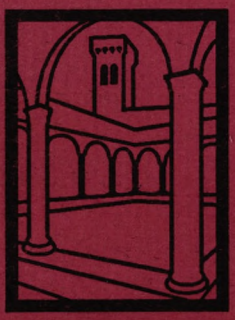

EUI WORKING PAPERS IN LAW

EUI Working Paper LAW No. 94/4

A Regulatory Framework for Foodstuffs in the Internal Market

Report on the Conference
6-7 May 1993, Florence
Organised by

FRANCIS SNYDER

European University Institute, Florence

EUROPEAN UNIVERSITY INSTITUTE, FLORENCE

DEPARTMENT OF LAW

EUI Working Paper **LAW** No. 94/4

A Regulatory Framework for Foodstuffs in the Internal Market

Report on the Conference
6-7 May 1993, Florence
Organised by

FRANCIS SNYDER

BADIA FIESOLANA, SAN DOMENICO (FI)

Printed in Italy in May 1994
European University Institute
Badia Fiesolana
I – 50016 San Domenico (FI)
Italy

Table of Contents

Notes on Contributors

Prof. Charles Castang is Professor at the University of Aix- Marseilles III, France.

Prof. Amanda Cleary is Professor at the University of Surrey, UK.

Dr Renaud Dehousse is Lecturer at the EUI, Florence, Italy.

Prof. Dieter Eckert is Professor of Law at the University of Bonn, Germany.

Mr Egon Gaerner is Head of Unit (DG III/E/1) at Commission of the European Communities, Brussels, Belgium.

Prof Christian Joerges is Professor of Law at the EUI, Florence, and at the University of Bremen, Germany.

Dr Barbara Maria Köhler is Research Fellow at the Wissenschaftszentrum Berlin, Germany.

Prof. Francis Snyder is Professor of European Community Law at EUI, Florence, Professor at the College of Europe, Bruges, Belgium and Honorary Visiting Professor of Law at the University College London, UK.

Tatjana Steidl is Research Fellow at the Wissenschaftszentrum, Berlin, Germany.

Prof. Rudolf Streinz is Professor of Law at the University of Bayreuth, Germany.

ACKNOWLEDGEMENTS

The conference was organised at the request of and with the financial support of the Commission of the European Communities. The organisation of the conference was made possible by the collaboration of Anne-Lise Strahtmann, Wolf Sauter and Aurora Voiculescu of the EUI Law Department. It also benefited from the help of Mme Jeannie Vergnettes, DG III, Commission of the European Communities. The conference would not have been feasible without the cooperation and efficiency of the staff of the Academic Service and the Operational Service of the EUI. This working paper was prepared with the help of Wolf Sauter and Nuno Venade. The principal organiser of the conference wishes also to acknowledge the invaluable support of M. Emile Noël, the then President of the EUI.

Francis Snyder
Florence, March 1994

INTRODUCTION

EGON GAERNER*

Since the primary objective of food law is to ensure the quality and safety of foodstuffs, the subject is naturally a sensitive one for consumers, producers, industry and the public authorities. As a result, the food sector is the subject of numerous regulations which have been laid down at the national level, or at the Community or wider international level.

Indeed, following the completion of the intensive programme of legislation set out in the Commission's White Paper on the realisation of the internal market, Community food legislation has become the essential basis for defining the rights and obligations of economic operators and consumers in this sector.

In the interests of transparency and ensuring a greater understanding of the Community legislation, the Commission considered that it was necessary to identify more clearly the general principles on which the rules are based, which are currently contained in a large number of legal instruments, and to restructure these principles in a single legislative act.

It was for this reason that the Commission invited three leading experts to prepare a first draft directive setting out a general approach to food law and to ask the European University Institute in Florence to organise a conference to debate the conclusions of the experts.

However, the role of the EUI has not been limited to the material organisation of the conference. It has also been able to provide the broad academic input necessary to put the work of the experts into a wider legal, economic and environmental context. I must express my sincere thanks to Professor Francis Snyder and his colleagues for the outstanding manner in which they have accomplished these tasks.

---

* Head of Unit, DG III/E/1,"Foodstuffs, Legislative, Technical and Scientific Aspects", Commission of the European Communities, Brussels, Belgium.

In addition, we have been able to benefit from the very high quality of the contributions made to the debate by officials from the regulatory authorities of the Member States and by representatives of the different interests involved: producers, industry, consumers and commerce.

Therefore, from the point of view of the Commission, the conference has entirely fulfilled its objective, by providing many of the elements necessary for the preparation of a "Green Paper" on a future general directive on food law, which it is our objective to present in the Spring of 1994. In addition, however, the conference provided a fascinating overview of the current status of food law, its broader context, and some insights into the challenges the future may hold.

May, 1993

PART I:

PRESENTATION OF PROPOSALS FOR A DIRECTIVE BY THE NATIONAL EXPERTS

1. Professor Charles Castang, University of Aix-Marseilles III

2. Professor Amanda Cleary, University of Surrey

3. Professor Dieter Eckert, Bonn

GENERAL PRINCIPLES FOR FOOD LEGISLATION IN THE EUROPEAN COMMUNITY

CHARLES CASTANG*

Summary of Contents:

Introduction

An Apparent Paradox

The first Community Directive on food, concerning additives, dates back to 1962. Since then hundreds of texts have been added to the Community's food law, whether in the form of directives, regulations, rulings by the European Court of Justice, or White and Green papers drafted by the Commission for the Council.

It is therefore legitimate to ask whether a proposal from the Commission of the European Communities to define the general principles governing this field is desirable. If such principles are necessary for the consistency of food law, they have certainly been left very late. If they are not, is there

* Professor of Law, University of Aix-Marseilles III, France.

really any point in adding yet again to legislation already considered extremely dense, if not even overdeveloped...

To put the problem in these terms would seem to be an oversimplification and to disregard the significant changes in approach to food law over the last three decades.

Background

For many years, the sole legal basis for the Directives on food was the Treaty of Rome itself. More specifically, it was one of the fundamental principles of the Treaty, namely "the free movement of goods" between the Member States.

However, as early as 1962 the preambles to the Directives on additives explicitly referred to protection of health and consumer protection, even though neither of these concepts is mentioned in the treaty.

Secondly, despite two attempts, in 1969 and 1973, to produce programmes to harmonise the national food law, until the 1980s the sectoral approach was preferred, only to end with the recognition that this type of harmonisation was impossible to achieve. In this respect, the Court of Justice's rulings (in the Cassis de Dijon case amongst others) played a decisive part in raising awareness of the need for a new approach, as defined in the Commission's communications to the Council, particularly in November 1985.

The Single Act itself, as ratified by the Member States in 1985, added a new dimension by declaring the environment an integral part of the various Community positions from then on. Finally, on 1 January 1993 the Single Market entered into force, based primarily on mutual recognition of national legislation, tempered by the Community legislation and monitored by the Court.

This makes it easier to understand the need now being felt for food manufactured and marketed in the various Member States (first six, now twelve, with more to come) to comply with the common principles which have gradually emerged in the course of time and either to enshrine these principles in a legal act or to define them in the light of the latest economic and sociological data. In this respect, the Maastricht Treaty

makes two fundamental innovations, by adding consumer and health protection to the Community's permanent objectives.
There is therefore ample cause for the Commission's concern to propose a framework directive applicable to all foodstuffs. Another question which must be asked, however, is whether a directive is the only appropriate form of legislation. In the light of the principles identified for food law, this study concludes that the answer must be no.

The questions raised

Three questions must be answered in order to determine the broad lines of food law:

- What is the objective of food law today?

- Which guiding principles must be applied to this objective?

- Which legal and administrative mechanisms should be employed to apply these principles?

This paper will attempt to provide concise answers to these three questions and to draw from them conclusions, concerning the general framework for the Community's activities in this field in the next few years.

1. Objectives of a General Directive

Today, a large body of opinion would like to make food law an integral part of consumer law, based, as such, essentially on the principles governing consumerism in the most developed countries.

Perhaps this attitude is the reaction to the opposite approach of a few decades ago which turned many of the rules on food law to the advantage of producers and trade. In particular, in the late 19th and early 20th century, fair trade was the overriding concern, although health protection was by no means ignored. The French legislation dating back to 1905 was a good example of this attitude.

Today, there is a tendency to give food law the opposite objective, *i.e.* to

protect consumers, particularly their health and their economic interests.

As a result, all too often food law appears to be a defensive weapon pointed at producers and members of the trade, who are driven solely by the quest for profit, to the detriment of consumers' legitimate interests.

Must we resign ourselves to this antagonism, which sometimes creates conflicts?
I think not. Instead, I propose three ideas:

1. food law is not a branch of consumer law;

2. conversely, nor is food law a branch of commercial law;

3. food law is an autonomous branch of law.

This system has a host of consequences, starting with the way in which the problems are tackled and structures designed to resolve them. In practice, if food law is considered an autonomous branch, the natural consequence would be to designate a separate structure, independent of the technocratic bodies currently in charge of this area, to formulate and administer the laws.

In short, this raises the question of power sharing within the Commission and, in any event, of the need for a global approach, if necessary including the establishment of coordinating bodies to arbitrate between the interests at play. Moreover, this global coordination approach should require an identical approach in each Member State; this is generally not yet the case because of the historical or administrative factors which still dictate the division of powers within the national governmental authorities.

2. The Principles of a General Directive

In accordance with the objectives outlined above, these principles must therefore fulfil the aspirations and rights of traders and consumers alike. These fall into three categories:

1- the principle of consumer safety and professional responsibility;

2- the principle of the guarantees which must accompany food on the market;

3- the principle of a global approach to food policy.

Consumer Safety and Professional Responsibility

This principle can be defined as the obligation, for members of the profession, to place on the market only food ensuring the safety necessary for the consumers' health under the foreseeable conditions of use.

This raises the question whether the measures already adopted by the Community on product safety cover this. In short, does the Directive of 19 June 1992 on general product safety apply to food?

On analysis of the product safety Directive, it is fair to consider that food falls within its scope. Article 1 states that "the purpose of the provisions of this Directive is to ensure that products placed on the market are safe". Article 2(a) adds that "product shall mean any product intended for consumers or likely to be used by consumers, supplied whether for consideration or not in the course of a commercial activity...". The same Directive also stipulates that "the provisions of this Directive shall apply in so far as there are no specific provisions in rules of Community law governing the safety of the products concerned." How, then, is this safety obligation to be put into practice? Article 3 partly answers this question but goes further than to state the principle that "producers shall be obliged to place only safe products on the market" backed up by an obligation to provide information.

In the case of food, it is legitimate to feel the need to go further and be more precise: in short, the safety obligation should be defined in greater detail and, above all, backed up by an additional obligation calling for self-policing, at the expense of the member of the trade concerned, before any product is placed on the market. In this way, this self-policing obligation should eliminate a large proportion of the potential risks which food could pose to the consumer. It must be stressed that such a legal requirement would be welcomed by professionals since it would, to a large extent, cover the quality management methods already widespread

in the agri-foods industry and recognised as particularly profitable for the industry, in terms of the returns which they yield.

Lawyers too should seize this opportunity to consider one of the fundamental tenets of the free-market economy, namely the justification of profit as the basic driving force behind trade. In particular, classical theory regards profit as the fair return for the economic risk which the entrepreneur accepts of his own volition. Today, however, the analysis of the conditions justifying profit should be taken further by adding the need for the entrepreneur to take all appropriate precautions to protect the consumer's safety, in the name of a genuine responsibility over and above his individual contractual liability.

More specifically, this safety obligation reflecting the social responsibility mentioned above should take the form of an obligation, on the part of the manufacturer or the member of the agri-food industry, to place on the market only foods offering irreproachable safety standards. This idea implies mandatory self-policing before placing the product on the market for the first time. Hitherto, only case law has upheld this idea, which must be demonstrated case by case with the appropriate legal arguments. Is it not time to express this idea in objective legal terms and make it the fundamental principle of all the legislation on food?

Moreover, imposition of this self-policing obligation would not mean that the policing would have to be defined and organised by the public authorities, whether at Community or national level. It would suffice for the member of the profession concerned to produce evidence, at the request of the competent authorities, that this self-policing is effectively carried out in the manner which the trader concerned sees fit.

One other consequence of the principle of food safety concerns the principle already accepted throughout the Community (although not yet formulated as a general concept) of "approved lists" of additives, processing technologies, materials in contact with foodstuffs, etc. There is all the more reason to formulate this principle explicitly considering that it is not seriously disputed, even though some Member States did not apply it until they joined the Community whereas in others it has been law since the beginning of this century.

Guarantees for Food on the Market

Besides safety, what else do consumers expect of the food they buy? And what are traders' main concerns with regard to the food market, as they strive for maximum profit in the face of competition?

In practice, this raises the twin questions of the information on the product label on the one hand and of the definition of quality on the other.

However, both these approaches suffer from too many preconceived ideas which must be demystified.

"Labelling" is the most direct link between buyer and seller. It is the simplest way of ensuring fair competition, by selling the food "for what it is". Lawyers call this the principle of the conformity of the product.

What, however, is the situation today? Indisputably, one of the Community's successes was to have adopted a whole series of directives laying down common rules on labelling for the individual Member States. Of course, this task is not yet complete, but care must be taken to avoid counter-productive perfectionism. The preconceived idea which must be combated is that the need for labelling (and information) is never completely satisfied. This is mistaken: today people are starting to think that an overabundance of information is equivalent to disinformation. One perfect illustration is the fashion for nutritional labelling, which many would like to make mandatory. Voluntary nutritional labelling is perfectly acceptable, but it would be a serious mistake to take it a stage further and make it mandatory (except, of course for foods for special diets).

In brief, today there is not so much a need to extend the labelling obligation as to monitor the information given, whether explicitly or implicitly. This should be covered by a regulation on "claims", which has yet to be produced.

"Quality" too is becoming a growing concern for consumers and members of the trade alike.

There is no need to become embroiled in interminable speculation about the meaning of "quality" in order to cover this problem in depth. If closer definition were absolutely demanded, it would be better to simplify

matters by taking a dual approach to defining quality. The first, derived from European standardisation, regards quality as no more than all the specifications defining the food in question. From this point of view, mandatory labelling throughout the Community perfectly guarantees this quality.

The other definition of quality, in the sense of "excellence" or "superiority", stems from widespread tradition in the Latin Community Member States. It is symbolised by the concept "designation of origin" which is so difficult to impose in some Anglo-Saxon countries.

Whatever the definition, however, the concept of quality reflects a demand on the market (from consumers and the trade alike) and is beginning to take firmer shape in the form of the idea of the guarantees which must accompany quality claims. In recent years this concept of guarantees has gained ground prodigiously, as is illustrated by the procedures for certification not only of products, but also of undertakings or even of production methods.

In the light of the foregoing, what role could be played by general Community legislation on "quality" (and its corollary "certification")?

It is clear from the Single Act and the new approach that the Community has no part to play in the definition of the quality parameters for food products. Only a national (or regional) approach can express the specific requirements of consumers and of the trade.

On the other hand, can complete freedom be left to impose or recognise quality requirements, to monitor application thereof and to decide how this quality is expressed externally now that food is to move freely on the single market? Clearly, the answer is no, and the Community must see to it that the quality rules are similar, if not identical, or, at any rate, comparable from one Member State to another. The objection that a European body independent of the Community could be made responsible for quality certification cannot justify non-intervention by the Community. The Community must ensure that the rules on quality definition and, above all, on approval certification for products and undertakings are appropriate. Nor can it ignore the standards demanded of the certification bodies.

By way of conclusion, any general Community legislation must explicitly provide for the possibility of action by the Community with a view to harmonisation of the rules, not only to protect the consumer but also to provide legal certainty for competing traders.

The Global Approach to Food Legislation

The earliest Community legislation on food, based directly on the free movement of goods provided for by the Treaty of Rome, could aim at no more than removal of technical barriers. However, very soon it proved difficult, if not impossible, to justify the Community's interventionism without reference to protection of human health. The preambles to the earliest Directives, the 1962 Directives on additives, contain perfect references to this point (cf. above).

In the context of the period up to the early 1980s, marked by a horizontal approach closely connected to the vertical approach, *i.e.* for defined foods or group of foods, there could be no question of building bridges to other field covered by the Treaty of Rome. Free movement and, pragmatically, health protection were the only legal bases.

The Single Act changed this situation by setting other objectives. For example, it established the legal principle that the environment is an integral part of the common policies.

This principle has significant consequences for food legislation, considering the impact of certain substances used in agriculture (fertilisers, pesticides, etc.) or of certain packaging materials or, more generally, the attitude to be taken to new products or production methods, in relation to ecosystems of perhaps even nutrition.

But is it certain that all this has affected the formulation of food law, at least so far? More radically, has the question yet been asked in these terms?

Whatever the answer, another important step should be taken with the ratification of the Treaty on European Union (the Maastricht Treaty), which expressly includes consumer protection as such and health protection amongst the Community's activities.

This clearly points to the conclusion that food law concerns not only the food itself but also the consumer and the environment in which he lives, which in turn must be protected. How then can food and nutrition be ignored, with all that they imply in terms of gathering statistics, epidemiological data, sociological data, etc.?

Naturally, it will not necessarily be possible to translate this global approach into legal terms but, logically, it should have major repercussions on the existing administrative structures and instruments for food law, and on those yet to be set up.

3. Procedures for Implementation of General Legislation on Food

Any legislation or action by the public authorities at the Community of national level must comply with two basic imperatives:

1. satisfy a clearly identified need;

2. be applied correctly by the partners involved.

A few general comments on the two series of measures adopted by the Community on both these points are set out below.

Identification of Needs

For many years the Community adopted programmes which, in the case of food (the 1969 and 1973 programmes), soon proved impossible to implement in full. Far more realistically, the new approach turned away from vertical harmonisation in favour of horizontal legislation and non-binding "soft law" such as standards, codes of practice, etc.

That leaves the question of the legal basis for such legislation. This is partly answered by Council Directive 93/5/EEC of 25 February 1993 on scientific cooperation. The preamble to the Directive recalls that "consumers are entitled to a Community food policy which promotes safe food particularly regarding nutritional, microbiological and toxicological issues". Article 1 is even more explicit and mentions "medicine, nutrition, toxicology, biology. hygiene, food technology, biotechnology, novel foods and processes, risk assessment techniques...." amongst the

disciplines to be taken into account in food legislation.

This confirms the global approach outlined in Part 3 of Section II.

While fully supporting this philosophy, it is however fair to ask how this is to be implemented.

Directive 93/5/EEC clearly opts for decentralisation, in preference to the idea of a centralised Community body along the lines of the food monitoring agency advocated by many. The idea of a European Food Agency, an advisory and executive body independent of the Commission, has been dismissed out of hand until now and has little chance of being taken into consideration in the future.

Since this choice has been made, it would be unrealistic to discuss the options again. Nevertheless, recommendations can be made as regards the content of any general Community legislation on food. More specifically, once the idea of a food monitoring agency has been abandoned, is it enough to rely on the existing Scientific Committee for Food and perhaps the Standing Committee for Food to exploit such a mass of diverse, complex data?

The objective of scientific cooperation in the Community goes far beyond the competence and resources of these two Committees which also meet only sporadically and are not equipped for proper exploitation of the data.

This, therefore, raises the question of a committee procedure tailored to the declared objectives... unless the decentralised option is a strategy to side-step the problem by taking an inherently honourable principle but diverting it form the objective which seems most appropriate.

Application of the Legislation

This vast subject can be tackled from various angles, starting with incorporation of the Community rules in the national legislation. A detailed inventory remains to be compiled.

At this early stage, the question of application can be limited to the aspect of food legislation in the Community. The idea seems to be emerging that the national inspection bodies should act as a coordinating network and

that the role of the Community's inspectors should be limited to auditing the existing national systems. The logic behind such a system is perfectly defensible, provided the Commission plays its full central coordinating role in this field too, with the minimum centralised structures which this implies. Similarly, the "coordinated programmes of inspections" drawn up by the Commission, starting with the Commission recommendation of 9 November 1992, must be based on a Community analysis of the problems and not on an inventory of national proposals, initially based, to make matters worse, on the restrictive concept of inspection by sampling and analysis, which is completely obsolete in 1993.

These two examples highlight the fact that if the general principles of food law cannot be reduced to a purely legislative approach, in the form of directives of regulations, administrative or organisational measures must play a front-line role in defining the general concept applicable to food policy.

4. Final Recommendations

1. Today it seems possible to lay down the general principles of food law. This is not superfluous, but essential.

2. Food law is an autonomous branch of law, responding to the interests and demands of consumers and the trade alike. Consequently, it must be administered by bodies independent of the various interests, in a spirit of cooperation, not confrontation.

3. Safety is the primary guiding principle for food law. It implies an obligation for clearly defined self-policing on the part of the trade.

4. Another principle, derived from the previous one, concerns approved lists. It too must be clearly formulated and incorporated in the national and Community law.

5. Mandatory labelling is necessary, but cannot cover all the socio-economic partners' needs.

As a result of the law in favour of labelling, the overabundance of information is producing considerable adverse effects, some of which

could be offset by rules on claims.

6. Quality and, more generally, "certified quality" cannot be reserved solely for national or professional requirements. It is the duty of the Community to take action. It has only just started to do so and must continue and step up its efforts.

7. Food law cannot be divorced from its general context and objective. It must be the fruit of a global, interdisciplinary approach closely linking the environment, nutrition and, more generally, consumer sociology.

8. The mechanisms to be set up and put into operation for this global approach do not yet exist at the Community level. Either they must be set up or the existing mechanisms must be adapted, by extending their powers and expanding their resources.

9. Even although the national authorities are responsible for carrying out the food inspections, these must be coordinated at the Community level. Their effectiveness must be constantly monitored. The Commission must take action to this end.

10. The foregoing proposal must be based on appropriate instruments of all forms: directives and/or regulations, recommendations in the form of green papers, Community administrative measures and negotiations with various international organisations in the public sector or the industry, etc.

THE OBJECTIVES AND FUNCTIONS OF FOOD LAW

AMANDA CLEARY*

Introduction

The exercise of drafting a framework regulation for Community food law, with which we as experts were invested by the Commission, was not purely legislative in nature. Having been given *carte blanche* for our drafts by the Commission, we were free to take into account the importance of the wider social and economic context of the legislation, rather than restricting ourselves purely to the legal issues. This freedom was appropriate, since more comprehensive action by the Commission of the EC is needed in order to clarify Community food law.

At present a lack of an overall policy at the Community level is manifest. We do not confront a single EC food policy, but rather a number of food policies, each with its own limited objectives. Hence the problem of the framework regulation is not in the first place that of formulating principles of Community food law, but rather that of identifying its objectives. This is what I have attempted to do in my draft directive.

In this context the danger of formulating a framework directive that merely seeks to bundle some aspects of current Community legislation is that it might result in a retrospective exercise of consolidation and codification. Such a directive would soon become irrelevant in the rapidly developing area of foodstuffs, since major changes in technology and regulation are in the wings, and more may be expected within the next few years. The aim of the directive can therefore not be restricted to placing a "roof" on the existing pillars of Community food law, as has been suggested elsewhere. Surely the goal cannot be erecting a structure that will form a monument to past achievements but obstructs change.

* Professor of Law, University of Surrey, UK.

1. The Objectives of Food Law in the Context of the Maastricht Treaty

Rather, imaginative thinking is called for. The starting point of a framework directive on food law must be the completion of the internal market. The European Union Treaty has extended the scope of Community law with a number of goals, and further stressed others, that are relevant to food law, notably concerning consumer protection, health protection, and the environment. This means that these elements, which were once seen as external to food law, must now be incorporated. Moreover, further changes must be anticipated.

In particular, the directive must aim at securing consumer confidence in food law and foodstuffs regulation, and establish a clear link between Community law and consumer expectations. In order to achieve this fundamental objective, the directive must include or take into account the following elements:

- a clear definition of objectives;

- the inclusion of the environmental dimension;

- the creation of an external organ charged with evaluation (an independent agency);

- the creation of mechanisms for the resolution of the political problems that accompany a sectoral approach;

- and take into account the evolution of the Common Agricultural Policy, which may lead to a more complete integration of the dimension of environmental protection, but carries the risk of abandoning the policy of quality control which remains indispensable.

To make clear how I have linked the objectives of Community food law to the recent developments in Community law, I refer to article 2 of my draft directive, which lists its purposes as the following:

- to ensure the safety of food and ultimately, to protect public health;

- to protect the consumer against deception and fraud;

- to maintain the free movement of goods and procure fair trading;

- to promote the enhancement of the quality of food and increase public confidence in all aspects of food production;

- to ensure that Community food law is implemented according to uniform optimum criteria by the Member States while maintaining the principle of subsidiarity;

- to take account of public concern over the protection of the environment, the conservation of natural resources, and the promotion of animal welfare in the chain of food production.

This approach embodies the shift in emphasis of food law that was called for above, which should be placed in the context of the Maastricht Treaty. It aims to provide for maximum flexibility and creates the necessary potential for anticipating future developments. Here I want to emphasise two of these developments in order to give an indication of the scope of the changes that will have to be accommodated. In the first place there is the question of subsidiarity, embodied in Article 3b of the Treaty on European Union. Although at this point not much can be said on the practical implications of subsidiarity, its general bearing on food law in the Community is clear. In spite of this reservation it should be emphasised that Article 3b does not rule out increased Community activity in areas where further policy coordination is necessary, which evidently can be understood to include food policy.

2. A European Food Agency

In the second place, as I have signalled above, and in the introduction to my draft directive there is the need for a European Food Agency. I am not proposing that this Agency itself should be established by the framework directive that is the subject of our current discussion, but the need for such a body is currently widely acknowledged. Such an Agency would have to be an politically independent, publicly accountable body. Its purpose would be to provide a practical solution to the political problems involved in formulating food law and the regulation of foodstuffs. Without assuming the competencies of the Commission, the Agency would

become a focal point in the discussion on foodstuffs regulation.

Concerning the likelihood of the emergence of a European Food Agency, it might be submitted that this proposal has come up time and again but so far has failed to receive support from the Member States. I would like to make some further observations on this. It should be noted that especially the new Member States do support the creation of such an Agency. For further illustration of the constructive attitude regarding the wider problems of restructuring food production in these countries (which after all contain the bulk of the farming population of the Community) I would also refer to the introduction of agro-environmental measures for example in Spain.

Finally, I want to draw attention to the changing role of the Common Agricultural Policy, especially, but not exclusively, in the context of the GATT Uruguay Round negotiations. As a result of these changes, for which the Blair House agreement and the McSharry proposals are emblematic, those aspects of the CAP that guarantee food quality risk being abandoned. As a consequence, food quality guarantees should form an essential element of the framework directive, and a central concern of the proposed Agency. At any rate, in the current fluid environment, the framework directive must be drafted so as not to stifle the possible future creation of a European Food Agency.

PRESENTATION OF A DRAFT GENERAL DIRECTIVE ON "FOOD LAW"

DIETER ECKERT*

Introduction

In my study addressing "the need for and feasibility of a framework directive on Community food law", I set out, among other things, to analyse existing Community food law directives and those Community food law directives under discussion. I have, in so doing, come to the conclusion that the general principles of a modern, forward-looking legislation on foodstuffs will for the greater part be implemented within the scope of future Community food law. This especially applies to the concept of preventive health protection, which is, for instance, reflected in the directives (or the proposals for directives) relating to additives and all kinds of undesired materials residues in or on foodstuffs.

In addition to this, I also pointed out that, even by today's standards, Community food law is closely regulated by many rules and provisions. Nevertheless, I held the view that a number of weighty reasons point in favour of a framework regulation on Community food law.

In particular, it is necessary to determine standardised definitions of terms and lay down common principles applying to substantive food law as to incorporate the existing and still to be promulgated individual Community provisions into such a general framework. Furthermore, in a common internal market, comparable rules of procedure must be adopted within the member states. This is especially valid with respect to the relevant measures taken by the public authorities and as regards the rights of those people affected by such measures. So much for the question of necessity.

The feasibility of such a project is decisively dependent on its being

* Professor of Law, University of Bonn, Germany.

limited to the essential food law provisions. Every other approach, especially one involving the incorporation of other provisions transcending the scope of Community food law, or an over-abundance of concepts regarding the policy on foodstuffs or health policy, would merely have a counter-productive effect on the whole process, if only due to the differences of opinion which would surely be forthcoming.

1. Objectives and Principles of EC Food Law

I see a realistic basic approach for a Community regulation in the communication issued by the EC Commission on "Community food law" on November 8, 1985. According to the latter, a Community framework regulation should be oriented to the following basic principles:

- limitation to the central area of substantive food law, *i.e.* to health protection, to the remaining field of consumer protection and to guaranteeing proper and appropriate consumer information;
- implementation of the principle of mutual recognition of non-harmonised legal provisions in force in the Member States;
- guaranteeing of the free movement of goods and fair trading practices on the basis of the aforementioned principles.

The possibilities and limits applying to a Community regulation based upon the EEC Treaty follow from the legal basis of Article 100a in conjunction with the general aims of Article 3 of the Treaty as extended by the Treaty on European Union.

In the study, with respect to the objectives of such a project, I held the view that a framework directive should be exclusively oriented to the needs of the Community. It thus cannot be a question of using such a directive to strive for a far-reaching harmonisation of the general food law provisions in force in the individual Member States. This, however, does not mean that an approach oriented on Community law might not lead to a basic restructuring of this legal field in several Member States which are presently still without a comprehensive system of food law.

A framework regulation on food law should, as far as possible, not regulate institutional issues. This also applies to the creation of new institutions, such as a European food agency, which is anyway a

controversial matter. In this connection it is, in my view, sufficient to implement the obligations contained in Article 23 of the draft I have submitted, concerning obligations to disclose information and furnish due and proper documentation to which the Member States or the EC Commission, respectively, would then be subject. As for the remainder, one should wait to see if the scientific cooperation between the Member States and the EC Commission, envisaged in Directive 93/5/EEC of February 25, 1993, leads to reasonable results.

Provisions concerning the process of Community legislation, such as rules on the participation of interest groups, should likewise not be taken up in a framework regulation on food law, due to their far-reaching consequences which go well beyond the scope of food law. The same applies to general provisions within the scope of substantive law, *e.g.* to provision relating to claims of damages *vis-à-vis* the administration in the case of unjustified intervention by the state or *vis-à-vis* the food industry on account of foodstuffs being unmarketable, or in the event that foodstuffs pose a risk to health.

The so-called due-diligence clause which has been brought into the discussion also transcends the scope of food law, since such a clause would have to apply to every action undertaken in the ordinary cause of business. Nor should the framework directive serve to harmonise the existing penal sanctions, not even in respect of determining maximum or minimum penalties. In this regard, a general obligation of the Member States to impose sanctions would, at most, come into consideration. Questions relating to guidance in nutritional matters should likewise not be addressed in the draft, especially since it is altogether doubtful whether the Community has, in this respect, any legal competence.

Another field which is problematical is that of the special food law provisions which serve to guarantee the high quality of foodstuffs. In this connection one must ask oneself which criteria for provisions beyond the regulations already embodied in Community food law should be applied. At most this would mean referring to the relevant European series standards and thus, among other things, would also mean promoting quality assurance systems.
Finally, I hold the opinion that rules on the composition of foodstuffs seen from the point of view of a healthy or high-quality diet are unrealistic, and also obstructive to innovations. They would doubtlessly prove to be

counter-productive.

2. The Draft Directive

I considered it important that I be fairly precise about which provisions should not be embodied in a Community framework directive on foodstuffs, since all the aforementioned points are presently being debated in conjunction with a Community framework directive, and because, as already mentioned earlier, it seems to me to be necessary to limit such a framework directive to the most essential factors in the interests of enhancing the directive's feasibility. However, such a limitation would, above all, also ensure the practicability of the Community food law provisions.

Before I turn to the draft in detail, may I draw your attention to the fact that the English version, as indeed the study and the explanatory note, contain a number of misleading translations which I cannot go into at present. Nevertheless I consider it important to point out that the frequent occurrence of the word "regulation" should in fact read "provision", so as to avoid confusion with the legal norm "regulation" as understood within the meaning of article 189 of the EEC Treaty.

The draft is subdivided into the following sections: field of application, general principles, definitions, health protection, protection against being misled and consumer information, duty to exercise due care, free movement of goods within the Community, terms of use and application and monitoring, possibilities of intervention on the part of the public authorities of the Member States, guarantees of recourse to the courts and the rights of those affected, Community procedures to avert health risks, movement of goods between Member States and non member countries and general rules and regulations.

Article 1 deals with the field of application, *inter alia*. Directive 92/59/EEC on product safety is declared to be inapplicable because a substantial part of the provisions it comprises does not take account of the special conditions applying to food law, and because there could thus also be inconsistencies between the provisions with respect to one another.

The rules of procedure contained in this directive, in as far as they are

applicable, have been incorporated in the draft. Among other directives, by contrast, Directive 88/182/EEC on information procedures is applicable in full.

Article 2 comprises, in a general way, the special purpose provisions which are binding for Community food law, namely:

- protection of the consumer against health risks and against being misled or deceived as well as guaranteeing proper product information;

- within the scope of this objective, guaranteeing of the free movement of goods as well as taking into consideration the vested interests of the business circles concerned and the needs arising in the fields of science and research;
- implementation of Community food law by the Member States according to uniform criteria and upholding the principle of subsidiarity;

- determining of Community procedures to avert health risks.

