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Risk ranking of pathogens in ready-to-eat unprocessed foods of non-animal origin (FoNAO) in the EU: Initial evaluation using outbreak data (2007–2011)



M.T. Da Silva Felício ^{a,*}, T. Hald ^b, E. Liebana ^a, A. Allende ^c, M. Hugas ^a, C. Nguyen-The ^{d,e}, G. Skoien Johannessen ^f, T. Niskanen ^g, M. Uyttendaele ^h, J. McLauchlin ^{i,j}

^a European Food Safety Authority, Via Carlo Magno 1A, 43126 Parma, Italy

^b Technical University of Denmark, National Food Institute, Mørkhøj Bygade 19, Building C, 2860 Søborg, Denmark

^c Department of Food Science and Technology, CEBAS-CSIC, P.O. Box 164, Espinardo, Murcia E-30100, Spain

^d INRA, UMR408, F-84914 Avignon, France

^e Univ-Avignon, UMR408, F-84000 Avignon, France

^f Norwegian Veterinary Institute, Section for Bacteriology – Food and GMO, Pb 750 Sentrum, N-0106 Oslo, Norway

^g European Centre for Disease Prevention and Control, Unit of Surveillance and Response Support, Food- and Waterborne Diseases and Zoonoses Programme, Tomtebodavägen 11a, 171 83 Stockholm, Sweden

^h Laboratory of Food Microbiology and Food Preservation, Department of Food Safety and Food Quality, Faculty of Bioscience Engineering, Ghent University, Block B, 4th Floor, Room B4.022, Coupure Links 653, B-9000 Ghent, Belgium

ⁱ Public Health England, 61 Colindale Avenue, London NW9 5EQ, United Kingdom

^j University of Liverpool, Institute of Infection and Global Health, L69 3GL, United Kingdom

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ABSTRACT

Foods of non-animal origin (FoNAO) are consumed in a variety of forms, being a major component of almost all meals. These food types have the potential to be associated with large outbreaks as seen in 2011 associated with VTEC O104.

In order to identify and rank specific food/pathogen combinations most often linked to human cases originating from FoNAO in the EU, a semi-quantitative model was developed using seven criteria: strength of associations between food and pathogen based on the foodborne outbreak data from EU Zoonoses Monitoring (2007–2011), incidence of illness, burden of disease, dose–response relationship, consumption, prevalence of contamination and pathogen growth potential during shelf life.

The top ranking food/pathogen combination was *Salmonella* spp. and leafy greens eaten raw followed by (in equal rank) *Salmonella* spp. and bulb and stem vegetables, *Salmonella* spp. and tomatoes, *Salmonella* spp. and melons, and pathogenic *Escherichia coli* and fresh pods, legumes or grains. Despite the inherent assumptions and limitations, this risk model is considered a tool for risk managers, as it allows ranking of food/pathogen combinations most often linked to foodborne human cases originating from FoNAO in the EU. Efforts to collect additional data even in the absence of reported outbreaks as well as to enhance the quality of the EU-specific data, which was used as input for all the model criteria, will allow the improvement of the model outputs. Furthermore, it is recommended that harmonised terminology be applied to the categorisation of foods collected for different reasons, e.g. monitoring, surveillance, outbreak investigation and consumption. In addition, to assist future microbiological risk assessments, consideration should be given to the collection of additional information on how food has been processed, stored and prepared as part of the above data collection exercises.

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1. Introduction

Foods of non-animal origin (FoNAO) are a major component of almost all meals and comprise a wide range of fruit, vegetables, salads, seeds, nuts, cereals, herbs, spices, fungi, and algae. These foods are consumed in a variety of forms ranging from those which are highly

processed or require cooking before consumption to ready-to-eat foods in which the constituents are raw or minimally processed (e.g. fresh-cut and prepacked salads).

Among all the reported foodborne outbreaks associated with either foods of animal origin (FoAO) or foods of non-animal origin (FoNAO) reported in the EU between 2007 and 2011, FoAO was associated with 90% of the outbreaks, 74% of the cases, 65% of the hospitalisations and 54% of the deaths. In contrast, FoNAO was associated with 10% of the outbreaks, 26% of the cases, 35% of the hospitalisations and 46% of the

* Corresponding author. Tel.: +39 0521036253.

E-mail address: mariateresa.dasilvafelicio@efsa.europa.eu (M.T. Da Silva Felício).

deaths (EFSA Panel on Biological Hazards (BIOHAZ), 2013). Trends in outbreak data on FoNAO are however strongly influenced by the 2011 VTEC O104 outbreak in Germany associated with sprouted seed consumption which illustrates a potential feature of FoNAO to cause very large outbreaks of considerable morbidity and mortality. If the data from this large outbreak in 2011 are excluded, FoNAO still caused 10% of the outbreaks, 18% of cases, but only 8% of the hospitalisations and 5% of the deaths in the EU (EFSA Panel on Biological Hazards (BIOHAZ), 2013).

Therefore, although there is a general tendency for the outbreaks associated with FoNAO in the EU to involve more cases than those associated with FoAO, these appear to be less severe, as there is a lower proportion of hospitalisations and deaths. This tendency has also been observed in the United States (Painter et al., 2013). Although 219 outbreaks were reported associated with FoNAO and this constituted only 10% of the total, this represents 57 deaths and 2798 hospitalisations. Given the importance of outbreaks caused by contaminated FoNAO, there is a need to evaluate the establishment of specific control measures for FoNAO sold as ready-to-eat, supplementing the general hygiene rules (European Parliament and Council, 2004) and existing microbiological criteria laid down for FoNAO (European Commission, 2005). Risk ranking is an important tool, which can help in prioritising control efforts and inform policy decisions including food regulation. A risk ranking tool (RRT) was published by the U.S. Food and Drug Administration (FDA) (Anderson et al., 2011), and this tool was applied to fresh produce in the USA.

We describe here the development of a RRT for pathogens in a wide range of ready-to-eat FoNAO involved with foodborne disease outbreaks caused by viruses, bacteria or parasites in the EU. This simple, transparent tool orders the priority of pathogen–commodity combinations according to specific criteria. This approach initially identified pathogen–food commodity combinations associated with human disease in the EU using data from reported foodborne outbreaks (European Food Safety Authority and European Centre for Disease Prevention and Control, 2009, 2010, 2011, 2012, 2013). Data from the Rapid Alert System for Food and Feed (RASFF) notifications (European Commission, 2011; European Parliament and Council, 2002; http://ec.europa.eu/food/food/rapidalert/index_en.htm), the scientific literature (e.g. from case–control studies and outbreak investigations) and expert opinion were also used to identify additional relevant pathogen–food associations.

The outcomes of the RRT were then derived from the severity of the health effect for each hazard, the degree of under-reporting and the incidence of illness, as well as from the criteria related to the probability of exposure and contamination, the dose–response relationship, growth potential of the hazard and shelf life of the commodity. To adequately target control measures, it is important to identify and prioritise the food/pathogen combinations most often linked with human illness.

