



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

Brussels, 25 April 2007
SANCO.C7/D(2007) 370277

**ACTION PLAN¹ TO THE TECHNICAL REPORT ON
INTERMEDIATE EVALUATION OF SANCO NON-FOOD SCIENTIFIC
COMMITTEES
MADE BY THE CONTRACTOR 'RAND'²**

¹ The Action plan relates to the recommendations and findings of the Intermediate evaluation of SANCO non-food Scientific Committees made by the contractor 'RAND'

² Available at SANCO's Webpage http://ec.europa.eu/health/ph_risk/documents/risk_eval_frep_en.pdf

Responsible Unit: Directorate C – Unit C7		Evaluation Manager	Date of Final report: 06.12.2006
No	Recommendation: Compare the organisation, performance and achievements of the Scientific Committees against external benchmarks		
1	<p>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.</p>		
Unit's response to recommendation¹:			
<p>While quantitative benchmarking of performance seems of limited applicability to the activities of the committees, due to the nature of their tasks and mission, comparison with the organisation, processes and procedures of other bodies delivering advice under comparable conditions may provide useful indications to evaluate the functioning of the committees, identify best practices and introduce the appropriate improvements.</p> <p>Since it is currently proposed to extend the terms of office of the Scientific Committees for a further 18 months, in view of ensuring the transition with the upcoming European Chemical Agency (ECHA) and prepare the necessary restructuring of the Committees, it is planned to perform the comparative assessment of the committees against external experience as part of the preparation of a proposal for the full restructuring of the Scientific Committees in 2008. This assessment will be carried out internally, but would involve contacts with other risk assessment bodies and consultations with scientists, stakeholders and other Commission services.</p>			
Action plan²:		Responsibility of implementation³: b	Due date for action(s) to be completed⁴:
<ul style="list-style-type: none"> • Prolongation of the terms of office of current members of Scientific Committees 		SANCO.C7	By April 2007
<ul style="list-style-type: none"> • Limited call for expressions of interest in membership of Scientific Committees 		SANCO.C7	By Autumn 2007
<ul style="list-style-type: none"> • Collecting and analysing information on organisation, practices, processes and procedures on key operating aspects in comparable risk assessment bodies and comparing with the functioning and experience of the Scientific Committees 		SANCO.C7	By end of 2007
<ul style="list-style-type: none"> • 'Scoping paper' (internal SANCO document outlining new initiatives) on the EU needs for risk assessment advice and options for the structure, profile, organisation of scientific advice needed to support the EU policy decision makers. This scoping paper will in particular take into account the results of the 		SANCO.C7 + other services	By Spring 2008

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<p>comparative analysis mentioned above.</p> <ul style="list-style-type: none"> • Full restructuring of the non-food Scientific Committees in light of the results of the evaluation 	<p>SANCO.C7 + other services</p>	<p>By December 2008</p>
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Responsible Unit: Directorate C – Unit C7		Evaluation Manager	Date of Final report: 06.12.2006
No	Recommendation: Improve the sharing of information across the Scientific Committees and other advisory bodies.		
2	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.		
Unit's response to recommendation¹:			
We see this recommendation in the perspective of a goal of continuous improvement as well as the longer term adaptation to new needs and challenges. A number of initiatives are in place (e.g.: Inter-committees coordination group; Meeting between the Chairs of the EU risk assessment bodies; meeting with the EP and stakeholders), and it is agreed that there is room for improvement in particular vis-à-vis the sharing/exchanging of information by continuing and reinforcing the ongoing and planned initiatives.			
Action plan²:		Responsibility of implementation³:	Due date for action(s) to be completed⁴:
<ul style="list-style-type: none"> • Regular meeting of the Inter-committees coordination group, Chairs and Vice-Chairs of the 3 non-food SCs – 4 meetings/year 		SANCO.C7	Ongoing
<ul style="list-style-type: none"> • Risk Assessment days event 2007 (meeting with EP and stakeholders) 		SANCO.C7	22 March 2007
<ul style="list-style-type: none"> • Regular Annual Risk Assessment Days in light of the results of the 1st experience 		SANCO.C7	By Summer 2008
<ul style="list-style-type: none"> • Follow-up to the 2nd meeting of Chairs of EU Risk Assessment bodies: <ul style="list-style-type: none"> ○ action plan ○ regular update at the Inter-committees coordination group 		SANCO.C7 + other services/bodies	Ongoing
		SANCO.C7	By April 2007
		SANCO.C7	Ongoing

