

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
3RD FLOOR, FOOD AND DRUG AUTHORITY BHAWAN
KOTLA ROAD, NEAR BAL BHAWAN,
NEW DELHI-110002

**DRAFT PROCEDURE FOR ESTABLISHMENT AND OPERATIONS OF THE
SCIENTIFIC COMMITTEE AND SCIENTIFIC PANELS**

Having regard to the Food Safety and Standards Act, 2006(Act No. 34 of 2006), enacted by the Parliament of India to consolidate the laws relating to food and establish Food Safety and Standards Authority of India for laying down science based standards for articles of food and regulate and monitor their manufacturing, processing, distribution, sale and import so as to ensure safe and wholesome food for human consumption.

Whereas:

Section 15 of the Food Safety and Standards Act, 2006 relates to the procedure for Scientific Committee and the Scientific Panels.

Section 15(4) of the said Act, specifies that the procedure for the operation of the Scientific Committee and the Scientific Panels shall be specified by regulations.

The Authority proposed to adopt the following Regulation.

Article 1: Appointment of Members of the Scientific Committee and Scientific Panels and their Terms of Office

1. The Members of the Scientific Committee and Scientific Panels shall be appointed by the Food Authority, acting upon a proposal from the Chief Executive Officer, following publication in the relevant leading scientific publications and on the Authority's website of a call for expressions of interest. Candidates found suitable for the position but not appointed shall be invited to be included on a reserve list.
2. When appointing Members, the Authority shall ensure a high level of collective scientific competence and expertise to fulfil the mandate of the Scientific Committee and Scientific Panels, and, consistent with this, a geographical distribution that reflects the diversity of scientific problems and approaches in India.
3. Members of the Scientific Committee and Scientific Panels shall be appointed for a three year term of office that may be renewed for such period.

4. The food Authority may from time to time re-constitute the Scientific Panels by adding new members or by omitting the existing members or by changing the name of the panel as the case may be.

Article 2: Delegation of responsibilities

1. The Members of the Scientific Committee and Scientific Panels are appointed in a personal capacity. They shall therefore not delegate their responsibilities to another member or to a third person.
2. If the Chair is not in a position to fulfil his/her function, he/she may be replaced by one of the vice-Chairs or, failing that, by another member in common accord, failing which by voting, of the Members.

Article 3: Number of Members in the Panels

1. The number of Members of a Scientific Panel should be sufficient to fulfil its mandate but shall not exceed 11.
2. The term of office of Members nominated at a later date shall terminate at the same time as other Members.

Article 4: Election of the Chairs and vice-Chairs of the Scientific Committee and Scientific Panels

1. The Scientific Committee and the Scientific Panels shall each choose a Chairperson and one vice-Chair from amongst their members for a period of three years, which shall be renewable for such period.
2. The Chair shall be elected by secret ballot, if a unanimous decision is not taken by the Scientific Committee or Scientific Panel. The Chief Executive Officer or his/her designated representative shall chair the election procedures. The procedure shall be as follows:
 - a. The names of those wishing to stand as candidates shall be notified to the Secretariat before the meeting or be announced at the meeting. Members may present themselves as candidates in their own name or proposed by another member.
 - b. Where there is a single candidate or where the other candidates withdraw, leaving a single candidate, that candidate shall be elected provided that he/she receives the majority of votes cast.

- c. Where there are several candidates, election shall take place in accordance with the following procedure. However, if there are only two candidates, the first ballot will not be held.
 - In the first ballot, the candidate who receives at least a two-thirds majority of the votes of all members is elected.
 - If none of the candidates receive a two-thirds majority of the votes of all Members, the two candidates who obtained the highest number of votes go forward to the second ballot. When it is not possible to determine who are the two candidates with the highest number of votes due to equality, there shall be a special ballot in order to obtain the two candidates for the next round.
 - In the second ballot, the candidate who receives at least a two-thirds majority of the votes of all Members is elected. If none of the candidates receive a two-thirds majority of the votes of all members, there will be a third round.
 - In the third round, the candidate who receives at least a two-third majority of the votes of all members is elected. If none of the candidates receive a two-thirds majority of the votes of all Members, the candidate who receives the majority of the votes of all members is elected.
 - If two candidates receive an equal number of votes after the third ballot, the name of the successful candidate will be drawn by lot.
 - d. Candidates may withdraw their candidature at any time during the procedure.
3. One Vice-Chair shall be elected following a procedure identical to that of the Chair. The vice-Chair shall be elected separately. The names of the Chair and Vice-Chair shall be recorded in the minutes of the meeting and shall be made public.

