INTEGRATED COMMENT AND REMARKS OF

THE SCIENTIFIC STEERING COMMITTEE (SSC) ON

THE WHITE PAPER ON FOOD SAFETY

Introduction

The Scientific Steering Committee (SSC) appreciates that the Commission has asked its comments on the White Paper. The White Paper has been discussed in two subsequent meetings of the SSC in March and April 2000. This document aims to be a reflection of the discussions held and is submitted to the Commission with the firm belief that the Commission will take these comments into serious consideration, especially since the document does include also some reflections on the past and present functioning of the SSC.

A European Food Authority (EFA)

A EUROPEAN FOOD AUTHORITY IN RELATION TO PUBLIC HEALTH

The SSC agrees that Food Safety principles are best achieved when performed by an INDEPENDENT body in a transparent, traceable, responsible, comprehensive and integrated way. At the same time the SSC felt that an opportunity to create an overall Public Health authority looking at all public health matters -not only food safety -, has been missed. While the SSC recognised that the creation of a general "European Food Safety and Public Health Authority" is a most difficult target to realise as it would need the involvement of several ministries per country, it nevertheless was concerned by the perceived ongoing process of fractionating public health matters over several services. For example, scientific advice directly related to food safety would be handled in one institution, but advice related to environmental aspects would be dealt with elsewhere although they are directly interrelated. Food safety is only one of the health criteria. Bringing together the 8 committees and the SSC in the Health and Consumer Protection Directorate General (DG SANCO) was an important step forward to combine the various elements of public health, which were previously dispersed over a number of Directorate Generals. Nonetheless, a number

of important aspects of public health remained outside DG SANCO: worker safety (Employment and Social Affairs Directorate General, DG EMPL), disease trends and socio-economic factors (DG EMPL), Radioactivity and Health (Environment Directorate General, DG ENV), Alcohol and beverages (Agriculture Directorate General), Waste disposal and health (DG ENV) and Research of public health issues (Research Directorate General). The reorganisation of the Commission has provided the unique opportunity to establish a single focal point for public health strategy and its implementation in the EU, which is needed because the issues are multifaceted. The Food Agency proposal however will fragment public health again. Food may be a priority for the Commission at this moment, but the next crisis could well be a drug, an industrial chemical, an environmental organism etc.

The SSC explicitly raised the question whether it was wise not to include the fields Cosmetics and Non-food Products, Medicinal products and Medicinal Devices and Toxicology, Ecotoxicology and Environment in the European Food Safety Authority, because this inclusion would guarantee not only an harmonised methodological approach for all routes of exposure when generating scientific advise, but also the taking into account of common, public-health oriented, risk assessment principles.

Moreover, there is a reasonable number of substances/compounds which are used and play an important role with respect to consumer's safety and health in all the different sectors mentioned, e.g. tallow and gelatine. Also, most Member States have a consumer legislation for food, cosmetics and non-food products.

+ In this context, the SSC was also concerned by the fact that the environmental problems and impacts related to public health were not sufficiently addressed, especially in view of the future enlargement of the EU to more the 20 states expected. Some of these future new Member States have huge problems with potential negative effects of their past environmental policy on public health. These matters presently do not seem to be addressed anywhere. Including public health related environmental aspects in the mandate of an "European Food Safety and Public Health Authority" (EFSAP) should carefully be considered in relation to the mandate of the European Environment Agency (EEA) in Copenhagen in order to be complementary.

The fact that environmental matters can and should indeed be included in the food safety and public health debate is best illustrated in the work of the Scientific Committee on Plants, which already puts, for example, its opinion on GMOs and pesticides in so far.

Several members suggested that the creation of a "Scientific Committee Sustainability" would be appropriate in this context.

+ A European Food Authority without Public Health as described in the White Paper may not sufficiently address and specify where the accountability of the EFA will rest: in public health or in the single market. It is not clear where, how and from what perspective, certain questions - other than licensing-related ones - on medicinal products or medical devices (as they are related to the Scientific Committee for Medicinal Products and Medical Devices) would be handled. In the case that a European Food Authority is established as described in the White Paper (i.e. without Public Health) it might be wise to consider to (nevertheless) include matters related to medicinal products, medical devices, cosmetic and non-food products, toxicology, ecotoxicology and environment in the mandate of the EFA, not for licensing-related aspects but for surveillance and public health monitoring purposes.

