A ranking method of chemical substances in foods for prioritisation of monitoring, based on health risk and knowledge gaps

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ABSTRACT

Chemical contaminants are present in all foods. Data on the occurrence of contaminants in foods that are often consumed or contain high contaminant concentrations are critical for the estimation of exposure and evaluation of potential negative health effects. Due to limited resources for the monitoring of contaminants and other chemical substances in foods, methods for prioritisation are needed. We have developed a straightforward semi-quantitative method to rank chemical substances in foods for monitoring as part of a risk-based food control. The method is based on considerations of toxicity, level of exposure including both occurrence in food and dietary intake, vulnerability of one or more population groups due to high exposure because of special food habits or resulting from specific genetic variants, diseases, drug use or age/life stages, and the adequacy of both toxicity and exposure data. The chemical substances ranked for monitoring were contaminants occurring naturally, unintentionally or incidentally in foods or formed during food processing, and the inclusion criteria were high toxicity, high exposure and/or lack of toxicity or exposure data. In principle, this method can be used for all classes of chemical substances that occur in foods, both unintended contaminants and deliberately added chemical substances. Foods considered relevant for monitoring of the different chemical substances were also identified. The outcomes of ranking exercises using the new method including considerations of vulnerable groups and adequacy of data and a shortened version based on risk considerations only were compared. The results showed that the resolution between the contaminants was notably increased with the extended method, which we considered as advantageous for the ranking of chemical substances for monitoring in foods.

1. Introduction

Food safety is an important prerequisite for good health. With the constant change in food production, processing and dietary habits, there is a continuous need for up-to-date knowledge on the presence of chemical substances in foods. Such knowledge is a critical part of risk assessments of chemical substances in food to ensure food safety. Therefore, monitoring of chemical substances that have a potential to pose a health risk is important (INFOSAN, 2009; van der Fels-Klerx et al., 2015). Data on the occurrence of chemical substances in highly consumed food items and in less consumed but highly contaminated food items are critical for risk assessments related to dietary exposure. Hence, prioritisation of chemical substances for monitoring in foods has to take into consideration i.a. potential health hazards, occurrences and the adequacy of data.

Health-based guidance values (HBGVs), i.e. tolerable daily intake (TDI) or tolerable weekly intake (TWI), define the amount of a specific contaminant that an individual can consume on a regular basis over a lifetime without any appreciable risk to health (EFSA, 2020). Comparison of the HBGVs to the estimated dietary exposure in a geographical region or a population group may be used to rank chemical substances according to the health risk (van der Fels-Klerx et al., 2015).

Abbreviations: BMDL, benchmark dose lower confidence limit; BMR, benchmark response; HBGV, health-based guidance value; MOE, margin of exposure; NOAEL, no observed adverse effect level; TDI, tolerable daily intake; TWI, tolerable weekly intake; VKM, Norwegian Scientific Committee for Food and Environment

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metals and metalloids, persistent organic pollutants (POPs), process-

2.1. Selection of chemical substances for ranking

monitoring infoods, based on their estimated risk for human health and

2.2. Ranking for monitoring method

Alternatively, the margin of exposure (MOE) may also be suitable to rank chemical substances according to risk. The MOE is calculated under consideration of a reference point such as the no observed adverse effect level (NOAEL) or the benchmark dose lower confidence limit (BMDL) for the critical health effect. NOAEL is the highest dose of a compound, at which no detectable adverse effects occur in experimental animals or in a population (EFSA, 2020). The benchmark dose (BMD) is the minimum dose of a compound that produces a distinct, low-level adverse health effect, i.e. a benchmark response (BMR), usually in the range of a <0.5 to 10% increase in a specific adverse effect (EFSA, 2020). The BMDL is the lower boundary of the 95% confidence interval of the BMD. MOE is the ratio of NOAEL or BMDL for the critical effect and the human exposure (EFSA, 2005a).

Owing to limited resources, there is a need for ranking of chemical substances in foods in accordance with their estimated health risk to enable risk managers to perform a knowledge-based prioritisation of chemical substances for monitoring. Here, we present a straightforward semi-quantitative method for the ranking of chemical substances for monitoring in foods, based on their estimated risk for human health and critical knowledge gaps.

2. Methodology

2.1. Selection of chemical substances for ranking

Expert judgement was used for the selection of chemical substances included in the ranking and for the identification of food items relevant for their monitoring. The chemical groups included were natural toxins, metals and metalloids, persistent organic pollutants (POPs), process-induced contaminants and food contact materials. Veterinary medicine residues and pesticides were excluded as ongoing monitoring programmes are in place in Norway. For other chemicals, there are no established monitoring programmes, therefore, a ranking serving as basis for prioritisation by the risk managers on which substances to monitor for the limited funds available for this purpose each year is needed. Criteria for the selection of chemical substances were high toxicity, high dietary exposure and lack of data on toxicity or occurrence in foods, as further described in the following section.

| Category | Description | Score |
|----------|-------------|-------|
| 1. Quantitative toxicity and exposure data available | The exposure was above the HBGV or the MOE* was too low | 6 |
| | The exposure was close to the HBGV or the MOE* was close to an acceptable value | 4 |
| | The exposure was well below the HBGV or the MOE* was sufficiently high | 2 |
| 2. Toxicity of the chemical | High toxicity | 3 |
| | Medium toxicity | 2 |
| | Low toxicity | 1 |
| 3. Dietary exposure to the chemical** | High exposure | 3 |
| | Medium exposure | 2 |
| | Low exposure | 1 |
| 4. Vulnerable groups | The exposure was high because of special food habits for one or more groups in the population, or one or more groups in the population were especially vulnerable due to, for example, specific genetic variants, diseases, drug use or age/life stages (<1 year, puberty, pregnant/nursing, elderly) | 0.5 |
| | The exposure was somewhat higher because of special food habits for one or more groups in the population, or one or more groups in the population were somewhat more vulnerable due to, for example, specific genetic variants, diseases, drug use or age/life stages (<1 year, puberty, pregnant/nursing, elderly) | 0 |
| | No population group with increased exposure because of special food habits or special vulnerability due to, for example, specific genetic variants, diseases, drug use or age/life stages (<1 year, puberty, pregnant/nursing, elderly) was identified | 0.5 |
| 5. Adequacy of toxicity data | Toxicity data were insufficient or lacking | 1 |
| | Some toxicity data were lacking | 0.5 |
| | Sufficient toxicity data were available | 0 |
| 6. Adequacy of exposure data (occurrence and/or intake) | Exposure data were insufficient or lacking | 1 |
| | Some exposure data were lacking | 0.5 |
| | Sufficient exposure data were available | 0 |

BMDL (benchmark dose lower confidence limit); HBGV (health-based guidance value); MOE (margin of exposure); NOAEL (no observed adverse effect level); TDI (tolerable daily intake); TWI (tolerable weekly intake).

