# EUROPEAN PARLIAMENT

1999



2004

Session document

FINAL **A5-0272/2000** 

12 October 2000

# REPORT

on the Commission White Paper on food safety (COM(1999) 719 - C5-0136/2000 - 2000/2082(COS))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: John Bowis

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## PROCEDURAL PAGE

By letter of 28 January 2000, the Commission forwarded to Parliament its White Paper on food safety (COM(1999) 719 - 2000/2082(COS)).

At the sitting of 17 March 2000 the President of Parliament announced that she had referred the White Paper to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Agriculture and Rural Development, the Committee on Industry, External Trade, Research and Energy and the Committee on Legal Affairs and the Internal Market for their opinions (C5-0136/2000).

The Committee on the Environment, Public Health and Consumer Policy had appointed John Bowis rapporteur at its meeting of 23 February 2000.

It considered the the Commission White Paper and the draft report at its meetings of 3 April 2000, 12 July 2000, 29 August 2000, 12 September 2000, 19 September 2000 and 10 October 2000.

At the last meeting it adopted the motion for a resolution by 53 votes to 0, with 3 abstentions.

The following were present for the vote: Caroline Jackson, chairman; Alexander De Roo, vice-chairman; John Bowis, rapporteur; Per-Arne Arvidsson, Maria del Pilar Ayuso González, Hans Blokland, David Robert Bowe, Philip Rodway Bushill-Matthews (for Marielle De Sarnez), Dorette Corbey, Avril Doyle, Alain Esclopé (for Jean Saint-Josse), Carlo Fatuzzo (for Peter Liese), Jim Fitzsimons, Marialiese Flemming, Karl-Heinz Florenz, Cristina García Orcoyen Tormo, Evelyne Gebhardt (for Carlos Lage), Laura González Álvarez, Robert Goodwill, Francoise D. Grossetête, Cristina Gutiérrez Cortines, Roger Helmer, Anneli Hulthén, Hedwig Keppelhoff-Wiechert (for Ria Oomen-Ruijten), Christa Klaß, Eija-Riitta Anneli Korhola, Bernd Lange, Marie-Noëlle Lienemann, Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Patricia McKenna, Jorge Moreira Da Silva, Emilia Franziska Müller, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Karl Erik Olsson, Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Ursula Schleicher (for Peter Liese), Horst Schnellhardt, Inger Schörling, Jonas Sjöstedt, María Sornosa Martínez, Bart Staes (for Hiltrud Breyer), Dirk Sterckx (for Chris Davies), Catherine Stihler, Nicole Thomas-Mauro, Marianne L.P. Thyssen (for Ria Oomen-Ruijten), Antonios Trakatellis, Kathleen Van Brempt (for Béatrice Patrie), Phillip Whitehead.

The opinions of the Committee on Agriculture and Rural Development, the Committee on Industry, External Trade, Research and Energy and the Committee on Legal Affairs and the Internal Market are attached.

The report was tabled on 12 October 2000.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

## MOTION FOR A RESOLUTION

# European Parliament resolution on the Commission White Paper on food safety (COM(1999) 719 – C5-0136/2000 – 2000/2082(COS))

## The European Parliament,

- having regard to the Commission White Paper (COM(1999) 719 C5-0136/2000<sup>1</sup>),
- having regard to its resolution of 6 January 1998 on the Commission Green paper on the general principles of food law in the European Union<sup>2</sup>,
- having regard to its resolution of 14 June 2000 on the Feira European Council, calling for the establishment of a strong independent Food Safety body and legislation<sup>3</sup>,
- having regard to Article 152 and 95 of the EC-Treaty,
- having regard to Rule 47(1) of its Rules of Procedure,
- having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinions of the Committee on Agriculture and Rural Development, the Committee on Industry, External Trade, Research and Energy and the Committee on Legal Affairs and the Internal Market (A5-0272/2000),
- A. Whereas the purpose of the White Paper is to reflect the crucial policy priority for the Commission to reach and assure the highest standards of food safety and to win back consumers in the European Union by proposing a radical new approach, mindful of the precautionary principle,
- B. Whereas the Commission proposes the establishment of an independent food body accompanied by a wide range of other measures to bring coherence to the corpus of legislation covering all aspects of food safety from "farm to table",
- C. Whereas the European Parliament, in its resolution of 6 January 1998, stressed the need to adopt a coordinating structure for foodstuffs which posed a potential threat to the consumer and establish a food alert network ; whereas the Parliament also recognised the importance of reorganizing the scientific committees so as to secure greater transparency, enhance specialist competence and ensure independence of their members,
- D. Whereas major structural changes are necessary in the way food safety issues are handled, having regard to the need to separate risk assessment and risk management ; whilst accepting that the European Food Safety Authority (EFSA) will have the right to make recommendations for and to be consulted by those ultimately responsible for risk management;

<sup>&</sup>lt;sup>1</sup> OJ C not yet published

<sup>&</sup>lt;sup>2</sup> OJ C 56, 23.02.1998, p. 3

<sup>&</sup>lt;sup>3</sup> Minutes of 15.06.2000, p. 13

- E. Whereas nutrition and healthy eating policies are important and where the impact upon food safety policy should be dealt with by the EFSA, while on a wider basis should be part of forthcoming legislation on health promotion;
- F. Whereas the EFSA should contribute towards improving and speeding up the decisionmaking procedures; whereas the political responsibility should rest entirely with the political bodies;
- G. Whereas the decision-making process establishing such an authority should involve the European Parliament according to the codecision procedure;
- H. Whereas a number of legislative proposals raised in the White Paper, if proceeded with, would allow European Parliament to examine them in detail; whereas a list of priority proposals should be proceeded with at the same time and timetable as legislation to establish a European Food Safety Authority;
- I. Whereas it is important to maintain Europe's rich cultural heritage of locally produced food, even where those foods do not meet all safety standards in full; whereas the position of these traditional foods could be secured by licensing producers and certifying the products,
- J. Whereas all sectors of industry participating in the food production chain should be kept informed of and consulted on developments in the establishment of a European Food Safety Authority, and the White Paper's Action Plan on Food Safety,

## Establishing a "European Food Safety Authority"

- 1. Agrees with the Commission that major stress must be laid on the safety of all food products, including animal feed and other agricultural inputs such as fertilisers and plant health products;
- 2. Calls on the Commission in view of the forthcoming Sixth Framework Programme to enhance and adapt the role of food safety research and extend it to cover consumer concerns regarding both the safety and the quality of products; believes that the JRC may play a role as one of the reference laboratories;
- **3.** Emphasises that adequate training of workers should be encouraged at all steps in the food chain in order to ensure full implementation of the HACCP principles;
- **4.** Appreciates the role of SMEs in maintaining the cultural diversity in food and food preferences throughout the European Union and underlines that SMEs should be empowered to comply with new food safety and hygiene rules;
- 5. Calls on the Commission to develop a strategy to empower and encourage candidate countries to comply with the highest food safety standards; calls on the Commission, to this end, to establish reliable and effective indicators to enable practical assessments to be made of the adoption by the applicant countries of the acquis communautaire with regard to food safety before accession;
- 6. Supports the establishment under Articles 152 and 95 EC of a European Food Safety

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Authority (EFSA) as a point of scientific reference for the European Union and Member States, based on the principles of scientific integrity, academic excellence, independence, accountability, transparency and comprehensibility; Calls on the Commission to take action along these lines, while subjecting the powers to be transferred to detailed scrutiny;

- 7. Calls on the Commission to present, as soon as possible, a detailed estimate of the costs of EFSA performing its duties properly;
- 8. Is of the opinion that the independence and high academic quality of the EFSA can only be guaranteed if the Commission and the other EU institutions give the Authority sufficient money and staff;

## Scope of the Authority

- 9. Considers that the primary responsibility of EFSA should be the assessment of risk in the field of food safety and the notification of that assessment simultaneously to the European Commission, the European Parliament and Member State Governments, who shall severally and collectively have responsibility for the management and control of assessed risk;
- 10. Accepts that the Authority must be able to recommend action to those ultimately responsible for risk management, and to be consulted by them;
- 11. Considers that the core of the EFSA's work should be the provision of scientific advice, the collection and analysis of scientific facts required to inform the Community's decision processes and the monitoring and surveillance of developments touching upon food safety, including the safety of drinking water;
- 12. Considers that the EFSA should ensure coordination, the creation of a network, and close cooperation with and between the national Food Safety Agencies of Member States and should take steps to maintain close ties with the main consumer protection organisations in order to promote exchanges of information on risk evaluation;
- 13. Believes that the EFSA should be responsible for providing all possible assistance to the Member States' national food safety agencies so that they can give accessible and comprehensible information to the public about its scientific conclusions and advice on food safety issues, while the Commission should remain responsible for communicating and explaining risk management decisions;
- 14. Believes that the EFSA may set its own priorities and take a pro-active approach in order to advise the Commission on matters of concern and to develop an early warning system to anticipate upcoming problems ; believes that the core of the EFSA's work should be in accordance with the priorities set out by the European Commission and the European Parliament ; further considers that the diversity of actors involved in risk communication is an additional guarantee of transparency but nevertheless believes that a clear division of tasks and responsibilities with regard to risk communication will have to be found between the EFSA and the Commission;
- 15. Takes the view that an independent Food Authority cannot have a legislative remit;

