International Symposium on Safety and Uses of Food Additives
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SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE

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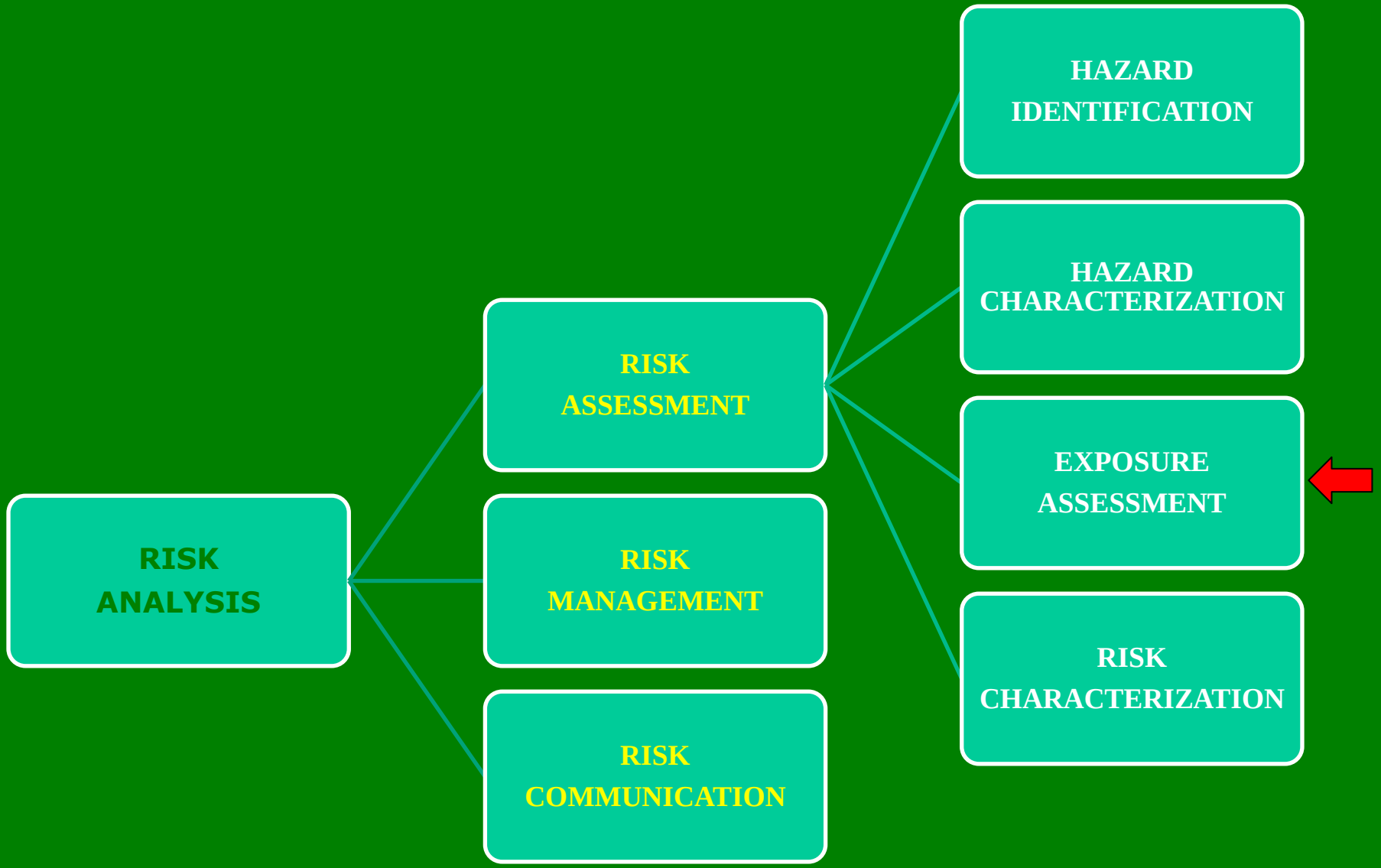
Exposure assessment

