Requirements on consumption data for the use in exposure assessment of pesticide residues in food

Ursula Banasiak

Christian Sieke

Overview

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- General principle

- Different kinds of exposure

2. Requirements on food consumption data

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- Chronic exposure

- Cumulative exposure

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Definition (Council Directive 91/414/EEC, Article 2)

Residues of plant protection products (pesticides):

one or more substances present in or on plants or products of plant origin, edible animal products or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites and products resulting from their degradation or reaction.

Pre-regulation - prospective assessment
- ➤ Risk assessment
- ➤ Estimation of Maximum Residue Levels

Post-regulation - retrospective assessment
- ➤ Enforcement/Monitoring of Maximum Residue Limits (MRLs)
- ➤ Risk assessment in context of the Rapid Alert System

Estimation of dietary exposure

RISK =

$$f(\textbf{HAZARD}, \textbf{EXPOSURE})$$

hazard = toxicity of the pesticide

EXPOSURE =

Intake of the pesticide via food and drinking water

$$= f(\textbf{RESIDUE, CONSUMPTION})$$

Estimation of dietary exposure

General equation:

Exposure = $\dfrac{\text{food pesticide concentration} \cdot \text{food consumption}}{\text{body weight}}$

„Consumption"   = amount of food consumed

„Dietary exposure"   = amount of pesticide ingested *via* food

- ➢ Short-term exposure covers a period of 24 hours
- ➢ Long-term exposure covers average daily exposure over the entire lifetime

The resulting dietary exposure estimate is compared with the relevant toxicological reference value
- ➢ **ARfD**   Acute Reference Dose
- ➢ **ADI**   Acceptable Daily Intake

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Estimation of dietary exposure

Single pesticide residues

- Only one pesticide

- Routinely used

- Short-term exposure
- Long-term exposure

- Deterministic approach

- (Probabilistic approach)

Multiple residues

- More than one pesticide

- Not yet routinely used,
  EFSA PPR opinion May 2008 expected

- Short-term exposure

- Long-term exposure

- (Deterministic approach)

- Probabilistic approach

Different requirements on consumption data needed

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Food consumption data – general requirements

> In general there is a lack of consumption data for most of the EU member states, and the existing food surveys apply different methodologies, are not all up-to-date, and cover different population subgroups.
> **PPR-Panel scientific opinion, *The EFSA Journal (2008) 704*, publication May 2008**

Consumption data should

be representative for the consumption over the whole year, the gender, the age and the socioeconomic characteristics of the population.

- ➢ cover sensitive subgroups (e.g. young children)

- ➢ cover consumption patterns for individuals at the upper end of distribution

- ➢ cover demographic characteristics of the individuals sampled

- ➢ Information on body weight of individuals

- ➢ Information on seasons and days of week

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Food consumption data – general requirements

Data reporting – required information

- **If only summary data are available**

  > deterministic approach, single pesticide only

  - Commodity
  - Type of commodity (raw, juice, juice concentrate etc.)
  - Statistical information (e.g. selected percentile, number of consumers)
  - Selected subgroup (e.g. general population, consumers only, heavy consumers)
  - Consumers data (e.g. mean/median body weight, age, gender)
  - Sampling method and time-frame of the sample (e.g. consumption per meal, person-days, averages across various survey days)

- **Reporting at individual respondent level**

  > probabilistic approach, multiple residues

  - Multiple food intake per day and person
  - Identification of specific subgroups on individual level
  - Estimation of distributions of food consumption

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Food consumption data – general requirements

Regulation (EC) No 178/2006 of 1 February 2006:
Annex I of Regulation (EC) No 396/2005 listing the food and feed products to which MRLs for pesticide residues apply

Data reporting - required information

- **Aggregation level**

➤ Format that allows matching the consumption data with the residue data in the dietary exposure assessment ("translation")

➤ Individual recipes used to reflect back to the different raw commodities (Use of standard recipes introduce some uncertainty)

➤ In case of processed food the contribution of raw commodities is added to the daily food amount per person
(e.g. apples includes apples in baked apple pie and apple juice)

Data requirements – acute exposure

FAO/WHO-Workshop (Annapolis, 2005)

www.who.int/entity/ipcs/food/exposure_assessment.pdf

Recommendations

➤ Large portion (LP) should be based on the 97.5th percentile of individual consumers from national survey results

