Joint application of total diet studies and food monitoring in a common risk assessment framework - How the BfR MEAL Study improves food safety in Germany

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EIDESSTATTLICHE ERKLÄRUNG

(gemäß § 10 der Promotionsordnung der Fakultät für Naturwissenschaften der Universität Paderborn)

Hiermit erkläre ich, dass ich die eingereichte Dissertation zum Thema „Joint application of total diet studies and food monitoring in in a common risk assessment framework - How the BfR MEAL Study improves food safety in Germany" selbständig verfasst habe. Alle genutzten Quellen und Hilfsmittel wurden in Zitaten angegeben. Ich habe gleichzeitig an keiner anderen Stelle eine Eröffnung des Promotionsverfahrens beantragt. Die vorliegende Dissertation wurde von keinem anderen Fachbereich bzw. keiner anderen Fakultät zurückgewiesen.

Paderborn, den 29.02.2024
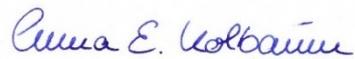
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LIST OF PUBLICATIONS & PRESENTATIONS

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Kolbaum AE, Jung C, Jaeger A, Libuda L, Lindtner O (2023a). Assessment of long-term dietary cadmium exposure in children in Germany: Does consideration of data from total diet studies reduce uncertainties from food monitoring programmes? Food Chem Toxicol, 184: 114404. https://doi.org/10.1016/j.fct.2023.114404

Kolbaum AE, Ptok S, Jung C, Libuda L, Lindtner O (2023b). Reusability of Germany s total diet study food list upon availability of new food consumption data-comparison of three update strategies. J Expo Sci Environ Epidemiol. https://doi.org/10.1038/s41370-023-00522-4

ORAL PRESENTATIONS

Kolbaum AE, Jaeger A, Lindtner O. 2021. Total Diet Study in Germany – The value of the BfR MEAL Study for food safety in Germany. 6th Asian-Pacific Symposium on Food Safety. The Korean Society of Food Hygiene and Safety. (Online presentation, 2021-11-11) [invited presentation, no conference proceedings available]

Kolbaum AE, Ptok S, Jung C, Libuda L, Lindtner O. 2023. Wie hat sich der Lebens-mittelverzehr seit 2002 verändert? — Erste Einblicke. [How has food consumption changed since 2002 – First insights]. Mini Symposium – KiESEL study. 60. Congress of the German Nutrition Society (DGE) (Presentation, 2023-03-19). Bonn, DE.

Kolbaum AE, Lindtner O. 2023. Enhancing Food Safety in Germany – The Interaction of Food Monitoring of the Federal States with the National Total Diet Study. International Society of Exposure Science (ISES) 2023 Annual Meeting (Presentation 2023-08-30). Chicago, Illinois, USA.

Kolbaum AE, Jung C, Jaeger A, Libuda L, Lindtner O. 2024. Bewertung der langfristigen ernährungsbedingten Cadmiumexposition von Kindern in Deutschland: Reduziert die Verwendung von Daten aus Total-Diet-Studien die Unsicherheiten von Lebensmittelüberwachungsprogrammen? [Assessment of long-term dietary cadmium exposure in children in Germany: Does consideration of data from total diet studies reduce uncertainties from food monitoring programmes?]. 61. Congress of the German Nutrition Society (DGE) (accepted for presentation, 2024-03-04). Kassel, DE.

SUMMARY

Food safety is critical to public health and economic stability. A key component of food risk assessment is exposure assessment, which is a function of food consumption and the presence of undesirable substances. Thus, for the reliability of exposure estimation and subsequent risk assessment it is of crucial importance that the data are fit for purpose.

In terms of data on substances in food, Germany has maintained since 1995 an established food monitoring system ("National Monitoring"), which has been complemented since 2021 by data from the first German Total Diet Study (TDS) (BfR-MEAL Study). Both datasets contribute to risk assessment, but follow different approaches. However, systematic strategies for their joint use in a food safety system are lacking.

This study aims to fill this gap. The first step was a comprehensive review of the establishment of the National Monitoring and the BfR MEAL Study in Germany to identify similarities and differences. The second study evaluated the quality of both programmes in terms of long-term dietary exposure assessment. The third study examined the suitability of the BfR MEAL Study for long-term update strategies of data on substances in food.

The first study used available data from both programmes and compared the number of foods investigated per substance. Information from the literature was used to methodically compare the two programmes according to a predefined scheme. The second study took cadmium, one of the most examined substances in the National Monitoring, as an example substance to estimate the long-term dietary cadmium exposure of children in Germany using both the National Monitoring and the BfR MEAL Study datasets. The quality of the results was rated using a systematic uncertainty analysis. The third study compares three strategies for updating the food list of the BfR MEAL Study using newly available consumption data for children and adolescents from the KiESEL and the EsKiMo II study. Coverage of food consumption and the number and type of foods needed to update the list were determined.

As a result, the BfR MEAL Study complemented the National Monitoring with information on more than 100 additional substances. For the substances investigated in both programmes, the BfR MEAL Study extended the range of foods investigated and

reduces the uncertainty with regard to changes in the content of substances in processed and prepared foods. In principle, the National Monitoring is best suitable for checking maximum levels and scenarios requiring information on variability (e.g., for acute risks). The strength of the BfR MEAL Study lies in the representativeness of the sampling, the coverage of consumption and analysing foods as consumed with low limits of reporting, and it is particularly suitable for long-term exposure assessments (chronic risks) and estimating the total dietary exposure. The second study confirmed these findings and identified significantly lower uncertainties in long-term cadmium exposure estimates using BfR MEAL Study data compared to National Monitoring data. The higher uncertainties using the National Monitoring data resulted in approximately three times higher intakes, as insufficient consumption coverage and lack of consideration of market shares had to be compensated by conservative assumptions. With regard to updating strategies, the BfR MEAL Study proved to be a suitable framework to keep the data on contents of substances in food up to date in the long-term. The criterion of covering more than 90 % of consumption was already met with the existing food list. Gaps at the level of sub-groups (main food groups, age groups) could be addressed efficiently and resourcefully on this basis.

The results highlight clear differences in the approach of the two programmes and demonstrate that the datasets complement each other in terms of scope, applicability and methodology for exposure estimation. The BfR MEAL Study covers exposure-relevant aspects that were inadequately covered by the National Monitoring so far and thus serves as a crucial component for food safety in Germany. In addition to the use of both datasets, the results suggest a future collaborative approach taking into account the advantages and challenges of each programme.

ZUSAMMENFASSUNG

Die Lebensmittelsicherheit ist für die öffentliche Gesundheit und die wirtschaftliche Stabilität von entscheidender Bedeutung. Ein Schlüsselelement bei der Risikobewertung von Lebensmitteln ist die Expositionsabschätzung, welche eine Funktion aus Lebensmittelverzehr und Gehalt an unerwünschten Stoffen ist. Die Qualität der Daten ist dabei entscheidend für die Aussagekraft der Expositionsabschätzung und der daraus resultierenden Risikobewertung.

Hinsichtlich der Gehaltsdaten verfügt Deutschland seit 1995 über ein etabliertes Lebensmittelmonitoring („Warenkorbmonitoring"), das seit 2021 durch Daten aus der ersten deutschen Total Diet Study (TDS) (BfR-MEAL-Studie) ergänzt wird. Beide Datensätze unterstützen die Risikobewertung, verfolgen aber unterschiedliche methodische Herangehensweisen. Bislang fehlt es an systematischen Ansätzen für eine gemeinsame Nutzung beider Programme in einem Lebensmittelsicherheitssystem.

Diese Lücke soll durch die vorliegende Arbeit geschlossen werden. Dazu sollte in einem ersten Schritt die Etablierung des Warenkorbmonitorings und der BfR-MEAL-Studie in Deutschland im Detail untersucht und Gemeinsamkeiten und Unterschiede herausgearbeitet werden. Die zweite Studie evaluierte die Qualität der beiden Datenquellen im Hinblick auf die Schätzung der Langzeitexposition. Die dritte Studie untersuchte die Eignung der BfR-MEAL-Studie für langfristige Aktualisierungsstrategien von Gehaltsdaten.

Die erste Studie verwendete verfügbare Gehaltsdaten aus beiden Programmen und verglich die Anzahl der untersuchten Lebensmittel pro Substanz. Informationen aus der Literatur dienten dem methodischen Vergleich der beiden Programme nach einem vorab festgelegten Schema. Die zweite Studie wählte Cadmium als einen der am umfangreichsten untersuchten Stoffe im Warenkorbmonitoring als Beispielsubstanz. Die langfristige Cadmiumexposition für Kinder in Deutschland wurde jeweils mit dem Datensatz des Warenkorbmonitorings bzw. der BfR-MEAL-Studie durchgeführt und die Qualität der Ergebnisse anhand einer systematischen Unsicherheitsanalyse verglichen. Die Dritte Studie verglich drei Update-Strategien, nach denen die Lebensmittelliste der BfR-MEAL-Studie aktualisiert werden könnte. Dazu wurden neu verfügbare Verzehrsdaten für Kinder und Jugendliche aus der KiESEL- und der EsKiMo II-Studie

ausgewertet und die Verzehrsabdeckung sowie Anzahl und Art der notwendigen Lebensmittel zur Aktualisierung der Lebensmittelliste ermittelt.

Im Ergebnis ergänzt die BfR-MEAL-Studie das deutsche Warenkorbmonitoring um Informationen zu mehr als 100 weiteren Substanzen und für die in beiden Programmen untersuchten Substanzen ergänzt die BfR-MEAL-Studie das untersuchte Lebensmittelspektrum und reduziert Unsicherheit bezüglich der Gehaltsveränderungen in verarbeiteten und verzehrfertigen Lebensmitteln. Grundsätzlich eignet sich das Warenkorbmonitoring vor allem für die Überprüfung von Höchstgehalten und für Expositionsszenarien, die Informationen zur Variabilität erfordern (z.B. bei akuten Risiken). Die BfR-MEAL-Studie hingegen hat ihre Stärke in der Repräsentativität der Probenahme, der Verzehrsabdeckung und der Analyse von verzehrsfertigen Lebensmitteln unter Verwendung sensitiver analytischer Methoden und eignet sich somit vor allem für langfristige Expositionsschätzungen (chronische Risiken) und Schätzungen über die gesamte Ernährung. Die zweite Studie bestätigte diese Ergebnisse und ermittelte deutlich geringere Unsicherheiten bei der Schätzung der langfristigen Cadmiumaufnahme unter Verwendung der BfR-MEAL-Studiendaten im Vergleich zum Warenkorbmonitoring. Die größeren Unsicherheiten unter Verwendung der Daten des Warenkorbmonitorings führten zu einer ca. dreifach höheren Cadmiumexposition, da die unzureichende Verzehrsabdeckung und die fehlende Berücksichtigung von Marktanteilen durch konservative Annahmen kompensiert werden mussten. Auch hinsichtlich der Aktualisierungsstrategien erwies sich die BfR-MEAL-Studie als geeignete Grundlage, um Gehaltsdaten auch langfristig aktuell zu halten. Das Kriterium, den Verzehr zu über 90 % abzudecken, wurde bereits mit der bestehenden Lebensmittelliste erreicht. Lücken auf Subgruppenebene (Lebensmittelhauptgruppen, Altersgruppen) könnten auf dieser Basis schnell und ressourcenschonend geschlossen werden.

Die Ergebnisse zeigen deutliche Unterschiede in der Herangehensweise der beiden Datenerhebungsmethoden und dass sich die beiden Datensätze sowohl in Art und Umfang als auch in ihrer Anwendbarkeit für die Expositionsabschätzung ergänzen. Damit deckt die BfR-MEAL-Studie expositionsrelevante Aspekte ab, die im Rahmen des Warenkorbmonitorings bisher nur unzureichend abgebildet werden konnten und liefert damit einen wichtigen Baustein für die Lebensmittelsicherheit in Deutschland. Neben der Nutzung beider Datensätze legen die Ergebnisse eine zukünftige gezielte Abstimmung beider Programme unter Nutzung der jeweiligen Vor- und Nachteile nahe.

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ABBREVIATIONS

ARfD	Acute reference dose
BfR	German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung)
BMEL	Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft)
BVL	German Federal Office of Consumer Protection and Food Safety
bw	Body weight
dl-PCBs	dioxin-like polychlorinated biphenyls
DON	Deoxynivalenol
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
LOD	Limit of detection
LOQ	Limit of quantification
LOR	Limit of reporting
ML	Maximum Level
mLB	Modified lower bound
MRI	Max Rubner-Institute
N-EtPFOSA	N-Ethylperfluorooctanesulfonamide
P50	50th percentile
P95	95th percentile
PAs	Pyrrolizidine alkaloids
PCB	Polychlorinated biphenyls
PCDDs	Polychlorinated dibenzo-p-dioxins
PFAS	Perfluoroalkylated substances
PFOA	Perfluorooctanoic acid
RAC	Raw agricultural commodity
RKI	Robert Koch Institute
RQ	Research question
TDS	Total diet study
TES	Total export study
TRV	Toxicological reference value

TWI	Tolerable weekly intake
U.S.	United States
UB	Upper bound
UPB	Paderborn University
WHO	World Health Organization

1 INTRODUCTION

Foodborne diseases represent a global concern, affecting around 600 million people worldwide annually (WHO, 2022). These diseases arise from various factors, including bacteria, viruses, parasites, toxins and chemical contaminants present in the food supply. The impact goes beyond individual health, affecting public health infrastructure and the economy through increased healthcare costs and reduced productivity (WHO, 2022). Consequently, ensuring food safety is a fundamental requirement at both the individual and societal levels. To address these challenges, significant resources are allocated by research institutions and governments to comprehend and manage the risks associated with foodborne diseases (BMF, 2022; EC, 2023). To address this challenge the risk analysis framework is the internationally agreed, comprehensive and evidence-based approach (FAO/WHO, 1997; WHO/ILO/UNEP, 2009), which is a collaborative approach among government agencies, scientific institutions, industry stakeholders, consumers, and other interested parties to assess, manage and communicate food-borne risks. The central component is the risk analysis, which encompasses hazard identification, hazard characterization, exposure assessment and risk characterisation (WHO/ILO/UNEP, 2009). Dietary exposure assessment is of particular importance in this process (FAO/WHO, 2023). It allows for the quantification of the risk associated with various hazards in the diet, providing a basis for understanding the potential harm to human health (FAO/WHO, 2023; WHO/ILO/UNEP, 2009); it helps to prioritise hazards based on the extent and frequency of exposure, allowing resources to be focused on the most important risks (ANSES, 2016; Nougadère *et al.*, 2014); and it supports the setting of regulatory standards and guidelines by providing the information needed to establish safe levels of exposure (BfR, 2023a). The accuracy of the exposure assessment depends on the quality and fit of the data (BfR, 2022c; Kettler *et al.*, 2015). This underlines the importance of robust data on food consumption and substance levels in food for the credibility and relevance of the estimates.

In Germany, the Federal Institute for Risk Assessment (BfR) has the central responsibility for assessing the risks associated with food (BfR, 2021). For its assessments, the BfR relies on population-representative food consumption data, such as the German National Nutrition Survey II (NVS II) or the German Children's Nutrition Study (KiESEL) (Brombach *et al.*, 2006; Krems *et al.*, 2006; Nowak *et al.*, 2022a; Nowak *et al.*, 2022b). For occurrence data, the German food monitoring (referred to as 'National Monitoring')

was the only systematic data collection on undesirable substances in food for almost three decades (Harms & Wend, 2016). With the BfR MEAL Study, the BfR conducted an additional data collection on substances in food between 2016 and 2021 (Ptok *et al.*, 2023). The aim of this Total Diet Study (TDS) was to reduce uncertainties associated with the use of monitoring data for exposure estimation (Sarvan *et al.,* 2017). TDS is an internationally recommended approach to collect data on background levels in food and to provide a reliable data base for long-term dietary exposure assessment (EFSA/FAO/WHO, 2011). Sample collection and preparation differ from traditional monitoring programmes in that almost the entire diet is considered, foods are prepared in ways typical for consumers and finally analysed as composite samples (EFSA/FAO/WHO, 2011; Lindtner *et al.*, 2024; Sarvan *et al.,* 2017). In contrast, surveillance programmes are mainly aimed at checking compliance with regulatory limits and analyse foods as individual units, mostly as raw agricultural commodities (RAC) or as simple processed foods (EFSA/FAO/WHO, 2011; Lee *et al.*, 2015; Lindtner *et al.*, 2024; Xiaowei & Bing, 2018). Both TDS and food monitoring can be carried out in many different ways (BfR, 2016; Lindtner *et al.*, 2024; Moy & Vannoort, 2013), which may present both opportunities and challenges for exposure assessment. Therefore, a combination of both programmes could be beneficial for a food safety system.

Although the TDS approach for dietary exposure assessment has received a lot of attention in recent years (Lindtner *et al.*, 2024; Moy & Vannoort, 2013), no common approach has been documented to integrate this approach together with food monitoring in a common food safety system. Thus, this research makes an important contribution to the possibilities of risk assessment by investigating the joint application of the BfR MEAL Study and the National Monitoring in a common risk assessment framework.

2 THEORETICAL BACKGROUND

2.1 Food safety and the risk analysis framework

A comprehensive and evidence-based approach to protect consumers and mitigate food-related risks is the risk analysis. Risk analysis comprises a structured framework of assessing, managing and communicating potential risks associated with food consumption (Figure 1) (FAO/WHO, 1997; WHO/ILO/UNEP, 2009).
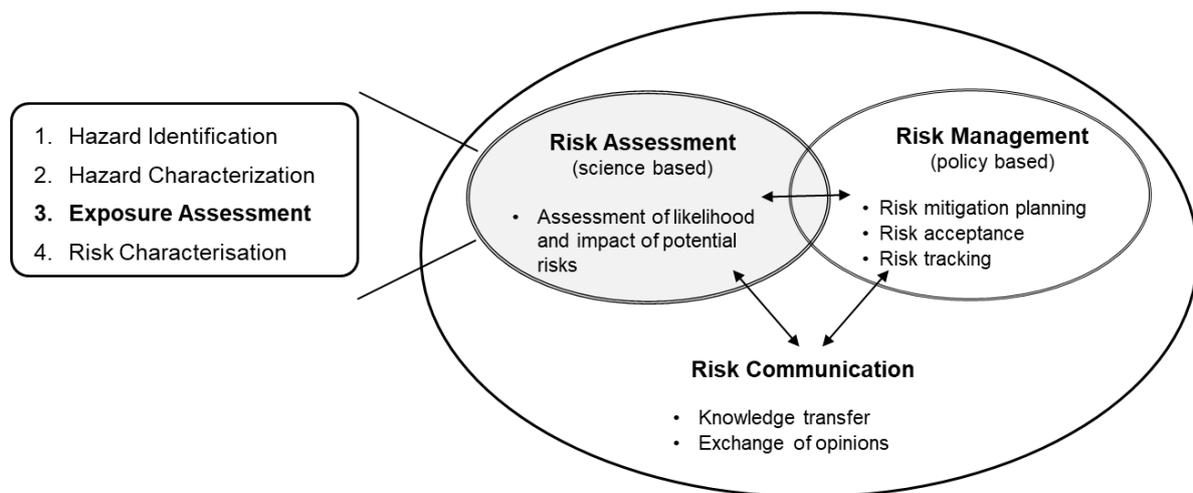
Figure 1: Risk Analysis Framework (modified from FAO/WHO, 1997).

Within this framework, risk assessment is recognised as a central component. It is a systematic process consisting of four key steps (WHO/ILO/UNEP, 2009):

(1) *Hazard identification*: Identification and description of potential hazards (e.g., microorganism, toxins or contaminants) in food or environment (for instance, cadmium has chronic toxic effects on kidneys and bones and was classified as a human carcinogen (EFSA, 2009)).

 (2) *Hazard characterisation*: Analysis of the nature and properties of identified hazards, including their toxicity, dose-response relationships, and potential for causing harm, in order to understand their potential impact on human health. In the result toxicological reference values (TRVs) are established, which determine safe exposure levels for the identified hazard (EFSA, 2023) (for instance, for cadmium a tolerable weekly intake (TWI) of 2.5 µg/kg body weight (bw) was established (EFSA, 2009)).

(3) *Exposure assessment*: Evaluation of the pathways, extent, and duration of the population of interest to the identified hazard, considering factors such as routes of exposure, population demographics, and exposure scenarios. In the result a numerical exposure value is estimated, that can be used to characterise the risk (for instance, in average the adult population in Europe is exposed to 2.3 µg cadmium/kg bw and week (EFSA, 2009)).

(4) *Risk characterisation*: Integration of hazard information with exposure data to estimate the likelihood and severity of the identified adverse effects. This step enables the quantification and final assessment of risks. For example, if the intake of a contaminant through foods exceeds the determined safe level (TRV) (for instance, the average exposure of adults in Europe to cadmium is near or slightly above the TWI, with certain subgroups likely to exceed the TWI. While the risk of kidney damage at individual level is low, overall population exposure should be decreased (EFSA, 2009)).

As a result, the risk assessment step provides the scientific basis on which informed risk management measures are developed. Risk management is the process of gathering information from all relevant parties in order to weigh up options for protection, prevention and control of consumer health. The risk analysis paradigm emphasises the formal separation of risk assessment and risk management, while stressing the need to share information through risk communication. This exchange of knowledge, findings and perceptions requires collaboration between government agencies, scientific institutions, industry stakeholders, consumers and other interested parties (WHO/ILO/UNEP, 2009). This collaborative approach ensures a well-informed and comprehensive strategy for managing food-related risks and protecting public health.

This risk analysis framework highlights the critical need for accurate exposure estimates to facilitate realistic risk assessments in the area of food safety. An accurate understanding of population exposure, together with the identification of key contributors, is essential for identifying and evaluating the impact of risk mitigation measures. Such assessments, as well as the measurement of the effectiveness of risk reduction strategies, can only be made if they are based on comprehensive and high-quality data that accurately reflect the true extent of population exposure. Robust datasets are therefore essential to ensure the reliability and validity of risk assessments in this context.

2.2 Food safety in Germany

In Germany, the Federal Ministry of Food and Agriculture (BMEL) holds the central responsibility for legislating and managing risks within the domains of agricultural policy and food safety. To ensure informed decision-making, the BMEL seeks scientific guidance from multiple specialized institutes focusing on food, nutrition, animal and plant health, and protection (BfR, 2021). The German Federal Institute for Risk Assessment (BfR) is the main actor with regard to food safety. The remits of the BfR include risks related to unwanted substances (such as heavy metals, mycotoxins or acrylamide), but also risks arising from over- or undersupply of nutrients (such as vitamins) (BfR, 2024).

In its risk assessment of food related hazards, the BfR follows internationally recognized scientific assessment criteria. This also involves the four steps of the risk analyses framework (Figure 1) as laid down in the BfR Guidance for the Assessment of Health Risks (BfR, 2023e). The result is an assessment report that includes qualitative or quantitative description of the risk, together with recommendations on actions and measures to minimise a potential risk.

Through a systematic and evidence-based approach, the German federal authorities, through the BMEL and the BfR, ensure the careful assessment and management of risks related to food safety, thereby contributing to the protection of public health and the well-being of consumers.

2.3 Dietary exposure assessment

Hazard can only be distinguished from risk in relation to the population of interest. Therefore, dietary exposure assessment focuses on assessing the intake of substances through the consumption of specific foods. Only through precise information on exposure, suitable risk mitigation measures can be derived. For this reason, exposure assessment holds particular significance in the risk analysis framework.

In food risk assessment, this process is primarily associated with the intake of potentially harmful substances, such as heavy metals, pesticide residues, or environmental

contaminants (e.g., dioxins). Dietary exposure consists of three key parameters and is computed following the general equation (Arnich *et al.*, 2012; WHO/FAO, 2009)

$$E_{i,j} = \sum_{k=1}^{n} \frac{C_{i,k} * L_{k,j}}{BW_i}$$

where $E_{i,j}$: exposure to contaminant j for subject i; $C_{i,k}$: food consumption of the food k by subject i; $k = 1\ to\ n$: the total number of foods consumed by the subject i; $L_{k,j}$: level of substance j in the food k; BW_i: body weight of subject i.

Which input parameters to select for food consumption and substance level depends on the hazard of the substance. Acute risks are defined as toxic health effects that occur within a short time (<24 hours) (EFSA, 2023). For example, a single high intake of ergot alkaloids can cause acute symptoms such as nausea, headache or high blood pressure, and even death from respiratory paralysis (also known as 'ergotism' or 'St. Anthony's fire') (EFSA, 2012b). In such cases, *short-term dietary exposure* is assessed, which combines single high food intake with high contamination levels (WHO/FAO, 2009). Single unit analyses or distributions on food consumption or substance levels provide the required parameters. For example, short-term exposure to pyrrolizidine alkaloids (PAs) by tea consumption was assessed by combining the 95th percentile (P95) of the measured PA levels in tea with the P95 of the days with maximum consumption per individual (BfR, 2020), which represent a single intake event.

If the substance of concern poses a chronic risk, *long-term dietary exposure* is assessed. Chronic risks are health effects that occur over time (e.g. lifetime) (EFSA, 2023). For example, cadmium intake can lead to kidney failure or increased risk of cancer if consumed repeatedly over time (EFSA, 2009). To account for lifetime exposure, long-term estimates combine average daily intake per individual over several days with average or high substance levels (WHO/FAO, 2009). A simplified representation of the choice of parameters is shown in Figure 2. For consumption, the average consumption over all reporting days is calculated for each food and the median (P50) or P95 is used to represent average or high consumers. For substance levels, the mean of the substance level distribution is used to represent varying contaminant intakes over time and the P95 is used to represent a scenario where consumers are exposed to highly contaminated foods over the long-term (e.g., brand loyalty) (Sarvan *et al.,* 2017).
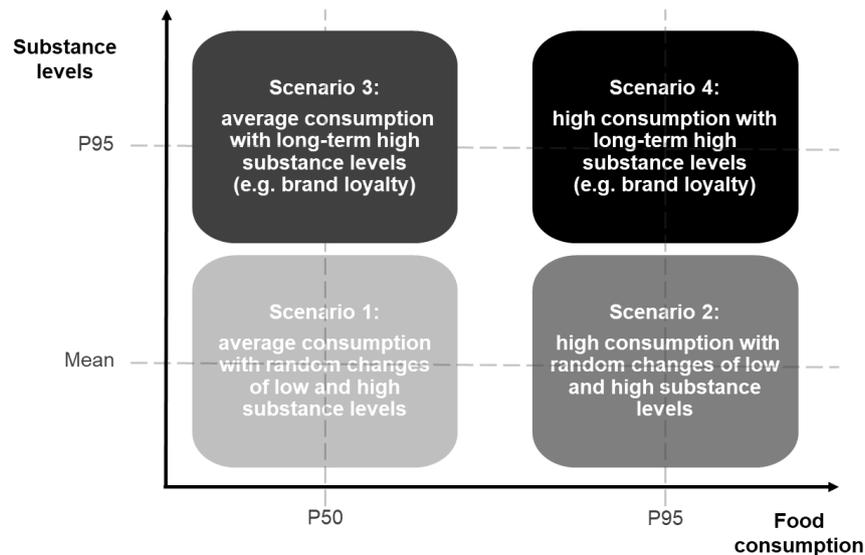
Figure 2: Simplified illustration of scenarios for deterministic long-term dietary exposure assessment (modified from Sarvan et al. (2017)).

The above approaches refer to deterministic exposure models where single values ('point estimates') for food consumption or substance levels are determined and subsequently combined (Stephenson & Harris, 2016; WHO/FAO, 2009). It depicts a simplified framework, which can be refined according to different needs, such as for origin-related exposure scenarios (Fechner *et al.,* 2020). Typically, point estimates are chosen that provide protection for most of the population. In contrast, probabilistic approaches use distribution-based models that take into account the full variability of the data, resulting in more realistic but less conservative (protective) estimates (Stephenson & Harris, 2016; WHO/FAO, 2009).

In summary, the requirements for substance occurrence data for the scenarios are different[1]. For the calculation of short-term and consumer-loyal scenarios, individual data or data distributions on substances are required, whereas the determination of the average long-term exposure can be performed with average substance values. These requirements have implications for the appropriateness of datasets for exposure assessment.

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[1] This also applies for food consumption data; however, this work focuses to the evaluation of occurrence data.

2.4 Relevance of occurrence data for dietary exposure assessment

The objective of an exposure assessment is to provide a reliable estimate to characterise the risk and derive appropriate risk management measures (FAO/WHO, 2023; WHO/ILO/UNEP, 2009). The accuracy of an estimate highly depends on the quality of the input parameters. As one of the key variables of the exposure model, the quality of occurrence data is of particular relevance for the quality of the risk assessment (EFSA, 2021). The data quality for a specific assessment cannot be defined generally. It has to be seen in context of the respective aim of the exposure assessment and the targeted scenario(s) (BfR, 2022c). If the data is fit for purpose depends on the completeness, representativeness, sampling strategy, sample preparation (e.g., single units vs. composite samples), sample size, depiction of time-based, spatial and inter-individual variations (regions, seasons etc.), analytical method/sensitivity, basis of measurement (e.g., dry weight or wet weight), or timeliness (BfR, 2022c; EFSA, 2021). Any shortcomings with regard to the objective of the assessment need to be identified and described systematically in order to derive appropriate strategies to deal with this limitation or to provide decision makers with information for the correct interpretation of the result. This process is also denoted as uncertainty analysis (BfR, 2022c).

