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**THE GENERAL PRINCIPLES OF FOOD LAW
IN THE EUROPEAN UNION**

Commission Green Paper

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Executive Summary

General Background

1. Food law is a matter of great public concern. A high level of security and effective public control is necessary to ensure that the food supply is safe and wholesome and to ensure the effective protection of the other interests of consumers.
2. With every household spending on average about 20% of its disposable income on food and drink, the sector is of vital importance to the European economy. The food and drink processing industries alone employ some 2.3 million people, and in 1996 consumption within the Community will reach about ECU 500,000 million.
3. The volume of Community legislation relating to foodstuffs has grown substantially, in particular as a result of the Internal market programme and the progressive implementation of the Common Agricultural Policy. Today, the vast majority of national food legislation has been harmonized at Community level. Even in areas which have not been harmonized, the application of the general Treaty rules, in particular Articles 30-36, provides a basis for the free movement of foodstuffs.
4. The new approach of the Commission on scientific advice and control, as laid down in the Communication on Consumer Health and Food Safety, which has followed the decision on the separation of responsibilities for the management of scientific committees, and for control activities from the responsibilities of the legislative departments, is not considered in this Green Paper, as it is mainly concerned with the substantive rules of Community law applicable to the foodstuffs sector. The Commission, as described in the above-mentioned Communication, has taken measures to raise the performance of its control services and to strive for their excellence by ensuring their independence, transparency and effectiveness.

The aims of the Green Paper

1. to examine the extent to which the legislation is meeting the needs and expectations of consumers, producers, manufacturers and traders.
2. to consider how the measures to reinforce the independence and objectivity, equivalence and effectiveness of the official control and inspection systems are meeting their basic objectives to ensure a safe and wholesome food supply and the protection of other interests of consumers.
3. to launch a public debate on our food legislation, and thereby,
4. to enable the Commission to propose appropriate measures for the future development of Community food law, where necessary.

As a starting point for discussion, the Green Paper identifies six basic goals for Community food law:

1. to ensure a high level of protection of public health, safety and the consumer;
2. to ensure the free movement of goods within the internal market;
3. to ensure that the legislation is primarily based on scientific evidence and risk assessment;
4. to ensure the competitiveness of European industry and enhance its export prospects;
5. to place the primary responsibility for safe food on industry, producers and suppliers, using hazard analysis and critical control points (HACCP) type systems, which must be backed up by effective official control and enforcement;
6. to ensure the legislation is coherent, rational and user friendly.

In order to achieve these goals, it is necessary to ensure that our regulatory approach covers the whole food chain "from the stable to the table". This gives rise to two issues:

1. the extent to which primary agricultural production and the processed foodstuffs sector should be brought within the same set of general rules;
2. the principle of producers' liability for defective products to be made obligatory for primary agricultural production (see Directive 85/374/EEC).

Simplification and rationalisation of Community foodstuffs legislation

1. Although desirable objectives, simplification and rationalisation cannot be allowed to result in a reduction in the level of protection of public health or consumer protection. Since 1985, the Commission has in general limited its internal market proposals in the foodstuffs sector to measures which are necessary for the protection of public health and of consumers.
2. It is important to ensure that the existing legislation strikes the right balance between general provisions and more detailed prescriptive legislation, between the use of binding legislation and recourse to voluntary instruments and between horizontal approaches and specific rules applicable to particular categories of foodstuffs.
3. The application of the principles of subsidiarity and legislative simplification in this area have produced mixed results. One particular problem has been the difficulty of ensuring that the practical application of the subsidiarity principle does not result in the progressive dismantling of the internal market as a result of new national legislative initiatives. In addition, the scope of Community legislation may need to be extended to cover certain areas where the internal market does not appear to be functioning effectively.

Review of existing legislation

1. Extensive consultation of the social partners during the preparation of legislation is an important means of ensuring that the legislation meets its goals. The social partners could be encouraged to participate more actively in the evaluation of the costs and benefits of proposed new legislation.
2. Greater use of Regulations instead of Directives would increase the transparency of the legislation and avoid difficulties arising from delayed or incorrect transposition. The Directive, should however, remain the instrument of choice for framework legislation.
3. There are serious difficulties in adapting existing legislation to technical and scientific progress which would be reduced by the greater use of simplified procedures.
4. The existing definitions which are contained in a variety of legal instruments should be rationalised and completed by new definitions of foodstuffs and placing on the market.
5. In the field of hygiene, 11 vertical veterinary hygiene directives co-exist with a general directive on the hygiene of foodstuffs. The Commission has already begun work on the simplification of the vertical directives, but their relationship with the general directive must also be considered. Priority should be given to ensuring that there is a coherent and consistent body of Community hygiene rules. This can best be achieved by the generalised application of HACCP-type principles, and by limiting detailed prescriptive regulations to cases where they are considered essential. The desire for consistency must also be balanced by the need to maintain the necessary degree of flexibility in the design and implementation of food hygiene regulations in order to ensure a high level of protection without imposing an unnecessary burden on business.
6. In the field of quality, it does not appear that the differences of approach resulting from the different objectives of internal market and agricultural legislation give rise to problems of incoherence or inconsistency.
7. In the field of labelling, binding labelling rules should ensure that consumers are provided with essential information about the foodstuff in a user-friendly manner. It is necessary to strike a balance which ensures that consumers receive all useful information, whilst avoiding unnecessarily detailed provisions. Manufacturers should remain free to provide additional information provided it is not misleading., although in some cases, legislation may be necessary to govern the provision of this additional information. In this context, the Green paper specifically invites comments on the approach followed in Community legislation to claims and nutritional labelling.

Maintenance of a high level of protection

1. The Treaty requires the Community to contribute to the maintenance of a high level of protection of public health, the environment and consumers. In order to ensure a high level of protection and coherence, protective measures should be based on risk assessment, taking into account all relevant risk factors, including technological aspects, the best available scientific evidence and the availability of inspection sampling and testing methods. Where a full risk assessment is not possible, measures should be based on the precautionary principle.
2. The importance of an independent source of advice which will command public respect is crucial. The independence and objectivity of scientific advice and scientific committees must be guaranteed at all levels. The Commission has taken steps to ensure central co-ordination of the number, scope, composition and activities of scientific committees so that a high level of competence and full consistency of its scientific advice is ensured and the necessary resources are provided. Every effort must be made to present scientific conclusions in a clear and cogent manner.
3. Scientific advice is of primary, but not exclusive, importance. Community legislation has on a number of occasions recognised that other factors, in particular consumer needs and concerns, must also be taken into consideration during the decision-making process.
4. The Community must have adequate means to take preventative action against serious and urgent public health risks. The Commission has a range of safeguard powers available, but it is important to verify that there are no gaps in the system. There may also be a need to improve communication to the public in the event of serious risks.
5. The Community has a variety of strategies available for the management and control of zoonoses (eradication, reduction, removal, treatment). The Commission invites comments on possible improvements to the arrangements for managing the risk of zoonoses.
6. The legislation should set out clearly the responsibilities of producers, processors, distributors and retailers to supply safe, wholesome food fit for human consumption, of specified quality and properly identified, as well as the responsibilities of the competent control authorities. It may be desirable to introduce general obligations on all economic operators to take all the steps necessary to ensure that only safe and wholesome food is placed on the market. Such obligations would be independent of consumer rights to redress in the framework of the Directive on liability for defective products.
7. The extension of the product liability directive to cover primary agricultural production should improve the overall level of protection of consumers, but should

not be considered as an alternative to appropriate product safety rules and effective official control systems.

8. Recent developments have highlighted consumer interest in food production methods. Community food legislation¹ does not require the labelling of production methods which do not have an impact on the food characteristics of the finished product. However, in certain cases, mandatory labelling schemes may be considered necessary, such as the recently adopted rules on the labelling of beef. Moreover, it may be necessary to consider an appropriate framework for voluntary labelling schemes designed to address this interest.

Ensuring the effective implementation of internal market rules

1. Timely and correct implementation of Community legislation is essential for the effective operation of the internal market. Greater use should be made of Standing Committees to consider questions regarding the interpretation of Community legislation, and unforeseen difficulties which may arise during its implementation. Consideration should be given to the establishment of a forum in which representatives of the Commission, member States and interested parties could discuss general issues relating to the implementation of the legislation.
2. The primary role of the Community in the field of control is not to replace the Member States, but to verify that the necessary controls are being carried out in an effective and equivalent manner throughout the internal market. The legislation should provide for appropriate enforcement and control measures. Whilst aimed at achieving a high level of protection, control and enforcement measures should take into account the principle of proportionality and should also provide for the targeting of controls on activities presenting the greatest risk. Steps should be taken to reinforce administrative and scientific cooperation between Member States and with the Commission in order to ensure equivalence of enforcement throughout the Community and to ensure effective mechanisms to prevent the marketing of unsafe food and to trace the origins of, and factors contributing to, outbreaks of food-borne disease. The fifth Research Framework Programme also has a role to play in this respect. In order to reinforce consumer confidence, efforts have been made in the Communication on Consumer Health and Food Safety to improve the transparency of the control system at Community level, and the need for greater transparency at national level should also be considered.
3. The sanctions for infringement of Community internal market legislation should be equivalent to the sanctions set out in domestic legislation, effective, proportionate and dissuasive.

¹ Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs
Regulation (EC) n° 374/97 on novel foods and novel food ingredients

4. There are mechanisms for examining new draft national legislation, principally under Directive 83/189/EEC where it contains technical regulations; the Commission also ensures respect for the Community rules on foodstuffs by the investigation of complaints. The new procedure for mutual information on national measures derogating from the principle of free movement of goods is also expected to make an important contribution in this respect.

In non-harmonized areas, the primary instrument for the management of the internal market remains the principle of mutual recognition, which requires that a Member State should allow to circulate freely in its territory goods produced or marketed in conformity with the rules, tests or standards found in another Member State which offer an equivalent level of protection to its own rules, tests or standards.

The External Dimension

1. The Community is both a major importer and exporter of food. As an importer, the Community is obliged to ensure that imported foods meet the same high standards as have been laid down for Community production. As an exporter, the Community must be able to reassure governments and consumers in third countries that food produced within the Community may be safely marketed in their countries.
2. The legislation should be compatible with the international obligations of the Community, in particular those arising under the WTO agreements. Equally, the Community must work in close partnership with the Member States, producers and industry to ensure that our major trading partners are also respecting their obligations. The Community should be able to participate fully in international standardisation activities relating to the foodstuffs sector. Where possible, the Community should negotiate equivalence agreements or mutual recognition arrangements with major trading partners to ensure in all cases, a high level of protection of the consumer.

PART I

INTRODUCTION

1. General remarks

Following more than 30 years of legislative activity, the great majority of national food law has been harmonized at Community level. Recent studies, in particular the study of the Impact and Effectiveness of the Internal market Programme on the Processed Foodstuffs Sector, have shown that the Community's legislative programme in the foodstuffs sector has had a generally positive impact, although some criticisms have been expressed of overly detailed legislation, fragmentation, difficulties of adapting the legislation to innovation, and problems in the day-to-day functioning of the internal market. In the light of certain recent events, in particular BSE, others have raised doubts about the capacity of the legislation to entirely fulfil its objectives to ensure a high level of protection of public health and consumer protection.

In contrast to legislation in most of the Member States, Community food law has developed piecemeal, over time, and there is no central unifying text setting out the fundamental principles of Community food law and clearly defining the obligations of those concerned. In recent years, there have been increasing calls for such a legislative framework, most notably from the European Parliament. In 1992, the Commission invited three eminent food law experts to consider the need for, and possible scope of, such a general directive. In May 1993, at the request of the Commission, the European University Institute of Florence organised a conference on this question bringing together the three experts and representatives from the Member States and the Commission, from agricultural, industrial and commercial interests, and from consumer groups.

The aim of this Green Paper is to:

- examine the extent to which the legislation is meeting the needs and expectations of consumers, producers, manufacturers and traders;
- consider how the measures to reinforce the independence and objectivity, equivalence and effectiveness of the official systems for the control and inspection of foodstuffs are fulfilling their objectives;
- invite a public debate on our food legislation to provide guidance to the Commission in its future legislative initiative on food, and accordingly;

- enable the Commission to propose measures allowing, wherever possible, to improve the protection of public health laid down in its measures for the internal market and the common agricultural policy, improve the coherence of Community food law, consolidate and simplify it, improve the operation of the internal market, and take into account the increasingly, important external dimension, notably the policies followed by our most advanced trading partners and the requirements of the WTO agreements.

The new approach of the Commission on scientific advice and control, as laid down in the Communication on Consumer Health and Food Safety, which has followed the decision on the separation of responsibilities for the management of scientific committees, and for control activities from the responsibilities of the legislative departments, is not considered in this Green Paper, as it is mainly concerned with the substantive rules of Community law applicable to the foodstuffs sector. The Commission, as described in the above-mentioned Communication, has taken measures to raise the performance of its control services and to strive for their excellence by ensuring their independence, transparency and effectiveness.

Before considering the policy options which are submitted for discussion, it is important to reaffirm the fundamental goals and achievements of EC food law, which should in no way be put into question. These are :

- the need to ensure a high level of protection of public health and safety, and of consumer protection;
- the need to ensure the free circulation of goods within the single market;
- the need for legislation to be based primarily on scientific evidence and risk assessment, in respect of our international obligations;
- the need to ensure the competitiveness of the European industry, allowing for flexible adaptation of the legislation to incorporate new technical developments as well as to enhance Community export prospects;
- the need to place the primary responsibility for safe food with industry, producers and suppliers, including imports from third countries, through self-checking provisions (so-called Hazard Analysis Critical Control Points systems or HACCP) backed up by official controls and appropriate enforcement;
- the need for legislation to be coherent, rational, consistent, simpler, user-friendly and developed in full consultation with all interested parties.

It is also necessary to stress that as the food chain becomes increasingly complex, with a growing number of interventions from primary producers through the agro-food industry to distributors and retailers, so it becomes essential to ensure that our regulatory approach covers all potential risks to the safety and wholesomeness of food, at all stages of the food chain, including factors arising upstream, from potentially hazardous inputs or environmental contaminants; factors arising during on farm production and factors arising during downstream manufacturing, processing distribution or storage.

For this reason, a further objective of this Green paper is to examine whether or to what extent processed foodstuffs and primary agricultural production can be brought within the scope of the general rules applicable to foodstuffs, despite their differences. Similarly, under the product liability Directive, it is left to Member States to determine whether to apply product liability to primary production. The extension of Community rules on product liability to all operators in the food chain, including primary producers is therefore also considered.

The Commission wishes to ensure that the consultation exercise covered by this Green Paper is as broad as possible. It therefore invites any other relevant comments and suggestions from interested parties. At the end of the consultation process the Commission will consider what changes may be necessary. These changes may consist of:

- a proposal for a general Directive on food law;
- consolidation and simplification of certain provisions, or reformulation of existing legislation;
- suggestions or proposals of a non-legislative nature, including changes in procedures or working methods.

