

Notice calling for claims, suggestions, views, comments etc from stakeholders within a period of 60 days on the draft amendment of Scientific Committee and Scientific Panels

- 2. Definitions:** - (1) In these Regulations, unless the context otherwise requires:
- (i) “Act” means the Food Safety and Standards Act, 2006;
 - (ii) “Chairperson” means the Chairperson of the Scientific Committee or Scientific Panel as the context may provide for;
 - (iii) “Chief Executive Officer” means the Chief Executive Officer of the Food Authority appointed under section 9 of the Act;
 - (iv) “Food Authority” means Food Safety and Standards Authority of India established under section 4 of the Act;
 - (v) “Invitee” means and refers to 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/ Scientific Panel on completion of the limited purpose of such invitation.
 - (vi) “Member” means a member of the Scientific Committee or Scientific Panel and includes the Chairperson of the Scientific Committee/ Panel;
 - (vii) “Scientific Committee” means the Scientific Committee constituted by the Food Authority under section 14 of the Act;
 - (viii) “Scientific Opinion” means a scientific output based on the risk assessment given by the Scientific Committee/ Scientific Panel;
 - (ix) “Scientific Panel” means the Scientific Panel(s) established by the Food Authority under section 13 of the Act;
 - (x) “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 meaning respectively assigned to them in the Act.
- 3. Appointment of Members of the Scientific Committee and/or the Scientific Panels and their Term of Office:**

- (i) Members of the Scientific Committee and/or the Scientific Panels shall be appointed by the Food Authority, acting upon a proposal from the Chief Executive Officer, following publication of a call for inviting expressions of interest on the website of the Food Authority or on a specific request to the expert made on the basis of a process of search/recommendations.
- (ii) The Food Authority shall ensure high level of collective scientific competence and expertise when 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 problems and approaches in India in order to fulfill the mandate of such scientific expertise;
- (iii) The term of the Scientific Committee and the Scientific Panel(s) shall be for a period of three years from the date of notification of their constitution;
- (iv) No member shall be appointed to the same Panel for more than two consecutive terms;
- (v) The term of office of a member appointed on the Scientific Committee or a Scientific Panel on a date after its notification but before the expiry of the term, such member shall continue to remain the member of such body for the residual term period. However, he shall be eligible for re-appointment for the fresh term in order to maintain continuity.
- (vi) Each Scientific Panel may comprise of as many members as required but the total strength of a Panel may not exceed 11.

4. Working Groups: -

- (i) The Scientific Committee may create 'Working Groups' consisting of members of the Scientific Committee and/ 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 a 'working group' shall be created on the recommendations of the Chairperson of the Scientific Committee with the approval of the Chief Executive Officer.

Provided that the Scientific Committee shall also nominate/ appoint the Chair of the Working Group;

Provided further that the number of external experts in a Working Group shall not exceed 50% of the total members of the Working Group.

- (ii) The Scientific Committee shall entrust the Working Groups with tasks which are clearly defined through their Terms of Reference (TORs), including the time-frame within which such task(s) is/ are to be accomplished.
- (iii) The Scientific Committee shall coordinate the functioning of the Working Group(s) and ensure that the tasks assigned are completed within a specified time-frame.
- (iv) Working Groups shall report to the Scientific Committee and shall be chaired by a Member of the Scientific Committee/ Panel.
- (v) The Working Group shall cease to function on completion of the task for which it is/was constituted.

5. External Experts:-

The Scientific Committee or the Scientific Panel may invite external experts for an identified task/issue/agenda item possessing relevant scientific knowledge. The Chairperson of the Scientific Committee/Panel may identify external experts from the list/pool of experts maintained in the FSSAI 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/Panel/ WG who shall prepare within the specific time period, the following:
 - (i) Record the outcome of the discussion on the technical agenda; and
 - (ii) Scientific opinion thereof in the format given in **Schedule-III**.
- (2) The work of the Rapporteur will be terminated as soon as the Scientific Committee or Panel adopts the report or the opinion.

7. Delegation of responsibilities: -

The Scientific Committee and each of the the Scientific Panels shall elect/ choose a Chairperson each from amongst themselves. If the Chairperson of the Scientific Committee/Panel is not in a position to discharge his/her functions, he/she may be replaced by another Member by consensus, who shall thereafter perform the functions of the Chairperson of such Scientific Committee/Panel.

8. Requests for Scientific Opinion - (1) The Chief Executive Officer shall make requests for scientific opinion to the Scientific Committee/Scientific Panel in the following manner, namely:-

- (i) for tasks on multi-sectoral issues falling within the competence 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 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 harmonized approach and consistency in the scientific outputs of Panels.

9. Meetings of the Scientific Committee/ Panel: - (1) Depending upon the number of tasks identified, the Scientific Committee and the Scientific Panels shall plan a schedule of their meetings for the ensuing calendar year in consultation with their Chairperson(s).

(2) Unless a meeting of the Scientific Committee or the Scientific Panel is scheduled at the time of previous meeting itself, the notice for a meeting of the Committee or the Panel shall be given with 15 clear days 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.

(3) In case of urgency, meetings of the Scientific Committee/ Panels may be called at shorter notices with the prior approval of the Chairperson concerned.

10. Approach to work and priortisation:

- (1) The Scientific Committee and/ or the Scientific Panels shall in the first instance in their meeting identify the tasks involved in any particular agenda and assign the tasks among various members individually or in groups, with timelines for completion of such tasks. These tasks include relevant research, published studies/ 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/ 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 consultaion in forming its opinion. However, such representatives can in no manner influnece 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/ Panel/ Working Group unless at least one third of its members are present including the Chair of Scientific Committee/ 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 chair 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 specified in sub-regulation (1) above, 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) The draft agenda of the meetings of the Scientific Committee/ Panels shall be drawn up by the Secretariat and shall be circulated to Members at least 10 working days before the meeting.
- (2) The agenda shall be prioritized and adopted at the beginning of the meeting. No business, which is not included in the agenda, shall be transacted at a meeting of the Scientific Committee/ Panel except with the permission of the Chairperson.

