



Risk-ranking of chemical hazards in plant-based burgers: An exploratory case study on recipe formulations

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ABSTRACT

Due to the increased popularity of plant-based products, new alternatives for animal-derived products are being developed. Before market introduction, food business operators (FBOs) should identify food safety hazards for these plant-based products to protect consumer health. A wide range of chemical hazards may be present in the ingredients used for these products. Ranking the hazards will help FBOs to focus on the most relevant ones and identify the most optimal recipe for such products. This study provides a two-tiered ranking approach. First, all potential hazards were identified based on their presence in the crop, detection above European Union (EU) legal limits, data gaps, and potential health risks. Second, a risk ratio method was applied for the most relevant hazards based on the chemical hazard in the crop, processing factors to establish (protein) ingredients, consumption data, and health-based guidance values. This structured approach was applied to a case study on plant-based burgers using five example recipes, which showed it was capable of comparing various recipes and indicated an optimal recipe to produce plant-based burgers with minimised food safety risks. As such, it can be used as a safe-by-design approach in the early development of new plant-based alternatives.

1. Introduction

Consumers are increasingly aware of the sustainability and animal welfare issues related to meat and dairy product consumption. As a result, there is a transition toward a flexitarian diet and reducing the overall consumption of animal-based products. One consequence of this protein transition is an increasing demand for alternative proteins from plant-based sources (He et al., 2020). Cereals, seeds, or legumes may be used to produce meat or dairy replacers, or proteins may be extracted from these sources before further processing. Fractionation, either dry or wet, is most frequently applied to obtain the protein concentrate or protein isolate from the crop. After extracting the proteins from the crops, further processing is needed to produce plant-based products, which frequently involves an extrusion step (Banach et al., 2022).

Currently, there is limited information on food safety hazards in plant-based products and the effects of processing on hazards (Augustin Mihalache et al., 2022; Banach et al., 2022). A recent review identified the potential presence of allergens, anti-nutritional factors, pesticides, and processing contaminants in plant-based products depending on the crop species and the processing applied to obtain the final product (Banach et al., 2022). Furthermore, natural toxins such as mycotoxins

and plant toxins may be found in plant-based meat and dairy alternatives (Augustin Mihalache et al., 2022). Since food business operators in the European Union (EU) are required to put products on the market that are safe for consumption (Regulation (EC) No 178/2002), it is necessary to identify food safety hazards as early as possible, for instance at the product development stage. Such a safe-by-design approach allows for early identification of potential hazards before market introduction and for choosing ingredients and processes to minimise food safety risks. This approach has been implemented in a broad range of disciplines, such as construction engineering, chemical engineering and software engineering, during the development of new products, equipment and processes (van Gelder et al., 2021). In the food-related field, it has primarily been advocated in the design of nanomaterials (Kraegeloh et al., 2018) and in crop breeding (Van der Berg et al., 2020). A safe-by-design approach for plant-based products implies that food safety hazards are identified upfront. Although several food safety hazards can be present in these products, not all of these are equally relevant. A risk ranking method can help prioritise hazard-food combinations and be used to select the most optimal plant-based products concerning food safety.

Various tools are available to rank hazards and foods, ranging from quantitative to semi-quantitative to qualitative (Sampedro, 2020; Van

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der Fels-Klerx et al., 2015, 2018). Depending on available resources such as time, budget, and data, a risk ranking method can be selected to fit the needs of the risk manager (Van der Fels-Klerx et al., 2015). A bottom-up approach based on food supply chain data is usually used for chemical hazards since epidemiological data related to exposure to hazards that is needed for a top-down approach is lacking. All risk ranking methods include estimations of the likelihood of a hazard's presence (i.e., the probability) and the severity of the hazard, specifically: Risk = Probably \times Severity (CAC, 2015). Methods for risk ranking have either ranked multiple hazards in one food product, a single hazard in multiple food products, or hazard-food combinations (Sampedro, 2020). In our study, combinations of hazards and foods (with protein as the main ingredient) are ranked. This is a complex scenario due to the higher probability of uncertainty in the analysis (e.g., unknown chronic exposure of an ingredient) and various metrics needed for comparison. Therefore, qualitative or semi-quantitative methods are preferred over quantitative methods in this study since less data is required to perform the analysis.

This research aimed to explore the possibility of ranking chemical food safety hazards and selecting the most optimal recipe for plant-based products produced in the EU. A semi-quantitative risk ratio method using the hazard quotient (HQ) was applied for this purpose and explored in a case study focusing on five recipes for plant-based burgers.

2. Materials and methods

2.1. Case study

A risk ratio method was applied to a case study on plant-based burgers using five example recipes (Table 1). The protein source and concentrations differed per recipe, while the remaining ingredients and concentrations were the same across the recipes. The main protein ingredients were selected based on the top 10 most frequently introduced plant protein ingredients in meat substitutes, in the EU and North America (the USA and Canada), for the years 2015–2020, according to the Innova database.¹ These included recipes composed of soy (concentrates and isolates), wheat (gluten), pea (isolate), potato (isolate), lentil, and faba bean as the primary protein sources.

