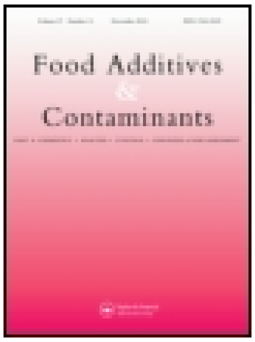

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Risk ranking of chemical hazards in foods: comparison of aggregating methods using infant formula as an example

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ABSTRACT

The aim of this study was to rank several chemical hazards present in one food item, namely infant formula. We first identified the substances potentially present in infant foods according to the results of the French infant Total Diet Study and to the available scientific literature. Second, we built three criteria to rank the hazards: severity, contribution to the total exposure, and risk characterisation. Each criterion was scored using quantitative or semi-quantitative scales. Third, in order to rank the chemical hazards, two approaches of aggregation of the three criteria were deployed. On the one hand, a multi-criteria decision analysis outranking method and on the other hand a semi-quantitative risk-matrix type method. We then tested these approaches on follow-on formulae for the 7–12 months population, for which contamination data from the French infant Total Diet study were available. The results of both methods showed that the six prioritised substances are the same even if not in the exact same order (acrylamide, inorganic arsenic, furan, chromium VI, lead and PCDD/Fs) demonstrating the robustness of these approaches.

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MCDA; PROMETHEE; scoring method chemical risk assessment

Introduction

Risk analysis is a concept that has tremendously grown in the last decades. It comprises three building blocks: risk assessment, risk management and risk communication. In spite of strict regulation for food production in Europe triggered by the food law (EU regulation 178/2002/EC; EC 2002) and the creation of the European Food Safety Authority, reducing risks due to dietary exposure is still a work in progress with a need for risk managers to use and develop risk-based methodologies (Van Asselt et al. 2012). One way to improve food safety is to prioritise food contaminants by considering their overall risks through risk ranking methods. Risk is defined as a combination of severity and likelihood associated to the presence of a hazard in food consumed by a population (FAO 1997). In 2020, the Food and Agriculture Organization released a guidance to rank chemical and biological hazards with a three-step approach (FAO 2020). The first step is the determination of the scope: purpose, what will be ranked, and the relevance. Secondly, the core of the approach is developed by selecting the risk ranking method, the risk ranking metrics and by compiling and evaluating data. The final step is then to operate the risk ranking analysis and report the results. Different risk ranking methods can be considered depending on available data such as risk matrix, scoring method, expert judgement or multi criteria decision analysis (MCDA) method (Van der Fels-Klerx et al. 2018). Usually one important step for these methods is to select food-hazard pairs in order to conduct the ranking (Stornetta et al. 2015). Chemical hazards can occur at every steps of the food chain and within the same food product. In the present study, risk ranking of chemical hazards has been performed with infant food formulae. Children under three years of age are a specific population for which it is important to reduce dietary risks related to contaminants.

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Because of their high consumption rate considering their bodyweight, risk associated with some substances on their still maturing systems cannot be ruled out. France has performed an infant Total Diet Study (iTDS) and estimated the exposure levels associated with 500 substances for non-breastfed children under three years of age (Hulin et al. 2014). For French infants and toddlers, lead, inorganic arsenic, nickel, polychlorinated dibenzo-p-dioxins and polychlorinated dibenzo-p-furans (PCDD/F) and PCBs, acrylamide, furan, Deoxynivalenol and its derivatives and T-2/HT-2 toxins were identified as substances of concern. Moreover, for ochratoxin A, aflatoxins, and bisphenol A the risks were also of concern (ANSES 2016). Recently, the Netherlands have conducted a Total Diet Study to assess infants and toddlers exposure to contaminants such as mycotoxins or trace elements and metals (Pustjens et al. 2022). In the Dutch infant TDS, exposure levels to aflatoxins, *Alternaria* toxins, and T-2/HT-2 toxins might be of concern. For inorganic arsenic, lead and cadmium, exposure levels for high consumers resulted in low margins of exposure or exceedance of the health-based guidance value (Boon et al. 2022).

