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THE CREATION OF THE EUROPEAN FOOD AUTHORITY

Institutional implications of risk regulation

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FOREWORD

Although it is not yet fully over, the "mad cow" crisis already ranks as one of the major events of the last fifteen years of European history. It has compelled politicians and civil servants, as well as experts and producers, to review their role in ensuring food safety at both national and European Union level. More generally, it has revealed far-reaching changes in our societies' attitudes towards food, scientific and technical advance, and acceptable risk.

For all its devastating consequences, the crisis has at least brought to the fore certain fundamental issues that had not previously been given much attention. What status should be given to scientific advice? What should be done when scientific findings are uncertain, insufficient or contradictory? Where should the responsibility of the expert stop and that of the politician begin? These are the new questions underlying the creation of the European Food Authority. Its genesis deserved to be retraced, as it offers precious insights into concerns that will be with us for some time yet.

To their credit, the current Commission and its President, as of their confirmation, set these issues as leading priorities and have now submitted an operational project. And the Member States very quickly accepted the principle of a European solution to match the geographical scale of the problem they were facing. We would like this type of conclusion – which is by no means self-evident – to be drawn more often when necessary. Areas such as combating international crime and protecting the environment spring to mind in this respect.

Nevertheless, the debate is far from closed, as can be seen from François Lafond's thorough and discerning analysis. For my part, I have noted two issues which deserve more detailed consideration. Why restrict ourselves to the area of food, since any new crisis born of the mismatch between scientific progress and our societies' need for safety will by nature be unexpected and probably different from the "mad cow" crisis? Are we sure that drawing such a clear line between scientific advice and political decision-making dispenses us from the need for any further reflection on "risk regulation" in an uncertain environment, just when the European public's demand for safety has never been greater?

I am grateful to François Lafond for having clarified, as far as was possible, issues which will doubtless remain sensitive for some time to come. I hope this study will contribute to promoting, within European society, that "risk culture" which the more clear-sighted among our political decision-makers are beginning to call for.

Jacques Delors

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INTRODUCTION

The signature of a new treaty allowing the European Union to envisage the accession of new members as of 2004 was not the only outcome of the European Council meeting in Nice in December 2000. In their conclusions, the Heads of State and Government also took note of the Commission's proposal on establishing new general principles and legislation on food and setting up a European Food Authority (EFA). The European Council meeting further invited "*the Council and Parliament to speed up work so that the future European Food Authority may become operational as from the beginning of 2002*"[1].

This reaffirmation of political will is hardly surprising, given the context and the various reasons which made the Community institutions and Member States realise the need to establish an EFA.

It would certainly have taken longer for such an organisation to be envisaged if the bovine spongiform encephalopathy (BSE) crisis had not given such a severe jolt to the Community system and called into question the way in which European scientific expertise was made available. Similarly, the operation of the internal market and the free movement of goods have been affected by successive food crises which, while being very different in nature, have nevertheless caused considerable concern among both the general public and governments. Consumers have realised that the food industry, in an area without national borders, could easily and quickly be weakened. Governments, meanwhile, have pondered the need to adopt national measures to protect individual and public health, in the knowledge that such measures could be seen as obstacles to the free movement of goods.

Establishing a new Community institution to deal with food matters thus has great significance and implications. Beyond the purely institutional considerations relating to the establishment of an EFA within the Community – its organisation, composition, probable working procedures and location – two sets of issues of a more theoretical nature can help us understand what is at stake.

Any new institution generally reflects a variety of views and interests, which tend to become more difficult to reconcile as the number of parties involved increases. To understand the issues underpinning the establishment of the EFA, we must take a close look at the Community's decision-making process (and, in this particular case, the codecision procedure) within the "institutional triangle".

Each component of the triangle would delegate certain functions to the proposed EFA, a fact which would inevitably revive the issue of the balance of powers between the three institutions. Perhaps less obviously than on other occasions when this balance was discussed, the creation of a new organisation would resurrect questions of delegation, transfer of sovereignty, legitimacy and effectiveness in decision-making, in a multilevel decision-making system[2].

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[1] *Presidency Conclusions*, Nice European Council Meeting, 7-9 December 2000, point 36, p. 9. (SN 400/00).

[2] To paraphrase the original concept of "multilevel governance" coined by Marks (G), Scharpf (F), Schmitter (P) and Streeck (W), *Governance in the European Union*, London, Sage Publications, 1996.

While the question of agencies is not specific to the Community context, creating them within the European Union draws particular attention to the problem, as they are not based on any pre-existing model and, in each case, give the impression of resulting from particular events and circumstances. The EFA is yet another illustration of the Community system's flexibility and ability to respond to society's needs. But is the response offered by the proposal for a regulation[3] up to the challenges involved?

The second point for discussion stems from the premise that the EFA also raises the question of the use of scientific advice by the political authority. If we accept that, in the near future, a large proportion of political decisions will require prior recourse to scientific advice, establishing scientific governance in our "risk societies" is becoming a very real necessity for the smooth running of our democratic societies[4]. So how can this scientific expertise resource be integrated in the institutional arrangements? How are decisions to be taken, in a situation where science is no longer an ally, providing decision-makers with certainties, but a variable like any other – imprecise, uncertain or contradictory?

If one of the instruments at the decision-makers' disposal (risk analysis, in this case) has become less accurate, how should the decision-making process be organised to avoid this uncertainty resulting in deadlock? It is not surprising that the precautionary principle has been such a popular response to this quandary.

Establishing the EFA is all the more important in the process of institution-building at EU level since the BSE crisis is still having an impact on the process of European integration, and that it is impossible to say with certainty that a similar crisis could not occur again.

Considered in perspective, the Commission's proposals could be seen as timid in the light of the developments that are taking shape. The BSE crisis speeded up Community action in the field of food safety and helped trigger a comprehensive reorganisation of scientific expertise in the Community, which is to culminate in the establishment of the EFA. This forced "Europeanisation" of food safety will be the subject of the first part of this paper.

To gain a better understanding of the key issues, however, we need to assess the various constraints involved in shaping the proposed institution. Two of these constraints are discussed in the second part of this study.

First of all, the somewhat rigid approach to risk analysis, broken down into three independent stages (assessment, management and communication) could turn out to be less useful in practice than conceptually. Attempting to reflect this division of tasks in institutional provisions and procedures might result in an oversimplified decision-making process, and could cause uncertainty as to the responsibility of each link in the chain. For what is at issue is the relationship between expert scientific advice and policy-making, particularly in conditions of scientific uncertainty.

Secondly, the concept of delegation inherent in establishing an authority seems not to be applied in the best possible way. There are generally two arguments put forward to justify the creation of an autonomous authority. The first relates to the ability of the new organisation to

[3] European Commission, *Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety*, 9 November 2000, COM(2000) 716 – provisional version, 75 p.
[4] Beck (Ulrich), *Risk society: towards a new modernity*, London, Sage Publications, 1992.

produce and provide political decision-makers with scientific advice which, as far as possible, are independent, objective, transparent and credible. The second is that the authority's status as an institution and the procedures that govern its operation should help restore consumer confidence. However, this confidence will last only if a number of conditions are fulfilled.

Lastly, the third part of this study analyses the main answers provided by the Commission in its White Paper on Food Safety[5] and the subsequent proposal for a regulation[6], which could be seen as reacting to the past rather than anticipating the future developments in our societies. With regard to its status and role, the EFA will have to demonstrate that its creation and the unanimity that initially prevailed when it was first mooted have not been unduly influenced by constraints and considerations unrelated to food safety and to the aim of achieving the best possible coordination between scientific expertise and European policy-makers.

[5] European Commission, *White Paper on Food Safety*, Brussels, 12 January 2000, COM(1999) 719 final, 61 p.
[6] European Commission, *Proposal for a Regulation, op. cit.*

1. STAGES IN THE EUROPEANISATION OF FOOD SAFETY

1.1. "*Shortcomings and malfunctionings*" uncovered by the BSE crisis

The Community legislation relating to food safety stems from the "functionalist" approach of the common agricultural policy and the establishment of the internal market, whose implementation and supervision remain to a great extent the responsibility of the Member States.

The Community's involvement in this field is based on the principle of free movement of goods and the need for technical harmonisation and standardisation of products. The Commission has gradually taken action to ensure human health and to give consumers greater protection, while taking care that intra-Community trade was not otherwise affected.

The Commission has adapted its institutional procedures, both at the request of the Council and on its own initiative, to this growing involvement in food matters. Partly in response to the complexity of the issues and the need to be able to draw on expert advice quickly, it has established scientific committees with a variety of working procedures. These bodies operate alongside the previously existing management and regulatory committees but in accordance with more specific rules[7].

