Luxembourg, 20.10.2016
SANTE C2 (2016)

COMMISSION Follow-up of the evaluation report

on the Functioning of the SANTE non-food Scientific Committees

INTRODUCTION

This follow-up table provides tasks planned to respond to the recommendations of the "*Second intermediate evaluation of the functioning of the SANTE non-food Scientific Committees (SCs)*". The findings of the Evaluation are expected to inform the continuation of the Scientific Committees (SCs) activities under the new term, which started at the end of April 2016[1], as well as possible reviews of the Rules of Procedure of the Scientific Committees[2].

[1] The new organisation of the SCs is laid down by Commission Decision of 07/08/2015; Members of the new Scientific Committees were appointed by SANTE Director General on 08/03/2016; the first meeting of the new Committees took place on 28 and 29 April 2016 in Luxembourg.

[2] http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2016_en.pdf

Table of Recommendations (*)

Recommendations	*Action suggested*	*Deadlines*	*Comments*
1 Effectiveness			
Responsiveness to Clients' Needs 1. Within the framework of a broader review of call for data and information policies, SCCS could consider the possibility of having recourse to dedicated public consultations to elicit information on industrial processes and other market practices, similar to those of ECHA.	SCCS, together with the mandating service (DG GROW), organises public consultations or calls for data whenever necessary to evaluate the safety of cosmetic ingredients. Generally, information on industrial processes and other market practises are not required. However, if necessary for the evaluation, the Secretariat is keen to organise calls for information or specific hearings with applicants on these topics.	Not applicable	
Separation between Risk Assessment and Risk Management and Confidence in the Soundness of Scientific Opinions 2. It is recommended to strengthen - in agreement with the requesting services - the practice of submitting requests for an opinion of a non-authorisation nature to public consultations to give stakeholders the opportunity of commenting on perceived overlapping with risk management issues.	Public consultations on mandates are already contemplated in the Rules of Procedures of the SCs and were implemented for specific opinions where contribution from stakeholders is valuable (e.g. Electromagnetic Fields). This possibility will also be considered for the future when necessary.	Already in place	
Impact and Communication and Dissemination 3. It is recommended to continue and possibly further strengthen the current dissemination policy of opinions in the scientific literature and focus on publications with an international visibility. This could eventually include participation to selected high level scientific conferences and fora at the international level.	An annual communication and dissemination plan is in place for the activities of the SCs. Publication of opinions in scientific journals targeting peer scientists is already included and will continue, subject to sufficient human resources allocated to the SCs Secretariat. Activities already include participating in selected high level scientific conferences and other events at the international level, but this could be reinforced, subject to budgetary allowances.	Already in place	
4. The requesting services should be routinely reminded to add a cross-link to the opinion in their policy pages.	The Secretariat will routinely remind the requesting services to disseminate the opinions on their websites.	From Q3 2016 onwards	

2 Efficiency *Cost of the Structure* 5. It is recommended to consider the possibility of subcontracting some parts of the preparation of the draft opinions to external contractors to increase the cost-effectiveness of activities should the need to carry out a major review program of substances arise.	This possibility will be considered when and if there is a major review programme regarding substances. At the moment this is not the case and outsourcing part of the work to external contractors is not deemed as good value for money.	/	
Secretariat Support 6. It is recommended to carefully monitor the level of staff resources available in the light of future needs to ensure that the Secretariat capacity to provide support remains sustainable.	The Secretariat has already requested a better planning to COM services and is regularly exchanging information with them to be able to properly plan any request for mandates. However, in some cases it is difficult to plan activities (cf. mandates on cosmetic ingredients -SCCS) because they depend on external applications which are not predictable.	Already in place	
7. It is recommended for the Secretariat to further strengthen the monitoring system to track down the long term impact of the opinions also in the areas covered by SCENIHR and SCHER and use related data as a basis for an internal quality control mechanism.	Since the new term (2016-2021), the Secretariat put in place a systematic reporting process from the requesting COM services during each plenary meeting of the Scientific Committees so that the (long-term) impact of opinions can be reported to the Committees. Further contacts with relevant services will be strengthened to ensure that the impact of the opinion will be systematically tracked.	From Q3 and continued all the term	
8. It is recommended for the Secretariat to consult with stakeholders and MS on the format and modalities of calls for data and information to make them more cost-effective and user-friendly (this includes the possibility of having more simplified submission modalities, the need for more extended deadlines for data submission, the provision of long list of relevant studies and related research strategies to stakeholders to react to and spot missing ones, to consider the language policy of contributions, the possibility of introducing dedicated public consultations on missing data / information gaps during opinion processing, etc.).	This point will be discussed with the SCs and via the requesting units to MS and other relevant stakeholders to review the format and modalities of calls for data.	By Q4 2017	

