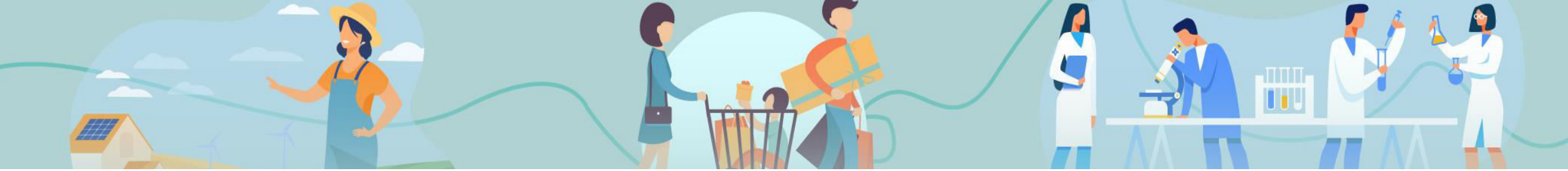

PARMA SUMMER SCHOOL

28 – 30 SEPTEMBER 2022, Parma

Risk Assessment of regulated products

JECFA, its role and contributions to CCFA

Angeliki Vlachou, Food Safety Officer, FAO,
Secretary JECFA

efsa European Food Safety Authority

UNIVERSITÀ DI PARMA 3S A N SCHOOL OF ADVANCED STUDIES ON FOOD AND NUTRITION

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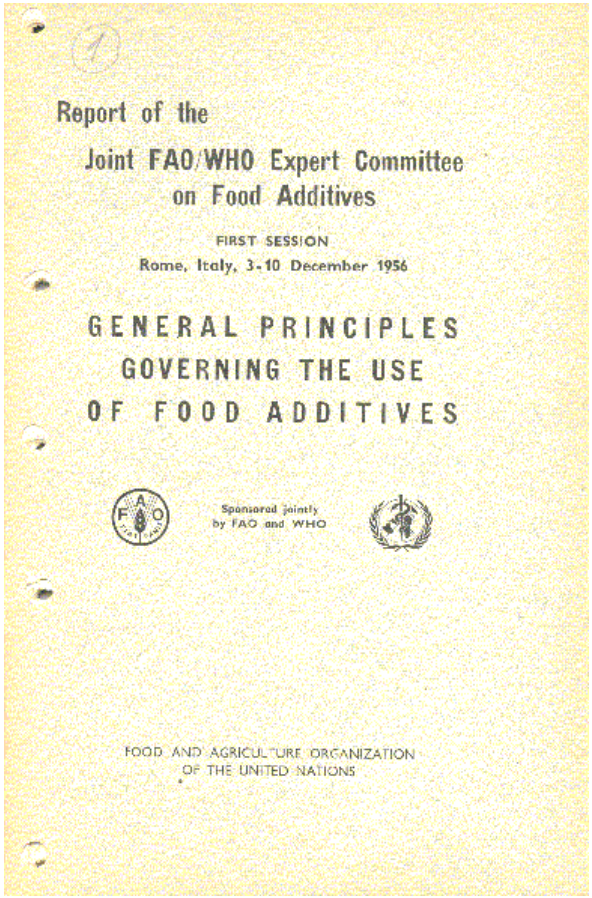
Outline

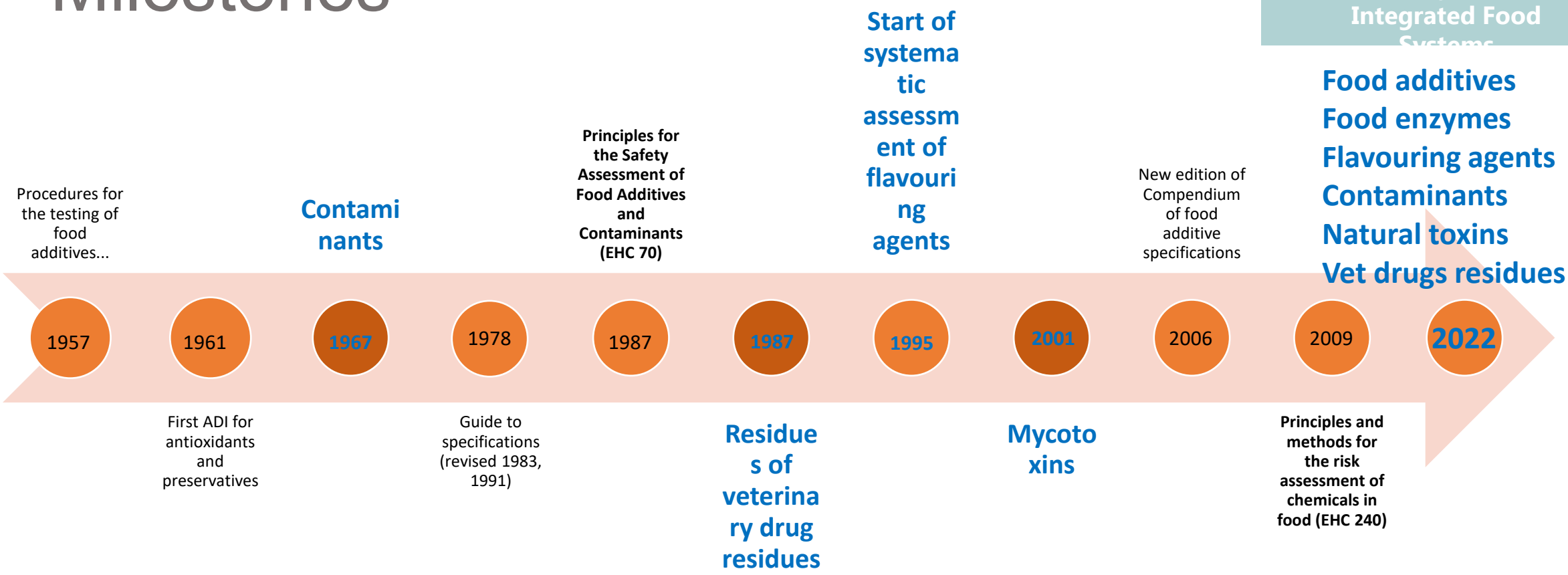
- Introduction of Joint FAO/WHO Expert Committee on Food Additives
- How it works in practice
- Outputs from JECFA consultation
- Enzymes' evaluation
- Q&A

