REVIEW OF THE JECFA PROCESS FOR ASSESSMENT OF FOOD ADDITIVES

MOEZ SANAA

TUESDAY 28TH MAY 2024

World Health Organization

Food and Agriculture Organization of the United Nations

JOINT FAO/ WHO EXPERT COMMITTEE ON FOOD ADDITIVES

"Evaluating food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food since 1956"

1. ABOUT JECFA?
2. RISK ANALYSIS
3. RISK ASSESSMENT POLICY
4. JECFA MEETINGS
5. JECFA VS IARC ASSESSMENT
6. PERSPECTIVES

MOEZ SANAA

ABOUT JECFA

ABOUT JECFA

INTRODUCTION

- **Committee Name**: Joint FAO/WHO Expert Committee on Food Additives (JECFA)
- **Administered By**: Food and Agriculture Organization (FAO) and World Health Organization (WHO)
- **Year Established**: 1956
- **Initial Purpose**: Evaluate the safety of food additives
- **Current Scope**: Evaluates food additives, contaminants, naturally occurring toxicants, and residues of veterinary drugs in food
- **Number of Evaluations**: Over 2600 food additives, 50 contaminants and naturally occurring toxicants, 75 veterinary drugs

ABOUT JECFA

PURPOSE

- **Primary Role**: Perform risk assessments and provide advice on food safety
- **Beneficiaries**: FAO, WHO, member countries, Codex Alimentarius Commission (CAC)
- **Advice Provided To**: Codex Committee on Food Additives (CCFA), Codex Committee on Contaminants in Food (CCCF), Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF)
- **Standards Developed By**: Codex Alimentarius Commission, based on JECFA evaluations

TUESDAY 28TH MAY 2024

World Health Organization

Food and Agriculture Organization of the United Nations

JOINT FAO/ WHO EXPERT COMMITTEE ON FOOD ADDITIVES

"Evaluating food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food since 1956"

1. ABOUT JECFA?
2. RISK ANALYSIS
3. RISK ASSESSMENT POLICY
4. JECFA MEETINGS
5. JECFA VS IARC ASSESSMENT
6. PERSPECTIVES

MOEZ SANAA

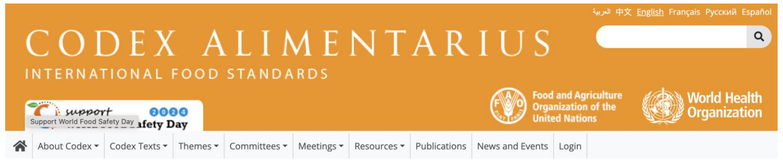
2

RISK ANALYSIS

Codex Alimentarius Commission

RISK ANALYSIS

- **Risk Analysis Principles**: Applied consistently, transparently, and documented, comprising risk assessment, risk management, and risk communication.
- **Risk Assessment**: Clear scope, transparent expert selection, based on scientific data, considering global data, and acknowledging uncertainties.
- **Risk Management**: Focuses on consumer health protection, structured approach, transparent decision-making, considering economic impact and developing countries' needs.
- **Risk Communication**: Promotes understanding and transparency, involving all interested parties, and ensuring effective communication throughout the process.



2

RISK ANALYSIS

Risk Based Food Safety System

Risk Analysis

Risk analysis is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied.

