

Fundamental principles and key points of collective expertise at the French Agency for Food, Environmental and Occupational Health & Safety (ANSES)

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## 1 FOREWORD

ANSES, the French Agency for Food, Environmental and Occupational Health & Safety, was established on 1 July 2010 following the merger of AFSSA (the French Food Safety Agency) and AFSSET (the French Agency for Environmental and Occupational Health Safety).

In its sphere of competence, the Agency's mission, according to Article L. 1313-1 of the French Public Health Code, is to conduct health risk assessments and provide the competent authorities, and more generally all stakeholders from civil society, with any information about these risks as well as the scientific and technical expertise necessary to draft legislative and statutory provisions and implement risk management strategies.

This expertise reflects the principles of impartiality, transparency, plurality and an adversarial process<sup>1</sup> set down in Article L. 1452-1 of the French public health code.

For expertise work, the Agency may receive solicited requests from its supervisory ministries or from other ministries, public authorities, bodies represented on its Board of Administrators, nationally approved associations for environmental protection, health quality, patient care and consumer protection, as well as associations providing assistance to victims of occupational hazards or diseases represented on the board of the French Asbestos Victims Compensation Fund (FIVA), trade unions, and professional and inter-professional organisations.

The Agency can also issue formal internal requests.

These formal requests, both internal and external, are requests for expertise and lead to the publication of an ANSES opinion.

# 2 INTRODUCTION

For ANSES, collective expertise can be defined as an expertise procedure fulfilling precise requirements with regard to scientific expertise and impartiality for which several experts<sup>2</sup> are selected and brought together to address a given issue, to hear all the conflicting, concurring or consensus opinions and theories expressed by their peers, in order to provide an interpretation, opinion or recommendation based on a demonstration and a decision once all the debates has been considered.

Collective expertise is to be preferred when stronger guarantees are needed with regard to:

- the completeness of the data or the existing state of knowledge on the issue in question;
- involvement of various different and complementary disciplines:
- a comparison of different opinions, theories or schools of thought;
- the expression of and reasoning behind any divergent opinions;
- the independence of the opinion.

The procedure, which is laid down in the founding texts of the expertise agencies, is intended to ensure optimal validity of the result.

ANSES thus systematically implements collective expertise for every health risk assessment. To do this, it appoints experts *intuitu personae* to Expert Committees (CESs), Working Groups (WGs) and Emergency Collective Expertise Groups (GECUs). Within this framework, the Agency takes measures

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Meaning that expertise for the assessment of health risks at ANSES is conducted with expert groups in order to promote scientific debate and to ensure its traceability, with the inclusion of divergent opinions.

<sup>&</sup>lt;sup>2</sup> See definition of expert in Annex 3

to prevent and manage any potential conflicts of interest relating to the themes to be addressed (cf. § 8 below).

Collective expertise can only succeed if fundamental principles are respected, namely the need for competent, independent and honest experts, collegiality, procedure which is transparent and open to the society, and control of traceability.

To ensure maximum compliance with these principles, the key points of collective expertise can be identified along with suggestions for managing them. They are described in this document, which applies to the Expert Committees (CESs), the Working Groups (WGs) the Emergency Collective Expertise Groups (GECUs) and to staff contributing to expertise work.

The organisational arrangements are specified in the documentation of the ANSES quality management system.

This document first discusses four major themes specific to collective expertise:

- establishment of the expert groups
- collective expertise and collegiality procedures
- expertise method
- results of the collective expertise.

It then addresses the general provisions for traceability, prevention and management of risks of conflict of interests, interaction between the Agency and the CES's, promotion of results and the openness of expertise to society.

### 3 ESTABLISHMENT OF THE EXPERT GROUPS

ANSES takes the necessary measures to ensure the competence and independence of its expert groups.

Public calls for candidates enable the Agency to set up groups of experts that are as representative as possible, and to restructure them regularly.

All the arrangements for establishing the groups and appointing the experts are specified in formal procedures.

### 3.1 General case

#### 3.1.1. Establishment of the Expert Committees (CESs)

The Director General of ANSES asks the Board of Administrators to create the CESs with regard to the required spheres of competence after consulting the Scientific Board.

