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SCIENTIFIC OPINION

Scientific Opinion on the risk posed by pathogens in food of non-animal origin. Part 1 (outbreak data analysis and risk ranking of food/pathogen combinations)[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2, 3]

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Abstract

Food of non-animal origin (FoNAO) is consumed in a variety of forms, and 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. A comparison of the incidence of human cases linked to consumption of FoNAO and of food of animal origin (FoAO) was carried out to provide an indication of the proportionality between these two groups of foods. It was concluded that outbreak data reported as part of EU Zoonoses Monitoring is currently the only option for EU-wide comparative estimates. Using this data from 2007 to 2011, FoNAO were associated with 10% of the outbreaks, 26% of the cases, 35% of the hospitalisations and 46% of the deaths. If the data from the 2011VTEC O104 outbreak is excluded, FoNAO was associated with 10% of the outbreaks, 18% of cases, but only 8% of the hospitalisations and 5% of the deaths. From 2008 to 2011 there was an increase in the numbers of reported outbreaks, cases, hospitalisations and deaths associated with food of non-animal origin. In order to identify and rank specific food/pathogen combinations most often linked to human cases originating from FoNAO in the EU, a model was developed using seven criteria: strength of associations between food and pathogen based on the foodborne outbreak data from EU Zoonoses Monitoring (2007-11), incidence of illness, burden of disease, dose-response relationship, consumption, prevalence of contamination and pathogen growth potential during shelf life. Shortcomings in the approach using outbreak data were discussed. 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 grain.

Key words

Food of non-animal origin, foodborne pathogens, foodborne outbreaks, food/pathogen combination, risk ranking

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[1] On request from the European Commission, Question No EFSA-Q-2012-00237, adopted on 6 December 2012.

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SUMMARY

The European Commission asked EFSA's BIOHAZ Panel to prepare a scientific Opinion on the public health risk posed by pathogens that may contaminate food of non-animal origin (FoNAO). In particular, this opinion addresses the first two terms of reference for the mandate, namely: (i) to compare the incidence of foodborne human cases linked to FoNAO and foodborne cases linked to food of animal origin (FoAO), and (ii) to identify and rank specific food/pathogen combinations most often linked to foodborne human cases originating from FoNAO in the EU.

For the *comparison of the incidence of foodborne human cases linked to FoNAO and foodborne cases linked to FoAO*, the BIOHAZ Panel concluded that: the analysis of the outbreak data reported as part of EU Zoonoses Monitoring allows attribution of human cases to food of non-animal origin or food of animal origin, and is currently the only option for obtaining a EU-wide comparative estimate of the proportion of human cases due to these two food groups. For the purpose of this analysis, EU Zoonoses Monitoring foodborne outbreak data from 2007 to 2011 was used. Amongst all the foodborne outbreaks reported where food of either non-animal or animal origin were implicated, the food of non-animal origin were associated with 10% of the outbreaks, 26% of the cases, 35% of the hospitalisations and 46% of the deaths. Trends in data on food of non-animal origin are strongly influenced by the 2011 VTEC O104 outbreak. If the data from this large outbreak is excluded, food of non-animal origin was associated with 10% of the outbreaks, 18% of cases, but only 8% of the hospitalisations and 5% of the deaths. There is a general tendency for the outbreaks associated with food of non-animal origin to involve more cases and to be less severe (e.g. lower proportion of hospitalisations and deaths) than those associated with food of animal origin.

There are shortcomings with this type of analysis which should be considered: (i) outbreak data is reliant on reporting which is incomplete, can vary between reporting countries, may be greatly influenced by rare events occurring during the monitoring period, or have bias due to the preferential investigation of types of foods perceived as higher risk or hazards which are easier to identify. For example, there is variation in the rates of reported outbreaks per population among countries. Nineteen countries reported foodborne outbreaks with strong evidence where food of non-animal origin were implicated and the Nordic countries, *i.e.* Denmark, Finland, Norway and Sweden reported 51.1% of these; (ii) large outbreaks, especially those associated with the food service sector and institutions, as well as those outbreaks of longer duration or associated with serious disease are more likely to be reported and investigated. More systematic use of molecular typing methods is contributing to better identification of outbreaks in certain Member States; (iii) data on most pathogens is often limited, and there may be considerable differences between the relative importance of different food types associated with outbreak versus sporadic cases; (iv) the use of outbreak data sets also excludes data where the etiological agent and/or the food sources have not been identified. It has not been possible to quantify the uncertainty caused by these shortcomings.

From 2008 to 2011 there was an increase in the numbers of reported outbreaks, cases, hospitalisations and deaths associated with food of non-animal origin. These trends occurred together with a decrease in the numbers of reported outbreaks, cases, hospitalisations and deaths associated with food of animal origin.

For the *identification and ranking of specific food/pathogen combinations most often linked to foodborne human cases originating from FoNAO in the EU,* the BIOHAZ Panel developed a multi criteria analysis model aimed at risk ranking combinations of food of non-animal origin commodities and specific pathogens. Seven criteria were used in the model which were: the strength of associations between food and pathogen, incidence of illness, burden of disease, dose-response relationship, consumption, prevalence of contamination and pathogen growth potential during shelf life. The first criterion (strength of associations) is based on the foodborne outbreak data from EU Zoonoses Monitoring. Food/pathogen combinations identified from other data sources were excluded from the model. Outbreaks associated with food products that (i) normally are subjected to a processing step which should inactivate vegetative cells (e.g. rice, pasta), (ii) include one or more cooked ingredients

(e.g. cooked vegetable salads), (iii) are very broad and heterogeneous (other processed products) or (iv) are unspecified (e.g. fruit unspecified) were excluded from the ranking, as the focus was on ready-to-eat unprocessed products.

Using all the seven criteria in the model, the five top ranking groups of food/pathogen combinations in the following decreasing order of priority were: (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 *Escherichia coli* and fresh pods, legumes or grain; (iii) norovirus and leafy greens eaten raw as salads; *Salmonella* spp. and sprouted seeds; and *Shigella* spp. and fresh pods, legumes or grain; (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 *Escherichia coli* and sprouted seeds; and *Yersinia* and carrots; (v) norovirus and tomatoes; norovirus and carrots; *Salmonella* spp. and nuts and nut products and *Shigella* spp. and carrots.

To explore the robustness of the model as well of the importance of each individual criterion, different scenarios were run: a reference model, which included all seven criteria in the analysis, scenario 2 without the consumption criterion, scenario 3 without the combined pathogen growth potential/shelf life criterion, scenario 4 without the dose-response criterion, and scenario 5 without the prevalence criterion. The analysis showed that excluding a single criterion from the model had limited effect on the top 5 ranking food/pathogen combinations. Excluding the consumption criterion (scenario 2) led to the biggest change in ranking order within the top 5 groups of combinations when compared to the reference scenario. Food commodities eaten rarely, but linked to many and/or large outbreaks ranked higher in this scenario and particularly included both combinations of *Salmonella* spp. and pathogenic *Escherichia coli* with sprouted seeds. Excluding the consumption criterion can be regarded as ranking the risk for the individual consumer as opposed to the EU population.

The model may overestimate the importance of some food/pathogen combinations, since only those reported in outbreaks in the EU as part of the Zoonoses monitoring are included in the model and additional food/pathogen combinations may be identified as important if data from future EU monitoring is included. The model used here is likely to underestimate the importance of diseases which appear to be of a more sporadic nature (such as those due to *Listeria monocytogenes*, *Campylobacter* spp. and parasites). It should be highlighted that when interpreting outputs from the model, consideration has to be given to the assumptions, limitations and uncertainties. The model outputs presented in this opinion are based on the reported outbreaks associated with consumption of food of non-animal origin within the EU between 2007 and 2011. Therefore, future fluctuations in the reported outbreaks are likely to impact on the current ranking.

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BACKGROUND AS PROVIDED BY EUROPEAN COMMISSION

In May 2011 a major outbreak of Shiga toxin-producing *Escherichia coli* (STEC[4]) O104:H4 occurred in Germany. About 4,000 people were reported ill with symptoms and the outbreak resulted in the death of more than 56 people. Other countries reported a certain number of people becoming ill by the same strain, most of whom had recently visited the region of northern Germany where the outbreak occurred. At the end of June 2011, there was a second cluster in Bordeaux, France, which was caused by the same *Escherichia coli* strain. In both cases, investigations pointed to the direction of sprouted seeds.

According to the 2009 Zoonoses Report[5], the majority of verified outbreaks in the EU were associated with foodstuffs of animal origin. Fruit and vegetables were implicated in 43 (4.4 %) verified outbreaks. These outbreaks were primarily caused by frozen raspberries contaminated with norovirus.

According to the US Centre for Disease Control and Prevention (CDC) 2008 report on surveillance for food borne disease outbreaks[6], the two main commodities associated with most of the outbreak-related illnesses originating from food of plant origin were fruits-nuts and vine-stalk vegetables. One of the main pathogen-commodity pair responsible for most of the outbreaks was norovirus in leafy vegetables. The pathogen-commodity pairs responsible for most of the outbreak-related illnesses were *Salmonella* spp. in vine-stalk vegetables and *Salmonella* spp. in fruits-nuts. In addition, as recently as September 2011, a multistate outbreak of listeriosis linked to cantaloupe melons caused 29 deaths in the US.

Regulation (EC) No 852/2004 on the hygiene of foodstuffs[7] lays down general hygiene requirements to be respected by food businesses at all stages of the food chain. All food business operators have to comply with requirements for good hygiene practice in accordance with this Regulation, thus preventing the contamination of food of animal and of plant origin. Establishments other than primary producers and associated activities must implement procedures based on the Hazard Analysis and Critical Control Points (HACCP) principles to monitor effectively the risks.

In addition to the general hygiene rules, several microbiological criteria have been laid down in Regulation (EC) No 2073/2005[8] for food of non-animal origin.

Following the STEC O104:H4 outbreak in Germany and France, the Commission already has asked EFSA for a rapid opinion on seeds and sprouted seeds. EFSA adopted a scientific opinion on the risk posed by STEC and other pathogenic bacteria in seeds and sprouted seeds on 20 October 2011. The current mandate intends to supplement the adopted opinion.

In view of the above, there is a need to evaluate the need for specific control measures for certain food of non-animal origin, supplementing the general hygiene rules.

TERMS OF REFERENCE AS PROVIDED BY EUROPEAN COMMISSION

EFSA is asked to issue scientific opinions on the public health risk posed by pathogens that may contaminate food of non-animal origin such as fruit, vegetables, juices, seeds, nuts, cereals, mushrooms, algae, herbs and spices and, in particular:

1. To compare the incidence of foodborne human cases linked to food of non-animal origin and foodborne cases linked to food of animal origin. This ToR should provide an indication of the proportionality between these two groups as regard humans cases and, if possible, human burden.

4 Also known as Verocytotoxin-producing *Escherichia coli* (VTEC).
5 EFSA Journal 2011;9(3):2090
6 www.cdc.gov/mmwr/preview/mmwrhtml/mm6035a3.htm?s_cid=mm6035a3_w
7 OJ L 139, 30.4.2004, p. 1
8 OJ L 338, 22.12.2005, p. 1

2. To identify and rank specific food/pathogen combinations most often linked to foodborne human cases originating from food of non-animal origin in the EU.

3. To identify the main risk factors for the specific food/pathogen combinations identified under ToR 2, including agricultural production systems, origin and further processing.

4. To recommend possible specific mitigating options and to assess their effectiveness and efficiency to reduce the risk for humans posed by food/pathogen combinations identified under ToR 2.

5. To recommend, if considered relevant, microbiological criteria for the identified specific food/pathogen combinations throughout the production chain.

The Commission would like an opinion on the first and second terms of reference by the end of December 2012. The outcome of the first and second terms of reference should be discussed between risk assessors and risk managers in order to decide which food/pathogen combinations should be given priority for the other terms of reference. The Commission would like an opinion on the other terms of reference by the end of 2013.

ASSESSMENT

1. Introduction

Food of non-animal origin (FoNAO) include those derived from plants and are ubiquitous in their distribution providing a major component of almost all meals. This broad range of foods and food components comprises a wide range of fruit, vegetables, salads, seeds, nuts, cereals, herbs, spices fungi and algae, which are commonly consumed in a variety of forms. Categorisation of FoNAO is discussed in Chapter 2.1. These foods should be nourishing and attractive, provide an essential part of a normal healthy diet and should be free of pathogenic agents or microbiological toxins which give rise to food poisoning. However recent incidents of infectious disease (particularly the >3,800 cases of infection due to VTEC O104 in 2011 associated with sprouted seeds) has highlighted the potential for large outbreaks with considerable morbidity and mortality to be associated with FoNAO.

The approaches used in this Opinion will be to:

1. consider data on the incidence of foodborne human cases linked to FoNAO and compare these to foodborne cases linked to food of animal origin (FoAO). Data on foodborne outbreaks and reported as part of the monitoring and collection of information on zoonoses based on the Zoonoses Directive 2003/99/EC will be used to estimate the proportionality between human disease associated with these two food groups. Methods for source attribution have previously been reviewed (EFSA, 2008), and five approaches were identified, i.e. microbial sub-typing, outbreak summary data, epidemiological studies, comparative exposure assessment, and structured expert opinion. Analysis of outbreak summary data was found to be currently the only method able to provide a EU-wide comparative estimate of the proportion of human cases due to FoNAO and FoAO. The comparative exposure assessment is very data intensive and the microbial sub-typing approach requires data from harmonised monitoring and the application of appropriate sub-typing methods. Such data is not available. Epidemiological studies, including case control studies are not available on an EU basis for all pathogens. Expert opinion has been used to highlight shortcomings of the outbreak approach.

2. risk rank specific food/pathogen combinations most often linked to foodborne human cases associated with outbreaks caused by FoNAO in the EU. A risk ranking model based upon a Risk Ranking Tool (RRT) published by the U.S. Food and Drug Administration (FDA) (Anderson et al., 2011) was developed. The tool is based on a simple, transparent, risk ranking algorithm that orders the priority of pathogen-commodity combinations according to a number of specific criteria. Initially pathogen-commodity combinations linked to foodborne outbreaks originating from FoNAO in the EU were identified using zoonoses monitoring data. Linkages between a certain pathogen-commodity combination and human disease in the EU and elsewhere, were also established using data from the RASFF notifications, the international literature (e.g. from case-control studies and outbreak investigations) and by expert opinion. The outcome of the model is a relative risk ranking based on the severity of the health effect for each hazard, the likelihood of under-reporting and the incidence of illness, as well as criteria related to the probability of consumption and contamination, the dose-response relationship, growth potential of the hazard and shelf life of the commodity.

Following consultation with the European Commission it was agreed to consider only disease caused by viruses, bacteria and parasites and to exclude:

i. hazards due to mycotoxins

ii. foods which are medicinal products, chewing tobacco and composite products ("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).

2. Production of food of non-animal origin (FoNAO)

2.1. Description of EU sector

The main production within the EU of selected FoNAO in 2010 is shown in Appendix A. As examples, by decreasing amount: rice and other cereals, legumes seeds and grain (around 295 million tonnes), potatoes (around 57 million tonnes), tomatoes (around 17 million tonnes) and apples and related fruit (around 13 million tonnes) (FAO, 2012). These amounts produced in the EU are in the same order of magnitude as FoAO (e.g. bovine milk, pig and poultry meat, eggs) (FAO, 2012). Some of these products are only produced for processing (e.g. sugar beet, rape seeds) whereas others are produced for both fresh consumption and processing (e.g. tomatoes, olive, apple, orange and grapes). In this latter case cultivars and/or pre-harvest practices may be different for either usage. An estimate of the EU production for the main food categories defined for the purpose of this Opinion in section 2.2 is presented in Appendix A (Table 25).

The EU also imports a considerable quantity of FoNAO and in 2009 these were (by decreasing amount): cereals (wheat, corn and barley, around 60 million tonnes), seed for oil and protein (rape seeds and soybeans, around 24 million tonnes), non-alcoholic beverages (around 7 million tonnes), palm oil (around 7 million tonnes), bananas (around 7 million tonnes), and potatoes (around 6 million tonnes).

The production of some specific types of FoNAO in the EU is restricted to regions with permissive climatic conditions, as for example for olive and citrus fruit production. In contrast, as a result of farming practices (e.g. use of greenhouses) and plant breeding, some types of FoNAO are produced in nearly all EU Member States, even if they were originally from warmer climates. These production practices within the EU, combined with a significant amount of imports for most of the commodities considered in this Opinion, results in a particularly wide range of origins for FoNAO available in the EU. Production in various EU Member States and imports are shown as illustrative examples in Appendix A (Figure 13) for strawberries, tomatoes, lettuces and chicory. This indicates the potential for a wide diversity of climatic and environmental conditions, and farming practices for a single FoNAO commodity placed on the market within the EU. Such diversity in production conditions correspond to various microbiological risk factors (see section 2.3).

2.2. Categorisation of foods in the scope of this opinion

The purpose of this categorisation of FoNAO is to permit a risk ranking with respect to the main biological hazards covered by the Opinion. It must therefore be compatible with the definition of the food commodities used in EU foodborne outbreaks databases and with EU food consumption databases. In addition, the risk ranking must be usable by risk managers. For these reasons, the conventional categories following botanical groups (e.g. citrus fruit, stone fruit, apples and related fruit, berries, melon, tomatoes, leafy vegetables, roots and tubers, etc) are retained. The categorisation of the final food categories have taken into account the following factors which may have an impact on their final microbiological risk:

- Potential for growth of the bacterial hazards (e.g. non acid fruits such as melon versus other fruit) or no growth (dry commodities, e.g. nuts, spices and dry herbs).

- Processing that may inactivate some hazards (e.g. heating), or modification of the physicochemical composition to prevent pathogen growth (e.g. fermentation, addition of salt, lowering pH).

- Production size, pre/post-harvest practices, and consumption practices led to differentiation of a single commodity out of a broader category, e.g. “strawberries” versus “other berries”.

- 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.

Some commodities were not included in broader categories because of their consumption patterns: e.g. a significant proportion of rice is consumed after home cooking, unlike other cereals which the majority is industrially processed.

With regard to risk, the classification proposed has several limitations because it excludes some major risk factors. Production practices are not considered because this information is not available in the databases on outbreaks and consumption. However, some commodities are produced under very different conditions, e.g. from open fields to hydroponic production, with very different risk factors (see section 2.3). Similarly, it is not possible to include more than limited information on processing and storage conditions, although this may strongly influence survival and growth of microbiological hazards.

The classification of FoNAO commodities is described in Table 1 showing some specific examples for each defined FoNAO category. The level of classification to be used (general or specific) for the search of association with foodborne outbreaks are in bold fonts.

Table 1: Classification of commodities of FoNAO for the purpose of this Opinion.

General commodity category	Specific categories	Examples of commodities
1. Fruit (non specified)		
Soft fruits	**2. Strawberries**	
	3. Raspberries	
	4. Other berries	Açai berry, barberry, bearberry, bilberry, blackberry, blackcurrant blueberry, boysenberry, chokeberry, chokecherry, cloudberry, cranberry, crowberry, elderberry, goji berry, gooseberry, huckleberry, juneberry, juniper berry, lingonberry, loganberry, marionberry, mulberry, nannyberry, ollaliberry, oregon grape, red currant, red and green grape, salmonberry, sea-buckthorn berry, serviceberry, tayberry
5. Citrus fruit		Citron, grapefruit, lemon, lime, mandarine, orange, tangerine
6. Apples and related fruit		Apple, hawthorn, loquat, medlar, pear, quince
7. Stone fruit		Apricot, Asian plum, cherry, elderberry, european plum, nectarine, peach
8. Tropical fruit		Asian palmyra palm, avocado, bael, breadfruit, canistel, coconut, date, dragon fruit, durian, guava, fig, jackfruit, jujube, kiwifruit, langsat, longan, longkong, lychee, mafai, mango, mangosteen, maprang, passion fruit, papaya, persimon, pineapple, pitaya, pomegranate, rambutan, roselle, santol, sapodilla, soursop, star apple, starfruit, sugar apple, tamarind, velvet apple
9. Melons		Bitter melon, horned melon, muskmelon (cantaloupe, wintermelon, galia), watermelon
10. Fruit mixes		Cut fruit, fruit salad
Vegetable fruits	**11. Tomatoes**	Tomatoes (grape, currant, plum, beef etc)
	12. Peppers and aubergines	Aubergine, pepper (bell, fresh, sweet, chilli, etc)

General commodity category	Specific categories	Examples of commodities
	13. Gourds and squashes	Butternut squash, button squash, courgette, cucumber, green spaghetti squash, hubbard squash, ivy gourd, kabocha, marrow, muscat, pepita squash, pumpkin, red hokkaido, tinda
	14. Fresh pods, legumes and grain	Azuki bean, black-eyed pea, chickpea, common bean, dolichos bean, drumstick, fava bean, green bean, horse gram, indian pea, kidney bean, lentil, lima bean, moth bean, mung bean, okra, pea, pigeon pea, ricebean, snap pea, snow pea, soybean, sweet corn, tepary bean, urad bean, velvet bean, winged bean, yardlong bean
Leaves	**15. Leafy greens eaten raw as salads**	Arugula, beet green, bitterleaf, bok choy, cabbage, celery, celtuce, ceylon spinach, chard, chicory, Chinese cabbage, collard greens, cress, endive, epazote, garden cress, garden rocket, komatsuna, lamb's lettuce, land cress, lettuce, mizuna greens, mustard, New Zealand spinach, radicchio, rapini, spinach, tatsoi, watercress, water spinach, wrapped heart mustard cabbage
	16. Fresh herbs	Basil, cilantro, celery, coriander, dill, fresh tea, marjoram, mint, parsley, peppermint, rosemary, sage, thyme
	17. Leafy greens mixed with other fresh FoNAO	Mixed green leaves and vegetables, mixed green leaves and fresh herbs
	18. Other leaves	Brussel sprouts, kale, pak choy, other cabbage not eaten raw
Root and tuberous vegetables	**19. Carrots**	Carrot (baby, coins, juice, sticks, grated, shredded, sliced, etc)
	20. Potatoes	Baked potato, boiled potato, fried potato
	21. Other root and tuberous vegetables	Ahipa, arracacha, bamboo shoot, beetroot, burdock, cassava, Chinese artichoke, chufa, daikon, elephant foot yam, ginger, gobo, hamburg parsley, horseradish, Jerusalem artichoke, jícama, komatsuna, manioc, mooli, parsnip, radish, rutabaga, salsify, scorzonera, skirret, swede, sweet potato, taro, tigernut, turnip, ulluco, water chestnut, wasabi, yacón, yam
22. Bulb and stem vegetables		Asparagus, cardoon, celeriac, celery, elephant garlic, Florence fennel, garlic , kohlrabi, kurrat, leek, lotus root, nopal, onion, Prussian asparagus, shallot, spring onion, welsh onion
23. Flowers and flower buds		Artichoke, broccoflower, broccoli, broccoli romanesco, cauliflower, Chinese broccoli, courgette flower, squash blossom, wild broccoli
Dry legumes, cereals, edible seeds and grain, flours and products thereof	**24. Cereals and dry legumes**	Barley, buckwheat, bulgur, fonio, maize (corn), millet, oats, quinoa, rye, sorghum, triticale, wheat
	25. Rice	Cooked rice
	26. Pasta	Cooked pasta
	27. Other dry legumes, cereals, edible seeds and grain, flours and products thereof (processed products)	Bread, breakfast cereals, cornflakes flours, polenta, semolina, tortilla, various edible seeds
28. Sprouted seeds		Alfalfa, basil cress, broccoli, borage cress, chick pea, coriander, fennel, fenugreek, garden cress, garlic, leek, lemon cress, lentil, mung bean, onion, pea, radish, shiso, sunflower, wheat

General commodity category	Specific categories	Examples of commodities
29. Fungi (mushrooms and yeasts)		Blewit, boletus, chanterelle, Gypsy mushroom, hedgehog mushroom, lion's mane mushroom, matsutake, morel, oyster mushroom, saffron milk cap, trompette du mort, truffles, yeast extract
30. Sea vegetables		Aonori, carola, dabberlocks, dulce, hijiki, kombu, laver, mozuku, nori, ogonori, sea grape, sea kale, sea lettuce, wakame
31. Nuts and nuts products		Almond, chestnut, coconut, hazelnut, macadamia nut, nut bars, peanut, peanut butter, pistachio, walnut
32. Spices and dry powdered herbs		Chilli, cumin, curry, nutmeg, pepper (black/white)
33. Beverages		Cocoa, coffee, herb teas, tea
34. Vegetable oils		Rape seed oil, sesame oil, soya oil, sunflower oil
35. Fermented, salted, or acidified vegetables or fruit		Miso, olives, pickles, sauerkraut, soy sauce, tempeh
36. Cooked vegetable salads		Potato salad, aubergine salad
37. Other processed products, sauces and dressings, purées, soup, and pastes (including canned and bottled products) and syrups		Canned bottled products, falafel, maple sugar-cane and corn syrups, pesto, tahini, tapenade, tomato sauce, tomato soup, vegetables in oil, vegetable soups
38. Dehydrated vegetables and fruit		Dehydrated vegetable soups, dried fruits, porcini mushrooms, (sun)-dried tomatoes
39. Others		Food supplements, plant extracts

When linking general commodity categories to specific hazards or outbreaks, for a minimal processing FoNAO (e.g. fresh cut, fresh juiced, mashed, frozen) attribution will be made to the broad commodity group: e.g. an outbreak linked to frozen strawberries would be attributed to strawberries.

There are some general commodity categories that include both products that are eaten raw, as well as products that are usually consumed after stringent processing. Outbreaks implicating commodities subjected to a stringent processing (e.g. heating, fermentation, pickle, etc.) were attributed to the processed product category (e.g. an outbreak linked to tomato sauce should be attributed to category 37 "other processed products") as the contamination with the pathogen would be linked to the processing rather than to the raw commodity. There are, however, some general commodity categories where all the specific examples included are generally consumed after stringent processing. This is the case for the following categories in Table 1: (category 24) cereals and dry legumes; (category 25) rice; (category 26) pasta; (category 27) other dry legumes, cereals, edible seeds, grain, flours and products thereof; (category 31) nuts and nut products; (category 32) spices and dry powdered herbs; (category 33) beverages; (category 34) vegetable oils; (category 35) fermented, salted or acidified vegetables and fruit; (category 36) cooked vegetable salads; and (category 38) dehydrated vegetables and fruit. In these instances, both products that are eaten raw as well as products that are usually consumed after stringent processing were considered in the same general category. Cooked vegetable salads (category 36) refers to salads, which usually contain cooked vegetables, e.g. aubergine or potato salads.

2.3. Considerations on risk factors for microbiological contamination during pre-harvest processes and harvest for selected commodities: tomatoes, watermelon, lettuce, pistachio nuts and spices

FoNAO comprises a wide variety of food commodities which includes, among others, fruits, leafy greens and fresh herbs, roots and tuberous vegetables, bulb and stem vegetables, flowers and flower buds, dry legumes, cereals, edible seeds, grain, flours, seeds for sprouting and sprouted seeds, fungi (mushrooms and yeasts), sea vegetables, nuts, spices and dry herbs (Table 1). This diversity results in variation within the production processes in terms of pre-harvest practices, inputs, production volumes, geographical location, environmental conditions, productivity and target markets and therefore it is not possible here to provide specific descriptions of each production system (FAO/WHO, 2008). For instance, fresh leafy vegetables are grown and harvested under a wide range of climatic and geographical conditions, using various agricultural inputs and technologies, and on farms of diverse sizes, including field production (open field or under cover) and greenhouse production (in soil or hydroponically).

However, although production processes vary between commodities, there are common production activities which apply to most of the fresh FoNAO. Figure 1 shows a summary of the most common activities included in the production processes.

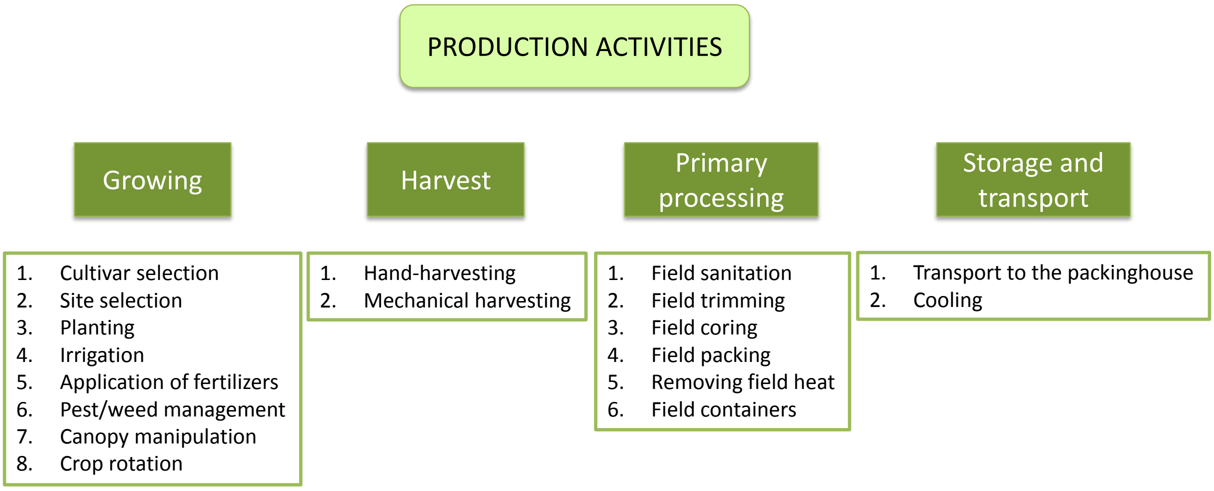

Figure 1: Common production activities involved in the production processes of different fresh commodities.

The majority of FoNAO is cultivated, and the production processes involve pre-harvest and post-harvest activities such as field preparation, planting, growth, irrigation, fertilization, harvest, storage and transport. However, growers may need to modify production practices depending on many factors, such as the needs of the crop, resources of the operation, and requirements, if any, imposed by the buyer or distributor (NACMCF, 1999). Therefore, growers will need to assess agricultural practices for each specific primary production area to assure the production of safe fruits and vegetables.

Furthermore, microbial food safety hazards and sources of contamination may also vary significantly by the type of crop, production systems and practices and from one particular setting/context to another, even for the same crop (Fan et al., 2009; FAO/WHO, 2008; Sapers et al., 2009; Warriner et al., 2009). There is a general agreement on the agricultural practices that increase the risk of exposure to potential microbial hazards, and these are listed in Figure 2 (CAC, 2003; EFSA Panel on Biological Hazards (BIOHAZ), 2011a; Jay, 2006; NACMCF, 1999).

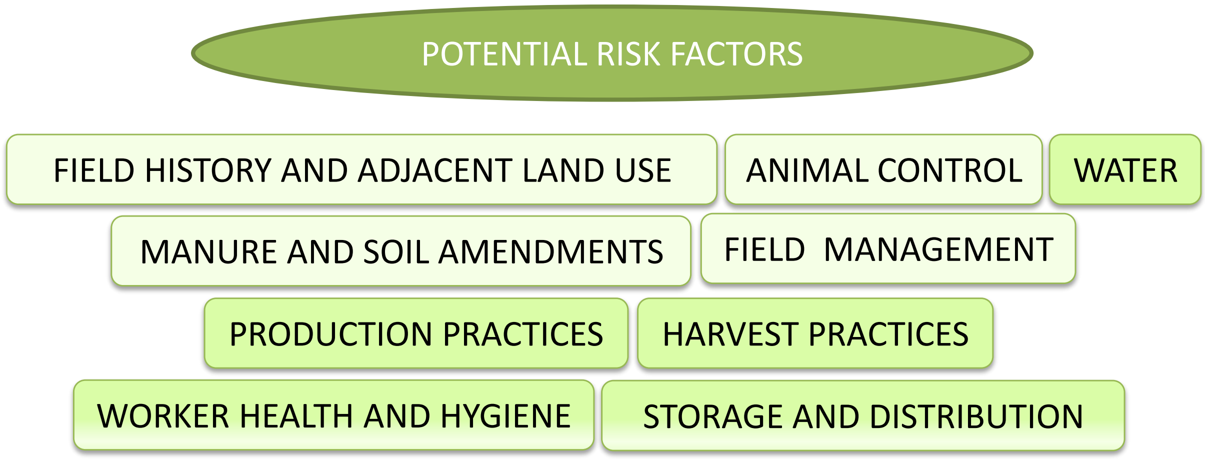

Figure 2: Potential risk factors commonly found on the farm.

Risk factors commonly identified on farms may include:

a) Field history and adjacent land use. The environment of the farm may influence the risk of contamination with microbial hazards, during primary production and after harvest (FDA, 2009c). Previous and present usage of the primary production area and adjoining sites could represent a source of microbial contamination.

b) Access by domestic or wild animals to the production sites or the water sources used in primary production (EC/SCF, 2002; FAO/WHO, 2008).

c) Water use for primary production which can contain microbial contaminants at levels that may adversely affect the safety of FoNAO. In the case of hydroponic production, water is used for both irrigation and as the growth medium and may present therefore a higher risk of microbiological surface and internal contamination (EC/SCF, 2002).

d) Field management, including field sanitation and sanitary facilities.

e) Production and harvest practices. All the production inputs, including chemical fertilizers, manures, compost or biosolids, pesticides and chemicals used in production can influence the risk of microbial contamination. Production systems might also influence the risk of exposure to microbial hazards, the use of soil-free systems, which avoid contact between the soil and the crop, might reduce the transfer of microorganisms from the soil (Selma et al., 2012).

f) Equipment and containers associated with growing and harvest can be sources of microbial hazards even if they are used following the technical specifications recommended by the equipment manufacturers for their proper usage and maintenance.

g) Sanitizing agents used during harvest to disinfect fresh produce or equipment. The use of authorized sanitizing chemicals can reduce cross-contamination of fresh produce from agricultural inputs or personnel who have directly or indirectly contact with fresh fruits and vegetables. Cross-contamination can be avoided by using water of equivalent quality to potable water with the addition of sufficient appropriate sanitizer.

h) Personnel health, hygiene and sanitary facilities: Production crews, visitors or other field personnel have been identified as sources of microbial hazards, particularly when hygienic and sanitary facilities are not available in close proximity to the field or in sufficient number.

i) Storage and transport from the field to the packing facility. Any area used to collect, transport, pack or store fresh commodities in the field that are not well maintained in a clean and sanitary manner can represent a microbial hazard.

Growth conditions and the location of the edible parts of the plant (e.g. those in contact with soil, soil surfaces, or aerial parts) will, in combination with intrinsic, extrinsic, production, harvesting and processing factors, affect microbial risk status of FoNAO at the time of consumption (EC/SCF, 2002). Based on these factors and taking into account the variety of food commodities included in the category of FoNAO (Section 2.2), a selection of specific commodities have been chosen to serve as illustrations of the most representative production practices.

2.3.1. Vegetable fruit: tomatoes

The process for tomatoes is complex and includes open field or greenhouse production, harvest practices, field packaging as well as repacking and other distribution operations (Figure 3).

Within the EU, there are generally two models for tomato production: the 'Dutch system' mostly used by North-European countries, where tomatoes are cultivated in greenhouses on substrates (principally rockwool) with a central hot water heating system, and computerized control of environmental conditions and watering. Alternatively, the "Mediterranean system", has greater heterogeneity, the basic elements being: field cultivation or in greenhouses without temperature or atmospheric control and cultivation in soil or soil-free environments under plastic or mesh (Tello, 2000).