Risk Assessment

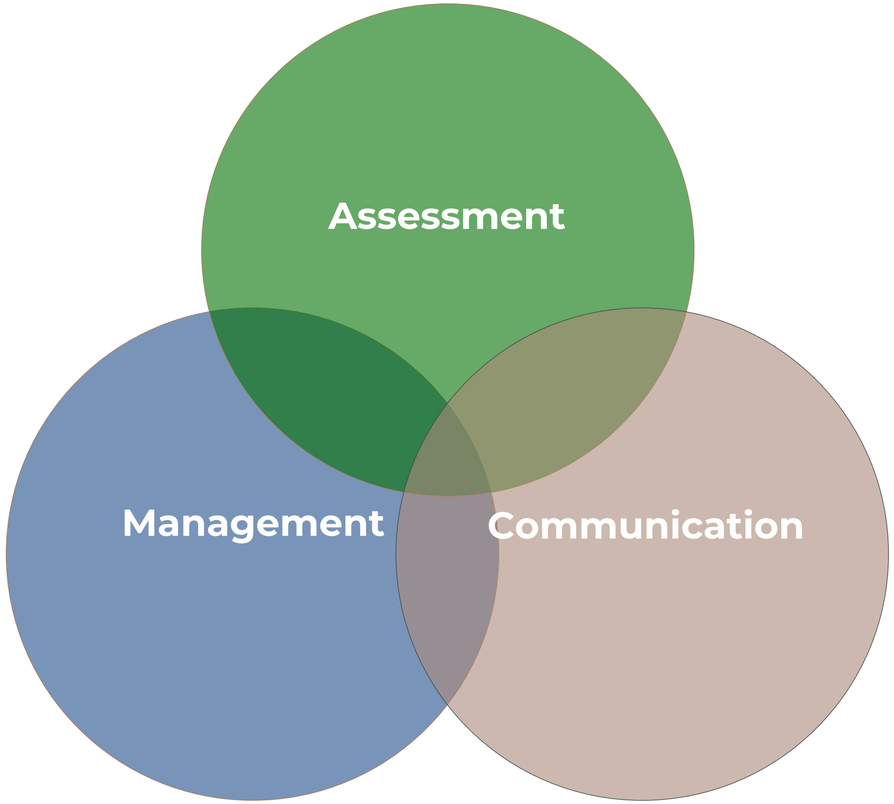
Scientific advice and information analysis.

Risk Management

Regulations and controls

Risk Communication

Dialogue with all stakeholders



TUESDAY 28TH MAY 2024

World Health Organization

Food and Agriculture Organization of the United Nations

JOINT FAO/ WHO EXPERT COMMITTEE ON FOOD ADDITIVES

"Evaluating food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food since 1956"

1. ABOUT JECFA?
2. RISK ANALYSIS
3. RISK ASSESSMENT POLICY
4. JECFA MEETINGS
5. JECFA VS IARC ASSESSMENT
6. PERSPECTIVES

MOEZ SANAA

RISKASSESSMENT POLICY

Risk Assessment Policy (Codex Alimentarius, CAC/GL 63 - 2007)

"Establishing a risk assessment policy protects the scientific integrity of the risk assessment and offers guidance to balance value judgements, policy choices, adverse health parameters for presenting risk to human health, source of data to be considered, and management of data gaps and uncertainties during the course of the assessment"

Ensure consistency, clarity and transparency

RISKASSESSMENT POLICY

SUBSTANTIVE

scoping judgements about what counts and what should be (or can be) discounted?

PROCEDURAL

Procedural Risk Assessment guidance.

INTERPRETATIVE

How much evidence?
Level of protection?
False positives vs false negatives?

4

JECFA MEETINGS

LIFE CYCLE OF AN EXPERT MEETING

CTF
Building capacity of Member states to engage on Codex

Year X-1

Questions raised during the meeting of different codex
CCFA
CCCF
CCRVDF
...

CODEX REQUEST

Year X

Selection of the Experts according to their active experience in the domain and their declaration of interests

Gender and Geographical representation

CALL FOR DATA AND EXPERTS OR MONOGRAPHERS

Year X+1

Secretariat
JECFA - JMPR - JEMRA - JEMNU - Ad hoc

Experts

Resource Persons

JOINT EXPERT MEETING

Report to Codex and Member States

MEETING PLANIFICATION AND PREPARATION

Definition of the objectives and the scope

Preparation of the background information

Meetings with consultants

PRE-MEETING(S)

Presentation of the objectives of the meeting and background information

Points to reflect on for the meeting

Experts training

REPORT

Finalization by the experts

Editing

Publication

TUESDAY 28TH MAY 2024

World Health Organization

Food and Agriculture Organization of the United Nations

JOINT FAO/ WHO EXPERT COMMITTEE ON FOOD ADDITIVES

"Evaluating food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food since 1956"

1. ABOUT JECFA?
2. RISK ANALYSIS
3. RISK ASSESSMENT POLICY
4. JECFA MEETINGS
5. JECFA VS IARC ASSESSMENT
6. PERSPECTIVES

MOEZ SANAA

4

JECFA MEETINGS

World Health Organization

Food and Agriculture Organization of the United Nations

Joint FAO/ WHO Expert Committee on Food Additives

"Evaluating food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food since 1956"

EXPERTS

Individuals serving in JECFA are independent experts with specializations in a range of scientific subjects.

They come from many different countries and organizations but act in their individual capacity and not as representatives of any institution or country.