The CESs correspond to the specific areas of expertise in which the Agency is called on to intervene.

In order to select experts for the CESs, ANSES organises public calls for candidates.

ANSES selects its experts according to the following criteria: competence, independence, availability, and, where appropriate, experience from a previous term of office. A balance between the disciplines required within groups is also taken into account.

An ad hoc investigative committee<sup>3</sup> reviews the candidates' applications, which include a curriculum vitae (CV), a public declaration of interests (DPI), and an indication of the candidate's expected

<sup>&</sup>lt;sup>3</sup> Made up of ANSES officials and specific to each group.

availability. A preliminary list of selected experts, accompanied by the report of the committee, is submitted to the Scientific Board for review.

The Director General appoints the experts who participate *intuitu personae*, as well as the chairmen, on the basis of the investigative committee's report and the opinion of the Scientific Board. The Director General also appoints one or several deputy chairmen.

For each CES, ANSES appoints a scientific coordinator from among its staff.

# 3.1.2. Establishment of the Working Groups

The Director General may set up working groups (WGs) to assist the CESs in risk assessment on specific topics.

The call for candidates is the preferred way of establishing the WGs, without prejudice to the specific cases stipulated in § 3.2.

The ways in which WGs are established are identical to those applicable to the CESs, except that they do not require the opinion of the Scientific Board.

A preliminary list of selected experts is submitted for review to the Chairman of the CES corresponding to the WGs.

The Director General appoints the experts *intuitu personae*, on the basis of the investigative committee's report and the opinion of the Chairman of the corresponding CES. He also appoints the WG Chairman.

For each WG, ANSES appoints a scientific coordinator from among its staff.

## 3.2 Specific cases

In addition to the public call for candidates procedure, in order to create expert groups or assign rapporteurs the Director General may appoint experts:

- from among already-appointed experts
- from among the scientists included on the list of qualified individuals (see below)
- or, in special cases where highly specialised profiles are required or if there are significant time restraints, eminent scientists may be approached directly.

The groups set up in this way are:

- either WGs appointed in specific cases, for example where there are significant time constraints for conducting the expertise (but without it necessarily being an emergency)
- or Emergency Collective Expertise Groups (GECUs)

Solicited requests in emergency situations are dealt with according to a specific protocol with the Agency's supervisory ministries and a special internal procedure which provides for GECU involvement. In each case, the Director General or his delegate confirms, for a given solicited request, whether the emergency procedure is to be applied.

To supplement the work of these groups, the Director General may appoint expert rapporteurs. At the time of their appointment, he establishes their missions, which may involve conducting expertise on a dossier or a specific question, a reread, a critical analysis of data, the raising of an issue requiring further investigation, etc.

In all cases, experts are appointed *intuitu personae* after review of their CV and their DPI with respect to the type of work to be undertaken.

Following public calls for candidates, ANSES establishes lists of individuals who are qualified in a given field. Candidates chosen by the selection committee according to identical criteria to those of § 3.1.1 are included on a list and can then be appointed by the Director General, following a new review of their dossier.

## 3.3 Establishment of a Project Review Allocation Group (GRED)

As part of the statutory assessment of applications for phytosanitary products, and following a decision by the Director General, a Working Group known as the Project Review Allocation Group (GRED) may be created within the Regulated Products Department (DPR). This group is responsible for managing projects at the end of the assessment process to select those needing full or partial examination by the CES for "Crop protection products: chemical compounds and preparations" and for establishing a list of those which may be exempted.

The GRED is made up of equal numbers of CES members and DPR assessors.

# 3.4 Maintaining the group and its skills

ANSES ensures that the workload of the expert group and the resources they are allocated (human and material) are consistent with the quality requirements of the collective expertise.

Whenever necessary, ANSES appoints new experts to ensure that the group's sphere of competence is fully covered.

ANSES takes the necessary measures to inform the experts about the relevant frame of reference for a given subject area to enable them to conduct the expertise.

# 4 DETAILS AND COLLEGIAL NATURE OF THE COLLECTIVE EXPERTISE

### 4.1 Participants

Expertise is managed by ANSES. In addition to CES involvement for risk assessment, it may include, where appropriate, one or more *rapporteurs* or, if warranted by the subject, a specific working group. In the case of a real emergency, expertise can be performed by a GECU.

