



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

"HEALTHY DEMOCRACY"

*Conclusions and Actions following the DG SANCO 2006
Peer Review Group on Stakeholder Involvement*

Without Attachments

The full report can be consulted at the following website:
www.sanco-stakeholderinvolvement.eu

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1. Executive Summary

1. 1 Introduction

This Synthesis Report reports on DG SANCO's 2006 Healthy Democracy Process. A draft of it was circulated to all participants who attended one or more meetings of the DG SANCO Stakeholder Involvement Peer Review Group and was discussed in detail at the final meeting on 1st December 2006. This final version includes both the comments made orally at the 1st of December meeting and the ones made in writing by 22nd of December 2006.

The responsibility for this report rests with the Chairman of process. The document is public and will be posted on DG SANCO website and may be posted and distributed at will, but only in its entirety and without modification.

The purpose of this report is twofold:

- to outline the key themes and recommendations that have emerged from the DG SANCO Healthy Democracy Process; and
- to give a proposed way forward for the process as a whole.

This document has been kept deliberately brief. More detailed reports of the research and meetings that underpin this work are contained in the Annexes.

1. 2 Rationale and History of the Healthy Democracy Process

Connecting with citizens and stakeholders is intrinsic to DG SANCO's mission and in early 2006 DG SANCO embarked on a new process to take this agenda further. Known as the Healthy Democracy process, this new process has built upon DG SANCO's extensive track record of stakeholder engagement in particular the 2005 DG SANCO Scoping Paper Guidelines¹. The purpose of the Healthy Democracy process is to improve stakeholder involvement and participation. In the long term, the aim is to establish a solid network of stakeholders and research bodies to improve its substantive performance.

The Healthy Democracy Process consists of three major components:

A. Establishing a DG SANCO Stakeholder Involvement Peer Review Group

The Peer Review Group was established in early 2006 to assist DG SANCO in reviewing its experience concerning stakeholder involvement and to identify best practices and improvements to the existing consultation system (see *Annex E*). It included a mixed representation of stakeholders affected by the different SANCO policy areas. Industry (federations and individual firms), Non-Governmental Organisations (NGOs) and Member States as well as local and regional authorities were all represented in the group. In addition to stakeholders, the group also included experts on public participation.

¹ weblink to be established.

The group met four times in the course of 2006 (13th June, 7th September, 11th October and 1st of December) and focused its work on four main issues: "Stakeholders & Inequalities" (WG A), "Feedback & Communication" (WG B), "Stakeholder Planning & Resources" (WG C) and "Comitology" (WG D).

B. Production of supporting materials

This Synthesis Report is the fifth and last of a series of reports. The other reports in chronological order are:

- Minutes from the 11th October Meeting (see *Annex B*)
- Minutes from 7th September Meeting (see *Annex C*)
- Report of the 13th June Meeting (see *Annex D*)
- Preliminary Report of Main Findings and Issues for Discussion (see *Annex E*)

C. A Conference in Spring 2007

The findings and the recommendations of the Peer Review Group will be shared and validated at a conference in spring 2007, involving all DG SANCO stakeholders, other DGs and EU Institutions and experts on public participation.

1.3 Key Recommendations

The Healthy Democracy Process has been founded on a principle of shared responsibility, recognising that the goals of this work cannot be achieved by DG SANCO alone. In that vein the findings contained in this document have been drawn directly from the Peer Review Group and been developed taking into account the comments received throughout the process.

The meetings of 7th September and 11th October provided an opportunity to discuss in detail the issues of 'Stakeholders and Inequalities', 'Feedback & Communication', 'Stakeholder Planning & Resources' and 'Comitology'. A total of 50 recommendations were generated through these discussions (for a full list of these recommendations see *Annex A*).

The Synthesis Report only highlights the Top-10 recommendations. In other words, those recommendations that are of central importance for the goal of this process and where the Chair considers possible to make concrete progress on them. The Top-10 recommendations listed below are explained in full details in Chapter 2 "Synthesis". Chapter 2 also includes per each recommendation a DG SANCO response.