The objective of this study was to take a further step by ranking quantitatively the chemical hazards based on their risk considering, beside the exposure, the nature and likelihood of occurrence of the health effect. To this end, two methodologies of aggregation were suggested and compared. Results are illustrated with infant formula.

Materials and methods

Case study

We selected follow-on formula as case study for the 7–12 months age class in the iTDS. For non breastfed infants, infant and follow-on formulae are consumed almost exclusively in the first 12 months of the child. For each hazard to which follow-on formula is a food contributor, the percentage of contribution to the total exposure, mean exposure, and the toxicological reference point or health-based guidance value were retrieved from the iTDS reports and updated with most recent literature. It is to be noted that within the 7 to 12 months age class, food diversification occurs. Due to the methodology used to gather consumption data, it was not possible to distinguish both populations.

Identification of chemical hazards

The 670 chemicals analysed in the iTDS were used as a basis to include potential chemical hazards in the final list. The selection process took into account the detection of the hazard in infant food products, the possible adverse effects associated with the hazard and expert judgement (Yeak et al. 2022). Additional chemical hazards, which were not searched in the iTDS, were also included based on recent reports from international agencies or scientific commities (EFSA, JECFA or The Joint Meeting on Pesticide Residues - JMPR). Data about the toxicological reference point (No observed adverse effect level (NOAEL), Lowest observed adverse effect level (LOAEL), Benchmark dose lower confidence limit (BMDL)) or the health based guidance value (ADI, TDI, Tolerable weekly intake (TWI) …) were extracted from these reports. As a starting point, health based guidance values established in Europe were considered endorsed; however, due to science progress some values established ouside Europe were selected (Table 2S).

Among the hazards identified, two of them were associated with threshold and non-threshold effects: acrylamide and furan. These two process-induced compounds have two toxicological reference points for neoplastic (carcinogenicity) and non-neoplastic effects (neurotoxicity and liver toxicity). In the text below, acrylamide_1 and acrylamide_2 refer to neoplastic and non-neoplastic endpoints, respectively. The same applies to furan. As a conservative approach, the most severe effect was considered for further analysis. Additionally, for chromium, as the contribution was expressed in total chromium in the French iTDS, hypotheses of speciation were used with 90% of total chromium considered chromium (III) and 10% of total chromium expressed as chromium (VI) in food. Regarding total chromium in tap water, 75% of total chromium was considered as hexavalent chromium and 25%

trivalent chromium. Speciation hypotheses were also used for inorganic arsenic, following EFSA's recommendations (EFSA 2014). Total arsenic results were converted in inorganic arsenic by considering that arsenic was present in its inorganic form in water, and that in food, 70% of arsenic was considered inorganic and 30% as organic.

For the 7 to 12 month old age class, follow-on formula was a contributor for 22 chemicals hazards.The percentage of contribution ranged from 1% to 89% (Table 1S).

Semi-quantitative method and multi-criteria decision analysis (MCDA) method

For each hazard identified, three criteria were calculated (details on their construction is provided in Results section). To aggregate these criteria and then rank the hazards, two methodologies were deployed in parallel.

In the semi-quantitative risk-matrix type method, the three criteria were multiplied. The higher the score was, the higher the risk was. The semi-quantitative risk-matrix type method was carried out in Excel 2016.