Comments on this Green paper should be addressed before 31 July 1997 to.

European Commission
Directorate General for Industry (Green Paper on Food Law)
200 rue de la Loi (RP 11 3/1)
B-1049 Brussels

2. The economic context

Within the Community, every household spends on average about 20% of its disposable income on food and drink. It is estimated that in 1996 consumption of food and drink and tobacco within the Community will amount to about ECU 500,000 million, while production will amount to ECU 510,000 million. The Community is both a major importer and a major exporter of foodstuffs. In 1994 exports from the Community reached ECU 34,250 million, while imports into the Community were valued at ECU 24,480 million, leaving a favourable trade balance of ECU 9,770 million, an increase of over 50% when compared with 1992. In some food sectors, however, there is a negative trade balance. For example there is a deficit of fisheries products in the Community which amounted to ECU 6,172 million in 1994. Over 2.3 million people are employed by the food and drink industries, nearly 50% of them in enterprises with less than 100 employees. A further 10 million people are employed in primary agricultural production. The food and drink sector is thus clearly of major importance for the European economy as a whole.

Between 1984 and 1992 both production and consumption of food and drink within the EC grew at a constant real rate of about 2-2.5% a year. However, in 1992-93, this rate of growth slowed to below 1%. Much of this growth is achieved through higher added value, as, particularly in Northern Europe, consumers switch from fresh foodstuffs to "convenience" processed foods. The major producers have reacted to this long-term change by investing heavily in increasing their production capacity, in the modernisation of equipment and in new technology. Smaller producers, on the other hand are finding themselves under growing pressure, not only as a result of the changing pattern of foodstuffs demand, but also because of the major changes taking place in the retail distribution system, notably due to the increasing concentration in food distribution and the growing role of the supermarkets' "own-brand" products in the market place. As a result, many smaller producers face a choice of seeking a niche in a quality market or of becoming suppliers of "own-brand" products for supermarkets.

Across the Community as a whole, there are still substantial regional variations in the market for foodstuffs, particularly between the northern and the Mediterranean regions. In Southern Europe, consumption of fresh food remains relatively high and the proportion of value added by the food processing industry is thus significantly lower. Nevertheless, in all regions there has been considerable diversification of the type and range of products available, and this trend is likely to continue as manufacturers seek to use the rules of the internal market to obtain new outlets for their products.

Against this background, it appears clear that the Community has a major role to play by promoting a transparent and stable regulatory environment as the foundation for further development of this vital sector. In particular, the transparency and efficient operation of the internal market is of major importance for the survival of the large number of smaller and medium-sized companies which must increasingly compete with the giants of the multi-national agro-food industry.

3. Background to the development of Community activities in the foodstuffs sector

The primary influences on the development of the Community's food law have resulted from the Common Agricultural Policy and the programme for the realisation of the internal market. There is also a distinct policy for fisheries and aquaculture, the Common Fisheries Policy.

For the future, the development of Community activities in this sector will also be strongly influenced by the new provisions added by the Maastricht Treaty concerning human health protection (Article 129), consumer protection (Article 129a), and the environment (Article 130r).

3.1 The Common Agricultural Policy and foodstuffs legislation

The common agricultural policy has had a significant impact on the development of food law within the Community. Measures taken to achieve the objectives of the CAP have inevitably also resulted in the development of legislation which affects the sale of foodstuffs of agricultural origin. Three points in particular may be noted:

1. One of the main features of the CAP has been the development of common organizations of the market for the major agricultural commodities, along with price support and intervention measures funded by the European Agricultural Guidance and Guarantee Fund (EAGGF). For these measures to operate effectively and to avoid fraud, it has been necessary in some cases to establish quality specifications to define those products eligible for support. In addition, as a market support measure, and sometimes in the absence of price support mechanisms, it has been considered necessary to lay down quality specifications for products. The nature and extent of these rules vary according to the common organization of the market concerned. In some cases the rules may have little impact on the marketing of the finished foodstuffs. In others, for example the common organization for wine, the rules constitute a comprehensive and self-contained marketing code.

2. To secure free movement of primary agricultural produce within the Community, it has been considered necessary to lay down detailed rules approximating the laws relating to human, animal or plant health. For example, the rules on veterinary hygiene have a profound influence on the use and marketing of foodstuffs of animal origin. It is also necessary to ensure that the techniques used in agricultural production do not themselves present a risk to public health. Thus, for example, detailed provisions have been laid down establishing limits for residues of pesticides or veterinary medicines in foodstuffs.
3. In its 1989 communication on the future of rural society, the Commission indicated its intention to promote a product quality policy at Community level. As a consequence, specific Community legislation has been adopted governing the use of quality marks or labels to identify products which are subject to a special production quality requirement (Regulation 2082/92), originate in areas known for their traditional production (Regulation 2081/92), or can be shown to be produced using special methods, such as organic foods.

More recently, there have been several other developments of importance for the consumer. The Council has recently adopted binding rules on the traceability of products of bovine origin, and consideration is being given to further measures to improve the traceability of other animal products. Proposals are also in preparation to extend organic labelling to cover foodstuffs of animal origin.

3.2 The Common Fisheries Policy

While the term primary agricultural production is usually taken to include fisheries products, fishing and aquaculture are covered by a quite separate Common Fisheries Policy (CFP). This provides specific provisions in Community food law for fishery products. The common organisation of the market involves a set of principles and rules dealing with common marketing standards, producers organizations, internal market price support mechanisms and a régime for trade with non-member countries. Structural assistance mechanisms for fisheries and aquaculture are implemented under the financial instrument for fisheries guidance (FIFG), which includes finance for improvement and control of quality and hygiene. Detailed rules relating to the conservation of limited fish stocks are an integral part of the CFP. The veterinary legislation applying to fish and shellfish is currently being reviewed as part of the project to simplify veterinary legislation on products of animal origin.

3.3 The development of the internal market in processed foodstuffs

The foodstuffs sector is an essential part of the internal market, both from the consumer's point of view and that of economic operators. Thus all measures taken at Community and national level have to take full account of the general principles of the internal market, and in particular the principle of the free movement of goods.

The Community has a variety of instruments at its disposal for the realisation of the internal market.

- application of the general principles governing the free movement of goods, notably the principle of mutual recognition derived from the case law of the Court of Justice (which requires that a Member state should allow to circulate freely in its territory goods produced or marketed in conformity with the rules, tests or standards found in another Member State which offer an equivalent level of protection to its own rules, tests or standards)
- detailed harmonization of national legislation in those cases where application of the principle of mutual recognition does not provide a sufficient basis for the internal market;
- the use of framework legislation, setting out certain general principles, but leaving Member States free to adopt stricter or more specific rules, provided these do not create unjustified restrictions on the operation of the internal market;
- the use of voluntary instruments, such as standardization or codes of practice.

Detailed harmonization of national foodstuffs legislation, in order to secure free movement, began in the earliest years of the Community. From 1962 to 1985, two approaches were followed:

- horizontal harmonization covering all foodstuffs, either to protect public health (e.g. additives) or for the protection of other consumer interests, such as the *provision of information or the prevention of misleading trade practices* (e.g. with regard to labelling)
- vertical harmonization laying down detailed specifications for a specific type of foodstuff; eight directives were adopted covering cocoa and chocolate products, sugars, honey, fruit juices and similar products, jams, jellies and marmalades, preserved milk, coffee extracts and natural mineral waters.

In addition, mention should be made of Council Directive 80/778/EEC on the quality of drinking water for human consumption. This Directive is of fundamental importance for the foodstuffs sector as all water used in a food production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption and affecting the wholesomeness of the foodstuff in its finished form must comply with the requirements laid down in that Directive.

Parallel with the legislative development at Community level, the Court of Justice has interpreted Articles 30-36 of the EC Treaty. Following the jurisprudence of the Court in the Cassis de Dijon case, the Commission completely reviewed its policy on the harmonization of foodstuffs legislation and in 1985 presented a communication to the Council and the European Parliament on the completion of the internal market in the foodstuffs sector (COM (85) 603 final). At the same time the scope of the principle of mutual recognition was clarified.

In accordance with the communication, Community food legislation would henceforth be limited to the harmonization of national rules justifiable in terms of the mandatory requirements identified by the Court, namely:

- the protection of public health;
- the protection of other consumer interests, notably consumer information;
- fair trading;
- the need to ensure appropriate official controls.

On the other hand, the Commission indicated that in principle it would no longer put forward proposals for the harmonization of quality specifications, such as rules relating to the composition or manufacture of foodstuffs which are not related to the protection of public health. Instead, the Commission believed mutual recognition could be achieved by reinforcing the labelling rules to guarantee consumer information and fair trading. In addition, the Commission encouraged the industry to develop quality policies based on the use of voluntary instruments.

In a further communication of 1989 on the free movement of foodstuffs within the Community the Commission summarized the principles in this area taking into account the jurisprudence of the Court. In its 1991 interpretative communication on the names under which products are sold, the Commission specified the system for mutual recognition of foodstuffs in non-harmonized areas together with the possibility of adopting sectoral provisions considered necessary for the implementation of other Community policies, for example, composition requirements, definition of organic production, quality marks for traditional foods, and designations of origin.

Virtually all the legislation set out in the Commission's 1985 programme has now been adopted, with the exception of the proposals relating to food irradiation, currently under consideration by the Council and the European Parliament. In addition, further measures have been adopted to take account of problems not foreseen in 1985, notably in respect of food hygiene, contaminants, and cooperation between the Commission and the Member States on the examination of scientific questions relating to food.

Since 1 January 1989, Member States have been required to communicate to the Commission, under the procedure for the provision of information set out in Directive 83/189/EEC, draft technical regulations relating to foodstuffs. Further specific notification procedures apply to national measures concerning food labelling, contaminants and food hygiene. These are described in Part 2, section 7.

Finally, consideration must be given to the fact that, in areas not covered by Community legislation, the developing case law of the Court of Justice provides a continuing basis for the free movement of foodstuffs.

4. The industrial policy dimension

In section 2, it was noted that primary agricultural production, and the processed food and drink sectors, are of major importance to the European economy. It is important, therefore, to maintain the competitiveness of these sectors as a means of achieving rising living standards and social welfare across the Community. In its recent Communication on Benchmarking the competitiveness of European industry, the Commission indicated that the primary responsibility for ensuring that firms remain competitive remains with the firms themselves. Nevertheless, the public authorities sustain competitiveness by putting in place the appropriate framework conditions under which enterprises operate, notably by providing the necessary infrastructure, putting in place an appropriate regulatory environment and specific initiatives, particularly in the areas of innovation, quality, the business environment for small and medium sized enterprises and economic cohesion. In this context, the Commission has recently taken a series of general initiatives, such as the Green Paper on Innovation, the working document on quality and the Multi-annual programme for SMEs, which are equally relevant to the foodstuffs sector. Certain of these issues, such as the need to ensure an appropriate regulatory environment, which is conducive to innovation, are touched on at various points in this Green Paper. The Commission considers that it is important to ensure that these industrial policy orientations are integrated into its regulatory approach to the foodstuffs sector, and it would invite comments on any further measures which may be necessary in this respect.

5. The consumer, food safety and health protection

As the previous sections have shown, Community rules applicable to foodstuffs have developed from the variety of different legal bases set out in the treaty, in order to serve different policy objectives. The legislation is also based on a complex division of responsibilities between the Commission and the Member States. The situation is complicated and difficult to understand, not only for the average citizen, but sometimes also for the specialist. This has led to criticisms that the Community lacks a coherent policy towards the foodstuffs sector as a whole, and approaches problems piecemeal. The general remarks at the beginning of this Part have identified a number of common goals which run all the way through Community food law.

The BSE crisis has highlighted the need for a European food policy centered on the requirement that only foodstuffs which are safe, wholesome and fit for consumption be placed on the market. Health protection in relation with consumption of foodstuffs is to be an absolute priority at any time and not only something to be looked at in emergency situations.

The Commission has already taken steps to adapt the structure of its services, so as to make it possible to fully reach this objective.

The Commission intends to develop a true food policy which attaches fundamental importance to the protection of the consumer and his health.

In order to build an effective food safety policy, major efforts will be deployed in order to ensure that:

- the most recent and complete scientific evidence is taken into account when deciding on legislative or other measures;
- a precautionary approach is the rule in case scientific evidence is incomplete or unconvincing one way or the other which makes a full risk assessment impossible;
- at all stages of the food chain, there is clear responsibility for the safety and wholesomeness of food. This implies corresponding provisions for liability in case of damages caused to the consumer's health by unsafe or unwholesome food;
- control measures are taken at all critical points throughout the food chain (primary production, processing, transport, handling and distribution, display at final point of sale). The same applies to imported foodstuffs.

- appropriate measures are taken to ensure the correct information of the consumer about the nature and content of foodstuffs
- the responsibilities of the various controlling agents (eg producers, Member States' authorities, Commission services...) as well as the nature of the control (eg on-site inspection, audit of control systems...) are clearly defined.

In this context, account must be taken of the fact that, following the entry into force of the Maastricht Treaty, the Commission has acquired new responsibilities to contribute to the attainment of a high level of human health protection (Article 129) of protection of consumers (Article 129a), and of the environment (Article 130r). In recent years, increasing attention has been given to issues such as nutrition and health. The revision of Article 129 of the Treaty is currently under discussion by the Inter-Governmental Conference.

Moreover, in recent years, increasing attention has been given to issues such as nutrition and health, which raises questions as to the role of the Community in such areas.

PART II

SIMPLIFICATION AND RATIONALISATION OF COMMUNITY FOOD LAW

1. Introductory remarks

In recent years, a number of criticisms have been expressed concerning the complexity, fragmentation and incoherence of Community food law, and of the difficulties of adapting the legislation to innovation. In particular it has been suggested that:

- certain provisions are unnecessarily detailed or prescriptive, and fail to take account of the development of internal control systems by industry to ensure the quality and safety of food products;
- there are instances of the duplication of legislative provisions, or of incoherences between different vertical rules applicable to specific sectors, or between vertical and horizontal rules;
- the complexity of the legislation and the slowness of Community legislative procedures makes it difficult to update the legislation to take account of technical and scientific progress.

At the political level, the Internal Market Council has also called on the Commission to consider the scope for the simplification of internal market legislation.

The objective of this Part is to consider the general approach of the Community to the foodstuffs sector, in the light of these criticisms, and to consider the scope for measures to simplify and rationalise Community food law.

2. General considerations

One of the essential responsibilities of the public authorities has been to ensure that an adequate supply of safe and wholesome food is available to consumers. Today, all developed countries have adopted a substantial body of legislation which seeks to guarantee that food is safe, wholesome and fit for human consumption, that commercial transactions are conducted fairly, and that the necessary systems of official control and inspection are put in place.