The risks of each plant-based burger recipe were ranked for chemical food safety hazards that can be present in the crop and the effect of processing. Processing can be broadly categorised into two types: (i) processing from crop to powder ingredients and (ii) mixing ingredients, cooking, extrusion, and shaping to obtain the final plant-based product. The first processing step may entail washing or peeling crops (e.g., for onions) and extracting proteins from the crop. Several steps are incorporated to extract proteins from the crops, depending on the raw material and the intended protein fraction. These can include peeling, dehulling, washing, milling, acidification, defatting, and drying. These protein powders can be further processed by extrusion to improve texture or used as such as ingredient to produce the plant-based burgers. Subsequent storage of the burgers and consumer processing were not incorporated in the analysis.

2.2. Approach

A two-tier approach was used to rank the hazard-ingredient combinations. Fig. 1 describes the steps and sources of input for each tier.

2.2.1. Tier 1. selection of most relevant chemical food safety hazards

Based on previous research and available monitoring data, a long list of chemical hazards was established in Tier 1. In order to determine the relevance of these hazards, the following criteria were scored as either 0 or 1: A) presence of the hazard in the crop (when a hazard was detected in a crop according to literature or monitoring data, a score of 1

was provided), B) hazard detected above EU legal limits (when a hazard was detected in a crop above the legal limit according to literature, monitoring data or RASFF notifications a score of 1 was provided), C) in case knowledge gaps about the hazard were identified, a score of 1 was provided, and D) in case human health risks were identified, a score of 1 was provided. More details on the references and data used as provided below.

A. Presence of the hazard in the crop. The following crops were used to obtain the ingredients for the plant-based burger recipes: potatoes, sunflower seeds, tomatoes, garlic, onions, wheat, faba beans, lentils, peas, soybeans, and black pepper. For these crops their potential presence was identified using both literature and monitoring data:

1. Our research team previously performed a hazard identification for several of the crops. The reports of that research was used as a starting point, i.e. previous research on wheat and sunflower seeds (Klüche et al., 2020), garlic and onions (Hoffmans et al., 2020), potatoes (Nijkamp et al., 2017), and tomatoes (Hobe et al., 2020). Within EU project SPICED² chemical hazards were identified for black pepper. For the legumes, i.e. faba beans, lentils, peas, and soybeans, additional literature review was performed to identify potential chemical hazards. The chemical hazards, as mentioned in the following papers, were included in the long list for legumes: Akoto et al., 2013; Ciminelli et al., 2017; Ciscato et al., 2010; Duan et al., 2016; Franzaring et al., 2019; He et al., 2020; Huang et al., 2017; Kala & Khan, 2009; Mawussi et al., 2009; Niyibituronsa et al., 2018; Olagunju et al., 2018; Oviedo et al., 2012; Yañez et al., 2019; Zhang et al., 2019.

2. The presence of the detected hazard in the crops indicated above in national monitoring data was obtained from ChemKAP³ (Quality Programme for Agricultural Products) for the years 2009–2018, national monitoring data obtained from the German Federal Institute for Risk Assessment (BfR)⁴ for the years 2015–2019, and RASFF notifications⁵ for the years 2010–2019 using the most recent data available at the time of the research.

B. Detection of the hazards above the EU legal limit.

1. Based on literature data (for references used, see A1).
2. Based on available monitoring data from ChemKAP and BfR (see A2).
3. Based on RASFF notifications (see A2).

C. Identified data gaps.

For some hazard-ingredient combinations, limited information was available, but previous research (Hobe et al., 2020; Hoffmans et al., 2020; Klüche et al., 2020; Nijkamp et al., 2017) had identified potential human health risks. Therefore, these hazards were seen as data gaps.

D. Potential health risk.

EFSA reports (EFSA, 2008; EFSA, Arcella, Eskola, & Gómez Ruiz, 2016; EFSA, Binaglia, Baert, Schutte, & Serafimova, 2019; EFSA CONTAM panel, 2012, 2014; EFSA CONTAM Panel et al., 2017; EFSA CONTAM Panel et al., 2018; (EFSA CONTAM Panel et al., 2020a–c)) were used to determine whether an ingredient had a relevant contribution to the dietary intake of the chemical hazard identified. In addition, for pesticides, the EU pesticide database⁶ was

² <https://cordis.europa.eu/project/id/312631>.

³ <https://www.rivm.nl/en/chemkap>.

⁴ https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/02_AmtlicheLebensmittelueberwachung/04_Monitoring/01_berichte_archiv/lm_monitoring_Berichte_Archiv_node.html.

⁵ <https://webgate.ec.europa.eu/rasff-window/screen/search>.

⁶ https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en.

¹ <http://www.innovamarketinsights.com/>.

Table 1
Processing and ingredients (g/100 g) for the five plant-based burger recipes.

