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TECHNICAL REPORT

Intermediate evaluation of Directorate-General Health and Consumer Protection non-food scientific committees

Final report

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Prepared for the European Commission

The research described in this report was prepared for the European Commission.

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Executive summary

This report describes the findings of an intermediate evaluation exercise of the SANCO non-food Scientific Committees:

- The Scientific Committee on Consumer Products (SCCP);
- The Scientific Committee on Health and Environmental Risks (SCHER); and
- The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

The Scientific Committees exist to provide the Commission with sound scientific advice to prepare policy and proposals in the areas of consumer safety, public health and the environment.² The Committees also draw the Commission's attention to new or emerging issues which may pose an actual or potential threat.³

This intermediate evaluation assesses the value of the advice of the Scientific Committees in the Commission decision-making process, and will also guide the Commission Services in the renewal of the Membership of the three Committees in 2007 and in a possible revision of the rules of procedure of the Scientific Committees.

DG SANCO specified the evaluation issues and the questions to be covered under these evaluation issues. The evaluation is based on information gathered from document review, five case studies, and interviews with selected informants.

The Commission specified that the scope of this intermediate evaluation would not include references to the use of scientific advice in policy-making outside SANCO. In order to further assess the value of the Scientific Committees, we suggest that if a full evaluation were to be conducted it should have a wider scope than this intermediate evaluation. In evaluation practice it is common to compare performance of the system under review relative to a counterfactual or to external benchmarks.

This Executive summary first presents the key findings of this study (A) and the recommendations for DG SANCO (B). Thereafter, it summarises the case studies (C) conducted as part of this intermediate evaluation, and summarises the views of interviewees (D).

² Specified in Articles 152 and 153 of the Treaty establishing the European Community.

³ DG Health and Consumer Protection (2006) Scientific Committees. Available at: http://ec.europa.eu/health/ph_risk/Committees/Committees_en.htm. Accessed on: 23.06.06.

A. Key findings

Below, we provide a summary of our findings, based on an assessment of the research and evidence presented in this intermediate evaluation.

1. **Good working relationships exist between the Committees, the Secretariats and the Commission Services.** These three groups rely on each other to provide scientific advice to inform risk management. The collaboration and cooperation between the Committee Members, the Committee Secretariats and the Commission Services appears to be working well.
2. **The Committees function effectively, but there is concern about the future availability of scientists.** Currently, the relevant conditions are met for the Scientific Committees to function effectively within the Commission's overall system: Committee Members possess the necessary knowledge, expertise and reputation, and apply these independently under the rules, terms and conditions set by the Commission. However, there are some concerns about the future sustainability of the supply of scientific Members to fulfil the Committees' tasks. This may lead to the current arrangements being unable to provide the necessary scientific advice adequately in the future.
3. **In some cases, Committees are reliant on external experts to get crucial work done.** Committees often use external experts to boost their capacity and thereby produce Opinions more effectively. Participants in the research consider the use of external experts to be good practice because they provide expertise that supports the soundness of the scientific advice, although there can be logistical obstacles to ensuring their involvement in the Committees' work. Independence is crucial in this regard; external experts often have multiple and various affiliations. It may be difficult in some cases to balance the trade-off between expertise and potential conflicts of interest.
4. **The importance of separating risk assessment and risk management is acknowledged, but sometimes the separation can be difficult to accomplish.** Those involved in the Commission's scientific advice system express an appreciation of the necessity of separating risk management considerations from the risk assessment perspectives taken by the Scientific Committees.⁴ However, application of scientific advice to legislation and policy comment is sometimes difficult because the advice necessarily avoids making practical recommendations.
5. **Scientific secretaries may sometimes face a high administrative workload, compared to scientific work.** If scientific work of the Secretariats is being "crowded out" or put under pressure by administrative work, it is reasonable to ask (a) whether all the elements of the administrative work are necessary, (b) if so, whether they can be done more efficiently, and (c) what the optimal allocation of work between scientists and administrators is, given the different interests involved.
6. **It is important to ensure that the data on which Opinions are based are of good quality and are submitted in a timely manner.** The late submission data (or the

⁴ The concepts of risk assessment and risk management are defined in Section 4.2.

timely submission of poor quality data) can delay the process of producing an Opinion, or prevent a Committee from reaching a conclusion altogether. There are concerns whether the Commission has adequate resources to check the comprehensiveness of data submissions to the Committees. When literature reviews are conducted, they are funded by the Members themselves, and currently it may not be possible for them to be comprehensive.