In recent years, a new range of issues concerning foodstuffs has emerged, as a result of increasing scientific knowledge and popular awareness of the links between nutrition and health, and also as a result of the new aspirations of consumers who are not only interested in "safe food" but are also increasingly concerned about the methods used in agricultural and food production.

As work towards the implementation of the internal market and the common agricultural policy has progressed, national rules have increasingly been replaced by Community legislation. Today, the vast majority of food law has been harmonised at Community level, and in many fields the scope for unilateral initiatives by the Member States is severely restricted. It follows that the Community must itself develop policies which provide for a high level of protection and meet the legitimate demands and expectations of consumers, but avoid legislation which imposes unnecessary burdens on producers and industry, the costs of which, of course, are ultimately passed on to consumers through higher prices.

As noted above, since 1985, the scope of Community food legislation has, in general, been limited to measures which are necessary for the protection of public health, for the protection of other consumer interests, and for the establishment of the necessary control provisions. Moreover, the fact that Community legislation has resulted in the replacement of 15 different and sometimes conflicting sets of rules with a single set of harmonized rules has of itself made a significant contribution to the simplification of food law.

Against this general background it should be clearly understood that there can be no question of wholesale deregulation and the dismantling of the system of protection which has been put in place. The objective is to provide a body of legislation which is effective, straightforward, simpler to understand, and more user friendly for those principally concerned, producers, industry, food businesses, enforcement authorities and consumers.

3. General regulatory approach

Food law is a matter of great public concern. Only a high level of security and effective public control can minimise the vulnerability of food to health scares which can have a major impact on consumer demand, industry profits and employment. An effective legislative and regulatory framework is therefore essential. Moreover, in view of the increasing complexity of food production and distribution, it is necessary to ensure that the entire food chain is covered. There is no point in strictly controlling parts of the food chain if contamination can be introduced at other points.

Nevertheless this regulatory framework must be designed and implemented in such a way as to take full account of the fact that the primary responsibility for the

production of safe and wholesome food lies with producers and industry. Thus, whenever possible, it should offer industry the flexibility to design and implement appropriate internal monitoring procedures, provided these are backed up by effective official control systems.

In some instances, specific detailed legislation may be necessary. This is particularly important in cases where treatments which are difficult to detect could otherwise be used to conceal the effects of unhygienic or unsound production methods.

In other cases, it is sufficient that regulatory requirements are worded in terms of their goals and intended result, rather than in terms of prescribing how that result is to be achieved. Once a clear legislative framework has been established setting out the goals to be achieved, economic operators can be left to implement the legislation, subject to the effective supervision of the control authorities, using HACCP-type systems, codes of practice and other appropriate instruments.

The difference between the two approaches is most clearly illustrated in the field of food hygiene, where they co-exist. For food products of animal origin, which are sensitive from the health point of view, a series of detailed vertical directives prescribe in some detail the hygiene requirements which must be observed. Other foodstuffs are covered by the general directive on food hygiene. Although it contains some prescriptive provisions, this latter directive aims at a more general approach, defining the objectives of food hygiene and leaving a large measure of flexibility for industry in its implementation. The area of food hygiene is considered in greater detail in Part III, Section 6.

Both approaches offer advantages and disadvantages. Since the more prescriptive approach requires the legislator to identify the major risk factors and the means of managing those risks, it often makes it easier for companies to identify their obligations and it facilitates the tasks of the control authorities. The more general approach, on the other hand, leaves industry with greater flexibility in the implementation of the legislation, and is thus likely to reduce compliance costs, but it must ensure a level of protection of public health which is equivalent to the more prescriptive approach. It is also likely to reduce the need for frequent updating of the legislation. However, it requires both food businesses and the control authorities to take a much more active role in analysing the hazards presented by different activities and ensuring that effective measures may be taken to control them. This may present particular difficulties for small businesses working in the sector, although the elaboration of industry wide codes of practice may provide a solution to this problem.

It should be noted that the two approaches are not necessarily mutually exclusive. Community legislation on food additives provides an example of a field in which they have been successfully combined. The legislation is based upon a rigorous safety evaluation of all additives. Only those additives which have been found to be safe for use in food may be used within the Community. Where the safety evaluation has led to the conclusion that it is necessary to establish a total acceptable daily intake (adi) for the protection of public health, prescriptive limits are set for the use of each additive in each food in order to ensure that human exposure does not exceed the adi. However, where the safety evaluation leads to the conclusion that an adi is not necessary, the concept of "quantum satis" is applied. This means that industry is free to use the additive in question, in accordance with good manufacturing practice, at a level no higher than is necessary to achieve the intended purpose, and provided that the consumer is not misled.

In these circumstances, the Commission considers that a balanced approach is necessary between detailed prescriptive legislation, and a more general legislative approach. It would invite comments on whether that balance is correctly reflected in current Community legislation.

4. Role of self regulation in the foodstuffs sector

Because of the sensitivity of the foodstuffs sector, there has always been some debate as to the extent to which the use of self-regulatory instruments, such as codes of practice or standards, is appropriate either as an alternative to regulation or to supplement it.

Where voluntary instruments are used, it is important that these instruments remain genuinely voluntary and that appropriate safeguards are applied in order to ensure that the procedures for their elaboration are transparent, open to all interested parties and provide for the necessary quality control of the work.

Hitherto, the use of voluntary instruments as an alternative to regulation has mainly taken place:

- in the field of compositional specifications for foodstuffs. In its 1985 Communication on the realisation of the internal market for the foodstuffs sector, the Commission announced that it would no longer bring forward legislative proposals to harmonize compositional specifications for foodstuffs, except where necessary for the purposes of the Common Agricultural Policy, and would encourage instead the use of voluntary standards in this field. Since then, the experience of standardization in this field at European level has not been particularly successful, and virtually no European standards have been adopted concerning quality specifications for foodstuffs, despite several attempts. However, at the national level, there has been an increasing use of standards, or equivalent instruments such as codes of practice, which brings with it the risk of new de facto barriers to intra Community trade.

- in the field of methods of sampling and analysis, where the experience at Community level has been much more positive, and a number of standards have been adopted.

In the field of food hygiene, voluntary instruments are being used to compliment the existing legislation. Article 5 of Directive 93/43/EEC encourages the development of codes of good hygiene practices which food businesses can use on a voluntary basis, and which can serve as guidelines for the implementation of the general principles of food hygiene laid down in the Directive. In addition, the Directive sets out a procedure for the recognition of the guides at Community level, and sets out certain guarantees to ensure that they are developed by representatives of the food businesses involved, and of other groups which are substantially affected, such as the competent authorities and consumer groups, that they meet the hygiene requirements laid down, that they are practicable, and that there is adequate consultation during their preparation. In addition to a number of initiatives at national level, the Commission is aware that a number of such guides are in preparation at the European level, notably in the fields of edible ices, patisserie and the sale of hot and cold foods and drinks by vending machines.

The Commission would welcome comments on the role of voluntary instruments in the foodstuffs sector. It would also welcome comments on the possibility of widening the scope of application of existing national voluntary instruments to cover the whole Community.

5. Horizontal or vertical approaches to food law

Because of the great diversity of the foodstuffs sector, it is sometimes necessary to consider whether preference should be given to a horizontal approach, which lays down general rules applicable to foodstuffs in general, or whether a vertical approach laying down specific rules for a particular sector should not sometimes be used.

Within the framework of the legislation adopted under the 1985 White Paper Programme for processed foodstuffs, priority has in general been given to horizontal measures which apply to all categories of foodstuffs (additives, flavours, extraction solvents, labelling, nutritional labelling, hygiene etc). Nevertheless, recourse to vertical measures has sometimes been considered necessary, notably in the case of foodstuffs for particular nutritional purposes, and quick frozen foodstuffs.

In the case of the rules governing primary production and products of animal origin, a more sectorally based approach has generally been used, although some general legislation has also been adopted, notably that dealing with designations of origin and specificities, and the use of the organic label.

Specific questions concerning the co-existence of horizontal and vertical texts in existing Community legislation are dealt with in Part III. In general terms, however, it may be noted that rather than favouring one approach over the other in every case, it is a question of finding the appropriate balance between the two approaches, both of which have their advantages and disadvantages. The horizontal approach makes it possible to take a general overview of a particular situation, and facilitates implementation, particularly for food businesses working in many sectors, including not only manufacturers, but also for commerce and distribution. The vertical approach, on the other hand makes it possible to adjust the legislation to the needs of a specific sector, particularly in cases where a more targeted approach to legislation has been judged necessary. It also makes it possible to envisage a more integrated regulatory approach which covers all aspects of a particular sector.

The Commission would particularly welcome comments on this issue.

6. Subsidiarity and legislative simplification

Article 3b of the EC Treaty states that in areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

For several years, it has been the practice of the Commission to include a 'Subsidiarity statement' in all new legislative proposals, to explain why the Commission considers that action at Community level is necessary. This statement also includes consideration of the objectives of the measure proposed and whether recourse to less binding provisions would be sufficient to achieve the objectives proposed. In addition, on 16 January 1996, the Commission adopted general guidelines on regulatory policy which are intended to promote the coherence of Commission activity, to rationalise and modernise the evaluation of the effects of its proposals, and to reinforce external consultations.

In response to the conclusions of the Edinburgh Summit of December 1992, the Commission has undertaken several initiatives to simplify existing Community legislation in the foodstuffs sector. These initiatives include a reconsideration of whether certain items of legislation are necessary, and the removal of unnecessarily restrictive provisions from existing legislation.

In April 1994 the Commission presented a proposal to amend Directive 89/398/EEC on foodstuffs for particular nutritional purposes in order to reduce the number of specific directives for particular categories of dietetic foods from 8 to 4. In effect, the

Commission proposed not to proceed with detailed directives concerning low sodium foods, gluten free foods, foods for diabetics and foods for athletes. While there is general agreement that there is no need for detailed directives on low sodium and gluten-free foods, and that general labelling provisions would suffice, there has been much controversy about the need for directives on foods for diabetics and foods for athletes. The Commission amended its proposal to accept an amendment from Parliament calling for a Directive on foods for diabetics. However, within the Council, a substantial majority of Member States contest the need for such a Directive, whilst a significant number of Member States insist on the need for a Directive on foods for athletes.

In addition, on 17 April 1996, the Commission adopted a package of 7 proposals to simplify the old compositional directives which were adopted in the 1970s concerning honey, sugars, preserved milks, coffee extracts, fruit juices and nectars, jams, jellies and marmalades and chocolate and chocolate products. Once again, this exercise has given rise to much controversy, notably in respect of the compositional rules relating to chocolate.

These two examples clearly show that legislative simplification is by no means an easy task. Provisions which are considered as unnecessarily restrictive by some, may be considered fundamentally important by others. The potential advantages of legislative simplification must be carefully balanced against the risks of reopening old controversies, and of the possibility of creating a long period of uncertainty for economic operators in the sectors concerned.

The Commission has presented proposals to consolidate, simplify and update the drinking water directive (COM (94) 612). A further Commission initiative for legislative simplification in the field of veterinary hygiene is examined in Part III, Section 6.

One particular problem in the food sector is the difficulty of reconciling the practical concepts of simplification and subsidiarity with the maintenance of a high level of protection, as well as with the effective operation of the internal market and the common agricultural policy. Each year, Member States take a number of legislative measures for reasons of protection of public health or for consumer protection. Such measures can create barriers within the internal market or problems for the functioning of the CAP, leading to calls for Community legislation. However, what is considered as necessary by one Member State may be considered as over-regulation by others. Nevertheless, if they are to be fully effective, the principles of subsidiarity and legislative simplification must be applied at national as well as at Community level.

In conclusion, it is important to emphasise the need to ensure that the right balance is found between the application of the principles of subsidiarity and simplification, on the one hand, and the needs of the internal market on the other. In order to ensure a high level of protection of public health and of consumers, the foodstuffs sector is and will continue to be highly regulated. In the absence of Community legislation, Member States will continue to adopt new legislation which they consider to be necessary to protect health or consumers. Unless an appropriate response can be found at Community level, there will be a constant risk of fragmentation of the internal market back into national markets.

7. National legislative initiatives

Although the volume of Community legislation relating to the foodstuffs sector has slowed substantially, the flow of new national legislation shows no sign of abating. Each year, the services of the Commission consider some 60-80 new national legislative initiatives relating to the foodstuffs sector under the procedures laid down in Directive 83/189/EEC.

In accordance with the procedure, Member States are required to notify draft technical legislation to the Commission which circulates the draft to the other Member States. A standstill requirement of 3 months initially applies. If the Commission, or a Member State, considers that the new measures will give rise to barriers to trade within the internal market, it may issue a detailed opinion, as a consequence of which a Member State must postpone the application of its measures for six months. In this case, the Member State must report on the action it proposes to take in response to the detailed opinion. The procedure also enables the Commission to defer the adoption of the national measure for up to one year to allow time for the preparation of proposals for legislation at the Community level, or for the adoption of pending proposals. In the CIA Security International case, the Court of Justice has recently held that the failure of a Member state to notify draft legislation in accordance with Directive 83/189/EEC will result in that legislation being unenforceable against individuals.

The procedure under Directive 83/189/EEC enables the Commission to comment on draft legislation, and to ask Member States to make changes which would minimise the effect on intra-Community trade. In a number of cases, the Commission has successfully persuaded a Member State to modify the draft in order to bring it into conformity with Community law, for example by the insertion of a mutual recognition clause into the national legislation. The application of this procedure is also important in that it highlights areas where further Community legislation may be needed.

However, further specific notification procedures also apply to the foodstuffs sector. The Community rules on food labelling, on contaminants and on food hygiene permit a Member State to adopt more specific rules than those adopted at Community level.

In line with the principle of subsidiarity, Member States can therefore adopt more detailed legislation to take account of the particular situation in their country. However, in order to protect the Community interest, and notably the operation of the internal market, the Commission is given powers to supervise the use which Member States make of this possibility. Thus Member States are required to notify the texts to the Commission, and allow the Commission three months to examine the draft. If the Commission has doubts about the effect of the legislation on the internal market, the Commission may issue a negative opinion. Subject to a favourable opinion from the Member States within the Standing Committee for Foodstuffs, the Commission may then require a Member State to amend or withdraw the text, or to postpone its adoption for a period, which may exceed one year, in order to allow the preparation of Community legislation.

In order to simplify the administrative procedures involved in notification, the Commission has introduced arrangements whereby all notifications are submitted initially to a single entry point. However, the later stages of the procedure differ considerably. Under Directive 83/189/EEC, if a Member State insists on maintaining its draft legislation, claiming it is justified under Article 36 of the Treaty, it may proceed to the adoption of the national text once the relevant standstill period has expired. In this case, the Commission must decide whether or not to refer the matter to the Court of Justice for a definitive ruling on whether the national measure is compatible with Community law. Under the specific procedures applicable to foodstuffs, the Commission has the possibility, subject to a Committee procedure, to require a Member State to amend or discontinue legislation which is considered unnecessary or disproportionate.

