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WHITE PAPER ON FOOD SAFETY

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EXECUTIVE SUMMARY

Assuring that the EU has the highest standards of food safety is a key policy priority for the Commission. This White Paper reflects this priority. A radical new approach is proposed. This process is driven by the need to guarantee a high level of food safety.

European Food Authority

The establishment of an independent European Food Authority is considered by the Commission to be the most appropriate response to the need to guarantee a high level of food safety. This Authority would be entrusted with a number of key tasks embracing independent scientific advice on all aspects relating to food safety, operation of rapid alert systems, communication and dialogue with consumers on food safety and health issues as well as networking with national agencies and scientific bodies. The European Food Authority will provide the Commission with the necessary analysis. It will be the responsibility of the Commission to decide on the appropriate response to that analysis. A European Food Authority could be in place by 2002 once the necessary legislation is in place. Before finalising our proposals we are inviting all interested parties to let us have their views by end April. A definitive legislative proposal would then be brought forward by the Commission.

Food Safety Legislation

The setting up of the independent Authority is to be accompanied by a wide range of other measures to improve and bring coherence to the corpus of legislation covering all aspects of food products from "farm to table".

Already the Commission has identified a wide range of measures that are necessary to improve food safety standards. The White Paper sets out over 80 separate actions that are envisaged over the next few years.

There have been enormous developments in the past decades, both in the methods of food production and processing, and the controls required to ensure that acceptable safety standards are being met. It is clear that, in a number of areas, existing European legislation has to be brought up to date.

Following the Commission's Green Paper on food law (COM(97)176 final), and subsequent consultations, a new legal framework will be proposed. This will cover the whole of the food chain, including animal feed production, establish a high level of consumer health protection and clearly attribute primary responsibility for safe food production to industry, producers and suppliers. Appropriate official controls at both national and European level will be established. The ability to trace products through the whole food chain will be a key issue. The use of scientific advice will underpin Food Safety policy, whilst the precautionary principle will be used where appropriate. The ability to take rapid, effective, safeguard measures in response to health emergencies throughout the food chain will be an important element.

Proposals for the animal feed sector will ensure that only suitable materials are used in its manufacture, and that the use of additives is more effectively controlled. Certain food quality issues, including food additives and flavourings and health claims, will be addressed, whilst controls over novel foods will be improved.

The risks associated with the contamination of foods have been brought into sharp focus by the recent dioxin crisis. Steps will be taken to address those areas where the existing legislation in this sector needs to be improved to provide adequate protection.

Food Safety Controls

The experience of the Commission's own inspection service, which visits Member States on a regular basis, has shown that there are wide variations in the manner in which Community legislation is being implemented and enforced. This means that consumers cannot be sure of receiving the same level of protection across the Community, and makes it difficult for the effectiveness of national authority measures to be evaluated. It is proposed that, in co-operation with the Member States, a Community framework for the development and operation of national control systems will be developed. This would take account of existing best practices, and the experience of the Commission's inspection services. It will be based on agreed criteria for the performance of these systems, and lead to clear guidelines on their operation.

In support of Community-level controls, more rapid, easier-to-use, enforcement procedures in addition to existing infringement actions will be developed.

Controls on imports at the borders of the Community will be extended to cover all feed and foodstuffs, and action taken to improve co-ordination between inspection posts.

Consumer Information

If consumers are to be satisfied that the action proposed in White Paper is leading to a genuine improvement in Food Safety standards, they must be kept well informed. The Commission, together with the new European Food Authority, will promote a dialogue with consumers to encourage their involvement in the new Food Safety policy. At the same time, consumers need to be kept better informed of emerging Food Safety concerns, and of risks to certain groups from particular foods.

Consumers have the right to expect information on food quality and constituents that is helpful and clearly presented, so that informed choices can be made. Proposals on the labelling of foods, building on existing rules, will be brought forward. The importance of a balanced diet, and its impact on health, will be presented to consumers.

International dimension

The Community is the world's largest importer/exporter of food products. The actions proposed in the White Paper will need to be effectively presented and explained to our trading partners. An active role for the Community in international bodies will be an important element in explaining European developments in Food Safety.

Conclusions

The implementation of all the measures proposed in the White Paper will enable Food Safety to be organised in a more co-ordinated and integrated manner with a view to achieving the highest possible level of health protection.

Legislation will be reviewed and amended as necessary in order to make it more coherent, comprehensive and up-to-date. Enforcement of this legislation at all levels will be promoted.

The Commission believes that the establishment of a new Authority, which will become the scientific point of reference for the whole Union, will contribute to a high level of consumer health protection, and consequently will help to restore and maintain consumer confidence.

The success of the measures proposed in this White Paper is intrinsically linked to the support of the European Parliament and the Council. Their implementation will depend on the commitment of the Member States. This White Paper also calls for strong involvement of the operators, who bear the prime responsibility for the daily application of the requirements for Food Safety.

Greater transparency at all levels of Food Safety policy is the thread running through the whole White Paper and will contribute fundamentally to enhancing consumer confidence in EU Food Safety policy.

CHAPTER 1: INTRODUCTION

1. The European Union's food policy must be built around high food safety standards, which serve to protect, and promote, the health of the consumer. The production and consumption of food is central to any society, and has economic, social and, in many cases, environmental consequences. Although health protection must always take priority, these issues must also be taken into account in the development of food policy. In addition, the state and quality of the environment, in particular the eco-systems, may affect different stages of the food chain. Environment policy therefore plays an important role in ensuring safe food for the consumer.

2. The agro-food sector is of major importance for the European economy as a whole. The food and drink industry is a leading industrial sector in the EU, with an annual production worth almost 600 billion €, or about 15% of total manufacturing output. An international comparison shows the EU as the world's largest producer of food and drink products. The food and drink industry is the third-largest industrial employer of the EU with over 2.6 million employees, of which 30% are in small and medium enterprises. On the other hand, the agricultural sector has an annual production of about 220 billion € and provides the equivalent of 7.5 million full-time jobs. Exports of agricultural and food and drink products are worth about 50 billion € a year. The economic importance and the ubiquity of food in our life suggest that there must be a prime interest in food safety in society as a whole, and in particular by public authorities and producers.

3. Consumers should be offered a wide range of safe and high quality products coming from all Member States. This is the essential role of the Internal Market. The food production chain is becoming increasingly complex. Every link in this chain must be as strong as the others if the health of consumers is to be adequately protected. This principle must apply whether the food is produced within the European Community or imported from third countries. An effective food safety policy must recognise the inter-linked nature of food production. It requires assessment and monitoring of the risks to consumer health associated with raw materials, farming practices and food processing activities; it requires effective regulatory action to manage this risk; and it requires the establishment and operation of control systems to monitor and enforce the operation of these regulations. Each element forms part of a cycle: thus, developments in food processing can require changes to existing regulations, whilst feedback from the control systems can help to identify and manage both existing and emerging risks. Each part of the cycle must work if the highest possible food safety standards are to be enforced.

4. These facts therefore demand a comprehensive and integrated approach to food safety. This does not mean that the EU should be exclusively responsible for all aspects of food safety. However, it demands that all aspects of food safety are addressed at EU level. For example, EU legislation has to be enforceable in an efficient way in the Member States in line with the principle of subsidiarity. Responsibility for enforcement above all should remain primarily a national, regional and local responsibility. However, the Internal Market means that these are not exclusively national responsibilities: each Member State has a duty towards not only to its own citizens but to all citizens of the EU and third countries for the food produced on their territory.

5. It is necessary to underline that the European food chain is one of the safest in the world and that the present system has generally functioned well. Food safety measures have formed part of the body of European legislation since the early days of the Community. Historically, these measures have mainly been developed on a sectoral basis. However, the increasing integration of national economies within the Single Market, developments in farming and food processing, and new handling and distribution patterns require the new approach outlined in this White Paper.

   Community and Member State food safety systems have been under unprecedented pressure during recent feed and food emergencies. These emergencies have exposed weaknesses which call for action by the responsible authorities (Commission, Member States and the Parliament), to re-enforce, improve and further develop existing systems.

6. Food safety needs to be organised in a more co-ordinated and integrated way. This will allow existing weaknesses to be addressed, whilst at the same time creating a genuinely world-leading food safety framework, which can deliver a high level of public health and consumer protection in accordance with the requirements of the EC Treaty. However, the most comprehensive system cannot function without the full collaboration of all parties involved. The proper functioning of any system depends decisively on the commitment of the Member States and operators, as well as third countries.

7. The European Union needs to re-establish public confidence in its food supply, its food science, its food law and its food controls. This White Paper on Food Safety outlines a comprehensive range of actions needed to complement and modernise existing EU food legislation, to make it more coherent, understandable and flexible, to promote better enforcement of that legislation, and to provide greater transparency to consumers. This will provide the response to the conclusions of the Helsinki European Council in December 1999.

   The Commission is determined to implement the actions outlined in this White Paper as a matter of priority. A detailed Action Plan on food safety with a precise timetable for action over the next three years is provided in the Annex. Under this timetable, the most important proposals should be put forward by the Commission before the end of 2000, allowing for a coherent and up-to-date body of food law supported by a new European Food Authority to be in place by the end of 2002. The Commission looks forward to the full co-operation of the Parliament and Council in the implementation of this ambitious programme.

   There has already been extensive consultation and discussion concerning improvements to the EU's food legislation arising from the Green Paper on the general principles of food law (COM (97) 176 final). This White Paper presents the changes the Commission proposes in this area. However, in addition, the Commission envisages the creation of a European Food Authority as a further measure. In respect of this proposal, the Commission wishes to elicit public debate, informed comment and broad consultation. Interested parties are therefore invited to submit comments on Chapter 4 of this White Paper by the end of April 2000.

CHAPTER 2: PRINCIPLES OF FOOD SAFETY

This White Paper makes proposals that will transform EU food policy into a pro-active, dynamic, coherent and comprehensive instrument to ensure a **high level of human health and consumer protection**.

8. The guiding principle throughout this White Paper is that food safety policy must be based on a **comprehensive, integrated approach**. This means throughout the food chain [1] ('farm to table'); across all food sectors; between the Member States; at the EU external frontier and within the EU; in international and EU decision-making fora, and at all stages of the policy-making cycle. The pillars of food safety contained in this White Paper (scientific advice, data collection and analysis, regulatory and control aspects as well as consumer information) must form a seamless whole to achieve this integrated approach.

9. The roles of all stakeholders in the food chain (feed manufacturers, farmers and food manufacturers/operators; the competent authorities in Member States and third countries; the Commission; consumers) must be clearly defined: feed manufacturers, farmers and food operators have the primary **responsibility** for food safety; competent authorities monitor and enforce this responsibility through the operation of national surveillance and control systems; and the Commission concentrates on evaluating the ability of competent authorities to deliver these systems through audits and inspections at the national level. Consumers must also recognise that they are responsible for the proper storage, handling and cooking of food. In this way, the **farm to table policy** covering all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale, will be implemented systematically and in a consistent manner.

