



The use of chemical occurrence data at European vs. national level in dietary exposure assessments: A methodological study



Salomon Sand^{a,b,*}, Fanny Héraud^a, Davide Arcella^a

^a Dietary and Chemical Monitoring Unit, European Food Safety Authority (EFSA), Parma, Italy

^b Risk-Benefit Assessment Department, National Food Agency, Uppsala, Sweden

ARTICLE INFO

Article history:

Received 23 April 2013

Accepted 12 August 2013

Available online 16 August 2013

Keywords:

Dietary exposure
Contamination
Consumption survey
Cadmium

ABSTRACT

A typical EFSA approach to assess dietary exposure is to combine data from national consumption surveys with chemical occurrence data that have been pooled across the EU Member States (pooled approach). This approach was compared to the case where occurrence data were stratified by country and used for food categories where national data were abundant (semi-pooled approach), using cadmium as a case study. Some differences in estimated dietary exposure were observed between the pooled and semi-pooled approach. They were explained by differences, between the national and the European occurrence data, with respect to (1) contamination values and (2) sample proportions of food items classified in the food categories the assessment was based on. The latter aspect highlighted the sensitivity of the approach of directly aggregating monitoring data into food categories. Both the pooled and semi-pooled approach tended to be conservative relative to approaches used at national level. This appears to be attributed to differences in the way the available occurrence data is aggregated. Refinement of the studied methodologies would include a better separation of the food items with high concentration from those with low concentration.

© 2013 Elsevier Ltd. All rights reserved.

1. Introduction

Assessment of dietary exposure is a central step in any risk assessment of substances whose presence in food can lead to adverse health effects. When performing dietary exposure assessment, the European Food Safety Authority (EFSA) usually combines country specific data on consumption with occurrence data (i.e. data on the concentration of a chemical in food) that have been pooled across the different European member states (e.g. EFSA, 2009, 2012). The assumption underlying this strategy is that consumption patterns may differ across Europe while, due to the free movement of goods throughout the European Union, the contamination level is similar. This is a simplification of reality and the validity of the assumption depends e.g. on the kind of substance and food under investigation. Moreover, the occurrence data across Europe provide, due to their high number, a larger basis for estimating concentration levels for particular food items or food groups. The EFSA approach differs in principle to that performed by individual Member States, since the latter approaches use national specific occurrence data in dietary exposure assessments and not the European pool of data. These different approaches may lead to discrepancies in results, as recently discussed by Sand

and Becker (2012) using Cadmium as a case substance, which may impact on the conclusion of a risk assessment. Also, Boon et al. (2009) indicated that estimates of higher percentiles of exposure (in a short-term exposure assessment) generally became more conservative when sampling concentration data on captan and tolyfluanide from a pooled database compared to a national database.

In a comparable setting, this study investigates the consequence using the European pool of occurrence data or national specific occurrence data for dietary exposure assessments. In line with the approach used by EFSA, the occurrence data are directly aggregated into food categories, without applying any weighting factor. Cadmium is used as a case substance. Occurrence data are relatively abundant for this compound which enables a comparison between using the complete European pool of data and national specific data for several countries.

In 2012, EFSA refined their dietary exposure assessment for Cadmium (EFSA, 2012). A first assessment was already conducted in 2009, as part of the EFSA opinion on Cadmium in food which established a tolerable weekly intake (TWI) of cadmium of 2.5 µg per kg body weight (EFSA, 2009). While the exposure assessment in 2009 was based on the Concise European Food Consumption Database (EFSA, 2009), the refined assessment was based on the more recent Comprehensive European Food Consumption Database (the Comprehensive Database). The Comprehensive Database contains consumption data of about 67,000 individuals from 22 European countries (EFSA, 2011a). The FoodEx classification

* Corresponding author at: Risk-Benefit Assessment Department, National Food Agency, Uppsala, Sweden. Tel.: +46 18175335.

E-mail address: salomon.sand@slv.se (S. Sand).

system for categorizing foods has also been introduced to improve the (accuracy) of matching the consumption and occurrence data (EFSA, 2011a). Use of the Comprehensive Database and classification system resulted in estimates of cadmium exposure that were lower than those previously calculated. The refined assessment still indicated, however, that children and adults at the 95th percentile of exposure could exceed the TWI (EFSA, 2012).

Besides investigating how results from exposure assessments may differ according to whether occurrence data at the European or national level are used, this study also provides an illustration of the principle of how to use national specific occurrence data in combination with data at the European level in exposure assessments. Potential refinements of the current approach used by EFSA are discussed, and the results obtained in these analyses are contrasted to those that have been reported in national exposure assessments.

2. Materials and methods

2.1. Cadmium occurrence and food consumption data

Cadmium occurrence data used in this study were previously described in EFSA (2012) and Ferrari et al. (2013). They originated from competent authorities of twenty two Member States, three European Economic Areas or other countries, as well as from food business operators in Member States. These data mainly represent results from monitoring programmes. They covered the period 2003–2011.

Consumption data from the Comprehensive Database (EFSA, 2011a; Merten et al., 2011) on seven countries were used in the present study: Germany, DE (MRI, 2008); Denmark, DK (Lyhne et al., 2005); Spain, ES (Ortega et al., 2011); France, FR (Dubuisson et al., 2010); United Kingdom, UK (Henderson et al., 2002); Ireland, IE (Kiely et al., 2001; Harrington et al., 2001); and Sweden, SE (Becker and Pearson, 2002). These countries were selected since they together reflect the variation in the amount of occurrence data submitted to EFSA by individual Member States, and the variation in the number of individuals covered in the consumption surveys submitted to EFSA by the Member States (Table 1). Consumption data at the individual (subject) level were used, and the analysis was restricted to cover adults 18–65 years of age.

Foods in the two databases were coded according to the FoodEx classification system, a four-level hierarchical system based on 20 main food categories that are further divided into food sub-groups (EFSA, 2011b). Consumption and occurrence data were matched at the second hierarchical level of FoodEx (FoodEx level 2). Exceptions were *Horse, asses, mules or hinnies meat, Goat milk, Bitter-sweet chocolate and Algae formula*, which were matched at the third level, FoodEx level 3, since they had much higher cadmium levels than the other foods classified in the associated FoodEx level 2 categories. In total, consumption and occurrence data were organized into 151 food categories. More food categories were used in EFSA (2012) and Ferrari et al. (2013). This is because more surveys were considered in those studies. All food categories for which consumption event were not reported in any of the surveys considered in this study were excluded from the analysis.