In the MCDA method, the hazards were compared with each other using the outranking PROMETHEE technique. The outranking methods were first introduced by Roy (1968). In PROMETHEE, the overall ranking of alternatives (here the chemical hazards) is generated using 'positive flows', 'negative flows' and 'net flows'. The positive flow, $\phi+$, indicates the degree to which the hazard is dominating all others, the negative flow, ϕ, indicates the degree to which the hazard is being dominated by all the others (Brans and Vincke 1985; Brans et al. 1986). The net flow, $\phi = \phi + \phi$, is used to rank overall the hazards: the riskiest hazard will get the highest net flow. The MCDA PROMETHEE method was run in R (version 4.1.2) with the package PROMETHEE package, using the R Studio interface (version 2022.02.3). The V-shape preference was adopted, with a preference set to 1 and the indifference to zero, for all criteria. The same weight was given to each criterion.

Results

Establishment of the risk ranking criteria

Three criteria were considered for the ranking (Figure 1): severity, contribution to the total exposure, and risk characterisation.

For the severity criterion, a decision tree proposed by the French Agency for Food, Environmental and Occupational Health & Safety was used (ANSES 2020). This decision tree associates a severity category to each chemical hazard according to the critical effect used to establish a health-based guidance value (HBGV) or a toxicological reference point (Figure 2). The term health-based guidance value refers to a dose level that can be ingested over a defined period (e.g. lifetime or 24 h) without appreciable health risk. Tolerable daily intake or acceptable daily intake

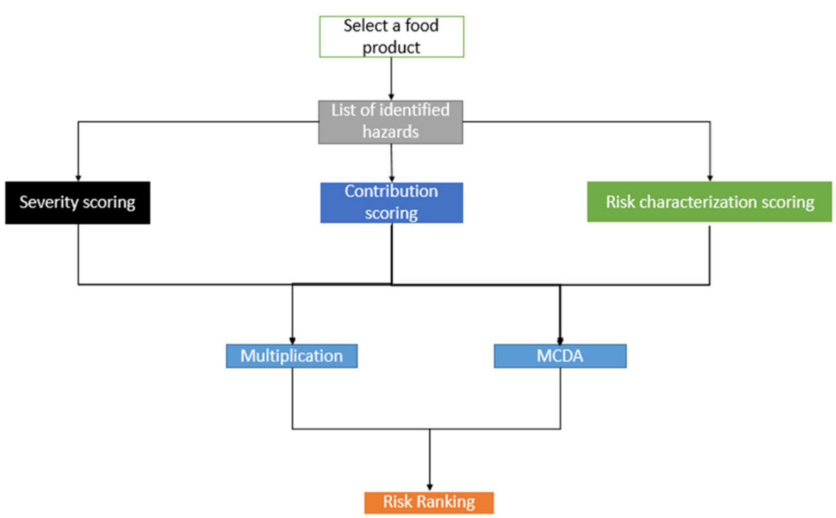

Figure 1. Risk ranking approach framework.