- **Recommendation I: Establish a "Stakeholder Dialogue Group" to get advice on process**

The Peer Review Group recommended the establishment of a Stakeholder Dialogue Group to advise DG SANCO on processes rather than on content.

- **Recommendation II: Improve Transparency through better "Forward Planning"**

The Peer Review Group recommended more transparency through greater access to timetables of individual consultations as contained in DG SANCO Annual Management Plan (AMP).

The Peer Review Group also recommended to refine DG SANCO web-tools in order to allow for a reminder by email on individual consultations and their planned timetable and for an easy mapping of upcoming consultations.

- **Recommendation III: More and Better Feedback**

The Peer Review Group stressed the importance of providing feedback to stakeholder views and recommended that, after each consultation, a synthesis report should be produced and circulated following each consultation to all consultees. The synthesis report should clearly state the main outcomes of the consultation and should provide reasons why certain stakeholder views were or were not taken on board.

- **Recommendation IV: Engage the Un-engaged & Going Local**

The Peer Review Group agreed that engaging the un-engaged is difficult and recommended publishing a list of affiliations/memberships of relevant European federations in all consultation documents and requiring that the federations consulted inform their respective affiliates/members.

- **Recommendation V: Driving Up Data Quality**

The Peer Review Group noted that quality and reliability of data is a big concern and recommended that, as from 2007, the source / basis of data used in the consultation process will be cited and explained.

- **Recommendation VI: Definition of Representativeness**

The Peer Review Group noted that achieving representativeness in consultation processes is a key challenge and recommended the establishment of criteria to ensure a representative stakeholder involvement.

- **Recommendation VII: Be Aware of Stakeholder Asymmetries**

The Peer Review Group acknowledged stakeholders asymmetries and recommended tailor-made methods for consultation which respect and adapt to the context of the stakeholders. Several participants also noted that additional funding to NGOs is required to ensure a more balanced participation.

- **Recommendation VIII: More Flexible and Longer Consultation Timeframe**

The Peer Review Group noted that the minimum timeframe of eight weeks is not always long enough and recommended that consultation timeframes should be variable in accordance with the purpose of the exercise. If the purpose is to go beyond "the Brussels village", more time than the standard eight-week period is needed.

- **Recommendation IX: Improvement of Inter-DG Coordination**

The Peer Review Group recommended that stakeholder consultations are properly coordinated from the centre, in order to ensure that they are mutually supportive and minimise the burden on stakeholders.

- **Recommendation X: More Transparent Comitology**

The Peer Review Group recommended the production of a clear and accessible guide to comitology (“Dummies Guide” to Comitology) that would help external parties to understand and engage where appropriate with comitology processes. The group also suggested to classify comitology measures in categories and to match these categories with different methods of stakeholder involvement.

2. Synthesis

In this section we seek to highlight the Top-10 recommendations that have emerged from the 7 September and 11 October meetings on the issues of “*Stakeholders and Inequalities*”, “*Feedback & Communication*”, “*Stakeholder Planning & Resources*” and “*Comitology*”. These Top-10 recommendations were discussed in detail at the final meeting of 1 December and agreed by all the members of the Peer Review Group. As indicated in the executive summary, the Top-10 recommendations are those recommendations of central importance for the goal of this process and where the Chair considers possible to make concrete progress on them.

Clearly a great many more ideas and recommendations emerged from the discussions than the 10 covered in this report. The point however of this document is not to be comprehensive, but to clearly outline what can be taken forward now by DG SANCO and can contribute to the wider European Transparency Initiative. Although the aim of this process was to primarily look at stakeholder consultation and involvement in DG SANCO’s field of activity, some of the recommendations made throughout the process lie outside the remit of DG SANCO. DG SANCO undertakes to pursue the latter category of issues internally and bring it to the attention of the Secretariat General.

