



# **Food Additives and Safety: the World Health Organization's Perspective**

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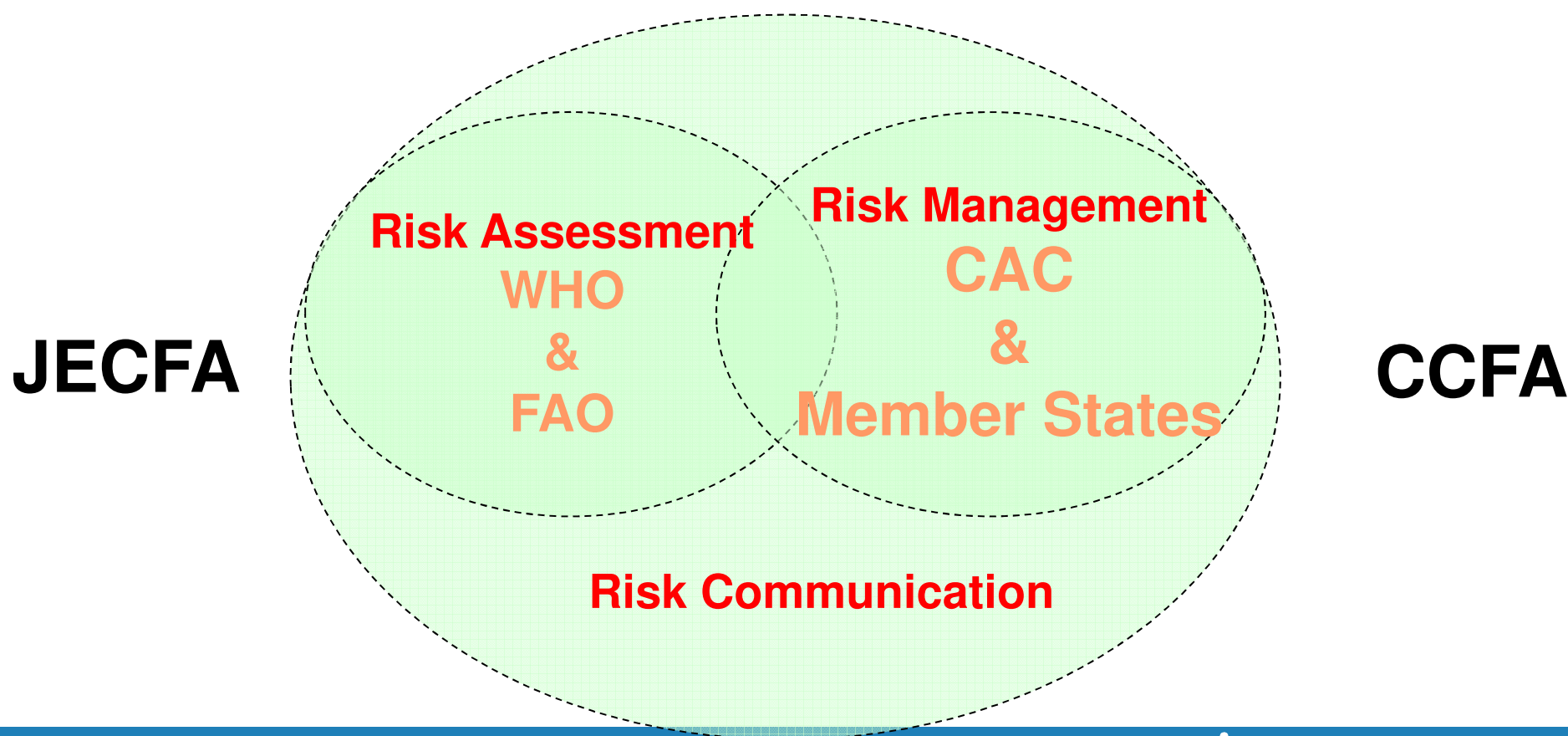
# Outline

