

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

Final report

Ruth Levitt, Stijn Hoorens, Michael Hallsworth,
Jennifer Rubin, Lisa Klautzer

TECHNICAL 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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Preface

The objective of this report is to describe the work and findings of the intermediate evaluation of SANCO non-food Scientific Committees. The remit of the research was set by the terms of reference to assess the value of the Scientific Committees in the Commission decision-making process. Since this was an intermediate evaluation without using external references, its aim was to draw findings from interviews, documents available from the Commission and its website, and five case studies. With this internal reference as the defining parameter for the scope of the study, the findings and recommendations reported here respond to the evaluation questions set by the Commission, through expert analysis and synthesis of the information and data collected during the course of the research.

In addition to the Commission and the relevant bodies, the report should be of interest to other policymakers and researchers who are concerned with using scientific advice in policy making processes, as many findings and recommendations may be applicable to other contexts than those of the three evaluated Scientific Committees.

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Abbreviations

BEUC	Bureau européen des unions de consommateurs (European Consumers' Organisation)
COLIPA	European Cosmetic Toiletry and Perfumery Association
DG	Directorate General (of the European Commission)
DG ENTR	Directorate General for Enterprise and Industry
DG ENV	Directorate General for Environment
DG RESEARCH	Directorate General for Research
DG SANCO	Directorate General for Health and Consumer Protection
EC	European Commission
ECB	European Chemicals Bureau
ECA	European Chemical Agency
EFSA	European Food Safety Authority
EU	European Union
GLP	Good Laboratory Practice
ICG	Inter-committee Coordination Group
JRC	Joint Research Centre (of the European Commission)
OECD	Organisation for European Cooperation and Development
PBT	Persistent, Bio-accumulating, Toxic
PM	Particulate Matter
RAR	Risk Assessment Report
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCNFP	Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers
SCCP	Scientific Committee on Consumer Products
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
TGD	Technical Guidance Document

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Finally, we are grateful to our colleagues at RAND, Dr Chris van Stolk and Prof Tom Ling, who provided useful and insightful comments during the Quality Assurance process.

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.

On March 3 2004, the Directorate General for Public Health and Consumer Protection (SANCO) of the European Commission established three Scientific Committees. The Scientific Committees exist to provide the Commission with the sound scientific advice it needs when preparing policy and proposals in the areas of consumer safety, public health and the environment.⁹ The Committees also draw the Commission's attention to new or emerging problems which may pose an actual or potential threat.¹⁰ These Committees are:

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

In its decision to establish these Committees the Commission stated that the Scientific Committees' scientific advice should be based on the principles of "excellence, independence and impartiality, and transparency".¹¹

The Commission has decided to obtain an intermediate evaluation to assess the value of the advice of the Scientific Committees in the Commission decision-making process. This evaluation will also guide the Commission Services for the renewal of the Membership of the three Committees in 2007 and for a possible revision of the rules of procedure of the Scientific Committees.

As specified by the European Commission in the Terms of Reference dated 10 March 2006, this is a limited, internal evaluation exercise, restricted to Members of the Scientific Committees, Secretariats of the Scientific Committees, and the relevant Commission Services in SANCO and other DGs. SANCO has specified the evaluation issues for this research. The Commission has also specified questions to be covered under these evaluation issues. The evaluation is based on information gathered from interviews, documents and five case studies. The Commission specified that the scope of this intermediate evaluation would not include references to the use of scientific advice in

⁹ Specified in Articles 152 and 153 of the Treaty establishing the European Community.

¹⁰ DG Health and Consumer Protection (2006) Scientific Committees. Available at: http://ec.europa.eu/health/ph_risk/Committees/Committees_en.htm (accessed June 23rd 2006).

¹¹ Commission Decision of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment (2004/210/EC), paragraph 7. Online at http://eur-lex.europa.eu/pri/en/oj/dat/2004/l_066/l_06620040304en00450050.pdf (accessed October 5th 2006).

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 would require expanding the evaluation scope to include a comparison of the functioning of the SANCO Scientific Committees with a representative set of other scientific advice systems. This could be informed by reviewing literature on systems in which scientific advice is used in the policy process. In addition, longitudinal analysis of a set of performance indicators could inform the assessment of the Scientific Committees' performance over time.

In order to further assess the value of the Scientific Committees, we suggest that a full evaluation would need to be set against external benchmarks, provide longitudinal analysis, or both.

The report presents the material in the following order. The following chapter elaborates on the scope and methodology of this intermediate evaluation. The findings from case studies are described in Chapter 3, followed by the views of interviewees in Chapter 4. An assessment of the key findings is presented in Chapter 5, and the report concludes in Chapter 6 with a set of recommendations that follow from the collected evidence. Four appendices have been included, which have details of (A) documents consulted, (B) respondents' affiliations, (C) process map of providing an Opinion, and (D) Interview core questions.

2.1 **Objective of the evaluation**

The objective of this interim evaluation is to assess the value of the advice of three non-food Scientific Committees in the Commission decision-making process. This evaluation will also provide evidence to guide the Commission Services:

- for the renewal of the Membership of the three Committees in 2007;
- a possible revision of the legal framework; and
- a possible revision of the Rules of Procedure for the Scientific Committees.

2.2 **Scope of the evaluation**

The evaluation is based on information gathered from interviews, contacts, documents and five case studies (tooth whiteners, hair dyes, chemicals, air quality, nanotechnology), with the Commission Services responsible for putting questions to the Scientific Committees, Members of Scientific Committees and the Commission's Scientific Secretariats. The design and scope of the evaluation are specified in the Terms of Reference dated 10 March 2006 as amended, together with guidance from the Evaluation Manager. This evaluation covers the period from the decision of March 2004 when the three Committees were set up by Commission Decision 2004/210/EC.

2.3 **Work plan**

We have organised this work into four separate tasks:

Task 1. Document review. What is the current practice of the three Scientific Committees that provide scientific advice to the European Commission? Based on general documentation and documentation associated with five case studies we provide an overview of the current practice of the Scientific Committees. These documents are listed in Appendix A.

Task 2. Interviews. What are the views of different interviewees on the current practice of the three Scientific Committees that provide scientific advice to the European Commission? Based on interviews discussing the five case studies and general issues we

provide an overview of the current practice of the Scientific Committees and the perceptions of their value. We interviewed the Scientific Committee Members, Members of the Scientific Secretariats, and the Commission Services involved in the five case studies. The affiliations of the respondents are listed in Appendix B.

Task 3. Analysis and internal synthesis workshop. What is the value of the advice of the three Scientific Committees in the Commission decision-making process? In an internal workshop we consolidated the evidence gathered in Tasks 1 and 2 to provide an objective overview of the current practice of the three Scientific Committees.

Task 4. Reporting. Preparation and delivery of the interim and (draft) final report to the Commission (Unit C7). These reports describe all findings from the previous three Tasks.

2.4 Evaluation issues

The Terms of Reference specified that the following issues should be investigated:

1. Efficiency and timeliness
2. Value (relevance and impact)
3. Coherence
4. Confidence in the soundness of Scientific Opinions
5. Independence and transparency
6. Interface between the Commission Services and the Scientific Committees
7. Input from Scientific Committee Members on the relevant questions.

For each of the evaluation issues, we have distinguished between three different perspectives: 1) Scientific Committees, 2) Commission Services, and 3) Scientific Secretariats. Consequently, the seventh issue “Input from Scientific Committee Members on the relevant questions” has been incorporated into the other six issues. Instead, we have included a category covering other specific issues arising from the case studies and interviews. In Chapter 4 these seven issues are operationalised and explained in more detail.

2.5 Methodology

To assess the value of the advice of the three non-food Scientific Committees on each of the evaluation issues, we have used several methods to gather evidence: 1) case studies; 2) document review; 3) process mapping; and 4) semi-structured interviews. These methods are briefly explained below.

2.5.1 Case studies

We have reviewed the current practices in the Scientific Committees by looking in detail at five case studies, to illustrate the breadth of the remit of the Committees:

1. Tooth whiteners (SCCP);

2. Hair dyes (SCCP);
3. Indoor air (SCHER);
4. Chemicals (SCHER); and
5. Nanotechnology (SCENIHR).

Committee activities from September 2004 to the start date of this intermediate evaluation in these five areas are distributed as shown in Table 1. Hair dyes and chemicals have had the most requests for Opinion. For the purpose of this evaluation we selected a maximum of four Opinions per case study. They have not been selected for their typicality, but rather because they reveal in detail the processes and activities and allow a deeper analysis. These selections were agreed with the advice of the Evaluation Manager.

For the Chemicals case study, four Opinions were selected. These were selected based on availability of material, and on the fact that Opinions on the four selected chemicals take account of the full decision making process from the request for Scientific Opinion of the legislative unit (or mandate or term of reference to the question), to Scientific Opinion and on to follow-up in the legislative process.

For hair dyes, four Opinions were selected to represent a range of types of Opinions, and were initiated and completed within the scope of this evaluation. Additionally, *Lawsonia inermis* (Henna) is a debated and sensitive issue. It has a long history of traditional use, especially amongst ethnic groups. The evaluations may pose a particular challenge for the managers.

Using a process mapping technique (further explained in Section 2.5.3) we have tracked the activities of the included Opinions for each of the case study areas. This enabled us to study the Opinions' life cycles and the issues that arose during this process. Consequently, issues specific to each case study were identified and pursued in interviews.

Table 1. Activities in case study areas

Case study area	Activities in Scientific Committees	Selected Opinions
Chemicals	<ul style="list-style-type: none"> ▪ 27 requests for Opinions ▪ 18 adopted Scientific Opinions ▪ Discussion in each plenary meeting 	<ul style="list-style-type: none"> ▪ Anthracene ▪ 2-butoxyethanol acetate ▪ Butoxyethanol ▪ Perfluorooctane
Indoor air	<ul style="list-style-type: none"> ▪ 1 request for Opinion ▪ 1 adopted Scientific Opinion ▪ Discussion in several plenary meetings 	<ul style="list-style-type: none"> ▪ Emission of chemicals by air fresheners
Hair dyes	<ul style="list-style-type: none"> ▪ Approximately 80 requests for Opinion ▪ Approximately 15 adopted Opinions ▪ Discussion of multiple substances related to hair dye decisions at each plenary meeting 	<ul style="list-style-type: none"> ▪ Isatin ▪ Acid blue 62 ▪ Personal use of hair dyes and cancer hazard ▪ Lawsonia inermis (Henna)
Nanotechnologies	<ul style="list-style-type: none"> ▪ 1 request for Opinion ▪ 1 adopted Scientific Opinion ▪ A 'Public Consultation' with 78 responses ▪ Discussion in several plenary meetings 	<ul style="list-style-type: none"> ▪ The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies
Tooth whiteners:	<ul style="list-style-type: none"> ▪ 1 main request for Opinion ▪ 1 adopted Scientific Opinion ▪ 1 public consultation with 26 detailed substantive scientific responses ▪ Discussion in several plenary meetings 	<ul style="list-style-type: none"> ▪ Hydrogen peroxide in tooth whitening products

Examples from the case studies are provided in this report to illustrate the preliminary findings. A brief background to the case studies and summary of the issues specific to these areas is provided in Chapter 3.

2.5.2 Document review

We have analysed relevant documents produced during the stages of providing an Opinion. We have reviewed the documents available in each of the case study areas in relation to the evaluation issues mentioned in the previous section. These documents included (if available):

- Requests for Opinion (Mandate);
- Draft Opinions;
- Adopted Opinions;
- Minutes of plenary meetings;
- Responses to public consultations;
- Press releases; and
- Correspondence between Commission Services, Committee Members and Secretariats.

In addition to documents specific to the case studies, we have reviewed a number of documents relevant to the general operations of the Scientific Committees. They have been used as input to the process mapping exercise, and to delineate issues relevant to the evaluation to be addressed during the interviews. These general documents included:

- Rules of Procedure (C7(2004)D/370235, 7 September 2004);
- Standard Operating Procedures (2004/201/EC, 24 April 2006) including Annex V Requests for Scientific Opinions from the non-food Scientific Committees: Guidelines for Commission Services;
- Minutes of the Meeting of the Chairs (7-8 December 2005);¹² and
- Minutes of the Meetings of the Inter-Committee Coordinating Group.¹³

The documentation that we used for this intermediate evaluation has either been provided by the Commission, or is available on the SANCO website. A full list of the documents we consulted is provided in Appendix A.

2.5.3 Process mapping

In order to describe and analyse the functioning of the Scientific Committees we have used a process analysis approach as a starting point (Davenport, 1993).¹⁴

Mapping the advice process of the SANCO Scientific Committees serves two objectives. First, the mapping clarifies understanding of the current practices of the Scientific Committees and their procedures; second, the mapping allows the observer to trace the progress of the selected Opinions in the five case study areas and identify specific queries in relation to the evaluation issues.

Using a limited number of symbols representing these processes, their inputs, outputs, and decision points, we have schematically mapped the path towards adopting an Opinion. The Standard Operating Procedures and the Rules of Procedure were the two main sources used for this exercise. We also had to make some assumptions or interpretations based on the context. We numbered the important stages in the process, and identified the relevant information requirements (information attributes) of these stages. The resulting process diagram is briefly discussed and displayed in Appendix C. We discussed a draft of this overall process map with the Evaluation Manager and incorporated those comments in the updated version shown in Appendix C. This has enabled us to link the information gathered for selected Opinions to this map.

2.5.4 Semi-structured interviews

In order to obtain the views of different Commission Services staff members and Scientific Committee Members on the current practices of the Scientific Committees, we conducted a series of interviews. These interviews were organised with three groups involved in the five case studies. These are:

1. Staff of the European Commission Services;
2. Staff of the Scientific Secretariats; and
3. Members of the Scientific Committees.

¹² Available at: http://ec.europa.eu/health/ph_risk/Committees/ev_20051207_en.htm

¹³ Available at: http://ec.europa.eu/health/ph_risk/Committees/coordination/coordination_en.htm

¹⁴ Davenport T. (1993) Process Innovation. Boston, Harvard Business School Press.