	Recipe 1	Recipe 2	Recipe 3	Recipe 4	Recipe 5
Processing	Cooking in water (100 °C) ^a	Extrusion and cooking in oil (160 °C)	Extrusion and cooking in oil (160 °C)	Extrusion and cooking in oil (160 °C)	Cooking in water (100 °C) ^a
Ingredients (g/100 g)					
Protein source					
Faba bean protein					16
Lentils				16	
Pea protein isolate			16		
Potato protein isolate	2				
Soy protein concentrate	12				
Soy protein isolate	2	8			
Wheat protein (gluten)		8			
Remaining ingredients					
Black pepper	0.5	0.5	0.5	0.5	0.5
Garlic	1	1	1	1	1
Onion	2	2	2	2	2
Potato starch	12	12	12	12	12
Sunflower oil	13	13	13	13	13
Tomato concentrate	4	4	4	4	4
Yeast extract	3	3	3	3	3
Methylcellulose	2	2	2	2	2
Malt extract	2	2	2	2	2
Acetic acid	1	1	1	1	1
Salt	1	1	1	1	1
Water	42.5	42.5	42.5	42.5	42.5

^a Burger in a plastic bag immersed in boiling water.

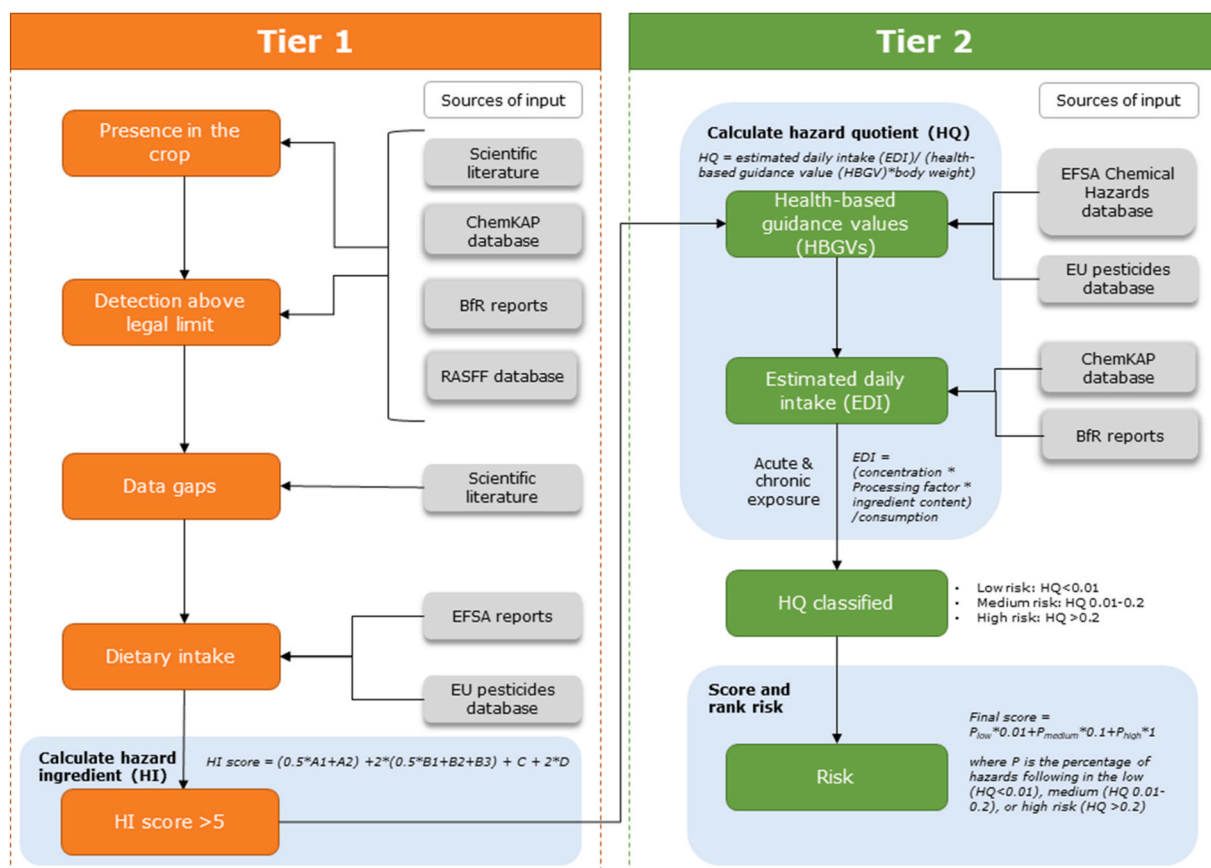


Fig. 1. Two-tiered approach and sources of input to determine the hazard-ingredient (HI) source, hazard quotient (HQ), and risk for the case study on plant-based burgers. BfR: German Federal Institute for Risk Assessment; RASFF: Rapid Alert System for Food and Feed; EFSA: European Food Safety Authority; EU: European Union.

consulted. For those pesticides detected above the EU legal limit at the time of the evaluation (criterion B2), a score of 1 was assigned in case pesticides were unauthorised or when the maximum residue levels (MRLs) was not based on the lower limit of analytical determination (LOD).