The Commission considers that in the interests of administrative efficiency, it is important to maintain the principle of one entry point for all notifications. On the other hand, during the later stages of the procedure, the extension of the powers which are provided by the labelling, contaminants and hygiene rules to cover the entire foodstuffs sector may provide a means for resolving the problem of reconciling the principles of subsidiarity and simplification with the operation of the internal market. In particular, it would enable the Commission, working closely with the Member States, to develop clear principles for the treatment of new national legislative initiatives, for defining the conditions under which they would be regarded as creating difficulties for the internal market, and the circumstances under which national initiatives would give rise to a need for new Community legislation.

On the other hand, it is clear that the development of such procedures must not be allowed to interfere with the fulfilment of the Commission's obligation to ensure the proper application of Articles 30-36 of the Treaty by Member States. The Commission would invite comments on this issue.

8. Need for further Community legislation to complete the internal market

In some non-harmonized areas, the Member States have frequently emphasised the difficulty of using mutual recognition clauses to resolve problems of free circulation. In areas where the protection of public health is involved, Member States may consider that their proposed or existing national legislation is justified for the protection of public health under Article 36, and therefore be unwilling to apply mutual recognition. In such cases, the need for further Community legislation must be considered in the light of the public health interests concerned, and in accordance with the principles described above.

Following an analysis of the complaints received in recent years relating to the free movement of foodstuffs, the Commission has identified three areas where the principle of mutual recognition cannot by itself solve the adverse effects on the internal market. The Commission therefore intends to initiate technical consultations as soon as possible on the need for, and possible scope of, Community legislation in respect of processing aids, the addition of vitamins and minerals to foodstuffs and dietary supplements.

PART III

REVIEW OF EXISTING COMMUNITY LEGISLATION

1. General considerations

The objective of this Part is to review, in the light of the general considerations described in the previous part, various measures which might be taken to rationalise or simplify existing Community legislation. It begins with a consideration of certain aspects of the Community's working procedures, such as the choice of legal instrument and the possibility to update the legislation in the light of technical and scientific progress. It also considers the scope for improving the coherence of the legislation through the introduction of common terms and definitions. It concludes with a review of the three main areas of Community food law (hygiene, quality and labelling) which have given rise to criticism that certain provisions are unnecessarily detailed or unnecessarily restrictive, or which give rise to difficulties arising from the co-existence of legislative texts of a horizontal and a vertical nature, including possible problems of coherence between those texts. However, the Commission would also invite comments on any areas which are not specifically mentioned here.

2. Transparency of Community legislation

Adequate consultation of the socio-economic interests affected by Community legislation before and during the decision-making process is the foundation of transparency. In order to be effective, consultation should not be limited to the technical aspects of a proposal, but should also enable the social partners to provide all relevant information and comment regarding the legislative approach envisaged and the costs and benefits of the proposed measure.

The Advisory Committee on Foodstuffs was established in 1975 by the Commission in order to provide a framework for the representation of the socio-economic groups primarily concerned by the foodstuffs sector, agriculture, commerce, consumers, industry and workers. It may give its opinion on any question relating to the harmonisation of legislation in the foodstuffs sector. Analogous Committees have also been established in the veterinary sector, and in the various agricultural product sectors. Meetings of these Committees provide a valuable opportunity to reconcile the various positions of the different parties on draft legislation. However, if they are to be effective it is necessary that documents are circulated in good time before each meeting and that the participants are able to consult fully with the various interests which they represent.

The services of the Commission are currently taking a number of steps to improve the consultation of the socio-economic partners during the preparation of Community legislation, including publication of notices of intention to legislate in the Official Journal, increased use of Green Papers and other consultation documents and increased contacts with interested parties. Nevertheless, difficulties still arise when the other institutions propose major changes to Commission proposals, the effects of which are often difficult or impossible to evaluate within the limited time available.

3. Use of the regulation as an alternative to directives

In certain cases, the Community has undertaken the approximation of national legislation in two stages. In the first stage, a framework text sets out the general criteria and principles applicable to the matter. In the second stage, a series of specific provisions are adopted to ensure the full and uniform implementation of these principles throughout the Community. These implementing provisions are sometimes extremely detailed, and leave little or no margin of discretion to Member States in their implementation. Examples include the specific Community provisions relating to additives, materials in contact with foodstuffs and extraction solvents.

In other cases, although contained in a single text, the provisions of Directives are also extremely detailed and leave little margin of discretion to Member States.

In such circumstances, the use of the regulation as an alternative to the directive may present several advantages:

- the use of the regulation facilitates the uniform application of the legislation throughout the internal market;
- the use of the regulation increases the transparency of Community law;
- since national implementing legislation is not necessary, the use of the regulation facilitates the rapid updating of Community legislation to take account of technical and scientific developments.

For these reasons it is suggested that consideration be given to greater use of Regulations in appropriate cases, both in primary and in secondary Community legislation. However, legislation which is limited in scope to the harmonisation of general principles and criteria, such as legislation on the official control of foodstuffs, would continue to be adopted by means of a directive.

4. Updating legislation to take account of technical and scientific progress

The ability to amend legislation rapidly to take account of technical and scientific progress is of fundamental importance. From the point of view of innovation, and the competitiveness of European industry, it is important that innovatory products can gain rapid access to a continental-scale market. From the public health point of view, also, it is important to be able to adapt the legislation quickly to take account of new risk factors which may emerge.

However, experience suggests that the Community does not possess the instruments which are necessary to respond to the quickening pace of innovation and the ever-increasing range of scientific knowledge.

One reason for this is the unwillingness of the Council and Parliament to delegate to the Commission the necessary powers for the technical implementation of Community legislation. Although the Council and Parliament have delegated significant powers to the Commission in fields such as contaminants, general food hygiene, materials in contact with foodstuffs, foodstuffs for particular nutritional purposes and food labelling, in other areas, such as food additives, extraction solvents and veterinary legislation, there has been much less delegation of competence to the Commission.

For example, in the field of food additives, any amendment to add or withdraw an additive from the positive list, or to enlarge or restrict the conditions of use of an additive, must be adopted using the co-decision procedure. Once allowance is made for the time necessary for an evaluation of the public health aspects by the Scientific Committee for Food, the preparation of a Commission proposal, and the completion of two, possibly three readings by the Council and Parliament under the co-decision procedure, an average of about 5 years is necessary to complete the procedure at Community level. This increases to 6-7 years if allowance is also made for the time necessary for the adoption of national implementation measures. In contrast, in most if not all Member States a similar decision would be taken rapidly by a ministerial decision, on advice from the competent national scientific advisory committee, and without the need for primary legislation.

Even if powers are delegated to the Commission, they are often subject to procedures which are inappropriately burdensome. For example, in a declaration on the powers of implementation of the Commission annexed to the Single European Act, the Intergovernmental Conference requested "the Council, to give the Advisory Committee procedure in particular a predominant place in the interests of speed and efficiency in the decision-making process, for the exercise of the powers of implementation conferred on the Commission within the field of Article 100a". However, in the foodstuffs sector, the Council has systematically rejected Commission proposals for a type I Consultative Committee, in favour of a type III Regulatory Committee, which requires a favourable opinion from a qualified

majority of Member States before the Commission can take a decision. In the fields of veterinary hygiene, the Council systematically has recourse to a type IIIb procedure which enables a simple majority of Member States to block any action at Community level.

The Commission considers that the adaptation of Community legislation to innovation and technical progress in the foodstuffs sector constitutes a serious problem which requires careful consideration. Comments received from interested parties on this matter will be considered in the light of the outcome of the institutional and intergovernmental discussions in progress.

5. Rationalisation of definitions used in Community foodstuffs legislation

Existing Community foodstuffs legislation already contains a series of definitions, including definitions of food additives, food flavourings, food processing aids, contaminants, pesticide residues, residues of veterinary medicines, materials and articles intended to come into contact with foodstuffs, labelling, nutrition labelling, nutrition claims, official control of foodstuffs and hygiene of foodstuffs.

Community veterinary legislation also includes definitions of meat, red meat, poultry meat, rabbit meat, farmed game, wild game, fishery products, bivalve molluscs, milk, milk products, egg products, eggs, snails, frogs legs, other products of animal origin and processed products.

In the past, doubts have sometimes arisen as to whether these definitions, apply only to those specific pieces of legislation in which they are contained or whether they apply more generally. To remove any further doubt, the Commission proposes to stipulate that these definitions are generally applicable to all Community legislation on foodstuffs.

5.1 Definition of "foodstuffs"

Although the legislation of most Member States contains a definition of "foodstuffs", the Community does not as yet have its own definition. The European Parliament has officially asked the Commission to make a proposal to this effect, because a Community definition would ensure that all Community legislation on foodstuffs will actually apply to the same products and substances in all Member States.

The following definition, based on that contained in the Codex Alimentarius, is suggested for consideration:

"Foodstuff" means any substance or product, whether processed, partially processed or unprocessed, intended to be ingested by humans, with the exception of tobacco as defined by Directive 89/662/EEC, medicinal products as defined by Directive 65/65/EEC, and narcotic or psychotropic substances controlled by Member States pursuant to the relevant international conventions.

This definition is deliberately wide in scope and is intended to cover all products intended for direct human consumption, including drinks and chewing gum, and all substances used in the manufacture, preparation and processing of foods, including raw materials, ingredients, contaminants and residues in the broadest sense.

The concept of ingestion is intended to cover all products which pass through the gastrointestinal tract, including products taken by mouth or nose or administered by gastric intubation. On the other hand, the definition would not cover products administered parenterally directly into the blood stream.

A further question concerns the application of the definition to primary production which may be intended either for human consumption or for industrial use (e.g. potatoes which may either be consumed as food or used for the production of industrial starch, or chemicals which may be used as food additives or for other industrial purposes.) Their inclusion within the scope of the definition would mean that producers would have to fulfil all the relevant obligations arising under Community food legislation, which may be inappropriately restrictive. However, it is obviously necessary to ensure that all substances used in food meet the requirements of Community legislation. The Commission would invite comments on this question.

5.2 Definition of "placing on the market"

The concept of "placing on the market" is used several times in Community food legislation, without being defined. A definition of marketing is included in the veterinary hygiene directives, but this is not entirely suitable for the purposes of foodstuffs legislation because it excludes retail sale. Other definitions of placing on the market are included in the new approach directives and Directive 90/220/EEC on the deliberate release of genetically modified organisms into the environment, but these also are not entirely appropriate to the foodstuffs sector.

One possible definition would be:

"placing on the market" means any operation the purpose of which is to supply foodstuffs to a third party, including supply for sale or any other form of transfer against payment or free of charge to a third party and storage with a view to supply to a third party, with the exception of supply for the purposes of scientific research conducted under the supervision of the Member States."

To ensure full compliance with Community regulations on health protection, the proposed definition covers not only commercial transactions but also charitable

operations and the provision of free samples. The definition would also apply to all types of supply of foodstuffs, including supply by restaurants, canteens, hospitals and the armed forces. However term "third party" has been used deliberately in order to exclude storage or the transfer of foodstuffs to family or friends within the family home.

6. Food hygiene

The field of food hygiene would appear to raise some of the most difficult questions for the simplification and rationalisation of Community food legislation.

For foodstuffs of animal origin, a series of 11 vertical directives establish specific conditions of hygiene for the categories of foodstuffs concerned: fresh meat, poultry meat; meat products, minced meat and meat preparations; rabbit; farmed and wild game; fish; shellfish; eggs and egg products; milk and milk products; and other products such as frogs legs, snails and honey. Further legislation covers the importation and control of foodstuffs from third countries. These directives set out specific regulatory requirements for those aspects of the products concerned which are considered particularly sensitive, while using a HACCP based approach for other aspects.

For foodstuffs which are not covered by these specific provisions, the general Directive on the hygiene of foodstuffs applies (Directive 93/43/EEC). This Directive applies a more generalized approach to hazard management, based on the application of HACCP principles and the development of voluntary codes of good hygiene practice.

The co-existence of these different texts has resulted in numerous criticisms of inconsistency and incoherence. Thus Article 1 (2) of the general hygiene directive requires the Commission to establish the relationship between the specific hygiene rules and those of the general directive and, if necessary, make proposals.

As a first step in this process, the Commission has launched a large scale consultation exercise on the inter-relationship between the vertical veterinary hygiene rules which apply to foodstuffs of animal origin. To this end, the services of the Commission have prepared a Guide to certain rules governing the production, marketing and importation of products of animal origin intended for human consumption. The guide envisages the consolidation of the provisions of 14 separate directives relating to animal and public health into a single text which would also covers the conditions of imports from third countries. Certain common principles, such as HACCP would be extended to cover all the Directives, and certain unnecessarily detailed provisions and contradictions in the texts would be eliminated.

At the same time the Commission has launched a consultation exercise on the possibilities for simplification of the rules. In particular, the Commission specifically invited comments from interested parties on the following points;

- the role of voluntary instruments such as standards or codes of practice in veterinary hygiene;
- temperature control requirements;
- the need and appropriateness of derogations for small and medium-sized enterprises;
- the international dimension of veterinary hygiene rules;
- the role of self-control by manufacturers and the role of the public authorities;
- authorization procedures and procedures for the approval of establishments;
- conformity marking .

Further questions have also been raised concerning the inclusion in hygiene legislation of quality or labelling provisions which are not directly related to food hygiene.

Once the relationship between the specific vertical hygiene directives has been clarified, consideration must be given to the relationship between them and the general directive on food hygiene. In this context, it would appear appropriate to give priority to ensuring that there is a coherent and consistent body of legislation relating to food hygiene. This can best be achieved by the application of HACCP principles and limiting detailed prescriptive provisions to cases where they are considered essential.

Nevertheless, it should be noted that there is scope for some flexibility in the manner in which HACCP principles are conceived and applied. According to the Codex Alimentarius Guidelines for the Application of the Hazard Analysis Critical Control Point System, HACCP is a system which identifies specific hazards and preventative measures for their control. The system consists of seven principles.

1. Identify the potential hazards associated with food production at all stages, from growth, processing, manufacture and distribution, until the point of consumption. Assess the likelihood of occurrence of the hazards and identify preventative measures for their control.
2. Determine the points/procedures/operational steps that can be controlled to eliminate the hazards or minimize their likelihood of occurrence (Critical control point (CCP)).
3. Establish critical limits which must be met to ensure the CCP is under control.
4. Establish a system to monitor control of the CCP by scheduled testing or observations.

5. Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
6. Establish procedures for verification which include supplementary tests and procedures to confirm that the HACCP system is working effectively.
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

In the general hygiene directive, the first five of these principles are implemented into Community legislation. However, it was not considered necessary to lay down formal requirements regarding verification and documentation. Each food business is left with the flexibility to decide what requirements are necessary, subject to the supervision of the competent authority. On the other hand, because of the nature of the foodstuffs concerned, the basic principles for own checks set out in the veterinary hygiene directives include detailed rules on keeping a written record for presentation to the competent authority. This example illustrates the need to maintain a degree of flexibility in the design and implementation of food hygiene regulations to ensure the maintenance of a high level of protection, whilst keeping the regulatory burden for business to a minimum. The search for consistency and coherence should not result in the imposition of a uniform system where it is inappropriate.