## Rapid Alert System

- 16. Believes that the Rapid Alert System which allows the rapid identification and notification of urgent food safety problems, should continue to be the responsibility of the Commission, working closely with Member States and physically within the EFSA, but that in due course it may be appropriate for the Rapid Alert System to be operated by the EFSA;
- 17. Calls for the immediate improvement of the Rapid Alert System and its extension to cover all areas of food safety, including animal feed which should be addressed on the basis of a continually updated positive list ; believes that such improvements must not be conditional on the creation of the Authority;
- 18. Considers that when a food safety emergency occurs the task of the EFSA will be to mobilise the necessary scientific resources to support the response of the Commission and the Member State or States concerned and that the EFSA may be asked to carry out follow-up tasks such as assessing and advising on procedures and surveillance methods in the light of experience of the emergency, including recommendations of priorities for action;
- 19. Believes that, when action is taken to address food safety emergencies, the precautionary principle should be applied in a proportional and responsible manner;

## Accountability

- 20. Considers that the Authority must act independently of outside pressure as well as of European Institutions and Member States, that special attention should therefore be given to the nomination and appointment of the Director of the EFSA as well as to management structures and funding in order to achieve a correct balance between independence and accountability ; believes that the EFSA must be publicly funded ;
- 21. Takes the view that the Director of the Authority should be appointed by the Commission, following an open selection process chaired by the Commission's Director General responsible for food safety issues and calling on outside advice from the various food safety interests as appropriate;
- 22. Considers that the nominee for the post of Director of the Authority should be invited to appear before the relevant Committee of the European Parliament to make a statement and to be cross questioned by that Committee before the final appointment; that this hearing should be held in public; and that the considered view of the Committee, following the hearing, should be taken into account by the Commission, when making the appointment;
- 23. Considers that not more than 12 members, including a balanced representation of people with consumer, public health, industry, SME, agriculture and scientific expertise, should comprise the Board of the EFSA and that members should be appointed for 3 years with one possibility of reappointment for one further term ; considers that the EP should be able to appoint 2 members to the Board of the EFSA;
- 24. Considers, in application of the principle of transparency, that the Commission should publish in the Official Journal of the European Communities a 'call for expression of

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interest' for the selection of scientific experts. This call should include an explanation of the selection criteria and procedure that will be applied;

25. Considers that the directors of the National Food Safety Agencies of Member States or the equivalent national competent body should comprise an advisory committee which shall meet regularly with the director and senior management of the Authority; calls on the Member States that do not yet have independent food safety agencies or institutions to establish them and focus on the following aspects : excellence, independence, accountability, efficiency of inspection and rapidity of reaction to emergencies;

## Transparency

- 26. Is convinced that there should be the maximum level of transparency in the operations of the Authority; that this should include publication of the names of members of the scientific committees and information about the way in which they are appointed and on their scientific backgrounds and a full declaration of interests, likewise, any working groups that the committees may establish; that the minutes of their meetings or reports submitted, including minority opinions, should be published in advance of meetings; and that at a later date consideration should be given to the possibility of the Board of the Authority meeting in public, such a decision to be informed by the experience of those national agencies that do so meet;
- 27. Believes that the findings and recommendations of the Authority should be addressed at the same time to the Commission, the Parliament and Member State Governments and that rapid and comprehensible presentations of the findings of the Authority should be made directly available to the public on the internet;
- 28. Emphasises the need for negotiation of equivalence agreements with third countries ;
- 29. Considers that the EFSA should present an annual report of its activities to the European Parliament and that the Director of the Authority should make regular visits to the European Parliament's Committee on the Environment, Public Health and Consumer Policy. Such presentations to the Committee should take place at least once a year or on demand of the Parliament's Committee on the Environment, Public Health and Consumer Policy;

#### Powers

- 30. Considers that the EFSA should be given powers to require Member States to provide such information, statistics and research reports and papers in their possession as the Board of the EFSA may consider necessary for the full assessment of a particular risk; the EFSA must also have the power to issue opinions on its own initiative;
- 31. Apart from cooperation and networking with other actors in this sector, the Authority should be given sufficient personnel and other necessary resources in order to bring added value to the field of food safety ;

#### Networking with national Agencies

32. Considers that the Authority should work in close cooperation with national food safety

agencies and institutions in the field of food safety so as to build upon, and where appropriate coordinate, their expertise and ensure that information on food safety is communicated to consumers in a clear and comprehensible format : further considers that there should be a two way exchange of views and information with centers of excellence in all relevant disciplines across the European Union and that this should be coordinated by the EFSA ; believes that the EFSA should use the experience of the EEA and its network of focal points and thematic centers;

33. Considers that, to avoid duplication, conflicts and misunderstandings between the Authority and national agencies, clear procedures and principles of cooperation with national agencies should be agreed, including when mandatory cooperation and information should be required; Considers that extra support may need to be given to candidate countries;

#### Relations with Commission and other services

- 34. Considers that the Authority should fully incorporate the work of the scientific committees and their sub-committees that deal with food safety and bring an added value of transparency and accountability;
- 35. Considers it essential that the Authority work in close cooperation with the European Medicines Evaluation Agency and the Food and Veterinary Office in order to benefit from the research and licensing procedures of the EMEA and the inspection and controls procedures of the FVO and to share knowledge and research between the organisations and believes that such cooperation will assist the EFSA when it puts forward proposals for further or amended controls to the Commission and Parliament. Clear spheres of responsibility must be established for the Authority vis-à-vis the FVO to avoid confusion and dispute;
- 36. Stresses that it is essential that the Commission coordinates its various departments including EMEA, the Food and Veterinary Office, the EFSA and National Food Agencies in order to ensure safety on the entire food chain, paying particular attention to possible loopholes related to the mandates of these different bodies; further clarification must be provided of the relationship between the JRC, the Scientific Committees and the Authority;
- 37. Considers that the Authority should develop contacts with the directorates general responsible for environment, agriculture, fisheries, industry, the internal market and external trade to ensure compatibility of their respective policies with the interest of food safety;
- 38. Considers that the Authority should consult and develop close links with relevant NGOs in order to take into account expertise from civil society;
- 39. Is of the opinion that the Directorate-General for Health and Consumer Protection should be formally obliged to respond to opinions from the EFSA within a fixed and reasonable space of time;

Relations with international bodies

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40. Believes that good practice should be sought out and emulated and that the work of international food safety agencies of good repute should be taken into account by the EFSA when planning its reseach and methodology : and that to this end a close relationship should be established with other relevant agencies such as the US Food and Drug Agency, the Codex Alimentarius, the WHO, the FAO, the OIE, and the WTO etc., giving particular assistance in providing scientific support to the Commission in WTO cases;

## Referral to the Authority

- 41. Stresses that the EFSA, at the request of the Commission, a competent national authority, including the national food safety agencies, or on its own initiative is competent to investigate any matter considered to require assessment; in its annual activity report to the European Parliament, the EFSA shall set out the requests made to it and the justifications for its own initiatives;
- 42. Believes that the European Food Safety Authority needs to be supported by a solid legislative framework ;

## **Regulatory Aspects**

- 43. Believes that the White Paper's Action Plan on Food Safety should be divided into four categories of (a) priorities for legislation, (b) less urgent items for legislation in due course, (c) consolidation measures and (d) matters more appropriate for health promotion activity; and further believes the 16 items in category (a) as listed below should be proceeded with at the same time and timetable as legislation to establish a European Food Safety Authority, on the grounds that it is essential that the Authority is put in place against a legal background of responsibilities that is as comprehensible as possible, so as to make it clear under what regime and in what areas the Authority is to function;
- 44. Considers that there must be certain guiding principles for all legislation in the field of food safety, an important aspect of which is to ensure traceability throughout the food chain from fodder and primary producers to the retail trade so that all ingredients are fully traceable at all stages and in all food in every location;
- 45. Endorses the Commission's position on risk reporting and on acknowledging the consumer as an equal interested party, but stresses that if there is a food crisis consumers must be informed in a very accessible, objective and clear way as to the extent, risks and possible consequences of the food safety issue that has prompted the crisis;
- 46. Is of the opinion that a number of areas, which are also of importance to food safety, such as the common provisions in legislation on fertilisers, plant protection, pharmaceuticals, the environment and waste should be examined to see if they are compatible with the measures proposed in the White Paper to improve consumer protection;
- 47. Calls on the Commission to consider the following action points as priorities for legislation alongside legislation establishing the EFSA:
  - i General Food Law Directive
  - ii Rapid Alert System Directive; Amendment of Directive 95/53/EEC to introduce