All criteria were scored as either 0 or 1. Since the focus of the research was on the EU, information obtained from global literature (criteria A1 and B1) was weighed at half the other criteria. Both the detection above the EU legal limits (criterion B) and potential health risk (criterion D) were evaluated as more important than potential presence (criterion A) or identified data gaps (criterion C). Consequently, factors B and D were multiplied by 2. Sub-scores for criteria A and B were added, and a hazard-ingredient (HI) score was obtained as follows:

$$\text{HI score} = (0.5 \times A1 + A2) + 2 \times (0.5 \times B1 + B2 + B3) + C + 2 \times D$$

2.2.2. Tier 2. ranking the most optimal recipe for the chemical food safety of plant-based burgers

A risk ratio method was applied to rank the recipes. As a result of the analysis in Tier 1, HI combinations with a final score >5 were evaluated further by calculating the hazard quotient (HQ). The HQ is defined as the ratio of exposure to an appropriate health-based guidance value (HBGV) such as the Acceptable Daily Intake (ADI) or the Acute Reference Dose (ARfD):

$$\text{HQ} = \text{EDI} / (\text{HBGV} \times \text{bw})$$

with EDI: estimated daily intake (mg/day), HBGV: health-based guidance value (mg/kg bw/day) and bw: body weight (kg).

The five recipes were used to determine the ingredient contents within each plant-based burger (Table 1), for which a serving size of 90 g was assumed. For chronic exposure, a weekly consumption was assumed (0.14 burger/day); for acute exposure, daily consumption was assumed (1 burger/day). The EDI was then calculated as follows:

$$\text{EDI} = (\text{concentration} \times \text{processing factor} \times \text{ingredient content}) / \text{consumption}$$

With concentration: average concentration of the chemical hazard in mg/kg ingredient; processing factor: the effect of processing on this concentration (see Annex 1); ingredient content: the amount of ingredient used in the burger in kg/burger (recalculated from Table 1 using a serving size of 90 g) and consumption: the daily consumption of burgers (1 for acute exposure and 0.14 for chronic exposure).

Monitoring data were used to determine the average concentration of a hazard in a crop. For most of the hazard-crop combinations, the ChemKAP database was used, and averages were calculated for the data from 2009 to 2018. In case data was unavailable, monitoring data from the BfR was used. Where possible, the effect of processing on the concentration of chemical hazards was obtained via a literature review or a pesticide database⁷ (Annex 1). In case no information was available on the effect of processing used for protein extraction, the moisture balance (i.e. the moisture content in the protein fraction divided by the moisture content in the crop) was used to estimate the final concentrations. All protein extractions investigated for the five example recipes contained a drying step. The moisture balance for fava bean protein isolate, pea protein isolate, potato protein isolate, soybean protein isolate, soybean protein concentrate, and wheat protein (gluten) used was respectively 0.35 (Boukid & Castellari, 2022), 0.94 (Maningat et al., 2022), 0.10 (Ekin, 2011; Norell et al., 2016, pp. 1–3), 0.38 (Riaz, 2004; Shih et al., 2016), 0.44 (Pietsch et al., 2019; Riaz, 2004), and 0.61 (Maningat et al., 2022; Riaz, 2004). The temperature applied to obtain the plant-based

burger, which is either cooking in water, as applied in recipes 1 and 5, or extrusion of protein ingredients followed by cooking of the burger in oil at 160 °C for recipes 2, 3 and 4, was used to determine whether the formation of processing contaminants was possible. Processing contaminants were assumed to be present only when the processing temperature was above 120 °C (Mottram et al., 2002), i.e., only applicable in recipes 2–4.

The effect on human health was expressed by using either the acute reference dose (ARfD) or a chronic HBGVs (such as acceptable daily intakes, tolerable daily intakes, etc.). These values were obtained from the EFSA Chemical Hazards Database,⁸ EFSA opinions (EFSA, 2012b, 2014, 2015; EFSA CONTAM Panel et al., 2020a), or the EU pesticide database.⁹

HQs were estimated for acute and chronic exposure assuming an average body weight of 70 kg for an adult (EFSA, 2012a). The obtained HQs for each hazard-ingredient combination were subsequently classified into high (score of 1 for HQ > 0.2), medium (score of 0.1 for HQ: 0.01–0.2), or low (score of 0.01 for HQ < 0.01). For each recipe, the scores in Tier 2 were then added, allowing us to compare the overall safety of the various recipes:

Final score: $P_{\text{low}} \times 0.01 + P_{\text{medium}} \times 0.1 + P_{\text{high}} \times 1$, where P is the percentage of hazards following in the low (HQ < 0.01), medium (HQ 0.01–0.2) or high category (HQ > 0.2).

2.3. Sensitivity analysis

Since the effect of processing on the protein ingredients is largely unknown, and only the effect of drying could be included for all protein ingredients, a sensitivity analysis was performed on the Tier 2 data to evaluate the effect of the processing factors used. In order to perform the sensitivity analysis, $0.5 \times \text{mean}$ (–50%), mean (0%), and $1.5 \times \text{mean}$ (+50%) values of both the processing factor for the raw ingredients and the processing factor for protein extraction were used as input parameters. First, the model output was calculated with the processing factor for raw ingredients as input at $0.5 \times \text{mean}$, the mean, or $1.5 \times \text{mean}$ for all hazard-ingredient combinations. The processing factor for protein extraction was kept at the mean values. Next to that, the model output was calculated with the processing factor for the protein extraction using either $0.5 \times \text{mean}$, the mean, or $1.5 \times \text{mean}$ for all hazard-ingredient combinations as input. In this case, the processing factor for the raw ingredients remained at the mean value. The results were plotted to determine the effect of the different input values for processing factors on the overall safety of the recipes.