For production of fresh tomatoes in fields, food safety considerations will be needed concerning management of, field site, land use, adjacent land use, agricultural inputs (e.g., irrigation water, fertilizers), workers and production practices (FDA, 2009c). For greenhouse production, there are the alternative options using soil or soil-less cultivation. Soil-cultivated tomatoes are grown under a greenhouse cover in a plot of soil using similar techniques to those used in the field. Soil-less culture (also called hydroponics) refers to growing tomatoes where the necessary fertilizers are delivered to the root system in balanced levels in water (Rutledge, 1999). It should be noted that the greenhouse environments are not enclosed systems (Guo et al., 2002) and crops grown in these environments are susceptible to insect pests and diseases (Snyder, 2007). However, while a greenhouse environment is excellent for growing tomatoes (and other vegetables), it is even better for propagating insect pests, disease organisms and foodborne pathogens (Nguyen-The and Carlin, 2000). Due to the higher temperature, higher relative humidity, and lush, green foliage, insects and diseases are constant threats once introduced into a greenhouse (Snyder, 2007).

Packing of tomatoes in the field includes practices to grade, sort, size, clean, pack or palletize tomatoes into containers for commerce. Field packed tomatoes may not have been cleaned or washed but they are not intended to be transferred to a packinghouse for further handling. These practices could represent a source of contamination (FDA, 2009c).

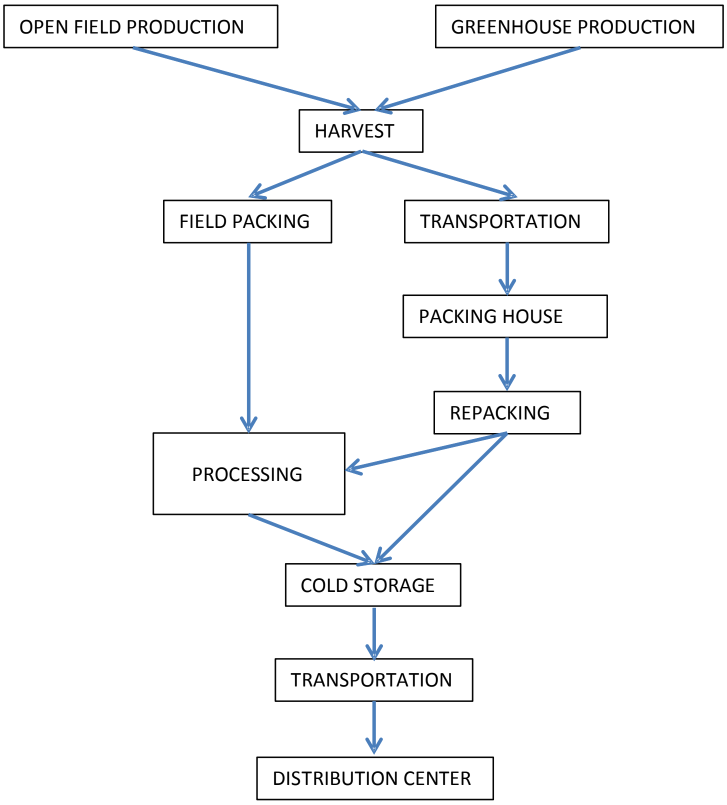

Figure 3: General supply chain flow for fresh tomatoes.

The distribution chain may be simple with direct sale to the consumer or very complex, with tomatoes being handled by a number buyers and other intermediaries where repacking for size and/or quality occur prior to retail sale Figure 3 (FDA, 2009c).

2.3.2. Melons: watermelon

Watermelon is a warm-season crop related to cantaloupe, squash, cucumber and pumpkin. Watermelons can be grown on any well-drained soil; however, a high percentage of watermelons are produced on plastic mulch (Boyhan et al., 1999).

The main production practices specific for the watermelons includes: (1) Land preparation, which compromises operations aimed to make the soil more suitable for seeding and seedling (or transplant) establishment, to enhance productivity by providing the best soil structure for subsequent root growth and development, and to help control disease; (2) Planting using precision seeding equipment, plug mix planting and transplant which help to reduce or eliminate the need to thin stands after planting; (3) the use of plastic mulch to warm the soil, reduce the maturation season, prevent weed growth and improve contact between the crop and the soil.

Specific microbial safety hazards and sources of contamination associated with watermelons apply to all types of melon and include: (1) The specific characteristics of the rind surfaces, which may favors adhesion and survival of human pathogens which are more difficult to eliminate from netted melon rind surfaces (Bradley et al., 2001; Parnell et al., 2005; Richards and Beuchat, 2004; Ukuku and Fett, 2002); (2) Melons may have direct contact with soil during growth and development but may be hand turned multiple times during growth to prevent ground spot development. Melon ground spots have been demonstrated to have significantly greater microbial populations than non ground spot areas of melon rinds (Parnell et al., 2005); (3) Cross-contamination can occur during crop handling. Melons are commonly unloaded from field containers by dry or water dump operations, where there is the potential for melon-to-melon, food-contact surface-to-melon, and melon-to-water-to-melon cross contamination (Castillo et al., 2004; FDA, 2009b); (4) Melons are commonly cooled by forced-air cooling or by use of a chilled water drench or flume immersion. The water use during cooling may be a significant source of microbial cross-contamination if of poor quality (FDA, 2009b). In addition, because of temperature differentials between the cooling water and the melon, infiltration of cooling water may occur into the melons through the stem scar and rind (Richards and Beuchat, 2004); (5) Melons can be top iced after cooling as a means of temperature control during transport and distribution. However, ice will melt at refrigeration temperatures during transportation, which may increase the risk of melon cross-contamination within and among pallets of melons (FDA, 2009b).

2.3.3. Leafy greens: lettuce

Lettuce is grown all year round in many different climatic and geographical conditions. Lettuce can be produced in both open fields and hydroponic systems. In the case of open fields, there are two different methods to produce lettuce: transplanting and direct seeding. Field lettuce needs to be sown on raised beds to aid water infiltration and retention and allow adequate soil aeration and drainage. Beds should be cultivated and formed to produce a fine soil tilth in which the seed can germinate readily without being affected by soil crusting. Bed size and width varies with soil type and irrigation method (Napier, 2004).

Lettuce is a rapid growing plant that needs a well-balanced nutritional program to produce a high quality, high yielding crop. Additionally, to achieve a consistent maximum yield of high quality lettuce, growers will need to irrigate their crops (Napier, 2004).

Once lettuce has reached its maturity stage, it is harvested by cutting the head close to the ground and trimming off excess leaves (Figure 4). The heads are washed if needed and are usually packed in the field. Most whole head lettuces are cut by hand and loaded onto harvest aids for packing in the field, however growers are moving towards mechanising this operation using harvesting machines. Lettuce is packed naked, film wrapped, and as hearts (i.e. romaine lettuce). Leaf lettuce is usually packed into waxed cardboard cartons and vacuum-cooled prior to storage in a cold room (Jackson et al., 1996). If supplying a processing market then the lettuce is loosely packed in large bins or crates. With some exceptions, whole lettuces heads for processing require heavier trimming with more of the outer leaves removed at harvest. The new baby-sized leaves using baby-leaf at an immature stage and multi-leaves at a mature stage have been developed recently as high quality lettuce varieties for the fresh-cut market. Benefits of baby-sized as compared to whole-head lettuce are the greater efficiency with higher percentage of usable product, the easier and faster processing and the minimal oxidation due to smaller stem diameter. Baby-sized lettuce are usually harvested by machine where the entire leaf is harvested reducing the cutting damage.

When evaluating the specific microbial safety hazards and sources of contamination associated with lettuces (and in general to all type of leafy greens) it should be taken into account that mechanical or machine harvest has become increasingly prevalent this may provide increased opportunity for surface contact exposure which may also increase the potential to introduce human pathogens (WGA, 2012).

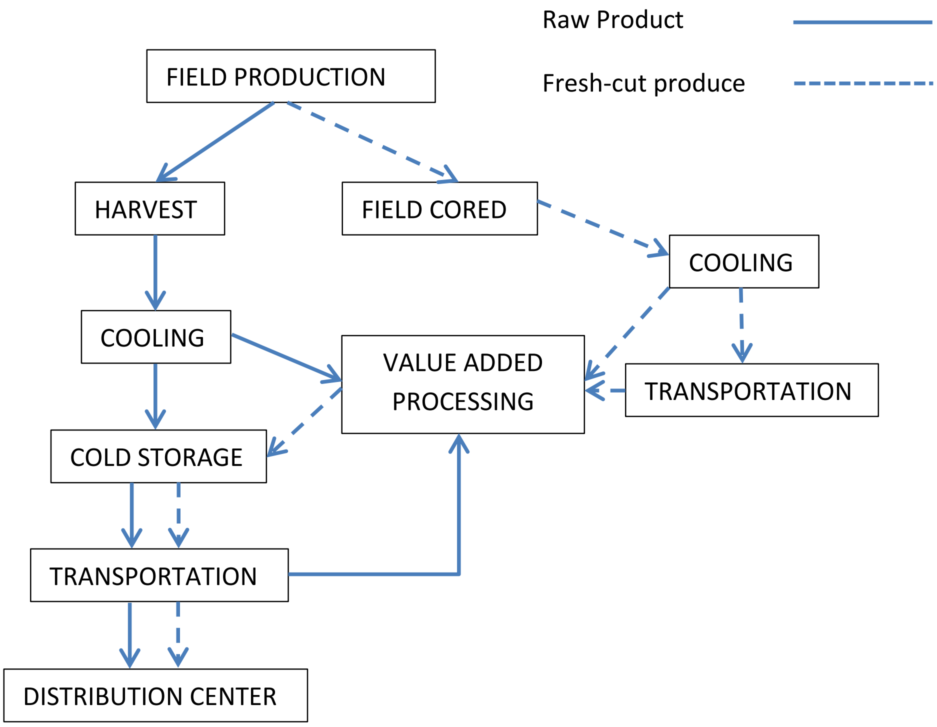

Figure 4: General supply chain flow for leafy greens (Adapted from (FDA, 2009a)).

2.3.4. Nuts: pistachio

Pistachios are grown in bushy, deciduous trees with one or several trunks and are usually mechanically harvested. The most relevant agricultural practices for pistachio nuts involve irrigation and harvest. The most common irrigation method uses micro-irrigation technology including drip and micro-sprinklers. There are also some areas that use flood irrigated or irrigation using solid-set low angle sprinklers to prevent contact between irrigation water and nuts or foliage. The tree is vigorously shaken and the falling nuts are collected on canvas-covered catch frames. Usually, harvest workers do not handle the nuts during this entire process. Due to the shaking process, nuts sometimes fly beyond the frames and the shell will come into contact with the soil, which presents a risk of contamination. The nuts are transported in bottom dump trailers to the processing facility where they are dehulled and dried. When harvested, the nuts are commonly about 30% moisture (CPRB, 2009). Microbial contamination is unlikely due to growing and harvesting practices as well as the common practice of roasting.

Food safety risks in minimally processed dry products like almonds, pistachios, and peanuts are different from high moisture foods. Therefore, the most likely sources of contamination by foodborne pathogens are animal wastes, particularly manures that have been added to improve soil texture and as a fertilizer.

2.3.5. Spices

Spices are commonly ground, crushed, or processed parts of seeds, bark or roots of plants. The climatic conditions required to grow most spices means that they are typically grown in tropical or semi-tropical non-industrialised countries where sanitation and food handling practices may be poor. The producers are often small-scale farmers who may not be fully aware of the need to protect their spice crops from conditions that lead to the presence and growth of pathogens. The European spice trade frequently relies on worldwide sourcing. Spice production takes place, for example in India, China, Mexico, and Indonesia, where farmers sell raw materials to collectors, who, in turn, sell them to processors. Overseas processors may or may not clean and treat spices before sale.

As a result of hygiene conditions in the growing regions, spices are particularly susceptible to microbial contamination with foodborne pathogens. Some pathogenic microorganisms are indigenous to the soil, and others come from dust, dirt, insects, and animal or human faeces that may come into contact with spices during growth, harvesting, and processing. Additional opportunities for introduction of pathogens between harvest and purchase by a consumer include the processes of washing, drying, transport, blending, packaging, storage, or distribution (ASTA, 2011).

When there is a problem with spices, tracing it back to its source can be difficult because of the vast number of small farmers whose harvest is consolidated together before reaching further processing.

Good Agricultural Practices have been defined to ensure that clean, safe spices are ultimately delivered to the consumer (ASTA, 2011). Specific microbial safety hazards and sources of contamination associated with spices includes:

a) Drying after harvest. The use of clean and elevated racks as well as mechanical air drying reduces exposure of raw species to microbial hazards (ASTA, 2011).

b) Storage for long periods of time. The exclusion of debris from packing and storage facilities is important to reduce the entry of potential microbial hazards.

c) The supply chain., Documentation on traceability of products should allow tracing a lot back to production, although this may be more difficult since spices are most often produced in tropical and semi-tropical non-industrial countries.

d) Spices and spice products such as pepper and curry paste often carry a significantly high load of spores of *Bacillus* species. Although these are not normally regarded as ready-to-eat foods they may be added to a ready-to-eat food as a garnish or seasoning, albeit as a very small proportion of the finished product. However, depending on the nature of the food to which they are added, outgrowth is possible and may then pose a health risk.

2.4. Considerations on risk factors for microbiological contamination during post-harvest treatments, including the main processing practices for whole fruit and vegetables, fresh cut produce, heat treated produce, dried fruit and vegetables, and salted, fermented and acidified fruit and vegetables

2.4.1. Fresh commodities

2.4.1.1. Preparation of whole fruit and vegetables

Most fresh-market products are currently harvested by hand into buckets or bags, which are then emptied into field bins for transport to packing or storage operations. However, soft fruits such as berries and some vegetables are packed directly in the field. This reduces both product handling and the time between picking and cooling, but has the disadvantage that quality control is more difficult than in a packing-house. In this case, careful field supervision is critical to avoid physical injuries of fresh commodities that might favour microbial growth.

During transport to packing or storage facilities, mechanical damage may occur and this can be detrimental for the product quality.

The typical unit operations in a mechanized packinghouse are shown in Figure 5.

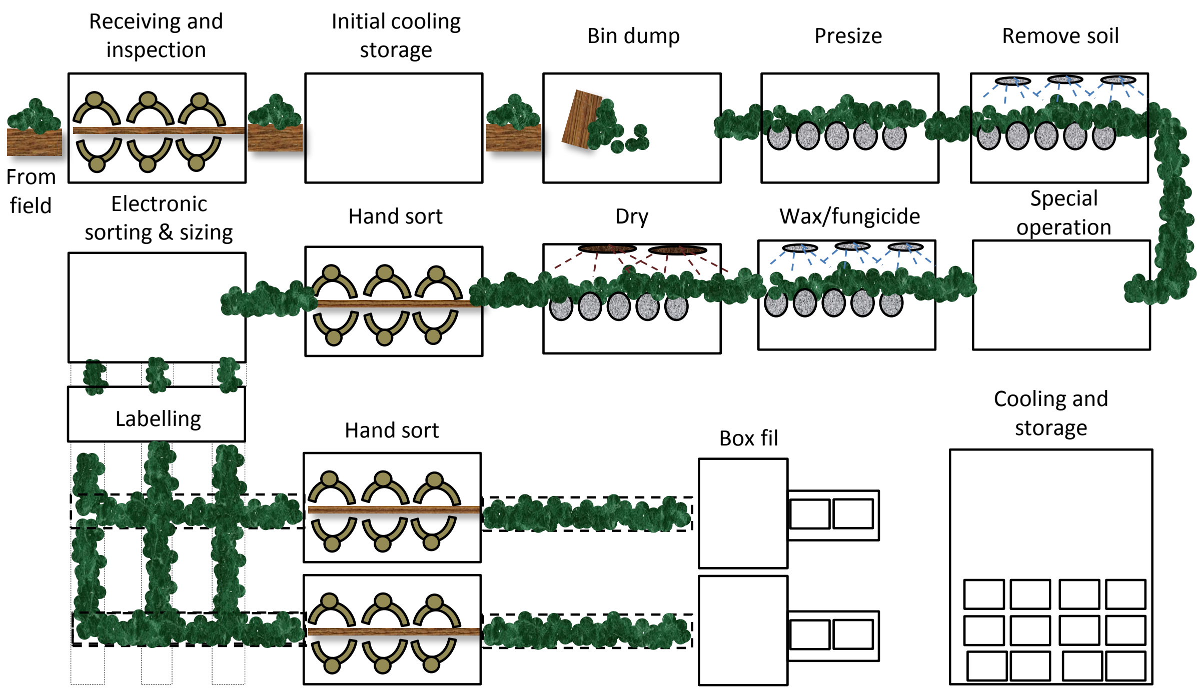

Figure 5: Schematic of the typical unit operations in a mechanized packinghouse (Adapted from (Thompson et al., 2002)).

Product is usually cooled very quickly to avoid quality loss and this also delays microbial growth. In fact, some products may be cooled before packing. This is common for products that are stored to extend the marketing period such as apples, pears, kiwifruit, citrus fruit, potatoes, cabbage, etc. For other products, cold storage allows them to be held for a short period before packing without appreciable loss of quality. However, products susceptible to chilling injury must be stored at higher temperatures. This is the case for bananas and cucumbers, among others, that are prone to undesirable physiological changes when exposed to temperatures, usually between 0 and 10 ºC. Therefore, products susceptible to chilling injury must be stored at higher temperatures. Some products are dried after harvest and before storage or marketing. This is the case of onions and garlic (Thompson et al., 2002).

Certain products, particularly tuberous root vegetables, grown close to the soil may need cleaning to remove soil and other contaminants. Sanitizing washes are sometimes applied using soft brushes followed by rinsing (Thompson et al., 2002).

A wide range of special operations may be needed to prepare the products for final sorting, including removal of unwanted leaves, stems and roots from some vegetables and waxing, etc. All these operations are generally specially designed to minimize product injury.

When an intact part of a plant is marketed, any microbial contamination present, is likely to reflect the environment through which the product has passed (EC/SCF, 2002; Johannessen et al., 2002).

2.4.1.2. Ready-to-eat fresh-cut produce

The minimal processing to which fresh-cut produce is subjected requires refrigerated conditions during storage to guarantee a reasonable shelf life of these highly perishable products. The processing steps include peeling, cutting and removal of the natural protection of fruits and vegetables. This can promote microbial growth and also allows physical and physiological changes, which reduce both quality and shelf life of the product (Gil and Allende, 2012).

Although fresh-cut produce is often considered safer from a microbiological point of view than FoAO, some recent foodborne outbreaks indicate the relevance of these food products as possible vehicles of foodborne pathogens (Brandl, 2006). Several authors have demonstrated that *Escherichia coli* O157:H7 attaches preferentially to the cut edges of lettuce leaves as well as to distinct features on the leaf surface such as trichomes, stomata, and cracks in the cuticle (Brandl, 2008; Takeuchi et al., 2000). In fact, fresh-cut produce is more susceptible to bacterial pathogen proliferation than intact fresh produce.

Most of the contamination of these types of products is ultimately traced back to pre-harvest sources (e.g. irrigation water, fertilizers, etc.). However, minimal processing may increase contamination by allowing cross-contamination of clean produce during cutting, washing and packaging (Lopez-Velasco et al., 2010).

One of the major concerns of fresh-cut produce is that none of the steps included in the processing chain will guarantee the inactivation of pathogens (Figure 6). During washing, some microorganisms will be removed from the product but pathogens can be spread from contaminated to uncontaminated parts (EC, 2002). Sanitizing agents or disinfection techniques for inactivating pathogenic bacteria may be applicable at this stage, however the efficacies must be evaluated, usually on a case-by-case basis (Gil et al., 2009).

Fresh-cut products are usually stored in Modified Atmosphere Packaging (MAP). MAP has been successfully used to maintain the quality of these products but it can also affect the type of microflora and their growth rates (Francis and O'Beirne, 1997). Several authors have demonstrated that the use of MAP may increase the potential for attachment and growth of facultative anaerobic pathogens such as VTEC O157:H7 and *Listeria monocytogenes* (Francis and O'Beirne, 1997; Lopez-Velasco et al., 2010; Takeuchi et al., 2001).

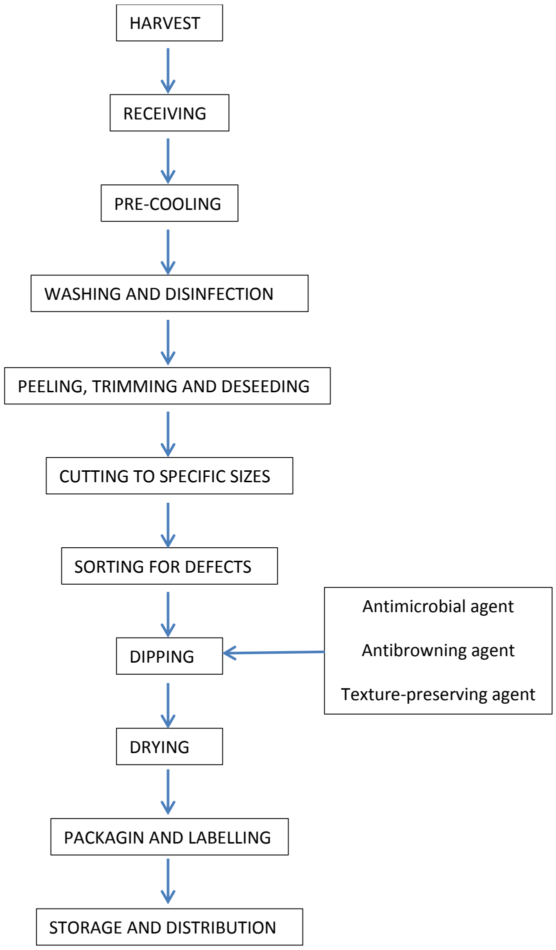

Figure 6: Common ready-to-eat process flow chart for fruit, vegetables and root crops (Adapted from (Jennylynd and Tipvanna, 2010)).

2.4.1.3. Fresh-cut, ready-to-cook produce (e.g. peeled potatoes, microwaved asparagus, garlic)

Ready-to cook produce is usually subjected to the same processing steps as fresh-cut produce but they are commonly packed using steam-in packages. Currently, packers of ready-to-cook vegetables are using polypropylene trays with a self-venting film overwrap that enables microwave cooking.

These products are subjected to mild heat treatments that may help to maintain quality and reduce, to some extent, the microbial load in the final product.

2.4.2. Heat treated products

Heat treatments applied to FoNAO have a very wide range of time temperature combinations. Low-acid canned products undergo treatments, which inactivate foodborne pathogens by several $\log_{10}$ cycles (e.g. a few minutes at 120°C) (Pflug and Gould, 2000). Acid canned products undergo milder heat treatments, which inactivate all foodborne pathogens except spore forming bacteria such as proteolytic *Clostridium botulinum*, which are prevented from growing by the acidity of the product (Pflug and Gould, 2000). Neither process will be further considered here as all the hazards relevant for this Opinion are eliminated or inhibited.

Lower heat treated FoNAO comprise cooked or pasteurized foods. The heat treatments used vary depending on the characteristics of each product. For example, cooking many vegetables to obtain the adequate texture requires at least a few minutes above 90°C, and for some products several minutes at 100°C. Inactivation of enzymes presents in fruit and vegetables, a frequent prerequisite to obtain a sensory stable product during shelf life, usually needs several minutes treatment above 80°C. Some products are pasteurised in the final package after the assembly of various ingredients at very diverse temperatures, but usually for several minutes at 70°C or higher. These heat treatments usually reduce by several log cycles non spore-forming bacterial pathogens, and the product must be stored refrigerated to limit growth of the bacterial spores that have survived the treatment (Nguyen-The and Carlin, 2000). Other products are assembled and packaged after heat treatment to limit contamination. The final product may nevertheless contain, in addition to the heat resistant bacterial spores, other foodborne pathogens resulting from cross contamination before packaging. A flow chart of some possible processes is shown in Figure 7.

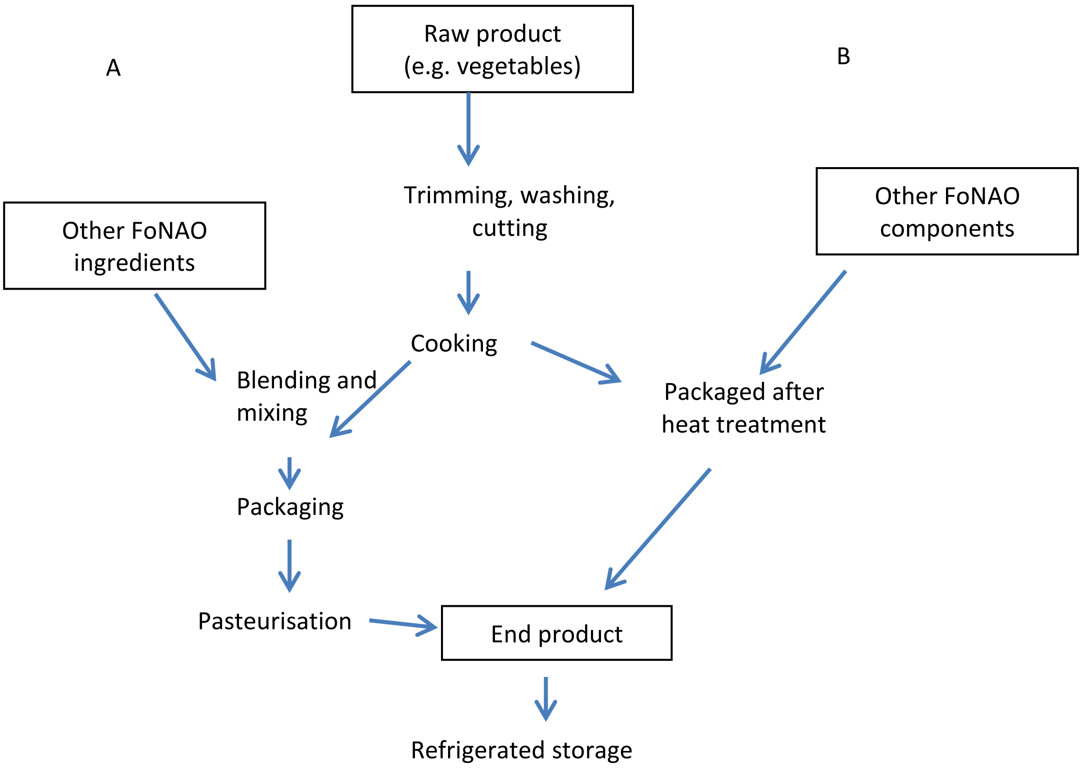

Figure 7: Simplified flow diagram of cooked chilled vegetables. A: pasteurized in final package (Adapted from (Afchain et al., 2008)), B: packaged after heat treatment

2.4.3. Frozen fruit and vegetables

Fruit and vegetables can be frozen in air blast or cryogenic freezers. More details on the techniques and conditions for various types of fruits and vegetables can be found in (Reid, 1996). Freezing breaks the membrane structure of cells which cause enzyme dislocation. In the case of vegetable, this can trigger enzymatic reactions independent of frozen storage temperatures, and leads to sensory deteriorations such as discoloration or off odour formation. For this reason, many vegetables and some fruits must be blanched before freezing, which comprises a short heat treatment of a few minutes at >80°C. Blanching can reduce by several $\log_{10}$ cycle non spore-forming foodborne pathogens. However, cross contamination after blanching is possible. Alternatively some fruits may be treated by antioxidant solutions before freezing (Reid, 1996) or frozen in syrup (Reid, 1996). A simplified flow chart of freezing processes for fruit and vegetables is presented in Figure 8.

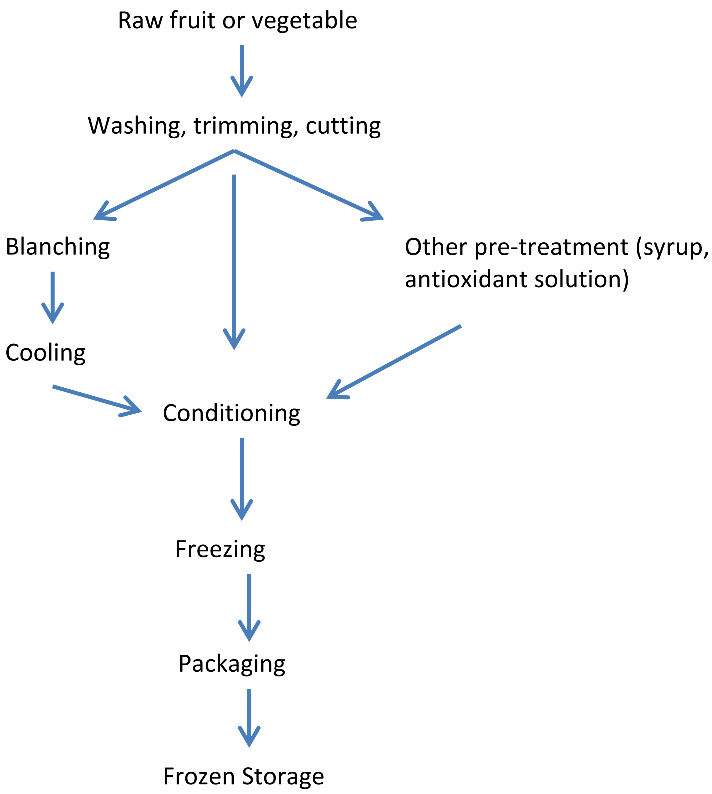

Figure 8: Simplified flow diagram of frozen fruits and vegetables

2.4.4. Fruit and vegetable juices

Fruits and vegetables juices are defined as non fermented juice extracted from the raw product by mechanical process which retains the odour, colour and flavor typical of the raw product (Stratford et al., 2000). In addition to the mechanical process, enzymes may be added, or a short heat treatment applied (e.g. 60°C for a few minutes, McLellan 1996), to help break the cell walls of the fruit or vegetable. Some fruit or vegetable juices must be clarified (using enzymes) and/or filtered. Antioxidant (ascorbic acid) may be added to prevent loss of sensory properties of the juice (Stratford et al., 2000). Fruit juices may receive no or only a mild heat treatment and be stored at refrigeration temperatures, or be pasteurized and are then shelf stable at ambient temperature. A high proportion of the fruit or vegetables juice is concentrated by water evaporation, stored frozen but also heat treated and stored at ambient temperature. The concentrate is most often obtained by water evaporation using heat, although membrane techniques may be used (McLellan, 1996). Fruits juices, fruit pulps and fruit concentrates may be used to prepare nectars by the addition of water (Stratford et al., 2000). Fruit juices and concentrates are also used in various soft drinks which will not be discussed further.

With respect to the control of biological hazards, fruit and vegetable juice may undergo a range of treatment (e.g. only mechanical and/or enzyme treatment) which should be considered similarly to those of canned foods. They may be stored in conditions preventing (freezing) or permitting growth of some bacterial hazards (e.g. under refrigeration temperatures). In addition, their pH can vary from too low to permit growth of bacterial pathogens (e.g. below 3.8 for many citrus fruit juices) to nearly neutral (most vegetable juices), some being close to the limit of growth of bacterial pathogens (e.g. around 4.5 as for some apple juices) (Stratford et al., 2000). A simplified flow diagram of the preparation of fruit and vegetable juice is presented Figure 9.

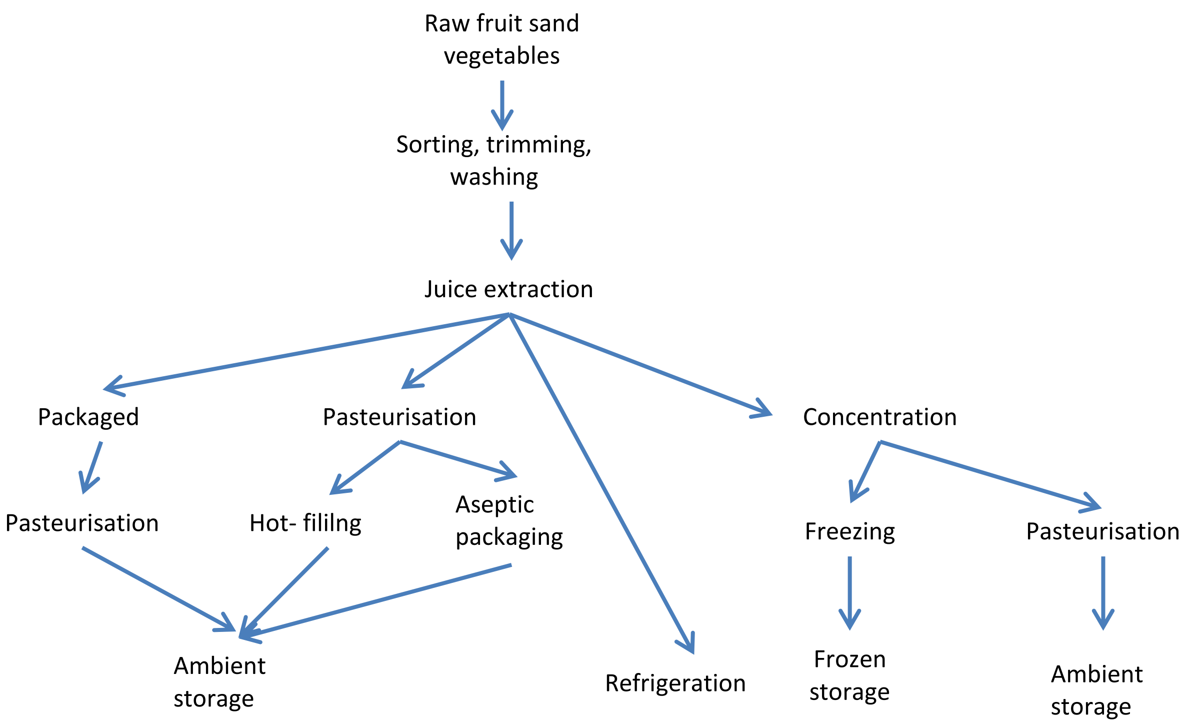

Figure 9: Simplified flow diagram of fruit and vegetable juice preparation.

2.4.5. Dried fruit and vegetables

Drying of fruit and vegetable has to overcome the high moisture content of these products, sensitivity to discoloration, and for many commodities, the presence of an impermeable cuticle. Fruit and vegetables can be sun dried (e.g. figs) or dried by forced hot air in specific equipment (e.g. prunes). Heat can also be achieved by microwave radiation. Osmotic dehydration can be an alternative to heat and freeze drying may also be used for high quality products in spite of its high energy cost, (Ratti and Mujumdar, 1996). Whenever the original colour of the product is preserved (e.g. dried apricot) antioxidant solution are used such as sulphites (Lund and Snowdon, 2000). The final moisture is usually below an a_w of 0.65 which is low enough to permit storage at ambient temperature without further treatment, but in some cases (e.g. prunes with a_w over 0.7) pasteurisation or addition of preservative such as potassium sorbate is needed (Lund and Snowdon, 2000). For some product (e.g. some raisins) a heat treatment before drying is applied to break the cuticle and facilitate removal of water (Lund and Snowdon, 2000). With respect to the hazards relevant to this Opinion, no steps are intended to inactivate pathogenic agents. Whenever heat is applied, it is usually dry heat at insufficient temperatures to reliably kill microorganisms. In addition, it is associated with water evaporation, which absorbed heat and may protect the microorganisms present. The a_w of the final product will not support growth of pathogenic bacteria but may enable survival. A simplified flow diagram of the preparation of dry fruits and vegetable is presented Figure 10.

