



A FRAMEWORK FOR SCIENCE ADVICE ON HEALTH: PRINCIPLES AND GUIDELINES

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INTRODUCCIÓN

European Science Advisory Network for Health (EuSANH), fundada en Septiembre de 2006, es una red de centros científicos asesores en salud pública en Europa.

El valor añadido de EUSANH es evitar la duplicación de trabajo, aprendiendo unos de otros y tener acceso a expertos de toda Europa.

Las actividades de EuSANH se centran en:

1. Intercambio de información entre sus miembros.
2. Coordinación de los programas de trabajo
3. Consultas mutuas entre los expertos nacionales.
4. Trabajo conjunto en la preparación de informes de asesoramiento a nivel europeo.

En toda Europa, los gobiernos quieren basar sus políticas frente a problemas complejos en la evidencia científica. Los Estados se enfrentan a menudo similares cuestiones, por ejemplo en torno a la vacunación, los productos químicos en el lugar de trabajo, la exposición a sustancias en el medio ambiente, la nutrición o las nuevas tecnologías en salud.

El asesoramiento científico en salud pública se define como el análisis solicitado o no de un problema de salud pública, de atención sanitaria o de política de salud, basado en el conocimiento científico actualizado, teniendo en cuenta también la opinión de expertos, la experiencia práctica y los valores e implicaciones éticas, culturales y sociales, con conclusiones y recomendaciones para la política de salud.

En un mundo donde el progreso científico es cada vez más rápido, un buen asesoramiento científico puede jugar un papel clave en el éxito de la toma de decisiones políticas en salud. En particular, los organismos científicos asesores pueden ayudar sistematizar y valorar la evidencia disponible y elaborar recomendaciones para los responsables políticos. De esta manera, pueden ser el puente entre la comunidad científica y los responsables políticos, allanando el camino para hacer efectiva la toma de decisiones basada en la evidencia.

La mayoría de los estados miembros de la UE tienen sus propios órganos consultivos nacionales que proporcionan asesoramiento científico. Sin embargo, muchos problemas de salud tienen una dimensión transnacional que requieren de una perspectiva internacional.

Todos los órganos de asesoramiento científico en Europa tienen que analizar y evaluar el estado de la ciencia para los gobiernos con el fin de asesorar sobre el diseño e implementación de políticas públicas. Mediante la colaboración, el intercambio de conocimientos y la experiencia, estos centros asesores pueden ser más eficientes.

Para llevar a cabo sus actividades, la red ha elaborado una metodología común. Esta metodología pretende facilitar la colaboración y mejora la calidad de la elaboración de informes de asesoramiento científico. En este texto presentamos las Guías y Principios para el asesoramiento científico en salud elaboradas por EUSANH. Estas Guías y Principios se han elaborado con el apoyo del 7.º Programa Marco, y constituyen uno de los productos del proyecto **Improving Science Advice**.

FOREWORD

The European Science Advisory Network for Health (EuSANH) is a network of science advisory bodies in Europe which are active in the field of health and provide independent scientific advice to their authorities. Currently, national science advisory bodies from more than half of the European member states are represented in the formal EuSANH organisation.

Collaboration within EuSANH received a strong impulse from European Funding in the 7th framework programme (2009-2011) for a three-year project entitled Improving Science Advice for Health in Europe (EuSANH-ISA). One of the activities during this project was the development of a common methodological framework for science advice on health. This report describes the principles and guidelines of that framework.

CONTENTS

INTRODUCTION.....	7
FRAMING THE ISSUE	9
PLANNING THE PROCESS.....	11
DRAFTING THE REPORT	13
FORMULATING THE RECOMMENDATIONS.....	17
REVIEWING THE REPORT	18
PUBLISHING THE REPORT	20
ASSESSING THE IMPACT	21
STATUS OF THE FRAMEWORK	22
FURTHER READING.....	23
ANNEXES	
A. DATABASES	24
B. DECLARATION OF CONFLICTS OF INTEREST: AN EXAMPLE.....	25
C. BACKGROUND INFORMATION ON EUSANH	31

INTRODUCTION

SCIENCE AND POLICY

In society there is a clear and growing recognition of the role of scientific and technical knowledge in advancing human health. However, scientists usually do not speak with one voice, the outcomes of their research often involve uncertainties, or they may address issues which have no direct societal applications or implications. On the other hand, practical issues of relevance to society are the very points of departure and reference for policy makers. Citizens moreover expect them to make sound decisions by bringing the best evidence to bear on the problems in question. Carrying out this task requires access to independent sources of sound science advice.

BRIDGING THE GAP

The worlds of science and policy have their own position, language and dynamics. How can the two meet? When one thinks in terms of distinct and contrasting concepts characterizing each world —facts versus values, objectivity versus subjectivity, or truth versus power—, science advice seems almost a paradox. Studies of scientific advising have shown, however, that it is not possible to draw sharp boundaries between facts and values. Negotiation among scientists as well as between scientists and policy makers is one of the keys to the success of the advisory process. Scientific knowledge and information must always be discussed and evaluated within the context of political problems. This usually involves a process of gradually adjusting divergent or complementary scientific viewpoints. At the same time, however, standards of adequacy for scientific evidence and inference are applied. As long as this is done in a transparent manner, the conclusions and recommendations of advisory committees will be viewed as highly credible. Thus, a firm scientific underpinning may be provided for public policy development.