3. Results

A comprehensive list of chemical hazards that could be present in each crop used for the plant-based burgers was established based on available scientific literature and monitoring data. The list contained a total of 1063 hazard-ingredient combinations in the following categories: cleaning agents and disinfectants (n = 15), environmental pollutants or processing contaminants (n = 50), food additives and flavourings (n = 25), metals and elements (n = 119), mineral oils (n = 5), mycotoxins (n = 185), pesticides (n = 592), pharmaceuticals (n = 15), plant toxins (n = 12), processing aids and additives (n = 7), radionuclides (n = 16), and other hazards (n = 22). Based on the scores for Tier 1, found with criteria A to D, a final list of 107 hazard-ingredient combinations was obtained in Tier 2 (Annex 1). The HQs were calculated and classified for these combinations to rank the recipes for the plant-based burgers (Table 2).

Table 2 shows that the differences between the recipes on acute

⁷ <https://www.rivm.nl/en/chemkap/fruit-and-vegetables/processing-factors>

⁸ <https://zenodo.org/record/3693783#.YnuNsubXpZ>.

⁹ https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en.

Table 2
Hazard quotient (HQ) scores per recipe based on acute and chronic effects.

	Recipe 1	Recipe 2	Recipe 3	Recipe 4	Recipe 5
Acute effects	0.010	0.010	0.010	0.010	0.011
Chronic effects	0.055	0.071	0.051	0.053	0.026

effects are negligible. Most of the hazard-ingredient combinations resulted in a low HQ score of 0.01. Only omethoate in beans resulted in an HQ of 0.0368, which is classified as medium (HQ score of 0.1). For chronic effects, the highest HQ score of 1 was obtained for several hazard-ingredient combinations, i.e. for acrylamide in potato starch when heated above 120 °C, for aflatoxin B₁ in sunflower oil, and for ochratoxin A in soybeans. This result is primarily due to the low HBGVs of these compounds. Since recipe 2 contains all three ingredients and is extruded at 160 °C, this recipe had the highest overall score for chronic effects. Recipe 5 showed the lowest effect on chronic health impacts since it does not contain soybeans and no extrusion is included, so acrylamides are not formed. The results for recipes 1, 3, and 4 were comparable.

A sensitivity analysis was performed to evaluate the effect of using processing factors on the outcome of the risk ranking. For acute effects, the results showed that the output was not sensitive to changes in the processing factor for raw ingredients or protein extraction. The results on chronic exposure for the processing factor of the raw ingredients (i.e., the processing applied from harvest until raw material for protein extraction, such as washing) were similar to the results of the processing factor of the protein extraction.

Fig. 2 shows the results for chronic effects per recipe for the processing factor used for protein extraction.

Results showed that recipe 2 is the most sensitive for the processing factor for protein extraction, showing a difference of 0.020 in the output when using 0.5 × mean of the processing factor for protein extraction. Recipe 5 shows a slight sensitivity to the processing factors, with a 0.001 higher outcome when 1.5 × mean of the processing factor was used as input. Therefore, even though the input changed between −50% and +50% around the mean, the output was not primarily affected. Recipes 1, 3, and 4 are not sensitive to changes in the processing factor, as the output remains constant when varying the input values. The low sensitivity to changes in the processing factor can be explained by the fact that the model output is classified, i.e., the HQs are classified into low, medium, and high using threshold values of 0.01 and 0.20. As a result, the input can change, but the output can remain in the same HQ class. The results for recipe 2 are caused solely by the results for mycotoxins. The final score for mycotoxins using 0.5 × mean is 0.177, while the final score using 1.5 × mean is 0.319. The only hazard-

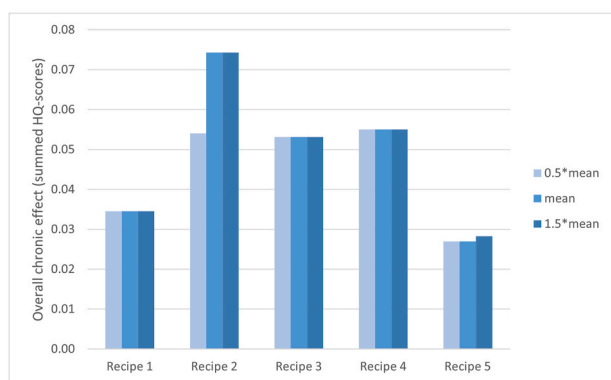


Fig. 2. Results per recipe of the sensitivity analysis on the effect of the processing factor (PF) for protein extraction by changing the input between −50% and +50% as related to the mean PF. The figure shows the overall chronic effect reported as hazard quotient (HQ) scores.

ingredient combination changing is deoxynivalenol (DON) in wheat, where the higher mean results in an HQ score of 0.1 and the lower mean in an HQ score of 0.01. In recipe 5, changing the processing factor for protein extraction between 0.5 × mean and 1.5 × mean resulted in the following change in the group of pesticides: chlorate in beans changed from an HQ score of 0.01 using 0.5 × mean to an HQ score of 0.1 using 1.5 × mean.