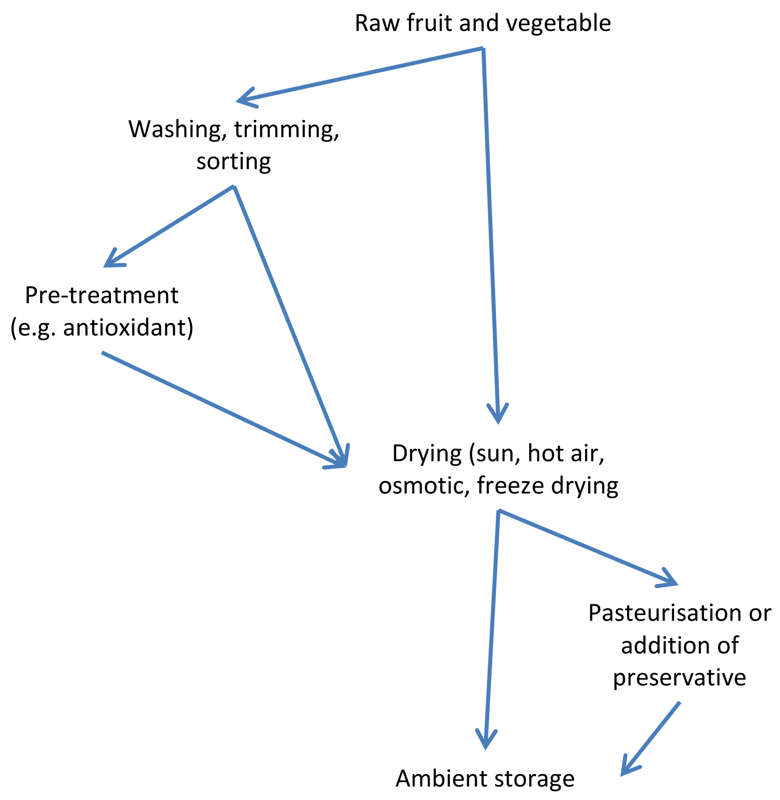

Figure 10: Simplified diagram of fruit and vegetable drying

2.4.6. Salted, fermented and acidified fruit and vegetables

Fermented fruits and vegetables are commonly consumed in the EU and include, olives, cabbage, cucumber, legumes, seeds and soya sauce. Olives, cabbage and cucumber are preserved by the addition of salt, absence of oxygen and acidification caused by lactic acid fermentation (Nout and Rombouts, 2000). Salt treatment causes juice to be released from fruit and vegetable tissue, providing nutrients for growth of microorganisms present at their surfaces. The presence of nutrient together with the combination of salt and absence of oxygen create conditions which select lactic acid bacteria. Some pre-treatment may be needed before fermentation, such as lye treatment in the case of green olive to remove bitterness. Salt may be added as crystals or brine. The finished product may be sold directly or desalted and then usually pasteurized to ensure stability at ambient temperature (Nout and Rombouts, 2000). Many vegetables are simply preserved by direct addition of salt and acids (vinegar) without fermentation (pickling). These vegetables can be stored refrigerated or pasteurized and stored at ambient temperature. The salt added during fermentation varies from 2-2.5% (sauerkraut) to 8% (cucumber) w/w of raw vegetables or the brine in which products such as olives are immersed may contain up to 10% salts w/v (Nout and Rombouts, 2000). The pH obtained at the end of fermentation, combined with the salt content and the competitive microflora may exert an inhibitory or lethal effect against foodborne pathogens, although this varies with the type of product. For instance, the pH of fermented cabbage (sauerkraut) and of fermented green olives were reported as slightly below 4 (Nout and Rombouts, 2000). However, this is not always the case, and, for example, black olives have been the cause of *Clostridium botulinum* outbreaks indicating a pH of above 4.4 (Nout and Rombouts, 2000). Figure 11 illustrates the processing of salting and acid fermentation of vegetables and fruit.

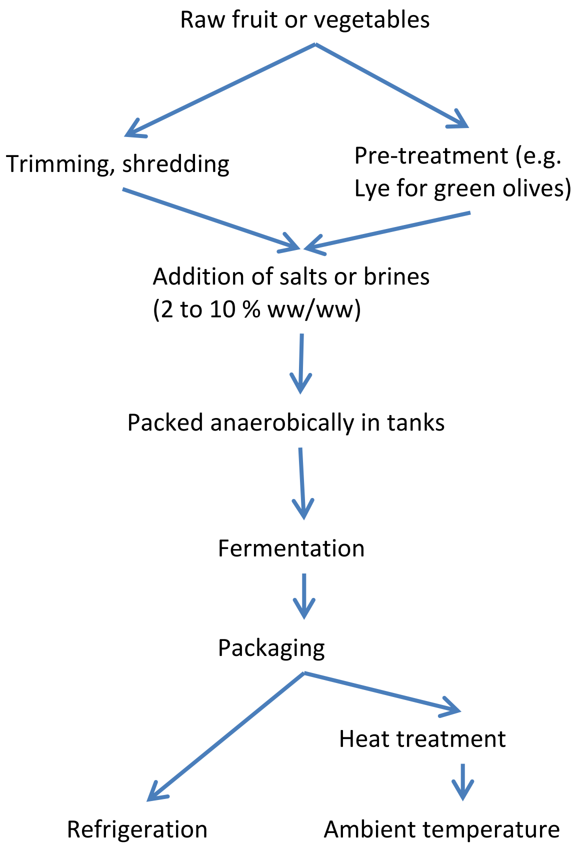

Figure 11: Simplified diagram of fermented vegetables production (Adapted from (Nout and Rombouts, 2000)).

3. Data on biological hazards in FoNAO

3.1. EU foodborne outbreaks associated with FoNAO

EFSA coordinates the annual reporting of zoonoses, zoonotic agents, antimicrobial resistance, foodborne outbreaks and animal populations in the European Union (EU) under the Directive 2003/99/EC[9] as well as with analysing and summarising the data collected. For the data collection purpose, EFSA has created a web-based reporting application. In order to keep the web application abreast with the changing reporting requirements and to ease the reporting, the web application is updated each year.

Data is being collected on a mandatory basis for the following eight zoonotic agents: *Salmonella* spp., thermotolerant *Campylobacter* spp., *Listeria monocytogenes*, verotoxigenic *Escherichia coli*, *Mycobacterium bovis*, *Brucella* spp., *Trichinella* spp. and *Echinococcus* spp..

The zoonoses reporting also includes data on foodborne outbreaks and has been mandatory for reporting from EU Member States since 2005. Starting from 2007, harmonised specifications on the

[9] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40.

reporting of these outbreaks at the EU level has been applied[10]. This data set represents the only comprehensive data source at an EU level (including Norway and Switzerland) for comparisons between FoAO and FONAO. For the purpose of this analysis, data from 2007 to 2011 has been extracted and used. It is important to note that the foodborne outbreak investigation systems at the national level are not harmonised between Member States. Consequently, the differences in the numbers and types of reported outbreaks, as well as the causative agents, may not reflect differences in food safety between Member States; rather than indicate differences in the efficiency and sensitivity of the national monitoring systems for identifying and investigating foodborne outbreaks. This zoonosis reporting nevertheless represents the most comprehensive set of data in the EU.

In 2010, modified reporting specifications for foodborne outbreaks were implemented, and the distinction between 'verified' and 'possible' foodborne outbreaks was changed to 'strong' or 'weak' based on the strength of evidence implicating a suspect food vehicle. In the former case, i.e. where the evidence implicating a particular food vehicle was strong, based on an assessment of all available evidence, a detailed data set was reported for foodborne outbreaks. Where no specific food vehicle was suspected or where the evidence implicating a particular food vehicle was weak, only a limited data set was reported and these were classified as having weak evidence[11].

Table 26 in Appendix B shows detailed information (i.e. the number of human cases, hospitalisations and deaths) for the outbreaks with a strong evidence of association with FoNAO reported from EU countries, Norway and Switzerland between 2007 and 2011. The strength of the evidence related to an outbreak to be reported to EU level is based on an assessment of all available categories of evidence (i.e. descriptive, epidemiological or microbiological evidence)[11]. When more detailed information on the implicated foodstuff was available, foods were further categorised to match the categorisation proposed here in section 2.2. (Table 1). No outbreaks were reported for the following food categories: (i) citrus fruit; (ii) apple and related fruit; (iii) stone fruit; (iv) tropical fruit; (v) fruit mixes; (vi) peppers and aubergines; (vii) gourds and squashes; (viii) leafy greens mixed with other fresh FoNAO; (ix) other leaves; (x) other root and tuberous vegetables; (xi) flowers and flower buds; (xii) other cereals and dry legumes (processed products); (xiii) fungi (mushrooms and yeasts); (xiv) sea vegetables; (xv) beverages; (xvi) vegetable oils; (xvii) fermented, salted, or acidified vegetables or fruit or (xviii) other processed products, sauces and dressings, purées, soup, and pastes (including canned and bottled products) and syrups.

For some foodborne outbreaks no detailed information was available to be able to identify the specific implicated FoNAO. Because of this lack of information it was not possible to take these foodborne outbreaks into account when addressing ToR 2 (i.e. identifying and ranking specific food/pathogen combinations most often linked to foodborne human cases originating from FoNAO in the EU). Because specific information regarding some other variables under analysis (e.g. causative agent, number of human cases, hospitalisations and deaths) was available, this subset of foodborne outbreaks has also been included at the bottom sections of Table 26 (Appendix B) under the following merged food categories: 'vegetables and juices and other products thereof' and 'cereal products including rice and seeds/pulses (nuts, almonds)'. The bottom sections of Table 26 (Appendix B) also show reported foodborne outbreaks for (i) FoNAO, which may include one or more cooked ingredients (e.g. cooked vegetable salads), (ii) foods which normally are subjected to a processing step which should inactivate vegetative cells (e.g. rice, pasta and cereals), (iii) other processed FoNAO and (iv) non-specified fruit.

It should be noted that the numbers of cases, hospitalisations and deaths for all of the foodborne outbreaks reported in the bottom sections of Table 26 (Appendix B) were considered when addressing

[10] EFSA (European Food Safety Authority), 2007. Report of the Task Force on Zoonoses Data Collection on harmonising the reporting of foodborne outbreaks through Community reporting system in accordance with Directive 2003/99/EC. EFSA Journal,123, 1-16.

[11] EFSA (European Food Safety Authority), 2011. Updated technical specifications for harmonised reporting of foodborne outbreaks through the European Union reporting system in accordance with Directive 2003/99/EC. EFSA Journal, 9(4):2101, 24 pp.

ToR 1, i.e. comparing the incidence of foodborne human cases linked to FoNAO and foodborne cases linked to FoAO.

Table 26 shows that 19 countries reported foodborne outbreaks with strong evidence where FoNAO was implicated. Nordic countries, *i.e.* Denmark, Finland, Norway and Sweden reported 51.1% of the foodborne outbreaks with strong evidence where FoNAO was implicated. There is a great variation between reporting practices and rates between countries: some countries did not report any outbreaks with strong evidence, whereas others provided data on a large number of outbreaks with strong evidence. This is also supported by variation in the numbers of reported outbreaks per population between countries. Therefore, the differences in reporting rates reflect differences in ability to identify and investigate foodborne outbreaks as well as reporting practices and levels of food safety.

The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2010 reported an increase in the number of reported outbreaks caused by vegetables and highlights the substantial number of norovirus outbreaks attributed to vegetables reported in 2010 (EFSA/ECDC, 2012).

In order to provide a general overview of the most frequently reported combinations of foodborne pathogen and FoNAO, Table 2 provides a summary of the food type and pathogen group combinations for which more than one outbreak was reported between 2007-2011 with the aggregated numbers of human cases, hospitalisations and deaths. Combinations of pathogen and FoNAO type were ranked by the number of outbreaks reported. When the same number of outbreaks was reported for more than one combination of pathogen and food type, these combinations were ranked by number of human cases.

It should be noted that Table 2 does not include outbreaks implicating : (i) FoNAO, which may include one or more cooked ingredients (e.g. cooked vegetable salads), (ii) foods which normally are subjected to a processing step which should inactivate vegetative cells (e.g. rice, pasta and cereals), (iii) other processed FoNAO, (iv) non-specified fruit nor those (v) where no detailed information was available to be able to identify the specific implicated FoNAO. These excluded outbreaks correspond to 45% of all reported outbreaks implicating FoNAO from 2007-2011 and are distributed as follows:

(i) 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%;

(ii) FoNAO, which may include one or more cooked ingredients (e.g. cooked vegetable salads): 11.4%;

(iii) merged food category ‘vegetables and juices and other products thereof’: 9.1% and

(iv) merged food category ‘cereal products including rice and seeds/pulses (nuts, almonds)’: 0.4%.

The highest number of foodborne outbreaks was reported for the combination norovirus and raspberries (27 outbreaks) followed by norovirus and leafy greens eaten raw as salads (24 outbreaks). The remaining most frequently reported combinations are: *Salmonella* spp. and sprouted seeds (11 outbreaks), *Salmonella* spp. and leafy greens eaten raw as salads (7 outbreaks), *Bacillus* spp. and spices and dry herbs (7 outbreaks), *Shigella* spp. and fresh pods, legumes or grain (4 outbreaks), VTEC and sprouted seeds (3 outbreaks) and norovirus and bulb or stem vegetables (2 outbreaks).

Table 3 shows aggregated data from 2007 to 2011 for reported outbreaks where FoNAO were implicated. Causative agents were ranked according to the associated total numbers of human cases. Pathogenic *Escherichia coli* shows the highest number of human cases which is mostly due to the large VTEC O104 outbreak in Germany in 2011 associated with sprouted fenugreek seeds (3,793 human cases, 2353 hospitalisations and 53 deaths).

Table 2: Number of outbreaks reported for most frequent[(a)] combinations of foodborne pathogen and FoNAO[(b)] (2007-2011)

Foodstuff implicated[(c)]	Causative agent	Number of outbreaks	Human cases	Number of cases hospitalised	Deaths	Number of reporting countries	Distribution of outbreaks per country[(d)] (n = number of outbreaks)
Raspberries	Norovirus	27	913	3	0	3	DK(13), FI(10), SE(4)
Leafy greens eaten raw as salads	Norovirus	24	657	1	0	3	DK(22), FI(1), NO(1)
Sprouted seeds	*Salmonella* spp.	11	521	76	1	8	DE(1), DK(1), EE(1), FI(2), NO(1), NL(1), SE(1), UK(3)
Leafy greens eaten raw as salads	*Salmonella* spp.	7	438	29	0	5	DE(1), FI(1), NO(1), SE(3), UK(1)
Spices and dry herbs	*Bacillus* spp.	7	343	0	0	4	BE (1), DK (2), FR (1), FI(3)
Fresh pods, legumes and grain	*Shigella* spp.	4	268	3	0	3	DK(2), NO(1), SE(1)
Sprouted seeds	VTEC	3	3,830	2,381	53	3	DE(1), DK(1), NL(1)[(e)]
Bulb and stem vegetables	Norovirus	2	18	0	0	2	DE(1), FI(1)

(a) This table lists all food type and pathogen group combinations for which more than one outbreak was reported between 2007-2011 with the aggregated numbers of human cases, hospitalisations and deaths. Combinations of pathogen and FoNAO type were ranked by the number of outbreaks reported. When the same number of outbreaks was reported for more than one combination of pathogen and food type, these combinations were ranked by the number of human cases.

(b) 136 foodborne outbreaks have been excluded due to the fact that the implicated foodstuffs were composite products. In total 219 foodborne outbreaks associated to FoNAO were reported from 2007-2011. Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, is preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'.

(c) Outbreaks implicating: (i) FoNAO, which may include one or more cooked ingredients (e.g. cooked vegetable salads), (ii) foods which normally are subjected to a processing step which should inactivate vegetative cells (e.g. rice, pasta and cereals), (iii) other processed FoNAO, (iv) non-specified fruit or (v) outbreaks where no detailed information was available to be able to identify the specific implicated FoNAO were excluded.

(d) Belgium (BE), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Germany (DE), Netherlands (NL), Norway (NO), Sweden (SE), United Kingdom (UK). Data from Spain has not been included in this table because it was provided outside the EFSA's Zoonosis database and in a different format of aggregation.

(e) In 2011, in addition to the outbreaks reported by Germany, Netherlands and Denmark, France reported 15 VTEC O104 cases in humans associated to 'vegetables and juices and other products thereof' without any additional foodstuff information (please see Appendix B). Therefore these cases could not be attributed to the combination of sprouted seeds and VTEC.

Table 3: Reported outbreaks (in decreasing number of cases) where FoNAO[(a)] were implicated in reporting countries[(b)] in accordance with Directive 2003/99/EC, 2007-2011

Causative agent	Year	Total number of foodborne outbreaks	Human cases	Hospitalisations	Deaths
Pathogenic *Escherichia coli*	2007	1	45	0	0
	2011	7	4,189	2,477	54
Total pathogenic *Escherichia coli*		**8**	**4,234**	**2,477**	**54**
Norovirus	2007	3	506	0	0
	2008	1	29	0	0
	2009	15	665	0	0
	2010	36	985	2	0
	2011	20	531	3	0
Total Norovirus		**75**	**2,716**	**5**	**0**
Salmonella spp.	2007	12	409	27	0
	2008	5	202	62	0
	2009	3	39	3	0
	2010	9	433	56	1
	2011	8	257	50	0
Total *Salmonella* spp.		**37**	**1,340**	**198**	**1**
Bacillus cereus	2007	8	224	0	0
	2008	7	170	2	0
	2009	10	102	0	0
	2010	10	144	0	0
	2011	15	316	4	0
Total *Bacillus cereus*		**50**	**956**	**6**	**0**
Shigella spp.	2007	1	200	0	0
	2008	2	198	6	0
	2009	3	68	3	0
	2010	1	2	1	0
	2011	2	77	6	0
Total *Shigella* spp.		**9**	**545**	**16**	**0**
Staphylococcus aureus	2007	9	158	24	1
	2008	4	56	8	0
	2009	6	75	0	0
	2010	1	27	27	0
	2011	4	70	4	0
Total *Staphylococcus aureus*		**24**	**386**	**63**	**1**
Clostridium perfringens	2007	1	19	0	0
	2008	1	2	0	0
	2009	3	107	0	0
	2011	2	5	4	0
Total *Clostridium perfringens*		**7**	**133**	**4**	**0**
Clostridium botulinum	2010	1	5	4	1
	2011	2	48	1	0
Total *Clostridium botulinum*		**3**	**53**	**5**	**1**
Clostridium spp.[(c)]	2009	1	2	2	0
Total *Clostridium* spp.[(c)]		**1**	**2**	**2**	**0**

Causative agent	Year	Total number of foodborne outbreaks	Human cases	Hospitalisations	Deaths
Cryptosporidium spp.	2008	1	87	4	0
Total *Cryptosporidium* spp.		**1**	**87**	**4**	**0**
Yersinia pseudotuberculosis	2008	1	50	10	0
Total *Yersinia pseudotuberculosis*		**1**	**50**	**10**	**0**
Yersinia enterocolitica	2011	1	21	4	0
Total *Yersinia enterocolitica*		**1**	**21**	**4**	**0**
Hepatitis A virus	2010	1	13	0	0
	2011	1	7	4	0
Total Hepatitis A virus		**2**	**20**	**4**	**0**

(a) Including: cereals and meals, cocoa and cocoa preparations, coffee and tea, coconut, fats and oils (excluding butter), fruits, fruits and vegetables, juices, mushrooms, nuts and nut products, other FoNAO, ready-to-eat salads, dried seeds, sprouted seeds, spices and herbs, vegetables. 136 foodborne outbreaks have been excluded due to the fact that the implicated foodstuffs were composite products. In total 219 foodborne outbreaks associated to FoNAO origin were reported from 2007-2011. Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, is preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'.

(b) EU countries including Norway and Switzerland. Data from Spain has not been included in this table because it was provided outside the EFSA's Zoonosis database and in a different format of aggregation.

(c) Reported as *Clostridium* spp.

3.2. EU foodborne outbreaks associated with FoAO (for comparative purposes)

According to the ToRs of this scientific opinion, EFSA is asked to compare the incidence of foodborne human cases linked to FoNAO and foodborne cases linked to FoAO. This ToR should provide an indication of the proportionality between these two groups as regard humans cases and, if possible, human disease burden.

Therefore, for the purpose of this analysis and using the same reporting criteria, data on occurrence of outbreaks where FoAO were implicated which was reported in EFSA's Zoonoses web-based reporting application from 2007 to 2011 was extracted.

Table 4 shows aggregated data from 2007 to 2011 for reported outbreaks where FoAO were implicated. Outbreaks with the following implicated foods were aggregated: milk, dairy products, fish, fishery products, crustaceans, shellfish, molluscs and products thereof, eggs and egg products and meat and meat products. Causative agents were ranked according to the associated total numbers of human cases from the aggregated outbreaks where FoAO were implicated.

Table 4: Reported outbreaks (in decreasing number of cases) where FoAO were implicated [12] in reporting countries[13] in accordance with Directive 2003/99/EC[14], 2007-2011

Causative agent	Year	Total number of foodborne outbreaks	Human cases	Hospitalisations	Deaths
Salmonella spp.	2007	387	4,697	847	3
	2008	431	5,465	893	7
	2009	182	2,492	570	6
	2010	153	2,674	505	5
	2011	118	1,673	393	3
Total *Salmonella* spp.		**1,271**	**17,001**	**3,208**	**24**
Clostridium perfringens	2007	41	1,198	3	0
	2008	19	733	3	0
	2009	20	519	5	0
	2010	8	253	1	0
	2011	7	520	0	0
Total *Clostridium perfringens*		**95**	**3,223**	**12**	**0**
Clostridium botulinum	2007	15	31	26	0
	2008	9	26	20	0
	2009	10	34	34	1
	2010	4	10	10	0
	2011	3	10	10	0
Total *Clostridium botulinum*		**41**	**111**	**100**	**1**
Clostridium spp.[(a)]	2009	1	3	3	0
Total *Clostridium* spp.[(a)]		**1**	**3**	**3**	**0**
Viruses[(b)]	2007	28	731	56	0
	2008	28	428	24	0
	2009	7	302	2	0
	2010	23	642	2	0
	2011	19	338	5	0
Total Viruses[(b)]		**105**	**2,441**	**89**	**0**
Staphylococcus aureus	2007	93	864	120	2
	2008	52	553	41	0
	2009	37	294	101	2
	2010	16	453	156	0
	2011	9	113	77	0
Total *Staphylococcus aureus*		**207**	**2,277**	**495**	**4**

[12] Including: milk, dairy products, fish, fishery products, crustaceans, shellfish, molluscs and products thereof, eggs and egg products, meat and meat products. In total there were 1859 foodborne outbreaks associated to FoAO reported from 2007-2010. Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, are preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'.

[13] EU countries including Norway and Switzerland. Data from Spain have not been included in this table because they were provided outside the EFSA's Zoonosis database and in a different format of aggregation.

[14] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40

Causative agent	Year	Total number of foodborne outbreaks	Human cases	Hospitalisations	Deaths
Parasites[c]	2007	33	552	296	0
	2008	36	426	259	1
	2009	37	561	257	0
	2010	13	269	74	0
	2011	5	32	28	0
Total Parasites[c]		**124**	**1,840**	**914**	**1**
Campylobacter spp.	2007	21	188	13	0
	2008	15	357	3	0
	2009	6	49	7	1
	2010	25	357	10	0
	2011	32	574	14	1
Total *Campylobacter* spp.		**99**	**1,525**	**47**	**2**
Bacillus cereus	2007	24	288	2	0
	2008	13	237	3	0
	2009	13	149	11	0
	2010	3	9	3	0
	2011	9	130	3	0
Total *Bacillus cereus*		**62**	**813**	**22**	**0**
Pathogenic *Escherichia coli*	2007	9	137	6	0
	2008	11	327	7	0
	2009	13	156	61	0
	2010	1	4	2	0
	2011	4	29	14	0
Total pathogenic *Escherichia coli*		**38**	**653**	**90**	**0**
Other causative agents (*Shigella* spp., *Vibrio* spp., *Yersinia* spp., other bacterial agents)	2007	6	46	6	0
	2008	1	7	1	0
	2009	3	16	1	0
	2010	5	179	14	0
Total other causative agents		**15**	**248**	**22**	**0**
Listeria monocytogenes	2007	1	21	21	5
	2008	1	14	7	0
	2009	3	40	40	11
	2010	2	22	18	3
	2011	2	20	20	20
Total *Listeria monocytogenes*		**9**	**117**	**106**	**39**

(a) Reported as *Clostridium* spp.
(b) Including: Calicivirus, Norovirus, Hepatitis A virus and Flavivirus
(c) Including: *Sarcocystis* spp. and *Trichinella* spp. (*Trichinella spiralis* and *Trichinella* spp., unspecified)

Table 5: Comparison of reported foodborne outbreaks of non-animal and animal origin 2007-2011[(a)]

Oubreaks due to:	Total number of foodborne outbreaks (%)	Human cases (%)	Hospitalisations (%)	Deaths (%)
FoNAO	219 (10)	10,543 (26)	2,798 (35)	57 (46)
FoAO	2,065 (90)	30,230 (74)	5,090 (65)	68 (54)
Total	2,284	40,773	7,888	125

[(a)] Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, is preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'. Data from Spain has not been included in this table because it was provided outside the EFSA's Zoonosis database and in a different format of aggregation.

The annual totals of outbreaks, outbreak cases, hospitalisations and deaths associated to FoNAO and FoAO for 2007 to 2011 is shown in Figs 12-15.

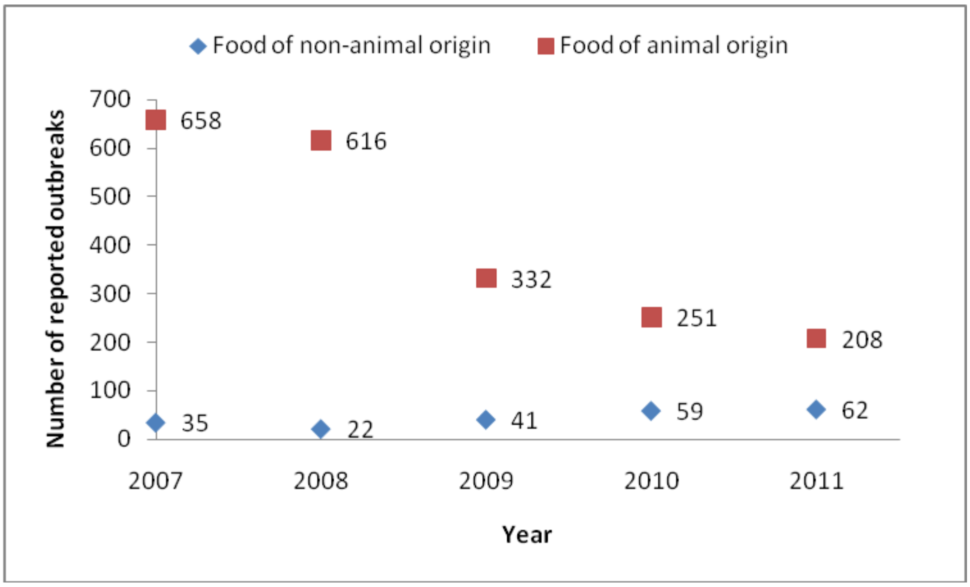

Figure 12: Number of reported outbreaks where FoNAO or FoAO was implicated [15] in reporting countries[16] in accordance with Directive 2003/99/EC[17] from 2007 to 2011.

[15] Including: milk, dairy products, fish, fishery products, crustaceans, shellfish, molluscs and products thereof, eggs and egg products, meat and meat products. In total there were 1859 foodborne outbreaks associated to FoAO reported from 2007-2010. Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, are preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'.

[16] EU countries including Norway and Switzerland. Data from Spain have not been included in this table because they were provided outside the EFSA's Zoonosis database and in a different format of aggregation.

[17] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40

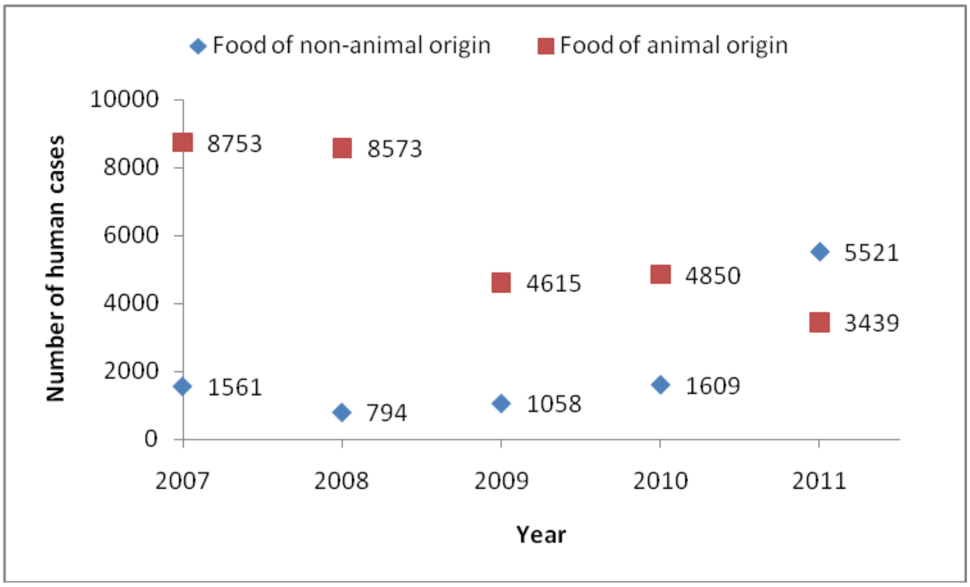

Figure 13: Number of reported human cases where FoNAO or FoAO was implicated [18] in reporting countries[19] in accordance with Directive 2003/99/EC[20] from 2007 to 2011.

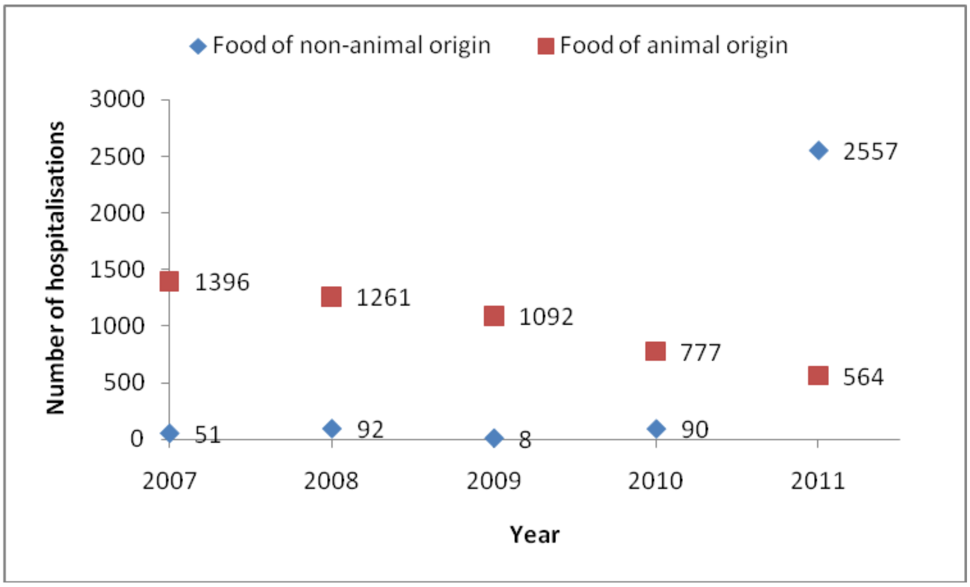

Figure 14: Number of reported hospitalisations where FoNAO or FoAO was implicated [21] in reporting countries[22] in accordance with Directive 2003/99/EC[23] from 2007 to 2011.

[18] Including: milk, dairy products, fish, fishery products, crustaceans, shellfish, molluscs and products thereof, eggs and egg products, meat and meat products. In total there were 1859 foodborne outbreaks associated to FoAO reported from 2007-2010. Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, are preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'.

[19] EU countries including Norway and Switzerland. Data from Spain have not been included in this table because they were provided outside the EFSA's Zoonosis database and in a different format of aggregation.

[20] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40

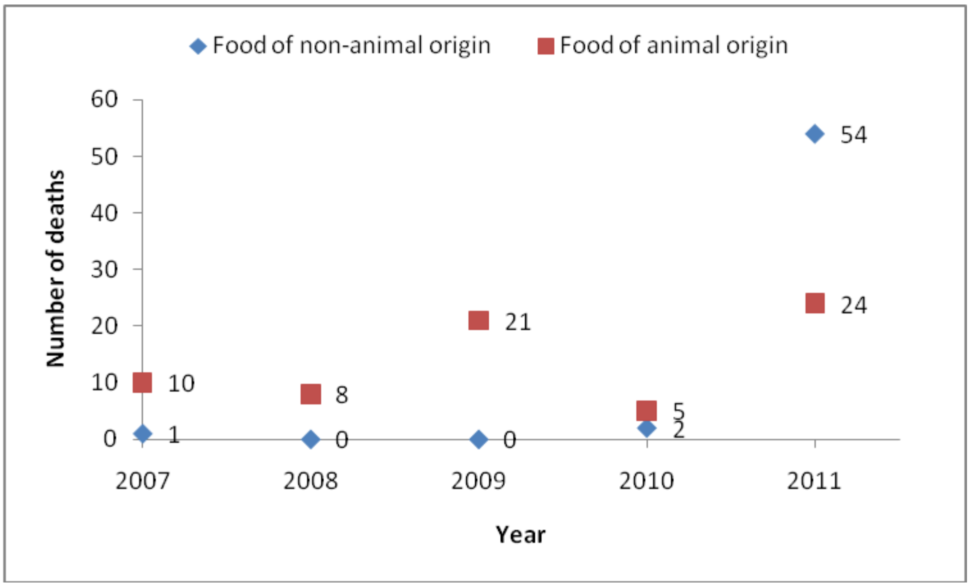

Figure 15: Number of reported deaths where FoNAO or FoAO was implicated [24] in reporting countries[25] in accordance with Directive 2003/99/EC[26] from 2007 to 2011.

Amongst all the foodborne outbreaks reported between 2007 and 2011 where either FoNAO or FoAO were implicated, the FoNAO were associated with 10% of the outbreaks, 26% of the cases, 35% of the hospitalisations and 46% of the deaths (Table 5). There was a considerable increase in these percentages when including data from 2011 which is strongly influenced by the 2011 VTEC O104 outbreak in Germany associated with sprouted seed consumption. For comparison, the same data for 2007-2010 implicated FoNAO as associated with 8% of the outbreaks, 16% of the cases, 5% of the hospitalisations and 6% of the deaths.

