Chapter 53
The German Approach to Estimating Dietary Exposures Using Food Monitoring Data

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Introduction

Currently (since February 2012) Germany is conducting a pilot total diet study (TDS) as member of the TDS-Exposure Project [1], which is supported by the European Commission. Within the pilot project, infrastructure and expertise will be established for future implementation of a full German TDS. Presently, the existing data gap can be partly filled by the extensive national food monitoring program. Thus, national exposure assessments for food as done by the Federal Institute for Risk Assessment (BfR) mainly rely on matched data from the food monitoring program and national food consumption surveys. This chapter will give a short overview on the data available in Germany for dietary exposure assessment. The German approach using data from food monitoring instead of TDS will be demonstrated using the example of cadmium exposure via food. Advantages and disadvantages of both approaches will be elaborated.

German Food Monitoring Program

The German food monitoring program is a systematic approach for choosing food items from the German market to be analyzed for certain substances. The main focus is directed on residues of plant protection products but also environmental

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G.G. Moy and R.W. Vannoort (eds.), *Total Diet Studies*, DOI 10.1007/978-1-4419-7689-5_53,

contaminants, such as dioxins, polychlorinated biphenyls, heavy metals, and other contaminants. The food monitoring program has been performed by the Federal States of Germany since 1995. The program is coordinated by the Federal Office of Consumer Protection and Food Safety (BVL) that compiles all of the data generated in Germany. Data are made available to the BfR for exposure assessments of the German population. In order to use the monitoring data to obtain a representative estimate for the dietary exposure of a substance in Germany, a sampling design that differs from other monitoring programs is needed. One main difference is that random instead of targeted sampling is applied. Another difference is that the foods to be examined are part of a representative food basket.

Between 1995 and 2002, a food basket based on the National Nutrition Survey I [2] has been analyzed, including a total of 31,000 samples from 130 food items. The food basket and methods used for this monitoring period are described in Schroeter et al. 1999 [3]. The results and risk assessments for selected contaminants were published by the BVL in 2003 [4]. In 2007, the BfR was assigned by the Federal Ministry of Food, Agriculture, and Consumer Protection (BMELV) to propose a refined concept for the national monitoring of pesticide residues in food. The aim of the new design was to update the food basket using more recent nutrition surveys and to discuss ways to improve representativeness of the data. Hence, a food basket was developed from consumption data for German children as documented in the VELS-Study, [5] which started to be used in 2010. To also obtain data for adults, some food items that are normally not eaten by children but by adults (like beer, wine, and coffee) have been added to the food list. The selected foods cover 90 % of the whole diet based on the long-term mean consumption. The food basket consists of 64 food items with high variability in residue levels and 36 food items with low variability expected. The latter group will be analyzed every 6 years in a sample size of 188 samples per food item, all other in a 3-year cycle and with half of the sample size. The sample sizes are a compromise for statistical accuracy in estimating mean and high percentiles, on one hand, and financial and practical feasibility, on the other hand. Overall, in the new pesticide monitoring scheme, about 3,600 samples are analyzed each year.

The food basket and detailed recommendations regarding the study design were published by Sieke et al. in 2008 [6]. There are several criteria for representativeness given, that might be desirable from a scientific point of view. It should be mentioned that even if data are derived by random sampling, not all of these criteria could be controlled because of practical reasons.

After establishing the updated pesticide monitoring program, the BfR was asked to broaden the approach and make it useable for other contaminants as well. The pesticide monitoring is focusing on raw agricultural commodities (RACs) due to regulations for pesticide residues that are generally for nonprocessed foods to ensure safety of both processed and nonprocessed food. Thus, in a first step, only contaminants could be considered that will not be affected by preparation of foods or where the processing factors are well known. For all other contaminants, e.g. processing contaminants, such as acrylamide, polycyclic aromatic hydrocarbons, 3-monochloropropanediol-esters, and phthalates, other approaches like TDS have to be discussed in future.

In contrast to the former food basket from 1995 to 2002, which was a single food list valid for all contaminants, now agent specific food baskets were defined.

