

FOOD SAFETY AND STANDARDS (TRANSACTION OF BUSINESS AND PROCEDURE FOR THE SCIENTIFIC COMMITTEE AND SCIENTIFIC PANEL) REGULATIONS, 2016

CHAPTER 1

GENERAL

1. **Short title and commencement.** – (1) These regulations may be called the Food Safety and Standards Authority of India (Transaction of Business and Procedures for the Scientific Committee and Scientific Panels) Regulations, 2016.
(2) They shall come into force on the date of their publication in the Official Gazette.
2. **Definitions.** — (1) In these regulations, unless the context otherwise requires, -
 - a) “Act” means the Food Safety and Standards Act, 2006 (34 of 2006);
 - b) “Chairperson” means the Chairperson of the Scientific Committee or Scientific Panel as the context may provide for;
 - c) “Chief Executive Officer” means the Chief Executive Officer of the Food Authority appointed under section 9 of the Act;
 - d) “Food Authority” means Food Safety and Standards Authority of India established under section 4 of the Act;
 - e) “Invitee” means a subject matter expert, who may be invited to share his knowledge on the subject and ceases to continue his association with the Scientific Committee or Scientific Panel on completion of the limited purpose of such invitation;
 - f) “member” means a member of the Scientific Committee or Scientific Panel and includes the Chairperson;
 - g) “Scientific Committee” means the Scientific Committee constituted by the Food Authority under section 14 of the Act;
 - h) “Scientific Opinion” means a scientific output given by the Scientific Committee or Scientific Panel;
 - i) “Scientific Panel” means the Scientific Panel established by the Food Authority under section 13 of the Act;
 - j) “Schedule” means a Schedule appended to these regulations.

(2) Words and expressions used in these regulations and not defined, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.
3. **Appointment of Members of the Scientific Committee and the Scientific Panels and their term of office.** —
 - (1) The Food Authority shall ensure high level of collective scientific competence and expertise while appointing Members of the Scientific Committee and the Scientific Panels so as to ensure that the constitution of the Committee or the Panels reflects the diversity of scientific issues and approaches in India in order to fulfill the mandate of such scientific expertise.
 - (2) The term of the Scientific Committee and the Scientific Panel shall be for a period

of three years from the date of notification of their constitution, except for the reasons to be recorded in writing.

(3) No member shall be appointed to the same Committee or Panel for more than two consecutive terms, except for the reasons to be recorded in writing.

(4) The term of office of a member appointed to the Scientific Committee or the Scientific Panel on a date after its notification but before the expiry of its term, such member shall continue to remain the member of such committee or panel for the remaining term. Subject to sub-regulation (3), he shall be eligible for re-appointment for fresh term in order to maintain continuity.

(5) Each Scientific Panel shall comprise of as many members as required but the total strength of a Panel shall not exceed eleven.

(6) The process of selection of members of Scientific Committee and Scientific Panel may be as per the guidelines laid down by the Food Authority from time to time.

4. **Working Groups.** — (1) The Scientific Committee may constitute working groups consisting of members of the Scientific Committee or Scientific Panels and also include therein such number of external experts, particularly, in the case of subjects which do not fall within the competence of any of the Scientific Panel or on multi-sectoral issues falling within the competence of more than one Scientific Panel. Such working group shall be constituted on the recommendations of the Chairperson of the Scientific Committee with the approval of the Chief Executive Officer.
- (2) The Scientific Committee shall also nominate or appoint the Chairperson of the working group:
- Provided that the number of external experts in a working group shall not exceed fifty percent of the total members of the working group.
- (3) The Scientific Committee shall entrust working groups with tasks which are clearly defined through their terms of reference, including the time-frame within which such tasks are to be accomplished.
- (4) The Scientific Committee shall coordinate the functioning of working groups and ensure that the tasks assigned are completed within a specified time-frame.
- (5) Working groups shall report to the Scientific Committee and shall be chaired by a member of the Scientific Committee or Scientific Panel.
- (6) The Working Group shall cease to function on completion of the task for which it was constituted.
5. **External Experts.** —The Scientific Committee or the Scientific Panel may invite external experts possessing relevant scientific knowledge for an identified task, issue or agenda item. The Chairperson of the Scientific Committee or Scientific Panel may identify external experts from the list or pool of experts maintained in the Food Authority or after carrying out a search in consultation with other members for the required competence.
6. **Rapporteurs.** — (1) The Scientific Committee or Scientific Panels or Working Groups shall designate a rapporteur from among their members with the approval of Chairperson of the Committee or Panel or Working Group, who shall prepare within the specific time period, the following, namely: -

