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Methodology for risk-based monitoring of contaminants in food – A case study in cereals and fish



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ABSTRACT

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In this study, a methodology was developed that can be used as input for risk-based monitoring plans for chemical contaminants in food products. The novel methodology was applied to a case study in which cereals and fish were evaluated simultaneously for the possible presence of mycotoxins and heavy metals. The methodology was based on hazard quotients that were estimated by dividing the daily intake - using concentrations of the contaminants in the different food products and consumption of the respective products combined per product group - by the health based guidance value (HBGV) or reference points used for assessing potential health concerns (RPHC). The most relevant hazard-product combinations were further ranked based on the volume of import of the ingredients, per import country and a defined contaminant prevalence level per country. For fish, the hazard quotients were around ten times lower compared to the highest hazard quotients in cereals. Consumption of molluscs, mackerel-type fish and herring-type fish contaminated with mercury contributed most to the HBGV or RPHC. The top 25 hazard-product combinations for various age groups included: aflatoxin B1 in combination with wheat, rice (products), maize (products), and pasta, zearalenone in combination with wheat (products), T2/HT2-toxin in combination with rice (products), and DON in combination with wheat (products). The methodology presented showed to be useful in identifying the most relevant hazard-food-age group combinations and the most relevant import countries linked to these that should be included in the monitoring. As such, the method can help risk managers in establishing risk-based monitoring programs.

1. Introduction

Food safety management is complex as a wide variety of food safety hazards are present in a range of food products. In order to control these hazards, monitoring programs that aim to determine the presence of hazards in food are in place. These programs are part of verification and validation of Hazard Analysis Critical Control Points (HACCP) in companies, or part of official control programs by competent authorities. Due to European Union (EU) legislation and budgetary reasons, monitoring programs are increasingly risk-based focussing on those products and hazards that pose the highest risk to human health. A risk-based approach implies a prioritized collection and analyses of samples from food products based on risk ranking of hazards in the particular food products. The following steps can be distinguished in the risk based approach: what should be monitored (risk ranking of food safety hazards and food products) and where should be monitored (risk based surveillance) (Van Asselt et al., 2012). For the first step, different methods of risk ranking are available such as expert judgement, flow charts or decision trees, risk matrix, disease burden approaches, scoring method, risk ratio, or risk assessment (Van der Fels-Klerx et al., 2018). Once the hazard-product combinations are defined, the next step is to identify where should be monitored, i.e. the countries, locations and/or companies that are important to inspect (Van Asselt et al., 2013). These two steps have been combined previously in a method for risk based monitoring of contaminants in animal feed produced in the Netherlands. The method aims to rank the various feed ingredients based on the risk for animal and human health related to the presence of contaminants in the ingredients. In the ranking, the country of origin of the feed materials, the presence of the contaminant in the ingredient originating from that particular country and inclusion of the ingredients in feeds for various animal species is taken into account (Van der Fels-Klerx et al., 2017). The method has been applied in the so-called RiskFeed model, which is currently in use by the Netherlands Food and Consumer Product Safety Authority. According to our knowledge, this is the first method combining what (food-hazard combinations) and where (which countries) to monitor on a risk-basis. It aims to help in the prioritization of

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Fig. 1. Flowchart of methodology, the numbers correspond with the formulas.

contaminants and feed ingredients to include in the National Control Program Animal Feed. The model covers a wide range of feed materials produced and imported to the Netherlands for feed production. Currently, such a model ranking hazard-product combinations for food, including the country of origin of the food or their ingredients and consumption patterns, is lacking.

In this study, a case is used to develop such a model. The case study referred to a selected group of contaminants and food products, in this case mycotoxins and heavy metals in cereal based foods and fish in the Netherlands. Heavy metals can impact human health (Martin & Griswold, 2009). Environmental contamination is caused mainly by waste from industrial processes (Kim et al., 2015). One exposure route for humans to heavy metals is eating fish from polluted ecosystems, as heavy metals can accumulate in fish (Sheikhzadeh & Hamidian, 2021). Cadmium, amongst other heavy metals, is classified as group 1 carcinogens by the International Agency for Research on Cancer. Although levels of heavy metals in cereals are usually low, due to the high consumption of these products they contribute to the dietary intake of heavy metals. EFSA established that cereals had the highest contribution to the dietary intake of cadmium (EFSA, 2012a). Apart from the presence of heavy metals, cereals are susceptible to contamination with mycotoxins, secondary metabolites from fungi. This contamination can cause serious health problems in humans as mycotoxins have, among others, carcinogenic effects as mentioned by Khodaei et al. (2021).

Since currently a method to rank food products for potential chemical hazards including what and where to monitor is lacking, the aim of this study was to develop such a method for risk based monitoring of chemical contaminants in food, and to demonstrate the methodology by applying it to a case study.