Important though science advice may be, measures to be taken always also have political, economic, social or cultural aspects that must be considered. That is where science advice ends and policy begins. Weighing these aspects is up to policy makers and politicians and takes place within the context of political and societal values, beliefs, and objectives.

SOUND SCIENCE ADVICE

Scientific advice on health is defined as the solicited or unsolicited analysis of a defined public health, health care or health policy problem, based on updated scientific knowledge, considering also relevant expert judgment, practical experience, and ethical, cultural and societal values and implications, with conclusions and recommendations for health policy. The principles and guidelines contained in this framework address how high-quality science advisory reports should be produced which may be effectively used in policy decision making. They have been formulated

after extensive discussions among the participants of the EuSANH-ISA project with input from various international experts (see acknowledgements). Also, related frameworks developed by other organisations have been considered in these discussions. The principles and guidelines are not only relevant as a quality seal to current EuSANH members, however. Because all national and international health authorities face similar problems and are expected to base their decisions and programmes on the best available evidence, this methodological framework may help any advisory body in providing sound science advice.

Table 1. Framework for science advice on health

STEPS	PRINCIPLES	GUIDELINES
Framing the issue	Need	1 <i>Policy makers and science advisors should regularly discuss emerging issues requiring advice</i>
		2 <i>Science advisors should do so in interaction with the health research community</i>
		3 <i>In formulating a request for advice, policy makers and science advisors should determine in close cooperation the set of questions to be addressed</i>
		4 <i>Science advisors should discuss with policy makers whether a European or international perspective is appropriate</i>
Planning the process	Timeliness	5 <i>In framing the issue policy makers and science advisors should discuss the scope and duration of the task, considering the stage within the policy making process when scientific advice is needed</i>
		6 <i>The advisory body should develop operation procedures to manage the entire advisory process</i>
Drafting the report	Credibility	7 <i>Select committee members on the basis of professional excellence and with an appropriate range of expertise</i>
		8 <i>Select committee members who reflect the diversity of scientific opinions</i>
	Independence	9 <i>Screen for conflicts of interest in order to avoid advocacy</i>
		10 <i>Committee members should carry out their deliberations in closed meetings in order to avoid political and special interest influence</i>
		11 <i>The committee should be responsible and accountable for the final report</i>
	Relevance	12 <i>Consider adding a policy maker to the committee as an official observer</i>
		13 <i>Consider organising stakeholder hearings</i>
		14 <i>Where appropriate, specify ethical or legal principles involved</i>
	Transparency	15 <i>Specify data and data sources used in producing the report</i>
		16 <i>Document and explain all assumptions made and methods used in interpreting and synthesizing the data</i>
		17 <i>Identify and describe all uncertainties involved</i>
		18 <i>Indicate where and how expert judgment is applied</i>
Formulating the recommendations	Feasibility	19 <i>Consider the potential consequences of the recommendations made to policy makers</i>
		20 <i>Where appropriate, identify policy options based on data and research evidence</i>
Reviewing the report	Quality	21 <i>The final draft report should undergo an independent peer review</i>
		22 <i>Guarantee continuity in producing advisory reports on similar issues</i>
		23 <i>Check whether the final draft report is consistent with other reports of the advisory body</i>
		24 <i>Specify the response to the comments made in the peer review</i>
Publishing the report	Openness	25 <i>Make the report publicly available</i>
		26 <i>Where more active dissemination is required, issue press statements, press releases or press briefings</i>
		27 <i>Where more clarification is required, organise meetings with policy makers and target groups</i>
Assessing the impact	Accountability	28 <i>There should be a follow-up procedure that monitors the policy makers' actions in response to the advisory report</i>
		29 <i>The advisory body should regularly perform a (self)assessment, both of the impact of its reports and of its performance</i>

FRAMING THE ISSUE

PRINCIPLE: NEED

1. Policy makers and science advisors should regularly discuss emerging issues requiring advice

Identification of priority issues should preferably be the outcome of an ongoing dialogue between policy makers and science advisors. Both have their own roles and responsibilities. Policy makers are expected to identify issues arising from societal or political developments, sometimes in interaction with stakeholders. Science advisors should keep a close track of scientific developments. In identifying topics for advice both parties should consider questions like:

- Is there a (potential) threat to health or an opportunity to advance health of the population at large or of specific subgroups?
- Does answering the request for advice require an interpretation and synthesis of scientific knowledge and information?
- Is advising right now appropriate because of societal or political urgency?

The clearer a “Yes” to these questions, the higher the priority of the topic under consideration. The frequency of the recommended consultations between policy makers and science advisors may vary, depending on local conditions and the pace of policy.

2. Science advisors should do so in interaction with the health research community

Scientific advisory bodies should put in place a systematic method to keep track of scientific and technological developments of potential relevance for policy making. One possibility is having permanent panels of experts closely monitoring developments in various fields of science and technology. In this context it is also important to maintain close contacts with professional scientific organizations and research institutes.

