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This translation of the rules of procedure of expert committees from French to English produced by Santé publique France is for information purposes only. Only the French version is authentic.

Rules of procedure for Santé publique France expert committees

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This document sets out how expert committees operate during their term of office.

This document is appended to the Rules of procedure of Santé publique France. It supports the agency's document which describes, specifically, the steps of the expert assessment pursuant to the principles of the Health Expertise Charter[1] and the roles of the Santé publique France teams within the various divisions.

This Charter defines expertise and the health expertise activities subject to it as follows: "*Expertise is generally understood, under the terms of the French AFNOR[2] standard NF X 50-110, as a set of activities whose purpose is to provide a commissioner, 'in response to a question, with an interpretation, opinion or recommendation that is as objectively founded as possible, based on available knowledge and proof, accompanied by a professional judgement'.. [...] The health expertise assessment activities covered by this charter are those whose purpose is to shed light on health, health security and safety matters for decision-makers and support their decision-making in this field by providing an interpretation, an opinion or a recommendation that is as objectively founded as possible, drawn up based on a critical analysis of the best available knowledge and proof founded on explicit criteria, accompanied by a professional judgement based on the experience of the experts*."

The French version of this document is **published on the agency's website** as part of the initiative for transparency over procedures for 'collective expertise', i.e. expert advice delivered in collective settings, implemented by Santé publique France.

The French version of this document (version 1 – October 2023) was **approved by the Management Board** on 24 November 2023 (deliberation 2023-26 relating to the rules of procedure for Santé publique France's expert committees).

Note: to simplify the text, male pronouns used throughout the text shall be understood to be neutral. Signature and approval by the executive director shall be understood in light of the decision of the executive director to delegate signature within the agency.

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[1] Decree no. 2013-413 of 21 May 2013 approving the Health Expertise Charter provided for in article L.1452-2 of the French Public Health Code Available at: https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000027434015

[2] French national organisation for standardisation

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Contents

TERM OF OFFICE AND COMPOSITION OF AN EXPERT COMMITTEE

1. Article 1 – The committee's term of office (scope and remit)

1.1. An expert committee is set up (defining the length of term of office, scope and remit of the committee, skills required of its members) subject to the opinion of Santé publique France's Scientific Advisory Board[3]. The remit of an expert committee may be defined by mandates from external mandate requestors (decision-makers) outside the agency or from the agency itself[4] on its own initiative (self-tasking) in view of its remit.

1.2. The scope and remit of an expert committee are set out in the committee's framework document, defining the context, the question(s) raised, the objectives, the methodology for responding, the areas of work identified, the pre-identified resources, the matters for attention and the main steps of the provisional timetable.

1.3. The division in charge of an expert committee appoints one (or more) staff member(s) to provide scientific coordination for the committee.

1.4. The expert committee's projects are completed and the planned deliverables are finalised and adopted (see Article 11) before the end of the committee's term of office. If additional time is needed to complete this work, the expert committee's term can be extended by decision of the executive director of Santé publique France, in response to a request from the division in charge of the committee.

1.5. The expert committee may make a proposal to the agency to study a question falling within its area of expertise, or suggest that it broaden the scope of a mandate falling within its remit, if it believes this to be relevant and if the following three criteria are met:

(i) the question has a public health justification, falls within the agency's remit, and can be incorporated into the agency's work programme taking into account the resources available,

(ii) it does not affect the conduct of the work set out in the committee's term of office, and

(iii) the executive director of Santé publique France agrees that it is relevant to obtain this additional expertise. In this context, the chief executive may decide, if necessary, to consult the agency's Scientific Advisory Board on the matter.

1.6. If the question proposed by the expert committee is deemed admissible by the agency, it is considered to be a self-initiated mandate (self-tasking) by the agency and is formalised in a new framework document.

1.7. If the scope of the question posed by a mandate from a mandate requestor outside the agency is broadened, this change is formalised in a discussion with the requestor in accordance with the provisions on the admissibility of mandates laid down by the agency in its expert assessment process, and specified in the expert assessment contract where applicable.