The interviewees were selected by DG SANCO prior to submission of the proposal. A letter went to each of the selected interviewees from the Evaluation Manager explaining the study and asking them to make time available to be interviewed. In the interviews, we addressed the evaluation issues specified in Section 2.4. The questions for the interview protocols were specified by the Commission in the Terms of Reference. Additional questions arose during the analysis of the case study material and the general documentation. We consolidated a set of interview protocols tailored to each interview appropriate to the individual's involvement in a case study area and/or general processes. An overview of the general questions (i.e. those not specific to case studies) and the case study-specific questions is available upon request. It must be stressed that these protocols were guidelines not prescriptions; the interviewees were invited to focus on issues that they deemed most important for this evaluation.

Eighteen individuals have been interviewed through face-to-face meetings. They were attended by two RAND Europe analysts, who had specific responsibilities for leading the interview and writing up the interview reports. The relevant analyst then structured and clustered the write-ups of these interviews along the lines of the evaluation issues. The write-ups have been validated with the interviewees, and collated in a separate Project Memorandum.

The interview reports were analysed in Task 3, and findings were clustered under the existing evaluation issues or specific other findings. If many respondents commented on specific aspects of an evaluation issue, sub-issues were identified. Chapter 4 reports on the clustered findings from these interviews.

In order to describe accurately the activities of the Scientific Committees for the purpose of this intermediate evaluation, we have reviewed documents related to five case studies. Additionally, we interviewed Commission Services staff, Committee Members and Secretariat staff who have specific knowledge and expertise in these areas. The case studies brought to light issues specific to these five areas in which the Scientific Committees operate. This section provides a brief background of the five areas and an overview of the case study-specific evaluation issues. All evaluation questions have been investigated in each case study. For reasons of efficiency however, this section only discusses the 3 or 4 most relevant issues.

3.1 **Tooth whiteners**

3.1.1 **Introduction**

The Scientific Committees' involvement in the issue of the use of hydrogen peroxide in tooth whitening products has a long history. The former Scientific Committee on Cosmetics and Non Food Products intended for Consumers (SCCNFP) had already been consulted repeatedly by the Commission Services and expressed its views on the safety of hydrogen peroxide in tooth whitening systems. The initiative to request an Opinion based on additional data was driven by the industry's interest in offering tooth whitening products with up to 6% hydrogen peroxide freely and directly to consumers.

A public consultation was held on the basis of a preliminary Opinion that was subsequently adopted. As the Opinion stated that there was a lack of good clinical data and epidemiological studies assessing the possible adverse effects within the oral cavity, the Commission Services asked SCCP for guidelines on the protocols of such studies. The guidance document by SCCP, which was subsequently adopted, provides the industry with such a framework for the studies to be undertaken according to the Commission's 'Strategy paper for regulation of the use of hydrogen peroxide in tooth whitening products' (05/ENTR/COS/50 Working document Working Group 22 June 2005 "Strategy paper for regulation of the user of hydrogen peroxide in tooth whitening products"). This strategy promotes the provisional allowance of tooth whitening products with up to 6% hydrogen peroxide for a limited period of 3 years. The inclusion of this preliminary allowance in the directive has been proposed but has not yet been adopted.

3.1.2 Case-study-specific issues

Separation between risk assessment and risk management is crucial but sometimes problematic. The clear functional separation between risk assessment and risk management is a fundamental principle to ensure the independence of risk assessment. This separation requires that the processes of risk assessment and risk management as well as the roles of participants are well defined. Against this background the role of SCCP and the other Scientific Committees is strictly limited to risk assessment. Their objective is to provide scientifically sound Opinions that inform the relevant Commission Service in charge of the risk management. The Opinion on Hydrogen Peroxide in tooth whitening Products (SCCP/0844/04) provides a good example of the difficulty of drawing a clear boundary between risk assessment and risk management. The adopted Opinion stated that the “use of tooth whitening products containing > 0.1 to 6.0 % hydrogen peroxide (...) is considered safe after consultation with and approval of the consumer's dentist”. The Commission Services responsible for risk management perceived this rather as an attempt to enter in to risk management terrain. The Commission Services would have preferred a comprehensive list of concerns leaving the decision on how to address these to the responsible risk manager.

Scientific Opinions are relevant for legislation. Another important issue to be highlighted in the context of this case study is the relevance of the Scientific Opinions for legislative activities. In this particular case, industry was seeking to raise the permitted level of a substance (hydrogen peroxide) in tooth whitening products from 0.1 to 6%. The Commission Services requested an Opinion by SCCP. The Opinion stated that there was a lack of good clinical data and epidemiological studies. Subsequently, knowing that the products had been on the US market for 10 years, the Commission Services drafted a “Strategy paper for regulation of the use of hydrogen peroxide in tooth whitening products”. This strategy was based on four pillars: 1) provisional allowance of products; 2) information aspects; 3) monitoring system; and 4) commitment of industry to submit data in order to answer SCCP concerns. Industry agreed to provide data within the established 3- year deadline and handed in some study protocols asking for the confirmation of their appropriateness. The Commission Services had to balance the need to provide industry with a framework for the requested studies (minimising potential arguments about the lack of adequate studies at the end of the 3-year period), while making sure not to lock SCCP a priori into adhering to findings of specific studies (thereby leaving SCCP freedom to assess study results once submitted). Consequently, it was agreed that SCCP would not provide a formal Opinion on the study protocols handed in, but instead would provide a guidance document on the studies to be conducted. The subsequently adopted SCCP guidance document provided industry with a framework for the studies requested according to the Commission's ‘Strategy paper for regulation of the use of hydrogen peroxide in tooth whitening products’ and helped the Commission to increase the pressure on industry to guarantee a timely delivery of adequate data.

This Opinion was highly relevant for stakeholders. The tooth whitening case study presents a clear example of the importance of an SCCP Opinion for stakeholders such as industry and professionals. The request for an Opinion on hydrogen peroxide in tooth whitening products was driven by industry's interest in the authorisation of free distribution of products with a higher level of hydrogen peroxide on the market. Such

industry-driven requests are characteristic of SCCP work that is often triggered by industry submissions regarding a particular substance and its use in cosmetic products. The wider interest in this Opinion was also emphasised by the fact that 24 submissions from a variety of stakeholders (doctors, industry, health care associations etc.) were handed in when the preliminary Opinion was subjected to a public consultation. Such a public consultation is established ad hoc by the Scientific Committee and provides stakeholders with the possibility of submitting material or issuing statements relevant to the Opinion. In this particular case the public consultation did not make a clear contribution to the finally adopted Opinion (very few changes were integrated), but reaffirmed SCCP in its position.

3.2 Hair dyes

3.2.1 Introduction

Hair dyes (now termed ‘hair dye substances’) have been one of the prime areas of focus for SCCP and its predecessor SCCNFP for many years. 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 the many chemical ingredients encompassed within ‘hair dye substances’ have resulted in successive changes in the guidelines for assessment of hair dyes.¹⁵ The guidelines now provide a clear checklist of requirements for submissions and SCCP has recommended that any substances not submitted by industry for evaluation by the Committee should be banned. The requirement that substances be re-evaluated to comply with new guidelines has generated over 100 new submissions by industry. These submissions alone generate an enormous volume of work for SCCP relative to the other Committees.

Successive changes in guidelines, the incompleteness of a significant proportion of submissions by industry, the inconclusive nature of some of the data, and the attendant ambiguity of certain conclusions in the Opinions, have together meant that there are hair dye substances that have been subject to successive resubmissions and ongoing scrutiny for many years. The sheer volume of work on hair dye substances has dictated that external experts play an important part in evaluating submissions and expediting this process. The hair dye substance evaluations are relevant to several ongoing Working Groups (for example the Working Group on Genotoxicity), in addition to the case-specific ones set up for individual submissions. The Working Group Co-ordinator plays an important role at the interface of the relevant Working Groups in this case.

3.2.2 Case study-specific issues

There is ongoing evaluation of the numerous substances found in hair dyes. The widespread use of hair dyes by the public, combined with the severity of health threats with which such use has been associated (ranging from skin irritations, to allergic reactions, and to a possible link between certain hair dye substances and cancer), have led to ongoing scrutiny of hair dyes by SCCP and its predecessor body SCCNFP. This ongoing scrutiny

¹⁵ DG ENTR Second Step on Evaluation of Hair Dyes, Minutes of 5th SCCP Plenary Meeting, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_mi_005.pdf, p.2

has resulted in successive changes to evaluation guidelines for hair dye substances. The stringent current evaluation guidelines have necessitated reanalysis of some, and investigation of other, substances. SCCP proposed that all substances with absent or inadequate submissions should be subject to a ban. The task of going through all the submissions represents an enormous volume of work for SCCP. The sheer volume of submissions has entailed a significant role for external experts in the evaluation of submissions for hair dye substances. Evaluations of submissions covered content that cut across Working Groups.

Industry plays a pivotal role in providing information. The submissions evaluated by SCCP come from industry. The hair dye products containing the substances under investigation have wide commercial use and therefore represent a significant financial interest for cosmetic companies and manufacturers of their products. The stringent evaluations to which the substances should be subjected include many types of trials and tests clearly delineated in the form of a template of studies to be submitted for each substance. These pro formas for substance submissions also specify or request information about standards to which conduct of the research complied. These standards include Good Laboratory Practice and a range of EC (primarily) and international (occasionally) guidelines. The provision of full information, obtained according to SCCP requirements, is not universal and SCCP has proposed to ban all substances for which full information based on robust data is not provided. Most recently this has led to SCCP's endeavour to create a positive list of hair dye substances approved for safe use by SCCP. The issue of provision of adequate information has important implications for the type and amount of work for SCCP. That is, when submissions are inadequate, time is wasted returning submissions and requesting further studies or further documentation. This inefficiency has led some SCCP Members to suggest that there should be sanctions for industry for poor submissions so that their incentive to produce adequate and 'complete' information is increased.

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. This led eventually to rewriting of the Consumer Products Safety guidance for the EC.¹⁶ Further, this work is now viewed internationally and cited as the 'gold standard' state of knowledge in the field (as evidenced, for example, by reference in media around the world when the banned list was made public in July 2006). There is also evidence that the knowledge gained about the substances and their effects has influenced medical science by improving the ability to diagnose certain skin irritations and reactions, by requiring clear labelling of substances in products and thereby allowing dermatological advice about which substances patients with allergies and sensitivities should avoid.

¹⁶ See: http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/currentGPSD_en.htm

3.3 Indoor air

3.3.1 Introduction

Recently, there has been increased legislative action regarding the issue of indoor air quality. For example, one of the actions included in the EU Action Plan on Environment and Health is to ‘improve indoor air quality’. This context informed the drafting of a mandate for SCHER to examine indoor air pollution. However, in January 2005 (as this mandate was being drafted), the European Consumers’ Organisation (BEUC) produced a report that tested the emissions of chemicals by air fresheners. This report quickly became the focus of debate, and legal action, between BEUC and industry.

The subsequent Indoor Air Request for Opinion had four sections to its Terms of Reference, one of which requested the Committee to produce an Opinion on the BEUC report within a deadline of 6 months. This Opinion formed the basis for the Indoor Air case study. A SCHER Working Group was created, which gave priority to the evaluation of the BEUC report, while also considering wider Indoor Air pollution issues (as stipulated by the remaining three points in the mandate).

The ensuing Air Fresheners Opinion generated press attention, and led to BEUC dropping its legal action. The Opinion has contributed to SCHER’s general Opinion on Indoor Air Pollution, which is scheduled for adoption later in 2006.

3.3.2 Case study-specific issues

Even Opinions with a specific focus in the mandate can have a wide impact. The mandate for the Air Fresheners Opinion was narrow: to assess a particular report by the European Consumers’ Organisation (BEUC). However, this Opinion demonstrates that even Opinions with specifically focused mandates can have wide-ranging consequences. For example, the Air Fresheners Opinion will have an impact on Commission Services dealing with Consumer Protection, Environment and Enterprise. Its conclusions (particularly those on incense) have directly informed the forthcoming general Opinion on Indoor Air. This general Opinion on Indoor Air has resulted in a Commission proposal for the Council and Parliament that now incorporates a 3-year monitoring campaign for PM_{2.5} (a certain size of particulate matter), which stipulates, for the first time, that the nature of this particulate matter must be monitored.

The air fresheners Opinion touched on issues that were topical and media impact. The Air Fresheners Opinion was particularly topical. It analysed a report by BEUC, published in January 2005, which claimed that emission of substances such as volatile organic compounds, sensitising substances and benzene represented serious health concerns. Industry gave the report a critical reception and two companies initiated legal proceedings against BEUC. The District Court at The Hague found against BEUC, which launched an appeal. Thus, SCHER was entering an area of controversy by producing this Opinion. As one informant put it, the issue of Air Fresheners was “huge” when the Opinion was requested, and this general interest was reflected in the 6-month deadline imposed (see Deadlines, below).

The publication of the Opinion was featured as the lead story in ENDS Environment Daily on 7th February 2006.¹⁷ It led to BEUC withdrawing its appeal against the court ruling and issuing a press release that called for more research to be done into the health effects of air fresheners.

There is a pragmatic approach to adherence to and enforcement of deadlines. The BEUC report had caused some alarm amongst consumers and thus an urgent assessment of this report was appropriate. Therefore, a 6-month deadline was requested for the production of the Air Fresheners Opinion. This deadline was not met because the Plenary Meeting decided that further work was required; the Opinion was adopted two months later. This illustrates the comments by informants that the Commission does not have the power to impose a “deadline” in the strict sense of the term, but rather that the schedule for the adoption of an Opinion is subject to negotiation. In this case, the need for the Opinion was not sufficiently urgent to demand the use of accelerated procedures. In addition, the case of the Air Fresheners Opinion demonstrates the Commission’s general view that the emphasis should be on producing a high-quality Opinion that will have an impact, even if this is produced a few months after a requested deadline. There was an acknowledgement that, in the words of one Commission Services staff member, “you have to give people time to do their work”.