10. A successful food policy demands the **traceability** of feed and food and their ingredients. Adequate procedures to facilitate such traceability must be introduced. These include the obligation for feed and food businesses to ensure that adequate procedures are in place to withdraw feed and food from the market where a risk to the health of the consumer is posed. Operators should also keep adequate records of suppliers of raw materials and ingredients so that the source of a problem can be identified. It must be emphasised however that unambiguous tracing of feed and food and their ingredients is a complex issue and must take into account the specificity of different sectors and commodities.

11. This comprehensive, integrated, approach will lead to a more **coherent, effective and dynamic** food policy. It needs to address the shortcomings which flow from the current sectoral, rigid approach, which has limited its ability to deal rapidly and flexibly with risks to human health. The policy needs to be kept under constant review and, where necessary, be adapted to respond to shortcomings, to deal with emerging risks, and to recognise new developments in the production chain. At the same time, the development of this approach needs to be **transparent**, involving all the stakeholders and allowing them to make effective contributions to new developments. The level of transparency already achieved by making public

[1] Throughout this White Paper, the term ‘food chain’ covers the whole of the feed and food chain

scientific opinions and inspection reports should be extended to other food safety related areas.

12. **Risk analysis** must form the foundation on which food safety policy is based. The EU must base its food policy on the application of the three components of risk analysis: risk assessment (scientific advice and information analysis) risk management (regulation and control) and risk communication.

13. The Commission will continue to use the best available science in developing its food safety measures. The organisation of the independent scientific advice, and the role of a new European Food Authority in providing this advice, will be dealt with in Chapter 4. The Commission recognises that consumers and the food industry need to be confident that this advice is being produced to the highest standards of independence, excellence and transparency.

14. Where appropriate, the **precautionary principle** will be applied in risk management decisions. The Commission intends to present a Communication on this issue.

15. In the decision making process in the EU, **other legitimate factors** relevant for the health protection of consumers and for the promotion of fair practices in food trade can also be taken into account. The definition of the scope of such legitimate factors is presently being studied at international level particularly in Codex Alimentarius. Examples of such other legitimate factors are environmental considerations, animal welfare, sustainable agriculture, consumers' expectation regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods.

CHAPTER 3: ESSENTIAL ELEMENTS OF FOOD SAFETY POLICY: INFORMATION GATHERING AND ANALYSIS – SCIENTIFIC ADVICE

Information gathering and analysis are essential elements of food safety policy, and are particularly important for the identification of potential feed and food hazards.

16. Methods and indicators to identify problems are manifold. They may include data derived from controls carried out along the feed and food chain, disease surveillance networks, epidemiological investigations and laboratory analysis. Correct analysis of data would facilitate study of the evolution of known food hazards and the identification of new ones; it would thus become possible to better define and adapt food safety policy as necessary. The role of Member States in information gathering is crucial, and needs to be well defined.

Monitoring and surveillance

17. The Commission collects a large amount of information on issues relating to food safety. The major sources of information are networks for public health monitoring and surveillance (in particular communicable disease reporting systems under Decision 2119/98), surveillance plans of zoonoses and residues, rapid alert systems, information systems in the agricultural sector, environmental radioactivity monitoring and research activities and associated research networks. However, the existing systems have been developed independently from each other and therefore co-ordination of the different sources of information is not always done. Moreover, a large amount of the available information is not fully exploited. Integration of data collection systems and analysis of data should be the two guiding principles in this area in order to draw maximum benefits from the current systems for data gathering. The Community needs a comprehensive and effective food safety monitoring and surveillance system integrating all the above sources of information The expertise of the Commission Joint Research Centre could provide a useful support in this matter.

The first objective should be an on-going and day to day management of the information to allow a real time response to potential hazards. Secondly, such a system would enable the Commission to develop a more pro-active and forward-looking role. It should aim at the early identification of potential hazards to prevent crises arising rather than reacting to them. It would also facilitate long-term policy planning and priority setting.

Alert systems

18. In general, the Rapid Alert System for Food functions well for foodstuffs intended for the final consumer. Various other types of notification systems exist in different areas, such as transmissible diseases in human and animals, animal products stopped at the external borders of the EU, movements of live animals and the ECURIE system in case of radiological emergency. But once again, integrated use of the information is difficult, because of the difference in objectives and scope of these systems. In addition, certain areas are not covered at all, for example, animal feed.

The creation of a comprehensive and harmonised legal framework enlarging the scope to all food and feed of the current Rapid Alert System is necessary. It should extend obligations of economic operators to notify food safety emergencies and ensure appropriate information of consumers and trade organisations. Furthermore, an appropriate link with other rapid information systems must be made. This system should also be extended to third countries for incoming and outgoing information.

Research

19. Scientific excellence requires investment in R&D to expand the scientific knowledge base with regard to food safety. Under the Fifth Framework Programme for Research, Community R&D projects on food safety are carried out on the basis of multi-annual work programmes. These programmes include indirect action (shared cost actions) and direct action executed by the Commission Joint Research Centre. Their objectives are mostly geared towards improving scientific knowledge and contributing towards a sound scientific basis for policy and regulation. The Fifth Framework Programme has been oriented towards a problem solving approach with citizens and their needs at its centre. Research actions will be carried out in particular on advanced food technologies, safer methods of food production and distribution, new methods for assessing contamination and chemical risks and exposures, the role of food in promoting health, harmonised systems of food analyses.

However, in specific cases where a potential human health problem has been identified, the initiation of ad hoc and immediate research is often necessary. At present, these needs could be partially covered by the Commission Joint Research Centre, but the present system must be endowed with overall flexibility and adequate financial resources to be able to finance R&D projects in direct response to food emergencies. Therefore, budgetary and administrative procedures, including a regular revision of the research work programme and dedicated and targeted calls for proposals, must be created in order to respond to urgent challenges.

Scientific co-operation

20. Scientific information is compiled by national institutions and organisations throughout the Community on a wide range of issues relating to food safety under the Scientific Co-operation or SCOOP system. Only in a limited number of areas has co-ordination of scientific information been undertaken to build a European picture, when in many cases it is precisely this EU dimension which is lacking to provide the information necessary for an EU risk assessment. Priority setting for the collation of scientific information must be enhanced and co-ordinated with the work programme of the Scientific Committee(s). Scientific co-operation should also be initiated in third countries as appropriate.

Analytical support

21. A system of Community Reference Laboratories has been established for products of animal origin to give specialised analytical support to the Commission and to laboratories in the Member States. They develop detection methods and assist laboratories in the Member States to apply these methods. Effective central management needs to be provided in order to ensure that these laboratories become a real network of Community laboratories at the service of the EU policy. Given its scientific capabilities and infrastructures, the Joint Research Centre could perform

this task. In addition, the establishment of Community Reference Laboratories for new areas should be examined.

Scientific information underpins Food Safety policy. It is clear that scientific advice on food safety must be of the highest quality. It must be provided in a timely and reliable manner to those responsible for taking decisions to protect consumer health.

The current system for scientific advice

22. The system for the provision of scientific advice to the Commission was completely reorganised in 1997 with emphasis on the fundamental principles of excellence, transparency and independence. Scientific opinions are currently provided by eight sectoral Scientific Committees[2], of which five cover, directly or indirectly, the feed and food areas. In addition, a Scientific Steering Committee has been set up which provides advice on multidisciplinary matters, BSE, harmonised risk assessment procedures, and co-ordination of questions which cut across the mandates of more than one of the sectoral Committees (e.g. anti-microbial resistance). This co-ordination task is particularly important because food safety questions are increasingly addressed as a continuum from the farm to the table. The Committee Secretariats are provided by the Commission services.

Members of these Committees are chosen following rigorous assessment of their scientific excellence in their field of competence. Their independence is guaranteed through the strict application of declarations of interests.

In the field of radioactive contamination of feed and food, specific groups of scientific experts have been established under Article 31 of the Euratom Treaty.

The nature of the questions put to the Committees

23. Many of the questions concern the evaluation of dossiers submitted by the industry for Community authorisation (pesticides, novel foods, food and feed additives). Others questions concern specific health problems e.g. contaminants or microbiological risk. A third category concerns broader assessments of risk as typified by anti-microbial resistance.

Obligatory consultation of the Committees

24. Some food safety legislation requires the Commission to consult a scientific committee prior to making proposals which may affect public health. This situation is not systematically reflected in other legislation in the food safety sector and will have to be reviewed in order to ensure that all food safety legislation is adequately based on independent scientific advice.

Limitations of the current system

25. Since the reform, the Committees have provided some 256 opinions, many of which include evaluations of a large number of individual substances. It has become evident

[2] Food, Animal Nutrition, Veterinary-Public Health, Plants, Animal Health and Animal Welfare, Cosmetic products & non-food products, Medicinal products and medical devices, Toxicity, Eco-toxicity and Environment

that the existing system is handicapped by a lack of capacity and has struggled to cope with the increase in the demands placed upon it. Furthermore, the recent dioxin crisis could only be managed by delaying work in other areas and has shown the need to have a system which is able to respond rapidly and flexibly. This lack of capacity has led to delays which have consequences both for the Commission's legislative programmes, and hence its ability to respond to consumer health problems, and for industry where commercial dossiers are involved. This situation will be exacerbated by the increased demands that will be placed on the scientific committees resulting, for example, from the proposed programme for reform of food legislation as set out later in this White Paper.

The need for systematic provision of risk assessment data

26. Risk assessment depends upon the availability of accurate, up-to-date, scientific data. These may include, for example, epidemiological information, prevalence figures and exposure data. Support mechanisms for the provision of such information barely exist and need to be established. As the European Union enlarges, data covering the new Member States will also need to be taken into consideration. The need to develop effective information gathering systems at European and world level requires a new approach, which will make the best use of available resources.

The need for scientific networks

27. In many areas, the lack of capacity identified above could be addressed by reducing the amount of time-consuming preparatory work required of Committee members and external experts.

Community risk assessments for pesticides, biocides and chemicals are already underpinned by networks of Member State institutes, which are established under sectoral legislation. This has greatly enhanced the work and efficiency of the relevant scientific committees. It allows an effective peer review system, and thereby provides a means of making maximum use of Member States' expertise without being prejudicial to the independence of the Committees. Networks also have great potential for the collection of data. This approach needs to be extended and consideration must be given to the better exploitation of existing networks.

Concluding remarks

28. In the light of the shortcomings outlined in this Chapter, it is clear that reinforced systems are required to respond to the overall objective of improving consumer health protection and restoring confidence in the EU's Food Safety policy. Improvements will therefore be made in the areas of monitoring and surveillance, the rapid alert system, food safety research, scientific co-operation, analytical support and the provision of scientific advice. The setting up of a European Food Authority responsible for, inter alia, these areas is considered in the next Chapter. The report 'The future of scientific advice in the EU' by Professors Pascal, James and Kemper will be taken into account for the establishment of the Authority, as well as for the improvement of the present system in the transitional phase.

CHAPTER 4: TOWARDS ESTABLISHING A EUROPEAN FOOD AUTHORITY

The Commission envisages the establishment of an independent European Food Authority, with particular responsibilities for both risk assessment and communication on food safety issues.