4

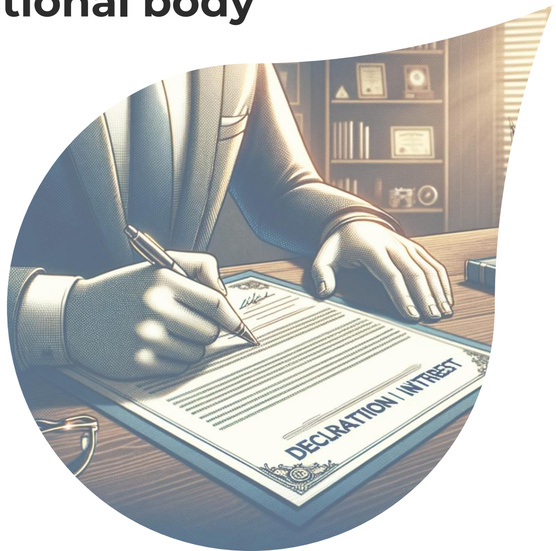
JECFA MEETINGS

DECLARATION OF INTEREST

Any <u>potential or perceived</u> interests will be evaluated before any tasks are assigned

Interests to be considered include the following examples:

- **Experts have worked for or have an interest in the sponsoring company**
- **Experts have performed some of the studies to be evaluated**
- **Experts have recently been closely involved with preparing an evaluation of a compound for a national or supranational body**



4

JECFA MEETINGS

DECLARATION OF INTEREST

- According to WHO rules and procedures, expert meetings are private in nature, and participation is by invitation only
- The data used and discussions held at the meeting are to be held in strict confidence
- Experts must accept these rules and confirm with signature that they will adhere to them
- On request, original documents must be returned

4

JECFA MEETINGS

DECLARATION OF INTEREST

- **By consensus**
- **Minority opinion if consensus cannot be reached, published in the report**
- **No vote!**

4

JECFA MEETINGS

EACH MEETING IS DIFFERENT

- **Due to the variations in the agenda, the actual members and experts will vary from meeting to meeting**
- **Continuity is secured by the Joint Secretariat, longer serving members, and, most important, by all participants who share the responsibility to maintain JECFA/JMPR/JEMRA's reputation as the leading international body for risk assessment in foods**
- **JECFA generally meets twice a year (Geneva / Rome):**
  - **At least one meeting examines food additives and/or contaminants.**
  - **The second meeting of the year may examine veterinary drug residues.**

4

JECFA MEETINGS

RULES FOR WORK

- **Due to the variations in the agenda, the actual members and experts will vary from meeting to meeting**
- **Continuity is secured by the Joint Secretariat, longer serving members, and, most important, by all participants who share the responsibility to maintain JECFA/JMPR/JEMRA's reputation as the leading international body for risk assessment in foods**
- **JECFA generally meets twice a year (Geneva / Rome):**
  - **At least one meeting examines food additives and/or contaminants.**
  - **The second meeting of the year may examine veterinary drug residues.**

4

JECFA MEETINGS

CORE PRINCIPLES OF SCIENTIFIC ADVICE

Key Principles

- **Soundness** — Need for scientific excellence (experts, process)
- **Responsibility**
  - Accountability
  - Safeguard the integrity of the process
  - Consider experts answerable for their views
- **Objectivity** — Neutrality of experts and advice
- **Fairness**
  - Conduct of process
  - Respect of all participants for each other and for their scientific views
- **Transparency** — Mechanisms that ensure that process and advice are clearly understandable to others
- **Inclusiveness**
  - Group balance
  - Minority scientific opinion
  - Balance of required skills and expertise

4

JECFA MEETINGS

SAFETY ASSESSMENT

- **Hazard Identification**: Identification of potential adverse health effects based on all available data.
- **Hazard Characterization**: Establishment of a dose-response relationship and identification of a No-Observed-Adverse-Effect Level (NOAEL) or Lowest-Observed-Adverse-Effect Level (LOAEL).
- **Exposure Assessment**: Estimation of the likely intake of the additive from all dietary sources.
- **Risk Characterization**: Integration of hazard identification, hazard characterization, and exposure assessment to determine the risk to human health.

4

JECFA MEETINGS

ESTABLISHMENT OF ACCEPTABLE DAILY INTAKE (ADI)

- Based on NOAEL/LOAEL, an ADI is calculated using safety factors to account for uncertainties.
- ADI is expressed in milligrams per kilogram of body weight per day (mg/kg bw/day).

