Food and Agriculture Organization of the United Nations

World Health Organization

MODULE I: Guidance on the process and procedures for members and FAO experts invited to attend a meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) on the evaluation of residues of veterinary drugs in foods

FAO JECFA Secretariat

March, 2016

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1. Overview

As discussed in the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition published in 2007, "FAO/WHO scientific advice is provided through the convening of established expert committees (known as expert bodies) and other expert meetings and ad hoc consultations on issues related to the safety assessment of chemicals in food.[1] JECFA is the expert body responsible for the provision of scientific advice on residues of veterinary drugs in foods. Information of FAO activities related to food safety and quality can be found on the FAO website.[2]

JECFA is convened by FAO and WHO under their respective terms of reference for Expert Committees. Article VI of the Constitution of FAO authorizes the Director General of FAO to "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". This includes joint committees with other organizations, such as the World Health Organization.[3]

Through the publication of reports and monographs, JECFA advises FAO, WHO, their Member States and the Codex Alimentarius Commission, through the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), regarding the safety of veterinary drug residues in edible products of animals.

The guidance contained in this document is intended to inform the FAO Joint Secretary, Members of JECFA appointed by FAO, FAO Experts invited to participate in a JECFA Meeting and Sponsors regarding their roles and responsibilities in the evaluation of residues of veterinary drugs in food by JECFA. Annex 1 outlines the procedures by which veterinary drugs may be placed on the agenda for a JECFA Meeting, while Annex 2 outlines the procedures for issuing the call for data. Close adherence to these guidelines by everyone involved ensures 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.

2. Relationship with CCRVDF

The CCRVDF refers substances to JECFA based on priorities that it establishes using criteria that are in accord with accepted procedures of the Codex Alimentarius Commission, as stated in the "Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods".[4] These Risk Analysis Principles also state that "the responsibility for risk assessment lies primarily with the Joint FAO/WHO Expert Committee on Food Additives

[1] FAO. (2007) FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition; available at ftp://ftp.fao.org/docrep/fao/010/a1296e/a1296e00.pdf or http://www.who.int/foodsafety/publications/nutrition-advice/en/

[2] FAO. (2015) http://www.fao.org/food/food-safety-quality/scientific-advice/en/

[3] FAO. (2015) "Basic texts"; available at http://www.fao.org/legal/home/legal-office/en/

[4] CAC. (2015) Codex Alimentarius Commission Procedural Manual, 24th edition; available at http://www.codexalimentarius.org/procedures-strategies/procedural-manual/en/

(JECFA)." The role of JECFA is further described in the "Risk Assessment Policy for Residues of Veterinary Drugs in Foods*"* in the Codex Alimentarius Commission Procedural Manual.[4]

This includes:

- JECFA provides CCRVDF with science-based risk assessments conducted in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and incorporating the four steps of risk assessment. JECFA should use its risk assessment process for establishing acute reference doses (ARfD) or Acceptable Daily Intakes (ADIs) and proposing Maximum Residues Limits (MRLs), and/or responding to other questions from the CCRVDF.
- JECFA should take into account all available scientific data and assessments in conducting the risk assessment. It should use available quantitative information to the greatest extent possible and also qualitative information.
- Constraints, uncertainties and assumptions that have an impact on the risk assessment should be clearly communicated by JECFA.
- JECFA should provide CCRVDF with information on the applicability, public health consequences and any constraints of the risk assessment to the general population and to particular sub-populations and, as far as possible, should identify potential risks to specific groups of populations of potentially enhanced vulnerability (e.g. children).
- Risk assessment by JECFA should be based on realistic exposure scenarios.
- When the veterinary drug is used both in veterinary medicine and as a pesticide, a harmonised approach between JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) should be followed.
- MRLs, that are compatible with the ADI or ARfD, where appropriate, should be recommended for target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animals species to which a veterinary drug can be administered according to good veterinary practice based on appropriate consumption figures. When requested by CCRVDF, extension of MRLs between species will be considered if appropriate data are available.[5]
- While considering extrapolation of MRLs:
  - There should be a reasonable expectation that two food producing species that are biologically/physiologically related will generally exhibit a similar pattern of metabolism, distribution and depletion of veterinary drug residues (e.g., ruminant to ruminant).
  - There should be a reasonable probability that a unique metabolite(s) of toxicological concern is unlikely to occur in species in which MRLs are being extrapolated;
  - JECFA should, when requested, assess different risk management options and present, in its report the implications of these different risk management options for the CCRVDF to consider.
- When scientific data are insufficient to complete an evaluation, JECFA should indicate the data gaps and propose a timeframe in which data should be submitted. JECFA may also recommend guidance according to point 10 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