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[3] Decree no. 2016-523 of 27 April 2016 on the creation of the national public health agency. Available at: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000032465745

[4] French Ordinance no. 2016-462 of 14 April 2016 creating the National Public Health Agency states that the agency "*may take up any matter falling within its remit as defined in 1, 2, 3, 4 and 6 of Article L. 1413-1*" (Article L1413-5 of the French Public Health Code).

Article L. 1413-1: *"The tasks of the agency are:*
1. Epidemiological observation and monitoring the health of populations;
2. Monitoring health risks to populations;
3. Promoting health and reducing health risks.
4. Developing prevention and health education." [...]
"6. Issuing health alerts"

2. Article 2 – Members

2.1. The members of an expert committee are selected following a public call for candidates, once their skills and experience have been assessed, and the interests listed in their public declaration, which can be accessed on the website dpi.sante.gouv.fr, have been examined.

2.2. Members of the expert committee update their public declaration of interests whenever there is any change, and at least once a year.

2.3. Membership of one of the agency's governance bodies (the Board of Directors, Scientific Advisory Board, Ethics and Professional Conduct Committee or the Guidance and Dialogue Committee [3]) is incompatible with membership of an expert committee, while in office. Similarly, Santé publique France employees cannot be members of an agency expert committee[5].

2.4. The rules laid down by Santé publique France's Internal Professional Conduct Committee ("Comité interne de déontologie" CID in French) state that members of expert committees must not have a contractual relationship with the agency or be a member of another agency committee during their term of office[6].

2.5. The executive director of Santé publique France is responsible for appointing the members of an expert committee[7], once the applications have been assessed and on the recommendation of the division in charge of the expert committee, and once the CID has identified any potential conflicts of interest. The term of office of an expert committee is a maximum of 4 years. Members may be reappointed no more than once if the committee's term of office is renewed. In accordance with the health expertise charter[8], any change in a member's interests during the term of office that may lead to a conflict of interest may result in the appointment being withdrawn, as the impartiality and independence conditions of the appointment would no longer be met.

2.6. Members of an expert committee sit in their personal capacity (*intuitu personae*) and therefore cannot be represented by a substitute. Members have voting rights.

2.7. Members of an expert committee may only sit on it if their public declaration of interests is up to date, if they have carefully read the Health Expertise Charter[8] and if they have signed the "Confidentiality and commitment clause to attend meetings". The experts undertake to take part in the meetings, not to disclose, in any form whatsoever and to any person whatsoever, the information exchanged and the content of the debates, and not to use the data, documents, or information provided by Santé publique France and the deliverables produced as part of the committee's work unless expressly authorised to do so by the agency.

2.8. In the event of a breach of the "Confidentiality and commitment clause to attend meetings", the committee chair (article 3), the scientific coordinator of the division in charge of the expert committee and the chief scientist may consult over taking steps to have the expert in question replaced.

2.9. The members of an expert committee are required to examine and analyse the meeting documents submitted before each meeting. They take part in the discussions and, where applicable, in the approval and voting in accordance with the procedures set out in Article 11.

2.10. If a member of an expert committee wishes to resign, he/she must inform the scientific coordinator of the division in charge of the committee in writing.

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[5] Opinion of the Scientific Advisory Board of Santé publique France of 8 June 2017.

[6] Further to its meeting of 7 October 2022.

[7] The same applies to the members of the working groups attached to them.

[8] French Decree no. 2013-413 of 21 May 2013 approving the Health Expertise Charter provided for in article L.1452-2 of the French Public Health Code. Available at: https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000027434015/

2.11. In the event of a vacancy, the members of an expert committee are replaced under the same conditions, i.e. by a public call for candidates (see Article 2.1). The new members are then appointed for the remainder of the committee's term of office. Any new appointment is formalised in a new appointment decision signed by the executive director of Santé publique France.

