EXPOSURE ASSESSMENT OF FOOD ADDITIVES WITH PARTICULAR EMPHASIS ON FLAVOURINGS AND COLOURANTS

By

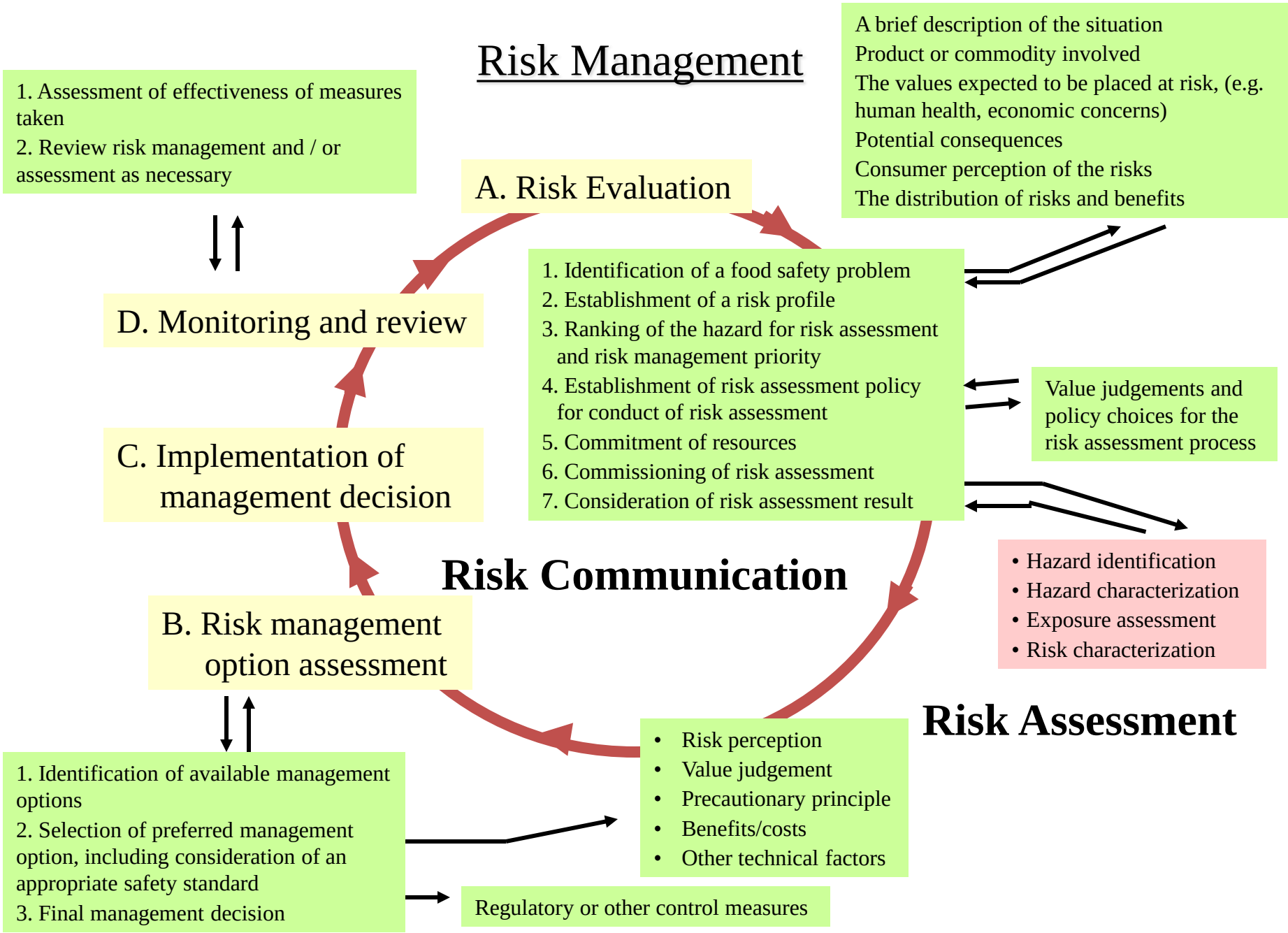
Dr Michael E. Knowles

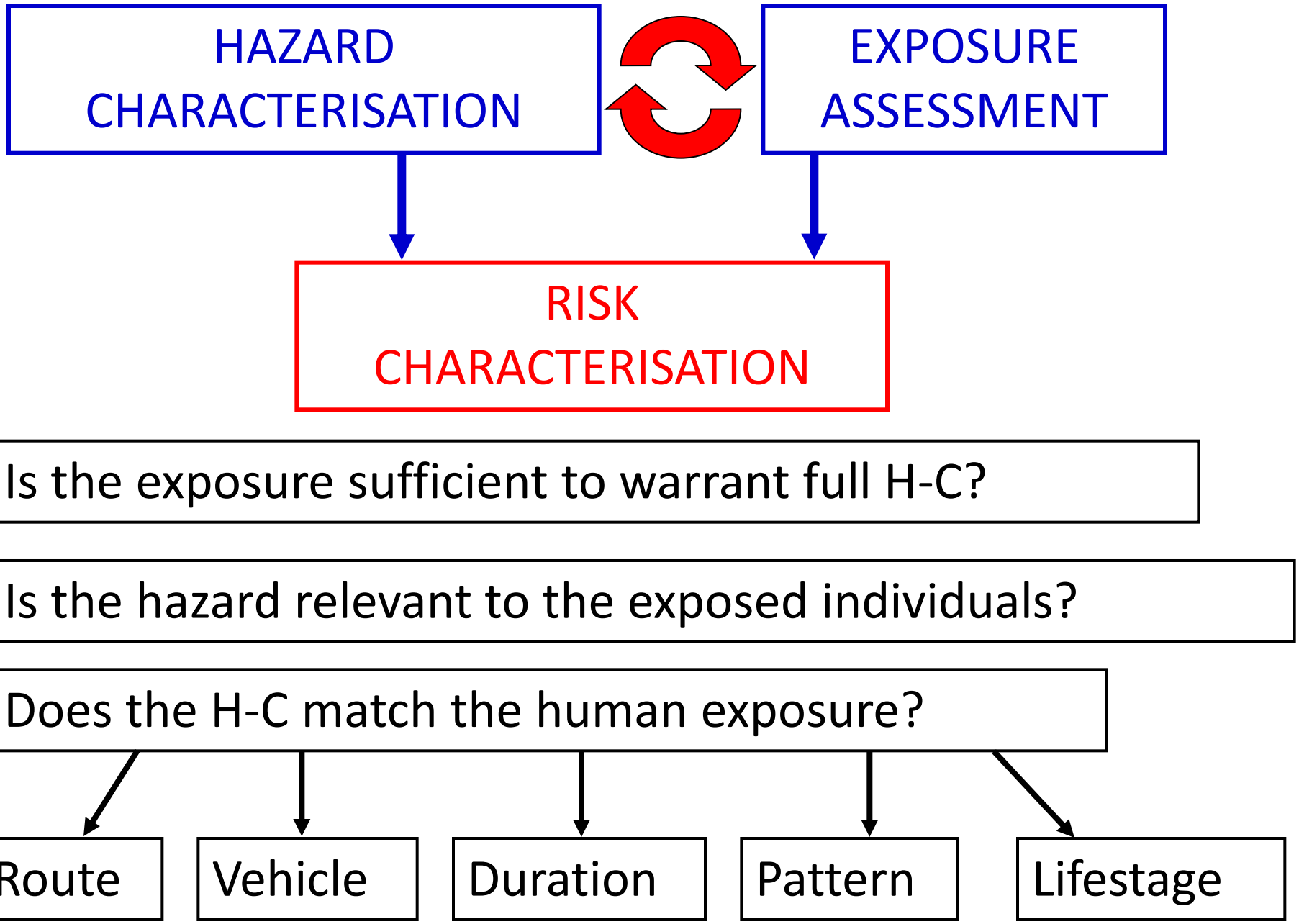
20th SAAFoST Biennial International Congress & Exhibition
7-10 October 2013 , CSIR Convention Centre , Pretoria, South Africa

The presentation will hopefully show :

- That exposure assessment is a key element of risk assessment and a tool for risk management
- It's theoretically simple but practically complex due to data deficiencies
- A pragmatic approach for additives & flavours
- Refined assessment with probabilistic modelling – FACET methodology
- ILSI Europe's ' GUIDEA '

Risk Management




HAZARD CHARACTERISATION
EXPOSURE ASSESSMENT
RISK CHARACTERISATION
Is the exposure sufficient to warrant full H-C?
Is the hazard relevant to the exposed individuals?
Does the H-C match the human exposure?
Route
Vehicle
Duration
Pattern
Lifestage

THREE MAIN QUESTIONS FOR EA

- Which substances are present in what amounts in a given food/diet (including information concerning factors influencing their levels and qualities such as bioavailability)
- How much of the foods containing these substances are consumed and what is the consumption of potentially relevant risk groups, including high users?
- What are the conditions and the probabilities of consuming occasionally or regularly high amounts of such foods which at the same time contain high levels of the substance(s) in question?

