The role of JECFA for CCFA

How does JECFA perform safety assessments: scope, data needs, process and outcome

Angelika Tritscher, WHO Secretary JECFA
Markus Lipp, FAO Secretary JECFA

Food and Agriculture Organization of the United Nations

World Health Organization

Overview

- Introduction
- Toxicological assessment
- Development of specifications
- Exposure assessment
- Output from JECFA consultation
- How it works in practice
- Q&A

CODEX ALIMENTARIUS

Standards need to be based on science and be implemented and useful to governments and food chain operators

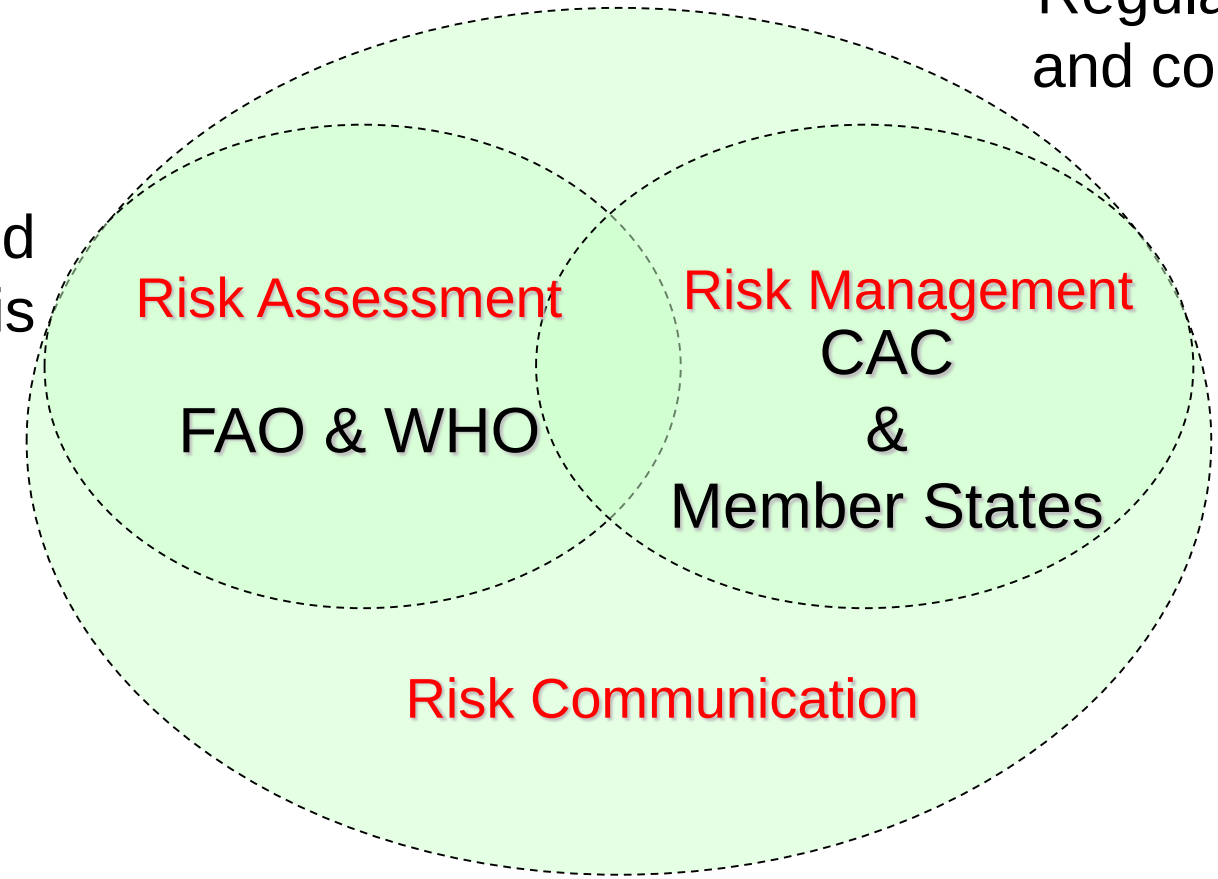
Food and Agriculture Organization of the United Nations