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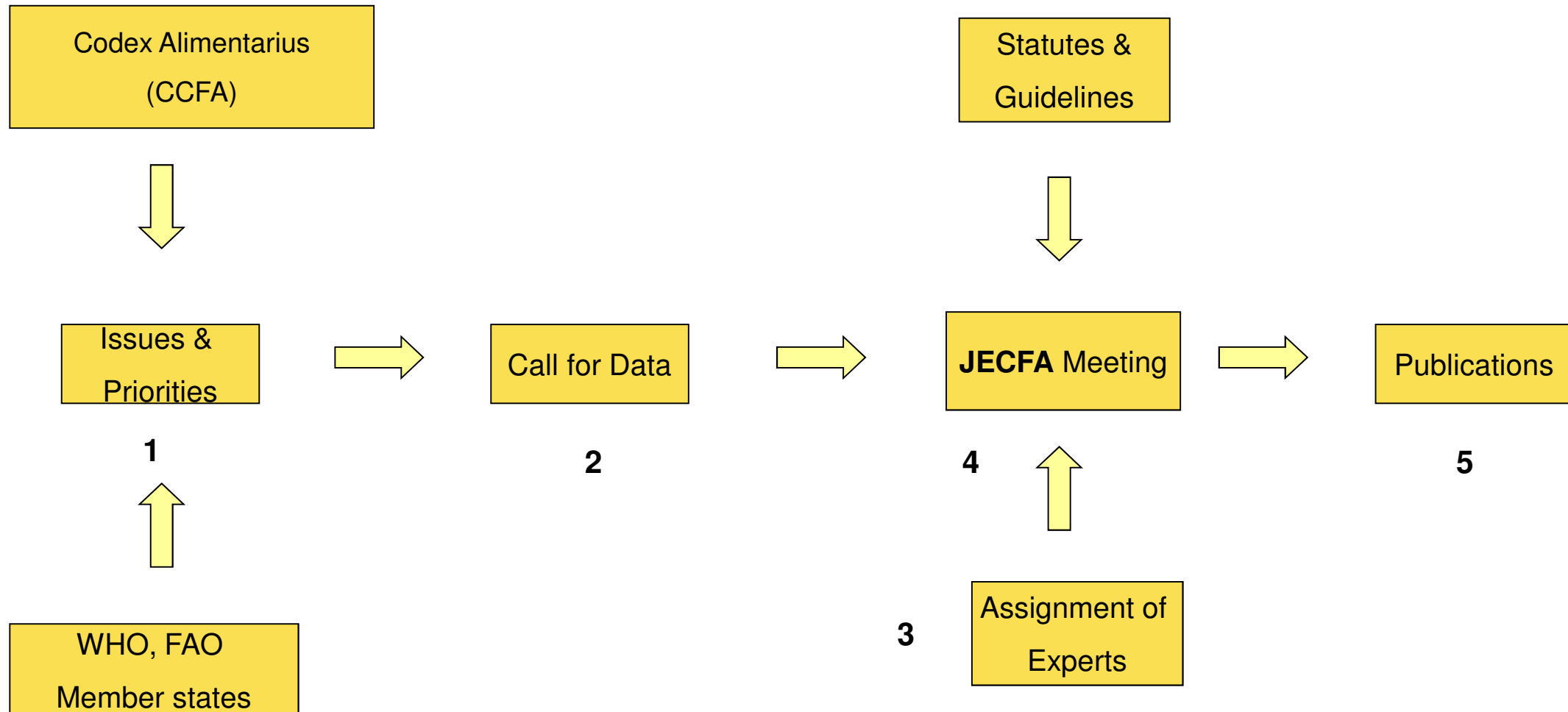
- International risk analysis framework
- Selection and prioritization of compounds
- Data needs
- Evaluation of new dossiers
- Re-evaluation of food additives