2. Materials and methods

2.1. Categorisation of FoNAO

FoNAO commodities were classified into categories, i.e.: strawberries; raspberries; other berries; citrus fruit; apples and related fruit; stone fruit; tropical fruit; melons; fruit mixes; tomatoes; peppers and aubergines; gourds and squashes; fresh pods, legumes and grains; leafy greens eaten raw as salads; fresh herbs; leafy greens mixed with other fresh FoNAO; other leaves; carrots; other root and tuberous vegetables; bulb and stem vegetables; flowers and flower buds; sprouted seeds; fungi (mushrooms and yeasts); sea vegetables; nuts and nuts products; spices and dry powdered herbs; beverages; dehydrated vegetables and fruit and other processed products.

The purpose of this categorisation of FoNAO was to allow a risk ranking with respect to the main biological hazards covered by the model. To allow analysis in the RRT, this categorisation had to be compatible with

the definitions of food commodities used in EU foodborne outbreak databases and with EU food consumption databases. The categorisation of FoNAO also took into account factors which may have an impact on the microbiological risk, namely: (i) the potential for growth of the bacterial hazards (e.g. non-acidic fruits such as melon versus acidic fruits) or for no growth (dry commodities, e.g. nuts, spices and dry herbs); (ii) the processing, as defined by Article 2 in the Regulation (EC) No 852/2004 on the hygiene of foodstuffs, i.e. any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes; (iii) the production volumes, pre/post-harvest practices, and consumption practices leading to differentiation of a single commodity out of a broader category, e.g. “strawberries” versus “other berries” as well as; (iv) the expert knowledge concerning specific commodity/hazard combinations e.g. raspberries (as a single category not including “other berries”) and outbreaks associated with viruses and other pathogens.

Since the focus of this risk ranking was on unprocessed FoNAO, the following product categories were not included in the ranking: (a) FoNAO normally subjected to a processing step (e.g. rice, pasta) which inactivates vegetative pathogens; (b) FoNAO including one or more cooked ingredients (e.g. cooked vegetable salads); (c) foods which could not be classified since they were unspecified (e.g. fruit unspecified) or contained a broad range of heterogeneous processed constituents in the EU foodborne outbreak databases; (d) medicinal products and chewing tobacco; and (e) composite products.¹

2.2. Development of the risk ranking tool

The modelling approach was a semi-quantitative risk ranking adapted from Anderson et al. (2011), applying seven specific criteria: (1) strength of associations between human disease and food–pathogen combinations, (2) incidence of illness, (3) burden of disease, (4) dose–response relationship, (5) prevalence of contamination, (6) consumption and (7) pathogen growth potential during shelf life. These criteria were selected in order to assess the risk by evaluating the consequences of human disease (criteria 1 to 3), and the probability of exposure (criteria 4 to 7) (EFSA Panel on Biological Hazards (BIOHAZ), 2012a). For each criterion, the available data were grouped into scoring categories, which were defined and assigned a numerical, ordinal score. Higher scores corresponded to prioritised food/hazard combinations. The definition of the scoring categories was based on the data available and finally reviewed by expert opinion. For each food/pathogen combination, a reference (scenario 1) or baseline score was calculated by a summation of the scores from all seven criteria. The approach does not provide uncertainty estimates (e.g. confidence intervals), however, the use of broad categories for the semi-quantitative scoring indirectly takes into account data uncertainties. When insufficient quantitative data were available, qualitative data based on, for example, expert opinion was used. The impact of four additional model scenarios was considered by exclusion of specific criteria: scenario 2 excluding the consumption criterion; scenario 3 excluding the combined pathogen growth potential/shelf life criterion; scenario 4 excluding the dose–response criterion; and scenario 5 excluding the prevalence criterion. The model was set up in MS Excel.

2.2.1. Criterion 1: strength of associations between human disease and the food–pathogen combination

The European Food Safety Authority (EFSA) coordinates the annual statutory reporting of zoonoses, zoonotic agents, antimicrobial resistance, foodborne outbreaks and animal populations in the European Union (EU) (European Parliament and Council, 2003). Data are collected

¹ Foodstuff intended for human consumption that contains both processed products of animal origin and products of plant origin and includes those where the processing of a primary product is an integral part of the production of the final product: Decision 2007/275/EC.

on a mandatory basis including information on infections caused by specific zoonotic agents, antimicrobial resistance, contamination of food and foodborne outbreaks. Reporting information on foodborne outbreaks has been mandatory for all EU Member States since 2005, with harmonised specifications on the reporting being applied since 2007. For the purpose of this analysis, EU Zoonoses Monitoring foodborne outbreak data reported from 2007 to 2011 were used (European Food Safety Authority and European Centre for Disease Prevention and Control, 2009, 2010, 2011, 2012, 2013). Food/pathogen combinations were identified and classified as having a weak, moderate, strong or very strong association with human disease, and allocated of 1, 2, 3 and 4 respectively (Table 1). Only data from outbreaks reported as part of EU Zoonoses Monitoring could be classified as moderate to very strong and consequently considered in the risk ranking model. RASFF data, information from sporadic cases, historical outbreak data from the EU and outbreak data from outside EU were all considered as having a weak association. Since the origins and hence the contamination of the food commodities associated with these weak associations may be very different from similar products currently consumed in the EU, it was concluded that they were not sufficiently comparable to be included in the RRT. Detailed information (i.e. the number of human cases, hospitalisations and deaths) for the outbreaks with evidence for moderate, strong or very strong association with FoNAO reported from EU countries, Norway and Switzerland between 2007 and 2011 can be found in EFSA Panel on Biological Hazards (BIOHAZ) (2013).

When detailed information on the implicated foodstuff was available, foods were further categorised to match the FoNAO commodity categorisation mentioned above. When linking general commodity categories to specific outbreaks, for a minimal processed FoNAO (e.g. fresh cut, fresh juiced, mashed, frozen) attribution was made to the broad commodity group: e.g. an outbreak linked to frozen strawberries was attributed to strawberries.

2.2.2. Criterion 2: incidence of illness

Less severe diseases have a higher degree of under-reporting than diseases causing more severe symptoms: e.g. sporadic foodborne diseases caused by Norovirus or microbiological intoxications are rarely reported and EU notification rates are not available. However, it can be estimated that these hazards are still responsible for many cases of disease. For other foodborne infections like human salmonellosis, it is also well recognised that the reported number of cases only reflects a proportion of the estimated total number of cases and that the degree of under-reporting varies considerably among countries, depending on the surveillance systems. In an attempt to consider the impact of under-reporting, estimates for the hazard-specific estimated number of illnesses in the EU were included in the model.

