Statement of the Scientific Steering Committee on: Scientific advice to the Commission from its scientific committees, with special reference to the Scientific Steering Committee (SSC) and its interdisciplinary advice on TSE/ BSE adopted on 26 May 2000

Background

The advice given to the European Commission by its scientific committees can have great influence on both consumers and the industry in member and non-member states. The Scientific Steering Committee (SSC, which includes among its membership, the chairman of the eight scientific committees) therefore considers it important that the organisation and working procedures behind the scientific advice are transparent. They are briefly presented in the present statement, which gives special reference to SSC and uses as an example the SSC's interdisciplinary advice on BSE/ TSE.

Organisation for scientific advice

The European Commission has repeatedly stated that sound scientific advice is an essential basis for community rules on consumer health, including not only consumer health in its strict sense, but also animal health and welfare, plant health and health of the environment. The Commission has therefore established a scientific advisory system (re-organised in 1997) through which this need for scientific advice can be provided. The core of the new system comprises the Scientific Steering Committee and eight scientific committees covering the specific areas of: human food, animal feed, animal health and welfare, veterinary measures relating to public health, plants, cosmetic and non-food products, medicinal products and medical devices, toxicology, ecotoxicology and the environment.

The mandate of the SSC includes co-ordinating the work of these eight committees, promoting co-operation between them on subjects of mutual interest (or requiring their complementary experiences and competencies) and providing to the Commission advice on multi- and interdisciplinary matters not covered by the mandate of these committees. The mandates of the scientific committees are given in Commission Decisions 97/404/EC (for the SSC) and 97/579/EC (for the other 8 Committees). All these committees adopted, in the beginning of their mandate, rules of procedures, which are publicly available. (See for example the SSC rules of procedure adopted at its plenary meeting 26/27 March 1998 and attached to the minutes of this meeting.)

Excellence

Since 1997 the Member States no longer propose to the Commission members of the scientific committees. In order to obtain suitable expertise, international calls for expression of interest to participate in the nine scientific committees were published in 1997 in the European Union Official Journal. The evaluation procedure for the more than 1100 applications received was designed in such a way that the eventually selected Members would be of the highest possible quality.

In a first step, eight of the members of SSC were nominated by the Commission and selected on the basis of scientific experience and scientific managerial aptitude. Guided by them, the Commission subsequently nominated the members of the other eight committees. Some members are from countries that are not Member States. The members of these committees later nominated their chairpersons. In addition to their chairmanship, they are also members of the SSC. The SSC is thus composed of 16 members and is, like all committees, supported by a secretariat of qualified persons with a scientific background.

Independence

The Commission nominates the members of SSC and the 8 committees. A condition of their membership is that they only represent themselves, not their mother-institute or country. Consequently a member can not be replaced if he/she

is not able to attend a meeting. The administrative management and secretariat of the scientific committees is done by the Health and Consumer Protection Directorate General (DG SANCO, formerly DG XXIV) which emphasises the primary importance of the consumer. To guarantee their independence, the Committee members have to make a declaration of possible interests at the beginning of each meeting and a general, written one, at the beginning of each calendar year.

If an incompatibility or conflict of interest arises for a member, he or she may - at the discretion of the Committee as a whole - be requested either not to participate at all in the discussions or to contribute only to the scientific debate but not to the elaboration of the conclusions or in a vote (should the need for a vote arise). Furthermore the composition of each committee of at least 16 very experienced scientists, from various disciplines and from various countries, is an excellent buffer, which compensates for possible individual biases in the development of a final opinion by the Committeee. An other safeguard is the stepwise approach followed by the Scientific Steering Committee when preparing most of its opinions, and which is clearly illustrated by the way TSE-related issues are handled (described in an attachment.)

As a part of their independence, Scientific Committees not only respond on questions from the Commission, but according to the Commission Decision, they are also able to draw the attention of the Commission to any specific or emerging consumer health problem.

Transparency

Opinions adopted by the scientific committees are made publicly available via internet and upon request. In this way they are not only widely available but also open for permanent scientific scrutiny and criticism. In addition to this Committees may adopt "pre-opinions" that are published on the INTERNET and open for scientific comments within a specified deadline. These are taken into account when an opinion is finally adopted.

Interdisciplinary advice

Science is in continued evolution and almost daily new facts, confirmations of existing hypotheses or doubts on what was thought to be a proven fact, emerge. It is therefore very important that the discussions in the Scientific Committee meetings are between active scientists with different, but complementary, fields of expertise and backgrounds. And when necessary, specific working groups can be established, which include external experts providing complementary experience and are chaired by a member of the Committee.

Considering the frequent multidisciplinary nature of the issues dealt with, there is inevitably a difference in the degree of involvement of an individual expert in a particular issue. Single factors of personal scientific interest, experience (intuition), personal approach to uncertainties and personal values (preferences) may be over weighted, in spite of the independence, integrity and an excellency of the members. Therefore, a full and equal consideration with appropriate weighting is hard to be achieved for any of the individual experts.