3. In formulating a request for advice, policy makers and science advisors should determine in close cooperation the set of questions to be addressed

The first and most important step in preparing a science advice is determining its focus and formulating its underlying question(s). Usually policy makers phrase their questions differently from scientists, and it is crucial that both parties spend some time together in formulating the right questions to avoid misunderstandings, especially when the topic proves to be complex or controversial. Well-formulated questions can subsequently provide clear guidance to the advisory process, including what expertise is needed. The scope of the questions matters as well. This point is addressed by [guideline 5](#). Questions to be answered by science advice should avoid asking about what is the “best” policy option or solution for a problem. They should rather ask which are the expected outcomes of the different alternatives at hand or

what are the pros and cons of various options according to state-of-the-art scientific knowledge¹. “Best” is a concept that implies some judgment or value system. The request for advice will be better formulated if these values are explicitly mentioned.

4. Science advisors should discuss with policy makers whether a European or international perspective is appropriate

Policy makers and science advisors in Europe are increasingly aware that many countries face similar health problems. Even where national administrative traditions have a strong hold, the scientific aspects of policy issues display many common characteristics. This also justifies assessing whether a European or international perspective is appropriate when preparing a science advice. One step further is considering whether it is fruitful to share work between scientific advisory bodies in producing a report. This may be a path worth following when scientific expertise is unequally distributed among countries and there is an opportunity to draw on internationally available expertise.

Some additional remarks should be made, however. While science is international and scientific analyses and conclusions recognize no borders, evidence-based policy recommendations have to take into account the national, regional or local situation.

- Implementing a new policy or programme may require different levels of resources in different countries, depending on the available infrastructure. As a consequence, criteria of cost-effectiveness to be applied may differ as well.
- Acceptability of the proposed recommendations may also vary, due to different political, social, or cultural environments. Therefore, it is important to provide an analysis of these contexts and how they may affect the implementation of the recommendations. This topic is elaborated further in the chapter on formulating the recommendations.

1 For example, researchers working with systematic reviews formulate “answerable clinical or public health questions” according to the PICO approach (Participants, Interventions, Comparisons, Outcome).

PLANNING THE PROCESS

PRINCIPLE: TIMELINESS

5. In framing the issue policy makers and science advisors should discuss the scope and duration of the task, considering the stage within the policy making process when scientific advice is needed

A common tool used for analysing the policy process is the so-called policy cycle. It encompasses at least the following stages: agenda setting, policy formulation, policy implementation, and policy evaluation. Given this general characterization, policies may have variable dynamics. Sometimes, policy makers have to operate within a tight time frame, depending on political and societal developments. Scientists, on the other hand, have their own methodological principles and quality assurance procedures to ensure that sound products will be provided. It is up to policy makers and science advisors to link both worlds.

In this context, at least the following questions should be addressed.

- How urgently is the advice required? For example, at the agenda setting stage political and societal pressure may be relatively low. Similarly, there can be situations where the final results of on-going research programmes are needed to answer key questions to policy formulation. Under such circumstances less emphasis may be placed on the desired delivery date of an advisory report. However, where ‘hyped’ subjects are concerned, policy makers often want advice at short notice. Much then depends on the scope of the requested advice.
- Is there room for variability in scope of the task? If urgent reporting is required for policy reasons, it will be necessary to investigate whether the number or complexity of the questions posed can be limited. This may also involve prioritization of questions. There are some potential drawbacks, however. One of the main problems is the risk of compromising scientific diligence. Interim reports may also be an option. The credibility of a scientific advisory body could, however, be seriously affected if the conclusions in the final report would be different. In any case, it is essential to manage the expectations that policy makers may have.

6. The advisory body should develop operation procedures to manage the entire advisory process

Once the scope and duration of the task have been determined, it is necessary to make a work plan. This is a tool for planning, executing and monitoring the set of activities described in various guidelines of the methodological framework. Attention should be given to the durations of the various activities necessary to complete the work and to the timely involvement of experts, policy makers or stakeholders, depending on the working method chosen. Progress of the advisory process should be measured against the objectives and duration agreed upon in this early phase.

Major delays, if any, should be discussed in good time with policy makers requesting the advice.

Guideline 29 addresses ways to analyse the performance of a scientific advisory body. This will encompass an analysis of individual advisory processes. Comparing what went well and what went less well will yield insights that can facilitate the management of future advisory processes.

DRAFTING THE REPORT

PRINCIPLE: CREDIBILITY

7. Select committee members on the basis of professional excellence and with an appropriate range of expertise

Selection of appropriate committee members is essential for the quality, authority and impact of an advisory report. Given the fact that questions submitted to an advisory body are generally complex, the committee must include experts with the specific expertise and experience needed to address the issues involved. The committee members should not only be recognized experts in their field, but also be willing to collaborate and to conceive new approaches in tackling a problem. It may sometimes be appropriate to include lay persons with relevant experience as well. Usually, it is important to look beyond the limits of existing policy sectors and to make connections visible that may help policy makers find suitable solutions.

8. Select committee members who reflect the diversity of scientific opinions

Having the right expertise is not sufficient for success. It is also important to ensure that different experiences and perspectives are adequately balanced, especially when uncertainties and ambiguities have to be addressed by the committee. Sometimes there may be different schools of thought and it is essential to take these into account during the advisory process. This is also a tried and tested way of diminishing bias arising from preconceptions.