Rapid Alert System for feed

- Regulation on the Feed ; Regulation on Novel Feed ; Amendment of Decision 91/516/EEC on Feedingstuffs Ingredients, including by-products from fat processing; Amendment of Directive 79/373/EEC on Labelling of compound feedingstuffs; Amendment of directive 96/25/EEC on the circulation of feed materials (introduction of a positive list instead of a negative list)
- iv Amendment of Regulation 258/97 on Novel Foods and Ingredients; Regulation on labelling of GMO-free Foodstuffs; Regulation on GMO seeds
- v Amendment of Decision 98/272/EC on TSE surveillance
- vi Maximum residue levels of Pesticides Directive
- vii Amendment of Directive 1999/29/EC with regard to Maximum Dioxin Limits for oils and fats.
- viii Amendment of Directive 92/117/EEC on Zoonoses
- ix Amendment of Directive 96/23/EC on Residue Monitoring
- x BSE Measures
- xi Amendment of Regulation 194/97 on setting maximum levels for certain contaminants in foodstuffs (laying down European PCB standards)
- xii Regulation on Pesticide Residues in Food; Regulation on the evaluation of existing pesticides active substances
- xiii Directive on addition of nutrients to food based on the principle of safety
- xiv Amendment of Food Labelling Directive 79/112/EEC to address enhanced function claims and disease reduction claims and encompassing a overhaul of food allergy labelling and the labelling of food claims
- xv Communication on an action plan on nutrition policy; Recommendation on European dietary guidelines xvi Amendment to Directive 91/321/EEC on infant formulae and follow-on formulae; Amendment to Directive 96/5/EEC on processed baby foods
- 48. Is concerned that the Action Plan does not include a fundamental review of EU legislation on food labelling, as promised in the Green Paper on EU food policy; Considers that in any such review, a clear distinction must be made between the important twin aims of ensuring traceability and providing clear and comprehensible consumer information;
- 49. Believes it is important for the new food legislation to be as simple and as transparent as possible and that the simplicity and clarity of the new food legislation is of particular importance for small and medium-sized enterprises;
- 50. Calls on the Commision to institute a review of official controls to identify where they may be inadequate and bring forward proposals;
- 51. Calls on the Commission to ensure that consumer protection associations are more closely involved in the information policy on the existing legal framework for food safety;
- 52. Instructs its President to forward this resolution to the Council and Commission.



## EXPLANATORY STATEMENT

"Der Mensch ist, was er isst"-Ludwig Feuerbach long ago gave us the text for our homily on food safety. Public concern is that if we are not careful, we shall no longer "be" after we have eaten or at least that we shall not be well.

Since the Garden of Eden, mankind has done well to be careful about what we eat – but at least Adam and Eve ate the apple from the Tree of Knowledge.

Knowledge – information – is what we seek as consumers and, if we cannot acquire the knowledge through our own intellect and experience, we want to be able to trust those who set out to advise us – farmers, food manufacturers and processors, retailers, governments, consumer advisory groups and scientists. Above all, we need a body of science as a reference point for us, whether we are consumers or policy makers or contributors to the food chain. Despite the fact that, as the White Paper makes clear, the European food chain is one of the safest in the world, concerns over mishaps, poor practice and scandals have exercised the media, the public and their elected representatives in recent years. The list is long, ongoing and potentially endless given that absolute safety is not an attainable goal. Olive oil, contaminated wine, Perrier water, E-coli, Listeria, salmonella, polluted drinking water, BSE, dioxins, sludge and slurry entering the human food chain, pesticides, animal feed, GMOs - all in their time and in their way have caused concern, fear, panic and public inquiry. No-one suggests we can live in a world where the vagaries of accident, chance, and human error will somehow be excluded. Everyone accepts that there will be errors of judgement or lack of knowledge on the farm, in the processing, and in the kitchen. We can, however, expect and work for a world in which risk is identified as early as possible, assessed scientifically, managed effectively and, as far as possible, prevented for the future. European Union action is appropriate because, in a single market, risk does not stop at national borders. By the same token, it does not stop at the Union's external borders and we need to work closely with countries, near and far, who supply our food and feed and with the experts and systems they too have set up to assess and manage food safety risk.

Safety must be our focus and science our method. We must not dilute a clear and comprehensible set of actions to reassure the public that their food is safe, by mingling with these actions a wish-list of healthy eating messages and measures. This is not to say healthy eating is not important. It certainly is; but it is, and should be, developed as part of our Health Promotion Programme, which is itself the subject of another important White Paper.

This report to Parliament, in response to the Commission's White Paper has been informed by discussions with MEPs, MPs, representatives from Member States, the Commission, the Council, the Committee Secretariat, NGOs, agriculture and industry; all with both human and animal welfare in mind. While there are a number of views on detail, there is a broad agreement on the main principles.

These principles are that a new scientific body responsible for food safety risk assessment should be established; that it should be established on the legal basis of articles 152 and 95; that it should be as independent as is compatible with accountability; that it should be as open and transparent in its proceedings as possible, subject only to the needs of objective research and of commercial confidentiality; that it should liaise closely with national and international bodies already established in this field; and that it should, by its method of operation gain the

respect of its peers, the confidence of the public and the willingness of member state governments to accept its conclusions. The interested bodies that would be relevant would include the United States' Food and Drugs Agency (FDA), The World Health Organisation (WHO), European Medicines Evaluation Agency (EMEA) and Commission bodies such as the Food and Veterinary Office (FVO).

It is important that the scientific body that is established should make it clear in its title what it is and what it is not. The White Paper talks of a 'European Food Authority', which has connotations of little Jimmy being told to eat up his greens. Firstly, the word 'Authority' is wrong. It implies a body with sweeping powers. This not what we see, or what the White Paper proposes. Instead, the White Paper suggests, and we concur, that the new body should be responsible for the assessment of risk and the explanation of its conclusions and recommendations but not the management or control of risk, which should properly remain with the European and National institutions. Nor would 'European Food Agency' be much of an improvement because it sounds like a distributor of food aid to areas of drought and famine. The word that specifies the area of responsibility of the body is 'safety' and the nomenclature of 'European Food Safety Agency' (EFSA) should be used. This indeed was the terminology used by the Parliament in its recently adopted plenary resolution on the Feira Council.

The key to EFSA's successful operation will be its Director. He or she should be appointed, after open competition, by the Commission, but the Commission should make the appointment only after its nominee for the post has attended a public hearing by the Environment Committee and the representatives of AGRI and ITRE, at which he or she will be able to be questioned by members and from which the committees considered view can help to inform the Commission's final decision.

Thereafter, the Director shall present his annual report to Parliament at a meeting of the ENVI committee and each report by its scientific committees and endorsed by its board, on a particular risk should be submitted to the ENVI committee at the same time as it is submitted to the Commission and to the Member States and their national agencies.

The value of the Agency will emanate as much from the excellence of its knowledge as from the efficiency of its working methods. It must be, and be perceived as, a lean, focussed Secretariat for the major players in European food science and not merely as another layer of bureaucracy.

In the case of a food safety emergency, the Agency must be able to access and mobilise all necessary information from all sources so that a final and indisputable analysis of the situation can be made and public fears can be allayed as quickly as possible. If further research or surveillance should be required, the Agency should be in a position to demand it.

There should be a small headquarters, easily accessible by the Commission and Parliament, with a small professional staff of scientific and administrative support with sufficient funds to service the scientific committees effectively. The Director will establish and maintain a network of specialists, from academia, industry, and from other bodies, who may be called to participate in the assessment of a risk in an area for which they have expertise. This may sometimes involve bringing a small group together and sometimes arranging for it to confer and liaise by electronic means. If there is one criticism of and from the existing scientific

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committees, it is of inadequate secretarial support and poor compensation for the inconvenience of leaving their main work to advise the Commission.

Currently, there are eight scientific committees advising the Commission. Five of them cover food and feed. Over these, in a co-ordinating role and advising on multi-discliplinary matters, is a Scientific Steering Committee. It is logical to assume that the Steering Committee and the five food and feed committees will have their work subsumed by the EFSA and that they will therefore come to an end once their work at the time of the establishment of the EFSA has been completed. If some of their work is outside the scope of the EFSA, then they will have to be reduced and revised. It is important not to have any in-house committee duplication and possible conflict with the work of the EFSA. The Joint Research Centre (JRC) however has a rather different role, providing a research resource for all Directorates in the Commission. There is no reason why this should not continue, on the understanding that it takes care to avoid work which might duplicate or conflict with the work of the EFSA.

The Agency will also be responsible for communicating its assessment in a clear, straightforward and comprehensible manner to the general public. Successful communication will be crucial to the Agency's success and should take into account the varying natures of the different audiences and their expertise so as to answer successfully the queries of both scientists and laymen. Communication tools should take the form both of an Internet site and available spokesman who should be in a position to deliver relevant facts unhindered by external pressure to doctor or misrepresent them.