2. Material and methods

2.1. Methodology

The risk ranking in this study was based on the risk ratio method (Van der Fels-Klerx et al., 2018). This is a quantitative method that compares the estimated human exposure with a health based guidance value (HBGV) or reference points for potential health concerns (RPHC). The risk ranking is expressed in the so-called hazard quotient (HQ), in which the estimated daily intake of the contaminant via food ingestion is divided by the HBGV or RPHC (Goumenou & Tsatsakis, 2019) as indicated in Eq. (1):

$$HQ = \frac{EDI\left(\frac{\mu g}{day}\right)}{HBGVorRPHCpercontaminant(\mu g/kgbw/day)^*bodyweightperagegroup(kgbw)}$$

(1)

Table 1

Results of the hazard quotients (HQs) for cereal products based on the ${\rm EDI}^1$ and ${\rm HBGV}^1$ or ${\rm RPHC}^{1.}$

Product	Hazard	Age group	EDI ¹ (µg/	(HBGV or RPHC) *	HQ
Gloup			uay)	Dw (µg/kg)	
Wheat	AflaB1	toddler	0.0245	0.0006	44.4
Rice	AflaB1	toddler	0.0180	0.0006	32.7
Wheat	AflaB1	child	0.0356	0.0014	26.0
Rice	AflaB1	child	0.0632	0.0014	25.6
Rice	AflaB1	adult	0.0430	0.0032	19.5
Wheat	AflaB1	adolescent	0.0406	0.0026	16.7
Rice	AflaB1	adolescent	0.0382	0.0026	15.8
Wheat	AflaB1	adult	10.2232	0.0032	11.8
Wheat	ZEN	toddler	0.5303	3.4500	3.0
Rice	T2HT2	toddler	26.4050	0.2760	1.9
Wheat	DON	toddler	0.0010	13.8001	1.9
Maize	AflaB1	toddler	14.8601	0.0006	1.7
Wheat	ZEN	child	1.0338	8.5727	1.7
Rice	T2HT2	child	0.0019	0.6858	1.5
Maize	AflaB1	child	1.8586	0.0014	1.4
Rice	T2HT2	adult	38.3814	1.6248	1.1
Wheat	DON	child	17.9432	34.2908	1.1
Wheat	ZEN	adolescent	0.0006	16.0797	1.1
Pasta	AflaB1	toddler	1.1936	0.0006	1.0
Rice	T2HT2	adolescent	0.0012	1.2864	0.9
Pasta	AflaB1	child	15.9352	0.0014	0.9
Wheat	ZEN	adult	46.3445	20.3103	0.8
Wheat	DON	adolescent	0.0018	64.3189	0.7
Pasta	AflaB1	adolescent	0.0019	0.0026	0.7
Maize	AflaB1	adult	0.0632	0.0032	0.6

¹ EDI: estimated daily intake (μ g/day); HBGV: health based guidance value (μ g/kg bw/day); RPHC: reference points for potential health concerns (μ g/kg bw/day); bw: body weight (kg).

Table 2

Results of the hazard quotients (HQs) for fish products based on the EDI^1 and $\text{HBGV}^{1.}$

Product Group	Hazard	Age group	EDI¹ (µg∕ day)	HBGV ¹ * bw ¹ (µg/kg)	HQ
Mollusc	Lead	adult	0.0880	4.0621	0.02
Mackerel-type fish	Mercury	adult	0.8931	46.3888	0.02
Herring-type fish	Lead	adult	0.0557	4.0621	0.01
Mackerel-type fish	Mercury	toddler	0.0879	7.8799	0.01
Mackerel-type fish	Mercury	adolescent	0.4017	36.7261	0.01

¹ EDI: estimated daily intake (μ g/day); HBGV: health based guidance value (μ g/kg bw/day); bw: body weight (kg).

The estimated daily intake (EDI) used in Eq. (1) is calculated in amounts per day as:

country. Three classes were used to classify the country index as low, medium and high. The same classes were used as previously determined by Van der Fels-Klerx et al. (2017) based on expert knowledge, literature and contaminant data from historical monitoring plans and from the RASFF database (see Appendix D). The qualitative classification of low, medium and high was converted into quantitative values expressed as 0.01, 0.1 and 1, respectively to allow for an estimation of the weighted import volume per country per product group (Eq. (3)):

$$Weighted import volume = Import volume \left(\frac{Mg}{year}\right)^* Countryrisk$$
(3)

The various steps in the risk ranking are indicated in Fig. 1.

2.2. Case study

The developed methodology was applied to a case study consisting of a selected set of ingredients used for food production in the Netherlands and a selected set of chemical contaminants. To this end, grain and fish ingredients were selected since these two commodities can both be eaten unprocessed or in processed from, as part of composite products. The products are described in more detail in section 2.4. The products are combined one on one with a range of mycotoxins and heavy metals similarly chosen as in the RiskFeed model (Adamse et al., 2017). Hazards with regulated maximum limits or guidance values were included in the analysis, i.e. the mycotoxins Aflatoxin B1, Deoxynivalenol (DON), Ochratoxin A, T-2 toxin and HT-2 toxin, and Zearalenone (ZEN) and the heavy metals lead, cadmium, mercury as heavy metals (EC, 2002, 2006; EU, 2013). Arsenic was not included as no regulatory limits are available for total arsenic.

2.3. Input data

2.3.1. Concentration data

Data on the concentration of the contaminants under study were obtained from the KAP (Quality Agricultural Products) database. The KAP database includes the results of the official monitoring program of chemical contaminants in feed and food in the Netherlands over multiple years (KAP, 2021). Data from the period 2008–2018 were retrieved from this database for the considered contaminants and food ingredients. These data include, amongst others, the type of ingredient/product, the contaminant, date of sampling, date of analyses, analytical method used, analysed concentration, and country of origin. Per contaminant, the available concentration data were averaged per food ingredient.

