

## NVS II Model Documentation

|   |    |
|---|----|
| Introduction.....   | 1  |
| Consumption data – German Nutrition Survey II.....                                    | 1  |
| Conversion of the consumed products into raw agricultural commodities.....            | 2  |
| Model description .....   | 3  |
| Selection of “person-days” .....  | 3  |
| Selected (sub-)populations.....   | 3  |
| Deterministic parameters for selecting the portion sizes.....                         | 4  |
| “Mean” vs. “individual” bodyweight approach.....                                      | 4  |
| Acute intake assessment – IESTI Case 2 .....  | 5  |
| Additional model aspects .....  | 8  |
| Consideration of the edible portion.....  | 8  |
| Fat content in raw commodities of animal origin .....                                 | 8  |
| Highest contributor to mean portion size in long-term dietary intake assessment ..... | 8  |
| Glossar .....   | 10 |

### Introduction

For the estimation of dietary risks arising from pesticide residues in foods representative exposure models are required. Consumer risk assessment needs to be conducted e.g. within the authorisation of plant protection products or to interpret results from enforcement and monitoring programs. Depending on the purpose of the risk assessment, focus is either on long-term exposure (based on mean daily consumption data) or on short-term exposure (based on large daily portions).

Based on German consumption data for children aged 2 to <5 years, the Federal Institute for Risk Assessment (BfR) already developed an exposure model in 2005 (VELS-model<sup>1</sup>). Although young children pose a vulnerable subpopulation, differences in the consumption patterns of children and adults require an extension of the available models to cover as much of the total population as possible.

### Consumption data – German Nutrition Survey II

The German Nutrition Survey II (NVS II) was conducted by the Max Rubner-Institute (MRI) between November 2005 and December 2006<sup>2,3,4,5</sup>. Individuals aged 14 to 80 years were questioned in four waves, providing representative data for the German population including consideration of seasonal differences. The basic module of the NVS II study consisted of dietary history protocols covering the previous 4 weeks (15371 individuals, DISHES tool) and of 2x 24h Recall interviews (13926 individuals plus 1156 individuals with 1x 24h Recall inter-

<sup>1</sup> Banasiak, U., Heseker, H., Sieke, C., Sommerfeld, C. und Vohmann, C. (2005) Abschätzung der Aufnahme von Pflanzenschutzmittel-Rückständen in der Nahrung mit neuen Verzehrsmengen für Kinder. Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz 48:84–98.

<sup>2</sup> Brombach C. et al, Die Nationale Verzehrsstudie II - Ziel: Aktuelle und belastbare Primärdaten für die Ernährungsberichterstattung des Bundes generieren, Ernährungs-Umschau 53 (2006) Heft 1, Karlsruhe

<sup>3</sup> Krems C. et al, Methoden der Nationalen Verzehrsstudie II, Ernährungs-Umschau 53 (2006) Heft 2, Karlsruhe

<sup>4</sup> Anonymus, Nationale Verzehrsstudie II - Ergebnisbericht Teil 1, Max Rubner-Institut, Bundesforschungsinstitut für Ernährung und Lebensmittel, 2008, Karlsruhe, [http://www.was-ess-ich.de/uploads/media/NVS\\_II\\_Abschlussbericht\\_Teil\\_1\\_mit\\_Ergaenzungsbericht.pdf](http://www.was-ess-ich.de/uploads/media/NVS_II_Abschlussbericht_Teil_1_mit_Ergaenzungsbericht.pdf)

<sup>5</sup> Anonymus, Nationale Verzehrsstudie II - Ergebnisbericht Teil 2, Max Rubner-Institut, Bundesforschungsinstitut für Ernährung und Lebensmittel, 2008, Karlsruhe, [http://www.was-ess-ich.de/uploads/media/NVSII\\_Abschlussbericht\\_Teil\\_2.pdf](http://www.was-ess-ich.de/uploads/media/NVSII_Abschlussbericht_Teil_2.pdf)

views, EPICSOFT tool). An additional subsample consisting of 2x 4 days weight protocols was conducted with 1021 individuals.

For the utilization of the NVS II data in pesticide exposure assessment the long-term (or mean) daily consumption are as well required as the large portions per day which are used for short-term exposure assessment. In the current model it was decided to use the data from the 24h Recalls only, because they provide consumption data on individual level and on a 24h basis, allowing to calculate both mean and large portion sizes. In future revisions the 2x 4 day weight protocol subsample will also be taken into account.