- (i) record of the outcome of the discussion on the technical agenda; and
 - (ii) scientific opinion thereof in the format given in **Schedule-I**.
- (2) The work of the rapporteur will be terminated as soon as the Scientific Committee or Scientific Panel adopts the report or the opinion.
- 7. **Delegation of responsibilities.** —The Scientific Committee and each of the Scientific Panels shall elect or choose a Chairperson from amongst themselves. If the Chairperson of the Scientific Committee or Scientific Panel is not in a position to discharge the functions, such Chairperson may be replaced by another member by consensus, who shall thereafter perform the functions of the Chairperson of such Scientific Committee or Scientific Panel.
- 8. **Requests for Scientific Opinion.** — (1) The Chief Executive Officer shall make requests to the Scientific Committee or Scientific Panel for scientific opinion in the following manner, namely: -
 - (i) for tasks on multi-sectoral 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, to the Scientific Committee; and
 - (ii) for tasks mandated to an existing or new Scientific Panels constituted from time to time by the Food Authority.

(2) The Scientific Committee may also be requested to provide guidance on procedures, methodologies and such matters that provide harmonised approach and consistency in the scientific outputs of Scientific Panels.
- 9. **Meetings of the Scientific Committee or Scientific Panel.** — (1) Depending upon the number of tasks identified, the Scientific Committee and Scientific Panels shall plan a schedule of their meetings for the ensuing calendar year in consultation with their respective Chairpersons.

(2) Unless a meeting of the Scientific Committee or the Scientific Panel is fixed in the previous meeting itself, then, fifteen days notice for a meeting of the Committee or the Panel shall be given to the members before the date of the meeting.

(3) The notice for cancellation of a meeting, whether scheduled in advance or otherwise, shall be given at least five working days before the date of the meeting.

(4) In case of urgency, meetings of the Scientific Committee or Scientific Panels may be called at shorter notices with the prior approval of the Chairperson concerned.
- 10. **Approach to work and prioritisation.**—(1) The Scientific Committee and Scientific Panels in the meeting at the first instance shall identify the tasks involved on any particular agenda and assign the tasks among various members individually or in groups, with timelines for completion of such tasks and these tasks shall include relevant research, published studies or literature, related to the available scientific evidence for the risk assessment required for the identified and assigned tasks and the scientific opinion thereof.

(2) As provided in the Act, the Scientific Committee or Scientific Panel shall afford an opportunity of scientific presentations to the representatives of concerned industry and consumer groups in one of its initial meetings and take the scientific literature submitted by them on record for consultation in forming its opinion and such representatives

cannot influence the decision making process of the Committee or the Panel.