➤ If a food consumption survey includes multiple days of record per participant, individual consumer days should be used

➤ Estimating exposure in a single commodity use food consumption data for only those people who consume the single food (consumers only)

➤ Estimations in multiple commodities should be conducted for both consumers only and total survey population

➤ Commodity eaten predominately fresh (apples): LP derived for raw commodity

➤ Commodity consumed processed (cereals): LP should relate to the processed commodity (bread, flour)

Data requirements – chronic exposure

FAO/WHO-Workshop (Annapolis, 2005)

www.who.int/entity/ipcs/food/exposure_assessment.pdf

Difficult to obtain representative data to reflect to lifetime exposure (data collected over a period of few days)

Recommendations

➢ Data from surveys needs to be adjusted for the estimation of long-term consumption

➢ As approximation for a specific food, use the overall average food consumption on a national or group level

➢ Methods combining food frequency data with information on the amount of consumption

➢ Statistical models that use the correlation among the days of consumption to estimate the typical intake

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Data requirements – cumulative exposure

EFSA-Workshop (Parma, 2006)

http://www.efsa.europa.eu/EFSA/Scientific_Document/comm_colloque_7_en,0.pdf

Recommendations

➢ In dietary surveys, data should be collected on separate, non-consecutive days rather than on consecutive days

➢ Raw data of all the different food consumption surveys should be made available rather than aggregated consumption data

➢ Food codes used for consumption surveys and residue monitoring programs should be harmonized

➢ EFSA should conduct a EU-wide food survey that is representative for all the 27 Member States

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Estimation of dietary exposure

Single pesticide residues

- Only one pesticide

- Short-term exposure,
  one commodity

- Deterministic method

- **Large portion (LP)**
  97.5th percentile, eaters only

- Long-term exposure,
  more than one commodity

- **Mean value of all**
  consumption data

Multiple residues

- More than one pesticide

- Short-term exposure, one or
  more than one commodity

- Probabilistic method

- **Distribution of consumption data**
  single commodity: eaters only
  > 1 commodities: total survey population

- Long-term exposure,
  more than one commodity

- **Distribution of all**
  consumption data

Food consumption databases

Food consumption surveys (FCS) at an individual or household level

- Records/food diaries

- Food frequency questionnaires

- Dietary recall

- Total diet survey

Food production statistics (FPS)

Represent foods available for consumption for the whole population, typically in the raw form as produced

Data collected on population-based methods represent the total annual amount of a commodity available for domestic consumption per year:
annual consumption ÷ 365 = daily consumption

Food balance sheets (about 15% overestimation, e.g. WHO GEMS/Food Cluster diets)

Food consumption databases - used by BfR

VELS-Model DE

(Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von PSM)

- consumption data for children (collected 2001/2002)
- age: 2 to <5 years
- average body weight: 16,15 kg
  http://www.bfr.bund.de

New national consumption study (NVS II) DE

- raw data 2008, not yet evaluated
- age: 14 – 80 years

WHO/FAO JMPR-Model

- acute: 8 national consumption studies
- chronic: 13 cluster diets
  http://www.who.int/foodsafety/chem/acute_data/en/index.html

EFSA-Model (PRAPER[1] collected national consumption models)

- 19 acute and 22 chronic European diets
  http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620776373.htm
  [1]PRAPER: Pesticide Risk Assessment Peer Review Unit

Recommendations

Scientific Opinion of the PPR Panel on request by EFSA on cumulative dietary risk assessment of pesticide residues

Publication expected for May 2008

➢ Overview of the food consumption data available at European level

➢ How to use them in dietary exposure assessment of pesticide residues

Recommendations with regard to food consumption data

➢ Raw survey data from national food consumption databases should be accessible for risk assessment purposes

➢ A harmonized consumption survey be performed on the European level, e.g. along the lines of the 4 European GEMS/Food cluster diets, and not along the lines of country borders

(further recommendations for cumulative dietary risk assessment!)