The Agency also mobilises its internal skills to support the expert groups.

The participants in the collective expertise are the experts, ANSES officials and its General Directorate.

#### 4.1.1. Expert members of the groups

Experts examine the dossiers on the agendas, and participate in the work and discussions and in the validation and/or adoption of the results of the collective expertise. They undertake to abide by the Code of ethical standards and the provisions of this document that apply to them.

The Chairman of the group ensures that discussions and deliberations are conducted efficiently in accordance with the agenda. Together with the scientific coordinator, he is responsible for implementing procedures for the prevention of conflicts of interest during the work.

#### 4.1.2. ANSES officials

The officials responsible for coordinating and managing the expertise need to ensure that it is conducted efficiently to meet the requestor's requirements (deadlines, questions asked, etc.) and in accordance with the regulations, the organisation defined by ANSES and the NF X 50-110 standard. To this end, they may ask the groups to improve certain measures in the event of deviations from the current regulations or the planned expertise calendar.

They ensure that the work complies with ANSES procedures. They undertake to abide by the Code of ethical standards and the provisions of this document that apply to them.

ANSES officials provide scientific and technical assistance for the expertise in their area(s) of specialisation.

With regard to the assessment of regulated products, they can scientifically evaluate dossiers to which the CESs can refer in order to reach their findings and make recommendations.

#### 4.1.3. The ANSES General Directorate

Finally, the General Directorate issues an Opinion on the basis of the arguments and conclusions of the collective expertise.

# 4.2 Collegiality of expertise

Collegiality is a characteristic quality of expertise. Its execution ensures that the result is based on scientific demonstration and conclusions following the discussions of an expert group.

The group's Chairman is responsible for the collegiality of collective expertise.

Each expert testifies to his suitability for collective expertise by participating in the discussions and by the added value he brings to the group's work, which may be scientific knowledge, critical arguments, and any participation in the discussions.

The collegiality of expertise must be ensured in every phase of the work by:

- presenting input data for the collective expertise,
- coordinating and conducting discussions,
- considering divergent opinions,
- collective preparation of the result of the expertise, which may include expressing divergent opinions,
- deliberation for adoption of the expertise product

ANSES ensures that the collegial process is traceable, mainly through reports validated by the group.

### 5 EXPERTISE METHOD

A method must be established for each expertise area. It may be set legally by the regulations, selected from among already-existing methods or developed ad hoc. In the latter case, it must undergo a specific validation process.

The ANSES document entitled "Framework memorandum on the collective expertise methodology applied at ANSES" specifies the key points of this step.

# 6 RESULTS OF THE COLLECTIVE EXPERTISE AND ADOPTION METHODS

# 6.1 Deliverables

The end results, or deliverables, associated with each participant or group of participants are as follows:

Participant or group of	Products		
participants Rapporteur	✓ Documents (reports, notes, slide presentations, etc.)		
Working Group	<ul> <li>✓ Document including the discussions and conclusions or</li> <li>✓ Collective expertise report</li> <li>which reflects, if applicable, the comments of the CES as work is presented</li> </ul>		
Emergency Collective Expertise Group	<ul> <li>✓ Document including the discussions and conclusions or</li> <li>✓ Collective expertise report</li> </ul>		
Allocation Group for Review of Dossiers	✓ Minutes of meeting		
Expert Committee	With a WG:  ✓ Document including the discussions and conclusions in common with the WG  or  ✓ Expertise report produced jointly with the WG  or		
	✓ Summary and conclusions memo for tracking the adoption of the WG's work, and which is integrated in the collective expertise report		
	Without a WG:  ✓ Document containing the discussions and conclusions of the CES  or  ✓ Collective expertise report		
Agency	✓ Opinion based on the collective expertise, including the discussions and conclusions of the experts		

All these products on which the opinion is based are authenticated (identification, date, signature), namely the document including the discussions and conclusions and the collective expertise report.

## 6.2 Validation and adoption methods

ANSES defines how the results of the collective expertise are to be written up and then validated and/or adopted.