It is generally recognised that in order to be effective, any system of food hygiene legislation must cover the entire food chain, from primary production until the point of consumption. The general food hygiene directive covers all stages of food production and distribution after primary agricultural production. However, there is no general Community legislation covering the hygiene of products of non-animal origin at the primary agricultural production stage. The Commission would invite comments on whether the existing rules to ensure the safety and hygiene of primary products of non-animal origin, such as the rules on pesticide residues, and contaminants are sufficient.

In the case of foodstuffs of animal origin, the primary production stage is covered by the veterinary hygiene rules. These directives cover all stages from primary production to distribution. However, retail sale is, in general, excluded from the scope of the veterinary hygiene rules, and the general hygiene directive therefore applies. The Commission would invite comments on whether the retail supply of products of animal origin should continue to be covered by the general directive, or whether it should be brought within the scope of the veterinary hygiene directives.

7. Food quality

In its 1985 communication on the completion of the Internal Market in the foodstuffs sector, the Commission indicated that it would no longer bring forward proposals for vertical legislation imposing qualitative specifications for particular categories of product. Instead, the Commission indicated that it would rely on the use of labelling, together with the application of voluntary instruments, to provide the basis for mutual recognition of national rules in accordance with the principles laid down by the Court of Justice.

In accordance with this approach, the question of quality standards and certification within the internal market (relating to products or companies) is left to the voluntary initiative of operators. Obviously, however, these instruments should be used in compliance with the rules on misleading information and should not create barriers to trade. Moreover, to ensure that these instruments are reliable, operators should be encouraged to adhere to the standards recognized at international and European level, in particular the ISO 9000 and EN 29 000 series. Subsequently, the Commission has taken a series of general initiatives designed to encourage the development of a European quality policy.

A rather different approach has been followed in the agricultural sector. It is not possible, given the specific objectives of the CAP, to envisage removing all possibility of laying down qualitative specifications concerning product composition. Within the framework of the common organisations of the market, quality specifications are necessary for example where financial support is provided under the Community budget.

Where quality promotion and certification policy is concerned, specific measures have been introduced, particularly with regard to rural development. These instruments relate to organic farming products, certificates of specific character relating to traditional products and protected geographical indications.

Generally, the Commission does not consider that the differences of approach followed under internal market and agricultural legislation give rise to inconsistencies or distortions of competition. Nevertheless, in the context of the simplification of the veterinary hygiene rules, it may be worth reviewing the quality provisions contained in the legislation. In principle it would appear that where they are necessary, quality provisions should have their place in specific quality legislation, and be removed from veterinary legislation, unless a health link is established. The Commission would welcome comments on this point.

8. Food labelling

Council Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs was explicitly designed to constitute a single legislative framework for the compulsory rules on the labelling of foodstuffs. The Directive has been now been amended many times. The most recent amendments, adopted by the European Parliament and the Council in 1996, introduce the principle of quantitative declaration of ingredients (QUID) and makes changes to the rules on the labelling of the sales name of the product to take account of recent case law of the Court of Justice. The Commission intends to present a proposal for the formal consolidation of the Directive as soon as possible.

Directive 79/112/EEC is based upon the principle of functional labelling. The objective of the Directive is to ensure that consumers are provided with the essential information as regards the composition of the product, its manufacturer, and its methods of storage and preparation which are necessary to ensure consumer safety and fair competition. Producers and manufacturers are free to provide whatever additional information they wish, provided that this is accurate and does not mislead the consumer.

In addition to the rules laid down in Directive 79/112/EEC, a number of vertical texts contain specific mandatory labelling provisions, such as the Community rules on wine, fresh fruit and vegetables, eggs, and the specific directives on foodstuffs for particular nutritional purposes. The Commission would invite comment on whether it would be desirable to consolidate these separate provisions into a single labelling text, or whether in the interests of flexibility, it is preferable that these requirements should continue to be set out in specific texts.

Recently, some concern has been expressed that certain aspects of the labelling rules have become unnecessarily detailed. In particular, there have been occasions, both at Community and at national level, where legislation has required information which is already included on the label, for example in the list of ingredients, to be repeated more prominently elsewhere on the label. In the Sauce Béarnaise case, however, the Court recognises that the inclusion of information in the list of ingredients is in many instances sufficient information for the consumer.

However, concern has also been expressed that other aspects of the labelling rules may not always provide sufficient information for the consumer. For example, the Commission has recently been asked to consider amending the labelling rules to provide for more information about the possible presence of known allergens in foodstuffs, even in cases where the allergens are present at very low levels, including trace levels. Likewise, criticism has also been expressed of the current rules regarding the labelling of compound ingredients of foodstuffs. Under current legislation, it is not necessary to list the ingredients of a compound ingredient separately, if the compound ingredient makes up less than 25% of the finished product. Thus, for example, in the case of a tart which contains less than 25% of pastry, it is sufficient to include the mention "pastry" on the list of ingredients, and it is not necessary to list all the ingredients of the pastry separately. It has been suggested that this upper limit of 25% is too high, and should be reduced to, perhaps, 5%.

In addition to the core mandatory labelling requirements, certain Community legislation has been adopted to govern the provision of additional information by producers or manufacturers on a voluntary basis. For example, within the Community nutritional labelling is not obligatory. However, if manufacturers wish to make nutritional claims or to provide nutritional information they must do so in accordance with a standardised format. Similarly, Council Regulation (EEC) 2092/91 sets out rules governing the use of the organic label on vegetables and vegetable products, and the Commission has recently proposed rules for the use of the organic label on products of animal origin.

It is important that Community labelling legislation should strike the right balance between mandatory core labelling requirements and the use of voluntary instruments. The Commission would invite comments on whether the legislation does strike the correct balance.

As noted above, producers or manufacturers are currently free to make whatever statements or claims they like on the labelling of foodstuffs, provided those claims are correct and not misleading. The responsibility for verifying such claims lies with Member States. In recent years the range of claims being made on food labels and in the advertising of foodstuffs has increased dramatically. Health claims present particular difficulties because the alleged beneficial effects of a particular foodstuff may be the subject of scientific discussion, making it difficult for the competent

authorities to verify the claim made. The Commission is aware of certain cases where the Member States have adopted different positions on the acceptability of certain claims, leading to problems for the free movement of the foodstuffs concerned. At one stage, the Commission had envisaged bringing forward specific legislation to cover food claims, by defining the circumstances under which certain claims may be made. However, this work encountered a number of technical difficulties, and has been shelved, at least for the time-being. Instead consideration is being given to reinforcing the provisions of the misleading advertising directive. The Commission would specifically invite comments on the approach which should be followed at Community level to the regulation of claims, including not only compositional claims such as 'light' and 'low-fat', but also health and similar types of claims which are increasingly being made on so-called 'functional foods'.

In addition, during 1997 the Commission intends to undertake a review of the nutritional labelling directive, in particular, in order to up-date certain provisions of the Directive to take account of new scientific information. In this context, the Commission would specifically invite comments on whether nutritional labelling should be made compulsory and whether the nutritional information required is sufficient to guarantee proper information for the consumer. This will provide the occasion for the Commission to consider other comments relating to that Directive. At the international level, the relevant Codex Alimentarius standards are also under review.

Finally, the regulation on novel foods, which include inter alia foods containing GMOs or produced from GMOs has been adopted recently. This regulation contains labelling requirements on the presence of certain materials such as GMOs. The Commission attaches great importance to the correct implementation of these labelling rules.

PART IV

MAINTENANCE OF A HIGH LEVEL OF PROTECTION

1. General considerations

Article 100a (3) of the Treaty requires the Commission, in its internal market proposals concerning health, safety, environmental and consumer protection to take as a base a high level of protection. Article 129 of the Treaty provides that health protection requirements shall form a constituent part of the Community's other policies. Moreover, Article 129a requires the Community to contribute to the attainment of a high level of consumer protection through the internal market measures adopted pursuant to Article 100a and by specific action which supplements and supports the policies of the Member States to protect the health, safety and economic interests of consumers and to provide adequate information to consumers.

In his speech to the European Parliament on 18 February 1997, the President of the Commission made a plea for the gradual establishment of a proper food policy giving pride of place to consumer protection and consumer health. In this spirit, the Union must provide itself with the necessary means of action, identifying two imperatives:

- the closer involvement of the Parliament in the decision-making process; to this end the Commission will make more use of Article 100a for proposals in the veterinary and phytosanitary field having as their principal objective the health of the consumer, whilst trying to persuade the Intergovernmental Conference to accept that all legislative decisions should be taken by co-decision;
- the need to give the Community true powers in the field of health.; thus the Commission has presented a concrete proposal to the IGC for a substantially revised Article 129, involving three major improvements:
 - an improved procedure for coordinating the policies pursued by Member States
 - the possibility, where necessary for harmonization at Community level in the field of human health;
 - co-decision on health matters.

So far as food safety is concerned, there can be no scope for compromise. The Treaty requires the Commission to take as a base a high level of protection in its proposals and to ensure that public health requirements are fully integrated into its policies. This level of protection must be kept under constant review, and where necessary it must be adjusted to take account of new information, or of a re-evaluation of existing information. The aim of this Part is to review how these objectives are integrated into the Community's policies for the management of the internal market and the common agricultural policy, and to invite suggestions for possible improvements.

2. The role of scientific advice in the preparation of food safety legislation.

In principle, the Commission considers that the prior consultation of independent scientific experts is the best means of guaranteeing scientific objectivity and consistency of hazard analysis during the preparation of rules relating to public health. To be effective, the process of risk assessment must cover the entire food chain. For example, in assessing the safety of a chemical found in food, all sources of human exposure to the chemical must be considered, including its presence as a contaminant in food or drinking water, and human exposure resulting from its use as a food additive, a pesticide or a veterinary medicine. A number of scientific committees have responsibilities which relate to the foodstuffs sector, including the Scientific Committee for Food (SCF), the Scientific Veterinary Committee, the Scientific Committee for Pesticides, the Scientific Committee for Animal Nutrition, and the Scientific Committee for Toxicity and Eco-toxicity. An integrated approach to risk assessment may require consultation of several of these Committees. Each Committee's risk assessment will include particular features not covered by the other committees, for example good veterinary or agricultural practices. The involvement of several committees is therefore necessary, but coordination is essential in order to avoid repeated evaluation of the same risk or unnecessary duplication of effort.

In addition, it should be noted that the Committee for Veterinary Medicinal Products, which is attached to the European Medicines Evaluation Agency in London, is responsible for the evaluation of the safety of residues of veterinary medicines in foodstuffs of animal origin.

A number of existing Community legislative texts provide for the compulsory consultation of the SCF before the adoption of legislation which may have an effect on public health, for example in the fields of additives, contaminants, food hygiene, materials in contact and novel foods.

If the scientific assessment process is to be credible and command public confidence, sufficient guarantees must be provided of the objectivity and independence of the scientific advice received. With this objective in mind, the Commission has developed a new approach on the scientific advice which is laid down in the Communication on Consumer Health and Food safety recently presented to the Council and European Parliament. This new approach will reinforce the three main principles of scientific excellence, independence and transparency of the Scientific Committees by:

- ensuring that the scientific qualification and competence are the criteria for selecting members of the scientific Committees and that the selection process is transparent vis à vis the European Parliament, Members States, economic operators and consumers.
- ensuring that members of the Scientific Committees are free from interests which may be in conflict with the requirement to give independent advice. In this respect requirements and procedures for declaration of interests will be extended.
- operating an overall policy of transparency in the whole process of scientific advice. In particular European Institutions and national authorities as well as well all interested parties, including consumers, both individuals and associations, will have access to information on the working procedures of the Committees and to their advice.

Furthermore the regrouping of all Scientific Committees under the same Commission Directorate General will ensure a greater synergy and a better co-ordination of their work.

The Commission will also continue its efforts to:

- consolidate the principle of obtaining Community scientific advice before drafting Community foodstuffs provisions that could affect public health (although certain exceptions will be necessary, in particular in the case of urgent safeguard measures).
- apply a single procedure to assess all relevant risks (the ‘one door, one key’ principle)

On the other hand, it is important to note the limits of the role of the scientific committees. At both the Community level and the global level, a clear distinction is drawn between the concepts of risk assessment and risk management. According to definitions which are under consideration by Codex Alimentarius, risk assessment is a scientifically based process consisting of the identification and characterization of hazards, the assessment of exposure and the characterization of the risk. Risk management, on the other hand, is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. While the task of risk assessment may be delegated to scientific advisory bodies, the task of risk management remains the responsibility of the regulatory authorities, and at Community level of Council, Commission and the European Parliament.

Particular difficulties may arise in those cases where, because of scientific uncertainty or an absence of data, the Scientific Committees are unable to undertake a comprehensive risk assessment. In such cases, in accordance with the obligation to provide a high level of protection, it would appear necessary to take a conservative approach to risk management through the application of the precautionary principle.

Likewise, the Community's framework research programme should make particular efforts in respect of research and applications intended to improve knowledge and techniques making it possible to improve the assessment of epidemiological and food risks, and of the means of reducing such risks.

A further problem concerns the collection of the data which is necessary for the evaluation of risk. In the case of new substances, the applicant is clearly responsible for collecting and submitting the data necessary for review. In order to assist applicants, guidelines and similar documents are used to describe the information which will be necessary for evaluation. However, in the case of contaminants, or new risk factors arising for existing substances there may be difficulties in obtaining the necessary data. In order to meet this problem, the Community has established procedures for scientific cooperation between Member States and the Commission for the examination of scientific questions relating to food.

3. Scientific cooperation relating to food

The principles of the scientific cooperation process were formalised in Directive 93/5/EEC, on assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food, adopted on 25 February 1993. The Directive sets out the principle that Member States shall take the necessary measures to enable their competent authorities and bodies to co-operate with the Commission and lend it the assistance it needs in the scientific examination of questions of public interest relating to food, particularly in the field of public health, through disciplines such as those associated with medicine, nutrition, toxicology, biology, hygiene, food technology, biotechnology, novel foods and processes, risk assessment techniques, physics and chemistry.

In order to enable the cooperation process to operate effectively, each Member State is required to designate a single authority which is responsible for cooperation with the Commission and distribution of work to the appropriate institute. The principal tasks to be carried out in the scientific cooperation process include matters relating to;

- the drawing up of protocols for the assessment of risks relating to food components and elaborating methods of nutritional evaluation;
- assessing the nutritional adequacy of the diet;
- examining test data submitted to the Community and the production of a monograph for the SCF;
- carrying out food intake surveys;
- conducting investigations relating to the components of diets in various Member States or of biological or chemical food contaminants;
- helping the Commission honour the Community's international commitments by providing expertise on food safety questions.