2.2. Exposure assessment

Health effects of cadmium are considered to relate to long-term exposure (EFSA, 2009). Estimation of the long-term dietary exposure was performed by using a non-parametric bootstrap approach. This method was implemented in Matlab (version 7.11) and accounts for the uncertainty around the input data (Sand and Becker, 2012):

- I. For each food category n concentration values were randomly drawn with replacement, where n is the total number of concentration values available for that food category. The mean cadmium concentration was then estimated for each food category. No weighting was performed when estimating the mean occurrence (concentration).
- II. For a given consumption survey the data (over all food categories) for p individuals were randomly drawn with replacement, where p is the total number of individuals in that survey.
- III. The dietary exposure was estimated for each individual by combining the corresponding consumption data with estimates of the mean cadmium concentration for each food category. Observe that the consumption data used for each individual, with respect to each food category, was an average value over the number of survey days, i.e. consumption in g/kg b.w. per day. The population mean and 95th percentile of exposure were then estimated, as well as the percent of the population exceeding the EFSA cadmium TWI = 2.5 µg/kg b.w. per week.
- IV. The procedure above (steps I – III) was repeated 500 times. For each quantity (the mean, 95th percentile and proportion above the TWI) the mean of 500 iterations was calculated and the 90% confidence interval.

The approach described above was performed by considering two different scenarios for the chemical occurrence data:

Scenario 1 (pooled approach): The mean occurrence was based on the complete pool of data for each food category and Member State.

Scenario 2 (semi-pooled approach): The mean occurrence for each food category was based on national specific data if a sufficient number of total and positive analytical results were available according to the criteria for left censored data (EFSA, 2010): [N samples ≥ 50 OR N positive samples ≥ 25] AND [N samples below the limit of detection (LOD) or the limit of quantification (LOQ) $\leq 80\%$]. For food categories not satisfying the criteria the complete pool of data were used. The criteria for left censored data was established by EFSA to decide whether or not a modelling approach can be applied for describing the complete distribution of concentration values, both above and below the LOQ/LOD (EFSA, 2010). In this work it is used as data quality criteria. While the formulation of the criteria may not appear straightforward, the main feature is that the proportion of censored results (i.e., result below the LOD/LOQ) is not allowed to be too large ($\leq 80\%$) and at the same time the number of quantified results are not allowed to be too low (≥ 25).

As recommended by the WHO, the exposure was assessed with different scenarios regarding the censored results (GEMS/Food-Euro, 1995). As one case (lower bound assumption) all the non-detected and non-quantified results were set equal to zero. As another case (middle bound assumption) all the non-detected results were set to half the LOD and all non-quantified result were set to half the LOQ.

3. Results

Exposure estimates associated with scenario 1 (pooled approach) and scenario 2 (semi-pooled approach) are presented in Table 1 by survey, and the mean relative source contribution is illustrated for each survey in Figs. 1A–G (for scenario 2).

The effect of using national specific data according to the semi-pooled approach is most pronounced in three surveys. For DK, ES and FR, an increase in the mean and the 95th percentile of exposure can be observed, relative to scenario 1, for results based on both middle and lower bound estimates (Table 1). The proportion of individuals with exposures exceeding the TWI increases from 5%, 21%, and 15%, in scenario 1, to 9%, 42%, and 41%, in scenario 2, for DK, ES and FR, respectively (results based on middle bound estimates). The observed changes in exposure are supported by the uncertainty analysis; i.e. confidence intervals are not overlapping between the scenarios (Table 1).

For other surveys (DE, UK, IE and SE) only minor differences in the estimated exposure is observed between scenario 1 and 2 (Table 1). Considering both middle and lower bound estimates the mean and the 95th percentile of exposure changes by less than 0.2 µg/kg b.w./week between scenario 1 and 2 for DE, UK, IE and SE. The proportion of individuals with exposures exceeding the TWI generally differs by 1–2% between the two scenarios. These changes appear not to be supported by the uncertainty analysis since confidence intervals associated with estimates under scenario 1 and 2 are generally overlapping (Table 1).

Among the countries investigated, Germany has submitted the most occurrence data. Consequently, estimates based on the complete pool of occurrence data (scenario 1) may to a high extent already reflect the German data. As is shown in Fig. 1A, even though national occurrence data are used for several (61 out of 151) categories in the case of DE, only smaller changes are observed for individual food categories between scenario 1 and 2. And for UK, IE, and SE, the criteria for left-censored data (that dictated the extent of using national specific data) was only satisfied for 5–6 food categories, and only a few (or none) of these selected categories were among the most important ones (Figs. 1E–G). As a consequence, only minor differences were observed between the pooled and semi-pooled approach for UK, IE, and SE. The surveys (DK, FR, ES) for which a more clear difference between the two scenarios is observed correspond to countries that have submitted an intermediate level of occurrence data and for which national data were used for at least four of the top ten food categories in the semi-pooled approach (Fig. 1B–D).

Table 1
Estimated cadmium exposure ($\mu\text{g}/\text{kg}$ b.w. per week) according to scenario 1 (pooled approach) and scenario 2 (semi-pooled approach).

| Country | $N_{\text{ivd}}/N_{\text{oc}}^{\text{a}}$ | Scenario ^b | $N_{\text{cat}}^{\text{c}}$ | Middle bound estimates ^d | | | Lower bound estimates ^e | | |
|---------|---|-----------------------|-----------------------------|-------------------------------------|------------------|--------------------------|------------------------------------|------------------|--------------------------|
| | | | | Mean | P95 | Proportion exceeding TWI | Mean | P95 | Proportion exceeding TWI |
| DE | 10,491/48,700 | 1 | 151 | 1.50 (1.48–1.53) | 2.61 (2.54–2.66) | 0.06 (0.05–0.07) | 1.22 (1.18–1.24) | 2.21 (2.13–2.27) | 0.03 (0.03–0.03) |
| | | 2 | 61 | 1.57 (1.53–1.64) | 2.71 (2.63–2.80) | 0.08 (0.07–0.09) | 1.33 (1.28–1.38) | 2.38 (2.32–2.44) | 0.04 (0.03–0.05) |
| DK | 2822/5971 | 1 | 151 | 1.57 (1.54–1.61) | 2.47 (2.40–2.56) | 0.05 (0.04–0.06) | 1.30 (1.27–1.34) | 2.11 (2.04–2.18) | 0.02 (0.02–0.03) |
| | | 2 | 23 | 1.77 (1.71–1.83) | 2.81 (2.69–2.95) | 0.09 (0.08–0.12) | 1.50 (1.45–1.57) | 2.44 (2.33–2.58) | 0.05 (0.04–0.06) |
| ES | 410/8119 | 1 | 151 | 2.02 (1.92–2.13) | 4.32 (3.74–5.04) | 0.21 (0.18–0.25) | 1.74 (1.64–1.84) | 3.97 (3.36–4.74) | 0.16 (0.13–0.19) |
| | | 2 | 12 | 2.70 (2.48–2.92) | 5.84 (5.13–6.38) | 0.42 (0.36–0.49) | 2.28 (2.06–2.54) | 5.29 (4.57–5.90) | 0.30 (0.23–0.39) |
| FR | 2276/21,888 | 1 | 151 | 1.79 (1.76–1.83) | 3.12 (3.03–3.23) | 0.15 (0.13–0.16) | 1.54 (1.50–1.57) | 2.79 (2.69–2.88) | 0.08 (0.07–0.09) |
| | | 2 | 27 | 2.45 (2.32–2.57) | 4.44 (4.16–4.69) | 0.41 (0.36–0.46) | 2.20 (2.09–2.34) | 4.10 (3.83–4.37) | 0.32 (0.27–0.37) |
| UK | 1724/838 | 1 | 151 | 1.66 (1.62–1.69) | 2.68 (2.60–2.77) | 0.07 (0.06–0.09) | 1.37 (1.34–1.40) | 2.30 (2.21–2.40) | 0.03 (0.02–0.04) |
| | | 2 | 6 | 1.60 (1.55–1.67) | 2.53 (2.39–2.73) | 0.05 (0.04–0.08) | 1.31 (1.26–1.38) | 2.13 (2.00–2.37) | 0.02 (0.01–0.04) |
| IE | 958/3091 | 1 | 151 | 1.97 (1.92–2.02) | 3.21 (3.09–3.32) | 0.19 (0.16–0.21) | 1.63 (1.59–1.68) | 2.71 (2.61–2.81) | 0.09 (0.07–0.10) |
| | | 2 | 5 | 1.85 (1.80–1.91) | 3.03 (2.93–3.14) | 0.15 (0.12–0.17) | 1.60 (1.56–1.65) | 2.68 (2.58–2.77) | 0.08 (0.06–0.09) |
| SE | 1210/876 | 1 | 151 | 1.76 (1.72–1.81) | 2.84 (2.74–2.98) | 0.10 (0.08–0.12) | 1.44 (1.39–1.49) | 2.39 (2.29–2.53) | 0.04 (0.03–0.05) |
| | | 2 | 6 | 1.69 (1.63–1.75) | 2.75 (2.62–2.89) | 0.08 (0.07–0.10) | 1.39 (1.33–1.44) | 2.32 (2.18–2.47) | 0.03 (0.02–0.05) |