From 2008 to 2011 there was an increase in the numbers of reported outbreaks cases, hospitalisations and deaths associated to FoNAO (Figures 12-15). These trends occurred together with a decrease in the numbers or reported outbreaks, cases, hospitalisations and deaths associated with FoAO (Figures 12-15). There is however a general tendency for the outbreaks associated with FoNAO to involve more cases than those associated with FoAO. Trends in data on FoNAO however are strongly influenced by the 2011 VTEC O104 outbreak in Germany associated with sprouted seed consumption

[21] Including: milk, dairy products, fish, fishery products, crustaceans, shellfish, molluscs and products thereof, eggs and egg products, meat and meat products. In total there were 1859 foodborne outbreaks associated to FoAO reported from 2007-2010. Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, are preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'.

[22] EU countries including Norway and Switzerland. Data from Spain have not been included in this table because they were provided outside the EFSA's Zoonosis database and in a different format of aggregation.

[23] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40

[24] Including: milk, dairy products, fish, fishery products, crustaceans, shellfish, molluscs and products thereof, eggs and egg products, meat and meat products. In total there were 1859 foodborne outbreaks associated to FoAO reported from 2007-2010. Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, are preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'.

[25] EU countries including Norway and Switzerland. Data from Spain have not been included in this table because they were provided outside the EFSA's Zoonosis database and in a different format of aggregation.

[26] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40

which illustrates a feature of FoNAO that there is the possibility of causing very large outbreaks which can be of considerable morbidity and mortality. However if the data from this large outbreak is excluded, FoNAO still caused 10% of the outbreaks, 18% of cases, but only 8% of the hospitalisations and 5% of the deaths. Therefore although there is a general tendency for the outbreaks associated with FoNAO to involve more cases than those associated with FoAO, these are less severe in that there is a lower proportion of hospitalisations and deaths.

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 infectious disease risks associated with consumption of FoNAO, particularly in North America with associations between salad and leafy greens with norovirus, VTEC and *Salmonella* spp. (Barton Behravesh et al., 2011; Hall et al., 2012; Wendel et al., 2009). Similar to what has been previously reported in other foodborne outbreak data analysis studies (Greig and Ravel, 2009; Pires et al., 2012) the approach taken in the scope of this opinion is limited by the fact that there are limitations to the categorisation of food at international levels which presents difficulties with standardisation. Also the *a posteriori* categorisation of FoNAO established in the scope of this opinion is influenced by the content of EFSA's zoonoses database, which is not uniformly populated over time nor across EU Member States. Therefore some pathogens and food vehicles may be artificially overestimated and others underestimated. Nevertheless, EFSA's zoonoses database represents the best current source in the EU to link cases, pathogens and vehicles. As previously noted (EFSA, 2008), the use of outbreak data has a major advantage: this data is 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 which should be considered. Outbreak data is reliant on reporting which is incomplete and can vary between Member States, and may be greatly influenced by rare events occurring during the study period, or preferential investigation of types of food perceived as high risk (e.g. FoAO). 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 is often limited, and although important trends may be evident from outbreaks, there can be considerable differences between the relative importance of sources to outbreak related and sporadic cases. The use of outbreak data sets also excludes outbreaks where the etiological agent and/or the food source has not been identified. In addition, extrapolating information from outbreak data sets in an attempt to describe a foodborne disease burden is not straightforward. The method will underestimate the importance of diseases which are of a more apparently sporadic nature (such as those due to *Listeria monocytogenes*, *Campylobacter* spp. and parasites) or of more general risks such as antimicrobial resistance. It has not been possible to quantify the uncertainty caused by these shortcomings, but they are believed to be equally applicable to both FoNAO as well as FoAO. In addition, the approach of using outbreak data reported as part of EU Zoonoses Monitoring is at the moment considered to be the only option for providing a EU-wide comparative estimate of the proportion of human cases due to FoNAO and FoAO. This is because there is no EU wide harmonised monitoring of FoNAO and the only data available is from individual surveys differing in both focus and sampling design making data comparison at the level of specific food-pathogen combinations inappropriate. Since the analysis is based on human outbreak cases only and these results cannot be extrapolated to sporadic cases as explained above, it is not possible to estimate the incidence of illness associated with FoNAO and FoAO, respectively.

3.3. EU Zoonoses Monitoring data on occurrence of foodborne pathogens in FoNAO

Data on the occurrence of foodborne pathogens in FoNAO which was reported as part of EFSA's Zoonoses web-based reporting from 2004 to 2011 is summarised in Tables 27 and 28 in Appendix C. Data on occurrence of *Listeria monocytogenes* in FoNAO for 2004 is excluded, since it was not possible to allocate the data to the required subtotals in the columns in Table 28. For the purpose of this analysis, all FoNAO were aggregated and data is presented at an EU level per hazard (total and number of samples positive and number of countries contributing) for each reporting year.

All reported investigations have been included in the analysis as well as those reported as imported foods. Regarding the framework of sampling, data from environmental sampling as well as clinical investigations is excluded, whereas data reported as part of a Hazard Analysis and Critical Control Points (HACCP) or other controls as well as data from surveys, monitoring and surveillance is included. Investigations where the framework of sampling was not reported were also included in this analysis. According to the guidelines for the annual reporting of zoonoses, zoonotic agents, antimicrobial resistance, foodborne outbreaks and animal populations in the European Union (EU) under the Directive 2003/99/EC[27] the following definitions apply for the framework of sampling:

- *HACCP (Hazard Analysis and Critical Control Point):* programme designed to effectively control processes by identifying Critical Control Points (CCP), establishing critical limits for each CCP, monitoring CCP, gathering data, record keeping, implementing corrective actions and verification procedures. HACCP is applied by the food or feed business operators (*Codex Alimentarius*).

- *Monitoring:* system of collecting, analysing and disseminating data on the occurrence of zoonoses, zoonotic agents and antimicrobial resistance related thereto. As opposed to surveillance, no active control measures are taken when positive cases are detected (Directive 2003/99/EC).

- *Surveillance***:** a careful observation of one or more food or feed businesses, food or feed business operators or their activities (in the context of the food and feed control Reg. (EC) No 882/2004). In general, it means a close and continuous observation for the purpose of control. As opposed to monitoring, active control measures are taken when positive cases are detected. This type of programme does not necessarily have a defined target for diseases/contamination occurrence reduction.

- *Survey:* study involving a sample of units selected from a larger, well - delineated population. This (target) population is the entire set of units to which findings of the survey are to be extrapolated. The units to examine are to be selected randomly (Rothman, 1986 and Noordhuizen et al., 2001).

Table 6 summarises the total number of samples investigated as well as the total number of positive samples for each reported foodborne pathogen for the period from 2004 to 2011. It should be noted that monitoring and surveillance schemes for most zoonotic agents reported via EFSA's Zoonoses web-based application are not harmonised between Member States, and findings must, therefore, be interpreted with care. The data presented may not necessarily derive from sampling plans that are statistically designed, and may not accurately represent the national situation regarding zoonoses. Results are generally not directly comparable between Member States and sometimes not even between different years in one country.

[27] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40.

Table 6: Reported occurrence of *Salmonella* spp., pathogenic *Escherichia coli, Campylobacter* spp., *Listeria monocytogenes*, *Staphylococcus aureus*, *Yersinia* spp., *Cronobacter* spp. and viruses in FoNAO in the reporting countries in accordance with Directive 2033/99/EC[28], 2004-2011[(a)]

Foodborne pathogen	Number of reporting countries[(b)]	Total number of samples	Total number of positive samples	Prevalence (%)
Salmonella spp.	26	121,869	584	0.48
Pathogenic *Escherichia coli*	21	11,240	31[(c)]	0.28
Campylobacter spp.	13	4,631	34	0.73
Listeria monocytogenes[(d)]	24	32,988	884 [(e)]	2.68
Staphylococcus aureus	4	703	12	1.71
Staphylococcal enterotoxins	4	43	3	6.98
Yersinia spp.	4	1,000	236[(f)]	23.60
Cronobacter spp.	1	25	0	0.00
Viruses	1	88	0	0.00

(a) Data for the year 2011, extracted by EFSA's Unit on Biological Monitoring on 24/09/2012, is preliminary, until the publication of 'The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Foodborne Outbreaks in 2011'.
(b) EU countries including Norway and Switzerland
(c) The 31 positive samples were reported as follows: 15 samples positive for *Escherichia coli* O157, 11 positive for VTEC unspecified and 3 positive for non-O157 VTEC.
(d) Available 2004 data on occurrence of *Listeria monocytogenes* in FoNAO is excluded, due to the fact that this data did not allow extraction of the total number of positive samples.
(e) Counts > 100 cfu/g were observed for 22 samples (0.07%)
(f) The 236 positive samples were reported as follows: 173 positive for *Yersinia enterocolitica;* 59 positive for *Yersinia* spp. unspecified; 5 positive for *Yersinia kristensenii* (one sample was positive both for *Yersinia enterocolitica* and *Yersinia kristensenii*).

3.4. Rapid Alert System on Food and Feed (RASFF) notifications on FoNAO

Under Regulation EC N 178/2002 (art. 50) the Member States of the European Union are obliged to notify to the EC any event and measure taken regarding consignments of food and feed (e.g. withholding, recalling, seizure or rejections of imported consignments not complying with food legislation) where a potential risk to human health has been identified. The RASFF team at the EC maintains daily updates of the database. EMRISK serves as the EFSA single contact point to provide scientific and technical support to the RASFF team (EC/178/2002 art. 35 and 50).

The database includes detailed information on each notification, including the type and date of notification, the reason for notification (i.e. description of the subject related to the hazard and product under concern), the hazard(s) identified, the nature and traceability of product(s) involved, the country of notification, the country of origin, the laboratory analyses performed with corresponding contamination levels detected, and the size of the consignment.

The subsets of variables considered relevant for this analysis included the reference number of the notification, the date of notification, the type of notification (e.g. feed, food, food contact material), the alert category (e.g. alert, information, news), the reason for notification (e.g. description of the hazard found in a specific commodity), the hazard category, the specific hazard, the product category, the specific product, the notifying country, and the country of origin.

In order to facilitate the analysis, data has been reclassified where needed. In order to allow for counting the frequency with which each hazard was notified, replicates have been created for each

28 Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40

notification containing multiple hazards. Each replicate contains a single specific hazard, such as for example a chemical substance or a pathogen. The replicates were assigned a number in a separate row, once for each replicate. The same has been done for each replicate for a specific hazard category. For example, if a notification mentioned two chemical and one biological hazards, three replicates were created, i.e. two for the chemical hazards and one for the biological hazard. The following categories of biological hazards have been excluded from the analysis: *Citrobacter* spp., coliforms, *Cronobacter* spp., *Enterobacter* spp., *Enterobacteriaceae,* microbiological contamination *Pseudomonas aeruginosa* and streptococci.

For the purpose of the current analysis we have limited the analysis to "alert", "information", "border rejections" and "news" notifications, excluding "follow-up" notifications, notified between Jan 2001 to Dec 2011. Excluding follow-up notifications assures that notifications included refer to independent events. However, it can not be excluded that a limited number of notifications included in the analysis could refer to the same event. The analysis has been limited to FoNAO, namely the following RASFF product categories: (i) cereals and bakery products (ii) cocoa and cocoa preparations, coffee and tea (iii) fruits and vegetables (iv) herbs and spices (v) non-alcoholic beverages (vi) nuts, nut products and seeds (vii) other food product / mixed. Product variable has been recoded in order to generate all the specific FoNAO categories listed in Table 29.

Detailed information regarding the retrieved RASFF notifications is provided in Appendix D, (Tables 29 to 31). Table 30 shows that the combinations of foodborne pathogens/food products which were most frequently notified are: *Salmonella* spp. in 'Other herbs and spices' and *Salmonella* spp. in 'mixed and other produce' with 184 and 111 RASFF notifications respectively.

Table 31 provides a summary of the information available for the RASFF notifications regarding 14 foodborne outbreaks associated to FoNAO. In addition to these the following 5 news notifications were also recoded as foodborne outbreaks: (i) UK *Salmonella* Newport outbreak associated with lettuce (October 2004), (ii) USA/Canada *Salmonella* Lichtfield associated with cantaloupes from Honduras (March 2008), (iii) USA *Salmonella* Saintpaul outbreak initially attributed to tomatoes (June 2008), (iv) USA *Salmonella* Typhimurium outbreak associated with peanut butter (January 2009) and (v) Australia/France/Netherlands hepatitis A virus outbreak associated with semi-dried tomatoes from Turkey (November 2009 - March 2010).

When interpreting statistical data from the RASFF database, it should be noted that figures in the RASFF are not fully comparable across the different Member States. In fact, whilst RASFF notifications are based on existing EU legislation, food safety events reported by Member States strongly depend on national surveillance programs and by the efficiency of national laboratory facilities. These may vary substantially from country to country. Incident notifications may follow reports of illness, or detection of viruses in a food product, or both. Another limitation is that the filtering of the notifications to be sent to the RASFF at a national level is only partially harmonised across Member States and an unknown proportion of food incidents occurring at a national level are not notified. Thus, RASFF notifications are not based on fully harmonised notification criteria and are not statistically representative neither of the occurrence of foodborne pathogens in food products nor of the distribution of foodborne outbreaks associated to FoNAO. Consequently, these figures have to be interpreted with care.

3.5. Foodborne outbreaks and incidents associated with FoNAO from scientific literature

The aim of this section is to identify food/pathogen combinations that were not detected in the analysis of EU Zoonoses Monitoring data (2007-2011), or in RASFF notifications, but which are likely to occur in the EU. These food pathogen combinations were identified by expert-guided review of peer-reviewed literature but not a systematic literature review and included either:

- those reported in Europe over the period 2007-2011 which were part of outbreaks, sporadic cases or identified by analytical epidemiological studies

- or not included in any of the above but considered relevant for the EU. This category included episodes reported in the EU outside the period 2007 -2011 or those from other regions of the world. This review includes data from individual case and outbreak reports as well as case control studies.

3.5.1. *Salmonella* spp.

Consumption of FoNAO not already identified as associated salmonellosis includes: vegetables including tomatoes and peppers (CDC, 2005; Greene et al., 2008; Gupta et al., 2007; Mody et al., 2011; SSI, 2011), fresh herbs (Elviss et al., 2009; Pezzoli et al., 2008), types of whole, fresh, pulped, frozen or juiced fruits (e.g. melons, oranges, papaya, mangoes)(CDC, 2006a, 2010, 2011b, 2012a, 2012b; Gibbs et al., 2009; Loharikar et al., 2012; Noel et al., 2010; Sivapalasingam et al., 2003; Vojdani et al., 2008); salads and other leafy greens (Barton Behravesh et al., 2011; CDC, 2006b; Gajraj et al., 2012; Nygard et al., 2008); nuts, seeds and derived products, e.g. almonds, peanuts, coconut and sesame seeds (Brockmann et al., 2004; Cavallaro et al., 2011; Koch et al., 2005; Rabsch et al., 2005; Rimhanen-Finne et al., 2011; Teoh et al., 1997; Unicomb et al., 2005; Ward et al., 1999), corn or rice snacks (Joseph et al., 1991).

3.5.2. Verocytotoxin-producing *Escherichia coli* (VTEC)

Outbreaks of VTEC infection in Europe during 2007-2011 and identified as associated with consumption of FoNAO included; shredded lettuce in Denmark (Friesema et al., 2008); and handling loose raw leeks and potatoes in UK (HPA, 2011). From data prior to 2007 in the EU, the following foods were associated with VTEC outbreaks: handling raw vegetables, particularly potatoes in the UK (Morgan et al., 1988); and lettuce in Sweden (Soderstrom et al., 2008). For VTEC outbreaks outside the EU, the following additional associations were reported: apple juice in the US (Besser et al., 1993); vegetables in the US (Cieslak et al., 1993); lettuce and spinach in the US (Ackers et al., 1998; CDC, 2006b, 2010); white radish sprouts and celery cabbage kimuchi in Japan (Kimura et al., 2006; Michino et al., 1999); and in-shell hazelnuts (CDC, 2011a). Outbreaks associated with pathogenic *Escherichia coli* other than VTEC, have implicated lime and/or banana leaves in Sweden (Livsmedelsverket, 2000); and Lollo biondo lettuce in Denmark (Ethelberg et al., 2010b).

3.5.3. *Campylobacter* spp.

Foods associated with foodborne *Campylobacter* spp. disease are rare, or rarely reported. No additional associations between *Campylobacter* spp. and FoNAO consumption were identified in the EU during 2007-2011.

In the EU prior to 2007, analytical epidemiological studies amongst sporadic cases identified consumption of lettuce in Ireland (Danis et al., 2009), salad products in Wales (Evans et al., 2003). Consumption of raw peas (Gardner et al., 2011) and melon (Bowen et al., 2006) were reported as associated with outbreaks of *Campylobacter* spp. infection in the US. Amongst sporadic cases in infants in the US, one study identified eating fruit and vegetables prepared in the home as a significant risk factor (Fullerton et al., 2007).

3.5.4. *Shigella* spp.

Outbreaks of shigellosis in Europe identified as associated with consumption of FoNAO in Europe during 2007-2011included an outbreak in Denmark (and Australia) associated with baby corn (Lewis et al., 2009), fresh basil in Norway (Guzman-Herrador et al., 2011) and handling salad in Austria (Kuo et al., 2009).

From data prior to 2007, lettuce was associated with shigellosis outbreaks in Europe (Frost et al., 1995; Kapperud et al., 1995). In the USA, outbreaks were associated with fresh parsley (CDC, 1999) and tomatoes (Reller et al., 2006), and raw carrots (Gaynor et al., 2009) and salad preparation (Dunn et al., 1995).

3.5.5. *Yersinia enterocolitica* and *pseudotuberculosis*

Outbreaks of *Yersinia pseudotuberculosis* infection in Europe during 2007-2011 included those associated with raw and grated carrots in Finland, usually after storage at refrigerator temperatures (Jalava et al., 2006; Kangas et al., 2008; Rimhanen-Finne et al., 2009) and *Yersinia enterocolitica* with bagged 'raddichio rosso' salad in Norway (MacDonald et al., 2011).

From data prior to 2007 or outside Europe, consumption of salads has been associated with *Yersinia enterocolitica* outbreak in Japan (Sakai et al., 2005). *Yersinia pseudotuberculosis* has been associated with consumption of iceberg lettuce in Finland (Nuorti et al., 2004), non-commercially produced bean sprouts in US (Cover and Aber, 1989) and soya bean curd in the US (Tacket et al., 1985).

3.5.6. *Listeria monocytogenes*

The consumption of a wide range of contaminated food types have been associated with transmission of listeriosis, however because of difficulties in investigation, for the majority of cases, a specific food vehicle is not identified. In the EU during 2007 to 2011, analytical epidemiology identified a significant risk amongst sporadic cases in England and Wales with consumption of pre-packed mixed salad vegetables (Little et al., 2010) and mixed salads (Gillespie et al., 2010). Rice salad was associated with an outbreak of gastrointestinal listeriosis in Italy in 1993 (Salamina et al., 1996).

Consumption of the following FoNAO have been associated with incidents of listeriosis in the EU prior to 2007: salted mushrooms in Finland (Junttila and Brander, 1989), vegetable rennet in England (Kerr et al., 1988). Consumption of the following foods has been associated with transmission of human disease outside the EU: coleslaw salad in Canada (Schlech et al., 1983); alfalfa tablets in Canada (Farber et al., 1990); raw broccoli and cauliflower in the US (Simpson, 1996), cantaloupe melon in the US (CDC, 2011b), and celery in the US (Gaul et al., 2013).
In addition there were epidemiological associations without microbiological confirmation in an outbreak associating consumption of raw celery, tomatoes, and lettuce amongst hospitalized cases in the US (Ho et al., 1986). Risks were associated with consumption of fruit and vegetables FDA risk assessment on foods consumed in the US, but these were identified as of low predicted relative risk[29].

3.5.7. *Staphylococcus aureus*

No additional associations between *Staphylococcus aureus* and FoNAO consumption were identified in the EU. However outbreaks of *Staphylococcus aureus* foodborne poisoning were reported as associated with, mushrooms in two outbreaks in the US (Hardt-English et al., 1990; Lindroth et al., 1983), and rice balls in Japan (Seok Seo and Bohach, 2007).

3.5.8. *Bacillus cereus* and other *Bacillus* species

Bacillus cereus food poisoning has frequently been linked to heat treated foods which support growth of this bacterium, particularly in case of storage at inadequate temperatures (EFSA, 2005). Diarrhoeal or emetic diseases are frequently mild and self-remitting, although some fatal cases have been reported, food poisoning caused by this bacterium is likely to be considerable under diagnosed. Among FoNAO associated with *Bacillus cereus*, cooked rice and pasta dishes have been major causes of emetic foodborne *Bacillus cereus* (EFSA, 2005). Other FoNAO have caused *Bacillus cereus* foodborne illnesses and these have included: home-grown sprouted seeds, vegetarian meat substitute, vegetable purées, potato salads, orange juice from concentrate, onion powder (EFSA, 2005). Since 2007, *Bacillus cereus* foodborne outbreaks within the EU have been implicated with breakfast cereals (Duc et al., 2005), pasta salad (Dierick et al., 2005), pasta (Saleh et al., 2012), spaghetti meal (Naranjo et al., 2011), rice pudding (Kamga Wambo et al., 2011), vegetable purée (de Buyser et al., 2008), and with fried rice in Japan (Ichikawa et al., 2010). Rare foodborne episodes have been caused by other *Bacillus* species, *Bacillus subtilis* (Kramer and Gilbert, 1989), *Bacillus licheniformis* (Kramer and

[29] www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm184072.htm

Gilbert, 1989), *Bacillus pumilus* (From et al., 2007). *Bacillus subtilis* has been associated with bread, crumpet, vegetables dishes, and *Bacillus pumilus* with rice (Kramer and Gilbert, 1989).

3.5.9. *Clostridium botulinum*

The consumption of a wide range of food types have been associated with the growth of *Clostridium botulinum* and botulism, particularly where domestic preservation practices have been used. The following additional FoNAO types have been associated with transmission in the EU between 2007 to 2011: Preserved olives in Finland and Italy (Cawthorne et al., 2005; Jalava et al., 2011). Prior to 2007, other FoNAO have been associated with cases botulism in the EU including: garlic preserved in oil in Denmark (Lohse et al., 2003). Home bottled mushrooms in England (Roberts et al., 1998) and home preserved asparagus in Italy (Zanon et al., 2006). Other FoNAO associated with botulism outside the EU have included include: canned, bottled, vacuum packed and preserved vegetables in the US (Date et al., 2011; Horwitz et al., 1975; Roberts et al., 1998; Zanon et al., 2006), vegetable products and juices in the US (CDC, 2006a; Sheth et al., 2008); dried and fermented bean curd in the US and Taiwan (CDC, 2007a; Lai et al., 2011), an alcoholic vegetable drink in the US (Vugia et al., 2009); vegetables in oil in the US and Canada (Lohse et al., 2003; Morse et al., 1990; St Louis et al., 1988); aluminium foil-wrapped baked potatoes in the US (Cawthorne et al., 2005; Pingeon et al., 2011); preserved olives in Finland and Turkey (Jalava et al., 2011; Swaan et al., 2010) and potato salad as well as potato soup in the US (Bhutani et al., 2005; CDC, 2011c; Seals et al., 1981). Consumption of corn syrup has been epidemiologically identified as a risk factor for infant botulism in the US (Olsen and Swerdlow, 2000; Spika et al., 1989).

3.5.10. *Clostridium perfringens*

Clostridium perfringens is generally associated with growth in protein rich meat, or less commonly fish, meals following poor temperature and time control. An outbreak has been reported in Japan associated with a consumption of a spinach and fried bean curd dish (Miwa et al., 1999).

3.5.11. Norovirus

The following additional FoNAO types that have been associated with outbreaks of norovirus infection in the EU during 2007 to 2011: raspberries, including fresh frozen products in Finland (Maunula et al., 2009); lettuce in Denmark (Ethelberg et al., 2010a) and prepared salad in Austria (Schmid et al., 2007) and fruit in the US (Hall et al., 2012). Prior to these reports raspberry consumption was also associated with norovirus outbreaks in Denmark, Sweden and France (Cotterelle et al., 2005; Falkenhorst et al., 2005; Le Guyaderm et al., 2004).

3.5.12. Hepatitis A virus

Hepatitis A infection was associated with semi-dried tomatoes (including those preserved in oil) in several EU countries during 2007-2011 (Carvalho et al., 2012; Fournet et al., 2012; Gallot et al., 2011; Petrignani et al., 2010). Fresh and subsequently frozen raspberries were associated with outbreaks of hepatitis A in the UK (Ramsay and Upton, 1989; Reid and Robinson, 1987). An outbreak of hepatitis A in England in 1989 was identified as associated with bread (unwrapped rolls, sandwiches or filled rolls) that was contaminated by food handlers (Warburton et al., 1991). The following additional FoNAO types have been associated with transmission of hepatitis A outside the EU; raw blue berries in New Zealand (Calder et al., 2003) and frozen strawberries in the US (Hutin et al., 1999), lettuce in the US (Rosenblum et al., 1990) and green onions in the US (Wheeler et al., 2005).

3.5.13. Other viruses

No specific information was identified on relevant infections associated with other viruses and consumption of FoNAO.

3.5.14. Protozoan and Metazoan Parasites

Amongst the protozoan and metazoan parasites, a range of agents have been associated with human infections associated with transmission via consumption of FoNAO. Within the EU during 2007 to 2011, the following associations were identified amongst outbreaks of infection caused by protozoan parasites: *Cryptosporidium hominis* and items in a salad bar in Denmark (Lewis et al., 2009) and *Cyclospora cayetanensis* and sugar snaps in Sweden (Insulander et al., 2010). Epidemiological associations were suggested between *Cryptosporidium* spp. or *Giardia* spp. and mung bean sprouts in Norway (Robertson et al., 2005). Analytical epidemiological studies amongst sporadic cases of toxoplasmosis identified significant associations between infection and consumption of unwashed raw vegetables or fruit in Northern Portugal (Lopes et al., 2012). Studies prior to 2007 in the EU identified an outbreak of *Cyclospora cayetanensis* infection associated with contaminated salad in Germany and analytical epidemiological analysis of sporadic toxoplasmosis cases in France identified frequent consumption of raw vegetables outside the home as a significant risk factor (Baril et al., 1999) and eating unwashed raw vegetables or fruits in Norway (Kapperud et al., 1996).

Outbreaks in the US and Canada have identified association between: *Giardia* spp. and raw, sliced vegetables (Mintz et al., 1993); *Cryptosporidium parvum* and fresh pressed apple juice (Blackburn et al., 2006; Millard et al., 1994); *Cyclospora cayetanensis* and raspberries (Herwaldt and Beach, 1999; Ho et al., 2002) fresh basil (Lopez et al., 2001) and Tai basil (Hoang et al., 2005) and snow peas (CDC, 2004).

Amongst the metazoan parasites reported as causing infection in the EU, there is some conflicting results for an association between consumption of unwashed strawberries and *Echinococcus multilocularis* infection (Wahlstrom et al., 2012). The association between *Fasciola hepatica* infection and water-cress consumption has long been recognised and also was identified within analytical epidemiological studies in France (Mailles et al., 2006; Rondelaud et al., 2001) as well as in South America (Marcos et al., 2006). *Ascaris lumbricoides* infection was associated with an outbreak in Scandinavia associated with consumption of imported vegetables (Raisanen et al., 1985).

3.5.15. Other hazards including those occurring outside Europe

Other microbiological hazards may occur through consumption of FoNAO, which are of a generic nature, and these include the antibiotic resistance and toxic amines. Since antibiotic resistance and toxic amines hazards are of a generic nature and cannot be identified as associated with any one individual pathogen or groups of pathogens, these are not further considered, however FoNAO may be of importance as a vehicle for exposure to consumers.

Contamination of fresh food of plant origin has been increasingly recognized in many parts of the world as a source of pathogens (Lynch et al., 2009). Moreover, these food products may serve as a vehicle of ESBLs, as demonstrated by the recent description of *Enterobacteriaceae* carrying CTX-M genes in spinach, parsnip, bean sprouts and radish (Raphael et al., 2011; Reuland et al., 2011a) and SHV-2 in ready-to-eat salads (Campos et al., 2011). ESBLs have been detected in Dutch vegetables. Out of 79 analysed samples, four yielded ESBL-producing *Enterobacteriaceae* (5%). ESBLs were found in parsnip, bean sprouts and radish; this means that three (17,6%) of the vegetable types were contaminated with ESBLs. Of the four positive samples, three were from vegetables of organic origin. The ESBL-producing strains were *Enterobacter cloacae* (in two samples), *Citrobacter braakii* (in one sample) and *Klebsiella pneumoniae* (in one sample). Three strains carried a blaCTX-M-1, and one a blaSHV gene (Reuland et al., 2011b). Recently a large outbreak produced by CTX-M-15-producing *Escherichia coli* O104:H4, and linked to the consumption of contaminated sprouts has occurred in Northern Europe[30].

Other microbiological hazards may occur which could not be further assessed. For example high levels of beta-haemolytic *Pseudomonas fluorescens* were detected in beetroot collected during seven

[30] http://ecdc.europa.eu/en/healthtopics/escherichia_coli/epidemiological_data/Pages/Epidemiological_updates.aspx

outbreaks (124 cases) in Finland in 2010 with of sudden onset gastrointestinal illness of with incubation times around 40 minutes and average duration of five hours (Jacks et al., 2012). Consumption of raw beetroot was strongly associated with the outbreaks and no foodborne pathogen or toxins were found in either clinical specimens or beetroot samples. *P. fluorescens* are spoilage bacteria but a toxin-producing capability and adverse effect on human health has not been reported previously.

For foods consumed outside the EU, microbiological hazards occur which have not been recognised within Europe, often because the specific foods or food preparation practices do not occur. For example large outbreaks of severe food poisoning of high mortality occur in Asia associated with consumption of *Burkholderia gladioli* contaminated fermented soybean and coconut-based product known as 'tempe bongkrek' (Somprasong et al., 2010). Outbreaks of botulism have been associated with a commercially produced fried lotus-rhizome (Otofuji et al., 1987). Furthermore, parasitological hazards can be considerably more important in other parts of the world. For example in South America, there is epidemiological evidence for *Trypanosoma cruzi* infection associated with beverages made from either contaminated fresh produce (sugarcane juice, açai or bacaba juice, palm wine, guava juice and passion-fruit juice), or contaminated oranges (Pereira et al., 2009).

3.6. Ecology, survival and methods to detect microbiological hazards in FoNAO from scientific literature

In general, survival, growth and multiplication of microorganisms in food depend on various factors which may be classified simply into those that are intrinsic or associated with the food material and those that are extrinsic or associated with the environment surrounding the food. Data on the survival, limits for growth and growth prediction of foodborne pathogens has been recently reviewed (EFSA Panel on Biological Hazards (BIOHAZ), 2012c): and the major effects of pH, water activity and temperature on the growth and survival of the individual pathogens will be briefly outlined in section 4.3.7.

3.6.1. *Salmonella* spp.

Animals are the natural reservoirs of *Salmonella* spp. and pork, poultry, and other meat types, eggs and dairy products are the most commonly implicated sources in salmonellosis outbreaks. Surveys of fresh produce have revealed contamination with *Salmonella* spp. in commodities such as tomatoes, lettuce, salad greens, sprouting seeds, fruit juice, cantaloupe melons and nuts. Contamination usually results from either direct contact with animals and animal faeces, or indirect contact via soil, water, factory sites, equipment etc.

Methods for detection of *Salmonella* spp. in FoNAO are well developed and analytical reference methods standardised and widely adopted across laboratories testing food, including that for Official Control: EN/ISO 6579 are specified in Commission Regulation EC No 2073/2005, Microbiological Criteria for Foodstuffs. Alternative methods based on immunoassays and PCR are also available for rapid detection.

3.6.2. Pathogenic *Escherichia coli*

Pathogenic *Escherichia coli* causing gastrointestinal disease derive from the faeces of animals and humans which is the direct or indirect source of contamination for FoNAO. Person to person transmission is common. Survival for prolonged periods of time in soil, manure and manured soil has been reported together with survival on the surface of vegetables.

These pathogenic *Escherichia coli* can be divided into six groups based on different virulence factors, clinical symptoms and serotypes: Shiga-toxin producing *Escherichia coli* (STEC also known as verocytotoxin producing *Escherichia coli* (VTEC), enteropathogenic *Escherichia coli* (EPEC), enteroaggregative *Escherichia coli* (EAEC), enterotoxigenic *Escherichia coli* (ETEC), enteroinvasive *Escherichia coli* (EIEC) and diffusely adherent *Escherichia coli* (DAEC). Amongst *Escherichia coli* capable of causing intestinal disease VTEC are strongly associated with the most severe forms of the infection.

Although the detection and quantification of generic *Escherichia coli* is commonly performed, the detection of pathogenic *Escherichia coli* is more problematic. Methods are most developed for VTEC serotypes (O157 as well as O26, O111, O103, O145 and O104) and an international method (ISO/TS 13136) is available. Alternative methods are also available for VTEC.

3.6.3. *Campylobacter* spp.

Thermotolerant *Campylobacter* spp. (particularly *Campylobacter jejuni and Campylobacter coli)* commonly occur in the faeces of wild birds, broiler chickens and sometimes other animals including also rodents and insects. Contamination results from direct or indirect contact with avian or mammalian faeces and survival of *Campylobacter jejuni* in water or on various types of fresh produce may occur which is sufficient to pose a risk to the consumers.

Detection and quantification of *Campylobacter* spp. can be achieved by the use of cultural methods, and standard methods (ISO/TS 10272) are available. DNA based detection methods are also commercially available. However, the results from rapid/alternative methods should preferably be confirmed by isolation of the bacteria as the methods may detect for example DNA from dead cells (PCR).

3.6.4. *Shigella* spp.

Shigella spp. are a group of enteric pathogens exclusive to humans, hence contamination of FoNAO results from direct or indirect contamination from human faeces, hence the importance of infected food handlers. Shigellae can survive in water and on the surfaces of FoNAO. There is very limited food surveillance data for the presence of *Shigella* spp. in FoNAO, particularly outside outbreaks of infection. Although there is an international standard method (BS EN ISO 21567), isolation from foods is notoriously difficult.

3.6.5. *Yersinia enterocolitica* and *pseudotuberculosis*

Yersinia enterocolitica and *Yersinia pseudotuberculosis* can be found in the intestinal contents of a range of animals and is commonly isolated from different environments such as lakes, rivers, wells, and soil although *Yersinia pseudotuberculosis* is probably less widely distributed in the environment. There is limited information available on the occurrence of *Yersinia enterocolitica* and *Yersinia pseudotuberculosis* in FoNAO and the ISO 10273 and NMKL 117 isolation methods are currently under revision. PCR based methods are also available.

3.6.6. *Listeria monocytogenes*

Listeria monocytogenes is widespread in the environment and commonly occurs in sewage, sewage sludge, silage, soil, straw, hay, grass, vegetable materials, animal feed, drains, machinery, and surface waters(Colburn et al., 1990; Farber and Peterkin, 1991). Consequently FoNAO will commonly be contaminated by this bacterium.

Methods for detection of *Listeria* spp. (including *Listeria monocytogenes*) in FoNAO are well developed and analytical reference methods standardised and widely adopted across laboratories testing food, including that for Official Control: EN/ISO 11290-2 and EN/ISO 11290-2 are specified in Commission Regulation EC No 2073/2005, Microbiological Criteria for Foodstuffs.