Article 3 comprises definitions of terms which are essentially oriented to the definitions of already existing directives or to the *Codex Alimentarius*.

Article 4, Paragraph 1 contains the general rule on protection against foodstuffs posing a health risk and against foodstuffs unfit for human consumption. By virtue of paragraph 2 the Community regulations on preventive health protection are incorporated in the directive, *i.e.* this concerns the regulations on additives, on certain procedures, on novel foods, on residues of all kinds, as well as materials and articles which may come into contact with foodstuffs.

Article 6 comprises the existing product regulations in force throughout the Community (*e.g.* cocoa directive, jam directive).

Article 7 contains, in paragraph 1, the general principles on proper and appropriate consumer information with express reference to the relevant Community labelling regulation.
Paragraph 2 contains the important general principle that even copy-cat foodstuffs or foodstuffs which do not conform to a legal or voluntary standard are not unmarketable *per se*, providing sufficient labelling is carried out.

Article 8 contains the duty to carry out self-monitoring procedures which may go so far as to set up quality assurance systems.

Article 9 incorporates the rulings of the European Court of Justice relating to the free movement of goods. At the same time an attempt is made to solve the still unsettled problem of the use of certain trade names. In this context, the country of origin of a foodstuff or its composition may have to be identified if the same or similar trade names are in use in different Member States. Under certain conditions it shall be possible to ban a trade name.

Articles 10 and 11 deal with the implementation of monitoring procedures. Special attention is drawn to the principle that the Member States are individually responsible for carrying out monitoring during the food manufacturing process in accordance with the principle of subsidiarity.

Article 12 specifies the possibilities of intervention which the Member States must at least dispose of for them to be able to implement the Community food law. These possibilities of intervention reach from issuing public warnings to destroying the foodstuffs in question. Worthy of special mention is the fact that very detailed rules have been laid down with respect to the sensitive issue of issuing public health warnings.

Article 13 contains the principle of proportionality regarding the means to be used. It has been decide that, as a rule, coercive measures are only to be used if an appropriate caution was of no avail.

Articles 14 and 15 lay down in detail the rights of the persons concerned. This applies in particular to the guarantee of recourse to the courts, to the obligation to substantiate one's case and to an appropriate cautioning of those concerned, instructing them about their rights; but is also applies to the revoking of unjustified measures, including public warnings.

Articles 16 and 17 regulate procedures to avert health risks where any matters arising in this field are referred to committee to committee proceedings on a case-to-case basis.

Articles 18 and 19 deal with the movement of goods between Member

States and non-member countries. Basically, foodstuffs that are imported must comply with Community rules and regulations.

Article 20 comprises the rules on the proceedings for the so-called regulation committee pursuant to version IIIa of the proceedings, as specified in the decision on terms if procedure dated July 13, 1987.

Article 21 is supposed to ensure that the certificates issued by the individual Member States attesting the marketability of foodstuffs take the shape of standard form certificates. This provision would doubtless gain considerable significance with regard to the practical implementation of the free movement of goods, especially since the Member States are made expressly accountable for the correctness of the certificates.

Article 22 is supposed to ensure a proper application of Community law by virtue of a constant flow of information on the current legislative situation and, if necessary, through the influence brought to bear on the executive authorities. A crucial point is certainly the inclusion of the courts in this process, although in this respect cautious wording was chosen.

For the further development of Community law, the knowledge of all relevant data accruing in the Member States is of crucial importance. Article 23 thus provides for an obligation to pass on information, to which the Member States are subject, and also prescribes the collection of such data as well as its evaluation by the EC Commission, in order that the Member States may be placed in a position which enables them to adopt the required measures.

Ladies and gentlemen, this overview of the draft concludes my presentation. I hope to have succeeded in conveying to you my opinion on the necessary and feasible contents of a Community framework regulation on foodstuffs, and that I have managed to make my draft more readily understandable. I thank you for your kind attention and patience.

Part II: Contributions

1. "Reasons and Objectives for the Conference"
   MR EGON GAERNER, CEC

2. "Some Reflections on the Crisis of the Harmonisation Model"
   DR RENAUD DEHOUSSE, EUI

3. "Social Regulation by the European Community: The Case of Foodstuffs"
   PROF. CHRISTIAN JOERGES, EUI/BREMEN

4. "Implementation and Effectiveness of Legislation"
   PROF. FRANCIS SNYDER, EUI

5. "Public Perception of Regulation: New Technologies in Food Conservation – Food Irradiation"
   DR BARBARA MARIA KÖHLER AND TATJANA STEIDL, WISSENSCHAFTSZENTRUM, BERLIN

6. "Economic Aspects of Technical Regulations"
   PROF. RUDOLF STREINZ, BAYREUTH

[1]

REASONS AND OBJECTIVES FOR THE CONFERENCE

EGON GAERNER

Introduction

Today's meeting at the European Institute in Florence, in a setting conducive to reflection and discussion, brings together those whose responsibility it is to draw up legislation on foodstuffs, be it at Community or national level, representatives of social and professional sectors directly affected by such legislation and experts from the academic spheres. In this opening statement I wish to address the following questions: Why are we here today?; What are the reasons for this conference and what are its objectives?

First of all, let me say that bringing together the architects, the practitioners and the experts concerned with food law - in the framework of a working seminar, with limited numbers, informally and free to express opinions - should enable us to build on these initial reasons and objectives. I firmly believe that receiving your contributions, ideas and suggestions on how to improve food legislation is one of the prime objectives of this conference. I would now like to set out briefly the reasons for this conference, and its objectives

1. Why hold this Conference?

The law is not a lifeless entity: on the contrary, it is highly dependent on technical, scientific social change. It is therefore essential that we identify the ways in which the law needs to change, especially at the present time when everyone is expecting the internal market to function smoothly.

There is no doubt that the general thrust of food law policy as drawn up in 1985 is still valid now, namely:

- Community harmonisation focused on essential requirements: health, safety, consumer information and fair trading;

- a horizontal approach ensuring coherence of legislation and its scientific basis.

Some thought should be given, however, to certain new elements, which are not at variance with existing factors:

- the essential aim of the policy conceived in 1985 in the revised White Paper was to construct the foundations of Community legislation for completing the internal market, without a precise idea of the problems concerning implementation and monitoring of the legislation, even though the revised White Paper made the need for State monitoring one of the essential requirements: this was a new departure in 1985;

- the Sutherland report and the conclusions of the Edinburgh summit at the end of 1992 stressed certain problems of lack of coherence in food law;
- the European Parliament also recently asked the Commission to pursue greater coherence and consolidation in provisions regarding food hygiene;

- negotiations within GATT and the *Codex Alimentarius* propose to define fundamental concepts in food legislation, which presupposes that the Community can defend a strong and coherent concept of its food law within these international forums. Here I should mention specifically the discussions in progress on the principle of regulations based on a scientific evaluation of the risk, on the definition of concepts for risk evaluation, and concepts for monitoring and certification;

- conditions for the production and processing of foodstuffs are also constantly changing: foods are processed to a greater degree, new ingredients are used, the influence of biotechnology, the major development of internal food quality control systems in industry.

Overall those professionally involved with foodstuffs are thinking about the quality of foodstuffs and implementing more and more internal quality control instruments, which is reflected in greater demands on their part

with regard to coherence, transparency and proportionality of the regulations;

- consumers, who are better informed and concerned about their health, want to have objective guarantees to give them complete confidence in the quality of foodstuffs.

Transparency and consultation in the implementation of regulatory decisions are of prime importance for them. High on the agenda also are means of increasing public awareness of scientific and technical developments and making more transparent the work of scientific experts which underlies the legal decisions.

The regulatory and monitoring authorities are changing also. This involves:

- accreditation of official laboratories for quality standards, taking account of risk evaluation systems, relations with companies based on greater confidence when the latter have introduced suitable internal control systems in relation to the regulations, greater cooperation between Member States and the Commission as regards scientific cooperation and official controls;

- finally, the major development of fields such as environment or nutrition calls for consideration to be given to how they link in with food.

There has already been a great deal of debate on many of these points and a number of Community instruments have been adopted (directives on official controls, directive on scientific cooperation, etc.);

However, we feel that it is particularly important to have an overall debate on the full range of issues and the guiding principles of food law.

Hence we have asked three leading experts to draft a directive reflecting the global approach to food law, and to present it to the conference.
For this reason we have also asked the European Institute in Florence to adopt an academic approach to these problems and give us indications on the best way to identify and overcome the obstacles and shortcomings.

Today and tomorrow we will be hearing contributions on the legal,

economic and social environment of food law, the various levels of regulatory action, the problems of coherence and proportionality, the technique in the legislation for taking account of risks and the conditions which provide the basis for the legitimacy of the regulations.

Here I would like to express my gratitude to Professor Snyder, who organised this conference on the university side with competence and enthusiasm.

We regard this academic contribution, much wider than our customary reflections, as vital groundwork for the more traditional consultations in the future with the Member States and the various players in the field of food legislation.

Having set out the reasons for this conference, let us turn to its key objective: to hold a full-scale debate on the guiding principles of food legislation.

2. Why Adopt a Global Approach?

Only a global approach will make it possible to overcome areas of difficulty and find the best solution to problems of coherence in food law.

(i) The definition of guiding principles and certain fundamental concepts will make for effective consolidation of texts in the field of food legislation.

Indeed, consolidation on guiding principles and common concepts is bound to be coherent by its very nature.

Such consolidation will also result in simpler texts which are more comprehensible and easier to apply, thus avoiding duplication and contradictions.

(ii) A global approach would make diversity possible while achieving coherence. In some cases (particularly risks, activities making tighter controls more necessary) specific regulatory schemes are necessary but it is essential to ensure their coherence and proportionality *vis-à-vis* the general approach.

(iii) A global approach ensuring the internal coherence of all food legislation will make it possible to defend Community law effectively in international negotiations.

(iv) A global approach would make for greater clarification and organisation of the role, rights and responsibilities of each player in the context of effective operation of the internal market. The structures of Community food law clearly show the various players, their roles and responsibilities:

- the European Community;
- regulatory and monitoring departments in the Member States;
- consumers;
- professionals;
- scientific experts.

(v) A global approach would make for better organisation of food law in relation to more general legal requirements as the basis of the legitimacy of all regulations, and thus the confidence of the public, in particular with regard to technological innovation.

Hence the following questions arise:

Is the principle of democratic debate embodied in practice in food law by the theoretically customary consultation of social and professional sectors and by consultation of the European Parliament regarding certain texts?

How are the principles of transparency and proportionality, or of scientific evaluation of risks, expressed in food legislation?

How does food legislation achieve a balance between apparently contradictory principles such as the right to health and safety, consumer protection and free competition.

This connection with more general principles on which society is based is especially necessary because it also makes it possible to delimit more effectively the sphere of regulatory action and procedures for action.

Finally, a global approach would ease interaction with related legislation,

such as environment and health legislation.

These are the reasons and objectives behind the organisation of this conference. Our role, however, is not to propose solutions. Above all, we want to have your ideas and suggestions, without formality, with the emphasis on exchanges of ideas and the freedom to voice opinions.

[2]

SOME REFLECTIONS ON THE CRISIS OF THE HARMONISATION MODEL

RENAUD DEHOUSSE

Introduction

In federal structures, the preservation of some degree of diversity is presented as one of the main reasons for the existence of a divided-power system. In contrast, in the European Community (EC) - a divided-power system of another kind - the emphasis has been laid on the approximation of national provisions, or harmonisation, as it later came to be known.

For a variety of reasons, some of which will be discussed in this article, harmonisation has been the main vector of Community intervention in a large number of areas. Why this has been so can be understood in relation to the main objective of the Community - the creation of a single market - and to the institutional context in which it had to operate. However, there are reasons to believe that the harmonisation model is now going through a crisis period, or even that the limits of its utility have been reached. Yet, systematic surveys of the harmonisation model, its place in the whole economy of the EC Treaty and its shortcomings have remained strikingly rare.[1] My (limited) ambition in the following few pages is to raise a number of issues which seem to deserve more attention than they have received so far.

---

1 See however Pipkorn, "Le rapprochement des législations à la lumière de l'Acte unique européen", 1 *AEL* (1990) 189 for a notable exception.

1. Why Harmonise?

Before explaining the reasons which have led to the current crisis of the harmonisation model, it is useful to try to briefly explain the reasons why harmonisation takes a central place in the functions carried out by the EC.

The primary goal of the Community was - and has largely remained - the creation of a single market, *i.e.* "the creation of an area in which goods, people, capital and services would move freely". To this end it is necessary to ensure that goods, persons, services, etc. originating from other Member states are not subjected to discriminatory treatment -- a concern underlying many provisions of the EC treaty.[2] But clearly, this does not suffice. The Community developed at a time when Member States had already equipped themselves with a set of provisions aimed at protecting their citizens' health and safety, be it in their capacity as workers, consumers, or simply as human beings with an interest in the preservation of their environment. Many of these provisions may impinge, albeit to varying degrees, on free trade, even when they do not purport to do so. To take but one example central to this symposium, rules on the quality of foodstuffs, even when they do not openly discriminate against foreign products, can hamper the free movement of goods: a ban on additives, for instance, may prevent the importation of goods produced in a foreign country where a less drastic prohibition exists.[3] The coexistence of distinct regulatory authorities, each with their own objectives, their own priorities, each endowed with different means of action and influenced by different administrative philosophies, can give rise to a variety of obstacles to trade.

Thus, one sees that diversity can adversely effect the creation of an integrated market. Trade wise, no problem would arise if all national regulations were identical, no matter how stringent or how lax. In such a context, harmonisation appears as a natural remedy: by harmonising national rules, one tries to remove differences which hamper free trade.

Two features of the Community approach to harmonisation are worth mentioning. First, harmonisation is primarily a legislative exercise: it is national laws that are being approximated. Secondly, it is a two-tier

---

2 See *e.g.* Articles 7, 30 and 59 of the EC Treaty.
3 Case 178/84 *Commission v. Germany* [1987] ECR 1227.

legislative exercise, as directives, which are the main instrument of harmonisation, are supposed to set objectives, but leave to national authorities "the choice of form and methods" with regard to implementation.[4] The specificity of this approach is highlighted when it is contrasted with that which has been practiced in other polities. In the United States, for instance, there has been a tendency to follow an administrative-type approach. Regulatory policies have been conducted mainly by specialised administrative agencies, acting under a general congressional mandate.

2. Why a decentralised Model?

Why such a decentralised model has been chosen in the EC is a matter for conjecture as the *travaux préparatoires* of the EC Treaty are not available. Still, a number of hypotheses can be advanced. Some have to do with the limited competences of the Community, others with the role Member States intended to retain in the Community policy process.

As far as competences are concerned, it is to be recalled that in principle, the Community, like all international organisations, has only been endowed with limited competences. The principle of attributed powers (*compétences d'attribution*), which was regarded as a general principle of law, has been enshrined in the Community constitution by article 3b, paragraph. 1, of the Maastricht Treaty, according to which:

"The Community shall act within the powers conferred upon it by this Treaty and of the objectives assigned to it therein."

As indicated above, the primary task of the Community was the creation of a common market; hence the emphasis on free trade in most of the Treaty. In contrast, the competence to deal with health and safety issues primarily remained vested with the Member States, and could even occasionally justify derogations to free trade principles.[5] The Community was given the power to act only if, and to the extent that, Member States' action hampers free movement. Article 100, for instance, provides that only those national provisions that "directly affect the establishment or the functioning of the common market" should be harmonised.

---

[4] Article 189 EEC.
[5] See *e.g.* Article 36.

Given this basic distribution of labour between the Community and the Member States, the harmonisation model presented great advantages. Community action aimed essentially at coordinating the behaviour of the Member States, rather than endeavouring to take away various responsibilities from them; hence, *inter alia*, the emphasis on directives, because of the margin of discretion they were meant to leave to the Member States. Compared to other regulatory techniques, harmonisation has the tremendous advantage of preserving many of the prerogatives of national administrations. The latter are still able to shape Community decisions, as decision-making largely remains a consensual exercise, in spite of the shift to majority voting in recent years. They also play a key role in the implementation process.

This power rationale is crucial to an understanding of the development of Community competences over the last few decades. National governments found it easy to accept an expansion of Community activities because of the power they enjoyed throughout the harmonisation process. One had a kind of positive-sum game, in which Community competences could be expanded without compromising too much of Member States' autonomy. In such a context, it is easy to understand the adverse feelings of many governments against proposals to delegate powers to autonomous bodies at a Community level, as this would deprive them of much of the control they enjoyed over the harmonisation process.

3. The Shortcomings of the Harmonisation Model

In spite of these obvious advantages, the harmonisation model suffers from a number of structural weaknesses. Decision-making, because it has remained a predominantly consensual exercise, tends to be a slow and cumbersome process, as a compromise must be reached among twelve national delegations, which are often influenced by diverging regulatory traditions. As a result, there is usually a considerable time-lag between the emergence of a new problem and the moment when a solution can actually be carried out.

Resort to a two-tier legislative process is also a source of considerable difficulty. The transposition of directives into national law often gives rise to huge bottlenecks, so much so that a Member State like Italy has felt it

necessary to delegate a general transposition power to the executive. Monitoring of implementation by Community bodies tends to focus on legislative transposition rather than on actual compliance, in spite of repeated commitments to pay greater attention to administrative practices. Gaps in the implementation then encourages a tendency towards over-regulation. Alarmed by the poor implementation record of their partners, which exposes their own producers to the competition of goods originating from laxer countries, some Member States have increasingly pushed for the adoption of extremely detailed directives, in the hope that this will help to ensure more uniform application.

Lastly, resort to a legislative technique can be ill-adapted to the objectives pursued by the Community. It is not always possible to anticipate in a legislative instrument the difficulties that will emerge in a given area and the responses they will follow. This is why health and safety policies often take the form of general objectives set in a legislative document, which also establishes specific procedures determining how upcoming problems will have to be tackled. Harmonisation of substantive requirements can therefore be insufficient to ensure uniform behaviour on the part of national administrations. Given the slowness of the decision-making process, it may also be insufficiently flexible: the adaptation of Community directives to technical progress has indeed notoriously proven to be difficult.

4. The Explosion of the Harmonisation Model

When combined together, these elements account for the emerging crisis of the harmonisation model. This crisis is manifested at the two levels discussed above: the competence level and the power level.

On the competence side, I have indicated that ensuring free trade was the main *raison d'être* of Community intervention, while the primary competence to deal with health and safety issues remained in the hands of the Member States. Yet, it is impossible to draw a clear line between these two levels, since divergence among national policies can create barriers to trade. An instrument like mutual recognition of national legislation, because it is exclusively concerned with ensuring free trade, can put health and safety at risk. If one insists on a strict application of the mutual recognition principle, Member States with high standards will be faced

with a dilemma: either maintaining their standards, or lowering them to avoid exposing their producers to competition from countries where regulatory policies are less stringent. Both solutions are unsatisfactory: the first one amounts to discrimination against their own producers, and the second can threaten the health of consumers, the safety of workers, or the quality of the environment.

Thus, it is only by integrating health and safety concerns in Community measures that these regulatory objectives can be reconciled with free trade. Though free trade concerns are at the basis of community intervention in the field of food law, for instance, health and environmental concerns play an important role as well. In other words, there is a tendency for the EC to encompass directives in its harmonisation objectives for which it was initially granted no explicit competence, which led first to a broad use of the generic powers granted to the Community by articles 100 or 235, and then to an enlargement of EC competences both in the Single Act and in the Maastricht Treaty.

In a similar fashion, Member States have come to realise that one cannot create a single market simply by harmonising substantive law. Divergences at the level of certification requirements, inspection procedures or product recall mechanisms, can create important obstacles to trade. This has led the Community to try to expand the range of its harmonisation activities, and to provide guidelines as to the means by which its directives should be given effect, including not only implementation mechanisms, but also potential sanctions as well as remedies to be made available. Occasionally, the Community has even been granted with the power to take administrative measures in order to prevent an uncoordinated reaction from the Member States.[6]

Conclusion

Though quite sensible in themselves, these two developments do threaten the stability of the harmonisation model, the very success of which was linked to the fact that it did not entail too radical an invasion of Member States' sphere of sovereignty. They have therefore elicited a strong

---

6 See *e.g.* the mechanism set up by the general product safety directive, OJ L 228 of 11 August 1992, p.24.

reaction on the side of national governments. The extraordinary success of the subsidiarity concept is a direct product of the expansion of Community competences, and some Member States have challenged the validity of Community attempts to intervene directly in criminal or administrative law matters.[7]

This is not to say that the above-mentioned developments must be regarded as illegal. Law being the science of imagination, as elegantly suggested by French playwright Jean Giraudoux, it is perfectly possible to construe the EC treaty in such a way that this evolution would be deemed legitimate. Much of the work has already been done by the European Court of Justice, with its rulings on Community competences[8] or on article 5. The real problem is rather of a political kind: the concept of attributed powers was a key element in the compact that presided over the setting up of the common market; calling it into question may undermine the legitimacy of the Community.

The Community is now at the cross-roads. On the one hand there are functional reasons to believe that the harmonisation model has become somewhat obsolete; one the other hand, the Member States – supported, it seems, by large segments of public opinion –, do not seem prepared to accept any substantial alteration of the balance of power between the Member States and the Community. The Community will therefore have to walk on a tight rope.

---

7 For a recent example, see the German challenge against the General Product Safety directive, OJ C 228 of 5 November 1992.

8 See *e.g. Commission v. Italy*, case 91/79, ECR [1980] 1099.

[3]

SOCIAL REGULATION BY THE EUROPEAN COMMUNITY: THE CASE OF FOODSTUFFS

CHRISTIAN JOERGES

1. Preliminary Remarks

The project of a general Community directive on food law relates to very general concerns that have attracted the attention of both lawyers and political scientists in recent years. Three issues of this debate should at least be mentioned:

1.1. Social Regulation

The protection of consumers against risks to health and safety forms part of the regulatory agenda of all Western societies. Foodstuffs law has a particularly long-standing tradition. The use of the term "social regulation" is only to remind us that foodstuffs law is undergoing changes that take place on a larger scale. Regulatory techniques are increasingly characterised by the introduction of scientifically based evaluations into regulatory decisions and by a refinement of pre-market and post-market controls.

1.2. The Institutional Structure of the EC

The term social regulation describes an activity that was not foreseen by the framers of the Treaty. The gradual emergence of regulatory policies at the European level therefore touches upon a broad scale of institutionally sensitive issues, such as the principle of enumerated powers, the attribution of administrative responsibilities to Member States, the delimitation of legislative and executive powers, the duties of co-operation under Article 5 and the principle of subsidiarity. This

background agenda has to be kept in mind when designing frameworks for a general Community foodstuffs policy.

1.3. The Emergence of a "European Fourth Branch of Government"

Regulatory policies have been entrusted in the United States and elsewhere to non-majoritarian institutions which are in a position to set priorities and define their programmes independently. One of the main issues ensuing from this interdependence is the search for an institutional framework ensuring political accountability, judicial control and the protection of individual rights. The growth of regulatory activities at the European level will initiate a similar debate.

2. Risks to Health as a European Policy Concern

2.1. The Internal Market Programme

The Community's internal market programme has been welcomed by most observers and criticised by others as a deregulatory move. In the meantime it has become apparent that the actual implementation of the internal market programme can be more adequately described as move towards modernisation and rationalisation of regulatory policies in Europe. This is undisputed for the whole field of technical goods and safety at work legislation. It is equally true in foodstuffs legislation where the Commission, already in its Communication of 1985, made it clear that its efforts would aim at a reorganisation of legislation rather than an abandonment of health protection.

2.2. The Interdependence of Market Integration and Safety Regulation

Although the legitimacy of the health protection objective of Community legislation is recognised in principle, the exact scope of the Community's competences under Art. 100a are by no means undisputed. In order to understand these disputes and their possible solutions, it is useful to point to some basic non-legal considerations on the indispensability of regulatory frameworks for the functioning of markets.

2.2.a. The Delegation of Safety Judgements

By its very definition, "food" is a means of survival. But it is equally true that risks to health cannot be detected and often not be judged by the consuming public. The assessment of safety thus involves an agency problem; the individual consumer needs to delegate safety assessments to some "agent" who has the expertise needed to take a responsible decision. The marketing of foodstuffs thus presupposes a response to this agency problem (the whole argument might as well be developed as an informational problem).

The consumer's "agent" need not necessarily be a public agency. Producers, trade and/or consumer organisations may all act in the public interest. But the agency relation is vulnerable. Its functioning depends on the consumers' reliance on the trustworthiness of his "agents" or, to put it differently, on the regulatory patterns ensuring the safety of food. This element of reliance or trust has to be taken into account both by firms and regulators. Its importance for the Community can hardly be over-estimated. Wherever the internal market objective necessitates changes of regulatory patterns, the Community will have to ensure the "trustworthiness" of the innovations it imposes.

2.2.b. Rationalising Regulation

Being confronted with different habits, traditions and regulatory techniques, the Community will have to promote solutions that rely on universally acceptable criteria. It cannot artificially reproduce patterns that have emerged within national societies and will therefore tend to resort to regulatory schemes that gain acceptance through their reliance on scientific standards. The strengthening of the role of the Scientific Committee, the furthering of risk assessment procedures and of quality controls within firms all fit into that pattern.

2.2.c. Strengthening the Autonomy of Consumers

The ECJ's Cassis-de-Dijon jurisprudence, the principle of mutual recognition and the restraints this principle imposes on national legislators all seem to reflect an anti-regulatory tendency. But the Community's deregulatory efforts are focusing on traditional (paternalistic) legislative

patterns which can hardly be defended as being indispensable means for the protection of health interests. The Community's tendency to substitute protective measures by consumer information policies can therefore be understood as a complementary development in the process of rationalising consumer protection. Both scientific evidence and consumer autonomy represent universally acceptable standards to which Community law can refer without interfering with, or getting involved in, culturally or historically contingent traditions of protection.

At this very general level the approaches taken by three *rapporteurs* are very much in agreement. They all place primary emphasis on the protection of health and they equally agree on the right of consumers not to be misled by improper information. Consensus is more difficult to achieve when health objectives are to be positively defined or when one tries to proceed from a negative definition of the right not to be deceived to a recognition of positive rights to information on nutritional aspects, production processes and environmental concerns.

3. Policy Coordination and the Level of Regulatory Activities: A Plea for Pragmatism

3.1. The Complexity of the Regulatory Issues

Health is an objective that can be narrowly understood or more broadly defined. Foodstuffs law does, for instance differentiate between different consumer groups and the specific concerns of infants and persons depending on specific diets. It could include general nutrition policy objectives such as the reduction of fat. It could, especially through labelling devices, support agricultural and environmental policies aiming at a reduction of the use of pesticides and even, as two of the *rapporteurs* suggest, the promotion of animal welfare. It will, on the other hand, be confronted with technological innovations and concerns for the competitiveness of the foodstuffs industry.

3.2. Tragic Choices

The debate on the objectives of foodstuffs law has two tragic choices that should be dealt with pragmatically.

3.2.a. Restricting Food Law Objectives

It is tempting to plead for a restriction of food law to health protection in a narrow sense and protection against misleading information. There is a broad Consensus on both objectives and legal techniques to implement them are readily available. On the other hand, public concern for nutritional policies and environmental issues will probably be growing. The Community may be faced with national initiatives furthering such concerns which then may create new barriers to trade.

3.2.b. The Expanding Objectives of Food Law

The demarcation line between health protection and long-term health and nutritional policies is not easy to define. Environmental protection is an objective that has to be taken into account in all policy areas. A broadening of food law objectives may gain wide public support and thus further the acceptance of Community legislation. On the other hand, expanding the objectives of foodstuffs law will provoke objections based on the limitation of Community competences. Furthermore, foodstuffs law can hardly take a lead in the furthering of environmental and other policy concerns.

3.2.c. A Compromise Formula

In view of the these difficulties the Community seems best advised to search for pragmatic solutions. A broadening of its food law objectives should be possible where there is consensus on specific regulatory objectives and/or techniques such as the protection of specific groups and consumer information. Informational polices could be coordinated with environmental and agricultural polices.

3.3. The Economic Implications of Health Standards

Stringent standards of protection impose costs on industry and consumers. The readiness to bear such costs depends on economic conditions and the importance attached by the public and policy makers to health considerations. The internal market objective, however, necessitates uniform standards of health protection. The Community's

decision-making process on health issues must to a certain degree be insulated against economic considerations. This is not to suggest that technological and economic considerations can be, or should be, completely eliminated. However, the credibility of Community law and the chance of arriving at a consensus depends on the readiness of giving priority to health considerations.

4. Institutional Issues: Towards a "European Fourth Branch of Government"

4.1. Achievements

The Community has quite successfully managed to overcome many of the institutional constraints impeding its regulatory activism. The clue to its success can be largely attributed to the functioning of its various committees which ensure the continuous cooperation of national administrations, the cooperation of societal actors, and, most importantly, the "pooling" of expertise.

4.2. Needs

The need to ensure scientifically based evaluations, to harmonise control techniques and administrative practices will undoubtedly grow with the perfectioning of Community legislation. The threefold tasks of "rationalising" social regulation, harmonising administrative practices and maintaining political consensus will in the long run require further institutional innovations.

Suggestions - Conclusion

One of the *rapporteurs* suggests that a European agency be established acting as an "independent publicly accountable body". This suggestion implies a gradual adaptation of the Community's regulatory frameworks to American examples. One has, however, to be aware of some fundamental differences of the European situation. All the European agencies which have so far been agreed upon have a consultative

function. (Even the EC Medicines Agency which comes closest to the American model does, at least formally, respect the regulatory responsibility of the Commission). Europe will have to live with a co-operative rather than a centralist model of social regulation. If one envisages a new European institution its competences and functions need to be carefully defined and probably be restricted to a "Food Policy Forum".

A more obvious step in the further evolution of the Community system would start from the existing committees and consider:

(1) the furthering of transparency of committee procedures;

(2) the improvement of judicial supervision of regulatory decisions;

(3) the strengthening of public participation and of political oversight by the European Parliament.

[4]

IMPLEMENTATION AND EFFECTIVENESS OF LEGISLATION*

FRANCIS SNYDER

Introduction

The problem of implementation and effectiveness of Community legislation is especially important in the foodstuffs sector. In the Commission's "Ninth Annual Report" on monitoring (1992), the foodstuffs sector emerged as the worst in delays in transposition of Community legislation. In 1991 the foodstuffs sector gave rise to 106 infringement cases, of which by July 1992 30 had been closed and 65 had seen reasoned opinions issued. Package meetings and Commission communications were the main instruments to resolve such problems. In 1991 the Commission held package meetings with France, Germany, Greece, Italy, Portugal, and Spain.

Against this background, my paper has two specific purposes. First, it considers what is meant by "implementation" and "effectiveness". Second, it reviews some of the principal means which are currently used to ensure the effectiveness of Community law, notably "soft law" and structural reform, or administrative cooperation between the Commission and the Member States.

1. The Challenge of Effectiveness

The deadline for the completion of the internal market passed at the beginning of 1993. Although the deadline was not legally binding, the mere fact it was stated in the Single European Act, and consequently in Article 8A EEC, focused a fierce spotlight on the effectiveness of

* This paper is drawn mainly from my article on "The Effectiveness of European Community Law: Institutions, Processes, Tools and Techniques", *Modern Law Review*, 56, 1993, pp 19-54.

Community law. This led to a concentration by politicians, administrators, judges, lawyers and academics on implementation, impact and compliance.[1] This in turn highlighted many achievements but also revealed numerous problems. The latter centred on the transposition of Community directives and national compliance with Community law, including Court of Justice decisions.

These concerns culminated in a Declaration on the Implementation of Community Law, annexed to the Maastricht Treaty. The Declaration enjoined Member States to transpose Community directives fully and adequately into national law within the specified deadlines; it also stated that, while Member States might take different measures to enforce Community law, these measures should result in Community law being applied with the same effectiveness and rigour as national law.

2. Effectiveness as a Policy Problem

The effectiveness of Community law is, first of all, an issue of public policy. The issue is not unique to the Community, yet the Community system has specific features. The implementation and the enforcement of Community law are carried out partly by the Commission, the Court of Justice and the Court of First Instance, but they are done primarily by the Member States through national administrations and national legal systems. The Community operates mainly by means of indirect administration, in which Community policies and laws, enacted by the Council or the Commission, are implemented by national authorities. These features pose specific problems with regard to the effectiveness of Community law.

Although commentators agree that the effectiveness of Community law has

---

[1] Beginning in 1985, the Commission issued periodic progress reports on the enactment and transposition of internal market legislation. Formal reports were also required under Art. 8b EEC. The Commission also issued occasional reports; see *e.g.* "National Measures for the Implementation of the White Paper on the Completion of the Internal Market: Situation as at 1.10.1990" (1990). Beginning in 1984, it has also made an annual report to the European Parliament on the monitoring of the application of Community law, of which the most recent are the Eighth Annual Report, COM(91)321 final (16 October 1991), OJ 1991 C338/1 and the Ninth Annual Report, OJ 1992 C250/1.

become increasingly problematic, it is difficult to evaluate the extent of non-compliance satisfactorily. Apart from the specific numbers, however, two types of non-compliance, or instances of the ineffectiveness of Community law, have a particular symbolic importance. First, it is clear that in the past decade the number and proportion of instances in which Member States fail to comply with a judgement of the Court of Justice has increased significantly.[2] As the Commission pointed out in 1989, "[t]his situation gives rise for concern as it undermines the fundamental principles of a Community based on law."[3] Secondly, there is the failure of Member States to transpose directives adequately or at all.