What is JECFA?

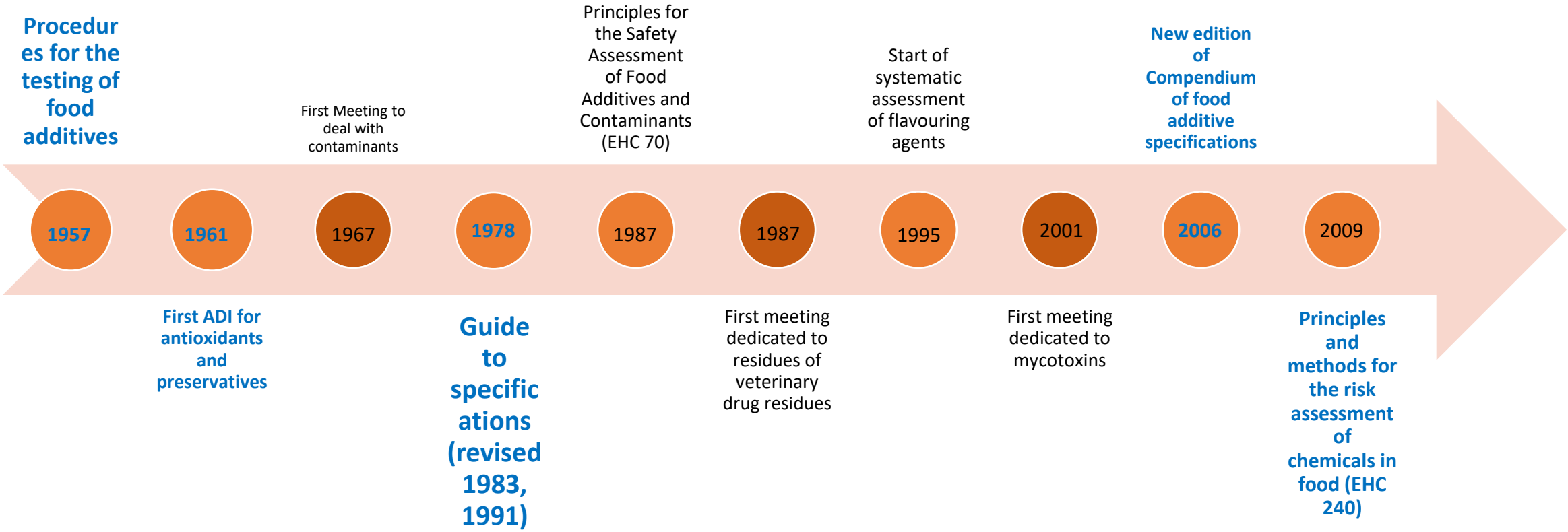
- Joint FAO/WHO Expert Committee on Food Additives
- Established in 1956 based on the outcome of the FAO/WHO conference on food additives (1955), to convene an expert committee on technical and administrative aspects of food additives in order to formulate General principles for their use.
- It restricted its discussions to non-nutritive substances added intentionally to food, generally in small quantities, to improve its appearance, flavour, texture or storage properties
- General Principles governing the use of food additives published in 1956.


Report of the
Joint FAO/WHO Expert Committee
on Food Additives
FIRST SESSION
Rome, Italy, 3-10 December 1956
GENERAL PRINCIPLES
GOVERNING THE USE
OF FOOD ADDITIVES
Sponsored jointly
by FAO and WHO
FOOD AND AGRICULTURE ORGANIZATION
OF THE UNITED NATIONS

Milestones


Procedures for the testing of food additives...
1957
1961
First ADI for antioxidants and preservatives
Contaminants
1967
1978
Guide to specifications (revised 1983, 1991)
Principles for the Safety Assessment of Food Additives and Contaminants (EHC 70)
1987
Residues of veterinary drug residues
1987
Start of systematic assessment of flavouring agents
1995
Mycotoxins
2001
New edition of Compendium of food additive specifications
2006
Principles and methods for the risk assessment of chemicals in food (EHC 240)
2009
Food additives
Food enzymes
Flavouring agents
Contaminants
Natural toxins
Vet drugs residues
2022