Starting in 2007, data has been collated on the total number of human cases of infectious diseases reported to the European Surveillance System (TESSy), maintained by the European Centre for Disease Prevention and Control (ECDC). TESSy is a system for collection, validation, analysis and dissemination of data and in which data on 52

diseases and special health issues are collected. For calculation of foodborne infections reported at the EU level for this report, the notified number of cases was multiplied by a 'disease multiplier', which is a hazard-specific value that expresses the degree of under-reporting without consideration of attribution to source (Tauxe et al., 2010). At the EU level, only a disease-multiplier for *Salmonella* spp. ($DMSa_{EU}$) was available (EFSA Panel on Biological Hazards (BIOHAZ), 2012b; Havelaar et al., 2012b). For the other hazards, disease multipliers were taken from a US study, where Scallan et al. (2011) estimated pathogen-specific disease multipliers consisting of a multiplier for under-reporting (for pathogens under passive surveillance only) and a multiplier for under-diagnosis (for diseases also under active surveillance). These disease multipliers were estimated based on different population surveys combined with data on the severity (e.g. bloody diarrhoea vs. non-bloody diarrhoea) (Scallan et al., 2011). In our model, the disease multipliers from Scallan et al. (2011) ($DMHaz_{Sc}$) were anchored to the EU estimate for *Salmonella* spp. under the assumption that the relative degree of under-reporting between hazards is the same in the US as in the EU, i.e. $DMSa_{EU} : DMSa_{Sc} = DMHaz_{EU} : DMHaz_{Sc}$. As an example, the anchored EU *Shigella*-disease multiplier ($DMS_{Sh_{EU}}$) was estimated as follows: multiplying the *Shigella*-disease multiplier estimated by Scallan et al. (2011) ($DMS_{Sh_{Sc}}$) by the disease-multiplier for *Salmonella* spp. at the EU level ($DMSa_{EU}$) and dividing this product by the *Salmonella*-disease multiplier estimate by Scallan et al. (2011) ($DMSa_{Sc}$), i.e. $((33.3 \times 57.5) / 29.3 = 65.3)$. The anchored EU *Shigella*-disease multiplier was thereafter multiplied by the average number of notified cases per year in the EU from 2007 to 2010 in order to estimate incidence of illness in the EU.

For noroviruses as well as toxin-producing bacteria (*Bacillus cereus*, *Clostridium perfringens* and *Staphylococcus aureus*), data on notified cases were not available in the EU. The number of cases was therefore estimated based on a burden of illness study available in the Netherlands (Havelaar et al., 2012a), where the estimated number of Dutch cases was extrapolated to the EU level, assuming that the incidence of these diseases is approximately equal in all of those in EU. To check this assumption, estimated incidence data from a UK study (Tam et al., 2012) were extrapolated to the EU level and compared with the estimates based on the Dutch data. Estimated incidence from the Netherlands or the UK incidences were extrapolated to the EU level as follows: national incidences per 100,000 inhabitants were multiplied by the EU population (498,500,000) (Eurostat, average from 2007–2010, <http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&init=1&plugin=1&language=en&code=tps00001>) and divided by 100,000. As an example, the incidence for *Bacillus* spp. extrapolated to the EU level from the Dutch data was estimated as follows: multiplying the estimated Dutch incidence per 100,000 (Havelaar et al., 2012a) by the EU population and dividing this product by 100,000, i.e. $(303.03 \times 498,500,000) / 100,000 = 1,510,606$. The estimated annual incidence of illnesses (cases per year in the EU) was scored as follows: score 1, <100,000 cases; score 2, 100,000–999,999 cases; score 3, 1,000,000–10,000,000 cases; and score 4, >10,000,000 cases.

Table 1

Scoring for criterion 1: strength of associations between food/pathogen combinations.

Score	Category	Details
1	Weak	(i) Have been reported in the EU as part of outbreaks, sporadic cases or analytical epidemiological studies but not in 2007–2011 Zoonoses Monitoring data set; or (ii) Considered by expert review as relevant to the EU from information in the worldwide literature and not included in (i) above; or (iii) Have been associated with a FBO RASFF notification (subset of 19 notifications) January 2001 to December 2011 and not included in (i) or (ii) above.
2	Moderate	Have been associated with a single outbreak reported in the EU (2007–2011 data Zoonoses Monitoring)
3	Strong	(i) Have been associated with 2–4 outbreaks reported in the EU (2007–2011 Zoonoses Monitoring data) or
4	Very strong	(ii) Have been associated with ≥ 5 FBOs reported in the EU (2007–2011 Zoonoses Monitoring data) and involving a total of <100 cases in the EU Have been associated with ≥ 5 FBOs reported in the EU (2007–2011 Zoonoses Monitoring data) and involving a total of ≥ 100 cases in the EU

FBO = foodborne outbreak; RASFF = Rapid Alert System for Food and Feed.

2.2.3. Criterion 3: burden of disease

The burden of disease criterion was measured by the disability adjusted life years (DALYs) per thousand cases. DALYs express the number of years lost due to ill-health, disability or early death. It considers both the acute illness (e.g. diarrhoea) and more long-term effects such as *sequelae* (e.g. reactive arthritis and irritable bowel syndrome), as well as mortality (Kretzschmar et al., 2012; Murray and Lopez, 1997). DALY estimates for specific foodborne infections at the EU level are not available, therefore the estimates published for the Netherlands were used (Havelaar et al., 2012a). The DALYs (per 1000 cases) were categorised as follows: score 1, <10; score 2, 10–99; score 3, 100–999; and score 4, >999.

2.2.4. Criterion 4: dose–response relationship

The dose–response relationship was estimated by expert knowledge of the behaviour and physiology of specific pathogens and categorised by arbitrarily attributing scores defined as follows: score 1 if growth of the pathogen is needed to high numbers for production of sufficient toxin which is likely to induce disease; score 2 if moderate pathogen growth is likely and expected to occur in order to induce disease; and score 3 if an absence of growth of the pathogen and presence of 'low' numbers are likely to be sufficient to cause disease.

2.2.5. Criterion 5: prevalence of contamination

Prevalence of contamination of the pathogen in the specific food category was based on data on the occurrence of foodborne pathogens in FoNAO, which were reported as part of EFSA's Zoonoses reporting from 2004 to 2011 (EFSA, 2013). Under-reporting was estimated on the basis of available data. The authors used their expert opinion to decide on a score for each pathogen. The prevalence of contamination of pathogens in FoNAO was scored as follows: score 1, if available studies indicated a zero prevalence; score 2, if available data did not allow overall conclusions on prevalence (unknown prevalence); score 3, if pathogens occur in FoNAO and cause outbreaks, are likely to originate from a human or animal reservoir and occur at low prevalence, typically <1%; and score 4, for pathogens which originate from the environment and when the prevalence is likely to be $\geq 1\%$, e.g. *Bacillus* spp. and *Listeria monocytogenes*.

2.2.6. Criterion 6: consumption

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been built from existing national information on food consumption at a detailed level (EFSA, 2011a,b). All subjects, with the exception of the infants (from 0 to 12 months of age), were pooled together to calculate the percentage of EU consumers at an EU level, for relevant FoNAO commodity categories based on the FoodEx categorisation system. Infants were excluded as they were not expected to be major consumers of ready-to-eat FoNAO commodity categories. For each FoNAO commodity category (e.g. leafy greens eaten raw as salads) "consumers" were defined as those who consumed any specific food belonging to this FoNAO category (e.g. any leafy green) at least once within the days of the surveyed period. Percentages given represent the numbers of consumers who consumed at least once during the surveyed period (ranging from 2 days to a maximum of 7 days) any specific food belonging to a FoNAO category out of a total of 52,852 individuals. Data was not available to subdivide the foods by preparation method: i.e. consumed tomatoes included any raw, cooked or processed tomato based product. Scores were allocated for percentages of consumers as follows: score 1, for $\leq 1\%$; score 2, for 1 to 2%; score 3, for >2 to 20%; and score 4, for >20%.

