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to ensuring that Europe's food is safe



Dietary exposure assessment at EFSA: bridging past experience and future challenges

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EFSA 10th Anniversary
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The EFSA Journal (2005) 249, 1-26

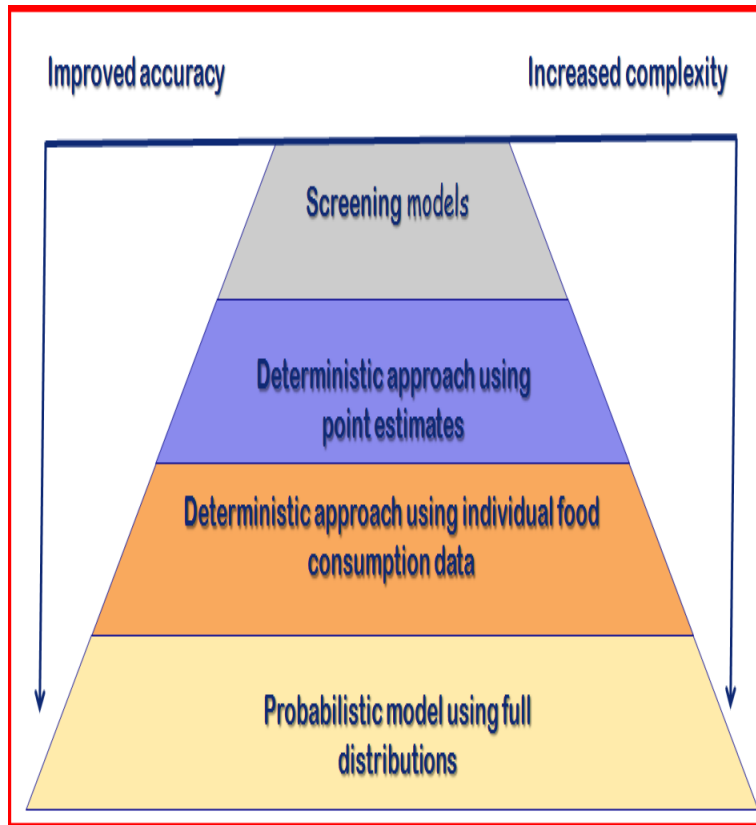
**Opinion of the Scientific Committee on a request
from EFSA related to Exposure Assessments**

(Request No EFSA-Q-2003-107)

(adopted on 22 June 2005)

- In-house resource for exposure assessment
- Concise food consumption database (short-term)
- Harmonised food consumption data at European level (long term)
- Stepwise approach
- Data warehouse

Approaches Used

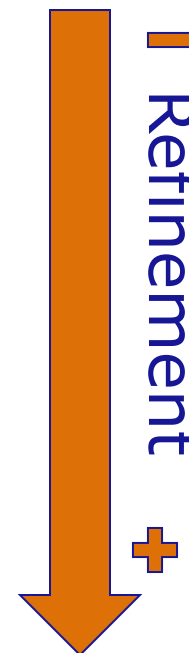


- Tiered approach
- Conservative screening methods
- Refined exposure estimates using food consumption data at individual level

Panel: ANS* (*re-evaluation of approved food additives*)

Three tier approach (*used until Feb. 2012*):

- Tier 1: Theoretical food consumption data x MPLs
(*conservative screening: Budget method*)
- Tier 2: National food consumption data x MPLs
- Tier 3: National food consumption data x
actual use levels



*Formerly AFC panel

Panel: ANS (*pre-market exposure assessment*)

- Guidance for Submission for Food Additive Evaluations



- **Food Additive Intake Model** (FAIM)



- User-friendly tool to estimate exposure for applicants
- Applicable to new food additives and new uses of approved food additives
- Uses summary food consumption statistics from EFSA comprehensive database

Panel: CEF* (*evaluation of flavouring substances*)

- **Maximized Survey-Derived Daily Intake**

$$\text{per capita intake} = \frac{\text{Annual production volume [kg]} \times 10^9 [\text{ug}]}{\text{Consumers}^* \times 0.6^{**} \times 365 [\text{days}]}$$

