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CHALLENGES RELATED TO RISK COMMUNICATION ASSOCIATED WITH SUGAR SUBSTITUTES IN FOOD

International Best Practices on the Review and Approval of Food Additives

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Outline

Reviewing Some Challenges Related to Communication Associated with the Approval and Use of Sugar Substitutes

Learnings and Perspectives

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Risk Communication is a Key Component of Risk Analysis

Pillars of a Robust Food Control System

Codex Definition of Food Risk Communication

- **Risk Communication** refers to the **interactive exchange of information** and **opinions throughout the risk analysis** process concerning hazards and risks, risk-related factors **and risk perceptions**, **among risk assessors**, **risk managers, consumers, industry, the academic community and other interested parties**, including the explanation of risk assessment findings and the basis of risk management decisions.

Food Additives

Any substance not normally consumed as a food in itself and not normally used as a typical ingredient of the food, intentionally added for a technological purpose *(adapted from Codex GSFA)*

- ❑ Only those that have undergone JECFA assessment and **are found not to present an appreciable health risk to consumers** can be used internationally:
  1. Safety assessment conducted by JECFA
  2. Maximum use levels established in Codex GSFA
  3. Development of national regulations permitting use of additive
- ❑ Additives are Associated with a Perception of Risk

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Why This Risk Perception?

Additives are Chemicals

- ❑ Some of Very Common Occurrence – e.g., Citric Acid
- ❑ We Forget that Chemicals Do Occur in Food
  - E.g. Hydroquinone (1,4-Benzendiol) is a natural constituent in pears, wheat, tea and coffee, rice, onions, cranberries and blueberries
    - Major Source of Exposure (low levels not triggering any negative effects)
  - Yet Taken individually:
    - The EU classified hydroquinone as both carcinogenic and mutagenic.
    - There is sufficient in vitro evidence to conclude that hydroquinone is genotoxic, however, only limited in vivo evidence.

The Issue – Hazard vs Risk?

HAZARD

RISK

The Difference is the EXPOSURE!

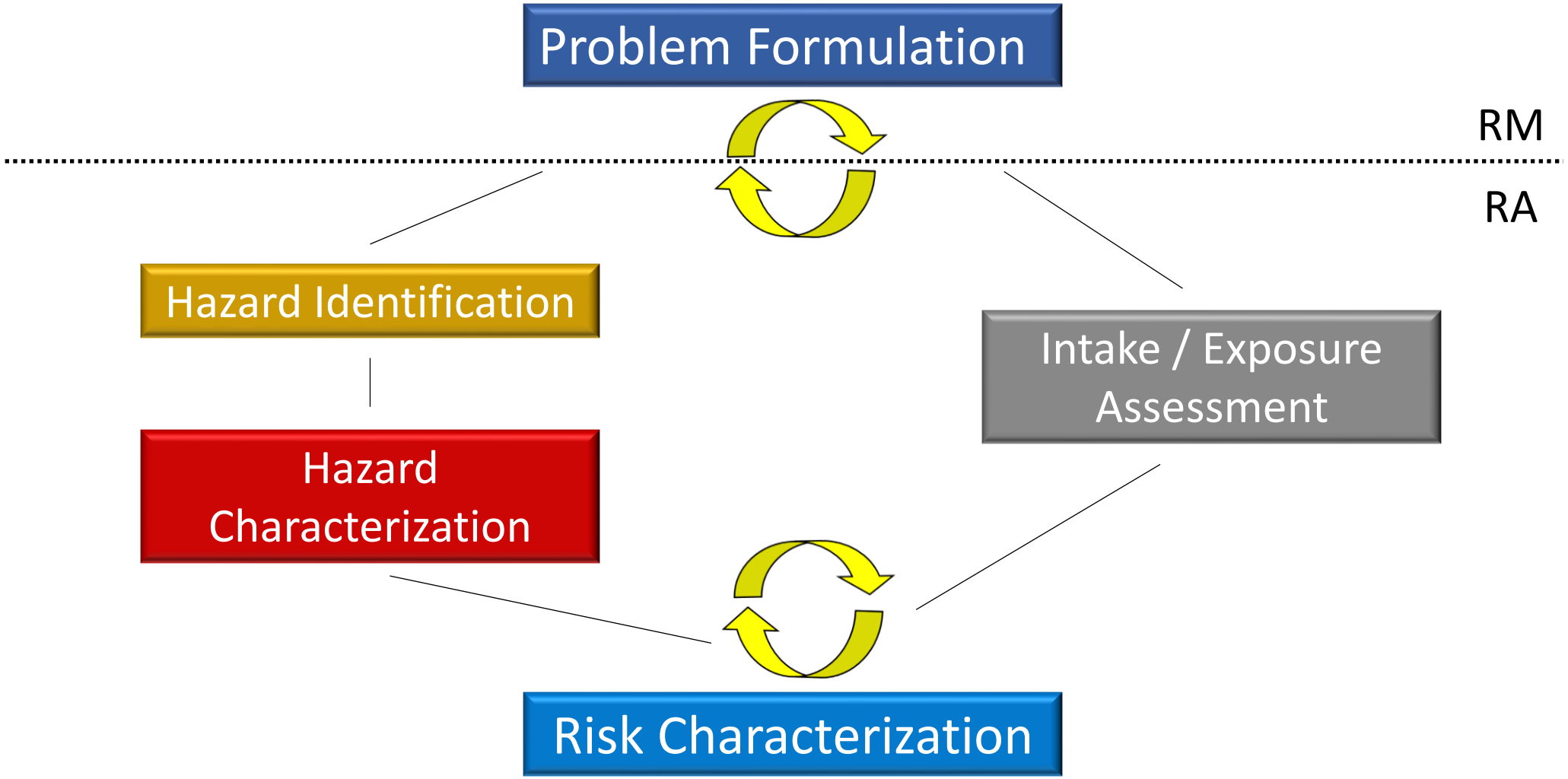
Key Concept – Hazard vs Risk?