3.6.7. *Staphylococcus aureus*

Staphylococcus aureus is a common member of the skin and nasopharynx of humans other animals and the presence of this bacterium in FoNAO most commonly results from food handlers, or cross-contamination with FoAO. *Staphylococcus aureus* have been rarely searched in FoNAO, and mostly with methods having high limits of detection, compared to other pathogenic agents. Methods for detection of coagulase positive staphylococci (including *Staphylococcus aureus*) in food are well developed and analytical reference methods standardised and widely adopted across laboratories testing food, including that for Official Control: EN/ISO 6888 are specified in Commission Regulation EC No 2073/2005, Microbiological Criteria for Foodstuffs.

3.6.8. *Bacillus cereus* and other *Bacillus* species

Bacillus spp. (including *Bacillus cereus)* is a group of spore forming bacteria which is abundant in soil and can contaminate any type of foods, in particular FoNAO. Because of the robust survival properties of the spores, commodities containing high numbers of *Bacillus cereus* are found among spices, cereals, vegetables and processed products. Some fermented FoNAO traditionally prepared in Asia and Africa are reliant on the activities of species of *Bacillus* and will contain high numbers of these bacteria. An internationally agreed standard method (BS EN ISO 7932) is available for *Bacillus cereus*.

3.6.9. *Clostridium botulinum*

Clostridium botulinum is widely distributed in the environment and consequently will contaminate a wide variety of raw and minimally processed FoNAO. *Clostridium botulinum* produces highly resistant spores that can survive many food processes. *Clostridium botulinum* is defined as a species on the ability to produce neurotoxin and comprises a heterogeneous group of organisms with a diversity of physiological properties. Methods for detection of *Clostridium botulinum* are consequently specialised, lacking in standardisation, potentially insensitive, labour intensive and involve the use of *in vivo* diagnostic tests: although the final requirement is becoming increasingly superseded by the detection of neurotoxin genes by PCR.

3.6.10. *Clostridium perfringens*

Clostridium perfringens occurs in the enteric tract of a wide range of animals and because of the robust survival of the spores is widely distributed through the environment including soil, raw FoNAO and food production environments. However since <5% of all *Clostridium perfringens* carry the enterotoxin gene and are capable of causing food poisoning, the ecological distribution of this bacterium as a food pathogen is not well understood. Detection and quantification of all *Clostridium perfringens* can be achieved by the use of cultural methods, and standard methods are available (BS EN ISO 7937), PCR based methods are also available to detect the enterotoxin gene.

3.6.11. Foodborne viruses

Foodborne viruses such as human Norovirus and Hepatitis A virus grow in intestinal tract of humans and although they are incapable of independent multiplication outside their hosts, they are capable of survival in faeces and the environment (particularly via water), where contamination of FoNAO can occur. Person to person transmission can occur and contamination via food handlers is of importance. ISO methods for the detection of foodborne viruses in food are under development (CEN/TC275/WG6/TAG4 working group) based on PCR based procedures and are being increasingly applied. However, RT-PCR amplification of small viral genomic sequences may not be representative for the presence of infectious virus particles on foods.

3.6.12. Parasites: *Cyclospora* spp., *Cryptosporidium* spp., *Giardia* spp., *Toxoplasma* spp. and others

Foodborne parasites grow in intestinal tract of their hosts (especially humans but for some also in wild or domesticated animals). Although they are incapable of independent multiplication outside their hosts, they are capable of survival in faeces and the environment (in soil but particularly via water in which they can survive for prolonged periods), where contamination of FoNAO can occur. Other possibilities of transmission includes handling of the produce by workers in the field or food handlers in the kitchen who were infected (with or without symptomatic carriage). Detection methodologies are based on separation techniques followed by recognition of the morphological cyst forms under the microscope as well as by PCR. Detection methodologies are of low sensitivity, specialized and labour intensive and thus often restricted to specialized reference laboratories.

4. Identification and ranking of specific food/pathogen combinations for FoNAO

4.1. Justification for approach

As recently reviewed by the BIOHAZ panel (EFSA Panel on Biological Hazards (BIOHAZ), 2012b), there exist several tools for risk ranking of specific food/pathogen combinations. Each of these has different advantages and limitations and the choice will depend on the questions that need answering as well as the data available. For this opinion, we adapted a RRT developed by the US FDA (Anderson et al., 2011), which particularly aims at risk ranking combinations of fresh produce commodities and specific pathogens. The linkage between certain commodities and specific pathogens is based on an analysis of reported foodborne outbreaks in the US and as explained in section 3.2., at the EU Monitoring data is the best available data or answering the ToRs of this opinion.

The FDA RRT is based on an assessment of nine criteria describing both the health impact and consequences of particular pathogens as well as factors related to dose-response relationships, consumption, prevalence of the hazards and the possibility of growth of the hazards during shelf life. Each criterion is given a score and in the end, the scores of all criteria are summed to provide a total risk score for each food/pathogen combination. The approach is to a large extent based on the input of quantitative data. However, for each criterion the quantitative data is divided into four categories, where each category is given a score, meaning that the final model outcome is presented on a semi-quantitative scale. The approach does not provide any uncertainty estimates (e.g. confidence intervals), but the use of rather broad categories for the semi-quantitative scoring indirectly takes into account data uncertainty. This also means that if insufficient quantitative data is available, qualitative data based on, for example expert opinion can be used as input as well. Taken together, the data availability, the use of broad risk categories and the possibility to apply qualitative or highly uncertain data made us develop an approach close to the RRT model.

4.2. Model

As described above the general modelling approach is a semi-quantitative risk ranking that takes into account factors such as the strength of association between the food commodity and pathogen in question, the severity of the disease in humans, and pathogen and commodity characteristics known to affect disease risk and/or probability of exposure. These factors are included in the model as seven specific criteria that can be divided into criteria describing the consequences of human disease (criteria 1 to 3) and criteria describing the probability of exposure (criteria 4 to 7):

1. Strength of associations between food and pathogen based on the foodborne outbreak from EU Zoonoses Monitoring Data
2. Incidence of illness
3. Burden of disease
4. Dose-response relationship
5. Prevalence of contamination
6. Consumption
7. Pathogen growth potential during shelf life

For each criterion, the available data was grouped into scoring categories, which were defined and assigned a numerical, ordinal score. The criteria, the definition of the scoring categories and the data applied are described in greater detail below. For each food/pathogen combination, the scores of the seven criteria were summed to give a total final risk score, thereby providing a ranking of all combinations.

To explore the robustness of the model as well of the importance of each individual criterion, different scenarios were run. The reference or baseline scenario included data on all seven criteria. Following this, further four scenarios were run, excluding each of the following criteria one by one: consumption, dose-response relationship, growth potential during shelf life and prevalence.

The model was set up in MS Excel.

4.3. Criteria considered

4.3.1. Strength of associations between food and pathogen

From data presented in previous sections (section 3.1., section 3.5. and Table 26 Appendix B), food/pathogen combinations were identified and classified as having a weak, moderate, strong or very strong association according to the definitions in the table below (Table 7). It was decided only to include outbreaks classified as moderate to very strong in the risk ranking model. Consequently, this ranking method only considers food/pathogen combinations that have been reported in outbreaks in the EU as part of the Zoonoses monitoring during the period from 2007 to 2011. The use of outbreak data from other countries such as the US was considered inappropriate as the origin and hence the contamination of the food commodities could be very different from similar products consumed in the EU. Other food/pathogen combinations not identified or prioritised in this risk ranking model may be important if data from subsequent monitoring or data from other sources are considered.

Table 7: Scoring for criterion 1: strength of associations between food/pathogen combinations

Score	Category	Number of outbreaks	Total cases
1	Weak	(i) Has 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) and not included in (i) or (ii) above.	NA
2	Moderate	Have been associated with a single outbreak reported in the EU (2007-2011 data Zoonoses monitoring /Appendix B)	Any cases
3	Strong	(i) Have been associated with 2-4 outbreaks reported in the EU (2007-2011 Zoonoses monitoring data/Appendix B) or (ii) Have been associated with ≥ 5 FBOs reported in the EU (2007-2011 Zoonoses monitoring data/Appendix B)	Any cases <100
4	Very strong	Have been associated with ≥ 5 FBOs reported in the EU (2007-2011 Zoonoses monitoring data/Appendix B)	≥100

FBO = foodborne outbreak

Table 8: 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	Pathogenic *E. coli*, Hepatitis A virus, Parasites
Raspberries	Norovirus	NR	.	.	*Salmonella*	fresh raspberry juice	Pathogenic *E. coli*, Hepatitis A virus, Parasites
Other berries	.	.	.	.	Norovirus	NR	Hepatitis A virus, Parasites
Citrus fruit	.	.	.	.	.	.	Parasites Pathogenic *E. coli*, *Salmonella*
Apples and related fruit	.	.	.	.	.	.	Pathogenic *E. coli*, Parasites
Tropical fruit	.	.	.	.	.	.	*Salmonella*, Parasites
Melons	.	.	.	.	*Salmonella*	watermelon	*L. monocytogenes*, *Campylobacter*
Fruit mixes	.	.	.	.	.	.	*Salmonella*, Norovirus, Parasites
Tomatoes	.	.	.	.	Norovirus, *Salmonella*	NR NR	*Shigella*
Peppers and aubergines	.	.	.	.	.	.	*Salmonella*
Fresh pods, legumes and grain	.	.	*Shigella*	baby corn, sugar snaps, sugar peas	Pathogenic *E. coli*, *S. aureus*	sugar peas frozen beans	*Campylobacter*, Parasites
Leafy greens eaten raw as salads	*Salmonella*, Norovirus	baby spinach, chopped lettuce, pre-cut iceberg lettuce, rucola (rocket) lettuce	.	.	*B. cereus*	lettuce	*Campylobacter*, Pathogenic *E. coli*, *Shigella*, *Yersinia*, Hepatitis A virus, Parasites
Fresh herbs	.	.	.	.	*C. perfringens*, *Shigella*	mix of herbs basil	*Salmonella*, Parasites

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	
Leafy greens mixed with other fresh FoNAO	.	.	.	.	*Cryptosporidium*, *Salmonella*, *Shigella*, *B. cereus*	pre- cut salad mix mixed lettuce leaves salad salad	*L. monocytogenes*, Pathogenic *E. coli*, *Yersinia*,
Carrots	.	.	.	.	*Shigella*, *Yersinia pseudotuberculosis* Norovirus	NR, raw grated carrot, NR	Pathogenic *E. coli*,
Other root and tuberous vegetables	.	.	.	.	.	.	*B. cereus*, Pathogenic *E. coli*
Bulb and stem vegetables	.	.	Norovirus	chopped onion, garlic water used for brushing lángos	*Salmonella*	onion	*Yersinia*, Hepatitis A virus Pathogenic *E. coli*,
Sprouted seeds	*Salmonella*	alfalfa sprouts, bean sprouts, mung bean sprouts	Pathogenic *E. coli*	sprouted fenugreek seeds	*S. aureus*	bean sprouts	*B. cereus*, *Yersinia*
Fungi (mushrooms and yeasts)	.	.	.	.	.	.	*S. aureus*
Nuts and nuts products	.	.	.	.	*Salmonella*	cashew nuts	Pathogenic *E. coli*
Spices and dry powdered herbs	*B. cereus*	curry, ground cumin, pepper, turmeric (curcuma)	.	.	*C. perfringens*, *Salmonella*	NR, NR	.
Beverages	.	.	.	.	.	.	*Salmonella* Parasites
Dehydrated vegetables and fruit	.	.	.	.	Hepatitis A virus	semi-dried tomatoes	*B. cereus*
Fruit (non specified)	.	.	Norovirus	NR	*Shigella*	NR	.
Cooked vegetable salads	Norovirus	broccoli salad, bulgur salad, mixed vegetable salad, prepared salad, raw chopped onion in salad, salads offered as buffet	*B. cereus*, Pathogenic *E. coli*, *Salmonella*, *Shigella* *S. aureus*	aubergine salad, boiled noodles with vegetables boiled wheat salad with raw olives and black olives from glass jars potato salad salad buffet pasta salad, potato salad	*Yersinia*	RTE salad mix	*C. botulinum*, *L. monocytogenes*

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	
Cereals and dry legumes	.	.	*B. cereus*	Buckwheat, bulgur wheat	.	.	.
Rice	*B. cereus*	rice (boiled, cooked, fried)	*S. aureus*	(cooked) rice	.	.	.
Pasta	*S. aureus*	boiled noodles, pasta, spaghetti	.	.	*B. cereus*, *Salmonella*	pasta meal, noodle	.
Other dry legumes, cereals, edible seeds and grain, flours and products thereof (processed products)	.	.	.	.	*Salmonella*, *S. aureus*	wheat product wheat product	.
Fermented, salted, or acidified vegetables or fruit	.	.	.	.	.	.	*C. botulinum*, *L. monocytogenes* Pathogenic *E. coli*
Other processed products, sauces and dressings, purées, soup, and pastes (including canned and bottled products) and syrups	*B. cereus* Norovirus	bean soup, Chinese noodle dish, Chinese rice dish, cooked smashed potatoes, kisir, pesto, rice and Indian lentils, rice with vegetables, risotto, tomato soup cooked peeled potatoes, cooked raspberry, mixed cooked legumes, sauce (frozen) raspberries, sushi-rice	*C. perfringens* *Salmonella*, *S. aureus*	curry potato dish, pea soup, tomato sauce falafel, noodle, potato mash Indonesian rice table, stewed eggplant			*C. botulinum*
Others	.	.	.	.	*Salmonella*	food supplement containing contaminated hemp flour	*L. monocytogenes*

NR: Not reported

Based on the data presented in Table 26 in Appendix B, 10 very strong, 14 strong, 31 moderate and 54 weak associations between FoNAO types and specific pathogens were identified (Table 8). FoNAO categories including food products that (i) normally are subjected to a processing step which should inactivate vegetative cells (e.g. rice, pasta), (ii) include one or more cooked ingredients (e.g. cooked vegetable salads), (iii) are very broad and heterogeneous (other processed products) or (iv) are unspecified (e.g. fruit unspecified) were excluded from the ranking, as the focus was on ready-to-eat unprocessed products (marked with bold in Table 8).

4.3.2. Incidence of illness

It is recognised that, less severe diseases have a higher degree of under-reporting than diseases causing more severe symptoms. In fact, sporadic foodborne disease caused by Norovirus or foodborne toxins is rarely reported and EU notifications rates are not available. However, these hazards are still responsible for many illnesses and in an attempt to consider this, the hazard-specific true number of illnesses in the EU was estimated. This was done by multiplying the notified number of cases with a so-called disease multiplier, which is a hazard-specific value that expresses the degree of under-reporting without consideration of attribution to source. The estimated true number of illnesses was then scored according to the categories shown in Table 9 without consideration of attribution to source.

A disease-multiplier for *Salmonella* spp. at the EU level has recently been published (EFSA Panel on Biological Hazards (BIOHAZ), 2012a; Havelaar et al., 2012). For other hazards, disease multipliers were taken from a US study (Scallan et al., 2011), but 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 and EU. The estimated disease multipliers are presented in Table 10 and the true number of estimated illnesses calculated by the product of the disease multiplier and the notified number of cases are presented in Table 11. For noroviruses as well as the toxin producing bacteria (*Bacillus cereus*, *Clostridium perfringens* and *Staphylococcus aureus*), data on notified cases was not available in the EU. The true number of estimated cases was therefore estimated based on a Dutch incidence of illness study (Havelaar et al., 2012), where the estimated true number of Dutch cases were extrapolated to the EU level (Table 11), assuming that the incidence of these diseases is more or less equal in all of the EU. To check this assumption, true incidence data from the UK (Tam et al., 2012) was extrapolated to the EU level and compared with the estimates based on the Dutch data. With the exception of *Clostridium perfringens*, the hazard specific number of illnesses fell within the same scoring category (Table 11). To explore the impact of the different scores for *Clostridium perfringens*, we ran the model using both score=2 (based on UK data) and score=3 (based on NL data) and found that it only had a minor impact on the order of the lower ranking food/pathogen combinations. It was therefore decided to use the estimates based on the Dutch data in the model. For illnesses caused by e.g. *Salmonella* spp. and *Cryptosporidium* spp., the scoring would also differ depending on which data set is used. For instance based on UK data, *Salmonella* spp. would be given a score=2, whereas the EU data and the Dutch data suggest a score=3. These differences may very well be explained by 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 11 where the respective incidence data considered for scoring are shown in bold.

Table 9: Scoring for criterion 2: incidence of illness.

Score	Incidence of illness	Score intervals
1	Low	< 100,000
2	Medium	100,000-999,999
3	High	1,000,000-10,000,000
4	Very high	>10,000,000

Table 10: Disease multipliers for each pathogen based on the US incidence of illness and anchored to the *Salmonella* spp. disease multiplier estimated at the EU level.

Pathogen	Havelaar et al., 2012	Scallan et.al., 2011	Disease multipliers anchored to the EU *Salmonella* spp. estimate
Bacillus spp.		747.15	1,466.3
Clostridium spp.		747.15	1,466.3
Cryptosporidium spp.		98.6	193.5
Hepatitis A		10.01	19.6
Norovirus		NA	NA
Salmonella spp.	57.5	29.3	57.5
Shigella spp.		33.3	65.3
Staphylococcus spp.		747.15	1,466.3
VTEC non-O157		106.8	209.6
Yersinia enterocolitica [(a)]		122.8	241

(a) Similar values has been assumed for all *Yersinia* spp.
NA: Not available

Table 11: Incidence of illness: estimated true number of illness per year in the EU. Only pathogens associated with outbreaks reported to EFSA through the zoonosis monitoring were included.

Pathogen	Estimated disease multipliers in EU [(a)]	Notification per year, average 2007-2010 (confirmed cases: ECDC database TESSy)	Incidence data at the EU level [(b)]	NL incidence data extrapolated to the EU level [(c)]	UK incidence data extrapolated to the EU level [(d)]	Score
Bacillus spp.	1466.3	NA	NA	**1,510,606**	NA	3
Clostridium perfringens	1466.3	NA	NA	**5,075,636**	853,885	3
Cryptosporidium spp.	193.5	6,972	**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
Salmonella spp.	57.5	123,774	**7,117,005**	1,057,424	406,432	3
Shigella spp.	65.3	6,332	**413,480**	NA	NA	2
Staphylococcus aureus	1466.3	NA	NA	**8,821,939**	NA	3
VTEC non-O157 [(e)]	209.6	3,741	**784,166**	NA	NA	2
Yersinia enterocolitica[(f)]	241	7,377	**1,777,797**	NA	NA	3

(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. (2012) (Table 10).
(b) Estimated true 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 ECDC database TESSy (The European Surveillance System).
(c) Estimated true number of illnesses in the EU based on the estimates from a Dutch incidence of illness study (Havelaar et al., 2012), with the estimates extrapolated to the EU level.
(d) Estimated true number of illnesses in the EU based on the estimates from a incidence of illness study in the United Kingdom (Tam et al., 2012), with the estimates extrapolated to the EU level.
(e) Two pathogens-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 information in Table 26. Therefore only the disease multiplier for VTEC non-O157 was applied in the model.
(f) Similar values have been assumed for all *Yersinia* spp.
NA: Not available

4.3.3. Considerations on human adverse effects – burden of disease

4.3.3.1. *Salmonella* spp.

Salmonella spp. is an important cause of gastrointestinal disease in humans most commonly resulting in mild to severe diarrhoeal illness. *Sequelae* may include reactive arthritis (Reiter's syndrom). Systemic infection may occur especially in susceptible patients such as the very young, very old and immune-compromised. All members of this species are considered as potentially pathogenic with respect to contamination of ready-to-eat foods and strains of *Salmonella* Typhi/Paratyphi cause more serious systemic illness known as enteric fever.

4.3.3.2. Pathogenic *Escherichia coli*

Pathogenic *Escherichia coli* are capable of causing mild to extremely severe infection which can manifest as both diarrhoeal as well as extra-intestinal disease. Amongst *Escherichia coli* capable of causing intestinal disease, VTEC are strongly associated with the most severe forms of the infection including haemorrhagic colitis (bloody diarrhoea, hemorrhagic colitis (HC)), thrombotic thrombocytopaenic purpura (TTP) and the haemolytic uraemic syndrome (HUS).

4.3.3.3. *Shigella* spp.

Shigellosis (bacterial dysentery) ranges in severity from mild watery diarrhoea to severe illness accompanied by febrile convulsions. The severity of illness is associated with the species involved. Infection with *Shigella dysenteriae* is usually most severe and some cases are also associated with the haemolytic uremic syndrome. Infection with *Shigella flexneri* and *Shigella boydii* can also be severe but *Shigella sonnei* in an otherwise healthy person generally presents as a few loose stools and abdominal discomfort. Shigellosis is also occasionally associated with reactive arthritis (Reiter‘s Syndrome).

4.3.3.4. *Yersinia enterocolitica* and *pseudotuberculosis*

Infection by *Yersinia enterocolitica* manifests as acute enteritis with abdominal pain which may simulate acute appendicitis. *Yersinia pseudotuberculosis* causes a range of disease severity from subclinical to severe gastrointestinal disease (acute ileitis, mesenteric lymphadenitis accompanied by fever, diarrhoea and intestinal pain). Other *sequelae* may include reactive arthritis. Infection occasionally results in a severe typhoid-like illness with fever and enlargement of the liver and spleen.

4.3.3.5. *Staphylococcus aureus*

Staphylococcus aureus is a cause of food poisoning due to the production of heat resistant enterotoxins following growth of the bacterium in food. Disease results in rapid onset of nausea, vomiting, abdominal pain and diarrhoea which is usually self limiting and does not require medical treatment.

4.3.3.6. *Bacillus cereus* and other *Bacillus* species

Bacillus cereus causes either emesis or diarrhoeal disease after consumption of foods where the bacterium has been allowed to proliferate. The emetic syndrome is caused by consumption of preformed toxin and results in rapid vomiting, nausea, stomach cramps, followed by diarrhoea which is usually self limiting and does not require medical treatment. The diarrhoeal disease results from production of toxin by viable organisms in the enteric tract and manifests as a profuse watery diarrhoea which is usually self limiting and does not require medical treatment. Similar diseases are caused, albeit less frequently, by other *Bacillus* species.

4.3.3.7. *Clostridium perfringens*

Clostridium perfringens causes gastroenteritis (abdominal pain, diarrhoea and nausea) following consumption of heavily contaminated food. The disease results from production of toxin by viable organisms in the enteric tract and is usually self limiting and does not require medical intervention.

4.3.3.8. Norovirus and hepatitis A virus

The principal foodborne viruses in the EU are noroviruses (NoV) and hepatitis A viruses (HAV). NoV belong to the Family *Caliciviridae*, and are well recognised for causing outbreaks of mild/self-limiting vomiting and diarrhoea. In people with co-morbidity or in the elderly, illness may be more severe and sometimes fatal.

The etiological agent of hepatitis A is the hepatitis A virus (HAV) which belongs within the family *Picornaviridae*. Hepatitis A infection mostly develops asymptomatically or subclinically among young children (under 5), while in older children and in the adulthood the infection usually becomes symptomatic. The clinical course of symptomatic hepatitis A is as an acute illness with symptoms of fever, malaise, anorexia, nausea, abdominal discomfort, dark urine and jaundice, and later elevated serum bilirubin and aminotransferases.

4.3.3.9. *Cryptosporidium* spp.

Within the genus *Cryptosporidium*, the major human pathogens are *Cryptosporidium parvum* and *Cryptosporidium hominis* which cause acute diarrhoea amongst the immunocompetent, particularly amongst children under 5 years of age. Infections can be life threatening in the immunocompromised, particularly those with AIDS.

4.3.3.10. Burden of disease

The burden of disease criterion is measured by the disability adjusted life years (DALYs) per thousand cases. DALYs expresses 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 or irritable bowel syndrome), as well as mortality. DALY estimates for specific foodborne infections at the EU level are not available. However, as there is no evidence showing that the severity of a foodborne infection as measured by DALY per thousand cases varies across countries in the EU, we used pathogen-specific DALY estimates published for the Netherlands (Havelaar et al., 2012). The DALYs were categorised according to the scorings shown in Table 12. For *Shigella* spp. and *Yersinia enterocolitica*, no estimates were available, but due to the nature and outcomes of the disease, these pathogens causes, we assumed that their DALYs would fall within the same category as *Salmonella* spp. (Table 13). For VTEC, the DALY estimate published by Havelaar et al. (2012) 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), as the duration and severity of these infections are assumed to be similar to that of O157 as briefly described in 4.3.3.2.

Table 12: Scoring for criterion 3: burden of disease

Score	DALY	DALY per 1,000 cases score intervals
1	Low	< 10
2	Medium	10-99
3	High	100-999
4	Very high	> 999

Table 13: Attributed scores for DALYs for all pathogens considered in the model

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

(a) Similar values have been assumed for all VTEC, although this may represent an overestimation for some non-O157 VTEC serotypes.
(b) Similar values have been assumed for all *Yersinia* spp.
NA: Not available

4.3.4. Dose-response relationship

The dose-response relationship was categorised according to the scorings shown in Table 14.

A score of 1 was allocated to emetic *Bacillus cereus* and *Staphylococcus aureus*, as these pathogens cause a foodborne intoxication (Table 15) 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 at >10^5 CFU/g in the food product. Similarly a score of 1 was allocated to diarrhoeal *Bacillus cereus* and *Clostridium perfringens* (Table 15) which causes food poisoning following ingestion of >10^5 CFU/g of vegetative cells of a toxigenic micro-organism which produces toxin in the small intestines during sporulation shortly after ingestion.

A score of 2 is defined as growth of the pathogen in the food is needed to induce disease in humans. However, as neither of these was included in the model, the score of 2 was not applied to any pathogen.

A score 3 was allocated to *Salmonella* spp., *Shigella* spp., pathogenic *Escherichia coli* (e.g. VTEC), *Yersinia enterocolitica*, Norovirus, Hepatitis A virus and to the protozoa *Cryptosporidium* spp. (Table 15), which all can cause infection by the uptake of low numbers of microorganisms in the food.

Table 14: Scoring for criterion 4: dose-response relationship

Score	Dose-response relationship
1	Pathogen growth to high numbers (>10^5 CFU/g) is needed for toxin production and induction of disease.
2	Pathogen growth is needed to induce disease in human (*e.g. Clostridium botulinum, Listeria monocytogenes).*
3	Low numbers can cause disease (e.g. *Salmonella* spp., *Shigella* spp., virus, protozoa).

Table 15: Attributed scores for dose-response relationship for all pathogens considered in the model

Hazard	Score
Bacillus cereus	1
Clostridium perfringens	1
Cryptosporidium spp.	3
Norovirus/Hepatitis A virus	3
Salmonella spp.	3
Shigella spp.	3
Staphylococcus aureus	1
VTEC [(a)]	3
Yersinia spp.[(b)]	3

(a) Similar values have been assumed for all VTEC.
(b) Similar values have been assumed for all *Yersinia* spp.

4.3.5. Prevalence of contamination

Prevalence of contamination of the pathogen in the specific food category was based on data from EFSA's Zoonoses database as well as expert knowledge and was scored according to the categories shown in Table 16. The presence of the infectious hazards in FoNAO is usually the effect of a series of adverse and uncommon contamination events. Thus, with the exceptions of *Bacillus cereus* and *Clostridium perfringens,* for the majority of pathogens in the different FoNAO categories, the overall prevalence is assumed to be either low (< 1%) or unknown (Table 17).

Data on the total number of samples investigated as well as the total number of positive samples for *Salmonella* spp. and pathogenic *Escherichia coli* reported in FoNAO as part of EFSA's Zoonoses web-based reporting from 2004 to 2011 are summarised in Table 6 and show a prevalence of respectively 0.48% and 0.28%. *Salmonella* spp. and pathogenic *Escherichia coli* are allocated a score of 3 for prevalence of contamination (Table 17).

For other pathogens such as *Shigella* spp. and *Yersinia* spp. there are limited surveys on prevalence in FoNAO in the EU. Those that are available generally were limited to specific countries, employed *ad hoc* sampling plans, were generated by PCR methods, and did not include information on virulence factors. In addition, available studies sometimes also showed conflicting results. The uncertainty around the data, made it impossible to make draw any conclusions about the prevalence level of these bacteria in FoNAO. Taken a conservative approach, these bacteria were, therefore, allocated a prevalence score of 2 defined as "unknown prevalence", meaning that the prevalence cannot be assumed to be zero (Table 17).

Norovirus, Hepatitis A virus as well as *Cryptosporidium* spp. were also allocated a score of 2 (unknown prevalence) largely because there are few surveys on these pathogens in FoNAO available and results may be biased due to the nature and sensitivities of the detection methodology. RT-PCR amplification of small viral genomic sequences may not be representative for the presence of infectious virus particles on foods (Knight et al., 2012). For *Cryptosporidium* spp., detection methodologies are of low sensitivity, specialized and labour intensive and still in the process of optimization by specialized reference laboratories.

Humans and animals are the most common carriers of *Staphylococcus aureus* (either on their skin, hair, nose or throat) but the bacterium may also persist in the environment. Prevalence studies of *Staphylococcus aureus* in FoNAO are limited and, if available, are normally used to monitor *Staphylococcus aureus* as an indication of the level of personal hygiene and performance of "Good Manufacturing Practices". Therefore this does not usually provide prevalence data on the presence of

Staphylococcus aureus as a contaminant in food. For this reason *Staphylococcus aureus* was also allocated a score of 2 (unknown prevalence).

Bacillus cereus and *Clostridium perfringens* are spore forming organisms, have intrinsic capacities to survive under adverse conditions and are commonly detected in soil, vegetation and surface waters. *Clostridium perfringens* is a common part of the intestinal flora of many wild animals and livestock. *Bacillus cereus* is commonly isolated from farm environments have been shown to be commonly present in FoNAO. Thus a score of 4 (prevalence > 1%) has been allocated to these bacteria (Table 17).

Table 16: Scoring for criterion 5: prevalence of contamination

Score	Prevalence	Explanation
1	Zero prevalence	Available prevalence studies indicate 0 prevalence.
2	Unknown prevalence	Not possible to draw any conclusions on the prevalence based on the available data.
3	Low prevalence (<1%)	Pathogens occur in FoNAO and cause outbreaks, and are likely to have an origin from human or animal contamination.
4	≥1%	Would also include e.g. *Bacillus* spp. and *Listeria monocytogenes*, which originate from the environment and may in some instances be underestimated.

Table 17: Attributed scores for prevalence of contamination for all pathogens considered in the model

Hazard	Score for prevalence of contamination
Bacillus cereus	4
Clostridium perfringens	4
Cryptosporidium spp.	2
Norovirus/Hepatitis A virus	2
Salmonella spp.	3
Shigella spp.	2
Staphylococcus aureus	2
Pathogenic *Escherichia coli*	3
Yersinia spp.[(a)]	2

(a) Similar values have been assumed for all *Yersinia* spp.

4.3.6. 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, 2011b). Competent organisations in the European Union’s Member States have provided EFSA with data from the most recent national dietary survey in their country, at the level of consumption by the individual consumer. This included food consumption data concerning infants (2 surveys from 2 Member States), toddlers (8 surveys from 8 Member States), children (16 surveys from 14 Member States), adolescents (14 surveys from 12 Member States), adults (21 surveys from 20 Member States), elderly (9 surveys from 9 Member States) and very elderly (8 surveys from 8 Member States) for a total of 32 different dietary surveys carried out in 22 different Member States. Due to the lack of data from some of the EU Member States and age classes, above all children, the data cannot be considered as fully representative of the EU population.

The preliminary version of the hierarchical food classification system ‘FoodEx’, developed by EFSA, was used to codify all foods and beverages present in the Comprehensive Database. FoodEx is a hierarchical system based on 20 main food categories that are further divided into subgroups up to a maximum of 4 levels (EFSA, 2011a).

Consumption data from the Comprehensive Database was used in the scope of this opinion to estimate the percentage of consumers, at EU level, for relevant FoNAO commodity categories based on the 4th level of the FoodEx categorization system. A list of these categories is reported in Table 19. 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, this means that this percentage is based on consumption data from 52,852 subjects. Infants have been excluded as they are not expected to be potential consumers of the FoNAO commodity categories. For each FoNAO commodity category (e.g. leafy greens eaten raw as salads) “consumers” has been defined as those who consumed at least once, within the days for which they reported their consumption, any specific food belonging to this FoNAO category (e.g. any leafy green).

Scores were allocated as follows: score 1 if the percentages of consumers was below or equal to 1%, score 2 for percentages of consumers ranging from 1 to 2% (inclusive), score 3 for percentages of consumers ranging from 2 to 20% (inclusive) and score 4 for percentages of consumers ranging above 20% (Table 18).

Table 18: Scoring for criterion 6: percentage of consumers reported to have consumed the food in question at least once during the period for which they were asked.

Score	Percentage of consumers (infants excluded)
1	Low (< 1%)
2	Moderate (1-2%)
3	High (>2-20%)
4	Very high (> 20%)

Estimates for the percentage of consumers for the relevant FoNAO commodity categories are reported in Table 19 together with the appropriate score, as defined above.

Table 19: Attributed scores for percentage of consumers for all FoNAO categories considered in the model

FoNAO category	Number of consumers	Percentage of consumers [(a)]	Score
Strawberries	4,422	8.4	3
Raspberries	1,514	2.9	3
Other berries	6,883	13	3
Melons	3,640	6.9	3
Tomatoes	30,681	58.1	4
Fresh pods, legumes and grain	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	1,033	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	8,322	15.7	3
Spices and dry powdered herbs	16,090	30.4	4
Dehydrated vegetables and fruit	5,316	10.1	3

(a) For each FoNAO commodity category (e.g. leafy greens eaten raw as salads) "consumers" has been defined as those who consumed at least once any specific food belonging to this FoNAO category (e.g. any leafy green).

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 included in the Comprehensive Database (Merten et al., 2011). The different dietary surveys presented differences with respect to a number of parameters affecting the level of detail and the accuracy of the collected data, such as: the dietary assessment method, the number of days per subject, the sampling design and the quantification of portion sizes. A cautious interpretation of the results is therefore always recommended when data from the Comprehensive Database is used.

The number of assessment days per subject affects the distribution of consumption, particularly at the upper tail. In particular, as survey duration increases, also the observed percentage of subjects reporting non zero consumption for commonly and rarely eaten foods becomes larger. The available food consumption data was collected on one day only per subject in 6 dietary surveys, all the other surveys ranged from 2 to 7 days per subject. Percentage of consumers is likely underestimated in dietary surveys with a limited number of days per subject. Dietary surveys with only one day per subject were therefore excluded when calculating the percentage of consumers for the FoNAO categories.

In addition, not in all dietary surveys food consumption was uniformly distributed over the four seasons. This issue is particularly relevant when assessing the consumption of seasonal foods, for which the estimates of percentage of consumers, as defined above, are likely to be underestimated.

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 large majority of the foods and household recipes ingredients reported in the Comprehensive Database.