2.12. The provisions relating to the publication on the agency's website of the composition of expert committees are defined by the CID.[9]

3. Article 3 – Chair

3.1. The chair of an expert committee is a member of the committee designated and appointed by the executive director of Santé publique France, following a proposal from the division in charge of the committee.

3.2. The chair is assisted by a scientific coordination team, made up of Santé publique France employees (and potentially employees from another organisation, in case of a joint mandate of this organisation and Santé publique France from a mandate requestor). If the chair is unable to attend a meeting, he may be replaced by a member of the committee designated by the other members present or by the vice-chair if there is one (article 3.6.).

3.3. The chair is the guarantor of the collective nature of the work carried out by the expert committee, complying with the principles of impartiality, transparency, plurality and adversarial debate set out in the Health Expertise Charter[8].

3.4. At each meeting of the expert committee, the chair approves the draft agenda prepared by the expert committee's scientific coordinator. With the support of the scientific coordinator, the chair:

- ensures at each meeting that committee members have no conflicts of interest in relation to any item on the agenda, and organises any steps that may be required to manage a potential conflict of interest in relation to items on the agenda[10];
- ensures at the start of the meeting that the quorum (see Article 11) has been met;
- either appoints rapporteurs (responsible for drafting) and other contributors to deal with each of the subjects on the agenda, or proposes the creation of working groups (WG) for the drafting, where necessary (see Article 9);
- may suggest to organise *ad hoc* hearings of any invested persons, i.e. any natural or legal person who may present and share information that shed light on the work of the committee (see Article 10);
- ensures that the approach for expert assessment agreed upon before the work began in consultation between Santé publique France and the mandate requestor is followed.

3.5. The chair:

- ensures that all committee members can take part in the debate, ask questions and express their opinions (paying close attention to the participation of all members, especially during "hybrid" meetings involving a mix of members participating in person and remotely);
- makes every effort to reach a consensus among the members of the expert committee;

[9] Dated 28 January 2021.

[10] Members of the committee (or working group) "may not take part in deliberations or votes if they have a direct or indirect interest in the subject under consideration" (Art. L 1451-1 of the French Public Health Code).

- where this is not possible, ensures that any minority and divergent opinions[11] can be expressed and tracked;
- ensures, in conjunction with the scientific coordinator, that the assessment is completed in accordance with the principles set out in the Health Expertise Charter[12] and within the deadlines set in consultation with the mandate requestor and laid down in the committee's terms of reference.

3.6. If it proves to be necessary to appoint a vice-chair, he is appointed in the same way as the chair and performs the same duties in the chair's absence.

MEETINGS

4. Article 4 – Plenary meetings

4.1. The expert committee adopts a schedule of meetings on the proposal of the chair in conjunction with the scientific coordinator. This timetable takes into account the deadlines that the agency must meet to deliver its work to the mandate requestor and the duration of the committee's term of office.

4.2. The initial timetable may be postponed in the event of new or additional urgent mandates falling within the expert committee's remit.

4.3. Meetings are held in person and/or remotely. Meetings are not open to the public.

4.4. The committee's assessment work is carried out without the involvement of the mandate requestor, i.e. the originator of the mandate giving rise to the expert assessment (except in the case of self-taking). However, if necessary and if required by the mandate requestor, they may be informed of the progress of the assessment, in line with procedures to be arranged between the agency and the committee chair; in addition, , update meetings may have been scheduled during the consultation prior to the mandate acceptance[13].

HOW THE COMMITTEE WORKS

5. Article 5 –Meeting invitation and meeting documents issued

5.1. Members of the expert committee (and any working groups, including those set up as a matter of urgency, Article 9) receive an e-mail invitation to attend from the division in charge of the committee, indicating the date, time and place of the meeting if it is a physical meeting, or the connection link to be used if it is a tele-meeting. The time frame

[11] A divergent minority position indicates disagreement with the majority position. A minority position may also be convergent or neutral, i.e. without any major disagreement but emphasising nuances or the absence of sufficient reliable data to issue a reasoned opinion.