For instance, the EFSA had to assess the risk related to the presence perfluoroalkylated substances (PFAS) in food based on a limited dataset of occurrence data in food (EFSA, 2020a). Not all foods consumed were analysed for PFAS and for others only a low sample size was available. The applied strategy was to use the measurements even with low sample size and to extrapolate the available analytical data to the consumption amounts of foods that were not measured (e.g., using data from apples for all fruits). Furthermore, the potential migration from food contact materials (e.g., non-stick coating of kitchen utensils) could not be included in the assessment, causing potential underestimation of exposure. Also, analytical limitations in terms of sensitivity resulted in numerous left-censored data[2], which further increased the uncertainties associated with the data processing scenarios. In this example the upper bound (UB) exposure was 4- to 49-fold higher than the lower bound (LB) exposure. As a result, it remained unclear whether the actual exposure assessed for this substance group was lower or higher than the estimated value (over- or underestimation) (EFSA, 2020a).

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[2] Measurements below an analytical limit of reporting, that cannot be quantified or detected

Another risk assessment on lead could not exclude the presence of targeted samples in the assessment (EFSA, 2012a). Targeted sampling focuses on foods or areas more likely to be contaminated and are originally not intended for risk assessment but for risk-orientated food surveillance (EFSA, 2021). This circumstance contributed to potential overestimation of lead intake for the European population (EFSA, 2012a).

An assessment of pesticides confirmed a risk for pregnant women for some of the examined residues. However, lacking occurrence levels under special local conditions or for particular production methods (e.g., rural areas or organically produced foods) did not allow conclusions for such subgroup scenarios (de Gavelle *et al.*, 2016).

The Canadian TDS found suspicious high lead levels in a composite sample of raisin pie. However, the pooling of different food samples did not allow to draw a conclusion on the source of the contamination or if the measured value accurately represented the average dietary intake from this food (Dabeka *et al.*, 2002).

With regard to the basis of the measurement, there are some substances and foods that are regulated and measured in fat weight, such as dioxins and dioxin-like polychlorinated biphenyls (dl-PCBs) (Regulation (EU) 2023/915)). As this does not correspond to the foods as they are consumed by the people, data conversions are required. Schwarz *et al.* (2014) solved this by a back calculation of the consumed foods to their fat content to be able to link occurrence data on dioxins and dl-PCBs with the consumption data. This was realised using simplifications based on default factors and standard recipes. Such simplifications always come along with inaccuracies in the exposure estimation (Kettler *et al.*, 2015).

These examples underscore the critical importance of the quality of the data but also of the special features (e.g., specific local conditions) for dietary exposure assessment and the resulting uncertainties associated to the estimate. However, these examples also illustrate that uncertainties are manifold and not every limitation is relevant for every specific risk assessment objective. The data pool of a functioning food safety system should therefore contain different type of data that allow all exposure-related questions to be addressed with sufficient certainty.

2.5 Occurrence data available for dietary exposure assessment in Germany

Germany benefits from a well-established and extensive database for both desired and undesired substances. The German Nutrient Database (BLS, Bundeslebensmittelschlüssel) serves as a comprehensive resource for evaluating energy and nutrient intake, derived from national consumption surveys (Haftenberger *et al.*, 2019; MRI, 2023). This database undergoes continuous updates, incorporating foods that are frequently consumed based on food consumption surveys and market or product research (MRI, 2023). Information concerning nutrient content is obtained from laboratory analyses, including contributions from the BfR MEAL Study (Bürgelt *et al.*, 2016) and literature searches (MRI, 2023).

A comprehensive source of data on contaminants in food is the German food monitoring (National Monitoring) (Harms & Wend, 2016). It is one of the most comprehensive monitoring systems in Europe. For example, Germany contributed 44%, 60% or 72% of the data used for EFSA opinions on lead, nickel or methylmercury (EFSA, 2010, 2012c, 2020b). Since 1995 the National Monitoring operates as a rolling system where food is sampled and analysed annually to check compliance with maximum levels and to provide data for risk assessment (Harms & Wend, 2016) (for details see section 5.2.1). So far, most of the BfRs risk assessments used National Monitoring data as data basis for substance occurrence in foods (e.g., dietary intake of polychlorinated dibenzo-p-dioxins (PCDD/F), dl-PCBs and PFAS from different fish species (BfR, 2023c), health risk assessment of ergot alkaloid intake via cereal products (BfR, 2023a) or health risk assessment of high aluminium levels found in green tea (BfR, 2019)).

In 2015, the BfR MEAL Study was set up as Germany's first TDS to improve exposure-related aspects of occurrence data (Sarvan *et al.,* 2017). Accordingly, it meets the three core TDS criteria: (1) the food selection covered ≥90 % of the diet of the German population, (2) foods were prepared 'as consumed' prior to analysis, and (3) similar foods were homogenised into composite samples to make it a cost-effective approach (EFSA/FAO/WHO, 2011; Ptok *et al.*, 2023; Sarvan et al., 2017). The field phase was conducted between 2016 and 2021, and the dataset includes information on beneficial nutrients as well as potentially harmful substances, e.g., contaminants, food additives or plant protection residues (Ptok *et al.*, 2023; Sarvan et al., 2017) (for details see

section 5.2.1). These data are now successively being integrated in the data pool of the BfR and is used for its risk assessment tasks (e.g., to assess the use of sweeteners in soft-drinks (BfR, 2023d), to estimate the iodine intake of the population in Germany (BfR, 2022a, 2022b), or the long-term dietary exposure to nickel via the total diet (BfR, 2022d)).

Thus, in terms of contaminants in food the BfR now has two main data sources available – the German food monitoring (National Monitoring) and the BfR MEAL Study (TDS).

2.6 Relevance of TDS and food monitoring for dietary exposure assessment

There are several publications pointing out general differences between TDS and food minoring methodologies (EFSA/FAO/WHO, 2011; Lee *et al.*, 2015; Lindtner *et al.*, 2024; Xiaowei & Bing, 2018). These characteristics were compiled and described in the *'Report including a Decision tree: for combining data from TDS and Food Monitoring programs in risk management'* (BfR, 2016) and are shown in Table 1 and summarised in the following.

TDSs are useful for long-term dietary exposure assessments. They provide information on almost the entire food range of the population concerned and examine the food in table-ready condition. Pooling of individual samples allows the analysis of diverse substances within one study, which makes TDSs a cost-effective approach and thus attractive for tracking trends. However, information on the variability of substances in the food is lost through pooling of single food samples to composite samples, which is why TDS results cannot be used to assess acute risks or check maximum levels. Because substance levels within a composite sample can be diluted, the effort of TDSs to achieve lowest possible detection and quantification limits should reduce this effect and reduce uncertainties due to left-censored data (BfR, 2016).

Table 1: Main differences between total diet studies (TDS) and food monitoring (modified from BfR (2016)).

Characteristic	Survey method	
	Total diet study	**Food monitoring**
Purpose	Long-term exposure assessment	Short-term exposure assessment Long-term exposure assessment
Food Sampling	representative >90 % of the diet	single food(s)/ food basket
Food preparation	preparation as usually consumed (table-ready)	as purchased (raw and already processed)
Substances	analysing of a lot of substances; including process related contaminants	selected substances in selected foods (focus on risk basis)
Sample preparation prior to analysis	sample pooling (composite sample analysis)	single sample analysis
Variability	poor information about variability	high information about variability
Analysis/ Sensitivity	high sensitivity (as sensitive as achievable)	poor sensitivity (detection limits oriented on legislative MLs)
Budget	cost-effective (pooling)	more cost-intensive (high sample numbers)

MLs: Maximum Levels

Data from food monitoring can be used for both long-term (incl. consumer-loyal) and short-term dietary exposure assessment. The latter is possible through the analysis of individual foods, as high percentiles can also be extracted from the occurrence data. In monitoring programmes, foods are usually analysed raw or in a simply processed state ('as purchased'). Mostly selected foods and substances are analysed, which are targeting regulated foods or substances, which can be attributed to the comparatively cost-intensive analysis of individual foods. Since most monitoring programmes are established to monitor maximum levels, detection and quantification limits are likely to be in the range of regulated levels (BfR, 2016).

The report mentioned above (BfR, 2016) added evidence to these characteristics by a comprehensive literature research on the application of TDS or monitoring data for dietary exposure assessment. All of the identified TDS (100 %) were assessing average long-term exposure, considering food preparation. Most of them covered the whole diet (79 %), some followed a reduced sampling (21 %). Forty percent were also considering trends over time in their analysis. None of the TDS addressed short-term or

high-percentile based long-term assessments. In contrast, short-term exposure was addressed by 8 % of the food monitoring assessments included in the literature research. Notably the majority of 91 % was also used for assessing average long-term exposure. However, in contrast to TDS these assessments were also specifying for high percentiles of exposure (7 %) or were specifically applied for refinement of previously identified high exposures (8 %). In the majority of cases raw or simply processed foods were analysed (98 %), although few evaluations also included prepared foods (6 %). Most monitoring assessments focused only on single foods or food groups (69 %). However, few of them were also addressing reduced food baskets (22 %) or even the whole diet (6 %) (BfR, 2016).

The report concluded that the two programmes focus on different areas of application and, based on this, proposed a decision tree on how a potential food safety system could be effectively built using both approaches, as presented in Figure 3. The concept is that a screening TDS with a limited number of food (groups) and a high level of food aggregation can provide initial data for further prioritisation. This dataset can subsequently be expanded by either a more detailed TDS or directly through food monitoring. Food monitoring complements the data with information on variability, e.g., to allow short-term or consumer-loyal exposure assessment. Once both programmes are in place, they can mutually inform and guide each other for more targeted sampling plans, and both can alert the food surveillance programme when suspicious occurrence levels or exposures are found (BfR, 2016).

I	(Screening) TDS *Formation of data base*
	• representative for whole diet (> 90%) • consideration of food preparation (as consumed) • high analytical sensitivity • mean background level of a lot of substances • chronic exposure • less detailed food list

II	Refined TDS Refinement of former data
	• data refinement • priority setting for further actions

III	Food Monitoring Complement of data
	• acute exposure • assessment of high percentiles • more variability

IV	Continous Monitoring Using FM/TDS data	
Benefits of TDS data for implementation of FM	**Benefits of FM data for implementation of TDS**	**Benefits of TDS and/or FM data for implementation of Food Surveillance**
• reduction of substance number • reduction of food groups • targeted identification for reasons of variability	• TDS-like approach instead of full TDS • identification of less consumed food but with high concentration • identification of food groups for pooling	• targeted surveillance of food with high concentration in mean • focus on food with high total intake (ML exceeding leads to ADI exceedance)

Figure 3: Proposed combined food safety approach using TDS and food monitoring data (modified from BfR (2016)). ADI: Acceptable Daily Intake; FM: Food Monitoring; ML: Maximum Level; TDS: Total Diet Study.

The proposed decision tree of TDS and food monitoring provides valuable insights into the potential of a combined approach. Nevertheless, there is currently no documented implementation of this approach in practice. In addition, the report focuses on the technical application of these two data sources for estimating dietary exposure, but does not address the impact of these different datasets on the reliability of the resulting risk assessments, and whether a more thorough consideration of the adequacy of these programmes and datasets can sharpen such decision scheme.

Further descriptions of the combination of TDS and food monitoring or surveillance data is rarely explicitly described in the literature. Nevertheless, there are some implications for how these assets can be combined to support food safety:

The Canadian TDS found conspicuous lead levels in a composite sample of raisin pie. In a follow up, a targeted survey of the Canadian Health Protection Branch on raisins

traced the contamination to raisins from Turkey, which were treated with a fungicide contaminated with high lead levels. Based on these finding new maximum levels for lead in raisins were adopted (Dabeka *et al.*, 2002; Dabeka *et al.*, 2022). Direct traceability can also be accomplished by preserving subsamples until the analysis of the TDS composite food, as demonstrated in the China TDS. Elevated levels of the organochlorine pesticide hexachlorohexane were found in composite samples of aquatic foods. The subsample analysis identified elevated levels of the hexachlorohexane in samples of aquatic foods from particular regions in the north of China where the pesticides were irregularly used (Zhao *et al.*, 2004). In fact, this is a more targeted approach when a TDS composite food is found to have high levels of a particular substance. However, this requires large storage capacities and stability of substances during storage. Effective collaboration with monitoring activities would make better use of resources and at the same time generate more than, e.g., 15 results from TDS subsamples to check a wider range of foods and possible sources of contamination.

Another example is the New Zealand TDS where elevated iodine levels in a composite sample of soya drink were detected. It turned out that one of the manufacturers used seaweed in the formulation of the product. The product was finally reformulated upon this finding (NZFSA, 2005).

Conversely, a TDS can also be a reaction to monitoring results. In response to the dioxin incident in Belgium, the Canadian TDS quickly sampled and analysed composites of dairy products to verify that contaminated products had not yet entered the Canadian market. This was possible by comparing the analytical measurements with previously analysed TDS samples from previous years. The authors noted that at that time, due to the complexity of the substances, only seven to 14 samples per week could be analysed. Therefore, it would not have been possible to provide this information in a timely manner through regular monitoring of individual foods (Dabeka & Cao, 2013).

The French infant TDS report illustrates how TDS results can support risk management measures by prioritising substances, providing recommendations for reducing exposure and suggesting research courses (ANSES, 2016). The risk assessments for each substance investigated in the TDS for infants were classified as being of concern, risk cannot be excluded, risk considered tolerable/acceptable or inconclusive (e.g., due to

missing TRVs). Further recommendations for reducing exposure to relevant substances were provided with the report. For example, nickel intake was identified as a 'concern' for children and it was recommended that exposure should be reduced via the identified main contributors, which were chocolate-based products. Research recommendations were also made on the need to lower the analytical limits for nickel in food and to collect data to enable acute assessments, indicating the need for a follow-up with monitoring activities.

These studies provide insights into how TDS and monitoring programmes might interact. Other studies illustrate how existing datasets can be used together. de Gavelle *et al.* (2016) conducted an assessment of the cumulative dietary exposure of pregnant women to pesticides. Although data on pesticides were available from several monitoring programmes, the authors gave higher priority to data from the second French TDS. This preference was due to the comprehensive coverage of dietary habits in the TDS, including consideration of seasonal and regional variations and changes in substances due to food preparation. However, the second French TDS did not cover all of the relevant foods of the food consumption dataset, which was derived in particular from pregnant women. In order to obtain a comprehensive view of the total dietary exposure, data from different monitoring programmes were added to the TDS dataset. The assessment showed that there were exceedances of the TRVs for certain substances, but only when UB assumptions were used. To improve the interpretation of these results, national monitoring data and monitoring data compiled by EFSA were used to justify UB assumptions for these pesticides. Specifically, if these substances were also not detected in the raw commodities measured in the monitoring programmes, the LB assumption was considered relevant. Conversely, if these substances were found in the raw commodities, it was considered that the results warranted further attention due to potential concerns (de Gavelle *et al.*, 2016).

Another study used the two datasets in reverse (Nougadère *et al.*, 2014). The acute risk of pesticides was assessed using French monitoring data. The results showed that the acute reference doses (ARfDs) were likely to be exceeded by fruit consumption. As the plant commodities in the monitoring programmes were analysed as RAC (i.e., together with their peel, e.g., avocado, banana or citrus fruits), the results were compared with the prepared samples from the second French TDS. The analytical values for two pesticides (bitertanol and prochloraz) were found to be below the detection

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limits in the TDS, which led to a down-prioritisation of these substances for further analysis (Nougadère *et al.*, 2014).

A study in the sub-Saharan region used monitoring data collected in the GEMS food contamination database to prioritise food/substance combinations for a so-called 'total export study' (TES) and introduced approaches to combine coefficients of variability obtained from monitoring data with mean occurrence levels generated by TDS to predict distributions in order to facilitate export controls and access to international markets (Armaroli *et al.*, 2020).

2.7 Conclusive considerations

Dietary exposure assessment is an essential tool in risk assessment to determine the extent to which individuals or populations are exposed to specific substances through their food consumption, helping to evaluate potential health risks and establish appropriate risk management strategies. Therefore, the reliability of the results is of crucial importance. The quality of occurrence data has a major influence on this reliability. Depending on the methods used to collect the data and the accuracy of the implementation of the data collection, they present different levels of uncertainty but also different suitability for areas of application. However, a food safety system should be able to respond flexibly to all possible scenarios with sufficient certainty. One solution for such a system would be to have a data pool that holds different types of data and allows data to be selected or combined as required.

With the completion of the field phase of the BfR MEAL Study in 2021, Germany has now two comprehensive datasets on substances in food available. While there is limited documented research on the combination of monitoring and TDS, the existing evidence points to their different applications in risk assessment. However, this research is mainly theoretical and based on observations from the literature and only few non-systematic examples for the combination of programmes or datasets were documented. Furthermore, the proposed combination approaches are not fully transferable to the German situation, as both the initial situation and the design of such data collections can vary greatly depending on the country.

Thus, a comparative analysis of the BfR MEAL Study and the National Monitoring is essential to understand their unique characteristics and roles within the German food safety landscape. Furthermore, the impact of data quality and different properties resulting from the respective study designs need to be included in these considerations. Only on the basis of this information effective strategies can be developed to optimise the use of both data sources in the context of risk assessment.

3 OBJECTIVES & RESEARCH QUESTIONS

From the above made considerations the following working hypothesis was derived:

The designs of the BfR MEAL Study (TDS) and the National Monitoring (food monitoring) address different aspects in terms of dietary exposure assessment and consumer health protection. Thus, the additional integration of the BfR MEAL Study data into the BfR assessment concept reduces uncertainties and contributes to improved food safety.

This hypothesis was substantiated by means of the following research questions (RQ):

1) What are the differences between the German National Monitoring and the BfR MEAL Study and how does the BfR MEAL Study contribute to an improved dietary exposure assessment?

2) Can the data from the BfR MEAL Study reduce uncertainties in long-term dietary exposure assessment compared to data from the National Monitoring?

3) Is the BfR MEAL Study also a suitable long-term concept for collecting and updating occurrence data on substances in food?

4 SIGNIFICANCE OF THE RESULTS

This study is the first to comprehensively compare the implementation of both TDS and food monitoring programmes at the national level and to propose a novel approach for their joint application. In the German context, these findings provide a basis for selecting the appropriate dataset, but also support the understanding and interpretation of results based on one or the other dataset. In addition, the research provides practical guidance for the development of a systematic and effective food safety system that effectively integrates both programmes.

Internationally, these results have implications for countries establishing or improving food safety systems. They provide valuable insights into the challenges and opportunities of using and combining TDS and food monitoring, and offer a practical example of how such integration can work, as demonstrated in Germany. For countries in the process of establishing their food safety systems, this research could provide guidance on how to build an efficient system that maximises the strengths of both programmes, in terms on cost efficiency, detection of non-compliant samples, addressing different food-born risks, and providing a basis for risk assessment of a wide range of substances and food.

5 METHODS & DATA

5.1 General procedure

The research questions were answered in three work packages (RQ1 to RQ3). Each of the RQs resulted in one peer-reviewed publication ((Kolbaum *et al.*, 2022; Kolbaum *et al.*, 2023a; Kolbaum *et al.*, 2023b), see also Appendix I to Appendix III).

In a first step (RQ1), all available information from the National Monitoring and the BfR MEAL Study were collected and described in one paper in order to transfer the theoretical considerations from section 2.6 to the German situation. The implications of the identified differences between the two programmes for dietary exposure assessment were investigated in RQ2 using a practical example. In the third RQ, different strategies for updating the data of the BfR MEAL Study were evaluated in order to assess their potential usability in the long-term.

Details on the realisation of the RQs are described in section 5.3 after the introduction of the applied datasets in section 5.2.

5.2 Used datasets

Datasets used for the here presented evaluations are summarised in Table 2 and described in detail below.

5.2.1 Occurrence data

BfR MEAL Study

The BfR MEAL Study (Mahlzeiten für die Expositionsschätzung und Analytik von Lebensmitteln [Meals for exposure assessment and analysis of foods]) is the first German TDS and followed the internationally recommended standards for a TDS (EFSA/FAO/WHO, 2011; Ptok *et al.*, 2023; Sarvan *et al.,* 2017). It was coordinated and conducted by BfR and funded by the BMEL. The course of the study is outlined in Figure 4. In a first step (1), a food list (referred to as 'MEAL food list') was compiled, taking into account the food consumption of children aged 0.5 to <5 years (VELS study) (Banasiak *et al.*, 2005) and adults aged 14 to 80 years

(NVS II) (Brombach *et al.*, 2006; Krems *et al.*, 2006) (details on food consumption surveys are reported in section 5.2.2). Foods were selected if they were part of at least 90 % of the diet in each of the main food groups and selected age or sex groups, or when they were a relevant contributor to exposure due to potentially high levels of one of the substances analysed in the study (Ptok *et al.*, 2023). A total of 356 foods (referred to as 'MEAL foods') were finally included. According to the TDS principles (EFSA/FAO/WHO, 2011), foods were pooled to form composite samples. In the BfR MEAL Study, 15 to 20 individual foods (so-called 'subsamples') were pooled into a composite sample (e.g., 15 different types of apples represented the average apple consumption in Germany) (Ptok *et al.*, 2023; Sarvan *et al.,* 2017). In the second (2) and third (3) step, the subsamples were collected and transported to the MEAL kitchen where they were prepared 'as consumed' (e.g., washed, peeled, cooked, etc.). Food collection took into account regional, seasonal or production type (conventional or organic) differentiations in case of suspected differences in substance contents (e.g., for the MEAL food 'rice' two different MEAL pools of organic or conventional production were collected) (Ptok *et al.*, 2023; Sarvan *et al.,* 2017). Shopping and kitchen preparation were supported by market share data and consumer surveys providing information on typical consumer behaviour (e.g., preferred brands or preparation methods) (Hackethal *et al.*, 2023; Stehfest *et al.*, 2019). After homogenisation of the subsamples into a composite sample (4), the final samples were analysed in-house at BfR or by contracted laboratories (5). More than 300 desirable and undesirable substances from nine different substance groups (e.g., elements and mycotoxins as well as nutrients) were analysed (Ptok *et al.*, 2023). The results are being successively integrated into the BfR data pool to support risk assessments and are made publicly available (6) (BfR, 2023b).

Information from the BfR MEAL Study and data on the number of foods and substances analysed for a quantitative description were used in RQ1 (section 5.3.1) (Kolbaum *et al.*, 2022) (APPENDIX I). Cadmium occurrence data from the BfR MEAL Study was used in RQ2 to estimate long-term dietary exposure (section 5.3.2) (Kolbaum *et al.*, 2023a) (APPENDIX II), and the MEAL food list was evaluated in RQ3 in the context of possible update strategies (section 5.3.3) (Kolbaum *et al.*, 2023b) (APPENDIX III).
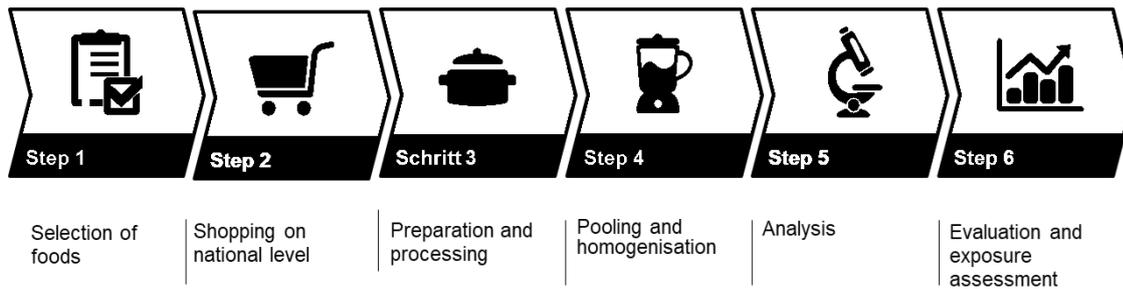
Figure 4: Procedure of the BfR MEAL Study (modified from Sarvan et al. (2017)).

National Monitoring

Since 1995 the National Monitoring (Harms & Wend, 2016) is the implementation of Regulation (EU) 2017/625 to establish food monitoring programmes for detection and prevention of the presence of potentially harmful substances, insurance of compliance with regulatory limits, and protection of human health in Germany. The German Federal Office of Consumer Protection and Food Safety (BVL) is in response of the coordination of the National Monitoring and the execution is down to the Federal States of Germany (Harms & Wend, 2016). Within a five-year cycle, a pre-defined food-basket is sampled. Initially, the food selection was based on the VELS study (children 0.5 to <5 years) (Banasiak *et al.*, 2005) (section 5.2.2) and the resulting food basket included 120 foods covering about 80 % of the average daily consumption (Sieke *et al.*, 2008a, 2008b). Over time, additional foods were included. The monitoring cycle 2016 to 2020 comprised 178 foodstuffs (AVV Monitoring 2016-2020). However, the whole food basket is not analysed for all substances. The annual choice of food/substance combinations is case dependent and is down to expected contamination, regulatory demands and resources (AVV Monitoring 2016-2020). The BfR is also involved in the yearly selection of food/substance combinations by providing expertise and needs in terms of risk assessment requirements. The range of analyses in the National Monitoring includes potentially harmful substances, such as residues of plant protection compounds and biocide products, elements or mycotoxins (Harms & Wend, 2016). According to the regulations, the foods are sampled at raw agricultural commodity (RAC) level (e.g., mycotoxins in cereal grains) or as purchased in simple processed products (e.g., lead in wine) (Regulation (EU) 2023/915). The sampling strategy is defined as non-risk oriented (in contrast to the food surveillance) and foods are analysed at individual level (Harms & Wend, 2016; Sieke

et al., 2008a). The raw data are sent annually to the BfR to support its risk assessment tasks and are also published in a processed form as reports (BVL, 2023a; Harms & Wend, 2016). Since 2003, monitoring projects extend the National Monitoring, addressing specific questions related to food contamination (Harms & Wend, 2016), e.g., PFAS in dried algae (BVL, 2022).

Methodological facts about the National Monitoring and the quantitative description of foods and substances analysed in the programme was used in RQ1 (section 5.3.1) (Kolbaum *et al.*, 2022) (APPENDIX I). The quantitative evaluations in RQ1 comprised all data collected between 2011 and 2019[3]. Cadmium occurrence data from the National Monitoring collected between 2011 and 2020 was used to estimate long-term dietary exposure in RQ2 (section 5.3.2) (Kolbaum *et al.*, 2023a) (APPENDIX II).

5.2.2 Food consumption data

VELS study

The VELS study (Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln [Food consumption survey to determine food intake by infants and small children for the estimation of the acute toxicity risk from pesticide residues]) is a food survey conducted by University of Paderborn on behalf of the BfR. Between 2001 and 2002 the food consumption survey of 804 children between 0.5 and <5 years (Banasiak *et al.*, 2005) was monitored. Dietary records were completed on three consecutive days at two different time points, resulting in six reporting days per individual.

The VELS data were used to evaluate the potential update strategies of the MEAL food list in RQ3 (section 5.3.3) (Kolbaum *et al.*, 2023b) (APPENDIX III). For the evaluations only non-breastfed children were considered (n =732).

KiESEL study

The KiESEL study (Kinder-Ernährungsstudie zur Erfassung des Lebensmittelverzehrs [Children's Nutrition Survey to Record Food Consumption]) was conducted

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[3] Only data until 2019 were available at the time of working on RQ1.

by BfR between 2014 and 2017 and updated the data from the VELS study (Nowak *et al.*, 2022a; Nowak *et al.*, 2022b). Food consumption of 1,008 children between 0.5 and <6 years was monitored by completing dietary records on three consecutive days plus one non-consecutive day, resulting in four reporting days per subject.

The KiESEL data was used to assess long-term dietary cadmium exposure for cadmium in RQ2 and potential update strategies of the MEAL food list in RQ3 (section 5.3.3 & 5.3.2) (Kolbaum *et al.*, 2023a; Kolbaum *et al.*, 2023b) (APPENDIX II, APPENDIX III). Only non-breastfed children were considered for the evaluations (n = 952). Two different formats of the KiESEL dataset were relevant for this work. One dataset included all foods 'as reported' by the subjects. This was used to estimate dietary exposure with BfR MEAL Study data in RQ2 (section 5.3.2) (Kolbaum *et al.*, 2023a) (APPENDIX II), and to assess and update the MEAL food list in RQ3 (section 5.3.3) (Kolbaum *et al.*, 2023b) (APPENDIX III). The second dataset partially disaggregated dishes, providing information at ingredient-level. However, the disaggregation only concerned dishes for which participants submitted a recipe. This 'disaggregated' dataset was used to estimate dietary exposure with National Monitoring data in RQ2 (section 5.3.2) (Kolbaum *et al.*, 2023a) (APPENDIX II).