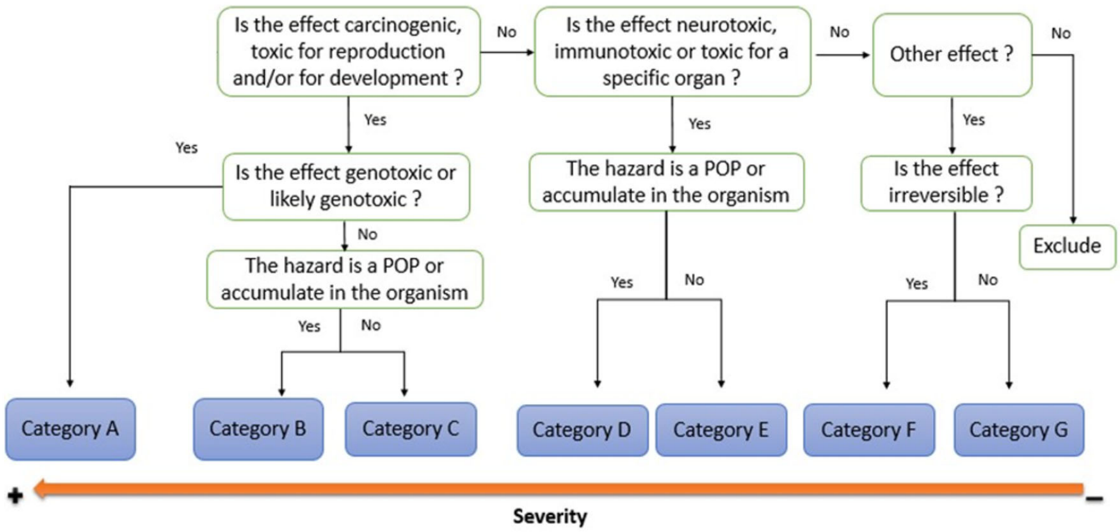

Figure 2. Decision tree for the attribution of the severity score (ANSES 2020).

are health-based guidance values, obtained by dividing the toxicological reference point (considered as point of departure for the establishment of the HBGV) by assessment factors accounting for interspecies and interindividual variability. The severity criterion included in the decision tree consider genotoxicity, carcinogenicity, reproductive toxicity, toxicity for a specific target organ, the reversibility of the effect and the accumulation potential of the chemical. Each hazard was assigned a severity category from A to G by decreasing order of importance and then scored from 1 to 10. The score of 10 was assigned to genotoxic and carcinogenic hazards.

The contribution criterion corresponded to the proportion of the total exposure attributable to one food item or one food category (ANSES 2016). This criterion was calculated using the percentage of contribution of the selected food item. Each substance was then scored from 1 to 5 depending of the range of contribution (from 0–20% to 80–100%).

Regarding the last criterion, in chemical risk assessment, as the final step to characterise the risk, the exposure is compared to a HBGV. However, for some hazards depending on the available data it is not possible to derive a HBGV. Therefore, a Margin of Exposure (MOE) approach is considered. This margin is the ratio of the toxicological reference point and the exposure and is compared to a critical margin of exposure (EFSA 2005). In this study, for the risk characterisation criterion, for chemical hazards with an HBGV available, the corresponding percentage of the HBGV based on the exposure was calculated and depending on the obtained value, each hazards received a score of either 1 or 6. For chemicals with no HBGV but with a reference point identified, the margin of exposure was calculated and if the obtained margin exceeded the critical margin of exposure, a score of 6 was attributed and when it was under that safety margin, it was attributed a score of 1. The procedure for this criterion is presented in Figure 3.

Selected methods for risk ranking

First, a semi-quantitative approach to rank chemical hazards in follow-on formulae was developed. The ranking score was obtained by multiplying the three scores. The semi-quantitative approach is based on the principle that the risk is a combination of severity, contribution and exposure (i.e. severity × contribution × human exposure). However, before making the multiplication, the three criteria were expressed in the same scale from 1 to 10 as indicated in Table 1.

As shown in Table 1, the hazards with the highest final score in follow-on formulae were PCDD/F, acrylamide, inorganic arsenic, furan and chromium (VI). PCDD/F and lead had a severity score of 6 due to reproductive effects and effects on neurodevelopment, respectively.

