



EFCOVAL
Dietary Exposure Assessment Workshop
28 September 2007
Rome, Italy



Annika Wennberg
Joint Secretary of JECFA at FAO
Food and Agriculture Organization of the United Nations



**Exposure assessment of
flavourings
in the international setting
of JECFA and Codex**



Overview of Presentation

- Introduction
- JECFA exposure assessment of flavourings
 - The procedure for safety assessment
 - Exposure assessment
- Recent considerations
- Codex and flavourings



Introduction

- Dietary exposure assessment methods used by JECFA for other food additives may also be used to evaluate flavourings but
 - Flavours are used in small quantities
 - Amounts that are used are limited by the technological function
 - Many flavours are also naturally occurring.
 - A wide variety of flavours is used in the food supply since flavour is a major criterion used by consumers to give variety to their diet
 - Flavours or flavour mixes are often provided to food manufacturers for use in their proprietary products. (data on specific levels in different foods are often not known, either by the flavour manufacturer or food manufacturer).
 - Use of flavours will be different in different brands and even in the same brand over time
 - Further processing and cooking may decrease the levels present at the time the food is eaten



Procedure for safety assessment

- JECFA initiated its work on the safety evaluation of flavourings (flavouring agents) in 1995
- A procedure with a risk-assessment decision tree approach was developed
 - Structural classes I, II or III (Cramer et al., 1978)
 - Threshold of Toxicological Concern for the 3 classes
 - Maximized Survey Daily Intake (MSDI) method as a surrogate measure of exposure
- MSDI dietary exposure is
 - A per capita estimate based on estimates of the amount of the flavouring substance produced for use in foods per year
 - Assumes that 10% of the population would consume the foods containing the flavour



MSDI approach

- Based on the amount of the flavouring agent disappearing into the food supply per year in specific regions
- Previously, data for United States of America and Europe have been used
 - with estimates of populations and
 - correction factors for under reporting of the amount

$$\text{Intake} \quad (\mu\text{g per person/day}) = \frac{\text{Annual volume (kg)} \times 10^9 \text{ } (\mu\text{g/kg})}{\text{Population of consumers} \times \text{corr. factor} \times 365 \text{ days}}$$

- Correction factors of 0.6 or 0.8 depending on reliability of data
- Recent surveys undertaken by the flavour industry to respond to request from JECFA on more up-to-date and reliable data on yearly production



MSDI approach (2)

- **In 2007, for the flavourings that were on the agenda of the 68th JECFA, the MSDIs were estimated by JECFA using new survey data from**
 - **United States of America from 2006 (28 million consumers)**
 - **Europe from 2005 (32 million consumers)**
 - **Japan from 2002 (13 million consumers)**
 - **A correction factor 0.8**

- **Estimation of dietary exposure based on annual production data is considered by JECFA to be a practical, conservative and realistic approach**

- **Designed to evaluate the intake of flavourings**
 - **on a long term basis, e.g. typical chronic intake**
 - **rather than assessments for individuals or unusual single time exposures, as there are no acute toxicity concerns**



Recent considerations

- JECFA has during recent meetings considered ways to improve identification and assessment of flavourings with:
 - **An uneven dissemination in the food supply**
 - **Used in few food categories with possibility of higher dietary exposure in individuals regularly consuming such foods**
 - **MSDI estimates consequently may be substantially lower than actual use levels**
- JECFA decided to focus on flavourings at the upper and lower ends of the distribution
- The flavour producing industry supplied data on recommended added use levels for such flavours



Recent considerations

- **The 68th JECFA meeting (June 2007) analysed the new data and explored a new method of estimation of intake using a single-portion exposure technique (SPET)**
- **SPET provides a dietary exposure estimate based on:**
 - **The data supplied by industry on use levels and food categories**
 - **Identification of the single food category that represents the highest dietary exposure based on a “standard portion size” and the estimation of exposure from all relevant food categories**
 - **The standard portion is taken to represent mean consumption, assuming daily consumption over a long period of time**
- **JECFA considered that the data supplied was of greater relevance than previously published information on use levels**
 - **As the data identified only those food categories where the flavour was actually used**
 - **Actual use levels employed by individual companies were kept confidential**



Future development

- **The 68th JECFA concluded as follows:**
 - MSDI and SPET provide different and complementary information
 - **MSDI provides an estimate of dietary exposure of a flavouring for an average consumer, but does not take into account use patterns**
 - **SPET provides a an estimate of dietary exposure for a regular consumer of the food products containing the flavouring**
 - Other methods for intake assessment that assume daily consumption of large portions several food categories containing the flavouring were overly conservative
 - Addition of SPET dietary exposure estimate in the relevant step of the Procedure would likely lead to extended evaluation only in a limited number of cases
 - Before a final decision is taken, evaluation of one further set of data on a representative sample of flavourings, in particular for flavours with intermediate and high production volumes, should be undertaken.



Codex Alimentarius Commission

- **Represents consensus among 174 members countries and the European Community**
- **Highly influential in food safety matters**
- **Reference point for WTO**
- **Many NGOs have observer status**
- **Adopts**
 - **General, specific and commodity standards**
 - **Maximum limits and guideline levels**
 - **Codes of practices**
 - **Sampling plans and guidance on analytical control methods**
 - **Guidelines**



Codex - flavourings

- **Codex draft guideline for the safe use of flavourings**
 - Based on a previous guideline on natural flavourings (CAC/GL 29 – 1987)
 - At Step 5 of the Codex procedure
 - Except part on maximum levels for certain naturally occurring substances with particular toxicity profile (comments requested at step 3)
 - Applies only to flavourings evaluated by JECFA and
 - determined to present no safety concern at the estimated levels of intake or;
 - have established JECFA ADIs and;
 - specifications for identity and purity have been adopted by Codex