EsKiMo II study

Between 2015 and 2017 the EsKiMo II study (Ernährungsstudie als KiGGS Modul [Eating Study as a KiGGS Module in KiGGS Module]) conducted by the Robert Koch Institute (RKI) surveyed the consumption for 6 to <12-year-old children (Brettschneider *et al.*, 2018; Mensink *et al.*, 2021). In total, 1,190 individuals completed dietary records on three consecutive days plus one non-consecutive day, resulting in four reporting days per subject. RQ3 used this dataset to assess and update the MEAL food list (section 5.3.3) (Kolbaum *et al.*, 2023b) (APPENDIX III).

The KiESEL and the EsKiMo II study were both part of KiGGS Wave 2 (German Health Interview and Examination Survey for Children and Adolescents) conducted by the RKI (Brettschneider *et al.*, 2018; Mensink *et al.*, 2021; Nowak *et al.*, 2022a; Nowak *et al.*, 2022b).

All described food consumption datasets in this section collected anthropometric data at individual level. The reported body weights were used to relate food consumption and dietary exposure per kg body weight (Banasiak *et al.*, 2005; Brettschneider *et al.*, 2018; Mensink *et al.*, 2021; Nowak *et al.*, 2022a; Nowak *et al.*, 2022b).

Table 2: Overview of used datasets.

Data type	Study	Data owner	Accessibility	Used for
Occurrence data 2016 - 2021 (TDS)	BfR MEAL Study (Ptok *et al.*, 2023; Sarvan *et al.,* 2017)	German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung (BfR))	Full data were made available by the data owners for free. Data is successively made available in a public use file at: http://www.bfr-meal-studie.de/en/public-use-file-en.html	RQ1 / RQ2 / RQ3 (Kolbaum *et al.*, 2022; Kolbaum *et al.*, 2023a; Kolbaum *et al.*, 2023b)
Occurrence data 2011 - 2020 (Food monitoring)	German National Monitoring (Harms & Wend, 2016)	Official laboratories of the Federal States of Germany	Full data were made available by the data owners for free. Data is available in aggregated form in annual reports and tables at: https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/02_AmtlicheLebensmittelueberwachung/04_Monitoring/lm_monitoring_node.html	RQ1 / RQ2 (Kolbaum *et al.*, 2022; Kolbaum *et al.*, 2023a)
Food consumption data for children (2001 - 2002) 0.5 - <5 years	VELS study (Banasiak *et al.*, 2005)	German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung (BfR))	Full data were made available by the data owners for free. Data is available in the EFSA Comprehensive European Food Consumption Database at: https://www.efsa.europa.eu/en/data-report/food-consumption-data	RQ3 /(Kolbaum *et al.*, 2023a)
Food consumption data for children (2014 - 2017) 0.5 - <6 years	KiESEL study (Nowak *et al.*, 2022a; Nowak *et al.*, 2022b)	German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung (BfR))	Full data were made available by the data owners for free. Public use file is in progress (state 12/2023) and will be made available at: https://www.kiesel-studie.de	RQ2 /RQ3 (Kolbaum *et al.*, 2023a; Kolbaum *et al.*, 2023b)
Food consumption data for children (2015 - 2017) 6 - <12 years	EsKiMo II study (Mensink *et al.*, 2021)	Robert Koch Institute (RKI)	Full data were made available by the data owners for free. Data is available as scientific use file at: https://www.kiggs-studie.de/ergebnisse/kiggs-welle-2/scientific-use-file.html	RQ3 (Kolbaum *et al.*, 2023b)

TDS: Total diet study   RQ: Research question

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5.3 Work Packages

5.3.1 Research Question 1: What are the differences between the German National Monitoring and the BfR MEAL Study and how does the BfR MEAL Study contribute to an improved dietary exposure assessment?

So far, the characteristics of the BfR MEAL Study or the National Monitoring have not been described and compared systematically with regard to their use for dietary exposure assessment. This comparison was conducted in RQ1 in two steps. Step one included a quantitative comparison of the foods and the samples analysed in each programme. First, the data from the National Monitoring between 2011 and 2019 was analysed and based on this a categorisation system was developed as presented in Table 3. The BfR MEAL Study data was also examined according to this system and both programmes were finally compared. In addition, three substances from one category each, served as examples for a more detailed comparison (Table 3).

Table 3: Categorisation to assess the coverage of analysed substances and foods in the BfR MEAL Study and the National Monitoring.

Category	Description	Amount foods	Example substance
A	substances with high data availability	n foods: ≥ 100	Cadmium
B	substances with medium data availability	n foods: 25-100	PCB 126
C	substances with low data availability	n foods: < 25	Iodine

PCB: polychlorinated biphenyl

The second step of this RQ involved a systematic comparison of the two programmes. The characteristics from the 'Report including a Decision tree: for combining data from TDS and Food Monitoring programs in risk management' (section 2.6) were taken as a starting point and extended or modified according to the specific situation in Germany. Each characteristic was described in detail and compared for the BfR MEAL Study and the National Monitoring using information from the literature or were illustrated with the selected example substances from Table 3. Table 4 displays the defined characteristics used for comparison of the programmes. The findings from step one

and two were used in the discussion to elaborate their implication for dietary exposure assessment and possible future interactions.

Table 4: Characteristics to describe the main differences between the BfR MEAL Study and the National Monitoring in Germany.

Characteristic
• Purpose
• Sample size and sample preparation
• Food stratification (differentiation in relevant characteristics)
• Choice of food/substance combination
• Sampling strategy
• Food preparation
• Analytical sensitivity

With regard to the main hypothesis of this work, the evaluations in RQ1 allowed conclusions to be drawn on the quantitative expansion of occurrence data for the analysed substances and foods, as well as on the characteristics of the study designs of both programmes and their implications for dietary exposure assessment.

5.3.2   Research Question 2: Can the data from the BfR MEAL Study reduce uncertainties in long-term dietary exposure assessment compared to data from the National Monitoring?

Based on a practical example RQ2 aimed to evaluate whether estimates based on a TDS, such as the BfR MEAL Study, are associated with less uncertainty for long-term dietary exposure assessment and are therefore more reliable compared to estimates based on the National Monitoring data. This was tested in three sub-hypotheses:

1) The BfR MEAL Study data achieves a higher coverage of food consumption than the National Monitoring.

2) Extrapolation from foods investigated in the National Monitoring to consumed foods is associated with considerable uncertainties.

3) Uncertainties due to left-censored data are lower for the BfR MEAL Study.

Selection of example and the framework conditions:

Cadmium was selected as example substance. RQ1 revealed that cadmium was one of the most comprehensively studied substances in the National Monitoring. Only eleven other substances (3 % of all substances included in the National Monitoring) were studied to a similar extent (Kolbaum *et al.*, 2022) (APPENDIX III). Thus, uncertainties associated with the other substances included in the National Monitoring were assumed to be either similar or greater. National Monitoring data from the latest two monitoring cycles of the years from 2011 to 2020 were used (Harms & Wend, 2016) (section 5.2.1).

Data for children from the KiESEL study (Nowak *et al.*, 2022a; Nowak *et al.*, 2022b) (section 5.2.2) were selected as food consumption dataset since children are the most sensitive group due to their higher consumption related to their bodyweight compared to older age groups.

In the daily working routine of the BfR, risk assessments have to be completed in a tight schedule. This was chosen as a real-life scenario were data processing need to comply with a short time frame. In this scenario, no comprehensive data adaptations were possible and solutions to deal with potential uncertainties need to be effective and conservative (EFSA, 2023).

Long-term dietary exposure assessment

In a first step, the food consumption data from the KiESEL study were matched to the MEAL foods or the Monitoring foods, respectively. For matching with the BfR MEAL Study data, the 'as consumed' dataset from the KiESEL study was used, for the National Monitoring data the 'disaggregated' dataset (see also 5.2.2). These reporting levels of consumption were most suitable for the respective occurrence datasets.

Cadmium measurements below the analytical limit of detection (LOD) or limit of quantification (LOQ) (referred to as 'left-censored data') were treated according to the modified lower bound (mLB) and upper bound (UB) approach. In the mLB approach, results below the LOQ were assigned the value of the LOD and results below the LOD were assigned the value zero (BfR, 2018). The use of these values leads to an underestimation of the cadmium levels (and the resulting exposure), as the unquantified values may lie between zero and the respective LOD or LOQ. In the UB approach, results below the <LOQ were assigned the value of the respective LOQ and results below the

<LOD were assigned the value of the respective LOD. In this approach, the contents (and resulting exposure) are overestimated (EFSA, 2023; WHO/FAO, 2009). The joint presentation of the mLB and the UB estimates shows the range in which the 'true' exposure levels lie and is an expression of uncertainty itself (WHO/FAO, 2009).

To estimate the long-term exposure the average food consumption (arithmetic mean over all reporting days related to the individual bodyweight; g/kg bw/day) was linked with the respective measured cadmium level on an individual basis. For total dietary exposure, the cadmium intake was summed per person and from the resulting exposure distribution over the study population, the 50th percentile (P50) and the 95th percentile (P95) were extracted to represent average or high exposed groups, respectively. Exposure was given in µg per kg body weight and week (µg/kg bw/week) to be able to compare with the TRV for cadmium of 2.5 µg/kg bw/week (EFSA, 2009).

The results based on BfR MEAL Study and National Monitoring data were compared and uncertainties during the assessment process were systematically documented and evaluated according to the BfR Guidance on Uncertainty Analysis in Exposure Assessment (BfR, 2022c).

With regard to the main hypothesis of this work, the evaluations in RQ2 allowed conclusions to be drawn on the reliability of dietary exposure estimations based on BfR MEAL Study data compared to estimations based on National Monitoring data and the implication for risk assessment.

5.3.3 Research Question 3: Is the BfR MEAL Study also a suitable long-term concept for collecting and updating occurrence data on substances in food?

The foods to be analysed in the BfR MEAL Study were defined in the initial MEAL food list ('MEAL food list 2016' in the following). As described in section 5.2.1, the MEAL food list was compiled on the basis of the most recent, representative consumption data for individuals in Germany and covered >90 % of consumption. For children, data from the VELS study (Banasiak *et al.*, 2005) (section 5.2.2) were used to identify the most relevant foods. In the meantime, more recent food consumption data for children from the KiESEL study (Nowak *et al.*, 2022a; Nowak *et al.*, 2022b) (section 5.2.2) became available. In addition, new food consumption data for children between 6 and <12 years were released from the EsKiMo II study (Mensink *et al.*, 2021) (section 5.2.2) – an age group that has not been considered for the MEAL food list so far.

RQ3 investigated how the food list of a TDS could be most effectively updated in line with new consumption data. The first step was to investigate whether there was any change at all in food consumption between 2001/2002 (VELS study) and 2014-2017 (KiESEL study). For this purpose, the average consumption amounts (g per kg body weight per day; g/kg bw/day) per main food group were calculated and tested for significant differences between the two surveys.

By evaluating three update strategies for the MEAL food list the RQ further assessed, if (a) the BfR MEAL food list from 2016 was also applicable to the newly available food consumption data from the KiESEL study, (b) if the resource saving approach to only consider small children (0.5 to <5 years) and adults (14 to 80 years) for the development of the MEAL food list was enough to cover also the food consumption of the middle age group (6 to <12 years) from the EsKiMo II study, and (c) the impact of different food list update strategies on coverage of the diet. The criterion for a sufficient coverage of the diet was the TDS principle to cover at least 90 % of the total diet or per main food group.

The three food list update strategies to assess the applicability of the MEAL food list 2016 to newly collected food consumption data are outlined in *Figure 5*.

Approach 1 assigned the consumption records of each individual of the consumption surveys (KiESEL or EsKiMo II) to the existing 356 foods of the MEAL food list 2016. Subsequently, the proportion (%) of the diet covered by the MEAL food list 2016 was calculated (a) over the total diet and (b) per main food group. This step allowed to assess whether the BfR MEAL food list 2016 also covered ≥ 90 % of the diet of the newly available food consumption data.

Approach 2 was set up according to Approach 1, but allowed for extension of the food list. Where coverage of diet below 90 % was identified in a main food group, additional MEAL foods were included to achieve 90 % coverage. This approach allowed a more refinded but still ressource-saving update of the MEAL food list.
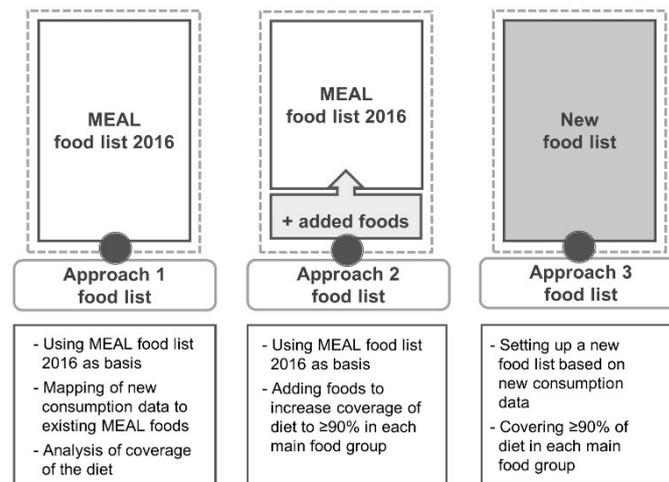
Figure 5: Update strategies. Outline of the three approaches tested in order to update the MEAL food list 2016 (Kolbaum et al., 2023b).

Approach 3 set up a new food list, independently from the exsitsing MEAL food list 2016. Consumption amounts (g/kg bw/day) per MEAL food and per age group were sorted in descending order in each main food group and foods were selected until ≥90 % coverage was achieved per defined age group and per main food group. This allowed for consideration of changed consumption habits and elimintaion of no longer relevant foods.

With regard to the main hypothesis of this work, the evaluations in RQ3 allowed conclusions to be drawn on the appropriateness of the BfR MEAL Study for resource-efficient update of exposure-relevant occurrence data.

5.4 Statistical analyses and evaluations

Data evaluations and visualisations were done with the statistical software R versions 4.0.3 (RQ1) and R version 4.1.1 (2021-08-10) (RQ2 and RQ3) (R Foundation for Statistical Computing, Vienna, Austria) and Microsoft Office Excel 2016 (RQ1, RQ2 and RQ3) (Microsoft Corporation, Redmond, WA, USA).

For comparison of food consumption data in RQ3, the non-parametric weighted Mann–Whitney U test for two independent samples with a significance level of $p \leq 0.05$ was applied.

A list of used R packages together with the applied versions and references is given in Table 5.

Table 5: Applied R packages for statistical analysis and data visualisation.

Package	Reference
data.table	Matt Dowle and Arun Srinivasan (2021). data.table: Extension of data.frame`. R package version 1.14.2. https://CRAN.R-project.org/package=data.table
dplyr	Hadley Wickham, Romain François, Lionel Henry and Kirill Müller (2021). dplyr: A Grammar of Data Manipulation. R package version 1.0.7. https://CRAN.R-project.org/package=dplyr
ggplot2	H. Wickham. ggplot2: Elegant Graphics for Data Analysis. Springer-Verlag New York, 2016. https://CRAN.R-project.org/package=ggplot2
haven	Hadley Wickham, Evan Miller and Danny Smith (2022). haven: Import and Export 'SPSS', 'Stata' and 'SAS' Files. R package version 2.5.0. https://CRAN.R-project.org/package=haven
here	Kirill Müller (2020). here: A Simpler Way to Find Your Files. R package version 1.0.1. https://CRAN.R-project.org/package=here
Hmisc	Frank E Harrell Jr (2021). Hmisc: Harrell Miscellaneous. R package version 4.6-0. https://CRAN.R-project.org/package=Hmisc
openxlsx	Philipp Schauberger and Alexander Walker (2021). openxlsx: Read, Write and Edit xlsx Files. R package version 4.2.5. https://CRAN.R-project.org/package=openxlsx
sjstats	Lüdecke D (2022). sjstats: Statistical Functions for Regression Models (Version 0.18.2). https://doi.org/10.5281/zenodo.1284472, https://CRAN.R-project.org/package=sjstats
stringr	Hadley Wickham (2019). stringr: Simple, Consistent Wrappers for Common String Operations. R package version 1.4.0. https://CRAN.R-project.org/package=stringr
tables	Duncan Murdoch (2020). tables: Formula-Driven Table Generation. R package version 0.9.6. https://CRAN.R-project.org/package=tables
tidyr	Hadley Wickham (2021). tidyr: Tidy Messy Data. R package version 1.1.4. https://CRAN.R-project.org/package=tidyr

6 PUBLICATIONS

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

Kolbaum AE, Jaeger A, Ptok S, Sarvan I, Greiner M, Lindtner O (2022). Collection of occurrence data in foods – The value of the BfR MEAL study in addition to the national monitoring for dietary exposure assessment. Food Chemistry: X, 13: 100240. https://doi.org/https://doi.org/10.1016/j.fochx.2022.100240

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.

Author's 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.

Licence

6.2 Assessment of long-term dietary cadmium exposure in children in Germany: Does consideration of data from total diet studies reduce uncertainties from food monitoring programmes?

Kolbaum AE, Jung C, Jaeger A, Libuda L, Lindtner O (2023a). Assessment of long-term dietary cadmium exposure in children in Germany: Does consideration of data from total diet studies reduce uncertainties from food monitoring programmes? Food and Chemical Toxicology, 184: 114404. https://doi.org/10.1016/j.fct.2023.114404

Abstract

Total diet studies (TDS) and food monitoring programmes are different approaches for collecting occurrence data on substances in food. This case study evaluated the practical applicability of TDS data (BfR MEAL Study) and monitoring data for the assessment of long-term cadmium exposure in children in Germany. Cadmium data from both programmes were combined with food consumption data from the KiESEL study. Uncertainties associated with both assessments were systematically described. Using monitoring data resulted in cadmium intakes approximately 3 times higher than the use of BfR MEAL Study data. Incomplete data and neglect of market shares and consumption weights were considered by conservative data adjustments to the monitoring data and mainly explain the higher estimates. Fewer data adjustments were necessary for BfR MEAL Study data, which covered almost the entire diet and considered consumer behaviour during sample collection and sample preparation. In sum, the use of the BfR MEAL Study data resulted in less uncertainty and more reliable exposure estimates for chronic assessments over the entire diet. However, description of variability and upper tails of substance distributions in food remain essential features of monitoring data. The integration of both programmes into a complementary system further improves food safety.

Author's contribution statement

Anna Elena Kolbaum: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Writing – original draft, Writing – review & editing. Christian Jung: Software, Writing – review & editing. Anna Jaeger: Software, Writing – review & editing. Lars Libuda: Conceptualization, Writing – review & editing. Oliver Lindtner: Conceptualization, Supervision, Writing – review & editing.

Licence

6.3 Reusability of Germany´s total diet study food list upon availability of new food consumption data-comparison of three update strategies.

Kolbaum AE, Ptok S, Jung C, Libuda L, Lindtner O (2023b). Reusability of Germany s total diet study food list upon availability of new food consumption data-comparison of three update strategies. Journal of Exposure Science & Environmental Epidemiology volume, https://doi.org/10.1038/s41370-023-00522-4

Abstract

Background: The German total diet study (TDS)-BfR MEAL Study-established its food list in 2016 based on food consumption data of children (0.5-<5 years) and adults (14-80 years). The list consists of 356 foods selected for analysis in order to ensure ≥90% coverage of the diet. Recently, new food consumption data for children (0.5-<6 and 6-<12 years) in Germany became available, which raised the opportunity to evaluate the applicability of the MEAL food list 2016 on new data.

Objective: We tested the hypotheses that the MEAL food list 2016 also covers ≥90% of the diet of the new collected food consumption data, and that the selection of foods from younger children and adults was sufficient to also cover the middle age group (6-<12 years). Strategies for updating the existing food list were assessed.

Methods: Three approaches evaluated the reusability and potential adjustment strategies of the existing food list. Approach 1 applied the existing food list to new food consumption data. Approach 2 allowed the extension of the existing food list to improve coverage of food consumption. Approach 3 set up a new food list based on the new data.

Results: The MEAL food list 2016 covered 94% of the overall diet of the new collected food consumption data. The diet of the middle age group was sufficiently covered with 91%. However, coverage on main food group or population subgroup level was <90% in some cases. Approach 3 most accurately identified relevant modifications to the existing food list. 94% of the MEAL food list 2016 could be re-used and 51 new foods were identified as potentially relevant.

Significance: The results suggest that a high investment in the coverage of a TDS food list will lower the effort and the resources to keep data updated in the long-term.

Impact: There is no established approach to update a TDS food list. This study provides comparative approaches to handle newly collected food consumption data for follow-on TDS activities. The results provide useful information for institutions planning or updating a TDS. Furthermore, new food consumption data for children in Germany recently became available and are here presented for the first time.

Author's contribution statement

Anna Elena Kolbaum: conceptualization, methodology, formal analysis, software, investigation, data curation, writing – original draft, writing – review and editing. Sebastian Ptok: Writing – original draft, writing – review and editing. Christian Jung: software, writing – review and editing. Lars Libuda: conceptualization, writing – review and editing. Oliver Lindtner: conceptualization, writing – review and editing, supervision.

Licence

7 DISCUSSION

The three RQs added consistently to the evaluation of the working hypothesis *'The designs of the BfR MEAL Study (TDS) and the National Monitoring (food monitoring) address different aspects in terms of dietary exposure assessment and consumer health protection. Thus, the additional integration of the BfR MEAL Study data into the BfR assessment concept reduces uncertainties and contributes to improved food safety.'* The first RQ characterised the two approaches for data collection and drew conclusions regarding their applicability for long-term dietary exposure assessment. The second RQ investigated whether these conclusions could be confirmed in practice. The third RQ examined the long-term applicability of the data from the BfR MEAL Study for the collection of occurrence data on substances in food. After discussing the individual research questions, the results were used to merge the complementarity of the two approaches, ultimately leading to a future perspective of a joint application of both programmes in a common risk assessment framework in Germany.

7.1 Research Question 1: What are the differences between the German National Monitoring and the BfR MEAL Study and how does the BfR MEAL Study contribute to an improved dietary exposure assessment?

The result of RQ1 (Kolbaum *et al.*, 2022) (APPENDIX I) showed, that the BfR MEAL Study complements the National Monitoring by more than 100 substances that have not been covered in the Monitoring so far. For those substances that were examined in both programmes the BfR MEAL Study expands the spectrum of investigated foods and in addition reduces uncertainties that arise due to the focus on unprocessed foods in the National Monitoring. According to the risk analysis framework the risk management depends on sound risk assessment to derive appropriate risk mitigation measures (section 2). With the amendment of the German data pool for several substances and foods the BfR is now equipped to react on more food borne risks, such as different arsenic species, substances migrating from food contact materials or acrylamide.

But not only the size of the data base, also the quality of the occurrence data is crucial for dietary exposure assessment (section 2.4). In this regard RQ1 had shown, that the characteristics of the BfR MEAL Study differ substantially from the National Monitoring.

On the one hand it was shown in RQ1 that the BfR MEAL Study is characterised by a more comprehensive coverage of food consumption. This is a basic TDS principle (EFSA/FAO/WHO, 2011) and confirmed by TDS conducted in other countries. For instance the French TDS covered the food consumption of children (<3 years) by 97 % (ANSES, 2016) and of children (3-17 years) and adults by approx. 81-88 % (Sirot *et al.*, 2009), the Italian TDS covered 99.7 % of consumption of children and adults (Cubadda *et al.*, 2016), and the Dutch TDS 96-98 % of the consumption of children (Boon *et al.*, 2022). In turn, RQ1 also demonstrated by categorising the substances into different number of foods analysed that food monitoring data consistently show lacks in coverage. This is in line with results from literature and can be best illustrated when considering EFSA opinions, since these evaluations collect available monitoring data from European countries and therefore have even more extensive data set available than the individual countries alone. For instance, the EFSA opinion on lead used 144,206 analytical results in food and beverages submitted by 21 European countries for dietary exposure assessment (EFSA, 2012a). Most of the samples covered meat and edible offal (>36 % of the samples) followed by vegetables and products thereof (12 %). Other food categories, such as coffee beverages or cocoa beverages, were lacking any or a representative number of samples, causing in turn the need to aggregate to higher food levels which introduced uncertainty in the exposure assessment. Notably, the main food group 'Composite dishes' was represented by <1 % of the results (EFSA, 2012a). The same can be observed for further examples such as for nickel or PFAS (EFSA, 2020a, 2020b). Also, other processed products, such as processed meat products (e.g., ham, cold cuts) or milk products (cheese, fermented milk products) were represented by proportionally low samples or few varieties (EFSA, 2012a, 2020a, 2020b). Thus, as already seen in qualitative comparison of food monitoring and TDS in RQ1, these examples also support that processed or prepared foods are less well represented in the monitoring data.

Further it shows that food monitoring samples seem to be mainly collected on the basis of risk-related considerations (foods with expected high contamination) (e.g., overproportioned sampling of lead in offal or perfluorooctanoic acid (PFOA) in fish and meat

(EFSA, 2012a, 2020a, 2020b), rather than on the basis of consumption weights. This is also in line with the second feature identified for the BfR MEAL Study in RQ1. This is a better representativeness in terms of the consideration of consumption weights, market shares, consumer behaviour (Kolbaum *et al.*, 2022) (APPENDIX I), which builds a strong contrast to the 'biased sampling' from the National Monitoring. The National Monitoring examined lead, PFAS or nickel also predominantly in meat (14 %) and vegetables (22 %) (lead), meat (31 %) and fish (29 %) (ex. PFOA), and grains or vegetables (both 20 %) (nickel). Other main food groups were represented with very few foods or not at all. In contrast, the BfR MEAL Study was covering all relevant foods related to their relevance for consumption and thus dietary exposure (Kolbaum *et al.*, 2022) (APPENDIX I).

The observations of RQ1 that there is an incomplete coverage and lacking represent-ativeness of the National Monitoring data can be reasoned by the purpose of the mon-itoring, which restricts selected food/substance combinations predominantly to regu-lated ones (Kolbaum *et al.*, 2022) (APPENDIX I). Regulated are mostly foods where high substance levels are expected (e.g. inorganic arsenic in Rice (Regulation (EU) 2023/915)). This can cause a right shift of the distribution when extrapolated to cover the whole diet. This is generally recognised as 'biased sampling' (Kettler *et al.*, 2015) and was also shown to apply for the National Monitoring in RQ2, when using the mon-itoring data for the assessment of dietary cadmium exposure (Kolbaum *et al.*, 2023a) (see section 7.2). The technical implementation alone of the BfR MEAL Study makes its data more applicable to population-based risk assessments and thus fills a data gap in the German food safety system that could not be addressed by the National Moni-toring until now.

Nevertheless, the comparison in RQ1 had also shown own implications of the National Monitoring sampling strategy for dietary exposure assessment. As indicated in section 2.3 certain exposure scenarios depend on information about variability (e.g., short-term exposure or consumer-loyal scenarios). The food pooling approach of the BfR MEAL Study precludes assessments that are based on substance distributions in food and also verification of compliance with regulatory limits. Further, the analysis of only pre-pared foods complicates the verification whether the measured substance levels are in line with existing regulations, e.g., direct comparison to maximum permitted levels.

Overall, the research from RQ1 clearly pointed out the added information regarding analysed substances and foods by the BfR MEAL Study as well as the differences in the data quality from the BfR MEAL Study and the National Monitoring. Different type of data is necessary to consider different exposure scenarios (section 2.4) and to operate a flexible food safety system (section 2.7). Thus, the additional integration of TDS-type data into the German data pool improves the possibilities for dietary exposure.

7.2 Research Question 2: Can the data from the BfR MEAL Study reduce uncertainties in long-term dietary exposure assessment compared to data from the National Monitoring?

Based on the findings from RQ1 the hypothesis of RQ2 was that utilising BfR MEAL Study data leads to less uncertainty and higher reliability in long-term dietary exposure assessment compared to estimates based on National Monitoring data.

The results showed that the estimates derived from the National Monitoring data were about three times higher than those based on the BfR MEAL Study data (Kolbaum *et al.*, 2023a) (APPENDIX II). This significant difference can be attributed to the application of conservative data adjustment strategies to account for uncertainties within the National Monitoring dataset. The results revealed that the main differences in design characteristics as identified in RQ1 were causative for the uncertainties associated with the National Monitoring data. The National Monitoring data covered only 38 % of KiE-SEL consumption without any further adjustments to the data (referred to as 'direct mapping'), and also within the sampled foods the market shares were not covered representatively. This was also identified in other exposure assessments using monitoring data as main reason for overestimation (Boon et al., 2017; Sprong & Boon, 2015). The implications of the use of food monitoring data for dietary exposure assessment is firstly, that right skewed data overestimate the substance intake, secondly, that these skewed data also have to be extrapolated to foods for which analytical values are missing, and thirdly, it is necessary to apply conversion and processing factors to link the data 'as measured' to foods 'as consumed'. Depending on the data gap and on the incomplete coverage of processed or prepared foods this leads to considerable uncertainty. For the cadmium example this applied to 68 % of the National Monitoring

data (Kolbaum *et al.*, 2023a) (APPENDIX II). Based on this outcome it can be reasonably concluded, that National Monitoring data in general is prone to overestimation, which is critical for the derivation of sound risk mitigation measures (section 2.1).