This was because some contaminants occur only in a few food groups or very specific food items. Thus, food items that may contribute highly to the overall exposure of a particular contaminant, may be missed when using a general food list that is characterized by highly consumed foods containing only low levels of the respective contaminant. Therefore, to avoid the chances of underestimating exposure, contaminant specific food lists were implemented.

The food lists are derived from consumption data for adults in the German National Nutrition Survey II. Since the survey includes very detailed food descriptions, the number of food items consumed is high. Therefore, a strategy was needed to reduce the number of food items for chemical analyses. This was done by defining homogenous food groups and by selecting a surrogate per food group. The surrogates will be used to extrapolate to all other foods within the food group. For example, "Edam" or "Tilsit" cheese will not be analyzed but "Gouda" samples were used instead. The resulting contaminant specific food lists were merged and also compared with the food list of the pesticide monitoring program to benefit from synergistic effects. Finally the new monitoring program was established in 2011 with about 3,400 samples to be analyzed per year.

The German National Nutrition Survey II

Besides data concerning contamination of foods due to hazardous substances, details about food consumption are crucial for exposure assessment. The German National Nutrition Survey II (NVS II) is the most recent national food survey in Germany providing information with regard to nutritional behavior of the young and adult population from the ages of 14–80. This study was conducted in 2005/2006 by the Max Rubner Institute (MRI) on behalf of the BMELV. About 20,000 people were selected randomly for a representative sample of the German population. The NVS II combines three different survey methods, namely, a dietary history, repeated 24-h recalls on two nonconsecutive days and further, the weighing records for a subsample of 1,000 people. In the dietary history, people were interviewed in a standardized way about their food consumption over the last 4 weeks using the software *DISHES* (Diet Interview Software for Health Examination Studies) [7]. Since environmental contaminants are primarily associated with chronic risks, the study design using a dietary history approach is appropriate for generating valid estimates of usual consumption for assessing exposure to cadmium via food.

The LExUKon Project: Aims and Methods

LExUKon [8] is the acronym for a German project for data preparation and standardization of procedures for exposure assessment of food-related exposure of environmental contaminants based on the NVS II. With this updated food consumption data, current exposure and the contribution of single food items or food groups to overall exposure can be calculated. LExUKon especially aims at establishing food categories that are compatible to food groups with maximum levels (MLs) as defined in the European legislation to check dietary exposure against contemporary health-based reference values.

To assess dietary cadmium exposure, food consumption data were matched with data from food monitoring at the level of categories for MLs. Since regulated categories consist primarily of unprocessed single foods, consumption data published by MRI could not be used directly [9]. However, food as eaten was broken down according to recipes. Besides the desired food level, this is also important to avoid underestimation of the consumption of some foods, such as herbs, oilseeds, and cocoa that are often part of composite foods. For the exposure assessment of cadmium, it was assumed that preparation of foods has no influence on the cadmium content apart from the drying process, which was considered by using concentration factors.

Although food monitoring provides considerable data for cadmium, some food items eaten in the survey remain without data. Therefore, data from the literature were added and homogenous food groups that had been defined were used to extrapolate from foods with measured cadmium values to similar foods.

Results on Cadmium from the LExUKon Project

Results of the LExUKon project allow the calculation of whether dietary exposure of the German population and some subgroups exceed the health-based reference value for cadmium. Figure 53.1 shows the level of dietary exposure to cadmium for the total German population, vegetarians and the highest exposed age group (14–18 year olds) compared to the Tolerable Weekly Intake (TWI) of

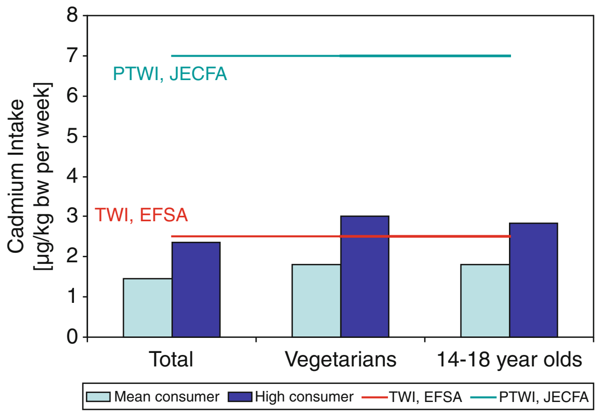

Fig. 53.1 Cadmium intake in Germany in different population groups compared to the TWI of EFSA and the PTWI of JECFA