The Commission contributed a staff paper to the 1991 Intergovernmental Conferences, which canvassed potential sanctions to ensure compliance with the judgements of the Court of Justice and the effectiveness of Community law more generally.[4] The list included countermeasures against a recalcitrant Member State; financial sanctions, to be imposed by the Court of Justice in an action for failure to comply with a previous judgement of the Court of Justice;[5] and more explicit requirements flowing from Article 5 EEC. The paper also canvassed an extension of the jurisdiction of the Court of Justice, including (a) the power for the Court to take its own decision, with direct effect, on the measures needed to transpose Community law into national law, (b) the power to declare national law incompatible with Community law or to annul it, and (c) the power to issue injunctions. Finally, the Commission proposed recognition of the financial liability of a Member State towards persons suffering harm from the failure of the State to meet its Community law obligations.[6]

---

2 From 1989 to 1990 the number of judgments delivered fell from 94 to 77 while the number not complied with rose from 12 to 25: see Commission, "Eighth Annual Report", *op cit* n 1 at pp II, 102-119.

3 "Seventh Annual Report to the European Parliament on Commission Monitoring of the Application of Community Law - 1989", OJ 1990 C232/1, at C232/5. See also European Parliament Resolutions of 11 April 1984, OJ 1984 C127/67, and 19 March 1990, OJ 1990 C68/172.

4 "Commission Opinion of 21 October 1990 on the proposal for amendment of the Treaty establishing the European Economic Community with a view to political union", p 81; and 'Contributions by the Commission to the Intergovernmental Conference, (Document drawn up on the basis of COM(90)600 and SEC(91)500)', pp 151-155: both published in "Intergovernmental Conferences: Contributions by the Commission", *E.C. Bulletin*, Supplement 2/91.

5 See now Arts. 169, 171 EC, as amended by the Maastricht Treaty.

6 See now Joined Cases C-6/90 and C-9/90 *Francovich and Bonifaci v Italy* [1992] IRLR 84.

In addition to contributing to the formulation of Community policy, the debate on the effectiveness of Community law has had more general implications. On the one hand, it has confirmed the that the implementation and enforcement of law are often highly political, in the sense that they require the exercise of power and a choice between competing values. Consequently the debate on the effectiveness of law, which might have seemed initially to be primarily of a technical character, has led to a salutory discussion of the politics of law, and politics more generally, at Community level.

On the other hand, the debate has stimulated a renewed interest in the advantages and disadvantages, not only of the role of law in European integration, but also of different strategies and indeed different degrees of economic and political integration. The effectiveness of Community law, different forms of economic and political integration, and the Community's institutional integrity are seen increasingly to be closely related.

3. Effectiveness as a Theoretical Problem

The effectiveness of Community law must also be conceived as a theoretical issue. Effectiveness may refer not only to compliance but also to implementation, enforcement and impact. Although these terms are often taken to denote distinct phenomena, they may represent different perspectives on the same phenomena, and sometimes the meanings of the terms overlap. There is no universally accepted definition of these terms, in particular with respect to Community law. Nor is there much empirical research with regard to Community law on these topics.

A commonly used approach to the effectiveness of Community law is that of implementation theory. The political process is defined as "a process of problem-solving by the politico-administrative system."[7] This approach distinguishes between four phases: adoption, implementation (incorporation), application and enforcement. Based on the traditional hierarchy of administrative organisation, used in implementation theory, and the formal stages of the legal process in the Community system, it can

---

7 Siedentopf and Ziller (eds), *Making European Policies Work: The Implementation of Community Legislation in the Member States*, 2 vols. (London: Sage, 1988), n 9, p 3.

be extremely useful in analysing the effectiveness of law as a problem of policy, in particular in identifying points of non-compliance with hierarchically superior rules.

Yet, even as a means to identify potential solutions to problems of policy, this kind of approach has substantial shortcomings. Most importantly, it reflects the top-down perspective of the policy-maker. Consequently it tends to minimise the extent to which the implementation and enforcement of law, whether by administrative means or by courts, might involve processes of negotiation, in which the specific characteristics of the various parties concerned are extremely important. This feature is likely to be especially prominent, and hence the shortcoming particularly great, in systems with divided-powers such as the Community.

For our purposes, the effectiveness of law should be conceived of in relatively broad terms, so as to emphasise the social meaning of law as well as positive norms. The effectiveness of law is not easily contained within legal doctrinal or administrative categories. In every legal system there is a gap between law in the books and law in action. It would be remarkable if Community law were any different. It is important to concentrate on those gaps which are (a) especially problematic and (b) capable of being at least partially closed using the instruments available.

Let us begin by conceiving of effectiveness as including implementation, enforcement and compliance, defining implementation as "the process and art of deliberately achieving social change through law." This is sufficiently broad to encompass perspectives at different levels of a divided-power system. It also conceives of implementation as a continuous process, not as a fixed state of affairs. The implementation of law involves conflict, negotiation, compromise and mutual adjustment.

Compliance can then be seen as a series of reactive behaviours that often takes place within organisations, such as national administrations. Consequently, it is essential to take account of the priorities, structures, incentives and ideologies of these organisations. This concept of compliance focuses less on outcomes and more on ongoing negotiations, political and legal processes and organisational change. "Effectiveness" is taken to mean the fact that "law matters: it has effects on political, economic and social life outside the law - that is, apart from simply the

elaboration of legal doctrine."[8]

4. Soft Law

One of the instruments that the Commission has used most actively to address issues of effectiveness is "soft law". The expression "soft law" refers to rules of conduct which in principle have no legally binding force, but nevertheless may have practical effects. Such measures are frequent in Community law. For example, according to Article 189 EEC, recommendations have no binding force. However, the Court of Justice has held that national courts are bound to take recommendations into consideration in deciding disputes, in particular where they cast light on the interpretation of national implementation measures or where they supplement binding Community provisions.[9] Declarations annexed to the treaties are generally considered to be political statements, but they too may influence Community practice.

In using soft law, the Commission follows a practice which has been employed for some time by national administrations. To give one example, beginning in 1980 after the *Cassis de Dijon* case[10], the Commission developed the quasi-legal form of the communication. In its 1985 White Paper it announced an intention to make greater use of this device. In the Commission's view, the legal basis of communications lies in Articles 5 and 155 EEC.

Three types of communication have been distinguished: informative, declaratory and interpretative. Communications play an vital role today in Commission efforts to ensure the effectiveness of Community law. They identify what is settled and what is in dispute, circumscribe the arena for debate, and define the agenda for negotiation and, if necessary, litigation. In other words, they aim to provide guidelines for negotiating the implementation of Community law.

---

8 Snyder, *New Directions in European Community Law* (London: Weidenfeld & Nicolson, 1990), p 3.

9 Case C-322/88 *Grimaldi v Fonds des Maladies Professionnelles* [1991] 2 CMLR 265.

10 Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Brantweinn* ('*Cassis de Dijon*') [1979] ECR 649. For the Commission's interpretation of this judgment, see Commission of the European Communities, 'Communication from the Commission concerning the Consequences of the Judgment given by the Court of Justice on 20 February 1977 in Case 120/78 ('*Cassis de Dijon*')', OJ 1980 C256/2.

The process of making soft law bears a striking resemblance to the process of making Community hard law under the 1966 Luxembourg Accords, which crystallised a procedure founded on the lowest common denominator. Like Commission soft law, they expressed the dominance of the Member States in the Community legislative process.

The making of Commission soft law differs, however, from the enactment of hard law under the Luxembourg Accords in one crucial respect. Under the Luxembourg Accords the dominance of the Member States was manifested explicitly before legislation was enacted. In the making of Commission soft law, this dominance, though implicit, is manifested expressly only when a Member State contests an already "adopted" measure in the Court of Justice. This in itself confers advantages on the Commission, though perhaps only in the short-term. Commission soft law thus is enacted and operates in the shadow of Community law.

5. Soft Law, Subsidiarity and Legitimacy

During the last decade, Community institutions have resorted to soft law with increasing frequency. This trend represents in part a predictable feature of administrative development, in part a comprehensible response to institutional inertia, and in part a questionable attempt to circumvent or avoid the implications of failures to reach political agreement.

Already an important source of Community rules, Commission soft law is likely to have an even greater impact on the Community system in the future. This is so for two reasons. First, the Commission is being asked now to assume administrative responsibility for managing a broader range of matters, often in conjunction with the Member States. Yet its means of action remain relatively limited and are being increasingly constricted. In debates concerning the Maastricht Treaty, the Commission has frequently been criticised. Its already constrained right to initiate legislation has been eroded, formally as well as in practice. The same could be said of its powers to implement Community legislation. As a result of such factors, the Commission may be expected to favour soft law over hard law.

Second, an increase in the use of Commission soft law, and Community soft law generally, is likely to result from the debate concerning subsidiarity as provided in the Maastricht Treaty. This likelihood,

however, raises issues of fundamental importance in the Community system, especially with regard to relations among Community institutions. The emerging dilemmas can be illustrated by focusing on what may be called "the paradox of subsidiarity".

In October 1992 the Commission made a communication to the Council and the European Parliament. In its view, subsidiarity involved not only the concept of subsidiarity *stricto sensu*, namely the question as to who should exercise legislative power. It also embraced the concept of proportionality, that is, the question as to whether and how the power should be exercised. This interpretation has been accepted by the European Council.[11] Furthermore, the principle of proportionality has been interpreted by both Community institutions and national governments to give priority to measures which are not legally binding, that is, to soft law. As expressed at the December 1992 European Council meeting in Edinburgh:

> "The form of action should be as simple as possible, consistent with satisfactory achievement of the objective of the measure and the need for effective enforcement. The Community should legislate only to the extent necessary. Other things being equal, directives should be preferred to regulations and framework directives to detailed measures. Non-binding measures such as recommendations should be preferred where appropriate. Consideration should be given where appropriate to the use of voluntary codes of conduct."[12]

The concept of subsidiarity was proposed initially as one answer to the European Community's legitimacy crisis. The conjunction of these interpretations gives priority, however, first to efficiency, and second perhaps to legality, but to both at the expense of legitimacy. Hence the new paradox of subsidiarity. In its narrow formulation, the principle of subsidiarity, understood here in the sense of proportionality, is apparently intended to decrease the intensity of Community action. Yet it appears to lead in practice to the result that Community action, when taken, is

---

11 See Conclusions of the Presidency, European Council in Edinburgh, 11-12 December 1992, Annex I to Part A, "Overall Approach to the Application by the Council of the Subsidiarity Principle and Article 3b of the Treaty on European Union".

12 Conclusions of the Presidency, European Council in Edinburgh, 11-12 December 1992, Annex I to Part A, "Overall Approach to the Application by the Council of the Subsidiarity Principle and Article 3b of the Treaty on European Union", p. 9.

increasingly discretionary and is subject only with difficulty to legal controls. In its broader formulation, referring to its initial purposes, the principle of subsidiarity is intended to increase the openness and democracy of Community decision-making and hence of the Community system. Yet the way in which the principle has been interpreted may lead to implementation by means of an inter-institutional agreement, a singularly untransparent Community instrument. It thus may simply worsen the problem of legitimacy.

The priority to be given to soft law thus appears to form one of the guidelines for the application of the subsidiarity principle and Article 3b of the Maastricht Treaty. Especially when soft law is used by itself however, this appears to lead in practice to the result that Community action is increasingly discretionary and is subject only with difficulty to legal controls.

6. Structural Reform

A second more general technique by which the Commission tries to ensure the effectiveness of Community law is structural reform. Structural reform means the reform or reshaping of legal, economic and political structures, including those of the Community or the Member States. It is a type of social, usually institutional adjustment, involving the reallocation of power. In the Community setting, such reforms are likely to affect the distribution of power between the Community and the Member States, among Community institutions and among various parts of the national governmental systems.

Structural reform may be undertaken by the judiciary, the administration or other parts of government. In the Community structural reform has more often than not occurred by administrative means, in particular by relations between bureaucratic organisations. Such relations have been referred to variously as bureaucratic interpenetration, structural coupling, or inter-organisational exchange. In Commission jargon they are now often called *parténariat*.

The general legal framework of structural reform by administrative means is the duty of Community loyalty or principle of sincere cooperation, the so-called "fidelity clause": Article 5 EEC, which applies both to the

Commission and the Member States. For the Commission this means that it is required to give active assistance to the national judiciary acting in the prosecution of offences under Community law. Refusal by the Commission to disclose documents which might otherwise be confidential or to permit officials to refuse to give evidence in national proceedings would breach Article 5, unless they were based on an order issued by the Court of Justice.

The "fidelity clause" affects the participation of the Member States in four different ways. First, Member States may have a legal duty, to consult the Commission, if there is any doubt as to whether a national measure is contrary to Community law, in order to avoid the risk of infringing Community rules. Secondly, Member States may have a duty to provide information the Commission believes it needs and requests. Thirdly, the Commission and the Member States have a reciprocal duty of cooperation in the Community sphere, that is, "when Member States are implementing Community measures or policies, are acting on behalf of the Community, or are using powers which are regulated by the Community."[13] Fourthly, Article 5 may conceivably be invoked to prevent a Member State from insisting on "linkage" between unrelated measures in Council discussions.

A similar rule might apply to negotiations in the form of inter-organisational exchange. Some forms of inter-organisational exchange are initiated by the Commission, acting on the basis of Articles 4 and 155. Current examples include dialogue with Member States in the preparation of transposing legislation, sectoral or "package" meetings, and horizontal meetings between the Commission and national administrations to review progress in the application of directives. Also important are exchanges of staff between the Commission and national departments responsible for applying Community law. Inter-organisational exchange is not necessarily limited, however, to national administrations.

Neither the fluidity of the setting nor the importance of negotiation, however, serves to expand the legal power of the Commission. As a technique for ensuring the effectiveness of Community law, these types of structural reform are largely incremental. There are forms of inter-organisational exchange which are broader in scope, often initially

13 Temple Lang, "Community Constitutional Law: Article 5 EEC Treaty" (1990) 27 *CMLRev* 645, at 655.

unforeseen or even unintended. The most striking examples are the changes in national administrations which have resulted from the practical requirements of Community membership.

These changes can be grouped into five categories. First, Community membership has led in some countries to changes in the relationship between the executive and the legislature. Secondly, Member States with divided-power systems have had to reconsider, and sometimes clarify, the constitutional allocation of powers with regard to the enactment, transposition and implementation of Community law.

Third, Community membership has required all Member States, not only to establish representatives in Brussels, known collectively as COREPER, but also to maintain continuing links between COREPER and national administrations. With the increasing development of the Community, these links have tended to give less prominence to ministries concerned with general diplomatic matters and more to technical ministries. Fourth, special administrative bodies dealing with Community matters have been established, special sections within some existing departments have been created and the substance of work in numerous departments has changed. Fifth, in virtually all Member States Community membership has led to the development of mechanisms to coordinate participation in the making and implementing of Community law.

For both the Commission and national administrations, structural reform serves useful purposes. The Commission is able to fulfil its functions only by entering into relations with national administrations, and vice versa. For example, each needs clients (*e.g.* national administrative support for Commission proposals), labour services (*e.g.* experts of different types) and other resources (*e.g.* information). Indeed, despite continuing problems concerning the delineation of organisational domains, whether in terms of legal competence or political terrain, such inter-organisational exchanges have become indispensable, both to segments of the Commission on the one hand and parts of national bureaucracies on the other.

In addition, inter-organisational exchange has been concerned increasingly with the effectiveness of Community law. Recent Commission monitoring reports note that "contacts between Commission departments and national authorities concerning the implementation of Community law have been

stepped up."[14] As the Commission pointed out:

> "Beyond the formal incorporation of Community directives into national law, there is the problem of how the rules are actually applied by the national authorities. Private individuals very rarely come into contact with Community law or the Community authorities, such contacts generally being established via national legislation or a national department. It is for this reason that consistency in application is important. As this is a matter of administrative practices rather than of legal rules, consistency can be guaranteed only by exchanges of experience. This was the approach adopted by the Mattheus programme in the customs field, and it is an approach which the Commission proposes to extend to other areas covered by a body of Community rules."[15]

In such exchanges the meaning of compliance - the effectiveness of Community law - is negotiated or "constructed" by the Commission and its national counterparts. At the same time these negotiations contribute to the gradual reshaping of both Community and national institutions.

Conclusion

The Commission has sought to ensure the effectiveness of Community law mainly by the process of negotiation. It has relied essentially on three tools: the Article 169 EEC procedure (not considered here), soft law and structural reform. These tools are all best viewed as different forms of negotiation. Among them, however, structural reform has assumed a special significance.

For three reasons, this should not be surprising. First, the increasing role of the Member States in the Community system has constrained the Commission, with the result that the other tools available to it are relatively ineffective or increasingly fragile. Secondly, the effectiveness of Community law, like its making, depends primarily on negotiation. Of all the tools used by the Commission, structural reform represents negotiation in the purest form. Consequently, and thirdly, structural reform seems to be the most appropriate tool for dealing with problems of effectiveness which

14 "Seventh Annual Report", *op cit*, n 3, p. C232/6; "Eighth Annual Report", *op. cit.*, n.1, p. iv.
15 "Seventh Annual Report", *op cit*, n 3, p. C232/7.

result from recalcitrance or administrative incapacity.

But administrative negotiation as a means of ensuring the effectiveness of Community law also has shortcomings. First though allowing potentially for a broad representation of interests, it may be limited in practice to those subjective interests expressed by governments or by powerful organisations. Hence it may tend to favour objective interests which are crystallised in everyday assumptions or which are embodied in largely implicit, organisational constraints.

The same generalisation may hold true of courts, though the use of courts by weaker parties to assert their interests in the *Francovich* case is instructive. In the process of administrative negotiation, however, the risk that other interests may be neglected is increased by the lack of publicity, the informal nature of any agreement and the relative lack of procedural safeguards. Secondly therefore, litigation, soft law and structural reform need to be assessed, not simply as part of Commission strategy for implementing Community law, but also with regard to the effectiveness of Community law in the broad social sense, including its legitimacy.

Third, the use of structural reform as a means of increasing the effectiveness of Community law must also be assessed at a more general level. The increasing inter-penetration of Community and national administrations risks accentuating an already great orientation in the Community towards administrative means of policy-making, techniques of problem-solving and political culture.

Political choices have often been treated as if they were ideologically neutral. It has been argued recently that the Community has already ventured too far down this road. Regardless of the merits of this argument, it is crucial - for citizens, national governments and the integrity of the Community itself - that political values be expressed in the Community system and at the level of the Community. For this reason, it is imperative that soft law and structural reform not be the only, or even the principal, means of ensuring the effectiveness of Community law.

[5]

PUBLIC PERCEPTION OF REGULATION: NEW TECHNOLOGIES IN FOOD CONSERVATION - FOOD IRRADIATION*

BARBARA MARIA KÖHLER AND TATJANA STEIDL**

Introduction

When discussing the reactions of the public towards regulation, it soon becomes clear that quite different concepts of the public have to be considered. In the first place, there is the public as consumers and participants in the market, expressing their opinion in market decisions. It is of interest here how these market decisions aggregate in reference to choices of the past, that is sales data, and in reference to the future, or sales prognosis with all its methodological problems. In the second place, there is the public as reflected in opinion surveys. Again, the validity of this information is limited, both by the way in which questions are posed as well as by the fact that attitudes, intentions and actual behaviour often diverge and are of course subject to change. In the third place, there is the public as represented by interest groups, consumer associations, environmental groups and other social movements. They do not, however, represent the entire public, although a very outspoken and usually well informed part, and, as far as consumer associations in Germany are concerned, they enjoy trust in specific questions and can be considered to be opinion leaders for the more general public. In the fourth place there is the public as it is reflected in the media, and finally, the public as a political agent electing its representatives, who act directly. These actions

* Parts of this paper are based on a study published in 1992: Barbara Maria Köhler, Tatjana Steidl *Gesellschaftliche Regulierung nahrungsbezogener Gesundheitsrisiken - Die Konservierungstechnik Bestrahlung von Nahrungmitteln* (Wissenschaftszentrum Berlin, 1992) at 92-212.

** Mailing address: Wissenschaftszentrum Berlin für Sozialforschung, Forschungsgruppe Gesundheitsrisiken und Präventionspolitik, Reichpietschufer 50, 10785 Berlin.

reflect in some way, but certainly not in every detail, the anticipated wishes of the manifold public.

Regulation of the irradiation of food was a process that not only involved policy makers and the public in its various forms, but scientists and trade and industry as well. The relationship between these social actors changed over the many years of this process. Central to all discussions of the introduction of this technology was the discussion of health risks, but this was by no means the only aspect that interested the public. The discussion of risk revolved around two core issues: Is this a technology able to solve nutrition related problems? And: Is there a health risk involved in the use of the technology itself? Actual societal practice (regulation) as expressed by usage of the technology as well as state rule setting does not correspond to the answers agreed upon by major parts of the scientific community, who had declared the technology to be without health risks to the consumer if applied in a prescribed manner.

But neither societal use nor governmental rule setting have followed this recommendation. With the exception of the Netherlands, no other government has so far permitted the unrestricted use of this technology. Internationally, states have adopted a wide range of regulations in respect to specified foods. The Netherlands granted full permission to use the technology up to 10 kGray in 1980, but withdrew this permission later. By contrast, irradiation of food is forbidden in the Federal Republic of Germany up to the present day. As for societal practice in other countries, as far as we could tell, industry has not even exploited the permissible regulations. For an explanation of this under-utilisation, reasons of relative cost or marketing restrictions which followed from differing rules in export markets have been given, for example in the Netherlands.

1. The Policy Making Arenas

The divergence of international regulation in contrast to scientific recommendations calls for an explanation. Using document analysis and expert interviews as research tools, we investigated the precedents of legislation in just one country, the Federal Republic of Germany.

Our findings can best be summarised or explained by an arena model of

successive decision making[1]. An arena is an assembly of actors, taken to be representatives of interest groups, although at some times they represent only themselves, and at others they represent institutionalised interests. These actors use all means at their disposal to shape and form a decision or series of decisions on an issue in the direction of desired outcomes. Important questions are how actors are accepted into an arena, how they are able to place issues of importance to them on the agenda, and under what condition arenas see their importance ended or reduced.

The three arenas we identified were successively:
- the international policy community;
- the international scientific community;
- and the national public arena in the Federal Republic, including its political representatives, in the early eighties.

The three arenas did overlap in time, but roughly followed each other in the course of the last forty years. Outcomes in each of these arenas set the stage for the succeeding arena with different actors, issues and decisions.

Let us, first of all, outline some of the issue/actor shifts in this process, or series of identifiable arenas. The influence of consumers or of the public is discernible particularly in the last one, but also in the first. In each case, we note that actors follow their own rationality, but each actor reacts to that public which they consider their legitimate audience.

First, there was a long phase during which very few persons seem too have been interested in this technology. Although it is true that after the action of radiation on living tissue became known at the end of the last century, the economic potential of this scientific finding was quickly recognised. Patents were taken out for food sterilisation as early as 1905. Irradiation of food however did not develop into an industrial technology at that time. This raises some interesting questions on the social and economic conditions for technological development which are also of importance for the relationship of risk and utility and its distribution between consumers and economic actors, which has formed an important aspect of the debate that took place in the Federal Republic at a much later date.

---

1 'Arenas' are political science constructs which have been used in the explanation of a large number of policy making processes.

The second phase saw a dramatic change in the availability of the technology, and a new, non-civilian, military market opened up. Nuclear technology and expertise were developing especially in the US, and the second world war had created new markets for goods of long duration especially for the military. As with all war related research, potential spin-offs for the civil sector were of considerable importance in discussing expenditure for military research in the US[2], in order to maintain the support of the public. In addition, the military sponsored research in this promising technology on a vast scale, in order to solve certain logistical problems. Research results however, did not fulfil their earlier promise and left many practical problems unsolved. As a result both the military and the food industry in the US lost interest in food radiation[3]. Meanwhile, the research activities in the United States and the US-Government programme "Atoms for Peace" had set off parallel research activities in other countries.

2. The first arena, the third phase. About 1950 - present

Moving into the third phase, we discern the first arena of that is of interest to us, the international policy arena, consisting of large intergovernmental agencies: The International Atomic Energy Agency (IAEA), the World Health Organisation (WHO), the Food and Agriculture Organisation (FAO), the Organisation for Economic Cooperation and Development (OECD), and the member states of these organisations. On the agenda were the peaceful uses of atom technology, the destruction of food resources by pests and deterioration, the solution to the world hunger problem and its health consequences, and the development of a new technology with a high economic potential. We will not go into the divergent interests between these organisations except to say that an early result of their joint interest in the application of this technology was the initiation of research among their member nations, and in 1964 the IAEA, WHO and FAO set up a Joint Expert Committee on the Technical Basis for the Legislation on Irradiated Foods (JECFI).

---

2 Other examples are antibiotics, medical techniques, for example in the treatment of burns, and new materials.

3 Urbain, in *Adv. Food Res.* 1978(24), at 156.

3. The second arena, the fourth phase. About 1964 - 1980

As a result both of the research in the US, and the activities in the international policy arena, a different arena develops, that of the international scientific community in that particular research area. This scientific community consists of researchers in governmental organisations and academia. Strangely enough, industrial research in the food industry seems to have been largely absent at this time. This is rather strange in a technology that was claimed to be so close to industrial application even then.

The scientific community has its own agenda and well established rules for decision making, its experimental procedures to follow as well as rules for the interpretation of results. Nevertheless, surprisingly enough, controversies developed over the scientific value of this or that finding. Some questions appear to be unanswered even today, for example that concerning the long term health effects of the consumption of irradiated food. Some research questions from the previous arena were not even tackled, such as establishing a comparative cost/benefit-analysis of combating hunger by this technology or by other means. Nevertheless, the Scientific Community does have its ways to settle certain controversies, and we will just give one example: JECFI at first developed standards of procedure to establish health effects of irradiated food[4], based on the model of existing test procedures for food additives. When it became clear that testing for the effects of each of the many chemical components developing at different irradiation levels in various kinds of food turned out to be impracticable, an interesting paradigmatic shift took place within the scientific community. It was decided to consider irradiation as a method for food treatment instead, and to test irradiated food as such for physiological effects on animal populations[5].

In 1970, an international research project was set up by the international policy actors OECD, FAO and IAEA, with a number of 19 participating states, that had increased to 24 by 1979[6]. One of the German federal research institutes on nutrition (at Karlsruhe) became the international

---

4 Joint FAO/IAEA/WHO Expert Committee (1965) The Technical Basis for Legislation on Irradiated Food. Report of the Meeting 21-28 April 1964, Rome.

5 We do not pass judgement on the value of this paradigmatic shift.

6 Diehl, in *Radiat. Phys. Chem.*, 1979(14), at 117-125. Compare the same author in: *Neue Züricher Zeitung*, 29.5.1991.

secretariat of this project. At this institute, research on food irradiation had been started in 1955.

After having proposed the wholesomeness of irradiated foods in previous years, in 1979 JECFI announced that irradiation of food did not present a health hazard. This announcement led to recommendations of the *Codex Alimentarius* Commission of the FAO/WHO on available food irradiation techniques and on standards of food irradiation (1983). Germany and Austria voted against these standards, although the relevant Commission of Federal Research Council (DFG) had accepted the non toxicity of the irradiation procedure[7].

Although major parts of the scientific community apparently agree today that the application of this technology would not endanger the consumer at least in the short run, the government of the FRG decided not to permit this technology. In the first place there were important voices within the scientific community of Germany that continued to express their dissent. Furthermore there were some experts in the German scientific community who took the trouble of a developing broader risk versus utility assessment than most other scientific bodies had done before. Thus, the Advisory Committee on Health Matters to the Federation (*Bundesgesundheitsrat*) arrived at much more prudent conclusions. It stated that existing technologies served quite well to decontaminate food.

As for other uses of food irradiation, for example to prevent sprouting in vegetables, it would have to be shown in each particular instance that this technology was more suitable than others and that it did not endanger health. Only on irradiation of spices, carriers of large numbers of germs on the one hand and a very small part of everyday food on the other, were recommendations more lenient. It should also be mentioned that in order to safeguard against imports from other countries where radiation was permissible, research on methods of detection was financed. Eventually, this led to the development of two such methods which were recently standardised for use in food control. However it was probably not the prudent view of the *Bundesgesundheitsrat*, but the events in the third arena which had influenced government to take its strict position on irradiation.

---

7 Compare "Bericht der Bundesregierung über die Behandlung von Lebensmitteln mit ionisierenden Strahlen" *Bt.-Drs.* 11/7574 of 18.7.90, at 5.

4. The third arena. The beginning of the eighties up to 1990.

Finally, at the beginning of the eighties, the public arena around food irradiation developed in the Federal Republic. We identified as potential actors the food industry and food distributors, the atomic energy industry, the consumers as represented by consumer associations (and in close interaction), and finally, political parties in parliament, and government[8]. Some representatives of the scientific community from the last arena engaged in the debate on the various issues that were taken up here.

Although up to that time consumer associations and environmental groups had followed the research results and legislative endeavour and had developed an opinion on these issues, it was particularly a series of events during 1983 that brought the issue of food irradiation to the attention of a larger public. These events were:

- an International consumers meeting on the topic of food irradiation that took place in the Federal Republic;

- the favourable recommendations by the *Codex Alimentarius* Commission;

- the prudent vote by the Advisory Committee on Health Matters to the federation (*Bundesgesundheitsrat*);

- a Dutch company was allowed to irradiate food within Germany, albeit only for export.

These events met a population much aware of questions related to food and food quality and its changes through technological modernisation of food production in agriculture and industry, which had become an important issue in the seventies in Germany especially among the younger, well educated generation. At this time food additives and pesticides and their role for health were popular issues. And there was another issue: The uses of radiation, which for many were still associated with the spread of nuclear technology and the nuclear disarmament movement, rather than for example with the use of X-rays, which is the other major use of radiation

8 Apart from conducting document analysis and expert interviews, we also analyzed media reports on controversies.

that the public experiences in everyday life. At the time, the Green movement had just entered parliament with a small but very active faction, and the older parties were taking up some of the environmental issues which made the Green movements so attractive to many voters.

This was the stage at which the public began to discuss the irradiation of food. Both the Consumer Union and health food shops (Reformhäuser) had started petitions against the use of irradiation for food, and the large number of signatures from their clients made it apparent that irradiated food would not be well received by consumers[9]. A 1984 survey carried out by an Association of the Food Industry (BLL) showed that 65% of the consumers would not buy irradiated food if so labelled, and other surveys during the eighties confirmed these results.

During this period, irradiation became a frequent topic in the media and our analysis shows that although both pro and contra views were reported, the opponents were more successful in making their arguments heard.

Public debate was paralleled by activities of the Green Party, then represented in the federal parliament. Its members pressed government hard for information and placed new questions on the agenda as well. To give just one example, when the argument of relative risk was used in comparing decontamination either by radiation or by the use of ethylene oxide, the Greens raised the demand that other methods of food decontamination should be studied more closely, and developed for industrial application.

The debate on food irradiation that took place in the media during this period took up arguments on health which had not been resolved to the satisfaction of all actors in the previous arena. Some of the other issues involved were:

- how reliable are experts in their scientific findings, which apparently can be interpreted with different conclusions depending on the institutional adherence of the expert (such as the health issue)?

- how is the quality of food affected (taste, smell, palatability) and other qualities which the consumer cannot detect prior to buying the food (loss of vitamins, loss of nutritional value)?

---

9 *Bt.-Drs.* 11/7574 of 18.7.90, at 10.

- does this new technology represent a move away from the natural and the familiar, away from the desirable immediate relationship between man and nature, making man dependent on a technical environment?

- how could the use of this technology be controlled, given that no tests were available at this time?

- and, if the technology was to be accepted at all, to what degree should the consumer be informed?

This development of public opinion seems to have been fairly stable and to have had an impact upon other actors in the arena. Given the strong opposition shown by surveys, the second actor, the food and food distribution industry, has apparently not pushed strongly for permissive legislation. Since the consumer market was considered more or less closed, the official viewpoint seems to have been that irradiation would only be of interest in the absence of an obligation to declare its use[10]. We do not know what the present opinion of the food industry is, but there are indications that irradiated raw materials have been used in the past and will probably continue to be used in the future depending on European legislation on this issue. Following a request of one of the consumers associations, in 1990 some companies have issued a declaration that they would not use irradiation even if this would be permitted by the EC[11]. Most of these companies did not form part of the health food movement, and there were ordinary supermarket chains and large producers among them.

Another actor in this arena is the nuclear industry. It has favoured food irradiation, since this offers secondary uses for its nuclear waste and by-products (although food irradiation by accelerator and by Co-60 do not use spin-offs from nuclear industry). Apparently, using exhausted fuel elements directly or even extracted Cs-137 is of economic interest, the latter being widely used in the US. Experiments on the use of exhausted core materials have continued.