3.4 Chemicals

3.4.1 Introduction

SCHER has been involved in the issue of chemical substances from its inception. Since September 2004, it has adopted 18 Scientific Opinions. We studied Opinions on four chemicals that had been suggested by the Commission to take into account the full process (legislative request / Scientific Opinion / follow-up in the legislative process).

The Opinions on Anthracene, 2-butoxyethanol acetate, and Butoxyethanol deal with the assessment of Risk Assessment Reports (RARs). The legal framework for this assessment is provided by Council Regulation 793/93, on the evaluation and control of the risk of existing substances. According to this Regulation, Member States prepare Risk Assessment Reports on priority substances, the reports are examined by the Technical Committee under the Regulation, and the Commission invites SCHER to give its Opinion. The Opinion on Perfluorooctane responded to the request for the assessment of the overall scientific quality of the RPA (Risk & Policy Analysts Ltd) report “Perfluorooctane sulfonate – Risk reduction strategy and analysis of advantages and drawbacks”¹⁸ and the evaluation of the contribution of the ongoing uses of this substance to the overall risks for the environment and to human health. This Opinion was also cited in the 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) presented by the Commission.

¹⁷ See: <http://www.ends.europedaily.com/articles/index.cfm?action=issue&No=2033>

¹⁸ A report prepared for Department for Environment, Food and Rural Affairs and the Environment Agency for England and Wales, August 2004.

3.4.2 Case study-specific issues

Opinions on RARs follow a standardised and straightforward procedure. In this case study, the majority of Opinions are on Risk Assessment Reports. Therefore, it provides insight in the execution of the Council Regulation (EEC) 793/93 on the Control and Evaluation of the Risks of Existing Substances and the preparation of RARs. The role of SCHER in the context of the RARs is clearly formalised; once a RAR has been prepared by the Member States the Joint Research Centre's (JRC's) European Chemicals Bureau (ECB) sends the document with a request for Opinion to SCHER (formally the request comes from DG ENV). As RARs are prepared in accordance with the Technical Guidance Document (TGD) and requests are frequent, this part of SCHER's work is highly standardised. The formulation of the Terms of Reference is straightforward adopting a pre-established phrasing. The significant number of requests for RAR Opinions has led to a well-established routine so that the involved parties (ECB, DG ENV and SCHER) do normally not need clarification in the early stages of the process. If clarifications are needed they are discussed regularly in the plenary meetings (or in complex cases in the Working Group meetings). Opinions on RARs follow a clear standardised structure and are relatively concise. To allow the processing of the maximum number of risk assessments for existing substances the Commission Services have launched attempts to establish a general timeframe of about four months for the preparation of these Opinions.

RAR Opinions have limited impact, but improve confidence. The Opinions of SCHER on RARs are of limited direct relevance for the practical work of the European Chemicals Bureau (ECB). The reason for this is that Opinions do sometimes address scientific issues that do not change the RAR's conclusions in respect of the risk for humans and the environment. This may be interesting from a scientific perspective, but may prove to be irrelevant in practice. Nevertheless, the fact that RARs are assessed by SCHER provides an indirect value as 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. Furthermore, SCHER's Opinions may fulfil a secondary role as they are indicating data gaps and methodological weaknesses that should be addressed by future research. Apart from routine requests for RAR Opinions, the ECB has issued occasional requests for Opinion when it was not clear how to deal with a particular issue. These unusual "non-standardised" Opinions have proved very helpful to the work of the ECB.

Some Opinions have significant relevance for legislation. The Opinion on PFOS (perfluorooctane sulfonate) was not initiated by the elaboration of a RAR. The request for Opinion was issued against the background of the intensive international discussion and the risk assessment strategy elaborated in the UK ("Perfluorooctane sulfonate – Risk reduction strategy and analysis of advantages and drawbacks", by Risk & Policy Analysts Limited). Although PFOS was not a priority substance, it clearly presented a cause for concern. Therefore, it was decided to request the assessment of the overall scientific quality of the report by Risk & Policy Analysts Limited and the evaluation of the contribution of the ongoing uses of this substance to the overall risks for environmental and human health. The subsequent Opinion has been referred to in the 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) presented by the Commission.

3.5 Nanotechnology

3.5.1 Introduction

The EU's Strategy and Action Plan for nanotechnologies underlined the importance of a safe approach to use and development of nanotechnologies, supported by suitable risk assessment. Owing to the scale on which they operate, nanoparticles can offer a particular challenge to existing risk assessment methodologies. Therefore, the Commission asked SCENIHR for an Opinion on the appropriateness of the current risk assessment methods for the products involving nanotechnologies.

Given that nanotechnology is an 'enabling' technology that can affect many different areas, several Directorate Generals were involved in the drafting of the mandate. Similarly, because the issue had a high profile and potentially affects many stakeholders, a Public Consultation was set up, which attracted a high volume of responses. An interviewee said the final Opinion was recognised by the scientific community recognises as a significant addition to knowledge on the issue, and which highlighted significant issues relating to current methodologies. It has also formed the basis for a subsequent mandate by DG Environment (DG ENV) relating to Technical Guidance Documents for nanomaterials.

The nanotechnology Opinion was particularly timely. The Royal Society in the UK had published its report on nanotechnologies in 2004; there had been communications from DG RESEARCH about nanotechnology; the EU Action Plan for nanotechnologies had been adopted in June 2005, and the nanotechnology Opinion was produced in October 2005. In addition, the Opinion was well-received by the scientific community.

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. These DGs were allowed input into the questions to ensure that the resulting questions addressed their various responsibilities. This was judged by Commission Services staff members to be a successful initiative that ensured that the format of the Opinion suited the Commission's requirements.

Scientific "background" constituted a large proportion of the Opinion. Since nanotechnology is a large topic and an evolving field, the Opinion contained an overview of the current state of knowledge relating to the area. This meant that the Opinion had a rather broad scope, and required a judicious editing process by the Working Group to ensure that only relevant material was included. Commission Services staff members claimed that there was a good balance between the extensive space provided in SCENIHR nanotechnology Opinion for the scientific background information, and the pages allocated to answering the Commission's questions specifically. One claimed that the Service recognised that the complexity of the issue demanded a solid explanation, and thus the format of the report suited the Commission Services well.

The Opinion resulted in outputs for research and policy work. The nanotechnology Opinion clearly stated where additional research was necessary, which made a link with colleagues at DG RESEARCH: the Opinion helped in the preparation of the 7th Framework programme specifying where research was needed. In addition, 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. The preliminary Opinion was used in meetings with the Member States, in specific Working Group meetings on different policies such as chemicals regulation, and in an OECD workshop in Washington.

This chapter provides the findings of the interviews conducted with staff members of the Commission Services and the Scientific Committees' Secretariats, and the Committee Members. The findings for each sector of inquiry (Efficiency, Relevance, and so on) are presented in turn. These findings are summarised in the form of answers to the questions set in the Terms of Reference. In addition, RAND Europe has created a final section called 'Other specific issues raised', in which we have placed issues that we decided were best considered separately from the preceding categories, or which do not fit into the preceding categories. The recommendations mentioned in this chapter are those suggested explicitly by one or more interviewees.

4.1 **Efficiency/timeliness**

"Efficiency" was understood to refer to whether the process of producing an Opinion operates in a smooth manner with appropriate mechanisms that are satisfactory for all participants.

How do the Commission Services concerned judge the overall efficiency of the process leading to the adoption of an Opinion? This assessment should cover the process from the initial contact with SANCO C/7 concerning the submission of the mandate up to adoption of the Opinion by the Committee.

The Commission Services judged the efficiency of the process for adopting an Opinion to be acceptable: there were very few comments that gave a purely negative view of process. There was acknowledgement that Committee Members are under time pressures that may affect the efficient operation of the Committee as a whole: not only must Members attend to full-time jobs, but they may have other professional commitments. Therefore, Commission Services were generally of the opinion that Committee Members "must be given time to do their work", on the basis that Members were committed to devoting as much time to producing Opinions as they could spare.

Are, generally, Opinions adopted in a reasonable/acceptable time?

On average, most Opinions are adopted in 4-6 months, although this figure varies between Committees. The Committees are working with the Commission Services to ensure that Opinions are produced in a timely manner. Commission Services staff members acknowledged that the length of time also depends on the subject matter: a wide-ranging, complex Opinion on an emerging topic is likely to take longer than the examination of

one particular substance. It was noticeable, however, that relatively few Commission Services staff members mentioned the fact that the length of time needed to adopt an Opinion is dependent on the timeliness and quality of the information submitted to the Committees. Nonetheless, while the quality of data submitted is an issue that extends beyond that of efficiency and timeliness, and a very important aspect for the functioning of the Scientific Committees, it is further discussed in Section 4.7.

When a deadline is given, are Opinions adopted in a timely manner?

The Commission Services do not have the power to impose a “deadline” in the strict sense of the word. Rather, the relationship between the Commission Services and Scientific Committees is one of mutual co-operation and negotiation: the Commission Services request, rather than demand, that an Opinion be produced by a particular date, and the Committee Members attempt to accommodate this request to the best of their ability. When a very important deadline is set, the Committees can produce an Opinion extremely quickly (over a few weeks) in order to meet this deadline. However, there was a general attitude amongst the Commission Services staff members that it was preferable to receive a totally solid Opinion slightly after a deadline than to receive an incomplete Opinion on time. Nevertheless, Committee Members stressed that they did attempt to comply with requested deadlines.

Recommendations?

It was recommended that the structure of the Committees should be altered: around 12 to 13 Members should be responsible for the quality of Opinions and other “horizontal” issues, with a large pool of associated scientists who could be picked *ad hoc* to work on particular areas.

4.2 Value of Scientific Opinions (relevance and impact)

“Relevance” was understood to mean the extent to which an Opinion answers the questions posed by the Request for Opinion.

Relevance

To what extent do the Opinions of the Scientific Committees respond to the questions asked by the Commission Services? Sufficiently?

The Opinions respond to the questions asked by the Commission Services to a sufficient degree. The Commission Services recognise that Scientific Opinions often must be complex because of the nature of scientific inquiry, which cannot always provide a clear “Yes” or “No” answer. It was noted, however, that there are some cases where an Opinion may be scientifically valid yet not suitable for the Commission’s purposes. Similarly, the Commission Services recognise that a particularly complex issue may require the inclusion of extensive scientific information as background. Nevertheless, the Opinions undergo an editorial process to ensure they are relevant to the questions set.

The Secretariat and Committee Members recognise that it is important for an Opinion to adhere closely to the questions posed. It was recognised that a major condition of receiving a relevant Opinion was the formulation of a clear mandate: the mandate can influence the

entire process of producing an Opinion. Since the creation of the mandate may be the most important task in the process, it requires significant time and resources.¹⁹ Both Commission Services staff members and Committee Members suggested that the clarity of the mandates could be improved, since occasionally they are phrased in an unclear manner.

How many times did you ask for a clarification?

The Commission Services generally work with the Committees and Secretariats to share information and eliminate ambiguities throughout the process of producing an Opinion. This minimises the need for clarifications at the draft Opinion stage. However, the Commission Services may make comments on certain sections or aspects of an Opinion if they believe they are unclear. This is because each word in an Opinion matters to the Commission Services, and may have a tremendous impact in terms of risk management.

Do the Opinions respect separation of risk assessment and risk management?

Risk assessment is a scientifically based process comprising four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.²⁰ Risk management is the systematic identification and implementation of all measures necessary for limiting exposure of risks, based on international, Community and national sources and strategies.²¹ Within the Commission there is a functional separation between risk assessment and risk management. This is essential in order to protect the scientific integrity of the risk assessment process and to ensure an appropriate balance of the various factors that affect risk management choices.²²

There was a widespread acknowledgment that it is important for the Committees to maintain a strict separation between risk assessment and risk management because they must be seen to be dealing with scientific fact only, rather than policy issues. While respecting this separation in theory, the Commission Services may occasionally wish an Opinion to “cross the line” and address usage and regulation issues; this usually leads to a discussion with the appropriate Secretariat. Indeed, the Secretariat and Committee Chair have an important role in preventing the Committee from straying into risk management areas when formulating an Opinion. However, there were some concerns that this separation was not always accomplished successfully, and all three parties may be responsible for this: the Commission’s questions may be posed in a manner that leads to risk assessment; the Secretariat may not raise necessary objections to these questions; the

¹⁹ ‘Requests for Scientific Opinions from the non-food Scientific Committees: Guidelines for Commission Services’ is provided as Annex V of the Standard Operating Procedures for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006). Interviewees did not make explicit reference to these guidelines.

²⁰ See: http://ec.europa.eu/health/ph_risk/risk_assess_en.htm.

²¹ See::

http://ec.europa.eu/taxation_customs/customs/cooperation_programmes/key_policies/community_interests/index_en.htm

²² See: http://ec.europa.eu/health/ph_risk/risk_assess_en.htm

Committee may not object, or may go beyond its remit and deliberately engage in risk management areas.

Recommendations?

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. The Secretariat is crucial in this regard, and should take a lead in assessing whether a question could lead to risk management matters.

The Commission needs to provide a realistic message about what can be expected from the Scientific Committees, since their different roles and limitations are not always apparent from an external perspective. Expectations should be managed to avoid the view that a Scientific Opinion can be transplanted straight into policy.

It might be desirable to allow Committees to release a preliminary Opinion which states explicitly that industry did not submit the necessary data, should this be the case. This preliminary Opinion could impose a deadline for the submission of this data by industry.

If SCHER criticises a RAR from a Member State, it should provide suggestions for improvements, which would then be communicated to Member States.

Impact

Impact of the Scientific Opinions provided by the Committees in assisting the work of the service in meeting its policy and legislative objectives: From a scientific viewpoint (e.g. new scientific information/interpretation)

The Scientific Committees do not carry out new research, but rather analyse and synthesise existing research. This work can have a significant scientific impact: Opinions can identify areas for further research (which is an important output on its own), and provide a robust overview of the current state of evidence in a particular area. Opinions can become the standard point of reference for subsequent research on a topic. The scientific community has judged certain Opinions favourably and SCHER was praised as “the guardian of truth” on certain issues by one journal.