PRINCIPLE: INDEPENDENCE

9. Screen for conflicts of interest in order to avoid advocacy

Guaranteeing independence from political, economic and special interest influence is of utmost importance to safeguard the authority of a science advisory body. One key element in this context is screening candidate committee members for potential conflicts of interest. Currently, a number of such screening procedures exist at the international, European and national levels. Common to them all is asking experts to fill out a declaration of interests before the start of each project. These include issues such as ownership or shares or other investments, membership in a management body, or consultancy, to name a few of the most important. Annex B contains the declaration of conflicts of interest which has been used in the pilot case study. Furthermore, the experts should be under a continuing duty to declare any activity, situation, circumstance or other fact potentially involving a direct or indirect interest. The assessment of these interests and whether or not they pose a conflict should be performed by the board of a science advisory body. The declarations of interests should be made public in one way or another.

Sometimes, there may be only a few experts with a particular expertise. If their input is judged vital to an advisory report but they have conflicting interests, it can be decided for them to act as advisors to a committee instead of becoming full members. They can attend to (some of) the deliberations of the committee, but cannot vote and do not bear joint responsibility for the final report.

10. Committee members should carry out their deliberations in closed meetings in order to avoid political and special interest influence

Committee members are independent scientists who have been screened for any conflict of interest and selected on the basis of professional excellence and with an appropriate range of expertise for the specific topic. In closed meetings committee members should freely discuss topics which may be societally or politically controversial. During this phase it would be counterproductive if scientific arguments and potential interests of stakeholders are mixed. External pressure, whether real, perceived or suspected, could easily compromise the whole process. Where appropriate, stakeholders hearings can be organised (see [guideline 13](#)).

11. The committee should be responsible and accountable for the final report

After the committee has carried out its deliberations in closed meetings and has reached conclusions and made recommendations on a certain health topic, each individual committee member needs to support the advice given. The final report should include their names and affiliations. When a committee member cannot subscribe to (a part of) the conclusion, a written minority position could be considered.

PRINCIPLE: RELEVANCE

12. Consider adding a policy maker to the committee as an official observer

After defining the questions to be addressed by science advice, it may be important to verify whether the first draft reports effectively address the issues as planned. Communication between policy makers and science advisors can be appropriate during later phases of the advisory process as well. In particular, it may sometimes be fruitful to discuss to what extent proposed recommendations are feasible. In other circumstances, however, skipping this option may be preferable for reasons of independence. Anyhow, policy makers should have only an observer status in the expert committee or attend meetings only under specific indication of the committee. It is up to science advisors to draw conclusions and make recommendations.

13. Consider organising stakeholder hearings

In many situations science advisors and policy makers are not only concerned with gaining a better scientific understanding of issues but also how other societal groups see these issues. There may be two reasons for this. First, stakeholder parties, from patient organisations and advocacy groups to professionals associations and commercial firms, often have their own experiential, local or traditional knowledge of a particular issue. Second, they are organisations with a concern or an interest in a topic, because they will be likely affected, either positively or negatively, by a decision to be made. Both science advice and policy making may profit from considering stakeholder input and perspectives.

When stakeholder hearings are judged to be appropriate or necessary, effectively planning and carrying them out include the following:

- It is essential to identify and invite all parties which have a stake in the issue and can be expected to contribute relevant knowledge and perspectives. One should be aware of the fact that this will usually increase the duration of the advisory process.
- When information is sought from such a wider range of sources, science advisors need to assess the quality of the input. They should make it clear to the participants in the hearings that scientific facts have to be distinguished from personal views.
- In formulating conclusions and recommendations, science advisors should specify how they have taken into account the multiple viewpoints received in the stakeholder hearings. Moreover, they should indicate the degree and nature of the uncertainties involved.

It is important to make a clear distinction between the roles and responsibilities of science advisors and policy makers. Policy makers have by their very position to address the concerns and interests of societal groups. This involves a separate process of stakeholder participation.

14. Where appropriate, specify ethical or legal principles involved

Analysing ethical or legal aspects of an issue may also be of crucial importance to acceptability of proposed recommendations in a science advisory report. In that case, ethical or legal experts should be members of the advisory committee preparing the report.

PRINCIPLE: TRANSPARENCY

15. Specify data and data sources used in producing the report

Health decisions have to be made in a context which, on many occasions, combines a plethora of information, without the existence of the necessary information. This combination could lead, with a lack of transparency, to controversial decisions. The use of evidence has to be incorporated in a transparent manner grounded in a deliberative approach, that ensures that all important data are considered.

It is usually wise to focus the literature search on a limited amount of well-known sources. As an initial step one can look for systematic reviews, other review articles, and national science advisory reports. If no compiled data like this can be found, one has to continue to search for original research articles in the appropriate databases. Making a systematic review is time consuming, however, and it has to be decided whether this is necessary for the science advice in question. In any case, the search terms and databases used should be mentioned in the advisory report. Some important databases are listed in Annex A of this framework.

Sometimes, it may be necessary to use confidential data. To a certain extent this will be at odds with the principle of transparency. However, the quality of conclusions or recommendations will then benefit from it.

16. Document and explain all assumptions made and methods used in interpreting and synthesizing the data

Judgments about evidence in public health and health care are usually complex. Systematic reviews or data in general provide essential, but not sufficient information for making well informed decisions. Reviewers and people who use reviews have to draw conclusions on the quality of the evidence, either implicitly or explicitly, and such judgments guide subsequent decisions. A number of organizations have employed systems to grade the quality (level) of evidence and the strength of the recommendations based on it⁽²⁾. This is a field in progress which deserves closer attention in the coming years.