Milestones

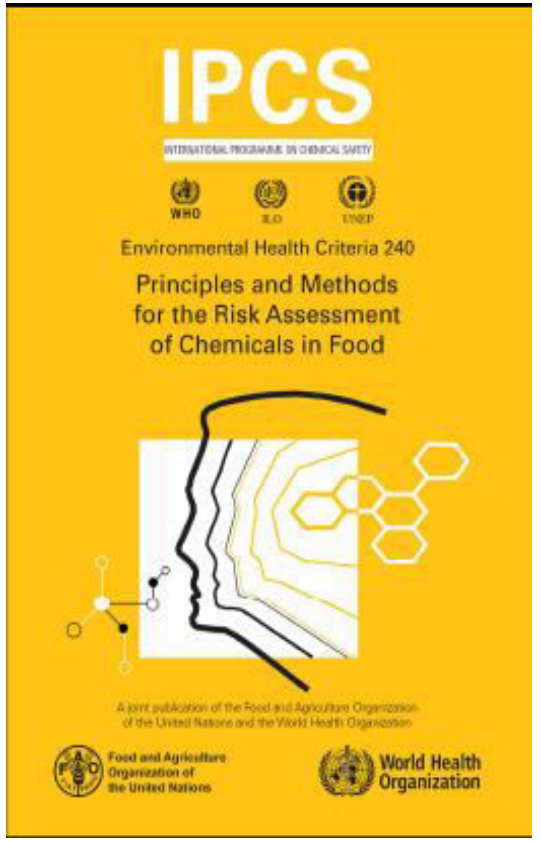

Procedures for the testing of food additives
1957
1961
First ADI for antioxidants and preservatives
First Meeting to deal with contaminants
1967
1978
Guide to specifications (revised 1983, 1991)
Principles for the Safety Assessment of Food Additives and Contaminants (EHC 70)
1987
1987
First meeting dedicated to residues of veterinary drug residues
Start of systematic assessment of flavouring agents
1995
2001
First meeting dedicated to mycotoxins
New edition of Compendium of food additive specifications
2006
2009
Principles and methods for the risk assessment of chemicals in food (EHC 240)

Principles and Methods

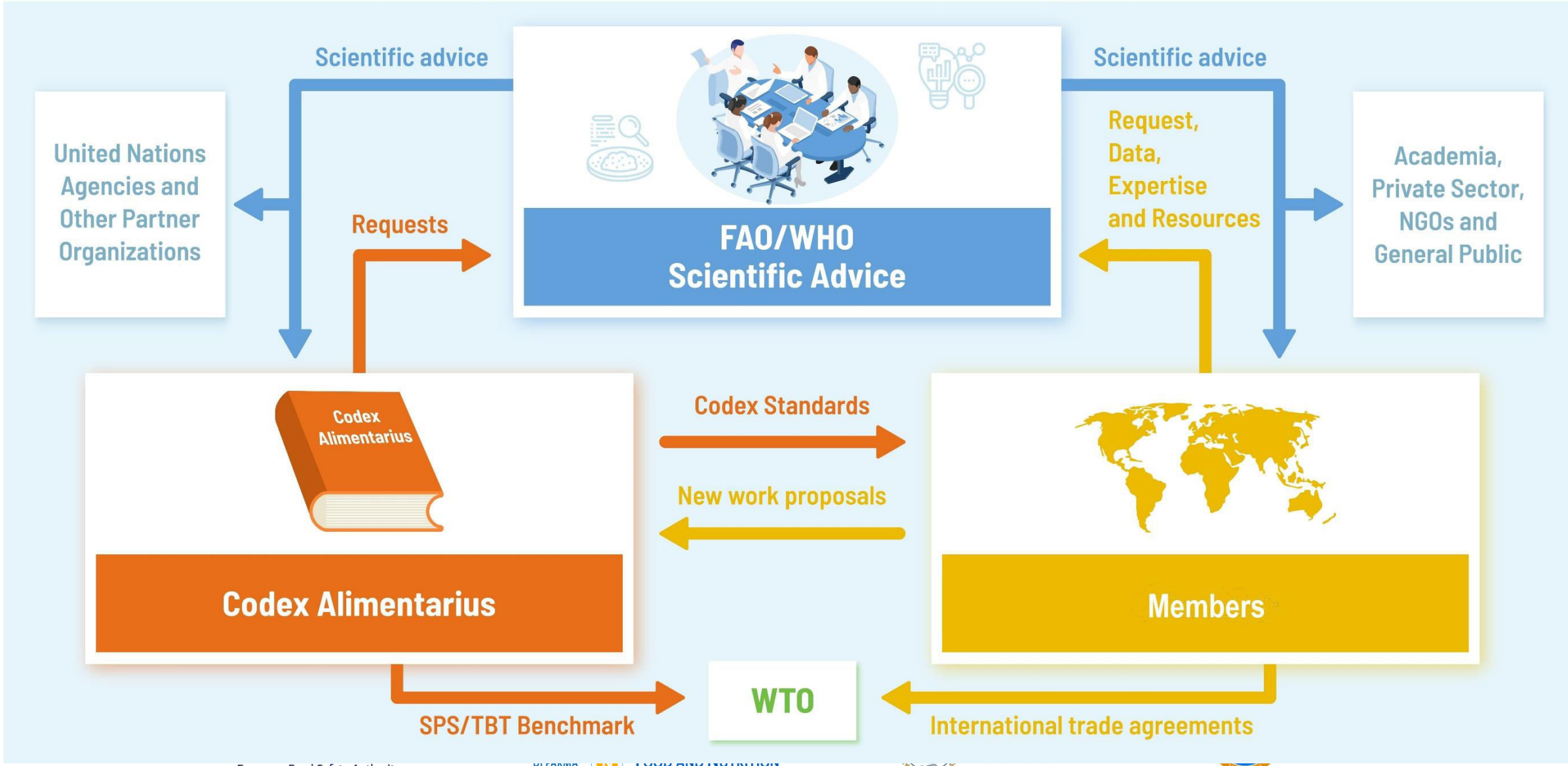
EHC 240: Principles and methods for the risk assessment of chemicals in food, WHO 2009