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<ul style="list-style-type: none"> • 3rd meeting of Chairs of the EU Risk Assessment bodies – scheduled 	ECDC+SANCO.C7	6-7 Nov. 2007
<ul style="list-style-type: none"> • To establish co-operation with other bodies in specific areas (e.g. nanotechnologies) 	SANCO.C7+other bodies	By 2008
<ul style="list-style-type: none"> • To identify Networks of scientific bodies (at National / International level, including academies etc) to exchange expertise / collaboration / dissemination of opinions (as done with the Federation of European Academies of Medicine, European Science Advise Network for Health) 	SANCO.C7+other bodies	Ongoing
<ul style="list-style-type: none"> • To organise EU or International conferences/seminars 	SANCO.C7+other bodies	By Autumn 2007
<ul style="list-style-type: none"> • To organise thematic ad hoc workshop(s) with representative from other scientific bodies 	SANCO.C7+other bodies	By end 2007
<ul style="list-style-type: none"> • To promote participation of members of the Scientific Committees in major international conferences or events of interest for the Scientific Committees <ul style="list-style-type: none"> ○ Example: Society of Environmental Toxicology and Chemistry (SETAC) conference in Porto 	SANCO.C7+other bodies	Ongoing By May 2007

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Responsible Unit: Directorate C – Unit C7		Evaluation Manager	Date of Final report: 06.12.2006
No	Recommendation: Increase the impact of Scientific Committees' work (Scope).		
3	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.		
4	Recommendation: 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.		
Unit's response to recommendation¹:			
The challenge of availability of external experts and members of the Committees is of fundamental relevance. It is a general challenge for the EU advisory bodies particularly in specific domains where expertise is limited. It requires action beyond the review of the impact of Committees' opinions. SANCO.C7 has already proposed an action plan to raise the profile of the Scientific Committees and increase awareness of their activities. It is intended to continue with the initiatives of the action plan in question in order to address the issues mentioned in the recommendation.			
Action plan²:		Responsibility of implementation³:	Due date for action(s) to be completed⁴: By
<ul style="list-style-type: none"> • Publicity (logo, video, leaflet, poster) 		SANCO.C7 + contractor	June 2007
<ul style="list-style-type: none"> • Dissemination of scientific opinions - media planning (press releases, e-news) 		SANCO.C7+A4+Spokes person	Ongoing
<ul style="list-style-type: none"> • Dissemination of scientific opinions (CD room; publication of abstracts in scientific journals) 		SANCO.C.7	Under preparation
<ul style="list-style-type: none"> • Contacts with association & Networks (e.g. Federation of European Academies of Medicine, European 		SANCO.C7+DGs	Dec. 2007

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<p>Science Advise Network for Health)</p> <ul style="list-style-type: none"> • Procedure for monitoring follow-up activities on adopted opinions (e.g. with services responsible; SANCO's interest, etc.) • Newsletter • Lay language summaries intended for non-scientists (3 opinions: tooth whitening, nanotechnology and sunbeds) to be published on the Public health webpage and announced in EU Health Portal • Lay language: framework contract – 4 years (4 opinions for 2007) • Inventory of formal and 'on-the-job' risk assessment training schemes of relevance to the work of the Scientific Committees • Redesigning of Webpage 	<p>services</p> <p>SANCO.C7</p> <p>SANCO.C.7</p> <p>SANCO.C.7</p> <p>SANCO.C.7+consultant</p> <p>SANCO.C7+contractor</p> <p>SANCO.C.7+A4 +webmaster</p>	<p>Ongoing</p> <p>May 2007</p> <p>Ongoing</p> <p>Ongoing</p> <p>Under preparation</p> <p>2007</p>
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Responsible Unit: Directorate C – Unit C7		Evaluation Manager	Date of Final report: 06.12.2006
No	Recommendation: Avoid Scientific Committees commenting on risk management issues.		
5	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.		
Unit's response to recommendation¹:			
Fully recognised and shared. The basic principles are well established. Some relevant tools and practices are also in place. Nevertheless, the need to improve the practical application of the principle is recognised. It is intended to reinforce the day to day application by organisational measures.			
Action plan²:		Responsibility of implementation³:	Due date for action(s) to be completed⁴:
<ul style="list-style-type: none"> • Two sectors have been created grouping the scientific committees and monitor activities (incoming requests and opinions). A closer monitoring of the strict application of separation between risk assessment and risk management will take place at sector level. • Common Guidelines for submission of requests to be circulated to other services (DGs). These guidelines cover in detail the issue of separation between risk assessment and risk management. • Revision of the Scientific Committees work programme, with particular attention to identification of cases where there is a risk of mixing up risk assessment and risk management. • Systematic application of the checklist on mandate received which also cover the issue in question 		<p>SANCO.C7</p> <p>SANCO.C7</p> <p>SANCO.C7 + other services</p> <p>SANCO.C7</p>	<p>Ongoing</p> <p>June 2007</p> <p>June 2007</p> <p>Ongoing</p>