2.3.2. Consumption data

Data on food consumption were derived from the most recent Dutch National Food Consumption Survey (VCP) data of 2012–2016 (Van Rossum et al., 2020). Data comprised food products, including types and

$$EDI\left(\frac{\mu g}{day}\right) = Concentration of contaminant per product \left(\frac{\mu g}{kg}\right) * \frac{Consumption per product and a gegroup \left(\frac{g}{day}\right)}{1000}$$
(2)

Once the HQs were calculated per contaminant, the top 25 food-age group combinations contributing most to the HBGV or RPHC were selected. For these products, the most relevant countries of origin were derived by combining import volumes of related ingredients (to produce the food) with a country index", which is an estimation of the contaminant being present in the particular food ingredient in that particular amounts of food, consumed in the Netherlands by a representative sample of adults (aged 1–79) on two individual days. Data were divided into four age groups: toddlers, children, adolescents and adults with the ages of 1–3, 4–12, 13–17, and \geq 18 respectively. The body weight per age group, calculated based on the VCP data (individuals in the dataset), is respectively 13.8, 34.3, 64.3, and 81.2 kg (Van Rossum et al., 2020). Gender differences were not included as the body weight differences and consumption patterns between age groups is larger than between sexes

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Fig. 2. Import volume weighted by the country risk score for top hazard-product combinations as shown in Table 1.



Fig. 3. Import volume weighted by the country risk score for top hazard-product combinations for fish as shown in Table 2.

within an age group (see e.g. https://www.wateetnederland.nl/).

2.3.3. Import data

Data on import of grain and fish raw materials and foods to the Netherlands were retrieved from EUROSTAT (Eurostat, 2021). Data included the imported volumes per product, with country of origin, averaged over the years 2015–2020. A time frame of 5 years was chosen since import volumes change fast over the years.

2.3.4. Health based guidance values

HBGVs and RPHC values were obtained from EFSA reports (Appendix E). For Aflatoxin B1, no HBGV was available; therefore, the Bench Mark Dose Level (BMDL₁₀) value of 0.4 μ g/kg bw/day was used as established by EFSA et al. (2020) taking into account a Margin Of Exposure of 10.000 (MOE) to obtain a RPHC value. A group Tolerable Daily Intake (TDI) for DON has been established by EFSA of 1 μ g/kg bw/day for the sum of DON, 3-Ac-DON, 15-Ac-DON and DON-3-glucoside (EFSA, Knutsen, Alexander, et al., 2017). This group TDI was used in the model as HBGV for DON. For OTA, EFSA established a BMDL₁₀ of 14.5 ug/kg bw/day for non-neoplatic effects with an MOE of 10.000. The BMDL₁₀ for non-neoplastic effects was included in the

model, as EFSA expressed that the uncertainty is high for these values and the risk may be overestimated by using these values (EFSA, 2020). EFSA established a group TDI for HT-2 and T-2 toxins of 0.02 ug/kg bw/ day, which is used for the sum of both toxins in the model (EFSA, Knutsen, Barregård, et al., 2017).

For cadmium, EFSA established a Tolerable Weekly Intake (TWI) of 2.5 ug/kg bw/day, which was converted to a RPHC for daily intake by dividing the TWI by 7 days (EFSA, 2009). For lead, a BMDL₀₁ of 0.5 μ g/ kg bw/day for developmental neurotoxicity in young children has been established by EFSA and for adults a BMDL₁₀ of 0.63 ug/kg bw/day for nephrotoxicity was established. In the model, the BMDL₀₁ of 0.5 was used for the whole population with an MOE of 10 (Boon et al., 2016; EFSA, 2010). EFSA established a TWI of 4 µg/kg bw for inorganic mercury and a TWI of 1.6 µg/kg bw for methylmercury (EFSA, 2012b). Since monitoring data is mainly available in total mercury, these values were corrected with a conversion factor of 1 for methylmercury and 0.2 for inorganic mercury in fish and fish products. For other food products, total mercury was regarded as inorganic mercury based on the approach of EFSA (EFSA, 2012b). The TWI for inorganic mercury of 4 μ g/kg bw and the TWI for methyl mercury of 1.6 ug/kg bw were converted to a RPHC for daily intake by dividing the TWI by 7 days.

2.4. Data processing

Conversions of product names and codes were necessary in order to link the data from the three different datasets (concentration data, consumption data and import data) with each other. Product categories were chosen based on a common level of detail in both the concentration and consumption datasets. Fish products were categorized into: carptype fish, cod-type fish, crustaceans, eel, flat-fish, herring-type fish, mackerel-type fish, mollusc, perch-type fish, and salmon-type fish. Cereals and the derived products thereof were categorized as: barley, breakfast cereals, buckwheat, maize, millet, oat, pasta, rice, rye, sorghum, spelt, and wheat. For the different data sets, i.e. the concentration data, the consumption data and the import data, conversions were needed to align all data into the same product categories. This allowed a connection between concentrations measured in ingredients to the food products containing these ingredients. Appendix A shows the conversion from food product names in the concentration dataset to the categories mentioned above. Next, concentrations of a particular contaminant in all products in one category were averaged. Appendix B shows the conversion from the products in the consumption data to the categories mentioned above. For the consumption data, the quantities of the consumed amounts were summed per category and divided by 2 for the total number of days that were recorded. For the import volumes from Eurostat, appendix C shows the conversion from the Combined Nomenclature (CN) codes obtained from Regulation (EEC) 2658/87 to the categories mentioned above.