The question then arises of the relationship of the EFSA with the Commission. It needs to be independent of pressures, real or imagined, to mould a report to suit Commission views. But it also needs to carry out work that the Commission and the Parliament considers urgent. The best way is probably to achieve this would be to expect the EFSA normally to give priority to items referred to it by the Commission or Parliament. To ensure its openness, at the very least Board minutes, reports and any minority report should be published on the Internet. The experience of the UK in requiring its recently established agency to meet in public should help to inform a future decision of whether this should also apply to the EFSA board.

The board should be of manageable size, be appointed by the Commission after open consultation, and include people with experience of food and feed research, production, manufacture, and consumption. It should not exceed twelve members, thus making it clear that no one Member State has a "right" to a nominee. Members should be appointed for three years with the possibility of one further term. In addition, and in order to promote mutual understanding, support and respect, the EFSA should have an Advisory Committee composed of the Director of each of the national agencies responsible for food safety in Member States (one per State). This Committee should meet with the EFSA Director and senior Management four times each year.

The one power the EFSA should have, if it is to be effective, is the power to require Member States to submit, on request, any facts, reports or statistics it has in its possession on a risk that is being assessed by the EFSA.

The White Paper suggests that the EFSA should also be responsible for the running of the Rapid Alert System. This system, which should certainly be enhanced and improved, not least to cover feed as well as food, has more to do with risk control and management than

assessment. It is, of course, right that the EFSA receive immediately any alerts from the RAS, but RAS management lies more properly in the Commission. The main democratic accountability reason for this – and indeed for not seeing the EFSA as totally independent of the Commission – is that Parliament must retain the right to call the Commission to account on a day by day basis for areas under the Commission's control. Were the RAS to be anywhere else than in the Commission, Parliament would cease to be able to carry out its democratic scrutiny effectively.

When the ENVI committee held its preliminary exchange of views on the White Paper, it suggested that it would be necessary to consider some at least of the other action proposals alongside consideration of the EFSA. Without this, the EFSA would be created in something of a vacuum.

Overall, however, the White Paper does not give a strategic background to such proposals. There have already been a number of pieces of a jigsaw arriving in Parliament – on labelling, on GMOs, on supplements and so on – without a clear idea of the overall strategy; or perhaps it is the philosophy behind the strategy that is missing, that one might have expected to find in the White Paper.

For example: what is the strategy on the replacement of crop spraying by genetically modified crops that require less spraying; what is the view on the debate that is an increasingly heard as to the point beyond which excessive hygiene requirements threaten immunity levels particularly in infants; what is the acceptable balance between risk prevention and informed consumer choice; how can one avoid the precautionary principle preventing innovation; and so on.

The action plan summarised in the annex follows references in the text. These are somewhat scattergun in their listing and might better be placed in the categories of:

- a) items for urgent legislation parallel to that enacted for the EFSA
- b) less urgent items
- c) consolidation measures
- d) items which more properly relate to health promotion

In addition, there are some items that are more to do with the budget than with legislation.

For the purpose of this report, only the items from category a) are listed. These, it is suggested, should be brought forward and follow a legislative path that is concurrent with that of the EFSA proposal.

Twelve areas of action from the White Paper are gathered together. These cover 18 of the 84 action plan proposals and these might be the items for early action and in the order of importance in which they are listed. There is one additional area mentioned separately and this refers to the Commission's proposal on controls. In this case it may be a mistake to rush into new controls before we are sure, in the light of experience under the new system, where there are loopholes or inadequacies. Hence the suggestion of a review in this area, with further proposals if found to be necessary.

The Commission has given us a list of legislative options that, if all were to be adopted, would

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take years of parliamentary time. We shall therefore need to be selective. Within those options are sensible and sometimes urgent measures that could help to improve our own food safety regime. Absolute food safety cannot be an achievable programme, both because absolute safety is not in man's gift to achieve and because new risks emerge and are created every day, so our task will never be finished.

We can be vigilant, learn lessons from past problems and how they were overcome, and improve procedures for dealing with future risks and crises. At the end of the legislative day we shall still be what we eat and mostly we shall continue to enjoy the process, but, where eating and drinking are concerned, we shall probably never quite have the confidence or the optimism to say with Dr Pangloss:"Tout est pour le mieux dans le meilleur des mondes possible."

12 September 2000

### OPINION OF THE COMMITTEE ON LEGAL AFFAIRS AND THE INTERNAL MARKET

for the Committee on the Environment, Public Health and Consumer Policy

on the Commission White Paper on food safety (COM(1999) 719 – C5-0136/2000 - 2000/2082(COS))

Draftsman: Evelyne Gebhardt

#### PROCEDURE

The Committee on Legal Affairs and the Internal Market appointed Evelyne Gebhardt draftsman at its meeting of 28 March 2000.

It considered the draft opinion at its meetings of 21 June 2000, 27 June 2000 and 12 September 2000.

At the last meeting it adopted the amendments unanimously.

The following were present for the vote: Rainer Wieland, acting chairman; Evelyne Gebhardt, draftsman; Maria Berger, Françoise D. Grossetête, Gerhard Hager, Heidi Anneli Hautala, The Lord Inglewood, Ioannis Koukiadis, Klaus-Heiner Lehne, Donald Neil MacCormick, Véronique Mathieu, Hans-Peter Mayer, Manuel Medina Ortega, Bill Miller, Feleknas Uca, Diana Paulette Wallis, Matti Wuori, Stefano Zappalà and Christos Zacharakis.

## SHORT JUSTIFICATION

#### The development of the legal bases for food safety

In 1992 a separate title on consumer protection was for the first time included in the Treaty on European Union. With the completion of the single market and the free movement of capital, goods and services arising from it, consumer protection had necessarily to come within the competence of the European Union.

In Article 153 of the Amsterdam Treaty the Community undertakes to take account of consumer protection in all political decisions and measures in all areas, as well as to promote the right of consumers to information and education and to protect their interests more

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effectively.

An EU policy on food safety is thus legitimised within the context of consumer protection and health protection policies.

## Two approaches to food safety

There are, roughly speaking, two ways of influencing food safety. Under the indirect approach, strict liability laws can force producers to take greater care and, in individual cases, provide assistance for consumers.<sup>4</sup> In order to exercise a direct influence on food safety, reinforced preventive surveillance and control mechanisms are necessary, in view of the regularly experienced difficulty in providing proof ('Did the dioxin-infected sausage consumed in 1999 cause the outbreak of disease in 2015?').

## Food policy guidelines

The Commission takes account of the principles contained in its food policy guidelines when it sets out to give the main responsibility for food safety to operators in this field. The intention is to create a chain 'from farm to table' within which there will be transparency and accountability.

The Commission intends to apply the precautionary principle in its decisions and to base food safety on four pillars:

- scientific advice (risk assessment),
- data collection and analysis (risk assessment),
- consumer information
- regulation and control.

## **European Food Authority**

At the heart of the Commission proposal is the establishment of a Food Authority which would provide scientific advice, gather and analyse information, provide information on risks and crises, assess and pass on information about risks, and even practise risk management.

The Commission has in mind an authority with legal personality and autonomy vis-à-vis the EU bodies, although the relationship between the authority's independence and its accountability remains unclear.

The basis of its work would be networking with national and international scientific bodies and establishments, interaction with relevant Commission bodies and an adequate budget.

## The legal problem

The establishment of a Food Authority raises legal problems, particularly as regards the definition and transfer of powers in the area of risk management. The decisive factor here is

<sup>&</sup>lt;sup>4</sup> See Product Liability Directive 85/374/EEC, last amended by Directive 99/34/EC.

the tasks with which the authority would be entrusted.

If the authority is to act autonomously, then official authority must be transferred to it. However, limits have been placed on the transfer of official authority by Court of Justice case law. The transfer must relate to precisely defined implementing powers, the exercise of which is fully supervised by the transferring bodies, without the authority to which the powers are transferred being given any margin of discretion.<sup>5</sup> A transfer of powers does, however, entail a shift of competences, which are thus removed from the sphere of influence of the bodies legitimised by the Treaties.

Legal provisions on food safety exist at both national and European level. It is, however, extremely doubtful whether a Food Authority could carry out local checks or impose sanctions, even in order to enforce the rules, or whether this would be desirable. The involvement of national authorities and compliance with certain national practice – for example the swearing out of search warrants – would be unavoidable.

## The way to proceed – legal possibilities

In accordance with Article 308 of the EC Treaty, a Food Authority can be set up by the Council, acting unanimously on a proposal from the Commission, after consulting the European Parliament. Articles 152 and 153 of the EC Treaty in particular provide for action by the EU in the areas of health and consumer protection. In addition, Article 3 of the EC Treaty establishes a high level of health protection as one of the aims of the Community. The authority could be given legal personality, so that it could, for example, conclude private-law contracts autonomously.