EXPOSURE ASSESSMENT CONCERNS

- ANALYSIS and FATE of the chemical of concern
- FOOD CONSUMPTION data
- Methodologies to integrate food consumption and chemical concentration to make the best estimate.

General Equation for Acute and Chronic Dietary Exposure

$$\text{Dietary Exposure} = \frac{\text{Concentration of chemical in diet} \times \text{Weight of diet consumed daily}}{\text{Body weight (kg)}}$$

-> expressed as mg / kg body weight / day

DATA REQUIREMENTS

Concentration:

> Regulated ML's

> Manufacturer's Use Levels

> Analysis

Consumption Patterns

> Total Diet Survey (TDS)

>Household Budget Surveys (HBS)

> 24 hr Recall / Dietary Questionnaire

> Individual Food Diary Records (weighed) + Interviews

> Duplicate Diets

> Biomarkers

-> General Population / Sub-Groups

FOOD CONSUMPTION DATA

- Four different types of data:
  - Food supply data
  - Data from household consumption surveys
  - Data from dietary surveys from individuals
  - Data from total or duplicate diet surveys

increased precision

DATA UNCERTAINTIES

Concentration

> Sampling and Analysis

Consumption Surveys

> Temporal- extrapolation to lifetime exposure
> Under / Over reporting
> Representativeness of population sample
>Other sources of exposure eg supplements , medicines
> Coding system not specific enough
> Portion size
> Processing

INTEGRATION OF FOOD CONSUMPTION AND CHEMICAL CONCENTRATION TO ASSESS INTAKE

- Except for duplicate diet studies we do not have consumption, occurrence and concentration data related to the same individual
- Therefore to create a real life exposure situation some type of modeling is necessary

MODELS: POINT ESTIMATES

- **Fixed** value for food consumption

  x fixed value for concentration $\rightarrow$ **Intake**

No insight in range of possible exposure, usually conservative, implausible intake estimates, very good for screening purposes

MODELS: SIMPLE DISTRIBUTION

- **Distribution** of food intake x **fixed** value for concentration
  → **range of intakes**

