Opening address

THE IMPORTANCE OF SCIENTIFIC ADVICE IN THE COMMUNITY DECISION MAKING PROCESS

by

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Welcome

I am very pleased to have this opportunity to welcome you to this joint first meeting of the 3 scientific committees which were set up by Commission Decision in March of this year. I should say immediately that Commissioner Byrne had hoped to welcome you himself but he has a meeting in the Netherlands today. I am however happy to confirm that he will come here tomorrow morning at 9 o'clock to greet you in person.

I welcome the opportunity to start the proceedings with a joint meeting of members. Not only does it give me the chance to meet all of you in one place, but it sets the tone for cooperation between the three committees. Although each of your three committees is independently responsible for its opinions, I want to stress the importance that you nevertheless function as a coherent whole and benefit from your combined expertise. We also need to ensure appropriate integration of your expertise with that of other relevant Community bodies and notably that of the European Food Safety Authority. The new Commission Decision and the draft rules of procedure that you will discuss for adoption later today, place strong emphasis on these aspects. The achievement of coherent risk management across the many industrial sectors that impact on the health of the citizen depends directly on the coherence of the underlying risk assessments.

I know that around 40 % of you were members of the previous committees and much of what I will say will be familiar. These members will also be aware of the new

elements that result from the recent adoption of the Commission Decision setting up the scientific committees and the changes presented in the draft rules of procedure.

New members will not be burdened by knowledge of the past but will certainly bring fresh thinking to our work.

Whether you are “old” or “new”, I wish to stress a number of operational matters which have a very direct influence on my job as risk manager, when I am called on to make decisions that affect consumer safety and public health.

Sound science

The importance of scientific advice for the Community decision making process is well established and growing. The Commission in general and DG SANCO in particular attach high importance to the use of sound science to underpin its work and strive therefore to ensure that its scientific advice is of the highest quality. But, scientific excellence is not enough. To be effective, the advice must enjoy the confidence of all stakeholders, consumers and industry alike.

Openness with stakeholders

But, establishing confidence is a two way process. The Commission’s 2001 White Paper on European Governance highlighted the importance for the Commission to involve civil society in the decision making process. In particular, it identified the need to have more effective and transparent consultation at the heart of EU policy shaping.

I believe that the nature of your work and the opinions you express, give your committees an important role in confidence building. It is therefore important that you also listen to the views of those stakeholders who are strongly affected by your opinions. In practical terms, this is why we have added a specific point in the recent Commission Decision on hearings. This is a matter which is amplified in the draft rules of procedure whilst taking account of the need to ensure that the process of "listening" does not, in any way, undermine the integrity and independence of your scientific advice.

In view of the importance of the Governance White Paper and the role that the Scientific Committees can play in achieving its aims, I have asked my colleagues to send you a copy for your examination.

Independence and transparency

Building and maintaining confidence is also the reason why we attach such importance to the notion of independence and, to the vital ingredient that gives external credibility to the process, transparency.

Nobody pretends that any of us is perfectly independent. I stress that links between members of scientific committees and industry or with other interested bodies are not discouraged. Indeed, we fully appreciate that such links are a normal and important part of the professional life of experienced scientists.

The important point is openness, which is why the declarations of interest are so important.

Declarations of interest ensure that the Committee as a whole can meet the requirements of independence. They also provide an important safeguard for individual members against accusations of undeclared relationships. Such accusations are easily made and can be difficult to counter, even when unfounded.

The new Decision on the Scientific Committees further strengthened the transparency of the process by requiring that annual declarations of interest are made public. In practice this means that they will be put on the DG SANCO home page. It is therefore important that you give very careful consideration to the declaration form before submitting it.

Scientific opinions

The essential output of your work is, of course, scientific advice. Your opinions are the formal statements which we use, in our capacity as risk manager, to formulate policies which may have far reaching affects on the health of the citizen or on the economic success of a commercial venture. As I said before, it is not sufficient that the opinions are based on excellent science.

- They must also be clear to the non-specialised reader. This may be me [an historian by training], other non-scientifically trained officials or the lay public who often have a burning desire to understand issues that affect themselves and their families.

- They should avoid ambiguity which only serves to allow the protagonists to select the part of the opinion that supports their case and to confuse policy making.

- They should use consistent language to describe similar conclusions across the wide range of areas covered. My colleagues tell me that in its work on harmonisation of risk assessment, the former Scientific Steering Committee had counted 18 different phrases used in scientific opinions for expressing "negligible risks". I would welcome continuation of this work to develop some form of risk assessment vocabulary.

Uncertainty

I know that it is relatively rare for the available scientific evidence to allow a complete and unequivocal risk assessment and that, in most cases, you are asked to use your experience and judgement to weigh evidence. It is however very important for the risk manager to have a feeling for the level of uncertainty or confidence in the advice.

The matter of uncertainty becomes very important especially when scientific advice underpins the public authority's decision to authorise or prohibit a product for sale in the Community or leads to the setting of limits. These are often decisions of importance for public safety but which may also have major economic implications that need to be taken into account by the risk manager. In cases where both the potential risk and scientific uncertainties are high, the risk manager may conclude that a precautionary approach is appropriate.