+ RELATION OF THE AUTHORITY WITH RISK MANAGEMENT

The SSC appreciates that inclusion of risk management principles in the mandate of the European Authority (EFA) although increasing transparency and independence, may not be considered for policy and logistic reasons. However, separation of risk assessment and risk management will necessitate a very effective interaction and communication between the two in order to prevent misunderstanding and misinterpretation.

+ The communication process and interaction between risk assessor and risk manager is an essential part in the preparation process of scientific advice. The present version of the White Paper does not elaborate on this important aspect. Throughout the process of risk assessment an effective dialogue between risk assessors (i.e. members of the Scientific Committees) and risk managers is essential. For such a dialogue a

more structured and transparent procedure avoiding unnecessary bureaucracy is necessary. It may comprise the following stages:

- 1. <u>Initiation of the process</u> drafting questions, identification of potential overlap with other organising committees, provision of information and the form and the schedule in which answers are required.
- 2. <u>Communication during the process</u> to discuss possible gaps in information that limits ability to answer questions, reconsideration of questions or updating of questions or mandate, and other procedural matters where a policy is required.
- 3. <u>Completion of the risk assessment</u> to discuss a (common) format for expressing risk in a clear and unambiguous way, and to discuss appropriate communication strategies and press communication.
- 4. <u>Follow-up</u> Effectiveness of Scientific Committees will improve and motivation will be strengthened when they are regularly informed (about actions taken as a result of their assessments and the measures taken through monitoring or other processes to evaluate the soundness of the risk assessment made and the effectiveness of controlling measures.

TRANSPARENCY: NOT ONLY SCIENTIFIC ADVICE

- + As indicated earlier the SSC strongly supports the vision of the Commission that INDEPENDENCE will increase faith and foster transparency.
- + Transparency in the communication process between risk assessor and risk manager as well as clear and transparent procedures for decision making and legislative action of risk managers are, in addition to a transparent functioning of an European Food Authority, a necessity in order to manage "food scares" and "food calamities" in a for consumers appropriate and understandable way.

The SSC would like to stress that transparency in the scientific advice is only one part of the process. The management of risks is per definition the process that is getting most public attention and should be transparent as well.

+ The inclusion of Risk Communication in an independent European Authority will also foster transparency and increase public faith. Risk Communication should pertain the population at large, policy organs, stakeholders and the scientific community as well. The SSC would however like to emphasise the importance attracting specific disciplines related to Risk Communication: the present disciplines represented in the SSC do not cover this important field of science.

RELATION OF THE AUTHORITY WITH NATIONAL STRUCTURES IN THE EU.

- + For an EU scientific advisory system to work effectively, optimal interaction with counterpart Member State structures should be aimed for, because these national structures will eventually be the counterparts in an EU-wide network. However, the White Paper does not yet sufficiently enough take into account the way scientific advisory systems are (planned to be) organised (or not) in the various Members States. How such networking should be organised and managed, is also insufficiently addressed. It is therefore not excluded that the EU advisory system may eventually appear to be not fully compatible with national processes for the generation and exploitation of scientific advice.
- + The possible role of Scientific Co-operation as mentioned in the White Paper should be questioned since its functioning is very much dependent on "good will" and finances of nationalities. The activity proved not to be as successful as anticipated in the past.
- + Several SSC members also mentioned that the expectations put in and results expected from the proposed networking with national agencies and institutions might not be justified. The staff of national agencies consists of civil servants that may eventually appear to be not always independent or to defend also national interests and not only scientific arguments. The objective qualifications of the national counterpart staff and criteria for their recruitment may also be of a different level as compared to the EU experts who will be identified on the basis of severe criteria announced in international calls for expression of interest and following the principles of excellence and independence.

An Authority will not be successful without an appropriate functioning monitoring and surveillance system in an EU-wide network, working in accordance with clearly defined principles and criteria together with applying the necessary quality control rules. Structure and organisation of the EU-wide network monitoring and surveillance system should be addressed in detail and should strongly be backed by existing systems functioning nationally.