In addition, CCRVDF may request comment on other issues from JECFA. An overview of the assessment process followed by JECFA in evaluating the safety of residues of veterinary drugs

[5] The request from CCRVDF may also include a request to recommend MRLs for other offals, such as lung tissue.

and recommending corresponding MRLs in animal-derived foods is provided in Chapter 8, Maximum Residue Limits for Pesticides and Veterinary Drugs of the publication Environmental Health Criteria 240, Principles and Methods for the Risk Assessment of Chemicals in Food (EHC 240).[6]

3. Administrative process and schedule for a JECFA meeting

3.1 Appointment to JECFA roster

FAO and WHO each establish rosters of experts from which individuals may be selected to serve at expert meetings such as JECFA. Several sources are used for identifying appropriate scientists to serve at JECFA. These include a call for experts, direct solicitations by FAO to governments and other organizations for identifications, unsolicited applications to FAO, experience in working with scientists at previous committee or other scientific meetings and reviews of scientific publications.

A formal call for experts interested in appointment to the FAO roster for the evaluation of veterinary drugs is issued every four years.[7] In addition, interested individuals may also submit an application during the intervening period.[8] Scientists are appointed to the FAO roster of veterinary drug experts by the Director-General, in consultation with the FAO Joint Secretary and independent advisers, 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, approaches and geographical representation. The selection of members is made after a careful consideration of the scientific credentials of the various candidates, and a balance of scientific expertise and other experience is considered essential.

3.2 Categories and Definitions of JECFA participants

FAO applies the same selection procedure for JECFA Members and FAO experts (Advisers), who must first be selected for a JECFA roster (see FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition[1] for process for selection of experts).

3.2.1 **Members** are invited on the basis of their particular expertise to consider the questions posed to the Committee, review available data, prepare draft evaluations in advance for discussion, draw appropriate conclusions, draft report sections and adopt the final report. The JECFA Chairperson, vice-chairperson, and rapporteurs are nominated from this group.

3.2.2 **FAO experts (Advisers)** are external resource experts who provide technical support to the JECFA Secretariat through the preparation of draft discussion documents in advance of meetings and the provision of technical advice during meetings. While these individuals participate in discussions, they cannot formally adopt the final report. They are selected and nominated according to the same rules that apply to the selection, nomination and declaration of interest of members**.**

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[6] Environmental Health Criteria 240, *Principles and Methods for the Risk Assessment of Chemicals in Food* (2009). A joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization, available at http://www.who.int/foodsafety/publications/chemical-food/en/.

[7] FAO. (2015). Call for data and experts; available at http://www.fao.org/food/food-safety-quality/scientific-advice/calls-data-experts/en/

[8] FAO. (2015) FAO Food Safety Expert Roster; available at http://www.fao.org/food/food-safety-quality/expert-roster0/en/

3.2.3 **Joint FAO/WHO Secretariat**, the professional staff members from FAO and WHO, who are responsible for the preparation, organization and appropriate follow-up of the meetings. The Secretariat may include consultants contracted by FAO to assist with particular issues before the Committee.

3.2.4 **Other participants**, such as representatives of the CCRVDF, observers invited by the JECFA Secretariat and editors for the meeting report and monographs. Such individuals do not usually participate in the discussions.

3.3 Invitation to participate in a JECFA Meeting

FAO chooses Members of JECFA for the evaluation of veterinary drug residues in foods on the basis of their scientific expertise in the areas under consideration, which include pharmacology, metabolism, analytical chemistry and veterinary medicine. A balance between academic and regulatory experience and geographical representation is important. Those selected from the roster for each meeting may attend either as JECFA members or as invited FAO experts (advisers) to prepare monographs, discussion papers and associated summary documents for inclusion in the meeting report. Members and FAO experts are invited directly by the Secretariat as independent scientific experts, and they do not represent their employers, governments, or other institutions.