7. **The resources needed to enable the Scientific Committees to improve on their current performance may not be affordable or available.** Increased time (and financial) resources might expand the capacity of the Committees and potentially thereby improve the quality of the protection from avoidable harm provided to Europe's citizens. In particular, some interviewees stated that pressure of time and/or resources may reduce the scope of literature searches and affect the ability to identify gaps in data submissions.
8. **The formulation of Requests for Opinions⁵ could be improved.** Formulating questions to put to the Committees appear to be particularly difficult when (a) the working language (English) is not the first language of many of the people involved, (b) the subject matter of the investigations demands the use of highly technical, specialist vocabulary, and (c) the boundary between risk assessment and risk management is unclear.
9. **Experiences with public consultations have been positive.** Public consultations have the potential to generate more useful information to be considered, signalling the Commission's interest to a wider audience, and enabling views and concerns to be aired that can help the Committees to formulate more coherent advice. On this evidence, the possibility of extending the role of public consultations merits investigation.
10. **There are opportunities to improve the Committees' relationship with the European Chemicals Bureau, but it may be advisable to delay taking actions to do so.** SCHER Opinions seem to rarely have a major impact on the work of the European Chemicals Bureau, since the main issues have often already been clarified by the time of SCHER's involvement. Further, there were recommendations that the flow of information between the two bodies could be improved. However, the proposed creation of the European Chemical Agency means that it may be better to delay any such attempts until the new Agency is fully functioning, which is projected to occur in 2008.

B. Recommendations

Based on these key findings, we have developed the following recommendations (a) to guide future evaluation of the Scientific Committees, (b) to further improve the functioning of the Scientific Committees, and (c) to provide better insights on risk assessment. It is important to read the findings and recommendations in full awareness

⁵ Requests for Opinions may also be referred to as "mandates".

that they have not been tested against external benchmarks such as other examples of scientific advice and risk assessment or risk management systems used by national governments, as such a comparison was beyond the scope of this study.

Improve the sharing of information across the Scientific Committees and other advisory bodies. Although the functioning of the Committees is currently effective, (as stated in Finding 2), it could be further improved if the Commission set up more opportunities during each year to enable some Committee Chairs, Vice-Chairs, Members and Scientific Secretaries (as appropriate) to meet and establish, in relation to their priorities, how to improve (a) their methods of working; (b) their sharing of scientific and operational knowledge; and (c) the learning across the Committees and other advisory bodies through improved information flows.

Increase the impact of Scientific Committees' work (Scope). Increasing the impact of the Committees' work may further stimulate scientists' desire to act as external experts and Committee members (addressing Findings 2 and 3). Therefore, a full evaluation of the Scientific Committees should include a selective review of the impact of the Committees' Opinions where the risk issues were of high visibility, or involved important timing considerations. This would identify where greater precision and focus could increase the impact of the Committees' work.

Increase the impact of Scientific Committees' work (Dissemination). As noted above, increasing the impact of the Committees could address the issues raised by Findings 2 and 3 (the future availability of scientists, and the importance of external experts). With this in mind, the Commission should take the following steps to improve the dissemination of the Committees' work: (a) identify the target audiences and prioritise them in terms of achievable impact; (b) ensure the form and content/language style of messages is fit for purpose, is readable and intelligible to non-specialists, and uses consistent language; (c) select channels of communication that are readily accessible to, and actively used by, target audiences; (d) monitor uptake and impact of the messages, and revise practice in the light of experience.

Avoid Scientific Committees commenting on risk management issues. With respect to Finding 4, at early stages of work on an issue, well before an Opinion is ready, and periodically thereafter, the Commission Services, Committee Members and Committee Secretariats should explicitly check whether four principles are being adhered to: (a) Scientific Committees should not be asked to comment on risk management issues by the Commission Services, or anyone else; (b) they should always decline to give comments on risk management issues if asked to do so; (c) they should never volunteer on their own initiative to give comments on risk management issues; and, furthermore, (d) the Commission Services should not accept comments on risk management issues, or statements of advice about risk management issues from Scientific Committees. It should be put on the record either that they are adhering to these principles, or if they are not, what steps are taken to correct the situation.