4.3.7. Considerations on the importance of factors influencing growth and survival of pathogens

4.3.7.1. Importance of growth in the food for some pathogens to cause illness

The assessment of pathogen growth potential during shelf life in the specific food category was based on available data in literature as well as expert knowledge. Growth in foods does not have the same impact on public health for all hazards. As stated in (EFSA Panel on Biological Hazards (BIOHAZ), 2012c), "for a given number of foods at consumption, some hazards have a higher probability to cause illness than others. In practice, this means that some hazards must 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." Section 4.3.4. of this Opinion provides indications on the dose-response of the main hazards relevant for FoNAO. For instance, the presence of any infectious particles of noroviruses, hepatitis A virus, VTEC, *Salmonella* spp., *Campylobacter* spp., or *Yersinia enterocolitica* on foods at consumption may have a high likelihood to cause illness. In contrast, *Listeria monocytogenes*, *Bacillus cereus*, *Clostridium perfringens*, *Clostridium botulinum*, *Staphylococcus 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).

For the hazards with a high likelihood to cause illness at low exposures, the risk factors associated with contamination of the food (e.g. irrigation of fresh produce with contaminated water close to harvest), and the presence/absence of inactivation steps before consumption (e.g. heat processing) have a major impact on the risk. For instance, initial contamination of the food during primary production or harvest with such hazards, without reliable steps causing inactivation, will represent a threat to consumers health.

In contrast, for hazards needing to grow or produce toxins in foods to cause illness, factors associated with contamination must be combined with conditions permitting growth for a significant risk of disease in the consumers to development.

Among the factors affecting microbial survival and growth in foods, the impact on the relevant hazards of water activity (a_w), pH, temperature and time of storage, temperature and time of thermal processes, are well documented (EFSA Panel on Biological Hazards (BIOHAZ), 2012c).

4.3.7.2. Impact of pH, a_w and temperature on pathogen growth

The minimum limits for growth of pathogens are summarised in a recent Opinion from EFSA's BIOHAZ Panel (EFSA Panel on Biological Hazards (BIOHAZ), 2012c). In general, a_w and pH (together with frozen storage) restrict the growth and toxin formation of foodborne pathogenic bacteria. There are however risks associated with hazards with the ability for survival but not requiring growth in food to cause illness (e.g. *Salmonella* spp. in low water activity foods such as nuts and seeds).

Most dry fruit and vegetables, dry cereal products, nuts, dry spices and herbs, have a_w below 0.88 (see section 2.4). Fermented and acidified fruits and vegetables and some fruit juices have pH ≤4.0 (see section 2.4). Some fruits and vegetables are placed on the market as frozen product (see section 2.4), which does not permit growth of pathogens. However, the exact pH and a_w of processed FoNAO such as juices or dry-semi dry products can vary to a large extent and must be verified on a case by case basis.

Many FoNAO represent a combination of reduced pH, a_w and temperature. For instance, fermented fruit and vegetables have usually both a low pH and high salt content (low a_w). Unpasteurized fresh fruit juices frequently have a low pH and are stored at low temperature. These combinations may inhibit foodborne pathogenic bacteria although each factor taken separately would not. This is commonly referred to as the hurdle technology as the basis for growth inhibition. Further details can be found in (EFSA Panel on Biological Hazards (BIOHAZ), 2012c).

4.3.7.3. Impact of temperature, pH and a_w on pathogens survival.

Heat treatments higher than a few minutes at 70°C for high a_w foods, such as those applied to many pasteurized, cooked or processed FoNAO (e.g. cooking of rice or vegetables) will reduce by 5 to 6 log_{10} units all the hazards relevant for this Opinion, except for spore forming bacteria (*Bacillus* and *Clostridium* species) and the heat resistant toxins from *Staphylococcus aureus* and emetic *Bacillus cereus*. Reliable inactivation of spores of pathogenic bacteria in high a_w foods can only be achieved by sterilisation treatments (e.g. 3 min at 120°C), as is the case for canned vegetables and fruits. Reduction of a_w causes a marked increase in heat resistance (increase in D values) of for example *Salmonella* spp.. The same was shown for hepatitis A virus (EFSA Panel on Biological Hazards (BIOHAZ), 2012c)(EFSA 2012). In the case of FoNAO the high heat resistance of foodborne pathogens in low a_w foods applies for instance for dry fruits and vegetables, nuts, or preserved fruits. This was, for instance, illustrated by the *Salmonella* outbreak associated with peanut butter in the US (CDC, 2007b, 2009) where the pathogen survived processing.

Some FoNAO are heated in the final package or aseptically packaged after heat treatment (e.g. some cooked chilled foods, and shelf stable fruit juices). However, for most other processed FoNAO which are not treated in their final package, or are not aseptically packaged, the potential for post- process contamination varies between pathogens (see Section 2.4). For instance, a tomato soup may be UHT treated and aseptically packaged, pasteurised in its final packaged, sold refrigerated, then cooked and served without protective packaging in catering.

The pH and a_w influence survival of foodborne pathogens, and interacts with temperature. With respect to FoNAO, the low pH of many fruit products, fermented or acidified fruits or vegetables, caused death of nonspore-forming pathogenic bacteria at ambient or refrigeration temperatures (EFSA Panel on Biological Hazards (BIOHAZ), 2012c). Examples of inactivation kinetics are given in (EFSA Panel on Biological Hazards (BIOHAZ), 2012c) which shows that for most pathogens, several days are needed for at least 3 log_{10} reductions. The duration of the fermentation process for fermented fruits and vegetables (some examples are presented in section 2.4) is presumably long enough to inactivate nonspore-forming pathogenic bacteria (Nout and Rombouts, 2000). In contrast, time elapsed during processing and consumption of unpasteurized fruit juices may be too short to permit inactivation of nonspore-forming pathogenic bacteria, even for acid fruits such as oranges. This is illustrated by the series of outbreaks linked to non pasteurized fruit juices in the US (Vojdani et al., 2008). Low a_w, such as in dried fruit and vegetables, nuts, seeds, legume grain, and cereals caused inactivation of nonspore-forming foodborne pathogenic bacteria but at a very slow rate. The inactivation is temperature dependant and is even slower when storage temperatures are decreased. For example the decline of *Escherichia coli* O157 and *Salmonella* spp. on dry seeds at 5°C over 10-12 months is not more than 1 log_{10}, in contrast a 2-3 log_{10} reduction is generally achieved after storage for one month at 37-38°C (EFSA Panel on Biological Hazards (BIOHAZ), 2011a).

4.3.7.4. Impact of other factors

Foodborne pathogens present on the surface of fresh produce or of fresh cut produce may be inhibited by the indigenous microorganisms, and may be limited by available nutrients (Lopez-Velasco et al., 2012; Nguyen-The and Carlin, 2000); (Wood et al., 2010) demonstrated the bactericidal effect of UV radiation on enteric bacteria in the phyllosphere and there is also a significant effect of temperature and light intensity on survival of *Escherichia coli* O157 in lettuce (Ottoson et al., 2011). Prior to harvest, reduction in relative humidity caused death of *Salmonella* spp. (Brandl and Mandrell, 2002) and of *Listeria monocytogenes* (Dreux et al., 2007) on the surface of parsley and cilantro leaves. The rate of decline reached several log_{10} within a few hours for *Listeria monocytogenes* on parsley leaves grown in open field conditions (Dreux et al., 2007). Bacteria are frequently present on the surface of plants as biofilms (Morris and Monier, 2003). Foodborne pathogens may also be internalised inside plant tissues, and the extent to which this may influence risk for consumers have been recently discussed for VTEC (EFSA Panel on Biological Hazards (BIOHAZ), 2011b). All these factors may have a strong influence on the fate of foodborne pathogens on FoNAO. However, their impacts have not been documented as well as for temperature, a_w, pH, and must be assessed on a case by case basis.

4.3.7.5. Pathogen growth potential / shelf life

Growth potential of the pathogen in the FoNAO as well as the shelf life of the FoNAO were scored individually according to Table 20. Subsequently both individual scores were summed, and the obtained values generated a combined score for pathogen growth potential/shelf life according to Table 21. Food borne viruses (including Norovirus and Hepatitis A virus) as well as for parasites including *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 22). As mentioned above, low a_w, such as nuts and nut products, spices and dry powdered herbs will not enable growth of enteric bacteria such as *Salmonella* spp. (and thus allocated a score 1 for pathogen growth potential) (Table 22). Microorganisms causing intoxications (*Bacillus cereus, Clostridium perfringens* and *Staphylococcus aureus* with the exception of some psychrotrophic *Bacillus cereus*) cannot grow under refrigeration conditions, and are largely inhibited in their germination (for the spore formers) and growth potential by the indigenous flora of raw fresh produce: these 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 *Staphylococcus aureus* and sprouted seeds for which the growth potential is not documented (and thus allocated a score 2) (Table 22). The same holds 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 is allocated a score 2. 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. They have no ability to grow under appropriate refrigeration temperature (<7°C) which is recommend for fresh-cut fresh produce. However, it has been documented that the growth of these pathogens is likely and possible to occur under specific circumstances, in particular if not kept under refrigeration (in the case of occasional temperature abuse in the supply chain during storage or transport), or at harvest or post-harvest stockage of crops at ambient temperature. Growth is possible if relative humidity is high enough in the environment or when condensation has occurred. The growth potential for *Salmonella* spp., VTEC and *Shigella* spp. is 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, tomatoes) (Table 22).

In the case of VTEC and *Salmonella* spp. and its association with sprouted seeds, a score of 4 is allocated because growth is possible and very likely at the elevated temperatures and humidity occurring during sprouting. Despite the fact that *Yersinia* spp. is a psychrotrophic pathogen and able to grow at low temperatures, 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 differences sources including the USDA Agriculture Handbook 66 (USDA, 2004), as well as other relevant documents (Cantwell, 2001; Kader, 2002; Kader et al., 2001; UCDAVIS, 2012). Due to the variable nature of the individual commodities, the shelf life differed among the individual commodities within a general commodity category. In these instances, the longest shelf life of a particular commodity was chosen and used for scoring to be as cautious 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.

Table 20: Scoring for pathogen growth potential and shelf life

Scores	Pathogen growth potential	Scores	Shelf life
1	No growth possible (e.g. too low pH, too low water activity, too low temperature (e.g. frozen), competing microflora)	1	Very short (0-7 days)
2	Poorly documented	2	Short (8-14 days)
3	Growth possible but not in all circumstances (e.g. only if temperature abused)	3	(15-28 days)
4	Growth possible and very likely	4	(> 28 days)

Table 21: Scoring for criterion 7: combined pathogen growth potential and shelf life

Score	Combined pathogen growth potential and shelf life
1	1
2	3-4
3	5-6
4	7-8

Table 22: Attributed scores for combined pathogen growth potential and shelf life for all food pathogen combinations considered in the model

Pathogen	FoNAO category	Pathogen growth potential score	Shelf life score	Sum of individual scores	Combined pathogen growth and shelf life score
Salmonella spp.	Raspberries	2	1	3	2
Salmonella spp.	Melons	3	4	7	4
Salmonella spp.	Tomatoes	3	2	5	3
Salmonella spp.	Leafy greens eaten raw as salads	3	2	5	3
Salmonella spp.	Leafy greens mixed with other fresh FoNAO	3	2	5	3
Salmonella spp.	Bulb and stem vegetables	3	3	6	3
Salmonella spp.	Sprouted seeds	4	2	6	3
Salmonella spp.	Nuts and nut products	1	-	1	1
Salmonella spp.	Spices and dry powdered herbs	1	-	1	1
VTEC	Fresh pods, legumes and grain	3	2	5	3
VTEC	Sprouted seeds	4	2	6	3
Shigella spp.	Fresh pods, legumes and grain	3	2	5	3
Shigella spp.	Fresh herbs	3	2	5	3
Shigella spp.	Leafy greens mixed with other fresh FoNAO	3	2	5	3
Shigella spp.	Carrots	2	2	4	2
Yersinia spp. [(a)]	Carrots	2	2	4	2
Staphylococcus aureus	Fresh pods, legumes and grain	1	-	1	1
Staphylococcus aureus	Sprouted seeds	2	2	4	2
Bacillus spp.	Leafy greens eaten raw as salads	1	-	1	1
Bacillus spp.	Leafy greens mixed with other fresh FoNAO	1	-	1	1
Bacillus spp.	Spices and dry powdered herbs	1	-	1	1
Clostridium perfringens	Fresh herbs	1	-	1	1
Clostridium perfringens	Spices and dry powdered herbs	1	-	1	1
Hepatitis A virus	Dehydrated vegetables and fruit	1	-	1	1
Norovirus	Strawberries	1	-	1	1

Pathogen	FoNAO category	Pathogen growth potential score	Shelf life score	Sum of individual scores	Combined pathogen growth and shelf life score
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
Cryptosporidium spp.	Leafy greens mixed with other fresh FoNAO	1	-	1	1

(a) Similar values have been assumed for all *Yersinia* spp.

4.4. Summary tables of model outputs

The reference model scenario considered in the scope of the risk ranking modelling approach included all model criteria described in sections 4.3.1. to 4.3.7 (scenario 1). In addition, four different model scenarios were considered with exclusion of specific model criteria: scenario 2 without consumption criterion, scenario 3 without combined pathogen growth potential/shelf life criterion, scenario 4 without dose-response criterion and scenario 5 without prevalence criterion.

The relative ranking positions for the top five considered food/pathogen combinations based on the final model scores are shown in Table 23 for all five scenarios. Food/pathogen combinations not on the top 5 in the reference model, but ranking first to fifth in any of the scenarios two to five are listed in Table 24.

Table 32 in Appendix E shows the comparative ranking positions for all food pathogen combinations in all considered scenarios and Tables 33 to 37 (Appendix E) show the individual model output tables for all considered scenarios.

Table 23: Relative ranking positions for the top five considered food/pathogen combinations based on the final model scores

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	*Salmonella* spp.	Leafy greens eaten raw as salads	First	First	First	First
Second	*Salmonella* spp.	Bulb and stem vegetables	Third	Third	Second	Second
	Salmonella spp.	Tomatoes	Third	Third	Second	Second
	Salmonella spp.	Melons	Second	Fourth	Second	Second
	Pathogenic *E. coli*	Fresh pods, legumes and grain	Third	Third	Second	Second
Third	Norovirus	Leafy greens eaten raw as salads	Fourth	Second	Third	Second
	Salmonella spp.	Sprouted seeds	First	Fourth	Third	Third
	Shigella spp.	Fresh pods, legumes or grain	Fourth	Fourth	Third	Second
Fourth	*Bacillus* spp.	Spices and dry powdered herbs	Fifth	Third	Second	Fifth
	Norovirus	Bulb and stem vegetables	Fifth	Third	Fourth	Third
	Norovirus	Raspberries	Fourth	Third	Fourth	Third
	Salmonella spp.	Raspberries	Fourth	Fourth	Fourth	Fourth
	Salmonella spp.	Spices and dry powdered herbs	Fifth	Third	Fourth	Fourth
	Salmonella spp.	Leafy greens mixed with other fresh FoNAO	Third	Fifth	Fourth	Fourth
	Shigella spp.	Fresh herbs	Fifth	Fifth	Fourth	Third
	Pathogenic *E. coli*	Sprouted seeds	Second	Fifth	Fourth	Fourth
	Yersinia spp.	Carrots	Fifth	Fourth	Fourth	Third
Fifth	Norovirus	Tomatoes	Sixth	Fourth	Fifth	Fourth
	Norovirus	Carrots	Sixth	Fourth	Fifth	Fourth
	Salmonella spp.	Nuts and nut products	Fifth	Fourth	Fifth	Fifth
	Shigella spp.	Carrots	Sixth	Fifth	Fifth	Fourth

Table 24: Food/pathogen combinations ranking higher than fifth in the reference model scenario which ranked first to fifth in scenarios two to five.

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)**
Ranked > fifth in scenario 1, but ranked 1-5 in scenarios 2-5	*Shigella* spp.	Leafy greens mixed with other fresh FoNAO	Fifth	NA	NA	Fifth
	Hepatitis A virus	Dehydrated vegetables and fruit	NA	Fifth	NA	Fifth
	Norovirus	Other berries	NA	Fifth	NA	Fifth
	Bacillus spp.	Leafy greens eaten raw as salads	NA	Fifth	Fourth	NA
	Norovirus	Strawberries	NA	Fifth	NA	Fifth
	C. perfringens	Fresh herbs	NA	Fifth	Fourth	NA
	C. perfringens	Spices and dry powdered herbs	NA	Fifth	Fourth	NA

NA: not applicable

4.5. Conclusions and discussion

- In summary, the panel developed a multi criteria analysis model, which was adapted from a model published by the US FDA, which particularly aims at risk ranking combinations of FoNAO commodities and specific pathogens. Seven criteria were used in the model:
  - **Strength of associations between food and pathogen**; the linkage between certain food commodities and specific pathogens is based on an analysis of reported foodborne outbreaks in EFSA's Zoonoses database from 2007 to 2011.
  - **Incidence of illness**, which was expressed as the estimated number of true cases/illnesses in the EU.
  - **Burden of disease**, which was quantified using disease-specific estimates for disability adjusted life years (DALYs) per thousand cases.
  - **Dose-response relationship** as estimated by expert knowledge of the behaviour and physiology of the specific pathogens.
  - **Consumption,** which was based on percentage of consumers in surveyed countries gathered in the EFSA Comprehensive European Food Consumption Database (Comprehensive Database).
  - **Prevalence of contamination** of the pathogen in the specific food category based on data from EFSA's Zoonoses database as well as expert knowledge.
  - **Pathogen growth potential during shelf life** in the specific food category based on available data in literature as well as expert knowledge.
- Using all the seven criteria in the model, the five top ranking groups of food/pathogen combinations in the following decreasing order of priority were:
  - *Salmonella* spp. and leafy greens eaten raw as salads;
  - *Salmonella* spp. and bulb and stem vegetables; *Salmonella* spp. and tomatoes; *Salmonella* spp. and melons; and pathogenic *Escherichia coli* and fresh pods, legumes or grain;
  - norovirus and leafy greens eaten raw as salads; *Salmonella* spp. and sprouted seeds; and *Shigella* spp. and fresh pods, legumes or grain;
  - *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 *Escherichia coli* and sprouted seeds; and *Yersinia* spp. and carrots;
  - norovirus and tomatoes; norovirus and carrots; *Salmonella* spp. and nuts and nut products and *Shigella* spp. and carrots.
- To explore the robustness of the model as well of the importance of each individual criterion, different scenarios were run: a reference model, which included all seven criteria in the analysis, scenario 2 without the consumption criterion, scenario 3 without the combined pathogen growth potential/shelf life criterion, scenario 4 without the dose-response criterion, and scenario 5 without the prevalence criterion. The analysis showed that excluding a single criterion from the model had limited effect on the top 5 ranking food/pathogen combinations.

- Excluding the consumption criterion (scenario 2) led to the biggest change in ranking order within the top 5 groups of combinations when compared to the reference scenario. Food commodities eaten rarely, but linked to many and/or large outbreaks ranked higher in this scenario and particularly included both combinations of *Salmonella* spp. and pathogenic *Escherichia coli* with sprouted seeds. Excluding the consumption criterion can be regarded as ranking the risk for the individual consumer as opposed to the EU population.

- The model may overestimate the importance of some food/pathogen combinations, since only those reported in outbreaks in the EU as part of the Zoonoses monitoring are included in the model and additional food/pathogen combinations may be identified as important if data from future EU monitoring is included.

- The model used here is likely to underestimate the importance of diseases which appear to be of a more sporadic nature (such as those due to *Listeria monocytogenes, Campylobacter* spp. and parasites).

- It should be highlighted that when interpreting outputs from the model, consideration has to be given to the assumptions, limitations and uncertainties.

- The model outputs presented in this opinion are based on the reported outbreaks associated with consumption of food of non-animal origin within the EU between 2007 and 2011. Therefore, future fluctuations in the reported outbreaks are likely to impact on the current rankings.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

General conclusions and approach

- Food of non-animal origin comprises a wide range of fruit, vegetables, salads, seeds, nuts, cereals, herbs, spices, fungi, and algae. Food of non-animal origin are commonly consumed in a variety of forms including: (i) as ready-to-eat foods in which the constituents are raw or minimally processed (e.g. fresh-cut and prepacked), and (ii) those which are processed with a heat or other inactivation treatments. Food of non-animal origin are a major component of almost all meals.

- Microbial food safety hazards and sources of contamination may vary significantly by the type of crop, production systems and practices, and from one particular setting/context to another, even for the same crop.

- The 2011 outbreak with approximately 3,800 cases, 2,353 hospitalizations and 53 deaths due to VTEC O104 and sprouted seeds highlights the potential for large outbreaks of considerable morbidity and mortality to be associated with food of non-animal origin. This is an example of how food of non-animal origin even with low consumption may have a considerable public health impact.

- Since antibiotic resistance and toxic amines hazards are of a generic nature and cannot be identified as associated with any specific food-pathogen combinations, these are not considered in detail. However consumption of food of non-animal origin may be of importance in exposure of consumers to these hazards.

Answers to the terms of Reference

TOR 1. To compare the incidence of foodborne human cases linked to food of non-animal origin and foodborne cases linked to food of animal origin. This ToR should provide an indication of the proportionality between these two groups as regard humans cases and, if possible, human burden.

- The analysis of the outbreak data reported as part of EU Zoonoses Monitoring allows attribution of human cases to food of non-animal origin or food of animal origin, and is currently the only option for obtaining an EU-wide comparative estimate of the proportion of human cases due to these two food groups.

- For the purpose of this analysis, EU Zoonoses Monitoring foodborne outbreak data from 2007 to 2011 was used. Amongst all the foodborne outbreaks reported where food of either non-animal or animal origin were implicated, the food of non-animal origin were associated with 10% of the outbreaks, 26% of the cases, 35% of the hospitalisations and 46% of the deaths.

- Trends in data on food of non-animal origin are strongly influenced by the 2011 VTEC O104 outbreak. If the data from this large outbreak is excluded, food of non-animal origin was associated with 10% of the outbreaks, 18% of cases, but only 8% of the hospitalisations and 5% of the deaths. There is a general tendency for the outbreaks associated with food of non-animal origin to involve more cases and to be less severe (e.g. lower proportion of hospitalisations and deaths) than those associated with food of animal origin.

- There are shortcomings with this type of analysis which should be considered:
  - Outbreak data is reliant on reporting which is incomplete, can vary between reporting countries, may be greatly influenced by rare events occurring during the

monitoring period, or have bias due to the preferential investigation of types of foods perceived as higher risk or hazards which are easier to identify. For example, there is variation in the rates of reported outbreaks per population among countries. Nineteen countries reported foodborne outbreaks with strong evidence where food of non-animal origin were implicated and the Nordic countries, *i.e.* Denmark, Finland, Norway and Sweden reported 51% of these.

  – Large outbreaks, especially those associated with the food service sector and institutions, as well as those outbreaks of longer duration or associated with serious disease are more likely to be reported and investigated.

  – Data on most pathogens is often limited, and there may be considerable differences between the relative importance of different food types associated with outbreak versus sporadic cases.

  – The use of outbreak data sets also excludes data where the etiological agent and/or the food sources have not been identified.

- It has not been possible to quantify the uncertainty caused by these shortcomings.

- Extrapolating information from the EU Zoonoses Monitoring foodborne outbreak data from 2007 to 2011 is not appropriate to compare the human burden of foodborne cases linked to food of non-animal origin or food of animal origin.

- From 2008 to 2011 there was an increase in the numbers of reported outbreaks, cases, hospitalisations and deaths associated with food of non-animal origin. These trends occurred together with a decrease in the numbers of reported outbreaks, cases, hospitalisations and deaths associated with food of animal origin.

TOR 2. Identify and rank specific food/pathogen combinations most often linked to foodborne human cases originating from Food of non-animal origin in the EU.

- The panel developed a multi criteria analysis model aimed at risk ranking combinations of food of non-animal origin commodities and specific pathogens.

- Seven criteria were used in the model which were: the strength of associations between food and pathogen, incidence of illness, burden of disease, dose-response relationship, consumption, prevalence of contamination and pathogen growth potential during shelf life. The first criterion (strength of associations) is based on the foodborne outbreak data from EU Zoonoses Monitoring. Food/pathogen combinations identified from other data sources were excluded from the model.

- Outbreaks associated with food products that (i) normally are subjected to a processing step which should inactivate vegetative cells (e.g. rice, pasta), (ii) include one or more cooked ingredients (e.g. cooked vegetable salads), (iii) are very broad and heterogeneous (other processed products) or (iv) are unspecified (e.g. fruit unspecified) were excluded from the ranking, as the focus was on ready-to-eat unprocessed products.

- Using all the seven criteria in the model, the five top ranking groups of food/pathogen combinations in the following decreasing order of priority were:

  – *Salmonella* spp. and leafy greens eaten raw as salads;

  - *Salmonella* spp. and bulb and stem vegetables; *Salmonella* spp. and tomatoes; *Salmonella* spp. and melons; and pathogenic *Escherichia coli* and fresh pods, legumes or grain;

  - norovirus and leafy greens eaten raw as salads; *Salmonella* spp. and sprouted seeds; and *Shigella* spp. and fresh pods, legumes or grain;

  - *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 *Escherichia coli* and sprouted seeds; and *Yersinia* spp. and carrots;

  - norovirus and tomatoes; norovirus and carrots; *Salmonella* spp. and nuts and nut products and *Shigella* spp. and carrots.

- To explore the robustness of the model as well of the importance of each individual criterion, different scenarios were run: a reference model, which included all seven criteria in the analysis, scenario 2 without the consumption criterion, scenario 3 without the combined pathogen growth potential/shelf life criterion, scenario 4 without the dose-response criterion, and scenario 5 without the prevalence criterion. The analysis showed that excluding a single criterion from the model had limited effect on the top 5 ranking food/pathogen combinations.

- Excluding the consumption criterion (scenario 2) led to the biggest change in ranking order within the top 5 groups of combinations when compared to the reference scenario. Food commodities eaten rarely, but linked to many and/or large outbreaks ranked higher in this scenario and particularly included both combinations of *Salmonella* spp. and pathogenic *Escherichia coli* with sprouted seeds. Excluding the consumption criterion can be regarded as ranking the risk for the individual consumer as opposed to the EU population.

- The model may overestimate the importance of some food/pathogen combinations, since only those reported in outbreaks in the EU as part of the Zoonoses monitoring are included in the model and additional food/pathogen combinations may be identified as important if data from future EU monitoring is included.

- The model used here is likely to underestimate the importance of diseases which appear to be of a more sporadic nature (such as those due to *Listeria monocytogenes*, *Campylobacter* spp. and parasites).

- It should be highlighted that when interpreting outputs from the model, consideration has to be given to the assumptions, limitations and uncertainties.

- The model outputs presented in this opinion are based on the reported outbreaks associated with consumption of food of non-animal origin within the EU between 2007 and 2011. Therefore, future fluctuations in the reported outbreaks are likely to impact on the current rankings.

RECOMMENDATIONS

It is recommended that:

- harmonised terminology is 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 prepared, processed and stored as part of the above data collections.

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APPENDICES

A. PRODUCTION IN THE EU OF FONAO

Table 25: Estimation of EU production in 2010 of FoNAO. Production of commodities listed in FAO (2012) which corresponded to the same category as defined in this Opinion (Table 1) were combined. The categories not described in FAO (2012) are not presented in this Table. (Source: from: http://faostat.fao.org/site/567/default.aspx#ancor (accessed on 3 May 2012)).

Categories	Tonnes
Fruits ns[(a)] and others	80,766
Strawberries	1,093,373
Raspberries	143,720
Berries others	467,638
Citrus fruits	10,030,312
Apples and related fruit	12,809,080
Stone fruits	6,956,829
Tropical fruits	1,195,154
Melon	4,780,784
Tomatoes	16,901,885
Pepper and Aubergines	3,033,035
Gourds and Squash	4,189,439
Fresh pods, legumes and grain	3,111,856
Leafy greens	3,023,166
Leaves others	12,023,790
Carrots and Turnips	5,165,897
Potatoes	56,840,811
Other tubers and Roots	87,478
Bulbs and stems	7,095,219
Flowers and buds	2,984,078
Rice	3,208,788
Other cereals, legumes seeds and grain	291,496,291
Mushrooms	944,866
Nuts	762,252
Fruit juices	1,509,982
Vegetable oils	19,860,924

(a) ns: not specified

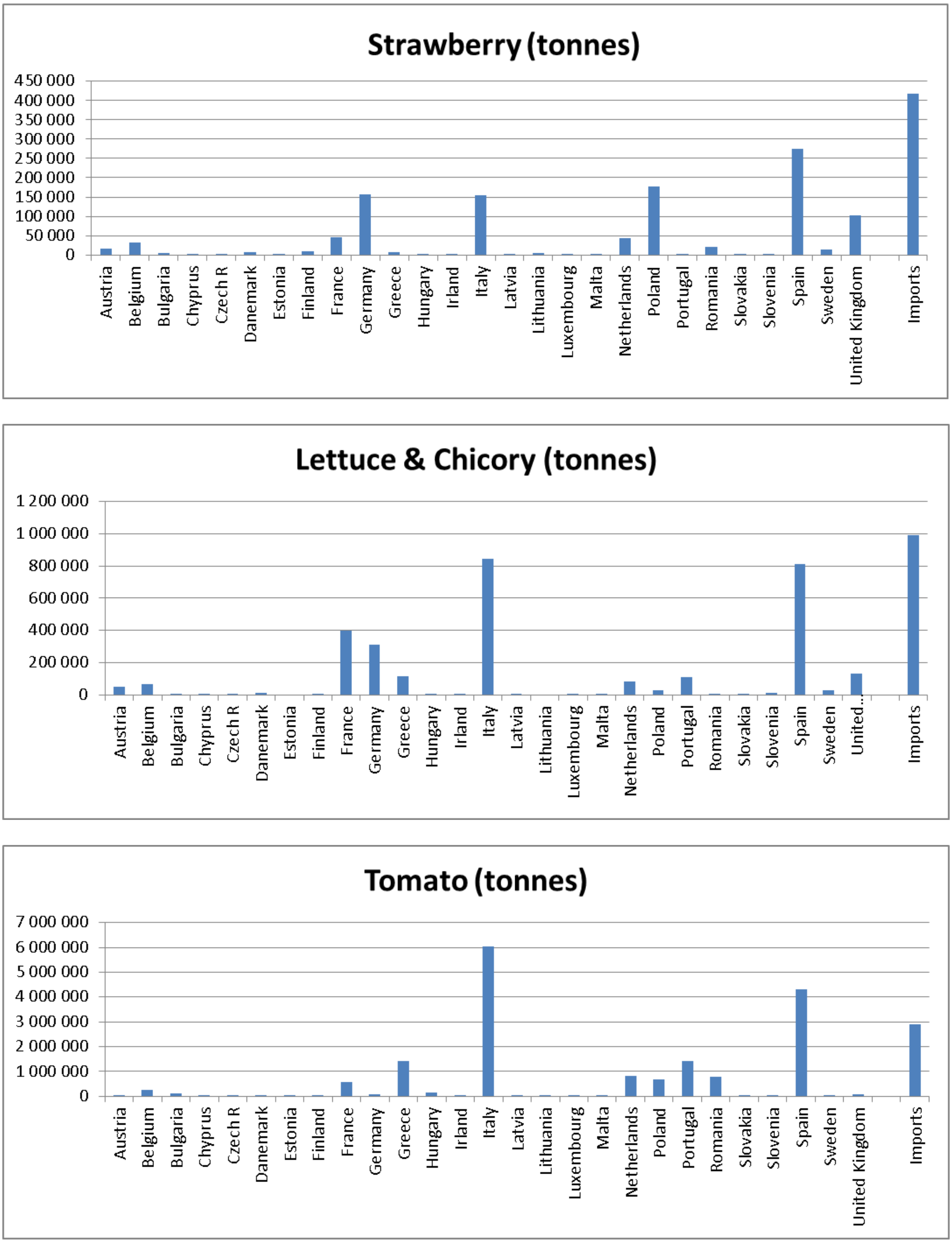

Figure 16: Production in 2010 of some commodities in EU Member States and imports in 2009 (FAO, 2012) (Source from: http://faostat.fao.org/site/567/default.aspx#ancor (accessed on 3 May 2012).

B. Data reported in the zoonoses database on occurrence of strong evidence foodborne outbreaks where FoNAO were implicated (2007-2011)

Table 26: Reported outbreaks associated to FoNAO in the reporting countries[31] in accordance with Directive 2003/99/EC[32], 2007-2011

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Strawberries	NR	Calicivirus	Norovirus (Norwalk-like virus)	2010	Sweden	Descriptive epidemiological evidence	7	0	0
Raspberries	Fresh fruit juice	*Salmonella* spp.	*S.* Panama	2008	Netherlands	Analytical epidemiological evidence; Laboratory detection in human cases	33	11	NR
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2009	Sweden	Analytical epidemiological evidence; Laboratory detection in human cases	130	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence; Laboratory detection in human cases	128	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence; Laboratory detection in implicated food	20	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence	10	0	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence; Laboratory detection in human cases	11	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence	40	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence; Laboratory detection in human cases	12	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Analytical epidemiological evidence; Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	30	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Analytical epidemiological evidence	60	0	0

31. EU countries including Norway and Switzerland. Data from Spain have not been included in this table because they were provided outside the EFSA's Zoonosis database and in a different format of aggregation.