3. Results

3.1. Data

Concentration data were available for 1870 cereal samples and 1283 fish samples. Consumption data contained data from 4313 participants including 852 records for cereals and 212 for fish. Annual import data, averaged over the years 2015–2020, showed that cereals are primarily imported from Ukraine (15894 \cdot 10⁶ kg) followed by France (5954 \cdot 10⁶ kg), Germany (4023 \cdot 10⁶ kg), Belgium (3778 \cdot 10⁶ kg), Brazil (3002 \cdot 10⁶ kg), and Romania (2335 \cdot 10⁶ kg). In the Netherlands, fish is primarily imported from Germany (983 \cdot 10⁶ kg), Norway (415 \cdot 10⁶ kg), Iceland (375 \cdot 10⁶ kg), United Kingdom (341 \cdot 10⁶ kg), and Russia (300 \cdot 10⁶ kg).

3.2. Results risk-ranking

When the HQ is exceeding 1, a human health effect may occur since then the EDI exceeds the HBGV or the RPHC. However, the latter is based on a total dietary intake and in our study, we examined single food products. Therefore, we assumed a contribution of the intake of a single food product to 20% of the HBGV or RPHC (or a HQ above 0.2) is a potential human health concern. Products with a HQ above 0.2 were wheat, rice, maize, and pasta. The hazard-product combinations which pose a potential health risk for toddlers, children and adolescents are: aflatoxin B1 in wheat, aflatoxin B1 in rice, and ZEN in wheat, followed by T2/HT2 in rice, DON in wheat, aflatoxin B1 in maize, and aflatoxin B1 in pasta (Table 1). And for adults, the hazard-product combinations which imply a potential health risk are: aflatoxin B1 in rice, aflatoxin B1 in wheat, T2/HT2 in rice, ZEN in wheat, and aflatoxin B1 in maize (Table 1). In general, the first eight highest ranked hazard-product-age group combinations all refer to aflatoxin B1 as the hazard, with HQ above 10.

Table 2 clearly shows that, based on the ranking performed with the risk ratio method, only cereals are present in the top 25 hazard-product combinations. For the fish products (presented in Table 2) the HQs are

around ten times lower than the HQs shown in Table 1. For fish, model outcomes show that the following hazard-product combinations contributed most to the HBGV: lead in molluscs, mercury in mackerel-type fish, and lead in herring-type fish.

3.3. Results country index

The top 25 hazard-products combinations all together include 4 different products: wheat, rice, maize, and pasta. As the weighing factor is similar for the main countries of origin for wheat in combinations with aflatoxin B1, zearalenone and DON, only one pie chart is shown for wheat. Based on the weighted import volume, Germany, France, Belgium, United Kingdom and Italy are relevant import countries for cereals: wheat, pasta and maize. For rice, the countries India, Thailand, Pakistan, Cambodia and Guyana are most relevant (Fig. 2).

Fig. 3 shows the weighted import data of the top 3 hazard-product combinations for fish. Germany, United Kingdom and France are the most relevant countries for mackerel-type fish. For molluscs, Germany, Denmark, and Ireland are the most relevant countries. Germany, France, and Norway are most relevant for herring-type fish.

4. Discussion

Various methodologies are available for risk ranking ranging from quantitative to qualitative approaches (Mathisen et al., 2020; Van Asselt et al., 2013; Van der Fels-Klerx et al., 2017, 2018). Examples of those methods are scoring methods, multi-criteria decision analysis, risk matrices, and expert judgement (Van der Fels-Klerx et al., 2018). Method selection depends on several factors, amongst other the availability and quality of data, and available time and budget. Previously, a scoring method was applied to rank hazard-product categories for feed in the RiskFeed model (Van der Fels-Klerx et al., 2017). Other currently published work on this topic also used a scoring method. For example, Li et al. (2021) scored severity (or toxicity) and probability (food consumption and contamination) of several chemical hazards, including aflatoxin B1, in vegetable oils. Mathisen et al. (2020) used a scoring method to rank chemical substances in food based on the estimated risk for human health and critical knowledge gaps. An example of a risk matrix method is a study in which the risk matrix method was applied to prioritize chemical hazards in spices and herbs (Van Asselt et al., 2018). The advantage of the risk matrix approach is the fact that the model is visually attractive and easy to understand. However, the disadvantage of both scoring methods and risk matrix methods is that values have to be classified in several categories and it can be difficult to set the right cutoff values for the different categories. The risk ratio method applied in this study does not need the use of thresholds as hazard quotients are calculated based on available data on concentrations and consumption (the estimated daily intake), and the human health effect of the chemical hazards studied (expressed in the HBGV or RPHC). The risk ratio method can be applied for a range of chemical compounds and it is most often used for pesticides (Van der Fels-Klerx et al., 2015). Labite and Cummins (2012), for example, quantitatively assessed the risk for human health of pesticides in Irish groundwater and their degradation products and also prioritized pesticides for monitoring programs. Sinclair et al. (2006) prioritized transformation products following the application of pesticides in drinking water in Great Britain and California. The risk based approach was based on pesticide usage and toxicity, combined with the formation, mobility, and persistence of the transformation products. The risk ratio method was also used for the prioritization of antibiotics, with a focus on the location, as consumption patterns and other behavioural characteristics have an impact on the risk quotients for human health (Oldenkamp et al., 2013).

