



Food additives

FAO guidelines on the structure and content of the document called "Chemical and Technical Assessment (CTA)"

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Introduction

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluates the safety of food additives that may be present in foods. As a part of these evaluations, the Committee found it useful, for each additive on its agenda, to have before it an informal internal document known as a *Technical Data Sheet*. This document, prepared by the committee expert assigned responsibility for preparing the specifications of identity and purity for the additive, usually contained a summary of the chemistry of the additive, its manufacture, its technological justification and its intended use levels and patterns.

During its 59th meeting, the Committee discussed the usefulness of the *Technical Data Sheet* and the role of specifications as part of the risk assessment process and concluded that

- the development of specifications is an integral part of the risk assessment of food additives;
- drafting of specifications require data on the manufacture and the composition of an additive at all steps of its development and safety testing;
- information on the technological functions and the current and intended uses is needed;
- the output from the risk assessment includes the specifications which relate to the material that was evaluated and to the product to be marketed;
- specifications should be continuously reviewed to account for changes in the manufacturing process, the use, and consumer intake of the additive.

Considering these conclusions, the FAO Joint Secretariat has adapted the format and structure of the *Technical Data Sheet* and renamed it as the *Chemical and Technical Assessment (CTA)* with the intention of making this document publicly available. The *CTA* will reflect and emphasise the role chemical characterization plays in the risk assessment of food additives. The following guidelines are addressed to sponsors, experts participating in meetings of JECFA, users of specifications and any other interested party.



They shall be read in conjunction with *the FAO procedural guidelines for food additives and food contaminants**.

Publication policy

The former *Technical Data Sheets* for food additives were used as internal Committee documents, in part, because detailed information on manufacturing processes could contain commercially sensitive data. Since all other deliberations of the Committee are publicly available, it was decided to make the *Chemical and Technical Assessments* available, as well; this requires that the legitimate interest of a manufacturer in protecting intellectual property will not be violated. The drafting expert responsible for preparing a CTA will identify those sections of a confidential nature and the Secretariat will ensure their removal before publication. This new publication policy will be enforced from the 61st meeting onwards. The CTAs will be available at the FAO JECFA website for download only; it is not anticipated to publish them in print.

General guidance to drafting experts

Guidance for the evaluation of food additives is available from the *Principles for the Safety Assessment of Food Additives and Contaminants in Food* (published as Environmental Health Criteria 70). Drafting experts preparing the CTAs are expected to pay specific attention to section 4 titled *Chemical Composition and the Development of Specifications*. Other important documents for consideration include the general notices and introductory sections of the *Compendium of food additive specifications* (FAO Food and Nutrition Papers 52, two volumes) and the *Guide to specifications* (FAO Food and Nutrition Papers 5 Rev.2). Additions and amendments since 1991 are available for both publications in the addenda to FNP 52.

Experts should as well consult documents from previous meetings of JECFA which can be identified using the on line edition of the *Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives* (available at <http://jecfa.ilsa.org>).

Experts are encouraged to perform their own literature research on the additive in question; limited assistance for this may be available from the Joint Secretariat at FAO.

Experts should follow the *FAO House Style* when preparing the draft document (available at www.fao.org/publishing) and use standard Word text-processing software.

In case of doubts or questions the experts should contact the FAO Joint Secretariat.

Structure of the Chemical and Technical Assessment (CTA)

All *Chemical and Technical Assessments (CTA)* should be written according to the following layout. A more detailed suggestion for structure is attached as an Annex of this document; authors are encouraged to apply this substructure where appropriate:

- Section 1: Summary
- Section 2: Description
- Section 3: Manufacturing
- Section 4: Chemical characterization
- Section 5: Functional use
- Section 6: Reactions and fate in foods
- Section 7: References

Sponsors of data are encouraged to submit their data package using the above format.

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



Comments on individual sections

1. Summary

This section forms the basis for the introductory paragraph of the safety evaluation of the additive in the report of a JECFA meeting (published as *WHO Technical Report Series*). All important elements from the *CTA* will be summarized using language understandable to a broader audience. The reports from JECFA meetings are the main communication tool of the Committee. They are intended to address a rather broad audience, among them risk managers, consumers, scientists, and food manufacturers, in both developing and developed countries.

2. Description

The following issues may be reviewed, as applicable: chemistry and nature of the product; historical use; development; natural vs. synthetic origin; related and competitive products. On a case-by-case basis other issues may be added.

3. Manufacturing

This section will normally be divided into two parts. The first part will describe the principle of the manufacturing process. When preparing this short text, the drafting expert or the Joint Secretariat may consult the sponsor to ask whether the proposed description potentially contains proprietary information.

