall take the necessary measures to enable the data collected in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.

5. Within one year from the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the scope of the Authority.

The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:

(a) for each system, the role which should be assigned to the Authority, and any modifications or improvements which might be required to enable the Authority to carry out its mission , in cooperation with the Member States;

(b) the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its scope.

6. The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

Article 33
Identification of emerging risks

1. The Authority shall search for, collect, collate, analyse and summarise all information and data enabling it to identify emerging risks in the fields within its mission.

2. Where the Authority has information leading to the suspicion of a serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as quickly as possible and forward any relevant information in their possession.

3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.

4. The Authority shall forward the information collected on emerging risks to the European Parliament, the Commission and the Member States.

Article 34
Rapid alert system

1. The Authority shall be responsible for the operation of the rapid alert system for food and feed established in Article 49.

2. The Authority, in consultation with the Member States and the Commission, shall set up the facilities necessary for the rapid transmission of information required for the operation of the rapid alert system.

Article 35
Networking of organisations operating in the fields within the Authority's mission

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list of competent and independent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular, preparatory work for scientific opinions, scientific and technical assistance, scientific studies, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 57(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent and independent organisations designated by the Member States, modalities setting out harmonised quality requirements and the financial rules governing any financial support**.**

4. Within one year from the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States.

SECTION 4

INDEPENDENCE, TRANSPARENCY AND COMMUNICATION

Article 36
Independence

1. The members of the Management Board and the members of the Advisory Forum shall undertake to act independently in the public interest.

   For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

2. The members of the Scientific Committee and the Scientific Panels, shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the lack of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

3. The members of the Management Board, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any special interests which might be considered prejudicial to their independence in relation to the items on the agenda.

Article 37
Transparency

1. The Authority shall ensure that it carries out its activities with a high level of transparency. It shall make public:

(a) the opinions of the Scientific Committee and the Scientific Panels as soon as possible after adoption, minority opinions always being included;

(b) the annual declarations of interest made by members of the Management Board, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels , as well as the declarations of interest made in relation to items on the agendas of meetings;

(c) the results of its scientific studies;

(d) its annual report of its activities.

2. The Management Board, acting on a proposal from the Executive Director, may decide to hold some of its meetings in public and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.

3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

Article 38
Confidentiality

1. By way of derogation from Article 37, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect human health.

2. Members of the Management Board, the executive director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and

members of the staff of the Authority, even after their duties have ceased, are subject to the requirements of confidentiality pursuant to Article 287 of the EC Treaty.

3. The conclusions of the scientific opinions delivered by the Authority in relation with foreseeable health effects shall not on any account be kept confidential.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

Article 39
Communication

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk-management decisions.

2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily understandable information, in particular with regard to the results of its work. To facilitate the public's understanding of its work, it shall develop and disseminate information material for the general public.

3. The Commission and the Authority shall ensure appropriate exchange of information on matters relating to their respective competence in the field of risk communication.

4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

Article 40
Access to documents

1. The Authority shall ensure wide access to the documents which it possesses.

2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1, taking into full account the general principles and conditions governing the right of access to the Community institutions' documents.

Article 41
Consumers and other interested parties

The Authority shall develop appropriate contacts with consumer representatives and any other interested parties.

SECTION 5

FINANCIAL PROVISIONS

Article 42
Adoption of the Authority's budget

1. The revenues of the Authority shall consist of a contribution from the Community and, in addition, any fees received by the Authority in payment for the services it provides.

2. The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 35.

3. By 31 March each year at the latest, the Executive Director shall draw up an estimate of the Authority's revenue and expenditure for the coming financial year, and shall forward it to the Management Board, accompanied by a list of posts.

4. Revenue and expenditure shall be in balance.

5. The Management Board shall, by 31 March at the latest, adopt the draft budget and forward it to the Commission which on that basis shall enter the relevant estimates in the preliminary draft general budget of the European Communities, which it shall put before the Council pursuant to Article 272 of the Treaty

6. The Management Board shall adopt the Authority's budget, adjusting it where necessary to the Community's contribution.

Article 43
Implementation of the Authority's budget

1. The Executive Director shall implement the Authority's budget.

2. Control of commitment and payment of all expenditure, and control of the existence and recovery of all the Authority's revenue shall be carried out by the Commission's financial controller.

3. By 31 March each year at the latest, the Executive Director shall forward to the Commission, the Management Board and the Court of Auditors the detailed accounts for all the revenue and expenditure in respect of the previous financial year.

   The Court of Auditors shall examine the accounts in accordance with Article 248 of the Treaty. It shall publish each year a report on the Authority's activities.

4. The European Parliament, acting on a recommendation from the Management Board, shall give a discharge to the Authority's Executive Director in respect of the implementation of the Budget.

Article 44
Fees received by the Authority

Within three years from the date of entry into force of this Regulation, the Commission shall publish, after consulting the Authority, the Member States and the interested parties, a report on the feasibility and advisability of introducing fees payable by undertakings for obtaining a Community authorisation and for other services provided by the Authority.

SECTION 6

GENERAL PROVISIONS

Article 45
Legal personality and privileges

1. The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.

2. The Protocol on the privileges and immunities of the European Communities shall apply to the Authority.

Article 46
Liability

1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.

2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.

3. The personal liability of its servants towards the Authority shall be governed by the relevant conditions applying to the staff of the Authority.

Article 47
Staff

1. The staff of the Authority shall be subject to the rules and regulations applicable to officials and other staff of the European Communities.

2. In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.

Article 48
Participation of third countries

The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.

Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to financial contributions and staff.

CHAPTER IV

RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES

SECTION 1

RAPID ALERT SYSTEM

Article 49
Rapid alert system

1. A rapid alert system for food and feed shall be established as a network. It shall involve the Member States, the Commission and the Authority, which is responsible for its operation. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network.