4

JECFA MEETINGS

RECOMMENDATIONS AND SPECIFICATIONS

- JECFA provides recommendations on the safe levels of use of food additives.
- Specifications for identity and purity are established to ensure consistency and safety of the additive.

4

JECFA MEETINGS

RECOMMENDATIONS AND SPECIFICATIONS

- JECFA provides recommendations on the safe levels of use of food additives.
- Specifications for identity and purity are established to ensure consistency and safety of the additive.

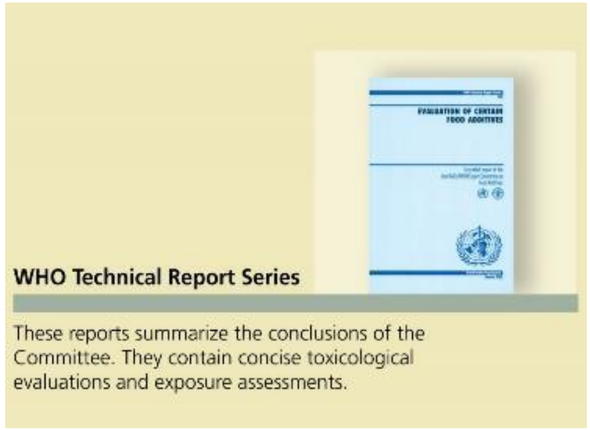
4

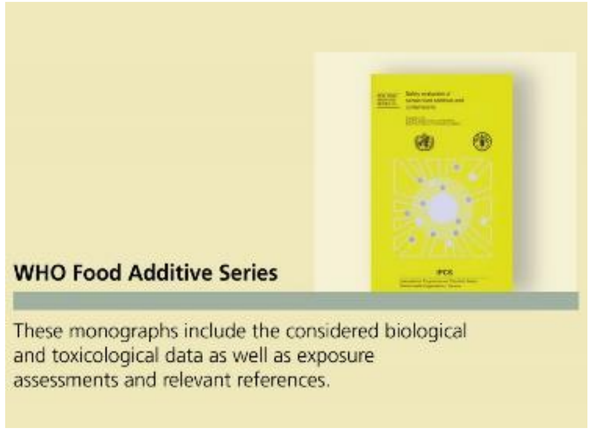
JECFA MEETINGS

PUBLICATIONS

JECFA reports and publications freely available (print / e-publication)

Summary report: 1-2 weeks after meeting, key conclusions only
Searchable database: http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx#





4

JECFA MEETINGS

REVIEW AND UPDATE

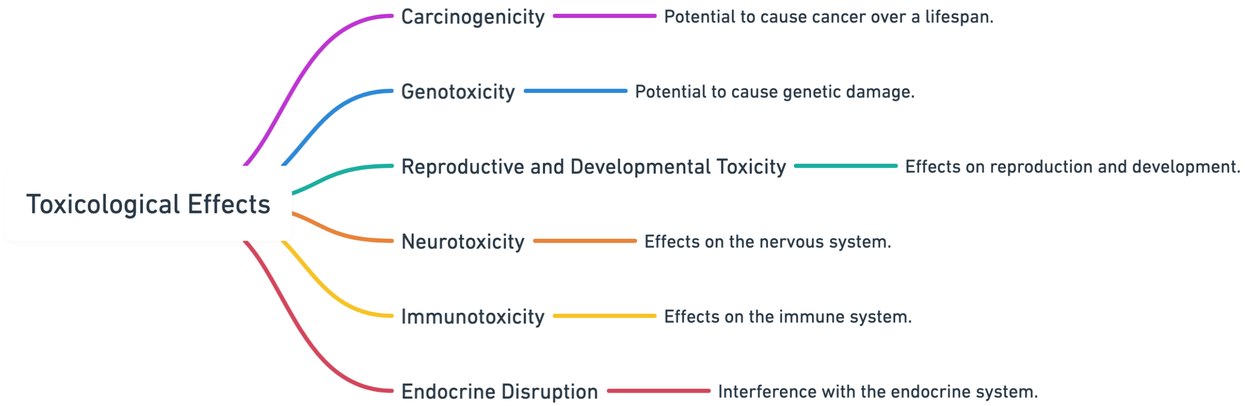
- Regular review and re-evaluation of food additives are conducted as new data become available.
- Revisions may be made to the ADI or other safety recommendations based on new scientific evidence.