The availability of high quality data is required to minimise subjective outcomes (Butler, 2011). Therefore, in the current study, the case study used was chosen based on the availability of concentration data and HBGVs or RPHCs. When more concentration data, consumption data, HBGVs or RPHCs are available, the prioritization can be expanded including a broader range of products and/or contaminants. This will provide a more accurate overview of the most relevant hazard-food combinations to include in a risk-based monitoring program.

Although all available data on concentration, consumption and toxicity were used in the case study, several assumptions needed to be made in the model calculations, which may have influenced the outcomes. For example, the estimated daily intake was based on the average concentration and average consumption data. A more worst-case approach could have been used including the P95 instead of average values. However, since we were interested in chronic toxicity, the average values were seen as more appropriate, as chronic exposure to P95 levels is unlikely. Furthermore, the country of origin is not necessarily the original country of origin as it also can be the country of transit. For example, Germany is known to have high transit volumes. Nevertheless, the results of the country index can help to steer inspections towards countries with high import volumes of 'risky' products. This country index may also be used by companies importing raw materials from abroad, although other elements such as availability and price also influence the choice for a certain importing country.

Results of our study showed that Aflatoxin B1 in cereals, like wheat, was primarily present in the top 25 most relevant hazard-food-age group combinations, which is primarily due to its high toxic (carcinogenic) properties. This is expressed in its low RPHC (the BMDL₁₀ of aflatoxin B1 is divided by the Margin of Exposure (MoE) of 10.000). Our findings of concerning AFB1 levels were in accordance with the risk characterisation of EFSA where MOE values ranging from 5000 to 64 were found based on the $BMDL_{10}$ of 0.4 ug/kg bw per day for dietary AFB1 exposure. MOEs below 10,000 were considered a health concern (EFSA et al., 2020). The same report describes the analysis of occurrence data of contaminants in food, based on national data submitted to EFSA, and 'grains and grain-based products' were the largest contributor to the mean chronic dietary exposure to aflatoxin B1 (EFSA et al., 2020). In a worldwide occurrence and dietary risk assessment by Andrade and Caldas (2015), total aflatoxin was found to be present in wheat in 874 out of the 2388 samples with a mean total aflatoxin concentration of 18 \pm 9 µg/kg. In maize, aflatoxins were found to be present in 2469 out of 9819 samples with a mean concentration of $28 \pm 6 \,\mu\text{g/kg}$ (Andrade & Caldas, 2015). The higher aflatoxin contamination in maize compared to wheat is in accordance with data of aflatoxin B1 in our study, although absolute concentrations in our study were lower: 0.9 µg/kg in maize and 0.3 µg/kg in wheat. The HQ of aflatoxin B1 in wheat was ranked higher than the HQ of aflatoxin B1 in maize in our study due to the high consumption of products containing wheat in the Netherlands by adults (128 g/day), adolescents (143 g/day), children (116 g/day), and toddlers (82 g/day) compared to a consumption of maize of 1-2 g/day on average. This is in accordance with the findings of EFSA et al. (2020), that in several (European) countries the main contributor to the upper bound dietary total aflatoxin exposure was wheat-based products (range 37-76.5%).

Apart from consumption values, body weights of the different age groups - relative to consumption - also influences the outcome. This is reflected by the fact that toddlers and children are frequently included in the top ranking of hazard-food-age group combinations as these consumer groups are more sensitive. For toddlers, the highest estimated daily intake of aflatoxin B1 was via wheat-based products. For children, wheat-based products had the highest estimated contribution to the daily intake of aflatoxin B1 followed by rice-based products. And for adults and adolescents, the EDI is highest for rice- and wheat-based products, followed by maize-based products and pasta. A mycotoxindedicated total diet study performed in the Netherlands showed that the highest contributor to dietary aflatoxin B1 exposure in the upper bound scenario was bread with 25% for children aged 2–6 years and 22% for people aged 7–69 years (Sprong et al., 2016).

Based on the risk ratio ranking, fish and the products derived thereof have HQs which are around ten times lower compared to the HQs of cereals. The HQs of fish were also below 0.2, the cut-off we set as a potential health risk. For fish, lead in mollusc was highest in the risk ranking followed by mercury in mackerel and lead in herring. For mercury, the primary source via food consumption is considered to be fish, and levels of mercury exceeding the maximum limits are found in fish muscle (Bosch et al., 2016).

5. Conclusions

This study applied the risk ratio approach to rank chemical hazardfood combinations, considering mycotoxins and heavy metals in cereal and fish based foods.

The HQs for the fish products were around ten times lower compared to the HQs of cereals implying monitoring should focus on cereals. For these cereals, monitoring should focus on mycotoxins, and more specifically on aflatoxins B1 in cereals imported from the countries of Germany, France, Belgium, United Kingdom and Italy. The presented methodology is the first one combining both risk-ranking and risk-based inspections. The procedure used is objective and transparent as long as the steps followed and information used is recorded. As such, it can be applied by food business operators (FBOs) and governmental institutes as input for their risk-based monitoring program.