^a N_{ivd} and N_{oc} is the number of individuals in the consumption survey and the number of samples on cadmium occurrence submitted to EFSA, respectively.

^b Scenario 1: The occurrence means for all food categories used in the assessment are based on the complete pool of occurrence data from European data providers. Scenario 2: For all food categories where national specific data satisfied the criteria for left censored data (see Section 2), this data were used for estimating the mean occurrence. For remaining food categories, the complete pool of occurrence data was used as a basis.

^c N_{cat} is the number of food categories used. For scenario 2 (semi-pooled approach), the value given is the number of categories that satisfy the criteria for left censored data. For scenario 1 (pooled approach) 116 categories satisfied the criteria. All 151 categories were, however, used since this is the reference case corresponding to the most recent EFSA cadmium exposure assessment (EFSA, 2012).

^d In the calculations, concentration values below the LOQ/LOD has been set to $0.5 \times \text{LOQ/LOD}$. The mean of all 500 iterations and a 90% confidence interval is presented for each quantity (population mean, 95th percentile, and the proportion exceeding the TWI = $2.5 \mu\text{g}/\text{kg}$ b.w./week).

^e In the calculations, concentration values below the LOQ/LOD have been set zero. The mean of all 500 iterations and a 90% confidence interval is presented for each quantity (population mean, 95th percentile, and the proportion exceeding the TWI = $2.5 \mu\text{g}/\text{kg}$ b.w./week).

For DK, the net increase in the mean exposure in the semi-pooled approach ($\approx+8\%$ of the TWI) is more or less a result of the increased contribution from the most important category “bread and rolls” only (Fig. 1B). For ES and FR, “fruiting vegetables” was identified as the individual food category for which the mean exposure changed the most in the semi-pooled approach (Fig. 1C and D). The mean exposure from this category increases by 15 and 5.2% of the TWI for ES and FR, respectively. For ES the overall increase in the mean exposure ($\approx+27\%$ of the TWI) depends to a high extent on the change for “fruiting vegetables” (+15% of the TWI) (Fig. 1C), while the overall increase in the mean exposure ($\approx+27\%$ of the TWI) also depends on changes in several other food categories for FR (Fig. 1D).

In Tables 2–4, details behind the difference between scenario 1 and 2 for “fruiting vegetables” (FR and ES) and “bread and rolls” (DK) are given. As can be seen, the national (FR and ES) occurrence means for FoodEx level 3 categories that are classified under “fruiting vegetables” are generally higher than the means for the complete pool (Tables 2 and 3). The weighted occurrence mean for “fruiting vegetables” (the sum of occurrence means for FoodEx level 3 categories that have been weighted by the percent of average consumption of each respective FoodEx level 3 category) differ by approximately a factor of 2–3 between the national and complete pool of data (Tables 2 and 3). This can be contrasted to the difference between the un-weighted means (that are used in the actual exposure assessment) which is about a factor of five (Tables 2 and 3). Thus, the difference in the un-weighted means (a factor of five) for FR and ES can be divided into two approximately equally large factors that describe (1) difference in contamination levels and (2) differences in sample proportions. For DK, the weighted occurrence means does not seem to differ much between the national data and the complete pool of data (Table 4). This indicates that the difference observed between scenario 1 and 2 for DK is mainly a result of differences in sample proportions of FoodEx level 3 categories between the national and complete pool of occurrence data (Table 4).

4. Discussion

This paper has investigated the effect of using occurrence data pooled across European countries (scenario 1: pooled approach) compared to national specific occurrence data (scenario 2: semi-pooled approach) in dietary exposure assessments using cadmium as a case study. The methodology used for exposure assessment in this study, which estimates the mean exposure over the days in a consumption survey, has been observed to provide more conservative estimates of upper tail percentiles compared to approaches that correct the variation in long-term exposure for the within-person variation (Boon et al., 2011). However, this is not considered to influence the comparison of the results obtained from the pooled and semi-pooled approach.

In the semi-pooled approach, national specific data were only used for food categories presenting a sufficient number of total and positive analytical results according to the criteria setup for the management of left censored data. The criteria for left censored data has been defined for the application of a modelling approach aimed at describing the complete distribution of concentration values (EFSA, 2010), and it was used as data quality criteria in this study. Indeed, average cadmium levels estimated from a limited number of total and positive results may lack in robustness and may increase the uncertainty around the exposure estimates. It is, however, recognized that results are dependent on the specific thresholds used in the statistical criteria. An addition or alternative to statistical criteria may for example be to consider the use of national specific data for food items or food categories that are of particular concern or importance at the national level.