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Thank you for your attention

Dr. Ursula Banasiak

Bundesinstitut für Risikobewertung

Thielallee 88-92 / D-14195 Berlin

www.bfr.bund.de

☎ 030-8412-3337

✉ ursula.banasiak@bfr.bund.de

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Risiken erkennen – Gesundheit schützen

Probabilistic exposure assessment

Calculation of exposition under consideration of probability
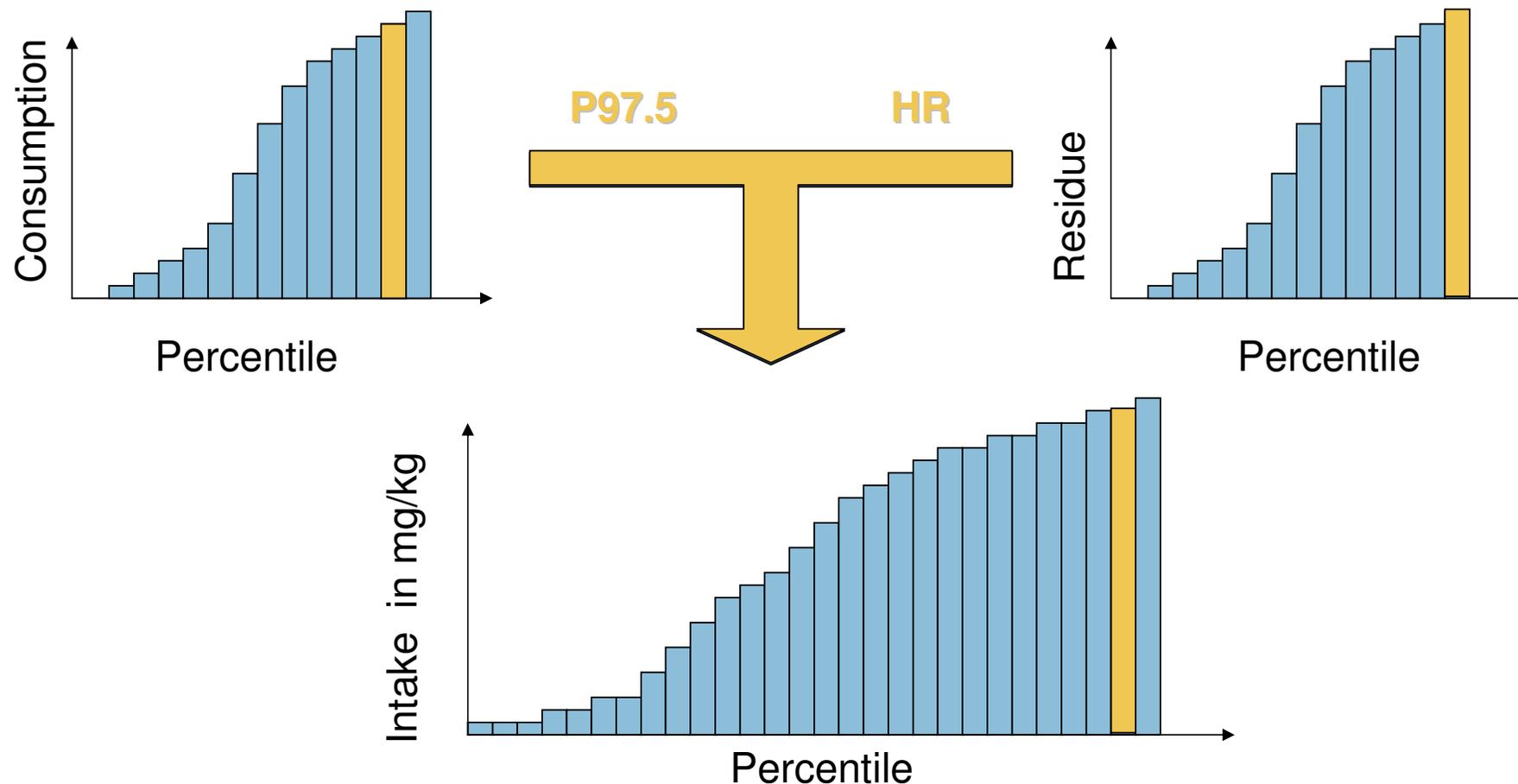
Estimation of dietary exposure – point estimate