"The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant"

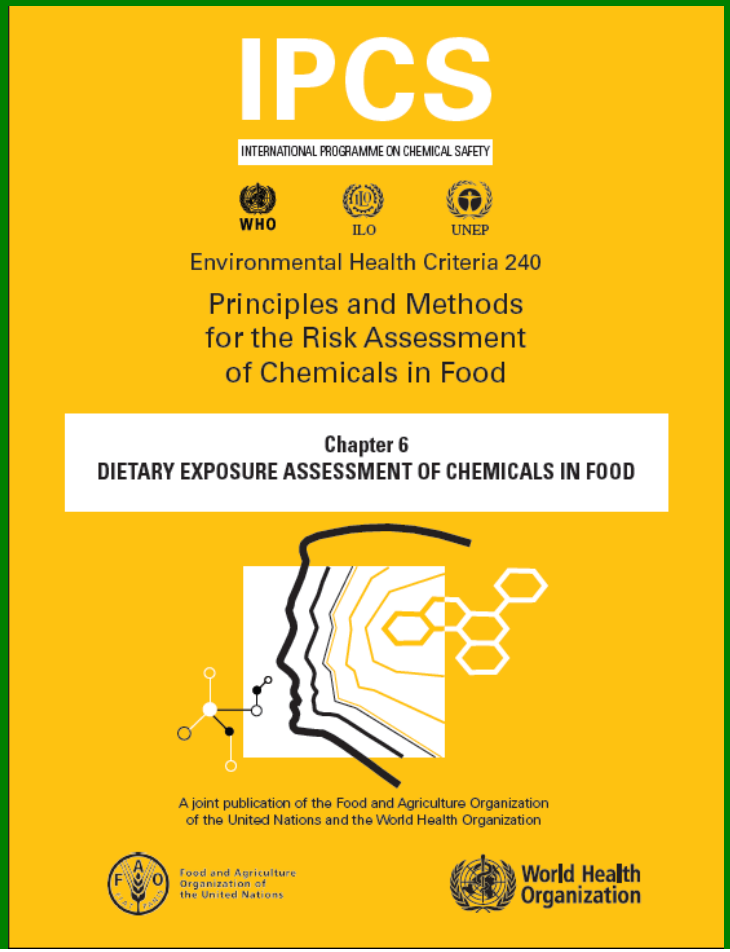
Codex Alimentarius Commission Procedural Manual, 21st edition


RISK ANALYSIS
RISK ASSESSMENT
RISK MANAGEMENT
RISK COMMUNICATION
HAZARD IDENTIFICATION
HAZARD CHARACTERIZATION
EXPOSURE ASSESSMENT
RISK CHARACTERIZATION

FAO/WHO Environmental Health Criteria 240 Principles and Methods for the Risk Assessment of Chemicals in Food

Combines food consumption data with data on the concentration of chemicals in food

The resulting dietary exposure estimate may then be compared with the relevant health based guidance value for the food chemical of concern (ADI)



GENERAL EQUATION

$$\text{Dietary exposure} = \frac{\Sigma\,(\text{Concentration of chemical in food} \times \text{Food consumption})}{\text{Body weight (kg)}}$$

