

Working Procedures of issues to Scientific Panels and Committee

Scientific Advice and its Core Principles

1. Scientific advice is the conclusion of a skilled evaluation taking account of the scientific evidence, including uncertainties. It may comprise an appraisal of the consequences of one or more options based on an analysis of available scientific knowledge and on scientific judgement. The purpose of scientific advice is to help risk managers, policy makers and others in decision making.

2. Scientific advice may take many different forms, from a response to a specific question or provision of scientific information related to specific needs, to a full quantitative risk assessment. Advice may be sought at any time throughout the risk analysis process or even subsequently. Effective dialogue between risk assessors and risk managers is essential for optimal advice.

3. FAO and WHO have adopted the following core principles in the provision of scientific advice :-

(i) **Soundness**, which includes the need for scientific excellence and applies to both participants and the process. It also covers the adequacy of competence and the ability of advice to withstand scrutiny by peers and the advice representing a suitable balance of expertise.

(ii) **Responsibility**, which encompasses the various aspects of accountability and applies to the need to safeguard the integrity of the process and to consider scientists answerable for their views. The scientific views need to be justified by evidence, careful data interpretation as well as maintenance of confidentiality as mandated. Scientific advice may also need to be updated on the basis of new knowledge.

(iii) **Objectivity**, which includes neutrality and applies to both participants and the advice provided. The opinion provided should be independent and unbiased and based on scientific knowledge. Where scientific advice is the outcome of a risk assessment, there should be adequate separation from risk management.

(iv) **Fairness**, which applies to the conduct of assessment process and requires respect of all participants and scientific views. Minority views should also be properly considered. The process should be conducted in an ethical manner.

(v) **Transparency**, involving the design and implementation of the mechanisms of generating scientific advice. There should be explicit documentation of all procedures, policies and practices.

(vi) **Inclusiveness**, comprising minority scientific opinion and the balance of skills and expertise necessary for the assessment.

4. There should be effective dialogue between Authority staff and the Scientific Panel/Committee to ensure that questions posed to the Panel are clearly understood and will finally help the Authority in the development of its policies and regulations.

5. **General:**

5.1. The Scientific Committee/Panels are responsible for providing Scientific Opinions to the Food Authority based on risk assessment. The Scientific opinion shall be developed in a consistent manner according to harmonized working procedures. The purpose of the document is to recommend how opinions should be set out, in accordance with the principles of the Act.

5.2. Scientific Opinions provided by the Scientific Committee and Scientific Panels should be robust and the evidential analysis stands up to challenges of credibility, reliability and objectivity.

5.3. The scientific output shall be based on risk assessment performed in a transparent manner and in accordance to accepted methodology of the Scientific Committee. Reference to and derivations from risk assessments done by other risk assessment bodies such as JECFA/JMPR or at the EU or equivalent bodies may be considered.

5.4. In providing for standards the data relating to the food consumption and the exposure of individuals to risks related to consumption of food shall be considered.

5.5. Where risk assessment leads the determination that a regulatory measure is indicated and in order to ensure that the measures adopted are proportionate and no more restrictive of trade than is required to achieve appropriate level

of health protection a regulatory impact analysis shall be done and the benefits of the measure(s) quantified and provided in the report of the Committee/Panels.

5.6. Where regulatory measures are taken based on the risk assessed the same shall be consistent with measures taken under similar risk situations.

Scientific Panels and Committee of FSSAI

6. Scientific Panels and Committee have been constituted by the Food Safety and Standards Authority to advise on a range of scientific issues with particular reference to determination of safety standards. The Panels and Committee meet periodically and are not expected to substitute in-house expertise of the Authority. The work of the Scientific Committee will be to assess food safety issues within particular areas of competence, and deliver options which will then be examined for possible future regulation or policy pronouncement by the Authority. Essentially the task of the Scientific Panels and Committee is that of risk assessment according to well laid out scientific procedures. Risk management and communication are basically the function of the Food Authority. Since the Panels are not likely to meet more than once a month, it may not be feasible to refer issues indiscriminately for their consideration. Panels are not expected to be entrusted with fundamental research on issues, collection of materials, analysis of raw data which has not been peer reviewed, preparation of briefs/notes etc.

Role of Secretariat

6. The Secretariat of the Scientific Committee and Panels should ensure that the briefs and the questions being put to the Scientific Panels are expressed very clearly. Even when draft committee papers are drawn up with inputs from external experts, they should be finally owned by the Secretariat. The Secretariat should have immediate access to persons with relevant scientific and technical expertise, whenever issues have to be quickly consulted and opinion given.

7. Authority may occasionally require advice on ad hoc basis to supplement the expertise available with regular Panel members. Such ad hoc groups may be assembled on specific issues that go beyond the ambit of any of the Scientific Panels. Similar secretarial support as provided to Scientific Panels may be provided to ad hoc groups.