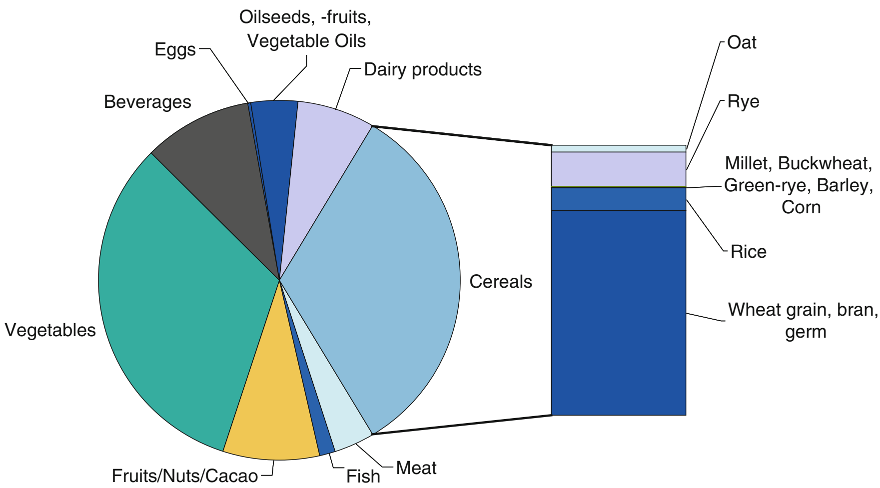

Fig. 53.2 Contribution of the main food groups to the intake of cadmium and disaggregation of the cereals group up to levels compatible with European regulation

2.5 μg/kg body weight per week established by European Food Safety Authority (EFSA) [10].

The upper reference line in Fig. 53.1 indicates the Provisional Tolerable Weekly Intake (PTWI) of 7 μg/kg body weight per week established by Joint FAO/WHO Expert Committee on Food Additives (JECFA) [11] in 1988. The figure demonstrates that consumers eating mean portions of all foods do neither exceed the PTWI nor the TWI. High consumers are defined according to EFSA [12] as high consumers of those two food groups contributing most to the overall mean exposure and average consumption for all other food groups. In the case of cadmium, the main contributors are the two food groups cereals and vegetables. Figure 53.1 reveals that high consumers nearly reach the TWI, while high consumers in the subpopulation of vegetarians as well as youths from 14 to 18 years exceed the TWI. Furthermore, it has to be kept in mind that the estimates only consider dietary exposure. Other sources contributing to cadmium exposure, such as inhalation of cigarette smoke must also be considered.

With respect to the fact that dietary cadmium exposure is relatively high, measures to reduce cadmium levels in food have to be discussed. Therefore, it is very useful to take a deeper look into the food groups established in the European Regulation (EC) No. 1881/2006 [13] amended by Regulation (EC) No. 629/2008 [14] and their contribution to cadmium exposure. Beyond this, the influence of regulated versus nonregulated food groups in relation to cadmium exposure can be compared in the LExUKon project. It has been calculated that 75 % of the mean dietary exposure is caused by regulated food items and 25 % by nonregulated food groups, like milk, oilseeds and cocoa. Figure 53.2 displays the contribution of the nine main