While food is a sector in which a great deal of Community legislation has been produced, we cannot really speak of a "common food policy".

On the contrary, the gradual adoption of measures using various legal bases and with diverse aims has caused the situation in the food sector to become extremely complex, with modes of operation that are sometimes described as *ad hoc*[8]. By establishing various types of committee (referred to as advisory, scientific and management committees) the European Commission had been able to coordinate its action in the food sector with that of the Member States and other players in the sector, in accordance with precise empirical requirements.

Similarly, the Court of Justice of the European Communities (CJEC) has stepped in to formalise certain Community practices.

However, these disparate arrangements were to be called into question by the bovine spongiform encephalopathy (BSE) crisis.

The British government's announcement on 20 March 1996 that there was a connection between BSE and the new variant of Creutzfeldt-Jakob disease (CJD) prompted a series of changes in the way the European Commission was organised and operated in relation to consumer protection. Its action in this area had hitherto been only marginal, because of the lack of explicit Community powers.

The European Parliament lost no time in exposing the sequence of events and responsibilities in a crisis which is not yet fully over. It severely criticised the Commission for the

[7] Vos (Ellen), *Institutional Frameworks of Community Health and Safety Legislation, Committees, Agencies and Private Bodies*, Oxford, Hart, 1999, 360 p.
[8] Vos (Ellen), "EU Food Safety Regulation in the Aftermath of the BSE Crisis", *Journal of Consumer Policy*, 23, 2000, 233.

shortcomings revealed by the BSE crisis, and the Member States for their successive instances of negligence. The first "Report on alleged contraventions or maladministration in the implementation of Community Law in relation to BSE" pinpointed a succession of operational problems at various levels, which had a cumulative effect[9]. These related to the composition and functioning of the Veterinary Scientific Committee, the functioning of the Standing Veterinary Committee and its *ad hoc* group (on BSE), the procedures and working methods followed, the relations between the Commission and the various committees, the lack of control and inspection by the Commission and the pressures exerted on civil servants, with the parliamentary report concluding that "*by virtue of the opaqueness, complexity and anti-democratic nature of its workings, the existing system of commitology seems to be totally exempt from any supervision, thereby enabling national and/or industrial interests to infiltrate the Community decision-making process. This phenomenon is particularly serious where public health protection is at stake.*"[10]

The sharing of responsibility for public health protection among various directorates-general came in for particular criticism, since no "*integrated approach*" could be established. According to the report, this lack of coordination, and the resulting presence of conflicting views in various departments was, in the case of BSE, further compounded by other malfunctionings. The report deplored both the lack of a powerful food authority such as the United States' Food and Drug Administration and the fact that there was no European health agency[11]. The American example is very frequently mentioned as a possible model, but we do not really know whether those who suggest it are truly aware of the implications of reproducing such an institution, or whether they are merely seeking to reassure the general public[12].

Finally, the report called on the Commission to propose without delay the creation of a "European Agency for Veterinary and Phytosanitary Inspection" responsible "*for all phytosanitary, animal health, food hygiene and safety and food quality controls*".

The European Parliament was not the only body to criticise the Community's action. A French parliamentary report[13] also summarised the European malfunctionings connected with the BSE crisis in three points:

- "the priority given to the economic requirements of the single market over public health concerns;
- an inability to ensure that the Community's general interest prevailed over particular national interests;
- poor coordination between so-called political decisions and so-called scientific advice."[14]

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[9] European Parliament, *Report on alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts*, Part A, Rapporteur Mr Manuel Medina Ortega, 7 February 1997, A4-0020/97/Part A, 51 p.

[10] *Ibid*., p. 37.

[11] *Ibid*., p. 18.

[12] For a descriptive summary of the role of the FDA, see Iva Frkic, *La structure et le fonctionnement du modèle américain de protection sanitaire : Food and Drug Administration*, Paris, Notre Europe working paper, August 2000, 90 p. (http://www.notre-europe.asso.fr/Iva.pdf).

[13] Assemblée nationale, *De la "vache folle" à la "vache émissaire"*, information report by the joint information task force on all the problems posed by development of the bovine spongiform encephalopathy epidemic, No. 3291, 15 January 1997, 2 volumes.

[14] *Ibid*., p. 100.

There is no doubt that the BSE crisis forced both the Member States and the Community institutions to acknowledge a number of shortcomings of the European integration process. Whether these related to the imbalance between the aims of implementing the internal market and ensuring health protection, or to organisational failings and deficiencies in the handling of issues involving considerable scientific uncertainty, everyone involved was subsequently obliged to take action.

The new drafting of the articles on consumer and health protection in the Amsterdam Treaty is a direct consequence of this state of affairs[15]. The aim is no longer merely to mitigate the side-effects of implementing the single market, but rather to deal with public health protection and consumer protection as key – and fully acknowledged – objectives of the European integration process.

In addition, scientific expertise was very quickly reorganised and integrated into the Community's decision-making processes.

1.2. The questioning of European scientific expertise

The Community has to intervene in ever more varied fields, involving an ever greater number of substances or products (including toys, cosmetics, pesticides and foodstuffs), to ensure the smooth operation of the internal market. Depending on the sector, this action is prescribed by Community legislation or case-law, with the aim of reconciling free movement and compliance with safety standards. The BSE crisis nevertheless revealed how important it was to avoid any lack of clarity in the composition, mode of operation and procedures of the scientific committees. A broad debate has therefore been undertaken to identify the best possible conditions for establishing European scientific advice. The credibility of the Community's activity in this field hinges on its ability to base its decisions on recognised expertise.

If we compare the grievances forwarded by the European Parliament to the Commission and Council in relation to their management of the BSE crisis and the proposals subsequently put forward by the Commission to deal with the issue, we can see that all the innovations proposed are designed to address – either directly or indirectly – the European Parliament's concerns. Parliament called on the Commission to ensure greater transparency and a change in the way the scientific committees operate, to establish a neutral and interdisciplinary science council responsible for appointing the members of the other committees, to strengthen control and inspection mechanisms, to draw up a framework directive on food law, to ensure the safety of products which circulate freely within the Community, to bring together all the activities dispersed among the various directorates-general within a single DG or "*Public Health Protection Unit*", etc.

The first stage in reshaping European scientific expertise began with the European Parliament's debate on the report by the Committee of Inquiry in 1997[16], when the President of the Commission, Jacques Santer, introduced a series of proposals, based on the

[15] Vos (Ellen), "EU Food Safety Regulation in the Aftermath of the BSE Crisis", *Journal of Consumer Policy*, 23, 2000, 235-8.
[16] Debate in plenary session of the EP, 18 February 1997, *EU Bulletin*, 1-2, 1997, 163-6.

"*shortcomings*" noted and on the following diagnosis: *"Our decision-making mechanisms are not necessarily capable of keeping pace with the astonishing advances being made in science.*"[17]

He wanted the scientific committees to be supervised by a Scientific Steering Committee, in compliance with the EP's request, under the sole authority of Directorate-General XXIV (Consumer Protection), which was to take over responsibility for public health. Selection of the scientists was to be more stringent. The way these committees were organised and run, the openness of their procedures, the publicity granted to their work, and the consideration of minority opinions and their publication along with the opinions given, were to become the rule for all scientific committees.

Once these broad policy lines had been drawn up, the second stage was the Commission's publication of the "Communication on Consumer Health and Food Safety"[18] in April 1997. This laid down new foundations for a policy on food and for reorganising European scientific expertise.

With the end-result sought being better health protection for consumers, and food safety being a precondition, the communication outlined three factors for improving procedures in order to achieve this goal: scientific advice, risk analysis and control and inspection. The first two heralded the future EFA[19].

The communication began by outlining the arguments which would subsequently be reiterated in all Community documents relating to scientific expertise. Scientific advice should be based on the principles of excellence, independence and transparency. To ensure the best possible quality of scientific advice, the procedures should be such as to avoid opinions being guided by interests other than scientific rigour. It should, similarly, be possible for all interested parties to follow (and thus check on) the rules being drawn up.

The communication also specified that the restructuring of scientific committees – which until then had occurred on an *ad hoc* basis – would henceforth be carried out within a rationalised and harmonised framework of procedures and operating methods. Lastly, a Scientific Steering Committee would be set up to coordinate the work and advise the Commission on selecting members for the various scientific committees.