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Authority under the rapid alert system. The Authority shall establish whether, on the basis of the notification, the product in question presents a serious risk to human health, necessitating rapid action. If this is the case, it shall transmit this information immediately via the rapid alert system. It may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate action by the Member States.

3. Where a national competent authority is notified by a food business operator pursuant to Article 14(2) or by a feed business operator pursuant to Article 15(2), it shall, after verification, inform the Authority via the rapid alert system. The Authority shall thereafter act as laid down in paragraph 2.

4. Without prejudice to other Community legislation, the Member States shall immediately notify the Authority under the rapid alert system of:

   (a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;

(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;

(c) any rejection of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Authority shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.

Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Authority shall immediately notify all the border posts within the European Union, as well as the third country of origin.

5. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Authority shall provide the latter with the appropriate information.

6. The Member States shall immediately inform the Authority of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system.

7. The Authority shall draw up a summary report of the information transmitted under the rapid alert system at sufficiently regular intervals to keep members of the rapid alert system well-informed, and shall forward it to those members.

8. Participation in the rapid alert system may be opened up to European Union applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

Article 50
Implementing measures

The measures for implementing Article 49 shall be adopted by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 57(2)**.** These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information and the specific rules applicable to information transmitted by business operators.

Article 51
Confidentiality rules for the rapid alert system

1. Information available to the members of the network relating to risk to human health posed by food and feed shall in general be available to the public. In general the public shall have access to information on product identification, the nature of the risk and the measure taken.

   However, the members of the network shall take steps necessary to ensure that the members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public if circumstances so require, in order to protect human health.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

SECTION 2

CRISIS MANAGEMENT

Article 52
General plan for crisis management

1. The Commission shall draw up, in close cooperation with the Authority and where appropriate with the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as "the general plan").

2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 55 and 56.

   The general plan shall also specify the practical and operational procedures necessary to manage a crisis, including the principles of transparency to be applied.

Article 53
Crisis unit

1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 55 and 56, it shall immediately notify the Member States and the Authority.

2. The Commission shall set up a crisis unit immediately, in which the Authority shall be involved and provide scientific and technical assistance if necessary.

Article 54
Tasks of the Crisis Unit

1. The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.

2. The crisis unit may call upon the assistance of any public or private person whose expertise is necessary to manage the crisis effectively.

3. The crisis unit shall take any measures necessary inform the public.

SECTION 3

EMERGENCIES

Article 55
Emergency measures for food of Community origin or imported from a third country

1. Where it is evident that food originating in the Community or imported from a third country is likely to constitute a serious risk to human health, the Commission, acting on its own initiative or at the request of a Member State, may immediately adopt one or more of the following interim measures, depending on the gravity of the situation:

   (a) in the case of food of Community origin:

      (i) suspension of the placing on the market of the food in question;

      (ii) laying down special conditions for the food in question;

      (iii) any other appropriate interim measure;

   (b) in the case of food imported from a third country:

      (i) suspension of imports of the food in question from all or part of the third country concerned and, where applicable, from the third country of transit;

      (ii) laying down special conditions for the food in question from all or part of the third country concerned;

      (iii) any other appropriate interim measure.

   Within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 57(2).

2. Where a Member State officially informs the Commission of the need to take emergency measures with regard to food or establishments in another Member State, or with regard to a third country or a food from a third country or an establishment in a third country, and the Commission has not applied the provisions in paragraph 1, the Member State may take interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

   Within 10 working days, the Commission shall put the matter before the Committee set up in Article 57(1) in accordance with the procedure provided for in Article 57(2) with a view to the extension, amendment or abrogation of the national interim protective measures.

   The Member State may maintain its national interim protective measures until the Community measures have been adopted.

Article 56
Other measures

Where it is evident that food originating in the Community or imported from a third country is likely to constitute a serious risk to human health and the Commission does not consider it appropriate to adopt an emergency measure pursuant to Article 55, the Commission may examine the situation as soon as possible within the Committee set up in Article 57 and adopt the necessary measures in accordance with the procedure referred to in Article 57(2). It shall follow the development of the situation and, if necessary, it shall amend or revoke, in accordance with the procedure referred to in Article 57(2), the measures taken.

CHAPTER V

PROCEDURES AND FINAL PROVISIONS

SECTION 1

COMMITTEE AND MEDIATION PROCEDURES

Article 57
Committee

1. The Commission shall be assisted by a Committee on Food Safety and Animal Health, hereinafter referred to as the "Committee", composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 58
Functions assigned to the Committee

The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairperson or at the written request of one of its members.

Article 59
Mediation procedure

1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.

2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on the contentious scientific issue from the Authority. The terms of that request and the time-limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.

SECTION 2

FINAL PROVISIONS

Article 60
Review clause

1. Within three years of the date established in Article 65, the Authority, in collaboration with the Commission, shall carry out an independent evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices of the Authority and the impact of the Authority, acting as such

   The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary, regarding changes in the Authority and its working practices. The evaluation and the recommendations shall be made public.

2. Within three years from the date established in Article 65**,** the Commission shall publish a report on the experience acquired from implementing Sections 1 and 2 of Chapter IV.

Article 61
References to the European Food Authority and to the Committee on Food Safety and Animal Health

1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Authority.

2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs, the Standing Veterinary Committee and the Standing Committee on Plant Health shall be replaced by a reference to the Committee on Food Safety and Animal Health.

3. For the purpose of paragraphs 1 and 2, "Community legislation" shall mean all Community regulations, directives and decisions.