World Health Organization

Risk Analysis Paradigm

Regulation and control

Scientific advice and information analysis



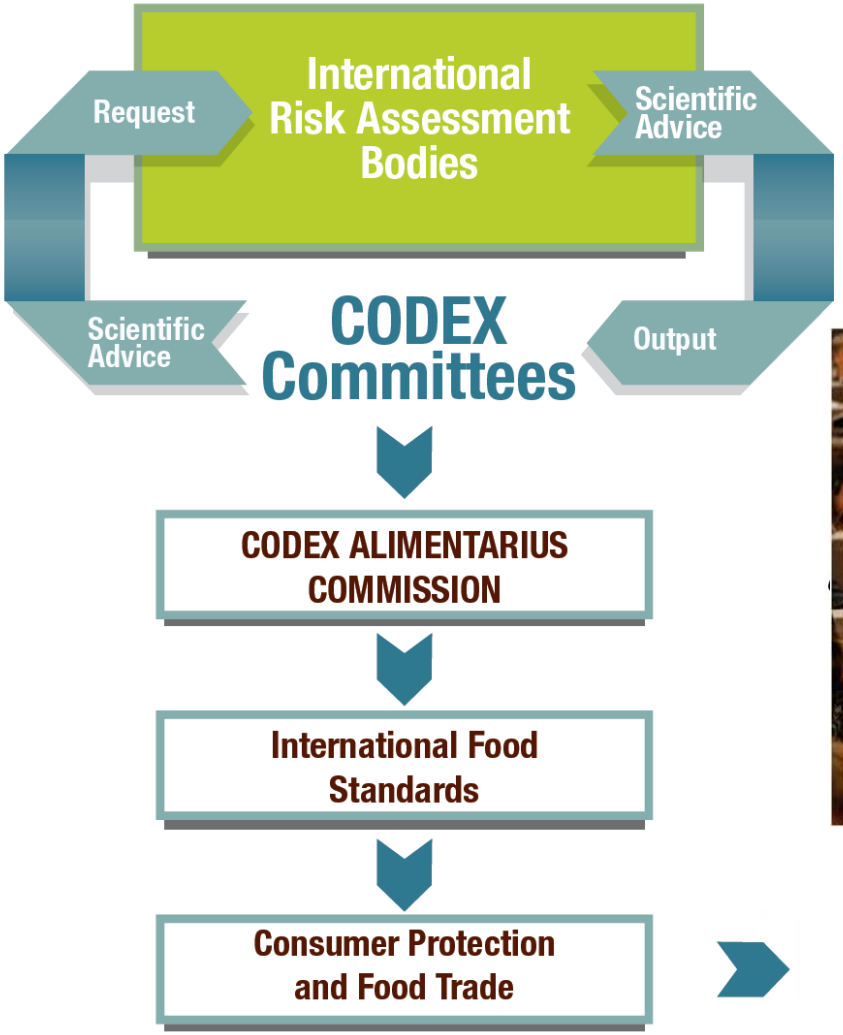
Dialog with all stakeholders

Food and Agriculture Organization of the United Nations

World Health Organization

The Scientific Basis of Codex

Joint FAO/WHO Scientific Advice Programme



Food Safety
Health/Nutrition Claim/Labelling
Fortification – Food for Special Dietary Uses
Safety Assessment of Novel Technologies

JECFA Areas of Work

- Risk assessment/safety evaluation of:
  - Food Additives
  - Processing aids (considered as food additives)
  - Flavouring agents (by groups of related compounds)
  - Contaminants
  - Natural toxins
  - Residues of Veterinary Drugs in animal products
- Specifications and analytical methods
- Residue definition, MRL proposals (veterinary drugs)
- Development and improvement of general principles

JECFA Output

- Summary Report:
  - Electronic summary containing only basic conclusions
- Report:
  - Concise summary of relevant information for evaluation and conclusion, including intake estimates
- Monographs:
  - Detailed description and evaluation of all available data used in evaluation
  - (1) Toxicological Monographs
  - (2) Specifications etc.

JECFA database

http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx

World Health Organization

Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

This searchable database contains the summaries of all the evaluations of flavours, food additives, contaminants, toxicants and veterinary drugs JECFA has performed. Each summary contains basic chemical information, ADIs/TDIs, links to the most recent reports and monographs as well as to the specification database, and a history of JECFA evaluations. The database is searchable by partial name or CAS number, by first character (letter or symbol), or by functional class.

Includes all updates up to the 79th JECFA (June 2014).