The second component, described much more sketchily in the communication, was the breakdown of risk analysis. If a decision is to be taken with the best possible information, risk assessment must be carried out to determine the probability that a dangerous situation will arise. This stage must enable decision-makers to act with full knowledge of the facts. Risk management – by the Commission – would thus start once an assessment had been performed,

[17] *Ibid*., p. 166.
[18] Communication of the European Commission, *Consumer Health and Food Safety*, 30 April 1997, COM(1997) 183 final, 35 p.
[19] The communication went at great length into the monitoring and inspection procedures, which are supposed to undergo extensive review, as mentioned as early as the European Parliament's first enquiry report. Being partly the responsibility of the Member States and the Food and Veterinary Office, which was reorganised in 1997, this question, albeit fundamental, of monitoring and inspections will not be investigated in depth in this survey.

in line with the level of protection desired. Last but not least, communication would allow all parties concerned to be informed of the risks[20].

That communication set out the beginnings of a Community response. While it described the organisational proposals at considerable length, it did not go into the theoretical design of a comprehensive framework for using scientific advice in Community procedures or for making the necessary changes to the treaties. For example, it provided no solution for dividing tasks between risk assessment and risk management. Lastly, the precaution principle was expressly mentioned only in the final version of the communication[21], while the first draft to be circulated just referred to a less specific "prevention principle": *"the Commission will be guided in its risk analysis by the prevention principle, whose application is particularly important in cases where the scientific basis is insufficient or some uncertainty exists"* (our translation).

The Commission's activities, whether on the initiative of or in collaboration with the European Parliament, have therefore taken the form of both an organisational review[22] and more *ad hoc* measures, such as the organisation of conferences with a view to sharing ideas in the area of food law and paving the way for policy solutions by comparing diverse options[23].

The reorganisation of scientific expertise within DG XXIV took place from April 1997 to March 1998. The establishment of the Scientific Steering Committee, restructuring of the eight specialist scientific committees[24], rearrangement of responsibilities within the DG itself (notably through the creation of a risk assessment unit) and adoption of new working methods together demonstrate that scientific advice was a major focus of attention, in line with the recommendations of the European Parliament.

Two years later, as if to emphasise the importance granted to scientific advice and verify the relevance of the measures taken, the Health and Consumer Protection Director-General requested an assessment from three members of the Scientific Steering Committee: Professors W. Philip James, Fritz H. Kemper and Gérard Pascal[25].

While acknowledging that the changes undertaken in 1997 had effectively improved the production of scientific advice, the scientists' report set out a variety of reasons for going even

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[20] The Health and Consumer Protection DG, and in particular the recently created unit responsible for risk assessment, organised an international conference on "Risk analysis and its role in the European Union" on 18-19 July 2000, which provided a comprehensive overview of the problem.

[21] *Op. cit.*, p. 19.

[22] The transfer of scientific committees and reorganisation of DG XXIV was started in February 1997 and further rationalised in July 1997, when an inter-services operations manual was published, establishing cooperation procedures between the various DGs involved
(see http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub01_en.html).

[23] The conferences were organised jointly by the European Parliament and the Commission: "Animal meal" (July 1997), "Food legislation and policy" (November 1997) and "The European Union and food safety: lessons to be learned from the BSE crisis" (November-December 1998). These resulted in publications, or in reports generally available on the Internet.

[24] They are the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Committee on Veterinary Measures Relating to Public Health, the Scientific Committee on Animal Health and Animal Welfare, the Scientific Committee on Plants, the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, the Scientific Committee on Medicinal Products and Medical Devices and the Scientific Committee on Toxicity, Ecotoxicity and the Environment.

[25] James (Philip), Kemper (Fritz) and Pascal (Gérard), *A European Food and Public Health Authority. The future of scientific advice in the EU*, report commissioned by the Health and Consumer Protection DG of the European Commission, December 1999, 74 p.

further in the same direction. The group's conclusions called on the Commission to start planning for the future without delay, and to prepare to deliver scientific advice on all health issues.

The changes made by the Treaty of Amsterdam, and in particular the mainstreaming of health issues in all Community policies, the general health situation in Europe, the increasing disparities that could be expected further to enlargement, the interests of the various parties involved (that are sometimes difficult to reconcile) and the loss of confidence in both scientific analysis and government practices, are all factors that the authors put forward as justifying the need to expand the reforms undertaken and create a new organisation, with broader functions. The report proposed the creation of a European Food and Public Health Authority, an independent body responsible for questions of public health[26], and for food safety and the environment. While reviewing the existing features, the three rapporteurs gave a precise description of the conditions required for a future authority to operate properly. Various issues were examined from the perspective of public health, but taking on board food and environmental considerations. These included strengthening the provision of scientific advice, establishing the various units, organising committees of experts, designing scientific assessment processes taking into account national and international production locations, and ensuring the necessary transparency of procedures.

The submission of this report, in December 1999, took place in a changed political context, as a new Commission had been appointed. In his first speech to the newly elected European Parliament, on 21 July 1999, President Romano Prodi announced that food safety would be one of the priorities during his mandate. Reaffirming the importance of making the European Union more directly relevant to the daily life of European citizens could make sense only if everything possible was done to restore consumers' confidence in their food. President Prodi's speech to the European Parliament on 5 October 1999 presented a three-year plan for food safety, partly echoing the initiative that had already been taken by the Commission[27].

With a view to clarifying responsibilities and regaining public confidence, the idea of creating an authority responsible for assessing risks, so that the best possible expert scientific advice could be made available, was thus clearly reiterated. But the best way of reorganising the decision-making process in the field of food has continued to be a bone of contention throughout the subsequent stages in the proceedings (green paper, white paper, and proposal for a regulation).

[26] Except for medicinal products, which would still be handled by the European Agency for the Evaluation of Medicinal Products, in London.
[27] Speech 99/121.

2. DESIGNING AN AUTONOMOUS FRAMEWORK

2.1. Risk analysis and its limitations

One of the main characteristics of contemporary politics is the increasing intervention in activities involving risk. The concern is not solely about the possible consequences of the government's decisions and policies that can present dangers for people or the environment. It is also about the unknown implications of some activities, since the need for action often takes place in a context where the scientific advice available is uncertain, incomplete or contradictory.

Risk analysis developed from case studies and from accidents (involving atomic energy or chemicals), which made it possible to refine the characteristics considered useful for assessing and specifying the real nature of hazards, and ways to anticipate and manage them and inform public opinion about them. The most widely used risk analysis model includes three stages – risk assessment, management and communication – each involving people, a logic and working methods specific to the activity being investigated.

This breakdown of tasks and roles raises the issue of the relationships between the experts, policy-makers and communicators with respect to risk analysis. Such relationships are more complex than the simple distinction between risk assessment, management and communication might indicate. The rationale applied by the various parties involved is not necessarily compatible, their timing might not match, and there is also an inconsistency in the "symbolic" issues at stake, since the parties do not necessarily agree on the importance or priority of each other's concerns[28].

Take the first stage: assessment. Those responsible for assessing a particular risk try to determine the extent of potential damage, the probability of it occurring, how the damage might be spread geographically or over time, whether it could be reversed, the delayed effects (related to a "latency period" between the original event and any possible impact of the event), and the inevitable degree of uncertainty of quantitative assessments. Lastly, a parameter integrating possible reactions on the part of the general public (in particular the extent to which it can be mobilised) is sometimes also included in the assessment[29].

Every society tries to monitor what it considers to be hazardous activities. Risks are defined as potential dangers from human activities or from natural phenomena that are evaluated and considered unwelcome by the great majority of people. Perception of a risk differs according to the field considered, the way the effects are taken into account and assessed, and the threshold chosen as a limit not to be exceeded.

What level of risk is accepted by any given society? How can differing levels of risk acceptability be reconciled? Scientific assessments and the analysis of how risk is perceived are integral parts of this evaluation process which results, once all considerations have been taken into account, in the development of risk management strategies. And as the explanatory memorandum of the proposal for a regulation points out, risk management is "*the process of*

[28] Ricoeur (Paul), "*Citation à témoin : la malgouvernance*", *Le Juste 2*, Paris, Ed. Esprit, 2001, 289-97.

[29] Most of the information comes from Renn (Ortwin) and Klinke (Andreas), *Prometheus Unbound. Challenges of Risk Evaluation, Risk Classification, and Risk Management*, Working Paper No. 153, Stuttgart, Center for Technology Assessment, November 1999, 46 p.

weighing policy alternatives in the light of the results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk to ensure the high level of health protection determined as appropriate in the European Community"[30].

We need not insist on the fact that drawing a clear line between the purely technical assessment of risks by scientists within an independent agency and the management of these risks by political authorities, in this case the Commission, is a somewhat artificial exercise. It reflects a linear conception of the relationship between science and political institutions, which no longer seems to correspond to reality[31]. Nevertheless, it is the approach adopted for the project to establish the EFA.

