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Collection of occurrence data in foods – The value of the BfR MEAL study in addition to the national monitoring for dietary exposure assessment

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ABSTRACT

Two different data sets of occurrence data are available in Germany at present: the German National Food Monitoring and the BfR MEAL Study. To determine the suitability of each data set for exposure assessment and to develop concepts for a target-oriented selection and application of data, possibilities, limitations and scope of substance as well as food selection is quantitatively compared. The National Monitoring data provides comprehensive information on the variability of substance levels. This enables short- and long-term exposure assessment and consumer-loyal scenarios. The BfR MEAL Study supplements the monitoring data set with > 100 substances or by complementing the food spectrum for substances already included in the National Monitoring. The study design benefits especially the long-term dietary exposure assessment for the German population including the total diet. Using both programmes enables case-dependent selection of the appropriate dataset and in combination both sets can contribute to enhanced consumer safety.

Introduction

Risk assessment is a scientific process consisting of hazard identification, hazard characterization, exposure assessment and risk characterisation (Food and Agriculture Organization of the United Nations & World Health Organization, 2019). Within this framework, the exposure assessment is an essential step, providing realistic estimations for the intake of a substance of interest. It incorporates the selection of appropriate data sources for consumption and substance concentrations in food and the method of combining the two data sets (Food and Agriculture Organization of the United Nations & World Health Organization, 2009).

In Germany, the German Federal Institute for Risk Assessment (BfR) is in charge of estimating the exposure to substances in foods and assessing the health-related risks in order to advise political circles and the general public (Herges, Kaus, Böl & Gollnick, 2017). In terms of occurrence data, Germany can rely on a comprehensive national food monitoring programme (referred to as 'National Monitoring' (Harms & Wend, 2016)). Since 1995, the National Monitoring systematically determines the occurrence of selected substances in foods. It is coordinated by the German Federal Office of Consumer Protection and Food Safety (BVL) and executed by the Federal States of Germany (Harms and Wend, 2016). The aim is to generate non-risk-oriented data to monitor the compliance with existing regulations for maximum limits and for dietary exposure assessments. In an annual plan, the selected food/substance combinations are specified from a representative food basket. About 50 foodstuffs are analysed per year (monitoring period 2016–2020) (Federal Office of Consumer Protection and Food Safety, 2016, 2017a, 2018a, 2019, 2020). The measurements include several undesirable substances such as residues of plant protection and biocide products, pharmacologically active substances, mycotoxins, elements, nitrate and nitrite or organic contaminants. Since 2003, particular projects extend the National Monitoring, addressing specific questions related to food contamination. The National Monitoring in Germany is one of the most comprehensive ones in Europe. For example, 44, 66 and 72% of the occurrence data for lead, nickel and methyl mercury, respectively, that was used to generate EFSA opinions, originated from the German National Monitoring (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2010, 2012, 2020).

Since 2016 the BfR is running Germany's first full-scale total diet study (TDS), the BfR MEAL Study ('meals for exposure assessment and analysis of foods') (Sarvan, Bürgelt, Lindtner, & Greiner, 2017). The

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overall aim of a TDS is to provide an extensive dataset of the background contamination in order to assess the long-term dietary exposure of the related population. Basic principles of a TDS are the coverage of at least 90% of the diet of the population of interest, preparation of foods ‘as consumed’ and the homogenisation of similar foods (‘pooling’) to composite samples prior to analysis (European Food Safety Authority, Food and Agriculture Organization of the United Nations & World Health Organization, 2011). Accordingly, the core food list of the BfR MEAL Study consists of 356 foods covering > 90% of the diet of the people living in Germany. More than 300 potentially beneficial or harmful substances are investigated from different substance groups covered in nine study modules. These are elements and environmental contaminants, perfluoroalkyl substances, mycotoxins, process contaminants, food additives, pesticide residues, pharmacologically active substances, substances migrating from food contact materials, as well as nutrients (Stehfest, Sarvan, Lindtner & Greiner, 2019). Foods are stratified regarding different regions, seasons or different types of production (organic or conventional), prepared in the BfR MEAL kitchen under consideration of typical consumer behaviour and analysed in contract laboratories as well as in-house after pooling (Sarvan et al., 2017).

The field phase of the BfR MEAL Study was completed in the second half of 2021. The datasets are subject of an extensive internal quality control and will be released successively afterwards. First results have been published for iodine (German Federal Institute for Risk Assessment (BfR), 2021), cadmium and lead (Ptok et al., 2020), methylmercury (Sarvan, Kolbaum, Pabel, Buhrke, Greiner & Lindtner, 2021) and arsenic (Hackethal, Kopp, Sarvan, Schwerdtle & Lindtner, 2021). With both programmes, the food monitoring and the TDS, risk assessment in Germany has the advantage of having two comprehensive data sources available. This circumstance requires concepts for a target-oriented selection and application of the acquired data. In general, food monitoring programmes and TDSs differ in their design and extend, and the collected data will meet different requirements for exposure assessment and risk management. The combination of both data sources will therefore enhance consumer safety in Germany. This article describes the conceptual differences between the two programmes in Germany from the exposure assessment point of view, elaborates the complementarity of the approaches and will introduce a decision scheme on how both approaches will be integrated in future risk assessment in Germany.

Material and methods

As a first step, an overview was created showing the number of foods and samples analysed per substance for the National Monitoring and in the BfR MEAL Study (Table S1, Supplementary Material). For the compilation of this overview, the raw datasets from the monitoring years 2011 and 2019 were used. Data from 2011 to 2019 were chosen to cover at least one full monitoring cycle (2011–2015) (data from 2016 to 2020 were not complete at the time of the present study). Since the datasets also included cosmetic products and commodities, substances relevant for foods only were extracted using information from the volumes of tables of the annual monitoring reports (Federal Office of Consumer Protection and Food Safety, 2021b). Data from the BfR MEAL Study were retrieved from the BfR MEAL Study Center and cover the field phase from November 2016 to June 2021. Plant protection and biocide residues were excluded in order to generate a dataset of manageable size.