4

JECFA MEETINGS

KEY CONSIDERATIONS IN JECFA EVALUATIONS

- **Toxicological Studies**: Essential for determining the potential health effects. Includes short-term, long-term, and specific studies on carcinogenicity, genotoxicity, reproductive, and developmental toxicity.
    - Absorption, Distribution, Metabolism, and Excretion
    - In vitro studies
    - Mechanistic Studies
    - Animal Studies
    - Human Studies
- **Exposure Data**: Accurate assessment of dietary intake from various food sources is critical.



4 JECFA MEETINGS

JECFA concluded that the data evaluated indicated no sufficient reason to change the previously established acceptable daily intake (ADI) of 0–40 mg/kg body weight for aspartame

World Health Organization

Health Topics | Countries | Newsroom | Emergencies | Data | About WHO

Home / News / Aspartame hazard and risk assessment results released

Aspartame hazard and risk assessment results released

العربية | 中文 | Français | Русский | Español

14 July 2023 | Joint News Release | Reading time: 3 min (778 words)

Assessments of the health impacts of the non-sugar sweetener aspartame are released today by the International Agency for Research on Cancer (IARC) and the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) Joint Expert Committee on Food Additives (JECFA). Citing "limited evidence" for carcinogenicity in humans, IARC classified aspartame as possibly carcinogenic to humans (IARC Group 2B) and JECFA reaffirmed the acceptable daily intake of 40 mg/kg body weight.

Aspartame is an artificial (chemical) sweetener widely used in various food and beverage products since the 1980s, including diet drinks, chewing gum, gelatin, ice cream, dairy products such as yogurt, breakfast cereal, toothpaste and medications such as cough drops and chewable vitamins.

"Cancer is one of the leading causes of death globally. Every year, 1 in 6 people die from cancer. Science is continuously expanding to assess the possible initiating or facilitating factors of cancer, in the hope of reducing these numbers and the human toll," said Dr Francesco Branca, Director of the Department of Nutrition and Food Safety, WHO. "The assessments of aspartame have indicated that, while safety is not a major concern at the doses which are commonly used, potential effects have been described that need to be investigated by more and better studies."

Media Contacts

Véronique Terrasse
Communications Officer, IARC
Communications Group
International Agency for Research on Cancer
Telephone: +33 472 738 366
Mobile: +33 645 284 952
Email: terrassev@iarc.fr

WHO Media Team
World Health Organization
Email: mediainquiries@who.int

The Washington Post
Democracy Dies in Darkness

BUSINESS

Aspartame may cause cancer, global health body says

One of the world's most common, and most studied, sweeteners comes under the microscope again. It is determined to be a 'possible carcinogen' and yet acceptable daily intake remains unchanged.

Branca from WHO emphasized that although aspartame's safety is not a major concern at common doses, further investigation is needed. Dr. Mary Schubauer-Berigan of IARC and Dr. Moez Sanaa of WHO called for more robust studies, including randomized controlled trials and long-term cohort studies, to clarify the relationship between aspartame consumption and cancer risk.

TUESDAY 28TH MAY 2024

World Health Organization

Food and Agriculture Organization of the United Nations

JOINT FAO/ WHO EXPERT COMMITTEE ON FOOD ADDITIVES

"Evaluating food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food since 1956"