Commitment I: Establish a "Stakeholder Dialogue Group" to get advice on process

The recommendation for the establishment of a Stakeholder Dialogue Group was specifically raised by Working Groups B & C respectively on “*Feedback & Communication*” and “*Stakeholder Planning & Resources*” and addresses concerns raised at 13 June 06 meeting such as “*understanding stakeholder needs*”. The Peer Review Group agreed that the Stakeholder Dialogue Group should advise DG SANCO only on process and not on content. Its role should be to ensure that DG SANCO stakeholder involvement processes are better tailored to stakeholders needs and to support mainstreaming best practice in DG SANCO’s consultations.

The terms of reference of this group have not been agreed, nor have practical issues such as membership, size or meeting schedule. However, at the 1 December meeting, a consensus was reached on the fact that the membership should be on a personal basis, change over time (e.g. 5 permanent + others rotating) and that it should be a relatively small group (possibly less than 15 individuals). Members also agreed that the composition of the group should be balanced and should be validated by the Peer Review Group.

- ***DG SANCO commits to establishing a group of stakeholders to advise on process. Members of the group will be selected through a call for expression of interest to be launched in March 2007. The group will be small (no more than 15 people), it will include a mixed representation of stakeholders (both industry and NGOs) affected by the different SANCO policy areas and its composition will change over-time. The mandate of the group will be drafted by DG SANCO and finalised by the Stakeholder Dialogue Group at its first meeting.***

Commitment II: Improve Transparency through better "Forward Planning"

Throughout the Healthy Democracy process the Peer Review Group made clear the link between the transparency of the decision-making and its credibility and legitimacy. Stakeholders will not participate if there is a perception that their contributions are not valued and taken into account in the decision-making system. At the 1 December meeting, the Peer Review Group noted that although the commitment to transparency is particularly relevant in the context of this recommendation, it is equally crucial in many of the Top-10 recommendations (i.e. feedback, comitology, etc.).

More concretely, the Peer Review Group considered that registering on DG SANCO website means receiving a large number of emails, without any guidance on how to identify the most relevant information to them. The group recommended the establishment of a better online early warning system (also for comitology decisions) that will give advance notice to stakeholder groups of emerging consultations and their planned timetable. It was felt that freeing up time thanks to a better designed online early warning system would be likely to improve the quality of consultation as stakeholders could better prepare and would have the time to build constructive relationships with other stakeholders and DG SANCO officials. There was also a strong feeling that if DG SANCO wished to engage with stakeholders outside the Brussels policy community more time would be required to establish relationships with these groups, and any early warning system would help with this.

The stakeholders in Working Group C on "*Stakeholder Planning & Resources*" expressed the need to be able to compare the different consultation processes through an activity tracker so informed decisions could be made about where and when to invest time.

The issue of consultation fatigue was also highlighted and it was stressed that it is not possible for stakeholder organisations to participate in all processes. It is important therefore for organisations to be able to make informed decisions about what processes to get involved with and to get a better access to planning tools such as the Annual Management Plan.

- ***DG SANCO agrees on the importance of transparency.***
- ***As of 2007 DG SANCO has begun to provide greater access to its Annual Management Plan (AMP). At the beginning of each year it will hold a public presentation on its AMP and will disclose timetables of individual consultations.***
- ***DG SANCO will also study how to refine its web-tools in order to allow for a reminder by email on individual consultations and their planned timetable and for an easy mapping of upcoming consultations, including major comitology decisions.***

Commitment III: More and Better Feedback

The Peer Review Group stressed the importance of providing feedback to stakeholder views in order to ensure that they continue to engage in the future. In this instance feedback is specifically meant in terms of a response from DG SANCO to stakeholders following any stakeholder engagement process. Working Group B dealt specifically with this subject and the detail of their discussions can be seen in *Annex C*.