32 Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Raspberries	NR	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence	5	1	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2010	Sweden	Analytical epidemiological evidence	21	0	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2010	Sweden	Descriptive epidemiological evidence	8	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2010	Finland	Analytical epidemiological evidence; Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	43	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2010	Finland	Analytical epidemiological evidence; Descriptive epidemiological evidence	90	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Descriptive epidemiological evidence	15	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Analytical epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	8	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Descriptive epidemiological evidence	12	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Descriptive epidemiological evidence	25	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Analytical epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	2	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Analytical epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	30	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Descriptive epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	5	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Descriptive epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	5	0	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Analytical epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	113	1	0
	Frozen raspberries	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Descriptive epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	6	1	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2011	Sweden	Descriptive epidemiological evidence	24	0	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2011	Finland	Analytical epidemiological evidence, Descriptive epidemiological evidence	19	0	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2011	Finland	Analytical epidemiological evidence, Descriptive epidemiological evidence, Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	41	0	0
Raspberries	**Total**	**Calicivirus (27 FBO)**					**913**	**3**	**0**
Other berries	NR	Calicivirus	Norovirus (Norwalk-like virus)	2011	Finland	Descriptive epidemiological evidence, Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	9	0	0
Melons	Watermelon	*Salmonella* spp.	*S.* Newport	2011	Germany	Detection of causative agent in food chain or its environment - Detection of indistinguishable causative agent in humans	17	8	0
Tomatoes	NR	*Salmonella* spp.	*S.* Strathcona	2011	Denmark	Analytical epidemiological evidence; Descriptive epidemiological evidence	43	0	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2007	Sweden	Analytical epidemiological evidence; Laboratory detection in human cases	480	NR	NR
Fresh pods, legumes and grain	Baby corn	*Shigella* spp.	*S. sonnei*	2007	Denmark	Laboratory detection in human cases	200	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Fresh pods, legumes and grain	Sugar snaps	*Shigella* spp.	*S. dysenteriae*	2009	Sweden	Analytical epidemiological evidence; Laboratory detection in human cases	35	0	0
	Sugar peas	*Shigella* spp.	*S. sonnei*	2009	Denmark	Analytical epidemiological evidence	10	0	0
	Sugar peas	*Shigella* spp.	*S. sonnei*	2009	Norway	Laboratory detection in implicated food	23	3	0
Fresh pods, legumes and grain	**Total**	***Shigella* spp. (4 FBO)**					**268**	**3**	**0**
Fresh pods, legumes and grain	Sugar peas	VTEC	VTEC O27:H30	2011	Denmark	Analytical epidemiological evidence;Descriptive epidemiological evidence	87	0	0
	Frozen beans	*Staphylococcus* spp.	*S. aureus*	2009	Belgium	Laboratory detection in implicated food	14	0	0
Leafy greens eaten raw as salads	Lettuce, chopped, bagged, ready-to-eat	*Salmonella* spp.	*S.* Enteritidis	2007	Germany	Laboratory detection in implicated food	15	11	0
	Baby spinach	*Salmonella* spp.	*S.* Paratyphi B var. Java	2007	Norway	Laboratory characterization of food and human isolates	10	0	0
	Baby spinach	*Salmonella* spp.	Other serotypes	2007	Sweden	Analytical epidemiological evidence; Laboratory detection in human cases	179	NR	NR
	Raw pre-cut iceberg lettuce	*Salmonella* spp.	*S.* Newport	2008	Finland	Analytical epidemiological evidence; Laboratory detection in human cases	86	NR	0
	Raw rucola lettuce (rocket)	*Salmonella* spp.	*S.* Napoli	2008	Sweden	Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	13	2	0
	Rucola (rocket)	*Salmonella* spp.	*S.* Napoli	2009	Sweden	Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	5	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	Mixed lettuce leaves	*Salmonella* spp.	*S.* Paratyphi B var. Java	2010	United Kingdom	Analytical epidemiological evidence; Descriptive epidemiological evidence	130	16	0
Leafy greens eaten raw as salads	**Total**	***Salmonella* spp. (7 FBO)**					**438**	**29**	**0**
Leafy greens eaten raw as salads	Lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence; Laboratory detection in human cases	77	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	4	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence	4	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence	3	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	3	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	2	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence	26	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Analytical epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	26	0	0
	Romaine lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	14	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Analytical epidemiological evidence; Descriptive epidemiological evidence	28	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence	11	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Leafy greens eaten raw as salads	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence	62	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Descriptive epidemiological evidence	35	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus)	2010	Denmark	Analytical epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	13	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Analytical epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	10	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Descriptive epidemiological evidence	16	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Descriptive epidemiological evidence	6	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Analytical epidemiological evidence; Descriptive epidemiological evidence	5	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	50	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Analytical epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	3	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Descriptive epidemiological evidence	21	1	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Descriptive epidemiological evidence	6	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Denmark	Descriptive epidemiological evidence	75	0	0
	Lollo Bionda lettuce	Calicivirus	Norovirus (Norwalk-like virus	2010	Norway	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	157	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Leafy greens eaten raw as salads	**Total**	**Calicivirus (24 FBO)**					**657**	**1**	**0**
Leafy greens eaten raw as salads	Lollo lettuce	*Bacillus* spp.	*B. cereus*	2010	Finland	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	2	0	0
Fresh herbs	Fresh basil	*Shigella* spp.	*S. sonnei*	2011	Norway	Analytical epidemiological evidence	46	4	0
Fresh herbs	Mix of herbs used in buffet dishes	*Clostridium* spp.	*C. perfringens*	2008	Denmark	Laboratory detection in implicated food	2	NR	NR
Carrots	Raw grated carrot	*Yersinia* spp.	*Y. pseudotuberculosis*	2008	Finland	Analytical epidemiological evidence; Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	50	10	0
	NR	*Shigella* spp.	*S. sonnei*	2008	Sweden	Analytical epidemiological evidence; Laboratory detection in human cases	145	5	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2009	Belgium	Laboratory detection in implicated food	2	0	0
Bulb and stem vegetables	Onion	*Salmonella* spp.	*S.* Haifa	2011	Sweden	Descriptive epidemiological evidence	30	0	0
Bulb and stem vegetables	Garlic water used for brushing lángos	Calicivirus	Norovirus (Norwalk-like virus)	2010	Germany	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	2	0	0
	Chopped onion	Calicivirus	Norovirus (Norwalk-like virus)	2011	Finland	Analytical epidemiological evidence, Descriptive epidemiological evidence	16	0	0
Bulb and stem vegetables	**Total**	**Calicivirus (2 FBO)**					**18**	**0**	**0**
Sprouted seeds	Bean sprouts	*Salmonella* spp.	*S.* Weltevreden	2007	Denmark	Laboratory detection in human cases; Laboratory detection in implicated food	19	0	0
	Alfalfa sprouts	*Salmonella* spp.	*S.* Weltevreden	2007	Finland	Analytical epidemiological evidence; Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	8	NR	0
	Alfalfa sprouts	*Salmonella* spp.	*S.* Weltevreden	2007	Norway	Laboratory characterization of food and human isolates	27	3	0
	Alfalfa sprouts	*Salmonella* spp.	*S.* Stanley	2007	Sweden	Analytical epidemiological evidence; Laboratory detection in human cases	51	NR	NR

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	Raw alfalfa sprouts	*Salmonella* spp.	*S.* Bovismorbificans	2009	Finland	Analytical epidemiological evidence; Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	28	0	0
	NR	*Salmonella* spp.	*S.* Bovismorbificans	2009	Estonia	Analytical epidemiological evidence; Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	6	3	0
	Bean sprouts	*Salmonella* spp.	*S.* Bareilly	2010	United Kingdom	Analytical epidemiological evidence; Detection of causative agent in food chain or its environment - Detection of indistinguishable causative agent in humans	231	32	1
	Bean sprouts	*Salmonella* spp.	*S.* Bareilly	2010	United Kingdom	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	21	3	0
	Bean sprouts	*Salmonella* spp.	*S.* Kottbus	2010	United Kingdom	Descriptive epidemiological evidence	4	0	0
	Mung bean sprouts	*Salmonella* spp.	*S.* Newport	2011	Germany	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans, Analytical epidemiological evidence, Detection of causative agent in food chain or its environment - Detection of indistinguishable causative agent in humans	106	26	0
	Taugé (mung bean sprouts)	*Salmonella* spp.	*S.* Newport	2011	Netherlands	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	20	9	0
Sprouted seeds	**Total**	***Salmonella* spp. (11 FBO)**					**521**	**76**	**1**
Sprouted seeds	Bean sprouts	*Staphylococcus* spp.	*S.* aureus	2008	Denmark	Laboratory detection in implicated food	42	NR	NR
Sprouted seeds	Sprouted fenugreek seeds	VTEC	VTEC O104:H4	2011	Denmark	Analytical epidemiological evidence	26	20	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	Sprouted fenugreek seeds	VTEC	VTEC O104:H4	2011	Netherlands	Analytical epidemiological evidence	11	8	0
	Sprouted fenugreek seeds	VTEC	VTEC O104:H4	2011	Germany	Analytical epidemiological evidence	3,793	2,353	53
Sprouted seeds	**Total**	**VTEC (3 FBO)**					**3,830**	**2,381**	**53**
Cereals	Wheat product	*Salmonella* spp.	*S.* Enteritidis	2007	Romania	Laboratory detection in implicated food	30	10	0
	Wheat product	*Staphylococcus* spp.	*S. aureus*	2007	Romania	Laboratory detection in implicated food	10	6	0
	Buckwheat	*Bacillus* spp.	*B. cereus*	2009	Poland	Analytical epidemiological evidence; Laboratory detection in implicated food	52	0	0
Nuts and nut products	Cashew nuts	*Salmonella* spp.	*S.* Poona	2011	Sweden	Descriptive epidemiological evidence	16	0	0
Spices and dry herbs	Curry	*Bacillus* spp.	*B. cereus*	2009	Belgium	Laboratory detection in implicated food	7	0	0
	NR	*Bacillus* spp.	*B. cereus*	2007	France	Analytical epidemiological evidence; Laboratory detection in implicated food	146	0	0
	White pepper	*Bacillus* spp.	*B. cereus*	2010	Denmark	Analytical epidemiological evidence; Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	112	0	0
	Turmeric / curcuma	*Bacillus* spp.	*B. cereus*	2011	Finland	Descriptive epidemiological evidence, Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	19	0	0
	Turmeric / curcuma	*Bacillus* spp.	*B. cereus*	2011	Finland	Descriptive epidemiological evidence, Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	4	0	0
	Jeera Ground Cumin	*Bacillus* spp.	*B. cereus*	2011	Finland	Descriptive epidemiological evidence, Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	3	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	Pepper	*Bacillus* spp.	*B. cereus*	2011	Denmark	Descriptive epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	52	0	0
Spices and dry herbs	**Total**	***Bacillus* spp. (7 FBO)**					**343**	**0**	**0**
Spices and dry herbs	NR	*Clostridium* spp.	*C. perfringens*	2007	France	Analytical epidemiological evidence	19	0	0
	NR	*Salmonella* spp.	*S.* Senftenberg	2007	Denmark	Laboratory detection in human cases	3	0	0
Dehydrated vegetables and fruits	Semi-dried tomatoes	Hepatitis virus	Hepatitis A virus	2011	United Kingdom	Descriptive epidemiological evidence	7	4	0
Cooked vegetable salads	Broccoli salad	Calicivirus	Norovirus (Norwalk-like virus)	2007	Denmark	(b)	14	0	0
	Salads offered as buffet	Calicivirus	Norovirus (Norwalk-like virus)	2009	Germany	Analytical epidemiological evidence; Laboratory detection in human cases	102	0	0
	Raw, chopped onion in salad	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence; Laboratory detection in human cases	52	0	0
	Mixed salad	Calicivirus	Norovirus (Norwalk-like virus)	2010	Norway	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	38	0	0
	Mixed vegetable salad	Calicivirus	Norovirus (Norwalk-like virus)	2010	United Kingdom	Descriptive epidemiological evidence	20	0	0
	Bulgur salad	Calicivirus	Norovirus (Norwalk-like virus)	2011	Sweden	Descriptive epidemiological evidence	70	0	0
	Prepared salads	Calicivirus	Norovirus (Norwalk-like virus)	2011	Germany	Descriptive epidemiological evidence	4	0	0
	Salad	Calicivirus	Norovirus (Norwalk-like virus)	2011	Finland	Descriptive epidemiological evidence	34	1	0
	Potato salad	*Salmonella* spp.	*S.* Enteritidis	2007	Germany	Laboratory detection in implicated food	14	0	0
	Potato salad	*Salmonella* spp.	*S.* Enteritidis	2007	Slovenia	Laboratory detection in human cases; Laboratory detection in implicated food	15	2	0
	Potato salad	*Staphylococcus* spp.	*S. aureus*	2007	Switzerland	Laboratory detection in human cases; Laboratory detection in implicated food	12	10	0
	Potato salad	*Staphylococcus* spp.	*S. aureus*	2009	Switzerland	Laboratory detection in implicated food	30	0	0
	Potato salad	*Staphylococcus* spp.	Staphylococcal enterotoxins	2010	Switzerland	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	27	27	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Cooked vegetable salads	Potato salad	*Staphylococcus* spp.	Staphylococcal enterotoxins	2011	Germany	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	5	3	0
	Pasta salad	*Staphylococcus* spp.	Staphylococcal enterotoxins	2009	Netherlands	Laboratory detection in implicated food	2	NR	NR
	Aubergine salad	*Bacillus* spp.	*B. cereus*	2007	Netherlands	Laboratory detection in implicated food	2	NR	NR
	Salad	*Bacillus* spp.	*B. cereus*	2010	Finland	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	2	0	0
	Boiled noodles with vegetables	*Bacillus* spp.	*B. cereus*	2007	Netherlands	Laboratory detection in implicated food	3	NR	NR
	Boiled wheat salad with raw Fennel and black olives from glass jars	*Escherichia coli*, pathogenic [(a)]	NR	2007	Denmark	Laboratory detection in human cases; Laboratory detection in implicated food	45	0	0
	NR	VTEC	VTEC O157	2011	United Kingdom	Descriptive epidemiological evidence	7	2	0
	Potato salad with onion	*Staphylococcus* spp.	*S. aureus*	2009	Slovakia	Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	17	0	0
	Salad	*Shigella* spp.	*S. sonnei*	2008	Austria	Analytical epidemiological evidence	53	1	0
	Salad buffet	*Shigella* spp.	*S. sonnei*	2011	Norway	Analytical epidemiological evidence	31	2	0
	Ready-to-eat salad mix	*Yersinia* spp.	*Y. enterocolitica* O9	2011	Norway	Analytical epidemiological evidence	21	4	0
	Pre-cut salad mix	*Cryptosporidium* spp.	*C. parvum*	2008	Finland	Analytical epidemiological evidence; Laboratory detection in human cases	87	4	0
Fruit (non specified)[(a)]	NR	Calicivirus	NR	2007	France	Analytical epidemiological evidence	12	0	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2009	Denmark	Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	8	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	NR	*Shigella* spp.	*S. flexneri*	2010	Poland	Analytical epidemiological evidence	2	1	0
Other processed products	Cooked raspberry	Calicivirus	Norovirus (Norwalk-like virus)	2008	Finland	Analytical epidemiological evidence; Laboratory detection in human cases	29	0	0
	Frozen raspberries (sauce)	Calicivirus	Norovirus (Norwalk-like virus)	2009	Finland	Analytical epidemiological evidence; Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	32	0	0
	Raspberries sauce	Calicivirus	Norovirus (Norwalk-like virus)	2011	Sweden	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	82	0	0
	Stewed eggplant	*Staphylococcus* spp.	Staphylococcal enterotoxins	2011	Denmark	Descriptive epidemiological evidence;Detection of causative agent in food vehicle or its component - Detection of	6	0	0
	Tomato soup	*Bacillus* spp.	*B. cereus*	2009	Netherlands	Laboratory detection in implicated food	12	NR	NR
	Tomato sauce	*Clostridium* spp.	*C. perfringens*	2009	Netherlands	Laboratory detection in implicated food	3	NR	NR
	Pea soup	*Clostridium* spp.	*C. perfringens*	2009	Netherlands	Laboratory detection in implicated food	4	NR	NR
	Bean soup	*Bacillus* spp.	*B. cereus*	2011	Belgium	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	178	0	0
	Mixed cooked legumes	Calicivirus	Norovirus (Norwalk-like virus)	2010	Germany	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	40	0	0
	Pesto	*Bacillus* spp.	*B. cereus*	2009	Netherlands	Laboratory detection in implicated food	2	NR	NR
	Potato mash	*Salmonella* spp.	*S.* Enteritidis	2008	Latvia	Analytical epidemiological evidence; Laboratory detection in human cases	35	21	0
	Potato mash	*Salmonella* spp.	*S.* Enteritidis	2008	Latvia	Analytical epidemiological evidence; Laboratory detection in implicated food	35	28	0
	Cooked, smashed potatoes	*Bacillus* spp.	*B. cereus*	2008	Finland	Laboratory detection in implicated food	5	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	Cooked peeled potatoes	Calicivirus	Norovirus (Norwalk-like virus)	2010	Germany	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	41	0	0
	Curry potato dish	*Clostridium* spp.	*C. perfringens*	2011	Netherlands	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	3	NR	NR
	Rice, boiled and fried	*Bacillus* spp.	*B. cereus*	007	Germany	Laboratory detection in implicated food	2	0	0
Other processed products	Rice	*Bacillus* spp.	*B. cereus*	007	Germany	Laboratory detection in implicated food	51	0	0
	Boiled rice	*Bacillus* spp.	*B. cereus*	007	Netherlands	Laboratory detection in implicated food	4	NR	NR
	Risotto	*Bacillus* spp.	*B. cereus*	007	Slovakia	Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	14	0	0
	Fried rice	*Bacillus* spp.	*B. cereus*	008	Netherlands	Laboratory detection in implicated food	5	NR	NR
	Fried rice	*Bacillus* spp.	*B. cereus*	008	Netherlands	Laboratory detection in implicated food	8	NR	NR
	Cooked rice	*Bacillus* spp.	*B. cereus*	008	Sweden	Laboratory detection in implicated food	5	0	0
	Cooked rice	*Bacillus* spp.	*B. cereus*	2008	Sweden	Analytical epidemiological evidence; Laboratory detection in implicated food	115	0	0
	Rice	*Bacillus* spp.	*B. cereus*	2009	Netherlands	Laboratory detection in implicated food	3	NR	NR
	Rice	*Bacillus* spp.	*B. cereus*	2009	Netherlands	Laboratory detection in implicated food	3	NR	NR
	Rice	*Bacillus* spp.	*B. cereus*	2009	Netherlands	Laboratory detection in implicated food	3	NR	NR
	Rice	*Bacillus* spp.	*B. cereus*	2009	Netherlands	Laboratory detection in implicated food	2	NR	NR
	Chinese rice dish	*Bacillus* spp.	*B. cereus*	2010	Netherlands	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	2	0	0
	Chinese rice dish	*Bacillus* spp.	*B. cereus*	2010	Netherlands	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	2	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	Rice	Bacillus spp.	B. cereus	2011	Denmark	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	4	0	0
	Rice	Bacillus spp.	B. cereus	2011	Sweden	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	3	0	0
	Cooked rice	Bacillus spp.	B. cereus	2011	Germany	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	2	2	0
	Cooked rice	Bacillus spp.	B. cereus	2011	Germany	Detection of causative agent in food chain or its environment - Detection of indistinguishable causative agent in humans	8	0	0
	Rice with vegetables	Bacillus spp.	B. cereus	2011	Denmark	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	1	0	0
	Rice	*Staphylococcus* spp.	*S. aureus*	2007	Netherlands	Laboratory detection in implicated food	4	NR	NR
Other processed products	Indonesian rice table	*Staphylococcus* spp.	*S. aureus*	2007	Netherlands	Laboratory detection in implicated food	2	NR	NR
	Cooked rice	Staphylococcal enterotoxins	Staphylococcal Enterotoxin A	2011	Portugal	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	50	0	0
	Sushi-rice	Calicivirus	Norovirus (Norwalk-like virus)	2009	Sweden	Analytical epidemiological evidence; Laboratory detection in human cases	28	0	0
	Pasta with semolina	*Staphylococcus* spp.	Staphylococcal enterotoxins	2007	Hungary	Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	120	8	1
	Pasta	*Staphylococcus* spp.	*S. aureus*	2007	Netherlands	Laboratory detection in implicated food	2	NR	NR
	Pasta	*Staphylococcus* spp.	*S. aureus*	2007	Netherlands	Laboratory detection in implicated food	2	NR	NR
	Boiled noodles	*Staphylococcus* spp.	*S. aureus*	2007	Netherlands	Laboratory detection in implicated food	4	NR	NR

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
	Spaghetti	*Staphylococcus* spp.	*S.* enterotoxins	2009	Belgium	Laboratory detection in implicated food	10	0	0
	Pasta meal	*Bacillus* spp.	*B. cereus*	2008	Netherlands	Analytical epidemiological evidence; Laboratory detection in implicated food	30	0	0
	Pastes	*Bacillus* spp.	*B. cereus*	2009	Slovakia	Laboratory characterization of food and human isolates; Laboratory detection in human cases; Laboratory detection in implicated food	16	0	0
	Noodle	*Salmonella* spp.	*S.* Enteritidis	2010	Hungary	Analytical epidemiological evidence	18	1	0
	Chinese noodle dish	*Bacillus* spp.	*B. cereus*	2010	Netherlands	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	2	0	0
	Chinese rice/noodle dish	*Bacillus* spp.	*B. cereus*	2010	Netherlands	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	2	0	0
Other processed products	Rice and Indian lentils	*Bacillus* spp.	*B. cereus*	2010	Germany	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	3	0	0
	Kisir	*Bacillus* spp.	*B. cereus*	2010	Finland	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	8	0	0
	Bulgur wheat	*Bacillus* spp.	*B. cereus*	2011	Denmark	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	11	0	0
	Bulgur wheat	*Bacillus* spp.	*B. cereus*	2011	Denmark	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	2	0	0
	Falafel	*Salmonella* spp.	*S.* Infantis	2010	Sweden	Descriptive epidemiological evidence; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	18	0	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Vegetables and juices and other products thereof[(a)]	NR	Calicivirus	Norovirus (Norwalk-like virus)	2009	Poland	Analytical epidemiological evidence; Laboratory detection in human cases	13	0	0
	NR	Calicivirus	Norovirus (Norwalk-like virus)	2011	Denmark	Descriptive epidemiological evidence	11	0	0
	NR	Hepatitis virus	Hepatitis A virus	2010	Netherlands	Analytical epidemiological evidence	13	0	0
	NR	*Salmonella* spp.	*S.* Enteritidis	2007	Germany	Laboratory detection in implicated food	38	1	0
	NR	*Salmonella* spp.	*Salmonella* spp.	2010	France	Descriptive epidemiological evidence	2	2	0
	NR	*Salmonella* spp.	*S.* Typhimurium	2010	France	Descriptive epidemiological evidence	5	1	0
	NR	*Salmonella* spp.	*S.* Enteritidis	2011	Poland	Analytical epidemiological evidence;Descriptive epidemiological evidence;Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent; Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	5	4	0
	NR	*Salmonella* spp.	*S.* Enteritidis	2011	Poland	Analytical epidemiological evidence; Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent ;Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	20	3	0
	Handling raw leeks, handling raw potatoes	Pathogenic *Escherichia coli*,	VTEC O157	2011	United Kingdom	Analytical epidemiological evidence	250	79	1
	NR	VTEC	VTEC O104:H4 - EAggEC positive vtx2 positive	2011	France	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	15	15	0
	NR	*Staphylococcus* spp.	*S. aureus*	2008	France	Analytical epidemiological evidence; Laboratory detection in human cases	8	8	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Vegetables and juices and other products thereof[(a)]	NR	*Staphylococcus* spp.	*S. aureus*	2008	France	Analytical epidemiological evidence; Laboratory detection in human cases	4	0	0
	NR	*Clostridium* spp.	*C. perfringens*	2009	France	Analytical epidemiological evidence; Laboratory detection in human cases	100	0	0
	NR	*Clostridium* spp.	*C. perfringens*	2011	Hungary	Analytical epidemiological evidence	45	1	0
	NR	*Clostridium* spp.	*Clostridium* spp., unspecified	2009	France	Laboratory detection in human cases; Laboratory detection in implicated food	2	2	0
	NR	*Clostridium* spp.	*C. botulinum*	2010	France	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	5	4	1
	NR	*Clostridium* spp.	*C. botulinum*	2011	Poland	Descriptive epidemiological evidence	3	2	0
	NR	*Clostridium* spp.	*C. botulinum*	2011	Poland	Analytical epidemiological evidence; Descriptive epidemiological evidence	2	2	0
	NR	*Bacillus* spp.	*B. cereus*	2009	France	Analytical epidemiological evidence; Laboratory detection in human cases	2	NR	0
	NR	*Bacillus* spp.	*B. cereus*	2011	France	Descriptive epidemiological evidence	7	0	0
Cereal products including rice and seeds/pulses (nuts, almonds)[(a)]	NR	*Bacillus* spp.	*B. cereus*	2007	Belgium	Laboratory detection in implicated food	2	0	0
	NR	*Bacillus* spp.	*B. cereus*	2008	France	Analytical epidemiological evidence; Laboratory detection in human cases	2	2	0
	NR	*Bacillus* spp.	*B. cereus*	2010	Belgium	Detection of causative agent in food vehicle or its component - Symptoms and onset of illness pathognomonic to causative agent	9	0	0
	NR	*Bacillus* spp.	*B. cereus*	2011	France	Descriptive epidemiological evidence	20	1	0

Foodstuff implicated	More foodstuff information	Causative agent	Zoonotic agent species/serovars	Year	Country	Type of evidence	Human cases	Hospitalisations	Deaths
Cereal products including rice and seeds/pulses (nuts, almonds)[(a)]	NR	*Bacillus* spp.	*B. cereus*	2011	France	Descriptive epidemiological evidence	2	1	0
	NR	*Staphylococcus* spp.	*S. aureus*	2007	France	Analytical epidemiological evidence	2	0	0
	NR	*Staphylococcus* spp.	*S. aureus*	2008	France	Analytical epidemiological evidence; Laboratory detection in human cases	2	0	0
	NR	*Staphylococcus* spp.	*S. aureus*	2009	France	Analytical epidemiological evidence; Laboratory detection in human cases	2	0	0
	NR	Staphylococcal enterotoxins	Staphylococcal enterotoxins	2011	France	Detection of causative agent in food chain or its environment - Detection of indistinguishable causative agent in humans	9	1	0
Other	Food supplement containing contaminated hemp flour	*Salmonella* spp.	*S.* Montevideo	2010	Germany	Detection of causative agent in food vehicle or its component - Detection of indistinguishable causative agent in humans	4	1	0

NR: not reported
(a) No additional information have been reported
(b) Based on the Kaplan criteria this is considered a Norovirus outbreak

C. DATA REPORTED IN THE ZOONOSES DATABASE ON OCCURRENCE OF ZOONOTIC AGENTS IN FONAO (2004-2010)

Table 27: Reported occurrence of *Salmonella* spp., *Campylobacter* spp., pathogenic *Escherichia coli*, *Staphylococcus aureus*, *Yersinia* spp., *Cronobacter* spp. and viruses in FoNAO in the reporting countries[33] in accordance with Directive 2033/99/EC[34], 2004-2011

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
Salmonella spp.	2004	at processing plant	Surveillance/Monitoring	71	0	1
			NR	2,579	1	1
		at retail	Surveillance/Monitoring	1,250	1	2
			Survey	2,963	32	1
			NR	1,679	7	0
		NR	Surveillance/Monitoring	33	1	1
			NR	5,620	64	7
	2005	at processing plant	Surveillance/Monitoring	3,218	1	2
			NR	42	0	1
		at retail	Surveillance/Monitoring	1,617	4	2
			NR	381	0	3
		NR	NR	3,042	18	12
	2006	at processing plant	Surveillance/Monitoring	3,708	0	2
		at retail	Surveillance/Monitoring	1,989	5	5
			NR	30	0	1
		NR	Surveillance/Monitoring	58	0	1
			HACCP and own checks	87	0	2
			NR	4,622	24	15

33 EU countries including Norway and Switzerland

34 Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. OJ L 325, 12.12.2003, p. 31–40

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
	2007	at processing plant	Survey	409	0	1
			Monitoring	22	0	1
			NR	3,667	1	3
		at retail	Surveillance/Monitoring	7,566	41	3
			NR	1,308	1	3
		NR	Monitoring	1,323	2	1
			NR	7,970	28	16
	2008	at catering	Surveillance/Monitoring	684	0	2
			HACCP and own checks	63	0	1
		at cutting plant	Surveillance/Monitoring	298	1	1
			NR	655	1	1
		at farm	Surveillance/Monitoring	3	0	1
		at hospital or care home	Surveillance/Monitoring	82	0	1
		at processing plant	Surveillance/Monitoring	1,595	1	7
			HACCP and own checks	3,023	0	2
		at retail	Surveillance/Monitoring	5,344	73	13
			Survey	131	0	1
			NR	330	0	1
		NR	Surveillance/Monitoring	3,027	13	4
			HACCP and own checks	413	0	2
			Survey	12	0	1
			NR	2,961	11	4
	2009	at catering	Surveillance/Monitoring	675	0	3
			HACCP and own checks	27	1	1

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
			NR	57	0	1
		at hospital or care home	Surveillance/Monitoring	9	0	1
			HACCP and own checks	1	0	1
		at packing centre	Surveillance/Monitoring	490	0	1
			HACCP and own checks	1	0	1
		at processing plant	Surveillance/Monitoring	863	0	5
			HACCP and own checks	1,801	1	3
			NR	70	0	1
		at retail	Surveillance/Monitoring	5,718	1	8
			HACCP and own checks	540	3	2
			Survey	390	1	2
			NR	3,367	109	4
		NR	Surveillance/Monitoring	956	3	2
			HACCP and own checks	196	0	1
			Survey	49	0	1
			NR	3,477	7	15
	2010	at catering	Surveillance/Monitoring	486	0	4
			HACCP and own checks	87	0	2
		at hospital or care home	Surveillance/Monitoring	3	0	1
		at packing centre	Surveillance/Monitoring	32	2	3
			HACCP and own checks	400	0	2
		at processing plant	Surveillance/Monitoring	770	3	6
			HACCP and own checks	2,810	0	2
		at retail	Surveillance/Monitoring	3,099	9	8
			HACCP and own checks	202	0	2
			NR	3,059	44	1

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
		NR	Surveillance/Monitoring	947	3	3
			HACCP and own checks	167	0	1
			Survey	36	0	1
			NR	2,218	2	9
	2011	at processing plant	HACCP and own checks	315	0	3
			Survey	172	0	1
			Surveillance/Monitoring	993	2	7
			NR	78	0	1
		at border control	Surveillance	1	0	1
		at retail	HACCP and own checks	121	0	2
			Survey	1,569	1	1
			Survey	23	0	1
			Surveillance/Monitoring	7,443	54	13
			NR	707	2	1
		at catering	HACCP and own checks	475	0	3
			Surveillance	342	0	3
			NR	98	0	1
		NR	HACCP and own checks	161	0	2
			Survey - national survey	25	0	1
			Surveillance	147	0	1
			NR	2,866	5	3
Total *Salmonella* spp.				**122,414**	**584**	
Campylobacter spp.	2004	at processing plant	NR	9	0	1
		at retail	NR	37	0	1
		NR	NR	211	2	2

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
	2005	at processing plant	Surveillance/Monitoring	12	0	1
		at retail	Surveillance/Monitoring	30	0	1
		NR	NR	209	2	1
	2006	at retail	Surveillance/Monitoring	21	0	1
			NR	200	0	1
		NR	NR	950	3	2
	2007	at retail	Surveillance/Monitoring	162	2	2
			NR	55	1	3
	2008	at cutting plant	Surveillance/Monitoring	761	2	1
			NR	178	5	1
		at retail	Surveillance/Monitoring	225	0	3
			NR	139	0	1
		NR	HACCP and own checks	20	0	1
	2009	at retail	Surveillance/Monitoring	17	0	1
			Survey	35	0	1
		NR	Surveillance/Monitoring	63	0	1
			NR	300	0	1
	2010	at processing plant	Surveillance/Monitoring	71	0	1
		at retail	Surveillance/Monitoring	18	0	1
		NR	Surveillance/Monitoring	8	0	1
			Survey	25	8	1
	2011	at processing plant	Survey	165	4	1
			Surveillance	10	0	2
			NR	3		1
		at retail	Survey	537	5	2

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
			Surveillance/Monitoring	126	0	3
			NR	67	0	2
		NR	HACCP and own checks	1	0	1
			Survey	25	0	1
			Surveillance	8	0	1
Total *Campylobacter* spp.				**4,698**	**34**	
Cronobacter spp.	2011	at retail	Surveillance	25	0	1
Total *Cronobacter* spp.				**25**	**0**	
Escherichia coli, pathogenic	2004	at processing plant	NR	337	0	1
		at retail	Surveillance/Monitoring	9	0	1
			NR	12	0	1
		NR	Survey	75	0	1
			NR	240	0	3
	2005	at processing plant	NR	20	0	1
		at retail	Surveillance/Monitoring	14	0	1
			NR	85	0	2
		NR	NR	302	0	5
	2006	at retail	Surveillance/Monitoring	9	0	1
		NR	NR	1,297	4	9
	2007	at retail	NR	2,030	0	4
		NR	NR	231	0	3
	2008	at cutting plant	Surveillance/Monitoring	11	0	1
		at retail	Surveillance/Monitoring	162	0	3
		NR	Surveillance/Monitoring	471	5	2

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
			HACCP and own checks	3	0	1
			NR	500	2	2
	2009	at processing plant	Surveillance/Monitoring	5	0	1
		at retail	Surveillance/Monitoring	35	0	1
			NR	1	0	1
		NR	NR	98	3	3
	2010	at retail	Surveillance/Monitoring	3	0	1
		NR	Surveillance/Monitoring	7	0	1
			Survey	18	1	1
			NR	372	6	3
	2011	at catering	Monitoring	42	0	1
		at cutting plant	Surveillance	17	0	1
		at processing plant	HACCP and own checks	2	0	1
			Survey	160	0	1
			Surveillance/Monitoring	275	0	7
			NR	39	0	1
		at retail	HACCP and own checks	4	0	1
			Surveillance/Monitoring	4,189	6	10
			Survey	75	0	2
			NR	133	0	2
		NR	Survey	1	0	1
			Surveillance	4	0	1
			NR	24	4	1
Total *Escherichia coli*, pathogenic				**11,312**	**31**	

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
Staphylococcus aureus	2010	at catering	Surveillance/Monitoring	12	0	1
			HACCP and own checks	20	0	1
		at retail	Survey	62	0	1
		NR	Surveillance/Monitoring	506	1	2
			NR	1	0	1
	2011	at catering	HACCP and own checks	12	3	1
			Survey	1	0	1
			NR	3	0	1
		at processing plant	HACCP and own checks	13	0	1
			NR	5	0	1
		at retail	Survey	1	0	1
			Monitoring	66	8	1
			NR	1	0	1
Total *Staphylococcus aureus*				**703**	**12**	
Staphylococcal enterotoxins	2007	at retail	NR	5	0	1
		NR	NR	2	0	1
	2008	NR	NR	23	1	1
	2009	at retail	Surveillance/Monitoring	1	1	1
	2010	at catering	Surveillance/Monitoring	3	0	1
		at retail	Surveillance/Monitoring	1	1	1
	2011	at catering	HACCP and own checks	1	0	1
			NR	1	0	1
		at processing plant	NR	2	0	1
		at retail	Survey	1	0	1
		unspecified	HACCP and own checks	3	0	1

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
Total *Staphylococcal* enterotoxins				**43**	**3**	
Yersinia spp.	2005	at farm	Surveillance/Monitoring	150	16	1
		at processing plant	Survey	26	13	1
		at retail	Survey	36	31	1
	2006	at farm	Survey	52	26	1
		at processing plant	Surveillance/Monitoring	162	110	1
		at retail	Surveillance/Monitoring	15	14	1
		NR	NR	21	1	1
	2007	at processing plant	NR	34	22	1
		NR	HACCP and own checks	1	0	1
			NR	6	0	1
	2008	at processing plant	Surveillance/Monitoring	1	0	1
		NR	Surveillance/Monitoring	1	0	1
			HACCP and own checks	1	0	1
	2009	NR	NR	31	2	2
	2010	at retail	Survey	62	0	1
	2011	at catering	HACCP and own checks	2	0	1
		at processing plant	Survey	244	0	1
		at retail	Survey	53	0	1
			Surveillance	1	0	1
			NR	93	0	1
		NR	HACCP and own checks	7	0	1
			Survey	1	1	1

Causative agent	Year	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of MSs contributing to the merged data sets
Total *Yersinia* spp.				**1,000**	**236**	
Viruses[(a)]	2009	at retail	Surveillance/Monitoring	47	0	1
	2010	at retail	Surveillance/Monitoring	41	0	1
Total Viruses				**88**	**0**	

NR: not reported
(a) Including: Calicivirus and Hepatitis A virus

Table 28: Reported occurrence of *Listeria monocytogenes* in FoNAO in the reporting countries[1] in accordance with Directive 2033/99/EC, 2004-2011

Year[(a)]	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of samples with counts > 100 cfu/g	Total number of countries contributing to the merged data sets
2005	at farm	Surveillance/Monitoring	26	0	0	1
	at processing plant	Surveillance/Monitoring	63	6	0	1
		NR	20	0	0	1
	at retail	Surveillance/Monitoring	1,542	15	0	3
		NR	127	1	0	3
	NR	NR	870	9	0	8
2006	at processing plant	Surveillance/Monitoring	72	6	0	1
	at retail	Surveillance/Monitoring	1,017	18	0	4
	NR	Surveillance/Monitoring	129	0	0	3
		HACCP and own checks	7	0	0	1
		NR	1,491	282	3	8
2007	at processing plant	NR	147	5	1	3
	at retail	Surveillance/Monitoring	315	2	0	2
		Survey	70	0	0	1
		NR	3,571	17	0	5
	NR	NR	196	2	1	5
2008	at catering	HACCP and own checks	354	5	1	2
	at processing plant	Surveillance/Monitoring	384	7	0	5
	at retail	Surveillance/Monitoring	2,015	25	1	10
		Survey	506	4	0	3
	NR	Surveillance/Monitoring	580	15	0	2
		HACCP and own checks	422	2	0	1
		NR	857	68	0	2

Year[(a)]	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of samples with counts > 100 cfu/g	Total number of countries contributing to the merged data sets
2009	at catering	NR	349	6	0	2
	at processing plant	Surveillance/Monitoring	368	10	1	5
		Survey	1	0	0	1
		NR	3	0	0	1
	at retail	Surveillance/Monitoring	1,485	25	0	5
		HACCP and own checks	336	19	0	1
		Survey	72	0	0	1
		NR	271	4	0	2
	NR	Surveillance/Monitoring	491	6	0	2
		HACCP and own checks	21	0	0	1
		NR	312	49	0	1
2010	at catering	Surveillance/Monitoring	155	3	0	3
	at processing plant	Surveillance/Monitoring	222	11	1	6
		NR	33	0	0	1
	at retail	Surveillance/Monitoring	1,827	29	3	7
		Survey	65	0	0	1
	NR	Surveillance/Monitoring	39	10	0	3
		HACCP and own checks	57	46	1	1
		NR	914	27	6	1
2011	at catering	HACCP and own checks	111	0	0	2
		Surveillance	429	9	0	4
		NR	96	1	0	1
	at processing plant	HACCP and own checks	10	0	0	1
		Surveillance/Monitoring	954	7	0	7
		Survey	15	1	0	1

Year[(a)]	Sampling stage	Sampling framework	Total number of samples	Total number of positive samples	Total number of samples with counts > 100 cfu/g	Total number of countries contributing to the merged data sets
		Survey - national survey	266	0	0	2
		NR	41	2	0	1
	at retail	HACCP and own checks	37	0	0	1
		Surveillance/Monitoring	5,766	57	2	13
		Survey	19	0	0	1
		Survey - national survey	544	0	0	2
		NR	718	11	0	1
	NR	HACCP and own checks	261	5	0	3
		Surveillance	142	1	0	2
		Survey	4	0	0	1
		NR	1,773	56	1	5
Total *Listeria monocytogenes*			**32,988**	**884**	**22**	

NR: not reported
1. EU countries including Norway and Switzerland
(a) Available data for 2004 was excluded for all reporting countries, as it did not allow to extract the required subtotals to fill in the columns in this table

D. RASFF NOTIFICATIONS

Table 29: Number of RASFF notifications on selected biological hazards, by hazard and product category (2001-2011).