Action for failure to act under Article 230 of the EC Treaty taken directly against a Food Authority is not provided for by the Treaties. The scope of Article 230 is restricted to certain EC bodies. Despite its extension as a result of the *Les Verts* judgment<sup>6</sup> to the European Parliament, which at the time was not included in the Article's scope, but was provided for in the Treaties, it is doubtful whether other agencies not provided for in the Treaties could be covered by the Article.

The same problem arises in the case of the other types of complaint, but can be solved by making the authority subordinate to the Commission and not allowing it to enact legislation of its own.

As regards sanctions, the provision of effective legal protection remains in doubt. The provision of temporary legal protection, for example by interim measures, is always linked to a main procedure. If necessary sanctions could be scrutinised by the Court of Justice under the terms of Article 229 of the EC Treaty. Under this Article jurisdiction may be transferred to the Court for regulations adopted jointly by the Council and Parliament, or by the Council, with regard to the penalties provided for in these regulations.

## Comparison with the Food and Drug Administration in the United Sates

<sup>&</sup>lt;sup>5</sup> Meroni, Case 9-56, judgment of 13 June 1958, ECR 1958, p. 11f.

<sup>&</sup>lt;sup>6</sup> Case 110-75, judgment of 15 June 1976, ECR 1976, p. 955f.

The FDA<sup>7</sup> cannot be compared to the Food Authority being considered by the Commission. The FDA has a staff of 9 000 (including 2 100 scientists) and a budget of US\$1.391 million (proposal for 2001).

The task of the FDA is to enforce the Federal Food, Drug and Cosmetic Act. This is achieved by means of inspections and, where necessary, sanctions (product withdrawals, for example).

The biological effects of commonly used chemicals are investigated at a toxicological research centre. In the area of drugs, the agency requires that medicaments should be demonstrably safe and effective. Where food is concerned, the FDA investigates samples for compliance with limit values and labelling requirements. Animal foodstuffs are examined from the point of view of potential harm to human health.

## Political assessment of the proposal for a Food Authority

The draftsman takes the view that the Commission's proposal cannot be accepted in that it sets out to establish a Food Authority which would be active at a quasi-legislative level. This would entail an erosion of the legislative powers of the European Parliament and the other bodies legitimised by the Treaties.

In addition, the Commission has very high expectations of the projected Food Authority. At the same time, however, it is clear that a number of central points have not been sufficiently thought through:

- The authority's area of competence is not clear (cf. paragraph 40).
- The Commission makes contradictory statements, referring sometimes to the primary responsibility of stakeholders (paragraph 9), at others to a sharing of responsibility among operators (paragraph 88). The question of liability should be looked at in this context.
- The relationship between independence and accountability is not clarified (paragraph 41).
- The draftsman takes the view that an authority such as the Food Safety Authority described in the White Paper needs a very high budget, which is unfortunately not specified. If these high financial requirements should not be met, it would be desirable for the Commission to look at other possible ways of achieving effective food and consumer protection. One might look here at the possibility of a network-like form of cooperation with the national authorities, coordinated by the Commission, or at a department within the Commission which would oversee the work of the national authorities.

The draftsman calls on the Commission to review the method of proceeding described in paragraph 37. A European Union body should make the best possible use of expert opinion, but should retain its own freedom of decision.

## Assessment of the proposed legislation

<sup>&</sup>lt;sup>7</sup> www.fda.gov

The White Paper makes it clear that the Commission has carried out a thoroughgoing review of the situation.

In the light of this review, the Commission clearly considers that a comprehensive reorientation of food policy is called for. It has not been discouraged by the enormity of the task, but has come up with possible solutions. It is trying to move away from a purely fire-fighting approach towards an active, preventive position.

The White Book on Food Safety contains extremely ambitious plans aimed at restoring the confidence of European citizens in the consumer protection offered by the EU. One of the highest priorities should, however, be to simplify the legislation. Citizens no longer wish to be confronted with a legislative jungle. Instead they expect a legislative framework laying down the principles of food safety, in which the legislation concerning individual industries and products is systematically incorporated. In this way, also, the overarching objective of health and consumer protection would emerge more clearly from the many specific objectives relating to individual products.



## CONCLUSIONS

The Committee on Legal Affairs and the Internal Market calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following points in its draft resolution:

## The European Parliament,

- 1. Considers a simplification of the legislation in the area of food and animal feed safety to be a priority, and expects the Commission to make it its priority to propose a legislative framework laying down the principles of food and animal feed safety; the legal acts covering specific industries and products should be systematically incorporated in this framework, so that the overarching objective of health and consumer protection enshrined in Article 3 of the EC Treaty stands out more clearly among the many specific objectives relating to individual products;
- 2. Points out, in addition, that action by the EU in the areas of health and consumer protection is made possible, in particular, by Articles 152 and 153;
- 3. Supports the intention of establishing the European Food Authority on the basis of Articles 95 and 152 of the EC Treaty and calls on the Commission to take action along these lines, while subjecting the powers to be transferred to detailed scrutiny;
- 4. Takes the view that an independent Food Authority cannot have a legislative remit;
- 5. Calls on the Commission to specify very precisely in its proposal for the establishment of a Food Authority those areas in which the authority is to work independently and those in which it is to implement decisions taken in the context of the EU legislative process;
- 6. Takes the view that at all events a European Food Authority should be assigned clearly defined tasks on the basis of the Treaties;
- 7. Calls on the Commission to clarify how the authority can work independently whilst at the same time being accountable to the Commission, the Council and Parliament;
- 8. Endorses the view that the main task of the future European Food Authority must be to assess risks on the basis of very high-quality scientific opinions; points out the importance of making a distinction between risk assessment by the Food Authority and risk management, which is the responsibility solely of the political authorities;
- 9. Points out that risk assessment must be based on a diagnostic approach but also presupposes that the European food authority will propose solutions;

- 10. Emphasises how very important it is for restoring consumer confidence that the Food Authority should be able to guarantee excellence; calls for the requisite top-level scientific know-how to be brought in from all quarters - private, public and academic which will also demonstrate the authority's independence;
- 11. Points out that the Food Authority should operate as part of a network, with all the centres of excellence in the disciplines concerned in the Union and with their counterparts throughout the world;
- 12. Calls on the Commission to include in its proposal for the establishment of a Food Authority realistic proposals for its funding; should it prove impossible to provide the large budget needed, it would be desirable for the Commission to look at other possible ways of achieving effective food and consumer protection; finds, however, that the authority should be funded from the Community budget rather than by means of levies;
- 13. Calls on the Commission to clarify the relationship and division of responsibilities between national inspection bodies and the supervisory Food Authority, in particular the legal aspects thereof;
- 14. Takes the view that the Commission must be authorised to verify that the national bodies responsible for monitoring food safety have sufficient expertise and that they operate in accordance with the common rules;
- 15. Calls on the Commission to continue with its efforts to transfer the main responsibility for safety of food and animal feed clearly to the producers;
- Calls on the Commission to specify the scope of the opinion it expresses in paragraph 37; calls for permanent cooperation and for better coordination, by the European Food Authority, of the work of the national agencies responsible for food safety;
- 17. Calls on the Commission to include in the Food Safety action plan provisions for modernising the criteria for classifying foodstuffs by commercial category and to give priority to classifying them according to their quality;
- 18. Recalls the importance of having a warning system that is managed as closely as possible to the grass-roots level, especially for SMEs and craftsmen, who must be able to obtain clear and accessible information; calls specifically for the detailing of arrangements for an early warning system that is especially effective and comprises diagnostic activity by the European Food Authority;
- 19. Considers it important to provide information for consumers that also highlights the progress made in the area of food safety in the European Union;
- 20. As in the case of competition law, the Commission departments responsible for food safety must be able to impose stiff fines if a national authority or business does not abide by the common rules.



# OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Consumer Policy

on the Commission White Paper on Food Safety (COM(1999) 719 - C5-0136/2000 - 2000/2082(COS))

Draftsman: María del Pilar Ayuso González

## PROCEDURE

The Committee on Agriculture and Rural Development appointed María del Pilar Ayuso González draftsman at its meeting of 28 March 2000.

It considered the draft opinion at its meetings of 19 April, 21 June and 10 July 2000.

At the last meeting it adopted the conclusions unopposed with 1 abstention.

The following were present for the vote: Friedrich-Wilhelm Graefe Zu Baringdorf, chairman; Joseph Daul, Vincenzo Lavarra and Encarnación Redondo Jiménez, vice-chairmen; Maria del Pilar Ayuso González, draftsman (for Michl Ebner); Danielle Auroi, Sergio Berlato, Niels Busk, António Campos, Alejandro Cercas Alonso (for Bernard Poignant), Michel J.M. Dary, Carlo Fatuzzo (for Agnes Schierhuber, pursuant to 153(2)), Carmen Fraga Estévez (for Arlindo Cunha), Georges Garot, Lutz Goepel, Willi Görlach, Michiel van Hulten (for Gordon J. Adam), María Izuierdo Rojo, Elisabeth Jeggle, Salvador Jové Peres, Hedwig Keppelhoff-Wiechert, Heinz Kindermann, Christa Klaß (for Francesco Fiori), Dimitrios Koulourianos, Albert Jan Maat, Xaver Mayer, Jan Mulder (for Giovanni Procacci), Neil Parish, Mikko Pesälä, María Rodríguez Ramos, Dominique F.C. Souchet, Struan Stevenson and Robert William Sturdy.