#### Conversion of the consumed products into raw agricultural commodities

To consider all plant and animal food commodities eaten within 24h in the same way as is needed in pesticide risk assessment, all food items reported as their “ready to eat” form were converted into their respective raw agricultural commodities (RAC). The same principle was already applied in the VELS model published in 2005. The definition of the RAC corresponded to Reg. (EC) No 600/2010, amending Annex I of Reg. (EC) No 396/2005, thus allowing direct correlation to MRLs established for pesticides in the EU.

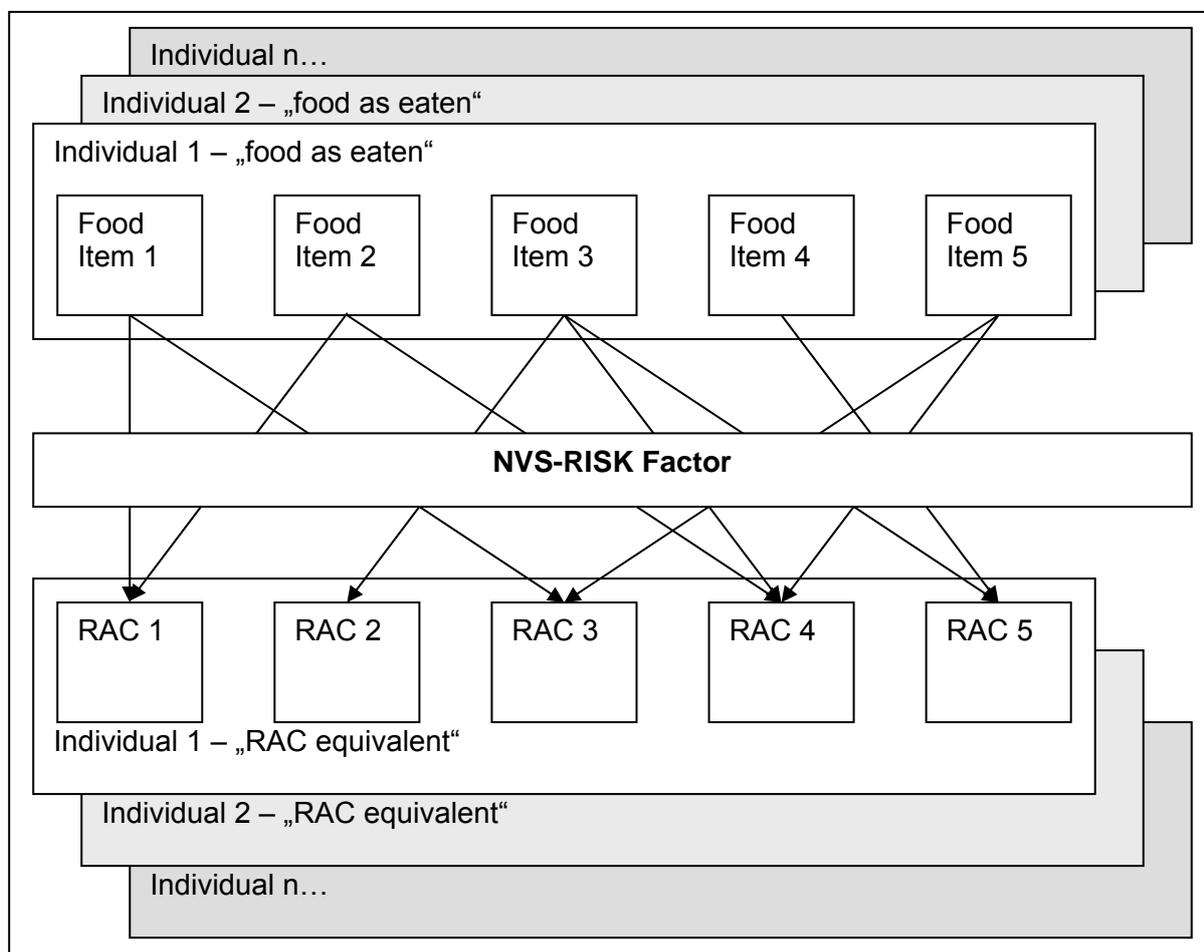
For the conversion detailed information on the composition including underlying recipes of processed foods as well as on the influence of processing itself was required for each food item reported in the 24h Recalls. BfR recently funded a project called NVS-RISK which was conducted by the University of Paderborn<sup>6</sup> and was finalized in 2010. Main purpose of NVS-RISK was to generate a database including recipes and processing/yield factors for each food item listed in the 24h Recalls of the NVS II and also for all ingredients and intermediate products. Based on this database and under consideration of weight loss effects and other influences from the processing itself, overall transfer factors were established and the amounts of RAC equivalents, that were present in the composed foods, were calculated.