From a legislation/policy viewpoint

The Commission Services staff members value the Committees’ Opinions highly and make extensive use of them in policy work. There are many instances where Opinions can have a significant and widespread legislative impact: for example, SCCP has had a great effect in the area of consumer safety. However, the scientific community has a tendency to err on the side of caution, which may reduce the extent to which the Commission Services can make direct use of the Opinions in policy-making. In addition, SCHER Opinions rarely have a major impact on the work of the European Chemicals Bureau, since the main issues have already been clarified by the time of SCHER’s involvement.

Monitoring of Opinion impact and feedback on Opinions

Mostly it was agreed that the Committees' involvement with an issue ends with the adoption of their Opinion on the topic. Little feedback is provided to the Committees regarding the impact of these Opinions.²³ There was some disagreement over whether and how the Commission Services monitor the impact of Opinions.

Other?

It was suggested that there should be greater 'publicity' for Opinions, but there was variation in whether it was considered desirable to generate general media attention or just publicity in the relevant scientific field. Committee Members generally advocated the latter. In addition, there were warnings that mass media publicity for Committees might lead to public interest that puts increased pressure on Committee Members. However, there was also a view that media attention generates positive feedback and increases the general acceptance of the Opinions.

Recommendations?

The Commission could redefine the Committees' roles so that they can take a more strategic, risk-scanning approach, rather than simply responding to problems or issues. This could increase the motivation of the scientists on the Committees.

There was a widespread view that the publicity for Opinions needs to be increased, and the majority believe this should be confined to an increased profile within the scientific arena (rather than mass publicity). This could be accomplished by better linking of the Committees' websites to other scientific websites and the publication of Opinions in scientific journals.

An instrument for monitoring the impact of Opinions could be introduced, possibly based on references to Opinions in legislation. Committees should be provided with increased feedback on the impact of their Opinions.

4.3 **Coherence**

"Coherence" was understood to cover the level of similarity between processes used by Committees and the exchange of information between the Committees (and other bodies, if appropriate).

Based on examples, are the Opinions/approaches coherent and consistent: Between the Committees?

The Committees do consult with each other to attempt to ensure that the standards and approaches they use are coherent. However, although the procedures involved in producing an Opinion are similar (Requests, Working Groups, Plenaries, and so on), there

²³ 'The Committees also greatly appreciate receiving feedback on the management actions that follow from their advisory work.' (Annex V of SOP for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006), section 5.1).

was a widespread view that it is problematic to compare processes across Committees because each deals with different types of data that require differing mechanisms. Committee Members in particular emphasised the varying demands created by the diverse contexts in which each Committee operates. For example, in general terms, SCCP has developed a more standardised procedure for dealing with data than SCENIHR. The latter may use more exploratory techniques based on expert judgement to predict future public health or environmental impact (a heuristic approach).

The Inter-committee Co-ordination Group was considered to have a central role in the ensuring coherence between the Committees. It appears that although this Group is effective at organising operational issues such as Committee selection, it has little impact in tackling wider issues. For example, a review of selected Opinions to judge their consistency was proposed in an ICG meeting, but has made little progress.

There is a case for attempting to standardise the use of terms between Committees. There have been some problems regarding the use of phrases such as “tooth whitening” and “hair dyes”. Some Committee Members argued that the current situation may lead to misunderstandings; others, however, claimed that this is not a pressing issue.

Similarly, coherence between Committees may be impeded by the fact that individual Rapporteurs have different writing styles and varying approaches to the composition of Opinions. In addition, if several individuals contribute material to the same Opinion, then this can weaken the Opinion’s internal coherence; however, such internal variations are usually reduced by discussions in plenary meetings.

With respect to other Community advisory bodies?

Contact and collaboration between the Committees and other advisory bodies can be rather limited, and the Committees are rarely consulted by such bodies. The Secretariats are the points of liaison: they contact other bodies that might have an interest in an Opinion, although perhaps this interaction could be improved. Some coherence is provided by the fact that the Committees often share Members with other advisory bodies. There was agreement that the meeting of Chairs was a useful initiative that could improve the coherence between Committees and other advisory bodies and therefore should be continued.

Over time?

There was consensus the Committees refer back to any existing Opinions they have produced on the topic they are current considering. They then re-assess these preceding Opinions on the basis of new evidence, and it is the Chair’s responsibility to ensure that new Opinions do not contradict preceding ones if there is no scientific basis to do so. In terms of continuity of processes, the manner in which Opinions are produced has changed over time owing to the advent of new scientific methods. Continuity is boosted by the fact that some Committee Members have been engaged in work for predecessor Committees, and thus have knowledge of how past studies were conducted.

Recommendations?

There should be increased coordination, both between the non-food Committees and between these Committees and other bodies (such as EFSA). The exchange of information

would be beneficial because there is often overlap between the findings and conclusions of these various bodies. This is particularly important given the multiple routes by which individuals can be exposed to a particular substance. Such coordination may require the creation of one body with oversight over the different areas and responsibility for monitoring exposure levels; it might also involve the Joint Research Centre in supplying data to fill evidence gaps.

4.4 **Confidence in the soundness of Scientific Opinions**

“Confidence” was understood to mean the extent to which a stakeholder considers an Opinion to be informed, accurate and trustworthy.

What is the level of confidence in the scientific soundness of the Opinions? At the level of the Commission Services responsible for the questions

The Commission Services have a high level of confidence in the soundness of the Committees’ Opinions. This is demonstrated by the fact that Commission Services staff members consult and quote Opinions when questions regarding a topic emerge, or when it is necessary to produce a reliable statement on an issue. The Commission Services staff members consider the Opinions to be sound enough to form the basis of their approaches to the European Parliament. The Opinions’ conclusions have not been met by serious challenges. The Commission Services’ confidence in the Opinions was also noted by the Secretariats and the Commission Services staff members themselves.

By stakeholders who are directly concerned by the advice (as assessed by the Commission Services concerned)

According to many Commission Services staff members, they have only heard positive comments from stakeholders regarding the soundness of the Committees’ Opinions. Indeed, it was suggested that the reputation of the Committees was such that industry often wishes to submit data on the properties of certain substances in order to have them “rubber stamped” by the Committees. Perhaps unsurprisingly, Commission Services staff members noticed that stakeholders tend to selectively quote statements from Opinions that support their particular interests, but this is difficult to avoid. The SCCP Members and Secretariat noted that there has been a difficult relationship between industry and SCCP in recent years, but this appears to have improved recently. A Scientific Committee’s Opinion often makes a useful contribution to the process of dealing with Risk Assessment Reports from Member States, because it can strengthen confidence in the soundness of a RAR. While an Opinion rarely makes significant changes to a Risk Assessment Report, if it opposed a Member State then there is uncertainty regarding how that Member State would react.

Other?

Public consultations were considered in a positive light by the majority of respondents. One of their obvious benefits is that they can attract valuable scientific comments and highlight issues Committee Members may have missed. It was also claimed that

consultations were reaching an increasingly large sphere, rather than just consulting peers in the field.²⁴ This was viewed positively because it was considered important to involve stakeholders in order to improve the acceptance of an Opinion at a later stage, even if they did not make solid scientific comments. There was recognition that consultations could establish whether an Opinion was clear and well-structured, and therefore be of use even if the content of an Opinion was not significantly altered.

The use of external experts was viewed as a valuable means of improving the scientific soundness of a resulting Opinion, since not all relevant areas of expertise can be contained in one Committee of a manageable size. Nevertheless, it was noted that external experts may cause problems of independence, since they may have links to industry and other interested parties. There are also logistical difficulties in obtaining input from the top experts in Europe, since they tend to be very busy. Nevertheless, such input is usually obtained. The Commission Services and the Scientific Committees did not feel that the quality of any Opinions had been adversely affected by a lack of expertise.

As well as improving the scientific soundness of an Opinion, external experts can speed up the process of producing an Opinion by increasing a Committee's capacity.

Recommendations?

There was a call for public consultations to be used more often, with the proviso that they are not suitable for all Opinions, but rather ones with a wide-ranging remit that invites a variety of approaches. It was also suggested that there could be consultation with, for example, NGOs, during the formulation of mandates in order to provide an alternative perspective. As well as involving stakeholders' confidence, this would increase the transparency of the process. In a similar vein, there was a suggestion from the Committee Members that there should be more interaction between the Committees and industry.

It was also suggested that more external experts should be used for certain aspects of Opinions; this could be accomplished through involvement in wider networks. Where appropriate, obstacles to using external experts should be removed.

4.5 **Independence and transparency**

"Independence" is understood to mean the extent to which Committee Members make decisions based solely on their scientific knowledge, without being influenced by non-scientific considerations.

Are the Commission Services satisfied with the level of independence?

²⁴ It is interesting to note that the publication of Requests for Opinions also provides stakeholders with increased opportunities to contribute to the scientific debate, as described in Annex V of the Standard Operating Procedures for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006).

Interviewees reported that they have not experienced many problems regarding independence of Committee Members. The Committees have adequate procedures for the declaration of Members' interests, which are stringently enforced. There was a general consensus that it is extremely important that Committees are seen to be neutral and independent. A perceived loss of neutrality or independence would damage the credibility of the Committees' Opinions, and the entire current system of risk assessment. Nevertheless, the demands for independence may also present problems for the Committees' functioning, since they can severely restrict the pool of potential experts who can contribute to Opinions. If fewer and fewer experts are available to contribute to Opinions, this might ultimately result in the Committee being unable to obtain the services of an expert in a particular area. If this happened, then it may well have a detrimental effect on the quality of an Opinion's discussion of the area in which expertise is lacking.

Commission Services staff members stated repeatedly that they did not wish to influence the scientific outcome of the Committees' work, nor did they have any expectation that a Committee would produce an Opinion in accordance with their views. Commission Services staff members said that they restricted their comments to requests for clarification and similar queries. In turn, the Committees strongly defend their right to independence from the Commission Services.

Are the Commission Services satisfied with the level of transparency?

The transparency of the Committees was considered to be good by Commission Services staff members, Secretariat staff members and Committee Members. It appears that the current system is working well. It was noted that transparency had increased greatly through increased publication of fully-referenced documents on the Internet. This does vary from Committee to Committee, however, given that some (SCCP, for example) deal with a greater proportion of substances that are covered under commercial confidence. In addition, public consultations were viewed as contributing to the transparency of the process of producing an Opinion.

However, it was acknowledged that there is a tension between the demands for transparency and the need to be able to work efficiently. For example, minutes of Working Group minutes are not published online because they are internal, functional documents that would take time to produce and disrupt the flow of debate. There was some suggestion that Opinions can be rather brief and do not give details of their reasoning, but this was not considered to be a major disadvantage.

Recommendations?

In the future one may consider revising the Declaration of Interest form to make what constitutes a direct interest even clearer.

4.6 **Interface between the Commission Services and the Scientific Committees**

"Interface" is understood to mean the relationships between the Commission Services staff members and the Committees during the process of producing an Opinion.

To what extent are the Commission Services satisfied with the interface?

The Commission Services staff members are satisfied with the overall functioning of the interface: the relationship is constructive and positive. From their point of view, the new Committees have adopted a “user-friendly approach”. There were some minor complaints regarding the Secretariat’s performance in co-ordinating the distribution of documents. There was a suggestion that the relationship between Commission Services and Committees becomes more complicated in multiple Directorates General are involved in one Opinion.

In the formulation of mandates

There was a general agreement that the formulation of the mandate is an extremely important stage of the process: it is vital that the Committee Members understand what is being asked of them, and that the questions are viable.²⁵ Therefore, there is a considerable amount of contact between Commission Services staff members and Committee Members at this stage, which appears to be beneficial. It appears that this contact is constructive, and attempts to reach agreement through negotiation, rather than being combative: the Committee Members attempt to understand the Commission Services staff members’ exact expectations, while the Commission Services staff members are ready to accommodate should the Committee Members indicate that a mandate lies outside the Committee’s remit.

Participation during Working Group and plenary meeting discussions

Commission Services staff members were satisfied with their ability to participate in Committee meetings. Mostly they were happy with the Secretariat’s performance in facilitating their participation, although the Joint Research Centre (JRC) claimed that there were delays in distributing information and documents relating to Working Group and plenary meetings.

Both the Secretariats and Committee Members said that the presence of Commission Services staff members at Committee meetings was useful because they could provide information and deal with any difficulties of interpreting the mandate at hand.

Flow of communication and feedback in both directions

The Commission Services consider the flow of communication to be good, especially since the Secretariats have been incorporated into SANCO. The Committees are responsive to the Commission Services’ needs and regularly attempt to consult with Commission Services staff members. Equally, the Commission Services attempt to inform the Secretariats of forthcoming work, although this is not always possible. While the process of forming a Technical Guidance Document (TGD) has produced difficult discussions between Commission Services and Scientific Committees in the past, this is being addressed through improving the flow of communication throughout the process. There

²⁵ The importance of the process is reflected in the fact that the Standard Operating Procedures provide guidelines for the formulation of Requests for Scientific Opinions (‘Requests for Scientific Opinions from the non-food Scientific Committees: Guidelines for Commission Services’, Annex V of the Standard Operating Procedures for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006)).

was a suggestion from the Committees that the flow of communication may prove unsatisfactory if the individual responsible for the Request for Opinion is unavailable, since this may lead to misunderstandings.

Other?

The Committees had mixed views regarding the level of support they received from the Secretariats. One view was that the Committee Members performed the majority of the work for creating an Opinion, with the Secretariat providing limited support: Committee Members having to check submitted dossiers of information themselves, for example. Another view was that the Scientific Secretaries did an outstanding job, particularly in editorial tasks. In addition, there was a certain feeling that the Secretariat may sometimes take decisions that are the preserve of Committee Members.

Recommendations?