In contrast to the data adjustments of the monitoring data, RQ2 had shown, that no (conservative) extrapolation or adjustment strategies were necessary using the BfR MEAL Study data, which is explanatory for resulting in about three-times lower exposure estimates compared to the National Monitoring data (Kolbaum *et al.*, 2023a) (APPENDIX II). Next to that RQ2 had also visualised the impact of analytical techniques and sensitivities on the exposure outcome. The work in RQ1 had already revealed that the LOQs applied in the BfR MEAL Study were lower compared to the National Monitoring (Kolbaum *et al.*, 2022) (APPENDIX I). RQ2 had shown that this led to a broader range between mLB and UB estimates using the National Monitoring data, which can be translated as a larger uncertainty range for this exposure outcome. Beyond that, also the high variation in sensitivities of the applied analytical methods affected the assessment. For example, high LOQs for certain cow milk samples in the monitoring caused the identification of cow milk as one potential main contributor to cadmium exposure under UB assumptions. However, cow milk is typically not highly contaminated with cadmium and clearly not relevant to control for cadmium (Kolbaum *et al.*, 2023a) (APPENDIX II). This example makes the influence of such – at the first sight small – uncertainties on potential approaches to mitigate the risk visible.

Based on these findings it can be reasonably assumed that the BfR MEAL Study data much better depict the real substance intake in a population in long-term exposure scenarios. In this regard, the selected example in RQ2 is of particular importance. Cadmium was identified in RQ1 as one of the most extensively monitored substances in the National Monitoring (Kolbaum *et al.*, 2022) (APPENDIX I). This means that all other substances analysed in the monitoring are subject to the same or greater uncertainties for dietary exposure assessment. The relevance for these findings becomes evident in the view of the risk analysis framework (section 2.1). The outcome of the dietary exposure assessment defines the distance to the derived TRV and consequently the risk that a population is exposed to. The risk management is in the responsibility to mitigate these risks and will derive respective measures, that in consequence also can have significant economic or societal impacts. The scope of these decisions emphasises the importance of precise risk assessments and thus the importance of having appropriate

data in place. Consequently, the integration of the BfR MEAL Study data is a clear asset to reduce uncertainties and improve food safety strategies.

7.3 Research Question 3: Is the BfR MEAL Study also a suitable long-term concept for collecting and updating occurrence data on substances in food?

In addition to methodological considerations, the timeliness of data presents a significant challenge in the field of public health, particularly with regard to dietary exposure assessment. This assessment relies on the availability of both occurrence and consumption data, as outlined in section 2.3. Therefore, it is crucial that both databases remain as current as possible. Food consumption data are the first input for a TDS to compile a food list to be sampled and analysed (EFSA/FAO/WHO, 2011; Ptok *et al.*, 2023; Sarvan *et al.,* 2017). Consequently, any update to food consumption data should be accompanied by an update of the food list and the respective occurrence data in a TDS approach or in a food monitoring.

The suitability of the BfR MEAL Study for long-term use was evaluated in RQ3 (Kolbaum *et al.*, 2023b) (APPENDIX III) using three distinct approaches, as detailed in section 5.3.3. These results demonstrated that a high investment in the establishment of the initial food list reduces the effort and resources required to update occurrence data in the future. Thus, the BfR MEAL Study already contributes to food safety by offering the possibility of efficient long-term update strategies.

For instance, based on the work of RQ3, BfR is currently using the proposed update strategy of approach 1; i.e., linking the new food consumption data from the KiESEL study and the EsKiMo II study with analytical data from the BfR MEAL Study, as there are currently no resources available for additional TDS activities. An example of the application of this approach is the assessment of iodine intake in children from the KiESEL study to evaluate the potential impact of reducing salt in industrially processed foods. Total dietary iodine intake could be assessed with reasonable certainty for the children of the KiESEL and EsKiMo II study because the existing MEAL food list covered 94 % or 91 % of their consumption, respectively (BfR, 2022b; Kolbaum *et al.*, 2023b). Another example concerns exposure to methylmercury from consumption of 'Fish, seafood and invertebrates'. Sarvan *et al.* (2021) first reported methylmercury intakes from these food sources using data from the VELS study for children and the

NVS II for adults. For children (VELS study), mean intake levels ranged from 0.15 to 0.18 µg/kg bodyweight per week. In an update, the newly available KiESEL consumption data were compared with the existing methylmercury levels from the BfR MEAL Study and confirmed these intake levels for the more recent food consumption data for children (ranging from 0.17 to 0.21 µg/kg bodyweight per week) (BfR, in press). The use of KiESEL consumption data for exposure assessment could be realised without major uncertainties, as the MEAL food list covered 89 to 100 % of the KiESEL consumption of the relevant food group. However, only 82 to 94 % of the EsKiMo fish and seafood consumption was covered, leading to potential underestimation of exposure for 6 to <9-year-old children (Kolbaum *et al.*, 2023b) (APPENDIX III). These examples show that the update of approach 1 is already being put into practice and is contributing to improved food safety in Germany through the reusability of the MEAL food list. However, they also show that there are gaps when looking at individual subcategories (food or population subgroups). Beyond that it has to be recognized that a well-functioning food safety system must not only be able to react quickly to changed consumption habits, but also to different other food risk relevant questions. These can be the reaction to quickly growing food trends, such as the vegetarian or vegan market or the risk related to particular subgroups of concern such groups with specific dietary needs or cultural habits. For example, there has been a notable shift in dietary habits in Germany among people older than 14 years, with a 45 % increase in those identifying as vegetarian or significantly reducing meat consumption between 2014 and 2022 (IfD Allensbach, 2023), and the production of meat substitutes in Germany has increased by 73 % between 2019 and 2022 (Statistisches Bundesamt, 2023). The subpopulation of celiac patients has been associated with increased intake of different mycotoxins due to a different choice of substitutes for gluten-containing products (e.g., maize-based products) (Brera *et al.*, 2014; Esposito *et al.*, 2016); and children with a migrant background tend to eat significantly more lamb or sheep meat than children without a migrant background in Germany (Nowak *et al.*, 2022a). In particular, sheep liver has been associated with high levels of dioxins or dioxin-like compounds (BfR, 2014). Thus, dietary patterns vary widely depending on the subgroup of interest, potentially influencing the intake of undesirable substances. Therefore, a food safety system should possess the flexibility to adapt to emerging trends and address unique dietary patterns of vulnerable consumer groups. With the initial food list 2016, the BfR MEAL Study

provides a 'backbone' that can be easily and resource-efficiently adapted to provide this flexibility (Kolbaum *et al.*, 2023b) (APPENDIX III).

Nevertheless, it is obvious, that updates do not only concern changes in food consumption, but also substance contents in food. Thus, to finally conclude on the suitability of the BfR MEAL Study as a long-term concept for updating occurrence data it must also be recognised, that TDSs have proven to be useful tools in tracking substance contents over time. For example, the Canadian TDS reported a reduction in *N*-Ethylperfluorooctanesulfonamide (*N*-EtPFOSA) levels in fast food products, which was attributed to the reduced use of these compounds in food packaging for oil resistance after the cessation of PFAS in 2000 (Tittlemier *et al.*, 2006). Other TDS studies have documented reductions in lead levels and associated exposures due to various interventions aimed at preventing lead contamination of food. For example, Spungen (2019) described a significant decrease in lead intake in U.S. children between 1980 and 2008, which was associated with improvements in agricultural and manufacturing practices, the elimination of lead from gasoline, and the removal of lead from food contact materials. The Chinese TDS observed a 40 % decrease in lead intake between 1990 and 2015, which was related to the ban on leaded gasoline in 1996 and the revision of national food safety standards for heavy metals in 2005 (Xiaowei & Bing, 2018).

The research in RQ1 and RQ2 had shown, that coverage of consumption is lacking for National Monitoring data (Kolbaum *et al.*, 2022; Kolbaum *et al.*, 2023a) (APPENDIX I, APPENDIX II) and an update would require a completely new set up of the food list. Nevertheless, the National Monitoring could benefit from the work carried out in RQ3 by including the most relevant foods in its investigations. Therefore, a future cooperation and coordination between the BfR MEAL Study and the National Monitoring programme seems advisable at this point, as proposed in section 7.4. Concerning trends of occurrence data over time, the National Monitoring can rely on a long history of monitoring cycles and due to its rolling system. However, visualising the cadmium measurements from the past ten years showed that only for 45 out of the 153 Monitoring foods were measured repeatedly (Figure 6). Two foods were measured three or four times, the remaining 43 foods were measured twice in ten years. Hence, the trends can be explored only for selected foods and to a limited extent at the level of occurrence but a trend in dietary exposure cannot yet be derived on the basis of the National Monitoring.
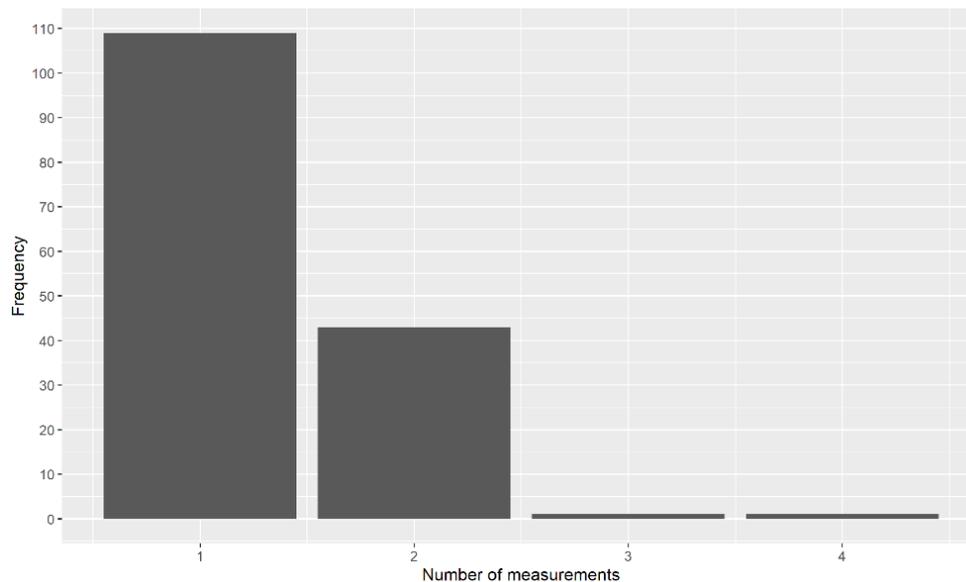
Figure 6: Frequency of repeated measurements per Monitoring food (as composed in Kolbaum et al. (2023a)) between National Monitoring years 2011 and 2020. Included were only foods with n ≥15 samples per year. Total number of foods N=153.

In sum, the BfR MEAL Study has demonstrated its potential as a suitable long-term concept for collecting and updating occurrence data on substances in food (Kolbaum *et al.*, 2023b) (APPENDIX III). These strategies involve updating the food list to align with new food consumption data, which is critical given that dietary exposure assessment depends on both occurrence and consumption data. Comparing the BfR MEAL Study with the National Monitoring, it is evident that the BfR MEAL Study with its TDS design is better suited for updating population dietary exposure data due to its coverage of a wide range of foods, allowing for effective trend analysis and evaluation of risk mitigation measures. On the other hand, it must be kept in mind that the National Monitoring is more appropriate for updating substance levels with acute toxicity in foods and focusing on highly contaminated or regulated foods.

7.4 Future perspective

Retrospectively aligning a dataset with an established data collection and an established system is a challenging task. A more efficient approach would be to leverage the inherent strengths of both programmes within a collaboratively managed system to achieve a fit-for-purpose data collection and evaluation process. A conceptual framework for such a system is proposed, as illustrated in Figure 7. This framework is informed by the findings and considerations of RQ1 to RQ3 (Kolbaum *et al.*, 2022;

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Kolbaum *et al.*, 2023a; Kolbaum *et al.*, 2023b) (APPENDIX I, APPENDIX II, APPEN-DIX III) and the corresponding theoretical background and discussions. It does not claim to be exhaustive and is intended to show first ideas how a future common orientation could work.

A collaborative approach to align data generation for risk assessment and surveillance aspects considers at least three consecutive process steps: (1) common orientation, (2) mutual alignment, and (3) combination of datasets.

(1) Common orientation:

Both programmes essentially share the same objective: collecting data on occurrence of substances in food, while including the most relevant foods in their analysis. This includes the continuous update or adaptation of the food list upon new food consumption data, emerging food trends or relevant population subgroups. A common food list needs to meet the specific objectives of both programmes and save resources if managed centrally. Furthermore, the common base would harmonise the data collection, which subsequently facilitates the combined use of results. For the purpose of chronic dietary risk assessment, the MEAL food list provides a more comprehensive and up-to-date coverage of food consumption compared to the food basket of the National Monitoring and could therefore be used as 'backbone' for future sampling in both programmes. The food list already contains industrially prepared foods as well as unprocessed ingredients. However, the common food list should be complemented by foods as defined in the relevant regulatory frameworks to be able to use it also for checking the compliance of the food market with maximum permitted levels for the National Monitoring. Trigger to update the food list or to establish project related food lists can arise from food consumption or occurrence data (section 7.3). In terms of food consumption, this can be the availability of new food consumption surveys, other indications for changes in the dietary behaviour of the population or the interest in specific subpopulations. In both cases, the 'backbone' food list is evaluated for available data and additional foods are only added when necessary, following the guidance from RQ3 (Kolbaum *et al.*, 2023b) (APPENDIX III). When additional or emerging substances need to be examined, the food list can be adjusted or expanded based on their expected presence in foods. This would be a comparable approach as already applied for the different substance modules of the BfR MEAL Study (Ptok *et al.*, 2023).

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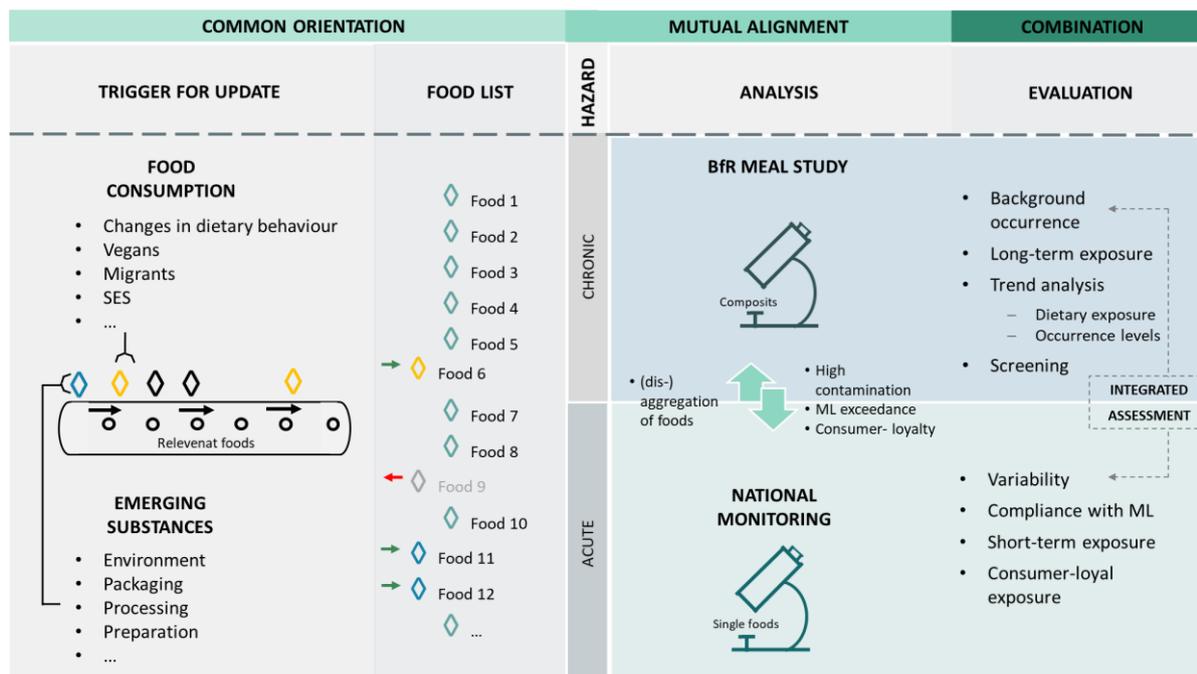
Figure 7: Conceptual scheme of a joint application of the BfR MEAL Study (TDS) and the National Monitoring (food monitoring) in a common risk assessment framework in Germany. ML: Maximum level   SES: Socioeconomic status.

(2) Mutual alignment:

The main purpose of the common food list is to keep track of the most relevant foods or to select those that are essential for a specific regulatory or research questions. The determination of the programme in which the food is finally analysed is based solely on the hazard posed by the substance to be tested. In the case of chronic toxicity, foods are analysed as composite samples according to the BfR MEAL Study design, whereas substances with acute toxicity are analysed as individual foods within the framework of the National Monitoring. Furthermore, the composition of the pooled MEAL foods, based on market shares, can also guide the representative selection of individual units in the National Monitoring. In addition to the more targeted allocation of analyses to the programmes, the results can also be used to align the programmes in their direction. For example, indications from the BfR MEAL Study can be used for refinement in the National Monitoring. These can be potentially relevant differences between stratifications (e.g., different substance level in organically produced foods or conventionally produced foods) or indications of exceedances of maximum levels. In such cases, the National Monitoring can contribute single unit assessments for further evaluations, significance

analyses or trace the source of the maximum level exceedance. This practical approach has already been successfully implemented in the BfR MEAL Study in response to cases such as high levels of aflatoxin B1 in chia seeds, elevated levels of copper in bovine liver or excessive levels of acesulfame K in soft drinks (Ptok *et al.*, 2023). In cases where consumer scenarios need to be assessed for a food that is not distinguished in the MEAL composite foods, the National Monitoring can provide the necessary information on either average or high occurrence levels (e.g., P95) to address the respective scenarios. If high levels of contamination are detected in a MEAL composite sample, a detailed analysis of individual units in the National Monitoring can provide information on the variability of the composite food. This information can in turn influence decisions on further aggregation or disaggregation of composite samples within the BfR MEAL Study. For example, elevated levels of nickel were detected within the MEAL food category 'Macadamia nuts, Brazil nuts, pecans' (BfR, 2022d, 2023b). A subsequent project monitoring initiative revealed that brazil nuts were primarily responsible for the elevated nickel levels (Hoepfner & Blume, 2024), possibly leading to disaggregation into individual nut types for further BfR MEAL Study analyses. In this approach the food list only needs to be analysed by the cost-effective TDS design to cover almost the entire diet. The more resource-intensive monitoring is applied – next to its regulative activities - more case-specific. Both programmes together effectively build a dataset with maximum information for dietary exposure assessment.

(3) Combination:

Essentially, these datasets are being used for their intended purpose. The data from the BfR MEAL Study provide a comprehensive overview of the background occurrence of substances in food, yielding more reliable results for long-term dietary exposure assessments. The cost-effective design of the BfR MEAL Study can be used for tracking trends in dietary exposure and occurrence data over time. Furthermore, TDS can be used to get a very informative overview of the contamination landscape in a diet. On the other hand, the National Monitoring provides insights into variability by generating distributions of substances in food, which are essential for distribution related exposure scenarios (e.g., short-term exposure) and verifying compliance with maximum permitted levels. Finally, there are

cases where the combined analysis of background occurrence with variability data improves the robustness of exposure assessments.

In sum, the common orientation simply merges the common idea of collecting occurrence data on most relevant foods to a joint working basis – the food list. Mutual alignment saves resources through case-specific selection of the appropriate programme for analysis and identifies opportunities for cross-coordination. Finally, the orientation of each programmes provides the most appropriate dataset for the respective purpose and the combination for dietary exposure assessment improves the significance of the results for risk management.

It is important to emphasise that the scheme presented is a conceptual representation and summarises the findings and discussion in terms of a framework of a potential future collaboration. It may not cover every conceivable scenario. For example, it is important to recognise that the scope of the National Monitoring cannot be limited exclusively to food/substance combinations relevant for acute toxicity, since monitoring compliance with maximum permitted levels is one of its primary objectives. Nevertheless, the data derived from the BfR MEAL Study can help to set priorities. In addition, the type of food preparation may play an important role in determining the appropriate programme. For example, the National Monitoring may not be well suited to investigate process contaminants due to the limited processing level of the selected samples. In such cases, a modification of the TDS programme may provide the necessary information, as demonstrated in the case of the 'process contaminants' and 'food additives' modules within the BfR MEAL Study (Ptok *et al.*, 2023). Similarly, the strategy of retaining samples from each TDS subsample of a composite food for tracing contaminants, as successfully implemented in the Chinese TDS (Xiaowei & Bing, 2018; Zhao *et al.*, 2004), demonstrates the flexibility of both programmes. Consequently, modified versions of these programmes are also plausible, aiming to maximise the utility of the existing structures.

7.5 Limitations

While the BfR MEAL Study and National Monitoring offer valuable insights into occurrence data on substances in foods and dietary exposure assessment, it is crucial to acknowledge and address limitations and uncertainties associated to the datasets to ensure that their combination is applied effectively in Germany's food safety system. These limitations were discussed thoroughly in RQ1 and RQ2 (Kolbaum *et al.*, 2022; Kolbaum *et al.*, 2023a) (APPENDIX I, APPENDIX II). Beyond this, other limitations and uncertainties are relevant in assessing the implications of this research for current and future activities.

The available information regarding the implementation of the National Monitoring system was limited. Only one publication and the official homepage provided a general overview of the monitoring system in Germany (BVL, 2023c; Harms & Wend, 2016). There were two publications that provided recommendations for the implementation of the National Monitoring with regard to the compilation of the food basket (Sieke *et al.*, 2008a) and the composition and size of the samples (Sieke *et al.*, 2008b). However, there was no documentation of the final execution of these recommendations. The sources for this research were these available resources, the analysis of published reports (BVL, 2023a), and examination of raw data submitted to the BfR, which could potentially lead to some information being omitted or incompletely described in this study. Furthermore, variability was recognized as a strength of the National Monitoring (section 7.1 and 7.2), but the actual sample size may vary, especially in more detailed investigations. This became apparent in Kolbaum *et al.* (2023a) (APPENDIX II), where data for infant formulae were available for three samples of milk-based infant formulae and 24 samples of soy-based infant formulae, revealing limited information on the variability of milk-based formulae. Although most of the foods in the National Monitoring are appropriate to have a fair chance of including samples with higher concentrations on the market, the sampling is not able to represent market conditions (as conventional or organic production, typical shopping venues etc.) or consumer behaviour. This has been identified as one of the main limiting factors of the National Monitoring data (Kolbaum *et al.*, 2022; Kolbaum *et al.*, 2023a) (APPENDIX I, APPENDIX II) (section 7.1 and 7.2). Therefore, the proposed scheme for a joint application of both programmes (Figure 7) has to take into account that the data derived from the National Monitoring will still lack representativeness if the National Monitoring data are used for

exposure assessment alone or in combination with data from the BfR MEAL Study. Whether and how these considerations can also be implemented in the National Monitoring should be the subject of future debate.

The data generation for the BfR MEAL Study was carried out between 2016 and 2021 (section 5.2.1) (Ptok *et al.*, 2023). It is worth noting that some of this data is now approximately seven years old. This becomes particularly significant when dealing with substances whose content might change over time due to various factors such as climatic variations, regulatory interventions, or advancements in analytical techniques. The importance of keeping data updated for accurate risk assessment was addressed in section 7.3. However, until update strategies are formally implemented, this limitation in the use of older data must be taken into consideration. Although the BfR MEAL Study was described as a comprehensive TDS covering various aspects relevant to consumers, it is not possible to consider all relevant questions. For instance, tap water from the BfR MEAL Study kitchen was used to prepare the MEAL foods (Kolbaum *et al.*, 2023a) (APPENDIX II). However, the water was found to have elevated levels of certain elements, such as copper or nickel, which can affect the exposure estimation (BfR, 2022d; Kolbaum *et al.*, 2023c). This is acceptable, since it is a more conservative approach, but is not representative for the general population. Although using tap water from the kitchen for food preparation is a commonly used approach in TDS (Dabeka & Cao, 2013; Vasco *et al.*, 2021), other TDS use tap water from the different sampling locations (D'Amato et al., 2013) or distilled water (FDA, 2022; Ingenbleek *et al.*, 2017; Muñoz *et al.*, 2005) to mitigate this influence. This limitation is substance specific, but shows that other uncertainties and limitation might arise for other use cases. Therefore, the future use of the data must unveil further limitations or possibilities for compensation with monitoring data (e.g., monitoring data for drinking water).

Both the BfR MEAL Study and the National Monitoring programme may not encompass specific scenarios or situations. This includes exposures resulting from specific situations, such as local conditions (e.g., polluted sites), individual preparation methods (e.g., non-stick cookware) or specific diets (e.g., vegan). Such data gaps must be identified and respective research questions need to define which programme is most appropriate to fill the data gap. In addition, substance specific factors might limit the choice between the programmes. The National Monitoring only analyses raw or simply

processed foods (Kolbaum *et al.*, 2022; Kolbaum *et al.*, 2023a) (APPENDIX I, APPEN-DIX II). This means that substances sensitive to processing methods, such as acrylamide, food additives, or plasticizers, may not be adequately captured by this approach. Nevertheless, certain monitoring activities have already tackled these substances in specific projects. For example, the BVL reported data on acrylamide in some industrially processed snacks and bakery products (BVL, 2023b). However, this did not include preparation in restaurants or at home. This, in turn, was reflected in the BfR MEAL Study by differentiating the MEAL pools between different preparation methods and degrees of browning, e.g., deep-frying or baking French fries (Ptok *et al.*, 2023).

The inherent variability of substances in food can also impact the applicability of the TDS design. The strategy of pooling subsamples into a single TDS composite food was tested with varying assumptions regarding the variability of the true mean substance levels. It was found that a minimum of 15 subsamples had a limited impact on the 95% confidence interval (Sirot *et al.*, 2009). According to the basic module of the BfR MEAL Study, an unstratified MEAL food comprised 20 subsamples, while a stratified MEAL food could consist of as many as 150 subsamples (Kolbaum *et al.*, 2022) (APPENDIX I). This approach ensures a comprehensive consideration of variable substance levels. However, there are substances for which an adapted sampling was applied to account for inhomogeneity within and between foods. For instance, mycotoxin sampling involved collecting at least three individual foods for each subsample, amounting to a minimum of 1.5 kilograms, which were then combined into one composite sample (Ptok *et al.*, 2023). Likewise, for pharmacologically active substances, a modified procedure, distinct from the pooling approach, was adopted. This decision was made to prevent excessive dilution effects on the occurrence of these substances in composite samples. As a result, 60 individual foods were sampled per food matrix and analysed separately for substance residues. In cases where quantifiable results were obtained, the samples were prepared according to typical kitchen procedures, and the impact of food preparation was assessed (Ptok *et al.*, 2023). These examples highlight that not every substance is suitable for inclusion in both of the programmes. However, these instances also illustrate that programme modifications can enhance data generation, and even hybrid approaches, as seen with pharmacologically active substances, are feasible. The exploration of such modifications and hybrid strategies should be considered for future implementation.

Section 7.3 had pointed out the dependency of the dietary exposure assessment on food consumption data. Therefore, it must be clearly stated that a key limitation in the proposed future concept of food safety lies in the dependence on current and high-quality food consumption data. RQ3 (Kolbaum *et al.*, 2023b) (APPENDIX III) demonstrated the adaptability of the BfR MEAL food list to incorporate new food consumption data. However, the VELS food consumption survey of children was updated about 15 years later by the KiESEL study (Banasiak *et al.*, 2005; Nowak *et al.*, 2022a; Nowak *et al.*, 2022b), while the most recent available data for adults were raised in 2005/006 in the NVS II (Brombach *et al.*, 2006; Krems *et al.*, 2006) restricting the significance of the data for current assessments or food selection for the TDS food list. This was also seen in EFSA opinions where not only limited occurrence data, but also low numbers of consumers or unspecified consumption events necessitated aggregation to higher food categories (EFSA, 2012a). Consequently, the effective integration of dietary exposure assessments into routine occurrence data collection must be accompanied by corresponding strategies for updating food consumption data or leveraging alternative data sources (e.g., official statistics, targeted consumer surveys or market share data).

Finally, it is important to note that the results presented in this study relate to the specific context of Germany. Consequently, the transferability of these findings to other food safety systems is limited. Nevertheless, these findings provide valuable insights and can serve as important directions for the establishment or improvement of food safety systems with regard to the collection of occurrence data on substances in food.

8 CONCLUSION & OUTLOOK

This study represents the first comprehensive exploration of a unified approach to using TDS and food monitoring data within a joint food safety system. Comparing the implementation of the BfR MEAL Study and the National Monitoring in Germany, it becomes evident that the purpose of each programme ultimately determines its characteristics and subsequent applications in risk assessment and food safety.