17. Identify and describe all uncertainties involved

Just as important as the selection, compilation and synthesis of data and research outcomes is the structured analysis of uncertainties and knowledge gaps. These uncertainties can involve all aspects of the question under review. The identification and description of knowledge gaps should preferably indicate what is needed to resolve them. This information is essential for policy makers, in order to be able to make decisions on funding of further research and resource allocation. In addition, it is then important to point out the need for follow-up evaluation.

18. Indicate where and how expert judgment is applied

In weighing the quality of evidence, integrating heterogeneous information, or interpreting uncertainties when data are lacking, experts have to rely to a lesser or greater degree on their tacit or implicit knowledge. Experts judgments are the expression of informed opinion, based on knowledge and experience in a particular discipline. For reasons of transparency, it is important to indicate explicitly where expert judgment comes in. There are various techniques for eliciting and structuring this type of judgment.

When preparing a European science advice the experts can bring in important information about experiences from their respective countries. These different experiences can be of added value to the background scientific data available.

2 One such system is GRADE. See www.gradeworkinggroup.org.

FORMULATING THE RECOMMENDATIONS

PRINCIPLE: FEASIBILITY

19. Consider the potential consequences of the recommendations made to policy makers

The advisory part of a report involves answering the questions posed by policy makers and formulating evidence-based recommendations. Although decisions are the prerogative of policy makers, recommendations should take into account the societal, legal, and political context in order to be useful. Depending on the (framing of the) issue, it may be necessary to analyse critical success factors for implementing the recommended actions or measures. These factors may include available resources, societal or cultural acceptability, and stakeholder participation. Sometimes it may be fruitful to provide different scenarios. See also [guideline 20](#).

Health Impact Assessment —a combination of procedures, methods and tools by which a policy, program or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population— may help policy makers choose between alternatives.

20. Where appropriate, identify policy options based on data and research evidence

Depending on the issue, a science advisory body may decide not to make clear recommendations to policy makers, but to provide policy options. This may be particularly appropriate when complex trade-offs have to be considered or the societal and financial impact of possible actions is large. In these circumstances the best science advisors can do is to compare different options with respect to a number of aspects, such as benefits, risks, and costs. Policy makers then have to decide how to weigh these aspects.

REVIEWING THE REPORT

PRINCIPLE: QUALITY

21. The final draft report should undergo an independent peer review

Peer review is the process of subjecting a document to the scrutiny of others who are experts in the same field. It helps to maintain standards, improve quality and provide credibility. In science peer review is routinely used to determine whether a scientific manuscript is suitable for publication. It is also a usual component of evaluation of projects submitted to obtain financial support.

Although committees preparing an advisory report already have a kind of built-in peer review mechanism—they should be multidisciplinary and reflect the diversity of scientific opinions according to [guidelines 7 and 8](#)—, additional referees will enhance the quality of the report. Such a review may take different forms.

- Members of the advisory body who do not serve on the committee may be asked to comment on the draft report.
- Another possibility is to let external experts in the relevant fields of science review the report.
- When few national scholars truly qualify as experts, an international peer review should be considered.

Whatever the form chosen, it is essential that participants in the peer review are screened for conflicts of interest as well.

22. Guarantee continuity in producing advisory reports on similar issues

Internal coherence between reports addressing similar issues will contribute to the quality of advice. Coherence does not mean that no variation or differences should be allowed, however. Different conclusions or recommendations then have to be explained, either because science provides new insights, questions are formulated differently or the perspective changes due to a new policy environment or the involvement of other stakeholders.

As to producing such reports, it will be efficient to involve, at least in part, the same experts. This will facilitate the identification of questions to be addressed and will usually speed up the process.

23. Check whether the final draft report is consistent with other reports of the advisory body

Consistency is important for the overall production of the scientific advisory body, and not only for reports on similar issues or in similar areas of activity. This concerns all aspects of the advisory process, from the methodology used in interpreting and synthesizing data to reviewing the final draft report. When the issues addressed by different reports have interfaces, consistency does not necessarily require that

recommendations be exactly the same, however. Again, such differences may sometimes be explained by differences in policy contexts.

24. Specify the response to the comments made in the peer review

According to [guideline 11](#), the committee should be responsible and accountable for the final report. Therefore, the role of the referees is only advisory: they should have no final say in the conclusions and recommendations. On the other hand, it is important that the committee indicates how the comments or suggestions made by the referees have been addressed. This also may take different forms, e.g. by informing the referees on editorial changes or adding an annex which contains a brief reaction.

PUBLISHING THE REPORT

PRINCIPLE: OPENNESS

25. Make the report publicly available

For a science advisory report a free access policy should always be considered. Moreover, some form of evaluation of dissemination activities should be routine. This involves identifying target groups which can be expected to have an interest in the report. In addition to policy makers and depending on the subject, these may include:

- Health care staff and managers (central and regional administrations, central services and directors of health centres).
- Health professionals (clinicians, nursing staff, educators).
- Health researchers.
- Patient organisations.
- Medical or other industry sectors.
- National, local and specialized press and media.

26. Where more active dissemination is required, issue press statements, press releases or press briefings

There may be reasons to inform press and media more actively on a report. Press statements will usually be issued. Press briefings may sometimes be considered, depending on the societal or political sensitivity of the report.

