



Joint FAO/WHO Expert Committee on Food Additives

Food additives and food contaminants

FAO procedural guidelines for the Joint FAO/WHO Expert Committee on Food Additives

Rome, February 2003

1	Introduction	1
2	Structure of the Committee.....	2
3	Selection of experts	2
4	Responsibilities.....	3
4.1	FAO Joint Secretary	3
4.2	Drafting Experts: Members and FAO Consultants.....	4
4.3	Sponsors and other data providers.....	4
5	Procedures	4
5.1	Joint Secretary	4
5.2	Drafting experts: Members and FAO Consultants	5
5.3	Members	5
5.4	FAO Consultants	5
5.5	Sponsors and other data providers.....	6
6	Considerations for specific categories	6
6.1	Food additives	6
6.2	Flavouring agents	7
6.3	Food contaminants.....	7
7	Interaction with sponsors.....	7
8	Publication and communication of opinions	7
	Annex 1 - Procedures for placing food additives and contaminants on the agenda	9
	Annex 2 - Procedures for issuing the call for data	10
	Editorial note:	11

1 Introduction

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is convened by FAO and WHO under their respective terms of reference for Expert Committees. This document describes the procedures used by FAO in its evaluation of food additives and contaminants; a separate document describes the procedures used by WHO*. While common procedures are used in most instances, separate guidelines for the two organizations have been prepared because they have differing rules and regulations for expert committees and because the expertise required and the work done by experts invited by the two organizations is different.

JECFA is convened according to Article VI of the Constitution of FAO (the text is available at www.fao.org/legal under "Basic Texts"); the Director-General on the authority of the Conference or Council may establish committees and working parties to study and report on matters pertaining to the purpose of the Organization and consisting of individuals appointed in their personal capacity because of their special competence in technical matters. Joint committees may also be established in conjunction with other intergovernmental organizations.

The committee evaluates substances in response to requests by FAO and WHO Member States and the Codex Alimentarius Commission (through the Codex Committee on Food Additives and Contaminants, CCFAC and the Codex Committee on Residues of Veterinary Drug in Foods, CCRVDF). Separate meetings

* All relevant documents mentioned in this guideline are available either at www.fao.org/esn/jecfa or www.who.int/pcs/jecfa.htm



are held to assess either (i) food additives and contaminants or (ii) residues of veterinary drugs in food. Because the procedures are significantly different for the two types of assessments, separate guidelines have been prepared for residues of veterinary drugs.

Through the publication of reports and monographs, JECFA advises FAO, WHO, their Member States, and the Codex Alimentarius Commission (through the Codex Committee on Food Additives and Contaminants, CCFAC) regarding the safety of food additives and contaminants that may be present in food. The reports of the meetings, which outline general considerations and summarize the evaluations of the substances on the agenda, are published by WHO in the *Technical Report Series*. Toxicological monographs, which are based on working papers prepared by WHO Temporary Advisers, are published in the *WHO Food Additives Series*. Specifications for the identity and purity of food additives, which are prepared by participants invited by FAO, are published in the Compendium of Food Additive Specifications (*FAO Food and Nutrition Paper 52*).

These notes are designed to provide guidance to the FAO Joint Secretary, FAO Consultants, Members and sponsors relating their roles and responsibilities in dealing with the evaluation of food additives and contaminants. The guidelines outline the tasks of the FAO Joint Secretariat and its role in servicing JECFA, time schedules to be followed in preparing for meetings, the appropriate handling of data, and appropriate relationships with sponsors and other data providers. Supplemental material is included that outlines the procedures by which substances may be placed on the agenda (Annex 1) and procedures for issuing the call for data (Annex 2). Close adherence to these guidelines by everyone involved will ensure that the concerns and views of all interested parties are taken into account in the decisions of JECFA and that the independence and integrity of the evaluations are maintained, both in appearance and in actual fact.

2 Structure of the Committee

At its meetings the Committee consists of *Members* and *Secretariat*, categories that arise from the legal frameworks given by the constitutions of FAO and WHO. *Members* are responsible for taking decisions based upon their expertise and experience, the scientific information before them, and advice provided by the *Secretariat*. The *Secretariat* consists of the FAO and WHO Joint Secretaries, other employees of FAO and WHO who assist with preparation for the meeting, and *WHO Temporary Advisers* and *FAO Consultants*.