## **INTRODUCTION**

The recent food crises have occasioned significant losses to the agricultural sector, the food industry and, in the last instance, the Community taxpayer. However, at all events, the social panic which occurred has pointed up the existing gaps in EU food legislation and the deficiencies in the mechanisms for scientific assessment, controls and communication with the consumer. This has given rise to a loss of public confidence in the Community institutions.

With a view to rebuilding trust and ensuring a high level of health protection, the Helsinki European Council of December 1999 urged the Commission to submit a White Paper on food safety.

The committee which drew up the White Paper examined the gaps in EU legislation, the deficiencies in the mechanisms for scientific advice, controls and communication with the consumer, and the requests of the various interested parties, notably the consumers. This examination led it to conclude that, in addition to the need to modify and complete existing law, it is necessary to harmonise its application in the Member States and strengthen coordination between the national and Community control systems. With a view to achieving these objectives, the Commission proposes the following instruments:

- the creation of a European Food Authority;
- the adoption of 84 legislative measures on food safety;
- the establishment of a Community framework for controls;
- transparency and consumer information;
- an active role at international level.

## **COMMENTS ON THE MAIN POINTS OF THE WHITE PAPER**

#### **Principles of food safety**

EU food policy is based on the international guidelines of the *Codex Alimentarius* concerning the principles of risk analysis and the three components of: (scientific) evaluation, management (legislation, controls and crisis management) and communication.

The Commission believes it is essential to introduce a <u>traceability system</u> for foodstuffs and animal feed and their ingredients, in order to make it possible to monitor their progress through all the links of the food chain. The practical application of this system will require significant efforts in terms of registration, labelling, etc.

Another key aspect is the principle of <u>responsibility</u>. The different links of the production chain will have to be identified in order to determine the responsibility of each agent at the various stages. This is vital for farmers, in view of the increasing complexity of production and processing in the agri-food sector.



## A new legislative framework

In its annex to the White Paper, the Commission presents an ambitious 'action plan' in which, by means of 84 legislative actions, it aims to cover exhaustively both the material and the procedural aspects. Its adoption would create a new legal framework for foodstuffs and animal feed, which would regulate, as a matter of priority, such areas as the definition of food safety procedures (especially early warning procedures and those for adopting emergency measures) and controls. Other measures would include hygiene, pollutants, additives, flavourings, colouring, labelling, animal welfare and health, animal diseases, etc.

### <u>The European Food Safety Agency (EFSA) – The Commission's powers in the field of</u> <u>food safety</u>

The Commission proposes separating responsibility for risk assessment from responsibility for risk control and management. The EFSA would thus be responsible for drawing up scientific reports, managing early warning systems and communicating with consumers.

It would be an independent body, exclusively scientific in nature and with the brief of improving the workings of the existing scientific assessment systems (at present there are eight sectoral scientific committees, responsible for various areas relating to foodstuffs and animal feed) and cooperating closely with the national scientific bodies. However, the legislative and monitoring functions would continue to be the responsibility of the Commission.

We consider that the Commission's proposal for the Agency does not go far enough and is not sufficiently concrete, especially as regards its status, its powers, and its relations with other bodies such as the Food and Veterinary Office and the existing network of scientific committees.

In any case, establishing an agency will not be sufficient to achieve the objectives set out in the White Paper. For this purpose, the Commission services will have to be restructured and a special independent administrative unit set up with responsibility for food safety and which would deal with all matters relating to risk management (including management of the early warning network) and passing on information about risks. The agency would be the body responsible for providing the Commission with independent scientific advice. This would make it easier for Parliament to fulfil its supervisory role with regard to the measures carried out by the Commission services in the field of food safety.

## **CONCLUSIONS**

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Consumer Protection, which is the committee responsible, to take into account the following conclusions in its report:

#### On the White Paper and the principles of food safety

- 1. Welcomes the global and integrated planning proposed by the Commission for the structuring of food safety measures with a view to achieving the highest possible standards of protection of human and animal health;
- 2. Agrees with the Commission that major stress must be laid on the safety of all food products, including animal feed and other agricultural inputs such as fertilisers and plant health products;
- 3. Notes, however, that consumers, in their choice of foodstuffs, also have responsibility for their own nutrition and health, that the cheapest food is not always the best value for money, and that consumers may consequently be expected to inform themselves about the processes involved in the manufacture of the food they eat
- 4. Considers that the single market necessitates that food safety rules should be implemented and monitored on the same effective and uniform basis in all the Member States, and that the necessary mechanisms should be established to define, at Community level, effective early warning and protection systems in case of crisis;
- 5. Agrees that the application of the three risk analysis components (determination, management and communication) must be the basis of food safety policy, but considers nonetheless that account must be taken of the different and specific characteristics of the agricultural production of raw materials;
- 6. Welcomes the Commission's intention to introduce a traceability system for foodstuffs and animal feed, which would make it possible to withdraw products from the market following detection of a health risk; considers, however, that the application of this system must be proportional to the end pursued and must not cause unnecessary economic hardship for farmers and stockbreeders; furthermore, considers the strict application of the 'polluter pays' principle to be essential in repairing economic damage;
- 7. Stresses the need to determine responsibility for food safety at each stage of the food chain, but insists that responsibility has to be limited to individual production stages, in such a way that each agent in the chain is considered responsible for the product up to the moment when it passes to the next stage;
- 8. Considers that if transparency is to apply it is essential to respect confidentiality and exercise caution, so as not to cause unnecessary hardship to farmers and the agri-food industry.

On the new legislative framework

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- 9. Considers that all necessary measures must be taken to guarantee quality, safety and hygiene for food products, including animal feed and other agricultural inputs, from the producer all the way to the consumer and taking account of the particularities of each link in the food chain;
- 10. Considers that the EU must, as a matter of priority, create a legal instrument enabling the Commission to adopt protection measures following the detection of a risk to human or animal health, since only on this basis will it be possible to deal with emergency situations at Community level;
- 11. Believes that the various legislative provisions should be worded clearly and as simply as possible, establishing, as far as this can be done, flexible procedures which can be managed and applied without difficulty, thus ensuring the highest standards of safety and helping the Community's agri-food sector to maintain its competitive position;
- 12. Considers that procedures should be established to enable the Commission to take rapid action in cases where controls reveal a serious failure to comply with food legislation;
- 13. Stresses the need for legislative proposals to include not only the strictly health-oriented aspects of food but also other aspects relating to fraud and deception of the consumer;
- 14. Reminds the Commission of the need for EU rules on the addition of vitamins and minerals to food products, with a view to facilitating consumer choice and strengthening the internal market;
- 15. Calls for the food labelling directive to be revised in such a way as, while not providing any less consumer information, to incorporate recent technological advances with a view to simplification and harmonise the inclusion of health claims, in the context of the *Codex Alimentarius* discussions;
- 16. Believes that suitable formulas should be established to enable the Community institutions to benefit from the participation of all interested parties, including agricultural producers' representatives, the agri-food industry and the consumers, in the management of the measures introduced under the new legislative framework;

# <u>On the European Food Safety Agency (EFSA) and the Commission's powers in the field of food safety</u>

- 17. Advocates the creation of a European Food Safety Agency (EFSA), which would be responsible for risk assessment and would be called on to operate the highest standards of independence and scientific excellence, becoming a point of reference for independent scientific evaluation; considers, nonetheless, that the creation of such an agency will not suffice if the objectives set out in the White Paper are to be attained;
- 18. Believes that responsibility for risk management (including management of the warning network) and risk communication should be a matter for the Commission, and that, with a view to improving the exercise of those responsibilities, the Commission should reorganise the services attached to its DG for Health and Consumer Protection and should create a specific administrative structure to be responsible for food safety, ensuring its

impartiality and independence vis-à-vis other administrative units, especially those dealing with economic interests or the management of agricultural or stockbreeding markets;