*MOE was too low/MOE was sufficiently high:

o For compounds that were genotoxic and carcinogenic (compounds for which no threshold of toxicity can be identified), a MOE < 10,000 based on the BMDL10 (the lower limit of an one-sided 95% confidence interval on the BMDL, corresponding to a 10% tumour incidence over control), would in general be considered as too low. Considerations with regard to a sufficiently large MOE that would allow to conclude on low risk have to be case-specific and based on the available data.

o For non-genotoxic compounds (for which a threshold for adverse effects can be identified), a MOE < 100 based on the no observed adverse effect level (NOAEL) or BMDL, would in general be considered as too low. Depending on the available data, the necessary size of the MOE may be judged differently.

**Based on occurrence and/or intake, or biomonitoring showing high total exposure, from food as one important source.
2.3. Identification of foods for monitoring of the ranked chemical substances

Food groups considered relevant for monitoring of the included chemical substances were identified by expert judgements based on available occurrence data in foods, preferably from national databases, or if not available, European or international data from databases or scientific papers. The respective food items were selected based on existing data showing considerable prevalence of specific contaminants.

### Table 2

| Chemical/chemical group                              | Category scored* | Score | Rationale for score                                                                                                                                                                                                 | References                      |
|------------------------------------------------------|------------------|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Lead (Pb)                                            | 7.5              | 1     | 6 Developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults were identified as the critical effects. Exposure assessment for the European population showed almost no margin of exposure to the BMDLs for the critical effects.                                                                 | EFSA (2010)                     |
|                                                      |                  | 4     | Foetus and children, and high consumers of game shot with ammunition containing Pb.                                                                                                                                 |                                 |
|                                                      |                  | 5     | Sufficient data were available.                                                                                                                                                                                         |                                 |
|                                                      |                  | 6     | Data on concentrations in small game shot with ammunition containing Pb were needed.                                                                                                                                    |                                 |
| Methyl-mercury (MeHg)                                | 7               | 1     | 6 MeHg is neurotoxic, and the prenatal and postnatal stages are the most vulnerable. The TWI is 1.3 µg/kg bw and the estimated 95-percentile exposure was in the range of the TWI.                                                                 | EFSA (2012b)                    |
|                                                      |                  | 4     | Pregnant women, and high consumers of fish with high levels of mercury may exceeded the TWI.                                                                                                                               |                                 |
|                                                      |                  | 5     | Sufficient data were available.                                                                                                                                                                                         |                                 |
|                                                      |                  | 6     | Sufficient data were available.                                                                                                                                                                                         |                                 |
| Arsenic, inorganic (iAs)                             | 6.5             | 1     | 6 Reference points for carcinogenic effect are the BMDL (10) of 0.3–8 µg/kg bw per day and the BMDL (05) of 3 µg/kg bw per day. The dietary exposure to iAs was within the range of the BMDLs.                                                                 | EFSA (2009b), JECFA et al. (2011) |
|                                                      |                  | 4     | High consumers of rice.                                                                                                                                                                                                  |                                 |
|                                                      |                  | 5     | Sufficient data were available.                                                                                                                                                                                         |                                 |
|                                                      |                  | 6     | Sufficient data were available.                                                                                                                                                                                         |                                 |
| Cadmium (Cd)                                         | 6.5             | 1     | 6 The TWI is 2.5 µg/kg bw. The exposure in the European population was in the range of the TWI, and the 95-percentile exceeded the TWI.                                                                                       | EFSA (2009a)                    |
|                                                      |                  | 4     | Individuals with low iron status have an enhanced intestinal Cd absorption.                                                                                                                                              |                                 |
|                                                      |                  | 5     | Sufficient data were available.                                                                                                                                                                                         |                                 |
|                                                      |                  | 6     | Sufficient data were available.                                                                                                                                                                                         |                                 |
| Aluminium (Al)                                       | 4.5             | 1     | 4 A TWI of 1 mg/kg bw and a provisional TWI of 2 mg/kg bw per day have been established. The mean dietary exposure in Norway varied from 0.22 to 0.89 mg/kg bw per week and for high consumers of Al-containing foods the 95-percentile exceeded the TWI but was below the pTWI. | EFSA (2008b), JECFA (2011), VKM (2013b) |
|                                                      |                  | 4     | High consumers of food with Al, and one- to two-year old children.                                                                                                                                                       |                                 |
|                                                      |                  | 5     | Sufficient data were available.                                                                                                                                                                                         |                                 |
|                                                      |                  | 6     | Sufficient data were available.                                                                                                                                                                                         |                                 |
| Organic arsenic (oAs)                                | 4               | 2     | 1 The toxicity was not well characterised.                                                                                                                                                                               | Molin et al. (2015), Taylor et al. (2017) |
|                                                      |                  | 3     | 1 Little information on exposure was available.                                                                                                                                                                         |                                 |
|                                                      |                  | 4     | 0 No particularly vulnerable groups were identified.                                                                                                                                                                    |                                 |
|                                                      |                  | 5     | 1 Toxicity data were needed.                                                                                                                                                                                             |                                 |
|                                                      |                  | 6     | 1 Occurrence data were needed.                                                                                                                                                                                           |                                 |
| Chromium (Cr)                                        | 3               | 1     | 2 The two main Cr oxidation states are Cr(III) and Cr(VI). The exposure in European populations was well below the TDI of 0.3 mg/kg bw per day for Cr(III). For Cr(VI), a BMDL (10) for diffuse epithelial hyperplasia in duodenum in female mice and a BMDL (05) for haematoxicity in rats were used to calculate MOE values, and these values indicated low public health concern. | EFSA (2014b)                    |
|                                                      |                  | 4     | 0 No vulnerable groups were identified.                                                                                                                                                                                   |                                 |
|                                                      |                  | 5     | 0 Sufficient data were available.                                                                                                                                                                                         |                                 |
|                                                      |                  | 6     | 1 Occurrence data were needed.                                                                                                                                                                                           |                                 |
| Nickel (Ni)                                          | 3               | 1     | 2 A BMDL (05) of 0.28 mg/kg bw for reproductive toxicity was established. Exposure assessment for the European population was between 80 and 150 µg/person per day and of no concern.                                              | EFSA (2015c)                    |
|                                                      |                  | 4     | 1 Intake of Ni from food could be a problem for allergic individuals.                                                                                                                                                  |                                 |
|                                                      |                  | 5     | 0 Sufficient data were available.                                                                                                                                                                                         |                                 |
|                                                      |                  | 6     | 0 Sufficient data were available.                                                                                                                                                                                         |                                 |