The semi-pooled approach describes in principal how exposure assessments at national level can be performed at a more detailed level (e.g. at a higher FoodEx level) by utilizing data at the European level for food categories where national data are lacking. The pooled approach is, however, a more straightforward approach compared to the semi-pooled approach. The assumption, or

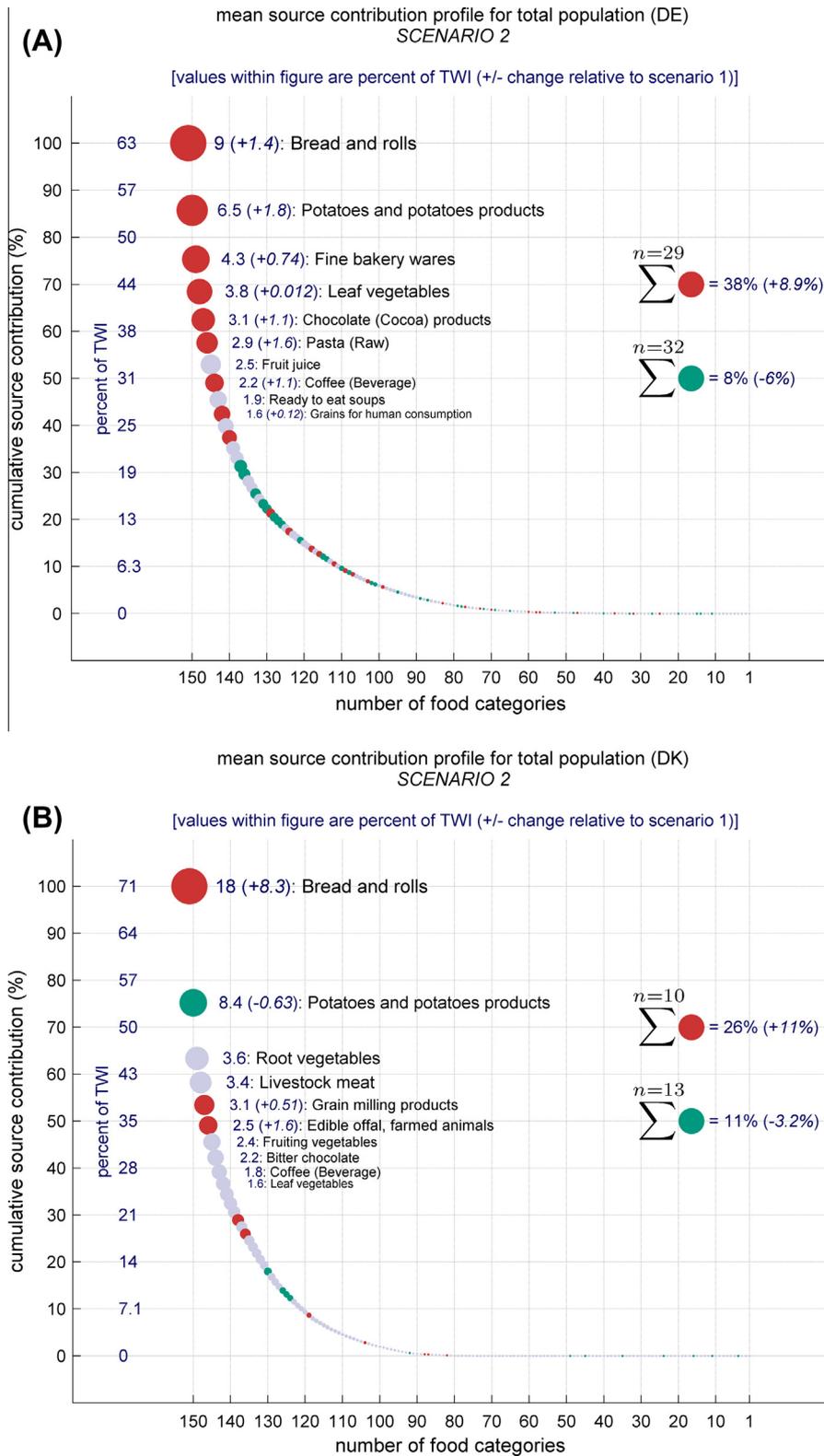


Fig. 1. Illustrations of the mean source contribution for Germany (A), Denmark (B), Spain (C), France (D) United Kingdom (E), Ireland (F) and Sweden (G) under Scenario 2 (semi-pooled approach). All 151 food categories are ordered from right to left, along the x-axis, according to their contribution to the mean exposure. The outer y-axis represents the cumulative source contribution, which has also been rescaled internally as percent of the TWI. For the ten most important food categories, the contribution to the mean exposure, as well as the change (\pm ; expressed as percent of the TWI) relative to scenario 1 (pooled approach), are given. Red circles indicate food categories for which the exposure increases relative to scenario 1, and green circles indicate food categories for which the exposure decreases relative to scenario 1. The sum of exposures (expressed as percent of the TWI) associated with red and green food categories are also indicated, as well as the corresponding changes (\pm ; expressed as percent of the TWI) relative to scenario 1. The values presented in the Figures are based on middle bound estimates. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