4. Decisions 68/361/EEC, 69/414/EEC, 70/372/EEC and 76/894/EEC are hereby repealed.

Article 62
Competence of the European Medicines Evaluation Agency

This Regulation shall be without prejudice to the competence conferred on the European Agency for the Evaluation of Medicinal Products by Regulation (EEC) No 2309/93, Regulation (EEC) No 2377/90, Council Directive 75/319/EEC[21] and Council Directive 81/851/EEC[22].

Article 63
Seat

The seat of the Authority shall be decided by the competent authorities, on the basis of a proposal of the Commission.

Article 64
Relationship between this Regulation and existing food law

Existing food law shall continue to apply until amended to ensure conformity with the provisions laid down in Chapters I and II.

Article 65
Commencement of the Authority's operation

The Authority shall take up its responsibilities on [……].

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21 OJ L 147, 9.6.1975, p. 13.
22 OJ L 317, 6.11.1981, p. 1.

Article 66
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Articles 49, 51, 52, 53, 54, 59 and 61(1) shall apply from the date provided for in Article 65.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

FINANCIAL STATEMENT

1. TITLE OF OPERATION

Proposal of a Regulation of the European Parliament and the Council of the European Union laying down the general principles and requirements of food law, establishing a European Food Authority, and laying down procedures in matters of food safety

2. BUDGET HEADINGS INVOLVED

B 3-4309 is the established budget heading which contains all appropriations to the new Authority.

Savings are expected on Budget headings and lines:

Part B of the Budget;

B 1-33, B 3-43, B 5-100 and B 5-721.

3. LEGAL BASIS

Article 37, 95, 133 and 152 of the EC Treaty.

4. DESCRIPTION OF OPERATION

4.1 General objective

This proposal will establish a European Food Authority (EFA) with its own legal identity. The Authority will contribute to the provision of the scientific basis for European food and related legislation, the establishment and maintenance of confidence in the European food supply and real improvement in the health protection of consumers.

The EFA will be responsible for the scientific assessment of risk to human, animal and plant health and contribute to the health and safety of workers in the food chain, data gathering, the evaluation and identification of emerging risks and assisting with crisis situations, particularly in the food supply, the rapid alert system, the evaluation of substances, processes and food. It will support the protection of the environment and consider technological questions. It will communicate information and advice within its field of competence. It will primarily service the needs of the Community through the provisions of timely, transparent, independent and excellent scientific information to the Commission, through the work of scientific committees and networks. The Authority will also contribute directly to the provision of food safety information to the general public and other stakeholders within the areas of its competence.

4.2 Period of the action covered and arrangements for renewal

The duration of the action is unlimited (annual subsidy).

The proposal for a regulation foresees (Article **[60])** that during the third year following the take-over of responsibilities by the Authority, the Commission will draw up a report reviewing the implementation and effectiveness of the Authority with, if necessary, proposals for the adaptation or extension of tasks. This will also include an evaluation of the adequacy of resources and make recommendations to ensure the effective functioning of the EFA in subsequent years.

5. CLASSIFICATION OF EXPENDITURE/REVENUES

5.1 Non compulsory expenditure

5.2 Differentiated appropriations

6. TYPE OF EXPENDITURE/REVENUE

Community subsidy of up to 100% of the expenditure to balance the budget.

7. FINANCIAL IMPACT

Assumptions

As the new Authority will have to start from scratch, start-up cost prior to the actual transfer of Scientific Committees will be necessary and are accounted for in period n. The period n will start at the date of the adoption of this Regulation. In the year n+1 the Authority will take up its responsibilities. However, given the importance of the work of the Authority, every effort will be made to have the Authority start as soon as possible after the adoption of this Regulation. The work capacity will increase very rapidly as the envisaged staffing level is achieved.

The calculations for resource needs are based on a 'stand-alone' entity (i.e. not reliant on the Commission's infrastructure).

Staff costs are shown on a 12-month basis and personnel and administrative expenditure is EUR 0.108 million a year per person. Costs for travel, immovable property and related services are based on actual rates at the Commission's work centres.

7.1 Method of calculating total costs of operation

(1) The preparatory phase prior to the functioning of the authority (year n), will require a subvention of:

Personnel expenditure	EUR 2.0 million
Administrative expenditure	EUR 3.6 million
Operational expenditure	EUR 3.4 million
Total	**EUR 9.0 million**

The Personnel Expenditure refers to a core start up team (35 people at the end of the start-up phase), which will be charged with the foundation work for the new Authority. Part of the administrative expenditure relates to one-off investments in equipment and IT (soft and hardware). Costs relating to building and infrastructure are based on the assumption that the Authority will operate initially within the Commission's buildings. The timing of related investment will depend to a great extent on a decision relating to the site of the Authority. The operational expenditure covers preparatory studies in the field of workflows, telematic and informatic systems, implementation planning, job description, the recruitment procedures, preparation for the launch etc.

(2) The functioning of the EFA in n+3 will necessitate an annual Community subvention of about EUR 44.4 million.

(a) Personnel expenditure

The Authority's work force of 255 staff in the year n+3 with average annual personnel cost of EUR 0.078 million per person will cause expenditure totalling approximately EUR 19.9 million. This work force will constitute: 145 A, 45 B, 61 C and 4 D.

(b) Administrative expenditure

The planned expenditure is around EUR 7.6 million annually and this will be reviewed after the start up phase has been terminated. It is assumed that the total costs in this category will not exceed EUR 0.03 million per year per person.

(c) Operational expenditure

The expenditure is estimated to be around EUR 16.9 million annually for the year n+3 and onwards.

(1) Cost of staff missions: EUR 0.4 million

When planning this expenditure reference was made to the actual expenditure of comparable agencies and specific job descriptions in the different tasks. The amount per mission within Europe is estimated at EUR 800 per day and EUR 1 200 per day for the rest of the world.