Since the objective of this data compilation is to compare the two programmes regarding their coverage of different substances and of foods in the diet, a categorisation system was developed. For this purpose, the list of substances from the National Monitoring was taken (Table S1, Supplementary Material) and sorted according to number of foods in which they were measured. This resulted in a visual differentiation of three categories of data availability (Figure S2, Supplementary Material).. Category A: substances with high data availability (n foods: ≥ 100); category B: substances with medium data availability (n foods: 25–100); and category C: substances with low data availability (n foods: < 25). The categorization is for exploratory purpose only and serves as basis to select example substances from each category for further comparison of the two programmes. The chosen examples from each category are cadmium (category A), the dioxin-like polychlorinated biphenyl PCB 126 (category B) and iodine (category C).

For the conceptual comparison of both data sources the report *"Report including a Decision tree: for combining data from TDS and Food Monitoring programs in risk management"* from the TDS-Exposure project (German Federal Institute for Risk Assessment (BfR), 2016) was used as a starting point. The report points out the main differences between the TDS and the monitoring design, describes their use in terms of risk assessment from a literature review, and introduces a general framework for a food safety approach combining both programmes. The present study extends this generic comparison by considering the specific situation of the National Monitoring and the BfR MEAL Study in Germany. Criteria for the comparison as reported in the TDS-Exposure project were *purpose, sampling food preparation, samples preparation, variability and analysis/sensitivity* (German Federal Institute for Risk Assessment (BfR), 2016). Table 1 is the basis for the following comparison between the National Monitoring and the BfR MEAL Study. If applicable, the findings will be illustrated, based on the three abovementioned substance examples from the National Monitoring and the BfR MEAL Study.

The significance for exposure assessment is elaborated in the discussion and the potential interaction of both programmes for future assessment activities is introduced in the outlook.

Data evaluations were done with R 4.0.3 and MS Excel 2016.

Results

The National Monitoring and the BfR MEAL Study differ markedly in terms of foods analysed per substance as summarised in Fig. 1 (see Table S1 in the Supplementary Material for more details). Fig. 1a illustrates the distribution of substances over the defined categories within the two datasets. In the National Monitoring, 318 (79%) of the substances were analysed in <25 foods (category C), 72 (18%) of the substances were analysed in 25–100 foods (category B) and the remaining twelve substances (3%) were analysed in >100 different foods (category A). In contrast, in the BfR MEAL Study 35 (11%) substances are allocated to category C, 58 (18%) are allocated to category B and the majority of 223 (71%) substances are allocated to category A. For most substances, the data of the BfR MEAL Study thus features a much higher coverage in terms of sampled food commodities. Fig. 1b directly compares the substances included in both datasets. 40% of the total 512 substances are covered by both data sources. Within this group, however, the majority is allocated to category C in the National Monitoring, while in the BfR MEAL Study the majority is allocated to category A. Substances only covered in the National Monitoring constitute 38% of all considered substances, of which the majority falls into category C and are covered in a limited number of foods (e.g. pyrrolizidine alkaloids). Substances that were measured exclusively in the BfR MEAL Study represent 22% of all substances considered. The majority of them is covered comprehensively over the whole diet and is allocated to category A.

Furthermore, Fig. 1 illustrates that >50% of the substances are analysed within only one of the programmes. Therefore, both programmes complement each other particularly due to the choice of substances. For the substances analysed in both programmes, the BfR MEAL Study complements the food spectrum for the majority of substances. Especially for the substances analysed in both programmes the characteristics of the two data sources need to be taken into account for further comparison. The characteristics that were compiled based on the findings from the TDS-Exposure project (German Federal Institute for Risk Assessment (BfR), 2016) are shown in Table 1 and are compared in the following sections.

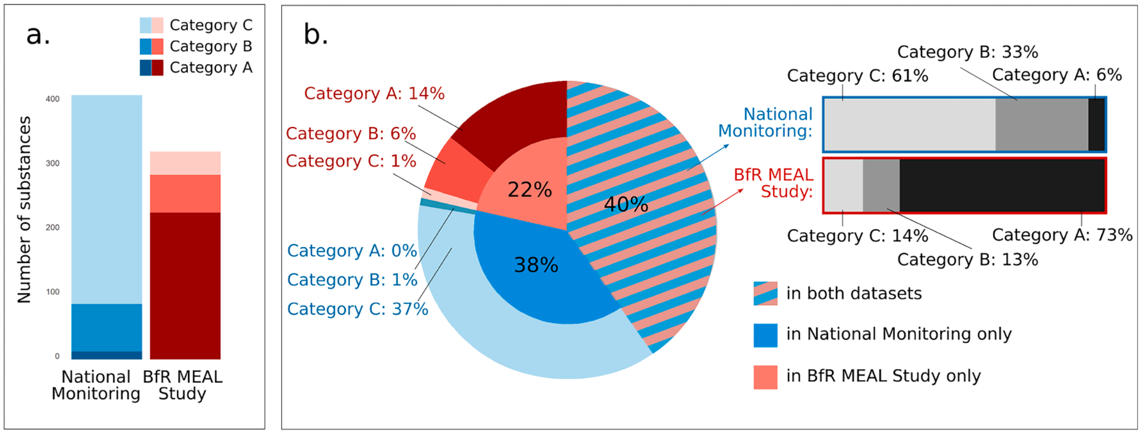

Fig. 1. Distribution of substances grouped by the number of foods analysed within the National Monitoring (2011–2019) and the BfR MEAL Study (2016–2021). (a) Total number of substances in the datasets allocated to categories A (n foods: > 100), B (n foods: 25–100) and C (n foods: < 25). (b) Portions of substances covered exclusively in one of both datasets or in both datasets and respective allocation to categories among the groups. Notation of percentages refer to the total number of 512 substances considered in the present study.

Table 1
Main differences between the BfR MEAL Study and the National Monitoring in Germany (modified from German Federal Institute for Risk Assessment (BfR), 2016).

	BfR MEAL Study	National Monitoring
Purpose	Description of representative background occurrences Realistic long-term exposure assessments	Monitor compliance with regulatory limits Provide data for risk assessment
Sample size and sample preparation	Analysis of food pools	Individual food analysis
Food stratification (differentiation in relevant characteristics)	Stratifications between regions, seasons and production type	No systematic stratifications
Choice of food/ substance combination	Selection based on consumption weights (covering > 90% of the diet) and substances relevant for risk assessment	Selection of mainly regulated foods/substance combinations oriented on a representative food basket
	Total sampling of the whole food list within ~ 2 years	Selection of predefined food/substance combinations per year. Total sampling of the whole food basket within 5 years.
Sampling strategy	Random sampling according to market shares	Random sampling according to availability (no specification on sampling strategy)
Food preparation	Foods are analysed „as consumed" ('from market to fork')	Foods analysed at RAC (raw agricultural commodity) or 'as purchased' level ('from farm to market')
Analytical sensitivity	Analytical sensitivity as good as technically possible	Analytical sensitivity according to official sampling provisions

Purpose

The National Monitoring was established to monitor the compliance with legal limits, follow long-term trends and to provide data for risk assessment (Harms and Wend, 2016). The BfR MEAL Study aims to describe the background occurrence over the entire diet and to provide data for exposure assessment with representative reflection of consumer behaviour (Sarvan et al., 2017). Both purposes result in a different study design leading to the differences described below.