3.4 Conflict of Interest

Both Members and FAO experts 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 scientist does not participate in its evaluation. When a Member or FAO expert is uncertain if a particular situation may be perceived as a potential conflict of interest, advice should be sought from the FAO Joint Secretary for JECFA.

3.5 Schedule for participants attending a JECFA Meeting

The typical schedule for a JECFA Meeting participant is detailed below.

- Prior to JECFA Meeting:
    - Call for data by Secretariat about 10-12 months prior to meeting date.
    - Invitations to experts about 6-9 months prior to meeting date.
    - Assignments to drafting experts and distribution of dossiers about 6 months prior to meeting date. A list of assignments is provided to all participants
    - First drafts of monographs and working papers submitted by drafting experts to FAO Joint Secretary 6-8 weeks prior to meeting date.
    - Distribution by FAO Joint Secretary of draft monographs and working papers for review by other members and invited FAO experts about 6 weeks prior to meeting.
    - Travel arrangements and hotel information from FAO 6-8 weeks prior to meeting.
    - Conference call for preliminary discussion of agenda items with Secretariat, members and invited FAO experts at least 6-8 weeks prior to meeting (after distribution of draft monographs). Additional calls on specific topics may be arranged when needed.
    - Training session for new members and FAO experts on the day before the meeting can also be arranged. Returning members or FAO experts requesting a refresher on Committee procedures may also attend.
- During JECFA Meetings:

  - Submission of first draft of summary for each substance on the agenda by drafting experts to FAO rapporteur at meeting opening.
  - Overview presentation by drafting expert for each substance at beginning of JECFA Meeting to identify key issues for discussion and decision by the Committee.
  - Discussions in both working groups and full Committee during JECFA Meeting to resolve issues, finalize decisions.
  - Preparation of revised summary text by drafting expert for each substance to reflect discussions and decisions (all revised versions to be provided to FAO rapporteur).
  - Provision of final summary text for substance or agenda item by the drafting expert to the rapporteur for final review and adoption by the Committee**. Note:** The final text of this document must reflect the Committee's decisions, not just the opinions of the assigned drafting expert and reviewer(s).
  - Adoption of final text of meeting report by the Members of the Committee and close of meeting.
- Subsequent to JECFA Meeting:
  - Submission of final draft of monograph by drafting experts to FAO Joint Secretary by date established at JECFA meeting, typically 1 month after the meeting. **Note:** The final content of each residue monograph is the responsibility of the assigned drafting expert and reviewer(s), but must be consistent with the information provided, the decisions taken by the Committee and the conclusions drawn in the meeting report.
  - Clarifications and editorial corrections to editors, as needed, pending publication (typically occurs within 6 month period following meeting).
  - Publication of monographs and meeting report, typically about 6 months after meeting, depending on length/complexity of monographs and meeting report.

3.6 Distribution of dossiers to drafting experts

The dossiers are typically distributed in electronic format (CD, DVD or other computer storage media, such as USB device). Materials may also be provided in hard copy, if required.

3.7 Pre-meeting teleconference

The FAO Joint Secretary will typically start arranging teleconferences or video conferences of all members and FAO experts invited to attend a JECFA Meeting about 6-8 weeks prior to the meeting. The participants assigned to each substance should identify during this discussion any issues requiring particular attention by the Committee, such as gaps in data for a substance under review. These teleconferences may be held in conjunction with WHO members or there may be an additional call including all JECFA participants invited by both FAO and WHO. Additional teleconferences to discuss specific issues related to substances on the agenda may be arranged for the participants assigned to drafting the discussion documents for the substance and other JECFA experts, as required, in preparation for the meeting of the full committee.

3.8 Travel arrangements and expenses

Members and FAO experts are invited directly by the Secretariat as independent scientific experts. Their travel arrangements are made by FAO according to the FAO rules and their travel expenses (including Daily Subsistence Allowance - DSA) are paid by FAO; honoraria are not provided. Invited members and experts shall identify on acceptance of the invitation any specific issues for their participation due to rules applied by their employers.