The rationale behind this sharp separation of responsibilities is that the failure to allocate precise roles would make it impossible to have a clear idea of who is responsible for what; and would do nothing to ensure either transparency in the processes or accountability for the decisions.

The Commission put forward three reasons for not including risk management among the responsibilities of the EFA. Firstly, such a transfer of power would involve an "*unwarranted dilution of democratic accountability*". Secondly, the functions of control and inspection (which are the Commission's responsibility) and of management should remain linked so that the Commission can act appropriately and consistently. Thirdly, to do anything else would require amendment of the treaty[32].

Assessment must be independent, objective and transparent, whereas risk management requires other factors to be taken into account: "*the feasibility of controlling a risk, the most effective risk reduction actions„… the practical arrangements needed, the socio-economic effects and the environmental impact*"[33].

A water-tight separation between the assessment stage and risk management in the food field was one of the main points called for by the majority of parties involved. For instance, during the Internal Market Council meeting of 16 March 2000[34], a majority of States (Germany, Denmark, Sweden, Ireland, Belgium, Austria, Finland and France) were clearly in favour of a sharp separation between the assessment and communication tasks devolved to the EFA and the risk management tasks that the Commission proposed leaving in the hands of the EU institutions. Only Luxembourg considered that this separation was not always practicable. The Grand Duchy agreed, however, that it was important to separate the drafting of legislation from its implementation. Luxembourg wished the EFA to play a part in risk management, notably in relation to individual decisions relating to the placing of products on the market.

The apparently consistent and unequivocal views put forward by the Commission on the need for a separation of roles, echoed by most of the Member States, were nevertheless contradicted in another Community document, relating to fishing policy. Following the publication of a communication, intended to launch broad debate, relating to the application of the precautionary principle and multiannual arrangements for setting total allowable

[30] *Proposal for a Regulation*, COM (2000) 716, *op. cit*., p. 9.
[31] Weingart (Peter), "Scientific Expertise and Political Accountability: Paradoxes of Science in Politics", *Science and Public Policy*, vol. 26, No. 3, June 1999, 151-61.
[32] White Paper, *op. cit*., p. 17.
[33] *Proposal for a Regulation*, COM (2000) 716, *op. cit*., p. 9.
[34] 2248th session, internal market (16/03/00), 6801/00 (Press 64).

catches (TACs)[35], a memorandum from the spokesman summarised as follows what had previously seemed a rather simpler situation:

"*For the Commission the precautionary principle, according to which a lack of certainty is not a sufficient argument for postponing difficult decisions, is the only answer to the dilatory attitude which has so often characterised decision-making in fisheries. However, application of this principle in practice presents some difficulties, such as the evaluation of the risk involved (and which the application of the principle should avoid) and the definition of what represents an acceptable level of risk.*

In attempting to answer these questions the boundary between scientists and decision-makers can become blurred. In theory, scientists interpret the risks associated with various scenarios while management bodies decide what is the acceptable level of risk. However, the setting by scientists of a 'safe' level of biomass (quantity of fish) that prevents the risk of collapse is already a choice. Decision-makers are therefore confronted by a situation where decisions about what is an unacceptable risk have already been made and according to criteria which they may not fully understand. Efforts have to be made to avoid confusing the various roles, although it may not be possible to avoid some overlap. "[36]

The debate on the nature of the relationship between policy-making authorities and scientific expertise or, if one prefers, between risk assessors and risk managers, is quite clear. Why, in our complex societies, where science plays a big part, continue to ignore that politicians are faced with a dilemma? If they always accept scientific advice and technical suggestions, will they really be able to avoid the criticism that they are shirking their responsibility and accepting that society can be moulded by experts? If, in contrast, they grant too little significance to scientific advice by including other factors, which are legitimate but not easily quantifiable, under what conditions could they do so without losing the support of public opinion?

That is the point made by the opponents of the precautionary principle, who reject the possibility that such a principle, whose legal nature remains unclear[37], might be based on "discretionary" considerations – considerations that go beyond risk assessment (which is then inadequate) and cost-benefit analysis (which is generally quantifiable).

To avoid abuse of the precautionary principle, and to allow a fair assessment of risks, the best possible solution is to ensure that the formal conditions for delivering scientific advice and making the policy decision are complied with. This also involves transparency, participation of the stakeholders, consideration and publication of all opinions, including differing views, etc. The EFA, in this sense, is a genuine step forward, as it makes it possible to rationalise the delivery of scientific advice and the workings of the scientific committees (the five scientific committees on food issues being incorporated into the new EFA).

Before Part 3, in which we go into the main characteristics of the EFA (as outlined in the proposal for a regulation) in greater detail, another constraint should be examined, since it

[35] Commission of the European Communities, *Communication from the Commission to the Council and the European Parliament - Application of the precautionary principle and multiannual arrangements for setting TACs*, Brussels, 1 December 2000, COM(2000) 803 final, 17 p.
[36] Press release, 11 December 2000, IP/00/1441 and *Bulletin Quotidien Europe*, 13 December 2000, No. 7862.
[37] European Commission, *Communication from the Commission on the precautionary principle*, Brussels, COM(2000) 1 and *Resolution on the precautionary principle*, European Council of Nice, 7-9 December 2001, Annexe III.

also had an impact on the institutional structure decided for the EFA. One of the reasons mentioned by the Commission to justify the need to separate assessment and management is that giving management powers to such an organisation would have required amendment of the treaties. But should we not take advantage of this new step in reorganising scientific expertise to grant the new body powers of its own, with respect to management for instance (a measure some people had called for on grounds of effectiveness)?[38]

2.2. Autonomy or institutional dependence?

While the considerations mentioned explain why Community action in the area of food safety is necessary, a more fundamental question remains. In what respect is an agency, distinct from the other EU institutions, a solution to restore public confidence with respect to food safety? In other words, what are the arguments for creating a new body, at the risk of making the EU landscape even more complex?

There is nothing new about establishing agencies, authorities, offices or "observatories". First in the United States, and then in Europe, the tendency has emerged in very diverse fields of activity and at differing paces[39]. The establishment of the EFA is taking place in an environment where there are already a dozen other agencies, with various duties and powers. The trend was given a particular boost in the 1990s. Attempts to classify these agencies in terms of function and procedures have no doubt highlighted their common characteristics, but have also – and more often – revealed their obvious differences[40].

The lack of an explicit legal basis relating to delegation, whether in the treaties or in secondary legislation, has fuelled discussion among legal experts for years[41]. Even inside the Commission, there seem to be differences of opinion between those who reckon that consideration should be given to granting agencies regulatory powers, and those who continue to be opposed (notably the legal service)[42].

We must first turn to the case-law of the Court of Justice of the European Communities to understand the legal context in which it proved possible to set up agencies. The Meroni judgement (case 10/56) has, since 1958, provided the guidelines for delegation within the Community's institutional framework, even though it was handed down in a very different context. For delegation to be envisaged, various conditions have to be fulfilled. Firstly, delegation can occur only in fields where the delegating authority has itself been given powers by the treaty. Secondly, delegation can involve only implementing powers that are precisely defined and wholly subject to review. Thirdly, delegation may not be presumed; that is to say, it must be expressly provided for. Lastly, delegation to an agency must not present any threat to the established balance of powers.

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[38] Micossi (Stefano), "*L'inutile Agenzia per la sicurezza alimentare*", *Il Sole 24 Ore*, 21 November 2000.
[39] Conseil d'Etat, *Rapport public 2001*, Paris, La Documentation française, 2001.
[40] Kreher (Alexander), "Agencies in the European Community – A Step Towards Administrative Integration in Europe", *Journal of European Public Policy*, 2 June 1997, 225-45; Chiti (Edoardo), "The Emergence of a Community Administration: The Case of European Agencies", *Common Market Law Review*, 37, 2000, 309-43.
[41] The existing European agencies were, with one exception, created on the basis of Article 235. For more details, refer to the book by Ellen Vos, *op. cit*.
[42] Yataganas (Xénophon A.), *Delegation of Regulatory Authority in the European Union. The Relevance of the American Model of Independent Agencies*, Cambridge (MA), Harvard, Jean Monnet Working Paper 03/01, 2001, p. 26.

Now that we have established the legal framework – which was not particularly favourable to the creation of agencies –, can we further identify the logic behind the creation of the existing agencies, and the reasons put forward in the particular case of the EFA?