# International Risk Analysis Framework

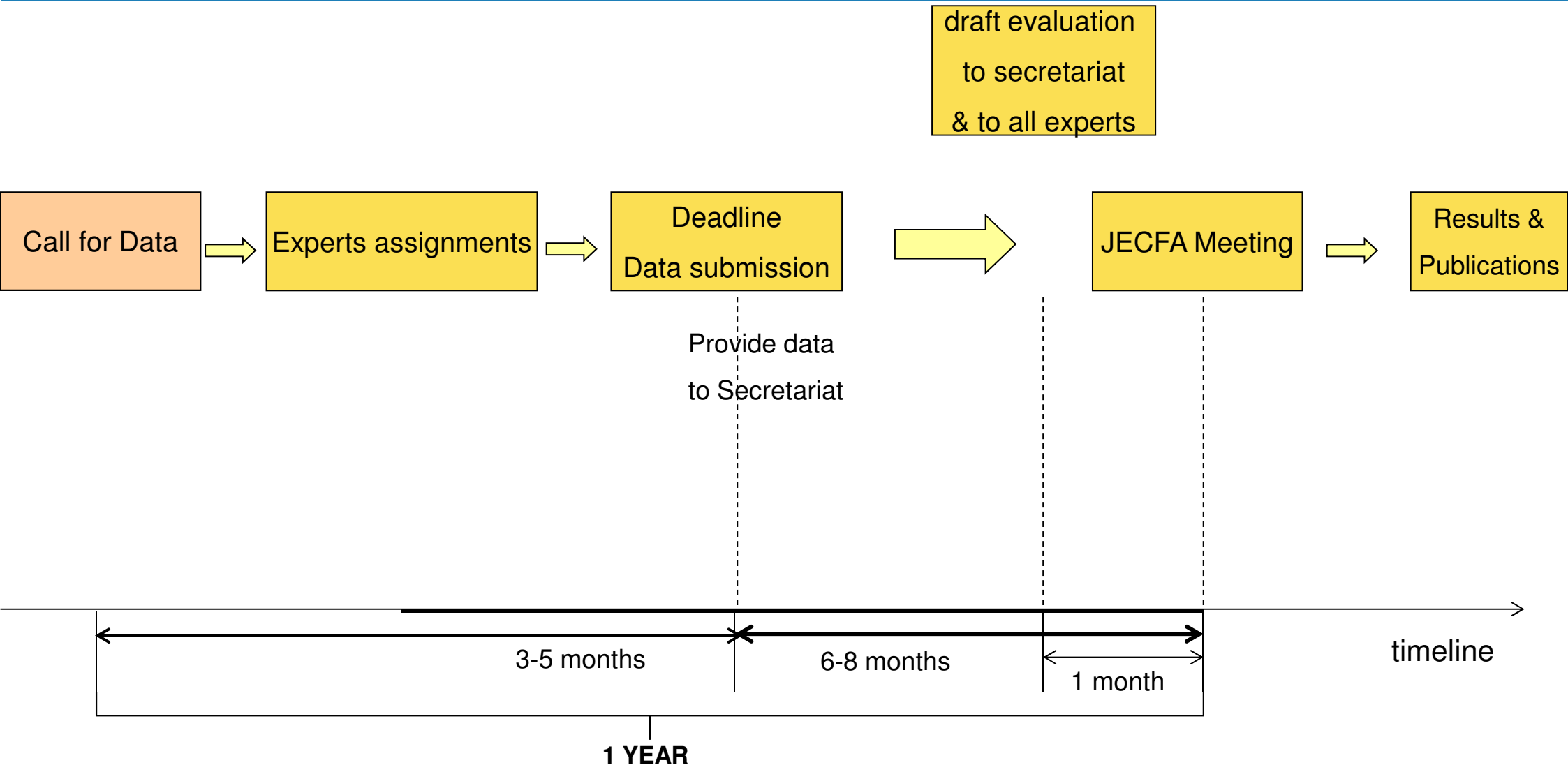
- Food standards are developed on the basis of scientific assessments
- Codex Standards are the international benchmark for trade



# JECFA: general process flow



# JECFA: general time lines



# Selection of compounds for evaluation

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- Establishment of a list of priorities by the CCFA Working Group
- Consideration of the list by the CCFA in session
- Establishment of the JECFA agenda by the JECFA Secretariat as a function of financial resources and expertise needed

# Call for data

- Biochemical data
  - Absorption, distribution, excretion, metabolism, effects on enzymes
- Toxicological data
  - Acute, short-term, long-term toxicity & carcinogenicity (mainly rats and mice, sometimes dogs)
  - Genotoxicity (in vitro and in vivo)
  - Reproductive and developmental toxicity (mainly rats)
  - Special studies (e.g. immunotoxicity, cardiovascular effects, thyroid function)
  - Studies on metabolites
  - Observations in humans
- Exposure data
  - Food consumption and concentration of additive