Sample size and sample preparation

To monitor the exceedance of regulatory limits in the food supply the National Monitoring analyses single food items. The typical target sample size is 47 to 188, depending on the expected variability of the substance concentration (Sieke, Lindtner, & Banasiak 2008a; Sieke, Lindtner & Banasiak, 2008b). Selected foods can be specific foods, such as orange juice, or more aggregated foods such as several types of tea (Federal Office of Consumer Protection and Food Safety, 2015). In latter cases, smaller sample sizes per specific food (e.g. black tea) are available. In contrast, the BfR MEAL Study analyses pooled food samples instead of single food items. That results in analytical data representing an average concentration, instead of individual data (European Food Safety Authority, Food and Agriculture Organization of the United Nations & World Health Organization, 2011; Sarvan et al., 2017). According to Sirot et al. (2009) a samples size of 15 subsamples[1] per pooled food results in an acceptable confidence interval between 15 and 25% for the mean value. According to the basic BfR MEAL Study structure, an unstratified food contains 20 subsamples and a stratified food contains up to 150 subsamples (e.g. when a food is sampled in different regions, seasons and for different production types), in order to cover the variability within the foods. In line with the basic TDS principles, purchased subsamples are thoroughly homogenised and pooled prior to analysis. This ensures valid estimates of mean substance concentrations analysed in pools, thus allowing the BfR MEAL Study to screen the selected food list for >300 substances in an efficient manner (Sarvan et al., 2017).

Food stratification

The National Monitoring foresees the reporting of additional information for some foods, e.g., production type for eggs or meat (Federal Office of Consumer Protection and Food Safety, 2017b, 2018b), but without specifying systematic sampling plans. Project monitorings can be set up on an annual basis, to also explore specific differentiations. For example, the analysis of copper in organically produced apples and potatoes in a project from 2007 (Federal Office of Consumer Protection and Food Safety, 2007). Such stratifications, however, are not included systematically in the monitoring programme. In the BfR MEAL Study, the food list for the core module, which considers environmental

[1] Subsamples are the individual foods included in a pooled sample

contaminants and elements, consists of 356 foods (Sarvan et al., 2021). These were screened for the expected variability regarding region, season or production type (Sarvan et al., 2017), resulting in 153 foods with further analysis regarding the regions north, south, east, west, differentiation between import or national season and/or differentiation between organic and conventional production. Due to the modular design of the BfR MEAL Study (Stehfest et al., 2019) the food list and stratifications are adapted for each module considering the specific conditions of each substance group. Therefore, additional stratifications regarding the degree of browning, the preparation methods, the used food contact materials and applicable regulations will also allow distinct evaluations of process contaminants, substances migrating from food contact materials and food additives.

Choice of food/substance combinations

The choice of foods for the National Monitoring is also based on a representative food basket derived from national consumption surveys (Harms and Wend, 2016). The number and selection of foods per five-year monitoring cycle is laid down in the General Administrative Provision on the performance of monitoring for foodstuffs, cosmetic products and commodities. In 2016–2020 the analysis of 178 foods was required (AVV Monitoring 2016-2020). The selected food/substance combination is case dependent and is down to expected contamination, regulatory demands and resources.

For the BfR MEAL Study, data from the National Consumption Survey II (NVS II) and the VELS Study were analysed to establish the food list (Sarvan et al., 2021). Based on the mean long-term consumption, foods covering at least 90% of the diet were selected. The remaining foods were further screened for potential contribution to exposure due to high concentrations regarding the selected substances (Sarvan et al., 2017). In total, 356 foods (approx. 900 pools) were included in the core food list (Sarvan et al., 2021). When regarded as appropriate the BfR MEAL Study also applies substance-specific food lists to save resources (e.g. for pharmacologically active substances or food additives). In those cases, the number of foods deviates from the food list of the core module.

The rationale of the BfR MEAL Study design aims at filling existing data gaps and reducing uncertainties for exposure assessment in the most cost efficient way. By that, measuring the whole foodlist of about 150 substances was realised in a 2.5 year period (field phase 1, November 2016 - May 2019) . The analysis of another 150 substances was finalised in the second field phase between June 2019 and June 2021.

The differences in the food/substance selection strategies of the National Monitoring as well as the BfR MEAL Study are illustrated in Table 2 by comparing the number of analysed foods and samples for the selected examples cadmium, PCB 126 and iodine. Fig. 2 additionally illustrates the numbers of foods analysed for all substances measured in both programmes.

Cadmium is regulated in a broad food range covering various plant and animal products (COMMISSION REGULATION (EC) No 1881/

Table 2
Amount of foods and samples per main food group for cadmium, the dioxine-like polychlorinated biphenyl PCB 126 and iodine. Comparison between the BfR MEAL Study (2016 – 2021) and the National Monitoring (2011 – 2019). [a] Total number of subsamples is given. Number of food pools is given in parenthesis. Note that the number of pools indicates the number of measurements, the number of subsamples comprises all individual food samples contained in the pooled samples.