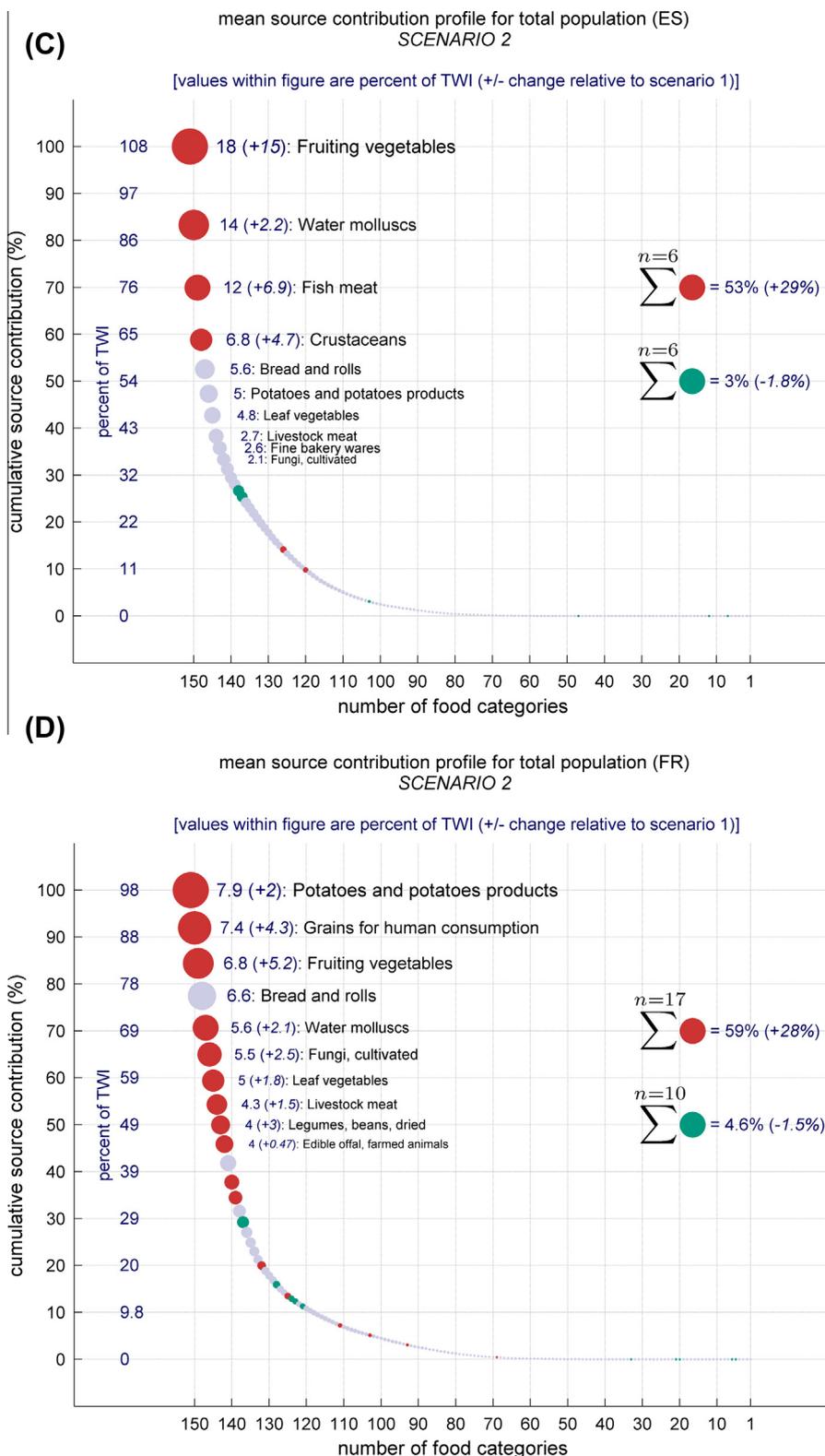


Fig. 1 (continued)

consideration, of constant contamination levels across Europe introduces a standardisation where differences in results between Member States will reflect differences in the consumption at the level of the food categories the assessment is based on. It may, however, be argued that if consumption differs between countries and individuals, the mean occurrence associated with a particular food category should also differ between the countries/individuals

(even if the contamination levels across Europe are similar) due to differences in consumption of individual food items (e.g. FoodEx level 3 items) classified in the food category. It may be of interest to consider approaches that account for this aspect when evaluating the potential variability in exposure across Europe.

In principle, the semi-pooled approach introduces such a framework at Member State level. While it may not yet perform

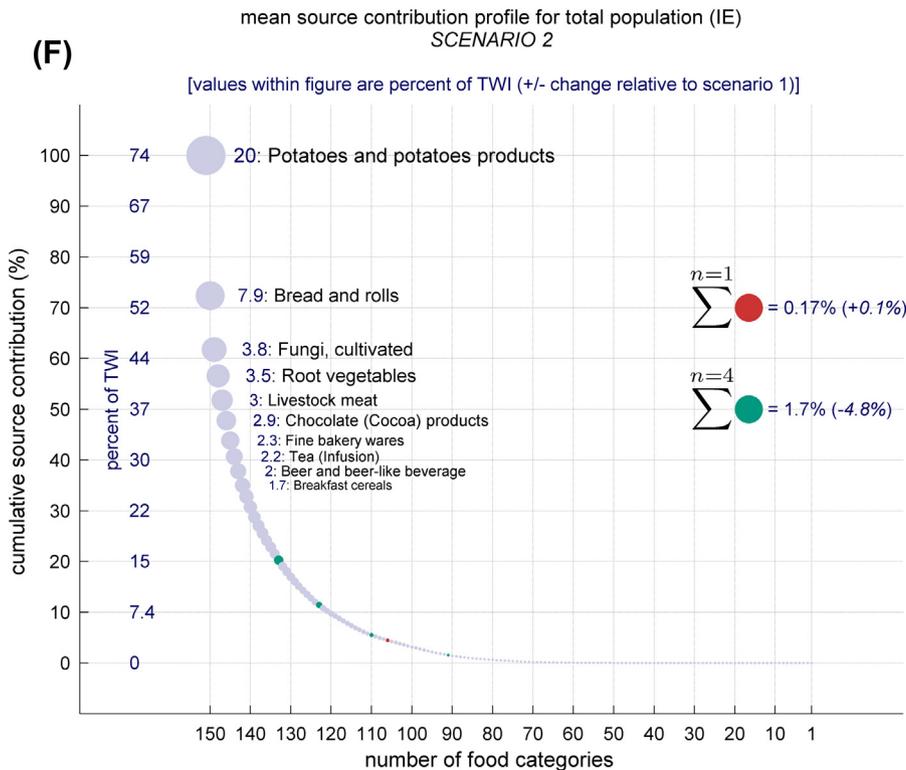
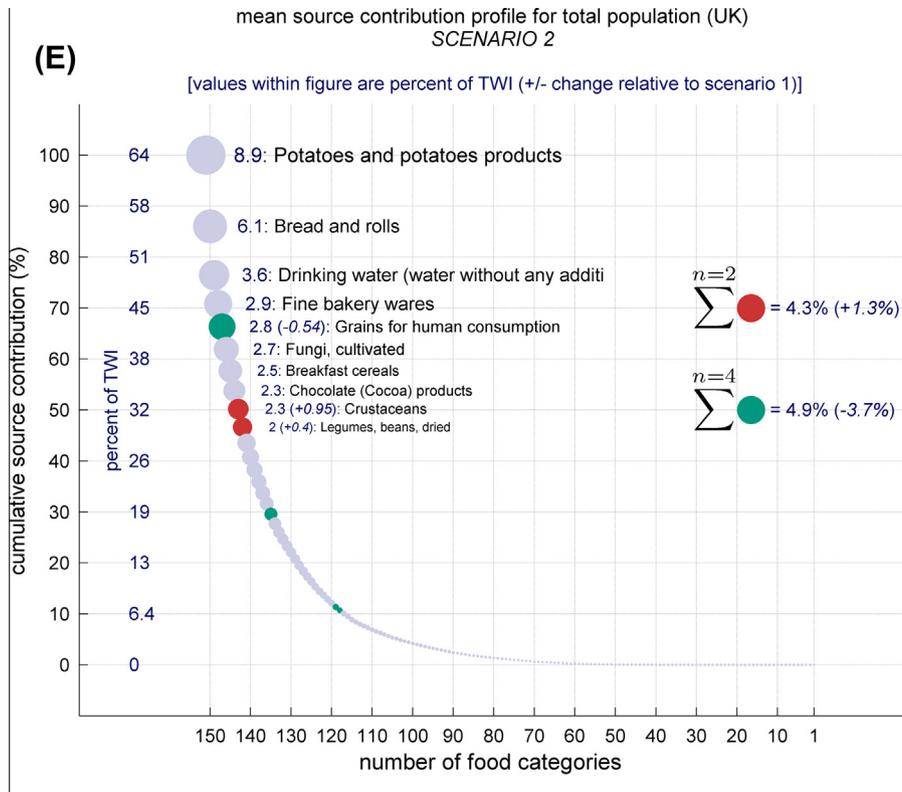