[12] The charter states specifically that: "*the interpretation, opinion, recommendation or report produced by the expert appraisal explicitly describes the method used to select all data used during the investigation and delivery of the expert appraisal and, in particular, cites the sources on which the conclusions of the expert appraisal are based. The interpretation, opinion, recommendation or report produced by the expert appraisal defines, as far as possible, how reliable the conclusions can be taken to be based on the quality of the work they derive from and explicitly identifies the points on which the state of available knowledge does not allow a decision to be reached with sufficient certainty. Divergent or minority views are also outlined*."

The charter also states that: "*In all cases, including where a single expert is used, the expert appraisal must:*
– draw on the completeness of the existing data or current knowledge on the question posed;
– weigh up different opinions, assertions or schools of thought against each other;
– express any divergent positions, with arguments set out"

[13] see Santé publique France's document describing the procedure and working instructions for the production of internal or external scientific advice, in French.

to send meeting invitations to members is set by the expert committee at its first meeting.

5.2. Meeting documents for the attention of the expert committee (and any of its working groups), including the draft minutes of the previous meeting and the agenda for the forthcoming meeting, may be sent to members by e-mail or via a shared online channel or platform made available by Santé publique France. As far as possible, the documents should be sent allowing sufficient time for them to be thoroughly read before the meetings. The time frame for sending documents is set by the expert committee at its first meeting.

6. Article 6 – Meeting agenda

6.1. The draft agenda is prepared by the scientific coordinator and approved by the chair.

6.2. The agenda should always include the following items:

- confirmation of quorum (see Article 11);
- checking for any interests in relation to items on the agenda;
- approving the minutes of the previous meeting (done during the meeting or indication in the minutes that the previous minutes have already been approved by e-mail or via the shared channel / platform, see Article 8.4);
- specific topics and participants (e.g. hearings), stating whether they are for information, discussion, approval or advice;
- any other business;
- date of the next meeting.

7. Article 7 – Attendance sheet

7.1. An attendance sheet is drawn up by the administrative secretariat of the expert committee before each meeting, and for each half-day of meeting, to enable the quorum to be checked and the compensation of participants to be calculated under the conditions laid down by decision of the agency's Management Board.

7.2. In physical meetings, it is signed by the participants. For tele-meetings, members' attendance should be tracked.

8. Article 8 – Recordings, decision record and minutes of meetings

8.1. Minutes are taken of each meeting of an expert committee. These minutes must show how all the items on the agenda have been dealt with (see Article 6.2.) including tracking identification and management of competing interests, as well as the result of the approvals/votes on the opinions/reports of the expert committee (see Article 11). The minutes are not made public except in the cases provided for below (see Articles 8.2–8.5).

8.2. Expert committee meetings are recorded and the recordings are retained, including tele-meetings[14]. The recording is kept for 10 years. Committee members are informed that meeting are recorded and have a right of access to them.

[14] Article L 1451-1-1 of the French Public Health Code: "*Public information concerning meetings of the expert commissions, boards and collective bodies mentioned in part I of article L. 1451-1 which are consulted as part of administrative decision-making procedures is organised, as appropriate, by the French Ministry of Health or by the authority, institution or body to which they report or to which they are attached. To this end, provision is made for: 1. Debates to be recorded and these recordings to be retained; 2. Without prejudice and where applicable, the audiovisual recordings of debates to be made available online, and minutes to be drafted including the agenda, reports of debates, and details about and explanations of votes, with minority opinions included, and these minutes to be made available for free on the websites of the French Ministry of Health or the authorities, institutions or bodies mentioned in the first paragraph.*"

8.3. A summary version of the meeting minutes of committee meetings is made public[14] on the agency's website, subject to protection of privacy and legally protected confidential information, in particular rules on the protection of national defence secrets and personal data. This summary version of the meeting minutes is kept for 10 years[15], then archived in accordance with the rules of the French Heritage Code.