Timeliness of Deliverables and Compliance with Deadlines			
9. It is recommended that the SC and particularly SCENIHR should consider strengthening the practice of splitting broad mandates into more specific ones to be processed in parallel also as a way to enhance their timeliness and compliance with deadlines.	This recommendation has already been implemented (e.g. for Synthetic Biology split into three parts, and Tobacco additives, split in two parts) and will also be implemented in the future for complex mandates. However, it is often impossible to proceed in parallel for different parts, because quite often the experts in the working group are the same and the subject of the opinion are interrelated and therefore the second part has to proceed from the conclusion of the first one.	Already in place	
10. It is recommended to closely monitor compliance with deadlines and tendency to recur to stop-the-clock procedures on opinions with mandatory deadlines. If stop-the-clock procedures tend to become routinary or exceed a certain threshold (e.g. 25% of cases) it would appear advisable for SCCS to have more extended recourse to collective technical meetings with stakeholders analysing the main shortcomings in past dossiers or provide applicant with the opportunity of having short clarification teleconferences before they submit a dossier to minimize risks of late discovery of misunderstandings in information requirements. It is understood that these could be perceived as a breach of independence by some stakeholders, but starting from 2013 these are also the few instances in which the need to spur innovation by reducing uncertainty as to the time-to-market of the underlying product has also been recognised as a wider political objective.	Dossier submitted to SCs (this is mainly the case of SCCS) should be complete in order to enable the Committee to perform risk assessment. This is not always the case, but SCs can check the documents only during the evaluation process which leads to the clock being stopped. Members regularly reviewed their SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation (SCCS/1564/15) in order to better inform the applicant about application requirements.	Check list Q4 2017 Hearing already in place	
11. It is recommended to establish a registry of questions to allow concerned stakeholders to track progress of risk assessment activities (the simple SCOEL ISO coding of the stage an opinion has reached could be used as a reference in this respect).	A checklist for the applicants will be developed by SCCS, together with DG GROW, to help them fulfil the requirement laid down in the SCCS Notes of Guidance. Clarification meetings (hearings) are already in place between SCCS and the applicant's ad hoc experts. The Secretariat can address this recommendation for the part concerning risk assessment. It is already possible for applicants to keep track of the mandates and opinions on the SCs website. However, the track system on the SCs website will be further developed to better meet the applicants' needs. However, applicants are mainly concerned about the part that is in	Q3 2017	

	the remit of risk managers (time elapsing before SCCS is mandated and after publication of final opinions). The Secretariat will coordinate with GROW to commonly address this recommendation, also for the part under the remit of GROW.		
3 Relevance *Adequacy of the Level of Indemnities.* 12. It is recommended to expand the range of indemnities available for single rapporteurs to be able to better modulate reward to level of effort and complexity of the underlying opinion, including when needed the achievement of pre-defined objectives.	Special indemnities have been aligned to the new provisions for Commission expert groups in the 2015 Decision establishing the SCs. This has resulted in increasing the experts' special indemnity and the Secretariat's flexibility to better match the compensation to the level of effort and the complexity of the opinion. Level of effort and complexity of the work is reflected in the criteria used by the SCs secretariat to allocate indemnities, not only for rapporteurs but also to chairs.	Already in place	
4 Coherence *Internal Coherence* 13. It is recommended to find ways to ensure that, irrespective whether there is a formal dissenting opinion or not, the rationale behind minority views in the scientific community or at a working group level on a controversial subject are always clearly explained and reflected in the text of the opinions (e.g. the different weight given to studies).	Templates of opinions already include the possibility of drafting a chapter on the minority opinion. This chapter, in case of a divergent opinion, needs to contain substantial/ clear explanations and to provide reasons for its inclusion, based on scientific grounds. This option has been used once during the term 2013-2016 for the preliminary opinion on SYNBIO I (definition).	Already in place	
External Coherence 14. The Commission should consider strengthening the institutional mechanisms and the fora available to promote methodological harmonisation between the various EU risk assessment bodies.	The Secretariat has recently established regular bilateral meetings with other EU bodies and mutual visits to encourage and allow for an exchange of information on the latest methodologies developed and used by the SCs. It includes for example, EFSA/ECHA but also SCOEL (DG EMPL) and JRC. It also ensures the participation of SCs' members in workshops and meetings on the methodology of these Union bodies. Continuation of such exchanges, both at Secretariat and members level, will be sought, including participation in/organisation of training sessions. The Secretariat has recently started to participate in ANSA meetings (the network of all EU agencies), with the view of increasing cooperation with EU bodies involved in risk assessment, and having the opportunity to discuss methodological issues.	Ongoing	