The group identified communication as being central to effective stakeholder engagement. Communication should be continuous before, during and after any scheduled event or process.

The stakeholders in Working Group A highlighted the issues of “restitution” (accountability) where following a consultation the Commission has a responsibility to produce high quality feedback.

Already at the 13 June meeting, the Peer Review Group recommended that DG SANCO should produce – within a reasonable timeframe and in any case before the next step is taken or attitudes are set in concrete – a short synthesis report following every stakeholder engagement process which will be circulated to all stakeholders/consultees. The stakeholders also suggested putting the synthesis reports online to support stakeholder responses as well as dedicated staff training on feedback.

The purpose of this synthesis report would be:

- To have a clear and agreed record of the process
- To be transparent about who was involved
- To indicate the next steps
- To be clear about what proposals from stakeholders DG SANCO is and is not taking forward

- ***DG SANCO commits that, as from January 2007, a synthesis report will be produced and circulated to all consultees following each consultation on proposals set out in the Commission Work Programme (WP) and in the Annual Policy Strategy (APS). The synthesis report will clearly state the main outcomes of the consultation and will provide reasons why certain stakeholder views were or were not taken on board.***

Commitment IV: Engage the Un-engaged & Going Local

The Peer Review Group agreed that engaging the un-engaged is difficult. A particular challenge is engaging groups who may not identify themselves as stakeholders or may not have a full understanding of the relevancy of EU policy to their experiences.

Engaging the right individuals, in terms of quality and representativeness, is a vital factor in order to achieve a successful involvement process. DG SANCO needs to better understand the wants and needs of the different parties whose involvement is required. It was thought that this could be done by researching stakeholder expectations to find out what they really want to achieve from engagement.

In order to ensure a better engagement, DG SANCO should 1) consider the use of Commission's delegations in Member States as platform for the debate 2) work together with existing stakeholders (in particular NGOs) to identify the "unengaged".

The Peer Review Group noted that the challenges of achieving representativeness and engaging hard-to-reach groups are exacerbated at the European level where there are few tangible connections between citizens and the Brussels institutions.

Working Group B also suggested making better use of European stakeholder networks to access wider groups of people. Working Group A suggested that the EC could invest in building links more directly with non Brussels-based stakeholders. In particular, the EC should use its delegations in Member States and local partners to build relationships with this wider group of stakeholders and their networks.

The responsibility for engaging people in consultations does not rest with DG SANCO alone, but is shared with European federations and networks. The European networks are, at present, an underused resource. The European networks should systematically ensure that their members are kept informed and there is an effective engagement at national, regional and local level. The group considered that greater involvement at national/regional/local level could also be facilitated by publishing a list of affiliations/memberships of relevant European federations in all consultation documents and requiring that the federations consulted inform their respective affiliates/members. This would also allow DG SANCO to have a better map of what countries/stakeholders are not covered by the existing networks of European stakeholders. This is

particularly important considering the recent enlargement of the European Union to 27 Member States.

- ***DG SANCO commits that, as from March 2007, a list of affiliations/memberships of relevant European federations will be published in all consultation documents and federations will be invited to inform their respective affiliates/members. It is clear that this commitment will also depend on the willingness of European federations to provide DG SANCO with membership/affiliation lists and to establish effective mechanisms to inform their affiliates/members.***

Commitment V: Driving Up Data Quality

The concerns on data could be grouped into two broad camps: those relating to judging the quality of information sources and those relating to the difference (asymmetries) in access to data between different stakeholders. According to the participants, the measures adopted to address these two concerns should not affect the existing rules on confidentiality.

In particular, the Peer Review Group noted that quality and reliability of data is a big concern. Data are often controversial and contested by stakeholders. The difficulty of accurately citing evidence especially in emerging fields where information sources are dispersed was also raised. For all data used by DG SANCO there should be clear quality indicators on how the data was assessed and how it will be used.