With the NVS-RISK database the contributions from different food commodities to each RAC were added on individual level, providing a single, aggregated portion size equivalent for the consumption period of 24h (see Figure 1). Sometimes the risk assessor needs to know which part of the aggregate portion size relates to raw eaten food and which to processed food. Hence limited information on the state of processing was maintained to enable differentiation of major pathways (raw/unprocessed, processed, dried, oil, distilled, peeled). However, in view of the aggregated nature of the portion size equivalents, it was decided to uniformly base all values on “RAC-equivalents” to achieve clear separation from actual portion sizes as determined in the NVS II survey.

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<sup>6</sup> Ptok, S., Hesecker H. (2010), Aufbereitung von Verzehrdaten der NVS II für die Risikobewertung von Pflanzenschutzmittelrückständen, Institut für Ernährung, Konsum und Gesundheit, Department Sport & Gesundheit, Fakultät für Naturwissenschaften, Universität Paderborn

Figure 1: Scheme for conversion of NVS II consumption data into RAC



### Model description

#### Selection of “person-days”

The NVS II 24h Recall data include information on the consumption pattern for two non-consecutive days for each individual (for a small subgroup only one day was reported). For the estimation of RAC-equivalents it was decided to handle each day as an independent intake event without assuming any correlation on individual level.

Thus in the NVS II model all information related to the number of consumers refers to “person days” instead of “individuals”.

#### Selected (sub-)populations

The 24h Recalls of the NVS II cover an age group of 14 to 80 years and were representative for the adult German population concerning age, sex and geographic location. Women in childbearing age pose a subpopulation demanding special consideration. Since unborn life is very sensitive, toxicological reference values based on developmental effects were occasionally established for some pesticides. To cover this effect, a module for women in childbearing age (14–50 years) was implemented into the NVS II model.

For a separate view on other vulnerable subpopulations such as immune disabled or elderly people, the data did not provide sufficient information so that specific modules within the model could not be developed.

Deterministic parameters for selecting the portion sizes

For the estimation of the long-term dietary intake model, the arithmetic mean of all person-days (including zero consumption days) was selected as representative RAC-equivalent for each commodity.

For the short-term dietary intake model, different percentiles depending on the number of available person-days were selected. The default percentile (P) for the portion size equivalent was P97.5 –as used by JMPR (Joint Meeting of Pesticide Residues)<sup>7</sup> and the EU<sup>8</sup>– for all commodities with >40 reported person-days (based on “eaters only”).

For commodities with less than 41 person-days the following percentiles were selected: 40 to >20: P95; 20 to >10: P90 and for 10 or less reported person days the maximum was used (based on “eaters only”). This approach is also followed in the VELLS model.

“Mean” vs. “individual” bodyweight approach

For the NVS II model two routines for deriving RAC equivalents and putting them in correlation to the bodyweight were established.

In the “mean bodyweight” approach the selected RAC equivalent (e.g. arithmetic mean or P97.5) and the arithmetic mean of the bodyweight were estimated independently. After correlating the RAC equivalent with residue data in the respective commodity (e.g. MRL, HR or STMR), the resulting residue in the selected portion equivalent is divided by the mean bodyweight to estimate the intake per kg bodyweight as last step of the calculation. This workflow follows the procedure of the current GEMS-food intake models<sup>9</sup> used by the JMPR as well as by most models established within the EU.