29. A key priority for the Commission is to take effective measures to ensure a high level of consumer protection through which consumer confidence can be restored and maintained. This task has many facets. First there is the confidence question itself – how is that to be achieved? Secondly, we must ensure that not only is confidence restored but, even more importantly, that it is retained. In other words, the system that is implemented to restore confidence must be sufficiently durable and flexible to ensure that consumer confidence is maintained on an ongoing basis.

In addition to the range of measures proposed in this White Paper, the Commission also envisages the establishment of a European Food Authority. The key criteria for establishing such an authority are considered in this Chapter. The Commission believes that major structural changes are necessary in the way food safety issues are handled, having regard to the experience over the last few years and the generally accepted need functionally to separate risk assessment and risk management. The establishment of a new Authority will provide the most effective instrument in achieving the changes required to protect public health and to restore consumer confidence. It is clear therefore that the primary focus of such an Authority will be the public interest.

This Chapter is designed to elicit public debate and informed comment. The Commission wishes to have a broad consultation on establishing a European Food Authority. Interested parties are therefore invited to submit comments by the end of April 2000.

Potential scope of the Authority

30. The role of an Authority must be defined in the context of the process of risk analysis, which comprises risk assessment, risk management and risk communication.

31. The objective of **risk assessment** is the provision of scientific advice. Extensive information gathering and analysis is a pre-requisite for sound and up-to-date scientific advice. Networks for monitoring and surveillance in the area of public health and animal health, information systems in the agricultural sector and rapid alert systems, as well as R&D programmes, play an important role in the generation of scientific knowledge.

32. Legislation and control are the two components of **risk management**.

Legislation comprises primary legislation adopted by Council alone or in co-decision with the European Parliament and implementing legislation adopted by the Commission under conferred powers. Legislation implies a political decision and involves judgements not only based on science but on a wider appreciation of the

wishes and needs of society. There must be a clear separation between risk management and risk assessment.

The Commission, in its role of guardian of the Treaty, is responsible for ensuring that Community legislation is properly transposed into national law and properly implemented and enforced by national authorities in the Member States. The control function is carried by the Commission's Food and Veterinary Office (FVO), which reports on its findings and makes recommendations. FVO reports are key elements for the Commission in deciding whether to take safeguard measures within the Community or for imports from third countries, or to take infringement proceedings against Member States. Furthermore, the Commission, in establishing agreements with third countries that recognise the equivalency of food safety controls under the WTO/SPS agreement, calls on the FVO for an evaluation of the health situation in the third countries concerned.

33. The inclusion of risk management in the mandate of the Authority would raise three very serious issues.

Firstly, there is a serious concern that a transfer of regulatory powers to an independent Authority could lead to an unwarranted dilution of democratic accountability. The current decision-making process provides a high degree of accountability and transparency, which could be difficult to replicate in a decentralised structure.

Secondly, the control function must be at the heart of the Commission's risk management process if it is to act effectively on behalf of the consumer, notably in ensuring that recommendations for action arising from control are properly followed-up. The Commission must retain both regulation and control if it is to discharge the responsibilities placed upon it under the Treaties.

Thirdly, an Authority with regulatory power could not be created under the current institutional arrangements of the European Union, and would require modification of the existing provisions of the EC Treaty.

For these reasons, it is not proposed to transfer risk management competencies to the Authority.

34. **Risk communication** is a key element in ensuring that consumers are kept informed, and in reducing the risk of undue food safety concerns arising. It requires scientific opinions to be made widely and rapidly available, subject only to the usual requirements of commercial confidentiality, where applicable. In addition, consumers need to be provided with easily accessible and understandable information relating not only to these opinions, but also to wider issues touching upon consumer health protection.

The advantage of an Authority

The broadest acceptance of scientific risk assessment is essential to ensure that action is effective, appropriate and rapid.

35. The responsibilities of the Authority would consist of the preparation and provision of scientific advice, the collection and analysis of information required to underpin

both that advice and the Community's decision making processes, the monitoring and surveillance of developments touching upon food safety issues and the communication of its findings to all interested parties.

Through the manner in which it discharges its functions, the Authority would have to demonstrate the highest levels of independence, of scientific excellence and of transparency in its operations. In this fashion it should be in a position rapidly to establish itself as the authoritative point of reference for consumers, the food industry, Member State authorities and on the wider world stage.

36. An Authority would be ideally placed to develop the flexible, rapid, response that the new challenges require. It would provide a single, highly visible, point of contact for all concerned. It would not only act as a point of scientific excellence, but would also be available to consumers to provide advice and guidance on important food safety developments. It would undertake information actions with a view to ensuring that consumers can make informed choices, and are better informed on food safety issues.

37. The Authority needs to work in close co-operation with national scientific agencies and institutions in charge of food safety. The creation of a network of scientific contacts throughout Europe and elsewhere, with the Authority at its centre, is designed to ensure that all concerned become associated with the analytical process, and have a clearer understanding and greater acceptance of the basis for the opinions that are generated.

The Commission and the other EU institutions will have a vital role to play in supporting the Authority and ensuring that the Authority is adequately resourced and staffed, and by taking full account of the opinions that the Authority generates.

Objectives of a European Food Authority

The principal objective of a European Food Authority will be to contribute to a high level of consumer health protection in the area of food safety, through which consumer confidence can be restored and maintained.

38. The Authority must meet the fundamental principles of independence, excellence and transparency to be successful in its mission. As an integral part of these principles, the Authority must demonstrate a high level of accountability to the European institutions and citizens in its actions.

Therefore the Authority must

- be guided by the best science,
- be independent of industrial and political interests,
- be open to rigorous public scrutiny,
- be scientifically authoritative and
- work closely with national scientific bodies.

39. This White Paper draws upon the Commission's experience of operating scientific advice, and an examination of a number of models already in place, such as the EU's European Medicines Evaluation Agency (EMEA) and the US's Food and Drug Administration (FDA). Account has also been taken of the report of Professors James, Kemper and Pascal on the 'Future of scientific advice in the EU'.

The Commission believes that a European Food Authority should have a legal existence and personality separate from the current EU Institutions in order to carry out independently its role in terms of risk assessment and risk communication, so as to maximise its impact on consumer health protection and confidence building.

40. As indicated earlier, the existing Treaty provisions impose constraints on the activities that can be attributed to the Authority, but this should not be taken to mean that a possible future extension of its competencies should be discounted. Such an extension should only be considered in the light of the experience with the functioning of the Authority and the confidence gained in its operation, including the possible need to change the Treaty.

41. **Independence:** The existing situation where scientists involved in the provision of advice are required to respect strict rules concerning their independence must continue into the new Authority. If consumer confidence is to be regained, the Authority will need not only to act independently of outside pressures, but to be accepted as doing so by all parties concerned. Nevertheless the Authority will need to be representative and accountable. The Commission will examine the range of options to ensure that the Authority strikes the correct balance in terms of independence and accountability, taking into account the views of the other institutions and stakeholders. Particular attention will need to be paid to the selection of the head of the Authority.

42. **Excellence:** To allow the Authority to act as a point of scientific excellence and reference, and to resolve disputes on scientific issues, it will need rapidly to establish its international pre-eminence. In addition to ensuring the excellence of independent scientists, this will require the identification and recruitment of the highest calibre of personnel, and the best use of available information systems. Particular attention will be paid to the staffing of the Authority, to ensure that it employs suitably qualified specialists, who can provide the necessary support for the independent scientists responsible for the generation of the scientific opinions, as well as collecting and analysing data relevant to its functions. In addition, systems will need to be established so that the best scientists in the different fields can be identified and called upon as required.

It will also be important that the Authority can respond with sufficient speed and flexibility to deal with food safety emergencies, as well as longer term projects.

43. **Transparency** involves not only the rapid, open, presentation of the findings and recommendations of the Authority, but also implies that the processes followed in reaching them are as open as possible, in order to respond to the fundamental right of access of citizens as laid down in the Treaty. This requires clear procedures, publicly available, governing the operation of the Authority. In addition, details of the Authority's working programme would be made widely available.

Although the discussions by which scientific opinions are reached will need to respect issues of confidentiality, their presentation and explanation must be undertaken as openly as possible. These opinions will continue to be made available to the Commission and the Parliament by the Authority as soon as they are available and, at the same time, published on the internet so that all interested parties are kept fully informed.

The tasks of the Authority

44. It is envisaged that the Authority would embrace scientific advice, the gathering and analysis of information and the communication of risk. These issues are dealt with in Chapters 3 and 7 of this White Paper.

45. **Scientific advice:** The scope of the Authority should be to provide scientific advice and information to the Commission on all matters having a direct or indirect impact on consumer health and safety arising from the consumption of food. Thus it will cover primary food production (agricultural and veterinary aspects), industrial processes, storage, distribution and retailing. Its remit will encompass both risk and nutritional issues. The Authority will also cover animal health and welfare issues, and will take into consideration risk assessments in other areas, notably the environmental and chemical sectors where these overlap with risk assessment in relation to food.

The Commission believes that the scientific work currently undertaken by the Scientific Committees related to food safety should be a core part of the proposed Authority. In this context, the structure and mandates of the existing Scientific Committees will be reviewed to ensure that scientific advice responds to the full range of responsibilities attributed to the Authority. The Committee(s) will provide opinions upon request by the Commission. In a proactive capacity, the Committee(s) should also signal new health hazards or emerging health problems and the Authority will have to follow-up such concerns.

46. The Authority will establish means for the rapid identification of scientific experts in the European Union, and elsewhere. In this manner, the Authority will need to access a world-wide network of scientific excellence, with the flexibility to respond rapidly to changing situations.

47. The Authority must be able to keep up-to-date with the most recent scientific developments and to identify gaps in on-going research or topics where it feels that rapid targeted work is necessary. The Authority would have its own budget for the commissioning of ad-hoc targeted and immediate research in response to unforeseen health emergencies, in liaison with the Commission Joint Research Centre, national scientific agencies and international organisations. Account should also be taken of the work of the networks established through the Community research programmes; mechanisms to enhance a two-way interaction between these Community research programmes and the Authority will need to be established.

48. The Scientific Committee(s) must be able to concentrate on the core task of preparing the scientific opinions. The Committee(s) will be supported by a scientific secretariat, which will be responsible for the interface between them and the risk managers. In addition, it will be necessary to establish in-house scientific support which will undertake much of the preparatory work for the Committee(s).

49. **Information gathering and analysis:** There is a pressing need to identify and use the information currently available throughout both the Community and world-wide on food safety issues. This would be a key task for the Authority, and represents an area where great scope for improvement exists. If properly exploited, this information can form a major element in ensuring that potential problems are identified as quickly as possible and that scientific advice addresses the wider health picture.

50. The Authority will be expected to take a proactive role in developing and operating food safety monitoring and surveillance programmes. It will need to establish a network of contacts with similar agencies, laboratories and consumer groups across the European Union and in third countries.

The Authority must be able to guarantee a real-time evaluation and response of the outcome of these programmes, ensuring that real or potential hazards are rapidly identified. In addition, the Authority will need to develop a predictive system that will allow the early identification of emerging hazards, so that crises can be avoided where possible.