		Cadmium				PCB 126				Iodine			
		BfR MEAL Study		National Monitoring		BfR MEAL Study		National Monitoring		BfR MEAL Study		National Monitoring	
No.	Main Food Group	N foods	n samples[a]	N foods	n samples	N foods	n samples[a]	n foods	n samples	N foods	n samples[a]	n foods	n samples
1	Grains and grain-based products	40	1540 (97)	14	1934	38	1490 (94)	0	0	40	1540 (97)	0	0
2	Vegetables and vegetable products	34	2306 (152)	42	4077	18	911 (60)	1	50	34	2306 (152)	2	161
3	Starchy roots or tubers and products thereof, sugar plants	8	410 (26)	1	122	7	245 (15)	0	0	8	410 (26)	0	0
4	Legumes, nuts, oilseeds and spices	20	440 (24)	22	2544	20	440 (24)	8	185	20	440 (24)	0	0
5	Fruit and fruit products	22	1010 (64)	18	1609	8	175 (10)	0	0	22	1010 (64)	0	0
6	Meat and meat products	35	1578 (101)	24	2673	35	1578 (101)	18	1458	35	1578 (101)	0	0
7	Fish, seafood, amphibians, reptiles and invertebrates	30	720 (39)	16	1832	30	720 (39)	7	454	30	720 (39)	0	0
8	Milk and dairy products	23	635 (37)	12	1282	23	635 (37)	1	129	23	640 (37)	3	301
9	Eggs and egg products	2	150 (10)	1	102	2	150 (10)	2	182	2	150 (10)	0	0
10	Sugar, confectionery and water-based sweet desserts	15	330 (18)	1	127	10	220 (12)	0	0	15	330 (18)	0	0
11	Animal and vegetable fats and oils	8	210 (13)	6	538	8	210 (13)	5	249	8	210 (13)	0	0
12	Fruit and vegetable juices and nectars	10	220 (12)	6	732	0	0 (0)	0	0	10	220 (12)	0	0
13	Water and water-based beverages	6	173 (41)	2	247	0	0 (0)	0	0	6	173 (41)	0	0
14	Coffee, cocoa, tea and infusions	9	210 (12)	5	458	7	160 (9)	0	0	9	210 (12)	0	0
15	Alcoholic beverages	8	190 (11)	3	318	8	190 (11)	0	0	8	190 (11)	0	0
16	Food products for young population	11	260 (15)	5	159	11	260 (15)	4	340	11	260 (15)	0	0
17	Vegan/Vegetarian products	7	150 (8)	3	348	7	150 (8)	0	0	7	150 (8)	0	0
18	Composite dishes	52	2670 (170)	0	0	52	2670 (170)	0	0	52	2670 (170)	0	0
19	Seasoning, sauces and condiments	16	350 (19)	2	149	16	350 (19)	0	0	16	350 (19)	0	0
	Sum	*356*	*13,552 (869)*	*183*	*19,251*	*300*	*10,554 (647)*	*46*	*3182*	*356*	*13,557 (869)*	*5*	*462*

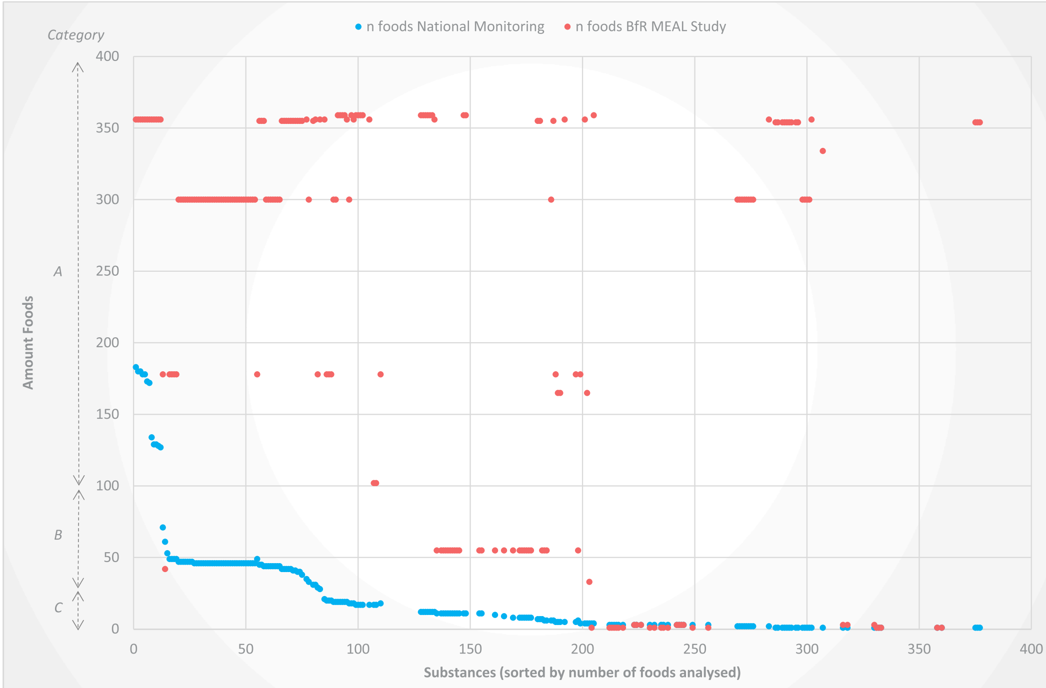

Fig. 2. Categorisation of substances analysed in the National Monitoring (2011–2019) as well as in the BfR MEAL Study (2016–2021) according to the number of foods analysed. Category A: n foods > 100, category B: n foods 25 – 100, category C: n foods < 25.

2006). The sampling in the National Monitoring is extensive with 19,251 measurements in 183 different foods including most of the main food groups. The extensive sampling of cadmium also applies for the BfR MEAL Study where cadmium was measured in 356 foods with 13,552 subsamples (869 pooled samples). According to Fig. 1a this extensive sampling (n foods > 100; category A) applies to twelve substances in the National Monitoring in contrast to 223 substances in the BfR MEAL Study. Looking at the main food group level, in two ('vegetables and vegetable products' and 'legumes, nuts, oilseeds and spices') out of the 19 main food groups there are more foods analysed in the National Monitoring than in the BfR MEAL Study (n = 42 compared to n = 34 and n = 22 compared to n = 20, respectively) (Table 2). In all other food groups (17 out of 19), the BfR MEAL Study considers a higher number of different foods per food group. Regarding the sample size, the National Monitoring analysed more samples in 13 out of the 19 main food groups. However, for this comparison also the distribution of foods and samples within the food groups need to be considered. As an example, in the BfR MEAL Study, 20 out of 35 foods in the food group 'meat and meat products' contain processed meat products, such as sausages or cold cuts (570 samples), followed by plain cooked meat (six foods with 380 samples), offal (seven foods with 588 samples) and game meat (two foods with 40 samples). In the National Monitoring 10 out of 24 foods are plain raw meat, and the remaining 14 are game meat and offal (seven foods each). Respectively, >50% of the 2,673 measurements in the National Monitoring come from game meat and offal. No processed products are included.