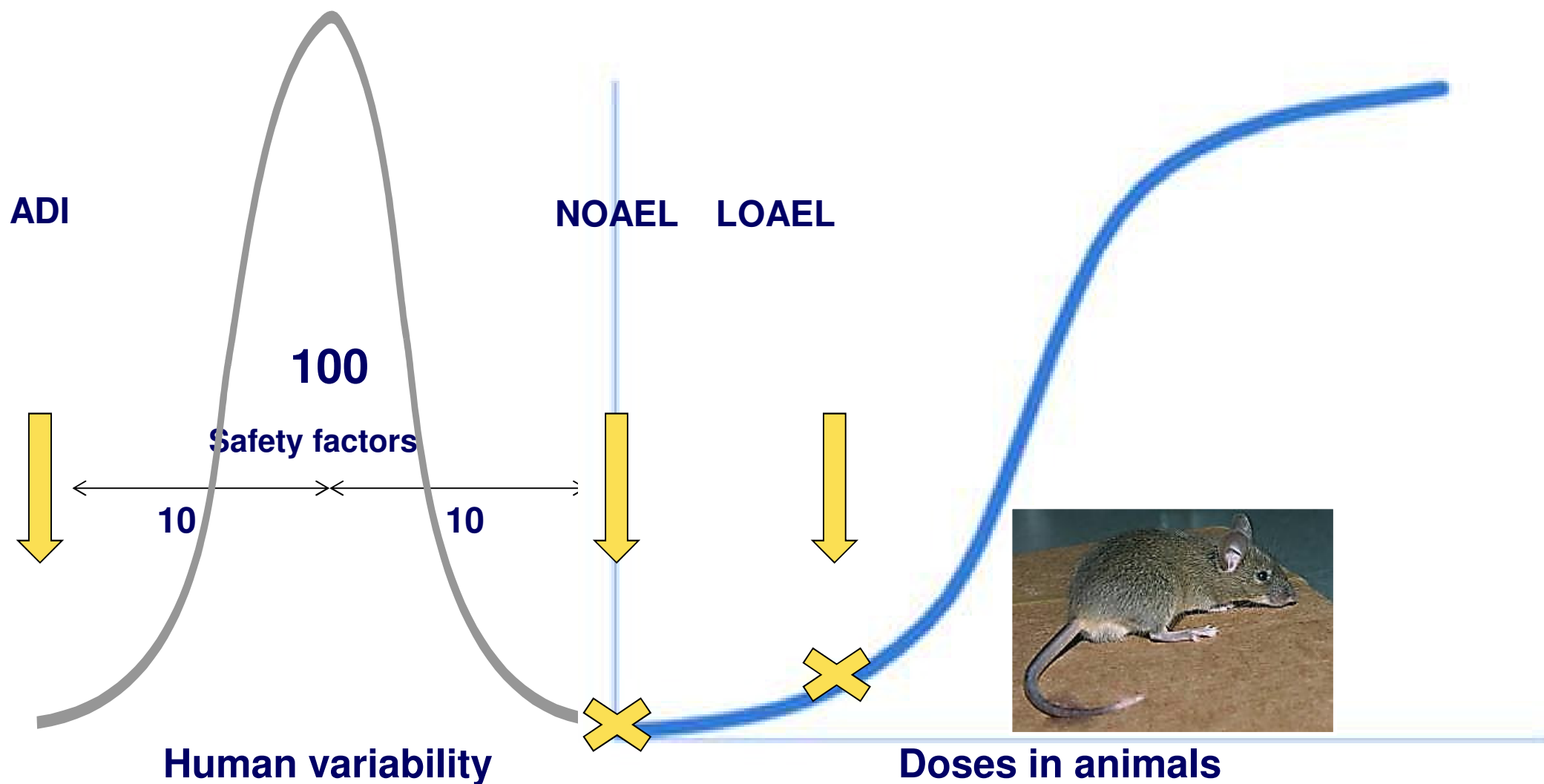
Reference: [http://www.who.int/foodsafety/chem/jecfa/en/tox\\_guidelines.pdf](http://www.who.int/foodsafety/chem/jecfa/en/tox_guidelines.pdf)