The federal government has not permitted food irradiation, although it has

10 Kume *et al.*, in: *Radiat. Phys. Chem.*, 1989, at 973-978.
11 Köhler and Steidl, *op. cit.*, at 80.

continued to invest in research on food irradiation technologies, food irradiation testing, and into questions on the quality of irradiated food and of health consequences. Food irradiation was prohibited in 1959, with exceptions to be granted under strictly controlled conditions. Following public opinion, this ban has not been lifted to the present day.

Why has the German consumer reacted against food irradiation so inflexibly even after the scientific community appeared to consider that health considerations had more or less been resolved? In the interviews we conducted we were given two answers to this question. On the one hand, there is the belief that German food law is stricter than that of other countries, and protects the interests of consumers concerning the proper treatment of foodstuffs. On the other, there is a special sensitivity among large parts of the German population towards all questions related to nuclear technology, nuclear power, and irradiation.

It is assumed this dates back to the large antinuclear movements of the seventies, and environmental groups as well as the consumer associations have linked these issues. Resistance against nuclear power plants that developed into a widespread movement in the seventies left behind a general climate hostile against nuclear energy. Proponents of irradiation expected that opposition would lessen over time, but this hope was destroyed by the fall out of the Chernobyl accident. A comparison of public opinion to Chernobyl in West Germany and France, where public opinion in general is much less negative on the issues of nuclear power and food irradiation, reveals considerable differences between the two countries.

The most prominent arguments of the opponents to food irradiation in Germany are related to health, while discussions of its utility, its environmental effects and the effects of the use of radioactive sources in the workplace, were less prominent. Shifting the debate to health, consumers try to use this as the sole legitimate basis for irradiation control. This is not a correct approach. It is in the nature of scientific decision making that there cannot be a definite declaration of safety for irradiated food. Yet elements of uncertainty remain concerning other methods of food conservation as well, including some that have been in use for considerable time. The experts we questioned were of the opinion that food irradiated in accordance with permissible standards was safe to use, even when they submitted other reasons to be critical of the introduction of this

technology. Experts obviously place a different emphasis on the various criteria than the general public.

Returning to these arguments, we note that the irradiation of food is only one of the uses of irradiation technology. We also find that food irradiation does not really solve any of the problems it was designed to do. It does not solve the problem of world hunger, and there are other techniques which are just as useful in conserving food. Especially the last point has been taken up by consumers and should in our opinion be weighed in decisions about new technologies in the food sector. There should be an assessment of negative and positive expectations and their chances of realisation (risks and utilities) in relation to the criteria that all of the parties concerned consider relevant.

Health - in the sense of no observed negative effect - is a necessary but not a sufficient criterion. Consumer rationality does not consider food solely as an economic entity: the consumer does not apply the rationality of *homo oeconomicus* but sees food in a wider context. These rationalities are as important as introducing a technology which does nothing but to prolong the period during which an item of food is acceptable as a commodity in the market, by a treatment designed to avoid problems that arise from the application of economic rationality - long storage and transport in a market anyway characterised by overproduction, with the side-effect that consumers become more dependent on the signs and symbols of a technical world at the expense of the sensual capabilities that are part of his culture.

The public does not view food from the point of view of health alone, and in our opinion it is right in doing so. That food should not be harmful is a basic precondition, "the least you can expect", so to speak, but nothing more. Eating is the most intimate exchange between man and nature; eating arrangements, food and its preparation are filled with cultural connotations, marking and defining the relationship between individual and society. When such strong symbolic notions are tied to food, it may be considered entirely rational for the public to protect their meaning. From this point of view, it would simply be inadequate to make health the one and only yardstick for legal decisions on food.

Conclusions

Can any conclusions be drawn on a definite process of legitimation for foodstuffs regulation at the Community level? In the radiation issue, the outcome in each arena set the frame for the following one, without however determining its outcome there. Thus, "Atoms for Peace" and the international policy arena set the agenda for the international research community to look for applications and determine health risks. Once this issue had been settled, the declaration of safety formed the starting point for the public arena in the Federal Republic. The results of the debate in Germany demonstrate that unexpected outcomes may develop because actors in different arenas may have other frames of reference, other sets of values, other interests, and will therefore raise different issues. The process of conflict resolution then leads to *equilibria* that are unexpected in view of the decisions and conclusions reached by previous arenas. When we apply these findings to future regulation in the European community, we are surprised to learn that at this level consumer arguments are supposed to be limited to health issues and fraud. Instead the opportunity to bring forward other concerns that relate to food should be strengthened and institutionalised.

[6]

ECONOMIC ASPECTS OF TECHNICAL REGULATIONS

RUDOLF STREINZ*

Introduction

In the context of the conference on the drafts of a proposal for a general food directive, I am very glad to contribute my statement on the topic "economic aspects of technical regulations". As it is my profession it will be a lawyer's point of view - but it includes the economic dimensions of the law, *i.e.* the consequences of legislation - or, in a broader sense, regulation - for the foodstuff industry and the distribution, and for the consumer. In order to widen my approach I sought to get information from practitioners in foodstuff production and I have discussed the topic and my lecture with an economist, an assistant of a colleague of mine, within our institute on food law in Bayreuth, using the interdisciplinary approach of this institution.

The topic covers a wide field, and I have tried to identify some of the main issues, taking into consideration all the questions the Commission wanted to deal with. Some questions coincide with other lectures of this conference, for example the problems of implementation and effectiveness of legislation. In these points I will try to be brief.

A) Economic consequences of EC foodstuff legislation

I. Economic objectives of the common market and the internal market

The economic objectives of the common market are laid down in article 2 of the EEC-Treaty. Having in mind the activity of the community as it is enumerated in article 3 we can say that welfare should be increased by the free movement of goods within a system ensuring that competition in the

* Professor of Law, University of Bayreuth, Germany.

common market is not distorted. Where it is necessary to abolish barriers against free movement of goods, national regulations should be harmonised. The internal market, which is defined in article 8a of the EEC-Treaty introduced by to the Single European Act is the attempt to realise and to secure the advantages of a common market.

The costs of the "Non-Europe" and the advantages of the internal market for the national economies of all member states, for enterprises and consumers have been discussed in the so called Cecchini-Report[1]. The White Paper of 1985[2], the Communication on the Completion of the Internal Market regarding Community Legislation on Foodstuffs[3] and the Communication on the Free Movement of Foodstuffs within the Community[4] listed up the consequences as well as the means to reach that aim. The most important consequence is the "new approach" combining harmonisation in the "horizontal" matters with mutual recognition of the "vertical" regulations of all member states[5]

II. Consequences of mutual recognition and harmonisation for the foodstuff industry

This new approach finds its basis in article 30 of the EEC-Treaty and in the case law laid down by the European Court of Justice, first in the case *Dassonville*[6], clarified in the famous *Cassis de Dijon* case[7] and confirmed

---

1 Cecchini, The European Challenge 1992. The Benefits of a Single Market, 1988. See furthermore Commission of the EC, Research on the "Cost of Non-Europe" Basic Findings, Vol. 42 Part A, The "Cost of Non-Europe" in the Foodstuffs Industry, 1988.

2 White Paper from the Commission to the European Council, Document COM (85) 310.

3 Document COM (85) 603.

4 OJ 1989, No. C 271, p. 3.

5 See Streinz, "Die Herstellung des Binnenmarketes im Bereich des Lebensmittelrechts. Rechtsangleichung und gegenseitige Anerkennung als ergänzende Instrumente", *ZfRV* 1991, p. 357 *et seq*. Regarding the implementation of this programme, see Streinz, "Entwicklung und Stand der Herstellung des Binnenmarkets im Bereich des Lebensmittelrechts", *ZLR* 1992, p. 233 *et seq.* and Welsh, "Enwiklung und Stand der Herstellung des Binnenmarktes im Bereich des Lebensmittelrecht. Aktueller Sachstandsbericht", *ZLR* 1992, p. 273 *et seq*..

6 Case 8/74, *Procureur du Roi/Dassonville*, [1974] ECR 837, [1974] 2 CMLR 436.

7 Case 120/78, *Rewe-Zentral AG/Bundesmonopolverwaltung für Branntwein*, [1979 ECR 649, [1979] 3CMLR 494.

in subsequent judgements[8]. According to these judgements a product legally made or brought into circulation in one EEC Member State could not be refused by another unless for substantive reasons duly given, *i.e.* the reasons listed in Article 36 or developed by the judgements of the European Court according for the "Cassis-formula" of the "mandatory requirements"[9].

The obstacles to the free movement of goods which remain because of these exceptions should be overcome by harmonisation. But this was made easier because the Community legislation on foodstuffs could be limited to provisions justified by the need to protect public health, to provide consumers with information and protection in matters other than health and ensure fair trading and to provide for the necessary public controls[10].

As the health of the EC citizen is indivisible it is necessary to get one rule based on a high level of health protection (*cf.* article 100a par. 3 EEC-treaty) applied on Community level ("full harmonisation"). Health protection also requests a minimum standard of control of foodstuffs in all Member States. Otherwise the necessary mutual confidence cannot be reached. This minimum standard is also indispensable for a system ensuring that competition in the Common Market is not distorted. It is a competitive difference and may be a location factor whether an enterprise is confronted with a strict or a slack public control of foodstuffs or with no control at all.

The combination of mutual recognition and harmonisation both opens to the food industry and its products the market of the whole Community as well as to distribution and consumers the free choice of all products offered within this market. So you could say it brings only benefits, at least for the industry. But this is not the only point of view. National industries are confronted with products from other countries (Member States or Third States) which now can enter into competition with their own products, because the barriers erected or secured by national law are inapplicable being inconsistent with the EEC-treaty or EC-directives or EC-regulations.

---

8 See G. Meier, "Die Cassis-Rechtsprechung des Gerichtshofs der Europäischen Gemeinschaften. Eine Entscheidungssammlung", 3. *Aufl.*, 1990 (looseleaf).

9 See the Communication of the Commission on the consequences of the judgment of the European court of Justice in the Case 120/78 *Cassis de Dijon*, OJ 1980 No. C 256, p. 2.

10 See Communication COM (85) 603 (note 3), p. 5 *et seq.* (No. 7-9).

If foreign products have lower standards and are therefore cheaper, inland products are in danger to be adjusted to this standard or to be left unsold. This is the problem of the "lowest common standard" which would in turn lead to a downward spiral of food quality[11]. This leads to demands to secure the "quality" of products[12]. But this, one must be aware of the fact, can only be reached by harmonisation, whatever the form of common rules may be. In the field of mutual recognition the only solution can be sought in adequate labelling rules, in the interest of the fairness of commercial transactions as well as in the interest of the defence of the consumer.

III. Definition of the term "technical regulations"

1.Problems of terminology

The term "technical regulations" is often used confusingly in science and practice. In the framework of the European Communities we are confronted with the problem that the terminology is not only confusing within the single Member States but also different between the languages. Therefore I think it will be useful to strive for clarification.

2.Criterion: The legally binding force - technical requirements and technical standards

Technical regulations can be set by public authorities or by private institutions, especially by organisations of standardisation but even by the enterprises themselves. Only the former are legally binding. According to the glossary of the EC I will call them "technical requirements"[13]. In

---

11 Gray, "EEC Food Law: The Perspective to 1992", *Alimentalex* 1991, p. 57 *et seq.* (59); Streinz (note 5), *ZfRV* 1991, p. 372.

12 See EC Food Law monthly No. 13/1993, p. 2 *et seq.* (3): Some trade associations are against making changes on vertical directives which define the "quality" of their products. Other branches of producers of foodstuffs want their products to be protected by "quality" requirements. See furthermore von Heydebrand u.d. Lasa, Free Movement of Foodstuffs, Consumer Protection and Food Standards in the European Community: Has the Court of Justice Got It Wrong?, *European Law Review* 1991, p. 391 *et seq.* (394 *et seq.*, 408).

13 See Schellberg, "Technische Harmonisierung in der EG. Ökonomie und Politik der gegenseitigen Anerkennung, Rechtsangleichung und Normung", 1992, p. 5 *et seq.* With

Community law such requirements can be enacted through directives and regulations in the sense of article 189 par. 2 and 3 of the EEC treaty. The regulations set by private institutions are called standards. Although they are not legally binding, they have great practical importance. In certain cases, namely according to the new conception in the field of technical harmonisation and standardisation[14], EC-directives refer to such standards, made by the CEN (Comité Européen de Normalisation)[15]. In this way such standards can also achieve legal importance. We have the same diversity of types of "regulations" in the Member States. Therefore the information Directive No. 83/189/EEC[16] provides different duties of the Member States in relation to formal "technical regulations" (article 8) and non-compulsory standards (article 2).

Whereas in this EC-document the terminus "regulations" is used only for "requirements", I want to deal with both types of "regulations" in a broader sense, *i.e.* the legally binding regulations as well as the voluntary standards, but I also want to point out the differences in relation to costs and benefits of both categories. I think this is useful having in mind the very controversial discussion within the Commission on further EC-steps towards new food law (*i.e.* regulations in the sense of requirements) or food standards[17]. Whereas some want to start "a programme of vertical legislation to fill the gaps left by the horizontal programme" - which in my view is obviously contrary to the new approach laid down in the Communication of 1985[18] -, others think that standards can fill the gap, if there is a gap at all.

3.Scope of technical regulations

a) Goods affected by technical regulations

---

further references.

14 Resolution of the Council of 7 May 1985 on a New Conception in the Field of Technical Harmonization and Standardization, OJ 1985 No. C 136, p. 1.

15 Anselmann, "Technische Vorschriften und Normen in Europa. Harmonisierung und gegenseitige Anerkennung", 1991, p. 28 *et. seq.*

16 Directive laying down a procedure for the provision of information in the field of technical standards and regulations, OJ 1983 No. L 109, p. 8.

17 See EC Food Law monthly No. 12/1992, p. 2 *et seq.*

18 See footnote 3.

Whereas the terminus "technical" may firstly be associated with industrial, mechanic or electronic goods, "technical regulations" may be used in connection with the quality of all goods, including foodstuffs, raw materials and so on. Consequently EC-Directive No. 88/182/EEC[19] included foodstuffs into the Information Directive.

b) Items of standardisation

Items of a standardisation can be not only materials, *i.e.* products, but also procedures and appellations. These can be determined both by legally binding "regulations", *i.e.* requirements, and by standards. Regulations of products, we find in Community law in the vertical directives, *e.g.* Directive No. 79/693/EEC on jams, extra jams, extra jellies, jellies marmalade and chestnut puree[20], regulations of appellations we find *e.g.* in the Regulation - in the sense of article 189 par. 2 EEC-Treaty - No. 1576/89/EEC on the denomination of spirits[21], regulations of procedures we find *e.g.* in the EEC-Directives on hygiene[22]. An example for product standards on national level is the *Deutsches Lebensmittelbuch*[23].

4."Technical" regulations (safety of products) and "quality" regulations (composition of foodstuffs)

"Technical" regulations might be understood - in a closer sense - as being limited to rules on the safety of products. But this is not necessarily so. Having in mind the broad sense of the terminus "technical" in this connection, regulations on the composition of foodstuffs, which may be called "quality" regulations, are also included. This leads to the problem of how to define "quality".

---

19 OJ 1988 No. L 81, p. 75.
20 OJ 1979 No. L 205, p. 5.
21 OJ 1989 No. L 160, p. 1.
22 See the directives which deal with the health conditions to be respected when processing meat, milk, eggs etc. for the production of meat, milk or egg products. An overview is given in the CIAA Status Report on Food Legislation in the EEC of 1st April 1993, p. 56 *et seq.* Now a Framework Directive on the hygiene of foodstuffs has been proposed (COM (91) 525 final, OJ 1992 No. C 24, p. 11, modified by COM (92) 547 final - SYN 376, OJ 1992 No. C 347, p. .... which shall be adopted in June 1993.
23 Bundesanzeiger No. 238 of 20 December 1978.

5.Definition of the term "quality"

In the course of preparing this contribution I have found in *Alimentalex* some reflections of a Commission official on "quality": "You speak of quality. What do you mean by that word? What is quality to you? Quality, quality is everything and quality is nothing"[24]. The contribution in *Alimentalex*, where these words are cited, does not only complain that the concept of quality is shrouded in vagueness and subjectivity, the author also recognises that "quality policy" is linked to vital Community considerations[25]. Some of these considerations, *i.e.* Common Agricultural Policy (The Rural Society, problem of surpluses, less favoured areas, producers' income), structural policy and environmental issues are strictly spoken not matters of food law, as the Commission itself confirms in its 1989 Communication on the Free Movement of Foodstuffs within the Community[26].

"Quality", on the other hand, relates to the essentials of food law, *i.e.* the protection of public health and the protection of the consumer against being misled[27]. Whereas the protection of public health in the unanimous point of view should be reached by requirements, *i.e.* legally binding regulations, it does not, in principle, intend to propose rules relating to product quality (rules on contents or recipes), *i.e.* requirements relating to composition and manufacturing[28], in contrast to those concerning the protection of public health with which foodstuffs must comply. "In principle" means that there should be exceptions. The Commission commits itself to promoting a policy on product quality ensuring approval and mutual recognition procedures for labelling and origin designations in the Community[29].

The just adopted EC-Regulations according to this approach are horizontal measures (cf. Regulations No. 2081/92/EEC[30] and No. 2082/92/EEC[31] to

---

24 Foley, Food quality assurance, certification and nutrition labelling - is an EEC policy position emerging?, *Alimentalex* 1990, p. 103 *et seq.* (103).
25 *Ibidem*, p. 103 *et seq.*
26 Footnote 4, p. 3 and 6, No. 4a and No. 4b.
27 Bigwood/Gerard, "Fundamental Principles and Objectives of a Comparative Food Law", Vol. 1, 1967, p. 20 *et seq.*; Vol. 2, 1968, p. 82.
28 See the Communication of the Commission (footnote 3), p. 9, No. 17.
29 See the Communication (footnote 4), p. 6, No. 3 and No. 4a.
30 OJ 1992 No. L 208, p. 1.

the protection of geographical indications and designations of origin for agricultural products and foodstuffs, and certificates of specific character for agricultural products and foodstuffs), which secure in the concrete case of application vertical aspects, or vertical measures (cf. the Regulation No. 1898/87/EEC to the protection of the designation milk and milk products[32]). Although to a certain extent these regulations protect also the consumer, their main issues are fair competition and protection of specific branches of production, what is outside the scope of "food law" in a strict sense[33]. Today we have a very intensive and controversial discussion on whether the European Community should intensify this kind of "quality policy" at all and if yes by what means[34].

IV. Conflict of interests

This discussion proves that there are different conflicts of interests within the foodstuff industry which lead to divergent statements on the economic use of technical regulations.

1.National industries

Every proposal of harmonisation meets the vital interests of the branches affected by this measure. Harmonisation means that the existing national regime ruling the matter must be changed to a certain extent. And it is exactly this extent of change in relation to the existing regimes of other Member States that is decisive for the starting position in the competition within the Common Market (Single Market). Therefore every national delegation within the EC-Council is urged by its national industry to achieve a regulation on Community level which is close to the existing national regime, except if the affected branch hopes to be freed from a cumbersome national regulation by a European solution.

---

31 OJ 1992 No. L 208, p. 8.

32 OJ 1987 No. L 182, p. 36.

33 See footnote 26 and Streinz, "Umfaßt der Binnenmarkt auch die Landwirtschaft?", in: Landwirtschaft im Binnenmarkt, Schriftenreihe des Instituts für Landwirtschaftsrecht an der Universität Passau, Bd. 4, 1992, p. 3 *et seq.* (28).

34 See *e.g.* Lister, "The naming of foods: the European Community's rules for non-brand food product names", *ELRev.* 1993, p. 179 *et seq.* (196 *et seq.*); Trevelline, "European Communities Standardisation Policy: A New Means to Regulate Foodstuffs", [1993] 2 *ECLR* 46 (p. 47 *et seq.*).

But even in this case we meet intense disputes about the concrete content of secondary EC-law, as you can see from the example of the directives on additives[35]. The competitive advantage a certain (national) branch has got by Community regulations or directives, is proved by the opposition to attempts to abolish or to reduce existing vertical directives in the course of the debate on subsidiarity. To give an example, the attitude of one association representing jam-makers was: "We want to keep the directive - it has done a lot to maintain quality levels ... Drastic changes to existing definitions would cause confusion"[36].

2.Branches of industry

This example proves furthermore that the single branches have quite different attitudes to technical regulations at least in the field of rules on composition or recipes, and the attitude of the same branch may diverge from Member State to Member State.

3.Types of enterprises (big industry, middle class, handicraft, distribution)

Finally, divergent attitudes emanate from the different types of enterprises. The interest of big industry in technical regulations may be quite different from that of middle class or handicraft enterprises or the distribution branch. The different problems I have come across are too manifold to give a clear picture. So I may confine myself to two examples: Especially middle class enterprises fear that a lower required standard of product quality than the standard they were used to observe and were forced to observe by national food law, at least in fact also by "standards" ("*Leitsätze*" of the German *Lebensmittelbuch*)[37] or other guidelines, would oust their "traditional" products from the market by unfair competition. They were urged to lower their product standards to the level of the cheaper products from other Member States, if national food law allows this at all (problem of reverse discrimination)[38].

---

35 See Bund für Lebensmittelrecht und Lebensmittelkunde (BLL). In Sachen Lebensmittel 1991/92, p. 105 *et seq.*; 1990/91, p. 108 *et seq.*; 1992/93 p. 72 *et seq.*

36 EC Foodlaw monthly No. 13/1993, p. 3.

37 See footnote 23.

38 See von Heydebrand u.d. Lasa (footnote 12), p. 407 *et seq.*

The argument, that free movement of goods needs the mutual recognition of different national standards, unless you want to harmonise them in direction of European standards on composition, and that the only solution can be a system of correct labelling, is countered by the assertion that consumers are not willing or able to read such labels[39]. But I wonder whether these branches would be satisfied with other minimum standards than those which apply on their (respective) national level.

For many reasons I think that CIAA is right having reservations about developing compositional standards for specific foodstuffs[40]. But the general problem is left unsolved, as the intensive discussion during a lot of EC-conferences proves[41]. Another problem is safeguarding proportionality in regulations which are in principle undoubtedly needed. This question arose in the context of Directive No. 64/433/EEC[42] to the regulation of problems relating to health in inter-Community trade, altered by Directives No. 72/462/EEC[43] and No. 92/5/EEC[44]. It was doubted whether the requirements which the directive imposed on slaughterhouses were undifferentiatedly necessary both for big enterprises and for handicraft enterprises[45].

B) Costs and benefits of technical regulations

From an economic point of view the costs and benefits of technical regulations are decisive. This balance has not only to be fed with figures related to operational analysis of the production but also with effects on the marketing of products, especially the confidence of consumers. Some of the costs and benefits arise from standards as well as from requirements, others are different in this connection. I will try to make the differences clear.

---

39 See *ibidem*, p. 408 *et seq.* See also Trevelline (footnote 34), p. 50 *et seq.*

40 See BLL (footnote 35), 1992/93, p. 175.

41 See EC Foodlaw monthly No. 12/1992, p. 2; No. 13/1993, p. 2 *et seq.*; No. 15/1993, p. 3.

42 OJ 1964, p. 2012.

43 OJ 1972 No. L 268, p. 69.

44 OJ 1972 No. L 57, p. 1.

45 See Beutgen, Wird den Metzgern das Handwerk gelegt?, EG-Magazin No. 10-1992, p. 33 *et seq.*

I. Incurring of costs and the principle of proportionality

1. Costs of the introduction of a new standard

a) Cost of the fixation of a technical standard[46]

A technical standard - either introduced by a voluntary standard or by a legally binding regulation (requirement) - requests the adaptation of the production to the new rule. This entails expenses. The old standard must be dissolved, the expenses made on it are lost for the future. The change affects especially the functions compatibility, information and control - I will come to these functions below. To give two examples: First an example for compatibility: changing traffic in Britain to the right side of the road would cause the adaptation of the whole system to the new standard. Now an example for information: changing the standard leads to the loss of the information content, which may cause legal uncertainty or confusion in the market. These costs must be taken into consideration and compared with the benefits of the new, international standard anyway. One should also have in mind the problem of competition, *i.e.* the lower losses of enterprises of those countries, whose national standards are close to the European standard.

This leads to the demand to introduce, if possible, a European standard in a field, which is up to date unsettled but needs regulation, according to the parole: "Do it right, do it once, do it international"[47]. The costs can also be reduced when a EC-Regulation is turned into national law in time, a problem, that concerns for example the German foodstuff branch. But this is the task of the national legislative organs. The Community, however, should coordinate the deadlines for the implementation of different directives concerning the same product, especially directives concerning the labelling of foodstuffs, to enable the industry to "do it once". This would reduce the (enormous) costs considerably.

b) Costs of international standardisation[48]

Costs for setting up the technical regulations themselves arise strictly

---

[46] See Schellberg (footnote 13), p. 103 *et seq.*

[47] See Geisendörfer, "Europa braucht einheitliche technische Regeln", in: DIN (ed.), *Referatesammlung Europäischer Binnenmarkt* 1992, 1989, p. 1 *et seq.*

[48] See Schellberg (footnote 13), p. 107 *et seq.*

spoken only private standardisation, *e.g.* within CEN. They are considerable, and the foodstuff branch requires more contribution from the Community[49]. As a whole, the benefits exceed the costs. But this result must be differentiated between countries which already have had standards and countries which did not. It may also be different in individual cases.

2. Costs of executing technical regulations

a) Cost of compliance with legal requirements - The principle of proportionality

Of course the compliance with legal requirements on production, composition and labelling of foodstuffs involves costs. The only question is whether the imposition of the requirement is proportional in relation to the public, *i.e.* Community interest which should be secured. Proportionality is not only a rule of reason but also a general principle of law, derived from German law[50], but recognised by the European Court of Justice as an integral part of the general principles of Community law, the observance of which the Court guarantees[51].

According to the principle of proportionality, a public authority may not impose obligations on a citizen except to the extent to which they are strictly necessary in the public interest to attain the purpose of the measure. If the burdens imposed are clearly out of proportion to the objective in view, the measure will be annulled. This requires the existence of a reasonable relationship between the end and the means. It implies both that the means must be reasonably likely to bring about the objective, and that the detriment to those adversely affected must not be disproportionate to the benefit to the public. It is to some extent analogous to the English

---

49 See *BLL* (footnote 35), 1991/92, p. 259 *et seq.*

50 See *e.g.* Ress, "Der Grundsatz der Verhältnismäßigkeit im deutschen Recht", in: Deutsche Sektion der internationalen Juristenkommission (ed.), Der Grundsatz der Verhältnismäßigkeit in europäischen Rechtsordnungen. Europäische Gemeinschaft, Europäische Menschenrechtskonvention, Bundesrepublik Deutschland, Frankreich, Italien, Österreich, 1985, p. 5 *et seq.*

51 See *e.g.* Hartley, "The Foundations of European Community Law", 2nd ed. 1989, p. 145 *et seq.* with further references. Kutscher, "Zum Grundsatz der Verhältnismäßigkeit im Recht der Europäischen Gemeinschaften", in: *Deutsche Sektion* (footnote 49), p. 89 *et seq.*

concept of reasonableness[52], and it is proved that this rule in substance is also an integral part of the (constitutional) law of France, Italy and Spain, probably of the constitutions of all Member States[53].

In the sphere of economic law, of which food law is a part[54], the affected right of the producer is the right to the free pursuit of an economic activity, which is recognised as a principle of Community law by the European Court of Justice[55]. But like all other fundamental rights - and perhaps in a special manner - this right cannot be regarded as absolute and unqualified, it is subject to limitations "justified by the overall objectives pursued by the Community"[56]. These objectives can be those of agricultural policy, of protection of the environment, and, as specific objectives of food law, the protection of consumers' health and the protection of the consumers against being misled.

Only these "goods", these objectives recognised by Community law can justify an infringement in the fundamental right of the producer, and this infringement must be likely and necessary to attain its objective and, if both can be approved, there should be a balancing of the goods involved on both sides, whether the imposed burden is disproportionate in relation to the public objective. It is obvious that these are questions on which opinions may frequently differ. Therefore it is important to know whether the European Court of Justice plays an active role or is led by judicial self-restraint. In general, the judicial review of Community acts, *e.g.* regulations and directives is cautious regarding the policy decision of the Council or the Commission, the Court does not interfere unless there is a very clear and obvious violation of the principle of proportionality[57].

Nevertheless we can find some judgements where the Court declared EC-Regulations or EC-Decisions (in the sense of article 189 par. 4) to be

---

52 See Hartley (footnote 50), p. 146.

53 See Teitgen, "Le principe de proportionalité en Droit Français", in: *Deutsche Sektion* (footnote 49), p. 53 *et seq.*; Ubertazzi, Le principe de proportionalité en Droit Italien, in: *Deutsche Sektion* (footnote 49), p. 79 *et seq.*

54 The economy is of course not the only dimension and scope of foodlaw.

55 See ECJ, Cases 63 and 147/84, *Finsider*, [1985] ECR 2857, p. 2882.

56 See ECJ, Case 4/73 *Nold* , [1974] ECR 491, p. 508, [1974] 2 CMLR 338.

57 Hartley (footnote 50), p. 147; see Rengeling, "Grundrechtsschutz in der Europäischen Gemeinschaft", 1993, p. 221.

void[58]. The reasoning in these cases was always that the measure was not recognised to be necessary[59]. This criterion is also decisive in the cases where the rule of proportionality was replied to national measures contrary to the rule of free movement of goods (article 30 EEC-treaty), which should be justified by mandatory requirements or article 36[60]. Although both types of cases are ruled by the same principle of proportionality, it is, however, questionable whether the Court is guided by a more rigorous judicial review against measures taken by the Member States against Community principles than against measures taken by the Community itself, because in the first case the effectiveness of Community law is involved. Nevertheless, when taking into consideration proportionality in legislative practice, the Community should not only have in mind the strict requirements of primary Community law, but also economic aspects, even if these are not strictly protected by law.

As a whole requirements justified by public health (safety of foodstuffs) are to a large extent proportional, as the safety of the person is of maximum value. On the other hand, requirements justified by protection of the consumer against being misled must be carefully reviewed in the sight of proportionality. Compulsory (not voluntary) labelling must be sufficient to inform the consumer as well as it must be possible in practice for the producer to install the required data on the label.

b) Costs of monitoring and control of foodstuffs

Having in mind that the monitoring of foodstuffs by the manufacturers or by the retailers themselves as well as the public control of foodstuffs cause costs the principle of proportionality must not be disregarded. Also in this field controls for the sake of public health are more justified than controls for the sake of other reasons. When assessing the proportionality of a measure one can take into consideration the benefits of an effective control of foodstuffs not only for the public but also for trade and industry. But in this context the benefits of a combination of private monitoring of products

58 See *e.g.* ECJ, Case 114/76 *Bela-Mühle/Grows-Farm*, [1977] ECR 1211, p. 1221, [1979] 2 CMLR 83; ECJ, Case 116/76 *Granaria/Hoofproduktschap voor Akkerbouwproukten,* [1977] ECR 1247, p. 1264, [1979] 2 CMLR.

59 See Streinz, "Bundesverfassungsgerichtlicher Grundrechtsschutz und Europäisches Gemeinschaftsrecht", 1989, p. 417.

60 See Case 120/78 (footnote 7), p. 662.

and public control of foodstuffs should be made as effective as possible[61].

The costs of public control of foodstuffs are settled non-uniformly within the Community and even - regarding special branches - within single Member States. In Germany, for instance, the general costs of the control of foodstuffs are paid by the public, even the costs of the sampling are reimbursed, whereas the costs of the meat inspection in slaughterhouses are financed by fees[62]. It should be considered whether this causes a distortion of competition in the Common Market and whether harmonisation is needed.

II. Benefits of technical regulations

Technical regulations yield benefits in general but also special benefits in the framework of European integration. Whereas the specific economic benefits result mainly from standards, other general benefits are generated by legally binding regulations as well as by acknowledged standards which are proved by a well-known mark. The special benefit of the really free movement of goods within the Internal Market or with respect to third countries may be reached by both types of technical regulations, but it needs in any case the guarantee of a legally binding rule.

1.Benefits of technical regulations in general

a) Specific economic benefits

The science of applied economics has worked out several functions of standardisation, which can be used for different goods, for the policy for a firm as well as for economic policy or general policy[63].

---

61 See Horst, "The points of view of social and economic partners - Industry", in: Commission of the EC, Second symposium on control of foodstuffs, 1992, p. 68 *et seq.* (69 *et seq.*).

62 The criterion is that the repressive control is firstly in the interest of the public and therefore it shall be paid by it whereas a preventive control shall be paid by the producer.