Experts who are invited by FAO as members or as FAO Consultants must be listed in the *FAO Roster of JECFA Experts*. Although experts are nominated for four years, JECFA is not a standing committee. Therefore, JECFA exists and can make decisions only during the time of the meeting itself. The Joint Secretariat conveys the decisions of the Committee to the executive heads of FAO and WHO and to interested institutions, including the Codex Alimentarius Commission (through the Codex Committee on Food Additives and Contaminants, CCFAC), and to individuals. The Joint Secretariat cannot modify or amend the interpretation of data by JECFA or its decisions. The only modifications to reports, monographs and specifications that may be made by the secretariat are those of an editorial nature; changes of a substantive nature can only be referred to a subsequent meeting for consideration.

3 Selection of experts

FAO chooses experts for JECFA on the basis of their scientific expertise in the areas under consideration, which include manufacturing and quality control of food additives, analytical chemistry for the qualitative and quantitative determination of substances occurring in food, food technology and good manufacturing practices of food production (or any related field). A balance between academic and regulatory experience and geographical distribution is important. Members and Consultants are invited directly by the Secretariat as independent scientific experts, and they do not represent their employers, governments, or other institutions. Their travel expenses are paid by FAO; honoraria are not provided.

Several sources are used for identifying appropriate scientists to serve at JECFA. These include direct solicitations by FAO to governments and other organizations for identifications, unsolicited recommendations to FAO, experience in working with experts at previous committee or other scientific meetings, and reviews of scientific publications.



Members and consultants of the committee invited by FAO must be included in the FAO Roster of JECFA Experts. All applicants are assessed by examination of the curriculum vitae and list of publications by an independent, external qualified expert and by the FAO Joint Secretariat. They are appointed by the Director-General giving consideration primarily to their technical ability and experience, but also endeavouring to ensure that the committee has the broadest possible international representation in terms of diversity of knowledge, experience, and approaches. Appointment to the FAO Roster of JECFA Experts is for a maximum of four years, it can be renewed.

Both Members and FAO Consultants are required to disclose in writing all circumstances that could lead to potential conflicts of interest. When an interest is declared on a particular substance, the Committee will discuss and adopt a decision whether the scientist may participate in the evaluation of this substance.

FAO applies the same selection procedure for JECFA Members and FAO Consultants. The procedure is described in more detail in the *Calls for Experts* for JECFA.

4 Responsibilities

4.1 FAO Joint Secretary

The FAO and WHO Joint Secretaries have overall responsibility for organizing the meeting, inviting participants, ensuring that the appropriate documentation is prepared, servicing the meeting while it is in session, and editing and publishing the report and evaluations in a manner that faithfully reflects the conclusions of the Committee. Specifically, the FAO Joint Secretary:

- schedules meetings and develops the agenda in collaboration with the WHO Joint Secretary assuring that FAO rules and procedures are followed;
- prepares and publishes, both in print and on the FAO and WHO web sites, requests for data for the meeting, in collaboration with the WHO Joint Secretary;
- identifies and arranges for the selection and invitation of Members and FAO Consultants;
- solicits and co-ordinates the submission of data and their distribution to appropriate Members and FAO Consultants; co-ordinates the preparation of working papers, ensuring liaison between the authors and peer reviewers;
- acts as FAO Secretary at JECFA meetings and represents JECFA at other occasions;
- prepares, in collaboration with the WHO Joint Secretary, summaries of the conclusions as soon as possible after the meetings and places them on the FAO web site;
- is, together with the WHO Joint Secretary, responsible for the technical editing of the reports and of the relevant sections of toxicological monographs;
- oversees the technical editing of specifications for food additives and flavouring substances and arranges their timely publication, both in print and on the FAO web site;
- works with CCFAC to ensure that as many priority substances as possible are evaluated by JECFA and to explain the basis for the evaluations after they have been performed;
- works with CCFAC to ensure that specifications for food additives, including flavouring substances, are reviewed by the Committee and forwarded as appropriate to the Codex Alimentarius Commission for adoption as Codex specifications;
- provides information about JECFA and its evaluations to governments, organizations and individuals and at scientific meetings;
- maintains an up-to-date *FAO Roster of Experts for JECFA* on food additives and contaminants from which future Members and FAO Consultants can be drawn; and
- updates the *Summary of evaluations performed by JECFA* (<http://jecfa.ilsa.org>).