# Toxicological Assessment

- Identification of critical endpoint
- Identification of the No Observed Adverse Effect Level (NOAEL)
- Identification of uncertainty/safety factors
- Derivation of reference value by dividing NOAEL by uncertainty factor
- Health based guidance value: ADI



# Toxicological Assessment

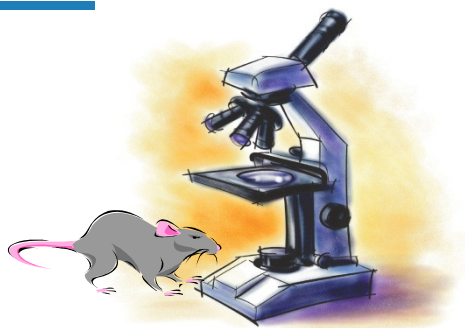


# Dietary exposure assessment

- Combining food consumption data with occurrence of contaminant in food
- Deterministic approach
  - Maximum Authorized Level \* high consumption / body weight
  - Maximum Authorized Level \* average consumption / body weight
  - Average use level \* high consumption / body weight
- Probabilistic approach
  - Combining the 2 distributions of consumption and concentration.

Reference: [http://www.who.int/foodsafety/chem/jecfa/en/intake\\_guidelines.pdf](http://www.who.int/foodsafety/chem/jecfa/en/intake_guidelines.pdf)

## Hazard Assessment



↓  
Key NOAEL

↓  
*Uncertainty Factors (Ufs)*



**Safety standard**

e.g.  $ADI = NOAEL / Ufs$

## Exposure Assessment



*Chemical analysis*

*Food consumption*

X

**Exposure**

**Safety assurance:**

**Exposure** < **ADI**



→ Safe

**Exposure** ≥ **ADI**



→ Management Action

# Prioritisation criteria for re-evaluation

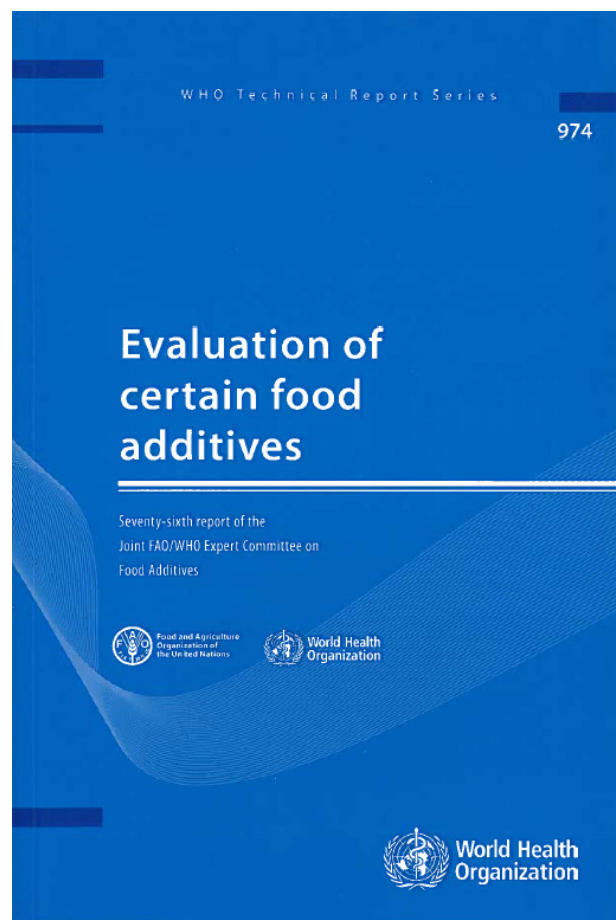
- Concern for public health expressed by Member States or raised by the JECFA Secretariat
- Sufficient data reflecting the current use patterns
- Status of authorization of the chemical at national level
- Raw toxicological data or detailed toxicological data to re-establish or modify the ADI