51. **Communication**: The ability to communicate directly and openly with consumers on food issues will give the Authority a high public profile. The Authority will need to make special provision for informing all interested parties of its findings, not only in respect of the scientific opinions, but also in relation to the results of its monitoring and surveillance programmes.

The Authority must become the automatic first port of call when scientific information on food safety and nutritional issues is sought or problems have been identified. It will also need to ensure that appropriate information on these issues is published, as part of its commitment to re-establishing consumer confidence. Clearly the Commission will continue to be responsible for communicating risk management decisions.

Reacting to crises

52. Where a food safety emergency occurs, the Authority will collect, analyse and distribute relevant information to the Commission and Member States, and will mobilise the necessary scientific resources to provide the best possible scientific advice. The Authority will have to respond rapidly and effectively to crises, and will take a key role in supporting the EU response. This will promote improved planning and handling of crisis situations at the European level, and will demonstrate to consumers that a pro-active approach is being taken to deal with problems.

53. The Authority will operate the Rapid Alert System, which allows the identification and rapid notification of urgent food safety problems. The Commission will be part of the network and will therefore be informed on a real-time basis. Depending on the nature of a crisis, the Authority may be requested to carry out follow-up tasks, including monitoring and epidemiological surveillance.

Networking with national agencies and scientific bodies

54. The European Food Authority must be a value-added structure: it should work in close co-operation with national scientific agencies and institutions in charge of food

safety and build upon their expertise. This would result in the creation of a network, designed to ensure the best and most effective use of existing structures and resources. One of the tasks of the European Food Authority will, therefore, be to link centres of excellence, allowing its in-house scientific staff to draw from the leading-edge scientific expertise in all the relevant disciplines across the European Union and at international level. Similarly, national bodies will be able to have access to a scientific base of the highest possible calibre. Through their dynamic two-way exchange, the role of the Authority will be progressively enhanced. This will lead, over time, to reliance on the Authority as the most authoritative source of knowledge on food safety matters in the EU.

55. Within the network system, best use of the existing scientific and technical capabilities and infrastructures of the Commission Joint Research Centre (JRC) should be ensured.

Interface with Commission services

56. The Authority and the Commission services must work very closely together from the moment that the Authority assumes its functions. This will concern, in particular, those charged with the preparation of legislation, law enforcement and the operation of controls and inspections (FVO), as well as the Joint Research Centre and those in charge of Community R&D. This will ensure that the Authority's findings can be used to the best effect possible, and that it is kept informed of issues of direct consequence for its own activities. At the same time, it will allow the Authority to be responsive to the needs of the Commission services. This interface should of course not blur the distinctive role assigned to the Authority.

Resources

57. The resource implications of setting up and operating the scientific advisory systems, information collection and analysis, and effective networks with scientific bodies in Member States should not be underestimated. In addition to its scientific and communication tasks, the Authority will have to carry a heavy workload in terms of administrative and financial management. The Authority will make extensive use of information and communication technologies, and promote their use by national agencies and institutions in charge of food safety. The efficacy of the Authority will ultimately depend on the adequacy, in terms of both size and quality, of the human, financial and physical resources allocated. It will only be possible to define the resources needed in the light of decisions taken after the consultation process and detailed feasibility studies. The detailed figures in this regard will be presented with the Commission's definitive proposal for the establishment of the Authority and take account of the forthcoming Commission debates concerning political priorities and the related allocation for operational and human resources.

Location of the Authority

58. The Authority will need to develop very close working links with the Commission services involved in food safety issues, and with the other EU institutions if it is to carry out its functions effectively and to be available for rapid consultation in crises situations. The Authority also needs to be easily accessible, not only for the scientists called upon to develop the scientific opinions, but also for all other stakeholders who need to seek the views of the Authority. This is not only important for the best use of

resources, but also to demonstrate the openness and availability of the Authority, in particular in its role in communication. In light of these considerations, the Commission considers that the Authority must be established in an easily accessible location.

Candidate countries

59. The candidate countries will be associated to the work of the Authority in line with the conclusions of the Luxembourg European Council which underlined the importance for these countries to become familiar with the working methods and policies of the Union. Specific arrangements will be developed in the up-coming work on the establishment of the Authority.

Implementation Timetable

The Commission believes that it is essential to have a very rapid implementation schedule for the establishment of the Authority.

60. The following timetable is foreseen for the formal establishment of the new Authority:

- White Paper published : January 2000
- Consultation period : end of April 2000
- Commission proposal : September 2000
- Enabling legislation : December 2001
- Authority starting operations : 2002

61. While the timetable set out is ambitious, particularly given the scale of the task, the Commission considers that it is achievable given its experience in establishing the EMEA. Not alone will it be necessary to have a rapid start up schedule for the new Authority, but it will also be necessary, in parallel, to improve the functioning of the existing system. The Commission will establish a dedicated team to ensure that there is rapid action on the range of issues identified in this Chapter of the White Paper.

62. The reinforcement of the present system of risk assessment and communication will be a key part of the range of measures necessary to ensure that the Authority can really become operational within two years. Having regard to the availability of resources over the next two years, the Commission will evaluate the possibility of reinforcing the existing scientific support and advice structures in the lead-in phase to the establishment of the Authority.

CHAPTER 5: REGULATORY ASPECTS

63. In Chapter 4, the Commission has highlighted why risk management must be left to an institutional framework with full political accountability. Notwithstanding the proposed creation of a European Food Authority, the drafting and making of legislation will remain the responsibility of the Commission, the Parliament and the Council.

64. The European Union has a broad body of legislation which covers primary production of agricultural products and industrial production of processed food. The legislation has evolved over the last thirty years, reflecting a blend of scientific, societal, political and economic forces, in particular in the framework of creating the Internal Market, but no overall coherence has been guiding this development. For this reason, the Green Paper on the general principles of food law in the European Union (COM(97) 176 final) already foresaw the need for a major review of food legislation.

65. Food production is extremely complex. Products of animal and plant origin present intrinsic hazards, due to microbiological and chemical contamination. Nevertheless, the current legal framework and operational set-up has in general afforded the EU consumer a high level of health protection. The real problem is not necessarily due to a lack of legal instruments, but the broad disparity in the means to respond to situations in specific sectors, or the multiplicity of actions which need to be triggered in the case where a problems spills over from one sector to another. One of the weakest links in the system is the lack of a clear commitment from all interested parties to give an early warning about a potential risk, so that the necessary scientific evaluation and protective measures can be triggered early enough to ensure a pro-active rather than reactive response at EU level.

The full range of measures proposed is presented in the Annex with an indication of the priority measures and likely timing, though resource constraints may affect the finalisation of some initiatives.

New legal framework for food safety

There is a need to create a coherent and transparent set of food safety rules.

66. The Commission intends to make proposals for a new legal framework laying down the principles to ensure a coherent approach and to fix the principles, obligations and definitions that apply in this field. The aim of these proposals will be to reflect the outcome of the extensive consultation which the Commission initiated in 1997 with the publication of its Green Paper on food law, to lay down the common principles underlying food legislation and to establish food safety as the primary objective of EU food law.

67. The Commission will make proposals including a General Food Law, which will embody the principles of food safety referred to in Chapter 2. These proposals will be subject to the fullest consultation with all interest groups at the earliest possible stage in their development and impact analysis of legislative proposals will be undertaken as appropriate. Individual legislation needs to be clear, simple and

understandable for all operators to put into effect. There also needs to be close co-operation with the competent authorities at the appropriate levels in the Member States to ensure proper and consistent compliance and enforcement and to avoid unnecessary administrative procedures.

68. These proposals will also provide the general frame for those areas not covered by specific harmonised rules but where the functioning of the Internal Market is ensured by mutual recognition, as developed by the European Court of Justice in its "Cassis de Dijon" jurisprudence. Under this principle, in the absence of Community harmonisation, Member States may only restrict the placing on the market of products lawfully marketed in another Member State when and to the extent that this can be justified by a legitimate interest such as the protection of public health and that the measures taken are proportionate. In this context, the Commission will continue to use all means at its disposal, either formal (infringement procedures) or informal (networks of Member States representatives and meetings, etc) in order to resolve disputes on obstacles to trade. Action for measures at Community level will be envisaged where a barrier to trade is found to be justified on food safety grounds.

New legal framework for animal feed

The safety of food from animal origin begins with safe animal feed.

69. Although legislation cannot prevent all incidents affecting the feed and food chain, it can set up appropriate requirements and controls allowing for early detection of problems and speedy corrective action. In this respect, the action needed in the **animal feed** sector is illustrative. The principles of food safety mentioned in Chapter 2 should become applicable to the feed sector, in particular to clarify responsibilities of feed producers and to provide a comprehensive safeguard clause. More specifically, the materials which may or may not be used in animal feed production, including animal by-products, need to be clearly defined. A positive list of feed materials would give the clearest response to the current lack of definition of feed materials but this task is complex and time-consuming. In the short term, the current negative list needs to be rapidly expanded. However the Commission is committed to working towards a positive list over the medium term. In addition, a revision of Community legislation will be proposed in order to exclude fallen animals (cadavers) and condemned material from the feed chain. The only material allowed to be used in animal feed would then be material derived from animals declared fit for human consumption.

A legislative proposal for the evaluation, authorisation and labelling of **novel feed**, in particular of genetically modified organisms and feeding stuffs derived therefrom, will be put forward.

Clarification between the different categories of products used in animal nutrition (additives, medicinal products, supplements) is necessary in order to avoid grey zones and to clarify which requirements apply in each case. The Commission will also pursue the prohibition or phasing-out of antibiotics used as growth promoters in the EU depending on their potential use in human and veterinary medicine as part of its broad strategy to control and contain antibiotic resistance.

Now that the origins and consequences of the dioxin crisis are becoming clearer, it has become obvious that the feed manufacturing industry should be subjected to the

same rigorous requirements and controls as the food producing sector. Lack of internal controls (good manufacturing practice, own-checks, contingency plans) and lack of mechanisms for traceability allowed the dioxin crisis to develop and expand throughout the whole food chain. Legislation will be proposed in order to correct these anomalies, including official approval of all feed producing plants as well as official controls at national and EU level. To align the framework for the feed sector with that of the food sector, a rapid alert system for feed shall be integrated into the rapid alert system for food.

Animal health and welfare

The health and welfare of food producing animals is essential for public health and consumer protection.

70. **Animal health** is also an important factor in food safety. Some diseases, the so-called **zoonoses**, such as tuberculosis, salmonellosis and listeriosis can be transmitted to humans through contaminated food. These diseases can be particularly serious for certain categories of the population. Listeriosis may cause encephalitis and spontaneous abortions; salmonellosis is an emerging public health problem. The availability of a correct picture of the situation is a pre-requisite for action. Therefore Community monitoring for food borne diseases and zoonoses is needed and harmonised reporting requirements need to be introduced. The information derived therefrom will facilitate the Commission in setting targets and in taking more effective measures to reduce the prevalence of zoonotic diseases.

Existing eradication and disease control programmes, such as those for tuberculosis and brucellosis, should be continued and where possible re-enforced; in particular, in those Member States whose status with regard to these diseases remains problematic. Particular attention should be devoted to the control of hydatidosis and Brucella militensis in Mediterranean regions. Information on zoonoses monitoring needs to be better exploited in order better to define programmes at EU level.