  according to food consumption pattern

More accurate, may still be conservative depending on assumptions

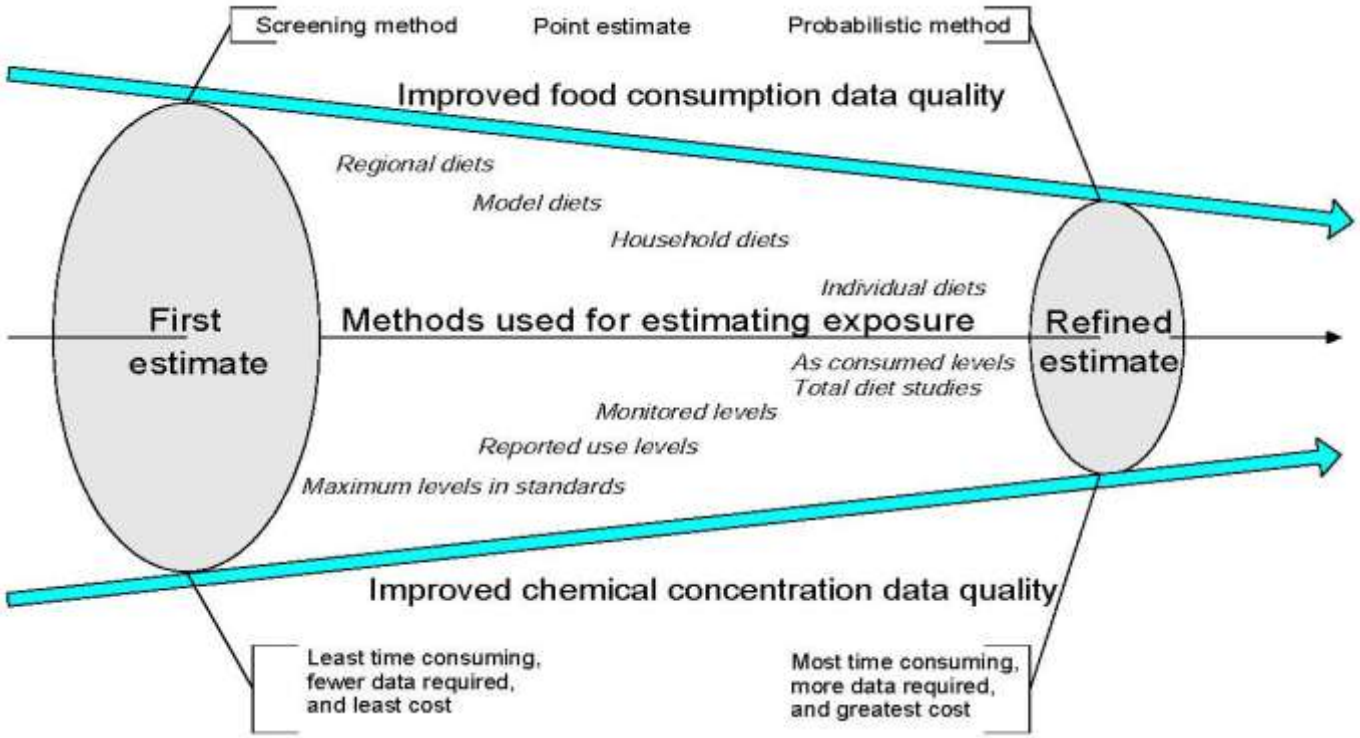
MODELS: PROBABILISTIC ANALYSIS

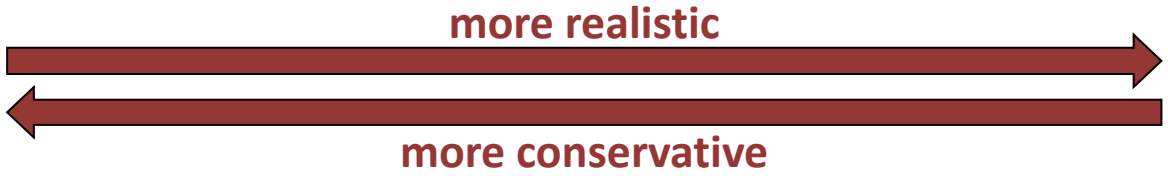
Distribution of food intake

x

Distribution of concentration → **Distribution** of intakes

A stepwise approach to exposure assessment *





* **Dietary Exposure Assessment of Chemicals in Food: Report of a Joint FAO/WHO Consultation, Anapolis, Maryland, 2005**

PRAGMATIC OR TIERED APPROACH TO ADDITIVE / FLAVOURING EXPOSURE ASSESSMENT

Tier 1 – screening methods

eg. Poundage Data ;Budget Method ; TAMDI (flavours)

Tier 2 – refined deterministic / point methods

eg. Combine consumption data with MPL of use ;
FAIM (in EFSA)
TDS ; Duplicate Diet Survey

Tier 3 – more refined assessments

eg. Combine consumption data with actual levels of use ;
probabilistic modelling
average / regular and high consumers
toddlers, children, adolescents, adults, elderley

Flavourings , Additives and Food Contact Materials Exposure Task- FACET

- EU FP 7 Project – 20 partners from industry , academia , public body research centres
- Objective – creation of an IT food chemical exposure survellance system – one stop portal on the web – sustainable beyond the life of the project to serve EU regulatory needs and protection of public health .

- The FACET Exposure Tool – down- loadable from the web

  - software , manual , technical guidelines , worked examples , links

  -probabilistic modeling

- Web Address

http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food

ADDITIVES EXPOSURE ASSESSMENT – FACET

Intake = **Σ** Quantity of Food Consumed X Usage Level of the Additive in the Food X Occurrence of the Additive in the Food

Specific Codification System

Distribution of Concentrations

Presence Probability

Customer Loyalty

ADDITIVES EXPOSURE – CASE STUDY: SUNSET YELLOW (ADI 1mg/kg bw/d)