Partial Name/CAS | **First Character** | **Functional Class**

Flavouring Agent

flavouring_agent

Food Additives

acid acidity_regulator adjuvant adsorbent anticaking_agent antifoaming_agent antioxidant antioxidant_synergist bleaching_agent bulking_agent carrier carrier_solvent chewing_gum_base_compound clouding_agent colour colour_retention_agent emulsifier emulsifying_salt enzyme_preparation extraction_solvent filtering_aid firming_agent flavour_enhancer flour_treatment_agent foaming_agent food_additive freezing_agent gelling_agent glazing_agent humectant leavening_agent lubricant neutralizing_agent nutrient_supplement preservative processing_aid propellant raising_agent release_agent salt_substitute sequestrant stabilizer sweetener synergist tableting_aid texturizer thickener yeast_food

Food Contaminant [all]

contaminant metals mycotoxin naturally_occurring_toxicant radionuclide

Veterinary Drug [all]

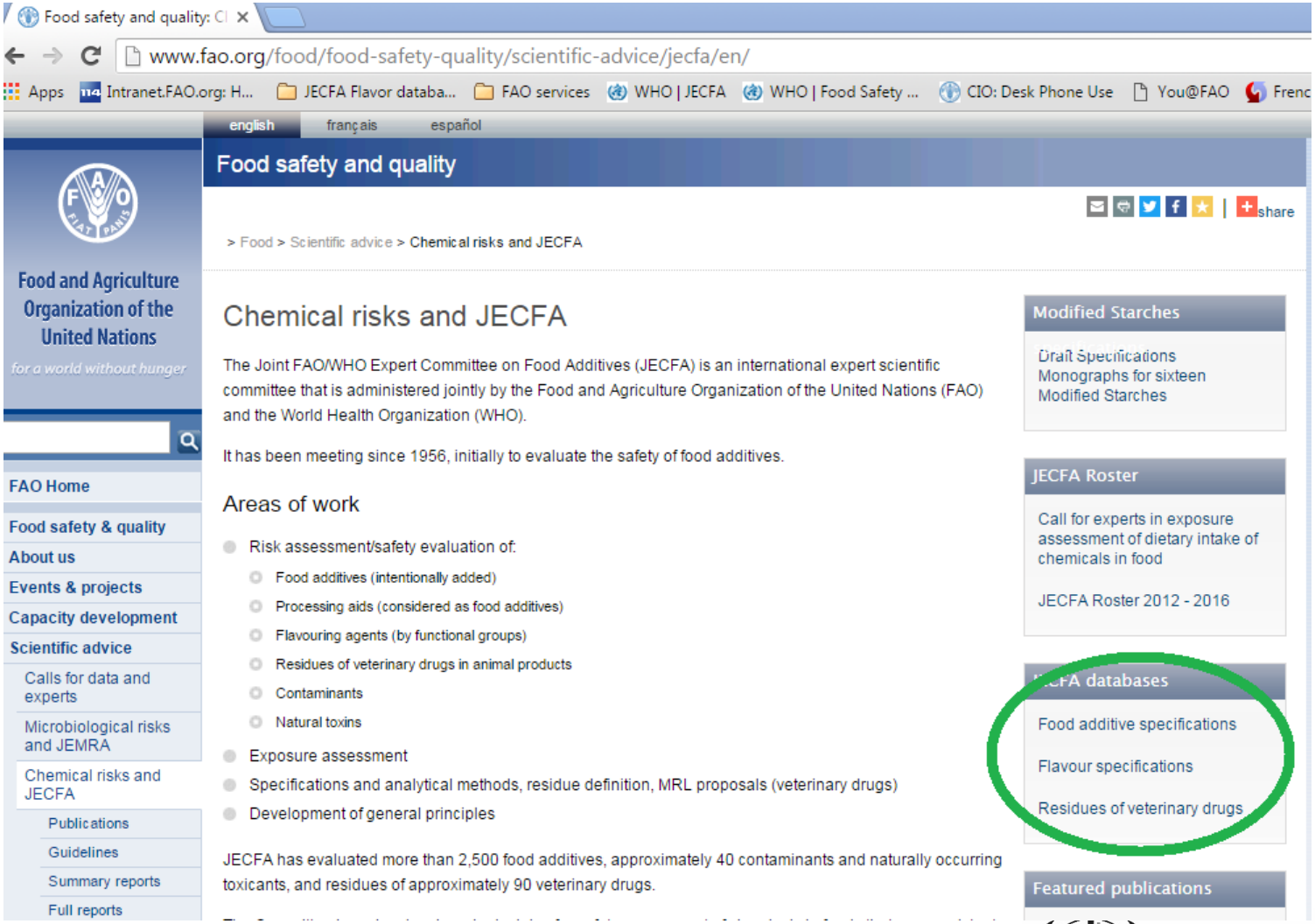
adrenoceptor_agonist anthelminthic_agent antifungal_agent antimicrobial_agent antiprotozoal_agent beta-adrenoceptor_blocking_agent glucocorticosteroid growth_promoter insecticide production_aid tranquillizing_agent trypanocide veterinary_drug