*Explanations of category numbers: 1) Quantitative toxicity and exposure data available; 2) Toxicity of the chemical; 3) Dietary exposure to the chemical; 4) Vulnerable groups; 5) Adequacy of toxicity data; 6) Adequacy of exposure data (occurrence and/or intake).
| Chemical/chemical group | Category scored | Score | Rationale for score | References |
|-------------------------|----------------|-------|---------------------|------------|
| T-2 toxins, HT-toxins and modified forms | 8.5 | 1 | A group TDI for T-2 and HT-2 of 20 ng/kg bw per day was established. The maximum dietary exposure for T-2 and HT-2 toxins exceeded the group TDI for most European population groups. | EFSA et al. (2017a) |
| | 4 | 1 | Infants, toddlers and other children. | |
| | 5 | 0.5 | Toxicity data for T-2 and HT-2 phase I metabolites were needed. | |
| | 6 | 1 | Occurrence data for T-2 and HT-2 in Norwegian grain and grain products and data for modified forms were needed. | |
| AFLAs | 7.5 | 1 | AFLAs are carcinogenic causing mainly liver cancer. The calculated AFLA-induced cancer risk exceeded the low-risk value at the current maximum level for chronic dietary exposure. | EFSA (2007), EFSA et al. (2018b) |
| | 4 | 0.5 | Children and vegetarians may have a higher exposure than the mean population. | |
| | 5 | 0.5 | A full risk assessment on human dietary exposure from AFLAs in food were needed considering the toxicological profiles of the different AFLAs. | |
| | 6 | 0.5 | Occurrence data for APLA in Norwegian grain and food products were needed. | |
| ENNs | 6.5 | 2 | Cytotoxic effects observed in cell studies have not been observed in vivo. There were no reports on acute ENNs-mycotoxicoses in humans or animals. | EFSA (2014a) |
| | 3 | 3.0 | There was a concern with respect to chronic exposure. | |
| | 4 | 0.5 | ENNs can cross the placenta. Toddlers have the highest dietary chronic and acute exposure to ENNs. | |
| | 5 | 1.0 | Toxicity data were needed. | |
| | 6 | 1.0 | Occurrence data in Norwegian grain and grain products were needed. | |
| AOH and AME | 6 | 2 | In cell assays observed genotoxicity was not confirmed in vivo after multiple applications of a dose exceeding the highest estimated exposure in humans by a factor of at least 104. | EFSA (2011b), EFSA et al. (2016) |
| | 3 | 2 | The mean dietary exposure in adults was determined at a level 106-times below the highest dose in a mice study that did not indicate genotoxic effects. | |
| | 4 | 0.5 | The dietary exposure in children was expected to be 2–3 times higher than in adults. For vegetarians, the higher intake of food of plant origin might increase the exposure. | |
| | 5 | 1.0 | Toxicity data for AOH/AME were limited. A NOAEL had not been determined, and a TDI had not been established. | |
| | 6 | 0.5 | More data on the occurrence of AOH/AME in Norwegian cereals were needed. | |
| DON and modified forms | 6 | 1 | The tolerable daily intake of 1 μg/kg bw per day was exceeded by up to 3.5 times in infants and small children for DON alone. | VKM (2013a) |
| | 4 | 1.0 | Infants in Norway had higher consumption of cereal-based foods than other European children. | |
| | 5 | 0.5 | More occurrence data were needed. | |
| | 6 | 0.5 | Data on chronic low-level exposure to DON were needed. | |
| OTA | 5.5 | 1 | TWI (120 ng/kg bw per day), FWI (100 ng/kg bw per day) and TDI (3 ng/kg bw per day) were established based on nephrotoxicity. For intake of OTA at 4 ng/kg bw per day, the cancer risk was negligible. European exposure data was below the TDI, but high consumers exceeded the TDI. | EFSA (2006), JECFA (2008), Kuiper-Goodman et al. (2010) |
| | 4 | 0 | No relevant vulnerable groups were identified. | |
| | 5 | 0.5 | More toxicity data were needed. | |
| | 6 | 1 | Occurrence data were needed. | |
| PAT | 3.5 | 1 | The provisional maximum tolerable daily intake (pmTDI) for PAT was 0.4 μg/kg bw per day. Using European exposure data from consumption of apple-based products, the calculated MOE values indicated no concern. | JECFA (1996) |
| | 4 | 0 | No vulnerable groups were identified. | |
| | 5 | 0.5 | More toxicity data were needed. | |
| | 6 | 1 | Occurrence data were needed. | |
| ZEN and modified forms | 3.5 | 1 | The group TDI for ZEN and modified forms was 0.25 μg/kg bw per day. Estimates of chronic dietary exposure were below or in the region of the TDI for all age groups. | EFSA (2016a) |
| | 4 | 0 | Specific vulnerable groups were not identified. | |
| | 5 | 1 | Data on estrogenicity and toxicokinetics of the modified forms (phase I and phase II metabolites) were needed. | |
| | 6 | 0.5 | Data on ZEN in maize-based products was needed. There was limited data on the occurrence of modified forms in food and feed. | |