For CES's, ANSES verifies with the Chairman of the CES that a quorum has been reached before validating the results or adopting the work. The rules for attaining a quorum are described in the Agency's internal rules and regulations.

During the validation steps, any divergent positions which persist at the end of the discussions must be acknowledged and tracked, whether they occur within a WG, a CES or a GECU, or between a CES and a WG. These opinions must be justified by the experts concerned and presented in the results of the expertise, specifying their names if they wish.

The Agency drafts its opinion incorporating the discussion and conclusions of the collective expertise, and where appropriate including further information it deems useful and which are dealt with in a specific chapter.

The opinion is sent to the CES for information purposes.

# 6.3 **Publication methods**

ANSES publishes the end products of the expertise: the Agency's Opinion including the discussions and conclusions of the expert groups together with, if available, the collective expertise report.

### 7 TRACEABILITY

The Agency defines procedures in order to control the traceability of the expertise process. This may be done using special software.

In this context, the Agency implements the session disclosure procedures provided for in article L. 1451-1-1 of the Public Health Code.

# 8 METHODS FOR PREVENTING AND MANAGING POTENTIAL CONFLICTS OF INTEREST

All experts and officials must comply with the Code of ethical standards which was issued to them when they were appointed or recruited.

ANSES provides information on the ethical rules of conduct for experts at the beginning of each CES's mandate.

Experts must update their public declaration of interests each time their situation changes, as well as systematically at least once a year.

Potential conflicts of interest are managed in two ways: prior to the start of the expertise before the experts have been nominated (cf. above), and throughout the expertise process.

ANSES tracks the analysis of the declared interests performed before each CES meeting, in keeping with the agenda, and pinpoints all risks of conflicts of interests. As a consequence, the expert(s) concerned by such conflicts are barred from participating in the work, discussion and deliberations on the point of the meeting's agenda which is at issue. An expert at risk of conflicting interests may only take part in hearings.

In addition, at the start of each expert group meeting, the Chairman must ask the experts if there are any specific interests to be investigated in light of the agenda.

ANSES publishes the experts' public declarations of interests on its website. More specifically, and in addition to the elements provided for in the minutes mentioned in article L. 1451-1-1 of the public health code, ANSES may, in an annex to the collective expertise reports, reiterate how it deals with related interests for the experts participating in the work.

# 9 SCIENTIFIC INTERACTION BETWEEN THE AGENCY AND THE CESS, AND PROMOTION OF WORK

The CESs may ask the Agency to authorise them to conduct studies and thematic work themselves, relating for instance to methodology, that they deem necessary in relation to the topics they were (or may be) requested to address.

The CESs, as well as all personnel in charge of expertise, must alert the Agency if they identify any health risks while conducting their expertise activities.

One way to promote the collective work of experts is through publication of the results and by the Agency's presenting the work in different ways to various audiences. For certain expertise work, the drafting of a scientific article may be considered, in accordance with procedures set down by the Agency.

ANSES must allow the experts to exploit their contributions to the Agency's work with the organisations to which they are affiliated, in accordance with the French Charter for scientific and technical expertise of 2 March 2010.

### 10 OPENNESS OF THE EXPERTISE PROCESS TO STAKEHOLDERS

ANSES has opened up its expertise process to society. It identifies stakeholders<sup>4</sup> potentially concerned by a risk in order to mobilise them, if necessary, during the expertise process.

Their involvement can take three forms:

Information: in order to make the results of work available and to ensure transparency, information is systematically issued through the publication of opinions. The Agency can also arrange for expertise work to be released to the stakeholders concerned, in the presence of the Chairmen of the corresponding groups, in order to facilitate their understanding and empowerment.

<sup>&</sup>lt;sup>4</sup> Other than public authorities and the scientific community, which are naturally considered as providers of information for expertise

- Consultation: namely in the form of auditions, in order to identify and if necessary integrate the data, knowledge and questions communicated by the stakeholders into the planning and implementation stages of expertise.
- Dialogue: in order to facilitate discussions between the Agency and the stakeholders on specific topics, namely through theme-based groups such as the dialogue committees.

This commitment was formalised by the signing of the Charter for Openness to Society by public organisations for research, expertise and assessment of health and environmental risks.