Commission Services staff members recommended that there should be more systematic dialogue between Commission Services and the Committees before the mandate is finalised. Currently, this only occurs in an *ad hoc* manner – it should be formalised. A similar system could be applied when Commission Services are invited to comment on a draft Opinion, giving Commission Services increased information, but not increased influence over the process.

The Secretariats need more support, in their view. It would be useful to employ a dedicated editorial staff to, for example, check references, rather requiring trained scientists at the Secretariat to perform this task. This role could also be filled by flexible staff who are employed on an *ad hoc* basis.

There was some support amongst Committee Members for the notion that the scientific secretaries could contribute more to Opinions, perhaps even participating in the writing of the Opinion's text. However, another view was that the role of the Secretariat should not extend into scientific areas, but instead concentrate on editorial and administrative duties.

4.7 Other specific issues raised

In this section we have placed issues that we decided were best considered separately from the preceding categories, or which do not fit into the preceding categories.

We have created two sections, 'Delivery of dossiers and data' and 'Quality of data', which are clearly closely linked. 'Delivery of dossiers and data' concerns the functioning of the process of data submissions by industry and others. 'Quality of data input' considers the wider issue of the quality of data which informs the Opinions, and which methods would produce the highest quality data input. In contrast to the other sections, we have placed recommendations for a particular issue directly below the relevant findings. We divided the recommendations in this manner because this section contains a wide variety of material, which means that placing all the recommendations together would be rather confusing.

Delivery of dossiers and data

For SCCP in particular, the timeliness and quality of the dossiers submitted to the Committees has a great impact on the efficiency of their work. The submission of dossiers has not always been a smooth process in recent years, and sometimes they have to be sent back because of missing or poor quality data. Even when dossiers are submitted, the Secretariat or Committee may have to scan the document to check for gaps, which can be a time-consuming process. Industry can lobby extensively and thereby delay the process because Opinions must be based on solid data. However, this situation may have improved recently.

Recommendations:

Increased funds are required to contract staff to work full time on dossiers.²⁶ The submission of information prior to the start of work on an Opinion should be formalised and incorporate a deadline for information submissions. This would prevent information from 'trickling in' and delaying the process.

There is a need for stronger and clearer guidelines for industry submissions; sanctions should be applied if the required data are not provided.

Quality of data input

The quality of data on which Opinions are based is crucial. In several cases SCCP could not come to a conclusion because it was provided with poor quality or incomplete data. There have been many instances where industry has tried to manipulate the process of submitting data to serve its own interests, although the situation has improved recently. The Commission does not have adequate resources to check if all the relevant data have been submitted to the Committees (and it is necessary to check this), so this task sometimes falls to the Committee Members.

Normally, SCHER and SCCP only work with documents that are supplied to them, although their scientists do conduct research themselves. There do not appear to be

²⁶ The financial aspects of the Scientific Committees are outside the remit of this evaluation. However, the interviewees made many comments on the subject, and so they are presented here as additional information.

guidelines for how such literature reviews should be conducted, although there are not concerns over the quality of the information utilised. When judging the quality of studies, SCHER tends to consider that studies which adhere to OECD or European guidelines are of higher quality.

SCENIHR depends far less heavily on information submitted by industry or other bodies than SCCP. Indeed, for SCENIHR, the method of obtaining information is a major issue. The Secretariats attempt to collect relevant information, but this presents a massive task. Most of the information used is collected from Members of the Working Group themselves, who know the field. Such literature searches must be funded by Members, and are usually based around published and peer-reviewed literature. However, these literature reviews may not be comprehensive, particularly in respect of work published in lesser-spoken languages.

Recommendations:

Since reviewing the literature and collecting the data are very time-consuming, it would be useful to have a mechanism for collecting, collating and even checking the quality of the data and information. A mechanism ought to catch the data in the public domain and transcribe them in a standard format. There also should be a mechanism that links the absence of data noted in Opinions with research commissioning.

The Committees need a formalised weight of evidence evaluation. If someone is externally evaluating an Opinion, they need to be able to trace why certain evidence was or was not used. The current *ad hoc* methods may not be acceptable for much longer.

The quality of the data input to Opinions would be improved if the Members of the Scientific Committees were involved in better, wider networks with other scientific bodies.

Technical Guidance Documents (TGDs)

There have been interchanges between SCHER and DG ENV regarding substances that are Persistent, Bio-accumulating and Toxic (PBT). This has led DG ENV to initiate a process to create a TGD for PBT assessment.

Resources

The current situation regarding resources was framed as a choice between limiting the work of the Committees and Secretariat or bringing in external contractors. Although outside the remit of this evaluation, the issue of special indemnities for Committee Members was considered to be an important issue. It is clear that it would not be possible to fully compensate the Committee Members for their work, and indeed they are motivated rather by professional interest and intellectual commitment. However, Committee Members were dissatisfied with the length of time it took to be reimbursed for travel and subsistence expenses.

Recommendations:

It was suggested that increased special indemnities should be provided to Rapporteurs, possibly on a sliding scale that correlates with the length of the Opinion they produce. Funds should be made available to allow Committee Chairs to take up the position full-time for fixed period.

Committee member appointment

There is a group of colleagues who have participated in the Committees for many years. Restructuring of the Committees has ensured that these Members have been eligible for re-election. However, it is becoming increasingly important to recruit new Members to the Committees (especially in SCCP, where there have been some recent resignations). To do this, Membership of the Committees must be attractive for scientists. There needs to be some means of recognising Members' intellectual contribution to Opinions, since they are currently anonymous. Universities are putting great pressure on some Members because of the time they commit to the Committees.

Language issues

Sometimes the English skill levels of Committee Members presents a barrier to them participating fully in Committee meetings and formulating Opinions precisely. This can be a particular problem given the preponderance of technical/scientific language that is used in the Opinion process. It can take time to revise sentences that are unclear.

In this chapter we discuss ten general topics concerning the functioning of the Scientific Committees. These topics are the ones to have emerged most clearly from all the material across the five case studies, the three groups of interviewees and the specific evaluation issues. Several other topics can also be found in places in the material, on which comment would be possible. However, these ten topics are the ones that we draw to the attention of DG SANCO. They are discussed in turn in the following sections of this chapter.

5.1 Working relationships between the Committees, the Secretariats and the Commission Services

The clear impression is that collaboration and cooperation between the Committee Members, the Committee Secretariats and the Commission Services staff members is working well on the whole. The three groups of individuals, and their respective Committees and Units, are reliant on each other for achieving the ultimate outcomes that the scientific advice process is designed to provide – risk assessment to inform risk management. Because this interdependence is recognised and understood by the three groups, there is scope for it to develop further and thereby improve the work and its impact.

5.2 Current functioning and future availability of Committee Members

For the Scientific Committees to function effectively within the Commission's overall system for obtaining scientific advice, several conditions have to be met. In particular, (a) individual scientists possessing relevant knowledge, expertise and reputation have to be willing and able to apply this knowledge and expertise to subjects identified by the Commission; and (b) to do so independently; and (c) to do so under precise rules, terms and conditions specified by the Commission. At the moment these conditions are being met, and sufficient numbers of Members have been appointed for the Committees to function according to the rules. Some informants have voiced concerns about the future sustainability of supply of scientists to become Committee Members. If their concerns are well founded, they provide an early warning that the Commission could be facing the significant risk that required scientific advice will not be available or adequate in quality using the current arrangements. The Commission needs to find out, at the least, the bases for these concerns. If a problem does exist, it merits further examination in good time.

5.3 The role of external experts

There is provision for additional scientists to contribute to the system by working with particular Committees on particular tasks at particular stages in the process. These external experts are an important component of the overall resource of scientific expertise on which the Commission can draw. Committees often use external experts to boost their capacity and thereby produce Opinions more effectively. In some instances and at some times Committees seem to be reliant on external experts to get crucial work done. Participants in the research consider the use of external experts to be good practice: because they provide expertise that supports the confidence in 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 with industry and other stakeholders. In today's environment, experts without any potential conflicts of interest are scarce. It may therefore become difficult for the Scientific Committees to balance the trade-off between expertise and potential conflicts of interest. In future, the quality of opinions may become at stake because of expertise in a particular area is not available.

5.4 Separation of risk assessment and risk management

"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."²⁷

"...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."²⁸

Here, the European Commission's Director General for Health and Consumer Protection, explains the complex challenges posed by risks. However, all the informants across the Commission's scientific advice system seem to grasp the points he makes, and to appreciate the necessity of separating risk management considerations as far as possible from the risk assessment perspectives taken by the Scientific Committees. Indeed, this point is

²⁷ Robert Madelin, Director General for Health and Consumer Protection, European Commission, *The importance of scientific advice in the community decision making process*, speech to Inaugural joint meeting of the Members of the non-food scientific committees, Brussels, September 7, 2004. Online at: http://ec.europa.eu/health/ph_risk/documents/ev_20040907_co01_en.pdf (accessed October 2, 2006).

²⁸ Madelin, *op cit.*

emphasised in the guidelines for formulating Requests for Scientific Opinions.²⁹ However, those who have to apply the scientific advice to legislation and policy comment that they sometimes encounter difficulties because the advice necessarily avoids making practical recommendations.

5.5 Workload of the Committees and roles of the Secretariats

Some informants made a distinction between scientific and administrative work needed by the Committees, and suggested that the scientists in the Secretariats could be unhelpfully encumbered by the burden of administrative work sometimes falling to them to undertake. This is difficult to assess without a more rigorous study, and any recommendations for change would need to be based on an objective analysis. If scientific work of the Secretariats is indeed being “crowded out” or put under pressure by administrative work (as suggested by some participants in the research), 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.

5.6 Quality and timeliness of data on which Opinions are based

For the Committees to produce robust Opinions, they need access to information and research that is intelligible, timely, and appropriate to the scope of the Opinion. These conditions can be difficult to achieve, for example where the subject matter is novel, or where the quantity of relevant information is potentially enormous and cannot all be studied, or where strong vested interests exist among external stakeholders. For example, the late submission data (or the timely submission of poor quality data) can delay the process of producing an Opinion, or prevent a Committee from reaching a conclusion altogether. In addition, interviewees stated that the Commission does not have 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. In sum, the quality and timeliness of the data on which Opinions are based is crucial. The findings from interviews indicate that, currently, there is a reasonable concern about the quality of data submissions. When a Committee encounters such difficulties, this may adversely affect the process of producing an Opinion, and indeed the quality of the Opinion itself.

5.7 The impact of time and resource pressures on Opinion quality

Another fairly obvious observation made by several informants is that under time pressure the quality of the scientific advice may be compromised. The result could be that information and arguments considered by the Committees may sometimes be put together in a rush, possibly compromising the accuracy, validity or reliability of aspects of the

²⁹ See Annex V of SOP for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006), section 2.2.

resulting Opinion. Informants recognise that time pressures can be a fact of life, and that the resources needed to do a better job may sometimes just not be affordable or available when needed. However, although outside the remit of this intermediate evaluation, some interviewees said that the work of the Committees is not well remunerated, and that increased time and financial resources might expand the capacity of the Committees. 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. In some instances, this may cause the quality of protection from avoidable harm provided to Europe's citizens by the Commission to be too weak. Whether these trade-offs can be resolved is worth considering. The transparency of the system can do a lot to mitigate criticism.

5.8 Formulating the Questions to put to the Committees

The document "Requests for Scientific Opinions from the non-food Scientific Committees: Guidelines for Commission Services" provides the Commission Services with guidelines for formulating questions for the Scientific Committees.³⁰ The way in which questions to the Committees are formulated has been raised by several informants, and is evidently a matter of concern. As with most investigative activities undertaken by teams, whether informal enquiries or formal research, the better the use of language to convey the purpose of the activity, the greater the chance that the purpose will be understood clearly and unambiguously by those who are responsible for achieving it. DG SANCO Unit C7 recommends that those who have little experience of drafting questions, or who are formulating unusual questions, should contact the Unit to receive advice.³¹ The need for advice is all the more significant when: 1) the working language (English) is not the first language of many of the people involved; 2) the subject matter of the investigations is often highly technical; 3) specialist technical vocabulary may be involved; and 4) the boundary between risk assessment and risk management may be fuzzy. Informants suggested that questions put to the Committees could sometimes be phrased more appropriately, with the result that the Committees could work more effectively, with greater focus and clarity of purpose, to address the Commission's questions in a timely and succinct manner. This observation could be tested, by taking examples of so-called poorly formulated questions, tracking their effect on the Committee, and comparing that with the effects of examples of so-called well formulated questions on the same Committee. A feature of scientific advice systems that may be less readily acknowledged by some scientists, is that total clarity, objectivity and absence of bias cannot be guaranteed in any process operated by human beings.

³⁰ Annex V of SOP for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006).

³¹ This recommendation is made in Annex V of SOP for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006), section 3.2.

5.9 Public consultations

Public consultations have won approval from several informants, who can see benefits from using them more often and more widely in the scientific advice process. Not only do they enable more information to come into consideration, also they signal the Commission's interest to a wider audience, and they enable views and concerns to be aired that can help the Committees to formulate advice that is more coherent. On this evidence, the possibility of extending the role of public consultations merits investigation.

5.10 Committees' relationship with the European Chemicals Bureau (ECB)

From the interview findings it can be concluded that SCHER Opinions rarely have a major impact on the work of the European Chemicals Bureau, since the main issues have already been clarified by the time of SCHER's involvement. Further, there were recommendations that SCHER could make suggestions on how to improve Risk Assessment Reports, although there have been recent attempts to facilitate information exchange of this type. Therefore, although the relationship between the Committees and the ECB is productive, there may be opportunities to increase the collaboration and scientific advice offered to the ECB. However, such an intention would be affected by the forthcoming introduction of the new Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation and the creation of a European Chemical Agency in Helsinki in 2008.³² The period of transition involved may disrupt attempts to increase contact between the Scientific Committees and the ECB, although the creation of the ECA may offer fresh opportunities to provide more scientific advice regarding chemicals. Therefore, it may be advisable to delay attempts to facilitate greater integration with the processes of European chemical regulation until the European Chemical Agency is fully functioning.