HAZARD

RISK

The Difference is the EXPOSURE!

Risk Assessment Procedure: A Scientific Process



Food Risk Perception

Substances Present in Food

Should NOT lead to Health Risks

(when consumed through food)

We Consider Exposure in Risk

Occurrence of Food Chemicals

Food consumption

We Consider High Consumption Scenarios

- Within a risk assessment process, mean consumption levels are often not sufficient

- It is fundamental to consider also non-average individuals, in particular high consumers
  - Those who consume relatively large quantities of foods

Short Term and Chronic Exposure

- **Scientists Consider Different Scenarios of Exposure:**
  - **Generally 97.5th percentile for consumers**
- Risk Assessment Considers Extreme scenarios

Various Target Populations Are Considered

Adult population

Pregnant women

Small children

Infants

Elderly

Special groups: vegetarians, diabetics, ethnic groups and different socio-economic strata …

But This Does NOT Seem to be Enough to Prevent Mis-Communication and Controversies!

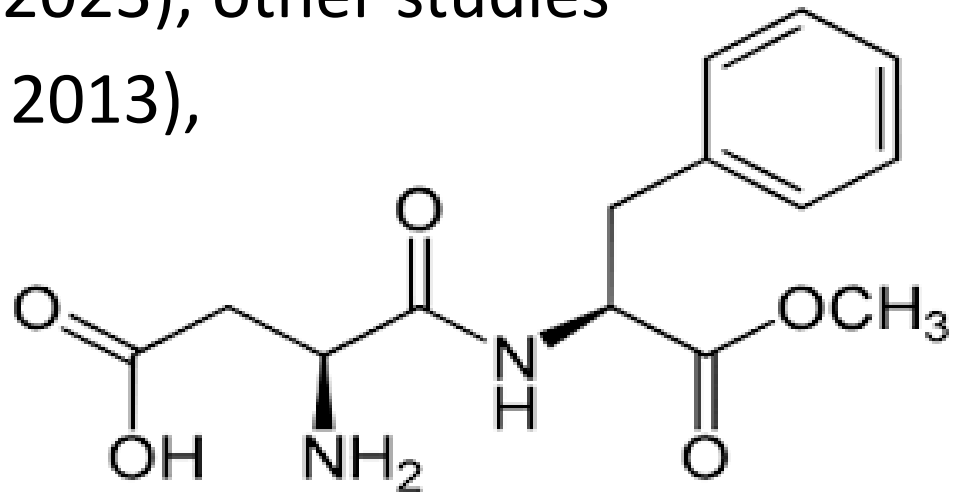
The Case of Sugar Substitutes

Non-Sugar Sweeteners

- High sweetness, low calorie, used in very small quantities
- Acesulfame K, aspartame, cyclamates, saccharin, sucralose, steviol glycosides…
- Different chemical structures
- Extensively studied for genotoxicity and carcinogenicity effects – no evidence of risk when approved as a Food Additive

Aspartame

- One of the most studied substances in the food supply
- ADI (mg/kg bw): 0-50 (FDA), 0-40 (JECFA, SCF, EFSA)
- Remains controversial despite sound evidence of its safety
  - No genotoxic potential: EFSA (2013), systematic literature reviews (Magnuson et al., 2007; Lea et al., 2021; Pavanello et al., 2023), other studies
  - No carcinogenic potential: EFSA (2006, 2009, 2013), FDA (2017), systematic literature reviews (Haighton et al., 2019; Wikoff et al., 2020; Pavanello et al., 2023), other studies