Review the work of the Committee Secretariats. With respect to Finding 5, the suggested focus of a recommended review of Committee Secretariats is as follows: (a) for each Committee and the Inter-committee Co-ordination Group, establish what operational tasks are essential for delivering their remits efficiently and effectively; (b)

establish who could most efficiently and effectively accomplish each task (e.g. by asking “Is this task best performed by Committee members, Commission Services staff members, Scientific Secretaries or Administrative Secretaries?”); (c) establish where the obstacles to efficient and effective working arise in each Committee/ICG; (d) if improvements can be identified, explain these and design an appropriate implementation programme.

Review the allocation of responsibilities to further ensure the data on which Opinions are based are of good quality and are submitted in a timely manner. As Finding 6 states, the timeliness and quality of data used in the Opinion process are crucial factors. Therefore, one means of addressing these factors could be to more clearly delineate and systematise responsibilities for the following two tasks: 1) Data submissions –checking that data submissions are complete and ensuring that they are provided on schedule; and 2) Literature searches –searching for data in the public domain and providing them to the Committees in a standard format, using a formalised weight of evidence evaluation. Doing so may require the Commission to facilitate a constructive and firm discussion between representatives of the Commission Services, Scientific Committees, industry bodies and consumer bodies.

Consider increasing the time and human resources available for the Scientific Committees. As noted in Finding 7, interviewees commented that time and resource pressures may adversely affect their ability to carry out literature searches and data quality checking. Viable means of improving this situation include increasing the time available to produce the Opinions, and increasing the human resources available to produce the Opinions. The findings suggest that the current length of the process is satisfactory. Therefore, the Commission could consider increasing its investment in the Opinion process to increase the research and administrative support available. Following on from the previous recommendation, it may be that these resources would be best used to create a system to improve data submissions and literature searches.

Ensure the division of labour between Commission Services and Scientific Committees is appropriate when formulating Requests for Opinions. With respect to Finding 8, at the early stages of work on an issue, and periodically thereafter, the Commission Services, Committee Members and Committee Secretariats should explicitly check whether the way work is allocated between them is entirely appropriate, and whether anything could compromise the Committee’s independence. They should put on the record either that there are no such issues, or if there are, what steps have been taken to correct the situation.

C. Case studies

The case studies brought to light specific issues that demonstrated how effectively the Scientific Committees operate. Five case studies on different areas were conducted by systematically studying documents (provided by the Commission) that were relevant to the process of producing the Opinions in question. These case studies were used to inform discussions in the subsequent informant interviews. These discussions provided specific examples of practice, which were incorporated into the interviewee findings that informed our recommendations. An overview of the case study-specific evaluation issues follows.

Tooth whiteners

Separation between risk assessment and risk management is crucial but sometimes problematic. The role of SCCP and the other Scientific Committees is strictly limited to risk assessment, providing scientifically sound Opinions that inform the relevant Commission Service in charge of risk management.

Scientific Opinions are relevant for legislation. Industry was seeking to raise the permitted level of a hydrogen peroxide in tooth whitening products. The SCCP's Opinion stated that there was a lack of good clinical data and epidemiological studies. SCCP provided industry with a framework for the studies requested and helped the Commission to increase the pressure on industry to guarantee the timely delivery of adequate data.

This Opinion was highly relevant for stakeholders. The request for an Opinion was driven by industry's interest in authorising distribution of products with a higher level of hydrogen peroxide. Such industry-driven requests are characteristic of SCCP work.

Hair dyes

There is ongoing evaluation of the numerous substances found in hair dyes. Findings about potential health threats associated with hair dye substances have provoked growing interest and scientific attention to assess the actual risk to consumers and hair care professionals. Evaluations of hair dye substances have resulted in successive changes in the guidelines for assessment of hair dyes.⁶

Industry plays a pivotal role in providing information. The hair dye products containing substances under investigation have wide commercial use and significant financial value. Industry does not always provide full information according to SCCP requirements. This has led to SCCP's attempt to create a list of hair dye substances approved for safe use by SCCP.

The work of SCCP has made a significant contribution to knowledge and practice. The findings emerging from the experiments and trials for hair dye substances have contributed to scientific knowledge in the field of consumer product safety.

Indoor air

Even Opinions with a specific focus in the mandate⁷ can have a wide impact. The mandate for the Air Fresheners was specifically to assess a particular report by the European Consumers' Organisation (BEUC). However, the Air Fresheners Opinion will have an impact on Commission Services dealing with Consumer Protection, Environment and Enterprise.