Article 5: Working Groups

1. The Scientific Committee may create Working Groups whenever they deem it necessary, particularly, in the case of subjects which do not fall within the competence of any of the Scientific Panels. In such cases, it shall draw on the expertise of those Working Groups when establishing scientific opinions and need external expertise or enhance their capacity to fulfil their mandates. Creation of Working Groups shall be consistent with the Authority's work programme and not more than is required to fulfil the mandate of the Committee. View of the Chairperson of the Authority will be obtained before notifying the working group

2. The Scientific Committee shall entrust the Working Groups with tasks which are clearly defined. In particular, the Working Group may be asked to undertake all necessary preparatory tasks in relation to a draft opinion. The Scientific Committee or Scientific Panels can require that these tasks be completed within a set period.
3. Working Groups shall report to the Scientific Committee that convened them and shall be chaired by a member of the corresponding Scientific Committee or Panel.
4. The names of participants of Working Groups shall be made public.

Article 6: External experts

1. Section 15 (5) (e) of Food Safety and Standards Act, 2006 specifies that external experts possessing particular and relevant scientific knowledge may be invited to contribute in the Working Groups of the Scientific Committee and Scientific Panels. The procedure for their selection shall guarantee the highest possible level of scientific excellence and independence. The Members and external experts of a Working Group shall be designated by its Chair in consultation with the Scientific Committee or corresponding Scientific Panels.
2. An external expert may be excluded from further activity within the Authority by the Chief Executive Officer for not contributing effectively to the work of the Scientific Committee and/or Panels and /or Working Groups or for actions which are conflicting with the Authority's internal rules. In those cases, or if an external expert wishes to terminate his/her co-operation with the Authority, the Chair may invite or appoint a replacement in accordance with the rules of procedure.

Article 7: Rapporteurs

1. The Scientific Committee, a Scientific Panel or Working Group may designate one or more Rapporteurs from among its Members or external experts who shall ensure that draft reports or opinions are prepared, if necessary within a set time period. The Rapporteur(s) shall work in close co-operation with the relevant Secretariat.
2. The work of a Rapporteur is terminated when the Scientific Committee or Panel adopts the report or opinion.

Article 8: Requests for scientific advice

1. The Chief Executive Officer shall assign requests for advice to either:
One of the Scientific Panels in accordance with their mandate as set out below;

- for the **Panel on food additives, flavourings, processing aids and materials in contact with food**: safety in use of food additives, flavourings, processing aids and materials in contact with food; associated subjects concerning the safety of other deliberately added substances to food and questions related to the safety of processes.
- for the **Panel on pesticides and antibiotics residues**: safety in use of pesticides and antibiotics and their residues in food; associated subjects concerning the safety of food from pesticides and antibiotics .
- for the **Panel on genetically modified organisms and foods**: genetically modified organisms, such as micro-organisms, plants and animals, their deliberate release into the environment and genetically modified food, including products deriving from GMOs.
- for the **Panel on functional foods nutraceuticals, dietetic products and other similar products**: functional foods, nutraceuticals, dietetic products, human nutrition and food allergy, and other associated subjects such as novel foods.
- for the **Panel on biological hazards**: biological hazards relating to food safety and food-borne diseases, microbiology, food hygiene and associated waste management.
- for the **Panel on contaminants in the food chain**: contaminants in food, associated areas and undesirable substances such as natural toxicants, mycotoxins and residues of non authorised substances not covered by another Panel.
- for the **Panel on labelling**: include all the labelling provisions; including the name of the food and any special requirement to ensure that the consumer is not deceived or misled about the nature of the food.
- for the **Panel on method of analysis and sampling**: all aspects of method of analysis and sampling of food; including the test methods needed to ensure that the commodity conforms to the requirements of the standards.

Or the Scientific Committee for tasks on multi-sectorial issues falling within the competence of more than one Panel, and on issues which do not fall within the competence of any of the Scientific Panels.

2. The Scientific Committee or Panel may ask the Secretariat to clarify a question or a task assigned to it.
3. Requests for scientific opinions shall be presented by the Secretariat. They will consist of the question, the scientific background and the public interest. Where necessary, a deadline will be specified.

4. A scientific opinion shall comprise the question posed by the Central Government, State Government, the Parliament, or the Authority itself, the background to the request, the information considered, the scientific reasoning and the opinion of the Scientific Committee or Panel.
5. The full scientific opinion shall be published without delay on the Authority's website.