Some participants suggested that when there is controversial information a panel of experts could be used to decide on what information is submitted, and if any further research needs to be undertaken. However, this idea was not agreed on by all as others thought this would not be a viable solution and would be the responsibility of the European Food Safety Authority (EFSA).

- ***DG SANCO commits that, as from March 2007, the source / basis of data used in the consultation process will be cited and explained.***

Commitment VI: Definition of Representativeness

The Peer Review Group agreed that the legitimacy of stakeholder involvement processes often hinges upon the ability of a stakeholder to represent a target group and having a representative group of stakeholders involved in a consultation. The group agreed that a minimum level of transparency is needed on a structured basis as to the purpose, governance, funding and target constituents of any stakeholder.

Concerns over stakeholder representation were raised at the 13 June and 7 September meetings. In particular the link between representativeness and the quality and legitimacy of the process were raised.

At present, there are not always the mechanisms in place for stakeholders to act as genuine representatives, or sufficient incentives for representative

stakeholder involvement. This is especially true for those stakeholder groups with limited resources.

As an example of the problem, stakeholders in Working Group B raised concerns over inequality in representativeness of Member States. In particular, the group registered a constant high representation from one Member State and a low representation from the New Member States. It was suggested that existing stakeholder networks in underrepresented areas be investigated.

The members stressed that quality of the contributions is as important as the weight of the stakeholder. They agreed more transparency on representativeness was needed and it could be useful to draw up "fiches" for each individual stakeholder with all the essential information. This issue should be looked in more details by the Stakeholder Dialogue Group. The group recommended the establishment of criteria to ensure a representative stakeholder involvement.

- ***DG SANCO commits to further discuss this issue with the Stakeholder Dialogue Group.***

Commitment VII: Be Aware of Stakeholder Asymmetries

The Peer Review Group acknowledged that stakeholders are different in their structures, capacities and decision-making processes. There exist great disparities in access to resources between stakeholders, which undermine the legitimacy and representativeness of involvement processes as certain stakeholders can engage with processes more easily. In particular, the asymmetry in access and production of information was seen as a key issue leading to stakeholder inequality.

On June 13 the stakeholders acknowledged that asymmetries exist within sectors themselves with different private, public and voluntary sector organisations having very different capacities to effectively contribute to stakeholder engagement processes. When designing the stakeholder engagement process, Working Group A and C highlighted the importance of making each consultation 'tailor-made' with careful consideration of the needs and capacity of those involved.

Working Group A highlighted that policy arguments are often won and lost on available evidence; therefore the ability of a stakeholder to produce evidence would affect the balance of any decision-made.

Working Group A acknowledged that stakeholder asymmetries brought the issue of stakeholder funding into sharp focus. It was noted that more funding will facilitate a more active involvement of certain groups. There was not however any agreement on how to provide such a support. Indeed fundamental differences were exposed on the role of government in providing financial support for group representation. The group identified 4 main categories of funding: 1. Core funding, 2. Funding for awareness raising, 3. Service contracts and grants and 4. Travel costs and reimbursement of expenses. None objected to the latter category of funding.

A consensus was reached however on the issue that whatever stakeholder funding does take place it should be made transparent. It was noted that the effectiveness of funding should be monitored through financial audits.

The group recommended tailor-made methods for consultation which respect and adapt to the context of the stakeholders. Several participants also noted that additional funding to NGOs is required to ensure a more balanced participation.

- ***DG SANCO commits to further discuss this issue with the Stakeholder Dialogue Group. Action towards more effective funding to reduce stakeholder inequalities has already been taken in the context of the Health Programme 2003-2008.***

Commitment VIII: More Flexible and Longer Consultation Timeframe

The Peer Review Group noted that it is important that there is sufficient interaction and engagement before a consultation to maximise the potential of the consultation. Stakeholders made it clear that there should be more time allocated at an early stage in the process to ensure all parties are clear and agree on the purpose of the consultation.