With 46 foods and 3,182 samples PCB 126 was chosen as an example for a medium comprehensive dataset from the National Monitoring (n foods 25–100, category B). PCB 126 is regulated in animal products, fats/oils and infant foods (COMMISSION REGULATION (EC) No 1881/2006). Therefore, in the National Monitoring foods were measured exclusively in the related food groups (with exception of a project monitoring of PCBs in herbs and spices in the food group 'legumes, nuts, oilseeds and spices', and the analysis of algae in the food group 'vegetables and vegetable products'; Table 2). In comparison, PCB 126 is extensively analysed in 300 foods (10,554 subsamples, 647 pooled samples) in the BfR MEAL Study. Samples are distributed over 17 out of 19 food groups. However, even in the main food groups where PCB126 is analysed in both programmes, more food items were included in the BfR MEAL Study compared to the National Monitoring. 72 substances from the National Monitoring can be assigned to the medium extensive sampling (n foods: 25–100; category B) (Fig. 1a). Of these, 67 were also analysed in the BfR MEAL Study, but with 178–359 food items (category A). Four of them were not included in the BfR MEAL Study and one (inorganic arsenic) was sampled in more foods in the National Monitoring (n = 61) compared to the BfR MEAL Study (n = 42) (Fig. 2, Table S1).

With five foods and 462 samples, iodine represents an example for category C (n foods < 25) in the National Monitoring. Iodine as an essential trace element is not regulated in terms of maximum levels in foods and thus data in National Monitoring are scarce. However, limited data is available derived from targeted projects related to milk products and algae. In case of the BfR MEAL Study, iodine can be assigned to category A with 356 foods, 13,557 subsamples (869 pooled samples). The measurements from the BfR MEAL Study are evenly distributed over the food groups (Table 2). In total, 318 substances from the National Monitoring cover only a very limited number of food items and are allocated to category C (Fig. 1a, Table S1). Nearly 200 of them are also not included in the BfR MEAL Study (e.g. pyrrolizidine alkaloids). The remaining substances are analysed in both programmes. Of these, nearly 100 substances were comprehensively covered in the BfR MEAL Study (55 to 356 foods; category A and B) and about 30 are considered with equal or lower number of foods in the BfR MEAL Study (category C) (all of them pharmacologically active substances). In addition to the examples presented in Table 2, Supplemental Table S2 compares the distribution of foods and samples over the main food groups for all substances measured in both programmes.

Food sampling

The strength of the National Monitoring, in contrast to other risk-oriented surveillance programmes, is the random sampling, since this sampling strategy more realistically depicts substance occurrences in foods (Harms & Wend, 2016). However, the monitoring manuals do not provide further specification regarding the implementation of the sampling strategy, such as market shares, consumer behaviour or other selection strategies that would lead to a representative selection of the consumed foods (Federal Office of Consumer Protection and Food Safety, 2021a). This may lead to sampling bias, e.g. due to convenience sampling governed by availability or other considerations. In contrast, the BfR MEAL Study uses a designed sampling strategy detailed with regard to all relevant stratifications and replacement rules in cases of non-availability of food items. In order to reflect the consumer's behaviour along all process steps, the sampling plan further considers empirical data on typically visited retailers, purchased brands and varieties as well as out-of-home consumption in Germany (Stehfest et al., 2019).

Food preparation

With regard to elements, environmental contaminants, and mycotoxins, foods are mainly regulated as raw agricultural commodities (RAC) or 'as purchased' (COMMISSION REGULATION (EC) No 1881/2006; Kontaminanten-Verordnung vom 19. März 2010). In order to determine possible exceedance of maximum limits, the National Monitoring takes samples throughout the whole supply chain up to the retail level, but does not include further processing ('from farm to market'). Further preparation steps are only considered for exceptions, such as the analysis of elements in tea infusions (Federal Office of Consumer Protection and Food Safety, 2015). However, kitchen treatment may affect the concentrations, such as the formation of acrylamide by heating (Jackson & Al-Taher, 2005), the decrease of pesticide residues by peeling (Scholz et al., 2018), or the dilution of compounds by boiling (e.g. for rice) (Mwale, Rahman & Mondal, 2018). To account for these effects in exposure assessment, the application of processing or yield factors is necessary and introduces uncertainties in the exposure assessment. Some substances that are relevant from a risk assessment perspective will not occur at RAC level (such as food additives). Especially these foods need to be sampled after industrial or household processing. In contrast to the monitoring, the intention of the BfR MEAL Study is to capture the concentration from the foods 'as consumed'. Therefore, the design considers changes in substance concentrations during processing. Foods are exclusively sampled at the retail level, and in addition to the shopping behaviour the reflection of consumer behaviour entails consideration of different recipes, preparation methods, and kitchen utensils, as well as other consumer preferences such as the preferred degree of browning ('from market to fork') (Stehfest et al., 2019). As an example, cadmium was analysed in the National Monitoring for wheat and rye grains or flour (Federal Office of Consumer Protection and Food Safety, 2015, 2016) but not for bread or fine bakery wares. In the BfR MEAL Study neither grains nor flour is analysed as a pooled sample. Instead, cadmium was determined in a variety of prepared foods containing wheat or rye such as found in the pools wheat bread, whole meal bread, grey bread, rolls, cakes, cookies and pizzas (Hackethal et al., 2021; Ptok et al., 2020).