27. Where more clarification is required, organise meetings with policy makers and target groups

In particular circumstances, both policy makers and target groups or stakeholder parties can be in need of additional clarification of problematic issues or implications ensuing from a report. Special meetings may then be helpful, where committee members provide further explanation and answer any questions participants in the meeting may have. As before, the different roles and responsibilities of science advisors and policy makers should be kept in mind, however.

ASSESSING THE IMPACT

PRINCIPLE: ACCOUNTABILITY

28. There should be a follow-up procedure that monitors the policy makers' actions in response to the advisory report

As mentioned in the introduction to the present framework, science advice is only one element in the policy process. Other factors, such as political, social and cultural values and objectives, or available resources, carry weight as well. Therefore, it can hardly be expected that all recommendations in a science advisory report will be automatically implemented, even if they are firmly evidence-based. Nevertheless, the quality of a report can also be judged from its impact. Impact is difficult to conceptualise and measure, since it takes many forms, can bear upon many target groups, and may have a long lag time. Yet, instrumental impact within policy departments, in the form of responses, of whatever kind, to the reports requested, is always very important for the strategic position of science advisory bodies and it should be closely monitored.

29. The advisory body should regularly perform a (self) assessment, both of the impact of its reports and of its performance

Accountability is an essential component of public service. It concerns the acknowledgement and assumption of responsibility for actions, products, and decisions, including the obligation of reporting, explaining and being answerable for the consequences. Being a public service organisation, a science advisory body should be regularly assessed with respect to the scientific quality, timeliness, impact, and costs of its reports. This assessment should be accompanied by a willingness to adapt its organisation and practices to further improve its effectiveness and efficiency.

STATUS OF THE FRAMEWORK

First, it must be emphasized that implementation of the guidelines presented here requires attention to specific circumstances, such as the legal or strategic position of the advisory body and the associated administrative traditions within which it has to operate. Put another way, each organisation should examine how the guidelines can be operationalised in its own situation. Operationalisations may also vary depending on the issue under analysis. In fact, the phrasing of various guidelines, e.g. “Consider ...” or “Where appropriate, ...” already explicitly invites advisory bodies to explore and compare alternative procedures. Second, the framework addresses the core business of advisory bodies, viz. appointing multidisciplinary committees to advise on request of government agencies. Sometimes other working methods may be considered, e.g. a working conference or an advisory letter, where experts are consulted outside of a committee setting. Many guidelines will then still provide valuable assistance. Finally, the framework should be considered from a dynamic perspective. In the coming years, all experiences and lessons learned should be updated and may lead to fine tuning or modifying the guidelines. In this context, the principles provide the robust architecture and will remain leading.

FURTHER READING

BIJKER WE, BAL R, HENDRIKS R. *The Paradox of Scientific Authority. The Role of Scientific Advice in Democracies*. The MIT Press, Cambridge Massachusetts, 2009.

Directorate General for Health and Consumers. *Rules of procedure of the scientific committees on consumer safety; health and environmental risks; emerging and newly identified risks* (2009). (http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_en.pdf)

EASAC. *Good Practice in Dialogue between Academies and Policy Communities*. Draft Guidance (2009). (http://www.easac.eu/fileadmin/dialogue_project/good_practice)

EFSA. *Transparency in Risk Assessment carried out by EFSA: Guidance document on procedural aspects*. The EFSA Journal 2006 353, 1-16.

EFSA. *Transparency in Risk Assessment – Scientific Aspects*. The EFSA Journal 2009 1051, 1-22.

GLYNN S, CUNNINGHAM P, FLANAGAN K. *Typifying Scientific Advisory Structures and Scientific Advice Production Methodologies* (2003). (http://ec.europa.eu/research/science-society/advice_final_report_en.pdf)

Government of Canada. *A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making* (2000). (<http://dsp-psd.pwgsc.gc.ca/Collection/C2-500-2000E.pdf>)

Government Office for Science. *The Government Chief Scientific Adviser's Guidelines on the Use of Scientific and Engineering Advice in Policy Making* (2010). (<http://www.bis.gov.uk/assets/bispartners/goscience/docs/g/10-669-gcsa-guidelines-scientific-engineering-advice-policy-making.pdf>)

Health Council of the Netherlands. *Science advice on public health at national and European level*. The Hague: Health Council of the Netherlands, 2005. Publication n°. A05/06E.

OXMAN A, HANNEY S Ed. *SUPPORT Tools for evidence-informed health policymaking* (STP). Health Res Policy Syst 2009, 7(Suppl 1):I1, S1-S18.

The National Academies. *Our Study Process*. Ensuring Independent Objective Advice (2010). (<http://www.nationalacademies.org/studycommittee/process.pdf>)

Reports in connection with the EuSANH-ISA project (see <http://europa.eu/sinapse/directaccess/EUSANH/Public-Library>):

- *National Institute of Public Health – National Institute of Hygiene. Policy Analysis*. Warsaw.
- *National School of Public Health, Management and Professional Development. Thematic Analysis*. Bucharest.
- *Institute of Health Carlos III. Analysis of the survey results of policy makers and SAB staff*. Madrid.
- *Swedish Council on Health Technology Assessment. Case pilot for a European Science Advisory Report: Determinants of a successful implementation of population based cancer screening programmes*. Stockholm.

ANNEXES

A. DATABASES

There are many databases in the field of health care and public health. A number of them are listed here.