The minimum timeframe of eight weeks is not always long enough, and when seeking involvement beyond Brussels-based organisations an extended amount of time may be needed.

Effective stakeholder involvement can take time, especially when:

- engaging with disperse groups (e.g. outside the Brussels policy community),
- translation is required,
- consensus is sought,
- building relationships is sought.

Therefore, stakeholders in each meeting expressed concern of the constraints imposed by the current eight week minimum consultation time. Especially in light of the UK Better Regulation Task Force (BRTF) finding that at least one quarter of the Commission's consultations do not comply with this minimum requirement.

Working Group A highlighted that the timing of stakeholder involvement should depend on when their involvement would be most productive. Early "upstream" involvement should be sought when more policy options remain open, while "downstream" one should be sought when the issue is more tangible, often requiring a higher degree of expertise. Working Group A suggested that a wide public involvement may be appropriate "upstream" in the decision-making process and as a decision becomes "closed-down" a more focused professional stakeholder involvement would be appropriate.

The group recommended that consultation timeframes should be variable in accordance with the purpose of the exercise. If the purpose is to go beyond “the Brussels village”, more time than the standard eight-week period is needed.

- ***DG SANCO agrees with this recommendation. There are already some cases (e.g. Timeshare) where DG SANCO extended the consultation period up to 12 weeks. Some of the concerns that have been raised can be addressed by the commitments made by DG SANCO in the context of recommendation II on better planning. The Stakeholder Dialogue Group could look more in details which consultations needs more time (i.e. more than 8 weeks). Stakeholders should systematically indicate in their feedback to the Commission whether the time allowed was considered adequate.***

Commitment IX: Improvement of Inter-DG Coordination

Cross DG Coordination was raised since the first meeting on 13 June, and remained an important element of discussions. It was felt that often Commission’s stakeholder consultations are not co-ordinated and this results in a loss of synergies and efficiencies. Cross DG Coordination could help in terms of:

- sharing best practice between DGs, and
- preventing stakeholder fatigue by avoiding conflicts between different stakeholder involvement processes and allowing stakeholders make best use of their time

Each DG should be aware of what consultations are happening across other DGs to ensure they are properly coordinated and mutually supportive, maximising value for the Commission and minimising the burden on stakeholders.

The group suggested a body responsible for monitoring and coordinating stakeholder involvement activities across all the DGs, in order to ensure that they are mutually supportive and minimise the burden on stakeholders.

- ***DG SANCO agrees and stresses that the SEC GEN has already established civil society contact groups to discuss best-practices and improve co-ordination.***

Commitment X: More Transparent Comitology

Working Group D was specifically dedicated to Comitology. The group noted that one problem of comitology is that the emphasis is on speed of decision-making rather than efficacy, legitimacy and transparency. At the moment, better regulation principles are not applied for the development of stakeholder involvement in comitology.

A central finding was that very few stakeholders had in depth knowledge of Comitology, although many perceived it as complicated and difficult to engage

with. It was felt that new Member States found engaging with comitology processes especially difficult and needed specific support to do so. Joint training on comitology was seen as a good solution for all sides to better understand the system of comitology and in particular for stakeholders to know when and how they can be involved in the process.

Stakeholders in Working Group D felt that there is an inherent tension between the rationale for comitology (i.e. to efficiently and speedily develop and deliver policy) and the needs of stakeholder involvement.

A clear priority was action to overcome the lack of understanding of the comitology process and in particular how stakeholders may or may not engage with this process.

In that vein the group recommended the production of a clear and accessible guide to comitology (“Dummies Guide” to Comitology) that would help external parties to understand and engage where appropriate with comitology processes. The group also suggested to classify comitology measures in categories and to match these categories with different methods of stakeholder involvement.

- ***DG SANCO will organise specific meetings to discuss the issue of comitology, between the chairs of comitology committees and the Advisory Group on the Animal Food Chain and Plant Health with the participation of the Stakeholder Dialogue Group.***

This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.