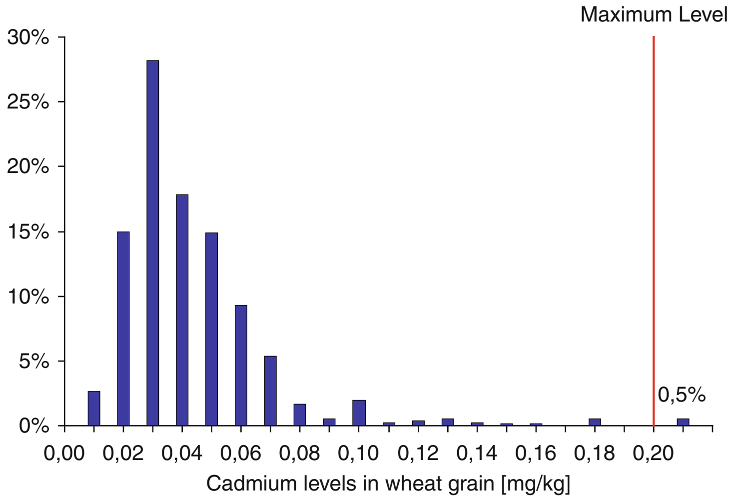

Fig. 53.3 Cadmium levels in wheat grain from the German food monitoring compared to the maximum level

food groups to cadmium exposure and illustrates the ability for further disaggregation of food categories using the example of cereals. On the basis of Fig. 53.2, it can be concluded that reducing MLs of cadmium in highly contaminated food groups, like seafood, offal or wild grown mushrooms, would hardly affect mean overall exposure. Instead it can be seen that due to high consumption levels, the main drivers of cadmium exposure are food groups like cereals or vegetables with mostly medium or low cadmium levels. Obviously, lower contaminated food groups can make a significant contribution to overall exposure when they are eaten in higher amounts.

Since wheat seems to be a main source for exposure to cadmium (see Fig. 53.2) the first thought to reduce cadmium intake would be to lower the ML of wheat. But as shown in Fig. 53.3, at least for the German market, it is obvious that most of the wheat samples have cadmium levels well below half of the MLs. Hence, even reducing the ML by half will probably have little effect on exposure.

Nevertheless, it has to be evaluated whether a reduction of MLs in food will be achievable under current conditions and how this would contribute to reducing cadmium exposure. The results of the LExUKon project are appropriate to be taken into account in such decisions.

Food Monitoring: An Alternative to TDS?

The aim of this section is to discuss whether the use of the German food monitoring program in the way described for the LExUKon project could be an alternative approach to TDS and to elaborate on common features and differences. A main objective of both approaches is to assess dietary exposure. The estimated weekly exposure of cadmium as reported for the German population in the LExUKon project (1.45 μg/kg body weight) is higher than estimates from the UK TDS 2009 [15] (1.09 μg/kg body weight per week with occurrence data from 2006), the First French TDS 2005 [16] (0.32 μg/kg body weight per week with occurrence data from 2000 to 2001) and the Second French TDS 2011 (1.12 μg/kg body weight per week with occurrence data from 2006) [17]. The differences between both French TDS studies are higher than the difference between the UK or Second French TDS and LExUKon. Hence it cannot be determined whether differences between TDSs and LExUKon are due to different national eating habits, the methods or due to over- or underestimation of one of the approaches. In contrast to this, one rather outdated duplicate diet study in an industrial area of Germany shows considerably higher values [18] (3.3 μg/kg body weight per week with occurrence data form 1994/1995) than the LExUKon estimate. This is also valid for the results based on EFSA's Concise European Food Consumption Database, [19] where the mean dietary exposure across European countries was assessed to be 2.3 μg/kg body weight per week and ranged from 1.9 to 3.0 μg/kg body weight per week. Due to the broad food categories of the EFSA's database, it can be concluded that the approach used in LExUKon is more precise than the EFSA approach. Compared to the values obtained in the duplicate diet study, it can be seen that the estimate of the LExUKon project does not result in gross overestimation, even if the duplicate diet will probably overestimate current exposure due to rather outdated cadmium data and likely highly contaminated regions.

The TDS trend analyses are also applicable for the German approach. Based on food monitoring data from the period 1995–2002 and the German Nutrition Survey I, BVL already had performed a German exposure assessment for cadmium in 2003. The estimate of 1.2 μg/kg body weight per week cadmium dietary exposures is very similar to the recent assessment in spite of the different methodologies used in the nutrition surveys. With the new design of the food monitoring, an appropriate database is already established for future trend analyses. That is also true for the food consumption data that are regularly collected by the MRI in the German Nutrition Survey [20] since 2008.