CINAHL (www.cinahl.com)

CINAHL[®], the Cumulative Index to Nursing and Allied Health Literature, is the most comprehensive resource for nursing and allied health literature. CINAHL has expanded to offer four databases including two full-text versions.

ClinicalTrials (www.clinicaltrials.gov)

The U.S. National Institutes of Health (NIH), through its National Library of Medicine (NLM), has developed this site in collaboration with the Food and Drug Administration (FDA). ClinicalTrials.gov currently contains 107,056 trials sponsored by the National Institutes of Health, other federal agencies, and private industry.

Cochrane Library (www.thecochranelibrary.com)

The Cochrane Database of Systematic Reviews (CDSR) includes all Cochrane Reviews and protocols prepared by Cochrane Review Groups in The Cochrane Collaboration.

CRD databases (www.crd.york.ac.uk)

The databases include approximately 21 000 systematic reviews, 11 000 economic evaluations and 10 000 health technology assessments.

Embase (www.embase.com)

Embase comprises over 24 million indexed biomedical records and more than 7,500 current, mostly peer-reviewed journals. The focus of the database is European journals and an important source of literature in other European languages than English.

INAHTA (www.inahta.org)

The HTA database contains records of published HTA reports and on-going projects from current and former INAHTA members and other HTA organizations.

PsycINFO (www.apa.org/psycinfo)

PsycINFO, by the American Psychological Association (APA), contains bibliographic citations, abstracts, cited references, and descriptive information across a wide variety of scholarly publications in the behavioural and social sciences.

Pub Med (www.ncbi.nlm.nih.gov/pubmed)

Pub Med comprises more than 20 million citations for biomedical literature from MEDLINE, life science journals, and online books.

B. DECLARATION OF CONFLICTS OF INTEREST: AN EXAMPLE



Registration no:



DECLARATION of conflicts of interest or potential conflicts of interest concerning experts/consultants engaged by the agencies listed above

Personal Information

First name:

Surname:

Employer:

Title:

I have read and understood the agencies' information concerning conflicts of interest and potential conflicts of interest.

Agency and Assignment

Agency/Agencies involved:

This declaration refers to my assignment, as follows:



1. Do you have, or have you had during the past 5 years, any formal association with a company or other interested party?

- | | |
|--|---|
| <input type="checkbox"/> Board of company/corporation | <input type="checkbox"/> Own company involved in area related to the assignment |
| <input type="checkbox"/> Consultant for company/corporation | <input type="checkbox"/> Other formal association |
| <input type="checkbox"/> Employee (full-time or part-time) of company/corporation | <input type="checkbox"/> Hold patent related to the assignment |
| <input type="checkbox"/> Member of professional/trade organization
Involved in start-up company | <input type="checkbox"/> No |

Ongoing assignments: specify company/corporation or interest group; describe work, remuneration, and year.

Completed assignments: specify company/corporation or interest group; describe work, remuneration, and year.



2. Do you have, or have you had during the past 5 years, any assignment from a company or other interested party?

- | | |
|---|---|
| <input type="checkbox"/> Involvement in marketing or product development | <input type="checkbox"/> Sole reviewer of research grant applications for research council of company/corporation |
| <input type="checkbox"/> Expert/scientific adviser to company/corporation | <input type="checkbox"/> Scientific advisor for company/corporate grants to researchers/research |
| <input type="checkbox"/> Participation with other experts to evaluate research grant applications for research council of company/corporation | <input type="checkbox"/> Other type of assignment for company/corporation or interest group |
| <input type="checkbox"/> Remunerated by company/corporation for lectures concerning your research and/or expertise | <input type="checkbox"/> No |

Ongoing assignments: specify company/corporation or interest group; describe work, remuneration, and year.

Completed assignments: specify company/corporation or interest group; describe work, remuneration, and year.



3. Do you have, or have you had during the past 5 years, any job, position, research grant, or other grant that involved a company or interest group?

- | | |
|--|---|
| <input type="checkbox"/> Professorship (or equivalent) funded by company/corporation | <input type="checkbox"/> Research grant for basic research from company/corporation |
| <input type="checkbox"/> Principal investigator | <input type="checkbox"/> Research grant for applied research from company/corporation |
| <input type="checkbox"/> Other position in clinical trial | <input type="checkbox"/> Other type of grant from company/corporation or interest group |
| | <input type="checkbox"/> No |

Ongoing assignments: specify company/corporation or interest group; describe work, type of grant/funding, remuneration, and year.

Completed assignments: specify company/corporation or interest group; describe work, type of grant/funding, remuneration, and year.



4. Other potential conflicts of interest involving company/corporation closely related to your area of expertise?

- | | |
|--|---|
| <input type="checkbox"/> Related to, or have close relationship with, someone in company/corporation | <input type="checkbox"/> Loan from company/corporation |
| <input type="checkbox"/> Shareholder in company/corporation | <input type="checkbox"/> Other potential conflict of interest involving company/corporation or interest group |
| | <input type="checkbox"/> No |

If you have checked any of the boxes above, please specify the company/corporation or interest group and describe the potential conflict of interest:

5. Is there anything else that might influence your judgment?

6. Can you think of anything in your Conflict of Interest Declaration that might call your impartiality into question?

- Yes No Uncertain

I pledge to immediately inform the agency involved if, during the time the assignment/project is ongoing, I take on any assignments or receive sponsorship from any company/corporation, professional/trade organization, or other interested party. I am aware that my signed Conflict of Interest Declaration is an official document and thereby normally public.