Food and Agriculture Organization of the United Nations

World Health Organization

FAO database

http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/

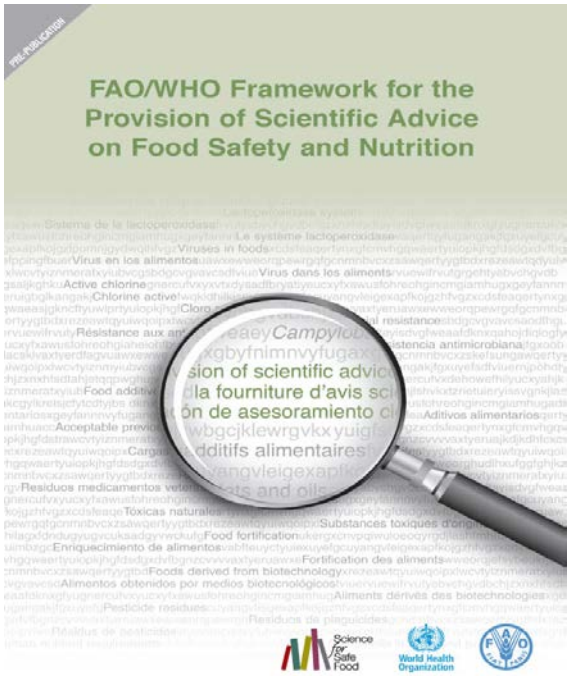


Food and Agriculture Organization of the United Nations

World Health Organization

Standard Process

- Identification and prioritisation of issues
- Call for data
- Selection of experts
- Meetings coordinated by FAO/WHO Secretariat
- Final reports adopted at end of each session
- Distribution and subsequent use of the expert advice

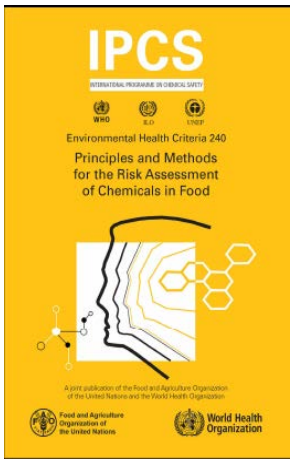


ftp://ftp.fao.org/docrep/fao/010/a1296e/a1296e00.pdf

Principles and Methods

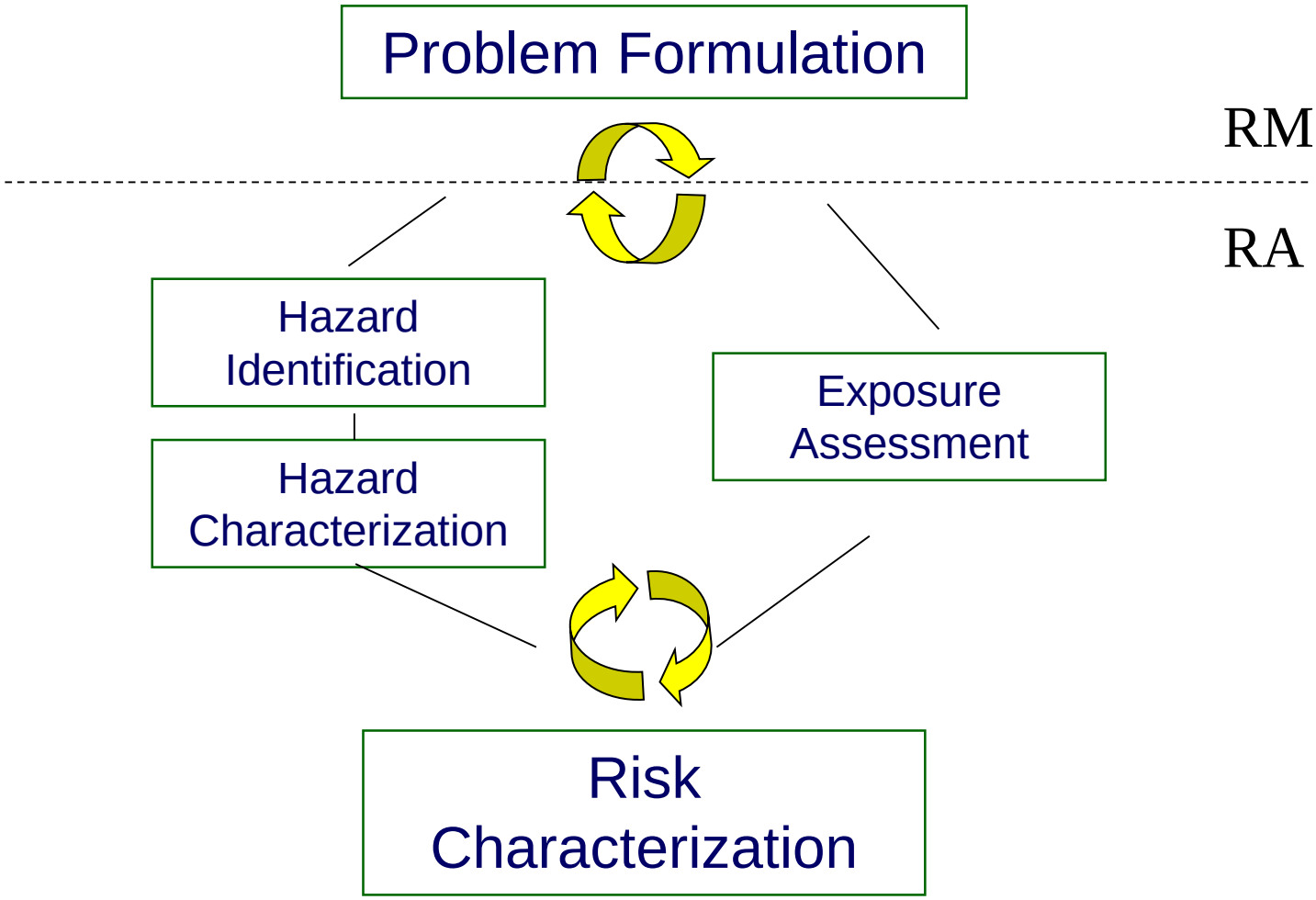
http://www.who.int/foodsafety/chem/principles/en/index1.html