Even though it is not a subject that lends itself easily to quantification, I would urge you to take account of the risk manager's need to understand the level of uncertainty in your advice and to work towards a systematic approach to this problem.

Breadth of opinions

I am also very conscious of the fact that exposure to hazardous substances or to physical effects may arise from more than one source and that we have tended in the past to examine risks on a narrow, sectorial basis. Whilst it is important that the Commission receives clear advice on risks in a specific context so that it can manage that area, it is also important that the Commission is alerted to other sources of exposure.

EFSA cooperation and diverging opinions,

We have attached considerable importance to the need to establish effective working contacts with other Community bodies with risk assessment responsibilities. The European Food Safety Authority, or EFSA, is of particular importance here given the high potential for use of similar industrial substances in food and non-food products and the overlaps arising from many widely spread, environmental contaminants.

Cooperation will be very important on a series of horizontal issues which cut across all sectors for example, the use of non-animal test methods for the safety

assessment of substances and modern approaches to the assessment of risks from genotoxic substances.

The Commission Decision recognises the potential difficulties arising if Community bodies give diverging views on related risks and the need to seek your assistance to avoid or resolve divergent views. Similar obligations are incorporated into legislation establishing the EFSA and the European Medicines Evaluation Agency (EMEA) and should minimise the risks of divergence in the future.

Separation of Risk Assessment and Risk Management

Following the experience on BSE in the mid 1990s, the Commission recognised the need to have a functional separation of administrative responsibility for risk assessment and risk management. This principle provides an important safeguard for the independence of the scientific advice by ensuring that it is not influenced by the policy preference of the operational departments. This separation is explicitly built in to the decisions setting up your committees and those of the European Food Safety Authority.

In simple terms, the job of the scientific committees is to describe the risk. It is the task of the risk manager to determine how to handle the risk after taking account of the economic, social and other legitimate factors in addition to scientific advice. There are however questions where the separation of risk assessment and risk management is difficult. As a simple but pertinent example, the question of setting acceptable levels of risk is clearly a broad societal issue. The question of whether it is

scientifically possible to reliably determine, for example, a specific excess cancer risk is, on the other hand, a legitimate scientific question. This does not preclude the possibility that you may be invited to make recommendations based on the comparative assessment of risks from pre-determined options.

My colleagues in the scientific secretariat are vigilant to this problem but I would also ask you to be careful to ensure that your opinions do not go beyond the realms of objective scientific advice.

The new scientific committees and their coordination

A few words about the new committees and their coordination. The recent Commission Decision setting up the three new committees took into account the experience of the work since 1997 and the needs of the Commission's services for scientific advice over the next 3 to 5 years. The mandates of the Scientific Committee on Consumer Products (SCCP) and the Scientific Committee on Health and Environmental Risks (SCHER) have been refined but remain rather close to those of their predecessors, the Scientific Committee on Cosmetics and non-Food Consumer Products (SCCNFP) and the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE).

The Scientific Committee on Newly Identified and Emerging Health Risks, the SCENIHR, however represents a new approach. It is designed to provide the Commission with the flexibility to manage, in principle, any kind of risk assessment that is not in the competence of another Community body. The impossibility of

establishing a permanent Committee having all possible expertise led to the proposal to have a Committee with a relatively small number of core members but which makes extensive use of the expertise in the other two committees and of associated members whose names have also been published in the Official Journal. The major innovation here is that the associated members appointed by the SCENIHR, have exactly the same rights and responsibilities as the permanent members for a specific question.

Of course, no structure is perfect and overlaps of both competence and expertise will be inevitable. We have therefore placed emphasis on co-ordination between the committees to ensure that they make best possible use of their combined and formidable expertise.

Coordination will be achieved through the three chairs working directly with the Secretariat, the detailed mechanisms being set out in the draft rules of procedure.

Work load and external expertise

Members of the previous Committees will know that participation in a scientific committee can take up a lot of time. I fully appreciate that this is not done for financial benefit although we have been able to secure a small indemnity for your participation at meetings and for Rapporteur work. By way of encouragement for new members, I would say that being a member can't be too bad, given the number of previous members who re-applied!

We actively encourage you to make best use of external experts and to benefit from the enormous reservoir of expertise in the Community and beyond, if necessary. Whilst it is important that your advice is seen to the best that can be obtained at today's state of the art, you must always remember that the Committee remains responsible for the opinions it adopts.

The next 2 days

The next day and a half will provide an opportunity for you to meet each other. You will be invited to examine and to adopt the common rules of procedure which will guide your work, to elect your chairs and vice-chairs and, importantly, to adopt your work programmes and meeting schedules for the next 12 months.

Closing remarks

Let me close then by thanking you for agreeing to contribute your expertise to ensure that the Commission and the broader Community get the best available scientific advice on a wide range of important questions. I also wish to express my sincere hope that you will all also enjoy a high level of professional satisfaction in your work over the next three years.