2.2.7. Criterion 7: pathogen growth potential and shelf-life

The assessment of pathogen growth potential during shelf life in the specific food category was based on available data in the literature as well as expert knowledge. Growth in foods does not have the same impact on public health for all hazards. Some hazards need to grow in the

food, or its ingredients, before consumption to reach numbers sufficient for a significant probability of causing illness. For other hazards, the numbers resulting from the initial contamination of the ingredient or from contamination during food handling are usually sufficient to cause illness. For instance, the presence of any infectious particles of Norovirus, Hepatitis A virus, VTEC, *Salmonella* spp., *Shigella* spp., *Campylobacter* spp., or *Yersinia enterocolitica* on foods at consumption has a high likelihood to cause illness. In contrast, *L. monocytogenes*, *B. cereus*, *C. perfringens*, *Clostridium botulinum* and *S. aureus* are generally required to grow in the food matrix prior to consumption to either produce sufficient toxins in the food to cause disease or invade tissues to cause severe infection (EFSA Panel on Biological Hazards (BIOHAZ), 2012c).

Pathogen growth potential in a given food was scored individually as follows: score 1, if no growth is possible under all storage circumstances (e.g. too low pH, too low water activity, too low temperature (e.g. frozen), too high numbers of competing microflora); score 2, if it is poorly documented; score 3, if growth is possible but not in all circumstances (e.g. only if temperature abused); and score 4, when growth is possible and very likely under normal production systems. The usual shelf life of specific FoNAO was scored individually as follows: score 1, if 0–7 days; score 2, if 8–14 days; score 3, if between 15 and 28 days; and score 4 if longer than 28 days. No score was given for a shelf life where no growth of the hazards will occur. Subsequently, both individual scores were summed, and the combined score for pathogen growth potential/shelf life was allocated as follows: score 1, for sum equal to 1; score 2, for sums of 3 or 4; score 3, for sums of 5 or 6; and score 4, for sums of 7 or 8.

2.3. Limitations and assumptions associated with the data used for the model

The categorisation of FoNAO used here has some limitations since it excludes some factors that may influence the risk of exposure. Food production practices were not considered because this information was not available in the databases on outbreaks or consumption. However, some commodities are grown under various agricultural production conditions, e.g. from open fields to hydroponic production, encompassing different risk factors for microbial contamination. Similarly, it was not possible to include more than limited information on processing, storage conditions and food preparation habits, although these steps may strongly influence survival and growth of microbiological hazards.

Besides the assumptions mentioned under criteria 2 above, the following additional assumptions associated with the data used in this model have been made: the use of outbreak data from EU Zoonoses Monitoring was considered as sufficiently representative to allow general conclusions to rank different food categories across the EU. The DALY estimates published for the Netherlands were considered as sufficiently representative for the entire EU and have not significantly changed over the study period. There are uncertainties regarding prevalence data used here since there is limited pan-European and unbiased prevalence data available. Furthermore the data from the EU Zoonoses Monitoring is aggregated to all FoNAO. However, using the combination of available data sources and expert opinion, we consider the scoring for prevalence of contamination to be sufficiently representative for all individual food types considered here. The consumption data were sufficiently representative across all of the EU and for all preparation methods of an individual food component.

3. Results and discussion

3.1. Strength of associations between human disease and the food–pathogen combination

Based on the data presented in (EFSA Panel on Biological Hazards (BIOHAZ), 2013), 10 very strong, 14 strong, 31 moderate and 54 weak

Table 2
FoNAO category/pathogen combinations where weak, moderate, strong and very strong associations were identified.

FoNAO category	Very strong Score = 4		Strong Score = 3		Moderate Score = 2		Weak Score = 1
	Pathogen	Reported food information	Pathogen	Reported food information	Pathogen	Reported food information	
Strawberries					Norovirus	NR	VTEC, hepatitis A virus, parasites
Raspberries	Norovirus	NR			Salmonella	Fresh raspberry juice	VTEC, hepatitis A virus, parasites
Other berries					Norovirus	NR	Hepatitis A virus, parasites
Citrus fruit							Parasites VTEC, Salmonella
Apples and related fruit							VTEC, parasites
Tropical fruit							Salmonella, parasites
Melons					Salmonella	Watermelon	L. monocytogenes, Campylobacter
Fruit mixes							Salmonella, Norovirus, parasites
Tomatoes					Norovirus	NR	Shigella
Peppers and aubergines					Salmonella	NR	
Fresh pods, legumes and grains			Shigella	Baby corn, sugar snaps, sugar peas	VTEC, S. aureus	Sugar peas Frozen beans	Salmonella Campylobacter, parasites
Leafy greens eaten raw as salads	Salmonella	Baby spinach, chopped lettuce, pre-cut iceberg lettuce, rucola (rocket)			B. cereus	Lettuce	Campylobacter, VTEC, Shigella, Yersinia, hepatitis A virus, parasites
	Norovirus	Lettuce					
Fresh herbs					C. perfringens, Shigella	Mix of herbs Basil	Salmonella, parasites
Leafy greens mixed with other fresh FoNAO					Cryptosporidium	Pre-cut salad mix	L. monocytogenes, VTEC, Yersinia
					Salmonella	Mixed lettuce leaves	
					Shigella	Salad	
Carrots					B. cereus	Salad	
					Shigella	NR	VTEC
					Yersinia	Raw grated carrot	
					pseudotuberculosis		
					Norovirus	NR	
Other root and tuberous vegetables							B. cereus, VTEC
Bulb and stem vegetables			Norovirus	Chopped onion, garlic water used for brushing lángos	Salmonella	Onion	Yersinia, hepatitis A virus, VTEC,
Sprouted seeds	Salmonella	Alfalfa sprouts, bean sprouts, mung bean sprouts	VTEC	Sprouted fenugreek seeds	S. aureus	Bean sprouts	B. cereus, Yersinia
Fungi (mushrooms and yeasts)							S. aureus
Nuts and nuts products					Salmonella	Cashew nuts	VTEC
Spices and dry powdered herbs	B. cereus	Curry, ground cumin, pepper, turmeric (curcuma)			C. perfringens	NR,	
					Salmonella	NR	
Beverages							Salmonella
							Parasites
Dehydrated vegetables and fruit					Hepatitis A virus	Semi-dried tomatoes	B. cereus

NR: not reported; FoNAO = foods of non-animal origin.

Table 3
Incidence of illness: estimated number of illness per year in the EU. Only pathogens associated with outbreaks reported to EFSA through the Zoonoses Monitoring were included.

Pathogen	Estimated disease multipliers in EU ^a	Notification per year, average 2007–2010 (confirmed cases: ECDC database TESSy)	Estimated number of cases at the EU level ^b	Estimated number of cases extrapolated to the EU level ^c	Estimated number of cases extrapolated to the EU level ^d	Score
<i>Bacillus</i> spp.	1466.3	NA	NA	1,510,606	NA	3
<i>Clostridium perfringens</i>	1466.3	NA	NA	5,075,636	853,885	3
<i>Cryptosporidium</i> spp.	193.5	6972	1,349,034	845,939	458,767	3
Hepatitis A virus	19.6	10,042	196,818	26,043	NA	2
Norovirus	NA	NA	NA	18,852,364	24,707,517	4
<i>Salmonella</i> spp.	57.5	123,774	7,117,005	1,057,424	406,432	3
<i>Shigella</i> spp.	65.3	6332	413,480	NA	NA	2
<i>Staphylococcus aureus</i>	1466.3	NA	NA	8,821,939	NA	3
VTEC non-O157 ^e	209.6	3741	784,166	NA	NA	2
<i>Yersinia enterocolitica</i> ^f	241	7377	1,777,797	NA	NA	3

NA: Not available; TESSy = The European Surveillance System.