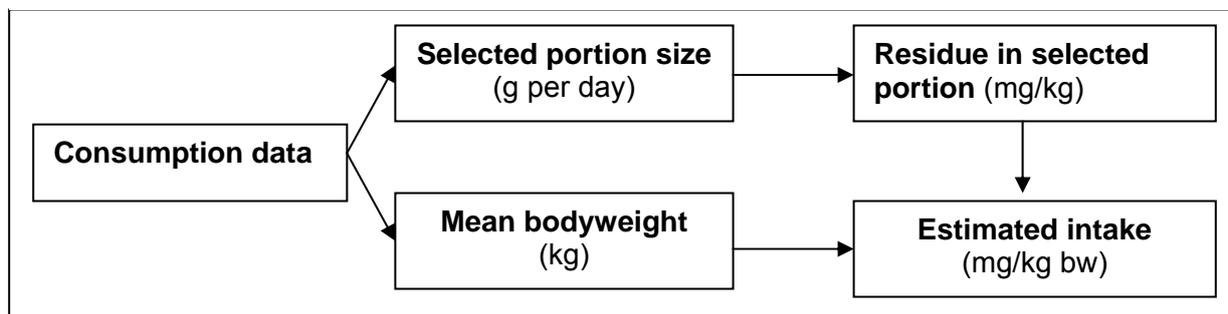
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<sup>7</sup> FAO manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed, Food and Agricultural Organization of the United Nations, Rome, 2009 Second edition

<sup>8</sup> Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs (<http://www.efsa.europa.eu/en/efsajournal/pub/32r.htm>). Calculation model “Acute and chronic consumer exposure REV2” ([http://www.efsa.europa.eu/en/mrls/docs/calculationacutechronic\\_2.xls](http://www.efsa.europa.eu/en/mrls/docs/calculationacutechronic_2.xls))

<sup>9</sup> Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food), World Health Organization of the United Nations, Geneva, <http://www.who.int/foodsafety/chem/gems/en/index.html>

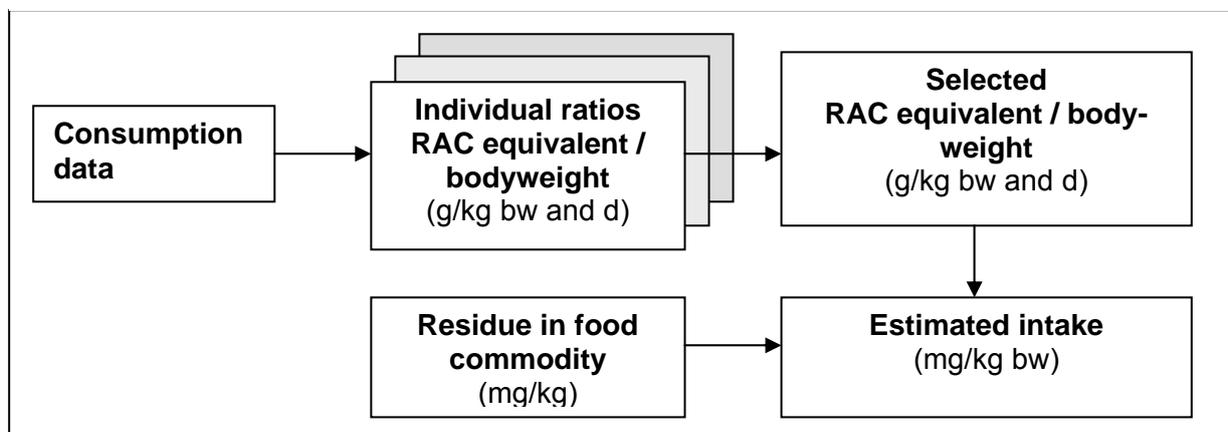
Figure 2: Workflow of "mean bodyweight" approach



Although the “mean bodyweight” approach is easy to use due to single deterministic values for the bodyweight and each food commodity, valuable information on consumption-bodyweight ratio on individual level is lost. Especially in the short-term dietary intake assessment this ratio may vary distinctively between individuals. Often RAC equivalents based on a “kg per bw” basis are higher after correlation of consumption and bodyweight on an individual level in comparison to the “mean bodyweight” approach.

It was therefore decided to include both approaches in parallel in the model. The “individual bodyweight” approach calculates the intake per kg bodyweight ratio on an individual level and then selects the appropriate percentile for the intake assessment (e.g. arithmetic mean or P97.5) based on this distribution. A general workflow is presented in Figure 3.