*Explanations of category numbers: 1) Quantitative toxicity and exposure data available; 2) Toxicity of the chemical; 3) Dietary exposure to the chemical; 4) Vulnerable groups; 5) Adequacy of toxicity data; 6) Adequacy of exposure data (occurrence and/or intake).
| Chemical/chemical group | Category scored* | Score | Rationale for score | References |
|-------------------------|------------------|-------|---------------------|------------|
| **Dioxins and DL-PCBs** | 8                | 6     | A TWI of 2 pg TE/kg bw per week was established and the estimated exposure for the European population was above the TWI. | EFSA et al. (2018c) |
| 4                      | 1                |       | Young women and children were sensitive groups. |           |
| 5                      | 0.5              |       | Data on the relative potency of individual DL-compounds were needed, in particular for PCB-126. |           |
| 6                      | 0.5              |       | Occurrence data for composite food (e.g. fish gravins, fish cakes) and land-based food (butter, cheese, eggs) were needed. |           |
| **PFOs and PFOA**      | 8                | 6     | Average exposure was above the provisional TWI in several dietary surveys. | EFSA et al. (2018a) |
| 4                      | 0.5              |       | High consumers of fish have higher exposure. |           |
| 5                      | 0.5              |       | Data on mode of action were needed. |           |
| 6                      | 1                |       | Data on occurrence in drinking water were needed. For occurrence data in foods, methods with lower LOQ should be used. |           |
| **NDL-PCBs**           | 5.5              | 2     | NDL-PCB congeners were considered to be of low toxicity. | EFSA et al. (2005g) |
| 3                      | 2                |       | NDL-PCB congeners are hardly degradable, highly fat-soluble, enriched in the food chain and can be measured at particularly high concentrations in certain types of seafood with high fat content (e.g. cod liver). |           |
| 4                      | 1                |       | Potentially vulnerable groups were young women nursing babies and people with a high consumption of fatty fish and fish products, seaall eggs and brown crab meat. |           |
| 5                      | 0.5              |       | Data on the toxic mode of action were needed. Interacting effects between different PCB compounds were likely and data were needed. |           |
| 6                      | 0                |       | Sufficient data were available. |           |
| **BTBPE, DBDPE, HBB**  | 4                | 1     | Oral exposure of rats indicated low toxicity. | EFSA (2012a) |
| 3                      | 1                |       | Most studies in food showed occurrence levels below the LOQ. |           |
| 4                      | 0                |       | There were no particular vulnerable groups. |           |
| 5                      | 1                |       | Toxicity data were needed. |           |
| 6                      | 1                |       | Occurrence data were needed. |           |
| **TBP**                | 4                | 2     | Current dietary exposure to TBP does not raise a health concern. | EFSA (2012c) |
| 4                      | 0                |       | No indication of susceptible groups. |           |
| 5                      | 1                |       | Toxicity data were needed. |           |
| 6                      | 1                |       | Occurrence data were needed. |           |
| **D6**                 | 4                | 2     | A MOE of approximately 40,000 was reported for the general population in Canada. | Danish Ministry of the Environment (2014), Environment Canada and Health Canada (2008) |
| 4                      | 0.5              |       | D6 was detected in human breast milk samples, and infants may therefore have a high intake. |           |
| 5                      | 1                |       | Toxicity data on acute inhalation toxicity, irritation, sensitisation, multiple dose toxicity, reproductive toxicity, mutagenicity, genotoxicity or carcinogenicity were needed. |           |
| 6                      | 0.5              |       | Occurrence data were needed. |           |
| **PBDEs**              | 3.5              | 2     | A BMDL10 was derived from effects on neurodevelopment in mice as the critical endpoint. MOE values were calculated and indicated no health concerns. | EFSA (2011a) |
| 4                      | 0.5              |       | Children (1 to 3 years) have high exposure. |           |
| 5                      | 0.5              |       | More toxicity data were needed to establish a HBGV. |           |
| 6                      | 0.5              |       | New occurrence data for food on the Norwegian market were needed. |           |
| **HBCDD**              | 3                | 2     | Current dietary exposure to HBCDD does not raise a health concern. | EFSA (2011c) |
| 4                      | 0                |       | There were no particular vulnerable groups. |           |
| 5                      | 0.5              |       | More toxicity data were needed. |           |
| 6                      | 0.5              |       | Updated occurrence data were needed. |           |

*Explanation of category numbers: 1) Quantitative toxicity and exposure data available; 2) Toxicity of the chemical; 3) Dietary exposure to the chemical; 4) Vulnerable groups; 5) Adequacy of toxicity data; 6) Adequacy of exposure data (occurrence and/or intake).
in the food groups or high consumption of these foods, as both can lead to high contaminant exposure of the consumers, and thus contributing most to the exposure of the population to a certain chemical.