4. Role of the FAO Joint Secretary for JECFA

4.1 Relationship with the WHO Joint JECFA 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 the publishing the report and evaluations in a manner that faithfully reflects the conclusions of the Committee.

4.2 Responsibilities of FAO Joint Secretary for JECFA

The FAO Joint Secretary:

- schedules meetings and develops the agenda in collaboration with the WHO Joint Secretary;
- prepares in collaboration with the WHO Joint Secretary and publishes on the FAO and WHO web sites, the calls for data for the meeting;
- identifies and arranges for the selection and invitation of Members and FAO Experts;
- solicits and co-ordinates the submission of data and their distribution to appropriate Members and FAO experts;
- co-ordinates the preparation of working papers, ensuring liaison between the drafting expert and peer reviewers;
- acts as FAO Secretary at JECFA meetings and represents JECFA at other occasions (e.g., meetings of CCRVDF);
- works with CCRVDF 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;
- prepares summaries of the conclusions as soon after the meetings as possible in collaboration with the WHO Joint Secretary and places them on the FAO web site;
- is, together with the WHO Joint Secretary, responsible for the technical editing of the reports;
- oversees the technical editing of monographs on maximum residual limits (MRLs) and arranges their publication;
- 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 veterinary drug residues from which future Members and FAO experts can be drawn;
- updates the *Summary of evaluations performed by JECFA*;[9] and
- is responsible for the FAO part of the joint representation of JECFA between meetings.

5. Responsibilities of FAO Members and FAO Experts

5.1 Core Principles

[9] FAO. (2015) Summary reports; available at http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/summary-reports/en/

All FAO and WHO activities related to the provision of scientific advice are carried out in adherence with the following core principles, as discussed in the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition[1]:

- Soundness
- Responsibility
- Objectivity
- Fairness
- Transparency
- Inclusiveness

Invited JECFA participants (members and FAO experts) are encouraged to read the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition to fully understand the expectations placed on them as participants in JECFA.

5.2 Freedom of opinion and expression

Members of expert advisory panels appointed by the Director-General to such joint committees and sub-committees shall retain complete freedom of opinion and expression. Therefore their participation in any collective decision which may entail administrative, financial or moral responsibility for another participating organization does not commit the Organization.[10]

5.3 Role of drafting experts

5.3.1 General responsibilities of drafting experts and reviewers

Draft monographs and summaries are prepared by drafting experts and reviewers assigned by the FAO Joint Secretary. The general responsibilities of drafting experts and reviewers (who may be either members or FAO experts) include:

- acting in their individual capacities as experts and not as representatives of any organization including their employer or other institutions they serve such as advisory committees;
- maintaining the integrity and security of all commercial data to which they have access as part of their work for JECFA;
- abiding by the terms set out in the instructions provided for the declaration of interests;
- working closely with each other to prepare working papers in the form of summaries of the data.

5.3.2 Work on typical agenda items for a meeting of JECFA

The work typically included in the agenda (and which may be assigned to a drafting expert) for a meeting of JECFA may include any of the following:

[10] WHO. (2015) Regulations for Expert Advisory Panels and Committees; available at http://apps.who.int/gb/bd/PDF/bd47/EN/regu-for-expert-en.pdf

- evaluation of a full dossier for initial review of a substance by JECFA (dossier prepared by a drug company or by a national authority) for the establishment of an ADI (and/or ARfD) and recommendation of MRLs;
- evaluation of a dossier submitted by a Sponsor for further review when the first review did not yield an ADI (or ARfD) or MRLs or to obtain MRLs for additional uses;
- evaluation of a dossier submitted by a Sponsor to address specific questions from JECFA arising from an earlier review of the substance;
- preparation of working papers on topics of interest to JECFA; and
- preparation of working papers responding to questions from CCRVDF or other groups to which JECFA may provide advice.