(2) Cost of meetings: EUR 5.0 million

These calculations are based on the following assumptions: (1) Travel and subsistence: meetings EUR 800 per person/day and EUR 1 150 per person/per meeting of two days; (2) EUR 350 indemnity per day (independent scientists only), to which one has to add logistics, interpretation, translation, etc. for such meetings.

(3) Cost of dossier evaluation and scientific studies: EUR 10.9 million

The cost of externalised preparatory work for dossier evaluation is EUR 6.4 million and for scientific studies is EUR 4.5 million.

(4) Other operational expenditure EUR 0.6 million

The costs for the collection and dissemination of the information are (EUR 0.2 million), the editing of reports (EUR 0.2 million), the organisation of seminars (EUR 0.1 million), and evaluations (EUR 0.1 million).

7.2 Itemised breakdown of cost

On the basis of current experience and understanding of workloads to be performed by EFA it is foreseen that the resources needed for the EFA to carry out its tasks effectively would be 339 staff. Within the total budget, there are some uncertainties about the volume and amount of external scientific work.

The present financial assessment provides detailed information for the start up period until the year n+3. The adequacy of current and future funding will be evaluated through a review, which will take place during year n+3 in order to ensure that years n+4 and beyond are adequately financed.

Commitment appropriations EUR 44.4 million (at current prices).

Year	N	n+1	n+2	n+3	Total
Staff	**35**	**111**	**168**	**255**	
(a) Personnel	2.0	8.6	13.1	19.9	43.6
(b) Administrative	3.6	3.4	5.1	7.6	19.7
(c) Operational					
Missions own staff	0.2	0.1	0.2	0.4	
Indemnities/Meetings	0.0	5.1	4.1	3.2	
Translation/Interpretation	0.2	2.5	2.1	1.8	
External Scientific Work	0.0	4.8	7.2	10.9	
Other	3.0	0.4	0.4	0.6	
Sub total	3.4	12.9	14.0	16.9	47.2
Grand Total	**9.0**	**24.9**	**32.2**	**44.4**	110.5
Year on year increase		178%	29%	38%	

7.3 Operational expenditure included in Part B of the budget

It is assumed that there will be an off set effect for the Community's budget in Part A and Part B. For savings in Part A see point 10.

By transferring activities, which are under the responsibility of DG Health and Consumer Protection and are financed in Part B of the Budget, into the European Food Authority an annual offset is expected. The main sources of these funds (EUR 4.6 million p.a.) are reimbursements of experts allowances, studies in the field of food safety, veterinary activities and the pesticides peer review.

For 2001:

B 1333	Pesticides peer review ECCO	EUR 0.8 million
B 5100	Scientific Committees	EUR 2.7 million
B 53002	Scientific Cooperation	EUR 0.3 million
B 5721	IDA	EUR 0.8 million

7.4 Schedule of commitment and payment appropriations

The Community subsidy will be paid once a year.

8. FRAUD PREVENTION

Article 43 of the proposed regulation foresees independent control of all revenue/expenditure of the EFA by a financial controller, who will be nominated by the Financial Controller of the Commission.

The Management Board will safeguard and make certain that systems in place for fraud prevention are in line with those implemented by the Commission - Article 24.

The personnel submitted under the Commission's staff regulation shall cooperate with OLAF to combat fraud.

It is stipulated in the Article 43 that the European Court of Auditors will audit the accounts conforming to Article 248 of the Treaty.

9. ELEMENTS OF COST EFFECTIVENESS ANALYSIS

Method of Working

There are few existing structures, which can be compared to a European Food Authority. However other organisations and parts of organisations were identified, which face similar challenges, undertake comparable tasks and operate at analogous levels of input/output as are envisaged for the European Food Authority.

The structures and organisations are:

(a) the existing structure within the Commission; the European Medicines Evaluation Agency; the European Environment Agency;

(b) United Kingdom: Food Standards Agency; Germany: Biologisches Bundesamt Braunschweig; France: Agence Française de Sécurité Sanitaire des Aliments; Ireland: Food Safety Authority of Ireland;

(c) Canada: Health Canada; USA: Food and Drug Administration;

(d) European Central Bank (ECB); North Atlantic Treaty Organisation (NATO); World Health Organisation, the Food and Agricultural Organisation and the Organisation for Economic Cooperation and Development.

The abovementioned have been analysed and information has been compared depending on relevance (e.g. ECB and NATO on communication and crisis management only). The outline given below takes these findings into account.

9.1 Specific and quantified objectives

The overall objective is to establish a European Food Authority (E F A) with its own legal identity. The European Food Authority will contribute to:

- the scientific basis of European legislation directly and indirectly related to the food chain;
- the establishment and maintenance of confidence within the European food supply,
- the visible improvement in the health protection of consumers and
- the effective functioning of the internal market.

To this end, the European Food Authority will be active in five key areas:

Task	**Staff**	**Expenditure n+3**			
		Personnel	**Admin**	**Operational**	
1: The provision of Scientific Opinions	138	10.8	4.1	7.8	22.7
2: Information gathering	26	2.0	0.8	5.3	8.1
3: Technical Advice	17	1.3	0.5	2.3	4.1
4: Emerging risks, rapid alert, support in case of a food safety crisis	18	1.4	0.5	0.1	2.0
5: Communications	9	0.7	0.3	0.5	1.5
6: Corporate Support	47	3.7	1.4	0.9	6.0
Sub totals	255	19.9	7.6	16.9	
Grand total					**44.4**

NB: by way of comparison, in 2000 EMEA will have an annual budget of some EUR 50 million and 210 staff to cover the field of medical evaluations (human and veterinary). Considering the wider scope and range of tasks to be undertaken by EFA the figures are moderate.