CRediT authorship contribution statement

R.G. Hobé: Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **E.D. van Asselt:** Conceptualization, Methodology, Project administration, Supervision, Writing – original draft, Writing – review & editing. **L. van den Heuvel:** Formal analysis. **E.F. Hoek-van den Hil:** Conceptualization, Methodology, Writing – review & editing. **H.J. van der Fels-Klerx:** Conceptualization, Funding acquisition, Methodology, Project administration, Supervision, Writing – original draft, 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

The data that has been used is confidential.

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Appendix A

Table A.1

Table A.1

The classification of product names in de concentration data per group and category.

Group	Category	Product
Fish	Carp-type fish	Bream, Catfish, Catfish (cultivated), Pangasius, Pangasius (aquaculture)
Fish	Cod-type fish	Cod, Haddock, Hake, Pollack, Whiting
Fish	Crustaceans	Crab, Crab (body), Crab (body brown), Crab (body white), Crab (claw), Crab (leg), Crustacean, Lobster, Norwegian lobster, shrimps
Fish	Eel	Eel, Eel (cultivated), Eel red
Fish	Flat-fish	Flounder fluke, Plaice, Sole (5), Sole (9), Turbot (cultivated)
Fish	Herring-type fish	Anchovy, Herring, Sardinella, Sardines
Fish	Mackerel-type fish	Mackerel, Skipjack tuna, Swordfish, Tuna, Yellowtail tuna (aquaculture)
Fish	Mollusc	Cockles, Cuttle-fish, Jacobsshell, Molluscs, Mussel, Oysters
Fish	Perch-type fish	Perch, Perch nile, Pike, Pike perch, Rock gunnel, Sea bass, Seawolf, Snapper, Tilapia, Tilapia (aquaculture)
Fish	Salmon-type fish	Salmon, Salmon (cultivated), Smelt sparkling, Trout, Trout (aquaculture)
Cereals	Barley (products)	Barley, Barley flour, Barley flour wholemeal, Barley brewery
Cereals	Breakfast cereals	Cereals maize based, Cereals mixed grains (224), Cereals wheat based, Cereals wheat based (Brinta), Muesli
Cereals	Buckwheat	Buckwheat, Buckwheat flour
	(products)	
Cereals	Maize (products)	Corn starch, Maize, Maize flour, Maize meal, Maize semolina, Popcorn, Popcorn maize, Torilla chips
Cereals	Millet (products)	Grits millet, Millet, Teff
Cereals	Oat (products)	Oat, Oat flour, Rolled oats
Cereals	Pasta	Cereal And pasta products, Cereal And pasta products with egg, Fried noodles, Lasagna, Lasagne, Macaroni, Millefeuille, Noodles, Pasta, Pasta with egg, Pasta raw, Pepper cake, Pizza mini, Puff pastry, Reacle waffle, Spaghetti
Cereals	Rice (products)	"Zilvervlies" rijst, Fried rice, Glutinous rice, Long grain rice, Puffed rice cakes, Red rice, Rice, Rice flour, Rice basmati, Rice basmati brown, Rice
	·1 ,	jasmine, Rice prepared, Sushi, Vietnamese rice spaghetti
Cereals	Rye (products)	Rye, Rye flour, Rye bread, Rye flour wholemeal
Cereals	Sorghum	Sorghum flour
Cereals	Spelt (products)	Spelt, Spelt flour wholemeal, Unripe spelt flour
Cereals	Wheat	Baking flour, Bran, Couscous, Currant bread, Currant/raisin bread, Khorasan wheat (kamut), Raisin bread, Semolina wheat, Wheat, Wheat flour,
		Wheat flour durum, Wheat flour white, Wheat flour wholemeal, Wheat loaves/rolls brown, Wheat loaves/rolls mixed flours, Wheat loaves/rolls
		white, Wheat loaves/rolls Wholemeal, Wheatrye bread

Appendix B

Table B.1

Table B.1

The classification of product names in de consumption data per group and category.