This White Paper makes proposals specifically designed to promote the health and welfare of animals only in so far as Food Safety policy is directly concerned. The Commission acknowledges that animal health and welfare issues in a broader context are important. In the context of this White Paper, it is recognised that **animal welfare** questions need to be integrated more fully with regard to food policy. In particular the impact on the quality and safety of products of animal origin intended for human consumption needs to be reflected in the legislation.

71. Most of the legislation relating to **BSE/TSE** has been adopted in the form of safeguard measures, taken on an ad hoc basis. By definition, the adoption of such measures does not involve all Community institutions. They also do not provide for a fully consistent approach. The Commission has addressed this problem in proposing to the Council and the European Parliament a comprehensive proposal based on Article 152 of the Treaty, which covers all measures to control BSE and other transmissible spongiform encephalopathies (TSEs). Until the adoption of this proposal, emergency measures will be taken to ensure a high level of protection during the interim period. The most important measures will be rules on removal of specified risk materials in combination with a provisional classification according to BSE status, reinforcement of the epidemiosurveillance system on the basis of testing

certain higher risk animals (fallen stock, emergency slaughtered cattle), updating of the feed ban and embargoes in the light of recent scientific advice.

In addition the Commission takes the view that further testing to establish the incidence of BSE across the Union is desirable. This will of course depend upon the availability of suitable post mortem tests. The Commission will keep this under active review and will make proposals for a suitable testing programme in the light of developments.

Hygiene

A co-ordinated and holistic approach towards hygiene is an essential element of food safety.

72. Over time, the Community has developed extensive requirements relating to **hygiene** of food. These include over twenty legal texts, which are designed to ensure the safety of food produced and placed on the market. However, these requirements were adopted as a scattered response to the needs of the Internal Market, taking into account a high level of protection. This has resulted in a series of different hygiene regimes according to whether the food is of animal or plant origin, which can only be justified for historical reasons. It has also left some areas out of the scope of the requirements, such as production of food of plant origin at the level of the farm (primary production). A new comprehensive Regulation will be proposed recasting the existing legal requirements to introduce consistency and clarity throughout the food production chain. The guiding principle throughout will be that food operators bear full responsibility for the safety of the food they produce. The implementation of hazard analysis and control principles and the observance of hygiene rules, to be applied at all levels of the food chain, must ensure this safety. The Commission shall examine how best to assist small and medium enterprises in implementing these requirements, in particular by supporting the development of guidance documents. In addition, a procedure for laying down microbiological criteria and, where necessary, food safety objectives will be introduced.

Contaminants and residues

Limits of contaminants and residues must be set and controlled.

73. The term "**contaminants**" traditionally covers substances which are not intentionally added to food. They can be the result of environmental contamination; they also can result from agricultural practices, production, processing, storage, packaging, transport or from fraudulent practices. Specific EU requirements only exist for a few contaminants, although many measures exist at national level. This is de facto leading to disparity in consumer health protection throughout the EU, but also to practical difficulties for control authorities and industry. The serious nature of this gap was highlighted during the dioxin crisis, where ad hoc limits, only valid for products of Belgian origin, were set in the framework of a safeguard measure. There is therefore an obvious need to define standards for contaminants throughout the chain leading from feed to food. The scientific basis for setting these limits needs to be addressed as a matter of priority.

74. Some substances are found in food as a result of intentional use. This concerns **residues of pesticides** in food of plant and animal origin and **veterinary medicines**

in food of animal origin. Community legislation has laid down rules for the establishment of maximum residue limits of these substances in food and agricultural products. Member States have an obligation to monitor compliance with these limits but there are no harmonised requirements and the monitoring activities vary among them. Moreover there is a limited number of accredited laboratories capable of carrying out monitoring in the Member States. As far as pesticides are concerned, the Commission aims at progressively setting limits for all pesticide/commodity combinations. Action to correct deficiencies with regard to monitoring and laboratory testing will be taken.

At present, there is a large number of **pesticides** on the market that have not yet been evaluated at Community level. In the meantime, new pesticides are being presented for obtaining a market authorisation. The approval procedure of new pesticides needs to be accelerated. In parallel, the review of the approval of existing pesticides needs to be streamlined so as to eliminate very rapidly products for which safety data are lacking or for which safety concerns have been identified. This will therefore promote the use of safer pesticides.

However, the performing of risk assessments for approving pesticides and setting maximum residue limits is hampered by the absence of sufficient accurate data about diets. In order to fill this gap, a major study to establish a database on diets will be carried out; this database will also be an essential tool for risk assessment of any other contaminant, additive, etc.

75. Legislation on the **radioactive contamination** of food and feed is taken on the basis of Article 31 of the Euratom Treaty, and in case of imports, on the basis of Article 133 of the Treaty. In this context, the post-Chernobyl legislation will be kept under constant review.

Novel Food

The Community provisions governing **novel foods** have to be tightened and streamlined.

76. The procedure for authorising the placing on the market of novel foods (i.e. foods and food ingredients which have not yet been used for human consumption, in particular those containing or derived from genetically modified organisms) should be clarified and made more transparent. Exemptions from these provisions need to be reviewed. Therefore, the Commission will adopt an implementing regulation to clarify the procedures laid down in the Novel Food Regulation (EC) N° 258/97 and will in due course also present a proposal to improve this Regulation in accordance with the revised regulatory framework for the deliberate release of GMOs under Directive 90/220/EEC. Furthermore, the labelling provisions have to be completed and harmonised.

Additives, flavourings, packaging and irradiation

There is a need to up-date and complete existing Community legislation with regard to additives, flavourings, packaging and irradiation.

77. The provisions relating to **food additives** and **flavourings** need to be amended in several respects. Firstly, implementing powers should be conferred on the

Commission to maintain the Community lists of authorised additives and the status of enzymes should be clarified. Secondly, the Community lists of colouring matters, sweeteners and other additives need to be updated. Thirdly, the purity criteria for sweeteners, colours and other additives have to amended and appropriate purity criteria for food additives made from novel sources have to be laid down. The Commission will further publish a report on the intake of food additives. Specific action concerning flavourings has so far concentrated on chemically defined substances. More work is needed to reflect innovation in this field and new insight in toxicological effects of substances naturally present in flavourings. The Commission will update the register of flavouring substances, establish a programme for their evaluation and lay down a list of additives authorised for use in flavourings.

78. The Commission will also consider changing the Community framework for **materials that come into contact with food** in order to enhance the administration of this sector and to improve the labelling requirements. The structure and transparency of the Directives on plastic materials will be improved and consideration will be given to an extension of these provisions to surface coatings. As regards the materials not yet under harmonisation (paper, rubber, metals, wood, cork), the Commission will continue to collaborate with the other European bodies active in this field (CEN, Council of Europe).

79. The Commission will further propose a Directive to complete the list of foodstuffs authorised for **irradiation** treatment, and publish the details of the irradiation facilities operating in the Member States, as well a list of third countries' facilities which are approved as equivalent. It will also elaborate a Directive on constituents of **natural mineral waters** and on the conditions of use for the treatment of certain natural mineral waters with ozone enriched air.

Emergency measures

The possibility for taking safeguard measures is an essential tool for managing food safety emergencies.

80. The dioxin crisis has demonstrated the lack of consistency of the present framework for the adoption of **safeguard measures** in response to an identified risk to consumer health. The Commission does not at present have a legal instrument to adopt a safeguard measure upon its own initiative either for feed or for a processed food of non-animal origin originating from one of the Member States. According to the sector, the mechanisms for adoption of safeguard measures are different. The adoption of a single emergency procedure applicable to all types of food and feed, whatever their geographical origin, is the only means to remove the disparities and close the loopholes. In this regard, the Commission will be making a comprehensive legislative proposal.

Decision making process

The decision making process needs to be streamlined and simplified in order to ensure efficacy, transparency and rapidity.

81. The EU food legislation can be based on various provisions of the EC Treaty: Article 95 in the case of measures for the completion of or the functioning of the Internal Market (taking as a basis a high level of consumer and health protection), Article 152

for measures in the veterinary and phyto-sanitary fields which have as their direct objective the protection of public health, Article 153 relating to consumer protection and Article 37 where agricultural aspects are preponderant. Depending on the legal basis, measures are adopted by the Council in co-decision with the European Parliament or after consultation of the European Parliament on proposal by the Commission.

Article 202 of the EC Treaty provides that in the instruments which it adopts, the Council shall confer on the Commission powers for the implementation of the rules which the Council lays down, save in specific cases where it may reserve the right to exercise directly implementing powers itself. Such transfer of competence should normally allow the Commission to transform rapidly the scientific advice it receives by amending the appropriate legislation or adopting appropriate decisions. In some cases however (in particular for food additives) implementing powers have not yet been conferred on the Commission with the undesirable result that updating positive lists of authorised substances (whether this is necessary to authorise a new substance, to ban the use of an authorised substance, or to modify the conditions of use of an authorised substance) can take several years after the formulation of the scientific advice.

82. Where implementing powers have been conferred on the Commission (for example flavourings, extraction solvents, contaminants, pesticide residues, materials in contact with food, diet foods, irradiated foods or quick-frozen foods), the current decision-making process for transforming scientific advice into legislation or decision is in some cases not satisfactory: the procedures applicable are disparate and cumbersome; different committees are involved; different modalities apply; resources are scarce and scattered.

83. All the procedures laid down by the EU food legislation for its implementation and its adaptation to technical and scientific progress need to be reviewed. In this respect the number of committees dealing with delegated legislation and the adoption of individual decisions should be reduced and streamlined. Better co-ordination should be introduced to ensure that food safety issues are addressed as a continuum from farm to table through the application of a single regulatory procedure for delegated legislation, a single management procedure for the adoption of individual decisions and an emergency procedure for all urgent matters of food safety. The new procedures should be in conformity with the recent Decision on comitology.

84. Clear and strict deadlines should be fixed for the Commission to prepare an amendment or decision, for the Standing Committee to reach an opinion and for the Commission to finalise an amendment or decision. Greater transparency should be considered at all stages of the regulatory process. Information and communication technologies should be used extensively to automate the production and tracking of amendments and decisions and to accelerate their circulation between all the parties involved.

CHAPTER 6: CONTROLS

A comprehensive piece of legislation will be proposed in order to recast the different control requirements. This will take into account the general principle that all parts of the food production chain must be subject to official controls.

Development of EU legislation

85. Legislative requirements setting out official controls at both national and EU level have been established in different pieces of Community legislation over a period of more than 30 years. Although these legislative acts have the same objective, their approach to the operation of these controls is different. They also contain anomalies, resulting in an incomplete legal basis for carrying out official controls in both Member States and third countries. There is a need to clarify and update existing food control legislation and to ensure that it covers all steps in the production. Furthermore, certain detailed meat inspection requirements need to be reviewed as they are no longer in line with modern food safety management practices.