Task 1 The provision of Scientific Opinions

The objective will be to provide excellent, high quality scientific opinions in food safety and nutrition, animal health and welfare and plant health to policy makers and risk managers in a timely and transparent manner. These opinions will be developed by top level, specialised scientists from Member States and where appropriate, other countries through Scientific Committee and panel meetings hosted by EFA.

The European Food Authority will need to attract leading scientists and assure a high degree of efficiency. However, this will only be possible if the procedures in the organisation are professionally managed, background scientific and technical information is gathered and processed in advance, the meetings are well prepared, the dossiers and monographs are of high quality and the number of meetings limited. Remuneration is foreseen for the work done in relation to the evaluation of dossiers by designated Member State organisations. In this way EFA becomes a contractual partner and can command and determine tight deadlines and require high quality evaluations of dossiers in the Member States.

The foreseen work loads in terms of dossiers for the secretariat and the scientific expertise, which support the Scientific Committee and panels have been structured according to the man days of work of scientifically trained personnel associated with them. This technique is in line with the working practice at the US FDA and led us to establish three categories of dossiers large = more than 20 man/days, medium 11-20 man/days and small. For the secretariat we used the same basis plus the number of meetings envisaged for the respective panel.

The following table gives the results and provides also a break down of the operational expenditure EUR 7.8 million (Meetings EUR 3.2 million; Dossier Authorisations EUR 4.4 million; Staff missions EUR 0.2 million):

	Committees/Panel	Projection n+3 Dossiers			*Staff*	Meetings	Dossier Authorisation
		Large	Med	Small		EUR million	EUR million
	The Scientific Committee	4	9	4	*7*	0.2	0
1	Food Additives[1#]	22	69	26	*20*	0.3	1.6
2	Feed Additives #	9	9	4	*7*	0.2	0.34
3	Plant Protection Products #	55[2]		(6 600)[3]	*38*	0.3	1.38
4	GMOs[4] #	8	51	48	*13*	0.2	1.04
5	Nutrition #	8	12	6	*7*	0.3	
6	Biological Hazards	8	8	6	*35*	1.2	
7	Food/Feed Contamination #	3	13	6	*6*	0.2	
8	Animal Health/Welfare	8	11	2	*5*	0.3	
	Total	**125**	**182**	**102**	***138***	**3.2**	**4.4**

1 Includes Additives, Materials in Contact with Food, Processing Aids, and Flavouring.
Includes apportionment of 13 staff for chemical exposure evaluation.
2 Based on longer-term number of dossiers; might peak at around 75 in 2005/2007.
3 Highly standardized procedure for Maximum Residue Levels.
4 Includes GM Feeds, GM Varieties, GM Plants.

The above figures for large and medium dossiers are based on current and prospective European legislation. The projections for large and medium size dossiers or ad-hoc questions from members of the current secretariat have been audited using the expectations from their main customers within the European Commission and parallel organisations. The overall implied growth rate of the number of dossiers is 7% year on year for existing work areas. New fields like Processing aids[5], GM feed, seeds and varieties as well as nutrition will account for 65 dossiers/ questions in year n+3. Under the proposed regulation Member States and Parliament will have the right to put forwards questions to the Authority.

Source	
	Share
Commission	76%
Member States	10%
European Parliament	12%
EFA/ other	2%

In order to satisfy future requirements the scientific committee and panels' support function will be required to perform existing and additional tasks:

- Preparatory work for scientific questions not undertaken by the Member States;
- Critical review of monographs and initial risk assessments in the wide range of subjects covered by EFA;
- Overall work programme for the Scientific Committee and panels, resource allocation, coordination, harmonisation;
- Organisation of meetings.

	Meetings	Days	Participants
Scientific Committee and Panels	21	38	18
Scientific Working Groups	87	140	10

- Application of rules of procedure of the Committee and panels;
- Management of individual questions ("project management") within required time-limits;
- Technical and administrative management of dossiers submitted as part of Community authorisation processes;
- Interface with petitioners, risk managers, and risk communicators;
- Secretariat to the committee and panels including organisation of meetings, minutes and follow up actions;
- Documentation management, archiving, dispatch and receipt of information.

The first two tasks are not performed in the existing structure and will absorb a considerable amount of time from the in-house experts.

[5] Will be treated by a sub panel to the panel on Food additives.

The main dossier evaluation for the authorisation of substances, processes and food technology procedures etc. will be undertaken to the fullest extent possible in cooperation with the Member States' organisations[6] working in the same field as the Authority. In this respect the time and resources put into this work by the designated organisations (private or public) in the Member States will be funded through a dedicated budget.

Dossier authorisations 90 Large at EUR 0.038 million

115 Medium at EUR 0.026million.

This will amount to a total of EUR 6.4 million. The amounts available for funding per authorisation are well below comparable prices in the European Medicines Evaluation Agency, and are less than the fees already levied in the pesticides area by Member States. Partial remuneration for work undertaken in the Member States is regarded as paramount, to enable EFA, as a contractual partner, to be able to insist on evaluation work being undertaken in a scientifically robust and timely manner.

It is assumed that small dossier evaluations and initial dossier assessment for acceptability/completeness checks will be undertaken in-house without referring to the resources of the Member States.

Variables: The demands for scientific opinions in some areas can be estimated and planned as there are legal or other predictable requirements (additives, pesticides, etc.). In other circumstances, a food safety crisis (dioxin, BSE), trade dispute (e.g. the ban on the importation of beef treated with certain growth promoting hormones), the characteristics of the workload in question, and therefore meaningful evaluation criteria, cannot be established in advance.