Fig. 1 (continued)

optimally in the context of enabling a standardized comparison between countries and/or accommodating national specific concerns, such endpoints may be better realized as the national specific occurrence databases expand (and e.g. better reflect the consumption in the different Member States). Also, the current semi-pooled approach used the same food categories that were used in EFSA (2012) for the pooled approach. This was decided after Cadmium

results at different levels of aggregation had been inspected for homogeneity, and based on this analysis it was decided to use FoodEx level 2 with the exception of horse meat, goat milk, chocolate and algal formulations that were kept separate (see Section 2). If such an analysis had been performed with respect to the national occurrence data, instead of the complete pool of data, other or additional exceptions may also have been done; e.g. “chilli pepper”

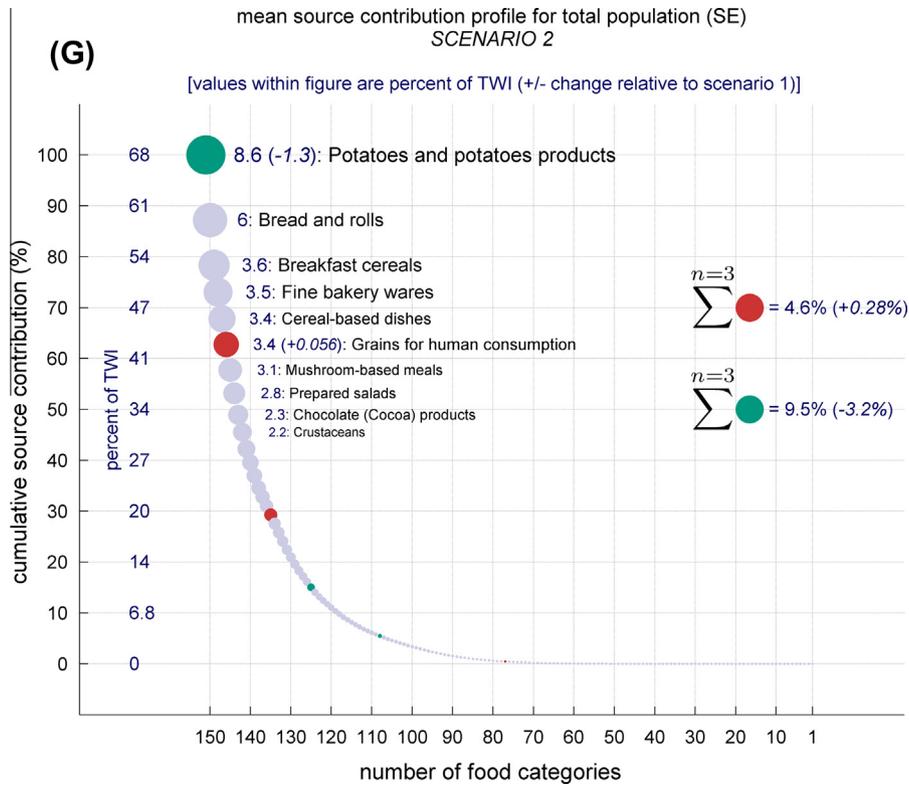


Fig. 1 (continued)

Table 2

Occurrence ($\mu\text{g}/\text{kg}$) and consumption data from France (FR) associated with FoodEx level 3 categories that were classified under the FoodEx level 2 category “fruiting vegetables”. Results based on the complete pool of occurrence data from the European (pool) are also shown.

| FoodEx level 3 | Mean occurrence (FR) | Mean occurrence (pool) | Percent samples ^a (FR) | Percent samples ^a (pool) | Average consumption in percent ^b (FR) |
|--|----------------------|------------------------|-----------------------------------|-------------------------------------|--|
| Tomatoes | 7.47 | 4.74 | 19 | 29 | 33 |
| Peppers, paprika | 26.2 | 7.83 | 10 | 28 | 15 |
| Chilli pepper | 179 | 91.7 | 14 | 2 | 0 |
| Aubergines (egg plants) | 7.60 | 2.88 | 15 | 5 | 8 |
| Okra, lady's fingers | – | 12.6 | 0 | 0.2 | 0 |
| Cucumbers | 0.67 | 1.33 | 6 | 23 | 9 |
| Gherkins | – | 0 | 0 | 0.04 | 5 |
| Courgettes (Zucchini) | 1.62 | 2.10 | 29 | 2 | 13 |
| Melons | 7.67 | 5.02 | 6 | 5 | 4 |
| Pumpkins | 1 | 3.66 | 1 | 0.8 | 6 |
| Watermelons | – | 1.46 | 0 | 0.6 | 0.2 |
| Sweet corn | – | 1.56 | 0 | 3 | 6 |
| Unspecified | – | 6.88 | 0 | 0.3 | 0 |
| Weighted mean for “fruiting vegetables” ^c | 7.79 | 3.93 | | | |
| Un-weighted mean for “fruiting vegetables” | 31.2 | 6.02 | | | |

^a Percent of samples in relation to the total number of samples ($n = 100$ for FR, and $n = 2694$ for the pool) considering all level 3 categories that are classified under “fruiting vegetables”.

^b The average consumption of each level 3 category in relation to the sum of the average consumption across all level 3 categories that are classified under “fruiting vegetables”.

^c The weighted occurrence mean has been calculated as the sum of the products between the mean occurrence and the corresponding average consumption in percent for level 3 categories.

(Table 2) and “peppers, paprika” (Table 3). Thus, a future refinement is to place more emphasis on the separation of foods with high concentration level from those with low concentration level.