Chronic exposure	**Acute exposure**
Aim: **Average daily intake over lifetime**	**Maximum daily intake**
- Toxicological threshold value: Acceptable Daily Intake (ADI)	Acute Reference Dose (ARfD)
- Consumption: Average consumption of all days	97,5te percentile daily consumption
- Residue: Supervised trials median residue (STMR) incl. values < LOQ	Highest residue

Estimation of dietary exposure

Deterministic approach	Probabilistic approach
Single portion	Distribution of consumption data based on individuals
One residue concentration	Distribution of residues
Estimation for a single commodity (acute)	Consideration of more than one commodity
Simple, transparent; model accepted in EU and at international level	Highly expensive on data, modeling. Model not yet accepted in EU and at international level
Overestimation of exposure, combination of worst-case assumptions	Result more realistic, depends from the parameters selected, „black box"

Example – German VELS Study

- Multi center study on 9 local points in Germany

- Study duration from June 2001 to September 2002

- 816 children aged from 6 months to 4 years

- Prospective food consumption survey:
  - 3-days weight protocol by the mothers
  - recovery after 3-6 months (infants after 4-8 weeks)
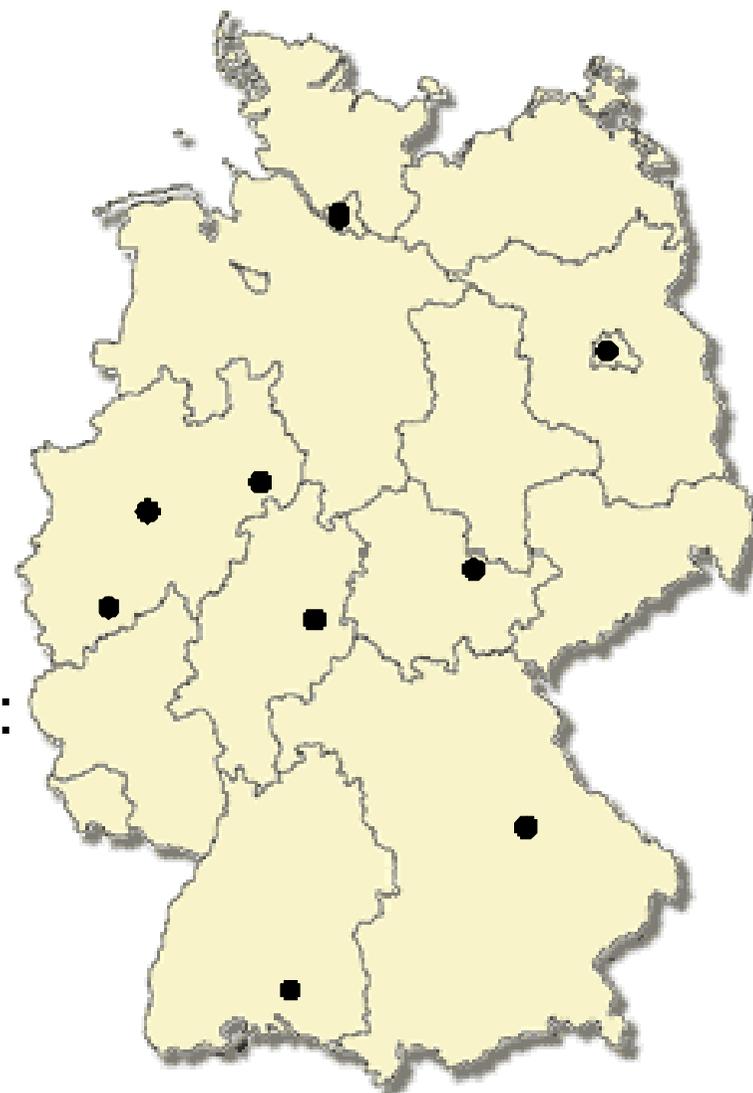
VELS Data – e. g. apple, pear

Consumption per day and person

Person No	Day	Apples, raw in g	Pears, raw in g
0012	1	0	0
0012	2	0	16,00
0012	3	0	0
0012	4	0	0
0012	5	206,00	0
0012	6	63,51	0

Mean daily consumption per person

Person No	Apples, raw in g	Pears, raw in g
0012	44,92	2,67