^a Disease multipliers for each pathogen based on the estimates published by Scallan et al. (2011) and anchored to the *Salmonella* spp. disease multiplier estimated at the EU level by Havelaar et al. (2012b). As an example, the anchored EU *Shigella*-disease multiplier (DMS_{hEU}) was estimated as follows: multiplying the *Shigella*-disease multiplier estimate by Scallan et al. (DMS_{hSc}) by the disease-multiplier for *Salmonella* spp. at the EU level (DMS_{aEU}) and dividing this product by the *Salmonella*-disease multiplier estimate by Scallan et al. (2011) (DMS_{aSc}), i.e. $((33.3 \times 57.5) / 29.3 = 65.3)$.

^b Estimated number of illnesses in the EU calculated by the product of the *Salmonella* spp. based disease multiplier and the notified number of cases as reported to the ECDC database TESSy (The European Surveillance System).

^c Estimated number of illnesses in the EU based on the estimates from an incidence of illness study available in the Netherlands (Havelaar et al., 2012a), with the estimates extrapolated to the EU level. Estimated Dutch incidence was extrapolated to the EU level as follows: national incidence per 100,000 inhabitants was multiplied by the EU population (498,500,000) and divided by 100,000.

^d Estimated number of illnesses in the EU based on the estimates from an incidence of illness study available in the United Kingdom (Tam et al., 2012), with the estimates extrapolated to the EU level. Estimated United Kingdom incidence was extrapolated to the EU level as follows: national incidence per 100,000 inhabitants was multiplied by the EU population (498,500,000) and divided by 100,000.

^e Two pathogen–food combinations related to outbreaks of VTEC non-O157 were included in the analysis (VTEC O104:H4 linked to fenugreek seeds and VTEC O27:30 linked to sugar peas) based on the reported EU Zoonoses Monitoring foodborne outbreak data. Therefore only the disease multiplier for VTEC non-O157 was applied in the model.

^f Similar values have been assumed for all *Yersinia* spp.

associations between FoNAO types and specific pathogens were identified. Further details of the food types associated with the outbreaks classified as very strong, strong and moderate are shown in Table 2. Pathogens included in the model based on the 10, 14 and 31 food/pathogen combinations classified as very strong, strong and moderate respectively, were: *B. cereus*, *C. perfringens*, *Cryptosporidium* spp., Hepatitis A virus, Norovirus, VTEC, *Salmonella* spp., *Shigella* spp., *S. aureus*, and *Yersinia* spp.

3.2. Incidence of illness

The estimated disease multipliers and the estimate of the number of cases of illnesses are presented in Table 3. The hazard-specific number of cases of illnesses based on NL or UK data fell within the same scoring category for all pathogens except *C. perfringens*. To explore the impact of the different scores for *C. perfringens*, the model outputs were calculated using both scores of 2 (based on UK data) and 3 (based on NL data) and found to have a minimal impact and only on the order of the lower ranking food/pathogen combinations (results not shown). Dutch estimates

were therefore used in the model. For illnesses caused by *Salmonella* spp. and *Cryptosporidium* spp., the scoring also differs depending on which data set was used. For instance, based on UK data, *Salmonella* spp. would be given a score = 2, whereas the EU data and the Dutch data, a score = 3. These differences may be due to true variations across countries in the EU. We, therefore chose to use notification rates reported at the EU level whenever available. The final ranking scores of this criterion for all the hazards are presented in Table 3 where the respective incidence data considered for scoring are shown in bold.

3.3. Burden of disease

For *Shigella* spp. and *Y. enterocolitica*, no DALY estimates were available from the Dutch study, but due to the nature and outcomes of the disease these pathogens cause, we assumed that their DALYs would fall within the same scoring category as that of *Salmonella* spp. (Table 4). For VTEC, the DALY estimate published by Havelaar et al. (2012a) is based on information on O157 only. However, for the purpose of this model, we allocated the non-O157 the same DALY category (score = 3), assuming that the duration and severity of these infections are within a similar range to that of O157.

3.4. Dose–response relationship

A score of 1 was allocated to emetic *B. cereus* and *S. aureus*, as these pathogens cause a foodborne intoxication i.e. a food poisoning due to the consumption of a food product which contains a microbial toxin produced during growth of a toxigenic microorganism generally at high numbers in the food product (Granum, 2007; Seo and Bohach, 2007). Similarly, a score of 1 was allocated to diarrhoeal *B. cereus* and *C. perfringens*, which cause food poisoning generally following ingestion of high numbers of vegetative cells of a toxigenic micro-organism that produces toxin after ingestion (Granum, 2007; McClane, 2007). A score of 2 is defined as moderate growth of the pathogen in the food is likely to be needed to induce disease in humans, e.g. *C. botulinum* and *L. monocytogenes*. However, from all pathogens considered in the model, none fell into this category. A score of 3 was allocated to *Salmonella* spp., *Shigella* spp., pathogenic *E. coli*

Table 4
Attributed scores for DALYs for all pathogens considered in the model.

Hazard	DALY per 1000 cases ^a	Score based on DALYs
<i>Bacillus cereus</i>	2.3	1
<i>Clostridium perfringens</i>	3.2	1
<i>Cryptosporidium</i> spp.	2.9	1
Norovirus	2.4	1
Hepatitis A virus	167.0	3
<i>Salmonella</i> spp.	49	2
<i>Shigella</i> spp.	NA	2
<i>Staphylococcus aureus</i>	2.6	1
VTEC O157 ^b	143	3
<i>Yersinia enterocolitica</i> ^c	NA	2

NA: Not available; DALY = daily adjusted life year.

^a Data derived from Havelaar et al. (2012a).

^b Similar values have been assumed for all VTEC, although this may represent an overestimation for some non-O157 VTEC serotypes.

^c Similar values have been assumed for all *Yersinia* spp.

(e.g. VTEC), *Y. enterocolitica*, Norovirus, Hepatitis A virus and *Cryptosporidium* spp., which can all cause infection by the uptake of low numbers of microorganisms in the food (EFSA Panel on Biological Hazards (BIOHAZ), 2012c), although it is recognised that the risk of infection increases with the dose.