Presently when using the semi-pooled approach (as implemented herein) differences in estimated exposure between countries can, besides differences in consumption, result due to 1) differences in chemical concentration values, and 2) differences

in sample proportions of food items classified in the food categories (Tables 2–4). The impact of the latter aspect highlights the sensitivity of the approach of directly aggregating monitoring data into food categories in relation to the level of food aggregation (i.e. the FoodEx level) the assessment is based on. It can be expected that the semi-pooled approach should indicate a greater variability and/or uncertainty in the estimated European exposure

Table 3
Occurrence ($\mu\text{g}/\text{kg}$) and consumption data from Spain (ES) associated with FoodEx level 3 categories that were classified under the FoodEx level 2 category “fruiting vegetables”. Results based on the complete pool of occurrence data from the European (pool) are also shown.

| FoodEx level 3 | Mean occurrence (ES) | Mean occurrence (pool) | Percent samples ^a (ES) | Percent samples ^a (pool) | Average consumption in percent ^b (ES) |
|--|----------------------|------------------------|-----------------------------------|-------------------------------------|--|
| Tomatoes | 0.9 | 4.74 | 27 | 29 | 61 |
| Peppers, paprika | 63.6 | 7.83 | 44 | 28 | 20 |
| Chilli pepper | – | 91.7 | 0 | 2 | 0 |
| Aubergines (egg plants) | 4.33 | 2.88 | 8 | 5 | 2 |
| Okra, lady's fingers | – | 12.6 | 0 | 0.2 | 0 |
| Cucumbers | 0 | 1.33 | 5 | 23 | 6 |
| Gherkins | 0 | 0 | 1 | 0.04 | 0 |
| Courgettes (Zucchini) | 0 | 2.10 | 4 | 2 | 3 |
| Melons | 0 | 5.02 | 4 | 5 | 2 |
| Pumpkins | – | 3.66 | 0 | 0.8 | 1 |
| Watermelons | 0 | 1.46 | 5 | 0.6 | 3 |
| Sweet corn | – | 1.56 | 0 | 3 | 0.5 |
| Unspecified | – | 6.88 | 0 | 0.3 | 0 |
| Weighted mean for “fruiting vegetables” ^c | 13.5 | 4.93 | | | |
| Un-weighted mean for “fruiting vegetables” | 28.5 | 6.02 | | | |

^a Percent of samples in relation to the total number of samples ($n = 73$ for FR, and $n = 2694$ for the pool) considering all level 3 categories that are classified under “fruiting vegetables”.

^b The average consumption of each level 3 category in relation to the sum of the average consumption across all level 3 categories that are classified under “fruiting vegetables”.

^c The weighted occurrence mean has been calculated as the sum of the products between the mean occurrence and the corresponding average consumption in percent for level 3 categories.

Table 4
Occurrence ($\mu\text{g}/\text{kg}$) and consumption data from Denmark (DK) associated with FoodEx level 3 categories that were classified under the FoodEx level 2 category “bread and rolls”. Results based on the complete pool of occurrence data from the European (pool) are also shown.

| FoodEx level 3 | Mean occurrence (DK) | Mean occurrence (pool) | Percent samples ^a (DK) | Percent samples ^a (pool) | Average consumption in percent ^b (DK) |
|--|----------------------|------------------------|-----------------------------------|-------------------------------------|--|
| Wheat bread and rolls | 34.4 | 24.2 | 50 | 16 | 25 |
| Rye bread and rolls | 11.6 | 11.9 | 26 | 4 | 25 |
| Mixed wheat and rye bread and rolls | – | 13.2 | 0 | 8 | 26 |
| Multigrain bread and rolls | – | 25.0 | 0 | 2 | 0 |
| Unleavened bread, crisp bread and rusk | – | 17.2 | 0 | 7 | 7 |
| Other bread | – | 18.2 | 0 | 2 | 0 |
| Bread products | 32.2 | 28.6 | 24 | 2 | 17 |
| Unspecified | – | 11.1 | 0 | 59 | 0 |
| Weighted mean for “bread and rolls” ^c | 16.8 | 18.4 | | | |
| Un-weighted mean for “bread and rolls” | 27.9 | 14.6 | | | |

^a Percent of samples in relation to the total number of samples ($n = 168$ for DK and $n = 2078$ for the pool) considering all level 3 categories that are classified under “bread and rolls”.

^b The average consumption of each level 3 category in relation to the sum of the average consumption across all level 3 categories that are classified under “bread and rolls”.

^c The weighted occurrence mean has been calculated as the sum of the products between the mean occurrence and the corresponding average consumption in percent for level 3 categories.

compared to the pooled approach; the mean and 95th percentile of exposure was 1.57–2.70 $\mu\text{g}/\text{kg}$ b.w./week and 2.53–5.84 $\mu\text{g}/\text{kg}$ b.w./week, respectively, for the semi-pooled approach, while the corresponding values were 1.50–2.02 $\mu\text{g}/\text{kg}$ b.w./week and 2.47–4.32 $\mu\text{g}/\text{kg}$ b.w./week for the pooled approach (Table 1). The lower number of food items (FoodEx level 3 items) covered by the national data may increase the risk of a poor match between the concentration sample proportions and the average consumption of those food items, i.e. for FR, ES, and DK the un-weighted and weighted means are more different for the semi-pooled approach compared to the pooled approach (Tables 2–4).

Recent exposure assessments at national level, which have utilized national specific occurrence data, have indicated differences compared to the results obtained by EFSA. This has for example been discussed in Sand and Becker (2012), where the median and 95th percentile of the cadmium exposure for the Swedish adult population was estimated to 0.91–1.02 $\mu\text{g}/\text{kg}$ b.w./week

and 1.59–1.73 $\mu\text{g}/\text{kg}$ b.w./week, respectively. In Arnich et al (2012) the mean and 95th percentile of exposure for adults in France was estimated to 1.12 $\mu\text{g}/\text{kg}$ b.w./week and 1.89 $\mu\text{g}/\text{kg}$ b.w./week, respectively (Arnich et al., 2012). And in Rose et al (2010) the mean and 97.5th percentile of exposure for adults in United Kingdom was estimated to 0.98–1.19 $\mu\text{g}/\text{kg}$ b.w./week and 1.75–2.03 $\mu\text{g}/\text{kg}$ b.w./week, respectively.

It can be noted that the national assessments for Sweden, France and United Kingdom presented above have used data from the same consumption surveys that are used in this study. The national exposure estimates are quite similar across the three countries, e.g. a mean/median exposure of around 1 $\mu\text{g}/\text{kg}$ b.w./week, and they are also lower than those resulting in this study under both scenario 1 and 2 (Table 1). A discrepancy between the results from the national assessments and those based on occurrence data (mainly monitoring data) submitted by the Member States to EFSA is thus apparent even in the case when the occurrence data submitted to

EFSA are stratified by country (for food categories that satisfied the selection criteria used in this study) (Table 1; scenario 2).

The reason for this discrepancy may be explained by several factors. For example, Arnich et al. (2012) and Rose et al. (2010) used occurrence data from total diet studies. Such studies are designed to assess the dietary exposure of the population, and in these studies Cadmium levels are measured in composite food samples combining individual samples taken according to market shares and/or purchase statistics. In Sand and Becker (2012), rarely consumed products, with high cadmium concentration, were excluded, and concentration values used for different food categories were also based on consideration of the most consumed foods (on average). The present study was based on occurrence data from monitoring programmes, which are in general designed to check compliance to maximum limits. When directly aggregating such data (without weighting), food items with relatively high concentration (that may be rarely consumed) can have a high impact on the mean occurrence for a particular food category (proportional to the number of samples). Moreover, the European pool of data includes a wide range of food items, some of which may be missing in the national datasets.