4. Discussion

This study relied heavily on existing literature and databases. However, there were some limitations to the data and information used for the ranking. National monitoring data were used to perform the calculations needed to estimate the HQ. These data contained information at the crop level as monitored in the Netherlands and Germany. Since the monitoring program includes imported products, the data used will be representative for other EU countries and can be used as such. However, the data only included concentrations of chemical hazards at crop level. Data on chemical hazards in protein ingredients obtained from these crops (e.g., pea protein isolate) were lacking, which is a limitation of this study. Therefore, when available, processing factors were used to estimate the protein fraction concentrations. Processing factors for pesticides are available in both national databases (such as the RIVM database¹⁰) and at EU level (EFSA database on processing techniques and processing factors¹¹). These databases contain processing factors for commonly applied food processing such as washing, baking, cooking in water, canning, etc. However, limited processing factors were available especially for the chemical hazards identified other than pesticides, and assumptions were made to incorporate the effect of processing. A worst-case approach was used, assuming heating or acidification did not affect the final concentration of the hazard(s) in the ingredients (with the exception of acrylamide that was assumed to be formed at temperatures above 120 °C (Mottram et al., 2002)). Analogous to the approach followed by RIVM in their pesticide database, if no data was available, it was assumed the hazard was not affected by processing and the concentration in the ingredient was assumed to be the same as in the crop. Using the moisture balance for protein extraction was another worst-case assumption, since we assumed the hazard was concentrated in the final product. The obtained outcome may, therefore, be an overestimation of the risks of the various recipes for plant-based burgers, and future research is needed to determine in which fraction the hazards end up (e.g. fat fraction). Overall, applying the same assumptions between the recipes when extrapolating the hazards from the crop to the protein ingredient and the potential probability of the risk allowed a mutual comparison. The methodology can thus be used to finally chose the safest recipe for a plant-based burger.

In addition, a sensitivity analysis was performed to estimate the effect of processing on the chemical hazards' risk ranking. This result showed that for some recipes, the processing factor did influence the outcome of the analysis. A recommendation is, thus, to perform more research on the fate of chemical hazards from crop to protein ingredients to derive processing factors better, as this information is currently lacking (Banach et al., 2022). Especially since plant-based meat and dairy alternatives are increasingly becoming available on the market, a more accurate estimation of potential chemical hazards and the probability of the risk is needed (Banach et al., 2022). Moreover, the long-term health implications of plant-based meat alternatives, given the dietary shift from animal-based to plant-based alternatives, have also been questioned (Toh et al., 2022). Research investigating the epidemiological impact of plant-based alternatives would provide insight into the exposure and the severity of risks of plant-based alternatives,

¹⁰ <https://www.rivm.nl/en/chemkap/fruit-and-vegetables/processing-factors>

¹¹ <https://www.efsa.europa.eu/en/supporting/pub/en-1508>.

subsequently allowing for a refined estimate of the risk.

The approach used in this study was successful in ranking the chemical food safety hazards related to plant-based burgers. Risk rankings should be performed transparently, indicating the data sources used, the thresholds identified, and the decisions made to reproduce the ranking outcomes (Sampedro, 2020). This study provides that, since a structured approach was followed where the data sources used in each step to derive a final risk ranking were indicated. Various methods are available to rank risks, but due to the complexity in this case in which multiple hazard-food ingredient combinations were to be ranked, a qualitative or semi-quantitative method is most appropriate. Various papers use a scoring method for risk ranking in which quantitative scores are attributed to various factors reflecting severity and probability. The outcome is then calculated by adding or multiplying these factors using scales or transforming them into qualitative terms (Sampedro, 2020). Multiple hazards in a single food product can be assessed, as was done for food safety hazards in seaweed (Banach et al., 2020). In their paper, an equal amount of factors had been attributed to severity and probability, although the stakeholder perspective on occurrence was weighed as half that of the other criteria due to limited input. Their qualitative scores were transformed into quantitative ones, allowing for a final ranking of the hazards evaluated (Banach et al., 2020). Chou et al. (2019) also prioritised multiple hazards (i.e., pesticides) in a single food product, i.e., crops. Probability and severity in their ranking are, however, not equally taken into account. Two factors for severity were added with a maximum score of 10. These were multiplied with crop consumption and occurrence of pesticides with a maximum score of 16 (4×4), attributing a higher weight to the probability or exposure of the hazard. Li et al. (2021) also applied a scoring method to prioritise a single hazard in multiple food products and multiple hazards in a single food product. For the complex situation of ranking multiple hazards in multiple food products, they applied fuzzy logic. In their approach, severity was less relevant (with a maximum score of 5) than consumption (maximum score of 10) and occurrence of the hazard (maximum score of 10). The resulting hazard-food combinations are primarily ranked based on hazards that are frequently found and products that are frequently consumed. Hazards with a high severity but lower probability will be ranked low. Scoring methods are appropriate semi-quantitative methods for risk ranking if severity and probability are weighed equal, as risk is defined as the combination of the probability of an adverse health effect and the severity of that effect as a result of the presence of a hazard in food (CAC, 2015). The risk ratio method we applied in our study provided a balanced perspective on the compilation of the risk, including severity and probability. The risk ranking method has frequently been applied in the field of environmental contamination and has subsequently been adopted in food safety where it is primarily used to rank pesticides (Van der Fels-Klerx et al., 2018). The novelty in this study is that the risk ratio was combined with a scoring method allowing to rank multiple hazards, not only pesticides but also other chemical hazards, and multiple food products simultaneously. The approach followed can thus be used in complex situations where multiple hazard-food ingredients are to be ranked. The drawback of this method is that only food safety hazards that have an HBGV can be considered. This method is less flexible in considering (re-)emerging hazards or hazards with limited or no monitoring data available that are needed to estimate the daily intake. However, the strength of the approach followed is that it is a transparent and objective method primarily based on quantitative data. It allowed us to rank chemical hazards in various recipes used to obtain plant-based burgers. As such, it provides insight into an unexplored food product that is increasingly coming to the EU market.