63 See Schellberg (footnote 13), p. 26 *et. seq.*

aa) Unification

Standardisation enables the unification of products and procedures. The uniform application of a standard yields scale profits, *i.e.* the costs of a unit or a process decrease with the increasing of the total number. A disadvantage, which must be taken into consideration, is that products may not respond to the different interests of consumers.

bb) Compatibility

Standardisation creates compatibility of products, designations and procedures, which means that systems or elements are "compatible" in respect of a certain function.

cc) Quality

A standard fixes the structure or function of a product or process defining certain levels of the functioning or the structural form of an article. Quality in this sense should not be understood as to hit the expectation of the consumer ("quality is when you get what you wanted") but as a scale for the level of utility, safety and so on, notwithstanding that certain levels may hit exactly the expectation of consumers. A technical regulation can prohibit certain levels of the functioning *e.g.* by the fixation of maximum quantities of additives. But it can also limit the designation of goods on those which comply with a certain level of functioning (*e.g.* the German purity regulation on beer). This function often is used for the pursuit of political goals.

dd) Information

A standard gives a description of the efficiency or state of a product. Production or distribution according to a standard is accompanied with detailed technical documentation or detailed special knowledge of the partner on the market. Standards make possible long-distance exchange of products with certainty on the state of products without an investigation in substance. One can obtain categories of products. A standard gives information about the composition of goods and the process of production and may facilitate decisions.

ee) Control

A standard is the single fixation of recurring tasks. From case to case regulation is replaced by a general regulation. The standard must be observed at any time and by everyone. This yields the regulation of the concerned system in the sphere of the enterprise as well as in the political sphere and in the framework of the self-management of the economy. This regulation shall guarantee the coincidence of processes with the demands of the system. The conformity of a product to the standard fixing the composition can also be guaranteed by standards *i.e.* standards fixing the process of controlling. In the intra-company sphere these standards are used for a internal control-system on quality, in the economy as a whole they are the basis to review if products are marketable.

b) Other benefits

aa) Confidence of consumers in the safety of products

Technical regulations may enhance the confidence of consumers in the safety of products. But this depends upon the knowledge of the consumer that a product is made according to certain technical regulations. In the sphere of national law this was often linked to the mere designation (*e.g.* "beer" is only beer brewed according to the purity rule) or the consciousness that products had to fulfil special quality standards (*e.g. Deutsches Lebensmittelbuch*) or the deviation had to be marked[64].

These are, however, not examples of safety, but of "quality" of products. The confidence in the "safety", *i.e.* to be free of health risks, depends upon the confidence in a foodstuff control system. Within a Common or Single Market the Community must give the basic rules to improve mutual confidence. I think that the Community is on the right way with the further development of EEC-Directive No. 89/397 on the official control of foodstuffs[65]. As for the rest, confidence depends on the image of the single firm.

---

64 See § 17 par. 1 No. 2a Lebensmittel- und Bedarfsgegenständegesetz of 15 August 1974, BGBl. I 1946.
65 OJ 1989 No. L 186, p. 23.

bb) Safety of products as an economic factor

Having in mind that the confidence of consumers in the respective products is decisive for the economic success of an enterprise it is evident that safety of products is a very important economic factor. This is proved by the fact that the greatest danger for an enterprise is not a penalty because of violation of the law but the detrimental, often ruinous effects of public warnings. Notwithstanding this fact, the liability for harmful products should not be neglected as it is a useful form of pressure.

cc) Product liability

Technical regulations can also facilitate the product liability of the producer. But this consequence derives to an important extent only from legally binding, cogent regulations *i.e.* requirements, not from voluntary standards. If a producer is forced by the law to do something he can rely on this requirement for exculpation[66].

2.Special benefits in the framework of European integration and international trade

a) Really ensured free movement of goods within the Internal Market

So far as a technical regulation on Community level exists or national technical regulations are expressively mutually recognised by a Community act the free movement of goods within the Internal Market is really ensured. The advantage is that producers do not have to pass national procedures of admission or to strive for their right deriving from article 30 of the treaty at the European Court. But it has to be emphasised that this can only derive from a legally binding Community act, either by setting up a technical regulation by secondary Community law or by initiating a standard on Community level, *e.g.* a CEN-standard or even certain national standards with a free commerce clause, perhaps demonstrated and proved by a special sign (cf. the EC-Regulation on toys[67]).

---

66 See Huth, "Die Bedeutung technischer Normen für die Haftung des Warenherstellers nach § 823 BGB und dem Produkthaftungsgesetz, 1992, p. 144 *et seq.*, 177 *et seq.* 305 *et seq.*, 351 *et seq.*

67 EEC-Directive No. 88/378 of 3rd May 1988, OJ 1988 No. L 187, p. 1. See especially

b) No costs for the change of a technical standard

The economically most important profit of this guaranteed free movement of goods is that enterprises do not incur the very serious costs for the change of a technical standard[68], in the worst case in respect of eleven countries.

c) Free movement of goods in respect of third countries (if relevant according to GATT principles)

If one has a common technical regulation on Community level this enhances the position in negotiations with third countries. Especially in food law we have the standards of the *Codex Alimentarius*. Free movement of goods, however can only be guaranteed when the Community as well as the third country have accepted the standard. For the *Codex Alimentarius* standards are neither requirements for industrial standards in the normal sense of the term but rather model laws regarding labelling, composition, additives, contaminants, pesticide residues and hygiene[69].

The *Codex* has got a considerable influence on EC food law because the Commission has represented the Member States in *Codex* meetings even before the EEC as an international organisation became itself a member of FAO on 26th November 1991[70]. In 1991 the EC Commission proposed a directive which enabled the EEC itself to accept *Codex* standards[71]. The drawing up of international standards for foodstuffs has been a painfully slow work. Too often some countries have agreed to a standard they did not like, knowing that they would not be obliged to apply it, instead of working out a meaningful and satisfactory standard[72]. Now the work is concentrated on horizontal harmonisation to get a binding basis for the trade within the GATT[73]. Such standards obviously influence the EC food law too for it would be impossible to have different regulations regarding health problems for products imported from third states and products

---

art. 4, arts. 5-8.

68 See Schellberg (footnote 13), p. 94 *et seq.*

69 Gray, "EEC Food Law and International Trade", *Alimentalex* 1992, p. 25 *et seq.* (31).

70 See *EuZW* 1992, p. 2; EC Foodlaw monthly No. 1/1992, p. 16.

71 Doc. COM/90/216 final.

72 See EC Foodlaw monthly No. 1/1992, p. 16.

73 See Gray (footnote 69), p. 31 *et seq.*

manufactured within the Community[74].

C) Control of foodstuffs

I. The importance of the control of foodstuffs in respect of the institution of a system ensuring that competition in the Common Market is not distorted

According to article 3 lit. f EEC Treaty the activities of the Community for the purpose to establish a Common Market shall include *inter alia* the institution of a system ensuring that competition in the Common Market is not distorted. This includes more than the provisions on competition law against concerted behaviour (cf. arts. 85 *et seq.*). All policies of the Community must consider this fundamental aim of Community law and avoid that they cause themselves - unintentionally - a distortion of competition. This danger would threaten if the free movement of goods - and here foodstuffs - was guaranteed but the public control did not have an equivalent level throughout the Community. Therefore, from an economic point of view, the efficiency of the control of foodstuffs is not only indispensable for the protection of health and for the concept of mutual recognition[75] but also necessary to obtain a system ensuring that competition in the Common Market is not distorted[76].

II. Distribution of competencies between the Communities and the Member States

This raises the question of the distribution of competencies between the Communities and the Member States. According to the general system of division of powers the implementation of Community law is left to the

---

74 See also Eckert, "Perspektiven der Lebensmittelrechtsharmonisierung in Europa", *EFLR* 1990, p. 27 *et seq.* (35 *et seq.*).

75 Whereas sanitary controls in the extent which is still allowed by Community law are in fact possible it is absolutely impossible to control permanently if foreign products are in conformity with the regulations or standards of the Member State where they were manufactured or brought into the market, see Streinz, "Deutsches und Europäisches Lebensmittelrecht. Der Einfluß des Recht der Europäischen Gemeinschaften auf das deutsche Lebensmittelrecht, Wirtschaft und Verwaltung" 1993, p. 1 (55 *et seq.*).

76 Also criminal law may distort competition in many ways see Sevenster, "Criminal law and EC law", *CMLRev* 29 (1992), p. 29 *et seq.* (56 *et seq.*).

Member States[77] and according to the principle of limited powers the Communities possess only those powers which were conferred on them. Therefore without an allocation of competence to the Community the control of foodstuffs is the task of the Member States and, as far as Community law is affected, their obligation according to article 5 EEC Treaty. Although all twelve Member States recognise the same scopes of food law - protection against damages on health and prevention of misleading, fraud and exploitation - their systems on control of foodstuffs are organised very differently[78].

In order to obtain a minimum level of uniformity in the implementation of food law in practice the Council Directive No. 89/397/EEC on the Official Control of Foodstuffs[79] seeks to harmonise the national provisions. In accordance with the principle of subsidiarity - in this case understood in a proper sense[80] the directive leaves to the Member States a certain margin of freedom in the implementation of the control in order to avoid the infringement in systems which have been proved and which are adapted to the special situation of each Member State[81]. The directive in this spirit furthermore leaves it up to the Member States to set up the control programmes which can ensure the prevention of offences against food law, but provides also coordinated programmes on foodstuff controls on the level of the Community having in mind the completion and the functioning of the Internal Market[82].

In fact, it is necessary that the Community has enough possibilities to ensure an effective control. But this is a quite delicate subject and the Member States - and especially some of the German *Länder* which are competent in the main fields of foodstuff control - show a to some extent

---

77 See Streinz, *Europarecht*, 1992, No. 467.

78 See Verardi, "The Current Situation regarding the control of foodstuffs: General look at the legal framework and administrative structures of the national control systems", in: Commission of the EC, Second Symposium on Control of Foodstuffs, 1992, p. 104 (109 *et seq.*).

79 See footnote 65.

80 The principle of subsidiarity is now *expressis verbis* confirmed in art. 3b par. 2 EC Treaty, which will be in force after the ratification of the Maastricht Treaty (see art. R par. 2 of the Union Treaty), OJ 1992 No. C 191, p 1. This principle has led to some confusion how to interpret it correctly. It is also relevant in food law, see Gray, "Subsidiarity and EC Food Law", 1992 and Streinz (footnote 74), p. 69 *et seq.*

81 See the last paragraph of the preamble.

82 Paragraph 15 of the preamble.

inconsistent point of view. There is, on one hand, a deep mistrust displayed by the majority of Member States to a supposed interference by the Community in sovereign areas of administrative authority. One must concede that the behaviour of the Commission regarding other subject matters, *e.g.* culture, television[83], was suitable to increase these reservations. On the other hand the same Member States complain about the non-uniform implementation of EC food law and of controls on foodstuffs within the Community. It is obvious that a solution to these positions must be reached.

Therefore I think that the increasing mutual cooperation between authorities in Member States and between the Commission and Member States as it has been established in the directives following the - I may call it "Framework" - Directive on the Official Control of Foodstuffs[84] is the right way[85]. It should be emphasised that the Commission thinks this co-ordination of control systems to be sufficient and is not in favour of establishing a European Food Agency[86]. Whereas article 13 lit. d of Directive No. 89/397/EEC[87] speaks about the possibility of establishing a Community inspection service including opportunities for all institutions and persons involved with controls to exchange information this does not necessarily mean the establishment of an own EC agency because this aim can also be reached by suitable forms of cooperation.

A suitable form of cooperation must include, however, effective means for the Community to move the Member States to fulfil their duties deriving from Community law in good faith as it is generally provided for in article 5 EEC Treaty. The argument that national inspection services would - even where the Community ideal is strongly supported - be led by a strong impulse not to bring discredit on national products and generally be oriented only on national interests, sometimes forced by economic lobbies

---

83 See the Green Paper on the Establishment of the Common Market of Broadcast - Television without Frontiers, Doc. Com (84) 300 final.

84 See *e.g.* Council Directive No. 89/662/EEC, OJ 1989 No. L 395, p. 13; Council Directive No. 89/608/EEC, OJ 1989 No. L 351, p. 34; Commission Decision No. 91/398/EEC, OJ 1991 No. L 221, p. 30. See Streinz (footnote 74), p. 60 *et seq.*

85 See also Priebe, "Inspection at Community level. Current regulations under agricultural legislation", in: Commission of the EC, "Second Symposium on Control of Foodstuffs", 1992, p. 122 (140 *et seq.*).

86 See the answer of the Commission to the question of MEP Mary Banotti, OJ 1991 No. C 311, p. 18.

87 See footnote 65.

which exert pressure on the public authorities to restrain the "fervent or over-zealous" inspectors brings some authors to the conclusion that a Community inspection service is necessary because it would be subject to such restrictions[88].

This argument must be taken very seriously, for there are also some further strong arguments in favour of the establishment of a Community foodstuffs inspection service[89]. But it is proved that also the Community organs can be subject to improper pressure both by economic lobbies and - contrary to article 10 par. 2 Merger Treaty - single Member States. On the other hand, the problem that Member States neglect their obligations deriving from Community law is a general one, as the reports of the Commission to the European Parliament on the control of the application of the Community law show[90]. This problem derives from the structure of the Community which is based on the Member States and needs their support in good faith.

This problem could even arise in a federal state when the implementation of the federal law is within the competence of the *Länder* and the possible sanctions of the federation are practically insufficient. The difficulties could only be abolished by shifting the structure of the Communities to a unitarian State which hardly anyone wants. Therefore one has to seek solutions within the existing system. In this framework there must be in fact an effective control of EC authorities not on foodstuffs but on the control systems of the Member States which cannot be sufficiently reached by the procedure according to article 169 EEC Treaty.

In this sense one may call this a Community Inspection Service of Foodstuffs, but this does not emerge a new authority or agency. The effectiveness of the implementation of Community Law is, as it is well known, threatened by the lacking sanctions. Art. 171 par. 2 EC Treaty according to the revision by the Maastricht Treaty therefore includes sanctions against Member States who do not obey a decision of the ECJ. But the procedure according to arts. 169 *et seq.* EEC Treaty is insufficient

---

88 Castang, "Possibility of establishing a Community inspection service for foodstuffs", in: Commission of the EC, "Second Symposium on Control of Foodstuffs", 1992, p. 154 (158 *et seq.*).

89 See *ibidem*, p. 155 *et seq.*

90 See 8th Report, Doc. COM (91) 321 final, OJ 1991 No. C 338, p. 1; 9th Report, Doc. COM (92) 136 final, OJ 1992 No. C 250 p. 1.

anyway, there is a need for prompt sanctions. If there is a serious lack in the control of foodstuffs in a Member State one could consider banning the foodstuffs which are concerned from the free movement of goods within the Community.

In this connection the question arises whether the Community should have the competence to impose sanctions against individuals in the field of food law as it has in the field of competition law.

This would include not only the competence to make the substantive law regarding the sanctions (criminal law or law concerning regulatory offences) but also the competence to punish individuals for offences, *e.g.* to impose fines[91]. This would necessitate an explicit allocation of competence in the EEC Treaty by alteration of this treaty according to article 236 EEC Treaty. Leaving aside the political feasibility it is questionable whether this would be useful or desirable. In my point of view the administration by Community organs should remain limited to certain fields[92]. Another question is whether the substantive law regarding the sanctions should be changed in favour of more competencies for the Communities.

In this context one must, however, have in mind that EEC directives can obligate the Member States to impose sanctions for the violation of Community law whereas this may imply some problems regarding the principle of democracy[93]. In general, this duty derives form article 5 par. 1 EEC Treaty[94]. EEC regulations, however, can not impose sanctions without a specific competence of the Communities[95], but obligate the Member States to do so[96]. Having in mind some deficits of this system[97] -

---

91 See art. 15 Council Regulation No. 17 of 6 February 1962 implementing Articles 85 and 86 of the EEC Treaty, OJ 1962, p. 204.

92 See Schweitzer, "Die Verwaltung der Europäischen Gemeinschaften", Die Verwaltung 1984, p. 137 (139 *et seq.*).

93 See Sieber, "Europäische Einigung und Europäisches Strafrecht", *ZStW* 103 (1991), p. 957 (965 *et seq.*, 972 *et seq.*). This principle, however, is kept up by the action of the Council in cooperation with the European Parliament according to art. 149 par. 2 EEC Treaty which must be used by acts according to art. 100a EEC Treaty, see Streinz (footnote 75), p. 31.

94 See ECJ, Case 68/88 *Commission v Greece* , [1989] ECR 2965, p. 2984 *et seq.*

95 See Sieber (footnote 93), p. 969 and Zuleeg, "Der Beitrag des Strafrechts zur europäischen Integration", *JZ* 1992, p. 761 (763 *et seq.*).

96 See *e.g.* art. 7 par. 6 Regulation No. 986/89/EEC, OJ 1989 No. L 106, p. 1.

which can, however, be avoided[98] - the question arises whether EEC regulations should not include the substantial provisions on sanctions themselves[99].

III. Fulfilling the task of foodstuffs control: public control of foodstuffs and private control of products - combination of both spheres

Whereas the official control of foodstuffs can only be a restricted one to random checking, the internal inspection by the companies themselves can be more systematical. It can include every processing step from the delivery of the raw materials to the outward delivery to the consumer. Therefore it seems to be very useful to coordinate the public control of foodstuffs and the private control of products. Of course the protection of the consumer against health risks is a public function and must not be left to the companies alone which are to be controlled. It is important not to obscure the responsibilities of both spheres.

This, however, does not prevent "cooperation" between public authorities and companies, notwithstanding that the rule of law must be respected[100]. By this way the public control of foodstuffs can to a considerable extent restrict itself to inspecting the company's own controls if these comply to a certain standard. This enables the state authorities largely to dispense of routine and thus duplicate controls and rather to concentrate on potential problem areas[101].

---

97 See Eckert, "Die Auswirkungen gemeinschaftsrechtlicher Vorgaben auf das deutsche Lebensmittelrecht -Verfassung- und vertragsrechtliche Fragen", in: Streinz (Hrsg.), "Deutsches und Europäisches Lebensmittelrecht", 1991, p. 57 (75).

98 See Streinz (footnote 75), p. 33.

99 See *ibidem* with further references. "The Forschungsstelle für Lebensmittelrecht, Bayreuth", and the Europäische Rechtsakademie Trier, will hold a Symposium on these questions in Trier in 1994.

100 Regarding this problem in general see Hufen, "Kooperation von Behörden und Unternehmen im Lebensmittelrecht", *ZLR* 1993, p. 233 *et. seq.*; Dannecker, "Strafrechtliche und strafprozessuale Probleme der Kooperation von Behörden und Unternehmen im Lebensmittelrecht", *ZLR* 1993, p. 251 *et seq.* Critically regarding to the term "cooperation" see Gorny, "Haftungsfragen bei der Kooperation von Behörden und Unternehmen", *ZLR* 1993, p. 283 *et seq.* (288).

101 Horst, "Point of View of Industry", in Commission of the EC, Second Symposium on Control of Foodstuffs, 1992, p. 68 *et seq.* (70).

Although there is no clear provision in favour of such a cooperation, article 5 No. 5 EEC Directive No. 89/397[102] states that examination of any control systems which the company may have established and the results thereof must be incorporated in the control work. Whereas there is no obligation for the companies to construct a certain own internal control system, the public authorities must, if a company has done so, take this private control system and its results into consideration when planning the public control system. This approach is in accordance with the principle of primarily preventive and not punitive controls. It makes, however, repressive controls not superfluous. This would also not be in accordance with article 4 par. 3 of the Directive which prescribes a control on every scale of the production and the trade of foodstuff.

Actually there are in existing secondary EC law some examples that the manufacturers' internal control of food production is used as a supplement to official control[103]. According to article 3 *et seq.* of Directive No. 85/397/EEC on the specific rules concerning the exchanges of heat treated milk[104], *e.g.*, the Member States must ensure that the milk is controlled by the firms under the inspection and responsibility of the public authority and the public authority must through regular control ensure that the milk meets the requirements laid down in the Directive. It is this directly stated in this Directive that the dairies must perform an internal control and that this must be planned in cooperation with the authorities.

Similar provisions are laid down in article 3, 7 of Directive No. 88/658/EEC concerning the trade with meat products within the Community[105]. Whereas these are very special provisions the questions is whether the internal control which covers much more than the examples mentioned above can be incorporated in to the public control work according to Directive No. 89/397/EEC, the Control Directive, in general. Art. 5 No. 5 of this Directive proves that this should be done. Weighing the costs against the benefits this coordination of controls is profitable for the public and the companies[106].

---

102 See footnote 65.

103 See Bergstrom-Nielsen, "Can the manufactures' internal control of food production be used as a supplement to official control?", in: Commission of the EC, Second Symposium on Control of Foodstuffs, 1992, p. 268 *et seq.* (269).

104 O.J. 1985 No. L 226, p. 13.

105 O.J. 1988 No. L 382, p. 15.

106 See Bergstrom-Nielsen (footnote 102), p. 274 *et seq.*.

In order to stimulate the companies to improve their control systems or to install a control system at all the existing advantages should be demonstrated and special advantages should be introduced, *e.g.* the right to use a special sign (*e.g.* an "e" mark) or considerable facilities regarding the control by public authorities. These privileges, however, are only justified if there are general standards of control regarding the requirements in substance as well as the procedures. This leads to the question, whether suitable standards already exist, *e.g.* the ISO 9000-series (EN 2900-series), which are included into the so-called "Global Approach" of the Communities.

IV. Applicability of the Global Approach for Conformity Assessment Procedures in respect of foodstuffs

Although the Global Approach[107] has been originally designed and promoted with a view to solve problems relating to testing and certification in the industrial, non-food sector, it can - to a certain extent - be also used in the food sector[108] too. At the second Symposium on Control of Foodstuffs, held at Rome in 1988, Farnell demonstrated that the Global Approach represented a broad framework for the development of consensus on testing and certification issues in every sector which should not be ignored by any sector[109]. He thinks that in the future some of the principles which have been developed for technical harmonisation directives for industrial goods may be applied in the food sector too[110].

---

107 See Communication No. 89/C 267/03 of the EC Commission "A Global Approach for Certification and Testing - Instrument for the Guarantee of the Quality of Industrial Products, O.J. 1989 No. C 267, p. 3; Decision of the Council of the EC No. 90/C 10/01, O.J. 1990 No. C 10, p. 1; Decision of the Council of the EC No. 90/683/EEC, O.J. 1990 No. L 380, p. 13

108 See Gorny, "Das Globale Konzept der EG-Kommission für Zertifizierung und Prüfwesen - Seine Bedeutung für betriebliche Kontrollsysteme von Lebensmittelherstellern", *Deutsche Lebensmittel-Rundschau* 1990, p. 44 *et seq.*, p. 76 *et seq.*

109 See Farnell, "The Global Approach of the EEC in the field of testing and certification", in: Commission of the EC, Second Symposium on Control of Foodstuffs, 1992, p. 254 *et seq.*

110 *Ibidem*, p. 264.

Whereas it is questionable whether quality standards on the composition of foodstuffs should be set up at all, and if they are to what extent[111], in the special field of the official control of foodstuffs the system of testing and certification according to the ISO 9.000 standards is suitable. Art. 5 par. 5 of Directive No. 89/397/EEC provides that the official control of foodstuffs shall comprise the examination of any verification system set up by the undertaking to be controlled. The matters which shall be verified, however, are enumerated in article 1 par. 2 of the Directive, *i.e.* the compliance of foodstuffs, of additives and so on with provisions aimed at preventing risks to public health, guaranteeing fair commercial transactions or protecting consumer interests, including provisions on consumer information.

These provisions are laid down in secondary EC law, *e.g.* the labelling Directive of the Council No. 79/112/EEC[112] or Council Directive No. 90/128/EEC on materials and articles intended to come in contact with food[113]. A system assuring compliance with such provisions, however, is nothing else but a quality assurance system in accordance with ISO 9.000 which is applicable when the conformity of a product with specified requirements has to be demonstrated[114]. This approach is confirmed by article 4 of the proposal of a Council Directive on further measures concerning the official control on foodstuffs[115] which provides the introduction of a quality assurance system according to generally accepted regulations[116].

D) Consequences for European regulation of foodstuffs

I. Matters which should be object of regulation

The "new approach" of the Communities which has been developed generally[117] but demonstrated especially on the example of foodstuffs[118] is

111 See Streinz, "Gibt es eine europäische Verkehrsauffassung?", *ZLR* 1991, p. 242 *et seq.* (270 *et seq.*); *BLL* 1992/93 (footnote 35), p. 173 *et seq.*
112 O.J.1979 No. L 33, p. 1.
113 O.J. 1990 No. L 349, p. 26.
114 Gorny, "European food quality. The prospective importance of ISO 9.000/EN 29.000", *EFLR* 1992, p. 13 *et seq.* (19).
115 O.J. 1992 No. C 51, p. 10.
116 See *BLL* 1992/93 (footnote 35), p. 33.
117 See White Paper (footnote 2), p. 18 *et. seq.*

in favour of a restriction of Community legislation. Experience has proved that this is the right way. Therefore EC food-legislation should also furthermore concentrate on horizontal legislation on labelling, public control and substances which actually or potentially cause damages to the public. There is no real need for vertical legislation. If the Community wants to set up certain standards for single products by reasons of agricultural or structural policy as it has announced in its Communication on the Free Movement of Foodstuffs[119] and as it has done *e.g.* in Regulation No. 1898/87/EEC on the protection of the appellation of milk and milk products[120] or Regulation No. 2081/92/EEC[121] and Regulation No. 2082/92/EEC[122] this is a legitimate issue, but it should be made clear that it is *stricto sensu* not food law. This is not only a demand of clarity but also of legal importance because the requirements of proportionality are other ones if the aim which is pursued is public health or are (only) agricultural interests.

II. Regulation by the legislative institutions of the Communities (Council - in cooperation with the European Parliament, Commission) - Reference to European standardisation organisations - Voluntary standards

Whereas the protection of public health is a main function of the State, substituted by the Community where the latter is competent [123], and whereas the realisation of this protection includes vice versa to impose duties to individuals (*e.g.* companies) the regulation of the "essentials" must be reserved to the Community's legislative organs, *i.e.* the Council - in cooperation with the European Parliament - or - in the field of delegated - the Commission powers[124]. Within this framework the committees of experts can have only a consultative function which is of course very

118 See the Communication, footnote 3.
119 See p. 13, No. 18 of the Communication (footnote 3).
120 O.J. 1987 No. L 182, p. 26.
121 Regulation No. 2081/92/EEC O.J. 1992 No. L 208, p. 1.
122 O.J. 1992 No. L 208, p. 9.
123 See Joerges, "The New Approach to Technical Harmonization and the Interests of Consumers: Reflections on the Requirements and Difficulties of a Europeanization of Product Safety Policy", in: Bieber/Dehousse/Pinder/Weiler (Eds.), 1992: One European Market, 1988, p. 175 *et seq.* (179).
124 See to this *Wesentlichkeitstheorie*, developed by the German Federal Constitutional Court, *e.g.* BVerfGE 45, 400 (417 *et seq.*), on the Community level see *e.g.* Rengeling (footnote 57), p. 220 *et seq.*

important and which has great influence but which cannot replace the political responsibility of the legislative organs. Whereas duties are imposed this is right for the rules on labelling, too. The regulation of the details, however, can be left not only to the Commission in cooperation with special committees according to the rules of the delegation of powers (article 145 par. 3, article 155 par. 4 EEC Treaty, Council Decision No. 87/373/EEC[125]), but also to European standardisation organisations like CEN.

This is exactly the approach of the new concept as it is laid down in Council Decision of 7 May 1985[126] which had been realised also in former times in Council Directive No. 73/23/EEC[127] and was further systematically pursued in a number of technical directives, firstly in Directive No. 87/404/EEC[128]. This approach can be followed in food law, too, so far as technical regulations on manufacturing, methods of analysis, monitoring, *etc.*, are concerned[129]. Whereas these standards are "voluntary", only the compliance with them guarantees the full advantages of the Common Market un-hindered by special controls[130]. It is, however, questionable whether this concept should be expanded to standards concerning the pure composition of foodstuffs because this would lead to another form of "vertical" harmonisation which should be replaced by mutual recognition according to the new concept. In my point of view it would be better to have in this field only "really" voluntary standards of companies or certain food branches which could be promoted by special labelling, protected by the law against unfair competition.

III. Provisions in the articles of the three drafts of a proposal for a general food directive

Taking a general look at the three drafts for a general food directive it

---

125 O.J. 1987 No. L 197, p. 33.

126 O.J. 1985 No. C 136, p. 1 See Anselmann, "Technische Vorschriften und Normen in Europa. Harmonisierung und gegenseitige Anerkennung", 1991, p. 28 *et seq.*; Griller, "Europäische Normung und Rechtsangleichung", 1990, p. 30 *et seq.*; Müller-Graff, "Technische Regeln im Binnenmarkt", 1991.

127 O.J. 1973 No. L 77, p. 29.

128 O.J. 1987 No. L 220, p. 48. See von Borries/Winkel, *Europäisches Wirtschaftsrecht*, 1991 (looseleaf), No. vor 210 *et seq.*

129 See BLL 1992/93 (footnote 35), p. 177 *et seq.*

130 See *e.g.* art. 4 of Council Directive No. 87/404/EEC (footnote 128).

seems that the draft of Professor Eckert is strictly oriented on food law questions *stricto sensu* whereas Professor Castang and - to a broader extent - Professor Cleary include other questions like the protection of the environment, the protection of animals or even general social issues. These topics of course concern legitimate and important policies, but I believe they should not be confused with food law. Food law has the task to protect the consumer against health risks and against misleading claims, and the rules within food law should be concentrated on and restricted to these objectives.

However, this does not mean that food law policy and the other policies mentioned above should not be coherent or coordinated. To give an example: To allow the manuring of the soil with mud deriving from purification plants is nonsense if this mud contains residues which reach foodstuffs and must not be in foodstuffs which shall be free to be sold. Therefore probably there may be a need to have some provisions also in food law to get this coherence with other policies. The substantive law, however, should remain separated. Only in this way the special problems of each field can be solved adequately, especially with respect to the principle of proportionality.

CONCLUSION

by

PROF. FRANCIS SNYDER

INTRODUCTION

Foodstuffs is a sector that affects every individual in the European Community. From the standpoint of regulatory policy, it involves two dimensions: first, the balance to be achieved between state and market, and second, the level of government at which regulatory policy and law is made. The Florence conference considered both dimensions. The fact that this was usually done in the guise of discussing the second shows, once again, how closely the two are related.

The achievement of a regulatory framework for foodstuffs may be achieved by the European Community, by the Member States, or by a combination of both. Within the past few years there has been a major discussion as to whether there should be a general framework directive on the free movement of foodstuffs within the Community, and, if so, what should be the form and contents of such a measure. Recently this discussion has been affected by the Sutherland Report on the Future of the Internal Market. It has also been directly influenced by the processes of ratification of the Maastricht treaty, especially the debate on the effectiveness of Community law, Community competence, the powers of the Commission, subsidiarity and other aspects of relations between the Community and the Member States, as well as negotiations between the Community and the United States within the GATT. It was in this context that this conference was organised.

The legal regulation of foodstuffs is not only highly political: it also involves extremely technical legal and scientific issues. Since 1962 European Community foodstuffs law has developed by means of different approaches and a variety of specific measures. The main approach since the 1985 White Paper has been the adoption of 'horizontal' framework directives. Consequently, in its 1989 Communication on the free movement of foodstuffs within the Community,[1] the Commission defined its strategy as 'combining the adoption of harmonised rules at Community level, which are applicable to all foodstuffs marketed in the Community, with the principle of mutual recognition of national regulations and standards for matters which do not require the adoption of Community legislative measures'. In 1989 the Council adopted Directive 89/397 on the official control of foodstuffs.[2]. In 1993 the Commission proposed a further directive on the subject of additional measures concerning the official control of foodstuffs. Most recently, the possibility of a general framework directive on the free movement of foodstuffs has stimulated a wide debate, not only the Florence conference but also numerous meetings of specialists within the trade.

MAIN QUESTIONS

The discussion at the conference focused on a number of related questions. These questions were raised by the presentation of the proposals for a draft directive and by the scientific reports by academic specialists. The former offered alternative (though overlapping) regulatory frameworks for foodstuffs, embodying different visions of the nature and level of regulation. The latter provided a series of theoretical perspectives, which helped to illuminate the choices of regulatory policy which are involved in formulating a framework directive. The following are some of the main questions raised during the conference.

First, is framework legislation needed? This question poses both a choice regarding the balance between state and market as well as a choice regarding the level of regulation. Any proposed legislation also raises the issue of a possible conflict between two different approaches, Community regulation used for Annex II products, and the 'new approach', especially

1 Communication 89/C271/03, OJ 20.10.89 C271/3.
2 OJ 30.6.89 L186/23.

mutual recognition, for other products. It also raises potential problems of coherence of policy, legislative texts, and principles and uniform definitions.

The policies of preventive consumer protection, food safety, public health and nutrition, and industrial and competition policy may not always be compatible. Moreover, from the legal standpoint, a framework legislation may be either a form of 'codification' or simply a *mise en ordre.* In either case, special difficulties arise in ensuring its coherence with other Community policies already enshrined in detailed legislation, in particular the Common Agricultural Policy or environmental policy. There are also problems linked to the limited field of application of existing directives. The reach of the subsidiarity principle is not yet known. Nor is it always clear what is included in health matters, for example. Indeed it has sometimes been suggested that the definition is a result of bargaining and compromise among Member States, mainly inspired by economic factors.

Problems also arise with regard to the uneven application of directives. The imprecision of legal texts masks differences in national legislation and/or practice. For example, there are differences between national laws concerning responsibility for defective products. Moreover, the legal text itself is only one factor to be considered in assessing the feasibility of regulation; others include size of market and industrial structure.