³² See: European Commission (2005) REACH: Commission welcomes Council's agreement on new EU chemical legislation. Press Release. IP/05/1583, 13/12/2005 Available at: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/1583&format=HTML&aged=1&language=EN&guiLanguage=en>

In addition to recommendations for improvement made by interviewees (see Chapter 4), the Project Team has developed a set of recommendations for the evaluation as a whole. As noted in the Preface, this project was designated as an internal evaluation that draws findings from interviews, documents available from the Commission and its website, and five case studies. In order to provide further expert analysis, such an evaluation would need to be set against external benchmarks, provide longitudinal analysis, or both. Therefore, the project team strongly recommends that the organisation, performance and achievements of the Committees are assessed against external evidence. In the absence of external reference points, it is not possible to state objectively how well or badly the Committees and the scientific advice system are working. External comparisons will help the Commission to make informed, more objective assessments on all the issues raised by this internal evaluation. External examples of risk assessment and management systems and approaches should be considered carefully, to identify appropriate benchmarks against which to assess the Commission's arrangements.

With this in mind, we present a set of recommendations for the evaluation as a whole, in addition to the recommendations for improvement made by interviewees (see Chapter 4).

Improve the sharing of information across the Scientific Committees and other advisory bodies.

More opportunities are set up 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.

The Scientific Committees are building valuable experience in handling the pressures from the Commission Services and from external stakeholders, particularly where the issues put to the Committees raise controversial aspects. The case study on indoor air, for example, brings in to focus the urgency of the need for an Opinion alongside the necessity of ensuring the quality of the Opinion is not compromised by too hasty working. There will be many other facets of the Committees' practices that they could discuss between themselves and the other European bodies, in order to maximise the learning and good practice. The 2 day workshop with Committees and other advisory bodies in November 2005 attracted appreciative comments.

Increase the impact of Scientific Committees' work (Scope)

A full evaluation of the Scientific Committees should include a selective review of the impact of the Committees' Opinions, with particular investigation of scope where the risk issues were of high visibility, or involved important timing considerations, with a view to introducing greater precision and focus to the impact of the Committees' work.

It is evident that potentially there are far more consumer risk topics eligible for the Commission's attention, and for the Scientific Committees to assess, than the system can currently handle, given its present design and resources. Logically, it is reasonable to ask on what basis such issues should be identified for attention, assessed, prioritised, dealt with or rejected, across the Directorates General, the Commission Services Units and the Scientific Committees? This question goes beyond the scope of this interim evaluation. However, it is pertinent to the workload and impact concerns that have been raised. It suggests that some principles and parameters could be developed, which would guide the Commission Services and Scientific Committees in future, to ensure impact is optimised.

Increase the impact of Scientific Committees' work (Dissemination)

The Commission takes 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, uses consistent language;
- (c) Select channels of communication that are readily accessible to, and actively used by, target audiences; and
- (d) Monitor uptake and impact of the messages, and revise practice in the light of experience.

Given the respect with which the Committees' work is already regarded inside and outside the Commission, the value it adds to consumer protection, and the value to current and future Members of the Committees of raising the profile of the Committees' work in the scientific community, there seems to be support for giving the work greater impact. Improved dissemination is one important way to contribute to greater impact. Several case studies illustrate that where other governments or professional bodies or industry bodies or media take an interest in a particular risk issue that a Committee is dealing with, the external debate and publicity can raise the profile of the issue and enhance the salience and impact of the Committees' contribution to knowledge and understanding.

A further aspect of the impact and influence of the Committees' work is revealed by the case study on nanotechnology risks. That Opinion included a large amount of scientific background information, which was well received by the scientific community. This raises two questions. One is whether such important work on emerging risks should be made more accessible to wider audiences. In that case, should the scientific background material on nanotechnology risks be published and disseminated in other, more accessible, formats or on other platforms? For example, at workshops or other events, in collaboration with other international and national regulators, on other websites, in summary forms, so as to reach out beyond the specialists to wider professional and representative bodies. The

second question is whether the formats specified for Opinions are optimal, where the Committees' work includes a significant or substantial contribution to knowledge.

Avoid Scientific Committees commenting on risk management issues

At early stages of work on an issue, well before an Opinion is ready, and periodically thereafter, the Commission Services staff members, 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) if asked to, they should always decline to give comments on risk management issues;
- (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;

and 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.

Risk management expertise is specifically not the expertise for which Scientific Committee Members have been appointed. Therefore they are not authorised to pronounce on risk management matters as experts, and anything they say on risk management must be regarded as equivalent to any other non-expert's comments. There are other mechanisms for obtaining non-expert comments. The case study on tooth whiteners demonstrates that the four principles above were not all robustly in place.

Review the work of the Committee Secretariats

The work of the three Committee Secretariats and the ICG (Inter-Committee Coordinating Group) is reviewed. The suggested focus of the review is as follows:

- (a) establish for each Committee and the ICG what operational tasks are essential for delivering their remits efficiently and effectively;
- (b) establish where the difficulties with efficient and effective working arise in each Committee/ICG
- (c) 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?");
- (d) if improvements can be identified, explain these and design an appropriate implementation programme.

As concerns have become apparent through the interviews and case studies, it is necessary to examine the effectiveness and efficiency of the Secretariats in some detail. The work undertaken by the three Committees shows different characteristics. This reflects differences in their subject matter scope, in the information they have to handle, and their methods of handling it. The specific activities of the Scientific Secretaries therefore vary and are not identical across the three Committees. As a generalisation, SCHER processes large numbers of Risk Assessment Reports, using a standard administrative approach, and

encounters relatively little variation. SCCP has to engage with potentially huge amounts of data, which it has to select and filter. SCENIHR has a broad and flexible field of work; its emphasis is on understanding new science and the implications of the science. The knowledge, skills and competencies most required by each Committee clearly vary.

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.

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.

The volume of data that Scientific Committees could need to process or locate to inform an Opinion is potentially enormous. This is particularly where scientific knowledge is advancing and industry standards or environmental standards need updating, for example, or where new regulations will have retrospective implications, or where the field of knowledge is emergent and growing rapidly, with significant consequences for a broad spectrum of stakeholders. There is already evidence, for example from the hair dyes substances case study, that a Committee can find itself devoting much time (a relatively scarce resource) to processing information submitted by industry which does not meet the required standard of content or quality or both.

Since the timeliness and quality of data used in the Opinion process are crucial factors, the Commission could review the responsibilities for data submissions and literature searches, which could potentially lead to the creation of a new system for dealing with these issues. 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 investment in resources for the Scientific Committees

The Commission could consider increasing its investment in the Opinion process to increase the research and administrative support available. It may be that these resources would be best used to create a system to improve data submissions and literature searches.

A significant risk has been identified by informants that access to the necessary scientific advice may not be sufficient, or adequate in quality, if current arrangements continue unchanged. The Commission needs, at the least, to evaluate the basis for these concerns. If a problem does exist, it merits appropriate action in good time. As noted above, two possible candidate areas for increased investment are the staffing resources allocated to the Committees for processing data submission and conducting literature searches. Increasing the level of special indemnities available to Committee Members may also help to attract and retain scientists.

Ensure the division of labour between Commission Services and Scientific Committees is appropriate when formulating Requests for Opinions.

At early stages of work on an issue, and periodically thereafter, the Commission Services, Committee Members and Committee Secretariats should explicitly check whether the

division of labour between them is exactly appropriate, and whether anything could compromise the Committee's independence; and put on the record either that there is no such occurrence, or if there is, what steps are taken to correct the situation.

Scientific Committees should not be asked to undertake, and should not undertake, investigative or analytic work or make comments and give other advice that is more appropriately handled by the Commission Services or industry or another body or individual. The relevant principle that should govern the Committees' work is that their independence from vested interests must not be compromised. In the tooth whiteners case, a review of the industry study protocols was proposed, which could have breached the Committee's independence.

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http://ec.europa.eu/health/ph_risk/documents/ev_20040907_rd01_en.pdf.

APPENDICES

Appendix A: Documents consulted

General documents
Commission Decision of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment (2004/210/EC)
Rules of Procedure of the Scientific Committees on Consumer Products (SCCP), Health and Environmental Risks (SCHER), Emerging and Newly Identified Health Risks (SCENIHR) SCs/01/04 final (C7(2004)D/370235) adopted on 7 September 2004
SOP for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006), including the following Annexes: I) Minimum requirements for a request for scientific advice – Check list II) Standard administrative notes and letters III) The role of the scientific secretariat IV) Meeting organisation (administrative) V) Requests for Scientific Opinions from the non-food Scientific Committees: Guidelines for Commission Services
Amended list of experts appointed as Members of the Scientific Committees (2004/C 250/07)
Minutes of the Meetings of the Inter-Committees Coordination Group (1-8).
Report of the First Meeting of the Chairs of Scientific Committees of Community bodies involved in Risk Assessment (7 and 8 December 2005). Brussels, 28 February 2006, C7/MM D(2006) 370004
Case study: Tooth whiteners
Scientific Committee on Consumer Products plenary meeting minutes
Scientific Committee on Consumer Products plenary meeting draft agendas
Request for a Scientific Opinion: Safety evaluation of hydrogen peroxide in tooth whitening products
Preliminary Opinion on Hydrogen Peroxide in tooth whitening Products (Approved by SCCP during the 2nd plenary of 7 December 2004) (SCCP/0844/04)
Opinion concerning Hydrogen Carbamide Peroxide in tooth whitening Products SCCNFP/0058/98 adopted in the 7th plenary meeting on 17 February 1999
Clarification of the Opinion concerning Hydrogen (carbamide) Peroxide in tooth whitening Products SCCNFP/0200/99 adopted in the 8th plenary meeting on 23 June 1999 (Clarification of SCCNFP/0058/98)
Opinion concerning hydrogen peroxide and hydrogen peroxide releasing substances used in oral care products SCCNFP/00158/99 adopted in the 8th plenary meeting on 23 June 1999
Opinion concerning Hydrogen (Carbamide, Zinc) Peroxide in Tooth Bleaching / Whitening Products SCCNFP/0602/02 adopted in the 21st plenary meeting on 17 September 2002
Opinion on Hydrogen Peroxide in tooth whitening Products Adopted by SCCP during the 3rd plenary meeting of 15 March 2005 (SCCP/0844/04)
Comments on SCCP preliminary Opinion on HPO
Summary of Comments on HPO Preliminary Opinion
Summary and conclusions of the Public consultation on a preliminary Opinion on hydrogen peroxide in tooth whitening products
24 submissions to the public consultation on a preliminary Opinion on hydrogen peroxide in tooth whitening products
III Submission on Hydrogen Peroxide in Cosmetic tooth whitening Products by COLIPA (24/11/03)
Petition by the Agence Française de Sécurité Sanitaire des Produits de Santé (French Agency for Health Safety for Health Products) to the SCCNFP (Scientific Committee on Cosmetic Products and non-food products intended for consumers) concerning tooth whitening products containing hydrogen peroxide or carbamide peroxide
Several industry submissions regarding hydrogen peroxide
Check list for Request for a scientific advice on relevant clinical and epidemiological studies on tooth whitening products (12/12/05)
Request for a scientific advice: Tooth whitening products – relevant clinical and epidemiological studies
Guidance document on Epidemiological and clinical studies on tooth whitening Products (Adopted by SCCP during the 7th plenary meeting of 28 March 2006) (SCCP/0974/06)
Proposed protocols for the TWP studies

BEUC POSITION PAPER ON TOOTH WHITENING PRODUCTS (26/07/05)
SCCP Concerns - final edited version - sept 05mb
Letter from the Norwegian Food safety Authority (Mattisynet) to the EU Commission as concerns the tooth bleaching issue (24 August 2005)
Case study: Chemicals
Scientific Committee on Health and Environmental Risks plenary meeting minutes
Scientific Committee on Health and Environmental Risks plenary meeting draft agendas
Technical Guidance Document on Risk Assessment in support of Commission Directive 903/67/EEC Commission Directive 93/67/EEC on Risk Assessment for new notified substances; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances; Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market
JRC email submitting the RAR on ANTHRACENE (CAS no. 120-12-7 EINECS no. 204-371-1) (02/08/06)
Request for a Scientific Opinion: Risk Assessment Report on Anthracene under Regulation 793/93
Check list for request for scientific advice on RAR on Anthracene HH (Regulation 793/93) (18/10/05)
Opinion on "Risk Assessment Report on Anthracene Human Health Part" (Adopted by SCHER during the 9th plenary of 27 January 2006)
European Union Risk Assessment Tracking System Status Report on ANTHRACENE
JRC email submitting the RAR on 2-butoxyethanol (EGBE) (CAS 111-76-2, EINECS 203-905-0, France, esr. n. 408) and the RAR on 2-butoxyethyl acetate (EGBEA) (112-07-2, EINECS 203-933-3, France, esr. n. 409) (22/12/05)
Request for a Scientific Opinion: Risk Assessment Report on 2-butoxyethanol under Regulation 793/93
European Union Risk Assessment Report 2-BUTOXYETHANOL CAS No: 111-76-2 EINECS No: 203-905-0 (Draft)
European Union Risk Assessment Report 2-BUTOXYETHANOL ACETATE CAS No: 112-07-2 EINECS No: 203-933-3 (Draft)
Request for a Scientific Opinion: Risk Assessment Report on 2-butoxyethyl acetate under Regulation 793/93
Check list for request for scientific advice on RAR on Butoxyethanol ENV (Regulation 793/93) (13/01/05)
Check list for request for scientific advice on RAR on Butoxyethanol acetate ENV (Regulation 793/93) (13/01/05)
European Union Risk Assessment Tracking System Status Report on 2-butoxyethanol
European Union Risk Assessment Tracking System Status Report on 2-butoxyethyl acetate
Opinion on Risk Assessment Report on 2-BUTHOXYETHANOL (EGBE: Ethylene glycol butyl ether) Environmental Part (Adopted by SCHER during the 10th plenary of 17 March 2006)
Opinion on Risk Assessment Report on 2-BUTHOXYETHANOL ACETATE (EGBEA: Ethylene glycol butyl ether acetate) Environmental Part (Adopted by SCHER during the 10th plenary of 17 March 2006)
Letter from DG ENTR regarding the Consultation of the CSTEE concerning RPA's report "Perfluorooctane Sulphonate – Risk reduction strategy and analysis of advantages and drawbacks" (30/06/04)
Check list for request for scientific advice on PFOS (21/09/04)
Request for a Scientific Opinion: RPA's report "Perfluorooctane Sulphonate – Risk reduction strategy and analysis of vantages and drawbacks" and additional questions
Perfluorooctane Sulphonate Risk Reduction Strategy and Analysis of Advantages and Drawbacks (Final Report)
Opinion on "RPA's report "Perfluorooctane Sulphonate - Risk reduction strategy and analysis of advantages and drawbacks" (Final report - August 2004) (Adopted by SCHER during the 4th plenary of 18 March 2005)
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/EEC) presented by the Commission Brussels, 5.12.2005; COM(2005) 618 final; 2005/0244 (COD)
Case study: Hair dyes
Scientific Committee on Consumer Products (SCCP) Minutes of 1 st -6 th Plenaries
SCCNFP/0635/03, final, Opinion of the Scientific Committee on Cosmetic Products and Non-food Products Intended for Consumers concerning Request for Re-evaluation of Hair Dyes Listed in Annex III to Directive 76/768/EEC on Cosmetic Products
SCCNFP/0720/03, final, SCCNFP Updated Strategy for Testing Hair Dyes for Their Potential Genotoxicity/Mutagenicity/Carcinogenicity
SCCNFP/0553/02 SCCNFP Assessment Strategies for Hair Dyes
SCCNFP/0553/02 SCCNFP Discussion Paper on Assessment Strategies for Hair Dyes
SCCNFP/0808/04 Opinion of the SCCNFP concerning Ring Study on Reaction Products from Typical Combinations of Hair Colouring Ingredients
SCCNFP/0797/04 SCCNFP Opinion concerning Use of Permanent Hair Dyes and Bladder Cancer, Updated 2004
SCCP/0930/05 SCCP Opinion on Personal Use of Hair Dyes and Cancer Risk
SCCP/0878/05 SCCP Opinion on Acid Blue 62
SCCP/0943./05 SCCP Opinion on <i>Lawsonia Inermis</i> (Henna)
SCCP/0876/05 SCCP Opinion on Isatin