There is a pragmatic approach to adherence to and enforcement of deadlines. A 6-month deadline was requested for the production of the Air Fresheners Opinion, which was not met because the Plenary Meeting decided that further work was required. This demonstrates the Commission's general view that the emphasis should be on producing a

⁶ DG ENTR Second Step on Evaluation of Hair Dyes, Minutes of 5th SCCP Plenary Meeting. Available at: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_mi_005.pdf, p.2.

⁷ Mandates may also referred to as "requests for Opinions"

high-quality Opinion that will have an impact, even if this is produced a few months after a requested deadline.

The air fresheners Opinion touched on issues that were topical and had media impact. The Air Fresheners Opinion was particularly topical and SCHER was entering an area of controversy by producing this Opinion. Publicity around the Opinion led to BEUC withdrawing a legal appeal and issuing a press release calling for more research into the health effects of air fresheners.

Chemicals

Opinions on Risk Assessment Reports (RARs) follow a standardised and straightforward procedure. Member States prepare RARs on priority substances, which are then examined by the Technical Committee under the Council Regulation 793/93. Opinions on RARs follow a clear standardised structure and are relatively concise.

RAR Opinions have limited impact, but improve confidence. The fact that RARs are assessed by SCHER provides an indirect value because such an Opinion issued by an independent scientific body is highly valued in the outside world and strengthens the credibility of the conclusions of the RARs.

Some Opinions have significant relevance for legislation. The Scientific Opinion produced on this substance has been referred to in a proposal for a Directive of the European Parliament and of the Council presented by the Commission.⁸

Nanotechnology

The nanotechnology Opinion was particularly timely. The Royal Society in the UK had published its report on Nanotechnologies in 2004; the EU Action Plan for nanotechnologies had been adopted in June 2005; and the Nanotechnology Opinion was produced in October 2005.

The process involved consultation between Directorates General regarding the mandate. Since nanotechnology is an “enabling” technology that potentially affects many DGs, the nanotechnology mandate was the subject of consultation between several different DGs, which were allowed input into the questions to ensure that the resulting questions addressed their respective responsibilities.

Scientific “background” constituted a large proportion of the Opinion. Nanotechnology is a large topic and an evolving field, and the Opinion contained a broad overview of the current state of knowledge relating to the area.

The Opinion resulted in outputs for research and policy work. The Nanotechnology Opinion clearly stated where additional research was necessary, thereby linking with colleagues at DG RESEARCH. The publication of the preliminary Opinion was used by various Commission Services and provided a useful input for activities stipulated in the nanotechnology action plan.

⁸ Proposal for a Directive of the European Parliament and of the Council, relating to restrictions on the marketing and use of perfluorooctane sulfonates (amendment of Council Directive 76/769/ECC).

D. Views of interviewees

The findings from interviews are structured according to the six evaluation issues specified by the European Commission and a seventh category, “specific issues raised”. This section summarises the responses to the interview core questions, specified in Appendix D. It must be emphasised that these findings and recommendations are the subjective views of the 26 interview respondents.

Efficiency/timeliness

- The Commission Services concerned judge the overall efficiency of the process leading to the adoption of an Opinion as acceptable, provided that Committee Members have sufficient time to do their part of the work.
- Opinions are generally adopted in 4-6 months.
- When deadlines are given, generally they are complied with.
- **Recommendation:** Consider modifying the structure of the Committees to produce a system whereby a core membership has general oversight of Committee operations and is responsible for Opinion quality, supported by an associated pool of scientists selected to work on particular issues.

Value of Scientific Opinions (relevance)

- The Opinions of the Scientific Committees respond sufficiently to the questions asked by the Commission Services, provided that the mandate is clearly written. Requests for clarification from the Commission Services can be minimised at draft Opinion stage by close sharing of information earlier on, while the work is in progress.
- There are concerns that the separation between risk assessment and risk management is not always fully respected, and all three parties (Scientific Committees, Secretariats and Commission Services) may be responsible for this situation.
- **Recommendation:** It is important to recognise that Opinions cannot necessarily be translated directly into policy statements.
- **Recommendation:** Where information provided to Committees is insufficient or unsatisfactory, a Preliminary Opinion could be issued.

Value of Scientific Opinions (impact)

- From a scientific viewpoint, the Committees’ work (which involves secondary analysis of existing research) adds to the body of knowledge and identifies areas for further research.
- The Opinions tend to be rather cautious in their approach and conclusions, which may make it more difficult to translate their content into legislation/policy.
- However, the Committees receive no systematic information about what happens in the subsequent stages of the process, or what impact their work has on legislation and policy.
- **Recommendation:** Publicise Opinions in the scientific community to a greater extent.