11. **Quorum and Consensus.** —(1) No business shall be transacted at a meeting of the Scientific Committee or Scientific Panel or Working Group unless at least ¹[two third] of its members are present including the Chairperson of the Scientific Committee or the Scientific Panel. In case the Chairperson is not able to remain present at a meeting so convened for any reason, whatsoever, the members present may elect one from amongst themselves to be the Chairperson for that particular meeting and transact the business.
 - (2) If at any time the number of members present at a meeting is less than the quorum as specified in sub-regulation (1), the person presiding shall adjourn the meeting after informing the members of the date, time and place of the adjourned meeting and it shall thereupon be lawful for the person presiding at such adjourned meeting to dispose of the business intended to be transacted at the original meeting, irrespective of the number of members present.
 - (3) The Scientific Committee and Scientific Panels shall adopt opinions by a majority if a consensus cannot be reached on any issue. However, the difference of opinion shall be duly recorded.
12. **Agenda.** —¹[(1) The draft agenda of the meetings of the Scientific Committee or Scientific Panels shall be drawn up by the Secretariat in consultation with the Chairperson of the concerned Scientific Committee or Scientific Panel and circulated to members at least ten working days before the meeting.]
 - (2) The agenda shall be prioritised and adopted at the beginning of the meeting and no business, which is not included in the agenda, shall be transacted at a meeting of the Scientific Committee or Scientific Panel, except with the permission of the Chairperson.
 - (3) Any related urgent questions or issues may be identified and included in the agenda at any time with the permission of the Chairperson before the end of the meeting, and the agenda shall be deemed to be modified to that extent and carried over to deliberations.
 - (4) 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 the meeting.
 - (5) Time-limits for the delivery of scientific opinions shall be decided by the Chairperson.
 - (6) The Chairperson of the Scientific Committee, Scientific Panels or Working Groups shall make special efforts to encourage the electronic mode as the primary working mode among members, through exchange of emails relating to agenda, circulation of documents, consensus building on matters relating to the tasks assigned and such exchanges shall be valid for the purpose of records of transactions.
13. **Emerging issues.** — (1) The Scientific Committee or Scientific Panels may draw the attention of the Chief Executive Officer to any specific or emerging issue falling within its jurisdiction which it considers can pose an imminent or potential risk to consumer health.
 - (2) The Chief Executive Officer shall determine the action to be taken including, if required, making a request for a scientific opinion or report on the matter. In any event, the Scientific Committee and the Scientific Panel shall be apprised of the decision taken in the matter.
 - (3) In cases where a scientific opinion has been tendered by the Scientific Committee or Scientific Panel, which may comprise any unintended or inadvertent omissions, and which

come to the notice of any member of the Scientific Committee or Scientific Panel at any stage before it is given final effect, the member concerned shall communicate his observations thereon to the Chief Executive Officer, who shall in turn refer the matter to the Scientific Committee or the concerned Scientific Panel for its reconsideration and resolution.

14. **Access to meetings including technical hearings.** — (1) The Chairperson of the Scientific Committee or Scientific Panel may authorise officers or representatives of the office of the Food Authority to be present in the meetings. If invited to do so, they may assist for the purpose of clarification or information but shall not seek to influence the decisions.

(2) The Scientific Committee or Scientific Panel may organise scientific hearings with individuals, petitioners or other stakeholder representatives, if considered necessary for the completion of a scientific opinion in the following manner, namely. —

(i) hearings shall be clearly indicated in the draft agenda or minutes of the meetings in which such hearings take place; and

(ii) the Scientific Committee or Scientific Panel shall not take any decisions during such hearings.

15. **Business by circulation.** — (1) In the event, where a matter is urgent or necessitate discussion at a meeting and where circumstances do not permit to meet immediately, or if the Chairperson of the Scientific Committee or the Scientific Panel so directs, a draft opinion or a statement may be referred to its members by circulation of papers either electronically or physically.

(2) Any proposal or draft opinion or statement circulated under sub-regulation (1), on being approved by one-third of the members of the Scientific Committee or the Scientific Panel, as the case may be, shall have effect and binding as if such proposal or draft opinion or statement was decided by the majority of members in the meeting.

(3) If the proposal or draft opinion or statement is not approved as specified in sub-regulation (2), the same shall be placed on the agenda for the next meeting of the Scientific Committee or Scientific Panel.

(4) Each proposal or draft opinion or statement circulated under this regulation and the result of such circulation shall be included in the minutes of the following meeting.

16. **Accelerated Procedures.**—(1) In this case the response may take the form of a statement or opinion by the Food Authority adopted either by the Scientific Committee or the relevant Scientific Panel, the development and adoption of the statement or opinion shall be undertaken by the Scientific Committee or the Scientific Panel, as the case may be, as far as possible in accordance with the Terms of Reference, under the directions of the Chief Executive Officer and taking into account the limited time allocated for the response to the query.

(2) The Chairperson of the Scientific Committee or the Scientific Panel, as the case may be, shall be informed of the query and the process and the experts from the Scientific Panels or the Scientific Committee or any external experts may be consulted before finalising the statement under sub-regulation (1).