3.5. Prevalence of contamination

For *Salmonella* spp. and pathogenic *E. coli*, data from EU and Zoonoses Monitoring 2004 to 2011 showed prevalences in FoNAO of 0.48% and 0.28% respectively and were allocated a score of 3 for a contamination rate of <1%. For *Shigella* spp. and *Yersinia* spp., although some data limited to specific countries were available, there were insufficient pan-EU data on prevalence in FoNAO: consequently prevalence scores of 2 (unknown prevalence) were allocated. Humans and animals are the most common carriers of *S. aureus* (either on their skin, hair, nose or throat), but the bacterium may also persist in the environment. Prevalence studies of *S. aureus* in FoNAO are limited and, if available, are normally used to monitor *S. aureus* as an indication of the level of personal hygiene and of the application of “Good Manufacturing Practices”. Therefore these do not usually provide prevalence data on the presence of *S. aureus* as a contaminant in food. For this reason *S. aureus* was also allocated a score of 2 (unknown prevalence). Norovirus, Hepatitis A virus and *Cryptosporidium* spp. were also allocated a score of 2 (unknown prevalence) because there are few surveys on these pathogens in FoNAO available. Results may be biased for some agents due to the nature and sensitivity of the detection methodologies. *B. cereus* and *C. perfringens* are spore-forming organisms, have intrinsic capacities to survive under adverse conditions and are commonly detected in soil, vegetation and surface waters. *C. perfringens* is found in the intestinal flora of many animals including livestock. *B. cereus* is commonly isolated from farm environments and has been shown to be commonly present in FoNAO (Granum, 2007). Thus based on expert opinion a score of 4 (prevalence >1%) was allocated to these bacteria.

3.6. Consumption

Estimates for the percentage of consumers of the relevant FoNAO commodity categories are reported in Table 5 together with the appropriate score, as defined above. The main source of uncertainty related to the estimates for the percentage of consumers is related to the methodological differences in the collection of the food consumption data

Table 5

Attributed scores for percentage of consumers for all FoNAO categories considered in the model.

FoNAO category	Number of consumers ^a	Percentage of consumers ^a	Score
Strawberries	4422	8.4	3
Raspberries	1514	2.9	3
Other berries	6883	13	3
Melons	3640	6.9	3
Tomatoes	30,681	58.1	4
Fresh pods, legumes and grains	21,449	40.6	4
Leafy greens eaten raw as salads	28,656	54.2	4
Fresh herbs	16,874	31.9	4
Leafy greens mixed with other fresh FoNAO	1033	2	2
Carrots	24,658	46.7	4
Bulb and stem vegetables	34,796	65.8	4
Sprouted seeds	275	0.5	1
Nuts and nuts products	8322	15.7	3
Spices and dry powdered herbs	16,090	30.4	4
Dehydrated vegetables and fruit	5316	10.1	3

FoNAO = foods of non-animal origin.

^a Percentage calculated on a data set of 52,852 individuals (EFSA Comprehensive European Food Consumption Database). For each FoNAO commodity category (e.g. leafy greens eaten raw as salads) “consumers” has been defined as those who consumed at least once during the surveyed period (ranging from 2 days to a maximum of 7 days) any specific food belonging to this FoNAO category (e.g. any leafy green).

included in the Comprehensive Database (Merten et al., 2011). A cautious interpretation of the results was therefore taken when using this database. In addition, not all dietary surveys of food consumption were uniformly distributed throughout the year. This issue is particularly relevant when assessing the consumption of seasonal foods, for which the estimates of the percentage of consumers, as defined above, are likely to be biased. Most countries used integrated standard recipe databases to disaggregate composite dishes, such as a cooked vegetable salad or ratatouille, into their main ingredients at a level that can be reported by the subjects. Information on the type of processing (boiled, fried, roasted, etc.) has not been provided for the majority of the food and household recipe ingredients reported in the Comprehensive Database.

3.7. Pathogen growth potential and shelf-life

The individual and combined scores for pathogen growth potential/shelf life are presented in Table 6. Foodborne viruses (Norovirus and Hepatitis A virus) as well as parasites (*Cryptosporidium* spp.) are incapable of independent multiplication outside their hosts, and are therefore allocated a score for pathogen growth potential of 1 (no growth possible) (Table 6). Foods with low water activities (a_w), such as in nuts and nut products, spices and dry powdered herbs will not enable growth of enteric bacteria such as *Salmonella* spp. and thus a score 1 was allocated for pathogen growth potential in these foods (Table 6). Microorganisms causing intoxications (*B. cereus* – with the exception of some psychrotrophic strains, *C. perfringens* and *S. aureus*) cannot grow under refrigeration conditions, and are largely inhibited in their germination (for the sporeformers) and growth potential by the indigenous flora of raw fresh produce. For these reasons they have also been allocated a score of 1 (no growth possible) for the selected commodities included in the risk ranking. Exception is made for the combination of *S. aureus* and sprouted seeds, for which the growth potential is not documented (and thus allocated a score 2) (Table 6). For the combination of *Salmonella* spp. and raspberries; it is expected that due to the more acid pH of raspberries, growth of *Salmonella* spp. is unlikely, but growth potential is poorly documented and thus a score of 2 was allocated. The combination of *Shigella* spp. and carrots was allocated a score 2 for growth potential because of lack of information, although it is known that spoilage flora of carrots is dominated by lactic acid bacteria which may outcompete *Shigella* spp. Overall, *Salmonella* spp., VTEC and *Shigella* spp., are predicted not to grow well on fruit or vegetables stored under appropriate refrigeration temperature (<7 °C), which is recommended for fresh-cut pre-packed produce. However, it has been documented that the growth of these pathogens is likely to occur under specific circumstances, in particular if not refrigerated (in the case of occasional temperature abuse in the supply chain during storage or transport), or at harvest or post-harvest storage of crops at ambient temperature (Jay, 2003a). Growth might occur if the relative humidity is high enough in the environment or when condensation has occurred. The growth potential for *Salmonella* spp., VTEC and *Shigella* spp. was allocated a score of 3 for most of the combinations with the selected commodities in the risk ranking (e.g. fresh herbs, leafy greens, melons, mixed fresh cut salad leaves, sugar snaps and tomatoes) (Table 6). For sprouted seeds with VTEC or *Salmonella* spp. a score of 4 was allocated because growth is possible and likely if elevated temperatures and high humidity occur during sprouting. Despite the fact that *Yersinia* spp. is a psychrotrophic pathogen and able to grow at low temperatures (Jay, 2003b), the combination of *Yersinia* spp. and carrots was allocated a score of 2, as carrots are rarely stored for long periods at refrigeration temperatures.

The shelf life attributed to the different commodity categories is based on information from different sources including the USDA Agriculture Handbook 66 (USDA, 2004), as well as other relevant documents (Cantwell, 2001; Kader, 2002; Kader et al., 2001; Tello, 2000; UCDAVIS, 2012). Foods within an individual commodity type have

Table 6
Attributed scores for criterion 7, combined pathogen growth potential and shelf life for all food/pathogen combinations considered in the model.