1. ABOUT JECFA?
2. RISK ANALYSIS
3. RISK ASSESSMENT POLICY
4. JECFA MEETINGS
5. JECFA VS IARC ASSESSMENT
6. PERSPECTIVES

MOEZ SANAA

IARC vs JECFA EVALUATIONS

IARC

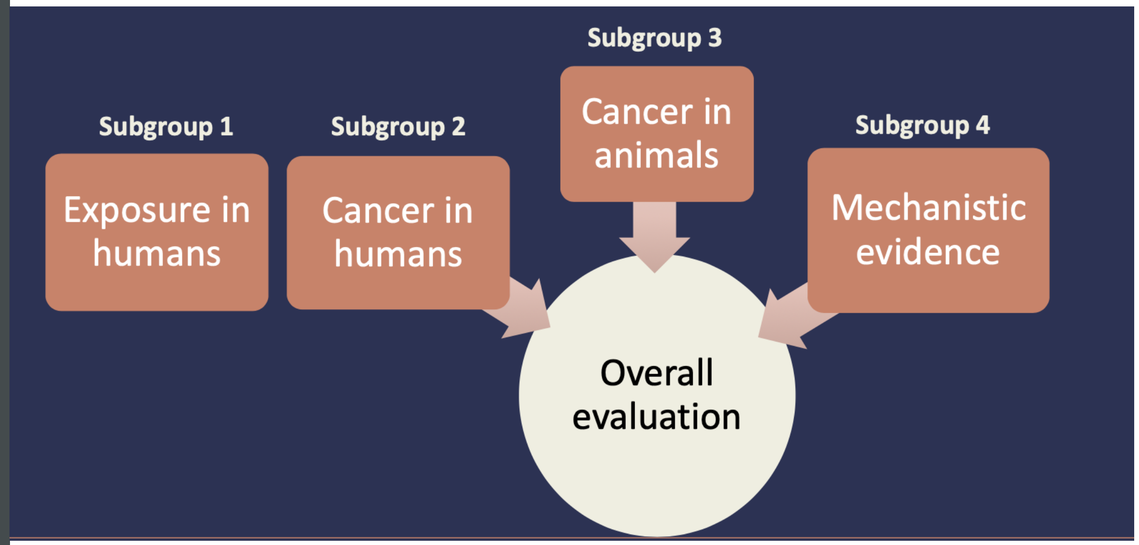
- **Cancer Hazard identification consdiering all type of exposure**

International Agency for Research on Cancer
World Health Organization

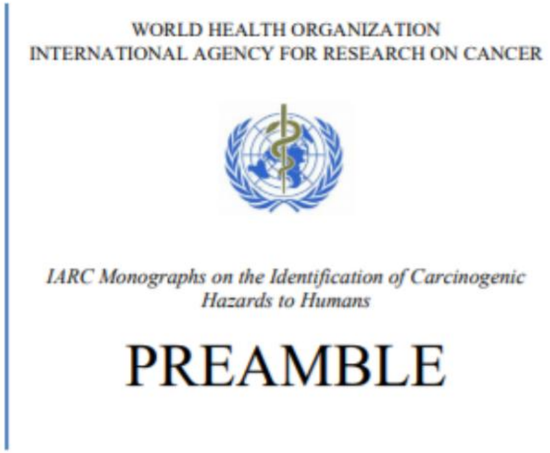
JECFA

- **Hazard identification – all toxicological effects considering only dietary exposure**
- **Hazard Characterization (ADI)**
- **Exposure Assessment (dietary)**
- **Risk Characterization**

IARC vs JECFA EVALUATIONS



Sufficient	*Limited*	*Inadequate*	ESLC
• Causal relationship has been **established** • Chance, bias, confounding could be **ruled out with reasonable confidence**	• Causal interpretation is **credible** • Chance, bias, confounding **could *not* be ruled out with reasonable confidence**	• Studies permit **no conclusion** about a causal association, or • **No data** were available	• High-quality studies covering the full range of exposure are consistent in not showing a positive association at any level of exposure


WORLD HEALTH ORGANIZATION
INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

IARC Monographs on the Identification of Carcinogenic Hazards to Humans

PREAMBLE

Preamble to the IARC Monographs (amended January 2019):
https://monographs.iarc.fr/wp-content/uploads/2019/01/Preamble-2019.pdf

Evidence Synthesis

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Sufficient	Strong (exposed humans)	
Limited	Sufficient		Probably carcinogenic (Group 2A)
Limited		Strong	
		trong (human cells or tissues)	
		rong (mechanistic class)	
Limited			Possibly carcinogenic (Group 2B)
	Sufficient		
		Strong	
	Sufficient	Strong (does not operate in humans)	Not classifiable (Group 3)
All other situations not listed above			

Sufficient for cancer in humans

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Sufficient	Strong (exposed humans)	
Limited	Sufficient		Probably carcinogenic
Limited		Strong	
	Sufficient	ong (human cells or	
Limited			carcinogenic (Group 2B)
	Sufficient		
		Strong	
	Sufficient	Strong (does not operate in humans)	Not classifiable (Group 3)
All other situations not listed above			