Analytical sensitivity

For monitoring programmes, the analytical sensitivity in terms of limit of detection (LOD) and limit of quantification (LOQ) needs to comply with the purpose of detecting exceedances of legal limits ('as good as needed'). According to TDS requirements the analytical methods should be sensitive enough to detect also low background concentrations and to overcome the dilution effect due to pooling ('as good as possible') (European Food Safety Authority, Food and Agriculture Organization of the United Nations & World Health Organization, 2011). Therefore, LOD and LOQ are often assumed to be lower in TDS compared to monitoring programmes (German Federal Institute for Risk Assessment (BfR), 2016; European Food Safety Authority, Food and Agriculture Organization of the United Nations & World Health Organization, 2011; Sarvan et al., 2017). To what extent this applies to the comparison between National Monitoring and the BfR MEAL Study is not completely verifiable. The analytical sensitivity cannot be compared directly for pooled or 'table ready' prepared samples with samples for single foods and unprocessed foods. This limits the relevance of a direct comparison because processing is an important design characteristic of TDS. Additionally, the BfR MEAL Study includes various complex matrices, which are not considered in the National Monitoring. Complex matrices often imply higher LOQs compared to unprocessed and routinely measured matrices. Nevertheless, a first insight in this comparison was generated by evaluating LOQs for the above-mentioned examples. Fig. 3 compares LOQs derived from the National Monitoring with applied LOQs in the BfR MEAL Study on main food group level and over all included samples. For cadmium and iodine, median LOQs used in the BfR MEAL Study are about 1.2- to 7-times and 3- to 17-times lower compared to those from the National Monitoring. For PCB 126, median LOQs are up to 6-times lower in the BfR MEAL Study, but roughly in the same order of magnitude within the pg/g range. The range of applied LOQs in the National Monitoring is wide, but the displayed minimum LOQs in the graph also show for the National Monitoring that the orientation on maximum limits does not always apply, and lower LOQs may be achieved. This comparison applies to the given examples and with the restrictions mentioned above. However, it gives a first indication that the BfR MEAL Study can accomplish the TDS requirement of striving at an analytical sensitivity to trace also background concentration levels that maybe below the demanded LOQs in National Monitoring. It should be noted that not all measurements from the National Monitoring could be considered for this evaluation, since some entries for LOD or LOQ are missing, or the minimum required LOD/LOQ instead of the actual achieved are reported. Furthermore, LOQs from 2011 onwards are included in the evaluations and analytical methods may have been improved ever since. Data were no further selected, because also data from early years need to be used for actual risk assessments when no, or not enough current data are available.

Discussion

The comparison of the National Monitoring and the BfR MEAL Study revealed that both programmes have advantages and disadvantages. These can be summed up into four main aspects relevant for exposure assessment, which regularly introduce uncertainties in the evaluations. These are *variability, representativeness, food preparation* and *left-censored data*. These will be discussed in the following from an exposure point of view.

The National Monitoring provides information on the *variability* on substances in foods by single food analysis. Derived statistical parameters such as mean or 95th percentile allow the calculation of long-term exposure (chronic risks) and also scenarios requiring high concentration percentiles, such as consumer-loyalty scenarios or short-term (acute risks) exposure assessments (Food and Agriculture Organization of the United Nations World Health Organization, 2009). Given that TDSs only provide mean values, the BfR MEAL Study dataset can be used to estimate the long-term exposure based on mean concentrations for average and high consumers, but is not suitable for exposure scenarios assuming high concentration levels (e.g. P95). In addition, sources of contamination can be traced back more easily based on individual samples compared to pooled ones. Thus, the information about variability within individual samples is a clear advantage of the National Monitoring. However, in terms of variability regarding certain stratifications the BfR MEAL Study data describes differences in the mean concentration levels between season, region or type of production, which are not systematically included in the monitoring.

The laboratories participating in the National Monitoring are instructed to use random sampling and the sample size of 188 aims to cover the 97.5th percentile of the concentration values on the market with a 95% probability. Depending on the expected variability, sample

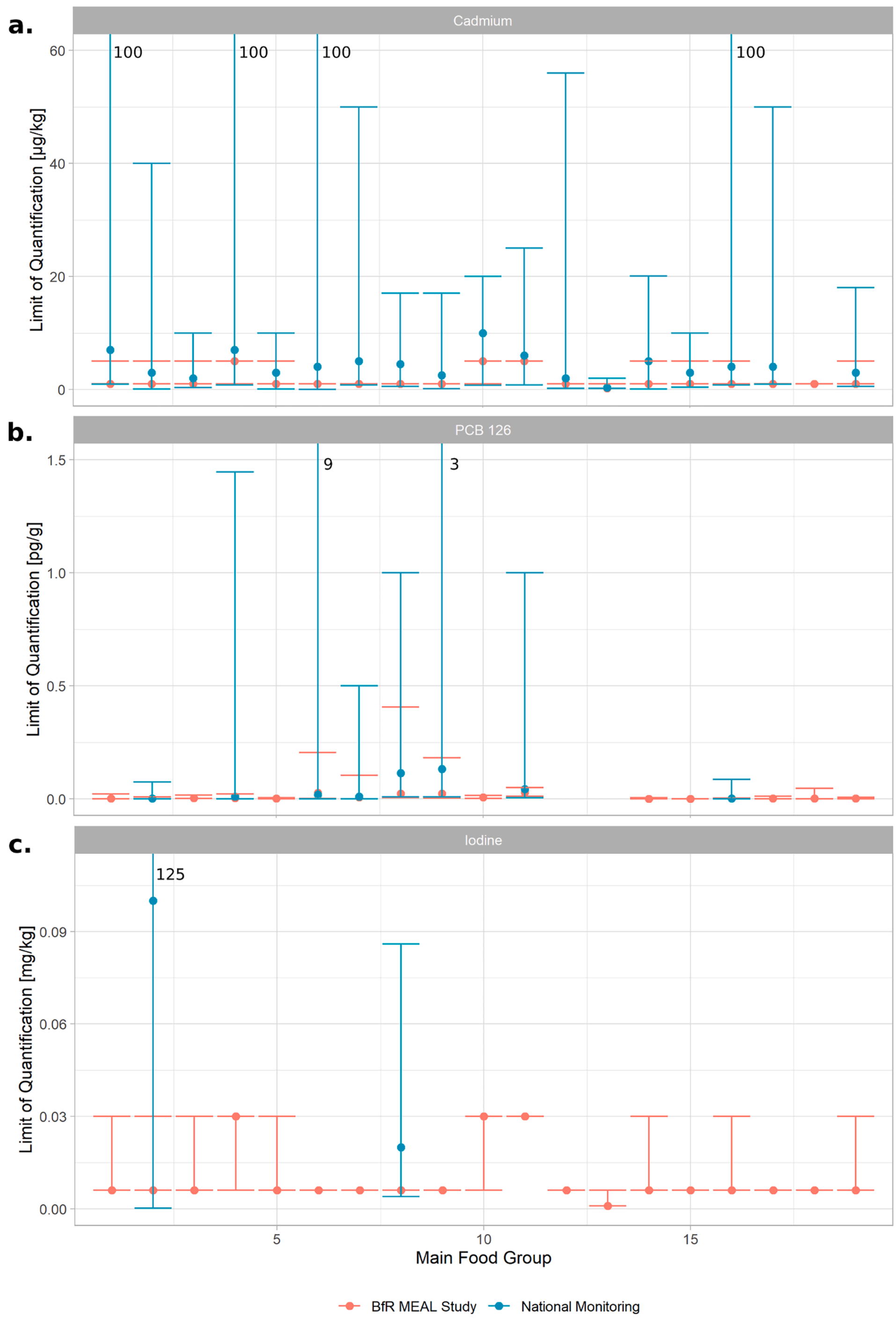

Fig. 3. Limits of quantification (LOQs) for (a) cadmium, (b) PCB 126 and (c) iodine reported for the measurements in the National Monitoring (2011–2019) and the BfR MEAL Study (2016 – 2021). Shown are the minimum and maximum LOQs distributed over main food groups. Dots indicate median LOQs.