Risk Communication Challenge – Part 1

- ❑ Approved for use in food & drinks early 1980s
- ❑ July 2005 Ramazzini study: aspartame causes cancer in rats
  - Presented in Ramazzini-led press conference, journal (not peer-reviewed) and scientific conference
  - International media frenzy
  - Data published WAS INCOMPLETE
  - After several requests, Ramazzini submits data to Food Regulators
  - Data Submitted was incomplete
    - No pathology slides (EFSA)
  - This has even led to Politization of the Debate (UK)

Media Amplification and Confusion (2005-06)


HEALTH: WEBMD

Study Links Aspartame To Cancer

July 28, 2005 / 6:53 PM EDT / WebMD

Artificial sweetener causes cancer in rats at levels currently approved for humans, new study suggests

Date: February 13, 2006

MP calls for total ban on 'cancer' sweetener

Fresh fears raised about aspartame

Manufacturers dispute study into lab rats fed sweetener

The European Food Safety Authority is reviewing "as a matter of high priority" the results of a large new study into aspartame, the artificial sweetener consumed by millions of people worldwide and used in more than 6,000 food and drink products.

NEWS HEALTH & MEDICINE

Not So Sweet: Cancers in rats that consumed aspartame

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Media Amplification – Analysis

- Why ???? Triggers
  - Cancer risk
  - Consumed by millions of people worldwide
  - Bias: Used by large corporations in the food industry
- Vacuum of Information for 10 Months
  - May 2006 EFSA report: no cancer concerns
    - Press conference and publication of full report on official website
    - Significant press coverage
- But damage was already done
  - Industry losses, negative image
  - Consumers misled by 10 months of misinformation

Sweetener's 'link to cancer' denied

By SEAN POULTER, Daily Mail
Last updated at 14:17 15 July 2005

The artificial sweetener aspartame, which is used in 6,000 diet food and pharmaceutical products, has been linked to cancer.

The additive - also known as NutraSweet - is found in Diet Coke, Candarel, Pepsi Max, Ribena Light, Muller Light strawberry yoghurt, Wrigley's Extra Spearmint chewing gum and many other products.

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Lessons Learned

Communication and Dissemination of Science Results

(extracted from Lofstedt, 2008)

Good practices 	*Ramazzini* 
Scientific peer-review journal	General media
Share data with regulators	Keep data secret
Dialogue with regulators	Little dialogue with regulators
Openness regarding funders	Secrecy regarding funders
Few if any press conferences	Many press conferences
Publish in best peer-review journals	Many non-peer-review journals
Proper risk communication	Faulty risk communication

More Recently……2023

- ❑JECFA scheduled aspartame reassessment for July
- ❑IARC decides to develop a monograph
- ❑Results published simultaneously by WHO in July

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Summary of findings of the evaluation of aspartame at the International Agency for Research on Cancer (IARC) Monographs Prog
FAO/WHO Expert Committee on Food Additives (JECFA) 96th meeting

Summary of findings of the evaluation of aspartame at the International Agency for Research on Cancer (IARC) Monographs Programme's 134th Meeting, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 96th meeting

14 July 2023 | Meeting report

JECFA: no need to change ADI

IARC: possibly carcinogenic

????

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More Recently……2023 (continued)

IARC

- ❑conducts ***hazard*** assessments
- ❑Different Approach of Selection of Experts (than JECFA)

International Agency for Research on Cancer

World Health Organization

JECFA

- ❑WHO/FAO Expert Body
- ❑Codex official body to assess additives based on ***risk*** (safe dose/limit)
- ❑Independent and Global Reference for Risk Assessment

JECFA EVALUATIONS
The Joint FAO/WHO Expert Committee on Food Additives (JECFA)