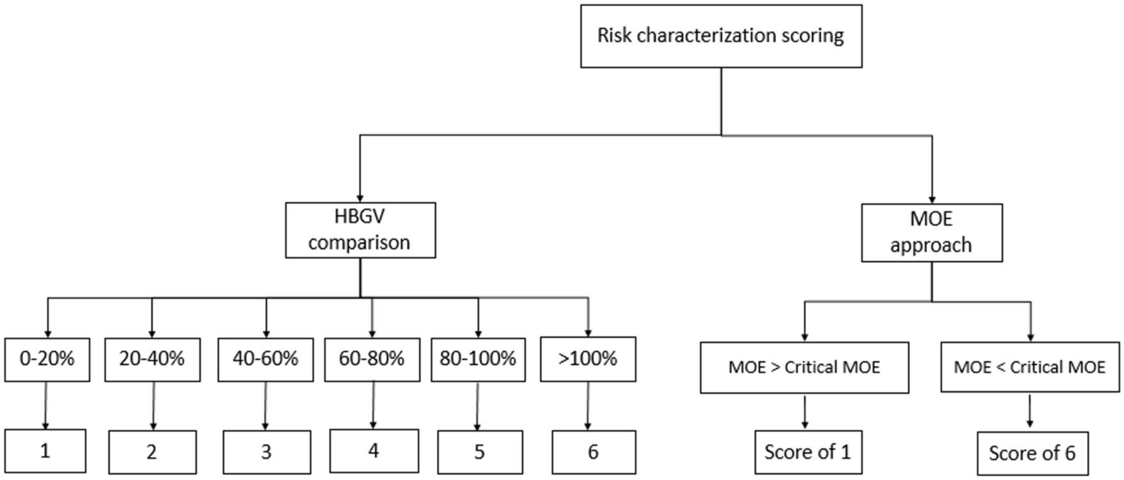

Figure 3. Decision tree used to build the risk characterisation criterion.

Inorganic arsenic, acrylamide and furan had a severity score of 10 due to their genotoxicity. Antimony, acrylamide_2, barium and BPA had the lowest scores due to low or moderate severity (range of scores within 1 to 3) and a low risk characterisation score (score of 1).

Second, the MCDA PROMETHEE method to rank chemical hazards with their initial scores (Table 1) was deployed. Results are presented in Figure 4. With the outranking method, the same five chemicals as for the semi-quantitative method have the highest rank: PCDD/F, acrylamide, chromium (VI), furan and inorganic arsenic. This is consistent with the fact that these five chemicals had, at the same time, high severity and risk characterisation values. Likewise, the same chemicals as with the semi-quantitative method were ranked at the bottom: antimony, acrylamide_2, barium and BPA. Again, these hazards had low values in severity and risk characterisation.

In other words, when there is no, or little, conflict between the criteria, the two ranking methods provide the same results. On the opposite, the difference of ranking between the two methods was exacerbated when the three criteria provided conflicting results. For instance, the cobalt had relatively low severity value (3 in a scale of 1 to 10) but high-risk characterisation value (6 in a scale of 1 to 6), cadmium had also relatively low severity value (4) and high risk characterisation value (5). These two hazards were ranked 17th and 19th, respectively, using the MCDA method. With the semi-quantitative methods, they were 10th and 7th, respectively.

Discussion

In spite of a low contribution to the total exposure, inorganic arsenic, acrylamide, furan, and chromium VI were ranked at the top of the chemical ranking scores in follow-on formulae. As these contaminants are carcinogenic with a genotoxic mode of action, their severity score is high and the risk cannot be ruled out, considering the values of the margins of exposure.

In risk ranking, it is possible to use quantitative, semi quantitative or qualitative methods. For biological hazards, risk ranking can consider the burden of disease associated with the hazards with metrics like Disabled adjusted life years (DALYs) and Cost of illness (CoI) (Van der Fels-Klerx et al. 2018). These metrics are not as straightforward for chemical hazards. Indeed, chemical hazard exposure induces chronic toxicity after repeated low exposure, but the link between the appearance of adverse effect and clinical signs cannot always be established. Some recent studies estimated the burden of disease for some chemical hazards such as aflatoxins or trace elements (Chen et al. 2022; Thomsen et al. 2022). However, these data were not available for all substances present in infant foods, a reason why alternative methods have been suggested here. Li et al. (2021) faced the similar issue: although they acknowledged that a quantitative ranking method based on DALYs would provide a

Table 1. Initial and final scores after scaling for each criterion.