Sufficient for cancer in animals + strong KCs in exposed humans

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Sufficient	Strong (exposed humans)	
Limited	Sufficient		Probably carcinogenic (Group 2A)
Limited		Strong	
	ufficient	Strong (human cells or tissues)	
		Strong (mechanistic class)	
Limited			
	Sufficient		
		Stro	
	Sufficient	Strong (does in hum	
All other situations not listed above			

Limited cancer in humans + either (or both) *Sufficient* cancer in animals or *Strong* mechanistic evidence

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Sufficient	Strong (exposed humans)	
Limited	Sufficient		Probably carcinogenic (Group 2A)
Limited		Strong	
	Sufficient	Strong (human cells or tissues)	
		Strong (mechanistic class)	
Limited			
	Sufficient		
		Stro	
	Sufficient	Strong (does in hum	
All other situations not listed above			

Sufficient cancer in animals and *Strong* mechanistic evidence in primary human cells or tissues

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Sufficient	Strong (exposed humans)	
Limited	Sufficient		Probably carcinogenic (Group 2A)
Limited		Strong	
	Sufficient	Strong (human cells or tissues)	
		Strong (mechanistic class)	
Limited			Possibly
	Sufficient		
		Strong	
	Sufficient	Strong (does not op in humans)	Not classifiable (Group 3)
All other situations not listed above			

Strong mechanistic class

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Sufficient	Strong (exposed humans)	
Limited	Sufficient		Probably carcinogenic (Group 2A)
Limited		Strong	
	Sufficient	Strong (human cells or tissues)	
		Strong (mechanistic class)	
Limited			Possibly carcinogenic (Group 2B)
	Sufficient		
			assifiable p 3)

- **Aromatic amines** (aniline, *ortho*-anisidine)
- **Epoxide** (Glycidyl methacrylate)

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Suff	nans)	
Limited	Suff		Probably carcinogenic (Group 2A)
Limited			
	Suffi	s or tissues)	
		Strong (mechanistic class)	
Limited			Possibly carcinogenic (Group 2B)
	Sufficient		
		Strong	
	Sufficient	Strong (does not operate in humans)	Not classifiable (Group 3)
All other situations not listed above			

Limited for human cancer alone

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Sufficient	Strong (exposed humans)	
Limited	Sufficient		Probably carcinogenic (Group 2A)
Limited			
	Sufficient	or	
		Strong (mechanistic class)	
Limited			Possibly carcinogenic (Group 2B)
	Sufficient		
		Strong	
	Sufficient	Strong (does not operate in humans)	Not classifiable (Group 3)
All other situations not listed above			

Sufficient for cancer in animals alone

IARC vs JECFA EVALUATIONS

Evidence of Cancer in Humans	Evidence of Cancer in Experimental Animals	Mechanistic Evidence	Evaluation
Sufficient			Carcinogenic (Group 1)
	Sufficient	Strong (exposed humans)	
Limited	Sufficient		Probably carcinogenic (Group 2A)
Limited			
	Sufficient		
Limited			Possibly carcinogenic (Group 2B)
	Sufficient		
		Strong	
	Sufficient	Strong (does not operate in humans)	Not classifiable (Group 3)
All other situations not listed above			

Strong for mechanistic evidence alone

TUESDAY 28TH MAY 2024

World Health Organization

Food and Agriculture Organization of the United Nations

JOINT FAO/ WHO EXPERT COMMITTEE ON FOOD ADDITIVES

"Evaluating food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food since 1956"