The FAO Joint Secretariat conveys the decision of the Committee to the executive heads of FAO through the established channels, and to interested institutions and individuals.



4.2 Drafting Experts: Members and FAO Consultants

Drafts of food additive specifications or other preparatory documents are prepared by drafting experts (Members or FAO Consultants). A second expert who attends the meeting as a Member will be assigned in advance of the meeting as a reviewer. The general responsibilities of Members and FAO Consultants include:

- acting in their individual capacities as experts and not as representatives of any organization;
- maintaining the integrity and security of all commercial data to which they have access as part of their work for JECFA;
- performing literature searches on the substances for which they have responsibility;
- abiding by the terms set out in the instructions provided for the declaration of interests; and
- working closely with each other to prepare draft documents (*Chemical and Technical Assessments*^{*}, food additive specifications, relevant sections of monographs) in sufficient time for distribution and review before the meeting.

4.3 Sponsors and other data providers

Manufacturers have the responsibility to provide all relevant published and unpublished data that are available on the food additives on the agenda, as described in the *Call for data* issued by the Joint Secretariat. Confidential information pertaining to manufacturing trade secrets (such as manufacturing processes), if submitted, should be clearly identified so that this information will not be published.

Data may also be provided e.g. by governments, national and international organisations, research institutes, universities. The term "sponsor" used in this documents includes them where appropriate.

5 Procedures

5.1 Joint Secretary

The Joint Secretaries distribute a call for data on the substances on the agenda 10-12 months in advance of the meeting, both in paper form and on the internet. The compounds are selected on the basis of priority lists established by CCFAC, requests by FAO and WHO and their Member States, and recommendations of earlier meetings of JECFA (see Annexes 1 and 2). The deadline for submission of data is ordinarily 6-7 months before the meeting.

The FAO Joint Secretary will contact relevant manufacturers' associations (with recognized NGO status with the Codex Alimentarius Commission) in order to identify potential sponsors.

Before the deadline for receipt of data, the FAO Joint Secretary will assign individual substances to scientists who have agreed to serve as drafting experts, taking into account their experience, expertise and available resources. Data and documents submitted to the FAO Joint Secretariat will be sent as early as possible to these drafting experts. If the dossier is large, the sponsor will be asked to send one copy directly to each of the assigned experts and one copy to the FAO Joint Secretariat at for use as a reference copy at the meeting.

The Joint Secretary will provide guidelines for the preparation of draft documents and procedural guidelines to the Consultants and Members, along with other information and instructions, at the time that the assignments are made or shortly thereafter.

The FAO Joint Secretary, in co-ordination with the WHO Joint Secretary, will encourage the scientists involved with the evaluation of a particular substance to contact and co-operate with the other scientists involved with its review. Both experts, the one responsible for drafting documents and the Member assigned

^{*} Previously also known as *Technical Data Sheet*. Content and function of the *Chemical and Technical Assessment* is described in a separate document.



for review will be encouraged to work together to prepare a consolidated version and to work with the WHO scientists on cross-cutting issues relating to toxicology and intake.

The FAO Joint Secretary will ask drafting experts to submit electronic files (or, if necessary legible written copies) of their consolidated draft papers to the FAO Joint Secretary no later than 1-1.5 months before the meeting. Upon receipt, the Joint Secretary will distribute the draft papers over the internet to the other experts responsible for the individual substance. Shortly before the meeting, the Joint Secretary will also produce a sufficient number of the draft or revised working papers for all participants for distribution at the meeting.

When a sponsor makes available unpublished proprietary data for evaluation, the Joint Secretary safeguards the data from unauthorized disclosure. To ensure that the copies that are sent to the FAO Consultants and Member are safeguarded, they are requested to acknowledge in writing that they accept the conditions that have been laid out for their use and storage. When the data are no longer needed, the Secretariat either returns the data file at the manufacturer's expense or destroys it, depending upon the wishes of the sponsor.