*Assumption: *10% of European population; **Under-reporting of production volume*

- ***modified* Theoretical Added Maximum Daily Intake**

$$\text{Intake} = \sum \text{Normal use level in food category (mg/kg)} \times \text{Intake of food category (g/d)}$$

Assumption: hypothetical consumer will consume a fixed amount daily of standard portions of flavoured food containing a specific flavouring at normal use levels

Panel: CEF

- Default conservative exposure scenario
- 60 kg consumer
- Consumes 1 kg of food daily
- Food in contact with 6 dm² of the food contact material containing relevant substance



Panel: PPR (*post-market exposure assessment*)



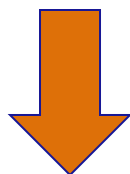
- Results from annual monitoring programmes: ~800 pesticides, 70,000 samples, 200 types of unprocessed food
- PRIMo: pesticide residue intake model (*summary food consumption from national surveys*)
- Acute & chronic exposure estimated based on international methodologies (*TMDI & IESTI*)

Panel: NDA (*pre-market exposure assessment*)

- Applicants are requested to provide data on baseline (where applicable) and anticipated dietary exposure
- Exposure assessments typically based on anticipated use levels in defined food categories and summary food consumption data from national dietary surveys or the literature
- Currently no guidelines on *standardised* dietary exposure methodology for novel foods

Panel: CONTAM

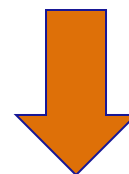
Occurrence levels in food



- Peer reviewed papers &/or official reports
- Ad hoc calls for data
- Continuous annual data collection (2010 -)