Group	Category	Product
Fish	Carp-type fish	Pangasius prep in microwave oven
Fish	Cod-type fish	Cod boiled, Cod dried salted bakkeljauw, Liver haddock tinned, Pollock Alaska steamed
Fish	Crustaceans	Crab in water tinned, Lobster boiled, Shrimps Dutch peeled boiled
Fish	Eel	Eel prepared in microwave oven, Eel smoked
Fish	Flat-fish	Plaice boiled, Sole prepared in microwave oven
Fish	Herring-type fish	Anchovy in oil canned, Anchovy prepared without fat, Anchovy raw, Herring pickled (sweet)sour, Herring raw, Herring salted, Sardines grilled,
		Sardines/pilchards in oil tinned
Fish	Mackerel-type fish	Mackerel fillet smoked, Mackerel in oil tinned, Mackerel prepared in microwave oven, Mackerel steamed, Tuna in oil tinned, Tuna in water tinned,
		Tuna prepared without fat, Tuna raw
Fish	Mollusc	Mussels boiled, Mussels pickled
Fish	Perch-type fish	Ocean perch prepared in microwave oven, Tilapia prepared without fat
Fish	Salmon-type fish	Rainbow trout prepared in microwave oven, Salmon farmed prep in microwave oven, Salmon farmed raw, Salmon pate/-mousse, Salmon smoked,
		Salmon tinned, Trout prepared in microwave oven
Cereals	Barley (products)	Barley easy cook raw, Barley whole grain raw
Cereals	Breakfast cereals	Breakfast cereal All-Bran flakes, Breakfast cereal All-Bran Fruit n Fibre, Breakfast cereal All-Bran Plus Kellogg's, Breakfast cereal Bambix Dromerig papje cereals&biscuit, Breakfast cereal Bambix Zonnige Ontbijtpap muesli, Breakfast cereal Bambix Dromerig papje cereals&biscuit, Breakfast cereal Bambix Zonnige Ontbijtpap muesli, Breakfast cereal Bambix Zonnige Ontbijtpap muesli, Breakfast cereal Choco chocos Plus, Breakfast cereal Choco moons Crownfield, Breakfast cereal Chocoschelpjes Perfekt/Markant, Breakfast cereal Coco pops Chocos Kellogg's, Breakfast cereal Coco pops Kellogg's, Breakfast cereal Coor pops Kellogg's, Breakfast cereal Frosties Kellogg's, Breakfast cereal Honey hoops Crownfield, Breakfast cereal Honey pops Kellogg's, Breakfast cereal Honey pops Loops, Breakfast cereal porridge 8 cereals with honey Bonbebe, Breakfast cereal porridge Bambix Zonnige Ontbijtp fijne gr, Breakfast cereal porridge Bambix Zonnige Ontbijtp 8 granen, Breakfast cereal porridge Bambix Zonnige Ontbijtp fijne gr, Breakfast cereal Special K Coriginal, Breakfast cereal Rice Krispies Kellogg's, Breakfast cereal Smacks Kellogg's, Breakfast cereal Special K Original, Breakfast cereal Tresor Kellogg's, Breakfast cereal Special K Original, Breakfast cereal Tresor Kellogg's, Breakfast cereal Weetabix original, Breakfast prod Albona 7-cereals-energy, Breakfast product 7 cereals energy, Corn flakes Golden Bridge, Muesli Country Store Kellogg's, Muesli crunchy Cruesli Balans, Muesli crunchy plain/w fruit, Muesli crunchy w chocolate, Muesli w fruit
Cereals	Buckwheat (products)	Buckwheat groats, Flour buckwheat
Cereals	Maize (products)	Bread corn, Bread corn w seeds, Bread corn w sunflower seeds, Cornflour, Cornmeal
Cereals	Millet (products)	Millet boiled
Cereals	Oat (products)	Oat bran raw, Oatmeal
Cereals	Pasta	Couscous boiled, Dough for pizza and savoury pie, Noodles boiled, Noodles instant prepared, Pasta gluten free cooked Schar, Pasta w fibre Honig vezelrijk cooked, Pasta white average boiled, Pasta white wo egg boiled, Pasta wholemeal boiled, Tortellini boiled, Wrap/Tortilla

Table B.1 (continued)

Group Category	Product
Cereals Rice (produc	s) Flour rice, Flour rice instant Bambix, Flour rice with vanilla Nestle Pyjamapapie, Rice brown boiled, Rice cake puffed plain without salt, Rice cakes puffed with caramel, Rice cakes puffed with chocolate, Rice cakes puffed with fruit flavour Goodies, Rice cakes puffed with salt, Rice cakes with spices, Rice multi-grain boiled, Rice white boiled, Rice white boiled with candied fruit, nuts and seeds
Cereals Rye (produc	s) Bread rye average, Bread rye dark, Bread rye light, Bread wheatrye wholemeal, Flour rye
Cereals Wheat, brea	Baguette brown, Baguette w cheese-onion, Baguette white, Baguette white w herb butter retail, Bread Blue Band Goede Start light brown, Bread Blue Band Goede Start white bread, Bread brioche, Bread brown gluten free prep w Glutafin, Bread brown Turkish, Bread brown w pumpkin seeds, Bread brown w seeds, Bread brown w sunflower seeds, Bread brown wheat, Bread brown wheat low sodium, Bread brown/wholemeal average, Bread brown/wholemeal w muesli, Bread C1000 Kids Wit, Bread ciabatta no filling, Bread currant, Bread currant w almond paste, Bread current wholemeal, Bread current/raisin w almond paste, Bread gluten free Pain Campagnard Schar, Bread linseed, Bread low in carbohydrates, Bread multigrain average w seeds, Bread multigrain gluten free Rustico, Bread multigrain wholemeal Becel, Bread Omega-, Bread pita white, Bread raisin, Bread raisin w almond paste, Bread raisin/current average, Bread sourdough wholemeal, Bread Tijger brown wheat, Bread Tijger white, Bread Tijger wholemeal, Bread toasted, Bread VollerKoren, Bread wheat malt, Bread wheat Wikorn, Bread wheat w itamins Vikorn Volvezel, Bread white average milk/water based, Bread white average w seeds, Bread white Brinta Vezelwit, Bread white gluten free Pan Carre Schar, Bread white gluten free prep w Glutafin, Bread white milk based, Bread wholemeal average w pumpkin seeds, Bread wholemeal average w seeds, Bread wholemeal average, Bread wholemeal coarse, Bread wholemeal coarse w pumpkin seeds, Bread wholemeal average w sunflowerseeds, Bread wholemeal Brinta Vezelbruin, Bread wholemeal coarse, Bread wholemeal fine w seeds, Bread wholemeal average w seeds, Bread wholemeal Brinta Vezelbruin, Bread wholemeal fine, Bread wholemeal fine w seeds, Bread wholemeal fine w sunflower seeds, Bread wholemeal w nuts, Breadsticks, Bun currant/raisin, Bun wholemeal w muesli, Cracker mini flavoured, Cracker WitaLU w added calcium, Crackers ream, Crackers matzes, Crackers rich in fibre gluten free, Crackers VitaLU, Crisp bread gluten free Fette Croccanti, Crispbread Cracottes V

Appendix C

Table C.1

Table C.1

Combined Nomenclature codes per group and category.