In addition, drafting a framework directive may require the specification of principles and concepts which are not yet defined in Community law. It may also require clearer choices of policy than might otherwise be necessary regarding the balance to be struck between state and market and the division of responsibility between the Community and the Member States.

Second, if there is to be general framework legislation, what legal form should it take? The differing merits and disadvantages of regulations and directives are well-known. However, the recent debate on subsidiarity promises to orient the Community towards a greater use of 'soft law', measures which in principle are not legally binding. These alternatives need to be assessed carefully with regard to the regulation of foodstuffs.

Third, what should general framework legislation contain? For example, should it define 'food law'? Should it lay down the principles or purposes

of food law? Should food law be concerned with food quality as well as with other aims such as public health, consumer protection and fair trading?

The proposed directives sometimes offer different answers to these questions. A brief list of the principles of food law, based on the proposals, would include the following: safety, public health, nutrition, conformity, the right to information, protection of the environment, respect for animal life, consumer protection, free movement of goods, fair trading, food quality and public confidence, adequate implementation, guaranteeing the legitimate interests of the industry, and ensuring the requirements of science and research. However, not all the proposals embody all of these principles, and even when two proposals contain the same principle they rarely express it in the same legal form.

Fourth, how should specific terms be defined? Among the terms and expressions that are defined in at least one of the three proposals are the following: 'foodstuffs', 'manufacture', 'placing on the market', 'first placing on the market', 'handling', 'safe', 'fit for human consumption', 'consumer', 'producer', 'distributor', 'professional', 'food additive', 'technological and processing aid', 'ionising irradiation', 'contaminant', 'contaminated food', 'pesticides', 'pesticide residues', 'residues of veterinary medicinal products', 'materials and objects in contact', 'materials and articles', 'certification', 'claim', 'total diet studies', 'labelling, and advertising and presentation of food'. These terms and expressions are defined in different ways, and each set of definitions has its particular coherence as part of a more general conception of food law and its aims in each specific proposal. This coherence sometimes involves (but does not always do so) explicit reference to a closed list of existing or additional specific Community legislation, for example concerning the essential requirements of health and safety.

Fifth, how would a framework directive be related to existing case law? In some instances, the former expressly restates the latter. Examples in the proposed directives concern legitimate expectation, mutual recognition, and mandatory requirements. In other instances the case law of the Court of Justice is assumed.

Sixth, how should responsibility be assigned among different parts of the food chain? Among the proposals made in the proposed directives are that

the responsibility for claims be placed on the professional; that the burden should rest on the producer or distributor to prove safety; that producer or distributor should be required to monitor the safety of all food within its control and notify the Member State; that responsibility should rest on anyone manufacturing, handling or marketing food to ensure compliance within his sphere of responsibility; that the producer or distributor be required to provide the consumer with all information necessary for the safe and best nutritional use of the food; and that the producer or distributor must supply to a regulatory body information regarding processed foods before first marketing or at the request of the regulatory body. Private and public laboratories would have delimited roles.

Guarantees should be established of quality, safety or conformity. The producer or distributor would be liable for damages in certain circumstances and subject to certain defences. Interim protection measures could be allowed by Member States. Among other proposals were those that individuals could refer matters to a court; if they had reasonable grounds to suspect that food was unsafe or unfit, they could request national authorities to test it; and consumer organisations as well as individuals might be entitled to claim compensation. It was also suggested that, for imported food, the Member State of first import be required to insure compliance, with the importer being responsible for carrying out necessary checks and controls on food from third countries and assume any liability.

Seventh, what should be the division of responsibility between the Community and the Member States? Leaving aside the issue of a proposed European Food Agency (EFA) (see below), Member States may have different specified duties; sometimes similar duties are couched in rather different legal terms. Duties may also be imposed on Community institutions. Some examples may be drawn from the proposals.

Thus, Member States may be obliged to adopt new legislation only by the procedure laid down in Directive 83/189. They may be obliged to adopt the necessary measures and ensure cooperation with a regulatory agency. Article 5 EC may be restated in a directive. Member States may be prohibited from enacting soft law affecting the sector.

Food inspection may be the duty of the Member States. They may be required expressly to ensure that guarantees regarding quality, safety or

conformity correspond to objective verifiable criteria. Member States may be required to test food on the request of a consumer having reasonable grounds to suspect the food is unfit or unsafe. A Member State may require a producer or distributor to inform the public and to remove or recall foodstuffs. The control of foodstuffs may be the duty and responsibility of the Member State, in the sense that Commission measures to ensure uniform control practices must be carried out in agreement with the Member States. Measures taken by Member States may be subject to procedural guarantees, the principle of proportionality and liability to compensate if not merited.

Member States may be required to inform other Member States and furnish certain information. They may be recommended to gather information and send it to the Commission; alternatively, they may be required to supply certain information. They may be obliged to make an annual report to the Commission, with the Commission to comment on the report, and the report and the comments to be published in the Official Journal. Member States may be required to inform the Commission of action affecting the free movement of goods. They may be obliged to collect statistics on food poisoning and to forward it annually to a regulatory agency. They may be entitled to prohibit imports or exports on reasonable grounds of suspicion of unsafety and upon informing a regulatory agency.

There may be a Community procedure for preventing or averting health risks. The Commission may be empowered to take certain measures in conjunction with Committee for Food Safety Emergencies. The Commission may be mandated expressly to take steps to adapt EC law as necessary. It may be stated expressly that both the Community and the Member States are required to comply with specified basic principles.

Eighth, what should be the respective roles of the Commission, the Council, the European Parliament and other Community/Union institutions? The proposals concern relations between the Commission, its committees, and the Council in particular. Thus, in order to prevent health risks the Commission may adopt the necessary measures or propose directives to the Council. It may take certain measures to avert health risks, in conjunction with Committee on Food Safety Emergencies. The Standing Committee on Foodstuffs make be entitled, on the basis of health risks, to take measures restricting marketing or to meet potential risks from imported food. It may be required to be consulted regarding the steps to

adapt EC law. The specific form of its procedure may be laid down. The Scientific Committee for Food may be required to be consulted regarding steps to adapt EC law.

In order to deal with potential health risks from imports, the Commission or a Member State may initiate the committee procedure, and the Commission may adopt the necessary measures or propose directives to the Council. The Commission may set up food monitoring agency with power to make recommendations. The proposed directives also provide that the Commission shall report to the Council, the European Parliament, the European Court of Justice, the Economic and Social Committee and the Member States on the transposition of directives by Member States. Alternatively, the Commission may be required to report periodically to the Council and the European Parliament and to submit proposals.

Ninth, to what extent is a new food regulatory body or monitoring agency necessary, and what powers could or should it have? The proposals for a directive present different views regarding the desirability, feasibility and role of such a body. One view is that the existing organs, especially the Committee on Food Safety Emergencies, are sufficient. An alternative position is that a food monitoring agency should be established with the power to make recommendations. A third position posits a regulatory agency or body with a more important role.

On this third view, such a body would be entitled to be informed of decisions taken by Member States to prohibit imports or exports. It would coordinate emergency prohibitions and if necessary impose time limits; approve additives [AC art 5(1)(ii)] and set down conditions for their use; put forward proposals to regulate production and supply of foods otherwise unfit for human consumption; collate and publish in statistics collected by the Member States on food poisoning; undertake total diet studies; carry out research and promote improvement of food quality; compile nutritional guidelines and publish nutritional standards.
It would also compile and publish information on processed foods to enable consumer to make informed choices; establish requirements concerning the information to accompany processed foods when marketed; and be entitled to propose measures on food production and supply. It would also be entitled to act as arbiter, subject to appeal to the European Court of Justice, concerning the suspension or restriction of free movement of foodstuffs, as well as to be consulted by the Commission regarding

legislative proposals to ensure their full application.

From the political standpoint, the questions of whether a new organ is necessary, and if so, what its role should be, are inherently controversial, especially in the light of the Maastricht Treaty and the subsidiarity debate. Nor is the legal position regarding the establishment of such an organ entirely free from ambiguity. Further consideration of this question is required: it could usefully draw on the recent contribution of the EUI to the deliberations of the Sutherland Committee[3].

Tenth, how are Community rules related to international controls?
It has been proposed, for example, that *Codex Alimentarius* codes on hygienic practice should apply in the absence of EC rules; that Member States cannot apply food law provisions not found *inter alia* in international law; that the *Codex* code of ethics for international trade may, at request of a third country importer, govern exports from the EC; and that the Community and Member States should expressly be required to cooperage with third countries, GATT, FAO, WHO and other relevant international organisations.

Eleventh, how can interest groups be integrated better in the enactment and enforcement of food law? The committees which are regularly consulted by the Commission are an essential part of the Community system. In the light of the recent debate on transparency, however, it may be suggested that they do not sufficiently convey in an open and comprehensible way to the public at large the various interests which may be concerned with the enactment of Community foodstuffs legislation.

Twelfth, what rules should govern trade in foodstuffs with third countries? For example, should the importer or the importing Member State be responsible for verification of imported foodstuffs? With regard to exports, should Community legislation or the legislation of the Member State of export apply, or a derogation to the *Codex*?

Finally, should an express deadline for transposition be laid on Member States? Should Member States be expressly required to inform the Commission of any incompatible national laws?

---

3 See R. Dehousse, C. Joerges, G. Majone and F. Snyder, in collaboration with M. Everson, 'Europe after 1992: New Regulatory Strategies', *EUI Working Paper* LAW No. 92/31 (1992).

SPECIAL FEATURES

In addition to its general scientific results, the conference had certain special features which should be noted. In the view of the participants, these special features were a distinctive part of the conference and helped very much to contribute to its success.

First, as a number of participants remarked, it proved to be an excellent idea to bring together Commission staff, representatives of interest groups, national specialists, academic exports and academic specialists in related fields. This format helped to foster communication and create networks: among people who often participate in the same legislative process but do not usually meet, and also among people who are specialists in related fields and whose special expertise may illuminate the process of making Community food law.

Second, the organisation of the conference also made it possible to achieve two aims simultaneously. On the one hand, a specific aim of the conference was to appreciate the proposed draft directives and alternative forms of regulation as means of dealing with a number of specific technical issues. On the other hand, a general aim of the conference was to view this specific legislation and other forms of regulation in a broader perspective, especially by situating them in a social, political and economic context. This double challenge is precisely that which currently faces the institutions of the European Community and the European Union. The conference organisers hoped that it would be possible to work on these two different levels - the specific and the general, the technical legal and the contextual - during the same conference and with participants of different but overlapping interests. They were very pleased to learn that, in the opinions of the participants, the conference achieved this ambitious objective. The conference may thus suggest the potential value of this format in relation to other topics.

ANNEXES

Annex I

Drafts for a General Framework Directive in the Foodstuffs Sector

a) Draft Directive by Professor Charles Castang

b) Draft Directive by Professor Amanda Cleary

b) Draft Directive by Professor Dieter Eckert

Annex II

Programme of the Conference

Annex III

List of Participants

[a]

DRAFT GENERAL DIRECTIVE ON FOODSTUFFS

PROF. CHARLES CASTANG
University of Aix-Marseille III

DRAFT GENERAL DIRECTIVE ON FOODSTUFFS

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas at present numerous individual food law provisions exist at Community level but there is as yet no self-contained body of Community food law;

Whereas it is necessary to establish uniform definitions and common principles of substantive food law and to incorporate in such a general framework the individual Community provisions that already exist or are still to be adopted;

Whereas, furthermore, in a common internal market comparable rules of procedure have to be applied in the Member States, and this is true as regards both the likely action by the authorities and the rights of persons affected by such action;

Whereas official food inspection is the duty and responsibility of the

Member States; whereas this does not, however, exclude action by the Commission to ensure a uniform system of inspection in the Community;

Whereas in order to avert health hazards appropriate methods have to be applied throughout Community food law,

Whereas the Member States and the Community should have at their disposal as many nutritional and epidemiological statistics as possible to provide better guidance for action relating to food law;

HAS ADOPTED THIS DIRECTIVE:

TITLE I: Scope and general principles

Article 1: This Directive sets out the general principles which should govern the marketing of foodstuffs in the European Community.

Article 2: Foodstuffs shall, from the time of first placing on the market and under the prescribed or reasonably foreseeable conditions of use, be as safe as necessary so as not to endanger the health of consumers.

This Article lays down the "principle of safety" which governs all food law.

Article 3: Foodstuffs placed on the market shall conform to the characteristics legitimately expected by the consumer, who shall be given enough information to enable him to make an objective choice.

Article 4 lays down another essential principle of food law, namely the "principle of conformity" and the "right to information".

Article 4: The production, processing, storage, packaging, transportation and marketing of

This Article establishes a

plant or animal foodstuffs or foodstuffs of animal origin shall take account of the agricultural and industrial practices which are most compatible with a safe environment and respect for animal life.

link between food law and the environment and thereby complements the provision of the Maastricht Treaty to make the environment a "Community policy". It also corresponds to consumer demands.

Article 5: Food law as enacted and accepted by the Member States and/or the Community shall be closely coordinated with national and/or Community nutritional policies to increase consumer protection and satisfaction, taking account of current scientific knowledge and the specific situations found within the Community.

This Article reflects the Chapter of the Maastricht Treaty which refers to "a high level of consumer protection".

TITLE II: Definitions

Article 6: For the purposes of Community food law the following definitions apply:

(a) "Foodstuffs" means products intended for human consumption in an unprocessed, processed or composed state, with the exception of tobacco products, cosmetics and pharmaceuticals.

(b) "Placing on the market" means supplying, stocking for human consumption,

offering for sale or delivering against payment or otherwise.

(c) "First placing on the market" means the supply of a foodstuff by the producer, manufacturer or importer.

(d) "Consumer" means any natural or legal person who procures or uses foodstuffs for consumption by himself or his family. Publicly or privately owned catering establishments, hospitals and canteens are also regarded as consumers.

(e) "Professional" means any natural or legal person, whether public or private, who sells foodstuffs or delivers them against payment or otherwise in the performance of a habitual activity.

(f) "Food additive" means any substance not normally consumed as a food in itself or used as a characteristic ingredient in food, whether or not it is nutritive, the intentional addition of which, for technological purposes, to foodstuffs during production, processing, preparation, treatment, packaging, transportation or storage results in, or can reasonably be expected to result in, its becoming, or its derivatives becoming, directly or indirectly, a constituent part of such foodstuffs.

(g) "Technological and processing aid" means any substance not consumed as a food ingredient in itself and intentionally used in the processing of raw materials, foodstuffs or their ingredients to fulfil a certain technological purpose during treatment or processing and which may lead to the unintended presence of

technically unavoidable residues of the substance or its derivatives in the final product, provided that these residues do not represent any health risk and do not have any technological effect on the final product.

(h) "Contaminant" means any agent or substance the presence of which in food is considered undesirable, except substances produced normally and naturally by the animals or plants themselves and food additives, *i.e.* products deliberately added.

(i) "Pesticides" means substances and mixtures thereof used for combating or controlling all kinds of pests. The term includes substances and mixtures thereof used as plant growth controllers, defoliants or desiccants. It does not include fertilisers.

"Pesticide residues" means substances present in food as a result of the use of a pesticide. The term also includes all pesticide derivatives, such as degradation, transformation, metabolic and reaction products, which can be regarded as toxicologically significant.

(j) "Residues of veterinary medicinal products" means pharmacologically active substances, whether active components, excipients or degradation products, and their metabolic products, found in foodstuffs obtained from animals to which the veterinary medicinal product in question has been administered.

(k) "Materials and objects in contact" means materials and objects which, as final

products, are intended to be brought into contact or are brought into contact with foodstuffs for their intended purpose.

(l) "Certification" means the procedure by means of which the conformity of a product or production process with a set of previously defined specific characteristics is certified.

(m) "Claim" means any information, message or other representation which states, implies or suggests that a foodstuff has particular characteristics, properties or effects.

TITLE III: Marketing

Article 7: Foodstuffs may not be placed on the market:

Art. 7 makes explicit, notably, the principle of safety laid down in Art. 2.

(a) where they contain additives which are not permitted under Community law or where they fail to comply with maximum quantities or other authorisation conditions;

(b) where they do not comply with Community provisions on the irradiation of foodstuffs;

(c) where Community rules of procedure for hygiene testing of new kinds of foodstuffs, substances or processes have not been observed;

(d) where the pesticide, veterinary medicinal product or contaminant residues in or on them exceed the maximum quantities laid down in Community provisions;

(e) where they do not comply with the other Community provisions on the use of pesticides or veterinary medicinal products;

(f) where, contrary to Community provisions, substances from materials and articles are transferred to them;

(g) where they do not comply with Community hygiene rules or, in the absence of such rules, with the codes of hygienic practice recommended by the *Codex Alimentarius* or where the foodstuffs are prepared, stored, transported or handled under conditions which do not comply with the above mentioned requirements.

Article 8: A foodstuff placed on the market must correspond to what the consumer legitimately expects.

This legitimate expectation is the result of laws, regulations and acknowledged use concerning the foodstuff, information provided by the persons marketing them, and the specific or implied terms of any contract between the consumer and the food professional.

This Article makes explicit the principle of conformity referred to in Article 3.

Article 9: Foodstuffs sold shall provide the user and the final consumer with all useful information about their characteristics such as their nature, composition, quantity, utilisation, method of use or storage, origin and source, and the name and address of a person responsible for them, in plain language by means of their labelling or any other appropriate means.

The presentation of foodstuffs, their labelling and advertising, their packaging and, in general terms, all information about them must be such that it does not lead to confusion in the minds of consumers and is not likely to mislead them.

Article 10: Foodstuffs of which the presentation, intended use or composition refer to terms defined by legislation or in constant use must be placed on the market accompanied by all the particulars needed to ensure that the consumer is fully informed.

Articles 9, 10 and 11 concern consumer information

Article 11: A food professional must be able to substantiate any claim he makes by reference to objective verifiable information.

TITLE IV: The Free Movement of Foodstuffs

Article 12 Subject to Article 8, foodstuffs lawfully manufactured in one Member State may be marketed in the other Member States. Where they do not comply with the provisions of those countries, consumers shall be protected against deception and fraud by appropriate marking. In the case of foodstuffs for which the same or a similar trade name is enshrined in the legislation of various Member States or is generally accepted, even in the event of different composition or otherwise different quality, if the consumer cannot be guaranteed adequate information by some other means the marking must indicate the origin or the recipe of the foodstuffs.

Article 13: A Member State may not prohibit the free movement of a foodstuff which complies with the requirements of Article 8 unless there are urgent reasons for so doing on the basis of Article 36 of the EEC Treaty and provided that the prohibition is in proportion to the harm to be prevented or that no appropriate measure other than prohibition can prevent the harm which would result from the free movement of that foodstuff.

The purpose of this Article is to enshrine in law the judgements of the Court of Justice arising from the "Cassis de Dijon" judgement

Article 14: Member States shall refrain from introducing in their internal legal system any provision on the marketing of foodstuffs other than the procedure laid down in Directive 83/189.

Article 15: Member States shall keep their administrative and judicial bodies permanently informed on Community provisions. They shall ensure that decisions made by their administrative authorities do not conflict with these provisions and that judgements of the European Court of Justice are quickly taken into account, if necessary by amendment of their legal or administrative provisions. Insofar as they are able they shall also ensure that appropriate remedies are found in cases where judgements of their courts conflict with Community food law.

Article 16: Member States shall refrain in particular, in order to ensure the legal certainty of intra-Community trade, from applying food law provisions which are not issued by the authority which has legislative or regulatory power or which are not to be found in Community or international law.

TITLE V: Rules of application and controls

Article 17: Member States shall ensure that guarantees of quality, safety or conformity which accompany the presentation of foodstuffs and which are issued by bodies not responsible for marketing foodstuffs correspond to objective, verifiable criteria which are relevant to the foodstuff in question and are kept at the disposal of consumers and the public authorities responsible for food inspection.

Article 18: Food inspection is the duty and responsibility of the Member States and must be carried out with due regard for the principle of proportionality between the aim pursued and the measures taken.

Article 19: Depending on the seriousness of infringements of food law provisions and in conformity with the principles of the Treaty and its applications, Member States shall take one of the following measures and shall state the reasons for which it is being taken:

-warning
-recall order
-provisional seizure
-seizure
-destruction
-marketing restrictions and measures
to bring the foodstuff into line.

Article 20: The measures provided for in Article 19 shall not prevent the possibility of

referral to the legal authority, at the request either of the inspecting authority or the party concerned.

Article 21: Any *interim* protection measures decided by the public authorities and any referral to the courts shall provide the persons to whom such measures apply with guarantees enabling them to submit their observations and defend their lawful rights within reasonable periods of time compatible with the exercise of such guarantees.

If, because of the serious risks which would result from marketing of foodstuffs which do not conform, emergency measures have to be taken immediately, the parties concerned must be able, by means of an easily implementable procedure, to vindicate their rights *a posteriori*, including those in respect of any compensation.

TITLE VI: Community procedures to prevent health risks

Article 22: Any measure restricting, for health reasons, the marketing of a foodstuff originating in a Member State (where it is freely marketed) must be communicated to the Commission, notwithstanding the procedures already in force under the Community system for the rapid exchange of information pursuant to Council Decision 89/45/EEC of 21 December 1988.

Article 23: Where the Commission is notified pursuant to Article 22, it shall seek the opinion of the Standing Committee on Foodstuffs and shall adopt the necessary measures or submit a proposal for a Directive to the Council.

TITLE VII: Trade with non-member countries

Article 24: Foodstuffs imported into the Community from non-member countries must comply with Community provisions.

The Member State in which the foodstuffs are first marketed shall ensure compliance with the above. Where necessary, it shall take appropriate measures to prevent the foodstuffs concerned from being released for free circulation within the Community and shall inform the Commission thereof.

Article 25: The professional who imports the foodstuff into the Community shall assume liability for it. He shall be responsible for carrying out the necessary checks and controls.

Article 26: Where there are factors indicating that a foodstuff imported into the Community poses a health risk, the Commission or any Member State shall initiate the procedure provided for in Article 23 with a view to taking the necessary protective measures.

Article 27: Foodstuffs exported from a Member State to a non-member country shall comply with the legislation in force in the Member State concerned or in the Community.

However, if so requested by the importer in the non-member country, the above provision may be departed from provided the foodstuff concerned also complies with the provisions of the Code of Ethics for International Trade as defined in the *Codex Alimentarius*. The exporter shall provide all necessary proof of

the conformity of the foodstuff at the request of the competent authority.

TITLE VIII: General provisions

Article 28: In order to prevent risks and to adapt food law to the rights and needs of consumers, it is recommended that the Member States gather nutritional or epidemiological data relating to food and send them to the Commission which, after consulting the Foodstuffs Committee and the Scientific Committee for Food, shall take the appropriate steps to adapt, where necessary, current Community law.

To this end the Commission may set up a "food monitoring agency" to make recommendations on the basis of the data supplied by the Member States.

The idea of a "food monitoring agency" has made substantial progress in recent months, both in the Community and in several Member States which are setting up a facility of this kind.

Article 29: Member States shall draw up an annual report on both the application of Community food law and the situation with regard to national food law and its application.

This report shall be sent to the Commission at the latest during the first quarter of the year following that to which it refers.

The Commission shall make its comments on the report known as soon as possible and at all events during the year in which it received the report.

The report and the Commission's comments shall be published in the Official Journal of the European Communities.

Article 30: The Member States and the Commission, notwithstanding the application of the laws in force, shall adopt all necessary measures to bring national and Community provisions into line with this Directive within two years. At the end of that period, the Commission shall draw up a report on the action taken in application of this Article. This report shall be sent to the Council of Ministers, Parliament, the Court of Justice and the Community or national authorities concerned. It shall be published in the Official Journal of the European Communities.

[b]

DRAFT FRAMEWORK DIRECTIVE ON FOOD LAW

PROFESSOR AMANDA CLEARY
University of Surrey

Summary of Contents:

1. Introduction: The Objectives and Functions of Food Law

Food law is generally understood as being that body of legal provisions which regulate the production, processing and sale of food; as such it has a distinctive character and is unique in its interdisciplinary relation to food sciences and technologies. In all countries, it is a collection of principles and rules derived from a number of different branches of law; and even though the extent to which food law can be said to belong predominantly to one or other recognised category of legal science (civil/criminal, public/private) varies considerably from one jurisdiction to another, all commentators agree that in the industrialised countries the objectives of food law are primarily the protection of public health and the promotion of fair trading. Within the European Community, there is the additional objective of achieving a free trade are and/or intra-Community exchanges, which has tended to obscure the other two.

Given the nature of these objectives, it is immediately apparent that it is

necessary for food law to reconcile conflicting interests. As A. Gérard has noted: "there is a fundamental difference between the two imperatives of protection of public health and ensuring fair trading." This simple observation is in essence the key to much of the current difficulty in developing effective food law at a time when the rapid progress in science and technology frequently leaves detailed regulations and standards outdated and obsolete. The problem is that the protection of health is not automatically achieved by ensuring conditions of fair trading, or *vice versa*; and certainly the completion of the internal market raises different issues again. While it should not be overlooked that consumers and producers have certain complementary interests and ultimately depend upon each other for their continued existence, beyond a certain point their interests necessarily diverge:

- All those involved in food production and processing must be overridingly concerned with profit, and the economics of the food industry are such that the freedom to innovate in all sectors is highly prized:

(i) technological methods of increasing production of basic agricultural commodities can be a very efficient method of cutting costs;

(ii) processors constantly seek means of "adding value", exploiting consumers' desire for greater convenience, and profits may also be readily increased by substituting cheaper ingredients for more expensive ones;

(iii) retailers seek to stimulate greater sales through ever more alluring modes of presentation.

- From a consumer viewpoint, choice and price are clearly important, but as people become increasingly aware of the link between diet and disease, so the emphasis is increasingly on health considerations. The consumer is an innately conservative creature as regards food, and only if it is perceived that there are effective legal safeguards is there confidence that health is protected. Indeed, there is general scepticism about "what goes into" processed foods, and distrust has been compounded by the disarray of governments when faced by food scares, *e.g.* BSE, listeria in cheese. The public does not view safeguards lightly: it is *sine qua non* that food should be safe and given that risk can never be entirely eliminated, all measures should err on the side of caution. Then, over and above basic

food safety, there is an increasing concern that food should be "healthy", *i.e.* not just wholesome but also nutritious. Quality is also of importance here.

Attempts to reconcile these discrepant interests characterise much of modern food law. It has fallen to the legislator or judge to hold the balance between them, and where the point of balance is fixed determines whether trade or consumer interests prevail. Ideally they should be counterpoised, but as the review below will show, this desirable goal has not yet been attained. The reasons for this will also be explored.

2. Food Law Developments to Date

Expert opinion as to the current state of food law is by no means united. A Gérard declares:

"All modern food law, whatever the national system, places the protection of the consumer's health in the forefront of the law maker's concern. Most systems, in fact consider this protective function as the dominant one."

Whereas A. Painter is of the view that:

"Most legislative action taken in the mid and late 20th Century has been the result of trade and industry seeking controls to maintain standards of fair trading"

That two such different views can be put by leading food law specialists is probably an indication of the confusion that has resulted form the *ad hoc*, piecemeal development of the subject at national, Community and international level *post* 1945.

2.1. The Common Law perspective

Given the general nature of the evolution of the Common Law, it is hardly surprising that the twin principles outlined above are nowhere enshrined in either British or Irish legislation. Although there is record of concern for the welfare of the population as early as the 13th century, the principle motivation behind the control of food manufacturing then, as now, was to protect the honest trader and legislation has always been fragmentary and

crisis led. It is interesting, but predictable, that the recent UK Food Safety Act, although promoted as "the first major overhaul of general food law for 50 years", is not a statement of the basic legal principles applicable to food and does not (despite its rather misleading title) even contain a general safety requirement for food.

While introducing a number of more stringent controls than before, it in fact preserves many of the provisions of earlier legislation and from the consumer's viewpoint, can at best be viewed as a framework Act capable of enabling greater protection in the future. In fact, during the course of the legislative process, the Government resisted attempts to introduce broad principles, preferring to rely on general offences and specific enforcement powers. This may be why, despite the declared aim of the Act being to strike a balance between consumer protection and "the needs of an innovative and competitive food industry by avoiding unnecessary burdens and controls", the leading commentary on UK food law still reads:

"The organised consumer movement which developed in the 1960s and 1970s has had only a peripheral effect upon food law."

Certainly, the development of the Common Law continues to be reactive and piecemeal, an approach exacerbated by the lack of a general food policy in both the UK and Ireland, where food is seen either as part of agricultural policy or an extension of industrial and commercial policy. Consumer confidence was not increased by the Ministerial decision of November 1989 to establish a Food Safety Directorate within the Ministry of Agriculture, Fisheries and Food. This served to confirm long-held suspicions that priority is given to food production rather than consumption. In Ireland this tendency is even more marked. Consumer and public interest groups continue to urge the creation of a distinct food ministry to ensure that consume interests are kept separate form those of food producers. It seems unlikely that this will occur in the foreseeable future.

2.2. The European Community Context

Since by 1989, about 70% of UK food law was directly derived from EC law, and measures have continued to be adopted apace, the inadequacies of the Common Law (and presumably other national systems) would be of

far less importance if Community legislation and case-law were based on a more even-handed respect for the twin objectives of fair trading and public health.

This has not been the case. Indeed, it is curious that a Community legal system which is based mainly in the Civil Law tradition should so closely resemble the Common Law development. As in the UK, there is an extensive body of legislation in the agri-foodstuffs sector, but it is a welter adopted on a pragmatic *ad hoc* basis rather than a comprehensive code based on a systematic approach. The reasons for this are principally political: the EC has no overall policy for food. Rather, it has a number of distinct and sometimes conflicting policies which all have varying degrees of impact on food marketing and production, *e.g.* agriculture, the 1992 programme, environment, consumer protection, competition, fisheries. However, deficiencies in the legal framework in which food law is adopted serve to exacerbate the policy *lacunae*.

In terms of the EC Treaty, food constitutes "goods" like any other and, therefore, falls within the scope of Article 2 and must be permitted to move freely throughout the common market. may foodstuffs are, of course, also agricultural products, and are subject to the additional considerations of the Common Agricultural Policy, but until recently agricultural harmonisation measures were usually taken under both Article 43 and Article 100, the specific power to harmonise legislation and the power used to almost to exclusion of all other as regards processed food. In theory, any measures adopted thereunder could deal comprehensively with the safety and nutritional aspects of the food in question, but the problems encountered in reaching consensus between the Member States on even the most rudimentary of matters discouraged such an approach.

The upshot has been that the use of Article 100 as the primary motor of EC food legislation has emphasised free trade above all in its content. Although there are marked differences of approach to the function of legislation in relation to processed foods and raw food commodities (a "minimalist" approach to the former, whereas it is unreservedly interventionist in the latter; application to all processed foods, but only to commodities intended for the Community market), it has been quite clear that the overriding priority is guaranteeing intra-Community trade and/or completing the Single Market. Considerations of fair trading appear to be

limited to some metrological and price indication controls and wider issues of competition policy, while the protection of public health tends to be viewed in terms of potential barriers to trade to be challenged under Article 30. Only as well publicised food scares have threatened to disrupt trade, have health issues been promoted to priority level for Commission action.

The judgements given by the European court of Justice have served to reinforce the trade orientation of Community law, an outcome hardly surprising when the majority of cases concerned with food have been brought under Article 30 and been concerned with the removal of trade barriers; public health has featured only as a possible defence available to the Member States seeking to justify their allegedly protectionist national regulations rather than as an objective in itself. Given that the European Court of Justice has consistently interpreted Article 36 as meaning that there must be "a seriously considered health policy" and "a real threat to human health" arguments that a product may be prohibited on the grounds of lower nutritional value have been given short shrift, *e.g. Commission v France* (Case 116/84, "Milk Substitutes").

Whether the adoption of the Single European Act has improved or worsened the situation is a moot point. Certainly there was scope for improvement as Article 100A gives extensive powers to the Community to harmonise food legislation using the qualified majority voting procedure and requires the Commission to base its proposals on a high level of health, safety, environmental and consumer protection. However, the Commission post-SEA approach was very much coloured by the failure of the 1969-1973 harmonisation, when it proved to be so difficult to reach agreement between the Member States on specific measures.

So, while in its Communication of 8 November 1985, the Commission stated it would be prepared to regulate in the field of essential public needs and that included the protection of public health and other "mandatory requirements" such as fair trading and consumer protection, the Commission has in fact chosen to interpret its own statement very narrowly. Much lip service has been paid to the principle of "subsidiarity" and the right of the Member States to set quality and nutritional targets at the national level; and even though some extremely valuable framework measures are now in place for additives, materials, articles in contact, dietetic foodstuffs and official control, much essential substance is

lacking, and it is to be feared that once the detail is to be agreed, lack of consensus will emerge again.

Worse, some extremely vital areas from a health viewpoint have yet to be tackled, *e.g.* biotechnology, contaminants. Thus it appears that the notion of a "high level of protection" has yet to be translated into practice; that it should be is all the more essential in the light of the current consumer information policy which is based on little more than labelling. This not only presupposes an unrealistically high level of public awareness and education, but also requires highly informative labels - unfortunately the measures taken regarding nutritional labelling do not fulfil that requirement.