- Environmental health criteria 240
- 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
- Last update in 2020 (food enzymes)

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

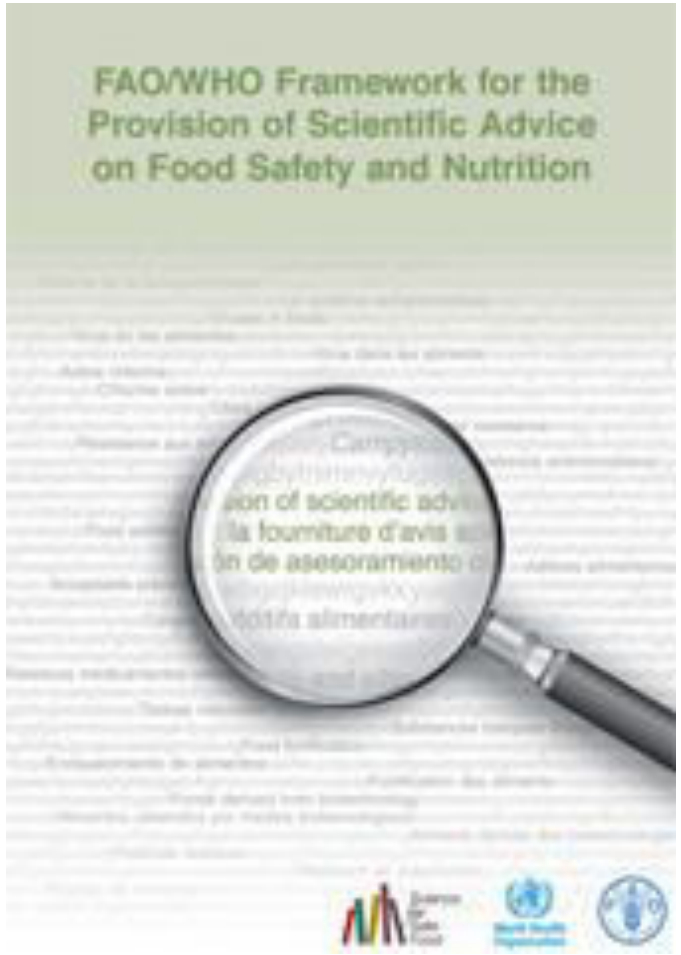


Provision of Scientific Advice



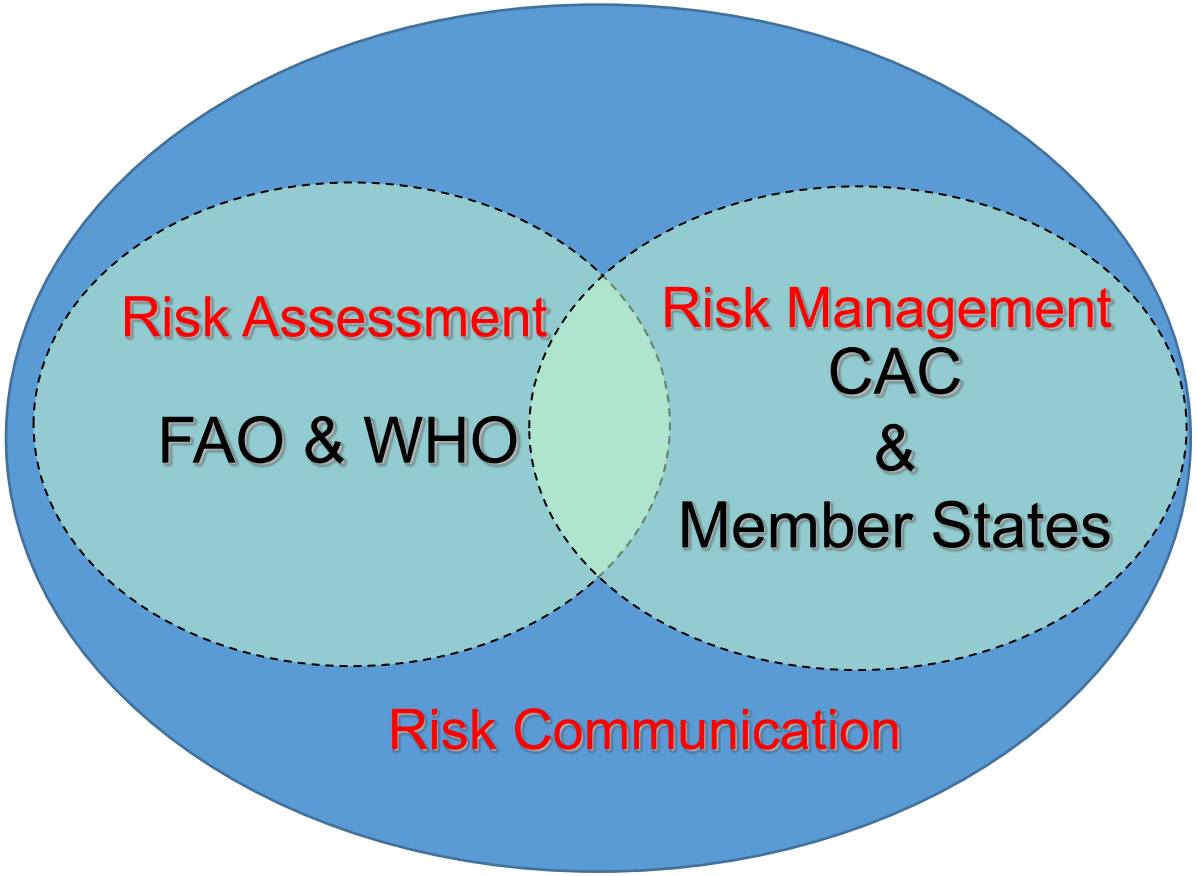
Framework - Role

- FAO/WHO have established a systematic framework for applying principles and guidelines for food safety risk analysis.
- Functional separation between risk assessment and risk management, ensures scientific integrity and independence, avoids confusion over the respective roles of risk assessors and risk managers, and reduces potential conflicts of interest.



Risk Analysis

Scientific advice and information analysis



Regulation and control

Dialogue with stakeholders

JECFA Advice to Codex