5.3.3 Role of drafting expert

The drafting expert is responsible for:

- the overall content of the monograph and review of any sections prepared by other reviewers;
- ensuring that the draft monograph is submitted to the FAO Joint Secretary in suitable format by the submission deadline;
- preparation of draft text for the residue section of the summary for inclusion in the meeting report (published in the WHO Technical Report Series);
- the presentation of a brief overview of key issues regarding the residues of the substance to the Committee (usually on the first day of a JECFA Meeting);
- taking the lead in identifying early on any issues requiring clarification by the Sponsor;
- taking the lead in responding to questions from other members and experts regarding residues of the substance during the JECFA Meeting;
- revising the draft text for the section of the meeting report dealing with residues of the substance to reflect Committee discussion and decisions;
- preparing the MRL recommendations and presenting them to the Committee;
- providing final text on residues of the substance to the FAO rapporteur for inclusion in the meeting report;
- providing a revised final text of the monograph to the FAO Joint Secretary within the deadline established at the JECFA Meeting;
- responding promptly to any questions from the FAO Joint Secretary or FAO editor(s) during preparation of the monograph for publication.

5.3.4 Role of reviewer

The reviewer is responsible for:

- preparing any sections of the monograph which have been agreed on with the drafting expert;
- reviewing the sections of the monograph prepared by the drafting expert;
- contributing to discussions on the substance during the meeting;

- assisting the drafting expert in revising drafts of the summary to reflect Committee discussion and decisions; and
- assisting, as needed, in final revisions to the monograph.

In the absence of the drafting expert, the reviewer assumes all responsibilities of the drafting expert.

5.3.5 Role of additional experts assigned to assist with dossier

Additional experts may be assigned to assist with the evaluation of a substance when special expertise is required. This typically has been a reviewer assigned to prepare the section of the monograph dealing with analytical methods, but could include any aspect of the evaluation of the compound. While such additional reviewers are expected to focus primarily on the content of the monograph and accompanying summary dealing with their assignment, they should be familiar with all content of the monograph.

5.3.6 Working groups

Some issues are complex, requiring a variety of expertise and experience with a cross-section of JECFA experts. In some instances, a working group (physical or electronic) may be assigned by the JECFA Secretariat to conduct an evaluation requested by CCRVDF or to respond to issues raised by CCRVDF. The size and structure of the working group will vary, depending on the assignment. It may include a FAO consultant tasked with preparing a working paper for discussion and consideration by the working group or a drafting expert may be assigned within the working group. Working groups are discussed further in Module II.

5.4 Conduct and responsibilities of drafting experts and reviewers

5.4.1 Prior to JECFA meeting

Prior to a JECFA Meeting, the drafting experts should maintain good communication between those assigned to a substance and with the FAO Joint Secretary. Details of any literature searches conducted as part of a review of a substance should be kept, including keywords and search engines used and these details should be included, when appropriate, in the working paper. All content of the draft monograph and summary documents should be checked to ensure there are no errors in transcription of data or interpretation.

Any unanticipated events which may interfere with the timely completion of an assignment or attendance at a full meeting should be immediately reported to the FAO Joint Secretary. Details of the dossier provided by the Sponsor are confidential and should only be discussed with the other reviewers assigned to the substance by the Joint Secretaries prior to the meeting.

5.4.2 During JECFA meeting

Comments made during the meeting should focus on scientific content and interpretation. Minor editorial suggestions (typographical errors, spelling and grammar) should be conveyed by e-mail to the senior author of a monograph or working paper for correction. All content of the draft monograph and summary documents should again be checked to ensure there are no

errors in transcription of data or interpretation introduced during document revisions. Information on issues discussed at the meeting is confidential and should not be discussed with anyone other than other members of the Committee and the Secretariat. All Committee assignments are to be completed in a timely fashion so that the work of the Committee can be completed within the scheduled dates for the meeting.

Invited experts (members and FAO experts) are expected to arrive for the meeting opening and remain in attendance until the formal closing of a JECFA Meeting. The primary responsibility of all participants is the work of the JECFA during the time period of the meeting and attempts to conduct work for their regular employer should be avoided except in emergency situations (in which case, the FAO Joint Secretary should be informed and arrangements made for another expert to lead discussions on the substance or any other JECFA assignment).

5.4.3 After JECFA meeting

Draft monographs are to be revised to reflect Committee decisions as contained in the meeting report and the final draft must be provided to the FAO Joint Secretary within a timeframe established during the JECFA meeting (typically 1 month after the meeting). A timely response is also required from authors of monographs or other working papers to any questions which arise during the finalization of these documents for publication by editors assigned by the FAO. Confidentiality must be maintained concerning Committee decisions until full reports are published.