Resorting to authorities, which can be given varying degrees of autonomy and independence, offers various advantages. In the first place, designing such organisations allows greater procedural transparency and greater flexibility in adapting to changes and developments. In technical fields these can occur very quickly. Whether the need is to redirect research or other activities without delay, to make a temporary response to a situation seen as short-lived, or to gain access to highly specialised staff, the Commission does not necessarily have the political means, material ability or will to deal with the situation as easily as would a smaller organisation[43]. In addition, specialist organisations often appear more credible to the public and to interested parties than a generalist administration.

Another argument often put forward is that such organisations would be able to side-step certain restrictions to traditional policy. Recourse to an independent authority could make it easier to take decisions that are unpopular or require long-term commitments, or to avoid measures being adopted solely for electoral reasons[44].

Lastly, for people responsible for collecting information, providing scientific advice or constructing indices and tools for comparison, these new bodies also make it possible to improve decision-making, thanks to the quality of the scientific information and advice made available. From this point of view, establishing the EFA would correspond to what some observers have called "regulation by information"[45].

Regulation by information is distinct from traditional direct regulation (by binding legal documents) in that it involves changing individual and institutional behaviour by improving the quality of scientific information and advice made available. When such details are available, they alter the intentions of decision-makers, either directly by modifying the original intent or indirectly by facilitating comparative studies and other “benchmarking” processes. The purpose is not so much to impose requirements than to raise awareness and persuade by supplying all possible information liable to result in "good practice". The implicit idea is that this learning process is bound to improve decision-making, since decisions will be taken in the best possible conditions in terms of information (and will thus inevitably be rational, optimal and predictable, at least in theory).

For the European Union, regulation by information operates better where comparable institutions exist at national level and where they form a network and cooperate – usually on a statutory basis – in a way that enables exchanges, sharing of information between partners with similar concerns and therefore comparison of data. The credibility of these arrangements depends to a great extent on the rigour and quality of their work, as assessed by their peers in particular, during repetitive operations where reputations are crucial, particularly in the eyes of public opinion.

[43] To avoid the Commission becoming a "mammoth administration" in the words of Xénophon A. Yataganas, *Delegation of Regulatory Authority in the European Union. The Relevance of the American Model of Independent Agencies*, Cambridge (MA), Harvard. Jean Monnet Working Paper 03/01, 2001, p. 7.
[44] Micossi (Stefano), *Il Sole 24 Ore*, 9 November 2000.
[45] Majone (Giandomenico), *La Communauté européenne : un État régulateur*, Paris, Montchrestien, 1996.

In addition to these reasons, we should mention once again the concept of delegation, which is used in various contexts to explain the basic dynamics of the European integration process, the role of commitology and the creation of agencies (as in the present case of the EFA).

Two varieties of delegation have been highlighted. In the first, the agency's role does not permit it to act freely beyond its mandate. Thus everything is arranged to minimise the possibilities for discretionary deviations or slippage[46]. This is the most common acceptation of the term.

In contrast, the case of the EFA[47], where the connection is between a power which delegates, once and for all, and an authority that receives the mandate, the aim would be to give the agency complete freedom of action, with no subordinate status applying either explicitly or implicitly. This should even be a well-known and very obvious fact. Whether or not delegation is successful depends on the general public's perception of the intention of decision-makers and of the action taken to implement it. According to this view, the general public's trust depends on the authority being independent of the delegating authority and being able to demonstrate that in the way it operates.

Given the historical background mentioned in Part 1, the Commission and the Member States are anxious to send a clear message to organisations in the food sector and to European consumers. Ensuring a high level of protection for human life and health should not be just an empty phrase. Consequently, strengthening the scientific and technical support needed to draw up Community legislation relating to the safety of foodstuffs and ensuring "independent, objective and transparent" assessment of risks will be carried out all the better if it is undertaken by an EFA which is distinct from the Community institutions and equivalent national organisations, and is preferably independent.

Yet beyond this possible autonomy – which is important if it is intended to make full use of the potential of such an organisation in political contexts that can be delicate (as is the case in the food sector) –, we need to examine the actual powers that the EFA will be able to exercise.

The logic underpinning the current growth in the number of agencies (what the Commission calls the "externalisation policy", as it also includes agencies responsible for managing programmes and ensuring compliance with regulations) leaves a number of questions unanswered. The tasks of these decentralised agencies – which in principle have no real executive power and are subject to a degree of budgetary supervision by the Member States, the Commission and the European Parliament – are admittedly innovative responses in terms of setting up European networks to encourage communication between national experts.

The agencies can also be regarded as a response to growing awareness on the part of the Community that the administrative instruments available to the Commission are increasingly inappropriate for the specialist tasks assigned to it. One of the major dangers facing the European integration process is a loss of faith in its regulatory activity[48]. The creation of

[46] Majone (Giandomenico), "Two Logics of Delegation: Agency and Fiduciary Relations in EU Governance", *European Union Politics*, No. 1, February, 2001, 779-809.
[47] An even more striking example to illustrate this category is the delegation of powers to the European Central Bank (ECB).
[48] Majone (Giandomenico), "The Credibility Crisis of Community Regulation", *Journal of Common Market Studies*, vol. 32, No. 2, 2000, 273-302.

agencies would give the Commission access to expert scientific and technical advice in specific leading-edge fields, with greatly increased flexibility.

However, this logic, which involves establishing a number of bodies with somewhat similar functions, yet without giving them real powers, could eventually prove counterproductive. In order for the delegation approach, as described, to play its full part in terms of gaining credibility with the public, the agency must also have the means to produce conclusive scientific advice and, where appropriate, exercise responsibilities that are clearly defined and can be precisely supervised by other institutions (notably the European Parliament).

Therefore, although legal constraints can explain part of the restraint shown in this area, it is not certain that the various parties involved (the European Parliament, the Member States and the Commission) would dare to take the policy to its logical conclusion, in spite of superficial enthusiasm expressed when needed to reassure the public. Yet just a minor amendment to the treaties would suffice to allow such a development.

In the Presidency report to the European Council meeting in Feira (June 2000), the chapter relating to qualified majority voting included a draft new paragraph 3 to be added to Article 7 TEC, which read as follows: "*Where this appears necessary in order to carry out any of the activities provided for in Article 3, the Council, acting in accordance with the procedure laid down in Article 251, shall establish an agency having legal personality and determine the rules applicable thereto.*"[49]

In a speech to the European Parliament, just before the informal European Council meeting in Biarritz (13-14 October 2000), President Prodi pointed out the dangers threatening the EU, referring in particular to the fragmented nature of the institutions, with two examples: the appointment of high-level representatives and the creation of agencies[50]. He challenged the desire expressed by "*some Member States in the intergovernmental conference to amend the Treaty to facilitate the creation of agencies on which the Council can then confer executive powers*". The President saw these agencies as "*conflicting centres of power*". They could be useful to the Commission, if the "*logic of the Community system*" were respected; that is to say they should operate "*under the authority of the Commission, which is answerable to [the European Parliament] for their actions*".

The issue is certainly far from settled. Two other Community agencies – the European Aviation Safety Agency[51] and the European Maritime Safety Agency[52] – are expected to be created shortly. The logic behind their establishment remain essentially the same, even though the aviation safety agency should be able to take individual decisions and "codify its practices".

This proliferation raises the broader issue of the role of agencies in an institutional structure that is already complex. Should they remain simple bodies providing scientific information and advice, helping ensure that the parties concerned and EU institutions have access to the

[49] Presidency Report to the Feira European Council, Part II – Annexes to Chap. 3, Establishment of decentralised agencies, June 2000, p. 89 (CONFEREN 4750/00).
[50] Speech at the plenary session, 3 October 2000, 00/352.
[51] Proposal for a Regulation of the European Parliament and of the Council on establishing common rules in the field of civil aviation and creating a European Aviation Safety Agency, *Official Journal of the European Communities*, C 154 E, 29 May 2001, 1.40.
[52] Proposal for a Regulation of the European Parliament and of the Council establishing a European Maritime Safety Agency, *Official Journal of the European Communities*, C 120, 24 April 2001.

same information – thus encouraging "regulation by information" and comparison of practices – or should they exercise a wider range of powers, as the logic of delegation may be thought to imply?

The White Paper on European Governance published on 25 July 2001 seems to indicate that the Commission would be in favour of creating more regulatory agencies, subject to certain conditions. These conditions, however, could well prove to be particularly restrictive[53]. The agencies would, for instance, not be able "*to adopt general regulatory measures*". In addition, the decision-making power they could be given would be granted only where "*a single public interest predominates*". In other words, they could not "*be granted decision-making power in areas in which they would have to arbitrate between conflicting public interests, exercise political discretion or carry out complex economic assessments*". Even if they were able to take certain decisions, the regulatory agencies to be created would be closely supervised and controlled[54]. What does this mean in practice?