Article 9: Risk-related issues raised by the Scientific Committee or Panels

1. The Scientific Committee or a Panel may draw the Chief Executive Officer's attention to any specific or emerging issue falling within its remit which it considers to pose an actual or potential risk to consumer health. The Scientific Committee shall also be informed of issues raised by a Panel.
2. The Chief Executive Officer shall determine the action to be taken including, if appropriate, a request for a scientific opinion or report on the matter. In any event, the Secretariat shall inform the Scientific Committee and the Scientific Panel of the Chief Executive Officer's decision.

Article 10: Secretariat of the Scientific Committee and the Panels

The Secretariat shall be responsible for providing support necessary to facilitate the efficient functioning of the Scientific Committee and Scientific Panels and shall ensure compliance with the rules of the Authority. Specific duties include but are not limited to:

- Ensuring best use of the Authority's resources and planning to meet priorities and time- limits;
- Providing information on the legislative/policy aspects of questions;
- Preparing the work of the Scientific Committee and Scientific Panels and their respective Working Groups, in consultation with their chairs;
- Drafting agendas and minutes of meetings;
- Co-ordinating the work carried out within and between the Scientific Committee or Scientific Panels and their respective Working Groups;
- Ensuring that the relevant background information is made available to the Scientific Committee, Scientific Panels or Working Group;
- Assisting the Chairs of the Scientific Committee, the Panels and their Working Groups in the preparation of draft opinions before adoption;

Article 11: Co-ordination of the work of the Scientific Panels

1. The Secretariat of the Scientific Panels shall seek to ensure:
 - that the Panels work in close co-operation with each other and the Scientific Committee where this is necessary,
 - the avoidance of overlapping or inconsistent opinions.
2. The Chairs of the Panels shall keep the Scientific Committee informed of their activities through regular reports at meetings of the Scientific Committee.
3. The Scientific Committee shall assure consistency in the approach to risk assessment and the presentation of scientific opinions.

Article 12: Planning of meetings, invitations, agenda, documentation, time limits

1. The Scientific Committee and Scientific Panels shall establish a schedule of its meetings for the forthcoming calendar year.
2. As a general rule, the Secretariat will confirm a meeting of the Scientific Committee, Panels or Working Group not less than 10 working days before the date of the meeting and shall give notification of cancellation not less than two working days before the date of the meeting.
3. Meetings of the Scientific Committee, Panel or Working Group may be called at short notice according to the urgency of the matter.
4. The draft agendas of the meetings of the Scientific Committee and Panels shall be drawn up by the Secretariat. The draft agenda shall be circulated to Members, generally before two weeks of the meeting. They shall be published on the Authority's website before the meeting. The agenda shall be adopted at the beginning of the meeting taking account of any agreed amendments.
5. Wherever possible, documents including reports and draft opinions prepared by a Rapporteur or external expert shall be made available to the Members and external experts one week before that meeting.
6. Time-limits for the delivery of scientific opinions shall be decided by the Authority. The Scientific Committee and Scientific Panels shall prioritise their work to ensure that time-limits are respected.

Article 13: Accelerated Procedures

1. An accelerated procedure may be followed in order to address an urgent matter and may be either:

- a. A fast-track response. In this case the response may take the form of a statement or opinion by the Authority adopted either by the relevant Scientific Panel or the Scientific Committee. The development and adoption of a statement or an opinion shall be undertaken by the relevant Scientific Panel or the Scientific Committee as far as possible in accordance with standard operating procedures, under the Chief Executive Officer's direction and taking into account the limited time allocated for the response to the question.
- b. A statement by the Authority prepared by the Authority's personnel. The Chair of the relevant Scientific Panel or the Scientific Committee shall be informed of the question and the process. Experts from the relevant Scientific Panel or Scientific Committee and/or any external experts may be consulted before finalising the statement.

Article 14: Written Procedure

In the event that the nature, urgency or circumstances do not necessitate or allow discussion at a meeting, a draft opinion or a statement may be adopted by written procedure. In this case, the Secretariat shall send the draft opinion to the Members of the Scientific Committee or Panel with a request for approval by a specified date. The draft shall be adopted if the majority of the Members of the Scientific Committee or Panel have expressed their approval before the deadline. If a majority is not reached, the draft opinion must be placed on the agenda for the next meeting of the Scientific Committee or Panel or, if the urgency requires this, an ad-hoc meeting shall be convened at the earliest date at which the quorum can be assured. The conclusion of the written procedure needs to be included in the minutes of the following meeting.

Article 15: Quorum and majority

1. A quorum of at least two thirds of the Members of the Scientific Committee or of a Panel shall have to be physically present in order for the meeting to be valid.
2. The Scientific Committee and Scientific Panels shall adopt opinions by a majority of their members.