5.2 Drafting experts: Members and FAO Consultants

Drafting experts must safeguard all proprietary data. He or she may not make copies of any part of the file or share or use the data for any purpose other than the JECFA assignment.

Upon completion of the assignment, drafting experts should either return the data file to the FAO Joint Secretariat or sponsor or destroy it, depending upon the wishes of the sponsor. Non-adherence to these procedures will result in removal of the drafting expert from the activity.

Drafting experts should perform literature searches on their assigned substances. It is extremely important that literature searches are performed, especially on substances that have been in use for a long time.

Each drafting expert will work closely with the Member assigned to peer review the draft documents to ensure that comments are considered and included. The drafting expert will submit a legible printed or electronic copy of the consolidated working paper to the FAO Joint Secretary 1-1.5 months before the meeting. It is extremely important that this timeframe be met, because this amount of time is necessary to distribute the working papers to the other experts responsible for the individual substance for review and comment. If significant comments are submitted, the drafting expert will revise the draft paper(s) and re-submit it to the FAO Joint Secretary in sufficient time so that copies can be produced before the meeting. To avoid the possibility of improper influence on the drafting expert by the sponsor, the expert should not send drafts to the sponsor.

5.3 Members

Members of JECFA are the decision-makers and, as such, are responsible for conducting the meeting. The chairman, vice-chairman, and both rapporteurs must therefore be Members of the Committee.

Members of the Committee may be assigned to act as peer reviewers of draft documents prepared before the meeting by the drafting experts. They will be expected to work with the drafting expert during the last stages of the preparation of draft papers. Copies of the dossiers on the substances on which they will be reviewing the draft documents will also be sent to them.

The Member will inform the Secretariat of relevant unpublished studies known to have been reported elsewhere, but which were not been included in the data package submitted. The Member should note the potential impact of the missing data on the evaluation.

Members are expected to be present throughout the entire meeting, because they constitute the Committee and have the responsibility for making the final decisions concerning the evaluations.

5.4 FAO Consultants

FAO Consultants are members of the secretariat of the meeting appointed for their scientific and technical expertise to provide advice to the Joint Secretaries and the Members of the Committee.



FAO Consultants also serve as drafting experts, as do the Members, for the preparation of the draft working documents. Consultants will inform the secretariat of relevant unpublished studies known to have been reported elsewhere, but which were not included in the data package submitted. The Consultant should note the potential impact of the missing data on the evaluation.

FAO Consultants are asked to be present throughout the entire meeting, because they have the responsibility to advise the Secretariat and the Members on the final decisions concerning the evaluations.

5.5 Sponsors and other data providers

Submission of data following the format described in the *Guidelines for the Chemical and Technical Assessments* is encouraged. Submission of summaries is not sufficient for a full evaluation. All reports must be complete and supported by the detailed data generated during the experimental phase of the study. Dossiers should be submitted in triplicate to the Secretariat at FAO Headquarters. If the documentation is considerably extensive, direct dispatch of the copies to the experts is preferred. The FAO Joint Secretariat will provide mailing instructions to sponsors.

If the sponsor would like to have the dossiers returned (at his expense) after they have been used by JECFA, it should be so indicated at the time of submission. If such instructions are not received, the files will be destroyed after a certain period of time.

Data should be submitted by the deadline established by the Secretariat. Late submission may result in a delay in the preparation of the working paper or may even delay consideration to the following JECFA meeting devoted to the evaluation of food additives and contaminants.

When data on substances having tentative specifications are not provided for consideration at the meeting in the year in which the tentative specifications expire, the tentative specifications are unlikely to be extended by the Committee unless the Secretariat receives an adequate explanation for the need for extra time to generate the required data.

Draft documents are sent to the sponsors for the exclusive purpose of verifying their accuracy and they are not to be distributed or used in any other way.

6 Considerations for specific categories

6.1 Food additives

Members and FAO Consultants invited by the FAO Joint Secretariat who are assigned to food additives are responsible for drafting specifications of identity and purity for the additives, whether these are revisions of existing specifications or specifications being drafted for the first time. For each additive the responsible drafting expert will also prepare a *Chemical and Technical Assessment* which evaluates the data on the quality and the functional use of the additive in question. The *Chemical and Technical Assessment* will be prepared with both a brief summary and a detailed review of the manufacturing process of the food additive. The detailed review will be kept confidential and be removed before the document is made publicly available on the internet.