As regards the agricultural products sector (unprocessed foodstuffs), the Commission appears to have fewer reservations about imposing standards and many of these have indirectly benefited both public health and fair trading, albeit at a price to the consumer's pocket! However, in this sector necessarily the interest of the producer are paramount, there are some basic weaknesses, *e.g.* no controls on butter or cheese, which both have considerable potential for food poisoning, feeble controls on pesticide use and residues.

The present approach tends to create an artificial dichotomy between public health and free trade considerations with the former an obstacle to the latter. This has been reinforced by judicial pronouncements to the effect that where there are no harmonised Community rules on individual aspects of foodstuffs, Member States can set their own rules. Thus, *prima facie*, in the event of inaction by the Community, Member States may procure public health protection by legislating at the national level. However, in reality this power is far weaker than it at first appears.

The European Court of Justice has held, on many occasions, that although public health falls within Article 36, the purpose of that article is not to reserve public health (or any of the other grounds) to the exclusive jurisdiction of the Member States. It merely allows national legislation to derogate from the principle of free movement of goods to the extent to which this is, and remains, justified in order to achieve the goals set out in the article (viz *Commission v Germany* (health control on imported meat), Case 153/78). Consequently, fear of infringement proceedings makes Member States reluctant to legislate in any are if this might be construed

as a trade barrier (especially in the light of Directive 83/189 on notification of Member States' draft technical regulations relating to foodstuffs); and this can create a real vacuum to the public's disadvantage.

3.2. International aspects

As all the Member States of the EC are also members of the *Codex Alimentarius* Commission, it is appropriate that the role of the *Codex Alimentarius* and the joint FAO/WHO Food Standards Programme should be considered at least briefly. The aims of the programme seek to protect the health of consumers and to ensure fair practices in the food trade, both its principal objective is to facilitate international trade in foodstuffs while seeking to provide for the consumer "a sound, wholesome product free from adulteration, correctly labelled and presented". It was hoped that the forum would permit an international consensus to be reached on both the health and economic aspects of food standards, but the tendency has been (as in the EC) to emphasise the trade rather than the health aspects, a tendency enforced by GATT influence. Moreover, with the general move away form sectoral/vertical control in Europe, *Codex* standards appear to be of declining legislative importance. In all events the *Codex* cannot be said to provide a comprehensive international framework for food law at present.

The principal conclusion to be drawn is that there is no systematic approach to food law at the national, Community or international level, and this has led to an imbalance between trade and health interests.

At EC level, this is largely the predictable result of the Community's economic origins, but now that the completion of the Single Market is in sight, other considerations should increasingly be given equal weight. For this to happen, it is essential that the legal framework in which food law is adopted, should be amended. A general directive on the fundamental principles of food law would provide the means to do this.

3. Objectives of the Proposed Directive

Given the development of food law to-date, it is reasonable that the overall objectives should be three-fold:

(i) To protect public health;
(ii) To ensure fair trading;
(iii) To create/maintain the free trade area.

However, if the public is to have real confidence in the safety and nutritional value of the food available in the Single Market of 1993, it will be essential for the first of these to be given equal weight, if not precedence.

As a starting point, the preliminary consumer protection of 1975 is useful, but the unique and complex nature of all matters pertaining to food is such that overly general provisions will be ineffective. The following suggestions are intended to overcome the problem:

- It is self-evident that food should be "safe", but the protection of health is not exclusively concerned with safety. If public health is to be improved (the objective of other EC programmes) then more will have to be done than merely considering basic safety. As the WHO report "Diet, Nutrition and the Prevention of Chronic Diseases" (1990) concludes: "Changes in diet and lifestyle can protect against premature deaths and the chronic diseases which affect people in their middle and later years". Interest in the nutritional aspects of food looks certain to increase (see that 1994 has been designated European Year of Nutrition) and the Directive should take account of this. This would be entirely in keeping with the Objectives and Guidelines for the Action Programme on Nutrition and Health: "to encourage to a greater extent consideration of nutritional and health aspects in the measures in the various relevant sectors of the Community and its Member States."

- Health protection should be achieved on a preventive basis wherever possible; where not, mechanisms of rapid seizure should be ensured throughout the Community, as well as comparable redress measures.

- The current product-orientation rather than health-orientation of EC food legislation must be abandoned if health protection is to look convincing. The Directive should facilitate this by placing a duty on the Commission to undertake total diet studies Community-wide and compile the essential, but lacking, data on actual intake of *e.g.* heavy metals and pesticide residues. In the absence of such information to permit rigorous

risk hazard analysis, statements about protecting public health are in danger of sounding somewhat hollow.

- The Directive must be comprehensive. Food should be defined as broadly as possible and all stages of production, processing, packaging, retailing and supply to the consumer should be covered. Also, the place of consumption should be irrelevant. The current distinction between agricultural and processed products should be abolished for safety and liability purposes.

- Equally, account should be taken of environmental considerations, *i.e.* food production, processing and packaging must be sustainable and respective of all the environment.

- There should be express provision for taking special needs into account and protecting special risk categories, *e.g.* allergies, pregnant women, children, the elderly, vegetarians.

- Quality should be reinstated as a matter for Community action. In a Europe where food is in overabundance, the emphasis on quantity appears indefensible. However, the Directive should verify that any schemes, etc., introduced to encourage better quality should be for the benefit of the consumer as much as the producer.

- Access to information will be essential if the public is to be convinced that health is paramount. This is especially so in the field of biotechnology, but also applicable in other areas of food technology. This is linked to the equally important issues of consumer representation in all aspects of the legislative process for food. The Directive should create an EC Committee in Food, with the representation of all interests: producers, consumers, food industry retailers, health experts and environmental specialists. The current fragmentary approach should be abandoned.

- Equivalence of enforcement should be required, to a minimum enforcement standard.
- Liability for breach of food law should be absolute and the burden of proof should lie on the transgressor.
- Despite the current lack of legislative competence, consideration should be given to harmonising sanctions and level of penalties. A solution modelled on competition policy might be appropriate.

- The current approach to consumer protection based largely on labelling needs to be reviewed. Given that the health aspects of food are at the forefront of most people's minds today, this approach does not satisfy consumer expectations. It is very difficult for the average person to have enough knowledge about food production and nutritional value to take informed dietary decisions; merely to provide certain details and then declare *"Caveat Emptor"* is to ignore this basic fact. The Directive must provide a mechanism to address this problem. Confidence would be increased if there were a single scientific committee with greater powers and status.

- It is clear that the current institutional arrangements will be inadequate for the Single Market of 1993 and that a body analogous to the EC Medicines Agency will have to be established to replace the existing closed, fragmented system. there needs to be a new, independent publicly accountable body, which in the text is referred to as the European Food Agency (EFA). It should have the widest possible membership (including consumer, environmental and health representatives, as well as MEPs) and it should seek to ensure that decisions about determining acceptable risk in food are not made on purely scientific grounds. The EFA will only help to promote public confidence in food if it is seen to consider a wider range of factors than the toxicological and assesses "benefit" and "need" particularly in relation to the groups which carry the greatest potential risks. It is envisaged that the EFA would be consultative to, and work in close cooperation with the Commission. There should therefore be provision for a central focal point in the Commission with overall responsibility for food.

The principal problem with a measure of this nature lies not so much in formulating a series of general principles as making them worth any more than the paper on which they are written. The danger lies in trying to graft such principles into a body of incomplete and piecemeal legislation with a view to the past or *status quo* rather than the future. If this exercise is largely retrospective clearly the objectives above will not be realised, and the Directive may well prove to be worse than nothing if its effect is a tendency to paralyse food law development.

If this Directive is to progress food law in the direction outlined above, the general principles must be complemented by provisions relating to

evidence, enforcement and accountability.

"OBJECTIVES OF THE PROPOSED DIRECTIVE" ON THE DEVELOPMENT OF FOOD LAW

Article 1

This directive lays down general rules which shall be applicable to all food produced and marketed in the European Community, notwithstanding existing provisions unless the requirements prescribed in those are more rigorous than those contained herein.

Article 2

The purpose of this directive is,

- to ensure the safety of food and ultimately, to protect public health;

- to protect the consumer against deception and fraud;

- to maintain the free movement of goods and procure fair trading;

- to promote the enhancement of the quality of food and increase public confidence in all aspects of food production;

- to ensure that Community food law is implemented according to uniform optimum criteria by the Member States while maintaining the principle of subsidiarity;

- to take account if public concern over the protection of the environment, the conservation of natural resources, and the promotion of animal welfare in the chain of food production.

Article 3

Definitions: "food" means any substance, ingredient, drink or other product intended for human consumption except:

- cosmetics, within the meaning of Council Directive 76/786/EEC,
- medicinal products within the meaning of Council Directive 65/65/EEC.

It shall include primary agricultural products within the meaning of Council Directive 85/374/EEC and materials and articles in contact within the meaning of Council Directive 89/107/EEC.

"safe means not presenting an unacceptable risk to the health and well-being.
of consumers.

"producers" means the producer of primary agricultural products, the processor of those products, the manufacturer of any food product and any other professional established in the Community who, by putting his name, trade mark or other distinguishing feature on the product, presents himself as its producer.

"distributor" means any other professional in the food supply chain in the Community.

"professional" means any natural or legal person, whether public or private, who supplies food in the course of a business.

"ionising irradiation" means treatment by irradiation sources, including X-rays, electronic beams or gamma rays.

"additives" shall have the meaning attributed by the Council Directive 89/107/EEC and shall include processing aids within the meaning of the same directive.

"contaminated food" means that containing:

- contaminants in water falling within the scope of Council Directive 80/778/EEC;
- contaminants in natural mineral waters falling within the scope of Council Directive 80/777/EEC;
- contaminants arising from materials in contact with food within the scope of Council Directive 81/109/EEC;
- marine biotoxins accumulated by molluscs within the scope of Council Regulation....;
- radionuclides within the scope of Council Regulation 3954/87;
- residues of substances having a pharmacological action in meat within the scope of Council Directive 86/469/EEC;
- residues of veterinary medicinal products in foodstuffs of animal origin within the scope of Council Regulation 2377/90;
- other contaminants within Council Regulation....;
- pesticide residues within the meaning of Council Directive 90/642/EEC at levels which the consumer would not reasonably expect, having regard to current scientific

knowledge;
- pathogenic bacteria and other microbiological matters at levels which the consumer would not reasonably expect, having regard to current scientific knowledge.

"fit for human consumption" means of such quality and substance as the consumer would reasonably expect, having regard to current scientific knowledge, ethical considerations, and social and economic need.

"total diet studies" means the compilation of such nutritional, scientific, sociological and consumption data as to provide information about the kinds of food that are habitually eaten.

"labelling, advertising and presentation of food" shall have the meaning attributed by Council Directive 79/112/EEC, as amended.

"consumer" means any natural or legal person supplied with food for consumption.

Article 4

1. Food shall not be produced or supplied to the consumer unless safe. It shall be for the producer or distributor to prove the safety food produced or marketed by him.

2. The producer or distributor shall monitor the safety of all food within his control and notify the competent authorities of the appropriate Member State where he has reasonable ground to suspect any defect in the food rendering it unsafe.

3. The Member States may require the producer or distributor to take all reasonable steps:

- to inform consumers of the risk;
- to remove the food from sale;
- if necessary, to recall the unsafe food.

According to the gravity of the situation, the competent authorities of the Member States may order one or more of the following measures:

- Warning or caution.
- Temporary removal from sale.
- Provisional seizure.
- Seizure and destruction.
- Restrictions on supply.
- Action to render the food safe.

Such orders shall specify the reasons for which they are made and shall be subject to the producer's or distributor's right to compensation in the event that they are found to be unjustified.

4. Where a Member State has reasonable grounds for suspecting that unsafe food is in circulation it may, upon informing the (EFA) of its decision, prohibit exports or the imports of that food as appropriate.

5. The (EFA) shall coordinate any

emergency prohibitions between the Member States, and if necessary, impose a time limit after which free circulation shall be reinstated.

Article 5

1. Food shall not be produced or supplied unless fit for human consumption. The foods below shall be deemed unfit for human consumption, but this shall not be considered as an exhaustive list:

(i) Food treated with ionising irradiation

(ii) Food containing additives other than those authorised in Community lists approved by the (EFA).

(iii) Food containing authorised additives which have not been used in accordance with the conditions laid down by the (EFA).

(iv) Contaminated food.

(v) Food failing to meet the nutritional and quality requirements within the articles below.

2. The EFA may put forward specific proposals to regulate the production and supply of foods which would otherwise be unfit for human consumption.

Article 6

Member States shall collect food poisoning statistics and forward them annually to the (EFA) for collation ad publication in the

Official Journal of the European Communities. The EFA may stipulate details of the information it requires to be collected.

Article 7

The (EFA), in conjunction with the Member States, shall undertake total diet studies in such regions of the European Community as to reflect the diversity of consumption patterns. These shall be completed by .....

Article 8

The (EFA) shall research and promote the improvement of the organoleptical qualities of food. Where appropriate, it shall publish quality standards which may concern minimum and maximum content requirements for specific foods.

Article 9

The (EFA) shall complete nutritional guidelines, taking into account data acquired under Articles 6, 7 and 8 above.

Article 10

Food shall not be produced or supplied without due regard to the improvement of public health. The (EFA) shall publish nutritional standards established in pursuance of Article 9. Health policy and nutritional considerations shall be a component of all Community policies, particularly agricultural

policy.

Article 11

The labelling, advertising and presentation of food shall be such as not to mislead or confuse the consumer. The producer or distributor shall provide the consumer with all information necessary for the safe and best nutritional use of food.

Article 12

1. Subject to the need to maintain the confidentiality of trade secrets and personal data, the (EFA) shall compile and publish such information on processed foods as to enable the consumer to make informed nutritional choices about food for consumption in the home or in catering establishments.

2. The producer or distributor shall supply such information to the (EFA) before marketing a food for the first time in the European Community or on request by the (EFA).

3. The (EFA) may require such of this information to accompany the food when offered for supply as it thinks fit.

Article 13

1. Food shall not be produced or supplied without due regard to best current agricultural and manufacturing practices, the

sustainability of the environment and the conservation of natural resources. Consideration shall be given to the improvement of animal health and welfare, in particular the transportation and slaughter of animals.

2. The (EFA) shall propose measures pursuant to the paragraph above.

Article 14

Member States shall adopt the measures necessary to ensure the optimum level of food law enforcement in general and compliance with this directive in particular. The competent authorities shall ensure mutual cooperation and exchange of information between the Member States and the (EFA). Particular attention should be paid to the need for uniformity of inspection practices and procedures.

Article 15

1. Save as otherwise provided herein, food lawfully and marketed in one Member State may be marketed without restriction in any other.

2. Where a Member State has reasonable grounds to suspect that food in free circulation in the European Community is nonetheless unfit for human consumption, it may suspend or restrict trade of that food informing the (EFA) of its decision.

3. The (EFA) shall act as arbiter, subject

to a right of appeal to the European Court of Justice (or Court of First Instance), using the procedures set out below.

- The (EFA) shall examine the reasons given by the Member State, deliver its opinions and take appropriate measures as soon as possible.

- Where the (EFA) is of the opinion that the Member State's measures must be cancelled or changed, it shall submit this opinion to the Commission which shall submit forthwith a proposal to the Council of measures to be taken. The Council shall decide by qualified majority.

- If, after a period of three months form the date on which the proposal was submitted to the Council. the latter has not made a decision the proposed measures shall be issued by the Commission.

Article 16

The competent authorities of the Member States shall, on request from a consumer who has reasonable grounds to suspect that food supplied by a producer or distributor in the EC is unsafe or unfit for human consumption, subject that food to all necessary tests to establish its status.

Article 17

1. Where a consumer suffers damage caused by the consumption of food, the producer or distributor shall be liable if the

food was unsafe or unfit for human consumption at the time that it was put into circulation by him.

2. The producer or distributor shall not be liable if he proves:

(a) that the food was safe and fit for human consumption;
or
(b) that the food was used contrary to instructions for storage, preparation, etc., which accompanied the food when supplied to the consumer.

3. Entitlement to claim compensation shall be open to both individual consumers and to consumer organisations without it being necessary in the case of the latter, for them to prove the injury sustained by each of their individual members,

Article 18

In the implementation of this directive the Community and the Member States shall co-operate with third countries, GATT, FAO, WHO, and other relevant international organisations.

Article 19

Food exported from a Member State to a third country shall comply with Community legislation or that in force in the Member State concerned. Exceptionally, if the importing third country so requests, this requirement may be waived provided that the

food satisfies the Code of Ethics for International Trade, as defined in the *Codex Alimentarius*.

Article 20

1. Member States shall bring into force, not later than 3 years from the date of notification of this directive, the laws, regulations and administrative provisions necessary to ensure the full implementation of this directive.
2. Not later than 2 years from the date of notification of this directive, each of the Member States shall inform the Commission which of the national laws, regulations, etc., contained in (Article 100B inventory) they consider to be incompatible with this directive and furnish details of the national programme proposed to ensure full compliance by the due date.

3. Member States shall communicate to the Commission the texts of the main provisions of national law which they subsequently adopt in the field governed by this directive.

Article 21

Every 3 years the Commission shall present a report to the Council and the Parliament on the application of this Directive and, after consultation with the (EFA), submit appropriate proposals to ensure its full application.

[c]

Draft Framework Directive on Community Food Law

PROFESSOR DIETER ECKERT,
BONN

Summary of Contents:

with explanatory notes

Part A The need for and feasibility of a framework directive on Community food law

I Introduction

1. Food law and the EEC Treaty

As in most of the Member States of the Community, food law has a special place in Community secondary legislation. This is apparent not only from the multitude of separate directives but also in the communications of the European Commission, which following its White Paper of 15 June 1985 deal exclusively with Community food law - in its communication of 8 November 1985 to the Council and Parliament on Community food law, its communication of 24 October 1989 on free trade in foodstuffs within the Community and its explanatory note on the trade names of foodstuffs of 15 October 1991. The development of Community food law has also been decisively influenced by a number of fundamental rulings of the Court of Justice of the European Communities following the "Cassis de Dijon" judgement of 20 February 1979, which also concerned a matter of food law. Generally speaking, food law in the Community having developed in this way has shown itself to be a key integrating factor and therefore a *sine qua non* for the creation of a Community internal market by 1 January 1993.

On the other hand, though unquestionably important in the EEC Treaty, food law does not receive equivalent treatment to, say, the environmental field in Title VII, inserted in the Treaty by the European Single Act of 20 February 1986. With regard to food law the EEC Treaty confines itself to ensuring the functioning of the internal market in accordance with the general provisions on the approximation of laws (formerly Article 100, now Article 100a). It is not until the Treaty on European Union that food law comes to be touched on, albeit indirectly, by the new Article 3(s) of the future EC Treaty. But even here it is not a case, as with environment, of a policy area as such; Article 3(s), a last-minute addition, speaks only

of "a contribution to the strengthening of consumer protection" as one of the Community's activities. Article 129a of the future Treaty, definitive on the issue, merely refers to Article 100a on the matter.

All the same, bringing in a special Title XI on consumer protection and including health matters are steps in the right direction. The principle of subsidiarity now set out in black and white in Article 3b, second paragraph, should also be of some importance to Community food law particularly as regards its application in Member States.

2. The legislative practice of the Community

It is still an open question whether or not limiting the Treaty to the functioning of the common market allowed the idea of general food legislation at Community level to surface. What is certain is that this approach, with the removal of trade barriers as the basic goal and consumer protection as justification, has had a marked influence both on European Community food legislation and on the jurisdiction of the European Court of Justice. In practice this has led to a large number of separate food regulations that have been passed or taken in hand as the need has arisen. There was no grand design behind this "pragmatic" style of harmonising the legislation: the two harmonisation programmes of 1969 and 1973 were largely confined to establishing timetables for individual projects, and the time periods set in these proved unrealistic anyway.

The first sign of any systematic tendency towards a Community food law worthy of the name is to be found in the Commission's communication of 8 November 1985 on Community food law, to which the European Court of Justice had made a decisive contribution with its "Cassis de Dijon" judgement. This communication, of course, restricts Community activity to the core areas of "health protection", "informing consumers and protecting them in areas other than health", "fair competition" and "official inspection". As regards vertical regulations, the principle of mutual recognition of the legal and administrative provisions of Member States, as developed by the European Court, will as a rule be applied.

The communication from the Commission does, admittedly, refer to "Community food law" for the first time, but it still does not go so far as

to provide for a general framework regulation for this area of law.

3. General principles of food law and Community food law

The work on approximating national food laws and regulations naturally followed the principles that have emerged both in the Community Member States and as a result of the work carried out in the framework of the FAO/WHO *Codex Alimentarius* Commission. These are:

- protection against health damage;
- protection against deception and fraud and ensuring fair trading practices;
- guaranteeing proper product information.

In addition to these "classical" principles of food law there is, at Community level, the fundamental Treaty objective of ensuring the free movement of goods in the Community. No particular reason is required for the conflicts that might arise out of these special axioms of Community law as compared with the "classical" principles of food law. It therefore falls to Community food law to take these particular problems into account, *i.e.* to reconcile the interests of the consumers, the food industry and science and research and the exigencies of the free movement of goods.

At the same time it is clear that in the light of the rapid development and increasing interpenetration of the economy, the progress being made in food technology, the new discoveries in science and research and, more generally, living conditions in a modern industrial society, food legislation can no longer confine itself as it once did to warding off immediate dangers. Instead it must be geared towards preventing potential health risks and economic disadvantages. One of the guiding principles of modern, forward-looking food law is therefore the principle of preventive health protection.

With these considerations in mind it is the task of Community food law to provide for "a high level" of consumer protection in accordance with Article 100a(3) of the EEC Treaty without unnecessarily impeding technical progress and economic development. In other words, *economic considerations and technical progress have to be measured against the*

requirements of preventive consumer protection just as consumer interests are measured against the principles of necessity and proportionality applying to legal action and confirmed by the judicial decisions of the European Court of Justice.

II The need for a framework directive

1. Review of Community food law

Analysis of those Community food directives that have been adopted so far and those still under discussion indicates that the general principles of food law described above will largely be applied in future Community food legislation by taking into account the principle of preventive consumer protection.

Thus, the important area of preventive health protection will to all intents and purposes be entirely covered by future Community regulations on additives, contaminants, "novel foods", residues of plant protection products and substances with pharmacological effect and the regulations on materials and articles coming into contact with foodstuffs, together with the existing and prospective regulations on general and specific food hygiene. In addition to these there are the rules on the application of certain processes and the extensive regulations that are to be expected on foods intended for special diets.

The Commission wishes to provide protection against deception and fraud, ensure fair trading practices and guarantee proper information for consumers by means of extensive labelling rules. There are, however, certain doubts here.

For one thing, the Commission has itself indicated that in some cases labelling does not provide an adequate solution: it has therefore prepared proposals or drafts aimed at protecting certain trade names. For another, the question arises as to whether more and more detailed labelling is really a commensurate solution in accordance with the principle of proportionality and whether it really helps the consumer. What may therefore be required is a general regulation.

Nevertheless, it can still be said that the generally recognised principles of

substantive national and international food law have been or will be embodied in Community food regulations. Moreover, the Community has adopted regulations in the field of food inspection and there are supplementary Commission proposals under discussion in this area. Finally, Commission regulations on general product safety are to be expected that may also have an effect, if only complementary, on Community food law.

2. Conclusion

All this has resulted in a substantial body of Community legislation on food. There are, nevertheless, some important reasons for having a framework regulation under Community law.

The main thing missing so far has been a uniform nomenclature. It will also be necessary to establish common principles of substantive food law and to incorporate the separate Community regulations already existing or still to be adopted into such a regulatory framework. With a view to the completion of the internal market by 1 January 1993 there is also a need for administrative practice in the individual Member States to lead to comparable results. It will also be necessary to keep a framework regulation for Community food law separate from the forthcoming general product safety directive.

It should not, therefore, be the aim of a framework regulation for Community food law to intervene drastically in existing Community law. Anyway, such interference would make it extremely difficult to prepare such a regulation. If existing separate directives thus have to be left essentially untouched by the framework regulation, this does not prevent them from being adapted to the principles established in the framework regulation as the work of harmonisation proceeds. Apart from that it is to be expected that the principles laid down in a general framework regulation will also have an effect on the application of the law in practice.

Of the legislative instruments possible under Article 100a of the EEC Treaty, preference is to be given to using the directive. The direct impingement of an EEC regulation on national food laws would fail to take account of the different types of and approaches to regulation by the

general food laws of Member States. As wine law has shown, it would lead to friction that might jeopardise the whole enterprise from the start. It would, therefore, also be likely that agreement between Member States on a common text for a regulation would be made much more difficult if not impossible to achieve.

Member States would therefore have to keep sufficient room in their regulations for the Community regulation to fit organically into their legal systems. What is more, a directive would also come closer to the principle of subsidiarity that has now been established by the Treaty on European Union in Article 3b, second paragraph, of the future EC Treaty.

III The feasibility of a framework directive

1. Basic features of a directive on food law

In accordance with the above specifications, the possible content of a general framework directive on common food law, a "food law directive" as it is referred to below, can be summed up as follows:

- setting generally binding objectives for regulations, *i.e.* providing for preventive health protection, protection against fraud and appropriate product information while taking into account the just interests of the food industry and the needs of science and research;

- establishing a nomenclature not yet regulated in Community law and bringing together existing definitions used in Community law in order to ensure that Community food law is applied uniformly;

- integrating the existing and prospective separate directives and the relevant judgements of the European Court of Justice in an all-embracing framework;

- filling in gaps in the regulations;

- general regulations on measures to ensure consumer protection and fair trading in practice (self-policing, possibilities of official intervention);

- general principles for the administrative action of the inspection

authorities of Member States and regulation of the rights of those concerned;

- regulations on mutual administrative assistance between the competent authorities in order to facilitate the prosecution of infringements of food laws and regulations in a market without internal frontiers;

- general protective clauses for the cases not so far settled in special directives in favour of Member States in the framework of a Community procedure;

- emergency procedures to avert acute health risks;

- non-applicability of the directive to be expected on general product safety.

2. Additional remarks

Laying down the main definitions is important for the further development of Community food law, first of all as a means of settling the language problem. Apart from that, however, such definitions are also indispensable for the uniform application of Community law by Member States and the European Court of Justice. The definitions which come into consideration first of all are those that are already used in Community law, *e.g.* for additives and processing aids, and therefore ought to be generally valid beyond the field of application of the directive in which they are found. It will also have to be studied to what extent definitions from the international field, particularly those of the *Codex Alimentarius*, can be used. It is important, finally, to work out a definition, at once comprehensive and precise, for the central term "foodstuffs".

Besides the existing preventive health regulations to protect the consumer it will be advisable to adopt a general regulation for protection against health damage as a "safety net" for all cases that have no specific regulation.

The same applies to providing such a catch-all to protect against deception and fraud, since it is doubtful whether Article 2 of the EC

labelling directive will be sufficient for that. It should include a regulation on the marketability of foodstuffs that do not have the usual marketable quality or that do not comply with a legally non-binding standard (*e.g.* a CEN standard), while making known the discrepancy.

The marketability clause according to the Court of Justice's ruling in the *Cassis de Dijon* case could be combined with a specific solution on protection against deceptive trade names, going as far as the possible exclusion of a trade name that does not correspond to the "European conception of trade", in accordance perhaps with the Court of Justice's rulings in cases where the consumer is not provided with sufficient information by additional labelling.

The sole responsibility borne by the person placing on the market could be defined in general terms, but avoiding any provision on the burden of proof (in the sense of a reversal of the burden of proof), as exists in many countries.

It would be useful to have a minimum list of standard possibilities of intervention by the national authorities, ranging from the public warning to a marketing ban. Such possibilities might be, say, detailed provisions on the rights of the parties concerned, such as prior consultation, the obligation to indicate the reasons for decisions, the guarantee of legal remedies.

It does, on the other hand, seem doubtful whether there is any point in including a provision on compensation for damages caused by unjustified official interventions in such a regulation relating to a specific product range. This might best be kept for a general regulation. The provision occasionally asked for, on the manufacturer's or importer's liability in respect of the consumer as the injured party, has no place in a framework directive on food law. The same applies to regulations intended to achieve the imposition of comparable sanctions in the event of the infringement of food laws and regulations.

It is important, finally, to clarify the relationship between a future "food law directive" and the future product safety directive. The general non-application of the directive to Community food law that is advocated in this memorandum is largely shared by the expert groups dealing with food law matters. In fact the provisions of the product safety directive scarcely

take sufficient account of the special requirements of trade in food, for the following considerations:

As regards food safety, this anyhow has to rest with those provisions of Community food law that already exist or remain to be amended, *i.e.* in particular the provisions on general and preventive health protection. Protection against fraud and guaranteeing proper consumer information are not dealt with, or not adequately, in the product safety directive. The situation is similar as regards the principles of the "Cassis de Dijon" judgement of the European Court of Justice. Furthermore, the procedures laid down in this directive for protecting against specific health risks differ in part from the procedures such as the so-called safeguard clause procedure that have been proving their worth for years in the Community's food laws. Also, in order to avoid any lack of clarity in cases of overlapping it is advisable to regulate the matter dealt with in the product safety directive in summary form in a "food law directive", in which case some provisions can by all means be taken over *mutatis mutandis*.

IV Concluding remark

A general "food law directive" put together in this way would as a result confine itself to substantive food law and its application. It would not, therefore, extend to the Community's legislative process, *i.e.* the regulation of institutional questions such as the participation of the parties concerned in the legislative process, scientific evaluation, setting up new committees or establishing a European Food Agency. Such provisions would, admittedly, be conceivable in the framework of a general directive of this kind, but where necessary they should continue to be laid down as separate regulations.

A directive with the content outlined would not necessarily require fundamental changes in the general food laws of Member States, even though in some countries where the overall concept of food law is less clearly defined than in Germany it might give cause for such changes. The aim of a "food law directive" should not be unification of law but model regulations in accordance with the subsidiarity principle. Such a regulation, binding in its aims, not only leaves room for the national peculiarities of Member States but according to experience so far it will

not fail to have its effect on the other food law systems in Europe, especially since accessions and associations are imminent. Thus a bridge will be created to food legislation with uniform criteria in a larger Europe.

V Summary

To sum up it can be said that there are a number of important reasons for having a framework directive on Community food law and that it will be possible to implement such a Directive both as regards its in content and in the same form as the usual Community regulations. The details can be found in the "Food Law Directive" with explanatory notes contained in Part B.

Part B

Draft EC Directive on Food Law

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas at present numerous individual food law provisions exist at Community level but there is as yet no self-contained body of Community food law;

Whereas a framework regulation that is both comprehensive and confined to essentials has to include all provisions that are necessary to protect the consumer against health damage and against deception and fraud as well as provisions to ensure the supply of appropriate information on the fundamental characteristics of products, regarding, amongst other things, healthy and appropriate nutrition;

Whereas with this objective of a high level of consumer protection the legitimate interests of the industrial circles involved, the requirements of economic and scientific development and the need to ensure the free movement of goods within the Community have to be reconciled;

Whereas it is necessary to establish uniform definitions and common principles of substantive food law and to incorporate in such a general framework the individual Community provisions that already exist or are still to be adopted;

Whereas, furthermore, in a common internal market comparable rules of procedure have to be applied in Member States, and this is true as regards

both the likely action by the authorities and the rights of persons affected by such action;

Whereas the official control of foodstuffs is the duty and responsibility of Member States; whereas this does not, however, exclude action by the Commission to ensure a uniform system of control in the Community;

Whereas in order to avert health hazards special methods have to be applied in the field of Community food law; whereas the general product safety Directive is not therefore applicable to foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1
(Field of application)

This Directive contains the general principles of Community food law. Provisions diverging therefrom in the special Community legislation, and the general Community regulations that are also applied to foodstuffs, are unaffected. The general product safety Directive is not applicable.

Article 2
(General principles)

The purpose of this Directive is, in the Community's food trade:

- to protect the consumer against damage to health and against deception and fraud, and to ensure the supply of appropriate information on the fundamental characteristics of products, including their suitability for healthy and appropriate

nutrition, without any unnecessary interference with economic and scientific development;

- within the framework of this objective, to guarantee the legitimate interests of the industrial circles involved, the requirements of science and research and the free movement of goods within the Community;

- to ensure that Community food law is implemented according to uniform criteria by Member States while maintaining the principle of subsidiarity;

- to establish Community procedures for averting health hazards.

The Community and Member States shall ensure that their measures comply with the above provisions.

Article 3
(Definitions)

For the purposes of Community food law the following definitions apply:

"Food" or "foodstuffs" means products intended for human consumption in an unprocessed, processed or composed state, with the exception of tobacco products, cosmetics and pharmaceuticals.

"Manufacture" means producing, making, preparing, treating and processing.
"Placing on the market" means offering for sale, stocking for sale or any other

commercial form of supply to third parties, against payment or otherwise.

"Handling" means weighing, measurement, packaging, repackaging, bottling, stamping, printing, refrigeration, storage, warehousing, transport and any other activity that cannot be regarded as manufacture or placing on the market.

"Consumer" means any person provided with foodstuffs for personal use or for use at home, against payment or otherwise. Consumers are also restaurants, hospitals, canteens and similar communal facilities.

"Food additive" means any substance with or without nutritive value which is not normally consumed as a food in itself nor used as a characteristic ingredient of food, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, handling, packaging, transport or storage results or may result in it or its by-products becoming (directly or indirectly) a component of such food.