sizes can be lower and are oriented on describing the mean concentrations with sufficient precision instead of high percentiles (Harms & Wend, 2016; Sieke et al., 2008a, 2008b). Since the approach of single food analyses is extensive, only a limited part of the food basket can be realised per monitoring year. Therefore, mainly regulated food/substance combinations are included in the monitoring and for none of the substances information on the entire food basket is available. Hence, the usage of data for a particular risk assessment needs to be evaluated according to availability and timeliness for each individual case. In terms of coverage of the total diet, the BfR MEAL Study shows clear advantages. The approach of pooling allows the analysis of a broader food list in a limited period. Additionally, the pools reflect the German food market considering market research data and additional surveys and are therefore *representative* for the purchased foods and applied consumer behaviours. Due to the consideration of the consumer behaviour in many aspects, the data are more realistic for representing real-life exposure. Therefore, the BfR MEAL Study is best suited for long-term dietary exposure assessments intended to cover the total dietary exposure. This is especially useful for risk characterisation because comparison with respective toxicological reference values can be based on overall dietary exposure. Due to the analysis of a whole food basket, the data can also identify the contribution from each measured food to the dietary exposure. This is especially important when discussing risk management measures for specific foods or food groups (e.g. for setting maximum limits) (Food and Agriculture Organization of the United Nations & World Health Organization, 2019). In addition, the BfR MEAL Study supplements the data from the National Monitoring with a large number of substances and foods for which no data are available so far, but which are urgently required in BfR's risk assessments.

For food/substance combinations for which data are available from both programmes, the BfR MEAL data reduce uncertainties that arise in the National Monitoring due to the focus on unprocessed foods. *Food preparation* can cause huge variations in occurrences due to many different processing methods, temperatures and durations (Jackson et al., 2005; Mwale et al., 2018; Scholz et al., 2018). Uncertainties arise from the necessity to apply processing factors when information from unprocessed foods are used to link results with dietary consumption (Kettler et al., 2015). The application of processing factors is not required for the BfR MEAL Study data. The variations during processing are already considered by preparing foods 'as consumed' for analysis. Furthermore, samples taken at RAC level are not suitable to monitor substances added during industrial processing. Chazelas et al. (2020) evaluated >120,000 packed products on the French market. 54% contained food additives and >10% even contained mixtures of more than five different food additives. Information on those substances can be added from the BfR MEAL Study data, since samples are only taken at retail level. However, when the objective is to set or revise regulatory limits, unpooled data at the RAC level are more relevant. In those cases, the National Monitoring data on RAC commodities is more appropriate.

If an analytical method is not sensitive enough, the analyte cannot be quantified or detected in the sample. The actual concentration will range between zero and the respective LOD or LOQ. High proportions of such *left-censored data* are therefore likely to introduce considerable uncertainties in exposure assessments, because assumptions need to be drawn for such non-detects (Kettler et al., 2015). Especially when upper bound exposure scenarios[2] result in a risk, the underlying overestimation needs to be refined to draw sound risk management conclusions. In the outlined cases above, the methods applied in the BfR MEAL Study indicate higher analytical sensitivity in the median of the different food groups compared to the National Monitoring. Additionally, the range of LOQs in the monitoring is very wide between the different laboratories. Therefore, the BfR MEAL Study data could be used for a refined assessment in cases where higher sensitivity is achieved.

Outlook

The sections above described the differences in the National Monitoring and the BfR MEAL Study and discussed their implications for dietary exposure assessment. Based on these findings, the following section will elaborate a scheme how these two data sources can complement each other for future risk assessments. This flowchart will therefore relate to a situation where the datasets are already available. A more generic scheme on involving TDS and food monitoring methodology in a combined food safety approach is provided in the TDS-Exposure report (German Federal Institute for Risk Assessment (BfR), 2016).

The conceptual approach for the decision process is outlined in a flowchart (Fig. 4). The kind of toxic effect of a substance (acute or chronic) guides the first decision, whether a short-term or a long-term exposure assessment is required. In case of acute toxicity the short-term exposure assessment needs to rely on results for single food items from the National Monitoring. In case a long-term exposure is of interest, it leads to the next question for how many foods the exposure should be estimated. The subsequent steps will check whether the relevant food/substance combinations are considered in only one or in both data sources to a similar extent. In the first case, i.e. that one substance is not analysed or only in a lower number of foods, the other data source will be used for exposure assessment. In the second case, i.e. if both data sources contain the food/substance combinations to the same extent, a case-dependent expert judgement is required. The criteria taken into account for such a decision are described in Table 1 and in the corresponding text. Because of the complexity of the data including specific features, scopes of application, overlapping and specific cases, this decision scheme is not appropriate to cover each potential risk assessment problem.

The combination of both approaches within one question can also be expedient. For example, if the BfR MEAL Study dataset is used for long-term total dietary exposure assessments based on mean concentrations for average and high consumption, the National Monitoring data can complement information to estimate the influence of consumer loyalty or give information on the source of the contamination at a lower production level (e.g. RAC). Also, in case of relevant and sufficient data being available in both data sources, a mathematical integration of results to improve the robustness of the estimates can be useful for individual food/substance combinations.

In addition, not only the question of the most suitable database should be discussed, but also how to combine both programmes in the future. The underlying considerations are based on a literature review carried out in the TDS-Exposure report, where the scientific literature was screened for the application of TDS and monitoring data and a flow chart for an optimal combination of both surveys was derived (German Federal Institute for Risk Assessment (BfR), 2016).