	Mean Intake	P97.5	Major Contributor
MPL	0.1284 ± 0.003191	0.3997 ± 0.02547	Bakery Wares (36%)
MPL + Occurrence	0.0008413 ± 0.000116	0.008957 ± 0.001324	Non-alcoholic beverages (49%)
Fitted Distribution	0.08037 ± 0.0019343	0.2391 ± 0.01037	salt,spices,sauces,soups (48%)
Fitted Distribution +Occurrence	0.001261 ± 0.0001618	0.01289 ± 0.002058	Non-alcoholic beverages (95%)
Fitted Distribution +Occurrence +Brand loyalty	0.001346 ± 0.0002906	0.01289 ± 0.002058	Non-alcoholic beverages (95%)

COMPARISON OF EXPOSURE ASSESSMENTS FOR SUNSET YELLOW (mg/kg bw /d)

	Toddlers(1-10yrs)	Adults (UK)
EFSA 2009		
Tier 1 : Budget Method	8.1	8.1
Tier 2 : Food consumption	0.3-2.5 (mean)	0.5 (mean)
data(s) - MPL	0.7-6.7 (95%tile)	0.5-1.1 (97.5%tile)
Tier 3 : Max .use levels	0.2-2.1 (mean)	0.3 (mean)
	0.6-5.8 (95%tile)	0.9 (97.5%tile)
EFSA 2011	Children (1-14 yrs)	
Tier 2 : revised use levels(4)	0.02-0.4 (mean)	
	0.08-1.2 (97.5%tile)	
FERA(UK) : probabilistic	0.275-0.410 (1-4yrs: non-loyal/loyal)	
modelling (NDNS) -	0.154-0.231(4-18 : non-loyal/loyal)	
97.5%tile.	0.071-0.092 (18-64 : non-loyal/loyal)	

ASSESSMENT OF DIETARY EXPOSURE TO FLAVOURINGS (1)

MDSI : maximised survey-derived daily intake – based on annual production , (assumes 40% non-reporting) , per capita x 10 for consumer variation.

- used by industry , JECFA ,EFSA, until recently

TAMDI : theoretical added maximum daily intake – assumes daily consumption of standard food (160.4g) and drink (324ml) portions and flavouring is always present at 'max use levels' .

-used by EU SCF

mTAMDI : modified TAMDI – assumes flavouring is always present at 'average use levels' reported by industry

- used in EFSA 2006 – 2011

ASSESSMENT OF DIETARY EXPOSURE TO FLAVOURINGS (2)

SPET : Single portion Exposure Technique – consumption daily of standard portion of a flavoured beverage or food containing the flavouring at normal occurrence, ie.usage levels .The category leading to the highest exposure in one portion is selected.

Used in combination with MSDI by JECFA from 2010

APET : Added portion Exposure Technique – consumption daily of one standard portion of a flavoured beverage and one standard portion of flavoured food containing the flavouring at normal occurrence ie. usage levels.The category of food and the category of beverage leading to the highest exposure in one portion are selected ;

ASSESSMENT OF DIETARY EXPOSURE TO FLAVOURINGS (3)

Deterministic assessment of dietary exposure in the population based on individual food consumption data

Consumption x homogenous use levels = exposure distribution

(see Hall&Ford, or Crispim et al, Food Additives & Contaminants ,1999 and Part A 2010 respectively)

Stochastic modelling of dietary exposure in the population based on individual food consumption data (FSM)

Consumption x each use level for each food in each category = exposure distribution

(see Lambe et al , Food Additives & Contaminants , 2002)

More realistic , ie. less conservative approach than the others and the basis of the FACET model.Often the TAMDI exceeded the FSM by many orders of magnitude yet the MSDI was generally within one order of magnitude (higher) of the 97.5%tile of the FSM . Supports the use of the MSDI as a pragmatic and conservative method for flavourings used across multiple food categories .