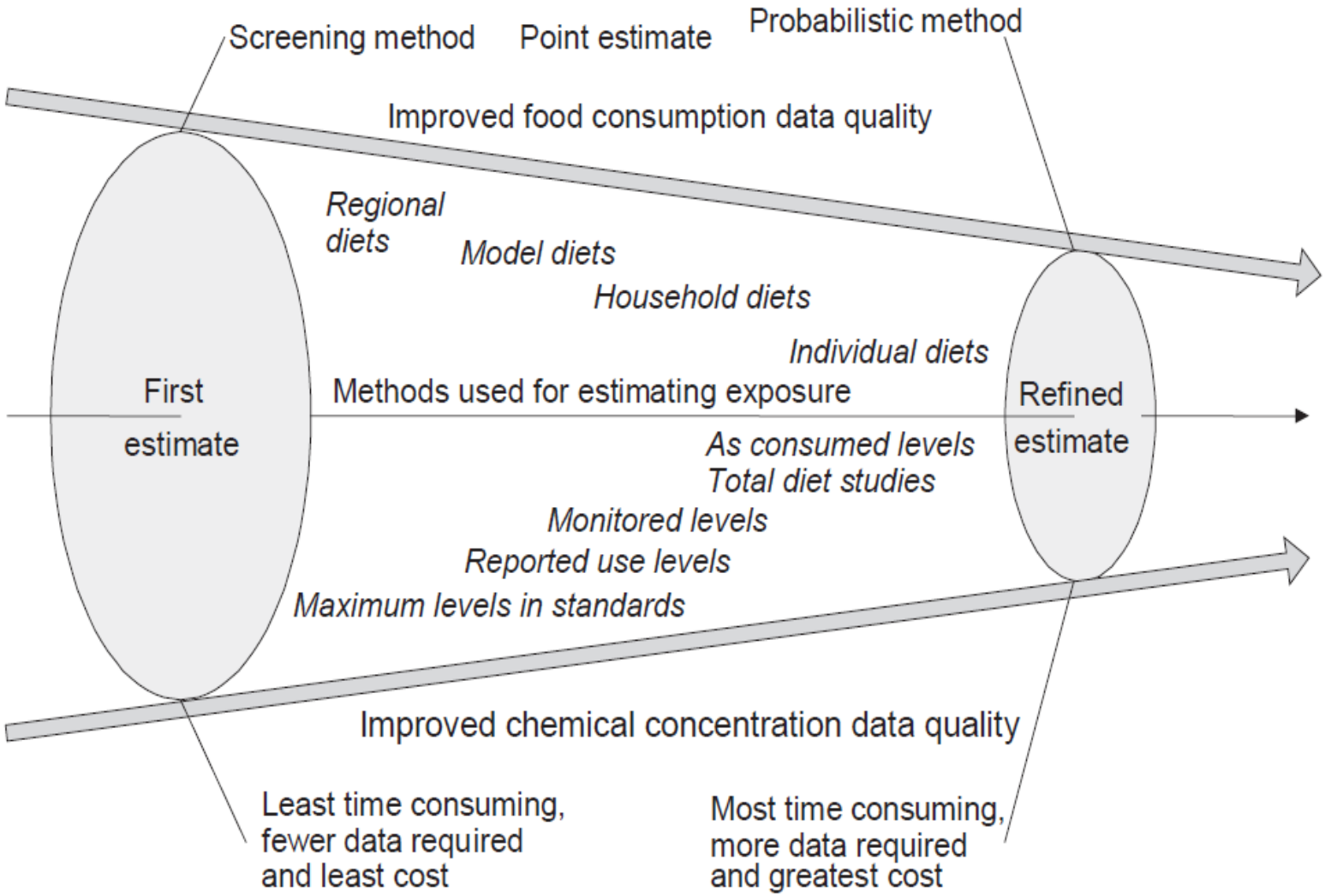


Fig. 6.1. Stepwise approach to obtaining realistic dietary exposure assessments

Ref.: EHC 240

Background

The Guidelines for Simple Evaluation of Food Additive Intake (CAC/GL 3-1989) were elaborated by a CCFAC ad-hoc Working Group on Intake of Food Additives and Contaminants and adopted in 1989, in response to requests from Governments for simple and inexpensive methods for estimating intakes of food additives

GUIDELINES FOR SIMPLE EVALUATION OF FOOD ADDITIVE INTAKE

CAC/GL 03-1989

CONTENTS

Background

In 2011 - Request from the Codex Alimentarius Commission to the CCFA to consider the need to revoke or revise the document

In 2012 - 44th Session of the CCFA - Agreed to establish an electronic Working Group chaired by Brazil to prepare a project document for new work on the revision of the guidelines

Background

The Committee considered that the Guidelines contains useful and simple guidance to facilitate the dietary exposure assessments of food additives, since some approaches for the estimation of the dietary exposure may be expensive and time consuming, and countries may therefore have difficulties in undertaking these studies at national level.