- 19. Considers that the EFSA should be responsible for providing the new Commission administrative structure responsible for food safety with the necessary scientific advice for the performance of its duties, via the reorganisation and coordination of the work of the existing scientific committees, with relations also being established with the national scientific bodies and agencies; the EFSA should also cooperate with the Food and Veterinary Office in Dublin and, on the Commission's request, undertake monitoring activities;
- 20. Considers that the EFSA should, within the framework laid down by the Treaties, have legislative and monitoring powers and should be backed up a network of laboratories for the purpose of verifying controls; believes that it should also be able to draw on the resources of the various independent scientific committees, which could be coordinated by an independent agency or scientific office responsible for assessing risks and communicating its findings to the EFSA;
- 21. Believes that the new Commission administrative structure responsible for food safety should have the task of representing the EU and defending its interests before international bodies such as the *Codex Alimentarius* and the WTO;
- 22. Believes that this new Commission administrative structure must exercise its powers at every link in the food chain, from the farm to the table and including primary production, animal feed and the remaining agricultural inputs, such as fertilisers and pesticides;
- 23. Calls on the Commission to define the powers and responsibilities of the EFSA and the new Commission administrative structure responsible for food safety, as well as the nature of their relations and coordination with the equivalent national scientific and monitoring bodies;
- 24. Believes that if the new Commission administrative structure responsible for food safety is to fulfil its task of facilitating ongoing dialogue between risk assessors and risk managers, as well as communicating with the public, it will be necessary to reach a clear definition of food safety procedures, especially early warning, crisis management and risk communication systems;
- 25. Lays major stress on the need for the new Commission administrative structure to coordinate with the national public health bodies in each Member State, in order to ensure the uniform application of the rules and principles of food safety throughout the Union;
- 26. Stresses the need to create suitable mechanisms to encourage the participation of agricultural organisations, consumers and the agri-food industry in the activities of the new Commission administrative structure, since this would have a positive impact on the development of its functions of communicating with and informing public opinion;
- 27. Considers that, in the international context, improved standards of scientific assessment in the EU and the independence and prestige of the EFSA could be of major benefit to the

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Union for the application of the precautionary principle in its food legislation and the defence of its positions in the face of possible conflicts;

## On controls

- 28. Emphasises the need for a Community framework to ensure that the controls made by the various national authorities are carried out on a standard and uniform basis, in such a way that hygiene levels, the standards required by national inspectors and the protection of public health operate at the same level throughout the Union; considers that such a Community framework should also help develop administrative cooperation between individual Member States and between Member States and the Union;
- 29. Considers that a control structure must be created with the power to ensure that the law is applied in an effective and uniform fashion throughout the Union, both for Union-made and third-country products, and that this structure should, in its control activities, exercise a supervisory role over the Member State control systems;
- 30. Calls on the Commission to work out an improved monitoring system, together with international cooperation and communication whereby, during the period of an embargo in the interests of consumer protection, there would be an automatic duty to notify the transport of particular foods or feedingstuffs, to inform the authorities in the country of destination, and to send a notification back to the country of origin; this crossborder monitoring and information system would also be applicable to spot checks in the trade within the Community in feedingstuffs and in meat and other foodstuffs;
- 31. Agrees with the Commission that official controls should apply at all stages of the production chain; stresses the importance of controls on animal health and feed in terms of their impact later on in the food chain;
- 32. Awaits the forthcoming adoption of the directive amending Directive 95/53/EEC on official inspections in the field of animal nutrition, which will enable the Commission, if necessary, to carry out on-the-spot inspections of both Community and third-country products;
- 33. Considers that health controls should be funded by all interested parties, since public health is a common good;
- 34. Considers it important to promote quality work and self-monitoring by operators in the food chain as a complement to quality inspection by the authorities and as a guarantee of food quality and safety; ultimately the control should be entrusted, as is the case already, to the Food and Veterinary Office in Dublin.

## OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Consumer Policy

on the Commission White Paper on Food Safety (COM(1999) 719 – C5-0136/2000 – 2000/2082(COS))

Draftsman: Dorette Corbey

## PROCEDURE

The Committee on Industry, External Trade, Research and Energy appointed Dorette Corbey draftsman at its meeting of 19 April 2000.

It considered the draft opinion at its meeting(s) of 25 May, 22 June and 12 July 2000.

At the last meeting it adopted the amendments unanimously with 2 abstentions.

The following were present for the vote: Carlos Westendorp y Cabeza, chairman, Nuala Ahern, vice-chairman, Dorette Corbey, draftsman, Konstantinos Alyssandrakis, Maria del Pilar Ayuso González (for Godelieve Quisthoudt-Rowohl), David Robert Bowe (for Harlem Désir), Yves Butel, Massimo Carraro, Gérard Caudron, Giles Bryan Chichester, Nicholas CleggWilly C.E.H. De Clercq, Claude J.-M.J. Desama, Jonathan Evans (for Umberto Scapagnini), Concepció Ferrer, Francesco Fiori (for Renato Brunetta), Glyn Ford, Jacqueline Foster (for Dominique Vlasto), Vitalino Gemelli (for Guido Bodrato pursuant to Rule 153(2)), Lisbeth Grönfeldt Bergman (for Angelika Niebler), Michel Hansenne, Malcolm Harbour, Wolfgang Kreissl-Dörfler (for Caroline Lucas), Werner Langen, Rolf Linkohr, Eryl Margaret McNally, Albert Jan Maat (for W.G. van Velzen), Erika Mann, Marjo Tuulevi, Matikainen-Kallström, Elizabeth Montfort, Reino Kalervo Paasilinna, Yves Piétrasanta, Elly Plooij-van Gorsel, Samuli Pohjamo (for Colette Flesch), John Purvis, Daniela Raschhofer, Mechtild Rothe, Christian Foldberg Rovsing, Paul Rübig, Ilka Schröder, Konrad K. Schwaiger, Esko Olavi Seppänen, Helle Thorning-Schmidt (for François Zimeray), Astrid Thors, Jaime Valdivielso de Cué, Elena Valenciano Martínez-Orozco, Guido Viceconte (for Peter Michael Mombaur, pursuant to Rule 153(2)), Alejo Vidal-Quadras Roca, Anders Wijkman, Myrsini Zorba



## SHORT JUSTIFICATION

## Introduction

The objective of the White Paper is to ensure that the EU has the highest standards of food safety. To this end, it proposes the establishment of an independent European Food Authority. This is to be accompanied by a range of legislative measures. The White Paper sets out more than 80 actions envisaged over the next few years. In particular, the Commission says that, following its Green Paper on food law (COM(97)176 final), and subsequent consultations, a new legal framework for food law will be proposed.

The committee on Industry, External Trade, Research and Energy (ITRE) welcomes the ambitious approach outlined in the White Paper. ITRE is aware of demands to broaden the scope of the EFA to include issues of nutrition and public health. However, the present opinion is limited to the measures outlined in the White Paper that touch upon the core competences of the committee on Industry, External Trade, Research and Energy.

## Research

Since 1997, the system for the provision of scientific advice on food has been reorganised on the basis of the three principles of excellence, transparency and independence. The European Community's Fifth Framework Programme for Research promotes research on food safety under its Key Action on 'Food, nutrition and health', which is part of the thematic programme 'Quality of life and management of living resources'. The principal area covered is 'Safe food: Tests to detect and processes to eliminate infectious and toxic agents - Dangers linked to contaminants, detection of their precise origin and strategies for safer food production'.

The proposed new EFA will have a key role to play in providing expert and independent scientific advice on food safety questions. This means that – especially in cases where a potential threat to human health has been identified - it will sometimes have to act in a faster and more flexible way than the multiannual research programmes normally permit.

The EFA should not become a new research centre, but rather bring together the best available knowledge. It has to gain credibility by communicating and cooperating with national and European research centres. It must be able to bring about the very best of science and to arrange appropriate peer review.

## Industry

Taken as a whole, the sector is a very large source of employment in Europe. A significant part (30%) of its 2.6 million workers are employed in small and medium sized enterprises (SMEs). Exports are worth around  $\notin$  50 billion a year.

The European food industry wants a system which can facilitate rapid approval

procedures. Subject to the appropriate safeguards, this is a valid request in terms of competitivity and economic viability. In order to exercise due caution, decision making should be both transparent and based on the best available scientific information. Erosion of the political responsibility should be firmly opposed.

The new framework for food legislation in the EU, and particularly the scope of activities of the EFA, should be shaped also to take account of industry's need for a 'level playing-field'. This is particularly relevant, for example, in questions of inspection and their impact on fair competition. The current situation is most favourable in the veterinary sector; other sectors need to catch up.

The comprehensive, integrated approach which the White Paper declares as the guiding principle of food safety policy is firmly supported. A working system requires communication throughout the production chain. The EFA could be the catalyst for beneficial and effective interactions among different branches of food industry, retail, agriculture, transport, consumers or others. In particular, the stakeholders can have a role in the monitoring process.

The White Paper is correct in identifying a need for improved public information on food safety, but if this is only a one-way, 'top-down' process it cannot succeed. Industry, farmers, consumers, regulatory authorities and other stakeholders need to be brought together in a structured dialogue that the EFA would be well placed to promote, notably by the involvement of these parties in a system of monitoring advisory committees. The idea of networking is good, but on its own it is not enough.

The food producers are responsible for the safety of food. The HACCP (Hazard Analysis Critical Control Point) system is a good instrument to ensure food safety, but unfortunately companies do not always comply with this.

Adequate training of workers should be encouraged at all steps in the food chain in order to ensure full implementation of the HACCP principles. The collected expertise, experience and ideas concerning food safety of employees should be fully recognized.