- **Recommendation:** There ought to be a mechanism whereby a question is modified in order to remove elements that might lead to a consideration of risk management issues.
- **Recommendation:** The Secretariat is crucial in this regard, and should take a lead in assessing whether a question could lead to risk management matters.
- **Recommendation:** Consider a proactive, risk-scanning remit for the Committees, alongside their current responsive mode of work.
- **Recommendation:** Monitor the impact of Opinions and report back to the Committees.

Coherence

- It is problematic to compare processes across Committees because each deals with different types of data that require differing mechanisms of processing these data.
- The Inter-committee Co-ordination Group has a central responsibility for the ensuring coherence between the Committees. However, it has little impact in tackling issues beyond operational ones.
- Coherence is hampered by varying approaches and styles to the formulation of Opinions.
- Contact and collaboration between the Committees and other advisory bodies can be rather limited, and the Committees are rarely consulted by such bodies. The meeting of Chairs is a useful initiative that will improve the coherence between Committees and other advisory bodies and therefore should be continued.
- Committees attempt to work consistently over time. Continuity is helped by the fact that some Committee Members were engaged in work for predecessor Committees, and thus have knowledge of past Opinions.
- **Recommendation:** It would be helpful to standardise the use of terms between Committees.
- **Recommendation:** Improve the exchange of information both between the Committees and between these Committees and other bodies involved in risk assessment.

Confidence in the soundness of Scientific Opinions

- There is a high level of confidence in the scientific soundness of the Opinions. The attitude of the external stakeholders has not been measured directly in this evaluation; the Commission Services and Committees think that Opinions are generally recognised and respected by most stakeholders.
- Public consultations are useful for increasing the soundness of Opinions.
- External experts are useful for improving the confidence in the soundness of Scientific Opinions.

- **Recommendation:** Where appropriate, Scientific Committees should use public consultations more often, to attract valuable scientific contributions and improve the acceptance of an Opinion.
- **Recommendation:** Where difficulties may arise when using external experts, resolve these as appropriate.

Independence and transparency

- The Commission Services are satisfied with the level of independence and transparency of the Scientific Committees. The Commission Services do not try to influence the Committees. Transparency is satisfactory to the Commission Services, Secretariats and Committees, although Working Group Minutes are not published.

Interface between the Commission Services and the Scientific Committees

- The Commission Services are satisfied with the flow of communication with the Committees, and with the two-way feedback. Some minor criticisms were made of Secretariats' ability to distribute documents in a timely and swift manner.
- Contact between the Commission Services and Committees is constructive in the formulation of mandates.
- Participation by Commission Services during Working Group and plenary meeting discussions is satisfactory.
- **Recommendation:** Formalise discussions preceding the final mandate between Commission Services and the Scientific Committees.
- **Recommendation:** Consider increasing the (administrative) staff available to the Secretariats.

Other specific issues raised

- The situation with regard to submission of dossiers and data differs from Committee to Committee. Sometimes dossiers contain missing or poor quality data, in particular for SCCP. This can require the Secretariats to embark on a time-consuming scanning process.
- SCHER and SCCP work with documents that are supplied to them, although their scientists do conduct research themselves. When the scientists conduct such research, the rationale they use to judge whether a piece of evidence should be included in their research (or not) is not transparent.
- When judging the quality of studies, SCHER tends to consider that studies that adhere to OECD or European guidelines have a higher quality.
- A Technical Guidance Document for Persistent, Bio-accumulating and Toxic assessments is being developed.
- Reimbursement of travel costs to Committee Members is too slow.
- New cohorts of Members may need to be found in the near future. If recognition of the contribution of Members to the work of the Committees is recognised more

generously; this will help to attract high calibre people with the right knowledge and experience.

- Achieving English language clarity can sometimes be difficult.
- **Recommendation:** The submission of information prior to the start of the work on an Opinion should be formalised, and it should be subject to a deadline.
- **Recommendation:** Stronger and clearer guidelines for industry submissions are needed; sanctions should be applied if the required data are not provided.
- **Recommendation:** It would be useful to have a mechanism for collecting, collating and even checking the quality of the data and information. The Committees need a transparent, standardised approach to evaluate the weight of items of evidence to improve the quality and value of Opinions.