WHO

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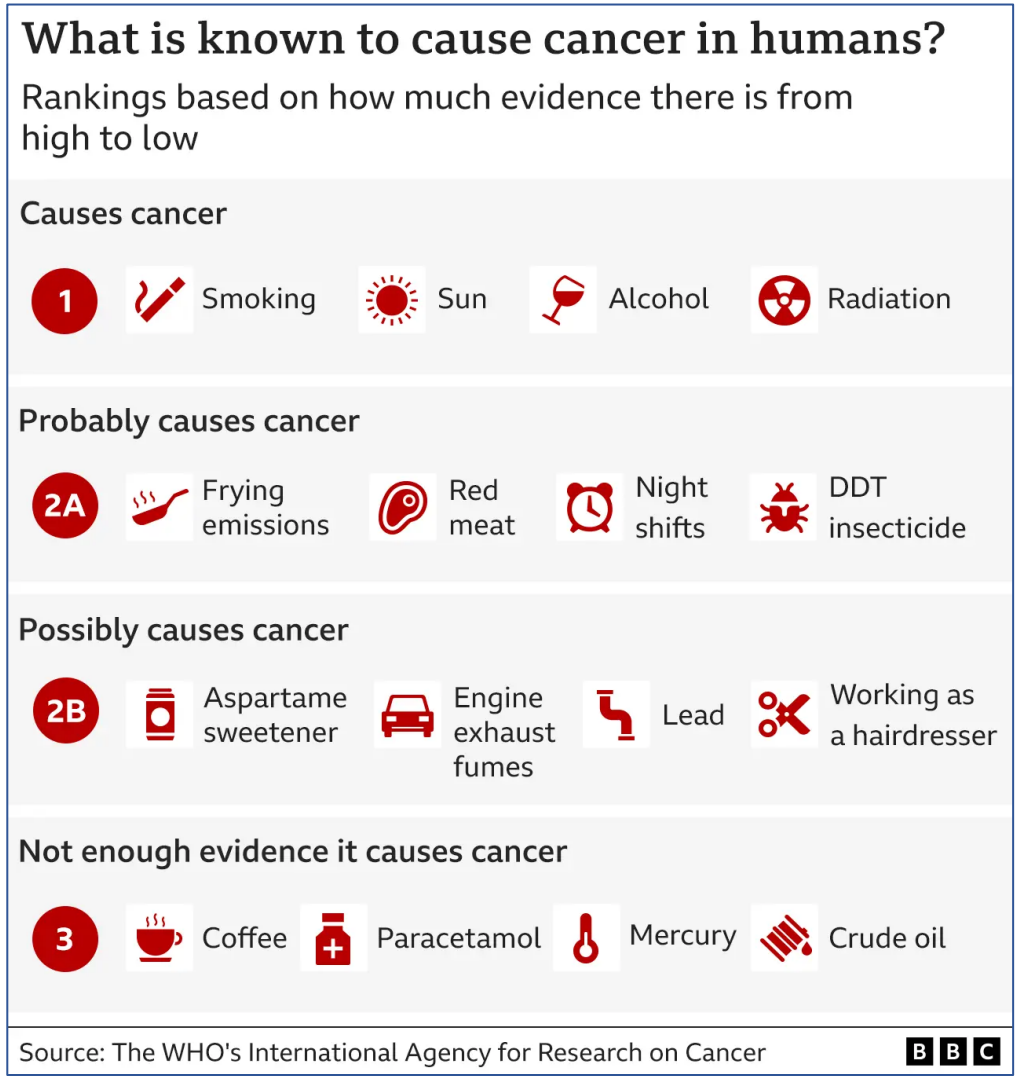
IARC study

- IARC uses 4 possible classifications
- Aspartame has been moved to “possibly carcinogenic”
  - 3 studies, connection to liver cancer
- “Possibly” refers to the strength of the scientific evidence
- IARC: "evidence was not of sufficiently high quality or convincing enough" and "this is really more a call to the research community"



JECFA Assessment

Based on cancer risk and other issues (e.g., heart disease, type 2 diabetes)

ADI unchanged

Media Amplification (2023) – Déjà Vu

Food additive added to thousands of products is a possible cancer-causing chemical

HEALTH / PUBLIC HEALTH

The WHO declared aspartame "possibly" causes cancer. Here's what that means.

Get ready for an earful about the health risks of Diet Coke, Trident gum, Equal, and other sugar-free items.

Most Popular Chewing Gums Contain This Cancer-Causing Sweetener, Chew On This Instead

WHO declares widely used sweetener aspartame a possible cancer cause, but intake guidelines stay the same

Cancer: Artificial sweeteners linked to greater risk of cancer – 'consumed by millions'

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Overall Analysis

- ❑Trigger of Assessment or Re-Assessment
- ❑Studies Not Issued by Authoritative Bodies
- ❑Difficulty to Position Results: What Does it Mean for Consumers?
- ❑Amplification of Message: Social Media and Beyond
- ❑Need for Concerted Action
- ❑Need for Common Messaging

Where Do We Go From Here …. ?

Some of the Guidance From Lessons Learnt and Research:

From Lofstedt (2008) https://link.springer.com/article/10.1057/rm.2008.11

- Academics, regulators and the media need to work together in developing responsible and credible risk communication strategies.

- Research organizations should in close collaboration work with policy makers to develop uniform scientific data with agreed-upon disclosure guidelines

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Overall Future Direction

- Risk should be communicated correctly and **responsibly**
- Not a one-way form of persuasion;
- should help consumers make better choices (Fishchhoff, 1995; 2007; Lofstedt, 2010)
- Learnings from Previous Experience
- Following Codex Guidance:

"The **interactive exchange** of information and opinions concerning risk among risk assessors, risk managers and other interested parties"

✓**Concerted and Collaborative Action**

✓**Leadership from Authoritative Sources**

✓**Keeping a Momentum: Overcome "Being Drowned by Noise"**

✓**Continued Learning and Improvement**

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