Revision based on updated references such as the EHC 240

Background

In 2013 – CCFA forwarded the project document to the Commission and the new work was approved. The eWG was reestablished to revise the text.

In 2014 – Presentation of the eWG report to the 46th Session of the CCFA.

The proposed timeline for completing the work is 2016

CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4c

CX/FA 14/46/6
November 2013

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-Sixth Session

Hong Kong, China, 17-21 March 2014

REVISION OF THE *GUIDELINES FOR THE SIMPLE EVALUATION OF FOOD ADDITIVE INTAKES* (CAC/GL 3-1989) (N08-2013)

Prepared by an electronic Working Group led by Brazil, with the assistance of Argentina, Australia, Belgium, Chile, China, European Union, Ghana, Greece, Indonesia, Iran, Japan, Malaysia, Mexico, Norway, Peru, Philippines, Poland, Russia, South Africa, Spain, USA, Calorie Control Council (CCC), European Chemical Industry Council (CEFIC), Federation of European Specialty Food Ingredients (ELC), Institute of Food Technologists (IFT), International Alliance of Dietary/Food Supplement Associations (IADSA), International Aluminium Institute (IAI), International Council of Grocery Manufacturer Associations (ICGMA), International Food Additives Council (IFAC), International Organization of Vine and Wine (OIV), the Natural Food Colours Association (NATCOL), World Association of Seaweed Processors (Marinalg International) and WHO/JECFA Secretariat.

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments at Step 3 on the proposed draft Revised Guidelines (Annex 1) are invited to do so no later than **31 January 2014** as follows: Secretariat, Codex Committee on Food Additives, China National Center for Food Safety Risk Assessment (CFSA), Building 2, No. 37 Guangqu Road, Chaoyang District, Beijing 100022, China, (E-mail: secretariat@ccfa.cc), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (E-mail: Codex@fao.org).

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex II to this document.

ANNEX 1

PROPOSED DRAFT GUIDELINES FOR SIMPLE EVALUATION OF DIETARY EXPOSURE TO FOOD ADDITIVES

CAC/GL 3-1989

(at Step 3)

Main revisions

- Title - GUIDELINES FOR SIMPLE EVALUATION OF DIETARY EXPOSURE TO FOOD ADDITIVES
- Terminology and content
- Examples - Calculation for Benzoic Acid and its Salts (INS 210-213), with updated data from Brazil

Approaches for the simple evaluation of dietary exposure to food additives

TMDI - Theoretical Maximum Daily Intake

EDI - Estimated Daily Intake

Both were considered appropriate as simple methods and retained in the document

TMDI

Calculated by multiplying the average per capita daily food consumption for each food by the maximum use level (ML) of the food additive established by national regulations or contained in the GSFA or by the proposed use levels by the food industry and summing the resulting exposure values to give total dietary exposure

TMDI

- It approximates the dietary exposure to a food additive
- Although sometimes criticized as being “too conservative”, the aim is not to assess true dietary exposure but to identify food additives for which a more comprehensive dietary exposure assessment is necessary. This must be made clear when results are presented, as should all assumptions made

TMDI

- It assumes that:

(a) all foods in which a food additive is permitted contain that additive
(b) the food additive is always present at the ML
(c) the foods in question containing the additive are consumed by people every day of their lives at the mean per capita level
(d) the amount of the food additive in the food does not change as a result of storage, cooking or processing techniques
(e) all foods permitted to contain the food additive are ingested and nothing is discarded

EDI

The EDI of a food additive is the amount of an additive ingested by the average consumer of the food based on a) the actual use of the additive by industry, or b) if the food additive is used according to Good Manufacturing Practice (GMP), an approximation as close as possible to the actual use levels

Data available

The first step is to identify and collect all data available in the country and check if these data can provide sufficient information to assess the dietary exposure to the food additive.