5.5 Role of the Committee

All decisions on Committee policy and procedures, the establishment of ADIs and ARfDs, and MRL recommendations are decisions of the Committee, not of individual members. These are reflected in the Committee's meeting report, published in the WHO Technical Report Series.[11]

The Committee shall draw up and approve its report before the closure of its meeting. The focus of discussion should be on the accuracy of the scientific content of the meeting report, not on minor editorial issues which can be dealt with by the editors. Scientific questions shall not be submitted to a vote. If the members of a committee cannot agree, each shall be entitled to have her/his personal opinion reflected in the report; this statement of opinion shall take the form of an individual or group report, stating the reasons why a divergent opinion is held. (See: Regulations for Expert Advisory Panels and Committees.[10])

5.6 Call for data and process management

The FAO Joint Secretary, in co-ordination with the WHO Joint Secretary, will encourage the scientists involved with the evaluation of a particular veterinary drug to contact and co-operate with the other scientists involved with its review and to work with the WHO scientists on cross-cutting issues relating to toxicology and residues. Prior to the JECFA Meeting, the FAO Joint Secretary distributes draft monographs to the Sponsor (without the evaluation and appraisal section), who will be asked to review it for its technical accuracy. Comments received from the

[11] WHO. (2015) JECFA Reports, WHO Technical Report Series; available at http://www.who.int/foodsafety/publications/jecfa-reports/en/

Sponsor will be provided to the drafting expert and reviewer(s) who prepared the monograph so that any necessary revisions can be made. Shortly before the meeting the Joint Secretary will provide electronic copies of any revised working papers to all meeting participants.

6. Role of Sponsor

6.1 Responsibilities of Sponsor

A substance is placed on the priority list established by CCRVDF for evaluation at the request of a Codex member state. The dossier for most substances is prepared by a drug manufacturer, referred to as the Sponsor, which has made a commitment to the member state to prepare the dossier for evaluation. In a few instances, the dossier has been provided by a regulatory agency in the member state.

Data should be submitted by the deadline established by the Secretariat. Late submission may delay consideration to the following JECFA meeting devoted to the evaluation of residues of veterinary drugs in food. Submission by Sponsors of summaries of data using the working paper format described in the *Scientific guidelines for the preparation of veterinary drug residue monographs, working papers and related summary documents for Joint FAO/WHO Expert Committee on Food Additives (JECFA) drafting experts and reviewers assigned by FAO* (Module II), is encouraged, but such summaries are not sufficient in themselves for an evaluation to be conducted by the Committee. Dossiers submitted by a Sponsor should include the full reports of all studies cited in the summary report they provide with the dossier. All reports must be complete, should include a statement of GLP status and must include the detailed data generated during the experimental phase of the study (i.e., the "raw data"). Dossiers should be submitted as follows: one copy going to the JECFA Secretariat at FAO Headquarters, one to each expert who is preparing the working paper. The Sponsor should obtain the addresses of the drafting experts from the FAO Joint Secretary. If the Sponsor wishes to have the dossiers returned at their expense after they have been used by JECFA, this should be stated at the time of submission.

Sponsors should submit all appropriate relevant data, and not just those necessary to comply with the data requirements. The Sponsor should respond promptly and fully to any requests relayed by JECFA experts or the Committee through the Joint Secretary for additional information or for clarification of data provided for review.

6.2 Relationship between the Secretariat, drafting experts, reviewers and Sponsors

It is important that Sponsors' information and views relevant to their submissions are fully taken into account, while at the same time it is important that JECFA's evaluations of the data are not influenced or inhibited by actions or views of the Sponsors. To ensure transparency, it is important that all contacts between the drafting expert (or reviewer) and the Sponsor are documented and copied to the FAO Joint Secretary. To accommodate these requirements, the following procedures for the interaction of drafting experts and reviewers with Sponsors have been established to ensure the transparency of the process:

- Direct interaction is encouraged, but must occur in a transparent fashion and with full knowledge and agreement of the FAO Joint Secretary.
- The drafting experts and reviewers may contact the Sponsor for clarification of issues, copying/keeping informed the FAO Joint Secretary.
- It is preferable to use e-mail rather than telephone for such contacts. The FAO Joint Secretary should be copied in any correspondence with the Sponsor. If a teleconference is requested or considered useful, the drafting expert (or reviewer) should involve the FAO Joint Secretary, who will set up the call.
- Copies of all exchanges of information and correspondence, including memoranda of telephone conversations, should be sent by the drafting experts 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 otherwise contact a drafting expert or reviewer except to inform him/her that additional information is available. Any other information that the Sponsor wishes to convey should be sent to the FAO Joint Secretary.
- The Sponsor should not contact the drafting expert (or reviewer) with repeated requests for progress updates or for information that is not appropriate to be shared, such as the draft proposal for MRLs; if this occurs, the drafting expert (or reviewer) should notify the FAO Joint Secretary.
- The Sponsor should have no contact regarding issues on the agenda of any JECFA Meeting with other members or experts invited to a JECFA Meeting by the FAO unless specifically requested to do so by the FAO Joint Secretary. The drafting experts and reviewers should report to the FAO Joint Secretary any undue industry pressure. The Secretariat will then consult with the FAO legal Office for guidance on appropriate actions to take.

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

The Secretariat may contact the Sponsor before and/or during the JECFA Meeting to request a response to questions which have arisen during the review of a substance by the Committee. Responses to these questions will usually be provided by e-mail in electronic format, but the Secretariat may make other arrangements (e.g., teleconferences, videoconferences), as appropriate.

7. Confidentiality issues

Rule 1 of the Regulations for Expert Advisory Panels and Committees states that the meetings of expert committees shall normally be of a private character.[12] They cannot become public except by the express decision of the committee with the full agreement of the Director--General. The need for confidentiality is also stated in the FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition.[1]

[12] Regulations for Expert Advisory Panels and Committees, http://apps.who.int/gb/bd/PDF/bd47/EN/regu-for-expert-en.pdf

The following statement defines the policy of the CCRVDF on the treatment of confidential information provided to enable JECFA to conduct a risk assessment:

> "The CCRVDF takes into account the protection of confidential information in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - Section 7: Protection of Undisclosed Information - Article 39, and makes every effort to encourage the willingness of Sponsors to provide data for JECFA assessment." (See the "Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods" in the Codex Alimentarius Commission Procedural Manual.[4])

When a Sponsor makes available unpublished proprietary data for evaluation, the Joint Secretary safeguards the data from unauthorized disclosure. To ensure that the copies sent to the drafting experts are safeguarded, they are requested to acknowledge in writing that they accept the conditions that have been laid out for their use and storage. The drafting expert must safeguard all proprietary data and 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, the drafting expert must either return the data file to the 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. When the data provided to the FAO Joint Secretary are no longer needed by JECFA, the data files are returned at the Sponsor's expense or destroyed, depending upon the wishes of the Sponsor. Data are usually kept by the Secretariat for five years.

8. Limitations

Participants (members and FAO experts) should not engage the assistance of staff within their home organization or other colleagues or scientific contacts to directly assess any contents of a dossier provided in confidence by a Sponsor. Experts may engage in general discussion of scientific approaches to data evaluation with experts who are not current members of the Committee, but specifics of the dossier must not be discussed or shared, except with other members of the JECFA and the Secretariat. Any member or consultant who needs guidance in a specific situation should consult the FAO Joint Secretary.

9. JECFA Publications

There are usually four publications prepared from each JECFA meeting. These include:

- A summary report giving the key conclusions by the Committee, published rapidly after the meeting, placed on the webpages of both Secretariats and circulated via Codex mailing lists (available at http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/summary-reports/en/).)

- The meeting report published by WHO in the Technical Report Series (available at http://www.who.int/foodsafety/publications/jecfa-reports/en/).

- The Compendium of residue monographs, prepared by the FAO experts, published by FAO in the FAO JECFA Monographs series (available at

http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-publications/en/). Individual residue monographs can also be accessed through the “Online Edition: "Residues of some veterinary drugs in foods and animals" (available at http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-vetdrugs/en/).