- All countries need to access reliable risk assessment of chemicals in food, but not all have the expertise and funds available to carry out separate risk assessments on large numbers of hazards.
- JECFA performs a vital role in providing a reliable and independent source of expert advice in the international setting, thus contributing to the setting of standards on a global scale for the health protection of all consumers and for ensuring fair practices in the trade of safe food.

Role of science in the Codex decision-making process

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"The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply."

Source: First statement of principle, Appendix - Codex Procedural Manual

Why are Codex Standards useful?

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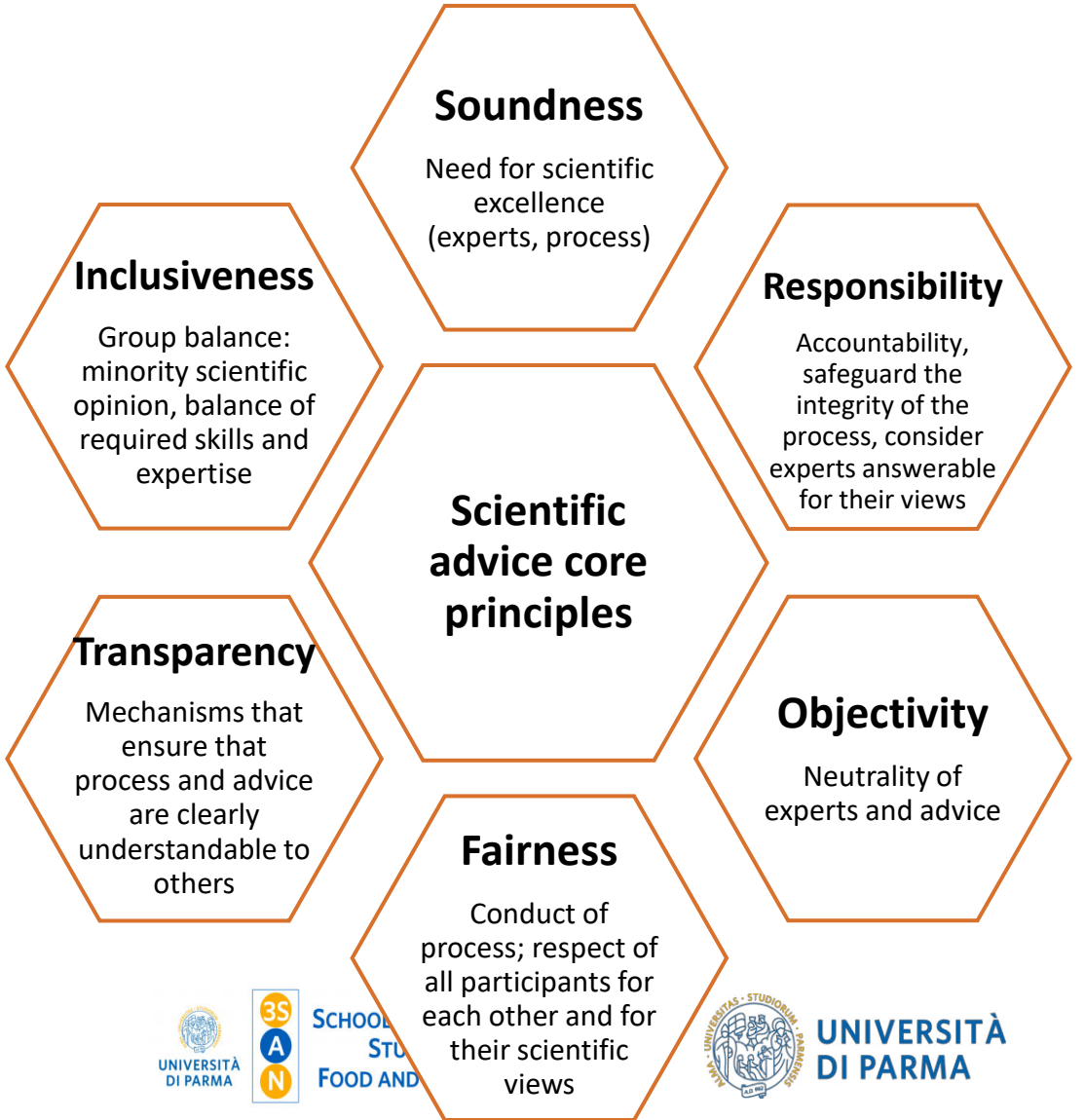
Scientific advice is used as reference point for International Food Standards, guidelines and codes of practice:

- Protect consumer health
- Enable fair practices in trade

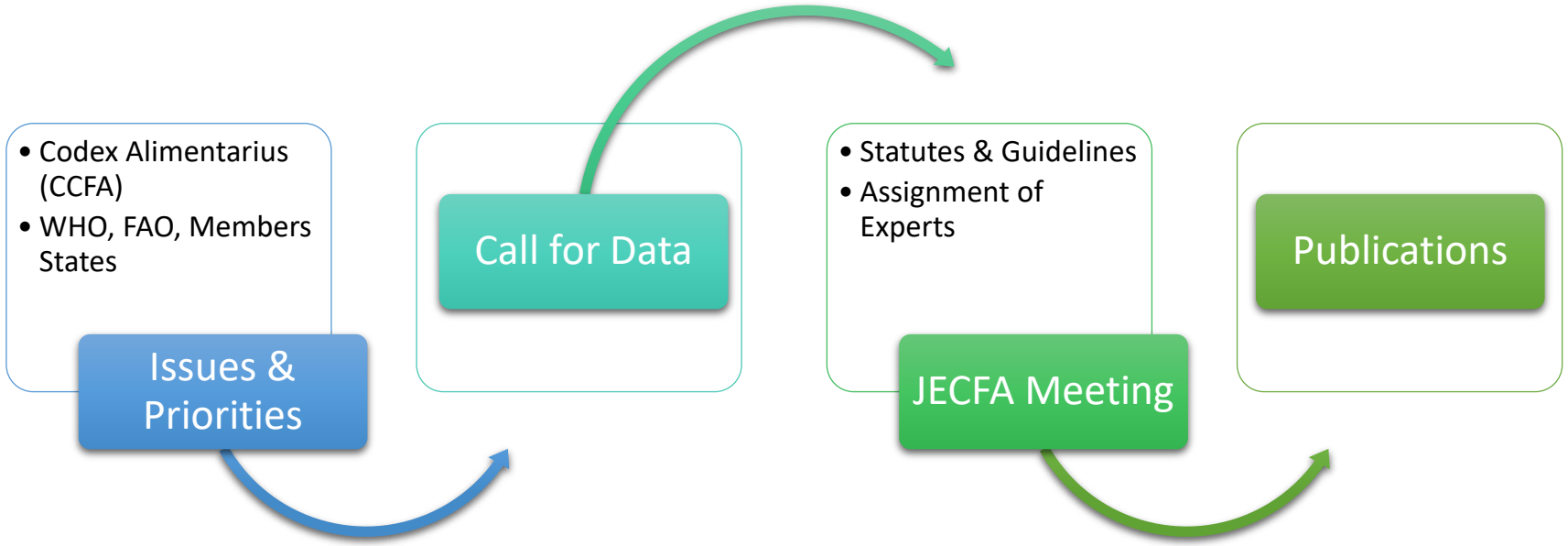
Codex standards are

- Recommendations
- Voluntary
- NOT national legislation

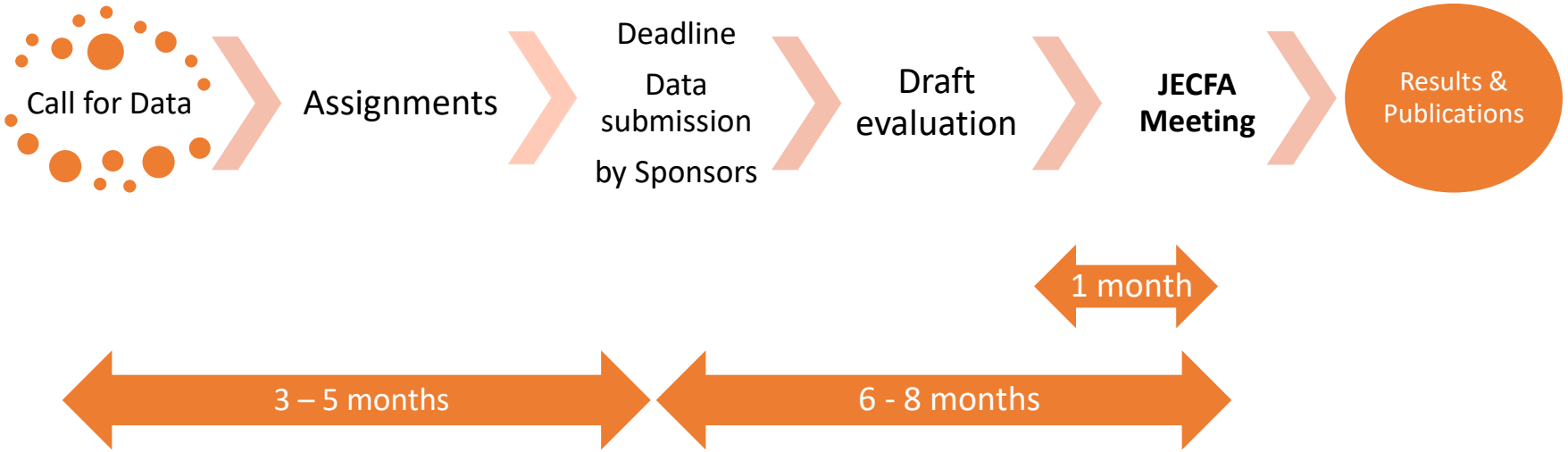
Core principles of scientific advice