Hazards	Criterion 1, C1 (%)	C1 Initial Score	C1 Final Score	Criterion 2, C2	C2 Initial Score	C2 Final Score	Criterion 3, C3	Critical MOE	C3, Initial Score	C3, Final Score	Result: score based on semi-quantitative
PCDD/F	24.2	2	4	B	6	6	122.5%		10	10	240
Acrylamide_1	1.6	1	2	A	10	10	811	10 000	10	10	200
Inorganic Arsenic	7	1	2	A	10	10	0.77–21	NA	10	10	200
Furan_1	3.7	1	2	A	10	10	1560	10 000	10	10	200
Chromium VI	2.2	1	2	A	10	10	2702	10 000	10	10	200
Lead	3.4	1	2	B	6	6	2.5	10	10	10	120
Cadmium	0.9	1	2	D	4	4	98%		8.33	8.33	66.67
Genistein	73.4	4	8	C	5	5	14,000	300	1.67	1.67	66.67
TBBPA	89.4	5	10	D	4	4	4,848,485	1000	1.67	1.67	66.67
Furan_2	3.7	1	2	E	3	3	76	100	10	10	60
Cobalt	8	1	2	E	3	3	126.9%		10	10	60
e	40.4	3	6	B	6	6	20	2.5	1.67	1.67	60
BDE-209	44.9	3	6	B	6	6	850,000	2.5	1.67	1.67	60
Aluminium	17.7	1	2	B	6	6	35.7%		3.33	3.33	40
Strontium	46.2	3	6	D	4	4	13.7%		1.67	1.67	40
Chromium III	22.2	2	4	C	5	5	1.2%		1.67	1.67	33.33
PAH4	12.4	1	2	A	10	10	91,892	10 000	1.67	1.67	33.33
Nickel	2.5	1	2	C	5	5	37.7%		3.33	3.33	33.33
4-Nonylphenol	38.1	2	4	C	5	5	0.8%		1.67	1.67	33.33
HBCDDs	18.1	1	2	B	6	6	1,019,253	24	1.67	1.67	20
Acrylamide_2	1.6	1	2	E	3	3	321	125	1.67	1.67	10
Barium	15.4	1	2	E	3	3	8.5%		1.67	1.67	10
BPA	9	1	2	E	3	3	2%		1.67	1.67	10
Antimony	20.8	2	4	G	1	1	1.16%		1.67	1.67	6.67

Notes: NDL-PCB: non dioxin like PCBs; PAH: polyaromatic hydrocarbons; PBDE: polybromodiphenylether; HBCDD: hexabromocyclododecane; TBBPA: tetrabromobisphenol A. The last column 'Result: score based on semi-quantitative' provides the score based on the semi-quantitative approach. The top rank (i.e. PCDD/F) corresponds to the highest risk, the bottom rank (i.e. Antimony) to the lowest risk.

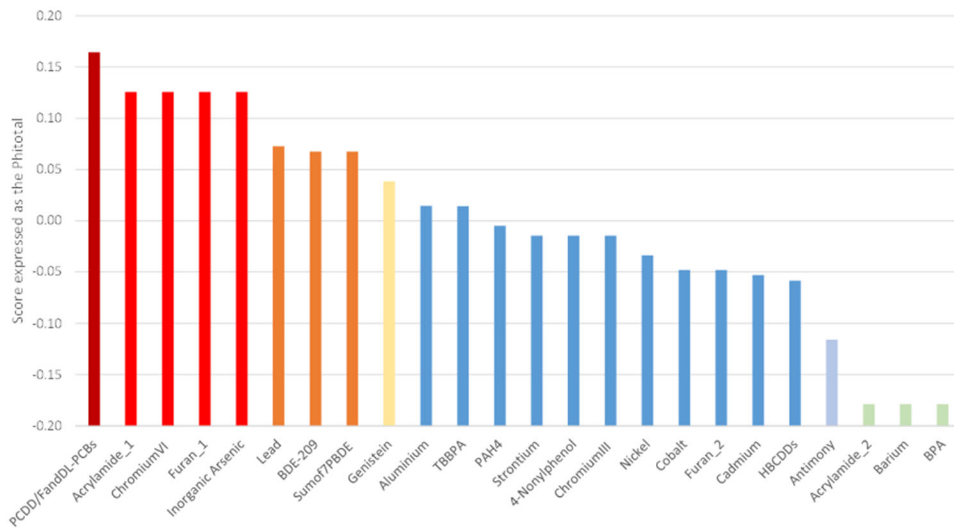

Figure 4. Ranking results based on the outranking PROMETHEE method: The top rank (i.e. PCDD/F and DL-PCBs) corresponds to the highest risk, the bottom rank (i.e. BPA) to the lowest risk.

definitive added-value, they did not take this route due to insufficient data.