8.4. Once they have been reviewed by the chair of the expert committee, the minutes are approved by the committee members either electronically or at the next meeting. The minutes are kept for up to 10 years from the end of the committee's term of office or after each renewal, after which time they are archived in accordance with the rules of the French Heritage Code.

8.5. In the event that a third party requests disclosure of approved meeting minutes, article 2 of the law of 17 July 1978[16] specifies that the right to disclosure applies only to concluded documents. Consequently, preparatory documents, exchanges, drafts and successive versions of the minutes prior to their approval are excluded.

9. Article 9 – Setting up working groups (WG)

9.1. The chair of an expert committee may, in conjunction with scientific coordinator, suggest that a working group (WG) be set up to write the draft opinion, which will then be discussed and approved by the plenary expert committee. The creation of a WG attached to an expert committee does not require the opinion of the Scientific Advisory Board. A lead member who is also a member of the expert committee may be appointed from among the members of this WG by means of a letter of assignment setting out the objectives of the WG, and the deliverables and deadlines, and signed by the executive director.

9.2. The WG is made up of members of the expert committee and, where appropriate, other external qualified persons, subject to a check of their public declarations of interest and a letter of appointment signed by the executive director.

9.3. The operating procedures of a WG follow the same principles as those of the expert committee described in these rules of procedure. Meetings are held in person and/or remotely (see Article 4.3).

9.4. If the lead member of the WG is not the rapporteur of the work to the expert committee, he appoints a rapporteur from the WG.

9.5. The WG lead member receives support from the scientific coordination team as needed.

9.6. The WG's draft opinion or report is presented to the plenary expert committee for information, discussion then final approval.

9.7. If an urgent opinion is requested from the expert committee in response to an urgent mandate that falls within its remit, an emergency working group (EWG) may be set up and attached to this committee.

9.8. The draft opinion is submitted electronically by the EWG for approval by the expert committee (see Article 11). Information will be provided at the next plenary meeting of the expert committee. If the deadline of the mandate requesting an urgent opinion does not allow time for approval by the full expert committee, it is approved by the members of the EWG and the chair of the expert committee.

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[15] Article R1451-9 of the French Public Health Code: *The minutes and recordings mentioned in article* R. 1451-6 *are retained by the administration, authority, institution or group concerned for a period of ten years.*

[16] French Law no. 78-753 of 17 July 1978, codified in Book III of the French Code of Relations between the Public and the Administration establishes the principle of freedom of access to administrative documents.
https://www.legifrance.gouv.fr/codes/id/LEGITEXT000031366350/.
Website of the Commission for access to administrative documents (Commission d'accès aux documents administratifs CADA in French): https://www.cada.fr

10. Article 10 – Hearings

10.1. The expert committee and the associated WG(s) may hold hearings with any invested persons, i.e. any natural or legal person who may present and share information that shed light on their work. These people do not have voting rights.

10.2. Persons being heard complete a public declaration of interests prior to the meeting. Their interests in the subject under consideration are declared orally at the beginning of the hearing and are recorded in the minutes of the meeting. They sign a confidentiality clause. In accordance with the provisions of the Health Expertise Charter, persons with conflicts of interest may be be invited to dedicated hearings if their recognised scientific expertise is considered by the expert committee and scientific coordination team to provide the committee with essential insight.

10.3. Hearings can be held in person and/or remotely.

10.4. The persons interviewed are informed, where applicable, that the hearing is being recorded and receive the minutes of their hearing for approval.

10.5. Subject to protection of privacy and legally protected confidential information, in particular rules on the protection of national defence secrets and personal data, the approved summary of the hearing may be made public when the opinion is published. The same applies to any scientific documents provided during their hearings by the persons interviewed, if these were taken into account when the opinion was drawn up and provided these persons agreed to their documents being made public. Where the summary of the hearing and associated documents relate to industrial and commercial secrets or protect national defence secrets, these are not published.