86. Existing legislation includes a system whereby Member States can collect fees to cover the costs of controls for products of animal origin. Member States may levy charges on importers for the control of a certain number of products of animal and non-animal origin for compliance with post-Chernobyl legislation. There are differences in the level of fees charged between, and within, the Member States. In addition, there is no legal basis for a similar system to be applied to controls of feed and food of non-animal origin.

87. The lack of uniformity in setting and charging control fees, and the extension of this principle to the areas not presently covered, will be included in this legislative review. Common objectives should be fixed at EU level with regard to the staff and equipment requirements, whilst guarantees should be introduced to ensure that fees are used only for the financing of controls.

Controls over the operation of EU legislation

88. Responsibility for safe food production is shared between operators, national authorities and the European Commission. Operators are responsible for compliance with legislative provisions, and for minimising risk on their own initiative. National authorities are responsible for ensuring food safety standards are respected by operators. They need to establish control systems to ensure that Community rules are being respected and, where necessary, enforced. These systems need to be developed at Community level, so that a harmonised approach is followed.

89. To ensure that these control systems are effective, the Commission, through the Food and Veterinary Office (FVO), carries out a programme of audits and inspections. These controls evaluate the performance of national authorities against their ability to deliver and operate effective control systems, and are supported by visits to individual premises to verify that acceptable standards are actually being met.

90. Recent food safety crises have highlighted deficiencies in national systems of control. At the heart of the problem is the lack of harmonised Community approach to the design and development of national control systems.

91. There is therefore a clear need for a **Community framework of national control systems**, which will improve the quality of controls at Community level, and consequently raise food safety standards across the European Union. The operation of such control systems would remain a national responsibility. This Community framework would have three core elements.

- The first element would be **operational criteria set up at Community level**, which national authorities would be expected to meet. These criteria would form the key reference points against which the competent authorities would be audited by the FVO, thereby allowing it to develop a consistent, complete, approach to the audit of national systems.

- The second element would be the development of **Community control guidelines**. These would promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy would take a comprehensive, integrated, approach to the operation of controls. These guidelines would also provide advice on the development of systems to record the performance and results of control actions, as well as setting Community indicators of performance.

- The third element of the framework would be enhanced **administrative co-operation** in the development and operation of control systems. There would be a reinforced Community dimension to the exchange of best practice between national authorities. This would also include promoting mutual assistance between the Member States by integrating and completing the existing legal framework. Furthermore, this would cover issues such as training, information exchange and longer term strategic thinking at Community level.

92. Development of this overall Community framework for national control systems would clearly be a task for the Commission and the Member States working together. The experience of the FVO will be an essential element in its development.

93. Since the establishment of the Single Market, the importance of having effective and harmonised health controls at the external borders of the European Union has become very clear. The current system, based on border inspection posts (BIPs) under the control of individual Member State authorities, only covers products of animal origin. Furthermore it fails to provide a sufficiently well co-ordinated approach to border checks. The legal basis for border checks needs to cover all products, and to identify a more effective Community-level control system.

94. It is necessary to consider whether the Commission needs to be given additional powers, in support of existing infringement procedures, where controls reveal significant non-compliance with EU rules. This must allow, in particular, rapid action to be taken in the face of immediate consumer health risks, and be based upon an effective and transparent follow-up of FVO inspection reports. As appropriate, it should also be possible to withhold Community financial support, or to reclaim funding already allocated.

CHAPTER 7: CONSUMER INFORMATION

Risk communication

Risk communication should not be a passive transmission of information, but should be interactive, involving a dialogue with and feedback from all stakeholders.

95. Risk communication consists of information exchange between concerned parties on the nature of the risk and the measures to control this risk. This is a fundamental responsibility for public authorities when managing public health risks. This can only function correctly if risk assessments and risk management decisions are transparent and public. Since 1997, the Commission has implemented a new approach to ensure transparency by making available to the public all information on scientific advice and on inspections and controls. This policy is a key element in risk communication and public confidence and has therefore to be actively pursued.

96. In all aspects related to food safety, it is essential that the consumer is a fully recognised stakeholder and that consumer concerns are taken into account by

- consulting the public on all aspects of food safety
- providing a framework for discussions (public hearings) between scientific experts and consumers
- facilitating trans-national consumer dialogue both at European and at global level.

97. It is important that all steps in policy making are taken in full openess. However good a new system may be, without this transparency the consumers will not be able to follow the development of the new measures and fully appreciate the improvements which they bring. Transparency will result in the necessary public scrutiny and ensure democratic control and accountability.

98. Finally, a more pro-active approach needs to be introduced concerning the communication of unavoidable risks for certain parts of the population. For instance women of childbearing age, pregnant women, infants, the elderly and immuno-deficient people should be warned more actively about the possible risks of certain foods.

Labelling and advertising

Consumers are to be provided with essential and accurate information so that they can make informed choices.

99. Binding labelling rules must, therefore, ensure that the consumer has the information on the product characteristics that determines choice, composition and storage and use of a product. Operators should be free to provide more information on the label, provided this information is correct and not misleading.

Within the WTO, labelling has become a trade policy issue in many different fields, including food safety, in relation to both the TBT and the SPS agreements. The Community has therefore indicated that it will pursue multilateral guidelines on

labelling. The guidelines should serve to avoid unnecessary disputes. This is of particular interest for the Community given our position on the consumer's right to know.

100. Further to the ongoing **codification of the Labelling Directive**, the Commission intends to propose a new amendment which would remove the current possibility not to indicate the components of compound ingredients, where they form less than 25% of the final product. Full ingredient labelling will not only ensure optimal consumer information as to the composition of a food product but will at the same time ensure the necessary information for those consumers who for health or ethical reasons have to, or want to, avoid certain ingredients. In this context, the problem of carry-over of additives still needs to be considered. Furthermore, for ingredients that are known allergens, but where only the name of the category needs to be indicated, an indication as to the presence of such allergens will be considered in order to enable susceptible consumers to avoid such products.

101. The Labelling Directive prohibits the attribution to any foodstuff of the property of preventing, treating or curing a human disease or reference to such properties. The Commission continues to consider that labelling and advertising of a foodstuff should not contain such health claims. It is indeed true that a good balanced diet is a prerequisite for good health, but claims that the intake of food can prevent, treat or cure one disease or another could in fact lead consumers to unbalanced dietary choices. The Commission will however consider whether specific provisions should be introduced in EU law to govern "functional claims " (for example claims related to beneficial effects of a nutrient on certain normal bodily functions) and "nutritional claims" (such as claims which describe the presence, absence or the level of a nutrient, as the case may be, contained in a foodstuff or its value compared to similar foodstuffs). Furthermore, the Commission will consider the need of bringing the requirements of the Nutrition Labelling Directive into line with consumer needs and expectations.

102. Complementary to the approach to labelling of foodstuffs, the means of redress that consumers and competitors enjoy against **misleading advertising messages** should be extended to allegations related to the above-mentioned types of claims. The Commission will make a proposal in this respect to amend the Misleading Advertising Directive and will ensure that advertising and labelling provisions in respect of claims provide for a coherent legislative framework.

103. The Commission will further consider the opportunity to revise or introduce specific labelling provisions for certain categories of foods. Specific rules, such as the obligatory indication of place of origin for fresh fruit, which provide better information to the consumer on these products, are not in contradiction with the general rules. The Commission will also clarify the provisions governing the labelling of **novel food**, and, in particular, products derived from genetically modified organisms, and will take an initiative with regard to the labelling of additives produced through genetic engineering and to the labelling of food and food ingredients produced without genetic engineering (so-called "GMO-free food").

Nutrition

Consumers show a rising interest in the nutritional value of the food they purchase, and there is a growing need to avail consumers of correct information about the food they consume.

104. Ensuring the protection of public health is not restricted to chemical, biological and physical safety of food. It should also aim at ensuring the intake of essential nutrients while limiting intake of other elements in order to avoid adverse health effects, including anti-nutritional effects. Scientific information has shown that an adequate and varied diet are very important factors in maintaining good health and overall well being. This may be particularly true now that new types of products are appearing on the market with modified nutritional value, which can influence the behaviour and well being of consumers either favourably or unfavourably. In addition, the information which would allow the consumer to make the correct choices is not systematically available in a clear and accessible way.

105. In respect of **dietetic foods** (i.e. foods intended to satisfy the particular nutritional requirements of specific groups of the population), the Commission will elaborate a specific Directive on foods intended to meet the needs resulting from intense muscular effort. It will also prepare a report on foods intended for persons suffering from diabetes, and define the conditions for making the claims "low-sodium" or "sodium-free" and "gluten-free". The Commission will also submit to Council and Parliament two proposals for Directives on **food supplements** (i.e. concentrated sources of nutrients such as vitamins and minerals) and **fortified foods** (i.e. and foods to which nutrients have been added). Finally, purity criteria will have to be laid down for nutritional substances which are added to food for particular nutritional use or which are present in food supplements and foods to which nutrients are added.

106. A number of actions at Community level have been organised in the context of the "Fourth and Fifth Research and Development Framework Programme". These actions provide some of the components which should be relevant to a nutritional policy. The Commission is considering the development of a comprehensive and coherent **nutritional policy** and will present an action plan for that purpose.

107. A number of aspects that have already been raised in this White Paper also apply to the establishment of a policy in this field. Successful implementation of a nutritional policy requires in particular efficient monitoring, data collection and data analysis. Information on food intake, diets and nutritional status should therefore be included in national and Community data collection systems. In addition, research and studies on nutrition should be promoted, scientific advice should be actively sought and the results thereof be made available in full transparency. Another important aspect of a nutritional policy is efficient and correct consumer information; in this respect, the Nutrition Labelling Directive plays a role. A special effort to establish appropriate information tools, including nutritional labelling but also information campaigns, should be put in place. Council Recommendations for dietary guidelines will be proposed. Appropriate communication to consumers will have to be ensured.

CHAPTER 8: INTERNATIONAL DIMENSION

The key principle for imported foodstuffs and animal feed is that they must meet health requirements at least equivalent to those set by the Community for its own production.

108. The Community is the world's largest importer/exporter of food products, and trades with countries all over the world in an increasing diversity of food products. With this extensive trade in food products, food safety cannot be seen as solely an internal policy question. Exactly the same concerns as regards zoonoses, contaminants and other concerns apply to food products in international trade, whether these products are to be imported into the Community or exported from the Community. In order to ensure that these requirements are met, our WTO obligations require either that we base those measures on international standards or in so far as they are not based on international standards, that the measures are scientifically warranted. In cases where scientific evidence is insufficient, provisional measures may be adopted on the basis of available pertinent information.

109. The international framework as regards food safety has developed significantly through the enhanced role of certain international organisations such as the Codex Alimentarius and the International Office of Epizootics (OIE) under the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO).

110. The Community plays an active role in the SPS Committee, and in other WTO committees, to ensure that the international framework encourages and defends the rights of countries to maintain high public health standards for food safety. In this context, the Community has the objective to clarify and strengthen the existing WTO framework for the use of the precautionary principle in the area of food safety, in particular with a view to finding an agreed methodology for the scope of action under that principle. The adoption of a global approach towards food safety as set out in the present White Paper will contribute to re-enforce the role of the Community in WTO.