3. Results and discussion

3.1. Chemical substances included in the ranking for monitoring

In total, 33 relevant chemical substances or chemical groups were selected by expert judgement as a proof of concept for the development of a ranking method. The inclusion criteria were high toxicity, high exposure and/or lack of toxicity or exposure data. All chemical substances were naturally occurring, unintentionally or incidentally in foods or formed during food processing:

- Metals and metalloids including aluminium (Al), inorganic arsenic (iAs), organic arsenic (oAs), cadmium (Cd), chromium (Cr), lead (Pb), methylmercury (MeHg) and nickel (Ni),
- Mycotoxins including aflatoxins (AFLAs), alternariol (AOH) and alternariol methyl ether (AME), deoxynivalenal (DON) and modified forms, enniatins (ENNs), ochratoxin A (OTA), patulin (PAT), T-2 toxin, HT-toxin and modified forms, zearalenone (ZEN) and modified forms.
- Persistent organic pollutants (POPs) including brominated flame retardants (polybrominated diphenyl ethers (PBDEs), hexabromocyclododecane (HBCDD), hexabromobenzene (HBB), decabromodiphenyl ethane (DBDPE), 1,2-bis(2,4,6-tribromophenoxy) ethane (BTBPE), 2,4,6-tribromophenol (TBP)), dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs), non-dioxin-like PCBs (NDL-PCBs), perfluoroalkyl substances (PFAS; perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA)) and siloxanes (dodecamethylcyclopentasiloxane (D6)).
- Process-induced contaminants including acrylamide, glycidyl esters (GEs), 3-monochloropropanediol (3-MCPD) and its esters, furans (furan, 2-methylfuran and 3-methylfuran), heterocyclic aromatic amines (HAAs) and polycyclic aromatic hydrocarbons (PAHs).
- Compounds in food contact materials, including bisphenol A (BPA), bisphenol S (BPS), bisphenol F (BPF) and bisphenol AF (BPAF) and the phthalates bis(2-ethylhexyl)phthalate (DEHP), butyl-benzyl-phthalate (BBP), di-n-butylphthalate (DBP), di-isodecyl phthalate

| Chemical/ chemical group | Category scored | Score | Rationale for score | References |
|--------------------------|----------------|-------|---------------------|------------|
| Furans 8.5               | 1              | 6     | The exposure to furan is of health concern for all age groups, particularly for infants and children. | EFSA et al. (2017b), VKM (2012) |
|                          | 4              | 0.5   | Infants have the highest exposure. | EFSA (2015a), VKM (2015) |
|                          | 5              | 1     | Toxicity data were needed to establish a TDI. | |
|                          | 6              | 1     | Occurrence data were needed. | |
| Acrylamide 8             | 1              | 6     | The MOE values across all age groups indicated a health concern. Similar results were found for Norwegian children. | EFSA (2016b), EFSA et al. (2018d) |
|                          | 4              | 1     | Children have the highest dietary exposure. | |
|                          | 5              | 0.5   | Data on developmental outcomes were needed. | |
|                          | 6              | 0.5   | Occurrence data for home-cooked meals and new types of crisp bread and biscuits were needed. | |
| GEs 8                    | 1              | 6     | GEs are converted to glycidol, which is genotoxic and carcinogenic, following ingestion. Most MOE values were below 25,000; values of 25,000 or higher were considered of low health concern. | EFSA et al. (2018d) |
|                          | 4              | 0.5   | Infants consuming formula only, and children consuming marine oil supplements. | |
|                          | 5              | 1     | Data on dose–response for carcinogenesis from chronic lifetime oral administration of glycidol and its esters were needed. | |
|                          | 6              | 0.5   | Data on GEs in refined fish oil were needed. | |
| HAAs 7                   | 2              | 3     | Several HAAs have been classified as possible (class 2A) or probable (class 2B) carcinogens. | IARC (2015) |
|                          | 3              | 2     | Information about the daily HAA intake can vary substantially among epidemiological studies. | |
|                          | 4              | 0.5   | Persons with high intake of meat, especially read meat prepared as well-done, will have high exposure. Persons with high activity of metabolic enzymes, both phase I and phase II, that affect the metabolism of HAAs in the direction of bioactivation are more vulnerable. | |
|                          | 5              | 1     | Toxicity data for other endpoints than mutagenicity, genotoxicity and carcinogenicity were needed. | |
|                          | 6              | 0.5   | Occurrence data were needed, especially taking food preparation methods into consideration. | |
| PAHs 6                   | 1              | 4     | PAHs were genotoxic compounds. The MOE for high consumers ranged from 9,600 to 10,800. | EFSA et al. (2018a), VKM (2011) |
|                          | 4              | 1     | People consuming food products containing increased PAH concentrations such as mussels from contaminated waters, grilled meat, food prepared using open fire etc., are more vulnerable. | |
|                          | 5              | 0.5   | Exposure to mixtures of PAHs is usual, and data on carcinogenic effects of mixtures were needed. | |
|                          | 6              | 0.5   | Occurrence data for food prepared on fire, grilled food, mussels from contaminated areas etc., were needed. | |
| 3-MCPD and its fatty esters 5.5 | 1 | 4 | The TDI of 2 µg/kg bw per day was not exceeded in the adult population. A slight exceedance of the TDI was observed for high consumers in younger age groups and in particular in scenarios considering infants receiving formula only. | EFSA et al. (2018d) |
|                          | 4              | 0.5   | Infants consuming formula only may exceed the TDI. | |
|                          | 5              | 0.5   | Data on developmental and neurodevelopmental effects, and effects on male reproduction and fertility were needed. | |
|                          | 6              | 0.5   | Occurrence data were needed. | |

*Explanations of category numbers: 1) Quantitative toxicity and exposure data available; 2) Toxicity of the chemical; 3) Dietary exposure to the chemical; 4) Vulnerable groups; 5) Adequacy of toxicity data; 6) Adequacy of exposure data (occurrence and/or intake).
Table 6

| Chemical/chemical group | Category scored | Score | Rationale for score |
|-------------------------|----------------|-------|---------------------|
| **Chemical/chemical group** | **Category scored** | **Score** | **Rationale for score** |
| **Chemical/chemical group** | **Category scored** | **Score** | **Rationale for score** |
| **BPF, BPS and BPA** | **6.5** | **3** | **2** Biomonitoring data showed an increasing exposure. **4** | **0.5** Knowledge on possible vulnerable groups was needed. **5** | **1** No threshold for toxicity had been established. **6** | **1** Data on occurrence in foods were needed. **EFSA (2015b), EFSA (2015c), EFSA (2015d), EFSA (2015e), EFSA et al. (2019), Sakhiet al. (2014)** |
| **Phthalates (DEHP, BBP, DBP, DIDP, DINP)** | **3.5** | **4** | **0.5** DEHP had adverse reproductive effects, which were transferred to future generations. The fetus was especially vulnerable to phthalate exposure. **5** | **0.5** More studies on immunotoxicity, neurotoxicity and endocrine effects were needed. **6** | **0.5** More occurrence data were needed. **EFSA (2015b)** |
| **BPA** | **3** | **4** | **0** There were no particular vulnerable groups. **5** | **0.5** More toxicity data were needed to establish a permanent TDI. **6** | **0.5** More occurrence data were needed. **EFSA (2013a)** |