The flowchart from the TDS-Exposure report is mainly referring to the situation where neither a food monitoring nor a TDS is in place. However, some aspects can also be applied to the situation in Germany. In a combined food safety approach, the BfR MEAL Study data can advise the monitoring for efficient and cost-saving activities. The present data can already be used to evaluate new food/substance combinations potentially relevant for the regular National Monitoring programme, e.g. when high mean concentrations or high exposure estimates are determined. For instance, evaluations of nickel in nuts or elements in chia seeds have already been adopted for project monitoring based on high mean concentrations found in the BfR MEAL Study. In the future, due to its cost-effective design, the BfR MEAL Study setup can be used to investigate new or not yet considered substances in a large variety of foods to identify whether there is a need for surveillance activities or to study the variance in relevant food (groups) in the National Monitoring. Moreover, new emerging food trends (e.g. vegan products or pseudo-cereals) or dietary behaviour of specific sub-populations can be screened for a huge variety of substances. These findings can efficiently direct the food/substance selection to generate refined information from the National Monitoring regarding variability or to trace back the source of contamination to a lower supply chain level (e.g. single ingredients or to RAC level). In addition to the National Monitoring, a second food basket routinely integrated in the BfR MEAL Study could be of great benefit to monitor substances also in industrially and household prepared foods. This could be of special importance for food additives, processing contaminants or similar substances for which it does not make sense to analyse them in unprocessed foods. The cost-effective design of TDSs makes these type of studies especially appropriate and has already widely been used for trend analysis (German Federal Institute for Risk Assessment (BfR), 2016). The first field phase of the BfR MEAL Study was realised in about two years and analysed the whole diet for about 150 substances. If routinely performed – as full scale or for selected substances – the population exposure can be tracked and increasing as well as decreasing trends can be identified at an early stage. In addition, trends in concentration levels can be tracked in a comprehensive and cost effective manner and be used to advise the

[2] An upper bound scenario is a worst-case scenario where all non-detects are assigned to the value of the respective LOD or LOQ (Food and Agriculture Organization of the United Nations et. al., 2009)

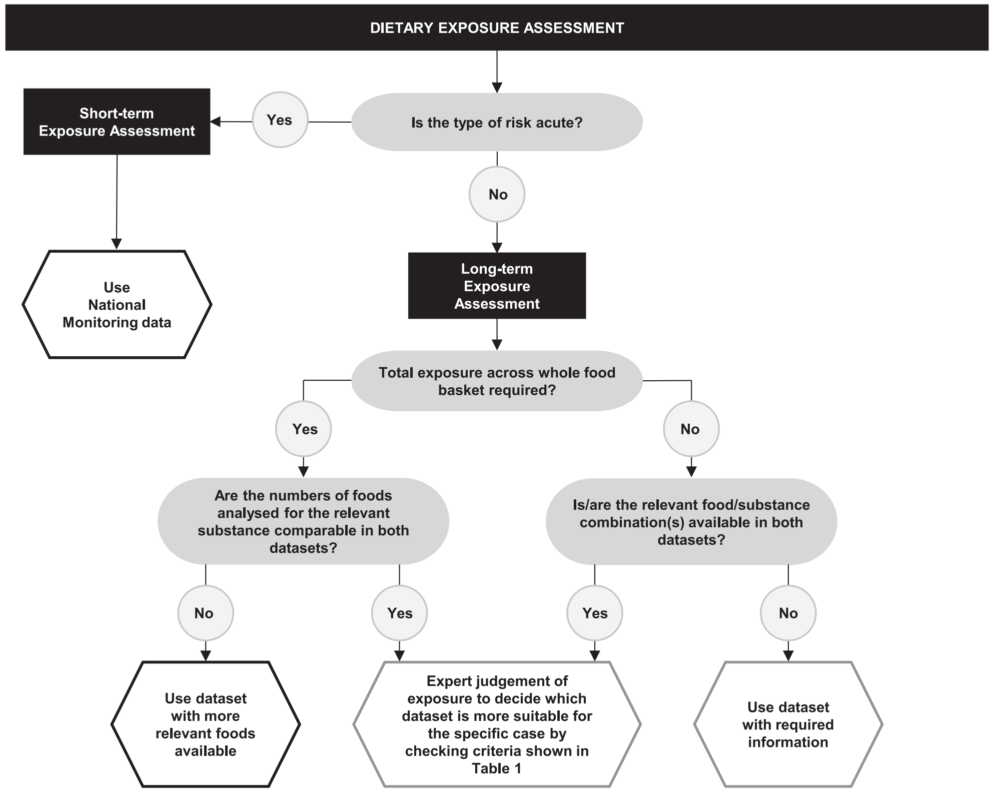

Fig. 4. Conceptual decision scheme on the choice between the application of BfR MEAL Study data or National Monitoring data in dietary exposure assessment.

monitoring to refine potential sources.

Vice versa, the National Monitoring data can advise future BfR MEAL Study activities. Information about high concentrations in low consumed foods can lead to inclusion into the food list, when this is of relevance for exposure. In addition, identified variability in the National Monitoring can advise the BfR MEAL Study design to further aggregate or differentiate pooled samples from the food list to direct an efficient orientation of the food list.

Conclusion

Using data from both programmes, the National Monitoring and the BfR MEAL Study, is a further step towards the recommendation from Codex Alimentarius, that 'quantitative information should be used to the greatest extent possible considering relevant production, storage and handling practices used throughout the food chain to achieve realistic exposure scenarios' (Food and Agriculture Organization of the United Nations & World Health Organization, 2019). The described characteristics clearly point out that both programmes have complementary features. First, the list of analysed substances is partly different and adapted to the design of each of the programmes. The comparison shows, that one of the main aims of the BfR MEAL Study could be reached by providing comprehensive additional data for substances and foods not analysed in the National Monitoring programme. Further, with their different study design regarding variability, representativeness, food processing and in certain cases analytical sensitivity, the data from both programmes are appropriate for different kind of questions within an exposure assessment. Hence, the effective selection or combination of both data sets will best inform future risk assessments and contribute to a better consumer safety. Accordingly, committees and expert groups with delegates of the Laender and federal institutions are already in place and allow continuation of a coordinated planning of the National Monitoring and the BfR MEAL Study.

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CRediT authorship contribution statement

Anna Elena Kolbaum: Conceptualization, Data curation, Investigation, Visualization, Writing – original draft. **Anna Jaeger:** Software, Formal analysis, Investigation, Visualization, Data curation. **Sebastian Ptok:** Data curation, Writing – review & editing. **Irmela Sarvan:** Data curation, Writing – review & editing. **Matthias Greiner:** Conceptualization, Writing – review & editing. **Oliver Lindtner:** Supervision, Conceptualization, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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