Pathogen	FoNAO category	Individual pathogen growth potential score	Individual shelf life score	Sum of individual scores	Combined pathogen growth and shelf life score ^a
<i>Salmonella</i> spp.	Raspberries	2	1	3	2
<i>Salmonella</i> spp.	Melons	3	4	7	4
<i>Salmonella</i> spp.	Tomatoes	3	2	5	3
<i>Salmonella</i> spp.	Leafy greens eaten raw as salads	3	2	5	3
<i>Salmonella</i> spp.	Leafy greens mixed with other fresh FoNAO	3	2	5	3
<i>Salmonella</i> spp.	Bulb and stem vegetables	3	3	6	3
<i>Salmonella</i> spp.	Sprouted seeds	4	2	6	3
<i>Salmonella</i> spp.	Nuts and nut products	1	–	1	1
<i>Salmonella</i> spp.	Spices and dry powdered herbs	1	–	1	1
VTEC	Fresh pods, legumes and grains	3	2	5	3
VTEC	Sprouted seeds	4	2	6	3
<i>Shigella</i> spp.	Fresh pods, legumes and grains	3	2	5	3
<i>Shigella</i> spp.	Fresh herbs	3	2	5	3
<i>Shigella</i> spp.	Leafy greens mixed with other fresh FoNAO	3	2	5	3
<i>Shigella</i> spp.	Carrots	2	2	4	2
<i>Yersinia</i> spp. ^b	Carrots	2	2	4	2
<i>Staphylococcus aureus</i>	Fresh pods, legumes and grains	1	–	1	1
<i>Staphylococcus aureus</i>	Sprouted seeds	2	2	4	2
<i>Bacillus</i> spp.	Leafy greens eaten raw as salads	1	–	1	1
<i>Bacillus</i> spp.	Leafy greens mixed with other fresh FoNAO	1	–	1	1
<i>Bacillus</i> spp.	Spices and dry powdered herbs	1	–	1	1
<i>Clostridium perfringens</i>	Fresh herbs	1	–	1	1
<i>Clostridium perfringens</i>	Spices and dry powdered herbs	1	–	1	1
Hepatitis A virus	Dehydrated vegetables and fruit	1	–	1	1
Norovirus	Strawberries	1	–	1	1
Norovirus	Raspberries	1	–	1	1
Norovirus	Other berries	1	–	1	1
Norovirus	Tomatoes	1	–	1	1
Norovirus	Leafy greens eaten raw as salads	1	–	1	1
Norovirus	Carrots	1	–	1	1
Norovirus	Bulb and stem vegetables	1	–	1	1
<i>Cryptosporidium</i> spp.	Leafy greens mixed with other fresh FoNAO	1	–	1	1

FoNAO = foods of non-animal origin.

^a Combined score for pathogen growth potential/shelf life was allocated as follows: score 1 for sum equal to 1; score 2 for sums from 3 to 4; score 3 for sums from 5 to 6; and score 4 for sums from 7 to 8.

^b Similar values have been assumed for all *Yersinia* spp.

considerable variation in shelf life. In these instances, the longest shelf life of a particular commodity was chosen and used for scoring to be as conservative as possible. When a FoNAO category was identified as not allowing growth (score 1 for pathogen growth potential), no shelf life score was allocated which gives a final combined pathogen growth potential and shelf life score of 1.

3.8. Model outputs

The relative ranking positions for the top five food/pathogen combinations considered based on the final model scores are shown in Table 7 for all five scenarios. More than one food/pathogen combination may have the same final model score and in this case these are presented under the same ranking group. Using all the seven criteria in the model, the top five ranking groups of food/pathogen combinations were in decreasing order of priority: (i) *Salmonella* spp. and leafy greens eaten raw as salads; (ii) *Salmonella* spp. and bulb and stem vegetables; *Salmonella* spp. and tomatoes; *Salmonella* spp. and melons; and pathogenic *E. coli* and fresh pods, legumes or grains; (iii) Norovirus and leafy greens eaten raw as salads; *Salmonella* spp. and sprouted seeds; and *Shigella* spp. and fresh pods, legumes or grains; (iv) *Bacillus* spp. and spices and dry powdered herbs; Norovirus and bulb and stem vegetables; Norovirus and raspberries; *Salmonella* spp. and raspberries; *Salmonella* spp. and spices and dry powdered herbs, *Salmonella* spp. and leafy greens mixed with other fresh FoNAO; *Shigella* spp. and fresh herbs; pathogenic *E. coli* and sprouted seeds; and *Yersinia* spp. and carrots and (v) Norovirus and tomatoes; Norovirus and carrots; *Salmonella* spp. and nuts and nut products and *Shigella* spp. and carrots.

The analysis showed that excluding a single criterion from the model had a limited effect on the top 5 ranking food/pathogen combinations.

3.9. Model limitations and considerations

It should be highlighted that when interpreting outputs from the model, consideration has to be given to the assumptions, limitations and uncertainties. EFSA's Zoonoses database represents the best current source in the EU to link cases, pathogens and food vehicles. As previously noted (EFSA, 2008), these outbreak data are readily available and provides an easily observable public health endpoint that can be used as a direct measure of attribution. However, there are shortcomings with this type of analysis. Outbreak data are reliant on reporting practices, which can be, incomplete, vary between Member States, greatly influenced by rare events occurring during the monitoring period, or be biased due to the preferential investigation of types of foods perceived as posing higher risk or caused by hazards which are easier to identify. For example, there is a variation in the rates of reported outbreaks per population among countries. Nineteen countries reported foodborne outbreaks with strong evidence where foods of non-animal origin were implicated and the Nordic countries, i.e. Denmark, Finland, Norway and Sweden reported 51% of these. Large outbreaks, outbreaks associated with the food service and institutions, and outbreaks that have a longer duration or cause serious disease are more likely to be investigated and reported. In addition data on certain pathogens are often limited, and although important trends may be evident from outbreaks, there can be considerable differences between the relative importance of sources of outbreak-related and sporadic cases. The outbreak data sets used here also exclude outbreaks where the etiological agent and/

Table 7

Relative ranking positions for the top five considered food/pathogen combinations based on the final model scores.^a

Reference scenario 1 including all criteria			Ranking position in			
Ranking position	Pathogen	FoNAO category	Scenario 2 (without consumption criterion)	Scenario 3 (without combined pathogen growth potential/shelf life criterion)	Scenario 4 (without dose–response criterion)	Scenario 5 (without prevalence criterion)
First (22)	<i>Salmonella</i> spp.	Leafy greens eaten raw as salads	First (18)	First (19)	First (19)	First (19)
Second (20)	<i>Salmonella</i> spp.	Bulb and stem vegetables	Third (16)	Third (17)	Second (17)	Second (17)
Second (20)	<i>Salmonella</i> spp.	Tomatoes	Third (16)	Third (17)	Second (17)	Second (17)
Second (20)	<i>Salmonella</i> spp.	Melons	Second (17)	Fourth (16)	Second (17)	Second (17)
Second (20)	Pathogenic <i>E. coli</i>	Fresh pods, legumes and grains	Third (16)	Third (17)	Second (17)	Second (17)
Third (19)	Norovirus	Leafy greens eaten raw as salads	Fourth (15)	Second (18)	Third (16)	Second (17)
Third (19)	<i>Salmonella</i> spp.	Sprouted seeds	First (18)	Fourth (16)	Third (16)	Third (16)
Third (19)	<i>Shigella</i> spp.	Fresh pods, legumes or grains	Fourth (15)	Fourth (16)	Third (16)	Second (17)
Fourth (18)	<i>Bacillus</i> spp.	Spices and dry powdered herbs	Fifth (14)	Third (17)	Second (17)	Fifth (14)
Fourth (18)	Norovirus	Bulb and stem vegetables	Fifth (14)	Third (17)	Fourth (15)	Third (16)
Fourth (18)	Norovirus	Raspberries	Fourth (15)	Third (17)	Fourth (15)	Third (16)
Fourth (18)	<i>Salmonella</i> spp.	Raspberries	Fourth (15)	Fourth (16)	Fourth (15)	Fourth (15)
Fourth (18)	<i>Salmonella</i> spp.	Spices and dry powdered herbs	Fifth (14)	Third (17)	Fourth (15)	Fourth (15)
Fourth (18)	<i>Salmonella</i> spp.	Leafy greens mixed with other fresh FoNAO	Third (16)	Fifth (15)	Fourth (15)	Fourth (15)
Fourth (18)	<i>Shigella</i> spp.	Fresh herbs	Fifth (14)	Fifth (15)	Fourth (15)	Third (16)
Fourth (18)	Pathogenic <i>E. coli</i>	Sprouted seeds	Second (17)	Fifth (15)	Fourth (15)	Fourth (15)
Fourth (18)	<i>Yersinia</i> spp.	Carrots	Fifth (14)	Fourth (16)	Fourth (15)	Third (16)
Fifth (17)	Norovirus	Tomatoes	Sixth (13)	Fourth (16)	Fifth (14)	Fourth (15)
Fifth (17)	Norovirus	Carrots	Sixth (13)	Fourth (16)	Fifth (14)	Fourth (15)
Fifth (17)	<i>Salmonella</i> spp.	Nuts and nut products	Fifth (14)	Fourth (16)	Fifth (14)	Fifth (14)
Fifth (17)	<i>Shigella</i> spp.	Carrots	Sixth (13)	Fifth (15)	Fifth (14)	Fourth (15)