Our risk-ranking method was applied to a scenario where a reversed engineering approach was followed, i.e., where the food product was separated, or de-formulated, into ingredients, and we quantified the risk for each of those components. Reverse engineering allows one to start from the food requirements and design or redesign the steps involved to

reach the target output (Thomopoulos et al., 2019). The data used to score the ingredients can be incorporated into other risk-based assessments and for new product developments. Overall, our results can be used in a safe-by-design approach in the early development of new plant-based alternatives. The method has been applied in a confidential research for a food company to evaluate its appropriateness in a real life setting. This showed it was capable of ranking recipes thereby helping in selecting the most optimal ingredients for plant-based products. Food business operators can thus use the methodology described to optimise recipes for plant-based products, which apart from burgers could expand to other meat alternatives as well as dairy alternatives such as plant-based yoghurt, milk or cheese. Ideally, concentration data on chemical hazards in the foreseen ingredients for the new plant-based alternatives are used for the calculations. However, when these data are lacking, data at crop level can be used combined with processing factors when available. The approach allows a comparison between ingredients to be selected for new recipes prior to product development.

Even more, since the results obtained within our risk-ranking method are scaled between 0 and 1, the results can be integrated into other methodologies, like a multi-criteria decision analysis (MCDA). In an MCDA, multiple criteria are included to rank various alternatives. The criteria can be included equally or weighed according to their relevance. Recently, Eygue et al. (2020) applied an MCDA to compare various emerging dietary practices with respect to microbiological and chemical hazards. Their approach allowed the comparison of multiple hazards in multiple food products. A broader perspective could be applied where chemical food safety is compared to other parameters relevant during product development, such as microbiological food safety and shelf-life, sustainability, nutritional value, consumer perception, and costs. Such an MCDA approach can provide another dimension to the reversed engineering concept and safe-by-design approach. For example, when stakeholder input is used, a weighted approach can be applied, allowing to select those ingredients and processes that lead to the optimal plant-based burger based on the needs of the evaluator/assessor. The results presented in this paper can be used as input for other decision analysis approaches, like an MCDA.

This study showed that the methodology followed can be used to rank chemical hazards in upcoming plant-based products. However, it also identified a major knowledge gap, i.e. the effect of processing. Therefore, further research is needed to explore the effect of protein extraction on chemical hazards to allow for a more precise estimation of the estimated daily intake. Furthermore, it would be worthwhile to explore the usefulness of the methodology for other hazards, such as microbiological hazards or allergens.

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CRedit authorship contribution statement

E.D. van Asselt: Conceptualization, Supervision, Writing – original draft, Writing – review & editing. **M. Focker:** Investigation, Methodology, Writing – review & editing. **R.G. Hobé:** Data curation, Methodology, Validation, Writing – review & editing. **J.L. Banach:** Data curation, Investigation, Methodology, 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

Data will be made available on request.

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Annex 1. Processing factors used for the effect of processing crops into (protein) ingredients

Hazard-Crop	Processing factor for raw products	Rationale ¹²	Processing factor for protein extraction	Rationale
Acephate - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Acetamiprid - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Benzalkonium chloride (BAC) - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Bifenthrin - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Bitertanol - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Carbaryl - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Carbendazim (sum) - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Carbofuran - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Chlorate - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Chlorfenapyr - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Chlorprofam - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Chlorpyrifos - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Cyproconazole - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Diazinon - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Dicofol - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Dimethoate (sum) - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Endosulfan (alpha + beta + sulphate) - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Ethion - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Fenpropathrin - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Fipronil - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Hexaconazole - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Indoxacarb - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Iprodione - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Methamidophos - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Methomyl - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Omethoate - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Phenothrin - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Profenofos - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Propargite - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Propiconazole - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)