To rank the chemicals, two methods were tested. Overall, they do not differ much in terms of ranking: the top and bottom chemical hazards were the same with both methods. However, it is important to keep in mind that minor differences were found for hazards ranked in the middle of the list as for instance cadmium and cobalt. Nevertheless, the methods differ on different points as detailed hereafter.

First, to give the same weight to each criterion, the semi-quantitative approach requires to normalise (express on the same scale) the scores for each criteria, before multiplying them. The MCDA method is much less sensitive to different scaling.

Second, the semi-quantitative method approach is specific to risk assessment. It follows in essence the schematic definition of the risk (likelihood multiplied by severity) with the slight difference that likelihood is here divided into two elements: contribution and risk characterisation. Li et al. (2021) have also adopted a risk matrix method (Risk = Severity × Probability) to score chemical hazard, although their severity and likelihood criteria were slightly built differently than ours. On the opposite, the outranking MCDA method is a generic technique that could be used in any domain (engineering, logistics, nanomaterials, etc.), although it has been advocated by the FAO (2020) to classify risks related to food safety. Recently, outranking MCDA methods have been carried out by Eygue et al. (2020) to evaluate simultaneously biological and chemical hazards associated with emerging dietary practices, and by ANSES (2020) to rank biological or chemical hazards of some food commodities.

Third, extend the ranking with other criteria (e.g. difficulty to find data, weight of evidence of toxicity for a given chemical, etc.) will be a challenge when using the semi-quantitative method. Indeed, multiplying 'values' requires having proper numerical values. When the multiplication is done with qualitative data reorganised as ordered values (e.g. low, medium, high evidence reorganised as 1, 2, 3), this brings approximation and potentially bias. On the opposite, extending the ranking with other criteria is straightforward in MCDA method.

Fourth, the multiplication of the three criteria is definitively straightforward, it could be done by any risk assessor or risk manager in Excel, it does not require any computer skills. The MCDA method, even if a package exists in R, required some programming expertise. That could put off some users.

Despite these methodological differences, as mentioned above, the ranking provided in follow-on formulae by both approaches are rather similar. Both have pros and cons; however, both are adapted to the food safety context. We are in favour of ranking chemical hazards in food with both methods run in parallel, comparing results and when occurred, trying to explain why a difference is observed.

Conclusions

A semi-quantitative risk-matrix type method and an outranking MCDA method were deployed to rank several substances in one food item (follow-on formulae), based on the criteria severity, contribution to the total exposure, and, risk characterisation. The strength of this approach is that it is relatively easy and rapid to set up and to run. However, it requires the percentage of contribution to the total exposure, which is not always available in chemical risk assessments. Nevertheless, it could be possible, when exposure data are not available, to use more classically food contamination level and food consumption (level and proportion of consumers) to build the contribution criterion.

The risk ranking methodology proposed here, based on two methods conducted in parallel, should be applied to other food products than follow-on formulae. This would make it possible to confirm or, conversely, to reject the fact of keeping both semi-quantitative and MCDA methods, as we do not yet have the necessary hindsight to be certain of the way in which risk ranking in chemistry should be approached. Not to mention that risk assessment is only one part of risk analysis, there is also risk management and risk communication. Regarding these last two aspects, each aggregation method has its advantages and disadvantages, which can be better evaluated once more case studies have been carried out.

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