Group	Category	CN codes ¹
Fish	Carp-type fish	03027200, 03032400, 03043200, 03046200, 030285*, 03038950, 03038955
Fish	Cod-type fish	030251*, 03025910, 030363*, 03044410, 030471*, 03047910, 0304952*, 030532*, 030551*, 03055310, 03056200, 03056910, 16041992, 03025200, 03036400, 03047200, 03049530, 03025500, 03036700, 03047500, 030494*, 030495*, 16041995, 030254*, 03025930, 03036950, 03025600, 03025920, 030368*, 03036930, 03047930, 03049560
Fish	Crustaceans	0306*, 16051*, 16052*, 16053*, 16054*
Fish	Eel	030192*
Fish	Flat-fish	03022*, 03033*, 03044300, 030483*
Fish	Herring-type fish	$03024200, 03055450, 03024100, 03035100, 03045950, 03048600, 03049923, 03054200, 03055430, 030243^*, 030353^*$
Fish	Mackerel-type fish	03024400, 030354*
Fish	Mollusc	0307*, 16055*
Fish	Perch-type fish	03027900, 03032900, 03043300, 03046300, 03027100
Fish	Salmon-type fish	030191*, 03031*, 030481*, 030482*, 03019911, 03021300, 03021400, 03021900, 030441*, 030442*, 03045200, 03054300, 03053910, 03054100, 03054300
Cereals	Barley (products)	01003900, 11029010
Cereals	Breakfast cereals	1104*
Cereals	Buckwheat (products)	01008,100
Cereals	Maize (products)	10059000, 110220*
Cereals	Millet (products)	10082900
Cereals	Oat (products)	10049000, 11029030
Cereals	Pasta	1902*
Cereals	Rice (products)	1006*, 11029050
Cereals	Rye (products)	10029000, 11029070
Cereals	Sorghum	1902*
Cereals	Spelt (products)	10019110, 11010015
Cereals	Wheat	11010011, 11010015

¹ CN-codes obtained from Regulation (EEC) 2658/87.

Appendix D

Tables D.1 and D.2

Table D.1

Country index scores belonging to the pie charts in Fig. 2.

	Aflatoxin B1	Aflatoxin B1	Aflatoxin B1	Aflatoxin B1	DON	T2/HT2	ZEN
	Wheat	Rice	Maize	Pasta	Wheat	Rice	Wheat
Germany	0.01		0.01	0.01	0.01		0.1
Belgium	0.01			0.01	0.01	0.1	0.1
France	0.01		0.01		0.01		0.1
UK	0.01				0.01	0.1	0.1
Italy	0.1			0.1	0.1		0.01
India		0.1				0.1	
Thailand		0.1		0.1			
Pakistan		0.1					
Cambodia		1					
Guyana		1					
China				0.1			
Poland							
Ukraine			0.1				
Romania			0.1				
Brazil			0.1				
Uruguay						0.1	
Paraguay						0.1	

2

Country index scores belonging to the pie charts in Fig. 3.

	Mercury	Lead	Lead	
	Mackerel-type fish	Mollusc	Herring-type fish	
Germany	1	0.1	1	
UK	0.1	0.1	0.1	
France	0.1		0.1	
Faroe Islands	1			
Norway	0.1		0.1	
Lithuania			1	
Denmark		0.1		
Ireland		0.1		
China		1		

Appendix E

Table E.1

Table E.1

Table with HBGV or RPHC of selected food safety hazards in the model.

Hazard	HBGV or RPHC	Reference
Aflatoxine B1 (AflaB1)	Based on $BMDL_{10}$ of 0.4 ug/kg bw/ day an MOE of 10.000 and potency factors for metabolites	(EFSA et al., 2020)
Deoxynivalenol (DON)	Group TDI of 1 µg/kg bw/day	(EFSA, Knutsen, Alexander, et al., 2017)
Ochratoxin A (OTA)	Based on a $BMDL_{10}$ of 14.5 ug/kg bw/ day for non-neoplatic effects with an MOE of 200	(EFSA, 2020)
HT-2 toxin + T-2 toxin	Group TDI of 0.02 μg/kg bw/day	(EFSA, Knutsen, Barregård, et al., 2017)
Zearalenone (ZEN)	Group TDI of 0.25 µg/kg bw/day	(EFSA, 2016)
Cadmium	Based on TWI of 2.5 ug/kg bw/day divided by 7 days	(FSA, 2009)
Lead	Based on $BMDL_{01}$ of 0.5 µg/kg bw/ day and an MOE of 10 (BMDL01 for toddlers and children is used for adolescents and adults too)	(EFSA, 2010)
Mercury (total)	based on TWI of 1.6 and 4 µg/kg bw divided by 7 days (including conversion factors to convert total mercury data)	(EFSA, 2012b)

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