Measurable:

– the provision of scientific opinions within agreed time scales in existing or future legislation, or as agreed with the Commission (90% of the dossier evaluation will be dealt with in <12 month);

– adherence to dead-lines in the approval/authorisation of foods or processes (Non-respect of dead-lines < 5% in terms dossiers and time);

– the number of dossiers completed annually for approval of a substance/process/food by panels 1-4 (90 large dossiers; 115 medium dossiers)

– the number of ad hoc questions completed annually;

– number of large microbiological risk assessments now 0 and in the future 4 per year.

The targeted outputs for a given time frame are closely linked to the resources especially allocated in this area.

[6] The current reservoir of experts/organisations to be used by the EMEA is well in excess of 3 000.

Measurable impact would include reduction in illness or disease, but as we have no overview of current information, this aspect cannot be measured in the short term. There are examples in third countries, where reduction of illness is assessed and costs to the economy calculated so that scientific effort can be prioritised. However in some areas e.g. where there are longer-term effects (exposure to chemical hazards) this approach is not feasible.

Periodic independent scientific audit will be incorporated into the work programme of the Authority.

Task 2 Information Gathering and Studies

The overall objective will be to ensure that the European Food Authority has an overview of trends in relation to the safety of the food supply. Such information can be used for a number of other functions within the Authority, e.g. support to the Scientific Committee and Panels, identification of emerging risks and Technical advice.

Therefore the management of certain established data collection and information networks will be incorporated into the European Food Authority, and where information gaps are identified, efforts made to fill these. In order to define in more depth the needs of the Authority, external feasibility studies will be requested.

A dedicated group of 23 staff will be responsible for management and coordination. Information will be actively gathered through access to databases and other sources in addition to the existing scientific networks. This information and data will also have to be processed and analysed.

In addition, it is foreseen that the Authority as stipulated in the White Paper on Food Safety will command critical, short term studies closely linked to the actual work programme of the scientific committee to support its role, e.g. on gaps in the data and other scientific or technical information:

30 scientific studies spread over the 8 areas at EUR 0.1 million each = EUR 3.0 million

The number of the items above, relates to the number of dossiers/ad hoc questions to be handled by the Scientific Committee and panels and covers also crisis scenarios, where the ability to utilise the Authority's own resources is crucial. The required budget was established taking into account the experience in comparable Authorities and Institutions in Member States and Third countries and will provide leverage for the Authority to have access to results. The pricing for such contracts are based on commercial rates from private sector research institutes.

To manage these specific non-standard contracts (tender, monitoring, evaluation) three members of staff are regarded as necessary.

Variables: The need for information and scientific studies can be predicted to some extent. But there are a number of variables, which remain uncertain e.g. the complexity of the information needed to support a scientific opinion, the nature of a request from the Commission's legislative services, whether the study is (partly) available or whether the expertise to do a study exists.

Measurable: Measurable aspects will include the number of information requests, their completeness and timeliness and the provision of information bulletins to the emerging risk and communications components.

Task 3 Technical advice

The objective is to enable the European Food Authority to examine technical questions relevant to food safety and other related issues in order to support the work of the Commission (regulatory services and Food and Veterinary Office) and the scientific committees (Task 1). The main emphasis will be on utilising the expertise within the Member States, and where relevant, the industry through coordination and if appropriate, through in-house expertise. To access the best expertise approximately 15 short studies on technological matters (EUR 0.05 million each) and three scientific studies (EUR 0.25 million each) are estimated to be necessary. It is planned to employ 17 people in this task.

Variables: The workload for some of the aspects covered in this area will be predictable (coordination of Guides to Good Practice), but in others e.g. ad hoc questions or technical information needed in a food safety crisis the workload will be less predictable.

Measurable: Outputs include the number of reports produced for the Commission, scientific committee and panels. Guideline documents can also be measured in terms of outcome produced.

The quantity of outputs would be in this area:

– 15 Technological questions (e.g. purity criteria, residue plans);

– approximately three large technological reports per year (150 pages) with subsequent conferences;

– two Guides to Good Practice per year (40 pages).

Task 4 Identification of emerging risks, rapid alerts and support in case of food safety crisis

The specific objectives for this task are threefold:

1. The European Food Authority must be well informed and be able to identify to the fullest extent possible, any emerging risks to human health from the food chain or animal feed supply and to inform the Commission, Member States and other stakeholders. This function will require a dedicated staff of six.

2. The objective of the European Food Authority with regard to the Rapid Alert System will be to ensure that accurate, precise information concerning hazardous feeds and foods is disseminated to the Member States, the Commission, and where appropriate agreements exist, to third country governments. (Staff 6).

3. The overall objective of the European Food Authority in relation to crisis situations will be to identify to the fullest extent possible a crisis situation and to support the Commission and the Member States in the resolution of that crisis thus regaining confidence in the European food supply. (Staff 6).

Variables: It is not possible to measure how many crises may be prevented, as it is not possible to estimate how many there may be.

Measurable: As one cannot quantify this prospective, safeguarding work in terms of non-emergency or increased food safety, a regular screening of the activity by recognised evaluators or experts in the field will have to take place.

Task 5 Communication

The aim of the European Food Authority and its Communication Strategy will be to establish the high profile of the Authority as an effective, authoritative voice in Europe. Communications will be pivotal to the European Food Authority's success and acceptance. The objective is to provide clear, rapid and factual information in a manner that can be understood by non-specialists and specialists alike.

The staffing (9) in this area needs to cover routine activities as well as a crisis situation. However it is envisaged that other staff members trained in media handling would also be involved in this task when the need arises.

Variables: In the main, the communications function should be predictable in relation to reports, publications and the translation of scientific opinions into lay language. However, in a food safety crisis or where there are growing concerns, the need for press briefings, information on the web-site etc. will be increased. It is not possible to predict the number of emergencies.

Measurable: The outputs will comprise: weekly press releases about the work achieved; campaigns (coordination) on food safety; announcements/communications/interviews to/ with the media thus reaching the general public; information leaflets; a web site; the annual report; conferences; the reports developed in Task 3, and most importantly the handling of the media during a crisis situation.