Building an opinion is therefore often not a straightforward exercise of adding and subtracting scientific evidence. Consequently a swift reaching of a consensus is often unachievable. On the contrary, the process may be laborious and involve: careful identification of the various views existing within the committee, feedback to subgroups (working parties) for specified detailed to be expressed **,** searches for additional information, evaluation and weighting within the overall context of each one's arguments, discussions to verify whether or not a particular argument should be taken into account and to what extent. In the course of such a process it is not uncommon that arguments that initially seemed to be of minor importance, suddenly gain in importance and vice versa once they are put in a certain context. Sometimes they even require a reconsideration from the start of a tediously built rationale.

Most committees try to reach a consensus, which increases the length of the process even more, but if such is impossible, minority or alternative views may be included in an opinion.

Reaching an opinion inevitably takes a considerable amount of time, often months than weeks. For example, the preparation of the TSE opinion addressing the issues of species barrier and the minimum infective doses that should be

used in risk assessments, took more than a year and went through 10 different drafts before it was adopted.

As a result of the organisation described above the SSC views are truly *multidisciplinary* and take into account the complementary contributions from the chairpersons of the different committees and through them from the members of these Committees. It is also *interdisciplinary* in the sense that the contributions from these various disciplines are eventually integrated in a wide integrated view which puts health and consumer protection related issues in an appropriate and balanced public health context.

***Attachment*:**

The SSC's stepwise approach towards advice on Transmissible Spongiform Encephalopathies (TSEs)

The SSC has a specific mandate to advise the Commission on scientific issues relating to Transmissible Spongiform Encephalopathies. This requires expertise from a variety of scientific disciplines such as veterinary sciences, human medicine, epidemiology, microbiology, biochemistry, animal nutrition, human nutrition, toxicology, animal waste processing, and environmental sciences. The SSC itself is not only composed of TSE/BSE experts, and this issue is therefore being handled by the TSE/BSE *ad hoc* Group, created soon after the establishment of the SSC and chaired by one of its members. The group reports directly to the SSC. To guarantee its multi- and interdisciplinarity in TSE-related matters, the SSC has followed a 3 stage approach:

The fundamental scientific aspects are in a **first stage** addressed by either a special working group or a sub-group of the TSE/BSE *ad hoc* Group. *Up-to now* more than 100 *specialised experts,* from *Member States and* third countries, *have contributed to these Working groups,* in addition to the SSC and the TSE/BSE *ad hoc* Group members themselves who always participate and chair these working group . The fields they have addressed so far, cover the various major aspects related to TSE, *namely:*

a) Safety for animals, humans and the environment of ruminant-derived products [1] , as well as related aspects such as intra-species recycling and recycling or disposal of animal waste. To date, more than 22 different experts contributed, out of which 15 are neither member of the SSC nor of the TSE/BSE *ad hoc* Group.

b) Epidemiology (covering aspects such as monitoring the evolution of the BSE epidemic in GB: surveillance and culling). To date, more than 12 different experts contributed, out of which 9 are neither member of the SSC, nor of the TSE/BSE *ad hoc* Group.

c) Fundamental science issues (for example vertical transmission of BSE and scrapie, BSE in sheep, breeding of sheep for scrapie resistance, etc.). To date, more than 15 different experts contributed, out of which 7 are neither member of the SSC, nor of the TSE/BSE *ad hoc* Group.

d) Human exposure Risk (including human exposure risk as such and other issues such as the safety of ruminant blood, infective dose, etc.) To date, more than 26 different experts have contributed, out of which 15 are neither member of the SSC, or of the TSE/BSE *ad hoc* Group.

In addition, approx. 50 external experts have contributed to the Geographical TSE risk assessment exercise carried out in 1999 and 2000.

In a **second stage** the TSE/BSE *ad hoc* Group discusses the scientific report prepared by a working group in detail, and prepares draft conclusions for the Scientific Steering Committee. The *ad hoc* Group may amend a working group document. However, if major questions arise with respect to the report (e.g., if the mandate was not fully covered or certain scientific questions were not or incompletely addressed), the report may be sent back to the working group. The *ad hoc* Group does not adopt opinions and its reports are considered to be a preliminary step towards the adoption of an opinion by the SSC. The *ad hoc* Group's report to the SSC may contain various alternative conclusions that may be drawn from same scope of scientific evidence.

In **a last stage,** the SSC discusses in detail both the report of the *ad hoc* Group and the detailed scientific report from the

working group. Again, if major questions arise with respect to these reports, they may be sent back to either the TSE/BSE *ad hoc* Group and/or the working group. The SSC may agree with the conclusions proposed by the *ad hoc* Group and adopt the conclusions as they are, possibly after minor amendments. It is, however, not obliged to do so and may agree on different conclusions or on one single of the alternative conclusions that may have been proposed by the TSE/BSE *ad hoc* Group. This is a logic, and intended, consequence of the specific mandate and composition of the scientific committees.

---

[1] For example, gelatine, tallow, dicalcium phosphate, hydrolysed proteins, hides, meat-and-bone meal and organic fertilisers.