The National Monitoring is primarily designed to verify maximum levels in food and focuses its resources on regulated food/substance combinations. Single-unit analyses provide substance distributions in individual foods, which are essential for short-term exposure assessments, consumer loyal scenarios, or to address foods not included or differentiated in the MEAL food list. However, their limitations in completeness and representativeness, especially with regard to consumer behaviour, as well as partially too high LORs, restrict their applicability for estimating long-term and total dietary exposure. In contrast, the design of the BfR MEAL Study is driven by the food consumption of the German population, taking into account consumption patterns, market shares and consumer behaviour. This makes it highly suitable for long-term dietary exposure assessment. The inclusion of almost the entire diet and lower, more consistent LORs further enhance its potential to reduce uncertainties in exposure assessment. Furthermore, the BfR MEAL Study complemented the existing dataset from the National Monitoring by more than 100 additional substances, and for those substances that were examined in both programmes the BfR MEAL Study expands the spectrum of investigated foods and reduces uncertainties by the consideration of table-ready foods. A practical case study comparing long-term cadmium exposure using both datasets gave evidence of the potential of the BfR MEAL Study to reduce uncertainties in long-term dietary exposure assessment compared to the National Monitoring and thus provides more reliable estimates for risk assessment. The initial substantial investment in the MEAL food list has further proven to be a robust 'backbone' for representative and comprehensive sampling, facilitating resource-efficient updates in response to potential developments in food safety.

For the TDS approach it could be demonstrated that an update of the food list triggered by more recent food survey data is possible with comparatively low effort. However, food safety is a complex system, sensitive to changes in consumer behaviour, techno-

logical advances, trade and the environment. Those changes are foreseen to be addressed in a national programme to monitor food consumption that is designed to provide updates in food consumption at much shorter intervals as in the past (MRI, 2024). Consequently, also the food lists of the BfR MEAL Study and the National Monitoring need to be coordinated with the updates of the food surveys in terms of timing. Moreover, strategies to adapt rapidly to these changes and to monitor their impact on public health are therefore essential. The integration of two systems addressing different aspects of dietary exposure and consumer health represents an innovative step forward in establishing a data toolbox that enables a rapid response to potential risks. This work has demonstrated that both programmes, due to their objectives and focus, address different aspects of dietary exposure assessment. In addition, the results underline that the aspects of the TDS approach have not previously been covered in German risk assessment. By enabling more realistic exposure assessments and cost-effective data maintenance, the BfR MEAL Study complements the characteristics of the National Monitoring, advancing toward a comprehensive and inclusive food safety system in Germany. Future work will further elaborate and prioritise the next steps towards a more aligned direction of both programmes.

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APPENDIX I

Supplementary material accessible at https://doi.org/10.1016/j.fochx.2022.100240
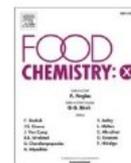
Collection of occurrence data in foods – The value of the BfR MEAL study in addition to the national monitoring for dietary exposure assessment

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A B S T R A C T

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

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 above-mentioned 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.
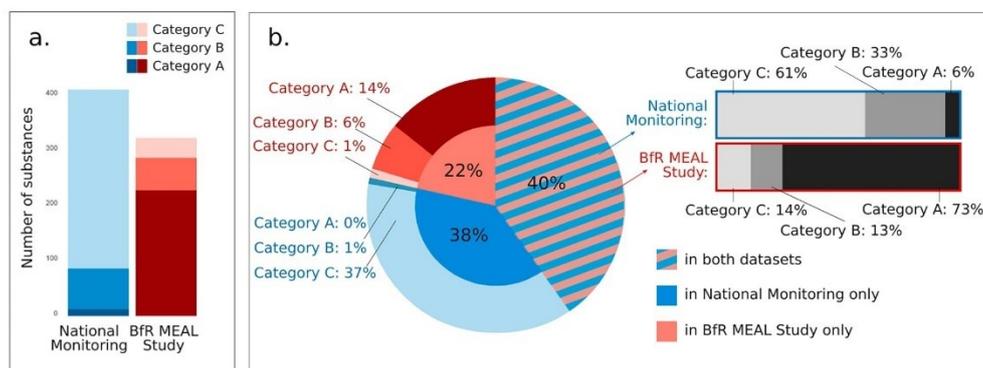
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Fig. 1. Distribution of substances grouped by the number of foods analysed within the National Monitoring (2011–2019) and the BfR MEAL Study (2016–2021). (a) Total number of substances in the datasets allocated to categories A (n foods: > 100), B (n 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

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

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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 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.

| No.	Main Food Group	Cadmium				PCB 126				Iodine			
		BfR MEAL Study		National Monitoring		BfR MEAL Study		National Monitoring		BfR MEAL Study		National Monitoring	
		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*

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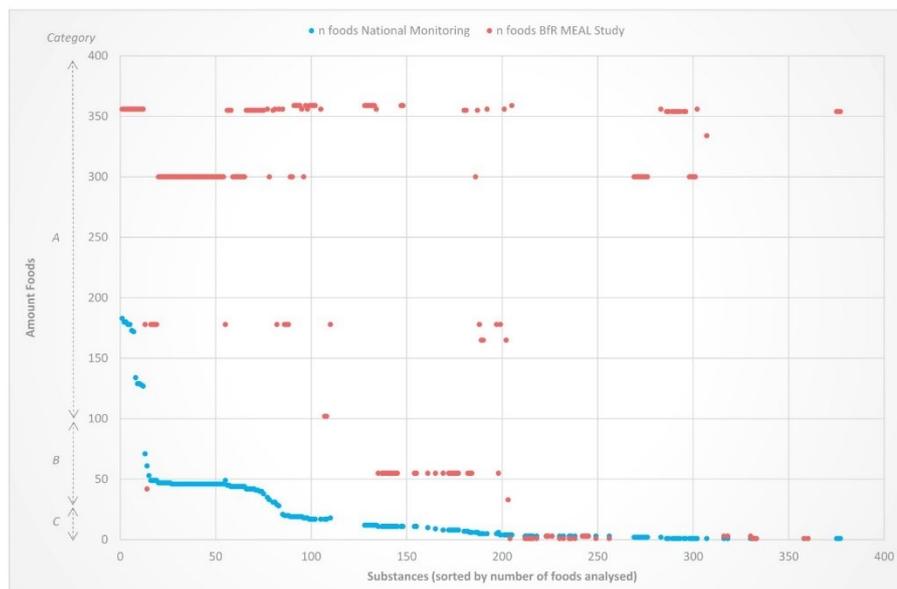
Fig. 2. Categorisation of substances analysed in the National Monitoring (2011–2019) as well as in the BfR MEAL Study (2016–2021) according to the number of foods analysed. Category A: n foods > 100, category B: n foods 25 – 100, category C: n foods < 25.

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

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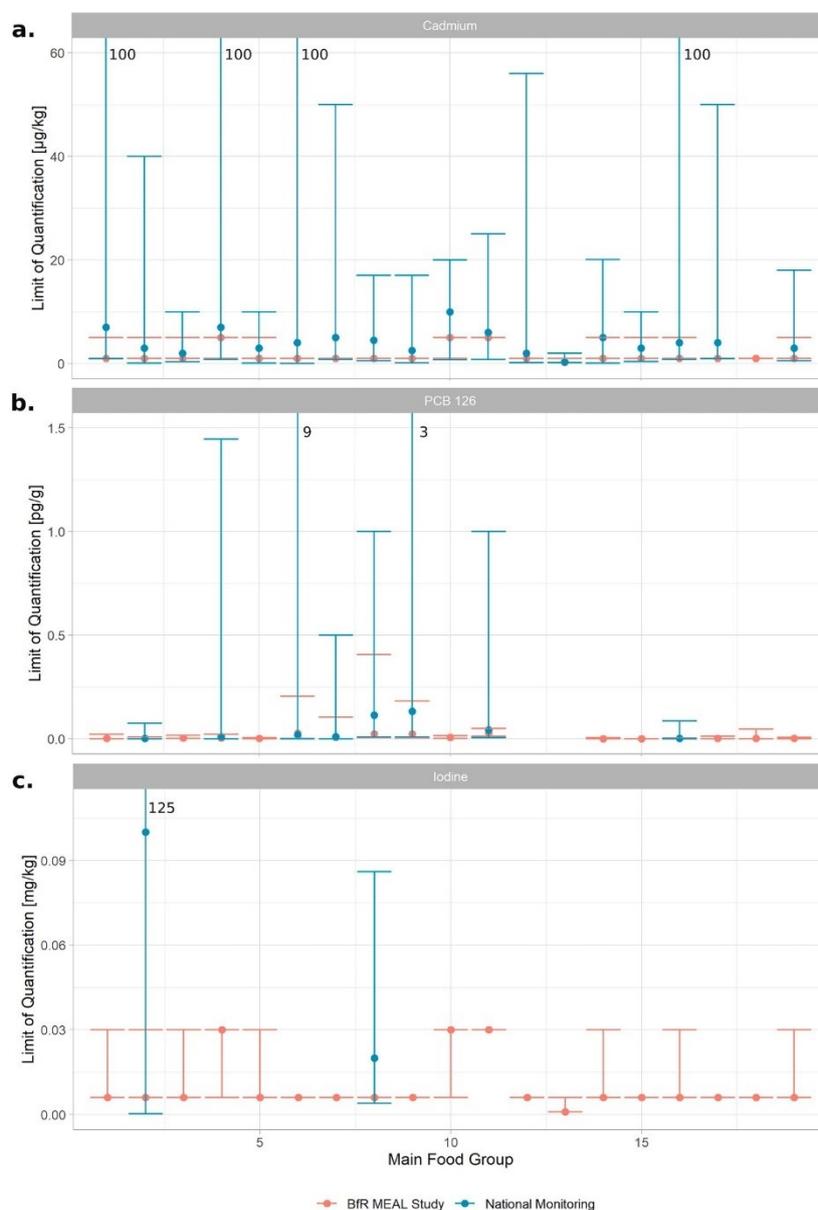
Fig. 3. Limits of quantification (LOQs) for (a) cadmium, (b) PCB 126 and (c) iodine reported for the measurements in the National Monitoring (2011–2019) and the BfR MEAL Study (2016 – 2021). Shown are the minimum and maximum LOQs distributed over main food groups. Dots indicate median LOQs.

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

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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 over-estimation 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,

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[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)

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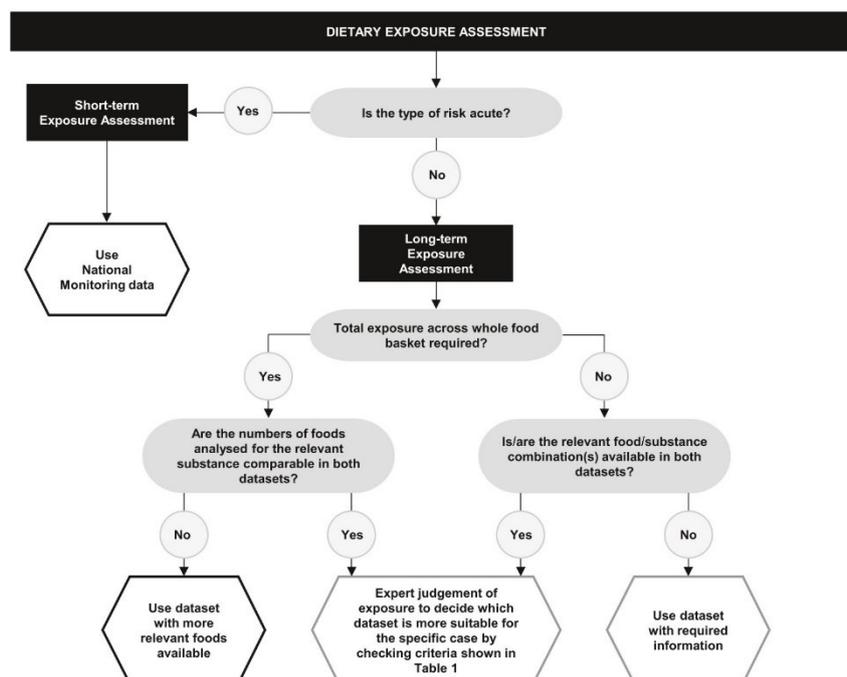
Fig. 4. Conceptual decision scheme on the choice between the application of BfR MEAL Study data or National Monitoring data in dietary exposure assessment.

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.

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

Supplementary data to this article can be found online at https://doi.org/10.1016/j.fochx.2022.100240.

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APPENDIX II

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Assessment of long-term dietary cadmium exposure in children in Germany: Does consideration of data from total diet studies reduce uncertainties from food monitoring programmes?

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ABSTRACT

Total diet studies (TDS) and food monitoring programmes are different approaches for collecting occurrence data on substances in food. This case study evaluated the practical applicability of TDS data (BfR MEAL Study) and monitoring data for the assessment of long-term cadmium exposure in children in Germany. Cadmium data from both programmes were combined with food consumption data from the KiESEL study. Uncertainties associated with both assessments were systematically described. Using monitoring data resulted in cadmium intakes approximately 3 times higher than the use of BfR MEAL Study data. Incomplete data and neglect of market shares and consumption weights were considered by conservative data adjustments to the monitoring data and mainly explain the higher estimates. Fewer data adjustments were necessary for BfR MEAL Study data, which covered almost the entire diet and considered consumer behaviour during sample collection and sample preparation. In sum, the use of the BfR MEAL Study data resulted in less uncertainty and more reliable exposure estimates for chronic assessments over the entire diet. However, description of variability and upper tails of substance distributions in food remain essential features of monitoring data. The integration of both programmes into a complementary system further improves food safety.

1. Introduction

Exposure assessment in relation to defined health-based guidance values is an important step within the risk assessment framework and for evaluating food safety, as it determines the level of the potential risk and the measures to be taken (FAO/WHO, 2023). Accordingly, the quality of the input data and the accuracy of the exposure estimate are crucial for the development of appropriate risk management decisions.

In general, all EU Member States are legally obligated to establish monitoring programmes to detect and prevent the presence of potentially harmful substances, to ensure compliance with regulatory limits, and guarantee protection of human health (Regulation (EU) 2017/625). Monitoring programmes are mainly characterised by food/substance selection based on regulatory demands, sampling of raw (raw agricultural commodities, RAC) or unprocessed products and single food analysis (BfR, 2016; Harms and Wend, 2016). In Germany, the food monitoring, referred to as 'National Monitoring' in the following, has been implemented since 1995 (Harms and Wend, 2016).

Beside from monitoring programmes, total diet studies (TDS) emerged as a recommended tool for collecting background occurrence data on substances in food (EFSA/FAO/WHO, 2011). TDS are characterised by assessing foods which cover >90 % of a population's usual diet, analysing foods 'as consumed' and pooling similar foods to composites samples prior analysis in a cost-effective approach (EFSA/FAO/WHO, 2011). Germany implemented its first full-scale TDS – the BfR MEAL Study – in 2016 (Sarvan et al., 2017).

To the best of our knowledge, Germany is pioneering in establishing an integrated system that combines both food monitoring and TDS for comprehensive risk assessment purposes. The opportunities, challenges, and potential complementary strategies of both programmes were highlighted in detail elsewhere (Kolbaum et al., 2022). The National Monitoring was described to have its particular strength in the description of the variability of substance levels in foods. In terms of

Abbreviations	
BfR	Bundesinstitut für Risikobewertung [German Federal Institute for Risk Assessment]
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit [Federal Office of Consumer Protection and Food Safety]
EFSA	European Food Safety Authority
LB	Lower bound
LEBTAB	Lebensmitteldatenbank
LOD	Limit of detection
LOQ	Limit of quantification
MAT	Moving annual total
NVS II	National Nutrition Survey II
mLB	Modified lower bound
NFS	Not further specified
RAC	Raw agricultural commodities
TDS	Total diet study
TWI	Tolerable weekly intake
UB	Upper bound

dietary exposure assessment, it is therefore particularly useful for short-term assessments and evaluating exposure related to specific consumer preferences (e.g., brand-loyalty). On the other hand, the BfR MEAL Study has its strength in representativeness and is well-suited for assessing long-term dietary exposure, due to the consideration of total food consumption and reflecting consumer behaviour in every step of the sample collection and sample preparation (Kolbaum et al., 2022).

Leveraging the strengths of both programs could enhance food safety (Kolbaum et al., 2022), but the systematic implementation of both programmes is a new endeavour. Up to now, the determination of their respective strengths and limitations is primarily based on theoretical considerations (BfR, 2016; Kolbaum et al., 2022). In order to transfer these considerations into practice, this case study examined the long-term dietary exposure to cadmium in children in Germany as an example for dietary contaminants using both, the National Monitoring data and the BfR MEAL Study data. Since short-term exposure assessments are only possible with monitoring data, this comparison only concerns the differences for long-term exposure. The underlying working hypothesis was that estimates based on a TDS such as the BfR MEAL Study are associated with less uncertainty for long-term dietary exposure assessment and are therefore more reliable compared to estimates based on the National Monitoring data. This was broken down to three sub-hypotheses:

1) The BfR MEAL Study data achieves a higher coverage of food consumption than the National Monitoring.
2) Extrapolation from foods investigated in the National Monitoring to consumed foods is associated with considerable uncertainties.
3) Uncertainties due to left-censored data[3] are lower for the BfR MEAL Study.

2. Material & methods

2.1. General procedure

Long-term total dietary exposure to cadmium in children (0.5-<6 years) in Germany was assessed in one estimate based on data from the BfR MEAL Study and in a second estimate based on data from the

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[3] Measurements below an analytical reporting limit, that cannot be quantified.

National Monitoring. This age group was selected as an example population due to their higher food consumption relative to body weight compared to adults, making them the most sensitive population. Cadmium was chosen as example element, since it was one of the most frequently analysed substances in the National Monitoring, and it can be reasonably assumed that the uncertainties associated with the other substances included in the National Monitoring are either similar or greater (Kolbaum et al., 2022).

At the same time, a scenario representing a timeframe from the typical working routine for a risk assessor was adopted, where typically the assessment must be provided within a tight timeframe in order to initiate immediate measures. Therefore, for this particular example, only the data available from the two programmes was utilized, and data adjustments were kept to a minimum.

2.2. Food consumption data

Information on food consumption was based on data from the Children's Nutrition Survey to Record Food Consumption (KiESEL study) which was conducted between 2014 and 2017 in Germany. Details on methods and the study population were published elsewhere (Nowak et al., 2022a, 2022b). In brief, the consumption records of 1,008 children between 0.5 and <6 years of age were collected by means of dietary records on three consecutive and one non-consecutive days. The food records were completed by the parents or carers as a weighing or estimation record documenting next to date, time and place of consumption several facets of the food, such as brand, fat content, fortification, organic/conventional, packaging or preparation (Nowak et al., 2022a, 2022b). The food entries were recorded according to standard operating procedures in the EATv3 software adapted specifically for KiESEL (Nowak et al., 2022b) and coded according to the system of the German Nutrient Database (Bundeslebensmittelschlüssel; BLS) (Hartmann et al., 2006; MRI, 2023; Nowak et al., 2022b) and the food database LEBTAB (Lebensmitteldatenbank) which was provided by the University of Bonn. For relating the consumption to body weight, the individually reported body weights were used. The present exposure assessment considered only non-breastfed children (n = 952).

Even if the same nutrition survey data underlies for both assessments, food consumption data were available in two formats. The first dataset included all foods 'as reported', while the second dataset partially 'disaggregated' dishes, providing information at ingredient-level. However, it should be noted that this disaggregation was applicable only to the dishes for which participants (or legal guardians) submitted a recipe (approximately 6 % of the BLS codes). This dataset therefore includes partly recipes and partly disaggregated foods or dishes.

2.3. Occurrence data

2.3.1. BfR MEAL Study

2.3.1.1. Sampling & analysis. The BfR MEAL Study is the first German full-scale TDS coordinated and run by the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung; BfR). Details on the methodology were described previously in Sarvan et al. (2017). Occurrence data on cadmium were published in Fechner et al. (2022) and Ptok et al. (2020). In brief, the food list for the BfR MEAL Study was developed by evaluating the food consumption data from representative samples of adults (14–80 years) from the National Nutrition Survey II (NVS II) (Krems et al., 2006) and a previous representative study in children from 2001 to 2002 (VELS study, age: 0.5-<5 years) (Banasiak et al., 2005). Consumed foods were categorised into 19 main food groups according to the European Food Safety Authority (EFSA) food classification and description system FoodEx2. Prerequisite of the selection of foods for subsequent substance analyses was to ensure

coverage of at least 90 % of the diet (g/kg body weight per day) within each main food group and include foods potentially contributing to exposure due to high contamination although less consumed. A total of 356 foods were finally chosen to be purchased and prepared in their consumed form for analysis (referred to as *MEAL food* in the following). Each MEAL food was composed of 15–20 single food items (so called *subsamples*). Sampling for element analysis occurred between 2017 and 2019, taking into account market shares and information about consumer shopping behaviours. For relevant foods, considerations were made for seasonal variations (import and national production season; or stable and pasture season) or regional variations (north, east, south, west), and potential differences between production types (organic or conventional). As a result, 869 pooled samples were obtained and subsequently analysed for cadmium content (Fechner et al., 2022). For drinking water, only analytical results from the MEAL kitchen were included, since this water was also used for food preparation. Given that the larger proportion of parents still tend to offer their children conventional foods (Nowak et al., 2022b), this assessment focused on conventional samples. Excluding regional drinking water samples and organic samples reduced the total amount of considered pooled samples (subsamples) from 869 (13,552) to 723 (11,362).

Analysis of cadmium was performed by an accredited contract laboratory using inductively coupled plasma mass spectrometry (ICP-MS). Limits of detection (LOD) were 0.0003 mg/kg (moist foods) or 0.002 mg/kg (dry foods) and limits of quantification (LOQ) were 0.001 mg/kg or 0.005 mg/kg for moist or dry foods, respectively. For drinking water, LOD was 0.00007 mg/kg and the LOQ 0.0002 mg/kg (Fechner et al., 2022) (Supplementary Table S1). Cadmium levels on main food group level or on MEAL food level were calculated as arithmetic mean of the respective pooled samples. For left-censored data, the modified lower bound (mLB) and the upper bound (UB) approach were applied. In the mLB approach, left-censored measurements were substituted with zero if reported as < LOD and with the corresponding LOD when reported as < LOQ. In the UB approach, left-censored measurements were replaced with the corresponding LOD if reported as < LOD and with the corresponding LOQ, if reported as < LOQ.

2.3.1.2. Dietary cadmium exposure assessment. For long-term dietary exposure assessment with BfR MEAL Study data, the cadmium levels from the MEAL foods were matched to the 'as reported' KiESEL dataset since both datasets were measured or reported at the same food level ('as eaten') and only few adaptations were required. These were the application of processing or conversion factors in few cases (e.g., converting sweetened tea to tea with sugar) or the application of standard recipes in cases a dish needed to be broken down to its components (e.g., separating spaghetti bolognese to 'pasta' and 'sauce with meat') in those cases without participant information on the exact recipe. Standard factors and recipes were derived from the BLS system (Hartmann et al., 2006; MRI, 2023) or from information available on product packaging.

The method for estimating total dietary exposure was previously described in detail (Kolbaum et al., 2023b). Briefly, the mean occurrence data of each MEAL food were linked to the respective daily average consumption (g/kg bw/day) from the KiESEL study at individual level using the following general equation (Arnich et al., 2012; WHO/FAO, 2020):

$$E_{i,j} = \sum_{k=1}^{n} \frac{C_{i,k} * L_{k,j}}{BW_i}$$

where $E_{i,j}$: exposure to contaminant j for subject i; $C_{i,k}$: food consumption of the food k by subject i; $k = 1$ to n: n is the total number of foods consumed by the subject i; $L_{k,j}$: level of substance j in the food k; BW_i: body weight of subject i.

Matching was performed according to the approach 1 adjustment strategy for new food consumption data on an existing TDS food list as described in Kolbaum et al. (2023a). Using this procedure, the consumed

items were aggregated and matched according to the existing foods defined in the MEAL food list. Consumed foods without a matching counterpart were excluded. This approach was considered acceptable given that the MEAL food list covers 94 % of the overall diet (Kolbaum et al., 2023a), accomplishing with the overall TDS goal of achieving at minimum 90 % of coverage (EFSA/FAO/WHO, 2011). Where MEAL foods were distinguished between regions, exposure was refined by matching the regional occurrence to the food consumption of subjects living in this region. Where MEAL foods were distinguished between seasons, the mean of the two seasons was used.

Long-term dietary cadmium exposure in the age groups 0.5 - <1 year, 1 - <3 years and 3 - <6 years was calculated as μg per kg body weight and week (μg/kg bw/week) and compared to the tolerable weekly intake (TWI) of 2.5 μg/kg bw/week (EFSA, 2009). Output parameters are the median (P50) to describe average exposure and the 95th percentile (P95) for high exposure. Estimates were done for the mLB and UB approach according to the handling of the left-censored data.

2.3.2. National Monitoring

2.3.2.1. Sampling & analysis. The National Monitoring programme in Germany is described in Harms and Wend (2016) and Kolbaum et al. (2022). In brief, a prescribed food basket is sampled in a five-year monitoring cycle. Food selection is based on representative national food consumption surveys, as suggested by Sieke et al. (2008a, 2008b), who proposed a food list covering more than 80 % of the average consumption of children between 0.5 and <5 years (VELS study). Substances to be analysed per food are defined according to expected contamination, regulatory demands and resources. In principle, sampling is carried out at RAC level (e.g., spelt grains) or 'as purchased', i.e., the pasta is analysed dry or the meat is analysed raw. In contrast to the TDS approach, food samples are measured at the individual level. The responsibility for sample collection and analysis lies with the Federal States of Germany, while the coordination is down to the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit; BVL).

For the present evaluation, cadmium data from the two latest monitoring cycles were used (2011–2015 and 2016–2020). Analytical methods could not clearly be determined from the datasets. After data cleaning, the final dataset comprised 19,229 measurements. LODs ranged between zero (not indicated LODs were set to zero) and 0.5 mg/kg. LOQs ranged between zero (not indicated) and 1 mg/kg (Supplementary Table S2). In 139 cases, a quantified value was indicated, although the measurement was below the limit of reporting. In these cases, the corresponding LOD or LOQ was assigned.

Foods were aggregated to the lowest aggregation level possible. This was in most cases a single food (e.g., 'chicken meat'). For cases when the match on single food level failed or sample size was too small, it was checked whether there were foods available that can be considered to have comparable cadmium concentrations within the next aggregation level. For instance, "Fungi (dry)" was aggregated from the reported foods "cultivated and wild mushroom mixtures (dry)" (n = 46), "cultivated mushroom mixtures" (n = 7), and "wild mushroom mixtures (dry/powder)" (n = 14). The final dataset for the National monitoring comprised of 159 food matrices (referred to as '*Monitoring foods*'), which were also assigned to the FoodEx2 main food groups according to the BfR MEAL Study procedure.

The cadmium occurrence data were evaluated using the mLB or UB approach as already described for the BfR MEAL Study data (section 2.3.1.1). For the presentation of the cadmium levels, the contents were averaged per main food group or per Monitoring food.

2.3.2.2. Dietary cadmium exposure assessment. The estimation of total dietary cadmium exposure for children of the KiESEL study based on National Monitoring followed the same basic principle as for the BfR

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MEAL Study (section 2.3.1.2), i.e., mean cadmium levels of Monitoring foods were matched with daily average food consumption at individual level. In contrast to the BfR MEAL Study data, the Monitoring foods were matched to the 'disaggregated' consumption dataset of the KiESEL study, since the disaggregated foods were more likely to match the unprocessed or semi-processed foods as measured in the National Monitoring (see section 2.2). No regional, seasonal or production type specific sampling was considered, since this information was not systematically available from the monitoring. Only foods having at minimum 15 samples were matched. This complies with the strategy, that a MEAL food is composed of at least 15 subsamples.

Two types of matching were applied to link occurrence with consumption data. In the direct matching, the Monitoring foods were linked as much as possible to identical foods from the KiESEL study (e.g., matching the consumption of 'fresh whole milk 3.7%' to the average cadmium level of 'cow milk'). When no direct match was available, additionally an indirect matching was applied. The indirect match enabled to increase coverage of the total diet. This is a commonly applied approach in case of incomplete data (Boon et al., 2017; EFSA, 2020). For the indirect matching aggregation to higher food hierarchies and application of processing or conversion factors was used. Foods were aggregated to main food group level, in cases where no specific cadmium value was available for the corresponding consumption record. For example, if there was no data available for consumption of 'vegetarian sausage', the average cadmium level of the main food group 'Products for non-standard diets and food imitates' was applied. In some cases, a lower aggregation level was chosen, e.g., the cadmium value of soya drink was applied to all plant-based drinks instead of the group mean value of the main food group 'Products for non-standard diets, food imitates'. When substitute levels were assigned to a food during indirect matching processing factors and food conversion factors were applied if relevant. Processing factors were applied where the alignment between consumption and occurrence data was necessary (e.g., conversion from dry foods to cooked foods, such as pasta or rice). Factors were available from the German Nutrient Database (BLS) (Bognár, 2002; Bognár and Piekarski, 2000; Hartmann et al., 2006; MRI, 2023) or from a collection used for plant protection product assessments (BfR, 2023a). Food conversion was applied in the main food group 'Grains and grain-based products', since only data for grains and their milling products was available (with exception of 'Dried durum pasta') and the consumption data mainly documented consumption of processed products such as bread, cakes, mueslis etc. Those consumption entries without direct cadmium measurement were categorised into three categories: grain milling products (e.g., oat bran), processed cereal products (e.g., cakes) and mueslis. For each category, one processing factor was defined and applied to all foods of this category. No further conversions or breakdown of recipes into ingredients was performed. Since the processing factors were selected in a conservative way (e.g., all grain milling products was assigned the factor from grain to groats (0.99) irrespectively if the main application was white flour), this procedure was considered as conservative enough to cover this uncertainty. The selection of conservative factors is a commonly applied approach to cover uncertainties (EFSA, 2018; Kettler et al., 2015). No further processing factors for cooking of foods (e.g., leaching of cadmium during cooking of potatoes) was applied, due to the diverse application of cooking and preparation methods. No cadmium measures were available for the main food groups 'Composite dishes' and 'Major isolated ingredients, additives, flavours, baking and processing aids'. The latter made up for <0.1 % of the total consumption and was neglected. In a conservative approach, consumption records from the group 'Composite dishes' were matched to the value of the main food group with the highest mean cadmium level, namely 'Sugar and similar, confectionery and water-based sweet desserts'.