- (3) Any related urgent questions or issues may be identified and added to the agenda at any time with the permission of Chair 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/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. These exchanges shall be valid for the purpose of records of transactions.
- 13. Emerging Issues.** - (1) The Scientific Committee/ Panels may draw the attention of the Chief Executive Officer to any specific or emerging issue falling within its remit 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/ Panel, which may comprise any unintended or inadvertent omissions, and which come to the notice of any member of the Scientific Committee/ 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 Panel for its reconsideration and resolution.
- 14. Access to meetings including Technical Hearings.** - (1) Chairperson of Scientific Committee/ Panel(s) may authorize officers/ 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/ Panel(s) may organise scientific hearings with individuals, petitioners or other stakeholder representatives, if considered necessary for the completion of a scientific opinion.

(i) Hearings shall be clearly indicated in the draft agenda/ minutes of the meetings in which these take place.

(ii) The Scientific Committee/ Panel(s) shall not take any decisions during the hearings.

15. Business by Circulation: - (1) In the event where the matter is urgent and where circumstances do not permit or necessitate discussion at a meeting, or if the Chairperson of the Scientific Committee/Panel (s) so directs, as the case may be, a draft opinion or a statement may be referred to its members by circulation of papers, 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 Scientific Panel, as the case may be, shall have effect and binding as if such proposal or draft opinion or statement were decided by the majority of members at 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 the 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 Chief Executive Officer's direction 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 Scientific Committee or any external experts may be consulted before finalizing the statement under sub-regulation(1).

17. Adoption of scientific opinions:- (1) The Scientific Committee and 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 Panels: - In pursuance to Section 10 (d) of FSS Act, 2006, the office of the Food Authority shall be responsible for providing necessary support to facilitate the efficient functioning of the Scientific Committee and the Scientific Panels. Specific duties of the Secretariat shall include but not limited to the following:

(i) Ensure best use of the Food Authority's resources and plan to meet priorities and time-lines;

(ii) Provide information on the legislative/ policy aspects of queries or scientific opinions;

(iii) Prepare the draft agenda including background information and minutes of the meetings for the Scientific Committee/ Scientific Panels/ Working Groups, in consultation with respective Chairperson;

(iv) The minutes of the meeting shall include:

❖ List of participants; and

❖ Record of decisions taken and opinions adopted

(v) 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 to third parties any information, specifically, identified by the Food Authority as 'restricted or

confidential”.

- (2) 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 in **Schedule-I**.
 - (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, shall even after their duties have ceased, not disclose information of the 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 make a Declaration of Commitment in **Annex-1 of Schedule-II** and an Annual Declaration of Interests in **Annex-2 of Schedule-II**, 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 in **Annex-3 of Schedule-II** 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 a 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 and/or Panel(s) and/or Working Groups or for absence from three consecutive meetings, or for actions which are in conflict with Food Authority's interests or terms and conditions. In these cases, or 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.

- 22.** In their quest for obtaining scientific opinions on a subject, the Chairperson of the Scientific Committee/ Panel may submit a proposal for organising a conference on a topical issue/ subject, along with the Budget therefor to the Chief Executive Officer, who may, in turn, approve such a proposal with a maximum budget of up to Rs. 15.00 Lakh. However, this amount may be reviewed by the Authority at periodic intervals.

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/ Panel(s)/ Working Groups/ External experts shall be reimbursed by the Food Authority in accordance with the Regulations/ scales laid down by the Food Authority.
- (2) Members of the Scientific Committee/ Panel(s)/ Working Groups/ External experts shall be paid a sitting fee of Rs. 4000/- for each day or part thereof for attending a meeting. The sitting fee may be suitably revised by the Authority every two years.
- (3) The Rapporteur member of the Scientific Committee or the Panel or the Working Group shall be paid an additional honorarium of Rs. 2000/- for discharging his/ her duties as a Rapporteur for each day or part thereof for meeting attendance.

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Schedule-I
[Refer regulation 19 (2)]
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 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, if the information is subject to a request for confidentiality 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- II
[Refer regulation 20 (1)]

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 the Scientific 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 Food Authority and to act independently and in public interest, without being influenced by any external influence.

Done at: _____ on _____ Signature: _____

Schedule -II
(Refer regulation 20(2))

Annex-2

Annual Declaration of Interest (ADoI)

(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(s):

- ❖ Any financial interests or benefits, including holding of stocks and shares, equity, bonds, partnership or property interests relevant to the Authority's mandate. 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 in the last five years in a field relevant to the 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).
- ❖ Interests the member may have had in the past or ongoing legal proceedings relevant to the Authority's mandate, 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 organizations which may have an agenda relevant to the Authority's mandate is to be declared. The role and position held is to be set out clearly.
- ❖ Close family member includes spouse or partner and dependent children living in the same household.
- ❖ 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).
- ❖ The Food Authority recognizes 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.
- ❖ 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-II
[Refer regulation 20(2)]

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 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:** _____

Schedule - III
[Refer regulation 6(1)(ii)]

Format for Scientific Opinion

The Scientific Committee/ Panel(s)/ Working Group shall submit its scientific opinion in the following format:

1. **Title:** Opinion of the Scientific Committee/Panel/Working Group [*insert name of Panel*] on the task query [*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/external experts who prepared (or made contributions to) the draft opinion.