8. It would be advisable to provide an induction programme for members of the Scientific Panels and Committee in which the main issues involved and functions of the Panels and Committee are explained.

9. Authority will periodically review whether there are any gaps in the responsibility of various Committee and Panels and whether any integration or creation of additional Panel is required. Over time, the number, responsibilities and membership of the Panels may be adjusted to account for new developments concerning food safety.

Coordination between Panels

10. Whenever there is an overlap between the work of Panels, linkage should be established between Panels. Alternatively, Member of one Panel could be invited to meetings of the other where items of mutual interest are being discussed. Panels should work in as consultative a manner as possible so that alternate opinions and interpretations can be considered. Wherever possible, Panels could also issue a draft opinion for public consultation before offering their final advice.

Agenda and Minutes

11. The agenda and papers for consideration should be available to members well in advance of each meeting. Minutes and summary reports may be disseminated soon after the meeting. Since the meetings of the Panels and advice are likely to increase in number, a mechanism for archiving them for quick retrieval should be instituted.

12. Conflict of interest provisions should apply to representatives of all sectors. It is the duty of the Chairperson of the Panel to ensure that every member of the Committee is heard, that no view is ignored or overlooked and that unorthodox and contrary scientific views are considered by the Committee. The Chair will also be responsible for ensuring that the proceedings of the Committee are properly documented by the Secretariat so that there is a clear audit trail showing how the Committee reached its decisions.

13. **Delivering Scientific Opinion**: As required by the Act the objective of this section is to provide harmonized working methods towards performing a risk assessment and presenting the scientific opinion.

13.1. A Scientific Opinion is a scientific output in the form of a concise document adopted by the Scientific Committee/Scientific Panel that addresses a risk assessment or an evaluation of a risk on the opinion sought by the Food Authority.

13.2. The Scientific Panel shall rely on risk assessment which may among other considerations comprise available evidence or information on risks identified, organized, and analyzed in a systematic way to get a clear, consistent presentation of the data available for practical decision-making. The results of the risk assessment process shall form the basis for the risk management process.

13.3. A draft opinion that has been prepared shall be placed on the agenda of the next meeting of the Scientific Committee and Panels for discussion and possible adoption. The Scientific Committee and Panels shall adopt opinions generally by unanimity, either during a meeting or through a written procedure.

13.4. The Scientific Panel may agree to a format for providing its scientific opinions. This may be in the form of the following:

13.4.1. **Title:** *Opinion of the Scientific Committee/Panel on [Name of Panel] on a request by [Food Authority/Self Tasking] related to [Description of the Task/Query]. Request No: [Reference No]*

13.4.2. **Summary:** It should be brief [1-2pages] summary of the opinion, reflecting the background, terms of reference and conclusions. This summary text should read easily, on its own. It will be used for communication of the opinions.

13.4.3. **Key Words:** that will quickly guide readers to locate the opinion in search activities

13.4.4. **Background and Terms of Reference:** as provided by the Food Authority or any other stakeholder.

13.4.5. **Assessment:** The actual risk assessment section on how the information was evaluated and which issues were considered of key-relevance for the opinion.

13.4.6. **Impact Analysis:** detailed analysis of the safety data, exposure analysis and related potential impact on safety and health. Measurable outputs relating to compliance costs along with projected mitigation in health of the population in general or segments as identified.

13.4.7. **Conclusions and recommendations.**

- 13.4.7.1. Statement on minority opinion(s) (if any)
- 13.4.8. **Documentation**: A list of the references and documentation on which the opinion is based.
- 13.4.9. **Scientific Committee/Scientific Panel Members**: A list of the names of the Scientific Panel/Committee members in alphabetical order and the_name(s) of members who declare an interest which excludes them from adoption of the_opinion.
- 13.4.10. **Acknowledgement**: If applicable, an acknowledgement with the names of the working group/external experts who prepared (or made contributions to) the draft opinion.
- 13.4.11. **Scientific or Technical Report**: is a document of compilation or collation of literature review, statistical data analysis, compilation of scientific evidence or survey. It is the comprehensive outcome that supports the Scientific Opinion. The scientific or technical report may be produced by a working group appointed by the Scientific Committee/Scientific Panel.
14. **Requests for Scientific Opinions: Agenda Setting**
- 14.1. Where the Authority accepts a request for a Scientific Opinion, it shall forward the same to the appropriate Scientific Committee or Scientific Panel for preparation of the opinion. The Authority may ask the applicant [or other stakeholder] for additional information where this is necessary in order to deal with the request. It may further indicate a time limit as provided in the working procedures described later.
- 14.2. The Requests for an opinion shall be defined by 'terms of reference' including background information, which together form the mandate for the Scientific Committee or Scientific Panel to work with.
1. Where necessary the Food Authority may formally request, under the terms of reference relating to a Scientific Opinion, a Regulatory Impact Analysis [RIA] based on the risk assessment and impact on health or safety of the particular subject or substance.
- 14.3. The agenda setting shall be made in a manner that seeks a scientific opinion on the subject under consideration and shall not in any way preempt the outcome of risk assessment or evidential supporting.