10.6. The minutes of meetings and draft opinions of the expert committee are not made available to the persons heard.

CONDUCTING DEBATES

11. Article 11 – Quorum and procedures for adopting draft reports and/or opinions

11.1. A quorum is reached when at least 2/3 of the members of the expert committee are present (in person or remotely).

11.2. If there is a quorum, the committee can sit and the draft opinions/reports on the agenda can be approved.

11.3. If the quorum is not met, the committee can sit and the draft opinions/reports on the agenda can be discussed but they cannot be approved.

11.4. The expert committee's opinion/report is presented in its complete and finalised version (including its summary, if applicable) for approval, which will ideally be reached by consensus.

11.5. If, even after discussions and amendments to the text of the opinion/report, a consensus cannot be reached, the chair puts the opinion/report to the vote of the expert committee.

11.6. Each member of the expert committee has one vote. The chair has the casting vote in the event of a tie. Voting is carried out (i) by a show of hands at the call of the chair during physical meetings, (ii) by verbal agreement during tele- meetings or in the discussion area of the video conferencing tool used for these meetings, or (iii) electronically.

11.7. If the quorum is not met, either the approval/vote is postponed to the next meeting or to an extraordinary meeting as decided by the chair in conjunction with the scientific coordinator, or the approval/vote is postponed and takes place electronically.

11.8. If approval is done by electronic vote, at least 2/3 of the Committee members must vote.

11.9. If a member of an expert committee or working group withdraws due to a conflict of interest, that member shall not be taken into account in determining the applicable

quorum rules and may not take part in the deliberations or vote on this issue. This must be recorded in the minutes of the meeting (see Article 8).

11.10. The expert committee's opinion or report will indicate whether it has been unanimously approved by the members. This is also stated in the minutes of the meeting.

11.11. If a vote is taken, the result of the vote must be explained, including the scientific reasoning behind any minority opinions (including abstentions) or divergent opinions (votes against) drafted by those expressing these views (with the responses of other committee members, if necessary). These details include names (unless the authors wish otherwise, in which case they are anonymised) and must appear as an appendix to the opinions or reports, in accordance with the Health Expertise Charter, as well as in the minutes of the meeting. The result of the vote is presented as follows: number of members who took part in the vote (i.e. voters present at the meeting or who voted electronically), number of members excluded from the vote because of a conflict of interest, number of votes for, abstentions and votes against.

PUBLIC INFORMATION

12. Article 12 – Publication

12.1. The agency's opinions are published, with the exception of those classified as national defence secrets. The format of publication is defined on a case-by-case basis, subject to protection of privacy and legally protected confidential information, in particular rules on protection of national defence secrets and in compliance with rules on the protection of copyright, industrial and commercial secrets, and personal data. Specifically, when cases relating to health events are described, the wording is adapted so that people cannot be directly or indirectly identified.

12.2. In its opinion, the agency indicates whether it endorses the conclusions of the expert committee or wishes to provide additional information. The agency's opinion contains the expert committee's opinion/report in its entirety, including its reasoning and conclusions, on the basis of which Santé publique France issues recommendations that help to define potential routes for management or action for the public authorities. The agency's opinion cannot be modified once it has been approved.

12.3. The agency's opinion will be published on its website once the mandate requestor (decision-maker) has been informed and within a time frame defined in the prior arrangements with the requestor (decision-maker), also covering emergency situations.

12.4. The agency's opinions may be presented to the mandate requestors (decision-makers) and/or stakeholders. With this in mind, the committee chair and/or other expert members may be asked by the scientific coordinator to take part in the presentation.

12.5. Communication campaigns can be organised if necessary, in conjunction with the requestor of the mandate which led to the expert assessment.

12.6. The scientific coordinator asks decision maker(s) who requested the scientific advice for written feedback on the usefulness of the agency's opinion as part of the decision-making process related to health, health security or safety. Any responses received are fed back to the chief scientist and the expert committee.