Figure 3: Workflow of "individual bodyweight" approach



### Acute intake assessment – IESTI Case 2

For the long-term dietary intake assessment the arithmetic mean, which can easily be expressed on an individual bodyweight basis, was selected as an appropriate RAC equivalent for the intake estimation. However for the short-term dietary intake assessment additional considerations are required to implement the established IESTI procedure<sup>7</sup>.

The IESTI concept defines three specific cases for the estimation of the short-term dietary intake, which represent different exposure scenarios:

Case 1 describes the situation for small commodities, which are distributed unblended from a single field or grower (e.g. small fruits and berries). The equation to estimate the exposure is

(*LP*: large portion, *HR/HR-P*: highest residue or highest residue after processing, *bw*: bodyweight, *E*: exposure):

$$E = \frac{LP \cdot [HR / HR - P]}{bw} \quad (1)$$

For Case 3, which applies in situations where the consumer is exposed via bulked/blended foods (e.g. cereal grains or pulses) and/or foods which have been industrially processed (e.g. orange juice), the corresponding equation is similar to Case 1, except that the highest residue is replaced by the supervised trial median residue (*STMR/STMR-P*), taking into account inter-field variation within the residue pattern:

$$E = \frac{LP \cdot [STMR / STMR - P]}{bw} \quad (2)$$

The equations for Case 1 and 3 (equations 1 and 2) provide a direct correlation between the large portion, the residue levels and the bodyweight, also allowing calculation of the consumption per kg bodyweight on an individual level without further adjustment.

In contrast to Case 1 and 3 the equations for IESTI Case 2 (equations 3 and 4) also consider the variability of residues (*v*) between individual units (*U*: unit weight) of the respective commodity. This variability factor *v* is multiplied with the residue in the first unit of a food commodity simulating the consumption of a single piece of food with a higher than average residue. Further differentiation is required to distinguish between scenarios, where more than one unit (Case 2a, e.g. apricots or mandarins) or less than one unit are consumed (Case 2b, e.g. watermelon or pumpkins):

IESTI Case 2a: 
$$E = \frac{(U \cdot v \cdot [HR / HR - P]) + (LP - U) \cdot [HR/HR - P]}{bw} \quad (3)$$

IESTI Case 2b: 
$$E = \frac{LP \cdot v \cdot [HR/HR - P]}{bw} \quad (4)$$

Especially for Case 2a (equation 3) unit weight, large portion and variability factor do not allow direct correlation of the portion size equivalent and the bodyweight on individual level. Since the large portion changes within individuals, the selection of Case 2a or 2b and the results of the equations need to be recalculated for each person-day.

As a solution the IESTI equation was rearranged to separate the residue level from all other elements. The exposure is then calculated in the following manner:

IESTI Case 2a: 
$$E = [HR/HR - P] \cdot \frac{U \cdot v + (LP - U)}{bw} = [HR/HR - P] \cdot \text{"RAC - equivalent"} \quad (5)$$

IESTI Case 2b: 
$$E = [HR/HR - P] \cdot \frac{LP \cdot v}{bw} = [HR/HR - P] \cdot \text{"RAC - equivalent"} \quad (6)$$

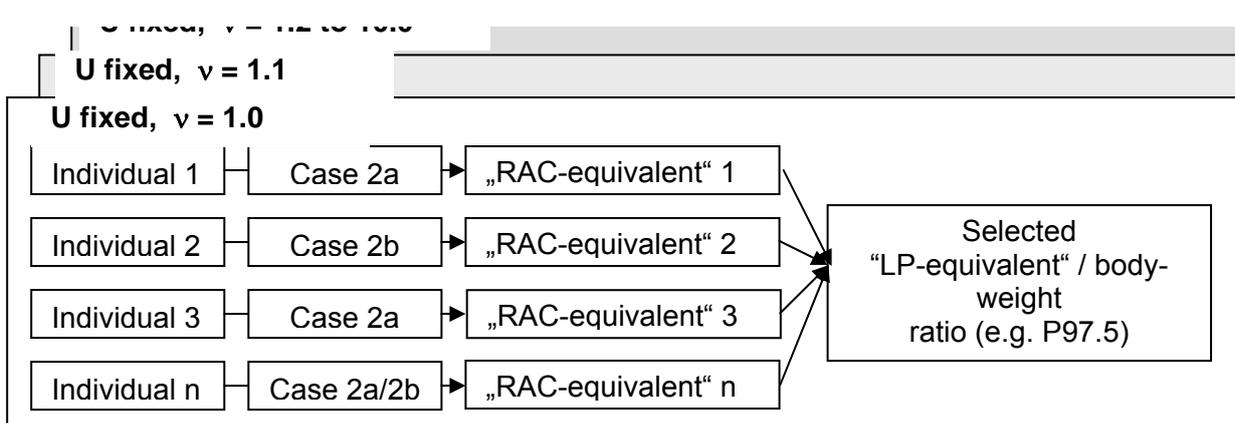
Apart from the large portion and the bodyweight, which are provided by the underlying consumption survey, the unit weight and the variability factor remain as variables. In a deterministic approach the unit weight describes one specific value selected from the distribution of