Task 6 Administration and Support

The requirements in the above mentioned 5 tasks lead to the following staffing numbers in the support functions:

Function	***Staff***	**Meetings in 000 EUR**
Executive Director / Legal Service	*5*	
Support to Management Board + Advisory Forum	*2*	450
General Administration / Quality Assurance	*11*	
Reception, Conference and Travel Management	*5*	
Finance	*8*	
Information Technology	*9*	
Archiving/ Document management	*7*	
Total	***47***	**450**

The staffing levels in this area are below similar organisations. In order to assure high quality outputs and efficient performance the Authority will implement a system of internal and external evaluations (peer reviews, bench marking and audits).

The following number of meetings and costs are planned:

	Meetings	Days	Participants
Management Board	3	4	17
Advisory Forum and Working	18	23	11

Groups			

A budget of EUR 0.1 million for evaluations and audits is allocated to the Executive Director.

9.2 Grounds for the Operation

The White Paper on Food Safety (COM(1999) 719) and the comments the Commission received during the consultative period.

In addition the work and studies undertaken in the report of three scientific Professors (Pascal, James and Kemper) December 1999 – "Report on the future of scientific advice in the European Union"- have been noted.

Subsidiarity

The proposal has been planned with regard to the principles of subsidiarity and cost effectiveness. Combining this fundamental element of European policy making with the necessary level of independence, the European Food Authority is conceived to be a coordinating organisation. Tasks that can be undertaken at the level of the Member States will be so undertaken.

Potential Cost savings

Even if one cannot forecast reduction in concrete numbers, it is prudent to assume that the sharing of information should reduce the duplication of effort in the Member States. It should be overall more cost effective to public expenditure in the area of human health, if risk assessment and safety evaluation is coordinated by the European Food Authority. Coordination and management of these activities, addressing issues for the whole European population while still using the same expertise and facilities within the Member States, will reduce the overall expenditure in this field.

Staff allocation in the Member States' organisations working in the same field as the Authority may shift as confidence grows that specialised resources can be accessed in other Member States. We expect these developments to be more prominent in smaller Member States and the new accession countries, which can focus their national resources on areas that are of specific importance to their population and industry.

9.3 Monitoring

The European Commission will be in daily contact with the new Authority, as it advises on the questions put forward by the Commission. The degree to which EFA meets agreed time-limits and outputs will be an impartial indicator of the Authority's performance.

It is laid down in the Regulation [Articles 25, 28 and 30] that the Authority will respond according to provisions to be established between the Commission and the Authority.

The European Commission will establish a small group to work as a dedicated interface between the Commission and the Authority.

In addition, the evaluation of the whole operation proposed in the Regulation, Article **[60]** will contribute to the assurance that the Authority will follow the needs of the Commission. Mechanism will be put in-place to tune the operation if the need arises. The findings of evaluations will be made available to the public.

10. ADMINISTRATIVE EXPENDITURE

(SECTION III, Part A of the GENERAL BUDGET)

Actual mobilisation of the necessary administrative resources will depend on the Commission's annual decision on the allocation of resources, taking into account the number of staff and additional amounts authorised by the budgetary authority.

10.1 Effect on the number of posts

Types of posts		Staff to be assigned Monitoring the operation		Source		Period
		Permanent Posts	Temporary Posts	Existing Resources Concerned	Additional Resources (net reduction)	
Members Staff	A	10		25	-15	Indefinite
	B			10	-10	
	C	2		15	-13	
Other resources						
TOTAL		12		50	-38	

Staff to be assigned: Personnel regarded as necessary to monitor the authority (8 scientific officials + advisors to Commissioner and Director General).

They must be in place before the Authority starts. The existing posts to be transferred relate mainly to Directorate C and include overheads. The phasing out of the above mentioned activities will be spread over the period n until n + 2.

10.2 Global financial impact on human resources and administrative expenditure

Head count of point 10.1 in EUR million decrease (-).

Budget heading	Amounts (net)	(of which additional)	Method of calculation
A B C	1.1 0.2	- 1.6 - 1.1 - 1.4	DG admin standard rates see part 7.2
Total	1.3	- 4.1	

The amounts given express the total cost of human resources and administrative expenditure for 12 months.

EUR 4.1 million is the global financial impact (savings) of reducing the number of posts at the DG Health and Consumer Protection by 38 (net). EUR 1.3 million is the money equivalent of having 12 new post in DG Health and Consumer Protection to monitor EFA.

A short-term increase of administrative expenditure for the Commission is initially expected due to the simultaneous housing of the old and new structure on the Commission premises, until such time that the Authority seat is established.

10.3 Other administrative expenditure as a result of the operation

Budget heading	Amounts	Method
A 700	– 0.3	Actual DG Sanco budget total in relation to staff numbers transferred 38 posts transferred/ 630 posts in DG Sanco = 6.0%
A 701	– 0.2	
A 702	0	
A 703.1*	0 Regulatory Committee	
A 703.2**	– 2.5 Scientific Committees	
A 704	– 0.1	
A 705		
Total	– 3.1	

*A 703.1 The amounts necessary to compensate government experts for attending meetings of the committee set up under Article 58 will not be changed by this Regulation.