1. ABOUT JECFA?
2. RISK ANALYSIS
3. RISK ASSESSMENT POLICY
4. JECFA MEETINGS
5. JECFA VS IARC ASSESSMENT
6. PERSPECTIVES

MOEZ SANAA

RISK ASSESSMENT

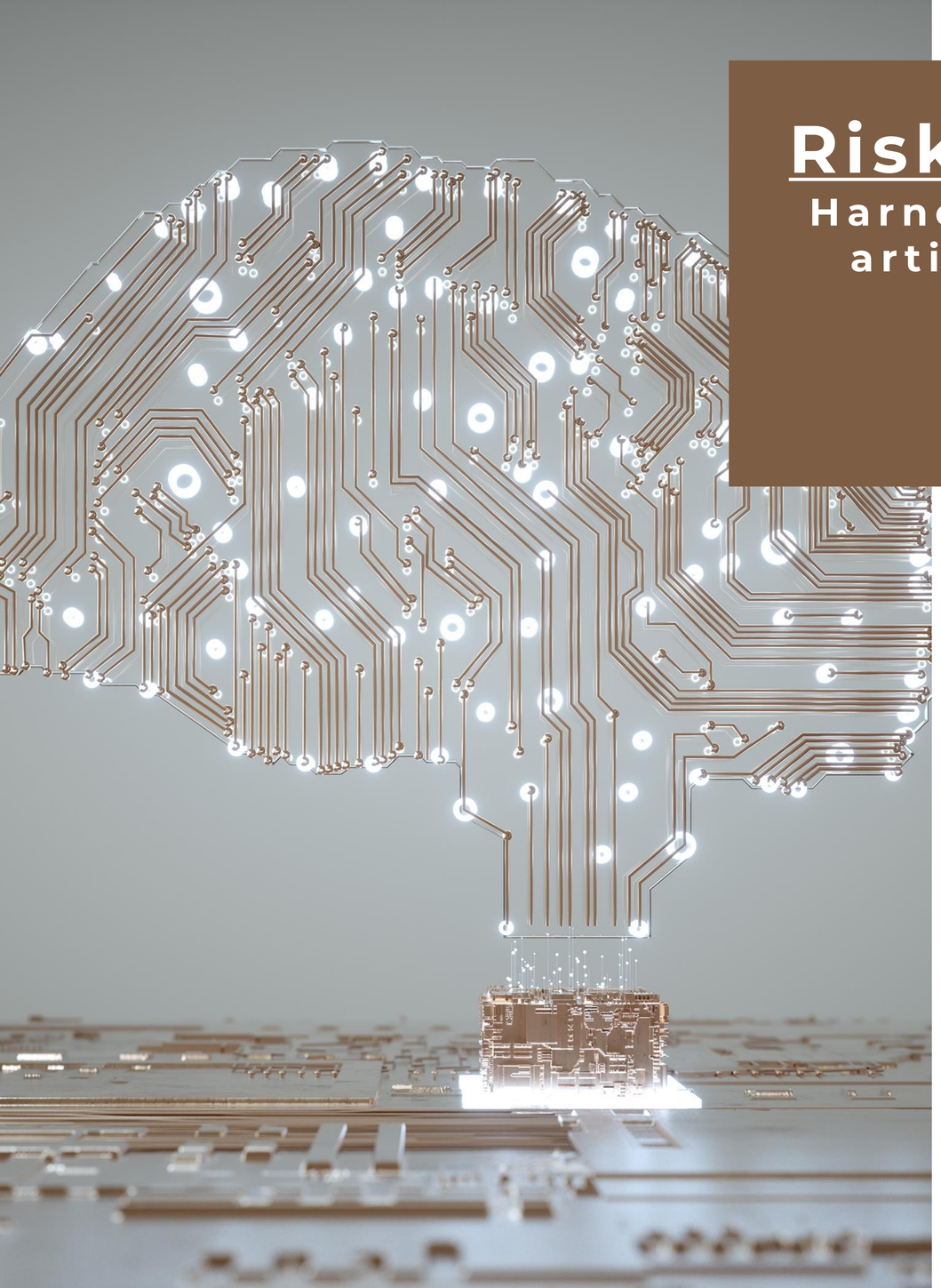
CHALLENGES

- Data Access and Sharing
- Uncertainty & Strength of Evidence
- Cross-disciplinary approaches
- Scientific Experts
- Increased complexity
- Innovation

Risk Assessment

Harnessing cutting-edge science to anticipate and tackle future challenges in risk assessment.

- Integration of non-animal methods (NAMs) in risk assessment frameworks, reducing reliance on traditional animal testing.
- Development of advanced computational models and in vitro techniques for hazard identification and dose-response assessment.
- Incorporation of high-throughput screening assays and omics technologies to enhance data generation and analysis.
- Collaboration with regulatory agencies and stakeholders to promote acceptance and implementation of NAMs in risk assessment practices.



Risk Assessment

Harnessing the power of artificial intelligence

- AI-enabled predictive modelling to assess the likelihood and severity of food safety risks based on various factors.
- Machine learning algorithms for analysing historical food safety data and identifying emerging risk trends.
- AI-driven decision support systems to prioritize inspection efforts and allocate resources effectively based on risk levels.
- Natural language processing tools for automating the review of scientific literature and regulatory documents to inform risk assessment processes.
- Tools facilitating data collection

TUESDAY 28TH MAY 2024

THANKS

END