Standard Process



General Timelines



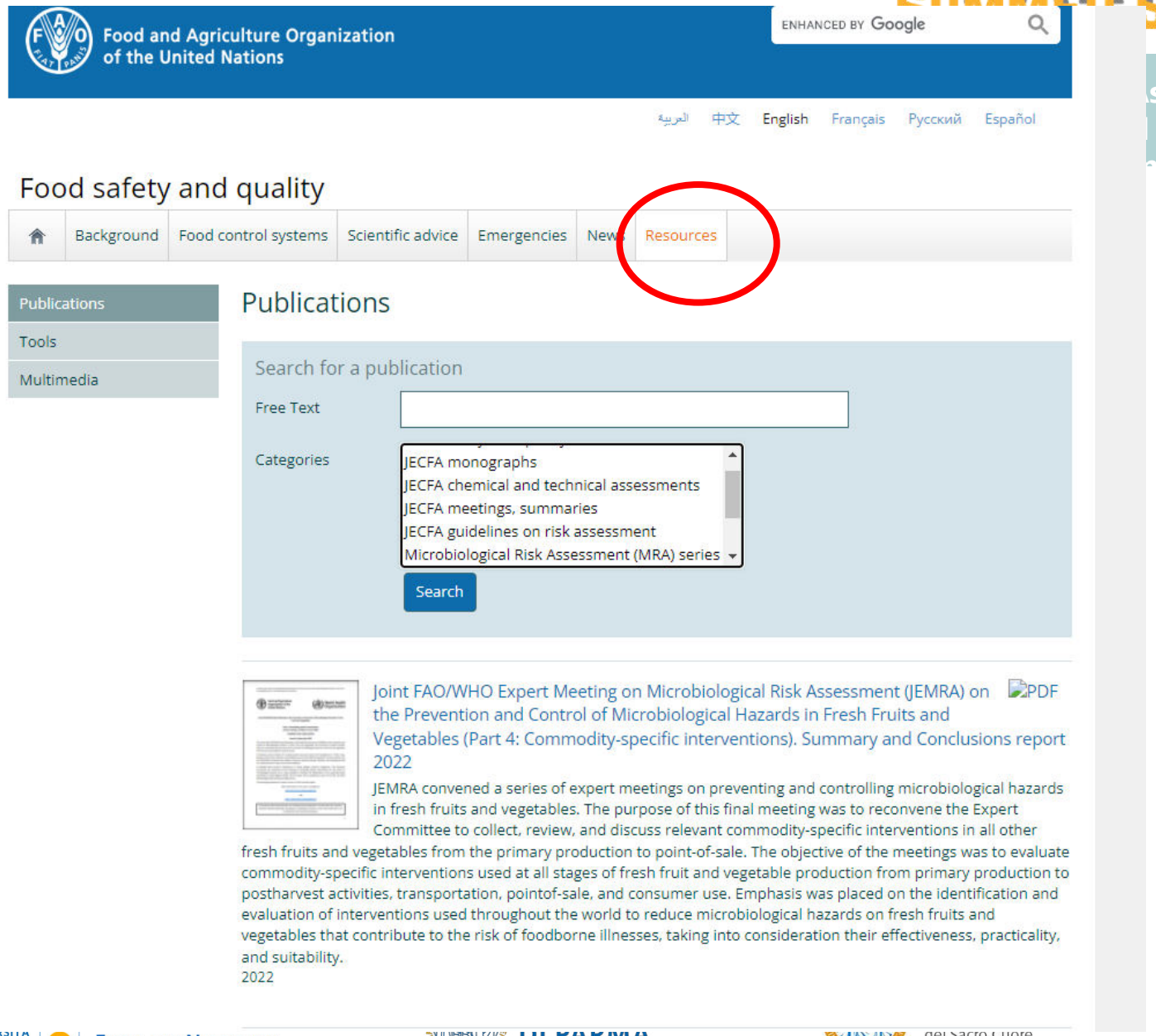
JECFA Outputs

- 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
    - Toxicological Monographs
    - Specifications
- Chemical and technical assessment (CTA)