*Explanations of category numbers: 1) Quantitative toxicity and exposure data available; 2) Toxicity of the chemical; 3) Viable exposure to the chemical; 4) Vulnerable groups; 5) Adequacy of toxicity data; 6) Adequacy of exposure data (occurrence and/or intake).**

3.2. Rationale for the scoring and ranking of individual chemical substances or chemical groups for monitoring

The chemical substances were evaluated and scored according to the methodology presented in Table 1. The scoring and the rationale for the scores given are shown in Table 2 for metals and metalloids, Table 3 for mycotoxins, Table 4 for POPs, Table 5 for process-induced contaminants, and Table 6 for compounds present in food contact materials. For metals and metalloids, the total scores ranged from 3.0 for nickel and chromium to 7.5 for lead. For mycotoxins, the total scores ranged from 3.5 for PAT and ZEN and modified forms to 8.5 for T-2 toxins, HT-2 toxins and modified forms. For POPs, the total scores ranged from 3.5 for PBDEs to 8.0 for dioxins and DL-PCBs, and PFOS and PFOA. For process-induced contaminants, the total scores ranged from 5.5 for 3-MCPD and its fatty esters to 8.5 for furans. For compounds in food contact materials, the total scores ranged from 3.0 for BPA to 6.5 for BPF, BPS and BPAF.

We have developed the ranking of chemical substances for monitoring in foods as a tool for prioritizing setting with regard to risk-based food safety control. The method allows the ranking of chemical substances in different chemical classes and is simply based on the scoring of risk and knowledge gaps by expert judgment considering existing data. Knowledge gaps regarding toxicity and exposure are usually not included in risk ranking methods developed by other agencies (NFA et al., 2018; van der Fels-Klerx et al., 2015). We considered the inclusion of such gaps essential for the comprehensive evaluation of the risk potential of dietary contaminants and for their potential inclusion in food monitoring programs. The method developed by us is useful for the ranking of dietary contaminants, such as metals, mycotoxins, persistent organic pollutants, process-induced contaminants and food contact materials, as shown in this paper. However, in principle, the method can be used for all types of chemical substances occurring in foods, including residues of regulated compounds used for a specific purpose in food production, i.e. food additives, flavourings, pesticides, veterinary medicines and packaging materials. The European Food Safety Authority (EFSA) published in 2015 an external scientific report called “Critical review of methodology and application of risk ranking for prioritisation of food and feed related issues, on the basis of the size of the anticipated health impact” (van der Fels-Klerx et al., 2015), which gave an overview of various risk ranking methods. The included methods ranged from rather simple methods such as the Hazard Index (HI), which is the Estimated Daily Intake (EDI) divided by the HBGV, to more complex methods considering the severity of the health hazard, such as Disability Adjusted Life Years (DALY)/Quality Adjusted Life Years (QALY) or Multi Criteria Decision Analysis (MCDA). The simple methods may be used without much prior experience, whereas the more sophisticated methods need specialist training and experience in order to use them in a correct and meaningful way.

The Swedish National Food Agency (NFA) has developed the “Risk Thermometer Tool” in cooperation with EFSA for the risk ranking of chemical substances and for better risk communication. The method,
which uses MOE, defined as NOAEL/exposure, and integrates severity by adjusting for the severity of the critical health effects, is called severity-adjusted margins of exposure (SAMOE) (NFA et al., 2018). The SAMOE values were divided into five risk classes corresponding to different levels of human health concern (1 - no concern, 2 - no-to-low concern, 3 - low-to-moderate concern, 4 - moderate-to-high concern, 5 - high concern). The SAMOE method depends, however, on good quantitative data for both exposure and toxicity, which are not always available.

Our method is designed specifically for ranking and not for risk communication. It is straightforward as it is based on expert judgement of the existing data and uses a simplified scoring system. Due to the consideration of information on vulnerable groups and missing toxicity and exposure data (categories 4–6, Table 1), the results have a built-in safety factor and uncertainty margin, allowing the ranking of chemical substances in foods for which little data are available. By setting the maximum total score for toxicity and exposure to 6 points and the maximum total score for vulnerable groups and adequacy of toxicity and exposure data to 3 points (Table 1), we have built-in weighing factors that ensure the balancing of existing data and expert evaluation. The method is suitable not only for known contaminants in food, but for all chemical substances that occur in foods, both unintended contaminants and deliberately added chemical substances, even if the knowledge level regarding occurrence and toxic potential might be rather low.

3.3. Ranking with or without consideration of vulnerable groups and data adequacy

The scoring of vulnerable groups and adequacy of data (categories 4–6, Table 1) in the ranking may be considered as “uncertainty-based scoring criteria”, whereas when they are included together with scoring based on existing knowledge of toxicity and exposure, the method can be considered as “the full ranking for monitoring method”. The impact of including the “uncertainty-based scoring criteria” in the ranking was evaluated using the chemical substances in the Tables 2 to 6. The results are shown in Table 7. Whereas ranking by setting scores for all categories, “the full ranking for monitoring method” (Table 1), delivered scores in the range from 2 to 9, the exclusion of the “uncertainty-based scoring” in a shortened version of the method, using only the risk-based categories 1–3 (i.e. toxicity and exposure; Table 1), delivered scores in the range from 2 to 6. Applying “the full ranking for monitoring method”, none of the chemical substances received the lowest or the highest possible score, while with the “shortened method” two-thirds of