- The collection of toxicology monographs, prepared by the WHO experts, published by WHO in the WHO Food Additive Series (available at http://www.who.int/foodsafety/publications/monographs/en/)

It is highly recommended that experts new to JECFA review recent JECFA publications to familiarize themselves with current issues on JECFA policy and with the style and format of reports.

Annex 1.

Procedures for placing veterinary drugs on the agenda for a JECFA Meeting

Requests for the evaluation of certain veterinary drugs and consideration of issues of a general nature by JECFA may come from a number of sources:

1. Codex committees

The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) refers substances to JECFA at Step 2 of the Codex Process based on priorities that it establishes using criteria that it has developed that are in accord with accepted procedures of the Codex Alimentarius Commission (CAC). The initial recommendation from JECFA is received by CCRVDF at Step 3 of the Codex Process. A substance may be held at Step 3 by CCRVDF, pending a request for further evaluation by JECFA, or at any subsequent step prior to Step 8. At times, CAC can also directly request JECFA for further evaluation while holding MRLs for a substance at Step 8, the final step in the Codex Step Process for adoption of a Codex MRL.

2. FAO and WHO Member States

FAO and WHO Member States may request the inclusion of veterinary drugs 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 meeting. In such cases, the result of the JECFA evaluation is provided to the member state and may also enter the Codex Step Process for the establishment of MRL at Step 3 through the JECFA report to CCRVDF. Therefore, it is more appropriate for a member state to make such requests through the priority list established by CCRVDF (request to JECFA at Step 2 of the Codex Step Process, JECFA recommendations to CCRVDF at Step 3).

3. Sponsors

For veterinary drugs not previously evaluated by JECFA, an industry Sponsor may forward a request for evaluation through the government of a Member State to CCRVDF, with a commitment to provide the relevant data (request to JECFA at Step 2 of the Codex Step Process, JECFA recommendations to CCRVDF at Step 3). Requests for the re-evaluation of a veterinary drug that has been previously reviewed by JECFA should also follow this process for inclusion on the Priority List established by the CCRVDF. Such requests may be made while the substance is still progressing through the Codex Step Process or, when there are existing Codex MRLs for the substance, through placement on the CCRVDF priority list (Step 2).

When JECFA has been unable to complete an evaluation and has requested a Sponsor to provide additional information for further consideration at a future JECFA Meeting, the evaluation process by JECFA is considered to remain active. The request for additional information specifies a date by which such information must be provided to JECFA, typically 1-3 years from the date of the initial evaluation. Such submissions may be made directly to the JECFA Secretariat by the Sponsor within the timeframe established by JECFA for the submission of the additional information. The substance will be usually be included in the agenda for the next scheduled meeting of JECFA dealing with veterinary drug residues in foods, provided the information is submitted within the deadline for submission established by the JECFA Secretariat in the Call for Data for that JECFA meeting. However, if such

information is not provided to JECFA within the timeframe established in JECFA's request for additional information and there is no indication from the Sponsor that such information will be provided, the further evaluation of the substance is then subject to a request to JECFA from the CCRVDF via the Priority List.

4. JECFA Secretariat

The JECFA Secretariat may place a veterinary drug on the agenda for re-evaluation even though no outside request has been received. Such re-evaluations are undertaken when the Secretariat considers that there is new information which may be relevant to the consideration of previous MRL recommendations made by JECFA. The results of such evaluations are provided to CCRVDF in the JECFA meeting report and any MRL recommendations may be considered by CCRVDF at Step 3 or a subsequent step, if appropriate.

5. JECFA itself

The Committee may establish a temporary ADI or recommend temporary MRLs, with a request for further data by a certain date. These veterinary drugs, which have the highest priority for evaluation, are placed on the agenda of the appropriate meeting by the Joint Secretariat. Temporary MRL recommendations from JECFA are typically held at either Step 3 or Step 5 of the Codex Step Process by CCRVDF.

Annex 2.

Procedures for issuing the call for data

The Joint Secretariat issues a call for data on the veterinary drugs 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 of this guidance document. 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, the JECFA Secretariat will have received a confirmation 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 FAO are sent to them.

When a Sponsor makes available unpublished proprietary data for evaluation, the Joint Secretary and the drafting experts 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 veterinary drug 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. Under this circumstance the veterinary drug will normally be placed on the agenda of a later meeting for evaluation.