17. **Adoption of scientific opinions.** —(1) The Scientific Committee and the Scientific Panels shall adopt the scientific opinions at their plenary meetings or the procedures

specified in regulation 16 or regulation 17.

(2) The Scientific Committee or Scientific Panel may adopt a preliminary opinion to be published on the Food Authority's website inviting scientific comments and suggestions within a period specified therein and shall take into consideration the comments received in forming its final opinion.

(3) The opinions of the Scientific Committee and Scientific Panels may include any minority opinion.

18. **Secretariat of the Scientific Committee and the Scientific Panels.** — (1) In pursuance of clause (d) of Section 10 of the Act, the office of the Food Authority shall be responsible for providing necessary support to facilitate efficient functioning of the Scientific Committee and the Scientific Panels. Specific duties of the Secretariat shall include but not limited to the following, namely: -

- (i) ensure best use of the Food Authority's resources and plan to meet priorities and time-lines;
- (ii) provide information on the legislation or policy aspects or queries or scientific opinions;
- (iii) prepare the draft agenda including background information and minutes of the meetings for the Scientific Committee, Scientific Panels or Working Groups, in consultation with respective Chairperson;
- (iv) the minutes of the meeting shall include:
 - (a) list of participants; and
 - (b) record of decisions taken and opinions adopted.

(2) The minutes may be posted on the Food Authority's website after their adoption.

19. **Confidentiality.** — (1) The members of the Scientific Committee, the Scientific Panels and the Working Groups and the external experts participating in the Working Groups, or acting as observers, shall not divulge any information, to third parties, specifically, identified by the Food Authority as 'restricted or confidential.

(2) The members of the Scientific Committee or Scientific Panels or Working Groups and external experts participating in the Working Groups or acting as observers, shall sign a declaration of confidentiality as specified in **Schedule-II**.

(3) The members of the Scientific Committee, the Scientific Panels and Working Groups and external experts participating in the Working Groups, or acting as observers, even after their duties have ceased, shall not disclose information of any kind covered by the obligation of professional secrecy.

20. **Independence.**—(1) The members of the Scientific Committee, the Scientific Panels and Working Groups and external experts shall undertake to act independently of any external influence by making a Declaration of Commitment as provided in **Schedule-III** and an Annual Declaration of Interests in **Schedule-IV**, 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) The members of the Scientific Committee, Scientific Panels and Working Groups and external experts at each meeting shall make a Specific Declaration of Interests as

provided in **Schedule-V** which might be considered prejudicial to their independence in relation to the items on the agenda.

21. **Replacement.** —A member of the Scientific Committee or Scientific Panel may be removed or replaced by the Food Authority, on a proposal submitted by the Chief Executive Officer, for not contributing effectively to the work of the Scientific Committee, Scientific Panels or Working Groups or for absence from three consecutive meetings, or for actions in conflict with the Food Authority's interests or terms and conditions. If a member wishes to resign, the Food Authority, acting on a proposal by the Chief Executive Officer, may appoint a replacement from the reserve list, if any maintained by the Food Authority.
22. **Conferences.** —In their quest for obtaining scientific opinions on a subject, the Chairperson of the Scientific Committee or the Scientific Panel may submit a proposal for organising a conference on a topical issue or subject, along with the budget therefor to the Chief Executive Officer, who may, in turn, approve such a proposal with a maximum budget upto fifteen Lakh rupees. However, this amount may be reviewed by the Authority from time to time.
23. **Reimbursement of expenses and sitting fees.** — (1) Travel and subsistence expenses incurred by members or external experts or rapporteurs in connection with meetings relating to the Scientific Committee, Scientific Panels, Working Groups or external experts shall be reimbursed by the Food Authority in accordance with these regulations.
 - (2) The members of the Scientific Committee, Scientific Panels, Working Groups or external experts shall be paid a sitting fee of four thousand rupees for each day or part thereof for attending a meeting and the sitting fee may be reviewed by the Food Authority after every two years.
 - (3) The rapporteur member of the Scientific Committee or the Scientific Panel or the working group shall be paid an additional honorarium of two thousand rupees for discharging the duties as a rapporteur for each day or part thereof for meeting attendance.