The diversity in food preferences throughout the European Union is of great cultural value. SMEs contribute to maintain this diversity by supplying regional and local products. Therefore, SMEs should be empowered to comply with new food safety and hygiene rules.

The concepts of safety and risk go hand in hand with that of liability. The Commission has recently published a Green Paper on 'Liability for defective products' [COM (1999) 396 final], and has launched a wide-ranging consultation exercise to determine whether or not to propose the revision of Directive 85/374/EEC. The situation with regard to food is always evolving. For example, it is only since 1998 that primary agricultural produce came within the scope of Directive 85/374/EEC.

Technical reports by regulatory agencies on incidents involving allegedly defective products are recognised as having a key role to play in facilitating admissions of liability or the abandonment of legal actions, as the case may be. The EFA can be a significant actor here.



## External trade

Disputes in Europe (beef) contribute to the idea that Europe is divided and does not speak with one voice. The EFA should have a role in clearing out differences in order to maximalise the effectiviness of external relations. The relationship of EFA to international for a needs to be clarified. The idea of giving a role to the EFA in EU relations with international organisations (Codex alimentarius, WHO, FAO) in the food safety sector is to be encouraged.

There is a specific need to promote the adoption of the 'acquis communautaire' in the candidate countries. A strategy to empower and encourage candidate countries to comply with the highest food safety standards is needed.

## The case for the EFA

In summary, ITRE can welcome the White Paper and in particular the plan to establish a European Food Authority. The need to improve food safety and to restore the consumers' confidence provide a strong case for establishing the EFA. However, EFA is confronted with a difficult divergence of aims. The EFA should be independent in order to gain credibility and the confidence of consumers while at the same time it should involve industry and maintain communication with all stakeholders in order be effective. Thus, the structure and work of the EFA must be conceived in a way that will do justice to legitimate public concerns over food safety stimulated by a number of incidents in recent years.

## CONCLUSIONS

The Committee on Industry, External Trade, Research and Energy calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following points in its draft resolution:

- 1. notes with satisfaction the Commission's proposals in the White Paper, and supports the integrated approach to food safety, which is intended to attain the highest possible level of protection of human and animal health;
- recognises that restoring public confidence and reducing international conflicts with regard to food issues is predicated on the appropriate allocation of different tasks in risk handling to the various actors involved; stresses therefore that the critical ingredients of any credible and successful system for assessing food safety are its technical and scientific competence in risk assessment and its independence from improper interference in decision-making in individual cases;
- 3. welcomes the idea of the EFA, urges its speedy establishment, and foresees that its seven most important tasks will be :
  - scientific evaluation of risks with guarantees of maximum independence,
  - monitoring, with involvement of all stakeholders through advisory

committees and/or working groups, in a transparent framework,

- communication, with involvement of consumers, thus requiring high visibility in the media for the Director of the European Food Authority,
- coordinating the activities of and standards set by national, regional and local food standards regulators, so as to ensure adequate common standards and their effective implementation without hazarding the vitally important single European market in foodstuffs,
- external representation, given a clear relationship between the EFA and international bodies in the food safety sector such as Codex alimentarius, WHO and FAO;
- legislative and supervisory powers,
- establishing levels of acceptable risk in food products and how to inform, advise and educate the consumer about the inevitable, if minimal, risks, by setting standards in labelling, advertising and other means of communication;
- 4. expects the proposed EFA to play its part in trade relations with the WTO and third countries regarding food safety standards with the objective of promoting free world trade in food products which meet internationally agreed and acceptable safety standards;
- 5. reiterates that the EFA should not be a new research institute but rather bring together the best available science; emphasises that the EFA should be provided with adequate resources in order to enable its work to the fast, flexible and effective; the Commission should give the EFA a co-ordinating role on scientific advice so it can communicate and cooperate with national and European research centres, based on the principle that independence, transparency and excellence should be the overriding concerns;
- 6. calls on the Commission to state details of the arrangements for cooperation between the EFA and existing national food safety agencies and their respective operational powers; calls for the present organisation of the European Union's scientific committees to be reviewed in order to arrive at a clear and consistent institutional structure relating to food safety;
- 7. calls for it to be possible not only for the Commission but for any Member State individually to request action by the future European Food Authority; however, this must not result in the Authority's operation being hampered by overwork; preconditions for requesting action must therefore be laid down which both ensure that the Authority can operate and take account of the interests of the Member States:
- 8. considers that the EFA should be located in a seat which meets the following criteria:
  - it should facilitate contact with major local production facilities, so as to exploit to the maximum the advisory role associated with scrutiny and turning to account of local diversity;
  - it should be situated in an area which has historically been a meeting place between different European traditions and types of production, divided between the continental and the Mediterranean;
  - infrastructural links with all the European capitals should be possible;

an academic and scientific infrastructure should be available locally which can interact with the Authority;

- 9. calls on the Commission in view of the forthcoming Sixth Framework Programme to enhance and adapt the role of food safety research and extend it to cover consumer concerns regarding both the safety and the quality of products; believes that the JRC may play a role as one of the reference laboratories;
- 10. reaffirms that the European Food Agency should become an institution which provides political decision-makers with the proposals for decisions which are required in order to take effective decisions on food safety;
- 11. emphasises that the new framework for food legislation in the EU should be shaped also to take account of industry's need for a 'level playing-field' which, however, allows scope for recognition of the special character of traditional (or local or regional) quality products, and notes that this is particularly relevant, for example, in questions of inspection and their impact on fair competition; notes that the internal market in food is not yet complete, and urges that legislation be harmonised, taking as a premise the most stringent safety standards;
- 12. considers that this new legislative framework should incorporate all measures required to ensure the quality, safety and hygiene of food products, including animal feedingstuffs and other agricultural inputs, taking account of the special characteristics of all links in the food chain
- 13. considers it urgently necessary for the EU to acquire a legal instrument enabling the Commission to take safeguard measures if a risk to human or animal health is reported;
- 14. stresses that European food legislation should rather comprise rules on how monitoring should be carried out than rules which reduce the diversity of Europe's cuisines and that at the same time we should rigorously respect the subsidiarity principle;
- 15. stresses the need to bring together industry, farmers, consumers, employees, regulatory authorities and other stakeholders in a structured dialogue under the aegis of the EFA to consider problems of guarantees, safety and quality, notably by the involvement of these parties in a system of monitoring advisory committees;
- 16. emphasises the important role in Europe's culture, diversity and economy of small and artisan food producers and processors and requires that the EFA does not inhibit this sector by excessively rigid and bureaucratic standards and procedures, but rather assists them in achieving levels of acceptable risk and simple means of advising consumers of any inherent risks;
- 17. emphasises that adequate training of workers should be encouraged at all steps in the food chain in order to ensure full implementation of the HACCP principles;

- 18. stresses that producers, consumers and authorities will benefit from an effective Rapid Alert System;
- 19. underlines that food safety is a matter of common concern that goes beyond issues of market competition and that best practice analysis and benchmarking should be the subject of dialogue between the social partners within companies but also at the national and European level; considers, however, that this criterion must not penalise traditional local products by leading to the imposition of a homogeneous model of industrial production, which moreover would be contrary to the multifunctional character of European agriculture;
- 20. considers that, as in the case of competition law, the Commission's departments responsible for food safety should be able to impose heavy fines if a national authority or a business does not abide by Community rules;
- 21. encourages SMEs to maintain to the maximum the cultural diversity in food throughout the European Union and underlines that each State should help its enterprises, artisans, microenterprises and SMEs gradually to comply with new food safety and hygiene rules;
- 22. appreciates the role of SMEs in maintaining the cultural diversity in food and food preferences throughout the European Union and underlines that SMEs should be empowered to comply with new food safety and hygiene rules;
- 23. calls on the Commission, in this connection, to ensure that the regulatory process which will result from the new approach to food safety does not turn into an extension to all producers of practices already adopted by particular economic operators on the basis of their specific requirements but incompatible with the environmental, economic and cultural diversity of the industry;
- 24. stresses the fundamental importance to all political decision-makers concerned of an approach which safeguards the multifunctional character of the agri-foodstuffs industry by means of the adoption of appropriately differentiated procedures, monitoring instruments and preventive measures which ensure a level of protection of consumers which is genuinely equivalent in terms of results but not necessarily homogeneous in terms of instruments;
- 25. recognises the key role of technical reports on incidents involving allegedly defective products in facilitating admissions of liability or the abandonment of legal actions and expects that the EFA can be a significant actor here, provided that its work gains a reputation for excellence and independence;
- 26. calls on the Member States to develop amongst themselves a strategy for general cooperation, and to encourage candidate countries without further delay to work towards compliance with the highest food safety standards;
- 27. calls on the Commission to develop a strategy to empower and encourage candidate countries to comply with the highest food safety standards; calls on the Commission, to this end, to establish reliable and effective indicators to enable



practical assessments to be made of the adoption by the applicant countries of the acquis communautaire with regard to food safety before accession.

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