On the basis of suggestions received from Member States, and of its own priorities, the Commission is required to prepare and update an inventory of tasks for scientific cooperation. The inventory includes a summary description of the task, the name of the co-ordinating country, the name of the other countries participating in the task and the time limit for its completion. The current inventory includes a series of tasks relating to the collection of information about chemical and microbiological contaminants of foods, flavours, dietary intake and exposure assessments and examination of scientific aspects of nutrition.

The management of each task is the responsibility of the coordinating institute. The Commission undertakes the overall management of the scientific co-operation process. The costs of the tasks are primarily met by the Member states concerned. The Commission provides limited additional financial support to cover the extra costs of coordinating and convening meetings with experts from Member States. Although it is still too soon to make a definitive judgement, the preliminary results suggest that scientific cooperation is a useful and very cost effective method of pooling information and resources on certain issues.

On the other hand it is important to recognise the complementary nature of the role of the scientific cooperation process and the role of the SCF. In the area of risk assessment, the role of scientific cooperation is to collect and collate the best available information available to Member States on a particular problem. This information is then transmitted to the SCF in order to provide a firm basis for the evaluation of risk by the SCF, which retains its role as the primary source of advice to the Commission on scientific questions relating to food. As a centre of independent scientific expertise, the Joint Research Centre can also contribute towards this policy.

4. Management of serious and urgent public health risks

Safeguard clauses are included in all Community legislation for the protection of public health. They allow Member States to apply restrictions to the marketing of a product or substance if there is good reason to suppose that it constitutes a danger, even though it conforms to existing Community regulations. A rapid alert system was formally established in 1984 for the exchange of information about serious and immediate risks to the health and safety of consumers, and subsequently incorporated into Directive 92/59/EEC. If necessary, the Commission can convene meetings of the relevant scientific committees at very short notice to consider the risk.

Moreover, with the completion of the single market the Community received important powers, in particular under Directive 92/59/EEC on general product safety, to intervene and remove from the internal market products which present serious and immediate risks to consumers. However, in accordance with Directive 92/59/EC, the Commission can only intervene on the basis of information which is received from a Member State.

In addition, the Commission has adopted a communication on the handling of urgent situations in the context of the implementation of Community rules (COM(93) 430 final of 16 December 1993). It describes the machinery already in place in various areas and proposes topics for consideration and discussion.

In addition, in the context of the veterinary health directives and Directive 93/43/EEC on hygiene, the Commission may in certain cases adopt provisional emergency measures, which are effective immediately, subject to ratification by a committee procedure within a very short period. In its order of 12 July 1996 in the application for interim relief brought by the United Kingdom against the emergency measures against BSE imposed by the Commission, the Court of Justice recognised that in the application of these procedures, paramount importance must be accorded to the protection of public health, even at the expense of serious, and possibly irreparable, damage to commercial and social interests.

There is however an important difference between the scope of the powers of the Commission under the safeguard clauses in the veterinary directives and in the general hygiene directive. The safeguard clauses in the veterinary directives apply both to risks arising from products imported from third countries and from products in intra-Community trade. The safeguard clause contained in Article 10 of the general hygiene directive, on the other hand, is limited to risks arising from products imported from third countries. The Commission would therefore invite comments on the desirability of extending the scope of the latter safeguard clause to include products in intra-Community trade.

Where a serious risk applies to several categories of products and thus triggers several emergency procedures, there must be adequate coordination to ensure the consistency of the various measures which are taken. It is also essential to ensure that the procedures are clearly understood by all those concerned in managing serious risks, including the competent authorities of the Member States, consumers and industry.

Finally experience suggests there may be a need to improve arrangements for the management of and responsibility for communication to the public in the event of serious risks. The operation of rapid alert and safeguard procedures requires cooperation and mutual confidence between Member States and full consideration of the needs of consumers and industry. Whilst reliable information about serious health risks arising from foodstuffs must be made available to the public as quickly as possible, it is important to avoid false alerts and alarmist messages. In some cases in the past, actions have been taken affecting a whole product category, when only one particular product was involved. Whenever possible, public information and warnings should be targeted at specific products and be commensurate with the nature of the hazard.

The Commission would invite comments on measures which might be taken to improve the capacity of the Community to deal with serious and urgent risks to public health relating to foodstuffs.

5. Radiological Emergencies

In normal situations, (i.e. a non-accidental situation), protection against contamination of foodstuffs by radio-active substances is ensured by Council Directive 80/836/EURATOM, which will be repealed with effect from 13 May 2000. This Directive is replaced by Directive 96/29/EURATOM.

Following the Chernobyl accident, a number of provisions dealing with accidental situations have also been adopted. The provisions currently in force following the Chernobyl accident are set out in Council Regulation 737/90 of 22 March 1990 which supplemented and adjusted the regulations adopted hitherto. This Regulation will remain in force until the end of March 2000.

The system that will be applicable in case of future accidents is laid down by Regulation 3954/87 of 22 December 1987, which provides that in the event of an accident, the Commission may impose predetermined maximum permitted contamination levels. This emergency action may then be adjusted according to the exact nature and scope of the incident concerned.

Council Regulation 89/2219/EEC of 18 July 1989 prohibits the export of foodstuffs with a contamination level exceeding the maximum levels permissible within the Community.

On 14 December 1987, the Council adopted Decision 87/600/EURATOM on Community arrangements for the exchange of information in the event of a radiological emergency. According to this mechanism, the information exchange also covers activity levels measured in foodstuffs and drinking water.

6 Zoonoses

As defined in existing Community legislation, zoonoses are any disease and/or infection which is likely to be naturally transmitted from animals to man. The most important zoonoses which may be transmitted by food include:

- viral contaminations, eg. Norwalk virus and hepatitis, type A, in shellfish;
- bacterial infections, eg. Salmonella, Campylobacter, E. coli, B melitensis, bovine tuberculosis;
- bacterial intoxications, eg. Staphylococcal enterotoxaemia, botulism;
- protozoal parasites, eg. Cryptosporidium, Toxoplasmosis;
- cestode infections, eg. Cysticercus bovis, cysticercus cellulosae;
- nematode infections, eg. Trichinellosis.

Specific Community rules have been adopted in respect of a number of the bacterial infections, eg bovine tuberculosis, bovine, ovine and caprine brucellosis, with a view to their control and eradication in the animal population (and thereby their elimination from the human population). These programmes are based on the principle of testing live animals and the slaughter of any giving a positive reaction. In some cases, vaccination is also employed as a means of reducing infection levels in the animal population. Considerable success has been achieved in respect of bovine tuberculosis and brucellosis, although matters are less well advanced for ovine/caprine brucellosis.

All of the Community legislation concerning the hygiene of products of animal origin intended for human consumption includes provisions which will serve to control the risk of spread of zoonoses from the animal to the human population. These range from the specific, eg ante and post mortem inspection of animals in abattoirs, through to the general, eg requirements for hygienic construction and operation of food processing premises and provisions for minimum processing conditions and storage/transport temperatures.

In addition to these vertical Directives which provide directly or indirectly for the control of zoonoses, the Council has adopted Directive 92/117/EEC concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications. The requirements of the Directive are, in essence, aimed at the monitoring and control of a series of zoonoses. Member States are required to report yearly on the occurrence, trends and sources of zoonotic infections (in the human population, domestic animals, animal feedingstuffs and wildlife) recorded during the previous year. The Directive also provides for actions to monitor, control and ultimately to eradicate some invasive salmonella serotypes in poultry breeding flocks.

Experience suggests that some of the time limits for Member States to take certain measures were over-optimistic and that certain technical provisions of the Directive need to be reviewed.

The Commission therefore invites comments on possible improvements to this Directive.

Options For Control Of Zoonoses

By their very nature, zoonotic agents can be found in at least two host species. In many cases, eg Salmonella, a wide range of different hosts may be infected, with clinical disease not necessarily being evident in all affected animals. It follows that control and eradication programmes can intervene at a number of different points in the infective cycle, and that it may be necessary to use more than one approach. In addition to the general principles of good hygiene at all stages of the food chain, as dealt with elsewhere in this Paper, specific strategies include:

- **eradication** of the agent from the animal population or the environment
- **reduction** in the level of infection in the animal population to a point where it no longer poses a threat to human health, eg processing of animal feedingstuffs, vaccination programmes, treatment of infected animals and destruction of clinically infected animals
- **removal** of the agent from the food chain, eg by specific treatment during the processing of the raw material, such that any agent is destroyed

Eradication is an expensive option, not only because of the need to organise labour and resource intensive testing programmes, but also to destroy infected animals. It is dependent upon the existence of an adequately sensitive and specific live animal test, as well as support from the farming community. Furthermore, success can only be anticipated where the disease has a limited host range (with no significant wildlife involvement). This approach can be justified where significant public health, animal health or economic problems are posed by the disease, eg bovine tuberculosis, brucellosis.

Reduction involves a series of different measures aimed at different points in the live animal production cycle. It is often used as a precursor to a full eradication programme. Even where this is not the intention, a coordinated programme to reduce disease levels in the animal population can have a significant impact on the degree to which the consumer is exposed to risk of infection. Such programmes generally require a high degree of cooperation between farmers, suppliers, processors and the official services.

Removal of the agent from the food chain generally involves the treatment of the food by a specific method, irrespective of whether the agent is present. It is particularly useful where the detection of the infective agent is either too expensive or unreliable. It can include heat treatment, drying, curing, pickling, freezing etc. Although effective, this approach does not generally preclude the possibility of reinfection, eg cooked meat stored with raw meat is often implicated in food poisoning outbreaks.”

7. Introduction of a general obligation to ensure that food is safe and wholesome

Existing Community legislation imposes a series of specific obligations on food producers to ensure that foodstuffs meet the requirements laid down in the Community rules. At national level, however, certain Member States have gone a step further. In addition to transposing existing Community legislation, they have also introduced into their domestic legislation a general obligation of food safety. Thus food businesses are required to ensure that only food which is safe, wholesome and fit for human consumption is placed on the market. Any food business which markets a food which is not safe, wholesome and fit for human consumption will commit an offence under the law of the Member State concerned, and will be liable to a criminal or administrative penalty.

The objective of this section is to invite comments on whether it would be appropriate to introduce at Community level a similar general obligation on food businesses to ensure that food is safe, wholesome and fit for human consumption. It is important to emphasise that such a general obligation of safety and wholesomeness would be an obligation owed by food businesses directly to the competent authorities under the penal or administrative law of the Member State concerned. It would thus be totally separate from the question of the liability of producers to consumers for defective products, which is covered in the following section. Moreover, the introduction of such a general obligation would not entail the introduction of new prior approval or notification systems by Member States.

7.1 The current situation at Community level

Although Community food legislation sets out a series of specific obligations on food businesses, with the exception of the general Product Safety Directive, it does not currently contain a general legal obligation that only food which is safe, wholesome and fit for human consumption should be placed on the market. Individual Directives approach the question in different ways: there is an explicit requirement in some vertical hygiene Directives for certain products to be fit for human consumption; an implicit requirement for this in other vertical Directives; and a requirement in the general hygiene Directive that the "preparation, processing, manufacturing, packaging, storing, transportation, handling and offering for sale or supply of foodstuffs shall be carried out in a hygienic way".

Article 3(1) Directive 92/59/EEC on general product safety imposes on manufacturers the obligation to place only safe products on the market. However, doubts have been expressed as to whether the concept of product safety which is laid down by Directive 92/59/EEC is rather different from the requirement that foodstuffs should be safe, wholesome and fit for human consumption. For example, food may be adulterated with substances which do not of themselves present a health risk, and would not make the foodstuff unsafe within the meaning of Directive 92/59/EEC. Nevertheless, such foodstuffs would not normally be considered as fit for human consumption.

The introduction of a general obligation of food safety and wholesomeness would thus serve to reinforce the overall level of consumer protection within the Community, by encouraging all food businesses to introduce their own internal safety and supervision procedures. This obligation of safety may also help simplify overall Community food legislation, since it would avoid the need for more specific regulations in areas where the general provisions would be sufficient to guarantee product safety. However, it would also be necessary to ensure that the introduction of a new obligation of safety and wholesomeness does not result in the creation of barriers to trade within the internal market. Thus, all measures should be compatible with the principles of the internal market, and particular the Treaty rules on the free movement of goods.

7.2 Scope of the general obligation of safety and wholesomeness

In order to be effective, any new general obligation of safety and wholesomeness should in principle apply to the whole food chain from primary production to the final sale of the foodstuff to the consumer. It must also take account of the fact that interactions between producers, manufacturers and distributors are becoming increasingly complex. Thus for example, in many cases primary producers have contractual obligations to manufacturers or distributors to meet specifications which cover quality or safety. Distributors increasingly have products produced under their own brand-name and play a key role in product conception and design.

This new situation should result in greater joint responsibility throughout the food chain, rather than dispersed individual responsibilities. Each link in the food chain should take the measures necessary to ensure food safety within the context of its own specific activities, applying HACCP-type principles, and other similar instruments. Where a product is found to be not up to standard, the liability of each link in the chain should be reviewed according to whether or not it has properly

fulfilled its own specific responsibilities. For example, it would appear wrong in principle to hold a food retailer responsible for the presence of an excessive quantity of food additives in a canned product over which the retailer has no control. However, where cooked sliced cold meats are found to be microbiologically contaminated at the point of sale, further investigation will be required to determine whether the contamination arose as a result of poor hygiene during manufacture, a failure to respect the cold chain during distribution or poor handling and storage at the point of sale.

This raises the question of the so-called "due diligence" defence. When a food business markets a foodstuff which does not conform to the safety requirements prescribed by Community or national law, that business may be liable to criminal or administrative penalties under the law of the Member State concerned. However, in some Member States the business will not be liable if it can demonstrate that it has taken all the steps which could reasonably be expected of it to ensure that the food meets the legal requirements ("due diligence"). Thus, compliance with the due diligence obligation constitutes an absolute means of defence in any subsequent judicial or administrative procedure. In other Member States however, the operator will still be liable, although the fact that the company has exercised due diligence will be taken into account in order to reduce the severity of the penalties imposed.

During preliminary consultations, the Commission received a number of requests that the introduction of a general obligation of food safety into Community legislation should be accompanied by the introduction of a "due diligence" defence.

The Commission is aware that determining the facts and circumstances which may render an operator liable to criminal or administrative penalties is a complex matter which depends very much on the structure of the different national legal systems.

However, it also considers that taking account of the obligation to take all reasonable care to ensure food safety in the sanctions system is an important means of recognizing the responsibility of companies to ensure that their products conform to the regulations. Accordingly, failure to fulfil the obligation should result in tougher penalties where products do not conform to the regulations, while fulfilment of the obligation should result either in application of the defence of due diligence or at least in less severe penalties.

The question of the "due diligence" defence should also be considered in connection with the possibility of extending the scope of the obligation of safety to primary production.