| Table 7 | Comparison of ranking performed considering risk- and uncertainty-based scoring categories (full method) or only risk-based scoring categories (shortened method). |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| a. Metals and metalloids | Risk and uncertainty | Ni Cr | oAs Al | Cd iAs | MeHg | Pb |
| Scores | 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 |
| Risk only | 2.0 3.0 4.0 5.0 6.0 |
| oAs, Ni, Cr | Al | MeHg, Cd, iAs, Pb |
| b. Mycotoxins | Risk and uncertainty | ZEN, PAT | OTA | ENNs, AOH and AME, DON | AFLAs | T-2 and HT-2 |
| Scores | 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 |
| Risk only | 2.0 3.0 4.0 5.0 |
| ZEN, PAT | ENNs, AOH and AME, DON |
| c. Persistent organic pollutants | Risk and uncertainty | HBCDD PBDEs DBDPE, BTBPE, HBB, TBP, D6 NDL-PCBs dioxins and DL-PCBs, PFOS and PFOA |
| Scores | 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 |
| Risk only | 2.0 3.0 4.0 |
| DBDPE, PBDE, BTBPE, HBB, HBCDD, TBP, D6 | NDL-PCBs |
| d. Process-induced contaminants | Risk and uncertainty | 3-MCPD PAH HAAs acrylamide, GEs furans | 3-MCPD, PAH |
| Scores | 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 |
| Risk only | 2.0 3.0 4.0 |
| 3-MCPD, PAH |
| e. Chemical substances in food contact materials | Risk and uncertainty | BPA phthalates | BPP, BPS, BPAF |
| Scores | 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 |
| Risk only | 2.0 3.0 4.0 |
| BPA, phthalates | BPP, BPS, BPAF |

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Table 8
Foods and beverages identified as relevant for the monitoring of the ranked chemical substances.

| Contaminant          | Baby foods | Bakery wares | Cereal grains and products thereof | Coffee/ tea products | Dairy products | Drinking water | Eggs | Fish/ seafood | Meat | Nuts/ seeds/ pulses | Spices | Vegetables/ fruit | Vegetable oils |
|----------------------|------------|--------------|-----------------------------------|----------------------|----------------|----------------|------|---------------|------|-------------------|--------|------------------|---------------|
| **Metals and metalloids** |            |              |                                   |                      |                |                |      |               |      |                   |        |                  |               |
| Lead                 | 7.5        |              | Cereal products and grains        |                      |                |                |      |               |      | Game meat (large and small game), minced meat from cervids |        |                  |               |
| Methylmercury        | 7          |              | Fish and other seafood           |                      |                |                |      |               |      |                   |        |                  |               |
| Cadmium              | 6.5        |              | Cereals and cereal products       |                      |                |                |      |               |      | Meat and meat products |        |                  |               |
| Inorganic arsenic    | 6.5        |              | Grain-based processed products, e.g. rice and wheat bread | Milk and dairy products | Drinking water |                |      |               |      | Fish and other seafood |        |                  |               |
| Aluminium            | 4.5        |              | Cereal products produced with baking powder |                      | Drinking water |                |      |               |      |                   |        | Agricultural products |               |
| Organic arsenic      | 4          |              | Fish and other seafood           |                      |                |                |      |               |      |                   |        |                  |               |
| Chromium             | 3          |              | Drinking water                    |                      |                |                |      |               |      |                   |        |                  |               |
| Nickel               | 3          |              | Plants accumulating nickel, e.g. cocoa |                      |                |                |      |               |      |                   |        |                  |               |
| **Mycotoxins**       |            |              |                                   |                      |                |                |      |               |      |                   |        |                  |               |
| T-2 toxins, HT-toxins and modified forms | 8.5 | | Norwegian wheat and oats | | | | | | | | | | | |
| AFLAs                | 7.5        | | | | | | | | | | | | | |
| ENNs                 | 6.5        | | | | | | | | | | | | | |
| AOH and AME          | 6          | | | | | | | | | | | | | |
| DON and modified forms | 6        | | | | | | | | | | | | | |

(continued on next page)
Table 8 (continued)

| Contaminant | Baby foods | Bakery wares | Cereal grains and products thereof | Coffee/tea dairy products | Drinking water | Eggs | Fish/seafood | Meat | Nuts/seeds/pulses | Spices | Vegetables/fruit | Vegetable oils |
|-------------|------------|--------------|-----------------------------------|---------------------------|----------------|------|--------------|------|----------------|--------|----------------|---------------|
| OTA         | 5.5        |              |                                   |                           |                |      |              |      |                |        |                |               |
| ZEN and modified forms | 3.5        |              |                                   |                           |                |      |              |      |                |        |                | Vegetable oil |
| PAT         | 3.5        | Baby food    |                                   |                           |                |      |              |      |                |        |                | Fresh fruit, fruit juices |

Persistent organic pollutants

| Dioxins and DL-PCBs | 8           | Buttery, cheese | Eggs | Fish and other seafood. Specifically composite food such as fish gratin and fish cakes |
| PPOS and PFOA      | 8           | Drinking water  | Fish and other seafood            |
| NDL-PCBs           | 5.5         | Buttery, cheese | Eggs | Fish and other seafood. Specifically composite food such as fish gratin and fish cakes |
| BTBPE               | 4           |                | Fish and seafood. Specifically fatty fish and fish liver |
| DBDPE               | 4           | Buttery, cheese | Eggs | Fish and other seafood |
| HBB                 | 4           |                | Fish and seafood                  |
| TBP                 | 4           |                | Fish and seafood                  |
| D6                  | 4           |                | Fish and other seafood            |
| PBDEs               | 3.5         | Buttery, cheese | Eggs | Fish and other seafood. Specifically composite food such as e.g. fish gratin and fish cakes |
| HBCDD               | 3           | Buttery, cheese | Eggs | Fish and other seafood. Specifically composite food such as e.g. fish gratin and fish cakes |

Process-induced contaminants

(continued on next page)
the chemical substances received the lowest or the highest score. The differentiation between the chemical substances was notably increased with the full method as compared to the shortened version. Compounds scored 2 by the shortened method were scored 3, 3.5 or 4 by the full method. Compounds scored 4 by the shortened method received scores of 4.5, 5.5, 6 or 6.5 by the full method (Table 7). With the full method, higher resolution between chemical substances was even possible for those receiving the highest scores, such as 6.5, 7, 7.5, 8 or 8.5. We therefore consider the inclusion of both risk-based and uncertainty-based ranking categories as advantageous for the identification and ranking of chemical substances in foods for monitoring. However, both methods ranked the contaminants largely in the same order.