Article 16: Access to meetings and confidentiality of individual views of participants

1. The representatives of the Authority's departments shall be entitled to be present in the meetings. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions. The

relevant industry and consumer representatives may also be invited for the meetings of the Scientific Panels only to clarify views and present viewpoints, the Panel being solely responsible for the finalising its views.

2. The individual views, whether expressed orally or in writing by Members or external experts during deliberations within the Scientific Committee, Panels or a Working Group, shall be confidential.

Article 17: Adoption of scientific opinions

1. The Scientific Committee and individual Panels shall adopt their scientific opinions at their plenary meetings or, exceptionally, by one of the procedures set out in Article 13 or 14.
2. The Scientific Committee or a Panel may adopt a preliminary opinion which will be published on the Authority's website with an invitation to provide scientific comments by a specified deadline. The Scientific Committee or Panel will take account of the comments received when adopting its final opinion.

Article 18: Minority Opinions

The opinions of the Scientific Committee and Panels may include any minority opinions. Minority opinions shall be attributed to their authors and shall include supporting argumentation.

Article 19: Technical Hearings

1. The Scientific Committee may organise scientific hearings with individuals, petitioners or other stakeholder representatives if it considers it necessary for the completion of a scientific opinion.
2. Hearings shall be indicated clearly in the draft agenda of the meeting during which it is to take place.
3. The Scientific Committee shall not take any decisions during hearings.

Article 20: Minutes

1. The Secretariat of the Scientific Committee and Scientific Panels shall prepare draft minutes of plenary meetings and meetings of working groups. These shall contain, *inter alia*:
 - the list of participants;

- a summary of discussions, including important minority stand points and agreed actions;
 - a record of decisions taken and opinions adopted.
2. The draft minutes shall be circulated to Members for comments and adopted not later than the next meeting.
 3. The minutes shall be placed on the Authority’s website after their adoption.

Article 21: The expenses of Members, external experts and indemnities

1. Travel and subsistence expenses incurred by Members or external experts or Rapporteurs in connection with meetings relating to the Scientific Committee or Scientific Panels shall be reimbursed by the Authority in accordance with the Regulations/scales laid down by the Authority.
2. Members and external experts shall be entitled to an indemnity of Rs.2000/- for each full day of meeting attendance to defray other costs, involved in their contribution to and participation in the work of the Scientific Committee or Panel. As a compensation for costs incurred by the preparatory work for meetings, the Chairs of the Scientific Committee, Scientific panels and Working Groups shall be entitled to one additional daily indemnity per meeting.
3. Each Rapporteur shall be entitled to an indemnity of Rs. 3000/- to defray costs linked to the co-ordination of preparatory work for draft opinions.

Article 22: Independence

1. Members of the Scientific Committee and Panels, Working Groups as well as external experts shall undertake to act independently of any external influence. For this purpose, they shall make a Declaration of Commitment (Annex. 1) and an Annual Declaration of Interests (ADoI) indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence.
2. These declarations shall be made annually in writing (Annex. 2) and shall be published on the Authority’s website.
3. The members of the Scientific Committee, Scientific Panels, Working Groups as well as external experts, at each meeting shall declare any Specific Declaration of Interests (SDoI) which might be considered prejudicial to their independence in relation to the items on the agenda. This declaration shall be made in writing before commencement of the meeting (Annex 3) and shall be published on the Authority’s website.

Article 23: Confidentiality

1. Members of Scientific Committee or Panels as well as external experts participating in their Working Groups, or acting as observers, shall not divulge to third parties information specifically identified by the Authority as “restricted or confidential”.
2. Members of the Scientific Committee or Panels and external experts participating in their Working Groups, or acting as observers, shall sign a written declaration (Annex. 4) that they will comply with the rules of confidentiality.
3. Members of the Scientific Committee or Panels and external experts participating in their Working Groups, or acting as observers, shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy.

Article 24: Dismissal of members

A member may be dismissed by the Authority, on a proposal of the Chief Executive Officer, for not contributing effectively to the work of the Scientific Committee and/or Panels and/or Working Groups, continued absence from meetings, or for actions which are conflicting with FSSA’s internal rules. In those cases, or if a member wishes to resign, the Authority, acting on a proposal of the Chief Executive Officer, may appoint a replacement from the reserve list.

Article 25: Entry into force

1. The present regulation shall enter into force on the date of its adoption.
2. The Authority may return to these rules whenever deemed necessary and adopt any modifications needed.