The Commission would welcome detailed comments on these matters.

8. Application of the principle of product liability in the foodstuffs sector

Council Directive 85/374/EEC on liability for defective products establishes the principle that a producer will be liable for a defect in his product. The Directive applies to foodstuffs as well as to other products. However, the definition of a product in Article 2 of the Directive excludes primary agricultural products and game. For the purposes of the directive, primary agricultural products means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. In principle, therefore, unprocessed agricultural products and game are excluded from the scope of the product liability directive, although Member States may choose to provide that these products are covered. So far, only Greece, Luxembourg, Finland and Sweden have availed themselves of this option.

In recent years, increasing demands have been heard, in particular from consumer organisations, for the inclusion of unprocessed primary agricultural production within the scope of the product liability directive. These demands have increased recently, as a result of the BSE scare.

In principle, the inclusion of unprocessed primary agricultural production within the scope of the product liability directive would constitute an important step in the protection of consumers under Community legislation. Nevertheless, it should not be thought that such an extension would constitute a solution to all the problems which may arise. Article 4 of the Directive provides that the injured person shall be required to prove the damage, the defect and the causal relationship between the defect and the damage. Experience has shown that it is very difficult to trace the precise source of outbreaks of food-borne disease. The longer the period between exposure to the contaminated foodstuff and the onset of symptoms, the greater these difficulties become. In the specific case of BSE, even if a link is proved with the new variant of *Creutzfeldt Jakob* Disease, the very long incubation period involved means that it will probably be impossible to prove that a particular product is responsible for the damage caused.

A further question concerns the difficulty of tracing the origin of the foodstuff from the point of sale to the consumer back to the point of production. The Community has recently adopted measures to ensure the traceability of products of bovine origin back to the point of production and it has been suggested that these rules might be extended to other products of animal origin. Consideration is also needed of whether further rules on traceability should be laid down in legally binding instruments, or whether these would better be covered by voluntary instruments. A number of major food retailers and distributors are known to be developing systems to improve the traceability of foodstuffs. In this context it should be noted that Article 1(3) of the product liability directive provides that "where the producer of the product cannot be identified, each supplier shall be treated as its producer..."

In these circumstances, it would appear that the extension of the scope of the product liability directive to cover unprocessed primary agricultural production should not be considered as an alternative to the development of appropriate product safety rules and effective official control systems but as an additional measure in its own right. The Commission would invite comments on this question.

9 Meeting the new aspirations of consumers

The principal concern of Community food law until now has been to ensure the free circulation of foodstuffs in the Community, largely through harmonized food legislation. In contrast, Community food law has not dealt to any great extent either with nutritional issues or with finding ways of meeting public concerns. This Green Paper, coming as it does at a time when public concerns about food and health are high, provides an opportunity to launch a debate about new approaches to these issues, both within general food policy and specific legislation.

Food law constitutes one of the main components of a policy on food and nutrition. It could play a role in increasing the awareness of Community citizens about their food purchases, diets and meal preparation, and could help encourage them to make healthy choices which would lead to improved health and the reduction of morbidity and premature mortality. In this process, a collaborative effort of the health sector, consumers, governments, industry and the Community itself would benefit all parties.

The Commission invites comments on what approach should be followed at Community level with regard to nutrition and health, which initiatives should be pursued and where this would require adaptations of Community food law.

In addition, consumers have become increasingly concerned about the methods by which their foods are produced. Increasing numbers of consumers wish to ensure that the foods which they eat are produced in a manner which is environmentally friendly and which meet the welfare needs of farm animals. Recent events, and in particular fears about the possible transmission of BSE to humans, have highlighted concerns that certain production methods may also have an impact on food safety.

Other discussions have focussed on the ethical and environmental impact of new scientific developments such as GMOs in foodstuffs and the application of cloning techniques.

Community legislation already contains many provisions which are intended to meet these concerns. Strict rules govern the use of pesticides and veterinary medicines in food production, in order to ensure that such use is kept to the minimum which is compatible with good agricultural or veterinary practice. Limits are being established to ensure that residues of pesticides and veterinary medicines, and contaminants of agricultural or environmental origin do not present a risk to the health of consumers. The Community has also adopted rules relating to the welfare of farm animals. The details of such rules fall outside the scope of this Green Paper. Nevertheless, they give rise to two important issues of direct relevance to food law: the safety issue and the question of consumer information.

So far as food safety is concerned, there is no scope for compromise. The previous sections of this part have described how risk assessment and risk management techniques are integrated into the Community's policies for the foodstuffs sector. The maintenance of a high level of protection implies that it would not, however, be appropriate to authorize unsafe foods or food production methods subject to a labelling requirement. If they are not safe, they cannot be permitted.

So far as labelling is concerned, at present, Directive 79/112/EEC only requires information on processes or treatments to be provided on food labels in cases where the omission of such information is likely to create confusion in the mind of the consumer, for example where products are powdered, freeze dried, deep-frozen, concentrated or smoked. In addition irradiated foodstuffs must always be labelled. However, Community legislation does not require the labelling of production methods or processes which do not have an impact on the food characteristics of the finished product. There have recently been extensive discussions between the Parliament, Council and Commission on the extent to which a systematic labelling requirement should be imposed on foodstuffs produced by modern biotechnology during the examination of the Commission's proposal for a Regulation on Novel Foods and Novel Food Ingredients.

In general, experience suggests that where there is a genuine consumer demand for more information about certain aspects of a foodstuff, this demand will frequently be met by producers and distributors on a voluntary basis, for example through labelling, telephone information lines or the Internet. It may be necessary to consider the need for new Community measures to encourage the development of such voluntary initiatives. Moreover, in certain cases, such as the recent beef labelling scheme, further mandatory measures may be appropriate. The Commission would invite comments on this question.

PART V

ENSURING THE EFFECTIVE IMPLEMENTATION OF INTERNAL MARKET RULES

1. General considerations

Now that the harmonization of national foodstuffs legislation has largely been completed, it is necessary to ensure that the internal market operates effectively in order to provide the benefits anticipated for producers and consumers.

The need to ensure efficient management of the internal market has been recognised by the Sutherland Report of October 1992: "The Internal Market after 1992; Meeting the Challenge" and by the European Council. A series of Commission communications to the Council have also emphasised the need for efficient operation of the internal market:

- Management of the mutual recognition of national rules after 1992 (COM (93) 669 final, 15 December 1993)
- Development of administrative cooperation for the implementation and application of Community legislation in the framework of the internal market (COM (94) 29 final, 16 February 1994)
- Making the most of the internal market (COM (93) 632 final, 22 December 1993).
- the action plan for the Internal Market (COM (97) 184)

More recently, the Internal market Council has adopted a series of resolutions which are intended to ensure that the rules governing the operation of the internal market are as simple and straightforward as possible. The possibilities for the simplification of Community food law have been extensively considered in Part II, and will not be repeated here.

The objective of this Part is to review the current arrangements for ensuring the effective implementation of Community legislation within the internal market, and to invite suggestions for improvements.

2. Transposition and application of Community law

In order to ensure the proper functioning of the internal market, it is clearly necessary to monitor of the transposition of Community directives by Member States and to verify that the Community rules are applied correctly. The Commission has arranged for a series of specific studies on the implementation of the foodstuffs directives, and the results of these studies are being analysed. Cases of incorrect implementation will be pursued with the Member States concerned.

In addition to national legislation transposing Community legislation, it is common practice for the national authorities to issue implementing instructions or guidelines for enforcement for official control bodies, especially when the legislation is very broad in scope. Such guidelines are intended to ensure that the legislation is applied uniformly throughout the Member State concerned, and to resolve practical implementation problems.

Nevertheless, such guidelines may cause problems for management of the internal market when Member States adopt different interpretations of the legislation, with the result that provisions are not applied uniformly throughout the internal market. It is important therefore that transparency be maintained at Community level and that these differences be resolved wherever there is divergence.

For several years, the Commission has followed an informal working practice of submitting questions concerning the implementation of Community legislation to the Standing Committees. A similar approach has been followed when unforeseen difficulties have arisen during the implementation of the legislation. In many instances, these discussions have resulted in agreement between the competent authorities of the Member States and the Commission about the manner in which the legislation is to be interpreted or applied. The Commission considers that this is a useful procedure which should continue, and that the conclusions of the Committee should be made more widely available to interested parties, it being understood that such conclusions have no formal legal status, and that in the event of a dispute, ultimate responsibility for the interpretation of Community law lies with the Court of Justice.

Finally, in the interests of transparency, all parties concerned should be encouraged to discuss the implementation and application of Community legislation openly in a forum where Member States can be consulted and where different socio-economic interests can express an opinion. To this end the Commission would invite comments on the desirability of convening periodic meetings with representatives from Member States, producers, industry, commerce and consumers to discuss general issues relating to the implementation of Community legislation. However, matters relating to the non-compliance of national legislation with Community law would be excluded from the scope of such meetings, and would continue to be dealt with in accordance with established Commission procedures.

3. Control and enforcement

In accordance with the Treaty, responsibility for control and enforcement of EC rules primarily rests with the competent authorities of the Member States. Community legislation has followed the traditional practice in the Member States which lays down specific rules for the inspection of foods of animal origin and more general principles for the inspection of other foods.

The main role of the Community in the field of control is not to replace the control and enforcement activities of the competent authorities of the Member States, but to control the manner in which they are implementing the relevant legislation in their own countries.

In order to guarantee the independence and effectiveness of control activities undertaken at Community level, the Commission has reviewed the organisation of its inspection and control services and has submitted to the Council and the European Parliament a Communication on its future policy in this field. In view of the important contribution of control activities to effective implementation of Community legislation, which is a matter of common effort between the Commission and national authorities, the Commission is willing to receive comments from interested parties on its new policy.

3.1 Veterinary controls

Legislation on controls in the veterinary sector, on foods of animal origin, is fully harmonized at Community level by vertical Directives which lay down the control provisions for each product or class of products (fresh meat, poultry meat, meat products, fish and fishery products, milk and milk products, etc). These rules are currently being reviewed with the aim of producing a codified, simplified, version (see part II, paragraph 8.1).

In the existing hierarchy of controls, the producer is responsible in the first place for producing food which is fit for human consumption; the national control authorities are responsible for the day-to-day enforcement of the Community rules for the specific products concerned; and the Commission is responsible for checking that the national authorities are applying the Community rules effectively and uniformly. It will be necessary to examine this present division of responsibilities for control of food. This question will need to be addressed as part of the ongoing simplification exercise for veterinary legislation, as well as in the light of the Commission's internal review of its inspection and control services.

The Commission sponsors regular training courses which bring together veterinary inspectors from several Member States to coordinate their approach to the application of Community legislation

The Commission's Community Office of Veterinary and Phytosanitary Inspection and Control has been responsible for carrying out on-the-spot checks in Member States, and in third countries exporting animals or animal products to the Community. The Office has recently been transferred to Directorate General XXIV "Consumer Policy and Health Protection, and in recognition of its new functions, it has been entitled "EC Office for Product Quality Control and Audit. The role of the Office is to monitor the performance of national control authorities in checking the implementation of relevant Community legislation, rather than to substitute for them. rather than to substitute for them. The office is presently able to cover only a part of its duties as specified in Community legislation.

The Commission has reviewed the role, responsibilities and manner of operation of this Office, and has submitted to the Council and the European Parliament a Communication on this matter.

3.2 Other Official Controls of Foodstuffs

Community legislation has laid down the general principles of the official control of foodstuffs. Control consists of inspection, sampling and analysis, inspection of staff hygiene, examination of written and documentary material and examination of verification systems set up by undertakings. Inspections shall cover all stages of production, manufacture, import into the Community, processing, storage, transport, distribution and trade. Products which are intended for consignment to another EC Member State must be controlled with the same care as products intended for marketing in the Member State concerned, and a product must not be excluded from control simply because it is intended for export from the Community.

In addition, procedures have been developed for administrative cooperation between the Member States on matters relating to control and enforcement in order to ensure that the necessary controls are being carried out effectively and equivalently across the Community. Thus, each year the Commission establishes a coordinated programme for the control of foodstuffs. The Member States exchange statistical information about the operation of the control systems, the number of inspections carried out and the nature of the infringements found. The competent authorities of the Member States are required to afford each other administrative assistance in all supervisory procedures relating to the legal provisions and quality standards applicable to foodstuffs and in all proceedings for the infringement of foodstuffs legislation. Exchanges of national food inspectors are taking place within the Karolus programme. In addition, a small centralized Community food control unit has been established to verify the equivalence and efficiency of the national control systems. These inspectors are currently completing their programme of first visits to each of the Member States.

The objective of these activities is to facilitate the operation of the internal market by establishing mutual confidence between the national inspectors, thus removing the need to repeat controls for products produced in other Member States.

Nevertheless, it should be emphasised that the official inspectorates of the Member States have limited resources and cannot inspect every batch of every product on a market where the consumption of foodstuffs is evaluated at some ECU 500,000 million.

Moreover, systematic official inspections would not be appropriate in view of the quality and safety control procedures developed in the industry in recent years.

For this reason, official inspections in all industrialized countries are focusing increasingly on the suitability and reliability of companies' own internal control procedures for meeting product conformity objectives. This means that public resources are used more efficiently, since inspection authorities can concentrate their efforts on those companies whose activities give grounds for concern, and reduce the frequency of official inspections of those companies which have introduced reliable and suitable control systems.

It would therefore seem appropriate, if a safety obligation is to be imposed on food companies, to include in Community provisions a general requirement that the official inspectorates should determine the intensity and frequency of inspections not only in accordance with the level of risk presented by foodstuffs and the operations concerned, but also as a function of the suitability and reliability of internal procedures introduced by companies for ensuring and verifying that foodstuffs conform to the required standards. Applying this principle would bring the general provisions on the inspection of foodstuffs into line with Article 8 of the general directive on food hygiene, which states that all food premises should be inspected at a frequency which has regard to the risk associated with the premises. In addition, due account should be taken, in the operation of the control systems of new tools which are being developed by the industry such as indicators of freshness which may be used to indicate whether there has been a break in the cold chain during the distribution of a product.

Finally, concerns have been expressed about the lack of transparency of certain aspects of food inspection and control activities, and the lack of consumer access to the work of the inspection systems. These questions have been addressed in the Commission's Communication on Consumer Health and Food Safety.

4. Sanctions

In its Communication on the role of sanctions in the implementation of Community legislation in the field of the internal market (COM (95) 162 final), the Commission concluded that the sanctions laid down by Member States for the infringement of internal market legislation should be equivalent to the sanctions set out in the corresponding provisions of national legislation, effective, proportionate and dissuasive. These general principles were endorsed by the Internal Market Council in its resolution of 6 June 1996. It would therefore appear that these principles should be introduced into Community food legislation. The Commission would invite comments on this question.