# 11 CONTINUOUS IMPROVEMENT

ANSES and the experts work to detect operational difficulties in order to analyse them and implement appropriate measures in a context of continuous improvement.

# **ANNEX 1: REFERENCE TEXTS**

External reference texts

- \* Laws and regulations applying to the Agency
- \* NF X 50-110:2003: Quality in expertise activities General requirements of competence for an expertise activity.
- \* FD X 50-046:2011: recommendations for application of standard NF X 50-110:2003
- \* NF EN ISO 9001:2008: Quality management systems Requirements
- \* French Charter for Openness to Society, October 2008, revised 9 September 2011
- \* French Charter for Scientific and Technical Expertise of 2 March 2010\* Quality charter for formal requests issued by the General Directorate for Health, 2 June 2009.

Internal reference texts

- \* ANSES Code of ethical standards
- \* ANSES internal rules and regulations
- \* Framework memorandum on the collective expertise methodology applied at ANSES
- \* ANSES Quality Policy

# **ANNEX 2: ACRONYMS**

CES: Expert Committee [comité d'experts spécialisé]

CV: curriculum vitae

DPI: public declaration of interests [déclaration publique d'intérêts]

GECU: Emergency Collective Expertise Group [groupe d'expertise collective d'urgence]

GRED: Allocation Group for Review of Applications [groupe de répartition pour l'examen des

dossiers]

WG: Working Group [groupe de travail]

### **ANNEX 3: DEFINITIONS**

• Chairman of the Expert Committee: CES expert appointed by the Director General to chair this CES.

The Chairman decides on the agenda in conjunction with the scientific coordinator, leads meetings, coordinates the involvement and contributions of the various members, and signs the meeting minutes after validation by the CES members. He is responsible for collegiality and, in collaboration with the scientific coordinator of the CES, must implement the procedures guaranteeing the independence of the expertise.

• Chairman of the Working Group: WG expert, appointed by the Director General, to chair this WG.

The Chairman decides on the agenda in conjunction with the scientific coordinator, leads meetings, coordinates the involvement and contributions of the various members, and signs the meeting minutes after they have been adopted by the WG members. He is responsible for collegiality and, in collaboration with the scientific coordinator of the WG, implements the procedures guaranteeing the independence of the expertise.

In most cases, the Chairman is also the *rapporteur* of the GT's work for the CES.

• **Collective expertise:** expertise conducted according to a procedure in which several experts are selected and brought together to address a given issue, to hear all the concurring, consensual or conflicting opinions and theories expressed by their peers, and to provide an interpretation, opinion or

recommendation based on what is demonstrated and on the professional judgement that ensues once all the discussions have been considered. (FD X 50-046:2011)

- **Collegiality of expertise:** a characteristic of expertise whose execution ensures that the result of the expertise is based on what is demonstrated and concluded once all the discussions of an expert group have been considered. (FD X 50-046:2011)
- **Consultation:** the gathering of information, position statements or comments from stakeholders via questioning. This consultation may be conducted in various ways, for example electronically over the Internet, by mail or through a live hearing.
- **Deputy Chairman of the CES**: CES expert appointed by the Director General to chair this CES in the Chairman's absence or in the event of a potential conflict of interest involving the Chairman, provided that he himself is not in such a situation.
- **Emergency (situation):** situation caused by a health emergency or other justified type of emergency. A health emergency is related to a verified sign or event likely to represent a grave or imminent danger for human, animal or plant health or safety.

It is mainly, but not exclusively, characterised by its propagation speed or the number and severity of incidents.

Other types of emergencies can be justified by situations involving specific issues within very constrained timeframes. In each case, the Director General of ANSES or his proxy will confirm whether or not the urgent procedure needs to be applied, within the context of the Agency's quality procedures. (Definition taken from the protocol setting down the relationship between ANSES and its supervisory ministries in emergency situations)

**Emergency Collective Expertise Group (GECU):** group of experts established by the Director General of ANSES to respond to a solicited request (external or internal) requiring the Agency's opinion in an emergency situation.

The members of this group are appointed by decision of the Director General after review of their dossier (CV and DPI).