Signature:

Date and place:



DECLARATION
Page 6 of 6



To be filled in by the agency

Agency notes/comments:

Agency decision:

73442 CE Edita, Västerås 2011-01

C. BACKGROUND INFORMATION ON EUSANH

EuSANH

EuSANH is a network of science advisory bodies in Europe, which are active in the field of health. Currently, national science advisory bodies from more than half of the European member states are represented in the formal EuSANH collaboration. Advisory bodies from more European countries are expected to join in the near future.

Mission, goal and method

The objective of EuSANH is to promote independent scientific advice on health issues to national and European health authorities and to support evidence-based health policy. Reports published to fulfil this objective may also be of interest to health professionals and the general public.

To achieve this goal EuSANH will focus on exchange of information (national reports), mutual consultation of national experts, coordination of work programs and the joint work on the preparation of European science advisory reports on health.

EuSANH project: Improving Science Advice for Health in Europe, EuSANH

EuSANH received European funding in the 7th framework programme of DG Research for a 3-year project (February 2009- January 2012) entitled: Improving Science Advice for Health in Europe, EuSANH, abbreviated EUSANH-ISA.

The general objective of this project is to improve the quality, effectiveness and efficiency of science advice for health across Europe

Science advice is any recommendation for policy action based on scientific knowledge, considering also expert judgment, ethical and societal values, and experience from relevant stakeholders. Many EU Member States have national science advisory bodies. However, many health issues have transnational dimensions. Moreover, the rapid increase of scientific knowledge and health issues to be addressed, exceed what can be dealt with by national bodies separately. Accordingly, international collaboration between national bodies will lead to more effective and efficient science advice, in support of decision-making at national and EU level.

The general objective has been translated into the following specific objectives and work packages

- Describe the functions and structure of existing national science advisory bodies for health in the participating European countries and carry out a thematic analysis of reports from each country
Work package 2, WP Leader NIPH-NIH; task leader SNSPMS
- Establish a common 'best practice' methodology for science advice
Work package 3, WP Leader ISCIII
- Develop a plan for communication and cooperation in the expanding network of science advisory bodies, taking advantage of the Sinapse electronic communication system.
Work package 4, WP Leader SHC
- Illustrate the common methodology and the functioning of the network by developing a pilot case study for a European science advisory report
Work package 5, WP Leader SBU
- Disseminate the results of the project during and at the end of the project
Work package 6, WP Leader GR, task leader SNSPMS

Advantages of the project go beyond 3 year period

A common methodology with improved transnational cooperation promotes open governance, as more evidence-based policy making in Europe will be more transparent to the public. The recently established European Science Advisory Network for Health coordinates activities among science advisory bodies within the EU, and is eminently suited to provide the infrastructure for these tasks. The consortium consists of six contractual partners supported by an External Advisory Committee. As improvement of science advice is a long-term goal, this coordinating action project will also aim at strengthening the network beyond the time frame of the project.

Management structure

The project management and coordination is the key to the success of the Coordination Action project. The Coordinator has overall responsibility for project management, the coordination actions and the dissemination of information. He is also responsible for all communication with the Commission.

The consortium consists of the following six beneficiaries all scientific advisory bodies and members of EUSANH

- Health Council of the Netherlands (GR), Coordinator
- Institute of Health Carlos III, Spain (ISCIII)
- The Superior Health Council, Belgium (SHC)
- Swedish Council on Technology Assessment in Health Care, Sweden (SBU)
- National Institute of Public Health - National Institute of Hygiene, Poland (NIPH-NIH)
- National School of Public Health and Management and Professional Development, Bucharest, Romania (SNSPMS)

The Steering Committee consists of one senior representative from each of the beneficiaries in the consortium, and is chaired by the Coordinator. It is responsible for all technical, strategic and management decisions in relation to the EuSANH-ISA Coordinating Action project and for reviewing the work programme and approving any changes. It is also responsible for reviewing the project progress and the technical quality and timely delivery of all project results.

Furthermore, an External Advisory Committee is invited to comment on the work programme and progress, and advise the Steering Committee. This committee will enable EuSANH-ISA to optimise its added value in science advice for health at the European level. This committee consists of scientific advisory bodies from European countries (all EuSANH members) and international (mostly European) organisations in the field of health: Czech Republic, National Institute of Public Health (NIPH); Finland, National Institute for Health and Welfare (THL); France, Haute Autorité de Santé (HAS); Germany, Institute for Quality and Efficiency in Health Care (IQWiG); German Institute of Medical Documentation and Information (DIMDI); Portugal (Ministry of Health); Switzerland, Swiss Federal Office of Public Health (FOPH); European Centre for Disease Prevention and Control (ECDC); Health Evidence Network (WHO Europe, HEN); European Food Safety Authority (EFSA); Federation of European Academies of Medicine (FEAM); European Observatory on Health Systems and Policies; European Academies' Science Advisory Council (EASAC); European Network for Health technology Assessment (EUneHTA); Institute of Medicine (IOM, US) and the London School of Hygiene and Tropical Medicine (LSHTM).

For more information and detailed reports on the EuSANH-ISA studies, please visit www.eusanh.eu or contact the EuSANH coordinating secretariat Ms Dorine Coenen, d.coenen@gr.nl or eusanh@eusanh.eu.