Done at New Delhi on _____

For the Authority,

ANNEX 1: DECLARATION OF COMMITMENT

Name: _____

Position:

- Member of the Food Authority
- Member of the Central Advisory Committee
- Member of the Scientific Committee
- Member of a Panel on _____
- Member of a Working Group on _____
- Expert (external) on _____

Pursuant to Section 4 of the Food Safety and Standards Act, 2006 establishing the Food Safety and Standards Authority of India, I hereby undertake to make all reasonable efforts to attend and participate in the meetings of the above body and to act independently of any external influence and in public interest.

Done at: _____ on _____

Signature: _____

Annex 2 ANNUAL DECLARATION OF INTEREST(ADoI)

(Please note that high quality of scientific expertise is by nature based on prior experience and that therefore having an interest does not necessarily mean having a conflict of interest)

Name: _____

Position:

- Member of the Food Authority
- Member of the Central Advisory Committee
- Member of the Scientific Committee
- Member of a Panel on _____
- Member of a Working Group on _____
- other expert (external)

Information on direct or indirect interests of relevance to the mission of the Authority

(1)Direct interests (financial benefits arising from, for example, employment, contract work, investments, fees etc.)

(2)Indirect interests (indirect financial, e.g., grants, sponsorships, or other kind of benefits):

(3)Interests deriving from the professional activities of the Member and his/her close family Members:

(4)Any membership role or affiliation in organizations/bodies/club with an interest in the working of the Authority:

(5)Other interests or facts that the undersigned considers pertinent:

Declaration : I declare that the information provided above is true and complete.

Done at: _____ on: _____ Signature: _____

(Please attach additional sheets whenever required)

Guidelines on interests

- Any financial interests or benefits, including holding of stocks and shares, equity, bonds, partnership or property interests relevant to the Authority's mission. The holding of financial interests connected with a pension or investment scheme contracted prior to membership and/or interests in unit trusts or similar arrangements would not, in principle, be of particular interest, providing that the Member has no influence on financial management.
- Professional experience carried out in the last five years in a field relevant to the Authority's mission. This should include all work, irrespective of whether the activities have been subject to regular or occasional remuneration (Board membership, executive or non-executive directorship, employment, consultancy, contractual interests, traineeship).
- Interests the member may have had in the past or ongoing legal proceedings relevant to the Authority's mission, with an indication of their implications, are to be declared.
- All assistance and support received by private and public undertakings or bodies are to be declared, where they are associated with direct or indirect pecuniary or material benefit and which have a bearing on the topic of the Panel/Committee. These include grants for study or research, fellowships or sponsorships for the last 5 years.
- Participation in public interest groups, professional societies, clubs and organisations which may have an agenda relevant to the Authority's mission are to be declared. The role and position held is to be set out clearly and precisely.
- When declaring interests, members should be as precise as possible. For example, shareholders are to indicate the company name and number of shares. In the case of professional experience, the position held and activities performed should be set out clearly and precisely.
- Close family member includes spouse or partner and dependent children living in the same household.
- When declaring interests, member should considered statements of personal opinion on issues relevant to the questions addressed by the Authority (e.g. publications, public statements); employment or family (e.g. the possibility of any indirect advantage or any likelihood of pressure which could arise from the member's employer, business associates or immediate family members).

- The Authority recognises that scientific expertise underpins the fulfilment of its mission and tasks and that the quality of such expertise is inherently based on prior experience. An “interest” declared is not automatically considered to be a conflict of interest. Interests of an intellectual nature are considered as indispensable to safeguard the quality and overall balanced objectivity of the scientific work.

ANNEX 3: SPECIFIC DECLARATION OF INTERESTS (SDoI)

(Please note that high quality of scientific expertise is by nature based on prior experience and that therefore having an interest does not necessarily mean having a conflict of interest)

Name: _____

Profession: _____

- Meeting of the Authority
- Meeting of the Central Advisory committee
- Meeting of the Scientific Committee
- Meeting of Panel on.....

Meeting of the Working Group on.....

Meeting dates	
Venue	

S. No.	Agenda Items	Whether the member has a conflict of interest. (YES/ No) If yes, please provide details to enable the chair to take a decision.

Declaration: I declare that the information provided above is true and complete.

Date: _____

Signature: _____

ANNEX 4: DECLARATION CONCERNING CONFIDENTIALITY

Name: _____

Position:

- Member of the Food Authority
- Member of the Central Advisory Committee
- Member of the Scientific Committee
- Member of a Panel _____
- Member of a Working Group on _____
- other expert (external) on _____

I hereby declare that I am aware of my obligation to respect confidentiality. I know that I am obliged not to divulge information acquired as a result of my activities in FSSA if this information is subject to a request for confidentiality. I shall also respect the confidential nature of the opinions expressed by other Members of the bodies indicated above or other experts during discussions in meetings or provided in written form.

Done at: _____ on _____

Signature _____