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Responsible Unit: Directorate C – Unit C7		Evaluation Manager	Date of Final report: 06.12.2006
No	Recommendation: Review the work of the Committee Secretariats.		
6	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.		
Unit's response to recommendation¹:			
It is recognised that the Scientific secretariats have both technical and administrative tasks. Their tasks are briefly described in point 18 of the Rules of Procedures adopted by the Scientific Committees. It should also be noted that since the renewal of the Scientific Committees in 2004 several new actions have been undertaken to increase transparency and dialogue with stakeholders, such as public consultations on draft scientific opinions. These actions are relevant for enhancing the quality of the scientific opinions. However, these actions have also contributed to increasing the administrative burden of the secretariat as well as of the members of the Scientific Committees. In order to ensure the best use of limited resources, it is intended to examine at the level of the recently created sectors how to streamline the administrative tasks and to outsource some of the tasks in question. Moreover, as stated in relation to recommendation 7, we intend to discuss with other Commission services whether and how part of the burden in particular for quality control of data and literature search could be shared with industry in certain cases.			
Action plan²:		Responsibility of implementation³:	Due date for action(s) to be completed⁴:
<ul style="list-style-type: none"> Two sectors have been created grouping the scientific committees and an official has been included in each team and consideration will be given to how administrative tasks may be redistributed Ad hoc projects under a framework contract – a 4 year's project (in particular on data collection, references review, literature search etc) 		SANCO.C7	Ongoing
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Responsible Unit: Directorate C – Unit C7		Evaluation Manager	Date of Final report: 06.12.2006
No 7	<p>Recommendation: 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.</p> <p>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.</p>		
Unit's response to recommendation¹:			
<p>This recommendation is fully shared. As said above, it is intended to examine with other Commission services and industry associations, how industry could ensure completeness and quality of data and help in data search and literature screening. In addition, certain tasks will be outsourced. Finally, the Risk Watch system will be operated systematically in the main areas of interest for the activities of the Committees in order to help identifying relevant information and data.</p>			
Action plan²:		Responsibility of implementation³:	Due date for action(s) to be completed⁴:
<ul style="list-style-type: none"> • Discussion with ENTR and relevant industry associations on how industry can ensure improved quality of dossiers and support search of data and literature screening . This may include a pre-screening of submissions • Risk watch operated systematically and extended as may be requested by Scientific Committees (media monitoring system – sent weekly to the members of the Scientific Committees and SANCO services) • Ad hoc projects under a framework contract – a 4 year's project (data collection, references review, literature search etc) 		<p>SANCO.C7 + ENTR + COLIPA</p> <p>SANCO.C7</p> <p>SANCO.C7</p>	<p>June 2007</p> <p>Ongoing</p> <p>Under preparation</p>

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Responsible Unit: Directorate C – Unit C7		Evaluation Manager		Date of Final report: 06.12.2006	
No	Recommendation: Consider increasing the time and human resources available for the Scientific Committees.				
8	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.				
The issues of data gaps, data quality, literature screening and reduction of administrative pressure of the secretariat are addressed in previous recommendations and the propose actions.					
Action plan²:				Responsibility of implementation³:	Due date for action(s) to be completed⁴:
See actions mentioned in relation to recommendations 6 and 7				SANCO.C7	Under preparation

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Responsible Unit: Directorate C – Unit C7		Evaluation Manager	Date of Final report: 06.12.2006
No 9	<p>Recommendation: Ensure the division of labour between Commission Services and Scientific Committees is appropriate when formulating Requests for Opinions.</p> <p>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.</p>		
Unit's response to recommendation¹:			
Agreed, with particular emphasis on the boundary between risk assessment and risk management.			
Action plan²:		Responsibility of implementation³:	Due date for action(s) to be completed⁴:
<ul style="list-style-type: none"> • Two sectors have been created grouping the scientific committees and an official has been included in each team and consideration will be given on how administrative tasks may be redistributed • Standard Operation Procedure checklist • Harmonise procedures and increase informal contact between desk officers for preparing the terms of reference (mandate) for scientific opinion, in particular with Directorate General Industry and Enterprise (DG ENTR) • Regular presentation at plenaries meeting of requests for opinion by originating service, in order to ensure that requesting sources assume responsibility for the quality of questions 		<p>SANCO.C7</p> <p>SANCO.C7</p> <p>SANCO.C7+ENTR.F 3</p> <p>SANCO.C7 + other services</p>	<p>Ongoing</p> <p>Ongoing</p> <p>End of 2007</p> <p>Ongoing</p>

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