all unit weights (normally the arithmetic mean), allowing the inclusion of a single value for each commodity into the equation. However the variability factor still remains as sole variable besides the residue level for the calculation of both equations for IESTI Case 2.

Following this approach the normal procedure of estimating the large portion and correlating it with the unit weight, the bodyweight and the variability factor is replaced by a “large-portion-equivalent”, merging all factors except the residue level. This “large-portion-equivalent” may then directly be used in the model by multiplying it with the respective residue concentration to obtain the intake per kg bodyweight.

Since this procedure depends on the selected variability factor  $\nu$ , the calculation has to be repeated for the range of variability factors relevant in the IESTI equation. Due to the nature of the variability factor it was decided to iterate the calculation with all variability factors from 1.0 to 10.0, using steps of 0.1 (see Figure 4).

Figure 4: Conversion of IESTI Case 2 to calculate the “RAC equivalent” based on individual bodyweight ratios



By using this iteration the model contains 91 “RAC-equivalents”, from which the appropriate value is chosen depending on the variability factor selected for the respective commodity. While  $\nu = 1.0$  represents the situation as used in Case 1 and 3 of the IESTI equation, a factor of 3, 5 or 7 corresponds to the default values used in frameworks like Codex Alimentarius (JMPR<sup>7</sup>) or on European level<sup>8</sup>. An example of the dependence of the RAC equivalent from the variability factor  $\nu$  is presented in Table 1.

Table 1: Selected RAC-equivalents depending on the variability factor

| Variability factor $\nu$ | RAC equivalent apple, raw (g/kg bw and day) | RAC equivalent pineapple, raw (g/kg bw and day) |
|--------------------------|---|---|
| 1.0                      | 8.51  | 6.00  |
| ...                      |   |   |
| 4.9                      | 20.01                                       | 29.40   |
| 5.0                      | 20.33                                       | 30.00   |
| 5.1                      | 20.67                                       | 30.60   |
| ...                      |   |   |
| 6.9                      | 26.48                                       | 41.40   |
| 7.0                      | 26.81                                       | 42.00   |

|      |       |       |
|------|-------|-------|
| 7.1  | 27.11 | 42.60 |
| ...  |       |       |
| 10.0 | 36.71 | 60.00 |

**Additional aspects considered in the model**

Consideration of the edible portion

For the consideration of all different food items consumed within 24h, the data were aggregated after converting all commodities into their respective RACs, providing a homogeneous basis for the calculation. When doing that, it has to be taken into account that most RACs as described in Reg. (EC) 600/2010 contain non-edible parts like peel, stems or fruit stones. One of the key aspects in the NVS-RISK project was a transparent distinction of relevant processing steps for each commodity – including quantitation of such steps as removal of non-edible parts before processing. Specific factors were provided allowing the estimation of the percentage of the commodity removed before consumption or processing. By applying this percentage to the total RAC-equivalent, the amount of edible portion of the respective commodities are taken into account, while the calculation may still be performed with aggregated data on a 24h basis. This approach is only applicable to the new NVS II model data.

Fat content in raw commodities of products of animal origin

As explained in the footnotes of Reg. (EC) 396/2005, the maximum residue levels in specific food commodities of animal origin are based on the fat content of the respective food items. Examples are mammalian meat, milk other than bovine, milk products or eggs.

In the NVS II model it was decided to include a further separation for specific commodities based to the fat content in the RAC, allowing direct inclusion of maximum residue levels for animal commodities into the estimation. For all kinds of meat (beef, pork, lamb/mutton, poultry) the separator was set to a fat content of 10%, identical to footnote 5 of Reg. (EC) 396/2005.