Following the preparation of the *Chemical and Technical Assessment* (CTA), the expert will prepare draft specifications in the standard JECFA format (see p 1ff of the *Compendium of Food Additives Specifications, FNP 52*). Drafting experts are also responsible for ensuring that all methods of analysis quoted are appropriate and that proposed specifications (e.g., limits for heavy metals) are in line with the Committee's current policy as elaborated in meeting reports (*WHO Technical Report Series*) and the addenda of the *Compendium of Food Additives Specifications, FNP 52*.

When proposing amendments to existing specifications, the drafting expert will provide in writing a reason for each proposal. After discussion at the meeting, the drafting expert finalises the specifications and ensures that electronic and paper copies of the final document are given to the FAO Secretary before the meeting finishes. A brief account of the reasons for changes to existing specifications accompanies the documents.



6.2 Flavouring agents

Members and FAO Consultants invited by the FAO Joint Secretariat who are assigned to flavouring agents that are evaluated according to the Committee's special procedure will be responsible for the drafting of specifications of identity and purity for these substances, whether these are revisions of existing specifications or specifications being drafted for the first time. The responsible drafting experts will draft the specifications in the standard JECFA format for flavouring agents.

Where proposals are made for amendments to existing specifications, a reason should be given in writing for each of the changes. After discussion at the meeting, the drafting expert will finalise the specifications and deliver electronic and paper copies of the final document are given to the FAO Secretary before the meeting finishes. These should be accompanied by a brief account of the reasons for any changes to existing specifications.

6.3 Food contaminants

The procedures employed for consideration of food contaminants may vary considerably from contaminant to contaminant. The issues on which Members and FAO consultants by the FAO Secretariat will normally be expected to provide information, include the occurrence of the contaminant in food, its analysis in food and means for reducing levels or eliminating its presence in food.

7 Interaction with sponsors

Sponsors' information and views relevant to their submissions should be fully taken into account. At the same time, JECFA's evaluations of the data must not be influenced or inhibited by actions of the sponsors, either in fact or in appearance. To accommodate these requirements, the following procedures for the interaction of experts with sponsors have been established:

- The experts may contact the sponsor for clarification of issues. If a drafting expert does not wish to communicate directly with the sponsor, the expert may communicate through the FAO Joint Secretary. However, direct interaction is encouraged.
- The drafting experts should send copies of all exchanges of information and correspondence, including memoranda of telephone conversations to the FAO Joint Secretary.
- The Joint Secretary will file these communications and will make them available to the Committee upon request.
- The sponsor shall not contact the drafting experts except to communicate that additional information is available. Other information that the sponsor wishes to convey should be sent to the FAO Joint Secretary.
- The drafting experts should report to the FAO Joint Secretary any undue pressure from any interested party. Such abuse will be reported by the Secretariat to relevant manufacturers' associations.

Experts not adhering to these procedures regarding interactions with sponsors may be removed from the activity.

8 Publication and communication of opinions

After each meeting of the Committee a summary report is published within a few weeks of the meeting, which sets out the main conclusions, including details of the ADIs and MRLs set by the committee. This summary is distributed in printed form and is available on the FAO and WHO web sites. The detailed conclusions of JECFA meetings are set out in reports published in the WHO Technical Report Series. These reflect the agreed view of the Committee as a whole and describe the basis for the conclusions. Toxicological and intake monographs are published after the meetings in the WHO Food Additive Series (FAS). These summarise the data used in the Committee's risk assessments and provide full references to the relevant literature. Specifications for the identity and purity of food additives developed at JECFA meetings are published in the *Compendium of Food Additive Specifications* (FAO Food and Nutrition Paper (FNP) Series No 52 and Addenda).



The Joint Secretariats will attend the meetings of CCFAC and present the relevant findings of the Expert Committee and provide, if necessary, additional clarification. Thereby the Joint Secretaries provide also JECFA with feedback from CCFAC.



Annex 1 - Procedures for placing food additives and contaminants on the agenda

Requests for the evaluation of food additives and contaminants and consideration of issues of a general nature by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) may come from a number of sources:

1. Codex Committees

The Codex Committee on Food Additives and Contaminants (CCFAC) refers substances to JECFA based on priorities that it establishes using criteria that it has developed that are in accord with accepted procedures of the Codex Alimentarius Commission.