5. Management of the Internal Market in non-harmonized areas

In sectors which have not been harmonized at Community level, the jurisprudence of the Court of Justice provides a basis for ensuring the free movement of foodstuffs. The primary instrument for the management of the internal market remains the application of the principle of mutual recognition, as it results from the case law of the Court of Justice following the Cassis de Dijon judgement.

In its interpretative communications, the Commission has presented its interpretation of the principles concerning the free movement of foodstuffs in the light of the case law of the Court. For example, in its 1989 Communication on the free movement of foodstuffs within the Community, the Commission set out its interpretation of the rules applicable in the absence of Community legislation. The Member States are required to admit to their territory foodstuffs lawfully produced and marketed in the other Member States. The importation and marketing of such foodstuffs may be restricted, in the absence of harmonized rules at Community level, only where such a measure

- can be demonstrated to be necessary in order to satisfy mandatory requirements (public health, protection of consumers, fairness of commercial transactions, environmental protection);
- is proportionate to the desired objective, and
- is the means of achieving that objective which least hinders trade.

In these communications, the Commission also described the major specific problems which concerned the free movement of foodstuffs, namely:

- trade description (i.e. the name under which imported foodstuffs can be sold);
- the presence of additives in foodstuffs.

Subsequently, the major problems described in the Communications appear to have been largely resolved, either as a result of the harmonisation of legislation or as a result of developments in the case law of the Court. However, other problem areas have emerged, such as those mentioned in Part II, Section 8.

Hitherto, the Commission has disposed of two main mechanisms for managing the internal market in non-harmonised sectors;

- the examination of draft national technical regulations which have been notified in accordance with Directive 83/189/EEC (considered in Part II section 7)
- the investigation of complaints that Member States are infringing the rules on the free movement of goods laid down by Articles 30-36 of the Treaty. Despite a certain reticence on the part of industry to bring forward formal complaints to the Commission, the foodstuffs sector still accounts for the largest number of complaints received by the Commission under Arts 30-36 of the Treaty. The Commission has taken a number of initiatives to rationalise and expedite the complaints procedures. In addition, the possibility of pursuing a complaint before the national courts, and if necessary obtaining a preliminary ruling from the Court of Justice in accordance with Article 177, constitutes an alternative means of redress

From 1 January 1997, the Commission has had available an important new mechanism for the management of the internal market. In accordance with the provisions of the Decision of the European Parliament and the Council establishing a procedure for mutual information on national measures derogating from the principle of the free movement of goods within the Community, Member States are required to inform the Commission of any measure which impedes the free circulation of a type of product or model of a product which is legally produced or marketed in another Member State, subject to the conditions laid down in the decision. The progressive implementation of this new procedure is providing the Commission with a much more accurate over-view of the true situation within the internal market, enabling it to take appropriate remedial action where necessary.

The Commission would invite comments on the free movement of foodstuffs in non-harmonized areas, and particularly on whether the principles described above have been fully implemented at national level, and are still valid.

PART VI

THE EXTERNAL DIMENSION

1. General considerations

The effects of the Community's food legislation are not confined to the Community alone. In accordance with the EEA agreement, Community food legislation is applied in Norway and Iceland, and it will shortly be applied in Liechtenstein. The applicant countries in central and eastern Europe and Cyprus are in the process of adjusting their legislation to apply Community rules in preparation for their accession to the Community. The customs union agreement between the Community and Turkey provides for the harmonization of legislation, legislation and negotiations with Switzerland are also at an advanced stage. A number of other third countries are also using Community legislation, which often closely reflects the relevant international standards established by Codex Alimentarius, as a model for their own legislation.

The principles of the internal market also apply to goods from non-member countries which have been put into free circulation. Such products must meet all the requirements which are laid down in Community legislation for products produced within the Community. For foodstuffs of animal or plant origin, there are specific veterinary and phytosanitary inspection and certification procedures which are undertaken at the point of entry into the Community, and specific controls relating to quality standards for unprocessed fruits and vegetables for export and import. The Community also carries out inspections in non-Community countries.

In other cases, there are no special procedures for the inspection or certification of imports and exports. Controls on products are undertaken on a random basis, at the point of entry, or at the point of destination, and the activities of importers may also be subject to control. Consideration may need to be given to better coordination of controls on imports. It is also worth recalling that foodstuffs are part of the list of products which are more specifically covered by controls performed under Council Regulation (EEC) 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries.

In addition, to being a major food importer, the Community is also a major food exporter. Indeed it is estimated that in 1996 the Community will have a favourable trade balance in excess of ECU 10,000 million in food and drink products. In these circumstances, it is important to ensure that the Community's own internal legislation provides adequate reassurances for our major trading partners, and that our exports do not encounter unjustified restrictions in gaining access to markets outside of the Community.

Recent years have seen important changes in the multilateral trading system applicable to foodstuffs, and in the bilateral relationships between the Community and its major trading partners.

2. The multilateral dimension

- Both the recent changes introduced by the WTO Agreements and those relating to the Codex Alimentarius have an impact on food law.

2.1 The WTO Agreements

Several of the agreements concluded at the end of the Uruguay round have had important effects on the foodstuffs sector. The Agreement on Agriculture is having significant effects on the conditions of international trade in foodstuffs. The implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights will facilitate the international recognition of denominations of origin and certificates of specificity which have been granted in accordance with the relevant Community regulations. However, it is the amendment of the Agreement on Technical Barriers to Trade (TBT) and the new Agreement on Sanitary and Phytosanitary Measures (SPS) which will have the most important consequences for Community foodstuffs legislation.

These two Agreements are designed to prevent technical legislation which is intended for the protection of the human health or safety, the protection of the health or life of humans animals or plants, consumer protection against deceptive practices and environmental protection being used to create or resulting in unjustified barriers to international trade. The Community is a full party to both agreements, which therefore apply both to Community legislation and to legislation adopted by the Member States.

The Agreements encourage WTO members to participate fully in the development of harmonised international standards with a view to reducing the barriers to trade arising from conflicting national rules. If a member observes the standards, guidelines and recommendations prepared by the relevant international organizations when adopting a measure, the measure in question is presumed to comply with the provisions of the Agreements. However, both Agreements also recognise the right of members, as Sovereign entities, to lay down measures which provide a greater level of protection than that provided for by the relevant international standards, providing that these measures do not result in unjustifiable restrictions on international trade.

In order to encourage transparency, both Agreements provide for the prior notification of draft measures which could affect international trade, thus giving the other WTO members an opportunity to comment on them.

The TBT Agreement applies to all products, including agricultural products, and covers all measures which could affect international trade. It does not, however, apply to sanitary and phytosanitary measures as defined in the SPS Agreement.

In order to achieve its objectives, the Agreement lays down a number of principles: the measures of the contracting countries should have a legitimate objective; the measures adopted should be appropriate or proportionate to those objectives, there should be no alternatives which cause less disruption to international trade and there should be no discrimination.

In the food sector, the aims which, under the TBT Agreement, might justify measures taken by a contracting party which diverge from the relevant international standards include: prevention of practices which might be misleading (misleading information), protection of human health or safety, protection of animal life or health, and protection of the environment.

Justification for measures taken to achieve these legitimate objectives might include scientific and technical data, related processing methods or the end-use of products.

The SPS Agreement applies to measures;

- to protect animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- to protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods;
- to protect human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests;
- to prevent or limit other damage from the entry, establishment or spread of pests.

The basic aim of the SPS Agreement is to maintain the sovereign right of any member to provide the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to international trade.

The measures which members adopt to achieve their chosen level of protection must be based on an assessment of risks to health, taking into account available scientific evidence, processes and production methods, inspection, sampling and testing methods and, in the case of animal and plant life and health, relevant economic factors.

Measures must not arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail. They must be not more trade-restrictive than required to achieve the appropriate level of protection, taking into account technical and economic feasibility. Members may introduce or maintain measures which result in a higher level of protection than would be achieved by measures based on international standards, guidelines or recommendations if there is a scientific justification or as a consequence of the level of protection the member determines to be appropriate.

Unlike the TBT Agreement, the SPS Agreement refers specifically to some of the international organizations whose standards, guidelines and recommendations it considers to be relevant. These are, for food safety the Codex Alimentarius Commission, for animal health and zoonoses the International Office of Epizootics and for plant health the International Plant Protection Convention.

WTO members failing to comply with the relevant international standards may be challenged in several ways:

- WTO Members considering that the national measures notified to them under the notification procedures conflict with the SPS and TBT Agreements may ask for justification;
- the national measures may be brought before the committees responsible for managing the Agreements; for example the SPS Agreement states that in the case of legislation having a major impact on international trade, a list of which is to be drawn up by the management committee, a Member which fails to apply an international standard will have to explain its reasons to the committee;
- disputes may be settled by special panels set up within the framework of the WTO.

2.2 Developments within the Codex Alimentarius

In 1962 the Food and Agriculture Organization and the World Health Organization set up a joint FAO/WHO committee on the Codex Alimentarius to prepare standards, recommendations and guidelines with a view to protecting consumer health, ensuring fair trading practices and facilitating international trade. By 1994, Codex had 146 member countries. It had established 237 commodity food standards, 41 codes of

practice covering hygiene and food technology. 185 pesticides had been evaluated leading to the establishment of 3,274 maximum residue limits for pesticides. 760 food additives and 25 contaminants had also been evaluated together with 54 veterinary drugs.

In March 1991 a conference on food standards, chemicals in food and international trade organized by the FAO and the WHO, in cooperation with GATT, built on the experience gained by GATT to plan future progress on the Codex Alimentarius and a new SPS Agreement.

The SPS Agreement gives international reference status to the standards, recommendations, guidelines and codes of good hygiene practice adopted by the Codex.

The Codex has started a radical overhaul of its approaches and procedures so that it can perform the role assigned to it under the SPS. This has resulted in a number of reforms to improve the efficiency of procedures for preparing and adopting standards. In addition, the content of a large number of Codex standards is being reviewed to take account of the new WTO Agreements. However, the relationship of Codex with the SPS Agreement needs to be clarified and refined further.

The Community is determined to play a constructive part in devising and implementing these new approaches, and to seek a high level of health and consumer protection, and must make sure it has the necessary resources to do this.

2.3 The consequences of these developments for the Community

These developments have several consequences for Community activities in the food sector.

1. The Community will increasingly be required to provide scientific justification for its measures at international level. The suggestions set out above for prior consultation of scientific committees should also be considered as proposals in connection with changes required of the Community at international level.
2. Since the Community must be able to justify measures which diverge from the relevant international standards, it is important to take account of the international dimension in the Community's scientific assessment work. The members of Community scientific committees must be able to cooperate with their other colleagues, particularly within the context of international committees of scientific experts like the Joint Expert Committee on Food Additives (JECFA) and the Joint Meeting on Pesticide Residues (JMPR), which are responsible for preparing the scientific assessments of hazards which form the scientific basis for preparation of Codex standards. International assessments of specific hazards should, where they exist, be taken into account as far as possible, without, however compromising the Community's level of protection.

3. The new situation provides the Community not only with a challenge, but also with an opportunity to ensure that new measures adopted by our major trading partners are also in accordance with their international obligations. In order to take the best advantage of this opportunity, the Community must be prepared to mobilise the resources necessary to scrutinise the measures which are prepared by our trading partners. This can only be achieved through a close partnership between the Commission, Member States and those whose interests are directly at stake, in particular Community producers and industry.
4. The Community must also be capable of playing a full role during the negotiations within Codex Alimentarius and other fora which lead to the adoption and acceptance of international standards. Full Community participation is essential in order to ensure that the Community interest is taken into consideration during the preparation of international standards which will be used as a reference point for judging the legitimacy of the Community's own legislation. The current situation where the Community is a full party to the WTO agreements, but is accorded only the status of an observer during the elaboration of international standards by Codex, constitutes an unacceptable anomaly, which must be remedied as soon as possible by the accession of the Community to full membership of Codex Alimentarius. A proposal to this effect has been presented to the Council; the latter has granted the Commission a mandate and negotiations have begun with the Codex Secretariat.

Likewise, given the competences of the Community in the field of plant protection, and taking account of the objectives of the International Plant Protection Convention (IPPC), the Community is participating in the review of the IPPC and intends subsequently to adhere to it.

As a corollary, Community participation in international scientific efforts to assess existing hazards should be increased. Directive 93/5/EEC on scientific cooperation already provides the basis for Community bodies to take part in international scientific cooperation. The proposal for a 5th framework programme also foresees such reinforced participation.

3. The bilateral dimension

Developments at global level also provide a general framework within which individual countries may also sign their own bilateral equivalence agreements. Article 4 of the SPS Agreement encourages the development of bilateral equivalence agreements, and the Codex Alimentarius Committee on Food Import/Export Certification and Inspection Systems is also preparing guidelines to encourage the development of bilateral agreements. These agreements make it possible to evaluate in practical terms those sectors where the regulations and guarantees provided by official inspection and certification schemes are recognized as equivalent, i.e. which, although they may be different, are considered to provide the same level of protection. Recognition of equivalence helps facilitate trade by simplifying the conditions of trade between the signatory countries.

Such agreements are particularly necessary when systems of legislation are based on the implementation during production or processing of prevention measures such as those based on HACCP principles. Proof that the system is being applied can be provided only by carrying out inspections in the companies themselves and not solely by inspecting the finished product.

These agreements also make it possible to manage public official inspection resources more efficiently without reducing the level of consumer protection by avoiding unnecessary repetition of inspections which have been properly carried out by the exporting country. In addition, they could facilitate technical cooperation between various countries in the area of scientific research, and the preparation of food regulations, and controls and certification.

In this context, it should be recalled that on 21 September 1992 the Council adopted a Decision authorizing the Commission to negotiate agreements between the Community and certain non-member countries on mutual recognition with a view to conformity assessment. In addition, on the basis of other Council mandates, the Commission has opened negotiations with a view to bilateral veterinary and phytosanitary equivalence agreements. An agreement with New Zealand has been agreed by the Council and signed. A proposal for an agreement with the Czech Republic has been completed and submitted to the Council. Negotiations are continuing with other trading partners, including Australia, Canada and the United States; South American countries, in particular Argentina, Chile and Uruguay and the associated countries of Central and Eastern Europe.

In order to facilitate the development of equivalence agreements outside the veterinary and phytosanitary sectors, consideration should be given to completing the existing provisions on official control with measures designed to:

- ensure that inspections of imported and exported products comply with international rules, particularly by taking account of proportionality in relation to hazards as proposed above and allowing agreements recognizing equivalence to be taken into consideration;
- allow the specific team of Community officials responsible for assessing and checking the equivalence and effectiveness of official food control systems in Member States as referred to in Directive 93/99/EEC also to cooperate with Member States in assessing and inspecting the official control systems of non-member countries within the framework of negotiating and managing an agreement recognizing equivalence.

In addition, the Community maintains a variety of bilateral contacts with its major trading partners on regulatory issues relating to the food sector, including the Trans-Atlantic Dialogue, and regulatory cooperation.

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