In contrast to meat, milk is processed into a large variety of food items including a broad spectrum of fatty and non-fatty products. For drinking milk it was decided to differentiate between whole milk (3.5–4% fat content), low-fat milk (1–3.5% fat content) and skim milk (<1% fat content). In addition, milk with adjusted milk fat levels of 4–10% and >10% prior to further processing was specified. A special distinction was made for butter (82% fat content).

For eggs the data was not appropriate for further differentiation according to the fat level. The consumption is solely based on whole eggs.

Highest contributor to mean portion size in long-term dietary intake assessment

Besides the differentiation of pathways (raw/unprocessed, processed, dried, oil, distillate, peel) it was decided to include information on the highest contributor to each aggregated RAC equivalent into the long-term dietary intake model. Additionally the quantitative contribution is given as the percentage of the total RAC equivalent. An example is presented below:

Strawberries, processed → highest contributor: jam (30%)

The “highest contributor” provides additional information for the evaluator when the influence of processing (processing factors) is taken into account.

In the first place the sensitivity of processing information on consumer exposure becomes quantifiable to a certain extent. In case of the example presented above only 30% of the total RAC equivalent may be attributed to the processing of jam.

Vice versa the sensitivity of processing information resulting in very high residue levels for single commodities is described better and may preclude unrealistic overestimations of the long-term intake. Referring again to the example above it can be concluded, that dried strawberries, which normally contain a much higher residue level than fresh fruits, contribute less than 30% to the total RAC equivalent, since jam already is the highest contributor with 30%. Applying the processing factor for dried strawberries to the whole RAC equivalent would strongly overestimate the true intake.

The information provided by the “highest contributor” is only applicable in long-term dietary exposure assessment since RAC equivalents are based on the arithmetic mean of the consumption from all person days.

In short-term dietary exposure assessment the upper end of the distribution of RAC equivalents may consist of totally different food commodities consumed, not allowing the calculation of an overall contribution to a deterministic value. Hence the “highest contributor” would not provide reliable information in short-term dietary exposure assessment.

## Glossar

- “24h Recalls”: Module of the NVS II, involving questioning of the foods eaten within 24h on two non-consecutive days (13926 individuals, plus 1156 1x 24h Recalls, EPICSOFT tool)
- “Case”: Part of the IESTI approach, describing different exposure scenarios for the short-term dietary intake assessment.
- “General population”: Term for all individuals reported in the NVS II (male and female, 14–80 years of age)
- “Highest contributor”: For the long-term dietary intake assessment the commodity with the highest contribution to the arithmetic mean of the RAC equivalent is reported. The value is expressed as percent of the contribution to the overall value.
- “IESTI”: International Estimated Short-Term Intake. Exposure model used in the short-term intake assessment of pesticide residues.
- “Individual bodyweight approach”: Calculation method for the RAC equivalent. The RAC equivalent is based on the individual ratio of the amount food consumed and the bodyweight for each person day.
- “Mean bodyweight approach”: Calculation method for the RAC equivalent. The RAC equivalent is estimated as an absolute value in g per day and correlated with the mean bodyweight of all individuals.
- “MRL”: Maximum residue level for pesticide residues established under Reg. (EC) 396/2005
- “NVS II”: German Nutrition Survey II
- “NVS-RISK”: Specific project by BfR and the University of Paderborn to derive recipes and processing factors needed to convert “foods as eaten” into their respective RACs.
- “Percent edible portion”: Since all RAC equivalents are based on the raw agricultural commodity which might include inedible parts, this factor was included into the model to quantify the percentage of the commodity removed before consumption or processing (e.g. peel, stalks or fruit stones).
- “Person-days”: Reported information on the total consumption of food items of one individual within 24h. Each “person day” is treated as an independent dataset. Since most participants of the NVS II 24h Recalls were questioned twice, the number of “person days” differs from the number of consumers for specific food items.
- “RAC”: Raw agricultural commodity. Potatoes, for example, are the RAC for French fries, cooked potatoes, mashed potatoes, gnocchi, potato soup etc.

“RAC-equivalent”: This term refers to a specific percentile (e.g. mean or P97.5) of the total consumption of different food items within 24h, aggregated from all sources and expressed as the respective raw agricultural commodity.

“Women in childbearing age”: All female individuals between 14 and 50 years were selected for this sub-population.