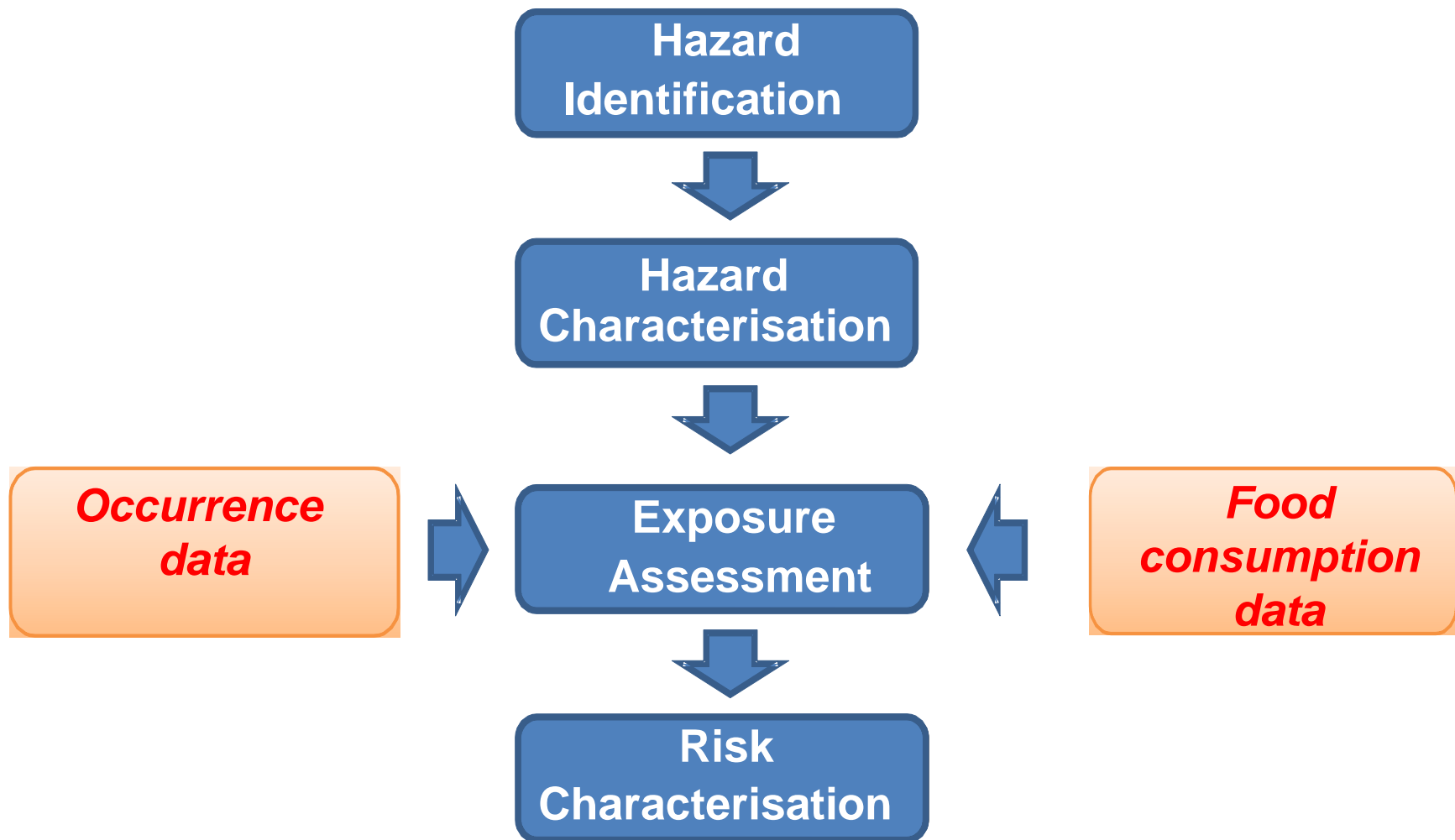


Food consumption



- Ad hoc data
- EFSA concise database (2008 - 2009)
- EFSA comprehensive database (2010 -)

Data Collection



Article 33 of (EC) No 178/2002 requires EFSA to:

'... search for, collect, collate, analyse and summarise relevant scientific and technical data ...'

'... work in close cooperation with all organisations operating in the field of data collection ...'

'... improve technical comparability ... to facilitate consolidation at Community level.'



Data collection

2002 -

2008

2008-2009

2010 -

- Ad hoc requests
- Expert group on chemical occurrence
- Pilot projects with member states on data collection harmonisation activities
- Standard Sample Description (SSD)
(Protocol harmonising the collection of a wide range of analytical results in several domains of EFSA activity)

	A	B	C	D	E	F	G	H
1	labSampleCode	lang	sampCountry	sampArea	origCountry	origArea	procCountry	prodCode
2	IT-2009-11-23-000001	en	IT	ITD52	IT	ITD5	IT	C03_2
3	IT-2009-11-23-000001	en	IT	ITD52	IT	ITD5	IT	C03_2
4	IT-2009-11-23-000002	en	IT	ITC3	IT	ITC3	IT	C03_2
5	IT-2009-11-23-000002	en	IT	ITC3	IT	ITC3	IT	C03_2
6	IT-2009-11-23-000002	en	IT	ITC3	IT	ITC3	IT	C03_2
7	IT-2009-AD-000256	en	IT		XC		AT	C14

Evolution of Occurrence Data

Pre SSD



- Ad hoc requests
- Different coding
- Irregular submissions
- Word / Excel / PDF..

SSD



- Coordinated approach
- Standardised coding
- Feedback to member states

Food Consumption Data

2005

- Scientific Colloquium: European food consumption database: current & medium term strategies



2007

- Expert group on food consumption

2008

- Concise European food consumption database (15 broad food categories, 19 countries, adults)

2011

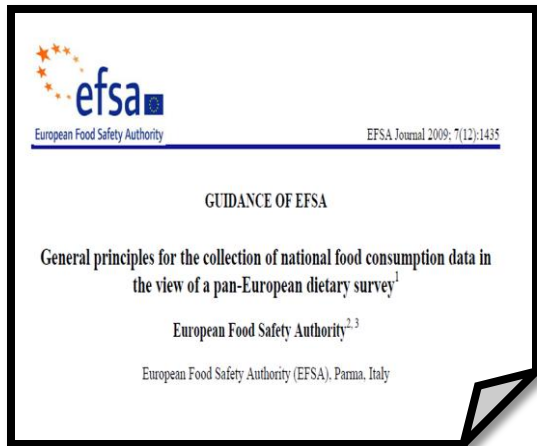
- Comprehensive European food consumption database (32 surveys, 22 countries, 6.3 million consumption records, infants to elderly)