FLAVOURING EXPOSURE ALGORITHM – FACET MODEL

1. Select flavouring

↓

2. Choose source of flavouring concentration information

↓

3. Find all foods which contain that flavouring

↓

4. Find all consumption events in the survey diary involving those foods

↓

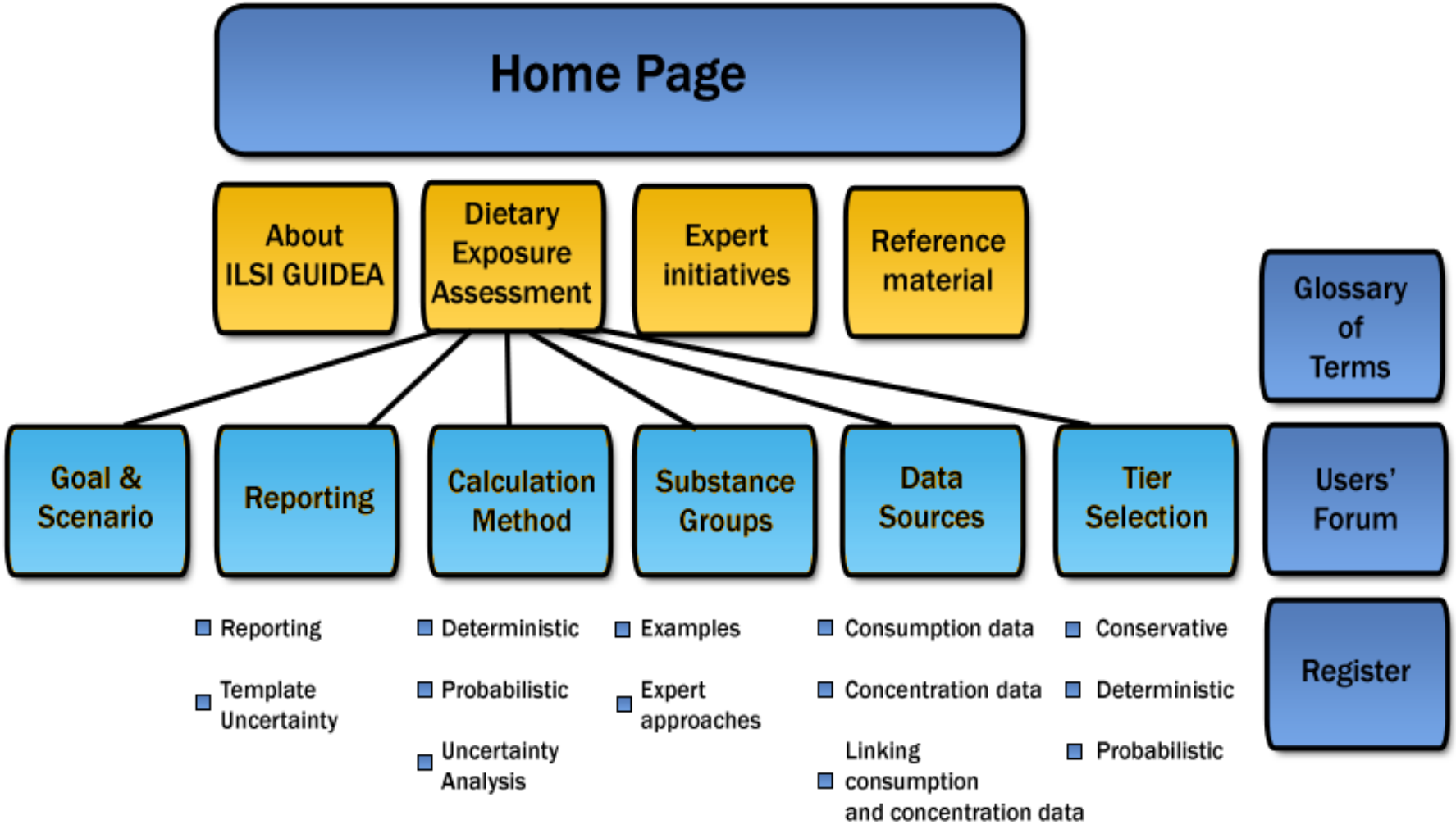
5. Determine the exposure to the flavouring at each eating event

↓

6. Collate exposures from each consumption event to give the distribution of exposure to the flavouring in the population .

ILSI EUROPE ‘ GUIDEA ‘

http://www.ilsi-guidea.org/index.php?title=Main_Page



Practical guide for conducting intake and exposure assessments – to encourage harmonisation leading to better health recommendations.

REFERENCES

- IPCS : EHC 240 : Principles and Methods for the Risk Assessment of Chemicals in Food , Chapter 6 “ Dietary Exposure Assessment of Chemicals in Food “
- R. Kroes et. al.’ Assessment of Intake from the Diet ‘ , Food and Chemical Toxicology , 2002 , 40 , 327-385
- FACET : “ Flavourings , Additives and Food Contact Materials Exposure Task “ : FACET UCD website
- EFSA : Food Additives Intake Model (FAIM) and related exposure papers on the EFSA website : www.efsa.europa.eu
- J. Lambe et al , Food Additives & Contaminants , 2002 , 19 , 2-14