2.4. Uncertainty analysis

In order to understand and compare the strength and limitations of the two exposure estimates an uncertainty analysis was performed following the BfR Guidance on Uncertainty Analysis in Exposure Assessment (BfR, 2022). Exposure scenario, exposure model, parameters of the exposure model, and method of exposure assessment were considered as sources of uncertainty. Identified uncertainties were classified as having 'small', 'medium' or 'large' impact together with the direction of their impact (under- or overestimation).

2.5. Statistical analysis

The statistical software R version 4.2.1 (R Foundation for Statistical Computing, Vienna, Austria) and Microsoft Office Excel 2016 (Microsoft Corporation, Redmond, WA, USA) were used for all calculations.

3. Results

3.1. Occurrence data

Table 1 and Table 2 show the cadmium contents on main food group level derived from the BfR MEAL Study and the National Monitoring, respectively. Thirty percent of the BfR MEAL Study samples and 52 % of the National Monitoring samples could not be quantified. The difference between mLB and UB values was small in both datasets, although the range between minimum and maximum was wider in the National Monitoring. In the BfR MEAL Study highest mean values were found in the main food groups 'Coffee, cocoa, tea and infusions', 'Legumes, nuts, oilseeds and spices', 'Vegetables and vegetable products' and 'Starchy roots or tubers and products thereof'. In the National Monitoring highest mean values were also found in the main food groups 'Vegetables and vegetable products' and 'Legumes, nuts, oilseeds and spices', with cadmium levels four- or two-times higher compared to the BfR MEAL Study measurements. However, the food group with the highest cadmium average was 'Sugar, confectionery and water-based sweet desserts' having cadmium average 13-times higher than the BfR MEAL Study average.

The top 10 foods with highest cadmium contents are displayed in Table 3 and Table 4. In the BfR MEAL Study, these were different vegetables (mushroom, algae, and spinach), cocoa powder, oilseeds, kidney and seafood. According to National Monitoring, the top 10 foods were also mainly represented by algae and mushrooms, offal, oilseeds and cocoa containing foods. In contrast to the BfR MEAL Study, spinach was not among the top 10, but the National Monitoring found a comparable level of 0.079 mg/kg (Supplementary Table S3). However, data were not directly comparable, since the BfR MEAL Study samples were prepared and already weighted according to market shares or consumption (Fechner et al., 2022; Sarvan et al., 2017). Other samples are not comparable since they were not analysed in one of the two programmes. For instance, 'squid/octopus' was not analysed in the National Monitoring, while 'wild boar liver' was not analysed in the BfR MEAL Study.

3.2. Long-term dietary exposure

According to the BfR MEAL Study, children had a median cadmium intake of 2.3 μg/kg bw/week or lower, which was at maximum 93 % of the TWI (Table 5). In all age classes, high exposure (P95) exceeded the TWI with cadmium intakes up to 3.7 μg/kg bw/week. Based on the National Monitoring data, a median cadmium intake of 8.0 μg/kg bw/week or lower was estimated. This was not only about 3-times higher compared to the BfR MEAL estimate, but also already exceeded the TWI. The high exposure estimates (P95) were about 4-times higher compared to the BfR MEAL Study assessment.

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Table 1
Cadmium contents of main food groups from the **BfR MEAL Study**. Table shows the whole range of available data before matching to food consumption.

Main Food Group	N foods[a]	n samples (food pools)[b]	% LC[c]	Cadmium content [mg/kg] mLB				Cadmium content [mg/kg] UB			
				min	median	mean	max	min	median	mean	max
Grains and grain-based products	40	1315 (82)	8	0	0.015	0.017	0.066	0.002	0.015	0.018	0.066
Vegetables and vegetable products	34	2006 (132)	13	0	0.004	0.023	0.320	<0.0005	0.004	0.023	0.320
Starchy roots or tubers and products thereof	8	290 (18)	0	0.007	0.015	0.023	0.072	0.007	0.015	0.023	0.072
Legumes, nuts, oilseeds and spices	20	380 (20)	25	0	0.009	0.032	0.265	0.001	0.009	0.033	0.265
Fruit and fruit products	22	830 (52)	60	0	<0.0005	0.002	0.011	<0.0005	0.001	0.002	0.011
Meat and meat products	35	1338 (85)	42	0	0.001	0.010	0.113	<0.0005	0.001	0.010	0.113
Fish, seafood and invertebrates	30	720 (39)	18	0	0.004	0.017	0.205	<0.0005	0.004	0.017	0.205
Milk and dairy products	23	430 (23)	70	0	<0.0005	0.001	0.006	<0.0005	0.001	0.001	0.006
Eggs and egg products	2	120 (8)	100	0	0	0	0	<0.0005	0.000	0.000	0.000
Sugar, confectionery and water-based sweet desserts	15	285 (15)	40	0	0.008	0.015	0.110	0.002	0.008	0.016	0.110
Animal and vegetable fats and oils	8	130 (8)	100	0	0	0	0	0.002	0.002	0.002	0.002
Fruit and vegetable juices and nectars	10	190 (10)	80	0	0	<0.0005	0.002	<0.0005	0.000	0.001	0.002
Water and water-based beverages	6	173 (41)	100	0	0	<0.0005	<0.0005	<0.0005	0.000	0.000	0.000
Coffee, cocoa, tea and infusions	9	165 (9)	78	0	<0.0005	0.035	0.282	<0.0005	0.001	0.035	0.282
Alcoholic beverages	8	145 (8)	100	0	0	0	0	<0.0005	0.000	0.001	0.002
Food products for infants and toddlers	11	200 (11)	18	0	0.008	0.008	0.021	<0.0005	0.008	0.008	0.021
Products for non-standard diets and food imitates	7	135 (7)	0	0.001	0.011	0.011	0.026	0.001	0.011	0.011	0.026
Composite dishes	52	2160 (136)	2	<0.0005	0.008	0.010	0.069	0.001	0.008	0.010	0.069
Seasoning, sauces and condiments	16	350 (19)	25	0	0.004	0.006	0.033	<0.0005	0.004	0.007	0.033
SUM	356	11362 (723)	30								

[a] N foods: number of MEAL foods (e.g., 'carrot').

[b] n samples: The number of samples indicates the total number of subsamples contained in the pooled samples (e.g., the MEAL pool 'carrot, from region east, conventional' is composed of 15 subsamples). Number of food pools (MEAL pools) is given in parenthesis (e.g., the MEAL food 'carrot' is divided into five MEAL pools of different regions, seasons or production type).

[c] LC: Left-censored; refers to the number of pooled samples <LOD/LOQ. A pooled sample was determined as LC if all measurements (e.g., duplicate determinations) were <LOD/LOQ. mLB: modified lower bound UB: upper bound.

Table 2
Cadmium contents of main food groups from the **National Monitoring**. Table shows the whole range of available data before matching to food consumption.

Main Food Group	N foods[a]	n samples[b]	% LC[c]	Cadmium content [mg/kg] mLB				Cadmium content [mg/kg] UB			
				min	median	mean	max	min	median	mean	max
Grains and grain-based products	15	1999	21	0	0.021	0.026	0.418	<0.0005	0.022	0.028	0.418
Vegetables and vegetable products	33	4104	27	0	0.006	0.095	6.330	0	0.007	0.096	6.330
Starchy roots or tubers and products thereof, sugar plants	1	122	10	0	0.014	0.017	0.119	0.001	0.014	0.017	0.119
Legumes, nuts, oilseeds and spices	20	2463	30	0	0.017	0.071	7.210	<0.0005	0.017	0.073	7.210
Fruit and fruit products	17	1630	83	0	0	0.002	0.103	<0.0005	0.002	0.004	0.103
Meat and meat products	18	2678	67	0	0	0.018	1.660	0	0.005	0.021	1.660
Fish, seafood, amphibians, reptiles and invertebrates	13	1842	66	0	0	0.011	0.760	<0.0005	0.005	0.015	0.760
Milk and dairy products	9	1282	95	0	0	0.001	0.025	<0.0005	0.004	0.004	0.025
Eggs and egg products	1	102	100	0	0	<0.0005	0.001	<0.0005	0.002	0.003	0.008
Sugar, confectionery and water-based sweet desserts	1	127	1	0	0.202	0.210	0.900	0.008	0.202	0.210	0.900
Animal and vegetable fats and oils	7	553	97	0	0	<0.0005	0.019	<0.0005	0.006	0.008	0.025
Fruit and vegetable juices and nectars	6	732	89	0	0	<0.0005	0.012	<0.0005	0.002	0.003	0.020
Water and water-based beverages	1	136	100	0	0	0	0	<0.0005	<0.0005	<0.0005	0.002
Coffee, cocoa, tea and infusions	7	474	60	0	0	0.037	0.861	<0.0005	0.003	0.038	0.861
Alcoholic beverages	2	318	100	0	0	<0.0005	0.001	<0.0005	0.002	0.002	0.010
Food products for infants and toddlers	3	160	26	0	0.012	0.013	0.160	0.001	0.012	0.015	0.160
Products for non-standard diets and food imitates	3	348	34	0	0.005	0.008	0.039	<0.0005	0.007	0.010	0.050
Composite dishes	0	0	–	–	–	–	–	–	–	–	–
Seasoning, sauces and condiments	2	159	13	0	0.010	0.019	0.073	<0.0005	0.011	0.019	0.073
SUM	159	19,229	52								

[a] N foods: number of Monitoring foods.

[b] n samples: number of samples per Monitoring food.

[c] LC: Left-censored; refers to the number of samples <LOD/LOQ (no indication about multiple measurements (e.g., duplicate measures) was given). mLB: modified lower bound UB: upper bound.

3.3. Main contributors to dietary exposure

Main contributors to dietary cadmium exposure on main food group level differed between the BfR MEAL Study and the National Monitoring in the top two main contributors (Fig. 1). 'Grains and grain-based products' were the main contributors using BfR MEAL Study data, whereas the use of the National Monitoring data identified 'Composite dishes' as main contributors, followed by 'Sugar, confectionery and water-based sweet desserts'. The remaining contributors were the same for both programmes, however, in a different order and with different

Table 3
Top 10 foods with the highest cadmium contents in the **BfR MEAL Study**.

Food[a]	related main food group	n samples (food pools)[b]	Mean cadmium content [mg/kg][c]
Boletus/porcini mushroom	Vegetables and vegetable products	11 (1)	0.320
Cocoa powder	Coffee, cocoa, tea and infusions	20 (1)	0.282
Sunflower seeds	Legumes, nuts, oilseeds and spices	20 (1)	0.265
Squid/octopus	Fish, seafood, amphibians, reptiles and invertebrates	20 (1)	0.205
Linseeds	Legumes, nuts, oilseeds and spices	20 (1)	0.185
Kidney (Mammals)	Meat and meat products	120 (8)	0.111
Algae	Vegetables and vegetable products	20 (1)	0.120
Dark chocolate	Sugar, confectionery and water-based sweet desserts	20 (1)	0.110
Spinach [conventional][d]	Vegetables and vegetable products	30 (2)	0.084
Mussels	Fish, seafood, amphibians, reptiles and invertebrates	20 (1)	0.084

[a] Prepared; measured 'as consumed'.
[b] Total number of subsamples is given. Number of food pools is given in parenthesis. The number of samples indicates the total number of subsamples contained in the pooled samples.
[c] All quantified values. No bounds indicated.
[d] Spinach is differentiated between organic and conventional production.

Table 4
Top 10 foods with the highest cadmium contents in the **National Monitoring**.

Food[a]	related main food group	n samples[b]	Mean cadmium content [mg/kg][c]
Algae (dry)	Vegetables and vegetable products	205	1.509
Poppy seeds	Legumes, nuts, oilseeds and spices	81	0.563
Fungi (dried)	Vegetables and vegetable products	67	0.358
Wild boar liver	Meat and meat products	3	0.230
Sunflower seeds	Legumes, nuts, oilseeds and spices	108	0.213
Dark chocolate	Sugar, confectionery and water-based sweet desserts	127	0.210
Cocoa powder	Coffee, cocoa, tea and infusions	87	0.189
Kidney (Mammals)	Meat and meat products	105	0.180
Linseeds	Legumes, nuts, oilseeds and spices	165	0.173
Blue mussel	Fish, seafood, amphibians, reptiles and invertebrates	70	0.159

[a] Not prepared; measured 'as sampled'.
[b] number of samples per Monitoring food.
[c] All quantified values. No bounds indicated.

proportions.

On food level, the BfR MEAL Study data identified bread and pasta of different types, as well as potatoes, ready-to-eat mixed meal for infants and toddlers and creamed spinach as main contributors. The top 10 foods explain together about 50 % of the total dietary exposure and differ only slightly in their proportions between mLB and UB estimates (Table 6). Looking at the evaluations using the National Monitoring data, the impact of food aggregation becomes evident. Foods aggregated to main food group level are marked as 'not further specified' (NFS).

'Composite dishes; NFS' and 'Sugar, confectionery and water-based sweet desserts; NFS', were the two main contributors explaining about 60 % of the cadmium exposure. Differences between the mLB and UB approach were visible but small. In the UB approach, cow milk, and 'Milk and dairy products; NFS' appeared under the main contributors, which were not apparent under mLB assumptions.

3.4. Uncertainty analysis

All identified uncertainties for this case study are detailed in the Supplementary Table S4. The following section outlines uncertainties that have either a medium or large impact on the exposure outcome. Uncertainties with this impact were only identified in the context of National Monitoring data, which we will discuss further.

The data from the National Monitoring were incomplete regarding the consumed foods recorded in the KiESEL study. Only 38 % of the data could be mapped directly without application of assumptions or adjustments. To account for this uncertainty, conservative data processing strategies were applied to capture also the potential contribution of none-covered foods. This very likely resulted in an overestimation of exposure.

The National Monitoring data did not reflect consumption weights or market shares. Regulated, and thus higher contaminated foods were likely to be overrepresented due to the purpose of the National Monitoring (Kolbaum et al., 2022). The extrapolation of potentially higher contaminated foods to foods or food groups not covered by the monitoring could have led to overestimation of exposure.

Sample preparation in the National Monitoring did not consider processing or household preparation of foods. Only main components of recipes were matched, which may have caused either under- or overestimation. Some foods were adjusted by processing factors, which may not be accurate or representative for all possible preparations or commercial products. Conversion from grains and grain milling products to consumable foods followed a conservative strategy, which very likely caused overestimation for the main food group 'Grains and grain-based products' due to its high consumption. The extrapolation of the highest food group mean to the main food group 'Composite dishes' further added to overestimation. The possible leaching of cadmium from kitchenware into food was not considered in the National Monitoring, leading to underestimation. However, this is only relevant for users of cadmium containing utensils.

Analytical results in the National Monitoring were generated by different laboratories using different analytical methods with varying LODs and LOQs. This may have contributed to overall uncertainty. Analytical sensitivity of applied methods led to 52 % of left-censored data, which was greater compared to 30 % left-censored data of the BfR MEAL Study, resulting in a higher uncertainty range between mLB and UB estimates.

4. Discussion

Using the two different datasets for the same risk assessment task resulted in substantial different outcomes for long-term dietary cadmium exposure. Dietary exposure assessed using National Monitoring data resulted in about three times higher estimates compared to BfR MEAL Study estimates with the identification of different main contributors.

This difference in the outcome can be attributed to the associated uncertainties. In line with the three sub-hypotheses, section 3.4 revealed three main uncertainties which were mainly related to the National Monitoring assessments. These were (i) incompleteness of occurrence data, (ii) lacking representativeness in terms of consumer behaviour and (iii) the impact of analytical sensitivity.

Sub-hypothesis 1. The BfR MEAL Study achieves a higher coverage of food consumption than the National Monitoring.

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Table 5
Dietary cadmium exposure [μg/kg bw/week] and comparison with the TWI in children from the KiESEL study based on occurrence data from the **BfR MEAL Study** and the **National Monitoring**.

| | Age (years) | N | mLB | | | | | UB | | | | |
| | | | P50 | | P95 | | | P50 | | P95 | | |
			expo-sure	% TWI	expo-sure	% TWI	% N > TWI	expo-sure	% TWI	expo-sure	% TWI	% N > TWI
BfR MEAL Study	0.5 - <1	57[a]	2.1	83	3.3	132	26	2.3	93	3.5	139	37
	1 - <3	308	2.1	84	3.5	140	29	2.3	92	3.7	148	39
	3 - <6	588	1.7	67	3.0	121	12	1.8	72	3.1	126	15
National Monitoring	0.5 - <1	57[a]	4.4	176	9.3	372	87	5.3	214	11.2	448	89
	1 - <3	308	6.5	259	17.6	703	96	8.0	322	19.4	775	100
	3 - <6	588	6.7	270	15.7	630	96	7.9	316	17.0	680	99

[a] Uncertainty due to small sample size N: Number of individuals mLB: modified lower bound UB: upper bound TWI: tolerable weekly intake; 2.5 μg/kg bw/week (EFSA, 2009).
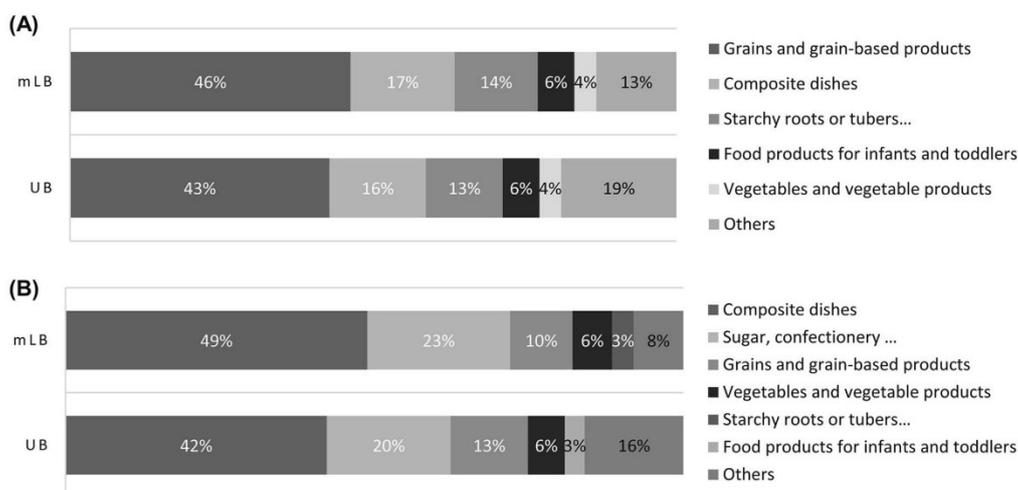

Fig. 1. Main contributors to dietary cadmium exposure (%) on main food group level (top 5) based on occurrence data from (A) the **BfR MEAL Study** and (B) the **National Monitoring**. mLB: modified lower bound UB: upper bound.

Table 6
Main contributors to dietary cadmium exposure on food level (top 10) based on occurrence data from the **BfR MEAL Study** and the **National Monitoring**.

| | mLB | | UB | |
	Food	% C.	Food	% C.
BfR MEAL Study	Wheat bread and roll, white (refined flour)	9%	Wheat bread and roll, white (refined flour)	8%
	Potatoes, peeled	7%	Potatoes, peeled	7%
	Durum pasta	5%	Durum pasta	4%
	Wheat and rye bread and roll, wholemeal	5%	Wheat and rye bread and roll, wholemeal	4%
	Rye-wheat bread (refined flour)	4%	Rye-wheat bread (refined flour)	4%
	Ready-to-eat mixed meal for infants and toddlers	4%	Ready-to-eat mixed meal for infants and toddlers	3%
	Fries/chips	4%	Fries/chips	3%
	Creamed spinach	4%	Creamed spinach	3%
	Egg pasta	3%	Egg pasta	3%
	Lye pretzel, soft	3%	Lye pretzel, soft	3%
	Others	*53%*	*Others*	*56%*
National Monitoring	Composite dishes; NFS	49%	Composite dishes; NFS	42%
	Sugar, confectionery and water-based sweet desserts; NFS	16%	Sugar, confectionery and water-based sweet desserts; NFS	14%
	Dark chocolate	7%	Wheat flour white	8%
	Wheat flour white	5%	Dark chocolate	6%
	Vegetables and vegetable products; NFS	4%	Vegetables and vegetable products; NFS	4%
	Potatoes	3%	Potatoes	3%
	Dried durum pasta	2%	Cow milk	2%
	Food products for infants and toddlers; NFS	2%	Dried durum pasta	2%
	Cocoa powder	1%	Food products for infants and toddlers; NFS	1%
	Seasoning, sauces and condiments; NFS	1%	Milk and dairy products; NFS	1%
	Others	*10%*	*Others*	*17%*

C.: Contribution mLB: modified lower bound UB: upper bound NFS: not further specified.

The National Monitoring data were only covering 38 % of the KiESEL consumption if not adjusted further (section 3.4). With regard to main food group level, highest coverage by direct mapping was achieved for main food groups that do not necessarily require much processing before consumption, such as eggs, milk, fruit, and products thereof (70 %–93 % coverage with direct mapping) (Fig. 2). In contrast, main food groups that require a lot of processing were not or only limited covered by the data. For instance, in the main food group 'Grains and grain-based products', only 3 % of the consumption was covered by direct mapping since grains, bran, flour or semolina were predominantly measured in this main food group. The reason for this approach is the general purpose of the National Monitoring to check compliance with permitted maximum levels which mainly refer to RAC (Regulation (EC) 2023/915).

In contrast, as a TDS, the BfR MEAL Study was designed to cover the total diet and reflect the consumer behaviour in each step of the process (Kolbaum et al., 2022; Sarvan et al., 2017). Ninety-four percentof the KiESEL consumption was covered by the MEAL food list, accomplishing with the TDS principle of covering at minimum 90 % of the overall diet (EFSA/FAO/WHO, 2011; Kolbaum et al., 2023a). Nevertheless, it has to be mentioned, that the BfR MEAL Study in addition aimed to cover also at least 90 % of consumption per main food group, which was not achieved in single cases (Kolbaum et al., 2023a). It has to be noted that the recorded foods without analytical counterpart were excluded and not covered with conservative assumptions. Accordingly, cadmium exposure might be underestimated on an individual level for some participants, while the impact on the overall exposure assessment was rated to be low.

Sub-hypothesis 2. Extrapolation from foods investigated in the National Monitoring is associated with considerable uncertainties.

If a food or a main food group is represented only by a few foods or selected varieties, the general applied approach is to assume that the same cadmium content is found in all other foods of that category. This approach was necessary in many cases when using the National Monitoring data as illustrated in Fig. 2. For example, the main food group 'Food products for infants and toddlers' was represented by only three

foods. The resulting mean cadmium level was about two-times higher compared to the mean level derived from the BfR MEAL Study (Fig. 3). A more detailed look into the samples further showed that also the available foods within this main food group did not represent the consumption habits or market situation. For instance, 'infant formulae (powder)' was represented in the National Monitoring by 24 samples of soy-based products and three samples of milk-based formulae. This resulted in a mean cadmium value for 'infant formulae' of 0.013 mg/kg (mLB and UB). However, the market share of soy-based formulae was <5 % in Germany (GfK, 2016; Mintel, 2023), resulting in an over-representation of soy-based formulae in the National Monitoring. The BfR MEAL Study 'Infant formulae, follow-on formulae for reconstitution with liquids (powder)' was composed of 15 subsamples weighted for different consumption amounts and market shares of brands and varieties. Soy-based formulae were not included due to its low relevance. Compared to the National Monitoring about three to six-times lower cadmium levels (0.002 mg/kg to 0.004 mg/kg; mLB and UB, respectively) were measured in the BfR MEAL Study, resulting in three to six-times lower intake estimates. This can be assumed to be relevant contributor to overestimation using National Monitoring data with regard to the selected population group. Fig. 3 visualises that almost all mean values of main food groups from the National Monitoring were higher than those from the BfR MEAL Study. Overall, the outlined case and the comparison over all main food groups supports the assumption that data derived from the National Monitoring are likely to be right-skewed and extrapolating right-skewed data adds to further overestimation. This circumstance with regard to monitoring programmes was recognised as 'biased sampling' before, since monitoring programmes are often coordinated by risk management with a necessary focus on recognised risks (e.g., nitrate in leafy vegetables) instead of a representative picture for exposure assessment (Kettler et al., 2015).

While extrapolation of right-skewed substance levels is likely to lead to overestimation, extrapolation of unrepresentatively sampled and prepared foods adds an unknown direction of uncertainty. Most of the foods in the National Monitoring required either conversion into food 'as consumed' or the application of processing factors. Standard factors are always a simplification and are associated with large uncertainties
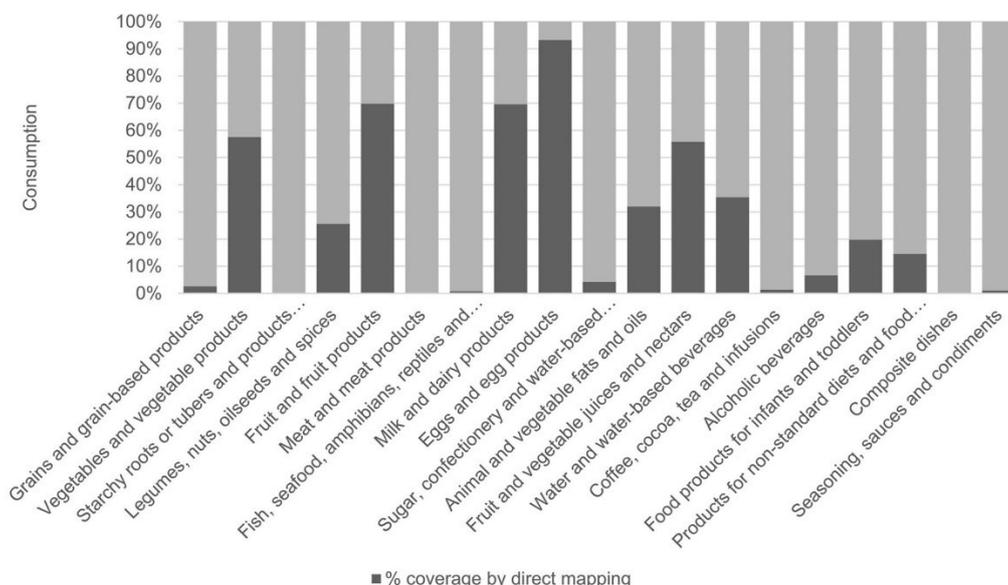

Fig. 2. Coverage of food consumption recorded in the KiESEL study by cadmium occurrence data from the National Monitoring. Shown is the coverage on main food group level by direct mapping.
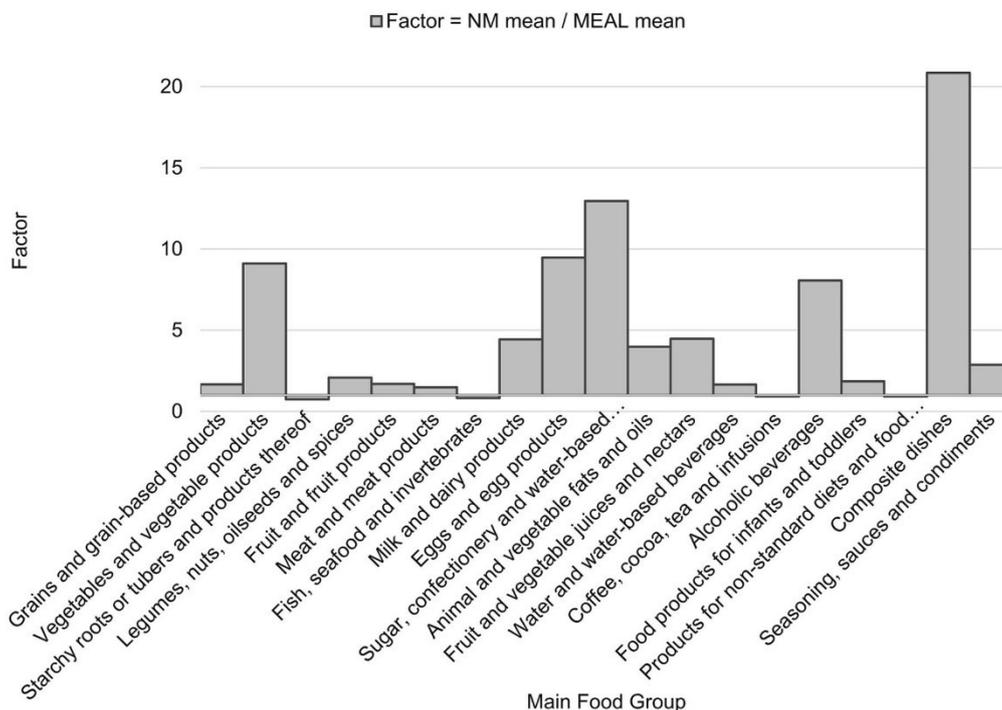
Fig. 3. Comparison of average cadmium contents on main food group level. Shown is the factor by which the mean values of the National Monitoring (NM) differ from those of the BfR MEAL Study (MEAL). Factor >1: higher mean cadmium content in the National Monitoring data. Factor <1: higher mean cadmium content in the BfR MEAL Study data. Compared are the mean values after mapping to the food consumption data (e.g., mammal kidney was not consumed by any child and was therefore not included in this analysis). Upper Bound.

themselves due to their huge variability and dependency on the observed substance. For instance, the cadmium content in boiled pasta was shown to be dependent on the content in the raw material (Cubadda et al., 2003), the cooking time (Lee et al., 2019), and showed also high variance between various samples under controlled conditions (Cubadda et al., 2003; Lee et al., 2019). Furthermore, the effect differed between the observed substances (Cubadda et al., 2003; Lee et al., 2019).