A TDS approach might be applicable for all contaminants and is only limited by financial resources. Following the German approach, some requirements have to be fulfilled. It can be used for contaminants that are not heat sensitive and therefore, no processing factors are needed other than for mixing, dilution and drying. It can even be applied to all other contaminants under the condition that processing factors are available. Nevertheless it has to be stated that this is not the case for most of the contaminants. Pesticide residues are an exception because often processing factors are known from the authorization process and compiled by the BfR [21]. An advantage of the German approach is that individual recipes can be used to aggregate from RAC level to composite foods. On the other hand, due to financial resources, TDS usually covers only standard recipes. For both approaches, only standard household preparation procedures are considered because nutrition surveys normally do not provide information of cooking or baking times. For instance, the time of heating a product, like toast or fried potatoes, varies markedly between households. This variability cannot be addressed within both approaches but will definitely have an influence on exposure assessments, e.g. for acrylamide.

Obviously, it will not be possible to have valid occurrence data for all contaminants in all foods of the diet. Hence, the exposure estimates both of TDS and German food monitoring program tend to underestimate the overall dietary exposure. However, the magnitude of underestimation can be reduced by choosing food surrogates within homogenous food groups as used in the German food monitoring program or other extrapolation strategies. Underestimation is also reduced by selecting food items that are frequently consumed and hence, representing a high percentage of the diet, as well as selecting foods which are known to have potentially very high concentrations (e.g. offal and shellfish for cadmium)[2]. As demonstrated for the LExUKon project, the underestimation is less in cases using RACs, recipes and processing factors. For contaminants with known processing factors, this is also a very cost-effective approach because there is a significantly smaller number of RACs compared to the high variety of processed and composite foods. Additionally the use of contaminant specific food lists as described for the new German food monitoring program will save resources and reduce the underestimation of exposure, because it also considers food items with low contribution to overall consumption, but high contribution to the exposure of a specific contaminant.

One of the advantages of the food monitoring program compared to most of the TDSs is the larger number of samples, which is also important for rarely consumed foods. Further, some TDS approaches face additional problems due to pooled samples. The analytical sensitivity has to be much higher for TDS otherwise it will result in many samples below the limit of detection that contribute to uncertainties in the exposure assessment. In case samples are not just composited within one food category, but also pooled with different food items, information regarding the contribution of several food items to the overall exposure will be lacking.

To discuss risk management measures, it is often necessary to calculate the contribution of single food items to overall exposure. Besides the above-mentioned problem of compositing, another difference of both approaches is that the calculation of the contribution of food items will be provided on different levels of disaggregation. For TDS, the information can be given on foods as consumed, which overcomes the need for processing factors. The German food monitoring approach is flexible regarding food categories and will be able to provide information on the level of food categories for several legislative scenarios, which is of most interest to risk management. That is also true for TDS given that the individual food approach is used in TDS where each food item is analyzed separately. Additionally there might be an advantage of the food monitoring approach in cases where costs can be shared with other food surveillance programs.

Considering the diversity of purposes of risk assessments and the high number of relevant contaminants as well as being aware of the advantages and disadvantages of both concepts, it can be concluded that both approaches should ideally complement each other. For some evaluations, like assessment of exposure of heavy metals, both approaches are adequate for exposure assessment. If the food monitoring approach identifies potential concerns, such as cadmium in cereals, then further refinement may be necessary, such as a targeted TDS approach, where foods are analyzed after being prepared ready for consumption, which will better assess the potential risk to the consumer.

Acknowledgements We want to thank the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), for initiating and financing the LExUKon project. Special thanks go to our colleagues Klaus Schneider and Markus Schwarz (Research and Advisory Institute for Hazardous Substances, FoBiG) as well as Werner Wosniok and Marion Wirschins (Institute for Statistics, University of Bremen) for the pleasant and successful cooperation in the LExUKon project.

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