"Processing aid" means any substance that is not itself consumed as a food ingredient but is used in the processing of raw materials, foodstuffs or their ingredients, for technological reasons during treatment or processing and that may leave unintended, technically unavoidable residues or derivatives of residues in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

"Pesticides" are substances and mixtures

thereof that are used for combating or controlling all kinds of pests. The term includes substances and mixtures thereof that are used as plant growth controllers, defoliants or desiccants. It does not include fertilisers.

"Pesticide residues" are substances that are present in foodstuffs as a result of the use of a pesticide. The term also includes all derivatives, such as degradation or transformation, metabolic and reaction products, which can be regarded as toxicologically significant.

"Residues of veterinary medicinal products" are pharmacologically active substances, whether active components, vehicles or degradation products, and their metabolic products, that are found in foodstuffs obtained from animals to which the veterinary medicinal product in question has been administered.

"Contaminants" means substances that are not intentionally added to food but are present in it as a result of manufacture or handling or of an environmental influence. The term does not include substances, apart from mycotoxins, that are found in or on the surface of food as a result of a lack of hygiene in manufacture, handling or placing on the market, or substances that have been produced in the food as a consequence of manufacture.

"Materials and articles" are objects which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs and are

intended for that purpose.

Article 4
(Health protection)

Foodstuffs likely to damage human health or are otherwise unfit for consumption may not be marketed.

Foodstuffs may be marketed only if they satisfy the valid provisions of Community law on the preventive protection of human health, especially those regarding:

- the use of additives;

- the use of particular treatment methods;

- the assessment of novel foods, substances or processes;

- the use of pesticides, veterinary medicinal products or their residues in or on foods;

- contaminants;

- the migration of substances from materials and articles to food.

Article 5

Foodstuffs must be manufactured, handled and placed on the market in such a way that they are not subjected to unhygienic or other negative influence. They must comply with the respective Community provisions and

with the provisions adopted by Member States for their implementation.

Article 6
(Consumer information and protection against deception)

Foodstuffs must when placed on the market satisfy the relevant special Community provisions regarding their quality, composition, labelling or other features.

Article 7

Foodstuffs must be labelled so as to inform the consumer unequivocally as to their essential characteristics and to avoid any deception or confusion with other foodstuffs. The labelling of the foodstuffs must comply in particular with Community provisions regarding general and nutritional labelling.
Foodstuffs may not be marketed with names, statements, advertising claims, illustrations, other information or packaging that are likely to mislead.

Subject to Community provisions to the contrary, foodstuffs that are not of the commercial quality existing in the Member State in which they are sold to the consumer may be placed on the market only if the discrepancy is unequivocally indicated in the labelling for the consumer. The same applies to a variation from any kind of standard that is not legally binding.

In applying this Article Member States assume that it will be understood by a sufficient number of consumers of average awareness.

Article 8
(Obligation to take due care)

Anyone commercially manufacturing, handling or marketing foodstuffs shall, within the sphere of his responsibility, ensure that the foodstuffs comply with Community provisions, the laws and regulations of Member States based thereon and any other laws, regulations and standards affecting the marketability of the foodstuffs.

Article 9
(The free movement of goods within the Community.)

Subject to Article 4, a foodstuff duly manufactured or marketed in one Member State may be marketed in the other Member States. Where it does not comply with the provisions of those countries or the concept of trade prevailing there, consumers must be protected against deception and fraud by appropriate labelling. "Appropriate labelling" is usually some indication of the origin of the foodstuff or of its recipe.

In the case of a foodstuff for which the same or a similar trade name is enshrined in the legislation of Member States or is commonly used in the trade despite differences in

composition or quality, the origin of the foodstuff or of its recipe must be indicated in the labelling.

The use of a trade name may be prohibited if a foodstuff lacks the characteristics that the consumers in the Community might justifiably expect of it.

Article 7, fourth paragraph, shall apply *mutatis mutandis*.

Article 10
(Ways and means of application and control)

The control of foodstuffs is the duty and responsibility of the Member States. Notwithstanding Community provisions, Commission measures to ensure uniform control practices shall be carried out in agreement with the Member States.

Article 11

The competent authorities of a Member State shall, when requested to do so with reasons being given, furnish the competent authorities of another Member State with information and send them whatever certificates and documents they need in order to monitor compliance with the food regulations. They shall examine the facts as reported by the requesting authorities of a Member State and inform them of the result of their examination.

The competent authorities of a Member State shall inform the competent authorities of

another Member State of all facts and circumstances that are important for the prosecution of infringements of the food law of the other Member State, particularly of any contravention that has come to their knowledge or of any justified suspicion of a criminal act.

Article 12
(Possibilities of intervention by the authorities of Member States)

In accordance with the gravity of infringements against food law provisions and in conformity with the Treaty, in particular Articles 30 and 36 thereof, Member States shall provide, *inter alia*, for the following measures:

- public warning;
- recall order;
- provisional seizure;
- seizure;
- marketing restrictions (*e.g.* obligations);
- marketing bans;
- destruction, rendering unusable.

Public warnings shall generally be considered where the marketing of foodstuffs would mean a hazard to public health provided that

such a hazard cannot be averted by other measures, in particular measures by the person or persons responsible for marketing (*e.g.* public information, recall).

Member States shall inform the Commission as to the action taken, insofar as it affects the free movement of goods within the Community.

Procedural guarantees and rights of the parties concerned

Article 13

In taking action the authorities of Member States shall comply with the principle of proportionality. As a rule penalties shall be imposed only where a due complaint has not met with success.

A party concerned by these measures may refuse to supply information in response to questions where answering them would subject it or one of its associates to the risk of criminal prosecution.

Article 14

Member States shall ensure that official action affecting the rights of a party concerned can be judicially investigated, insofar as the authority in question does not allow an appeal.

Article 15

Where any decision affects the rights of a party concerned, the reasons for the decision shall be given. The decision shall be delivered to the party concerned immediately. The party concerned shall be informed at the same time of the means of redress open to him under the laws and regulations of the Member State in question and of the periods of grace for lodging such appeals.

The party concerned shall be given the opportunity, where possible before delivery of the decision, to make comment and, where appropriate, to avert a danger or eliminate the consequences of an infringement. Where there has been no such prior consultation, in particular because of the urgency of the measures to be taken, the party concerned shall be given the opportunity to comment immediately after delivery of this decision.

Where a decision subsequently proves to be unjustified or out of proportion it shall be cancelled without delay. In the case of a public warning the cancellation shall be made public if the party concerned so requests.

Community procedure for averting health risks

Article 16

Where a Member State finds and duly substantiates that a foodstuff presents a hazard to human health, even if it is freely traded in one or several Member States, that Member State may provisionally suspend or

restrict trade in the product in its territory. The Member State shall forthwith inform the Commission or the other Member States thereof, giving reasons for its decision.

The Commission shall examine the reasons given by the Member State as soon as possible and consult the Member States in the Standing Committee on Foodstuffs. It shall then deliver its opinion forthwith and take the appropriate measures.

Where the Commission is of the opinion that the single-state measure must be cancelled or changed it shall initiate the procedure provided for in Article 20 with a view to suitable measures being taken.

Article 17

If a Member State has taken action in accordance with Article 16 to avert a direct risk, or if it considers it necessary for such action to be taken immediately, and if there are indications that the dangerous situation cannot be limited to its national territory, this Member State shall inform the Commission and the other Member States without delay, stating the facts of the case, notwithstanding Article 16, first paragraph, in the framework of a Rapid Information System for Foodstuffs.

The mode of operation of the Rapid Information System shall be established by the procedure set out in Article 20.

The Commission may take the necessary measures to avert the danger if it has arisen in more than one Member State. In this it shall

be backed by a "Committee for Food Safety Emergencies" consisting of representatives of all Member States and chaired by the Commission.

The Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on this draft within a period to be set by the Chairman, taking account of the urgency of the matter, which, however, may under no circumstances exceed one month. The opinion shall be delivered by a majority vote, as provided for in Article 148(2) of the Treaty for the adoption of decisions to be taken by the Council on a proposal from the Commission. In the Committee decision the votes of the representatives of Member States shall be weighted in accordance with the said article.

The Commission shall adopt measures that are immediately applicable. If, however, they do not coincide with the opinion of the Committee these measures shall be communicated forthwith by the Commission to the Council. In this event the Commission may postpone the implementation of the measures it has adopted for a period of 10 working days from the date of communication.

Within the period mentioned in the previous paragraph the Council may, by a qualified majority, take a different decision.

Measures adopted in accordance with this procedure shall be valid for a maximum period of six months. This period may be extended by the same procedure.

Member States shall take all the measures necessary to implement the decisions adopted under this procedure within 10 days.

Article 18
(Trade with non-member States)

Where foodstuffs are imported into the Community from non-member States they must comply with Community provisions. The Member State in which such foodstuffs are first placed on the market shall carry out the necessary checks. It shall if necessary take appropriate action to prevent the foodstuffs in question from coming onto the open market within the Community.

Article 19

Foodstuffs that are intended for export from the Community must comply with Community provisions or the provisions of the country of destination. When the competent authority so demands it must be credibly demonstrated that the foodstuffs comply with the provisions of the country of destination.

Article 20
(General provisions)

Where reference is made to the procedure set out in this Article the Standing Committee on

Foodstuffs (hereinafter referred to as "the Committee") shall be called upon by its Chairman or by the representative of one of the Member States to deal with the matter.

The Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on this draft within a period which the Chairman can set taking account of the urgency of the matter. The opinion shall be delivered by a majority vote, as provided for in Article 148(2) of the Treaty for the adoption of decisions to be taken by the Council on a proposal from the Commission. In the Committee decision the votes of the representatives of Member States shall be weighted in accordance with the said article. The Chairman shall not take part in the voting.

The Commission shall adopt the proposed measures if they coincide with the opinion of the Committee. If, however, they do not coincide with the opinion of the Committee or if no such opinion has been delivered, the Commission shall immediately present the Council with a proposal for the measures to be taken. The Council shall decide by a qualified majority.

If the Council has not made a decision after a period of three months from the date when the proposal was communicated to it, the proposed measures shall be adopted by the Commission.

Article 21

Requirements to be placed on certificates of compliance with the provisions of Community law, the laws and regulations of Member States or standards that are not legally binding or certificates attesting to the marketability of a foodstuff in a Member State by virtue of its commercial quality and the procedure for the issuance of such certificates shall be established as set out in

Member States shall ensure that certificates issued in their national territory comply with the requirements and procedures mentioned.

Article 22

Member States shall keep their administrative and judicial bodies permanently informed on Community provisions. They shall ensure that decisions made by their administrative authorities do not conflict with these provisions and that judgements of the European Court of Justice are quickly taken into account, if necessary by amendment of their legal or administrative provisions. Insofar as they are able they shall also ensure that appropriate remedies are found in cases where judgements of their courts conflict with Community food law.

Article 23

Member States shall keep the Commission permanently supplied with whatever nutritional, epidemiological or other data they have that may be important for adaptation of

Community food law to new scientific findings, technological and economic developments, the food habits of the population or other decisive developments. The Commission shall document these data, evaluate them together with its scientific committees and take whatever action is necessary.

Article 24

Member States shall annually draw up a report on the transposition of Community food law into national law and its application. These reports shall be transmitted to the Commission in the first quarter of the year following that of the report. The Commission shall publish the reports and its comments on them in the Official Journal of the European Communities.

Article 25

Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive not later than two years after its publication. They shall forthwith inform the Commission thereof.

Article 26

After the expiry of the period mentioned in Article 24 the Commission shall prepare a report on the measures taken to implement that article. This report shall be transmitted to the Council, the European Parliament, the

Court of Justice, the Economic and Social Committee and the Member States. It shall be published in the Official Journal of the European Communities.

Article 27

This Directive is addressed to the Member States.

Explanatory notes:

Introduction

At the Community level there are at present a large number of individual food regulations, generally issued as an ad hoc response to the need to approximate the different laws, regulations and administrative provisions of the Member States in order for the common market to work. The first systematic approach to establishing a Community food law worthy of the name is to be found in the Commission's communication of 8 November 1985 to the Council and the European Parliament. What still needs to be done, however, is to establish uniform definitions and common principles of substantive food law and to incorporate into such a regulatory framework the individual Community provisions that already exist and are still to be adopted. With a view to completing the internal market by 1 January 1993 there is, furthermore, a need to establish rules of procedure which will produce comparable results in the individual Member States.

This draft "food law" Directive is intended to take account of these requirements from the perspective of Community law, while observing the principle of subsidiarity now expressly laid down in Article 3b, second paragraph, of the Treaty on European Union and while maintaining the Member States' powers to issue regulations.

The content of the draft Directive

Article 1

The Directive applies to the whole area of Community food law, and therefore also to the laws, regulations and administrative provisions of the Member States, insofar as there are no specific provisions of Community law. The only exceptions are specific divergences in Community provisions, to which, however, these principles are also applied.

The general regulations that also apply to foodstuffs, such as Directive 83/189/EEC laying down an information procedure, as amended by Directive 88/182/EEC, and Directive 89/397/EEC on the official control of foodstuffs and the subsequent directives still to be expected, are applied without restriction. The future product safety Directive will not be applicable, however, since a substantial proportion of the provisions of substantive and procedural law laid down in that Directive do not take account in the necessary manner of the special circumstances of the food trade. Insofar as procedural law provisions of the future product safety Directive can be applied to the food trade their content will be taken over into this draft Directive (see in particular the provisions of Articles 9, 11, 12 and 17).

Article 2

Legislation and the interpretation of the laws, regulations and administrative provisions of the Community and the Member States must always be with a view to the objectives set out in this article.

Article 3

Experience has shown that for Community and national food law to be applied in a uniform manner it must be based on standard definitions. The article contains definitions that have not yet been fixed in Community law. They have been taken, in some cases in simplified form, from the Procedural Manual of the Codex Alimentarius Commission. The

definitions of the terms "manufacture", "placing on the market" and "handling" are given in order to simplify the text (see, for example, Article 3(j) and Articles 5 and 9). The article also lists the main definitions to be found in existing Community provisions, with some modifications to make them generally applicable. Attention is drawn in particular to the attempt to curtail the definition of "contaminants" as compared with that given in the Codex Alimentarius.

The definitions contained in the individual Community provisions should, where necessary, be aligned as soon as possible with those contained in this Directive.

Article 4

The prime object of Community food law has to be health protection, or preventive protection of the consumer. This is why the Community provisions to this effect, which cover the area fully or will do, are listed as examples in paragraph 2.

Irrespective of this, a general, comprehensive and justiciable provision protecting against health hazards and food not suitable for consumption is necessary to cover all the many cases where there are no special provisions for particular products. This catch-all is contained in paragraph 1.

Article 5

Owing to their particular importance the principles of hygiene are referred to in a general manner in this article. Since the forthcoming Community provisions will probably contain only general guidelines that will have to be put into effect by the Member States, their provisions are also referred to.

Article 6

This Article is intended to ensure that Community provisions applying to specific products ("vertical" directives) or groups of products (e.g. for

foodstuffs for special diets) are complied with.

Article 7

In paragraph 1 this article contains the general principles for appropriate consumer information, expressly referring to the relevant Community labelling provisions. Additional general provisions are necessary, however, to protect the consumer against deception and fraud. These are laid down in paragraphs 2 and 3. At the same time, paragraph 2 contains the important general principle that even food imitations and foodstuffs that are not of the usual commercial quality are not to be banned across the board but may be placed on the market provided that they are adequately labelled. This principle is important particularly for all non-binding standards, including any European Standards.

Article 8

Effective self-policing by those involved in the food trade (manufacturers, wholesalers, retailers, gastronomes, etc.) within their respective spheres of responsibility is - quite apart from official controls - crucial to the safety and the lawful manufacture of foodstuffs.

Article 9

It seems advisable to codify the rulings of the European Court on the free movement of goods and at the same time to find a solution to the not yet satisfactorily resolved problems of labelling and trade names. The "mandatory requirements" within the meaning of the Court of Justice's "Cassis de Dijon" judgement, which may be claimed by a Member State, are to be found in Article 4, which is referred to in this provision. The possibility of a ban on a trade name that does not correspond to a "European concept of trade" is derived from the relevant rulings of the European Court of Justice also quoted in the Commission's "explanatory notice" of 15 October 1991.

Article 10

According to the subsidiarity principle, now institutionally laid down in Article 3b, second paragraph, of the Treaty on European Union, it is the duty and responsibility of the Member States to carry out foodstuffs control. On the other hand, the Commission must have the possibility, by agreement with the Member States, of working towards a uniform and equally efficient system of control in all Member States.

Article 11

In an area without internal borders it has to be made possible to prosecute infringements of food laws supranationally. Cooperation between the competent authorities of the Member States is particularly important.

Article 12

In the interest of uniform control practices in the Member States the main courses of action open to the competent authorities and the prerequisites for action have to be laid down. In view of their possible economic effects, public warnings need a detailed provision.

Article 13

In the first paragraph the principle of proportionality of means is expressly laid down as an important procedural guarantee. It has to be observed in all official action.

The second paragraph contains provisions on the right to refuse to supply information that have not yet been approved at Community level. It must be looked into whether such a provision should be taken up in the EC control directive since the subject-matter is related.

Articles 14 and 15

It is necessary to lay down in detail the rights of those affected by official measures. This applies particularly to the guarantee of appeal, the obligation to indicate reasons, the instruction of the parties involved as to their rights, and also the cancellation of unjustified measures.

Article 16

The procedure for the examination at Community level of safety measures taken by a Member State in its national territory (the "safety clause procedure") contained in various separate directives has proved its worth and should therefore must be used, with appropriate adaptations, throughout Community food law.

Article 17

The emergency procedure provided for in this article applies to cases where a danger situation that has arisen in one of the Member States cannot be confined within its national territory. The procedure is based on Articles 10 and 11 of the forthcoming product safety Directive.

The special Rapid Information System for Foodstuffs, which has proved its worth in the past, should continue to be used in the future. The details are left to the regulating committee procedure laid down in Article 20.

Article 18

This article contains the principle that foodstuffs that are to be imported into the Community must comply with Community provisions. It seems practical to entrust the Member State in which the foodstuffs are to be placed on the market for the first time with carrying out the necessary measures, which must include preventing such foodstuffs from being forwarded on to other Member States.

Article 19

Exported foodstuffs must comply with either the Community provisions or those of the country of destination. The requirement in this article to provide credible evidence of compliance with the provisions of the country of destination when this is demanded by the authorities of the exporting country serves to make this provision practicable.

Article 20

This Article contains the rules of procedure for the so-called "regulating committee" under the terms of Procedure III, Variant (a), as laid down in Council Decision 87/373/EEC of 13 July 1987.

Article 21

Certificates as to the marketability of a foodstuff in a Member State will gain particular importance in the coming single internal market, not least in the light of the principle of mutual recognition of non-harmonised regulations. An important prerequisite for this is that the certificates must be comparable, and this must therefore be ensured by means of a Community procedure.

Member States are required to take appropriate steps to ensure that the certificates are correct and complete.

Article 22

In the execution of national food law and in the rulings of the courts of the Member States it is indispensable for the national legal and administrative provisions to be applied in accordance with the Treaty. This must be taken into account by keeping the administrative and judicial bodies permanently informed as to the development of Community law and by other measures which ensure that Community law (including the rulings of the Court of Justice) is observed.

Article 23

For Community law to develop further it is essential to have a knowledge of all the relevant data. This article therefore provides for such data to be collected and evaluated by the Commission so as to enable it if necessary to make use of its right of proposal or to take other action, ranging from precautions against health risks to making recommendations.

Articles 24 to 27

The reports provided for in Articles 24 and 26 should make clear to the authorities concerned and the general public the development of Community food law and its transposition into the laws and regulations of the Member States.

Articles 25 and 27 contain the usual concluding provisions.

ANNEX II

PROGRAMME OF THE CONFERENCE

A REGULATORY FRAMEWORK FOR FOODSTUFFS IN THE INTERNAL MARKET

EUROPEAN UNIVERSITY INSTITUTE,
FLORENCE,
6-7 MAY 1993

Thursday 6 May 1993

Morning Session:	Chair: Francis Snyder, EUI
10.00-10.15	Welcome Mr Emile Noël, President, EUI
10.15-10.30	Introduction to the Conference Francis Snyder, EUI
10.30-10.45	Presentation on the Conference Objectives Egon Gaerner Commission of the European Communities
10.45-11.30	Presentation of the Proposals for a Directive by the Experts, Parts I and II Charles Castang Amanda Cleary
11.30-11.45	Break
11.45-12.00	Presentation of the Proposals for a Directive by the Experts, Part III Dieter Eckert

12.00-13.00	Some Reflections on the Crisis of the Harmonization Model Renaud Dehousse, EUI followed by questions
13.00-15.00	Lunch: Sala Rossa
Afternoon Session:	Chair: Josef Falke, Bremen
15.00-16.00	Social Regulation by the European Community: The Case of Foodstuffs Christian Joerges, Bremen/EUI followed by questions
16.00-16.15	Break
16.15-17.15	Implementation and Effectiveness of Legislation Francis Snyder, EUI followed by questions
20.00	Conference Dinner: Ristorante Ottorino

Friday 7 May 1993

Morning Session:	Chair: Christian Joerges, Bremen/EUI
10.00-1100	Enforcement and Reception of Legislation Josef Falke, Bremen followed by questions
11.00-11.15	Break
11.15-12.15	Economic Aspects of Technical Regulation Rudolf Streinz, Bayreuth followed by questions

12.15-13.15	Public Perception of Regulation Barbara Maria Köhler, Wissenschaftcentrum Berlin followed by questions
13.15-15.00	Lunch: Refettorio
Afternoon Session:	Chair: Renaud Dehousse, EUI
15.00-16.15	Discussion with interventions
16.15-16.30	Break
16.30-17.00	General conclusions Francis Snyder, EUI

All sessions of the Conference were held in the Teatro, Badia Fiesolana. Simultaneous interpretation was provided into English and French. Transportation of participants was also provided between the city centre and the Badia Fiesolana on each of the two days of the conference.

ANNEX III

PARTICIPANTS

There were approximately forty official participants in the conference, in addition to a number of EUI researchers who attended specific sessions of interest to their projects. The official participants consisted (a) officials from the Commission of the European Communities, especially from DG III; (b) representatives of interest groups (agriculture, industry, workers, commerce, consumers) who are members of the Advisory Committee on Foodstuffs; (c) the representatives of the Member States who are experts in the sector and who were invited through the Permanent Representatives of the Member States in Brussels; (d) the three experts who had previously prepared the proposed draft directives; and (e) the academic representatives who presented the main scientific reports.

The detailed list of the participants is as follows:

(a) Commission of the European Communities
Dr E. Gaerner
Mr. Gonzalez Vaque
Mr De Klerck
Mr E. Previdi
Mme J. Vergnettes
Mr Vital

(b) Members of the Advisory Committee on Foodstuffs

Ms J. Ardagh (Industry, UK)
Ms A. Busk Jensen (Industry, Denmark)
Mr H. Kellner (Agriculture, Germany)
Mr D. Klein (Agriculture, Germany)
Mr D. Labatut (Commerce, France)
Ms Saunders (Consumers, UK)
Mrs C. Toussaint (Consumers, Germany)
Mr Van Ewijk (Commerce, Belgium)

(c) Representatives of the Member States

Mr Barreto Dias (Portugal)
Mr Christensen (Denmark)
Mr De Giovanni (Italy)
Mr De Peuter (The Netherlands)
Mr Flanagan (Ireland)
Ms Gross (Germany)
Mr Guidon (Ireland)
Mr Hadzidaki (Greece)
Mr H. Ferry-Wilzeck (France)
Ms Lockyer (UK)
Ms Love (UK)
Mr Ostergaard (Denmark)
Mr Q. Perez Bonilla (Spain)
Mr Porcelli (Italy)
Ms R. Sanchidrian Fernandez (Spain)
Mr Sielaff (Germany)
Mr A. M. Tomé (Portugal)
Mr Van Havere (Belgium)
Mr Van Hoogstraten (The Netherlands)
Ms H. Zylberman (France)

(d) The three experts

Prof Charles Castang (Marseille)
Prof Amanda Cleary (Hull)
Prof Dieter Eckert (Bonn)

(e) Academic representatives

Mr. E. Noël
President
European University Institute
Badia Fiesolana
I-50016 San Domenico di Fiesole (Fi)
Italy

Dr R. Dehousse
Department of Law
European University Institute
Badia Fiesolana
I-50016 San Domenico di Fiesole (Fi)
Italy

Dr J. Falke,
Zentrum für Europaische Rechtspolitik
Universität Bremen
Universitätsallee, GW 1
D-2800 Bremen 33
Germany

Professor C. Joerges, EUI/Bremen
Department of Law
European University Institute
Badia Fiesolana
I-50016 San Domenico di Fiesole
Italy

Dr B. M Köhler
Wissenschaftcentrum zu Berlin
Reichpietschufer 50
1 Berlin 30
Germany

Professor R. Streinz
Forschungstelle für Lebensmittelrecht
Universität Bayreuth
Postfach 10 12 51
D-8580 Bayreuth
Germany

Professor F. Snyder
Department of Law
European University Institute
Badia Fiesolana
I-50016 San Domenico di Fiesole (Fi)
Italy

EUI WORKING PAPERS

EUI Working Papers are published and distributed by the
European University Institute, Florence

Copies can be obtained free of charge
– depending on the availability of stocks – from:

The Publications Officer
European University Institute
Badia Fiesolana
I-50016 San Domenico di Fiesole (FI)
Italy

Please use order form overleaf

Publications of the European University Institute

To The Publications Officer
European University Institute
Badia Fiesolana
I-50016 San Domenico di Fiesole (FI) – Italy
Telefax No: +39/55/573728

From Name .....
Address. .....
.....
.....
.....
.....

❒ Please send me a complete list of EUI Working Papers
❒ Please send me a complete list of EUI book publications
❒ Please send me the EUI brochure Academic Year 1994/95

Please send me the following EUI Working Paper(s):

No, Author .....
Title: .....
No, Author .....
Title: .....
No, Author .....
Title: .....
No, Author .....
Title: .....

Date .....

Signature .....

Working Papers in Law

LAW No. 90/1
David NELKEN
The Truth about Law's Truth

LAW No. 90/2
Antonio CASSESE/Andrew CLAPHAM/Joseph H. H. WEILER
1992 – What are our Rights? Agenda for a Human Rights Action Plan

LAW No. 90/3
Sophie PAPAEFTHYMIOU
On a "Constructivist Epistemology of Law"

LAW No. 90/4
Joachim WÜRMELING
Legislativer Trilog im Institutionellen Dreieck der Europäischen Gemeinschaft. Das Verfahren der Zusammenarbeit nach Artikel 149 Absatz 2 EWGV.

LAW No. 90/5
Renaud DEHOUSSE
Représentation territoriale et représentation institutionnelle: réflexions sur la réforme du Sénat belge à la lumière des expériences étrangères

LAW No. 90/6
J. KORTE (ed.)/
A. E. KELLERMANN/
W. M. LEVELT-OVERMARS/
F. H. M. POSSEN
Primus Inter Pares: The European Court and National Courts.
The Follow-up by National Courts of Preliminary Rulings ex Art. 177 of the Treaty of Rome: A Report on the Situation in the Netherlands

LAW No. 90/7
Reiner GRUNDMANN
Luhmann Conservative, Luhmann Progressive

LAW No. 90/8
Bruno DE WITTE
The Integrated Mediterranean Programmes in the Context of Community Regional Policy*

LAW No. 90/9
Anne-Laurence FAROUX
Le Ministère de la Culture en France: Création et organisation

***

LAW No. 91/10
Christian JOERGES (ed.)
European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards
Vol. 1
Christian JOERGES
*The Juridification of Product Safety Policy**

LAW No. 91/11
Christian JOERGES (ed.)
European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards
Vol. 2
Gert BRÜGGEMEIER/
Hans-W. MICKLITZ
*Product Safety Legislation in France and in the United Kingdom**

*out of print

LAW No. 91/12
Christian JOERGES (ed.)
European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards
Vol. 3
Gert BRÜGGEMEIER/
Josef FALKE/Christian JOERGES
*Product Safety Legislation in the Federal Republic of Germany and in the United States**

LAW No. 91/13
Christian JOERGES (ed.)
European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards
Vol. 4
Josef FALKE/Christian JOERGES
*"Traditional" Harmonisation Policy, European Consumer Protection Programmes and the New Approach**

LAW No. 91/14
Christian JOERGES (ed.)
European Product Safety, Internal Market Policy and the New Approach to Technical Harmonisation and Standards
Vol. 5
Christian JOERGES/
Hans-W. MICKLITZ
*Internal Market and Product Safety Policy**

LAW No. 91/15
Christian JOERGES
Markt ohne Staat? Die Wirtschaftsverfassung der Gemeinschaft und die Renaissance der regulativen Politik*

LAW No. 91/16
Erk Volkmar HEYEN
Systemic Interference and Social Segmentation of Scientific Legal Discourse: Some Theoretical Perspectives and Empirical Results in the Field of Continental Administrative Law

LAW No. 91/17
Andrea SCHULZ
Verfassungsrechtliche Grundlagen der auswärtigen Kulturpolitik

LAW No. 91/18
Hans-W. MICKLITZ
Internal Legal Instruments for the Regulation and Control of the Production and Use of Chemicals and Pesticides*

LAW No. 91/19
Hans Ulrich Jessurun d'OLIVEIRA
Class Actions in Relation to Cross-Border Pollution. A Dutch Perspective*

LAW No. 91/20
Luis María DÍEZ-PICAZO/
Marie-Claire PONTHOREAU
The Constitutional Protection of Social Rights: Some Comparative Remarks

***

LAW No. 92/21
Aidan O'NEILL/Jason COPPEL
The European Court of Justice Taking Rights Seriously?

*out of print

LAW No. 92/22
Massimo LA TORRE
Linguaggio giuridico e realtà sociale. Note sulla critica realistica del concetto di diritto soggettivo

LAW No. 92/23
Renaud DEHOUSSE
Integration v. Regulation?
Social Regulation in the European Community

LAW No. 92/24
José Engrácia ANTUNES
Le Groupe de Sociétés.
La crise du modèle légal classique de la Société Anonyme

LAW No. 92/25
Christian JOERGES
Geschichte als Nicht-Geschichte: Unterschiede und Ungleichzeitigkeiten zwischen Friedrich Kessler und der deutschen Rechtswissenschaft
***
History as Non-History: Divergences and Time Lag between Friedrich Kessler and German Jurisprudence

LAW No. 92/26
Michael KING/Catherine KRATZ
La Notion d'Intérêt de l'Enfant en Droit: Vecteur de Coopération ou d'Interférence?

LAW 92/27
Massimo LA TORRE
A National-Socialist Jurist on Crime and Punishment - Karl Larenz and the So-Called 'Deutsche Rechtserneuerung'

LAW No 92/28
Diarmuid ROSSA PHELAN
The Application of United States and European Community Domestic Trade Laws to the Imports of Nonmarket Economy GATT Contracting Parties - A Time for Change

LAW No. 92/29
Susanne KALSS
Das Höchststimmrecht als Instrument zur Wahrung des Aktionärseinflusses

LAW No. 92/30
Massimo LA TORRE
Diritto, potere, dominio
Argomenti per una teoria non prescrittivistica del diritto

LAW No. 92/31
Renaud DEHOUSSE/Christian JOERGES/Giandomenico MAJONE/Francis SNYDER
In collaboration with Michelle EVERSON
Europe After 1992
New Regulatory Strategies*

LAW No. 92/32
Renaud DEHOUSSE
Does Subsidiarity Really Matter?

LAW No. 92/33
Diarmuid ROSSA PHELAN
"It's God we Ought to Crucify"

*out of print

***

LAW No. 93/1
Massimo LA TORRE
Reglas, instituciones, transformaciones. Consideraciones sobre el paradigma "Evolución del derecho"

LAW No. 93/2
Francis SNYDER
European Community Law and International Economic Relations: The Saga of Thai Manioc

LAW No 93/3
Aidan O'NEILL
The Government of Judges The Impact of the European Court of Justice on the Constitutional Order of the United Kingdom

LAW No. 93/4
Francis SNYDER
Law and Anthropology: A Review

LAW No. 93/5
Francis SNYDER
Soft Law and Institutional Practice in the European Community

LAW No. 93/6
Jason COPPEL
Individual Enforcement of Community Law: The Future of the *Francovich* Remedy

LAW No. 93/7
Massimo LA TORRE
Nostalgia for the Homogeneous Community: Karl Larenz and the National Socialist Theory of Contract

LAW No. 93/8
Heike GEHRKE
The Implementation of the EC Milk Quota Regulations in British, French and German Law

***

LAW No. 94/1
Yota KRAVARITOU/Sally SHELDON (eds.)
Abortion: Challenges to the Status Quo

LAW No. 94/2
Sally SHELDON
The British Abortion Act (1967) - A Permissive Reform?

LAW No. 94/3
Renaud DEHOUSSE
Comparing National and EC Law: The Problem of the Level of Analysis

LAW No. 94/4
A Regulatory Framework for Foodstuffs in the Internal Market. Report on the Conference (6-7 May 1993) organised by Francis SNYDER