In contrast, the depiction of consumer behaviour from shopping to final kitchen preparation is part of the TDS design (EFSA/FAO/WHO, 2011). In the BfR MEAL Study this was realised by using a data pool of representative consumption data, market share data and consumer surveys on food preparation, preferred degree of browning and use kitchen utensils (Hackethal et al., 2023; Stehfest et al., 2019). Therefore, extrapolation to different foods or broader food groups was not necessary and standard factors were only minimally required (see section 2.3.1.2.).

Sub-hypothesis 3. Uncertainties due to left-censored data are lower for the BfR MEAL Study.

Although achieved LODs and LOQs were low in both programmes (Supplementary Tables S1 and S2), the slight differences still had an impact on the exposure outcome and the range between mLB and UB estimates. In the National Monitoring 52 % of the data were left-censored resulting in 15 % higher exposure estimates in the UB scenario compared to the mLB scenario. In contrast, 30 % of the BfR MEAL Study data were left-censored with a difference of 7 % between mLB and UB estimates. The high inter-laboratory variation in the National Monitoring could be causative for this impact. Although there were small differences between the median of the applied LOQs of the

National Monitoring and the BfR MEAL Study, there was a huge range visible in the National Monitoring LOQs (Fig. 4). This has implications for the exposure outcome, especially when high LOQs affect highly consumed foods. For instance, cow milk appears under the top 10 main contributing foods in the UB approach using National Monitoring data, although cadmium was only detected in two out of 314 cow milk samples (Supplementary Table S3). LODs for cow milk ranged between 0.0 mg/kg and 0.005 mg/kg (median: 0.001 mg/kg) and LOQs between 0.0006 mg/kg and 0.017 mg/kg (median: 0.004 mg/kg). The resulting average exposure due to cow milk consumption was between 0.003 μg/kg bw/week (mLB) and 0.13 μg/kg bw/week (UB) based on the National Monitoring. For comparison, the applied limits of reporting in the BfR MEAL Study were 0.0003 mg/kg (LOD) and 0.001 mg/kg (LOQ) (BfR, 2023b), and the resulting average exposure was between 0 μg/kg bw/week (mLB) and 0.015 μg/kg bw/week (UB).

In summary, the evaluations have shown that the BfR MEAL Study data cover the food consumption more broadly and only minor data adaptations for linkage of occurrence and consumption data were necessary. In addition, left-censored data affected the exposure estimate less compared to the National Monitoring data. Considering the outcomes, it can be reasonably assumed that the assessment based on the BfR MEAL Study led to more reliable estimates.

This can also be confirmed when comparing the here presented cadmium intakes with European estimates from the past ten years and the latest EFSA Opinion (Table 7). Interestingly, the two TDS assessments on the one hand and the three monitoring assessments on the other hand are comparable to each other with TDS estimates resulting in lower cadmium intakes.

The assessments from the Netherlands also recognised about 2-times higher cadmium intakes compared to TDS results in their report (Sprong
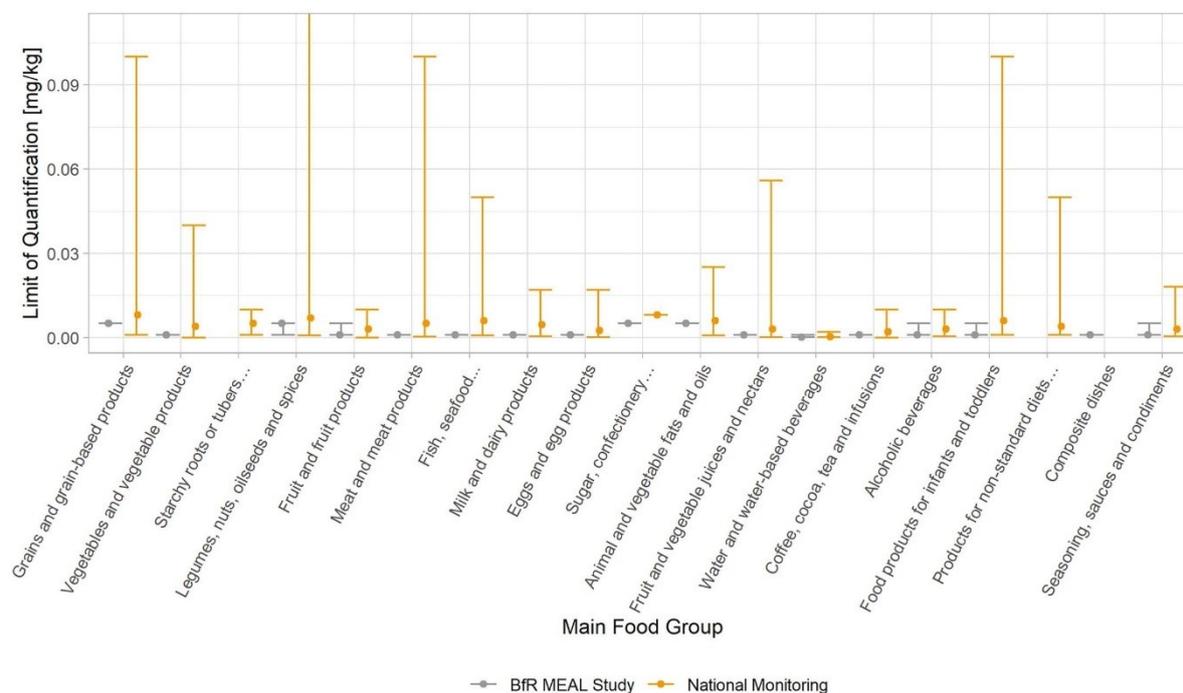
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Fig. 4. Limits of quantification (LOQs) for cadmium reported measurements in the National Monitoring and the BfR MEAL Study. Selected were only left-censored measurements. Shown are the minimum and maximum LOQs distributed over main food groups. Dots indicate median LOQs.

Table 7

Comparison of long-term dietary cadmium exposure [μg/kg bw/week] for children based on occurrence data from the BfR MEAL Study or the National Monitoring with exposure estimates from Europe from the past ten years, as well as the latest EFSA opinion.

Country	Cadmium exposure (μg/kg bw/week)	Age (years)	Study type	Reference
France	2.0 (LB) - 2.4 (UB) [b]	0.5 - <4	TDS	Jean et al. (2018)
Germany (BfR MEAL Study)	1.7 (mLB) - 2.3 (UB) [c]	0.5 - <6	TDS	present study
The Netherlands	3.5 (MB) [b]	2–6	monitoring	Sprong and Boon (2015)
Europe/EFSA[a]	1.9 (LB) - 7.8 (UB) [b]	<1 - <3	monitoring	EFSA (2012)
Germany (National Monitoring)	4.4 (mLB) - 8.0 (UB) [c]	0.5 - <6	monitoring	present study

[a] Range between lowest and highest determined cadmium intake in different countries.

[b] mean.

[c] median.

and Boon, 2015). Notably, also assessments for lead based on Dutch monitoring data were up to 5-times higher compared TDS estimates (Boon et al., 2017). Both observations were mainly attributed to the higher occurrence levels measured in the Dutch monitoring programme compared to the TDS measurements. In addition, the incomplete data in the monitoring programme were named as important limitation for these assessments, which is in line with the here presented findings (Boon et al., 2017; Sprong and Boon, 2015). In contrast to the current study the Dutch evaluations already applied refined assessment methods, including research on further occurrence data for missing food categories and the application of probabilistic Monte Carlo simulations considering food conversion models for primary agricultural products. Nevertheless, refinements seemed to have only a limited effect on overestimation.

A refined assessment would have been actually necessary for the assessments based on the National Monitoring results since the outcome resulted in a risk. If more time was available, refinement could be achieved e.g., by researching missing data, research and application of refined processing and conversion factors, further disaggregation of recipes, and weighting of average cadmium contents according to consumption weights if aggregation to broader food groups was required. Furthermore, uncertainty with regard to extrapolation could be reduced by a similar approach as used in the German LExUKon (Lebensmittelbedingte Exposition gegenüber Umweltkontaminanten; LExUKon) project, where consumption records for adults have been adapted according to the products 'as regulated' (Schwarz et al., 2014). Nevertheless, the comparison with refined assessments from other monitoring studies showed, that the effort indeed led to slight improvements but was still associated with noteworthy uncertainties and at the same time used much more time and resources. Those refinements are not always feasible when quick risk assessments are required. Consequently, the least uncertainties exist when the datasets to be linked are as identical as possible. The TDS approach addresses this fact with its principle to depict consumer behaviour where possible.

Finally, however, it must also be discussed that the conclusions drawn above relate to the long-term dietary exposure and to all respondents in the study population. The design of the National Monitoring bears advantages that are of crucial importance for dietary

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exposure assessment, which is clearly the information about variability due to single food analysis (Kolbaum et al., 2022). This information gets lost when single units are composed to a batch sample as done in a TDS. Knowledge about the distribution of substance levels in foods is mostly relevant for short-term exposure assessments (acute risks) or consumer loyal scenarios, where high substance levels contribute most to exposure (WHO/FAO, 2020). Next to that, the single food analysis allows the grouping or differentiation of foods as desired (depending on the sample size). This can particularly be of help in cases when the food of interest is not differentiated in the BfR MEAL food list. For instance, when the risk assessment addresses the risk by consumption of soy-based infant formula the BfR MEAL Study data cannot be used to address this consumer group, but a combination of data from the National Monitoring data and the BfR MEAL Study data could provide the required information.

5. Conclusion

Uncertainties associated with an exposure estimate are a limiting factor for the reliability of the results and thus for the risk assessment and the derivation of appropriate risk management measures. A key objective of this work was to identify and compare the uncertainties associated with the two main available datasets for occurrence data in Germany, namely the National Monitoring and the BfR MEAL Study.

The results and the discussion lead to the conclusion that the different orientation of the two programmes is reasonable for the different exposure outcomes. The risk-oriented food/substance selection of the National Monitoring leads to the neglect of foods with lower substance contents, which may be relevant for overall exposure due to their high mean consumption. In addition, the resulting right-skewness of the measurements leads to an error of overestimation when extrapolated to other foods. The measurement of RACs is also part of the orientation of monitoring programmes, which introduces additional uncertainties due to conversion to foods as consumed. The performance of monitoring activities requires the involvement of several laboratories, resulting in different and inconsistent analytical limits, which are suitable for checking compliance with legal limits but not necessarily for dietary exposure assessment. Comparison with the literature has shown that the effort required to refine assessments based on monitoring data is not proportional to the reduction in uncertainty and thus less useful in scenarios where a quick response to potential risks is required. Consequently, the smallest uncertainties exist when the datasets to be linked are as identical as possible. The TDS approach takes this into account with its principle of representing consumer behaviour wherever possible. In sum, it can be concluded that the estimates based on data from the BfR MEAL Study were associated with lower uncertainties for long-term exposure assessment and therefore the results were more reliable than estimates based on National Monitoring data.

Nevertheless, monitoring data is of vital value due to the depiction of distributions. Combining the strength of the BfR MEAL Study – the representativeness – and the strength of the National Monitoring – the variability – in a common food safety system can increase the significance of exposure estimates and the resulting risk assessments.

CRediT authorship contribution statement

Anna Elena Kolbaum: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Writing – original draft, Writing – review & editing. **Christian Jung:** Software, Writing – review & editing. **Anna Jaeger:** Software, Writing – review & editing. **Lars Libuda:** Conceptualization, Writing – review & editing. **Oliver Lindtner:** Conceptualization, Supervision, 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.

Data availability

A scientific use file for the KiESEL food consumption data for children (0.5–<6 years) is in preparation and will be made available via the BfR webpage https://www.kiesel-studie.de

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.fct.2023.114404.

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APPENDIX III

Supplementary material accessible at https://doi.org/10.1038/s41370-023-00522-4

ARTICLE   **OPEN**   Check for updates

Reusability of Germany´s total diet study food list upon availability of new food consumption data—comparison of three update strategies

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BACKGROUND: The German total diet study (TDS)—BfR MEAL Study—established its food list in 2016 based on food consumption data of children (0.5–<5 years) and adults (14–80 years). The list consists of 356 foods selected for analysis in order to ensure ≥90% coverage of the diet. Recently, new food consumption data for children (0.5–<6 and 6–<12 years) in Germany became available, which raised the opportunity to evaluate the applicability of the MEAL food list 2016 on new data.
OBJECTIVE: We tested the hypotheses that the MEAL food list 2016 also covers ≥90% of the diet of the new collected food consumption data, and that the selection of foods from younger children and adults was sufficient to also cover the middle age group (6–<12 years). Strategies for updating the existing food list were assessed.
METHODS: Three approaches evaluated the reusability and potential adjustment strategies of the existing food list. Approach 1 applied the existing food list to new food consumption data. Approach 2 allowed the extension of the existing food list to improve coverage of food consumption. Approach 3 set up a new food list based on the new data.
RESULTS: The MEAL food list 2016 covered 94% of the overall diet of the new collected food consumption data. The diet of the middle age group was sufficiently covered with 91%. However, coverage on main food group or population subgroup level was <90% in some cases. Approach 3 most accurately identified relevant modifications to the existing food list. 94% of the MEAL food list 2016 could be re-used and 51 new foods were identified as potentially relevant.
SIGNIFICANCE: The results suggest that a high investment in the coverage of a TDS food list will lower the effort and the resources to keep data updated in the long-term.

IMPACT: There is no established approach to update a TDS food list. This study provides comparative approaches to handle newly collected food consumption data for follow-on TDS activities. The results provide useful information for institutions planning or updating a TDS. Furthermore, new food consumption data for children in Germany recently became available and are here presented for the first time.

Keywords: BfR MEAL Study; Food monitoring; Food sampling; Food consumption; KiESEL study; EsKiMo II study

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INTRODUCTION

Total diet studies (TDS) aim to assure that substances in foods are at safe levels at long-term exposure. They are the recommended tool by EFSA, WHO and FAO to assess the background contamination in nearly the entire diet of a population of interest [1]. Only the assessment of the total diet allows useful risk characterization because the comparison with the respective toxicological reference values is then based on the overall dietary exposure. Consideration of the total diet further allows identification of contribution from each measured food, which is especially important when discussing risk management measures for specific foods or food groups. A TDS consists of three basic characteristics: covering at minimum 90% of the total food intake

(g/kg body weight) of the population of interest, preparing foods 'as consumed' and pooling similar foods to composite samples prior analysis [1]. The TDS food list is the core of the study. The selection of the foods and the aggregation level will determine the level of detail of the exposure assessment. Nevertheless, the extent of the food list is always a trade-off between scientific needs and resources. The core food list of the German TDS, the BfR MEAL Study ('meals for exposure assessment and analysis of foods'), was established in 2016 and includes 356 foods [2, 3]. Much effort and resources were put into a stepwise approach of aggregating and disaggregating foods from different food consumption surveys under consideration of the occurrence and variability of about 300 substances. As many other TDS, the BfR

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MEAL Study was initiated as a singular project. Therefore, the aim was that the food list should be able to cover the food consumption also in the long-term with sufficient detail. In addition, updates of food consumption data are often collected at irregular intervals and a well-developed food list is assumed to compensate potential changes in consumption habits until new data become available. For example, the currently used food consumption data for adults in Germany are from 2005/2006, which replaced data collected 20 years earlier [4], and until recently, the 2001/2002 collected food consumption data from the VELS study were the most recent data for children [5]. Both datasets have been used to compile the MEAL food list in 2016. Egan et al. (2007) [6] highlighted the necessity to consider changed consumption habits in a TDS by a comparison of exposure estimates based on the 1990 and 2003 US FDA's food lists. Both the changed food consumption amounts but also the accordingly adapted food list revealed an up to 46% increase of cadmium exposure in the US population.

With the KiESEL study, new food consumption data for children (0.5–<6 years) became available for Germany [7]. Based on the abovementioned statements, the hypothesis is that the MEAL food list 2016 also covers >90% of more recent food consumption data.

In the meanwhile, also new food consumption data for adolescents (6–<12 years) became available from the EsKiMo II study [8]. This age group has not been considered for the food list yet, due to the assumption that food consumption in relation to body weight will range between that of young children and adults. The second hypothesis therefore is that by considering young children and adults for the compilation of the MEAL food list 2016 the food consumption of the middle age group (EsKiMo II study) was also sufficiently covered.

This work tested the above-mentioned hypotheses and evaluated in three different approaches strategies to improve the food list when including new data. The results can advise future TDS activities in Germany or other countries for an efficient use of resources when developing or adjusting a food list.

MATERIALS AND METHODS
Food consumption data
Food consumption data used to establish the MEAL food list 2016 were the VELS study for children aged 0.5–<5 years and data from the National Nutrition Survey II (NVS II) for adults aged 14–80 years. Details on methods and data collection are described in Banasiak et al. (2005) [5] and Krems et al. (2006) [9], respectively. In brief, the VELS survey monitored food consumption of 804 individuals during 2001/2002. Data were collected by completing two-times a 3-day weighted dietary record. The NVS II was conducted 2005/2006. For compiling the food list, data from 13,926 participants who completed 24-h recalls on two non-consecutive days were used.

For the here presented re-evaluation and further development of the MEAL food list 2016, recent data from the KiESEL study (Children's Nutrition Survey to Record Food Consumption) for children aged 0.5–<6 years and the EsKiMo II study (Eating study as a KiGGS Module in KiGGS Wave 2) for children aged 6–<12 years were used. The KiESEL study included 1008 subjects whose legal guardians completed weighted dietary records on three days plus one non-consecutive day in 2014–2017. The KiESEL study involved 56 individuals that were at least partially breastfed. Since no information regarding the volume of the human milk was available, the present evaluation considered only data from non-breastfed children ($N = 952$). From the EsKiMo II study, data from 1190 children aged 6–<12 years were used who completed a three plus one day weighted dietary record. Data were collected 2015–2017. Details are described in Nowak et al. (2022) [7] and Brettschneider et al. (2018) [8].

All surveys provided sociodemographic and anthropometric data on individual basis.

MEAL food list 2016
To establish the MEAL food list 2016 data for children (VELS) and adults (NVS II) were assessed separately. In a first step, related components were aggregated to foods as consumed (e.g., instant tea plus water) to correctly assess mostly consumed foods. One principle in establishing the food list was to avoid the assignment of foods to a main food group if they contained components of two or more main food groups. Therefore, composite dishes containing separate prepared components from different main food groups, like pasta with tomato sauce, where broken down into their components. The high number of food items used in food consumption data were reduced by defining a grouping within each of the 19 FoodEx2 main food groups[1] (e.g., 'apple', 'banana' or 'strawberries' in the main food group 'fruit and fruit products'). Attributes like food species, kind of preparation, packaging, ingredients as well as expected substance levels and variability were considered in the process of food grouping (e.g., 'grapes' and 'raisins' were kept separately due to differences in water contents).

For each food, the consumption per kg body weight was determined on individual basis and subsequently averaged for different age groups (children) or age/sex groups (adults) separately. For selection which of the grouped foods are relevant for the MEAL food list 2016, foods were sorted in descending order related to their consumption within each main food group and for each age/sex group. For each of the age/sex groups the lowest number of foods was selected which cumulatively covered ≥90% of respective mean intake per main food group (equal to foods with highest mean intake). Further foods were added to the temporary food list, if they were focused in German risk assessments in the years before (e.g., 'sheep liver'). To optimize the food list and to reduce the final number of foods, foods present in only few age/sex groups and with low mean consumption were either excluded or aggregated with similar foods. With respect to the consideration of food trends, which were not relevant at the date of the food consumption studies, further foods like 'pseudo cereals' were also included in the food list. After the selection process, the final MEAL food list 2016 consisted of 356 foods (called 'MEAL foods' in the following; Supplementary Table S1).

Comparison of food consumption data. The first attempt was to uncover the changes in food consumption reported 2001/2002 (VELS) and 2014–2017 (KiESEL). Only non-breastfed children were selected for evaluation. While the whole KiESEL study population of 0.5–<6 years was applied for the food list assessment, the population was restricted to <5 years for the comparison with the VELS age groups. Mean food consumption (grams per kilogram body weight (bw) and day; g/kg bw/day) was estimated by averaging over reporting days on individual basis with subsequent averaging over main food groups per age group. Mean food consumption is reported for consumers only. For KiESEL weighting factors correcting for age, sex, region, regional structure, distribution of weekdays and parental education were applied, in order to ensure representativeness for children in Germany [7]. No weighting factors were available for the VELS study.

Approaches for updating the MEAL food list 2016
The abovementioned hypotheses were tested in three approaches (Fig. 1).

In *approach 1*, the existing MEAL food list 2016 was strictly followed for aggregating the consumed foods of the new surveys. Food records from the KiESEL and the EsKiMo II study were assigned to the 356 MEAL foods according to the method as reported for compiling the MEAL food list 2016. No new MEAL foods were established. In addition, the total food consumption per age group and per main food group was assessed in order to estimate the proportion (%) of covered consumption. This approach showed whether the existing food list complies with the TDS principle to cover in total at least 90% of food consumption for newly collected consumption data (KiESEL) (hypotheses 1). It also revealed if this also applies on a more detailed level, assessing the coverage per age group and per main food group. Furthermore, approach 1 tested whether this was also achieved for the middle age group (EsKiMo II) (hypotheses 2).

Approach 2 used the existing food list as base, but allowed for extension for further foods. Where coverage of the 'Approach 1 food list' was <90% in a main food group or age group, further foods were added according to their consumption amount until 90% was achieved. To do so, the remaining foods, that could not be assigned to one of the existing 356 MEAL foods, were aggregated to additional MEAL foods. The same aggregation scheme as for the MEAL food list 2016 was followed. In

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[1]Main food group 'Major isolated ingredients, additives, flavors, baking and processing aids' was not considered since these foods are included in foods-as-eaten.
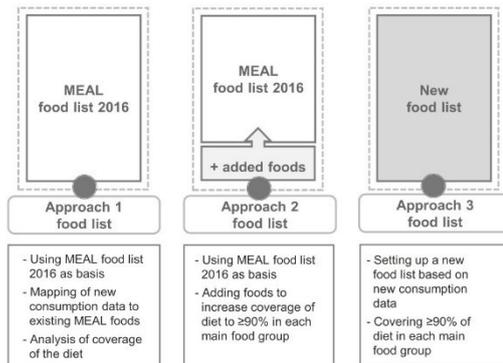
Fig. 1 Update strategies. Outline of the three approaches tested in order to update the MEAL food list 2016.

addition, foods with low consumer rate (<5%) were removed, as long as 90% consumption per main food group were still covered for each age group. This aimed to narrow the food list while at the same time meeting the 90% criterion. Consumer rate was defined as percentage of individuals with consumption on the total number of individuals in the same age group. For this approach, the 5% consumer rate cut-off criterion was just applied for foods not contained in the food list yet, in order to keep the structure of the initial food list. This procedure allowed foods with <5% consumers to be included in the foods list. In order to compare and discuss the impact of these low-consumer foods, a further evaluation excluding all foods with <5% consumers is displayed in the Supplementary Material and discussed along with the results. Approach 2 showed what measures are necessary to improve the coverage on a more detailed level.

In *approach 3*, a new food list was compiled independently from the existing food list. For each main food group the foods were selected according to their consumption amounts until 90% for each age group was achieved. Additional foods potentially relevant for exposure were included also if consumption amount or frequency was low. To identify these foods, risk assessments performed by the BfR since compilation of the food list 2016 were reviewed. Since this food list only considered foods relevant for children and adolescents (KiESEL and EsKiMo II), the selected foods were finally supplemented with those foods derived for the adults (14–80 years; NVSII) based on the initial food list. Again all foods with <5% consumers were removed or further aggregated, as long as 90% per age group were still covered. This approach considered changes in food consumption pattern. Foods no longer relevant were identified and removed from the food list. Others were added as representative part of the diet.

Data analysis
To compare the food consumption data reported in 2001/2002 (VELS) and 2014–2017 (KiESEL) a weighted Mann–Whitney U test with a significance level of $p < 0.05$ was used.

The statistical software R version 4.1.1 (R Foundation for Statistical Computing, Vienna, Austria) and Microsoft Office Excel 2016 (Microsoft Corporation, Redmond, WA, USA) were used for all calculations.

RESULTS
Comparison of food consumption data
Considering the total population of the VELS survey 2005/2006 and the KiESEL survey 2014–2016, the total food consumption reported in the KiESEL study was 6% higher compared to the VELS study (Table 1). Greatest increase was observed in the main food group 'Products for non-standard diets, food imitates' (e.g., soy drink, vegetarian sausages) (+45%). Highest decrease was observed for 'Food products for infants and toddlers' (−35%). In terms of age groups, 3–<5 year old children showed highest increase in total food consumption (+10%), followed by the age groups 1–<3 and 0.5–<1 years, with 7 and 5% increase, respectively. However, the latter was not statistically significant.

Notably, in all age groups, the relative consumption of 'Products for non-standard diets, food imitates' showed greatest change. It decreased by −677% for 0.5–<1 year old children (not significant), but significantly increased with age to a plus of 58% for 3–<5 year old children. Some notable changes were also a significant increase in the consumption of 'Water and water-based beverages' or 'Eggs and egg products', as well as a decline in 'Milk and dairy products'.

Approach 1
The existing MEAL food list 2016 covered 94% of the diet from the newly collected food consumption survey for children (KiESEL study) (Table 2). In addition, the MEAL food list 2016, based on food consumption data for young children and adults, also covered 91% of the diet for the middle age group of the EsKiMo II study. However, more detailed evaluations showed that the 90% criterion did not apply on main food group level and for different age groups. Especially the main food groups 'Products for non-standard diets, food imitates' and 'Alcoholic beverages'[2] were underrepresented. In line with this, 'Products for non-standard diets, food imitates' also showed significant changes in consumption, while 'Alcoholic beverages' showed a great relative decrease (non-significant) for the age group 3–<5 years (Table 1).

Approach 2
Approach 2 revealed, which foods should be added to comply with the 90% criterion also on age group or main food group level. Table 3 shows food consumption of the TDS diet based on the 'Approach 2 food list', the increase of coverage per main food group along with the impact on the MEAL food list, when additional MEAL foods are selected to reach coverage of ≥90% food consumption. For KiESEL 21 and for EsKiMo II 16 additional foods were identified as being part of 90% of the diet. In total, 32 foods were added to the original food list 2016, increasing the list from 356 to 388 foods (Supplementary Material Table S2). Main food groups with highest increase in foods were 'Legumes, nuts, oilseeds and spices' and 'Composite dishes' ($n = 5$ added foods) and 'Products for non-standard diets' as well as 'Sugar, confectionery and water-based sweet desserts' ($n = 4$ added foods). By the procedure applied, a coverage of 88–100% and 90–100% was achieved for KiESEL and EsKiMo II, respectively. Due to a high consumption proportion of not further specified nuts, the coverage of 90% could not be achieved for the main food group 'Legumes, nuts, oilseeds and spices' in the KiESEL study. This is also the reason for inclusion of five additional foods, since all consumed foods from this group needed to be selected for the age group 3–<6 years in order to increase coverage of food consumption to at least 88%. For all five foods, the consumer rate was <5%. For 23 of the 32 foods the proportion of consumers is <5%. Nine foods complied with both, being part of 90% of food consumption and having ≥5% consumers. If just foods with ≥ 5% consumers would be selected, then just these nine additional foods would be selected in total, but just a coverage between 30% (KiESEL) or 40% (EsKiMo II) to 100% would be achieved (Supplementary Material Table S3).

Approach 3
The 'Approach 3 food list' was compiled by reviewing food consumption amounts from KiESEL and EsKiMo II per age group and per main food group, selecting relevant foods to cover at least 90% of the diet and finally adding foods also relevant for adults (from NVS II study) from the MEAL food list 2016. Additionally, the screening for foods relevant for exposure lead to inclusion of two more foods. These were 'Growing-up milk, >12 month (powder)'

[2]Alcoholic beverages also include beverages such as malt beer or non-alcoholic wine

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Table 1. Comparison of mean food consumption (g/kg bw/day; consumers only) between children surveyed 2001/2002 (VELS study) and 2014–2017 (KiESEL study).