2. FAO and WHO Member States

FAO and WHO Member States may request the inclusion of food additives or contaminants on the agenda of JECFA through a direct request to the FAO and WHO Secretariats. Such a request must be accompanied by a commitment to provide the necessary data 6-7 months before the tentatively scheduled meeting of JECFA

3. Sponsors

For food additives not previously evaluated by JECFA, an industry sponsor may forward a request for evaluation through the government of a Member State to CCFAC, with a commitment to provide the relevant data. Requests for the re-evaluation of a food additive that has been reviewed by JECFA previously may be forwarded directly to the JECFA Secretariat. As with all other substances on the agenda, the Joint Secretariat includes the substance in the call for data for the meeting to ensure that all interested parties have the opportunity to submit data. With contaminants, governments would ordinarily request evaluations.

4. JECFA Secretariat

The JECFA secretariat may place a food additive or contaminant on the agenda for re-evaluation even though no outside request has been received.

5. JECFA itself

The Committee often establishes a temporary ADI or temporary specifications for a food additive, with a request for further data by a certain time. These food additives, which have the highest priority for evaluation, are placed on the agenda of the appropriate meeting by the Joint Secretariat.

A similar situation occurs when the Committee recommends that a contaminant be evaluated at a future meeting.



Annex 2 - Procedures for issuing the call for data

The Joint Secretariat issues a call for data on the food additives and contaminants on the agenda 10-12 months before the meeting, which is posted on the FAO and WHO web sites and is sent to Codex and other contact points. The substances are selected on the basis of priority lists that are established as outlined in Annex 1. The deadline for submission of data is normally 6-7 months before the meeting. The late submission of data may result in the postponement of the evaluation to a future meeting.

Before inclusion of a substance on an agenda for the first time, the JECFA Secretariat will have received a positive indication that there will be one or more submitters of data for the evaluation, or that the data are available from other sources such as a government organization or the published literature. For substances that are being re-evaluated, for example those that have a temporary ADI, the Secretariat assumes that the sponsor of the original evaluation will be providing the necessary data unless informed otherwise. The Joint Secretary will provide those submitting the data with the names and contact details of the individual(s) that have been assigned the responsibility to prepare the working paper. When for any reason the data submitter does not send information to the scientists preparing the working paper, the Joint Secretary will ensure that copies of the data that were sent to WHO Headquarters are sent to them.

When a sponsor makes available unpublished proprietary data for evaluation, the Joint Secretary and the drafting expert will safeguard the data from unauthorized disclosure. Drafting experts are required to acknowledge that they accept these conditions. When the data are no longer needed the Joint Secretary and the experts will either return the data file to the submitter at his/her expense or will destroy them, depending upon the data submitter's wishes. Those submitting data are requested to inform the Joint Secretary and drafting expert at the time that they submit them whether they wish data to be returned. In the absence of guidance, the data will be destroyed.

The JECFA Secretariat sometimes receives requests to include substances on the agenda that have been evaluated previously after the initial call for data has been issued. Such requests are considered in the light of (a) the time schedule of the meeting and (b) whether addition of the item on the agenda is urgent. Such late requests are generally discouraged, and the substance will not be placed on the agenda if notice is given so late that publication of a supplemental call for data is impractical, unless it is an emergency situation. Ordinarily the substance will be placed on the agenda of a later meeting for evaluation.



Editorial note:

Title: Food additives and food contaminants: FAO procedural guidelines for the Joint FAO/WHO Expert Committee on Food Additives

Version: 1.0

Date: 24/02/2003

Editor: FAO Joint Secretariat (ML)

Note: This document was prepared by the FAO Joint Secretariat based on discussions the Committee had at the 57th and 59th meeting. It is subject to revision following input from the Committee itself or any other interested party.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It has been meeting since 1956, initially to evaluate the safety of food additives. Its work now also includes the evaluation of contaminants, naturally occurring toxicants and residues of veterinary drugs in food.

More information on the work of JECFA is available at

www.fao.org/es/esn/jecfa/index_en.stm

www.who.int/pcs/jecfa/jecfa.htm