THE EUROPEAN AUTHORITY IN THE GLOBAL CONTEXT

- + A European Authority should primarily have independent scientific authority fed by an optimal scientific infrastructure with sufficient continuity.
- + A European Authority should have tight links with other similarly functioning international organisations such as those related to WTO, CODEX, OECD, WHO, FAO, OIE and the like. The SSC notes that this international dimension is insufficiently addressed in the White Paper.

THE EUROPEAN AUTHORITY AND SOCIETY

- + The SSC notes that the White Paper insufficiently discusses the importance of the stakeholders in the authority and their role. Consumers, producers and retailers have their own specific responsibilities in public health and food safety normally fostered by their associations.
- + A European Authority should have a management board and/or a scientific advisory board in which stakeholders may participate.

THE EUROPEAN AUTHORITY: ITS IMPLEMENTATION, ORGANISATION AND MANAGEMENT

+ The SSC notes that the White Paper lacks suggestions and/or proposals for the practical implementation, organisation and management of the Authority. In particular attention has to be given to information management using modern information technology. Moreover, the proposed planning schedule in annex to the White Paper is considered to be far too optimistic. In the organisational structure the SSC would like to see due attention for the systematic use and implementation of

scientific results (such as the 5^{th and 6th} Framework Programme) into the risk analysis process. In addition, the SSC sees the Authority primarily as a scientific and technical organisation rather than an "administrative" one and with close relation to the JRC Ispra. In the report "The future of scientific advice in the EU" as developed by Professors Pascal, Kemper and James many suggestions for structure and organisation are made.

- + The SSC advises the Commission to review the present expert committees with respect to functioning, tasks and goals. In such a review also the establishment of probably necessary new/other expert committees should be addressed. The SSC will certainly be happy to advise the Commission in this matter should it be asked to do so.
- + A European Authority should also be given the opportunity to advise the Commission on matters of concern, not necessarily asked for by the Commission. In addition, the Authority should also develop an early warning system, which will allow the Commission to anticipate upcoming problems.
- + The issue of resources and location of the Authority is insufficiently dealt with in the White Paper. In the light of the remarks that follow below it is advised to start a detailed analysis to define human, financial and physical resources needed as a first step before an authority is established.
- + The reorganisation of scientific advice in 1997 improved transparency of the scientific advice considerably, and was well received by community and policy organs. However, a serious drawback is the totally insufficient support due to lack of resources, leading to a backlog, which erodes the confidence of community and scientists as well in the Commission's position regarding scientific advice.

The SSC strongly advises to increase support. Secondment of scientists to work with the secretariat for back up to all working and possibly newly established committees is a MUST since the Commission will otherwise lose the commitment of the experts present in the committees. The SSC refers also to related comments made in the earlier mentioned report of Professors Pascal, Kemper and James.

Experienced experts are very much in demand, both nationally and internationally. In addition there is an increasing shortage of experts with the necessary breadth of experience. Moreover such experts are highly sought after by industry both to collaborate in research and to provide consultancy advice with obvious financial benefits to their Institutions and/or themselves.

Therefore the continuous support of world class European scientists can only be assured by appropriate remuneration for their time spent; both at home in their institutions and in Brussels. Appropriate remuneration most likely will also reduce their employer's reservation to lend their scientists to the European Commission.

IMMEDIATE ACTIONS

+ Important is an immediate follow-up on the SSC's comments about support. European scientists may be recruited on a temporary basis detached from their institutions for a limited period of time.

However, they should be able during the detachment to follow the scientific developments in order to maintain their expertise. The European Commission should also reflect which in-house expertise in specific areas is necessary. In-house experts should also have the opportunity to keep up with scientific developments.

The SSC recommends that, both for the immediate future as in the context of the White Paper, the Commission should urgently and explicitly address the comments made concerning the lack of sufficient support. Increased support by scientists will enhance the output of the Committees. As for the SSC this may mean that the SSC can also devote more time to equally or even more important matters than those related to TSE. The SSC recognises that thanks to the specific, multi- and interdisciplinary approach of the SSC, TSE matters have been put in their correct general context which goes beyond the pure scientific discussion of specific sub-issues which may eventually hide the overall public health picture. This approach should also be made possible for other important issues.