EHC 240: Principles and methods for the risk assessment of chemicals in food, WHO 2009



- Updated principles and methods
- Compiled all guidance developed by JECFA and JMPR since EHC 70 (1987) and EHC 104 (1990)
- Harmonize methods to the extent possible

Risk Assessment: A Scientific Process



World Health Organization

Hazard Assessment
Toxicology & epidemiology

Assessment Procedure

- Identification of critical endpoint/effect and critical study/data set
  - most sensitive species, most sensitive endpoint of relevance to humans, most relevant epidemiological study
- Identification of the Point of Departure (POD)
  - No/Low Observed Adverse Effect Level (N/LOAEL), Benchmark Dose (BMD, BMDL)
- Identification of uncertainties, assignment of uncertainty/safety factors
- Outcome: ADI, 'no safety concern',

Toxicological assessment – Data needs

- Biochemical data: e.g. metabolism
- Toxicological data:
  - in vitro and in vivo data to identify potential adverse health effect, dose–response relationships, mode of action
- Studies need to be undertaken with specific food additive intended for commerce, i.e. material tested needs to be clearly defined
- Comprehensive data set needs to allow characterization of toxicological profile to evaluate potential human health impact (simple in vitro test on cell toxicity is insufficient)

Toxicological assessment (cont'd)

Generally required are:

- metabolism and pharmacokinetic studies
- short–term toxicity, long–term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies
- epidemiological studies
- special studies designed to investigate specific effects, e.g. mechanism of toxicity, immune responses, or macromolecular binding

Tox Example: Cassia gum

Table of content from "WHO food additives series 62"

- Explanation
- Chemical and technical considerations
- Biological data
  - Biochemical aspects
  - Toxicological studies
  - Acute toxicity
    - Short-term studies of toxicity
    - Long-term studies of toxicity and carcinogenicity
    - Genotoxicity
    - Reproductive toxicity
  - Observations in humans
- Dietary exposure
  - Use in foods
  - Dietary exposure estimates
- Comments
  - Toxicological data
  - Assessment of dietary exposure
- Evaluation
- References

Specifications

Technological data:

- Specify in detail the exact nature of the compound
  - Chemical structure(s), CAS identifiers, etc
  - Production method incl. use of solvents, catalysts, etc
- Define appropriate analytical methods,:
  - to clearly define the material in commerce and compare with the material tested toxicologically
  - To measure any relevant impurities

Specifications cont'd

In particular the following information is need:

- A discussion of chemical composition, including natural variability of parameters and all potential impurities (natural occurring or through manufacturing process)
- A discussion in how this new product has chemical parameters that would allow its identification and be suitable to distinguish this new product from other similar products that are already in the market
- A discussion about the novelty or benefits from a technological point of view (what new and unique features make it necessary to introduce this on the market)

Relationship between the ADI and specifications: 69th JECFA report

Specifications are a necessary product of Committee evaluations:

- to identify the substance that has been biologically tested
- to ensure that the substance is of the quality required for safe use in food
- to reflect and encourage good manufacturing practice

Changes in specifications (impurities; composition) may raise questions on the material tested toxicologically

Exposure Assessment

Exposure = level in foods x amounts of foods consumed

- Information in which foods or food groups the additive is used and at which use levels
- Average and high consumption pattern

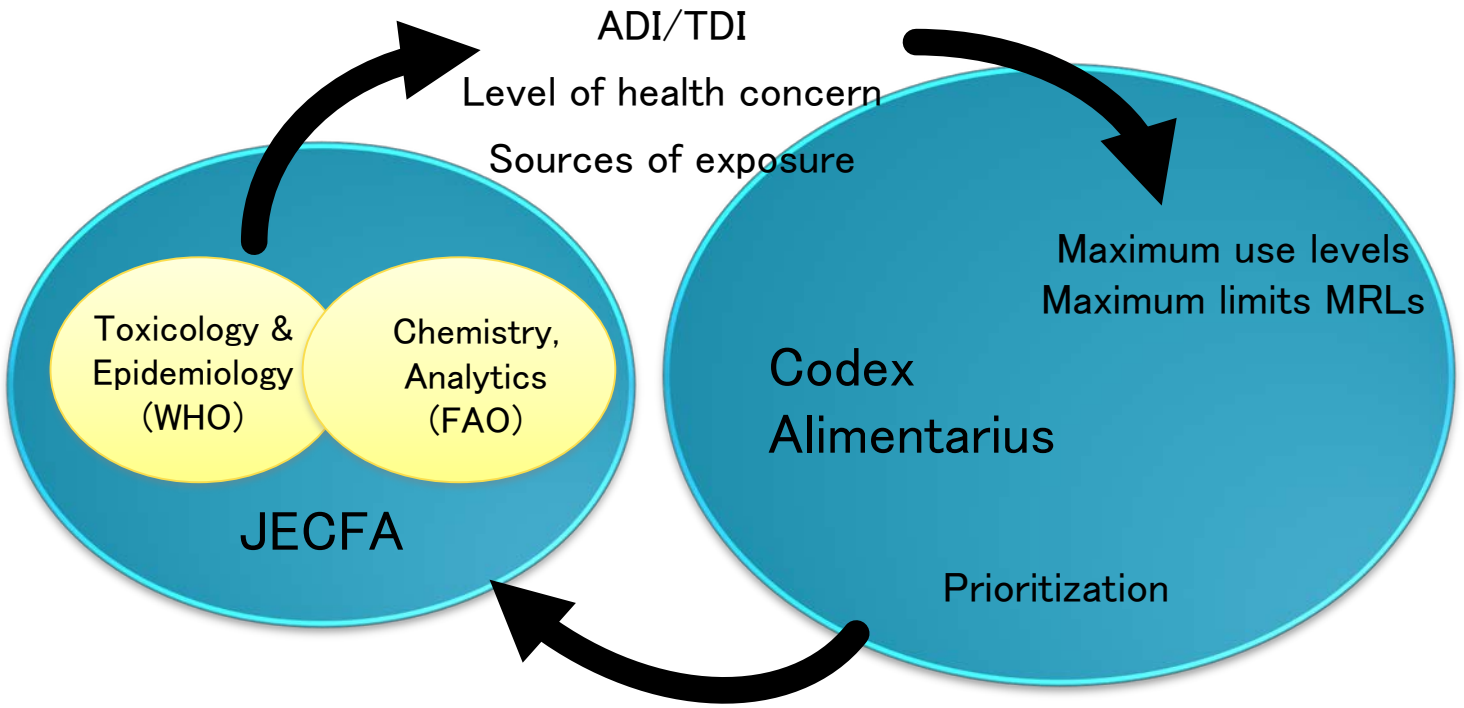
Exposure assessment cont'd

- Technical levels of use of the additive in the foods in which it may be used;
- Annual poundage of the additive introduced into the food supply;
- Estimation of additive intakes based on food consumption data for foods in which the additive may be used;
- Food consumption patterns; also considering different (age–) population groups