15. It is recommended to have provisions in the Rules of Procedure requiring to include in scientific opinions a standard section elaborating on the reasons behind apparent inconsistencies in conclusions or the methodologies used by other EU risk assessment bodies on similar subjects.	Template of SCCS opinions already includes a chapter on the conclusion that deal with "any other scientific" concern the SC may have, as requested by the mandate provided by COM services. Nevertheless, this recommendation will be put forward for the next revision of the Rules of Procedure.	Q1 2017	
5 Utility *Openness and Transparency of Operations* 16. It is recommended to publish the CV of the experts participating to WG activities on the SC website and to publish or make otherwise available upon request a document on the motivation behind their selection.	All the CVs of SCs members are already published on the website. For the experts, declarations of interest, commitment and confidentially are published. Publication of CVs will be done from the new term 2016-2021 onwards. Publication of the document explaining the selection of experts for specific WGs is available on request. The Secretariat prefers not to publish this document, in order to provide data protection for the non-selected candidates. However, in the Rules of Procedures, general criteria on the selection of external experts are illustrated and are publicly available.	Q4 2016	
17. Applicants should be asked if they prefer or not to waive the confidentiality on their proprietary studies, so as to allow a transparent disclose of the debate occurring in the SCCS commenting period. This would imply making studies potentially available to the public. The Rules of Procedure (RoP) should be modified accordingly.	Applicants are required, when they submit a dossier, to inform the SCs if there is any confidential data that cannot be referred to during the development of their opinion. Studies submitted are not always owned by the applicant but sometimes by other bodies (chemical enterprise - manufacturer) that make it even more complicate to ask for a waiver of confidentiality, because any request should be sent directly to the owner of the data/studies. This recommendation will be put forward to the SCCS for their consideration and if necessary RoP will be accordingly modified.	Q1 2017	
Interaction and Dialogue with Stakeholders 18. It is recommended to strengthen mechanisms for the provision of early information to interested parties on forthcoming opinions, and to enhance the recourse	See response to recommendations 2, 8 and 11.	/	Risk management issue

to calls for information.			
19. It is recommended to extend the duration of the commenting period on SCCS authorisation-related opinions to three months, to better cope with the needs of applicants. The Commission may consider also to drop the commenting period and replace it with a technical meeting with the applicant at the moment of dossier resubmission after a stop-the-clock procedure, or give such option to the applicant.	The SCCS has already extended the commenting period from 4 to 8 weeks (and even more during holiday periods) upon request of applicants/Member States via the mandating COM service. To extend the duration of the commenting period for SCCS opinions would result in non-respecting legal deadlines. 8 weeks is an adequate timeframe for opinions that are based on a submitted dossier containing all the necessary information. For complex applications, the period can be extended on a case-by-case basis. It should be noted that any new data/specific study should anyway receive a new mandate that will also provide a new opinion. Meetings requests from applicants are always considered by the SCCS and agreed on whenever the SCCS considers it useful/relevant at the stage of the procedure. RoP will be modified to include the possibility for the Commission to replace a commenting period with a hearing.	Ongoing. Modification RoP Q1 2017	Further delay not recommended by the Secretariat and the SCCS
Independence and Conflicts of Interest 20. It is recommended to better define in the Rules of Procedures the graduated restrictions to participation into SC activities related to the different stages already foreseen potential conflict of interest (with industry, with risk management bodies, etc.) and make their assessment more predictable (practices at SCOEL or EMA can be used as examples) and to add some clarification on how to deal with, (i) the authors of the studies reviewed, and (ii) experts who have taken public advocacy position on a dossier, by making public statements, including in their articles, on the need to take action or the suggested course of action. Any 'exception' – such as declared items that the Commission does not consider conflicting interests - should be clearly and transparently motivated. The 'waiver' procedure should be clearly codified. Similarly, the sanctions for breaches of trust need to be explicitly defined to prevent any discretion. The implications for the expert involved and the eventual repealing of affected opinions should be spelled out in the procedures.	The Commission adopted COMMISSION DECISION C(2016) 3301 of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups that also deal with conflict of interest issues. The Secretariat is developing standard operating procedures (SOP) on how to handle declarations of interest within its Committees: the issues raised in this recommendation will also be addressed.	Q4 2016	

(*) Source: *Final Report of Economisti Associati on the Second Intermediate Evaluation of the Functioning of the SANTE non-food Scientific Committees (April 2016)*

CONCLUSIONS

The recommendations from the final report of the '*Second intermediate evaluation on the functioning of the SANTE non-food Scientific Committees'* have been already implemented or are in the process of being implemented. This exercise shows that tasks to be performed are on track, if not yet concluded. The table includes the remaining activities to be implemented, together with the planned Timeline.