The White Paper on European Governance has not clarified the existing ambiguity regarding the sharing of powers and the role of agencies. Nor has the EFA, which could well see its responsibilities change after a few years' operation. This possibility was explicitly mentioned in the White Paper on Food Safety, which pointed out that a future extension of the EFA's powers could not be ruled out "*in the light of the experience with the functioning of the authority (…) including the possible need to change the Treaty*"[55].

[53] European Commission, *European governance – a white paper*, Brussels, 25 July 2001, COM(2001) 428, 40 p.
[54] *Ibid*., p. 29.
[55] *White Paper, op. cit*., p. 19 and quoted in press release:
http://europa.eu.int/comm/dgs/health_consumer/library/press/press37_fr.html.

3. GENESIS OF A EUROPEAN FOOD AGENCY

3.1. Central features of an overall approach

Since the debate on the European Parliament enquiry report, in 1997[56], during which the President of the Commission, Jacques Santer, presented a series of proposals, the process followed by the Commission may be seen as a model for the development of a new "Community policy", from the Communication on Consumer Health and Food Safety[57] to the Green Paper laying down the broad principles and guidelines envisaged by the Commission[58], and the White Paper on Food Safety published on 12 January 2000[59].

With the objective of launching a debate and involving the governments and all other parties concerned in drawing up the legislation, the White Paper gave details of an action plan (spread over 2000-2002) and a range of measures for improving Community legislation and making it consistent for all sectors and all aspects of food production. The Commission wished to adopt over 80 distinct measures (involving some 30 directives and regulations), forming a complete legal framework which covered animal feedstuffs, the animal health and welfare, hygiene, contaminants and residues, new types of food, food additives and flavours, packaging materials and ionising radiation.

Secondly, the revamping of controls was to give the Commission more tools for assessing the effectiveness of and compliance with control rules, the controls themselves remaining the responsibility of the Member States. To deal with the accumulation of provisions adopted over a period of time in this sector, the White Paper proposed rationalising the controls (singled out for criticism during the BSE crisis). While the primary responsibility remains that of the manufacturers, producers and sellers, national governments will retain responsibility for monitoring all the production and distribution processes. Meanwhile, the Commission, assisted by the Food and Veterinary Office, will assess the effectiveness of these controls through audits and inspections (both within and outside the EU).

Thirdly, the White Paper suggested that the information for consumers should include all the instructions needed, by way of comprehensible and full labelling, to allow consumers to make more informed choices.

Lastly, the international implications of the proposed measures entailed that the EU would have to increase its efforts to explain the situation to its trading partners, in order to avoid the possibility of trade disputes and enable the aims of the general policy to be presented within international bodies (notably the WTO and *Codex Alimentarius*).

From this point of view, the creation of an EFA responsible for assessing and communicating information on food safety risks was the central feature of the arrangements.

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[56] Debate in plenary session of the EP, 18 February 1997, *EU Bulletin*, 1-2, 1997, 163-6.
[57] See note 18.
[58] *The general principles of food law in the European Union*, Commission Green Paper, COM(1997) 176.
[59] European Commission, *White Paper on Food Safety*, Brussels, 12 January 2000, COM(1999) 719 final, 61 p.

** The White Paper*

As the Commission itself recognised, the White Paper fell far short of settling all aspects of the EFA's workings, notably with respect to human and budgetary resources and internal procedures. A number of fundamental questions remained vague (referrals, the exact relationship between the EFA and the Commission, the nature of networking with national agencies, the composition of the various internal bodies, possible differences in approach between the Community level and national agencies, and the running of the early warning system).

Reactions to the White Paper were numerous and fairly critical. The first comments of many observers related to the modest nature of the proposed EFA, since they still had in mind the repeated references President Prodi and Commissioner Byrne had made to the Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products. Some of them considered the EFA to be no more than a simple grouping, within an institution, of the existing scientific committees responsible for food matters. Others were of the opinion that the EFA should have been given genuine management powers[60].

More incisively, referring to the report that three of its members had drawn up at the request of the Commission, the Scientific Steering Committee considered that the opportunity should have been taken to establish a public health authority and not simply one for food safety, thus pursuing the efforts to bring together a variety of public health matters that were still dispersed among various DGs (workers' health, radioactivity, environmental matters, etc.)[61].

The authority proposed by the Commission perpetuates this fragmentation of public health administration, which could prove problematic: "*food may be a priority for the Commission at this moment, but the next crisis could well be a drug, an industrial chemical, an environmental organism, etc.*"[62]. Bringing together all the matters requiring scientific advice and risk assessment would make it possible to harmonise working methods and deal with public health as a whole. This aspect is all the more important since environmental and public health issues will become even more sensitive in the run-up to EU enlargement. For example, a European Food Safety and Public Health Authority, in collaboration with a European Environmental Agency, could well have such a mandate.

The European Parliament rushed to take advantage of these criticisms in order to try and influence the process under way, and in particular to strengthen its role and involvement in the EFA's activities. In its report on the White Paper[63], Parliament accorded great importance to questions of internal procedures and to the functioning of what it still preferred to call the "European Food Safety Authority". Alongside its comments on the referral procedures, Parliament (notably the Committee on Legal Affairs and the Internal Market) emphasised that there remained contradictions on the division of responsibilities and that the considerable financial resources required had not yet been sufficiently well defined.

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[60] *Libération*, 13 January 2000; *Financial Times*, 12 January 2000, Donald G. McNeil "At Birth, EU's Food Watchdog is on Defensive", *International Herald Tribune*, 13 January 2000.

[61] *Integrated Comments and Remarks of the Scientific Steering Committee on the White Paper on Food Safety*, 14 April 2000.

[62] *Ibid*., p. 2.

[63] European Parliament, *Report on the Commission White Paper on Food Safety*, Rapporteur for the Committee on the Environment, Public Health and Consumer Policy, John Bowis, 12 October 2000, A5-0272/2000 final.

Lastly, the MEPs[64] vehemently called for further details on the way the EFA would function; in particular, on the *early warning system* and how it would be triggered, on harmonisation of measuring instruments to facilitate comparisons, on relationships between the EFA and national agencies, and on the effective implementation of principles ensuring transparency and autonomy for the EFA.

Meanwhile, the Economic and Social Committee, while noting the new attitude of the Commission, considered that "*the EFA does not have sufficiently well defined scope to tackle many of the key issues facing the EU*"[65]. It wondered what mechanisms really could ensure the excellence and transparency of scientific advice.

** The proposal for a regulation*

The proposal for a regulation of 9 November 2000 gave more practical consideration to the regulatory and institutional framework that would help provide consumers with a high level of health protection in relation to food, with the ambition of restoring (and maintaining) consumer confidence.

The first advantage of this draft legislation is that it provides definitions making it possible to introduce legal certainty into an area which had hitherto been partly empirical, and to give all the parties concerned consistent criteria and benchmarks to facilitate comparisons. Apart from the central concern of the regulation – foodstuffs (including water and other beverages) – Articles 2 and 3 define expressions such as "*food law*", "*food business*", "*food business operator*", "*placing on the market*", "*risk analysis*" and its three components, and also "*hazard*" and "*traceability*", etc.

Secondly, the regulation also provides the beginnings of a definition of the precautionary principle under Community law (Art. 7)[66]. In a case where an assessment concludes that a "*risk to health exists but scientific uncertainty persists*", provisional risk-management measures may be adopted, while waiting for other scientific information to complement the assessment. While it is suggested that these measures should be proportionate and "*no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community*", the reaffirmation of the precautionary principle is nevertheless somewhat unclear with respect to the thresholds and mechanisms that are supposed to trigger it. The formula invoked – "*regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration*" – remains imprecise. Yet the principle is increasingly being used, particularly within multilateral frameworks. The Commission would benefit from this – oft disparaged – principle being defined with greater precision; the principle would thus become a genuine public-policy instrument, rather than a concept whose every aspect will have to be spelled out by the Court of Justice.

The European Parliament wished the parameters already set out in the Commission's communication to be repeated, so as to avoid adding other criteria, which "*would be poorly*

[64] An observation: of the 38 contributors (in addition to the general rapporteur and the Commissioner), it is worth noting that 21 of the speakers were women and 17 were men. Furthermore, the three draftspersons of the parliamentary committees were women (Ms Ayuso Gonzalès, Ms Corbey and Ms Gebhardt).

[65] Economic and Social Committee, "Opinion on the 'White Paper on Food Safety'" (200/C 204/06), *Official Journal of the European Communities*, C 204, 18 July 2000, p. 10.