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Hazard-Crop	Processing factor for raw products	Rationale ¹²	Processing factor for protein extraction	Rationale
Tetradifon - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Triadimenol - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Triazophos - Fava Bean	1	Not determined, assumption = 1	2.84	Based on moisture balance (Boukid & Castellari, 2022)
Carbendazim (sum) - Black pepper	1	Raw = dried & powder	1	Lack of data, assumption = 1
Deet (Diethyltoluamid) - Black pepper	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Metalaxyl - Black pepper	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Ochratoxin A - Black pepper	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Thiamethoxam - Black pepper	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Aflatoxin B1 - Garlic	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Mephosfolan - Garlic	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
2,4-Dichlorophenoxyacetic acid - Lentil	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Bromoxynil - Lentil	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Carbendazim - Lentil	1	Raw	1	Lack of data, assumption = 1
Chlorpyrifos - Lentil	1	Raw	1	Lack of data, assumption = 1
Chlorfenapyr - Onion	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Clothianidin - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Cyhalothrin-lambda - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Cypermethrin - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Dimethoate - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Imazalil - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Maleic hydrazide - Onion	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Methomyl - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Omethoate - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Procymidone - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Profenofos - Onion	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Propiconazole - Onion	1	Raw without skin	1	Lack of data, assumption = 1
Thiametoxam - Onion	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Carbofuran (sum) - Pea	1	Not determined, assumption = 1	1.06	Based on moisture balance (Maningat et al., 2022)
Dimethoate - Pea	1	Not determined, assumption = 1	1.06	Based on moisture balance (Maningat et al., 2022)
Lufenuron - Pea	1	Not determined, assumption = 1	1.06	Based on moisture balance (Maningat et al., 2022)
Mandipropamid - Pea	1	Not determined, assumption = 1	1.06	Based on moisture balance (Maningat et al., 2022)
Pyrimethanil - Pea	0.93	Based on washing	1.06	Based on moisture balance (Maningat et al., 2022)
Acrylamide - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Chlorpropham - Potatoes	0.027	Raw without peel	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Chlorpyrifos - Potatoes	1	Raw without peel	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Dicloran - Potatoes	1	Raw without peel	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Fipronil - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Fluazifop-p - Potatoes	1.2	Raw without peel	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Fluazinam - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Fludioxonil - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Fluopicolide - Potatoes	1	Raw without peel	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Fosthiazate - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Lead - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Pencycuron - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Promecarb - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)
Thiabendazole - Potatoes	1	Not determined, assumption = 1	9.81	Based on moisture balance (Ekin, 2011; Norell et al., 2016, pp. 1–3)

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Hazard-Crop	Processing factor for raw products	Rationale ¹²	Processing factor for protein extraction	Rationale
Deoxynivalenol (DON) – Soybean isolate	1	Not determined, assumption = 1	0.14	Washing/dehulling + drying/milling (Chilaka et al., 2019)
Deoxynivalenol (DON) – Soybean concentrate	1	Not determined, assumption = 1	0.14	Washing/dehulling + drying/milling (Chilaka et al., 2019)
Ochratoxin A – Soybean isolate	1	Not determined, assumption = 1	2.63	Based on moisture balance (Riaz, 2004; Shih et al., 2016)
Ochratoxin A – Soybean concentrate	1	Not determined, assumption = 1	2.25	Based on moisture balance (Pietsch et al., 2019; Riaz, 2004)
Aflatoxin B1 – Sunflower oil	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Malathion – Sunflower oil	1	Not determined, assumption = 1	0	Malathion is not fat soluble (see (EU) 396/2005 and log Pow = 2.89), assumption = 0
Piperonyl butoxide – Sunflower oil	1	Not determined, assumption = 1	2.5	Compound is fat soluble (Log P _{ow} = 4.75 according to pubchem ¹³ ; and hexane soluble, so a processing factor of 2.5 is assumed (Fediol, 2018)
Chlorantraniliprole - Tomatoes	0.94	Puree (7–24% total soluble solids)	1	Lack of data, assumption = 1
Chlorate - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Chlorfenapyr - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Chlorpyrifos - Tomatoes	1	Raw with peel	1	Lack of data, assumption = 1
Chromium - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Dinotefuran - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Ethephon - Tomatoes	1	Raw with peel	1	Lack of data, assumption = 1
Flonicamid - Tomatoes	1	Raw with peel	1	Lack of data, assumption = 1
Fluopyram - Tomatoes	1	Raw with peel	1	Lack of data, assumption = 1
Imidacloprid - Tomatoes	1	Raw with peel	1	Lack of data, assumption = 1
Perchlorate - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Piperonyl butoxide - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Pirimiphos-methyl - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Procymidone - Tomatoes	1	Raw with peel	1	Lack of data, assumption = 1
Propargite - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Pyraclostrobin - Tomatoes	1	Raw with peel	1	Lack of data, assumption = 1
Pyrimethanil - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Spiromesifen - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Tetraconazole - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Tetradifon - Tomatoes	1	Not determined, assumption = 1	1	Lack of data, assumption = 1
Chlorpyrifos-ethyl - Wheat	1	Not determined, assumption = 1	1.64	Based on moisture balance (Maningat et al., 2022)
Deoxynivalenol (DON) - Wheat	1	Not determined, assumption = 1	0.225	Average for gluten extraction (Schaarschmidt & Fauhl-Hassek, 2018; Schaarschmidt & Fauhl-Hassek, 2018)
Dichlorvos - Wheat	1	Not determined, assumption = 1	1.64	Based on moisture balance (Maningat et al., 2022)
Dithiocarbamates - Wheat	1	Raw	1.64	Based on moisture balance (Maningat et al., 2022)
Ochratoxin A - Wheat	1	Not determined, assumption = 1	1.64	Based on moisture balance (Maningat et al., 2022)
Zearalenone (ZEN) - Wheat	1	Not determined, assumption = 1	1.64	Based on moisture balance (Maningat et al., 2022)

¹¹ <https://pubchem.ncbi.nlm.nih.gov/compound/Piperonyl-butoxide>.¹² <https://www.rivm.nl/en/chemkap/fruit-and-vegetables/processing-factors>.

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