Food Additives and Safety: the World Health Organization’s Perspective

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Outline

- 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

1. Issues & Priorities
2. Call for Data
3. Assignment of Experts
4. JECFA Meeting
5. Publications

Codex Alimentarius (CCFA)

WHO, FAO
Member states

Statutes & Guidelines
JECFA: general time lines

- **Call for Data**
- **Experts assignments**
- **Deadline Data submission**
- **JECFA Meeting**
- **Results & Publications**

**timeline**

- **3-5 months**
- **6-8 months**
- **1 month**

**draft evaluation to secretariat & to all experts**

1 YEAR
Selection of compounds for evaluation

- 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

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

- ADI
- NOAEL
- LOAEL
- Safety factors
- Human variability
- Doses in animals

100

10

10

World Health Organization
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.

Hazard Assessment

Exposure Assessment

Key NOAEL

Uncertainty Factors (Ufs)

Safety standard

e.g. ADI=NOAEL/Ufs

Chemical analysis

Food consumption

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

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 Searchable database

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Essential information on individual additives
Thank you

Question?