Some third countries use sanitary and phyto-sanitary arguments without scientific justification in order to refuse the access of Community food products to their market. The SPS Agreement provides the right to obtain the risk assessment on which a third country measure is based. Such risk assessment should be carefully analysed in due time, in order to detect inconsistencies and weaknesses and to open the procedure of consultation foreseen by the SPS Agreement.

111. Work on the accession of the European Community to the Codex Alimentarius and the International Office of Epizootics will be pursued rapidly.

112. Consumers all over the world have the right to expect exported Community products to meet the same high standards that apply within the Community. The level of food safety required for products exported from the Community should therefore be at least that required for products placed on the market within the Community. The

need to establish Community export certification arrangements to ensure this will be examined.

113. The Community has already negotiated a number of bilateral international agreements on sanitary measures, which include the recognition of the equivalence of the sanitary measures applied by third countries. The possibility of negotiating further agreements will be explored. This includes the need for technical co-operation as well as co-operation on RTD with third countries. In order to meet the obligations laid down in the SPS agreement, the Community must ensure that all legislation concerning SPS measures provides for the possibility to recognise equivalency also on a case-by-case basis.

114. The process of negotiating agreements with neighbouring countries and territories, for example Norway, Switzerland, Andorra, under which they take on the Community 'acquis' for food safety and other sanitary and phyto-sanitary requirements, shall be continued.

115. As regards the future enlargement of the Community, it is essential that the candidate countries have implemented the basic principles of the Treaty, food safety legislation and control systems equivalent to those in place within the Community. This represents a significant challenge to those countries, both in terms of the upgrading of their production and processing facilities, and the implementation of the necessary legislation and control arrangements. The existing framework of Community assistance will assist, where necessary, the candidate countries to adopt the necessary legislation, including the establishment of relevant institutions to implement and enforce this legislation, in accordance with the priorities identified in the Accession Partnerships.

CHAPTER 9: CONCLUSIONS

116. The implementation of all the measures proposed in this White Paper will enable Food Safety to be organised in a more co-ordinated and integrated manner with a view to achieving the highest possible level of health protection.

Legislation will be reviewed and amended as necessary in order to make it more coherent, comprehensive and up-to-date. Enforcement of this legislation at all levels will be promoted.

The Commission believes that the establishment of a new Authority, which will become the scientific point of reference for the whole Union, will contribute to a high level of consumer health protection, and consequently will help to restore consumer confidence.

117. The success of the measures proposed in this White Paper is intrinsically linked to the support of the European Parliament and the Council. Their implementation will depend on the commitment of the Member States. This White Paper also calls for strong involvement of the operators, who bear the prime responsibility for the daily application of the requirements for food safety.

Greater transparency at all levels of Food Safety policy is the golden thread throughout the whole White Paper and it will contribute fundamentally to enhancing consumer confidence in EU Food Safety policy.

ANNEX

Action Plan on Food Safety[3]

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
I. Priority measures					
1.	Proposal for setting up a European Food Authority	To set up an independent European Food Authority.	29	September 2000	December 2001
2.	Proposal for laying down procedures in matters of food safety	To introduce a comprehensive safeguard measure covering the whole food chain, including feed. To establish a comprehensive Rapid Alert System covering all feed and food emergencies with harmonised requirements and procedures**,** including third countries on the basis of reciprocity.	80 18	September 2000	December 2001
3.	Proposal for a General Food Law Directive	To establish food safety as the primary objective of EU food law. To lay down the common principles underlying food legislation (in particular: scientific basis, responsibility of producers and suppliers, traceability along the food chain, efficient controls and effective enforcement).	67	September 2000	December 2001

[3] This action plan does not include all of the on-going actions resulting from the obligations in EU legislation.

NO	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
		To increase transparency, consistency and legal security.			
4.	Proposal for a Regulation on official food and feed safety controls	To establish a Community framework for official controls on all food and feed safety aspects along the feed and food chain by: -merging and completing existing rules for national controls and Community controls and inspections within the EU, at the borders and in third countries. -integrating existing monitoring and surveillance systems so as to establish a comprehensive and effective food safety monitoring and surveillance system from farm to table. -establishing a framework for organising consolidated annual programs for controls of foodstuffs. -merging existing Community rules on mutual assistance and administrative co-operation. -creating a Community approach towards a financial support for official controls.	Ch. 6	December 2000	December 2001
5.	Proposal for a Regulation on feed	To establish animal and public health as the primary objective of EU feed legislation To lay down common principles underlying feed legislation (in particular: scientific basis, responsibility of producers and suppliers, systematic implementation of hazard analysis and	69	December 2001	December 2002

NO	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
		critical control points (HACCP), traceability, efficient controls and enforcement). To recast all existing measures on feedingstuffs so as to create a comprehensive legislative tool increasing transparency, consistency and legal security.			
6.	Proposal for a Regulation on novel feed	To put into plan a centralised system for the authorisation of use in animal nutrition of non conventional products, in particular of GMOs and GMO derived feedstuffs.	69	September 2000	December 2001
7.	Amendment to the Annex of Directive 96/25/EC on the circulation of feed materials	To amend the definitions of feed materials listed in the Annex to Decision 96/25/EC, particularly with regard to oils and fats and animal products	69	September 2000	-
8.	Proposal for a Regulation on hygiene	To recast horizontal and vertical Directives on hygiene of food of plant and animal origin. To clarify responsibility of food operators and to introduce the systematic implementation of HACCP. To apply hygiene rules at all levels of the food chain, including primary production.	72	June 2000	June 2002
9.	Amendment to Decision 98/272/EC on epidemio-surveillance of transmissible spongiform encephalopathies (TSEs)	To reinforce TSE surveillance including a study on mandatory testing (rapid post-mortem test) on targeted groups of cattle. To reinforce TSE surveillance in small ruminants	71	March 2000 September 2000	- -
10.	Decision on the Member State and	To ensure efficacy of residue testing in Member States and	74	December 2000	-

NO	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
	third country residue programmes	third countries.			
11.	Proposal for amending Directive 89/107/EEC on food additives	To confer implementing powers for maintaining the lists of permitted food additives and to lay down specific provisions in respect of enzymes	77	December 2000	December 2001
12.	Proposal for amending Directive 95/2/EC on food additives other than colours and sweeteners	To update and revise the list of food additives other than colours and sweeteners	77	December 2000	December 2001
13.	Proposal for amending Directive 88/388/EEC on flavourings for use in foodstuffs	To clarify the scope and update definitions, to set maximum limits for toxic substances and to confer implementing powers to the Commission	77	December 2000	December 2001
14.	Proposal for amending Regulation 258/97 on novel foods and novel food ingredients	To make the necessary adaptations in the light of the conclusions of the report on the implementation of the Regulation and in accordance with the new regulatory framework of Directive 90/220/EEC	76	December 2001	December 2002
15.	Regulation on the labelling of GMO-free foodstuffs	To give operators the possibility to use labelling claims referring to the absence of use of genetic engineering techniques for the production of foodstuffs	76 103	September 2000	-
16.	Proposal for amending Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs	To remove the possibility not to indicate the components of compound ingredients forming less than 25 % of the final product and lay down a list of allergenic substances	100	December 2000	December 2001

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
17.	Proposals for Commission Directives to fix maximum residue levels (MRLs) of pesticides in food and agricultural commodities	To fix MRLs for pesticides residues for, inter alia: 36 pesticides with existing open positions in the residues directives that will automatically go to zero in July 2000 unless the Commission adopts other values To set MRLs at zero for 8 pesticides that were excluded from Annex I to Directive 91/414/EEC To set MRLs for new active substances included in Annex I to Directive 91/414/EEC	74	 June 2000 September 2000 Continuous process	-
18.	Communication on an action plan on nutrition policy	To develop a comprehensive and coherent nutrition policy	106	December 2000	-
II. Feedingstuffs					
19.	Proposal for amending Directive 70/524/EEC concerning additives in feedingstuffs	To consolidate the Directive. To fix maximum residue limits for additives. To clarify certain aspects of the procedure (evaluation reports) and the authorisation (generic versus specific).	69	July 2001	December 2002
20.	Amendment to Decision 91/516/EEC on the list of ingredients the use of which is forbidden in compound feedingstuffs	To introduce the changes deemed necessary to the list of feed materials the use of which must be prohibited in compound feedingstuffs, with particular reference to certain by-products from fat processing.	69	June 2000	-
21.	Amendment to the Annex of Directive 1999/29/EC on the undesirable substances and products	To fix the maximum limits of dioxins for oils and fats, and for other or all feed materials. To collect information on background contamination of PCB and dioxin-like PCB,	69	December 2000	-

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
	in animal nutrition	MRLs for other potential contaminants of feedingstuffs will also be fixed.			
22.	Proposal for amending Directive 96/25/EEC on the circulation of feed materials	Following reflection to decide whether an exclusive positive list of authorised feed materials should be established	69	December 2002	December 2003
23.	Proposal for amending Directive 95/53/EEC fixing the principles governing the organisation of official inspections in the field of animal nutrition	To foresee a legal basis for a safeguard clause in case of appearing or spreading hazards related to feedingstuffs likely to pose a risk to human health. To introduce an obligation for Member States to carry out a monitoring programme for contaminants in feedingstuffs. To introduce a Rapid Alert System for feed to be integrated in the Rapid Alert System for food. (to be integrated in action 2)	69	March 2000	March 2001
24.	Proposal for amending Directive 79/373/EEC on the marketing of compound feedingstuffs	To review current provisions for the labelling of compound feedingstuffs	69	January 2000	March 2001
25.	Proposal for amending Directive 95/69/EEC laying down the conditions and arrangements for approving and registration of certain establishments and intermediaries operating in the feedingstuffs sector	To introduce provisions for: – Approval or registration of manufacturers of compound feedingstuffs – Approval of manufacturers of certain feed materials – Improving traceability of feed materials and identification of critical points – Establishing a code for good manufacturing practice for	69	December 2000	December 2001

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
		animal feeding			
III. Zoonoses					
26.	Proposal for amending Directive 92/117/EEC on zoonoses	To improve monitoring and reporting system for diseases transmissible from animals to man and to reduce prevalence of specified zoonoses (e.g. salmonella)	70	June 2000	June 2002
27.	Decision on Member State and third country programmes for the control of zoonotic agents on animal products exported to the Community	To ensure that Member States implement adequate measures to control zoonotic agents To ensure that third country products are controlled to the same level as Community products	70	December 2002	-
IV. Animal health					
28.	Proposal for a Regulation on animal health requirements for products of animal origin	To recast existing animal health rules for products of animal origin	70	June 2000	June 2002
29.	Increase budgetary allocation for actions provided for in Council Decision 90/424/EEC on expenditure in the veterinary field	To enable actions necessary to improve animal disease eradication (brucellosis, tuberculosis etc) To create a task force for monitoring disease eradication in the Member States	70	May 2000	December 2000
V. Animal by-products					
30.	Proposal for amending Directives 90/667/EEC and 92/118/EEC on animal waste and derived products	To recast existing measures of animal by-products not destined for human consumption (meat and bone meal, rendered fats, manure etc.) To ensure that only animal by-products derived from animals declared fit for human consumption can enter the animal feed	69	June 2000	December 2001