2012-

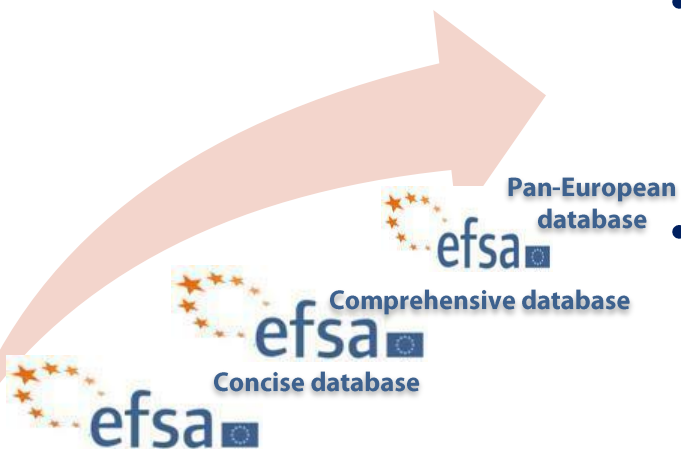
- Towards harmonised food consumption data at EU level



Towards Harmonised Food Consumption Data at EU Level



- General principles (2009)
- EU Menu project:
- Infants to elderly; all Member States (min. 80,000 subjects)
- 24h recall (*adults*); two non-consecutive days
- EFSA support to national dietary surveys in compliance with EFSA guidance





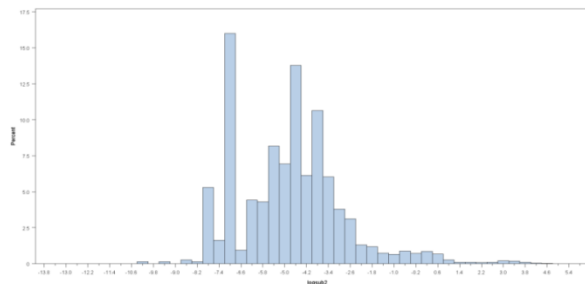
FoodEx

Future Challenges

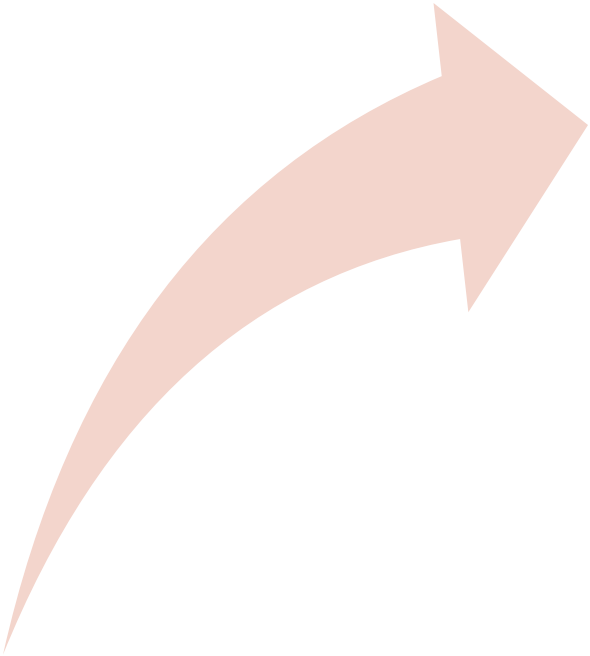


Towards more harmonised methodologies....

- Management of occurrence data
 - Pooled EU data
 - Treatment of left censored data
 - Total diet studies
- Estimation of usual intake
- Application of probabilistic modelling



Beyond 10th Anniversary.....

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- Biomarkers of exposure
 - Cumulative exposure



Thank you

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