**A 703.2 Scientific Committee: Travel/subsistence related to EFA tasks EUR 2.5 million. In comparison to the existing situation, A percentage calculation is applied to the DG Health and Consumer Protection global budget in order to identify the relative amount pertaining to the transferred posts. 630 is approximately the total of posts in DG Health and Consumer Protection.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS WITH SPECIAL REFERENCE TO SMALL AND MEDIUM-SIZED ENTERPRISES (SME's)

TITLE OF PROPOSAL

Regulation of the European Parliament and of the Council, laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety

THE PROPOSAL

1. Taking into account the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?

The regulation lays down at Community level the general principles and uniform definitions of food, food law and in particular food safety thus ensuring the effective functioning of the Internal Market. It relates to all stages of the production and distribution of food, from and including the primary production of food, up to and including its sale to the final consumer. It also covers animal produced for and/or fed to food-producing animals where this may have an adverse effect on food safety.

It will contribute to safeguarding the safety of food to the European Consumer. It establishes the scientific basis for European food law, the establishment and maintenance of confidence in the European food supply and strives to foster real improvements in the health protection of consumers.

THE IMPACT ON BUSINESS

2. Who will be affected by the proposal?

All sizes of businesses related to the production and trade of products and services in the food chain are affected. The proposal has a similar impact over the entire Community. It is not aimed at any particular region.

3. What will business have to do to comply with the proposal?

The main new additional obligations for business will depend on the national legislation already in place:

Obligations for food and feed business operators:

to ensure that all stages of production and distribution for which they are responsible are carried out in such a manner that foods and feeds comply with the provisions relevant to food law;

to inform the competent authorities if it considers or suspects that a food or feed placed on the market does not comply with the relevant safety requirements;

to inform the competent authorities of the action taken to prevent risks to the final consumer. In cases where the food presents a serious risk to health the food or feed business operator shall follow the procedures established;

to collaborate with the competent authorities according to the requests of the latter, on action taken to avoid risks posed by a food which they supply or have supplied;

not to export food from the Community if it does not comply with the relevant requirements of food law, unless otherwise requested by the authorities or stated by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country;

to identify the suppliers of food, feed, a food-producing animal or any other substance intended to be, or potentially to be incorporated into a food or feed supplied to their businesses and to be in a position to make available this information to the competent authorities on demand;

to have in place systems to identify to whom their products have been supplied and to make this available to the competent authorities on demand;

to adequately label and/or identify foods or feed which are placed on the market or is likely to be placed on the market in the Community to allow its traceability, in accordance with the relevant requirements of more specific provisions.

Obligations for a food business operator responsible for the production, importation, processing or manufacture of a food:

to initiate procedures to withdraw the food in question from the market, if it considers or suspects that a food which it has produced, processed or manufactured is not in compliance with the food safety requirement or consumer interests are otherwise adversely affected by the continued marketing of that food;

to adequately and effectively inform the consumers of the reason for its withdrawal, or in the last resort, recall from consumers products already supplied to them when other measures are not sufficient.

Obligations for a food business operator responsible for import, retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food:

to act with due care to help ensure compliance with the food safety requirement and that the marketing of the food does not adversely affect the interests of consumers;

to initiate, within the limits of their respective activities, procedures to withdraw such products from the market and participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities;

to effectively warn consumers of the risks posed by those products already supplied to them, and when necessary and as a last resort recall such products in order to avoid such risks;

not to export to non-Member States dangerous products according to the criteria of the Directive or the safety requirements established by specific Community legislation applicable to the product considered, unless it can be demonstrated that the use of such products would be compatible with a high level of consumer health and safety protection under the conditions and technical requirements of the destination country.

Obligations for a feed business operator responsible for the production, importation, processing or manufacture of a feed:

to ensure that feeds for which they are responsible do not have the potential to cause a food safety problem, and should ensure that practices are carried out in such a manner that food safety is not compromised;

to place only safe feed on the market linking this with the need to ensure that food, from animals fed on such feed is safe;

to withdraw their products from the markets and to inform the Competent Authorities where they become aware that a feed may affect food safety.

However, it should be noted that the requirements stated above exist to a greater or lesser extent in most Member States as their respective Food Law already incorporates food safety and consumer protection requirements.

The increased costs associated with the new obligations for SMEs will occur only to increase consumer safety and to set the same standards throughout the community, which will improve competition.

4. What economic effects is the proposal likely to have?

This proposal will establish an effective and consistent framework for ensuring protection of consumer health and safety, and equal requirements of food and feed business operators within the limits of this Regulation.

Certain provisions of the proposal will improve businesses' competitiveness. At present businesses, which do not respect the same standards to protect consumer health and safety might have an unfair advantage over those that do.

More effective food law will reduce such unfair competition between businesses within the internal market and also in the context of the globalisation of World trade. The whole business sector could also gain a marketing advantage in terms of the increased confidence by consumers.

The Regulation will help to provide clear references points for business and consumers in defining the requirements for food business operators and safe food. This in turn, will assist businesses and particularly SME's in penetrating the internal market as the standards that need to be attained will be harmonised and cover the whole food chain. Common assessment criteria and product safety standards will permit businesses to compete on a level playing field by ensuring them equal opportunities.

5. Does the proposal contain measures to take account of the specific situation of small and medium-sized firms (reduced or different requirements, etc.)?

The scope of the proposal is entirely horizontal and its provisions are generic. Therefore, it does not contain measures specifically aimed at or adapted for small and medium-sized firms. It is expected that subsequent legislation is likely to take account of SME's notably in the agricultural sector, as current national rules do.

CONSULTATION

6. Organisations that have been consulted about the proposal and who have outlined their main points.

During a meeting of the Advisory Forum on Foodstuffs, the following organisations expressed their views with regard to the General Food Law part of the proposal:

- Union Européenne de l'Artisanat et des PME
- CELCAA
- BEUC
- UGAL
- CIAA
- COPA/COGECA
- EURO-COOP
- Eurocommerce

In addition a large number of comments were received from the stakeholders on the Commission's white paper on food safety. All comments are available on the Web site: http://europa.eu.int/comm/food/fs/intro/wpfs_comm_index_en.html.