FoNAO = foods of non-animal origin.

^a The total sum of the scores attributed for each individual criterion is indicated in brackets for each food/pathogen combination and scenario.

or the food source has not been identified. It has not been possible to quantify the uncertainty caused by these shortcomings, but they are believed to be equally applicable to all types of foods. Despite of these shortcomings, however the outbreak data is the only source of pan-European data and this approach is likely to provide an initial comparative risk ranking which will provide a useful evaluation for a diverse range of foods of non-animal origin.

The specific characteristics of the reporting practices for foodborne outbreaks in the EU (e.g. food categorisation) do not allow for a comparison with similar data from other regions. However, there has been an increase in reported outbreaks associated with consumption of FoNAO, particularly in North America, with associations between salad and leafy greens, and Norovirus, VTEC and *Salmonella* spp. (Barton Behravesh et al., 2011; Hall et al., 2012; Wendel et al., 2009). The comparison of the outputs from the FDA RRT (Anderson et al., 2011) model with the results from our model showed similarities. In both studies, the following food/pathogen combinations occurred among the top-3 risk ranking groups: *Salmonella* spp. and tomatoes, *Salmonella* spp. and leafy greens, and *Salmonella* spp. and melons. In addition, the top-5 foods in both models included the same food types, but with different pathogens, e.g. berries, carrots, onions and herbs. It should be highlighted that the outputs from both models reflect distinct and totally independent data sets of reported foodborne outbreaks, and that the US model only included fresh produce.

Similar to what has been previously reported in other studies analysing foodborne outbreak data (Greig and Ravel, 2009; Pires et al., 2012), the approach taken in the scope of this study is constrained by the fact that there are limitations to the categorisation of food at international levels, which make comparisons difficult. Also the a posteriori categorisation of FoNAO established in the scope of this paper is influenced by the content of EFSA's Zoonoses database, which is not uniformly populated over time or across EU Member States. Therefore, misclassification of some food vehicles may occur.

It should be noted that 45% of all reported outbreaks implicating FoNAO from 2007–2011 were excluded from the risk ranking model, according to exclusion criteria that were established to put the focus on ready-to-eat unprocessed FoNAO products. The excluded outbreaks

were distributed as follows: (a) other processed products [including foods which normally are subjected to a processing step which should inactivate vegetative cells (e.g. rice, pasta and cereals), sauces and dressings, purées, soup, and pastes (including canned and bottled products) and syrups], 24.1%; (b) FoNAO, which may include one or more cooked ingredients (e.g. cooked vegetable salads), 11.4%; (c) 'merged' food categories 'vegetables and juices and other products thereof', 9.1% and (d) merged food category 'cereal products including rice, seeds, pulses or nuts', 0.4%. The hazards associated with these outbreaks were: *Bacillus* spp. (38.3%), *S. aureus* (19.6%), Norovirus (15.0%), *Salmonella* spp. (10.3%), *C. perfringens* (4.7%), pathogenic *E. coli* (3.7%), *C. botulinum* (2.8%), *Shigella* spp. (1.9%), *Clostridium* spp., *Yersinia* spp., *Cryptosporidium* spp. and Hepatitis A virus (less than 1.0% each).

The model outputs presented here are based on the reported outbreaks associated with consumption of FoNAO within the EU between 2007 and 2011. The model is therefore likely to underestimate the importance of specific agents, which appear to be rarely associated with outbreaks (such as those due to *L. monocytogenes*, *Campylobacter* spp. and parasites). In addition, future reported outbreaks are likely to impact on the ranking orders, and the results presented here should primarily be seen as a snapshot of the situation in the study period and does not have any predictive value on potential future outbreaks. However, using the risk ranking model on a regular basis with updated data will provide a tool that may also show trends in the importance of different food/pathogen combinations and thus provide priority for setting control measures.

When comparing the outputs from the reference risk ranking model (scenario 1), with the four additional scenarios, excluding the consumption criterion (scenario 2) led to the biggest change in ranking order within the top 5 groups of combinations. Food commodities rarely eaten but linked to many and/or large outbreaks ranked higher in scenario 2 and included particularly both combinations of *Salmonella* spp. and pathogenic *E. coli* with sprouted seeds. Therefore this supports the results of scenario 2 that by excluding the consumption criterion can be regarded as ranking the risk of consuming a single portion as opposed to ranking the risk at the EU population level. Currently the EFSA Comprehensive European Food Consumption Database is the

only available source of pan-European source for this type of data. Although there are uncertainties around the consumption data, we believe that these are sufficiently representative of the EU to be included in the risk-ranking tool.

Despite the inherent assumptions and limitations, this risk ranking model is considered valuable for risk managers, as it allows identifying food/pathogen combinations most often linked to foodborne human cases originating from FoNAO in the EU. Such information is necessary for risk managers evaluating the need for specific control options for certain FoNAO. Efforts to collect additional data even in the absence of reported outbreaks as well as to enhance the quality of the EU-specific data, which was used as input for all the model criteria, will allow improvement of the model outputs. Furthermore, it is recommended that harmonised terminology be applied to the categorisation of foods collected for different reasons, e.g. monitoring, surveillance, outbreak investigation and consumption. In addition, to assist future microbiological risk assessments, consideration should be given to the collection of additional information on how food has been processed, stored and prepared as part of the above data collection exercises.

4. Disclaimer

The authors MT Da Silva Felício, E Liebana and M Hugas are employed with the European Food Safety Authority (EFSA) in its Biological Hazards Unit that provides scientific and administrative support to the Biological Hazards Panel. The present article is published under the sole responsibility of the authors and may not be considered as an EFSA scientific output. The positions and opinions presented in this article are those of the authors alone and are not intended to represent the views or scientific works of EFSA. To know about the views or scientific outputs of EFSA, please consult its website under <http://www.efsa.europa.eu>. The author Taina Niskanen is employed by the European Centre for Disease Prevention and Control (ECDC) in the unit of Surveillance and Response Support as an expert working in the Food- and Waterborne Diseases and Zoonoses programme.

Potential conflicts of interest

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