Reference: [http://www.who.int/foodsafety/chem/jecfa/en/procedural\\_guidelines\\_additives.pdf](http://www.who.int/foodsafety/chem/jecfa/en/procedural_guidelines_additives.pdf)

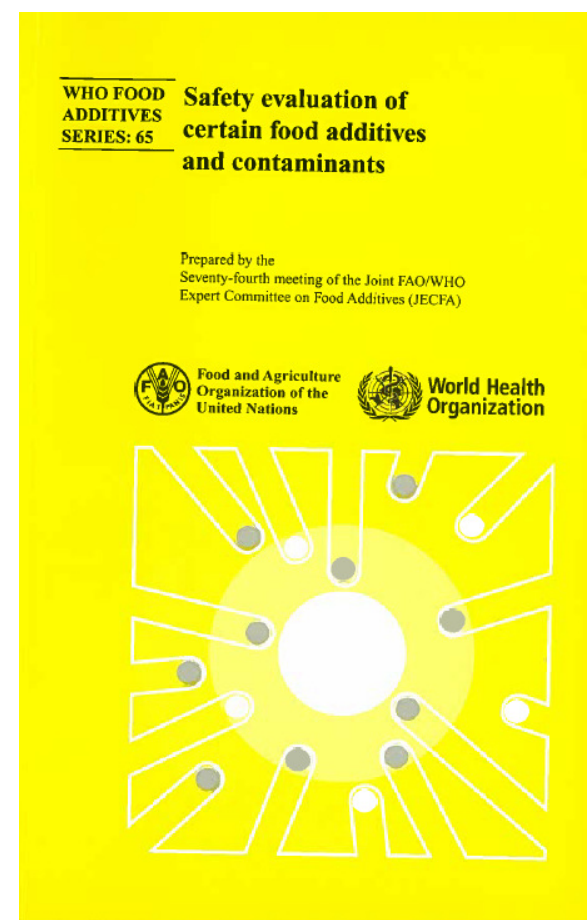
# Possible additional criteria for re-evaluation

- Time since last evaluation
- New information on changes in manufacturing process or specification;
- New data on biological properties of the compound;
- Advances in scientific knowledge connected to the nature or mode of action;
- Changes in consumption patterns, levels of use or dietary exposure estimates;
- Overall indication that previous evaluation may be changed

# JECFA Publications




## JECFA Monograph





## JECFA Report

# JECFA Searchable database

 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 71st JECFA (June 2009).


Partial Name/CAS

First Character

Functional Class

Partial name or CAS number:

Search


 World Health Organization

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

# JECFA Searchable database

## Essential information on individual additives

 World Health Organization

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


**BENZOIC ACID**    

**General Information**

Synonyms:	BENZENECARBOXYLIC ACID, CARBOXYBENZENE, DRACYLIC ACID, PHENYL FORMIC ACID
Chemical Names:	BENZOIC ACID
JECFA number:	850
INS:	210
COE number:	21
FEMA number:	2131
Functional Class:	Food Additives PRESERVATIVE

**Evaluations**

Evaluation year:	2002
ADI:	0-5 mg/kg bw (1996)
Comments:	No safety concern at current levels of intake when used as a flavouring agent (2002)
Intake:	See BENZOATES
Meeting:	46
Specs Code:	R
Report:	<a href="#">TRS 913-JECFA 59/112</a>
Tox Monograph:	<a href="#">FAS 48-JECFA 57/227 (2001)</a>
Specification:	<a href="#">COMPENDIUM ADDENDUM 12/FNP 52 Add. 12/67 (METALS LIMITS) (2004);</a> <a href="#">FAO JECFA Monographs 1 vol.1/147</a>
Previous Years:	2001, <a href="#">TRS 909-JECFA 57/73</a> , <a href="#">COMPENDIUM ADDENDUM 9/FNP 52 Add.9/140</a> , <a href="#">FAS 48-JECFA 57/227</a> . ( EVALUATION AS A FLAVOURING AGENT NOT FINALIZED AT THE FIFTY-SEVENTH MEETING (2001); FURTHER INFORMATION REQUIRED TO DETERMINE WHETHER THIS SUBSTANCE IS IN CURRENT US

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# Thank you

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## Question ?