How it works in practice

- Requests for scientific advice: CCFA prioritization working group
- Technological necessity of additive on priority list needs to be demonstrated
- Responsibility of requestors
- JECFA workplan and calls for data
- Timelines
- Data need to be available
- Sponsors need to respond to call for data (we need sponsor's help)

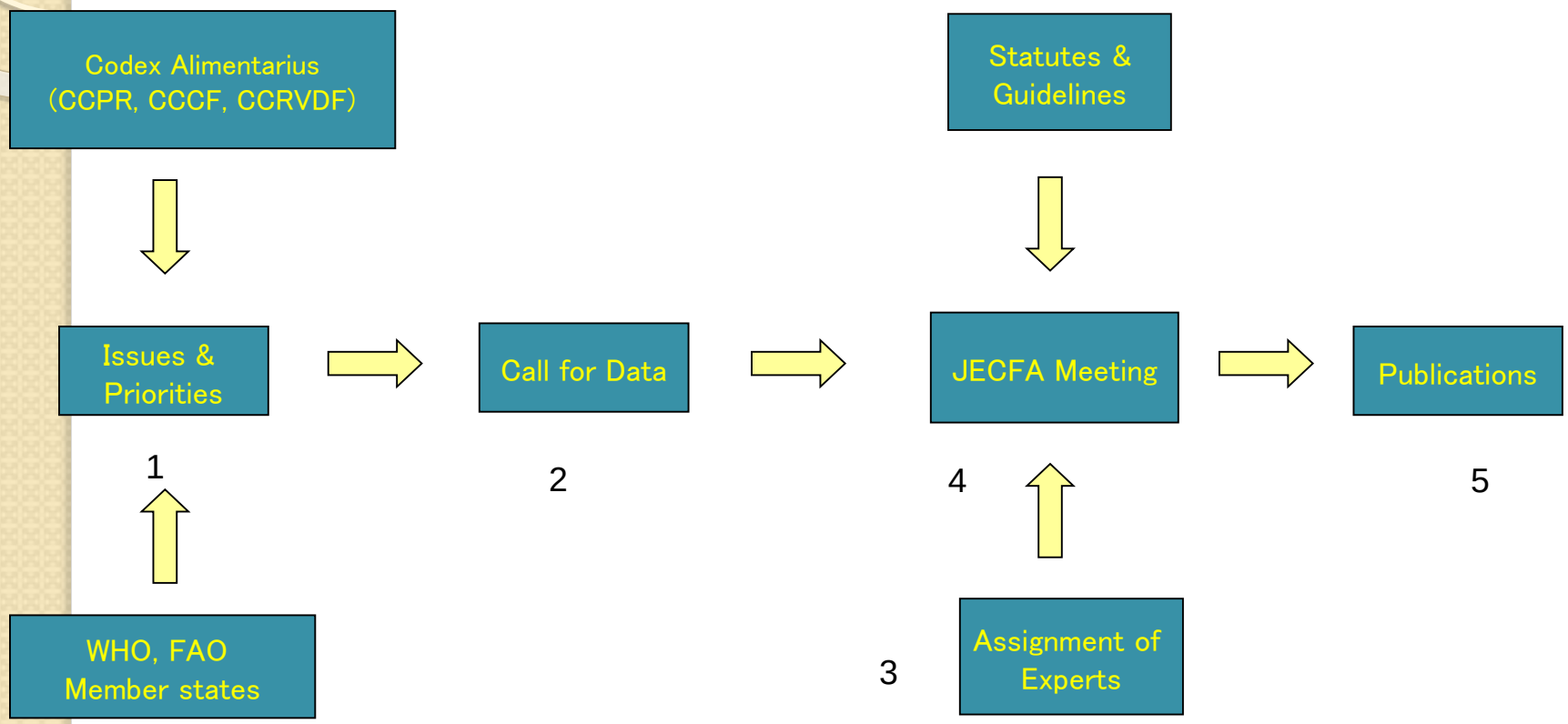
General procedure



FAO/WHO Secretariat to schedule meetings and set agenda

World Health Organization

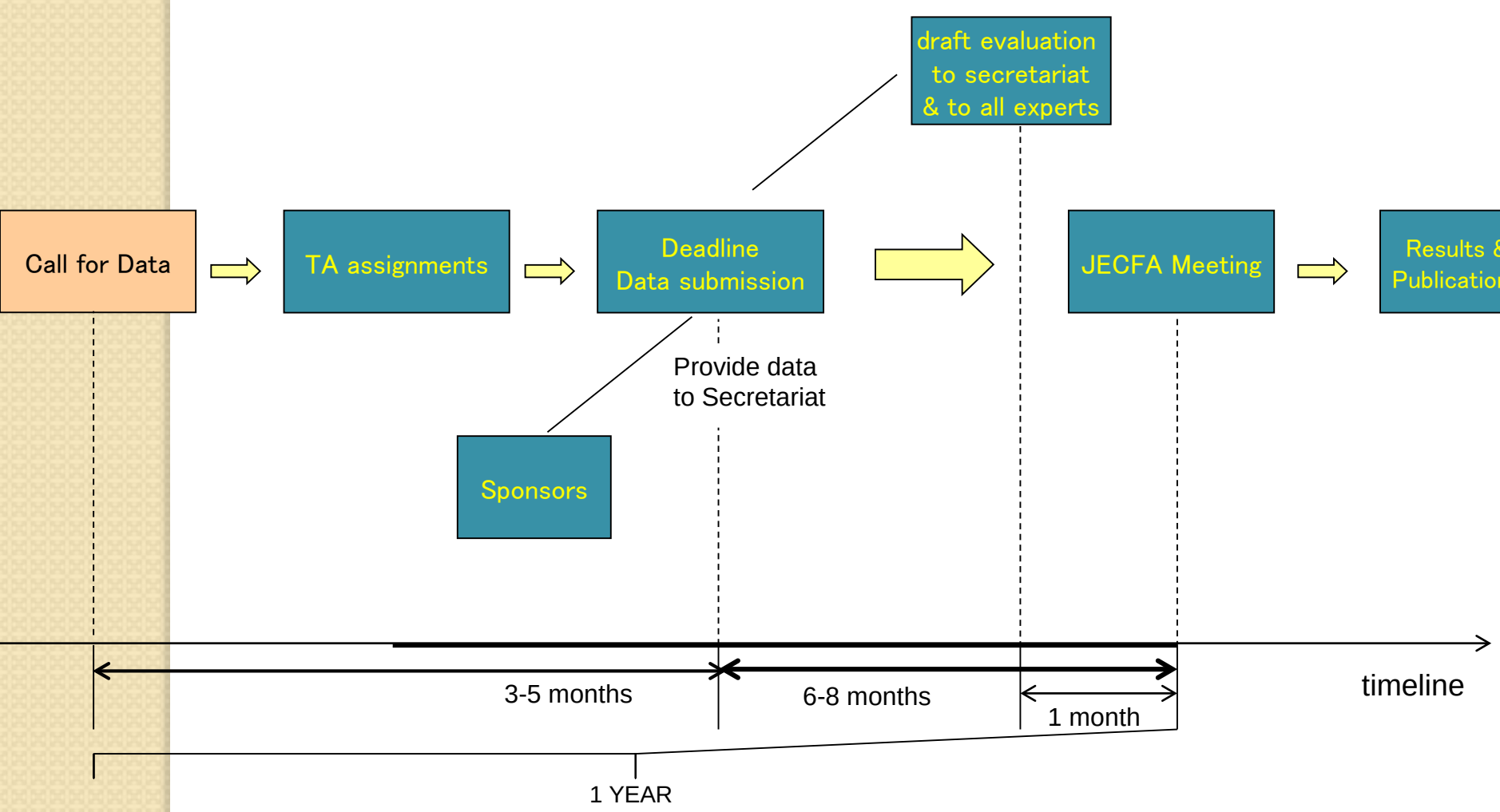
JECFA: general process flow



Food and Agriculture Organization
of the United Nations

World Health
Organization

JECFA: general time lines



World Health Organization

JECFA-CCFA: process flow and time lines

Example

82nd JECFA Meeting	June 2016
Requests for evaluation: 46&47th CCFA	2014&15
Final agenda and call for data published	August 2015
Deadline for data submission	December 2015
Draft monograph to experts	Mai 2016
Meeting	June 7-16, 2016
Summary report	end June, 2016
Report	6-8 months post meeting
Monograph	8-9 months post meeting

World Health Organization

What does it mean for you?

- If you request assessment: make sure there is a commitment by data owner to submit relevant and sufficient data to JECFA
- Agreed priority list:
  - Make sure the information is provided to relevant parties in your country (CCP but also data holders)
- JECFA call for data: distribute to relevant parties
- JECFA Secretariat is the primary point of contact (not Codex Secretariat)

Thank you!!
Questions??

Angelika Tritscher: tritschera@who.int

Markus Lipp: markus.lipp@fao.org