- 14.4. Where requests for scientific opinions are partially or completely overlapping on the same matter or subject the same may be modified accordingly by the Food Authority and presented to the Scientific Committee/Scientific Panel.
- 14.5. The SC/SP may request a revision of the terms of reference or query by the Food Authority, in order to clarify or elaborate on the matter, provided that the original objective is maintained.
- 14.6. Where a request had been previously forwarded and a scientific opinion provided or approval granted or sanctioned, a repeated request on safety shall only be taken up if new and relevant scientific evidence becomes available and a new risk assessment is warranted.
- 14.7. The Food Authority may request the Scientific Committee/Panels to provide guidance on procedures, methodologies and such matters that provide harmonized and consistency in the scientific outputs.

Structure of Query

15. It is necessary for the Authority to develop in-house expertise and institutional memory to capture the decision of the Panels and Committee and achieve the necessary integration before they are considered by the Authority. Since Members of the Panels and Committee are part time Members, large amount of primary data are not expected to be reviewed by them. The query to be made by the Panels and Committee should contain the following components :-

- (a) Brief of the issue which is referred to the Panel
- (b) Supporting documentation or its summary / views of stakeholders received
- (c) The specific issues on which advice of the Panel is required

16. Since risk management decisions are taken by the Authority, it may not be advisable to pass on this critical function to any Scientific Panel or Committee. It is only when a particular risk management option is required to be considered further on a specific issue that the matter can be referred to the Panel.

17. At the end of first year of membership it may be advisable for Members to prepare a report that reflects how they perceive their contribution towards the work of the

Committee. This will help in not only reviewing the contribution of members but also making appropriate changes in the constitution of Panels wherever required.

18. The number of Authority officials attending a meeting of the Panels should be kept to the minimum and their attendance limited to particular items wherever required. The sitting should be so arranged that the presence of observers does not inhibit the Panel's discussions. The Chair should limit contributions by non members during discussions.

19. The Chairperson of the Authority should meet with the Chairs of the Panels and Committee at least once a year to review the progress.

Panels as Advisory Bodies

20. There may be occasions when new ideas or proposals are being developed by the Authority and it is necessary to sound them off with individuals who can provide unbiased views and out of the box solutions. There may also be solutions available and already being implemented elsewhere. Expertise in the Panels can also be used for this purpose by circulating the concept note in advance and seeking their views which can be developed further. Very often, concepts can be circulated by email and views solicited quickly.

Risk Assessment

21. Risk assessment involves detailed analysis of data from the point of view of toxicology, allergenicity, molecular characterisation, environmental impact and food safety. Panels and Committee are not expected to carry out detailed risk analysis themselves based on data available. The process of risk assessment will have to be carried out by full time technical staff with the Authority or other agency specifically entrusted the task. It is only when the initial assessment reports are available that the Panel can be asked to review the procedure and the conclusions, if necessary.

22. Similarly, draft regulations are not expected to be drawn up by Panels and Committee. What Panels can provide is the framework for preparation of regulations and the broad areas that need to be covered.

23. It has been found that when review documents, briefs and options available for review of regulations are prepared, the required inputs are rarely available from the concerned ministries or departments. Authority also may not have skills in-house to develop such documents. In all such cases, individuals with the required skills may have to be identified outside the system and their skills utilised for preparation of documents. The required procedures have to be followed for selection of such outside experts as consultants. Preparation of such basic documents is critical to developing a set of regulations which are up-to-date, best of class and implementable.

Coordination between the Food Authority, Scientific Panels and Committee

24. Very often the Authority may be drawing up draft regulations/discussion papers parallelly with the work that is being done by the Scientific Panels and Committee. The inputs being received from the Scientific Panels and Committee will be utilised by the Authority in giving the final shape to the regulations. At any stage in the development of regulations, the Authority may seek the comments and views of the Scientific Panels and Committee so that through close interaction at every stage of the process, a draft regulation of acceptable quality emerges.

Publication of Scientific Opinion & Records.

- 25.1. The Scientific Opinion developed and adopted by the Scientific Committee/Panel shall be published on the website and to the public in a timely manner in order to disseminate the information to the public.
- 25.2. All Scientific Opinions documents and reports shall be documented in the standard formats, catalogued and made available on the Authority website.