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
		chain. To clarify responsibility of animal by-products operators To tighten up official control and to improve traceability			
VI. BSE/TSE					
31.	Decision on classification according to BSE status	Classification of individual countries in view of changes in BSE status (post-mortem tests)	71	June 2000	-
32.	Amendment to Decision 94/381 (feed ban) Decision on the removal of specified risk materials (SRMs) replacing Decision 97/534/EC.	To amend the Decision in the light of recent scientific opinions To replace Decision 97/534/EC laying down the rules on the prohibition of the use of materials that present risks as regards TSEs. Amendment of the TSE framework proposal accordingly.	71	March 2000	-
33.	Decision on the harmonisation of BSE rules for imports of live animals and products from third countries	To harmonise the BSE import rules for other third countries	71	September 2000	-
VII. Hygiene					
34.	Report on the testing of residues in Member States and third countries	To evaluate the performance of national and third country residue programmes.	74	December 2000	-
35.	Modification of the Annex to Council Directive 96/23/EC on residue monitoring	To re-enforce the monitoring and detection of PCBs and dioxines in food of animal origin.	74	June 2000	-

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
36.	Proposal for a Decision to review the ante-and post -mortem procedures for animals and meat	To make ante- and post-mortem inspections risk based, and to review inspection methods applied at present	72	September 2001	December 2002
37.	Decision on microbiological standards on certain foods	To fix the maximum limits of undesirable micro-organisms in foodstuffs, after risk assessment.	72	December 2001	-
VIII. Contaminants					
38.	Amendment to Regulation No 194/97 setting maximum limits for certain contaminants	To set up limits for several contaminants : ochratoxin A, cadmium, lead, 3-MCPD, dioxin and, possibly, PCBs.	73	December 2000	-
IX. Food additives and flavourings					
39.	Report on the intake of food additives	To provide an overview of the intake of food additives in the European Union	77	June 2000	-
40.	Proposal for amending Directive 94/35/EC on sweeteners	To update and revise the list of sweeteners for use in foodstuffs	77	December 2000	December 2001
41.	Amendment to Directives 95/31/EC, 95/45/EC and 96/77/EC on purity criteria for food additives (including sweeteners and colours)	To update and complete existing provisions. To introduce a general requirement for a new safety evaluation for permitted additives made from new sources or with new methods.	77	September 2000	-
42.	Amendment to Directive 81/712/EEC laying down Community methods of analysis for	To replace existing provisions with a set of general principles and a reference to other similar provisions	77	June 2001	-

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
	the respect of purity criteria				
43.	Decision amending the Community register of flavouring substances used in or on foodstuffs	To update the register	77	December 2000	-
44.	Regulation establishing a programme for the evaluation of flavouring substances	To set priorities and time limits for evaluation	77	June 2000	-
45.	Proposal for a Regulation on additives used in flavourings	To lay down a list of additives authorised for use in flavourings	77	June 2001	December 2002
46.	Proposal for a Regulation on smoke flavourings	To lay down the conditions for the production of smoke flavourings	77	June 2001	December 2002
X. Materials in contact with food					
47.	Proposal for amending Directive 89/109/EEC on food contact materials	To allow the update of specific Directives through regulatory procedure and to change or add provisions on the labelling of contact materials	78	December 2000	December 2001
48.	Amendment to Directive 90/128/EEC on food contact plastics	To update the list of authorised food contact plastics	78	December 2000	-
49.	Practical guide on food contact materials	To provide guidance on the application of Community provisions relating to contact materials	78	December 2000	-

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
XI. Novel foods/Genetically modified organisms					
50.	Regulation clarifying the authorisation procedure for novel foods and novel food ingredients	To clarify and make more transparent the procedure laid down in Regulation 258/97 for the authorisation of novel foods and novel food ingredients	76	September 2000	-
51.	Report on the implementation of Regulation 258/97 on novel foods and novel foods ingredients	To examine the application of the "novel food" legislation and assess its impact on public health, consumer protection and information, and the functioning of the internal market	76	December 2001	-
52.	Regulation on the labelling of food containing or derived from genetically modified organisms	To further harmonise the provisions governing the labelling of food, additives and flavourings containing or derived from GMO material	76 103	September 2000	-
XII. Irradiation of food					
53.	Proposal for amending Directive 1999/3/EC on foods and food ingredients treated by irradiation	To complete the Community list of foods and food ingredients which may be treated with ionising radiation	79	December 2000	June 2002
54.	Decision establishing the list of irradiation facilities	Publication of the list of irradiation facilities authorised in the Member States and those in third countries which have been approved by the EU	79	December 2000	-
XIII. Dietetic foods/food supplements/fortified foods					
55.	Directive on foods intended for intense muscular effort	To lay down specific provisions for foods intended to meet the expenditure of intense muscular effort, especially by sportsmen	105	December 2001	-

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
56.	Report on foods intended for persons suffering from diabetes	To assess the need for specific provisions for food for people with carbohydrate-metabolism disorders	105	December 2001	-
57.	Proposal for amending Directive 89/398/EEC on dietetic foods	To define the conditions for making the claims "low-sodium" or "sodium-free", and "gluten-free".	105	December 2001	December 2002
58.	Directive on purity criteria for nutritional substances in food for particular nutritional use	To lay down purity criteria for nutritional substances which are added to food for particular nutritional use or which are present in food supplements and foods to which nutrients are added	105	December 2002	-
59.	Directive on substances added for nutritional purposes in foods for particular nutritional uses	To establish a positive list of the various substances which may be added for nutritional purposes in foods for particular nutritional uses	105	June 2000	-
60.	Proposal for a Directive on food supplements	To lay down common criteria for marketing concentrated source of nutrients (vitamins and minerals)	105	March 2000	March 2001
61.	Proposal for a Directive on fortified foods	To lay down provisions for marketing foods to which nutrients such as vitamins and minerals have been added	105	September 2000	September 2001
62.	Amendment to Directive 91/321/EEC on infant formulae and follow-on formulae	To set up a list of pesticides not to be used in agricultural products intended for use in these formulae	105	November 2000	-
63.	Amendment to Directive 96/5/EEC on processed baby foods	To set up a list of pesticides not to be used in agricultural products intended for infants and young children	105	November 2000	-
64.	Amendment to Directive 80/777/EEC on mineral waters	To lay down a list of constituents of mineral waters and the conditions of use for the treatment of certain mineral waters with ozone enriched air	79	September 2000	-

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
XIV. Labelling of food					
65.	Proposal for amending Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs	To specify the conditions under which "functional claims" and "nutritional claims" may be made	101	July 2001	July 2002
66.	Proposal for amending Directive on nutrition labelling	To bring the provisions on nutrition labelling into line with consumer needs and expectations	101	July 2001	July 2002
67.	Proposal for amending Directive on misleading advertising	To clarify the scope of the Directive with regard to claims concerning in particular food, health and the environment	102	December 2000	July 2002
XV. Pesticides					
68.	Regulation on monitoring of pesticide residues in food	To improve co-ordination and quality of monitoring of pesticides in foods	74	March 2000	-
69.	Recommendation for a co-ordinated Community Monitoring Programme for pesticides residues in Foods for the year 2001	Recommendation for a co-ordinated Community Monitoring Programme for pesticides residues in Foods for the year 2001	74	December 2000	-
70.	Commission Decisions for pesticide active substances including in or excluding from Annex I to Directive 91/414/EEC	Pesticides active substances evaluated in the framework of Directive 91/414/EEC need, after the evaluation to be either included in Annex I or withdrawn from the market.	74	Continuous process	-
71.	Regulation on the evaluation of existing pesticides active substances	To fix a priority list of substances for evaluation at Community level; to introduce a notification procedure for all remaining	74	December 2000	-

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
		substances To lay out the ground rules for the final stage of the Community evaluation of active substances		September 2001	
72.	Proposal for amending Directive 91/414/EEC	*Inter alia*, to – extend competence to include genetically modifies organisms, – allow a harmonised Community regime to charge fees for the evaluation of new pesticides active substances – develop a fast-track procedure for low-risk substances, – clarify problems relating to data protection, work-sharing, parallel imports, classification and labelling, borderlines with biocides legislation etc.	74	June 2002	June 2003
73.	Directive to develop and adopt the Annexes to Directive 91/414/EEC	To develop Community data requirements for non-GMO microbial plant protection products To develop a harmonised set of risk and safety phrases To establish uniform principles for assessment of safety of micro-organisms as plant protection products	74	December 2000 December 2001 December 2001	-
XVI. Nutrition					
74.	Proposal for Council Recommendations on European dietary guidelines	To support the Member States in their development of nutrition policy at the national level To streamline the flow of information to enable consumers to make informed choices	107	December 2000	December 2001

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
XVII. Seeds					
75.	Proposal for a Regulation concerning environmental risk assessment in respect of genetically modified plant varieties	To lay down the specific conditions for the conduct of the risk assessment applicable to genetically modified varieties of agricultural and vegetable plant species, as required under Council Directive 98/95/EC, as required under Council Directive 98/95/EC.	69 76	March 2001	March 2002
76.	Directives on environmental risk assessment and the assessment principles laid down in Regulation 258/97, in respect of genetically modified plant varieties	To provide for technical and scientific guidance for the conduct of the assessment applicable to genetically modified varieties of agricultural and vegetable plant species.	69 76	June 2001	-
77.	Directives amending the Annexes of the Directives on the marketing of seeds	To lay down the details of the labelling requirement as established by Council Directive 98/95/EC for seeds of genetically modified plant varieties of agricultural and vegetable plant species. To lay down the growing conditions and other requirements for purity concerning the adventitious presence of genetically modified seeds in seed lots of traditional plant varieties	69 76	December 2000	-
78.	Proposal for a Directive amending Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine.	To lay down assessment procedures and labelling requirements for propagating material of genetically modified varieties of the vine	69 76	January 2000	June 2001
XVIII. Supporting measures					
79.	Proposal for a Regulation on the	To provide for a uniform legal basis to ensure adequate	Ch. 3	December 2000	December 2001

No	Action	Objective	Ref. in WP	Adoption by Commission	Adoption by Council/ Parliament
	financial support for food safety actions at Community level	Community financial support of actions necessary to enhance food safety (liaison and reference laboratories, exchange of officials, training of officials etc.)			
80.	Proposal for a Decision establishing a data base of dietary intakes across the whole EU population.	To create a basis of exposure data used in risk assessments and nutrition	74	December 2000	December 2001
81.	Decision on an Advisory Committee on Food Safety	To improve involvement of all stakeholders in the Community food safety policy by streamlining the existing Advisory Committees.	11	December 2000	-
XIX. Third country policy/ international relations					
82.	Proposals for agreements with third countries	To establish further agreements with third countries on veterinary and/or phyto-sanitary issues	113	Continuous process	-
83.	Proposal for accession of the European Community to Codex Alimentarius	To reinforce the participation of the European Union in the elaboration of international food standards	111	May 2000	December 2000
84.	Proposal for accession of the European Community to OIE	To reinforce the participation of the European Union in the elaboration of international animal health standards.	111	December 2000	December 2001