3.4. Identification of foods for monitoring

Food groups considered relevant for monitoring were identified by expert judgements based on available occurrence data in foods. The selected food groups included baby foods, bakery wares, cereal grains and products thereof, coffee/tea, dairy products, drinking water, eggs, fish/seafood, meat, nuts/seeds/pulses, spices, vegetables/fruits and vegetable oils (Table 8). For chemical substances in food contact materials, specific food groups could not be identified as their presence in food depends on the type of packaging material used and the character of the contact. Each food group identified as important contained at least one chemical with the highest scores (7.5 to 8.5) in this study. Three food groups stood out as especially relevant for monitoring: cereal grains and products thereof, fish/seafood and vegetables/fruits. These foods are included in the dietary recommendations published by the Norwegian Directorate for Health, saying: "Eat whole grain foods every day. Eat fish two to three times a week. Eat at least five portions of vegetables, fruit and berries every day." (Nasjonalt Råd for Ernæring, 2011). The relative importance of each food group varied for the different chemical classes. Whereas metals and metalloids, mycotoxins and process-induced contaminants should be monitored in cereal grains and products thereof, metals and metalloids, POPs and process-induced contaminants should be monitored in fish/seafood, and metals and metalloids, mycotoxins and process-induced contaminants should be monitored in vegetable/fruits. The chemical class identified as relevant for all food groups except drinking water, eggs, spices and nuts/seeds/pulses, was process-induced contaminants. All chemical substances from this class that were evaluated in the present study were scored 0.5 or 1 in category 6 (Table 5) with rationales for the scoring given as “Little data were available on exposure” or “Some exposure data were lacking”, showing that there is an urgent need for monitoring to allow exposure characterisation. As not all chemical substances can be monitored at the same time due to the limited resources available, prioritisation is needed. By restricting the number of the most important food groups for monitoring of each chemical/chemical group, analytical and sampling resources for monitoring could be planned by the risk managers in such a way that several highly ranked chemical substances could be analysed in the same food groups, thus saving resources. It has been suggested that food products consumed in significant quantities and those that may contain elevated contaminant levels should be sampled and tested with high frequency (INFOSAN, 2009). To make sure that foods recommended as healthy are also safe, data on the occurrence of contaminants in these foods should be available.

The actual use of this ranking for prioritisation is to be decided by the risk managers who are in charge of the monitoring. Which substances ultimately to be included in the monitoring will depend on the available funds for monitoring at the time and possibly also other concerns, such as how the various substances can be analysed together, time since last monitoring of the substance, alerts from other countries on health risk from certain substances, media interest etc.

| Contaminant                  | Total score | Baby foods | Bakery wares | Cereal grains and products thereof | Coffee/tea | Dairy products | Drinking water | Meat | Nuts/ seeds/ pulses | Fish/seafood | Vegetables/fruit |
|------------------------------|-------------|------------|--------------|-----------------------------------|------------|----------------|----------------|------|-------------------|--------------|-----------------|
| Furans                      | 8.5         | Jarred baby foods | Baby foods | Cereal based products | Cereal-based products | Cereal-based products | Cereal-based products | Cereal-based products | Cereal-based products | Cereal-based products | Cereal-based products |
| GHS                         | 8           | Jarred baby foods | Baby foods | Biscuits, crackers and crisp breads, bread products | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals |
| Acrylamide                  | 8           | Jarred baby foods | Baby foods | Biscuits, crackers and crisp breads, bread products | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals |
| HA                           | 7           | Jarred baby foods | Baby foods | Biscuits, crackers and crisp breads, bread products | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals |
| PAH (PAHs)                  | 6           | Jarred baby foods | Baby foods | Biscuits, crackers and crisp breads, bread products | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals |
| 3-MCPD and its fatty esters | 5.5         | Jarred baby foods | Baby foods | Biscuits, crackers and crisp breads, bread products | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals | Breakfast cereals |

Table 8 (continued)
4. Conclusions

A method for ranking of chemical substances in foods was developed. Subsequent use of the ranking is meant as a tool for risk managers in their prioritisation for food monitoring programs as part of a risk-based food control. The method is straightforward as it is based on expert judgement by risk assessors of existing risk- and uncertainty-based data and uses a simplified scoring method. The resolution between the chemical substances was notably increased with the full method, which includes vulnerable groups and adequacy of data, as compared with the shortened version. The methodology can be used to compare different classes of chemicals, as well as to compare subtypes of substances within the chemical classes. In principle, this method can be used for all classes of chemical substances that occur in foods, both unintended contaminants and deliberately added chemical substances.

At large, the obtained ranking mirrors the need for monitoring and research to obtain new data as have been identified in many risk assessments opinions by EFSA and VKM and highlighted in research papers.

CRediT authorship contribution statement

Gro Haarklou Mathisen: Conceptualization, Methodology, Writing - original draft, Investigation, Writing - review & editing. Jan Alexander: Methodology, Investigation, Writing - review & editing. Christiane Kruse Fæste: Methodology, Investigation, Writing - review & editing. Trine Hussy: Methodology, Investigation, Writing - review & editing. Helle Katrine Knutzen: Methodology, Investigation, Writing - review & editing. Robin Ørnsrud: Methodology, Investigation, Writing - review & editing. Inger-Lise Steffensen: Conceptualization, Methodology, Writing - original draft, Investigation, 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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