It is recommended to use national data on food additive concentrations, food consumption and body weight, and international toxicological reference values.

$$\text{Dietary exposure} = \frac{\Sigma\,(\text{Concentration of chemical in food} \times \text{Food consumption})}{\text{Body weight (kg)}}$$

Concentration of food additives in food

Pre-regulation

- Dietary exposure assessed for a food additive before it has been approved for use
- Concentration data should be available from or estimated by the manufacturer

Post-regulation

- Dietary exposure assessed for a food additive after it has been in the food supply for a period of time
- MLs established by national authorities
- MLs in the GSFA
- Actual use levels from food manufacturers or food processors
- Analytical data from monitoring and surveillance

Authorization for use of food additives

Specific use

Positive list of foods in which the additive may be used with an indication of the ML

Specified foods, according to GMP

Food industry can provide actual levels for the additive in different foods

Analytical data

According to GMP in all foods, but the use in certain foods is under specific provision

Requires close collaboration with the food industry and/or a rather complete sampling and analytical evaluation of the levels present in foods

Financial consequences may limit applicability

Food consumption data

Food consumption data reflect what individuals or groups consume in terms of solid foods, beverages (including drinking water), and food supplements.

Two general approaches to obtain information on the dietary habits:

Food consumption data

Inferred data on the movement and disappearance of food in a region or home

Population-based methods	**food balance sheets** **food disappearance data**
Household - based methods	**data on food purchased by a household** **follow-up of consumed foods or changes in food stocks**

Food consumption data

Personal data on the actual food consumption by an individual or household

Individual -based methods

- **food record**
- **24 h dietary recall**
- **food frequency questionnaires (FFQs)**
- **diet history survey**
- **food habit questionnaire**

Consider possible variation of food habits within subgroups of the population

Provide food consumption data for different sex, age, ethnic, economic, and regional populations

Food consumption data

Sub-population groups that consume large quantities of food in general or of specific food items may be taken into account by considering higher percentiles of food consumption data (e.g., 90th, 95th or 97.5th)

Body weight

- Should be representative of the individuals in the country or region or population sub-group of interest as much as possible
- The average body weight of 60 kg for adults and 15 kg for children are assumed for most populations
- For certain regions, the average body weight of the adult population may differ significantly, e.g. an average body weight of 55 kg is assumed for the adult Asian population
- For food consumption data collected using individual-based methods, it is recommended that the actual body weights of the survey participants be used

Criteria for prioritization of evaluation of dietary exposure to food additives

(i) Additives authorized for use at a high level in foods consumed in large quantities or by a significant proportion of the population

(ii) Additives consumed by potentially-at-risk subgroups (e.g., children, diabetics, pregnant women, elderly), as appropriate

(iii) Additives assigned a low ADI

JECFA - Additives that have been assigned a numerical ADI when they are used according to GMP

A low priority can be given to additives that have been assigned an ADI of "not specified" when they are used according to GMP

Proposed method for a simple evaluation of the dietary exposure to food additives STEPWISE PROCEDURE

Evaluation of the TMDI

- Determination of the levels of use
- Determination of the average consumption of the food in which the additive is permitted
- Obtain a better estimate of food consumption by replacing average values obtained from the national population-based method by average consumption for "eaters"

If the TMDI > ADI

Evaluation of the EDI

- Check the list of foods
- Check the actual levels of use
- Introduce these more refined data in the TMDI calculated

If the EDI > ADI

Check the need and the possibility to conduct a more refined exposure assessment and, when appropriate, discuss with the food industry reviewing the MLs of the additive and the foods in which it is used

THANK YOU

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