[66] Going further than the *Commission communication on the precautionary principle*, Brussels, COM(2000) 1 and the resolution adopted by the European Council in Nice, which are not legally binding.

defined or formulated"[67]. Meanwhile, along the same lines, the Economic and Social Committee said that it would be illogical for the precautionary principle, which was given so much attention, not to be better defined, notably as regards "scientific uncertainty", which would appear to be its basic motivation.

Other aspects of the proposal for a regulation deserve to be mentioned, since they alter the background against which the EFA will have to operate. The principle that primary responsibility for ensuring food safety lies with producers and suppliers is reaffirmed. There will be improved traceability of foodstuffs at all stages of production and distribution and, lastly, the Member States remain responsible for enforcing food law and controlling that requirements are fulfilled.

3.2. A new institutional configuration

The European Food Authority is given responsibility for six main functions:

- providing the Commission with scientific and technical advice on all matters related to the safety of foodstuffs, nutrition, animal safety and welfare, plant health and genetically modified organisms[68] (Article 28);
- seeking, collecting, collating and analysing information in the fields for which it is responsible (Article 32) ;
- monitoring developments in food safety matters (Article 30) ;
- identifying emerging risks (article 33) ;
- managing the rapid alert system (Article 34) ;
- communicating the results of its activities (Article 39).

The first five sections in chapter III of the proposal for a regulation set out the overall function and individual tasks, how the EFA will be organised, how it will operate, its "relationship to the world"[69] and the financial provisions. Without going over all of the document's provisions, we will look at four aspects that are set to determine more precisely how the EFA will operate: the composition of the management bodies, the relationships envisaged with national agencies, referral procedures and the rapid alert emergency procedures (described in chapter IV).

The EFA will be controlled by an *Executive Director* appointed for a period of five years by the *Management Board* further to a Commission proposal. It will also include an *Advisory Forum* and receive contributions from part of the scientific committees currently operating within the Health and Consumer Protection DG. The five committees concerned with food questions, which were restructured in 1997, are thus being rearranged into eight scientific

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[67] European Parliament, *Report on the proposal for a European Parliament and Council regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety*, Part 1: draft legislative resolution, rapporteur M. Whitehead, 31 May 2001, A5-0198/2001 final, part 1, p. 36.

[68] The EFA will have full responsibility for GMOs intended for use in human or animal food. In the case of GMOs not intended for food, the EFA's responsibilities will be limited to supplying scientific advice, and it will not be able to collect information or identify emerging hazards unless explicitly requested to do so by the Commission.

[69] The exact title of the section is "Independence, Transparency and Communication".

panels[70], coordinated by a *Scientific Committee*. This will replace the current Scientific Steering Committee, and will be composed of the chairmen of the eight scientific panels and six scientific experts who do not belong to any panel. In addition to the general coordination required to ensure consistency and harmonisation of working methods in the various scientific panels, the Scientific Committee will have competence for advice on multisectoral issues.

According to the Commission's proposal, the Management Board should be composed of four representatives appointed by the Council of Ministers, four appointed by the Commission, four appointed by the European Parliament and four representing consumers and industry. This composition is still the subject of fierce negotiations with both the European Parliament and the Member States.

The European Parliament is proposing to reduce the number of members to 12[71]. The Commission would suggest a list of candidates (including two representatives of consumers and two representatives from the food industry), based on merit criteria. The appointments would be subject to approval by the European Parliament. The Member States have meanwhile proposed that the number of their representatives be increased from four to 16. Of these, four would have experience in "*organisations representing consumers and other interests in the food chain*", there would be one representing the Commission, and the others would represent "*the highest standards of competence and the broadest possible geographic distribution*"[72].

This point of disagreement[73] could be indicative of the extent to which the Member States are determined, through an ambiguous formula, to keep a majority in the Management Board – a goal which could appear contradictory in two respects. First, in the light of the concept of delegation described above, the States' desire to control the Management Board (which adopts the work programme, the budget and internal rules) would jeopardise the credibility of an independent EFA in the eyes of the public. Secondly, this representation of the Member States would run counter to the demand that there should be a clear separation between risk assessment and risk management.

Together with the Management Board, the regulation provides for establishment of an Advisory Forum, composed of "*representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority*", these representatives being designated by each Member State (Art. 26). This body would be chaired by the Executive Director and should ensure cooperation between the EFA and the national authorities. It could also have a mediating role in the event of differing scientific opinions.

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[70] There is one panel on food additives, flavourings, processing aids and materials in contact with food; one on additives and products or substances used in animal feed; one on plant health, plan protection products and their residues; one on genetically modified organisms; one on dietary products, nutrition and allergies; one on biological hazards; one on contaminants in the food chain, and one on animal health and welfare.

[71] European Parliament, *Report on the proposal for a European Parliament and Council regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety*, Part 1: draft legislative resolution, rapporteur M. Whitehead, 31 May 2001, A5-0198/2001 final, part 1, p. 61.

[72] Press release, 28.06.01, IP/01/916.

[73] Explicitly mentioned in the *Amended Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety*, Brussels, 7 August 2001, COM(2001) 475 final.

This Advisory Forum is a key component in the arrangements, mainly because it is likely to become the hub of the network of national agencies responsible for risk assessment and the delivery of scientific advice in food matters. Although the regulation is not yet in force, the Commission has already convened an "Interim Scientific Advisory Forum" – which has already met three times –, to identify contacts in each country and establish, as soon as possible, links between national scientists and the Commission. David Byrne, the Commissioner responsible for health and consumer protection, wishes to speed up the formation of scientist networks, in a climate of "*collaboration, cooperation and trust*"[74]. He hopes that this will avoid "*conflict and contradictions in risk assessment methods and outcomes*" in the future[75].

Everyone will recall the crisis involving France and the United Kingdom regarding the Commission's decision in July 1999 to lift the embargo on beef exports. The general impression which remains is that Afssa, the newly created French food safety authority, and the European Commission's Scientific Steering Committee differed on the scientific interpretations of the risk associated with beef. The crisis did not involve only the persons responsible for risk assessment, since the French government scrupulously applied the recommendations made by its own country's agency. Once again, this situation indicates that:

- On the one hand, the relationship between scientific expertise and political decision-makers can quickly become less linear than theoretical models suggest, and that it can result in serious diplomatic tension[76]. This is all the more true given that some interpretations lay more stress on the normative differences and semantic subtleties distinguishing the two committees than on the real differences in scientific opinions[77].

- On the other hand, it may not be possible for the national authorities to adjust to changes at EU level as easily as would be desired, in spite of the high degree of integration within the Community. A lack of understanding, and suspicions of ulterior motives, emerge very quickly in relation to the validity of and interests behind the decisions taken.

The planned regulation provides, in Article 29, for the possibility that "*conflicting scientific opinions*" could arise. The EFA is not authorised to arbitrate on conflicts that may arise[78], but has an obligation to exercise vigilance in order to identify at an early stage any potential source of conflict. If differences of opinion persist after being identified despite the EFA's efforts, the parties in dispute will have to present a joint document to the Commission clarifying the "*contentious scientific issues*". In the event that one of the parties involved is a public body in a Member State, the parties are obliged to collaborate, with a view to resolving the conflict, or to present the Commission with a joint document on the scientific points at issue, after consulting the Advisory Forum.

Still concerning relationships between the EU and the Member States, a mediation procedure is also provided for, in Article 59. This allows a State to dispute a measure in the area of food safety that is judged contrary to the regulation or that affects the functioning of the internal

[74] Opening address by David Byrne, the European Commissioner responsible for health and consumer protection (http://europa.eu.int/comm/dgs/health_consumer/library/speeches/speech98_en.html).
[75] Press release, 07.05.01, IP/01/648.
[76] Resulting in this case in proceedings before the Court of Justice of the European Communities.
[77] Godard (Olivier), "Embargo or not embargo", *La Recherche*, No. 339, February 2001, 50-5.
[78] The explanatory memorandum states that the EFA is not empowered to act as a "*final, scientific, arbitrator in the case of conflicting scientific opinions in a manner which is binding on the parties concerned*" (p. 18).

market. The State can either refer the matter to the Commission, which then seeks to resolve the problem, or request an opinion from the EFA on the contentious scientific issue.
The initial objective adopted for the EFA was to organise its relationships with the national agencies very carefully to avoid any loopholes[79].