The second part, which is crucial to the evaluation, yet which shall be considered confidential and shall not be published, will contain a detailed description of the manufacturing process. The drafting expert will give specific attention to the nature and quality of raw materials, the intermediates, and the quality assurance during manufacturing. The drafting expert will also provide an overall assessment of the manufacturing process, which will include an assessment of the feasibility of manufacturing the product in food grade quality as described in the proposed specifications.

4. Chemical characterization

This section constitutes the core of the *CTA*. It serves two main purposes: first, to advise the toxicologist on potential issues arising from the chemical nature of the additive and second, to justify the proposed specifications for the food additive as it will be put into the marketplace.

In preparing the *CTA*, the drafting expert is expected to analyse all available information on the manufacturing process for the product and on the composition and quality of the product during development and as intended for marketing. In particular, for products that have been in use for a long time (e.g., many natural extracts), changes in manufacturing processes and in their quality over time should be considered. Possible differences in the quality of product batches used in toxicological studies need to be assessed and discussed critically. When discussing composition and potential impurities, the expert should address the issues that may be of relevance to the hazard identification.

The proposed criteria for purity and quality will be justified in detail in the *CTA*; enough information will be provided to allow the reader to understand the decision-making process. In this work, the drafting expert is expected to take into account previous decisions of the Committee on related compounds, consider the use of analytical methods that have been agreed by previous meetings (published in FAO Food and Nutrition Paper 5 Rev. 2 and 52 plus addenda, both available at www.fao.org/es/esn/jecfa), and the work of other standard setting bodies like the Food Chemicals Codex or the European Pharmacopoeia. Structure and format for the proposed specifications shall follow the guidance provided by the *General Notices Applying to the Standards, Tests and Assays of the Specifications Prepared by the Joint FAO/WHO Expert Committee on Food Additives* (FNP 52 Vol.1 pp 1-7).

Note: the proposed specifications are prepared as a separate stand-alone document.



5. Functional use

The safety evaluation of a food additive also includes an assessment of the proposed uses of the additive with respect to its efficacy and to possible undesirable effects on the food itself and an assessment of exposure of the consumer to the additive. The total consumer exposure depends on the foods in which the additive is used and the use level in these foods.

The *CTA* will first describe the technological function(s) of an additive in a manner that provides the reader (specifically, risk managers) with general information about the justification for its use. The basic food categories (e.g. soft drinks, baked goods) to which the substance might be added and the ranges of concentrations to achieve the desired technological effect will also be described. Any self-limiting conditions of use, as is sometimes expected for, e.g., sweeteners or colours, will be noted. Usually such descriptions are based on testing data obtained from model food systems or trial batches from marketed foodstuffs.

As noted above, consumer exposure to a food additive depends on the foods to which it is added and on its levels of use. Therefore, the drafting expert will give further and more detailed consideration to the food categories in which the additive may be used and to the corresponding use levels. In assigning a particular food category for use of an additive, the drafting expert will use the food categories of the General Standard for Food Additives of the Codex Alimentarius Commission. The drafting expert will exercise care to assign food categories that are unambiguous and sufficiently precise to reflect the current and intended market. If it appears that an initial category assignment is too broad, the expert may rely on information, if available, on the probability of the use of the additive in a specific food or food sub-category (e.g., use of the additive is prohibited or not foreseen for fresh vegetables). In preparing this discussion, the drafting expert will take into account the submission for the sponsor, any established use in the market, and other information available in literature.

6. Reactions and fate in foods

Substances added to food may react with other components of the food matrix or with environmental constituents. Based on data submitted by the sponsor, from literature research, and with knowledge of related compounds, the drafting expert will include in the *CTA* any potential hazards that might occur due to the use of a food additive after being added to food. Information on the chemical, thermal, and photo-stability of the additive when added to the proposed food categories may be of importance.

7. References

All documents used when preparing the *CTA* will be listed as full references at the end of the document. Style and format for the bibliography and its use in the text shall follow the *FAO House Style* (available at www.fao.org/publishing).



Annex (Recommended structure of the CTA)

**[Proposed name of the food additive]
Chemical and Technical Assessment (CTA)**

First draft prepared by NN

1. Summary
2. Description
3. Manufacturing
 - 3.1. Manufacturing principle
 - 3.2. Detailed description (confidential)
4. Chemical characterization
 - 4.1. Composition of the food additive
 - 4.2. Possible impurities (including degradation products)
 - 4.3. Analytical methods
 - 4.4. Rationale for proposed specifications
5. Functional use
 - 5.1. Technological function
 - 5.2. Food categories and use levels
6. Reactions and fate in foods
7. References



Editorial note:

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Note: The 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