Schedule – I

[See regulation 6(1)(ii)]

Format for Scientific Opinion

The Scientific Committee/ Scientific Panels/ working group shall submit its scientific opinion in the following

1. **Title:** Opinion of the Scientific Committee, Scientific Panel or working group [*insert name of Panel*] on the taskquery [*insert title of query or term of reference provided by Authority*] on a submission by [*Food Authority/Government/Self Tasking*] Request No: [*Reference No*]
2. **Summary:** It should be a brief [1-2pages] summary of the opinion, reflecting the background, terms of reference and conclusions. The conclusions should clearly state whether there is any evidence of an unsafe condition or none at the level of use along with conditions attached including the possibility of harmful effects on health but scientific uncertainty persists or the need for further scientific information for a more comprehensive risk assessment.
3. **Background and Terms of Reference:** as provided by the Food Authority or any other stakeholder.
4. **Detailed Assessment:** The actual risk assessment section on how the information was evaluated and which issues were considered of key - relevance for the opinion.
5. **Regulatory Impact Analysis:** Measurable outputs relating to mitigation of health of the population in general or specific segments as identified.
6. **Conclusions and recommendations**
7. **Statement on minority opinion(s), (if any)**
8. **Documentation:** A list of the references and documentation on which the opinion is based.
9. **Acknowledgement:** If applicable, an acknowledgement with the names of the working group or external experts who prepared (or made contributions to) the draft opinion.

Schedule-II

[See regulation 19 (2)]

Declaration of Confidentiality

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) 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 Food Safety and Standards Authority, and I hereby undertake not to divulge any such confidential information. 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 _____

Schedule-III

[See regulation 20 (1)]

Declaration of Commitment

Name: _____

Position:

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

I hereby undertake to make all reasonable efforts to attend and participate in the meetings of the Food Authority and to act independently and in public interest, without being influenced by any external influence.

Done at: _____ on _____ Signature: _____

Schedule –IV

(See regulation 20(1))

Annual Declaration of Interests

(Please note that high quality of scientific expertise is by nature based on prior experience and, 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 Scientific Panel on _____
- Member of a Working Group on _____
- Other expert (external) on _____

Information on direct or indirect interests of relevance to the mandate 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 for Annual Declaration of Interest

- (1) Any financial interests or benefits, including holding of stocks and shares, equity, bonds, partnership or property interests relevant to the Food Authority's mandate. Financial interests connected with a pension or investment scheme contracted prior to membership 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.
- (2) Professional experience in the last five years in a field relevant to the Food Authority's mandate. 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, and traineeship).
- (3) Interests the member may have had in the past or ongoing legal proceedings relevant to the Food Authority's mandate, with an indication of their implications, are to be declared.
- (4) 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 Scientific Committee or Scientific Panel. These include grants for study or research, fellowships or sponsorships for the last five years.
- (5) Participation in public interest groups, professional societies, clubs and organisations which may have an agenda relevant to the Food Authority's mandate is to be declared. The role and position held is to be set out clearly.
- (6) Close family member includes spouse or partner and dependent children living in the same household.
- (7) When declaring interests, member should consider statements of personal opinion on issues relevant to the questions addressed by the Food Authority (e.g., Publications, public statements); employment or family (e.g. the possibility of any indirect advantage or any likelihood of pressure could arise from the member's employer, business associates or immediate family members).
- (8) The Food Authority recognises that scientific expertise underpins the fulfillment of its mandate 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.
- (9) The details of interests declared may be kept confidential by the Food Authority unless its disclosure is necessary to establish objectivity and independence of the member involved.

Schedule - V

[See regulation 20(2)]

Specific Declaration of Interests

(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 Food 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	

Sr. 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.

Done at: _____ on _____ Signature: _____

Note. - The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 *vide* notification number File No. F.1-63/FSSAI/Tr. Business SC and SP/Reg/2015, dated the 2nd December, 2016 and subsequently amended *vide* notification no.:

1. F. No. F.2-63/FSSAI/Tr.Business SC and SP/Reg/2020 dated 12th January, 2021.