The example of the European Agency for the Evaluation of Medicinal Products (EMEA), which is considered by most observers as a success, was to serve as a model in terms of configuration and functioning. However, in the area of food, the small number and relative newness of national agencies has made it impossible to adopt the same approach. While food safety agencies do exist, notably in France, Denmark, the United Kingdom, Ireland, Sweden and Belgium, they differ somewhat in powers and functions[80]. The UK's new Food Standards Agency (in existence since the beginning of 2000), for instance, is not limited simply to risk assessment, but also has extensive powers to control, investigate, propose regulations, communicate and manage emergency procedures in the event of a threat to public health. While Germany's Federal Institute for Health Protection of Consumers and Veterinary Medicine (*Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin*) has no competence with respect to regulation, its duties in the field of consumer health protection seem broader than those of other national agencies (covering all foodstuffs, but also packaging, toys, plant health products, insecticides, chemicals, etc.).

Can it therefore be possible to network agencies that are either non-existent (for Italy and Luxembourg, for example), or have only recently been created and may be reluctant to give up part of their recently-acquired power or recognition, or have widely differing scopes and resources?

The European Parliament, like other organisations, has stressed how fundamental the question of relationships between a supranational food authority and the national authorities responsible for food safety issues is to the EFA's proper functioning and to the network envisaged. Its opinion on the White Paper already contained a number of recitals calling for the "European Food Safety Authority"[81] to promote real coordination between the agencies and suggesting the establishment of an advisory committee composed of the directors of national food safety agencies. This committee would hold meetings with the people in charge at the EFA (as is the case for the Advisory Forum) and invite Member States that did not have their own national agencies to create them[82]. Some countries clearly rejected this idea[83].

The third important point relates to referral to the EFA. According to the proposal for a regulation, the EFA can act on its own initiative or at the request of a Member State or competent body (notably a national food safety organisation) within such a State, the European Parliament or the Commission (Article 28).

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[79] The EFA is supposed to strengthen, rather than weaken, the national agencies. As a UK parliamentary report mentioned: "*It has a dual task of learning from others' experience and of providing an outreach service to Member States who are less advanced in developing national food safety systems; this will be particularly true of the candidate states for EU membership*" *in* House of Lords, Select Committee on the European Union, *A European Food Authority*, with Evidence, London, The Stationery Office, 16 May 2000, p. 27.

[80] Sénat, *Le contrôle de la sécurité alimentaire*, Working documents of the French Senate, Paris, No. LC 74, May 2000, 33 p.

[81] The European Parliament insisted on using this name, as "*food safety should be the Authority's primary concern*", amendment No. 1 to the proposal for a regulation, *op. cit.*, p. 6.

[82] Bowis report, *op. cit.*, p. 15.

[83] During the Internal Market Council meeting on 30 March 2000, Luxembourg opposed the proposal that States without a national authority should be obliged to create one.

The fourth crucial aspect of the EFA's workings, which is still the subject of animated debate between the Commission, the Council and the European Parliament, has to do with the establishment of the rapid alert system (RAS). The White Paper had already stipulated that the EFA was supposed to be responsible for managing the rapid alert system, making it possible to identify and provide real-time notification of food safety crises (for "urgent problems"). Such a system has already been established under the directive on general product safety. It requires Member States to notify the Commission of the measures they take to restrict the placing of a product on the market or to demand its withdrawal.

As envisaged by the proposal for a regulation, the rapid alert system brings together the Member States, the Commission and the EFA, the latter institution being responsible for its operation. It is the EFA's responsibility to check that the food product notified by a network member really does present a serious risk to human health and demands rapid action. If it does, the rapid alert system will enable the EFA to notify the other members of the network, and possibly supplement the information with additional scientific data, facilitating speedy action. The Member States are to inform the EFA of all measures to be undertaken following this notification.

Here again, we touch upon one of the two sets of issues discussed above. Entrusting the rapid alert system to the EFA amounts to delegating risk management, temporarily, to the authority for reasons of efficiency or speed of operation. The European Parliament, like the Member States, wishes the Commission to remain the body with overall responsibility for the rapid alert system, so as to avoid confusion for the parties involved (operators and national governments)[84].

[84] This line of argument was developed in Ms Béatrice Marre's *information report on food safety* in the National Assembly's delegation for the European Union, 28 June 2001 (http://www.assemblee-nat.fr/europe/c-rendus/c0151.asp).

CONCLUDING REMARKS

It is difficult to predict the exact form that the European Food Authority will finally take. The second reading in the European Parliament is likely to produce further changes to the proposal for a regulation submitted by the Commission on 9 November 2000. Over 200 amendments were tabled during the first reading, and some questions still need to be negotiated among the Member States (including the "symbolic" matter of the location)[85].

The Commission's ability to adapt and the momentum achieved are nonetheless remarkable. Though understandable given the extent of the malfunctions in the delivery of scientific advice noted during the BSE crisis, the speed with which the Commission sought to remedy the failings and propose a new legislative and institutional framework sets an example to follow.

Noting that public opinion in Europe was shocked by the succession of food scandals, Romano Prodi expressed the view that it was the European Union's duty and responsibility to act in such as way as to ensure its citizens' health. Food safety not only helps achieve this objective, but also is also a fundamental element of European culture. By making it a priority, President Prodi sent a clear and strong message to the European population. More than ever, the European integration process needs this ability to deliver a practical response to their aspirations.

In this respect, the inception and shaping of the EFA are far more than a mere institutional issue. Our study has highlighted two topical issues.

Firstly, it has stressed the importance of scientific advice in current European decision-making processes. The idea that scientific expertise can, by itself, resolve all the complicated issues in our multifaceted societies is as dangerous as that of dispensing with its assistance. The whole problem is to structure, organise and reconcile scientific advice with other features that are just as important for managing activities that entail a risk. Thinking that scientific expertise would in all cases be able to provide certainties and rational responses, in purely technical terms, amounts to "ideological deception"[86].

It is similarly difficult to imagine that strictly national solutions can make sense in a sector that had universal significance well before globalisation took hold[87]. The relationships between scientific expertise and political decision-makers could, if we are not careful, lead to confusion about responsibilities. The decision-makers could hide behind the opinions of experts, and the experts – while having a big influence on the shaping of decisions – could refuse to take responsibility for the decisions taken by those empowered to do so. The debate is far from over. The establishment of the EFA offers the beginnings of an answer, even if the strict separation advocated between assessment and management of the risks might not be as clear as some would like us to believe.

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[85] *Financial Times*, 5 September 2001.

[86] Kemp (Peter), *L'irremplaçable. Une éthique de la technologie*, Paris, Cerf, 1997, 121 p.

[87] The main objection that can be made to the Viney-Kourilsky report is that it does not give sufficient thought to the EU as an appropriate level at which to consider establishing "procedures for the delivery of scientific advice, decision-making and management to best identify hazards, control them and, as far as possible, avoid them becoming a reality", in Kourislky (Philippe) and Viney (Geneviève), *Le principe de précaution*, report to the French Prime Minister, Paris, 29 November 1999, p.124.

So that citizen-consumers are not left completely out of this practical exercise in contemporary democracy, the establishment of a rigorous and open framework and procedures, as intended for the EFA, should ensure that some form of control and open debate is possible, thus limiting the scope for a single interest to prevail[88].

The second lesson to be drawn from our study relates to the issue of establishing European regulatory authorities. All future debates on the development of the European Union and its various institutional expressions will seek, once again, to pose the questions of delegation, trust and legitimacy, which are fundamental to the Community. Creating an EFA is, in this sense, a practical institutional exercise in an area which European citizen-consumers consider to be particularly sensitive.

The fact that the model of an EFA, even of modest proportions, responsible for food risk assessment is preferred to other options indicates that the idea of delegating the resolution of common problems to a supranational organisation can be the only logical solution.

It is true that the choice is not neutral, and the various parties concerned do not necessarily have the same interests. Ambiguities remain. The final version of the regulation may boil down to a few minimalist solutions, so as not to disrupt the timetable for implementation (early 2002) confirmed at each of the European Council meetings in Nice, Stockholm and Göteborg, or because, in the context of the co-decision procedure, the Council, Parliament and Commission were not able to agree on some points. The essential steps will, however, have been taken.

It will, nevertheless, be necessary to wait several years to know whether the new body, through the quality of opinions delivered, the respect which it succeeds in inspiring, the efficiency of its networking with national agencies and the effectiveness of the rapid alert system in the event of a new food crisis, can live up to the hopes that led to its creation.

[88] The question of legitimacy is obviously more complicated. See Dehousse (Renaud), "European governance in search of legitimacy: the need for a process-based approach", *in* Forward Studies Unit Series, *Governance in the European Union*, Brussels, OOPEC, 2001, 185-205.

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