- **Eminent scientist:** scientist occasionally called upon by ANSES for a precise mandate, and appointed expert following review of his *curriculum vitae* and public declaration of interests.
- **Expert Committee (CES):** group of experts whose creation and area of expertise are defined by the Director General following the opinion of the Scientific Board and deliberation by the Board of Administrators.

CES members and its Chairman are appointed by decision of the Director General, after review of their dossier (CV and DPI) and the opinion of the Scientific Board.

- **Expert group:** group of experts set up expressly to conduct collective expertise.
- **Expert:** "person whose competence, independence and integrity earn him/her formal recognition as someone capable of conducting expertise work" (NF X 50-110:2003).
- **Expertise contract:** "agreement between the customer and expert body which specifies at least the query raised, the conditions for conducting the expertise and the expertise product to be provided." (NF X 50-110:2003)
- **Expertise of regulated products:** expertise conducted in accordance with a predefined regulatory framework .

This may include for instance dossiers submitted in connection with the implementation of the Regulation on biocidal substances and products.

• **Expertise:** "series of activities intended to provide a customer with a response to the query raised in the form of an interpretation, opinion or recommendation, as objectively based as possible, formulated on the basis of available knowledge and demonstrations, accompanied by a professional judgment.

**NB**: demonstrations include tests, analyses, inspections, simulations, etc." (NF X 50-110:2003).

- **Group's scientific coordinator:** ANSES scientific officer who supervises and coordinates the work conducted by an expert group.
- He is responsible for the traceability of the expertise and its implementation according to the organisational principles determined by ANSES. He must also, together with the Chairman, ensure implementation of the procedure ensuring the independence of the expertise. He may also be the request manager.
- **Interpretation:** "action taken by the expertise body in response to the query raised in order to explain and/or give a sense to data on the basis of a professional judgement" (NF X 50-110:2003).
- **Opinion:** "judgement resulting from an analysis or assessment in response to the query raised and which is not decisive, formulated by the expertise body on the basis of information known by the expert(s) and of current knowledge" (NF X 50-110:2003).
- **Professional judgement:** "intellectual process of appreciation, assessment, estimation or explanation leading to the formulation of an opinion on an issue or subject, based on professional experience in a specific field." (NF X 50-110:2003).
- **Public declaration of interests:** a form established by the Order of 5 July 2012 on creation of a standard document for the public declaration of interests referred to in article L. 1451-1 of the public health code, for the listing of interests.
- Qualified individual: scientist included on a list but without being appointed as an expert, following review of his dossier in the context of a public call for candidates.

  A qualified individual becomes an ANSES expert once he has been appointed a member of a Working Group or Emergency Collective Expertise Group, or a *rapporteur*, for a period and a mission defined in his mandate and after further review of his dossier.
- **Rapporteur:** expert appointed by decision of the Director General or his proxy, to conduct expertise under a specific mandate.

This mandate may involve conducting expertise on a dossier or a specific question, a reread, a critical analysis of data, the raising of an issue requiring further investigation, etc.

- **Recommendation:** "opinion formulated by the expertise body regarding what should or should not be done" (NF X 50-110:2003).
- Request manager: ANSES scientific officer responsible for planning, organising and coordinating the supervision of work relating to the investigation of a solicited request, with the experts and the relevant units and departments. He may be required to participate in the work itself. When a WG or a GECU is established, he becomes its scientific coordinator (*cf.* above for the definition) and is then responsible for the traceability and, in conjunction with the Chairman of the group, for the implementation of the procedure guaranteeing the independence of the expertise.
- **Result of the expertise:** "Response to the question asked, as specified in the expertise contract." (NF X 50-110:2003)
- **Risk assessment:** "scientifically-based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation." (EC Regulation no.

178/2002 of 28 January 2002)

NB: Risk assessment may be quantitative and/or qualitative.

- **Solicited request:** request issued by an approved authority or entity for expertise leading to an ANSES Opinion on clearly identified points falling within the Agency's sphere of competence. ANSES may also issue formal internal requests.
- Working Group (WG) (on collective expertise): group of experts established by the Director General of ANSES, whose mission is to conduct expertise work, in collaboration with ANSES and for the WG assigned to the CES. In the latter case, its products are adopted by the CES. The members of a WG are appointed by decision of the Director General after review of their dossier (CV and DPI).