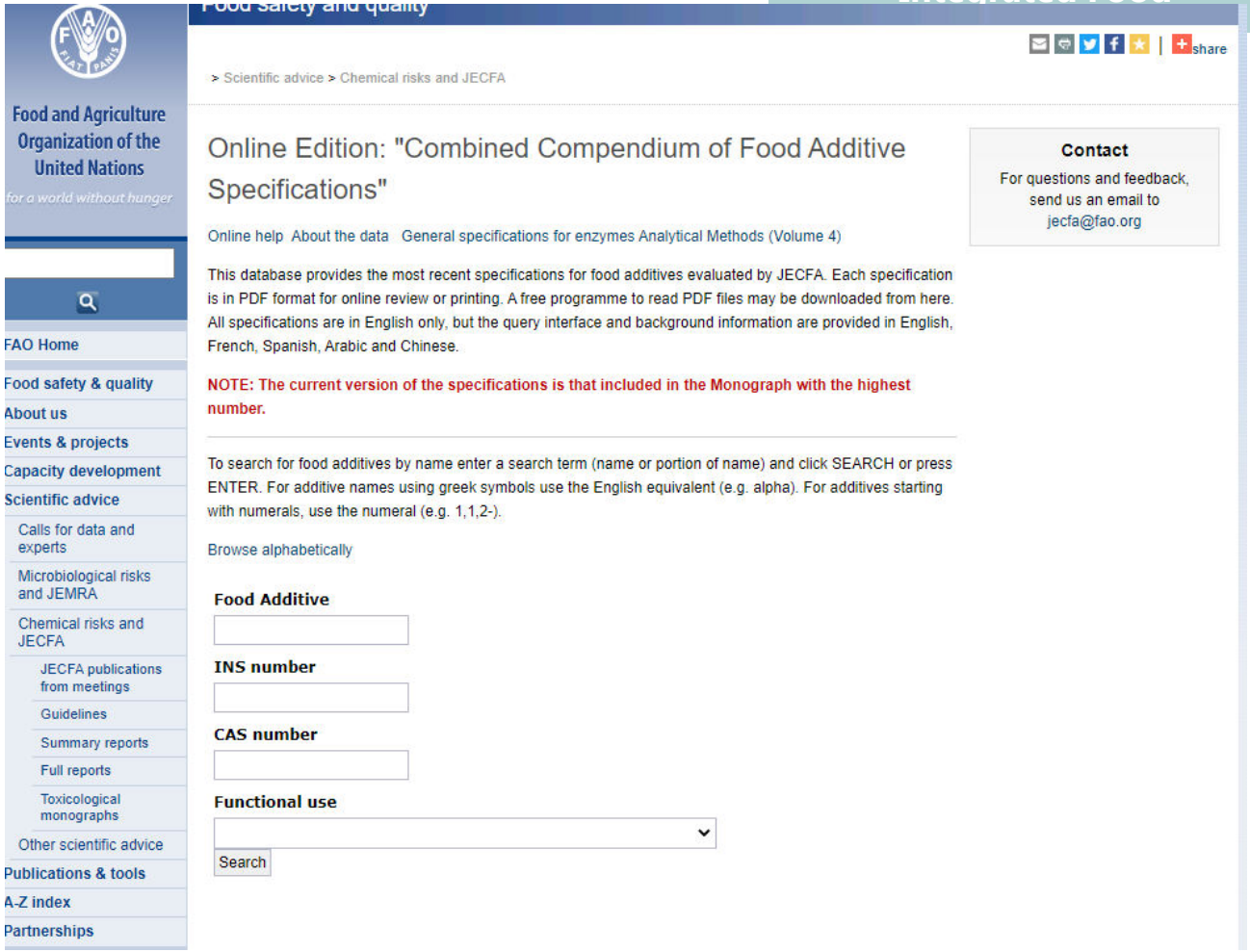
https://www.fao.org/food-safety/resources/publications/en/

FAO Publications

Website: https://www.fao.org/food-safety/resources/publications/en



FAO Databases



How are experts selected by FAO and WHO?

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Food Safety Aspects of Integrated Food Systems

- scientific experts are selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.
- scientific advice is the product of a group of experts selected to work in their personal capacity and not as representatives of their country/institution.

Selection criteria:

- scientific credibility,
- relevant experience,
- technical skills,
- geographical and gender balance,
- declaration of interests

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JECFA Meeting Report

Safety evaluations [3.1.1. α-Amylase (JECFA95-1) from *Geobacillus stearothermophilus* expressed in *Bacillus licheniformis*]

- ***Explanation***
- ***Genetic background***
- ***Chemical and technical considerations***
- ***Biological data***
  - ***Assessment of potential allergenicity***
  - ***Toxicological studies***
  - ***Observations in humans***
- ***Assessment of dietary exposure***
- ***Evaluation***
- ***Recommendations***

https://www.fao.org/food-safety/resources/publications/en/

FAO and WHO complement each other

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Food Safety Aspects of Integrated Food Systems

- FAO - Specifications (Chemistry and Analytics)

Purpose:

- ensure that the substance is of the quality required for safe use in food;
- reflect and encourage Good Manufacturing Practice (GMP) and maintain the quality of enzyme on the market.

Information

- Classification and Nomenclature of Enzymes
- Enzyme Preparations
- Active Components
- Source Materials
- Substances used in Processing and Formulation
- Purity

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

FAO and WHO complement each other

- FAO - Chemical and Technical Assessment (CTA)

The CTA will reflect and emphasize 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.

Information:

- Description
- Method of manufacture
- Identity and Characterization
- Functional Uses
- Fate in food

FAO and WHO complement each other

<u>WHO – Toxicological and epidemiological evaluation</u>

- Metabolism studies
- Short- and long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity, genotoxicity
- Epidemiological data
- Special studies (e.g. mechanism of toxicity, immune responses, or macromolecular binding)

<u>FAO/WHO - Dietary exposure assessment</u>

- Estimation of food enzymes' intakes
- Food consumption patterns (different (age-) population groups)

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