Age group	Total: 0.5–<5 y.					0.5–<1 y.				
Survey	VELS, total		KiESEL, total			VELS		KiESEL		
Main food group	Mean	N	Mean	N^a	Difference consumption	Mean	N	Mean	N^a	Difference consumption
Grains and grain-based products	8.2	722	9.4	690 (703)	+13%*	4.0	85	5.7	47 (69)	+30%
Vegetables and vegetable products	2.5	623	3.4	579 (590)	+26%*	2.8	52	3.2	20 (37)	+11%
Starchy roots or tubers and products thereof	2.5	611	2.5	536 (540)	+2%	2.5	53	3.9	17 (32)	+34%
Legumes, nuts, oilseeds and spices	0.3	160	0.4	148 (142)	+26%	0.5	4	0.4	3 (5)	−16%
Fruit and fruit products	7.4	708	8.5	677 (687)	+13%	7.0	82	8.1	49 (67)	+13%
Meat and meat products	2.0	642	2.4	602 (608)	+20%*	1.3	41	1.5	21 (32)	+16%
Fish, seafood and invertebrates	1.0	246	1.2	234 (242)	+20%*	0.7	9	0.7	2 (6)	−2%
Milk and dairy products	17.9	688	13.8	660 (669)	−30%*	13.0	59	8.2	21 (40)	−59%
Eggs and egg products	0.8	278	1.1	214 (233)	+25%	0.5	8	0.8	1 (3)	+42%*
Sugar, confectionery and water-based sweet desserts	1.2	629	1.3	543 (549)	+6%	0.3	24	0.1	8 (6)	−144%
Animal and vegetable fats and oils	0.5	644	0.4	547 (580)	−3%	0.5	62	0.5	34 (46)	+9%
Fruit and vegetable juices and nectars	9.2	554	9.6	418 (411)	+4%	4.8	44	7.8	17 (18)	+39%
Water and water-based beverages	28.2	725	37.5	697 (710)	+25%*	45.4	95	62.4	57 (80)	+27%*
Coffee, cocoa, tea and infusions	7.6	494	7.6	368 (384)	−1%	10.2	45	9.7	9 (10)	−6%
Alcoholic beverages^b	3.1	17	2.4	9 (8)	−29%	0.0	0	0.0	0	0%
Food products for infants and toddlers	19.1	296	14.2	282 (318)	−35%*	40.4	95	33.4	57 (80)	−21%*
Products for non-standard diets and food imitates	2.8	48	5.1	61 (57)	+45%*	5.5	5	0.7	3 (4)	−677%
Composite dishes	5.3	655	6.3	626 (640)	+15%*	5.9	46	9.2	35 (49)	+35%
Seasoning, sauces and condiments	1.2	552	1.4	527 (536)	+14%	1.0	20	0.9	7 (12)	−8%
TOTAL	93.7	732	99.2	701 (715)	+6%*	118.8	95	123.7	57 (80)	+5%

Age group	1–<3 y.					3–<5 y.				
Survey	VELS		KiESEL			VELS		KiESEL		
Main food group	Mean	N	Mean	N^a	Difference consumption	Mean	N	Mean	N^a	Difference consumption
Grains and grain-based products	8.6	340	10.3	306 (324)	+16%*	8.8	297	9.2	337 (310)	+4%
Vegetables and vegetable products	2.5	304	3.5	251 (271)	+28%*	2.4	267	3.3	308 (282)	+27%*
Starchy roots or tubers and products thereof	2.5	296	2.7	254 (257)	+6%	2.3	262	2.2	266 (251)	−5%
Legumes, nuts, oilseeds and spices	0.3	65	0.5	59 (59)	+45%	0.3	91	0.3	86 (78)	+6%
Fruit and fruit products	8.2	336	10.2	295 (313)	+19%*	6.5	290	7.1	333 (307)	+8%
Meat and meat products	2.0	318	2.4	268 (286)	+16%	2.0	283	2.5	313 (290)	+21%*
Fish, seafood and invertebrates	1.0	119	1.2	111 (115)	+13%	0.9	118	1.3	121 (121)	+26%*
Milk and dairy products	20.6	335	15.4	303 (320)	−34%*	15.7	294	12.6	335 (309)	−24%*
Eggs and egg products	0.8	131	1.1	97 (114)	+22%*	0.8	139	1.1	116 (116)	+26%*
Sugar, confectionery and water-based sweet desserts	1.1	315	1.1	224 (250)	−7%	1.4	290	1.5	312 (293)	+7%

Table 1. continued

| Age group | 1–<3 y. | | | | | 3–<5 y. | | | | |
| Survey | VELS | | KIESEL | | | VELS | | KIESEL | | |
Main food group	Mean	N	Mean	Nᵃ	Difference consumption	Mean	N	Mean	Nᵃ	Difference consumption
Animal and vegetable fats and oils	0.5	305	0.5	252 (273)	+5%	0.5	277	0.4	261 (261)	−14%
Fruit and vegetable juices and nectars	9.9	267	9.7	169 (171)	−3%	9.2	243	9.7	232 (222)	+6%
Water and water-based beverages	29.0	335	39.6	306 (322)	+27%*	21.7	295	31.3	335 (308)	+31%*
Coffee, cocoa, tea and infusions	9.1	228	8.6	145 (165)	−5%	5.7	221	6.8	214 (209)	+17%
Alcoholic beverages^b	3.9	5	5.9	2 (3)	+34%	2.7	12	1.6	8 (5)	−67%
Food products for infants and toddlers	10.3	161	10.3	164 (183)	0%	4.2	40	6.7	61 (55)	+38%
Products for non-standard diets and food imitates	2.6	27	5.2	35 (31)	+50%*	2.3	16	5.6	23 (22)	+58%*
Composite dishes	5.5	325	6.9	285 (302)	+21%*	5.1	284	5.4	307 (289)	+6%
Seasoning, sauces and condiments	1.2	277	1.4	229 (253)	+16%	1.2	255	1.4	290 (271)	+11%
TOTAL	99.3	340	106.6	308 (325)	+7%*	79.5	297	88.3	337 (310)	+10%*

y, year(s), N Number of consumers.
*Mean consumption value was significantly different, $p < 0.05$.
ᵃweighted number is presented (unweighted sample size is given in parenthesis).
ᵇgroup also includes malt beer.

and 'Wholemeal pasta'. Latter was generated by disaggregating wholemeal products from the existing MEAL foods 'Durum pasta' and 'Egg pasta'. Approach 3 resulted in a list of 391 foods (Supplementary Material Table S4). Greatest changes compared to the MEAL food list 2016 were again visible in the main food groups 'Legumes, nuts, oilseeds and spices', 'Products for non-standard diets and food imitates' and 'Sugar, confectionery and water-based sweet desserts' with a plus of six or five foods (Table 4). In the main food groups 'Food products for infants and toddlers' and 'Milk and dairy products' amount of foods was decreased by three or one foods (Table 4).

Figure 2 visualizes the reusability of the MEAL food list 2016 if a complete new selection was adopted based on new food consumption data. 340 foods were similar to the food list 2016, which corresponded to 96% of the original 356 foods. 16 foods of the original food list were no longer relevant (Supplementary Material Table S5) and 51 foods were newly included (Fig. 2A). Figure 2B further differentiates the foods related to the origin of the survey by which they became relevant. 31% of the 'Approach 3 food list' was relevant for adults only (NVS II). About half of the food list was relevant for all considered age groups (48%). 21% were included because of relevance for KiESEL and/or EsKiMo II only.

Forty-six of the 391 foods have consumer rates <5% (Supplementary Material Table S4). Likewise in approach 2, adopting the ≥5% consumer criterion would decease coverage of the diet considerably (Supplementary Material Table S6). However, in contrast to approach 2, 20 instead of nine new foods were identified complying with being part of 90% of food consumption plus having ≥5% consumer rate.

DISCUSSION

The BfR MEAL Study is a comprehensive project mandated by the Federal Ministry of Food and Agriculture (BMEL) and funded with about 13 million euro. Data on approximately 300 substances in >350 foods were collected 2016–2021. The data complement the existing food monitoring activities in many ways and improve consumer safety in Germany [10]. The already existing data basis from the BfR MEAL Study and the established infrastructure provide a valuable environment for ongoing data updates. The presented evaluations focused on the food list of the BfR MEAL Study, and how the accuracy during its establishment in 2016 leads to reusability and comparability, i.e., whether or to which extent the original food list is still applicable for future data usage or collection. The two hypotheses, that (1) the detailed food list of the BfR MEAL Study is also covering ≥90% of the diet of updated food consumption data and (2) that only consideration of young children and adults is enough to also cover food consumption of middle age groups in Germany, were approved by approach 1. Ninety-four percent and 91% of food consumption of updated data for children (KiESEL) and for the middle age group (EsKiMo II) was covered by the original food list 2016. Hence, the initial goal to select about 350 foods for the TDS food list when planning the BfR MEAL Study turned out to be a reasonable number when compiling a TDS food list, not only in terms of capturing average food consumption of diverse population groups, but also in terms of reusability for future food consumption updates. This was also supported by findings from approach 3, which showed that 96% of the original food list would also be chosen according to the new food consumption data (with the restriction that this is just based on data for children and parts of the food list originate from the NVS II data for adults).

Selecting at least 90% of food consumption for a TDS is recommended by EFSA, FAO and WHO [1] in order to capture the population's food consumption and thus the population's exposure. Nevertheless, when applying this criterion to overall food consumption, coverage is mainly driven by high contributing

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Table 2. Coverage of food consumption (%) for 'Approach 1 food list'.

Survey	KiESEL			EsKiMo II	
Age group	**0.5–<1 y.**	**1–<3 y.**	**3–<6 y.**	**6–<9 y.**	**9–<12 y.**
Main food group					
Grains and grain-based products	91	90	91	90	90
Vegetables and vegetable products	**80**	96	97	97	97
Starchy roots or tubers and products thereof	99	97	97	96	97
Legumes, nuts, oilseeds and spices	100	90	**81**	**87**	**85**
Fruit and fruit products	**86**	96	95	96	96
Meat and meat products	90	**86**	**80**	**83**	**84**
Fish, seafood and invertebrates	100	**89**	91	**82**	94
Milk and dairy products	100	98	99	94	96
Eggs and egg products	100	100	100	99	100
Sugar, confectionery and water-based sweet desserts	100	**87**	**86**	**85**	**78**
Animal and vegetable fats and oils	**81**	**84**	**86**	90	91
Fruit and vegetable juices and nectars	**85**	94	96	98	96
Water and water-based beverages	100	95	92	**89**	**89**
Coffee, cocoa, tea and infusions	100	100	100	100	100
Alcoholic beverages	—	**63**	**70**	100	100
Food products for infants and toddlers	98	93	98	97	100
Products for non-standard diets and food imitates	**36**	**58**	**30**	**40**	**71**
Composite dishes	**85**	**89**	90	**89**	**86**
Seasoning, sauces and condiments	100	**84**	90	90	91
TOTAL	94			91	

Shown is the coverage per main food group and over the total food list. Numbers in bold emphasize coverage <90%.

food groups, such as beverages or grain products. Foods or food groups with lower consumption could partly or completely be neglected. Therefore, more detailed selection based on main food groups and different age groups is useful, especially when it comes to exposure assessment for population subgroups. This became visible, when elaborating the coverage of approach 1 in more detail. This more differentiated evaluation revealed under-representation of certain main food groups or age groups, when applying the MEAL food list 2016 to the new food consumption data (Table 2), which would result in an underestimation of the exposure for concerned subgroups.

Strategies to deal with <90% coverage were evaluated in approaches 2 and 3. Both approaches lead to ≥90% coverage per main food group and per age group, however with different effort and different outcome in number and type of selected foods. Approach 2 identified 32 and approach 3 identified 51 additional foods, which need to be added to achieve ≥90% coverage on the detailed level. The reason for the lower amount of foods in approach 2 was that additional foods were just included when 90% coverage of food consumption was not achieved by the original food list. Approach 3 instead aims at reaching ≥90% coverage by rebuilding a completely new food list. Therefore, more foods per age group are included. All but three foods, identified from approach 2 are also included in approach 3 food list. That shows that approach 2 captures a great proportion of additionally relevant foods, but also that approach 3 does better fit the specific food consumption patterns of the new surveys and thus will result in more accurate exposure assessments. Furthermore, approach 3 allows identification and removal of foods no more relevant based on new food consumption data. This is important, when setting up a new sampling plan and helps to save resources in food sampling and analysis. Nevertheless, already collected data from those foods

should still be included in exposure assessment in order to use as much information as possible. Although approach 3 seems to be the most accurate update strategy, it hast to be kept in mind, that the more changes to the food list are made, the less comparable will repeated TDS studies be. Therefore, next to effort and resources also the potential standardization in repeated sampling should be a criterion when updating a food list. In both approaches, the number of foods increased from 356 MEAL foods to 388 or 391. A possible explanation could be that the observed change was rather driven by an increase in product variability on the market (e.g., various vegetarian products) than by a change in food choices. Nevertheless, it has to be considered, that selection of foods for a TDS food list is always a trade-off between scientific needs and available resources. In the here applied approaches 2 and 3 the criteria of being part of 90% of food consumption or having at least 5% of consumers was consequently applied per age group. This leads to a theoretical maximum food list. In some cases, it would be reasonable to exclude more foods or to reduce the number by aggregating some of the relevant foods into a common MEAL food. E.g. increasing the coverage of 'Alcoholic beverages' for KiESEL from 63 or 70% to >90% in approach 2 was achieved by including just one more food ('White wine/sparkling wine, non-alcoholic') with only four consumers (Tables 2 and 3). However, the impact on coverage was high since few individuals consume just a few foods in this group. In those cases, removing those foods would be acceptable. In other cases, such as 'Products for non-standard diets and food imitates' the different foods included were very variable with few consumers for each. In total, four foods need to be added to achieve a >90% coverage. Excluding those foods would reduce coverage down to 30% (Tables 2, 3 and Table S3). In such cases, further research of food consumption habits for specific populations groups or diets, or the inclusion of substance

Table 3. Mean food consumption of TDS diet* per main food group (g/kg bw/day), changes in the number of foods (n) in the MEAL food list 2016 and coverage of food consumption (%) for 'Approach 2 food list'.

Main food group	KiESEL 0.5–<1 y.	1–<3 y.	3–<6 y.	change n MEAL foods	EsKiMo II 6–<9 y.	9–<12 y.	MEAL foods	MEAL food list 2016 N foods	Approach 2 food list N foods	Total change n MEAL foods	KiESEL, total % coverage	EsKiMo II, total % coverage
Grains and grain-based products	4.4	9.2	8.2	0	7.6	5.6	0	40	40	0	90–91	90
Vegetables and vegetable products	1.0	2.8	2.7	+2	2.5	1.5	0	34	36	+2	94–97	97
Starchy roots or tubers and products thereof	1.1	2.2	1.7	0	1.6	1.4	0	8	8	0	97–99	96–97
Legumes, nuts, oilseeds and spices	<0.1	0.1	0.1	+5	0.1	0.0	+2	20	25	+5	88a–100	93–94
Fruit and fruit products	6.7	9.5	6.1	+1	4.6	2.7	+0	22	23	+1	96–97	96
Meat and meat products	0.5	2.0	2.2	+1	1.9	1.5	+1	35	36	+1	93–95	91–92
Fish, seafood and invertebrates	<0.1	0.4	0.4	+1	0.3	0.3	+2	30	33	+3	91–100	93–96
Milk and dairy products	3.1	14.8	11.2	0	8.2	5.7	0	23	23	0	98–99	94–96
Eggs and egg products	<0.1	0.3	0.3	0	0.3	0.2	0	2	2	0	100	99–100
Sugar, confectionery and water-based sweet desserts	<0.1	0.7	1.3	+1	1.1	0.8	+3	15	19	+4	94–100	90–95
Animal and vegetable fats and oils	0.3	0.4	0.3	+2	0.3	0.2	0	8	10	+2	97–100	99
Fruit and vegetable juices and nectars	2.4	5.0	5.3	+1	3.4	2.7	0	10	11	+1	99–100	95–97
Water and water-based beverages	62.2	37.4	28.4	0	27.5	23.1	+1	6	7	+1	92–100	93–94
Coffee, cocoa, tea and infusions	1.6	4.1	3.7	0	2.5	1.6	0	9	9	0	100	100
Alcoholic beverages	0.0	<0.1	<0.1	+1	<0.1	<0.1	0	8	9	+1	100	100
Food products for infants and toddlers	32.8	5.1	0.8	0	<0.1	<0.1	0	11	11	0	93–98	97–100
Products for non-standard diets and food imitates	<0.1	0.6	0.4	+2	<0.1	<0.1	+4	7	11	+4	96–100	94–98
Composite dishes	5.3	5.8	4.7	+2	4.4	3.7	+3	52	57	+5	91–93	90–91
Seasoning, sauces and condiments	0.1	0.9	1.1	+2	0.9	0.8	0	16	18	+2	91–100	90–91
TOTAL				+21			+16	356	388	+32	88–100	90–100

y, year(s) *TDS diet: consumption achieved by the intake of foods from the TDS food list. Shown is the average consumption over all individuals per age group.
a due to a high consumption amount of not further specified nuts 90% of coverage cannot be achieved.

Table 4. Mean food consumption of TDS diet* per main food group (g/kg bw/day), changes in the number of foods (n) in the MEAL food list 2016 and coverage of food consumption (%) for 'Approach 3 food list'.

Main food group	KiESEL 0.5–<1 y.	1–<3 y.	EsKiMo II 3–<6 y.	6–<9 y.	9–<12 y.	MEAL food list 2016 N foods	Approach 3 food list N foods	Total change n MEAL foods	KiESEL, total % coverage	EsKiMo II, total % coverage
Grains and grain-based products	4.6	9.5	8.4	7.8	5.8	40	44	+4	93–95	93–94
Vegetables and vegetable products	1.0	2.8	2.7	2.5	1.5	34	35	+1	94–98	97–98
Starchy roots or tubers and products thereof	1.1	2.2	1.7	1.6	1.4	8	8	0	97–99	96–97
Legumes, nuts, oilseeds and spices	<0.1	0.1	0.1	0.1	<0.1	20	26	+6	88a–100	93–94
Fruit and fruit products	6.7	9.5	6.1	4.6	2.7	22	23	+1	96–97	96
Meat and meat products	0.5	2.0	2.3	2.0	1.5	35	38	+3	95–96	94
Fish, seafood and invertebrates	<0.1	0.4	0.4	0.4	0.3	30	34	+4	93–100	94–97
Milk and dairy products	3.1	14.8	11.2	8.2	5.7	23	22	−1	98–100	94–96
Eggs and egg products	<0.1	0.3	0.3	0.3	0.2	2	2	0	100	99–100
Sugar, confectionery and water-based sweet desserts	<0.1	0.7	1.3	1.1	0.8	15	20	+5	94–100	92–94
Animal and vegetable fats and oils	0.3	0.4	0.3	0.3	0.2	8	9	+1	95–98	99
Fruit and vegetable juices and nectars	2.4	5.0	5.3	3.4	2.7	10	11	+1	94–98	96–98
Water and water-based beverages	62.2	38.3	29.2	27.5	23.1	6	7	+1	95–100	93–94
Coffee, cocoa, tea and infusions	1.6	4.1	3.7	2.5	1.6	9	9	0	100	100
Alcoholic beverages	0.0	<0.1	<0.1	<0.1	0.1	8	9	+1	100	100
Food products for infants and toddlers	30.8	5.1	0.8	<0.1	<0.1	11	8	−3	91–94	97–100
Products for non-standard diets and food imitates	0.0	0.6	0.4	0.1	0.1	7	12	+5	96–100	98
Composite dishes	5.3	5.8	4.8	4.4	3.7	52	55	+3	91–93	90–91
Seasoning, sauces and condiments	0.1	0.9	1.1	0.9	0.8	16	19	+3	91–100	93
TOTAL						356	391	+35	88*–100	90–100

y, year(s) *TDS diet: consumption achieved by the intake of foods from the TDS food list. Shown is the average consumption over all individuals per age group.
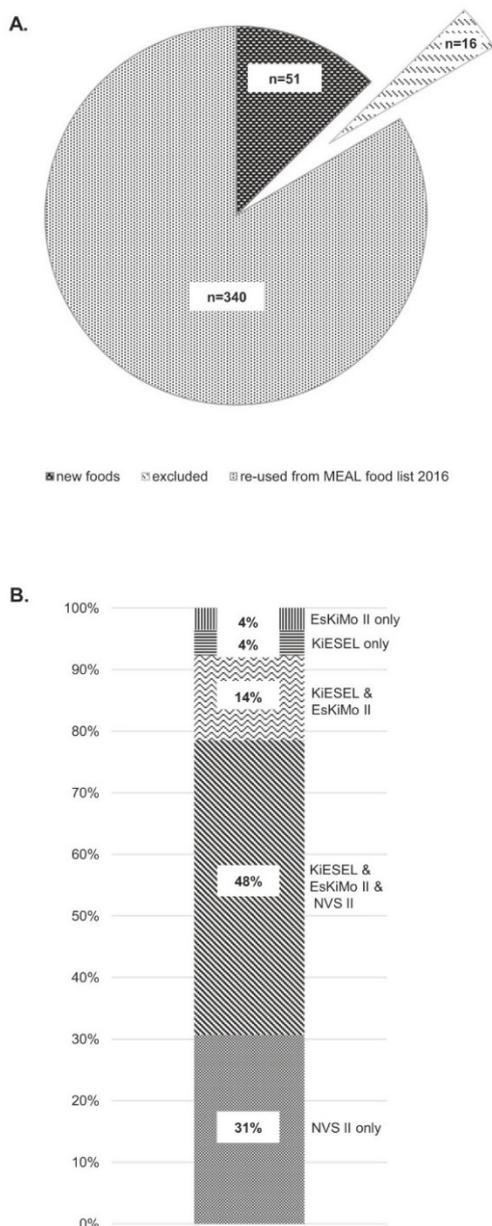a due to a high consumption amount of not further specified nuts 90% of coverage cannot be achieved.

A.

☒ new foods   ☒ excluded   ☒ re-used from MEAL food list 2016

B.

Fig. 2 Composition of the 'Approach 3 food list'. A Comparison with MEAL food list 2016. **B** Composition according to the underlying food consumption surveys (age groups covered by the surveys: KiESEL: 0.5–<6 years; EsKiMo II: 6–<12 years; NVS II: 14–80 years).

specific experts and experts of exposure and risk assessment could help to further narrow the food list. Especially the latter is a crucial step, since not only consumption and its coverage decide about exposure, but also the occurrence and variability of the

substances under investigation. Low consumed foods can have great impact on exposure if they potentially contain high levels of contaminants. Furthermore, high concentration foods should not be aggregated with foods of lower concentrations in order to identify and separately analyse exposure associated to these foods. This aspect has not yet been considered in the present evaluation and must be taken into consideration after selecting chemicals for a follow-on TDS.

Just few publications report on updated TDS food lists related to new food consumption data. Egan et al. (2007) [6] updated the US FDA's TDS food list from 1990 in 2003 based on new food consumption data for children and adults. Foods were grouped based on the similarity of their major ingredients. The most representative foods in terms of quantity were selected for the food list. This procedure corresponds to approach 3 of this study. The number of TDS foods remained similar with about 290 items in both US food lists. 75% of foods were common to both versions. Of the remaining 25% some were modified (e.g., other fat content) and about 15% were newly included. Although food consumption habits evolve differently in different countries and the present study just considers changes in child food consumption, the observed proportion of change is in line with 13% newly included foods in approach 3 in the present study. Sirot et al. (2009) [11] report on the update of the 1999 food list from the first French TDS to the second French TDS in 2006. The food list of the first French TDS 1999 contained 338 foods and was compiled according the approach of the US FDA's TDS food list [11, 12]. The second French TDS used updated consumption data but adopted another approach for food selection. A predefined number of foods was selected according to the criteria of representing most consumed foods in terms of quantity (not necessarily covering 90% of the diet) plus having at least 5% of consumer rate. In addition, known high contributors to exposure with regard to contaminants of interest were added. In total, 186 foods were finally included covering 82–91% of the diet [11]. This procedure is almost comparable to approach 3 when just foods with ≥5% consumers are included. In the present study, this approach would overall (i.e., measured over the total diet) cover approximately 93%. If foods relevant for adults only (NVS II) would be excluded from this calculation, coverage would be 89–91% (data not shown). Devlin et al. (2014) [13] compared different approaches to compile TDS food lists based on food consumption data from 14 countries from the EFSA Comprehensive Food Consumption Database. The approaches comprised (1) selection of foods covering >90% of diet based on main food group level, (2) excluding foods <5% consumer rate from the first approach, (3) selection of foods covering >90% of the diet based on the overall diet, and (4) excluding foods <5% consumer rate from the third approach. According to their results, all approaches reached at least 85% coverage of the diet. The authors also showed that exclusion of <5% consumer foods had small effect on overall coverage (about 2%), whereas the number of selected foods was considerably decreased by that approach for some countries. The here presented results confirm that overall food consumption was also covered by about 89 to 91% when excluding foods with <5% consumer rate. Indeed, it can be argued that this is acceptable given the fact that many foods can be excluded – and thus many resources saved for shopping, processing and analysis of these foods – while just losing about 2% [13] of overall coverage. However, when it comes to subgroup level (main food group or population subgroups) and applying 5% consumer rate cut-off, coverage was decreased down to 30% (Table S3) or even 2% (Table S6) per main food group. Hence, it turns out, that resources can be saved by considering the exclusion of foods with low consumer rate. Nevertheless, this needs to been seen in the context of subgroups and should to be decided case-by-case on expert

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based judgments to achieve a targeted and resource saving strategy.

CONCLUSION

The presented assessments proof reusability of the MEAL food list 2016 in different ways. The approach chosen when establishing the MEAL food list in 2016 has turned out to be comprehensive enough to cover also 90% of the consumption of newly collected food consumption data for children in Germany. In addition, the resource-saving approach to just consider young children and adults was sufficient to also cover indirectly the food consumption habits of the middle groups and standardization of food lists seems to be feasible without violating the 90% criteria for TDS.

Approach 1 turned out to be a quick and effective strategy, when new food consumption data become available. It has the least effort, requires the least resources, and in addition it has the advantage that there are no changes to the original food list, which makes results comparable for repeated TDS samplings. Nevertheless, in cases where comparability of food lists is not the priority, more accurate selection strategies could be applied to avoid underrepresentation and thus underestimation of exposure of certain main food groups or subpopulations. Approach 2 and 3 mainly differ in the effort. Thus, their application depends on available resources for evaluation of new food consumption data, and sampling and analysis of new foods. Both approaches lead to coverage of ≥ 90% of food consumption in different age and food groups. Approach 2 just added new foods to the existing list. Therefore, the coverage of an already existing food list can quickly be adapted. Approach 3 identified more accurately new foods and allowed exclusion of no more relevant foods. This allows more accurate exposure assessments for population sub-groups and helps to safe resources in case of repeated TDS sampling. However, when following trends, the changes in the food list need to be carefully evaluated, when comparing repeated measurements.

If and how low consumer rate foods should be excluded should be a case-related decision.

In conclusion, the great effort put into the initial food MEAL food list 2016 now allows a quick and resource saving update for future TDS activities in Germany.

DATA AVAILABILITY

Food consumption data for children (0.5–<5 years) from the VELS study [5] is available in the EFSA Comprehensive European Food Consumption Database (https://www.efsa.europa.eu/en/data-report/food-consumption-data). Furthermore, data publishing via a data repository linked to the homepage of the currently ongoing FNS-Cloud project (Food Nutrition Security Cloud; FNS-Cloud) (https://www.fns-cloud.eu/) is in progress. A scientific use file for the KiESEL food consumption data for children (0.5–<6 years) [7] is in preparation and will be made available via the BfR webpage https://www.kiesel-studie.de. Food consumption data from the EsKiMo II study for children (6–<12 years) years [8] were provided by Robert Koch Institute (RKI), Department of Epidemiology and Health Monitoring, within the framework of data provision for exposure and risk assessment at the German Federal Institute for Risk Assessment (BfR) and are not publicly available at the point of preparing this study. Information about public use are available at https://www.kiggs-studie.de/ergebnisse/kiggs-welle-2/scientific-use-file.html.

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AUTHOR CONTRIBUTIONS
AEK: conceptualization, methodology, formal analysis, software, investigation, data curation, writing – original draft, writing – review and editing. SP: Writing – original draft, writing – review and editing. CJ: software, writing – review and editing. LL: conceptualization, writing – review and editing. OL: conceptualization, writing – review and editing, supervision.

COMPETING INTERESTS
The authors declare no competing interests.

ETHICS APPROVAL
The here presented study used previously collected data. The KiESEL and the EsKiMo II food consumption surveys received a positive vote from ethics committees as indicated in Nowak et al. (2022) [7] and Brettschneider et al. (2018) [8].

ADDITIONAL INFORMATION

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