Case study: Indoor air
Scientific Committee on Health and Environmental Risks plenary minutes
Scientific Committee on Health and Environmental Risks draft agendas
Draft request for a Scientific Opinion: Risk assessment on indoor air quality with specific reference to the BEUC report on "Emission of chemical by air fresheners"
Request for a Scientific Opinion: Risk assessment on indoor air quality with specific reference to the BEUC report on "Emission of chemical by air fresheners"
Minimum requirements for a request for scientific advice. Subject: Risk assessment on indoor air quality with specific reference to the BEUC report on "Emissions of chemical by air fresheners" and the "INDEX" JRC report.
Opinion on the report "Emission of chemicals by air fresheners: Tests on 74 consumer products sold in Europe", adopted by SCHER during 9 th plenary, 27 th January 2005.
Email from Gigliola Fontanesi to SANCO colleagues, informing of adoption of Air Fresheners Opinion
BEUC press release titled 'SCHER report on the BEUC Opinion on air fresheners' (06/02/2006)
ENDS Environment Daily email, sent to Gigliola Fontanesi on 07/02/2006
BEUC press release titled 'BEUC seeks to end legal proceedings on air fresheners' (23/02/2006)
Email from Peter Wagstaffe to SANCO colleagues, forwarding the BEUC press release of 23/02/2006
Case study: Nanotechnology
Scientific Committee on New and Emerging Health Risks plenary minutes
Scientific Committee on New and Emerging Health Risks draft agendas
Note from Robert Madelin to Ms C Day, Mr H Reichenbach and Ms O Quintin, regarding the request for a Scientific Opinion on "the appropriateness of existing methodologies to assess the potential risk associated with engineered and adventitious products of nanotechnologies" to SCENIHR (02/12/2004)
Note from Catherine Day to Robert Madelin, responding to above request for agreement on request for Scientific Opinion on nanotechnologies (15/12/2005)
Note from Odile Quintin to Robert Madelin, responding to above request for agreement on request for Scientific Opinion on nanotechnologies (22/12/2004)
Note from Horst Reichenbach to Robert Madelin, responding to above request for agreement on request for Scientific Opinion on nanotechnologies (27/01/2005)
Opinion on the appropriateness of existing nanotechnologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, adopted by SCENIHR during the 7 th plenary meeting, 28-29 th September 2005.
Opinion on the appropriateness of existing nanotechnologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, adopted by SCENIHR during the 10 th plenary meeting, 10 th March 2006.
Submissions to the public consultation on SCENIHR's Opinion on The appropriateness of existing nanotechnologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies
Press and Communication Service's midday briefing, 'Nanotechnology: Commission launches consultation on how best to assess health and environmental risks' (20/10/2005)
Nanotechnologies: A preliminary risk analysis on the basis of a workshop organised in Brussels on 1-2 March 2004 by the Health and Consumer protection directorate general of the European Commission (2004)
European Commission, <i>Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009</i> (2005)
Questions and answers on risk assessment of nanotechnology products, MEMO/05/385 (2005)
Royal Society & Royal Academy of Engineering, <i>Nanoscience and Nanotechnologies</i> , Chapter 10 (2004)

Appendix B: Respondents' affiliations

Table 2. Respondents' affiliations of interviews conducted

Affiliation	Area	Medium	Date
SCHER Secretariat	General	Face-to-face	20 June 2006
ENTR F3	Tooth whiteners	Face-to-face	20 June 2006
ENTR G1	General	Face-to-face	20 June 2006
SANCO B3	Air Quality	Face-to-face	20 June 2006
ENV C03	Chemicals	Face-to-face	20 June 2006
SCCP	General	Face-to-face	21 June 2006
SANCO B3	Tooth whiteners	Face-to-face	21 June 2006
ENTR F3	Tooth whiteners; Hair Dyes	Face-to-face	21 June 2006
SCCP Secretariat	General	Face-to-face	22 June 2006
SCENIHR Secretariat	General	Face-to-face	22 June 2006
SANCO B3	Hair Dyes; Tooth whiteners	Face-to-face	22 June 2006
SCENIHR	General	Face-to-face	22 June 2006
SCCP	General	Face-to-face	27 June 2006
ENTR G2 ENTR G2 ENTR G2 ENTR G2	Chemicals	Face-to-face	29 June 2006
ENTR G2	Nanotechnology	Face-to-face	29 June 2006
SCENIHR	General	Phone	6 July 2006
SANCO C4	Indoor Air	Phone	6 July 2006
SCHER	General	Phone	10 July 2006
JRC I.3	Chemicals	Phone	11 July 2006
SANCO C4	Indoor Air	Phone	12 July 2006
ENV G	Nanotechnology	Phone	12 July 2006
SCHER	General	Phone	12 July 2006
JRC I.3	Chemicals	Phone	14 July 2006

Appendix C: Process map of providing an Opinion

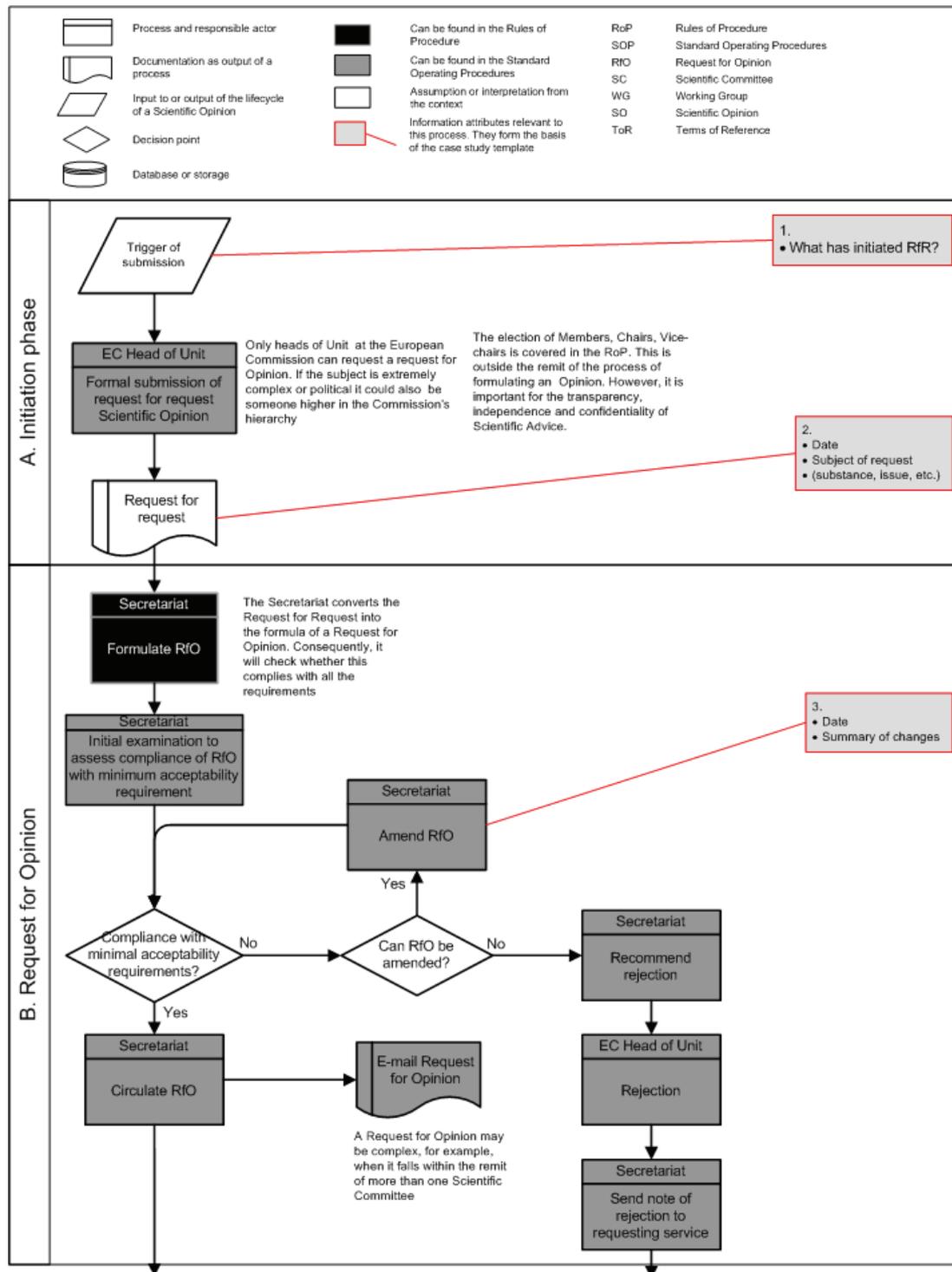
In order to describe and analyse the functioning of the Scientific Committees we have used a process mapping technique. As the mapping is mainly derived from information in the Standard Operating Procedures³³ and the Rules of Procedure,³⁴ it provides a schematic overview of the process of providing an Opinion in theory. In some instances, the process map may deviate from the process in practice. The Opinions' Database, mentioned in the Standard Operation Procedures – essentially a list of previous Opinions published online – is not identified as such by the stakeholders in the process. Such issues were clarified during the interviews, but they were not the focus.

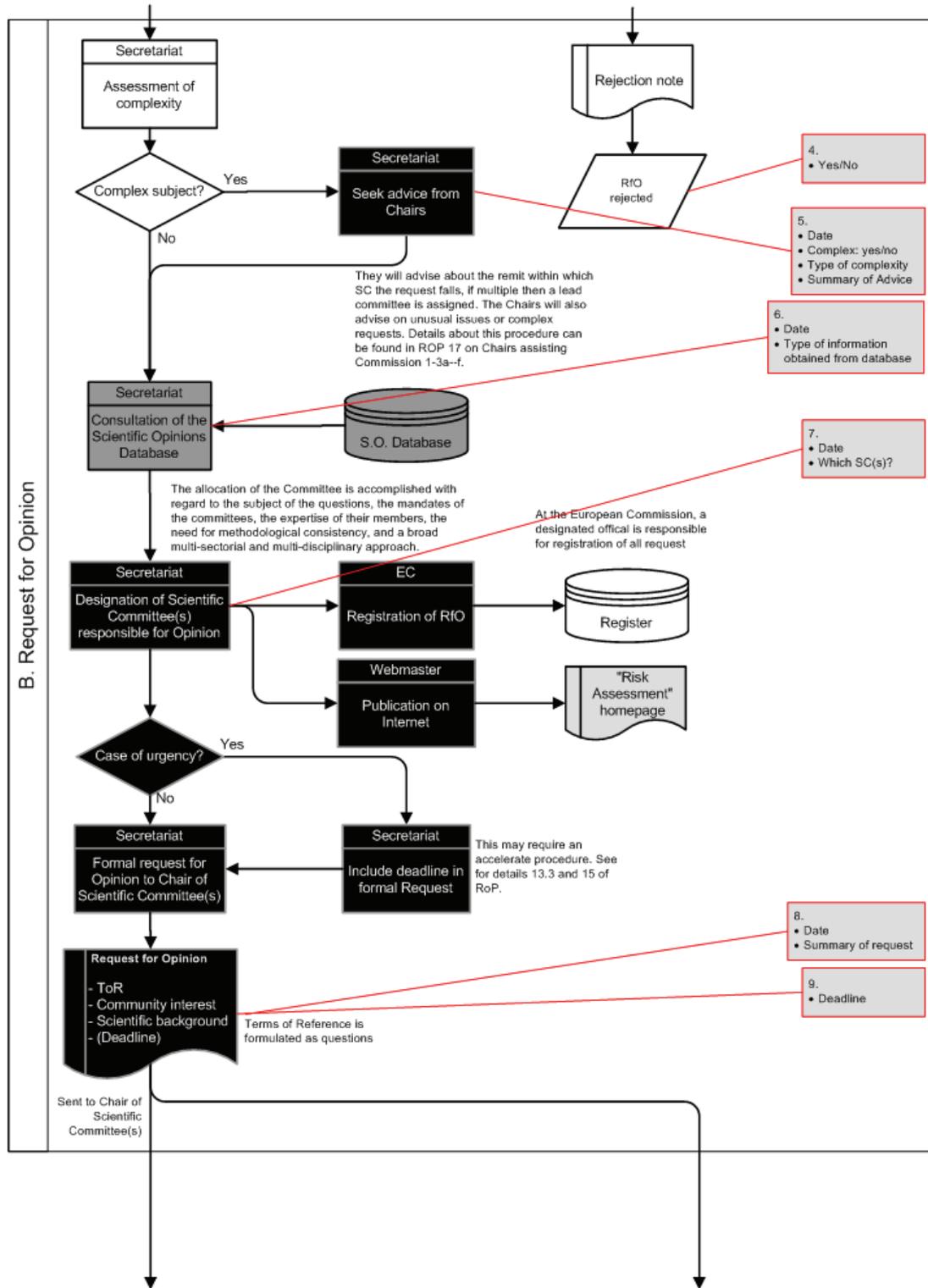
In this mapping, displayed on the following pages, we have distinguished 8 phases in this process:

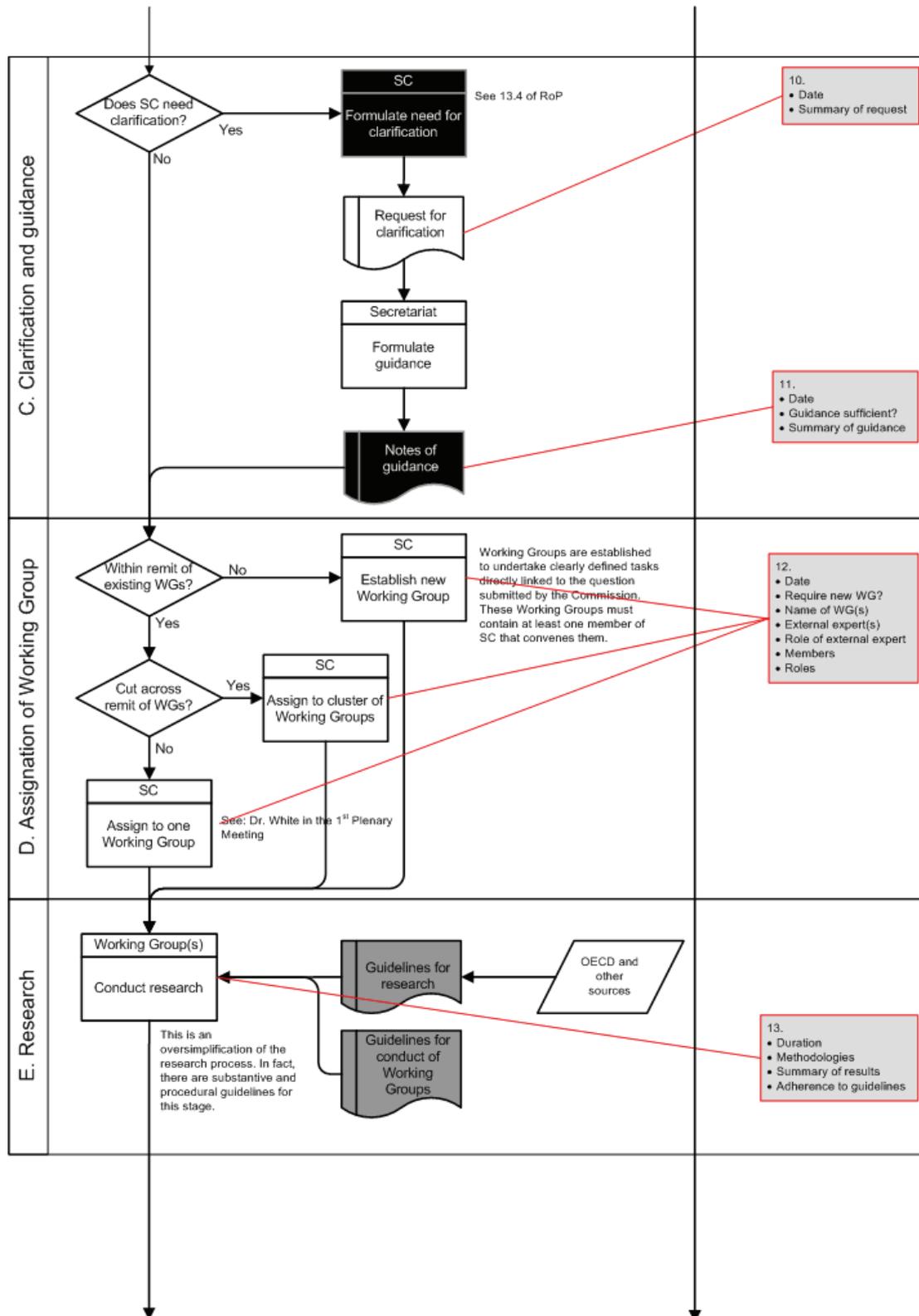
- A. Initiation phase;
- B. Request for Opinion;
- C. Clarification and guidance;
- D. Research of Working Group;
- E. Assignment;
- F. Documentation;
- G. Plenary meeting; and
- H. Completion.

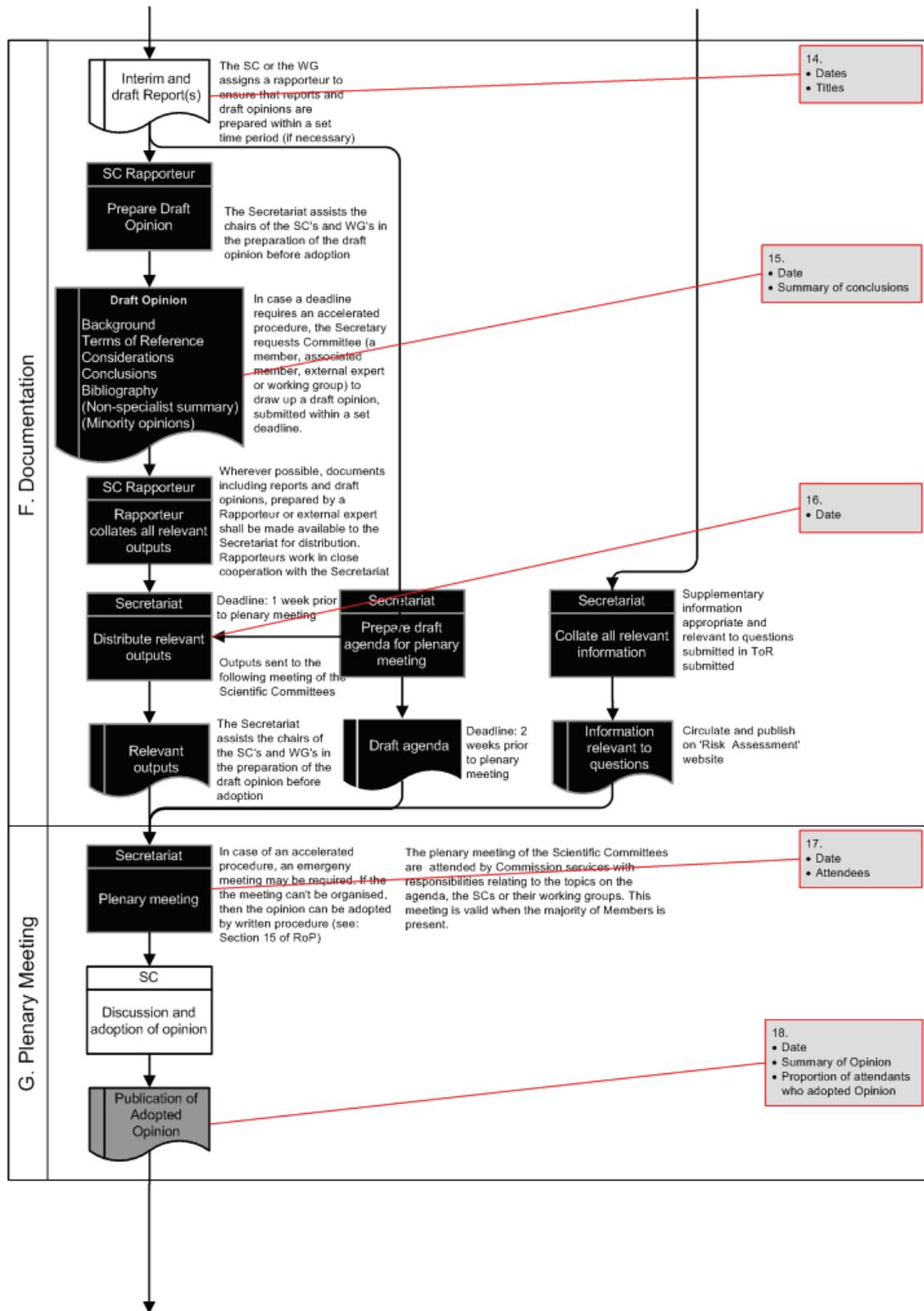
³³ SOP for establishing Opinions of the Scientific Committees set by Commission Decision 2004/201/EC (Draft 24 April 2006)

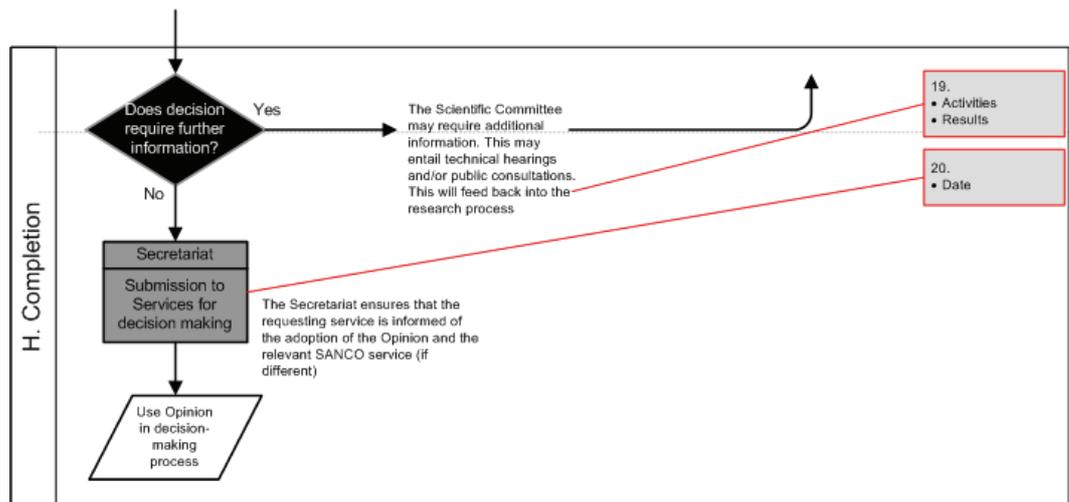
³⁴ Rules of Procedure of the Scientific Committees on Consumer Products (SCCP), Health and Environmental Risks (SCHER), Emerging and Newly Identified Health Risks (SCENIHR) SCs/01/04 final (C7(2004)D/370235) adopted on 7 September 2004











Appendix D: Interview core questions

1. Efficiency/timeliness

- A. How do the Commission Services concerned judge the overall efficiency of the process leading to the adoption of an Opinion? This assessment should cover the process from the initial contact with SANCO C/7 concerning the submission of the mandate up to adoption of the Opinion by the Committee.
- B. Are, generally, Opinions adopted in a reasonable/acceptable time?
- C. When a deadline is given, are Opinions adopted in a timely manner?
- D. Recommendations?

2. Value of Scientific Opinions (relevance and impact)

(i) Relevance

- A. To what extent do the Opinions of the Scientific Committees respond to the questions asked by the Commission Services?
 - Completely
 - Sufficiently? (please comment)
 - Not completely? (please comment, including actions taken if any)
- B. How many times did you ask for a clarification?
- C. Do the Opinions respect separation of risk assessment and risk management?
- D. Recommendations?

(ii) Impact of the Scientific Opinions provided by the Committees in assisting the work of the service in meeting its policy and legislative objectives

- A. From a scientific viewpoint (e.g. new scientific information/interpretation)
- B. From a legislation/policy viewpoint

3. Coherence

- A. Based on examples, are the Opinions/approaches coherent and consistent:
- Between the Committees?
 - With respect to other Community advisory bodies?
 - Over time?
- B. Recommendations?

4. Confidence in the soundness of Scientific Opinions

- A. What is the level of confidence in the scientific soundness of the Opinions (high, satisfactory, low – with comments and examples)?
- At the level of the Commission Services responsible for the questions
 - By stakeholders who are directly concerned by the advice (as assessed by the Commission Services concerned)
- B. Recommendations?

5. Independence and transparency

- A. Are the Commission Services satisfied with the level of independence and transparency? (Comments and examples to be given)
- B. Recommendations?

6. Interface between the Commission Services and the Scientific Committees

- A. To what extent is the service satisfied with the interface?
- In the formulation of mandates
 - Participation during Working Group and plenary meeting discussions
 - Flow of communication
 - Feedback in both directions
- B. Recommendations?

7. For Scientific Committee Members only

- A. Input from Scientific Committee Members on
- Involvement in mandate
 - Clarity of questions
 - Data quality

- Information and support from Commission Services
- Feedback on Opinions
- Other

B. Recommendations?

This report was produced by a contractor for Health & Consumer Protection Directorate General and represents the views of the contractor or author. These views have not been adopted or in any way approved by the Commission and do not necessarily represent the view of the Commission or the Directorate General for Health and Consumer Protection. The European Commission does not guarantee the accuracy of the data included in this study, nor does it accept responsibility for any use made thereof.