In summary, the pooled and semi-pooled approaches tend to be conservative relative to the approaches used at national level. This is a practical observation that in principle could change depending on the level of food aggregation used and the type of occurrence data (risk oriented sampling vs. the data on the most consumed food items) that is submitted to EFSA by the Member States. Matching of consumption and occurrence data was to a large extent performed at FoodEx level 2 in this assessment. Results suggest that refinement of the exposure assessment methodologies investigated, where monitoring data is directly aggregated into food categories, includes better separation of food items with high concentration from those with low concentration. This would imply more variation in the FoodEx level used for matching consumption and occurrence data across foods.

5. Disclaimer

The work was performed during the time the author Salomon Sand worked as Seconded National Expert at the Dietary and Chemical Monitoring Unit with the European Food Safety Authority (EFSA). The authors Fanny Héraud and Davide Arcella are employed with the European Food Safety Authority (EFSA) in its Dietary and Chemical Monitoring Unit. The present article is published under the sole responsibility of the authors and may not be considered as an EFSA scientific output. The positions and opinions presented in this article are those of the authors alone and are not intended to represent the views or scientific works of EFSA. To know about the views or scientific outputs of EFSA, please consult its website under <http://www.efsa.europa.eu>.

Conflict of Interest

The authors declare that there are no conflicts of interest

References

- Arnich, N., Veronique, S., Riviere, G., Jean, J., Noel, L., Guerin, T., Leblanc, J.-C., 2012. Dietary exposure to trace elements and health risk assessment in the 2nd French total diet study. *Food Chem. Toxicol.* 50, 2432–2449.
- Boon, P.E., Svensson, K., Moussavian, S., van der Voet, H., Petersen, A., Ruprich, J., Debnach, F., de Boer, W.J., van Donkersgoed, G., Brera, C., van Klaveren, J.D., Busk, L., 2009. Probabilistic acute dietary exposure assessments to captan and tolylfluamid using several European food consumption and pesticide concentration databases. *Food Chem. Toxicol.* 47, 2890–2898.
- Boon, P.E., Bonthuis, M., van der Voet, H., van Klaveren, J.D., 2011. Comparison of different exposure assessment methods to estimate the long-term dietary exposure to dioxins and ochratoxin A. *Food Chem. Toxicol.* 49, 1979–1988.
- Becker, W., Pearson, M., 2002. Riksmaten 1997–1998. Kostvanor och näringsintag I Sverige. Metod-och resultatanalys. (Dietary habits and nutrient intake in Sweden 1997–1998). Livsmedelsverket (National Food Administration), pp 1–201.
- Dubuisson, C., Lioret, S., Touvier, M., Dufour, A., Calamassi-Tran, G., Volatier, J.L., Lafay, L., 2010. Trends in food and nutritional intakes of French adults from 1999 to 2007: results from the INCA surveys. *Br. J. Nutr.* 103 (7), 1035–1048.
- EFSA. 2009. Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on cadmium in food. In *The EFSA Journal*. European Food Safety Authority, pp 1–139.
- EFSA. 2010. Management of left-censored data in dietary exposure assessment of chemical substances. In *EFSA Journal*. European Food Safety Authority, p 96.
- EFSA. (2011a). Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. In *EFSA Journal*. European Food Safety Authority, p 34.
- EFSA. 2011b. Evaluation of the FoodEx, the food classification system applied to the development of the EFSA comprehensive European food consumption database. *EFSA J.* 9 (3), 1970–1997.
- EFSA. 2012. Cadmium dietary exposure in the European population. In *EFSA Journal*. European Food Safety Authority, p 37.
- Ferrari, P., Arcella, D., Héraud, F., Cappé, S., Fabiansson, S., 2013. Impact of refining the assessment of dietary exposure to cadmium in the European adult population. *Food Addit. Contam. Part A* 30, 687–697.
- GEMS/Food-Euro. 1995. Reliable Evaluation of Low-Level Contamination of Food. Report of the Workshop held in Kulmbach, Federal Republic of Germany, 26–27 May 1995, 47 pp.
- Harrington, K.E., Robson, P.J., Kiely, M., Livingstone, M.B., Lambe, J., Gibney, M.J., 2001. The North/South Ireland food consumption survey: survey design and methodology. *Public Health Nutr.* 4 (5A), 1037–1042.
- Henderson, L., Irving, K., Gregory, J., Bates, C.J., Prentice, A., Perks, J., Swan, G., Farron, M., 2002. National Diet and Nutrition Survey: Adults aged 19 to 64 years. TSO, Ed., London. <<http://food.gov.uk/multimedia/pdfs/ndnsprintedreport.pdf>>.
- Kiely, M., Flynn, A., Harrington, K.E., Robson, P.J., Cran, G., 2001. Sampling description and procedures used to conduct the North/South Ireland Food Consumption Survey. *Public Health Nutr.* 4 (5A), 1029–1035.
- Lyhne, N., Christensen, T., Groth, M.V., Fagt, S., Biloft-Jensen, A., Hartkopp, H., Hinsch, H.-J., Matthiessen, J., Möller, A., Saxholt, E., Trolle, E., 2005. Dietary habits in Denmark 2000–2002, Main results. Danish Institute for Food and Veterinary Research, Department of Nutrition, Copenhagen.
- Merten, C., Ferrari, P., Bakker, M., Boss, A., Hearty, A., Leclercq, C., Lindtner, O., Tlustos, C., Verger, P., Volatier, J.L., Arcella, D., 2011. Methodological characteristics of the national dietary surveys carried out in the European Union as included in the European Food Safety Authority (EFSA) Comprehensive European Food Consumption Database. *Food Addit. Contam. Part A Chem. Anal. Control Expo. Risk Assess.* 28 (8), 975–995.
- MRI. 2008. Ergebnisbericht der Nationalen Verzehrsstudie II – Teil 1 (Report of the National Nutrition Survey II – Part 1). Max Rubner-Institut (MRI), Karlsruhe – Germany, p 144. <http://www.was-esse-ich.de/uploads/media/NVS_II_Abschlussbericht_Teil_1.pdf>.
- Ortega, R.M., Lopez-Sobaler, A.M., Ballesteros, J.M., Perez-Farinos, N., Rodriguez-Rodriguez, E., Aparicio, A., Perea, J.M., Andres, P., 2011. Estimation of salt intake by 24 h urinary sodium excretion in a representative sample of Spanish adults. *Br. J. Nutr.* 105 (5), 787–794.
- Rose, M., Baxter, M., Brereton, N., Baskaran, C., 2010. Dietary exposure to metals and other elements in the 2006 UK total diet study and some trends over the last 30 years. *Food Addit. Contam. Part A* 27 (10), 1380–1404.
- Sand, S., Becker, W., 2012. Assessment of dietary cadmium exposure in Sweden and population health concern including scenario analysis. *Food Chem. Toxicol.* 50, 536–544.