	Hazard													
	Bacillus	**Calicivirus**	***Campylobacter***	***Clostridium***	***Escherichia coli*** [(a)]	**Foodborne Outbreak**	**Hepatitis A Virus**	***Listeria***	**Norovirus**	**Parasitic Infestation**	***Salmonella***	***Shigella***	***Staphylococcus***	**Total**
Product														
Cereals And Bakery Products	1	0	1	0	0	2	0	1	0	1	8	0	0	**14**
Cocoa And Cocoa Preparations, Coffee And Tea	0	0	0	0	4	0	0	0	0	0	4	0	0	**8**
Fruits And Vegetables	16	2	10	13	14	15	3	5	18	2	194	1	3	**293**
Herbs And Spices	30	0	0	7	40	0	0	0	0	0	326	1	1	**405**
Non-Alcoholic Beverages	1	0	0	0	0	0	0	0	0	0	0	0	0	**1**
Nuts, Nut Products And Seeds	10	0	0	2	1	2	0	0	0	4	149	0	1	**169**
Other Food Product / Mixed	0	0	0	0	0	0	0	0	0	0	11	0	0	**11**
Total	**58**	**2**	**11**	**22**	**59**	**19**	**3**	**6**	**18**	**7**	**692**	**2**	**5**	**904**

(a) *Escherichia coli* notifications may refer to pathogenic and non-pathogenic strains.

Table 30: Number of RASFF notifications on selected biological hazards, by detailed product information and hazard (2001-2011)

Product	**Corresponding FoNAO Category /ies**	**Biological hazard**													**Total**
		Bacillus	**Calicivirus**	***Campylobacter***	***Clostridium***	***Escherichia coli*** [(a)]	**Foodborne Outbreak**	**Hepatitis A Virus**	***Listeria***	**Norovirus**	**Parasitic Infestation**	***Salmonella***	***Shigella***	***Staphylococcus***	
Acai Berry Juice	Other berries	1	0	0	0	0	0	0	0	0	0	0	0	0	**1**
Pip fruit	Other berries/ apples and related fruit/ melons	0	0	0	0	0	0	0	0	0	0	3	0	0	**3**
Soft fruit	Strawberries/ Raspberries/ Other berries	0	2	0	0	0	5	0	0	16	0	0	0	0	**23**
Tropical/other fruits	Tropical fruit	2	0	0	0	1	0	2	0	0	1	14	0	1	**21**
Melons	Melons	0	0	0	0	0	0	0	0	0	0	2	0	0	**2**
Cantaloupes	Melons	0	0	0	0	0	1	0	0	0	0	0	0	0	**1**
Tomatoes	Tomatoes	0	0	0	0	0	3	1	0	0	0	1	0	0	**5**
Peppers	Peppers and aubergines	0	0	0	0	0	0	0	1	0	0	0	0	0	**1**
Leafy green	Leafy greens eaten raw as salads	0	0	6	0	3	4	0	1	2	0	33	0	0	**49**
Tea	Fresh herbs/ spices and dry powdered herbs/ beverages	0	0	0	0	4	0	0	0	0	0	4	0	0	**8**
Basil	Fresh herbs/ spices and dry powdered herbs	0	0	0	0	16	0	0	0	0	0	49	1	1	**67**
Coriander	Fresh herbs/ spices and dry powdered herbs	0	0	0	0	1	0	0	0	0	0	24	0	0	**25**
Mint	Fresh herbs/ spices and dry powdered herbs	0	0	0	0	6	0	0	0	0	0	8	0	0	**14**
Peppermint	Fresh herbs/ spices and dry powdered herbs	0	0	0	0	5	0	0	0	0	0	21	0	0	**26**
Other herbs and spices	Fresh herbs/ spices and dry powdered herbs	20	0	0	5	12	0	0	0	0	0	184	0	0	**221**
Black pepper	Spices and dry powdered herbs	4	0	0	1	0	0	0	0	0	0	22	0	0	**27**
Chilli	Spices and dry powdered herbs	4	0	0	0	0	0	0	0	0	0	11	0	0	**15**
Mixed and other produce	NA	0	0	3	2	6	1	0	2	0	0	111	1	0	**126**
Spring onions	Bulb and stem vegetables	0	0	1	0	0	0	0	0	0	0	1	0	0	**2**

Product	Corresponding FoNAO Category /ies	Biological hazard													Total
		Bacillus	Calicivirus	*Campylobacter*	*Clostridium*	*Escherichia coli* [(a)]	Foodborne Outbreak	Hepatitis A Virus	*Listeria*	Norovirus	Parasitic Infestation	*Salmonella*	*Shigella*	*Staphylococcus*	
Crucifers	Leafy greens eaten raw as salads/ flowers and flower buds/ other root and tuberous vegetables	1	0	0	0	0	0	0	0	0	0	2	0	0	**3**
Cereals and cereal products	Cereals and dry legumes/ rice/ pasta/ other dry legumes, cereals, edible seeds and grains, flours and products thereof	1	0	0	0	0	0	0	0	0	0	3	0	0	**4**
Rice	Rice	0	0	0	0	0	1	0	0	0	1	3	0	0	**5**
Corn	Cereals	0	0	1	0	0	1	0	1	0	0	2	0	0	**5**
Sesame seeds	Other dry legumes, cereals, edible seeds and grains, flours and products thereof	6	0	0	0	1	0	0	0	0	0	80	0	0	**87**
Other seeds and nuts	Other dry legumes, cereals, edible seeds and grains, flours and products thereof/ nuts and nut products	6	0	0	3	0	1	0	0	0	4	73	0	1	**88**
Seeds for sprouting	Sprouted seeds	0	0	0	0	0	1	0	0	0	0	3	0	0	**4**
Sprouted seeds	Sprouted seeds	0	0	0	0	3	0	0	0	0	0	4	0	0	**7**
Mushroom	Mushrooms, fungi and yeasts	13	0	0	11	1	1	0	1	0	1	23	0	2	**53**
Other FoNAO	NA	0	0	0	0	0	0	0	0	0	0	11	0	0	**11**
Total		**58**	**2**	**11**	**22**	**59**	**19**	**3**	**6**	**18**	**7**	**692**	**2**	**5**	**904**

(a) *Escherichia coli* notifications may refer to pathogenic and non-pathogenic strains.
NA: not applicable

Table 31: Summary of the RASFF notifications regarding food borne outbreaks (from 2000 to 2011).

Date	Reference	Notifying Country	Reason for notification[35]	Microbiological hazard	Product	Origin	Distribution	Comments
May 2003	2003/123	Italy	Suspicion of food poisoning outbreak	--	Tinned/canned raw sliced mushrooms	Netherlands	--	Two persons were hospitalised after having consumed the tinned product concerned, among foods. Serum and faeces from one patient were analysed to identify *Clostridium botulinum* toxins and spores, but results of tests were negative.
March 2006	2006.ASW	Denmark	Suspicion of food poisoning outbreak	Microbiological contamination (suspicion)	Frozen raspberry	Serbia and Montenegro via Czech Republic	Denmark	25 persons affected
August 2007	2007.0568	Denmark	Suspicion of food poisoning outbreak	*Shigella sonnei*	Baby corn	Thailand	Sweden	Approx. 45 persons affected of which 8 patients had positive stool cultures for S*higella sonnei.* Patient-interviews and food histories suggest that the outbreak is caused by contaminated baby corn imported from Thailand.
August 2007	2007.0582	Sweden	Suspicion of food poisoning outbreak	*Salmonella* Java	Baby spinach (product not rinsed)	Italy	No	107 persons infected with *Salmonella* Java. Case-control studies and tracing of food products make it highly likely that baby spinach was the sources of this outbreak of *Salmonella* Java.

[35] As indicated in the RASFF notification

Date	Reference	Notifying Country	Reason for notification[35]	Microbiological hazard	Product	Origin	Distribution	Comments
October 2007	2007.0769	Netherlands	Suspicion of food poisoning outbreak	STEC	Pre-cut iceberg lettuce	Netherlands	Iceland	Early in October of 2007 an increase of human STEC incidence was noticed by STEC surveillance. 36 patients were notified. E. coli O17 was found in patient stools. Molecular typing (PFGE) results of 30 patient isolates showed that 29 isolates were of the same unique molecular type that had not been seen in the Netherlands before. One isolate was slightly different but still had a 97% match with the outbreak type. Analyses of patient questionnaires hint at pre-cut iceberg lettuce as possible outbreak source. At the same time, a STEC outbreak occurred in Iceland as well. As in the Netherlands, iceberg lettuce was mentioned as probable outbreak source. Comparing molecular types of Dutch and Icelandic patient isolates revealed identical types, thus strongly indicating a common outbreak source. Some Icelandic patients had consumed mixed pre-cut lettuce originating from a Dutch distributor.
August 2009	2009.1082	Finland	Suspicion of food poisoning outbreak	*Salmonella* Bovismorbificans	Alfalfa seeds[36] for sprouting	Italy via Sweden	Finland, Sweden, Estonia	About 40 persons affected. Of these, about 20 cases ate ready to eat sprouts manufactured from the Finish company. 1out of 10 samples from alfalfa seeds packages were positive for *Salmonella* Bovismorbificans. Two other *Salmonella* serotypes were also found in this seed sample: *Salmonella* Umbilo and *Salmonella* Szentes but these were not linked to any cases. The *Salmonella* Bovismorbificans strains from patients and from the seed sample were PFGE-genotyped and were identical confirming the epidemiological result. Eight Finnish persons who travelled to Estonia were affected. Four of them were tested and positive to the same type of *Salmonella* Bovismorbificans as last summer in the outbreak in Finland. Also five Estonian persons who ate sprouts in Estonia had *Salmonella* Bovismorbificans in November-December.

[36] The Italian producer stated that they produce and market the seeds exclusively for agriculture; the labels on the products stated "Do not use for food, feed or oil purpose". Before trading, the product has been analysed for pesticides residues, *Salmonella* and *Escherichia coli* with negative results.

Date	Reference	Notifying Country	Reason for notification[35]	Microbiological hazard	Product	Origin	Distribution	Comments
May 2010	2010.0562	Sweden	Suspicion of food poisoning outbreak	Calicivirus	Frozen raspberries	Poland	Sweden	Two patients have been tested positive for calicivirus. Out of 70 persons, 43 fell ill. Raspberries were served as dessert.
May 2010	2010.0564	Sweden	Suspicion of food poisoning outbreak	Calicivirus	Frozen blackberries	Serbia	Sweden	Two patients have been tested positive for calicivirus. Out of 70 persons, 43 fell ill. Blackberries were served as dessert.
November 2010	2010.1563	Denmark	Suspicion of food poisoning outbreak	Suspicion Norovirus	Frozen crumbs of raspberries	Serbia via Sweden	Denmark, Sweden	App. 50 out of app. 200 persons fell ill. Different items were served but the most likely agent to have caused the disease seemed to be raspberry smoothies.
April 2011	2011.0505	Norway	Food poisoning	Suspicion of *Yersinia enterocolitica* O9	Radicchio rosso in ready-made salad mix	Italy, via the United Kingdom	Norway	20 persons have been diagnosed with yersiniosis. *Yersinia enterocolitica* O:9 has been detected in faecal samples from the patients. Epidemiological investigations of patient information indicated readymade salad mix as the most likely source of infection. A PCR-screening has indicated the presence of pathogenic strains of *Yersinia enterocolitica* in the salad 'radicchio rosso' imported from the supplier in Italy. The outbreak strain was not detected in the product by conventional isolation methods.
June 2011	2011.0842	France	Suspicion of food poisoning outbreak	Suspicion of VTEC O104:H4	Organic seeds for sprouting fenugreek	Egypt packaged in United Kingdom, via Germany and Netherlands	Several MSs and third countries.	(EFSA Technical Report www.efsa.europa.eu/en/supporting/doc/176e.pdf) On 24 June, France reported12 a cluster of patients with bloody diarrhoea, after having participated in an event in the Commune of Bègles near Bordeaux on the 8th of June. As of 28th June, eight cases of bloody diarrhoea and a further eight cases with HUS have been identified. Eleven of these patients, seven women and four men, between 31 and 64 years of age, had attended the same event in Bègles. Infection with *Escherichia coli* O104:H4 has been confirmed for four patients with HUS. Six of the cases reported having eaten sprouts at the event on the 8th of June.

Date	Reference	Notifying Country	Reason for notification[35]	Microbiological hazard	Product	Origin	Distribution	Comments
July 2011	2011.1020	Denmark	Suspicion of food poisoning outbreak	Norovirus	Frozen raspberries	Serbia, via the united Kingdom	Denmark	6 persons fell ill after consuming a homemade cake consisting of meringue, whipped cream and frozen raw raspberries. There were no leftovers neither of the cake nor of the raspberries used. Investigations performed showed, that the raspberries used could be from 4 different batches, the batch YA01 11131 being the most likely. Norovirus GI was detected in YA01 11131. Norovirus GGII.7 was detected in samples from one seriously affected and hospitalized person.
July 2011	2011.0924	Denmark	Food poisoning outbreak	Enterotoxigenic *Escherichia coli* O27:H3	Mange tout (peas) (sugar peas)	Kenya, via Netherlands	Denmark	Cases of illness possibly connected to a canteen delivering lunch to 6 companies, approximately 250 persons total. Preliminary investigation showed that 87 of 241 persons became ill. Enterotoxigenic *Escherichia coli* (ETEC) O27:H3 was isolated from 4 of 6 faecal samples. Investigative interviews were performed and the illness seemed correlated with eating lunch on the 9 or 10 June. A full scale cohort study was performed including all dishes served in the canteen where the patients ate in the period 9-10 June. Specifically eating a salad composed of asparagus, broccoli and mange tout peas with a dressing of vinegar and oil seemed significant. Both asparagus and broccoli were steamed prior to serving. The peas were served raw in both salads. The two mentioned salads both contained peas from the same possible lot 148/NM 02 as described under product traceability. Unfortunately no stock from that consignment was left on the market. Samples have been taken from later shipments from the same exporter and none of these samples showed presence of *Escherichia coli*.

Date	Reference	Notifying Country	Reason for notification[35]	Microbiological hazard	Product	Origin	Distribution	Comments
November 2011	2011.1630	Denmark	Food poisoning outbreak	*Salmonella* Strathcona	Datterino tomatoes	Italy	Denmark	The outbreak included a total of 40 culture confirmed human cases. To detect the source of the outbreak detailed patient interviews were carried out and electronic purchase records were collected. A case-control study was carried out; which found that eating small, elongated tomatoes sold in the retail chain, was strongly associated with illness. The overall conclusion of the investigations was that the datterino tomatoes were the source of the outbreak in Denmark with a high probability. In Denmark the tomatoes in question had been sold during September and the first part of October 2011. Since no stock was left it was not possible to perform microbiological analyses on the tomatoes. There had been also 14 *Salmonella* Strathcona cases in Germany and 1 in Austria.

E. Comparative table of ranking in all considered scenarios and individual model output tables

Table 32: Ranking positions for all considered food pathogen combinations in all model scenarios[(a)]

Reference scenario 1 (including all criteria)		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)	
Salmonella	Leafy greens eaten raw as salads	*Salmonella*	Leafy greens eaten raw as salads	*Salmonella*	Leafy greens eaten raw as salads	*Salmonella*	Leafy greens eaten raw as salads	*Salmonella*	Leafy greens eaten raw as salads
Pathogenic *E. coli*	Fresh pods, legumes and grain	*Salmonella*	Sprouted seeds	Norovirus	Leafy greens eaten raw as salads	*Bacillus*	Spices and dry powdered herbs	Pathogenic *E. coli*	Fresh pods, legumes and grain
Salmonella	Bulb and stem vegetables	Pathogenic *E. coli*	Sprouted seeds	*Bacillus*	Spices and dry powdered herbs	Pathogenic *E. coli*	Fresh pods, legumes and grain	Norovirus	Leafy greens eaten raw as salads
Salmonella	Tomatoes	*Salmonella*	Melons	Norovirus	Bulb and stem vegetables	*Salmonella*	Bulb and stem vegetables	*Salmonella*	Bulb and stem vegetables
Salmonella	Melons	Pathogenic *E. coli*	Fresh pods, legumes and grain	Norovirus	Raspberries	*Salmonella*	Melons	*Salmonella*	Melons
Norovirus	Leafy greens eaten raw as salads	*Salmonella*	Bulb and stem vegetables	Pathogenic *E. coli*	Fresh pods, legumes and grain	*Salmonella*	Tomatoes	*Salmonella*	Tomatoes
Salmonella	Sprouted seeds	*Salmonella*	Leafy greens mixed with other fresh FoNAO	*Salmonella*	Bulb and stem vegetables	Norovirus	Leafy greens eaten raw as salads	*Shigella*	Fresh pods, legumes and grain
Shigella	Fresh pods, legumes and grain	*Salmonella*	Tomatoes	*Salmonella*	Tomatoes	*Salmonella*	Sprouted seeds	Norovirus	Bulb and stem vegetables
Bacillus	Spices and dry powdered herbs	Norovirus	Leafy greens eaten raw as salads	*Salmonella*	Spices and dry powdered herbs	*Shigella*	Fresh pods, legumes and grain	Norovirus	Raspberries
Norovirus	Bulb and stem vegetables	Norovirus	Raspberries	Norovirus	Carrots	*Bacillus*	Leafy greens eaten raw as salads	*Salmonella*	Sprouted seeds
Norovirus	Raspberries	*Salmonella*	Raspberries	Norovirus	Tomatoes	*C. perfringens*	Fresh herbs	*Shigella*	Fresh herbs
Pathogenic *E. coli*	Sprouted seeds	*Shigella*	Fresh pods, legumes and grain	*Salmonella*	Melons	*C. perfringens*	Spices and dry powdered herbs	*Yersinia*	Carrots
Salmonella	Leafy greens mixed with other fresh FoNAO	*Bacillus*	Spices and dry powdered herbs	*Salmonella*	Nuts and nut products	Norovirus	Bulb and stem vegetables	Norovirus	Carrots
Salmonella	Spices and dry powdered herbs	Norovirus	Bulb and stem vegetables	*Salmonella*	Raspberries	Norovirus	Raspberries	Norovirus	Tomatoes
Salmonella	Raspberries	*Salmonella*	Nuts and nut products	*Salmonella*	Sprouted seeds	Pathogenic *E. coli*	Sprouted seeds	Pathogenic *E. coli*	Sprouted seeds
Shigella	Fresh herbs	*Salmonella*	Spices and dry powdered herbs	*Shigella*	Fresh pods, legumes and grain	*Salmonella*	Leafy greens mixed with other fresh FoNAO	*Salmonella*	Leafy greens mixed with other fresh FoNAO
Yersinia	Carrots	*Shigella*	Fresh herbs	*Yersinia*	Carrots	*Salmonella*	Raspberries	*Salmonella*	Raspberries
Norovirus	Carrots	*Shigella*	Leafy greens mixed with other fresh FoNAO	*Bacillus*	Leafy greens eaten raw as salads	*Salmonella*	Spices and dry powdered herbs	*Salmonella*	Spices and dry powdered herbs

Reference scenario 1 (including all criteria)		**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)**	
Norovirus	Tomatoes	*Yersinia*	Carrots	*C. perfringens*	Fresh herbs	*Shigella*	Fresh herbs	*Shigella*	Carrots
Salmonella	Nuts and nut products	Hepatitis A virus	Dehydrated vegetables and fruit	*C. perfringens*	Spices and dry powdered herbs	*Yersinia*	Carrots	*Bacillus*	Spices and dry powdered herbs
Shigella	Carrots	Norovirus	Carrots	Hepatitis A virus	Dehydrated vegetables and fruit	Norovirus	Carrots	Hepatitis A virus	Dehydrated vegetables and fruit
Bacillus	Leafy greens eaten raw as salads	Norovirus	Tomatoes	Norovirus	Other berries Strawberries	Norovirus	Tomatoes	Norovirus	Other berries
C. perfringens	Fresh herbs	Norovirus	Other berries	Norovirus	Strawberries	*Salmonella*	Nuts and nut products	Norovirus	Strawberries
C. perfringens	Spices and dry powdered herbs	Norovirus	Strawberries	Pathogenic *E. coli*	Sprouted seeds	*Shigella*	Carrots	*Salmonella*	Nuts and nut products
Hepatitis A virus	Dehydrated vegetables and fruit	*Shigella*	Carrots	*Salmonella*	Leafy greens mixed with other fresh FoNAO	*Bacillus*	Leafy greens mixed with other fresh FoNAO	*Shigella*	Leafy greens mixed with other fresh FoNAO
Norovirus	Other berries	*Bacillus*	Leafy greens eaten raw as salads	*Shigella*	Carrots	Hepatitis A virus	Dehydrated vegetables and fruit	*Bacillus*	Leafy greens eaten raw as salads
Norovirus	Strawberries	*Bacillus*	Leafy greens mixed with other fresh FoNAO	*Shigella*	Fresh herbs	Norovirus	Other berries	*C. perfringens*	Fresh herbs
Shigella	Leafy greens mixed with other fresh FoNAO	*C. perfringens*	Fresh herbs	*Bacillus*	Leafy greens mixed with other fresh FoNAO	Norovirus	Strawberries	*C. perfringens*	Spices and dry powdered herbs
Bacillus	Leafy greens mixed with other fresh FoNAO	*C. perfringens*	Spices and dry powdered herbs	*Cryptosporidium*	Leafy greens mixed with other fresh FoNAO	*Shigella*	Leafy greens mixed with other fresh FoNAO	*Cryptosporidium*	Leafy greens mixed with other fresh FoNAO
Cryptosporidium	Leafy greens mixed with other fresh FoNAO	*Cryptosporidium*	Leafy greens mixed with other fresh FoNAO	*Shigella*	Leafy greens mixed with other fresh FoNAO	*S. aureus*	Fresh pods, legumes and grain	*S. aureus*	Fresh pods, legumes and grain
S. aureus	Fresh pods, legumes and grain	*S. aureus*	Sprouted seeds	*S. aureus*	Fresh pods, legumes and grain	*Cryptosporidium*	Leafy greens mixed with other fresh FoNAO	*Bacillus*	Leafy greens mixed with other fresh FoNAO
S. aureus	Sprouted seeds	*S. aureus*	Fresh pods, legumes and grain	*S. aureus*	Sprouted seeds	*S. aureus*	Sprouted seeds	*S. aureus*	Sprouted seeds

(a) Food pathogen combinations ranking the same position are listed in table sections delimited by bold border lines.

Table 33: Model output for reference scenario 1 (including all criteria)

Pathogen	FoNAO group	Consequences criteria 1	2	3	Total score	Exposure criteria 4	5	6	7	Total score		Final total score SUM	Consequences	Exposure
Salmonella	15	4	3	2	9	3	3	4	3	13	Leafy greens eaten raw as salads	22	9	13
Salmonella	22	2	3	2	7	3	3	4	3	13	Bulb and stem vegetables	20	7	13
Salmonella	11	2	3	2	7	3	3	4	3	13	Tomatoes	20	7	13
Pathogenic *E. coli*	14	2	2	3	7	3	3	4	3	13	Fresh pods, legumes and grain	20	7	13
Salmonella	9	2	3	2	7	3	3	3	4	13	Melons	20	7	13
Salmonella	28	4	3	2	9	3	3	1	3	10	Sprouted seeds	19	9	10
Norovirus	15	4	4	1	9	3	2	4	1	10	Leafy greens eaten raw as salads	19	9	10
Shigella	14	3	2	2	7	3	2	4	3	12	Fresh pods, legumes and grain	19	7	12
Norovirus	22	3	4	1	8	3	2	4	1	10	Bulb and stem vegetables	18	8	10
Pathogenic *E. coli*	28	3	2	3	8	3	3	1	3	10	Sprouted seeds	18	8	10
Salmonella	17	2	3	2	7	3	3	2	3	11	Leafy greens mixed with other fresh FoNAO	18	7	11
Yersinia	19	2	3	2	7	3	2	4	2	11	Carrots	18	7	11
Salmonella	32	2	3	2	7	3	3	4	1	11	Spices and dry powdered herbs	18	7	11
Shigella	16	2	2	2	6	3	2	4	3	12	Fresh herbs	18	6	12
Bacillus	32	4	3	1	8	1	4	4	1	10	Spices and dry powdered herbs	18	8	10
Norovirus	3	4	4	1	9	3	2	3	1	9	Raspberries	18	9	9
Salmonella	3	2	3	2	7	3	3	3	2	11	Raspberries	18	7	11
Norovirus	11	2	4	1	7	3	2	4	1	10	Tomatoes	17	7	10
Norovirus	19	2	4	1	7	3	2	4	1	10	Carrots	17	7	10
Salmonella	31	2	3	2	7	3	3	3	1	10	Nuts and nut products	17	7	10
Shigella	19	2	2	2	6	3	2	4	2	11	Carrots	17	6	11
Hepatitis A	38	2	2	3	7	3	2	3	1	9	Dehydrated vegetables and fruit	16	7	9
Norovirus	4	2	4	1	7	3	2	3	1	9	Other berries	16	7	9
Shigella	17	2	2	2	6	3	2	2	3	10	Leafy greens mixed with other fresh FoNAO	16	6	10
Bacillus	15	2	3	1	6	1	4	4	1	10	Leafy greens eaten raw as salads	16	6	10
Norovirus	2	2	4	1	7	3	2	3	1	9	Strawberries	16	7	9
C. perfringens	16	2	3	1	6	1	4	4	1	10	Fresh herbs	16	6	10
C. perfringens	32	2	3	1	6	1	4	4	1	10	Spices and dry powdered herbs	16	6	10
Cryptosporidium	17	2	3	1	6	3	2	2	1	8	Leafy greens mixed with other fresh FoNAO	14	6	8
S. aureus	14	2	3	1	6	1	2	4	1	8	Fresh pods, legumes and grain	14	6	8
Bacillus	17	2	3	1	6	1	4	2	1	8	Leafy greens mixed with other fresh FoNAO	14	6	8
S. aureus	28	2	3	1	6	1	2	1	2	6	Sprouted seeds	12	6	6

Criteria 1: strength of associations between food/pathogen combinations; criteria 2: incidence of illness; criteria 3: burden of disease; criteria 4: dose-response relationship; criteria 5: prevalence of contamination; criteria 6: consumption; criteria 7: combined pathogen growth potential and shelf-life.

Table 34: Model output for scenario 2 (without consumption criterion)

Pathogen	FoNAO group	Consequences criteria 1	2	3	Total score	Exposure criteria 4	5	6	7	Total score		Final total score SUM	Consequences	Exposure
Salmonella	15	4	3	2	9	3	3	NA	3	9	Leafy greens eaten raw as salads	18	9	9
Salmonella	28	4	3	2	9	3	3	NA	3	9	Sprouted seeds	18	9	9
Salmonella	9	2	3	2	7	3	3	NA	4	10	Melons	17	7	10
Pathogenic *E. coli*	28	3	2	3	8	3	3	NA	3	9	Sprouted seeds	17	8	9
Salmonella	22	2	3	2	7	3	3	NA	3	9	Bulb and stem vegetables	16	7	9
Salmonella	11	2	3	2	7	3	3	NA	3	9	Tomatoes	16	7	9
Pathogenic *E. coli*	14	2	2	3	7	3	3	NA	3	9	Fresh pods, legumes and grain	16	7	9
Salmonella	17	2	3	2	7	3	3	NA	3	9	Leafy greens mixed with other fresh FoNAO	16	7	9
Norovirus	15	4	4	1	9	3	2	NA	1	6	Leafy greens eaten raw as salads	15	9	6
Shigella	14	3	2	2	7	3	2	NA	3	8	Fresh pods, legumes and grain	15	7	8
Norovirus	3	4	4	1	9	3	2	NA	1	6	Raspberries	15	9	6
Salmonella	3	2	3	2	7	3	3	NA	2	8	Raspberries	15	7	8
Norovirus	22	3	4	1	8	3	2	NA	1	6	Bulb and stem vegetables	14	8	6
Yersinia	19	2	3	2	7	3	2	NA	2	7	Carrots	14	7	7
Salmonella	31	2	3	2	7	3	3	NA	1	7	Nuts and nut products	14	7	7
Salmonella	32	2	3	2	7	3	3	NA	1	7	Spices and dry powdered herbs	14	7	7
Shigella	16	2	2	2	6	3	2	NA	3	8	Fresh herbs	14	6	8
Bacillus	32	4	3	1	8	1	4	NA	1	6	Spices and dry powdered herbs	14	8	6
Shigella	17	2	2	2	6	3	2	NA	3	8	Leafy greens mixed with other fresh FoNAO	14	6	8
Norovirus	11	2	4	1	7	3	2	NA	1	6	Tomatoes	13	7	6
Norovirus	19	2	4	1	7	3	2	NA	1	6	Carrots	13	7	6
Shigella	19	2	2	2	6	3	2	NA	2	7	Carrots	13	6	7
Hepatitis A	38	2	2	3	7	3	2	NA	1	6	Dehydrated vegetables and fruit	13	7	6
Norovirus	4	2	4	1	7	3	2	NA	1	6	Other berries	13	7	6
Norovirus	2	2	4	1	7	3	2	NA	1	6	Strawberries	13	7	6
Bacillus	15	2	3	1	6	1	4	NA	1	6	Leafy greens eaten raw as salads	12	6	6
C. perfringens	16	2	3	1	6	1	4	NA	1	6	Fresh herbs	12	6	6
C. perfringens	32	2	3	1	6	1	4	NA	1	6	Spices and dry powdered herbs	12	6	6
Cryptosporidium	17	2	3	1	6	3	2	NA	1	6	Leafy greens mixed with other fresh FoNAO	12	6	6
Bacillus	17	2	3	1	6	1	4	NA	1	6	Leafy greens mixed with other fresh FoNAO	12	6	6
S. aureus	28	2	3	1	6	1	2	NA	2	5	Sprouted seeds	11	6	5
S. aureus	14	2	3	1	6	1	2	NA	1	4	Fresh pods, legumes and grain	10	6	4

NA: Not applicable; criteria 1: strength of associations between food/pathogen combinations; criteria 2: incidence of illness; criteria 3: burden of disease; criteria 4: dose-response relationship; criteria 5: prevalence of contamination; criteria 6: consumption; criteria 7: combined pathogen growth potential and shelf-life.

Table 35: Model output for scenario 3 (without combined pathogen growth potential/shelf life criterion).

		Consequences criteria				Exposure criteria						Final total score		
Pathogen	**FoNAO group**	**1**	**2**	**3**	**Total score**	**4**	**5**	**6**	**7**	**Total score**		**SUM**	**Consequences**	**Exposure**
Salmonella	15	4	3	2	9	3	3	4	NA	10	Leafy greens eaten raw as salads	19	9	10
Norovirus	15	4	4	1	9	3	2	4	NA	9	Leafy greens eaten raw as salads	18	9	9
Salmonella	22	2	3	2	7	3	3	4	NA	10	Bulb and stem vegetables	17	7	10
Salmonella	11	2	3	2	7	3	3	4	NA	10	Tomatoes	17	7	10
Pathogenic *E. coli*	14	2	2	3	7	3	3	4	NA	10	Fresh pods, legumes and grain	17	7	10
Norovirus	22	3	4	1	8	3	2	4	NA	9	Bulb and stem vegetables	17	8	9
Salmonella	32	2	3	2	7	3	3	4	NA	10	Spices and dry powdered herbs	17	7	10
Bacillus	32	4	3	1	8	1	4	4	NA	9	Spices and dry powdered herbs	17	8	9
Norovirus	3	4	4	1	9	3	2	3	NA	8	Raspberries	17	9	8
Salmonella	9	2	3	2	7	3	3	3	NA	9	Melons	16	7	9
Salmonella	31	2	3	2	7	3	3	3	NA	9	Nuts and nut products	16	7	9
Salmonella	28	4	3	2	9	3	3	1	NA	7	Sprouted seeds	16	9	7
Shigella	14	3	2	2	7	3	2	4	NA	9	Fresh pods, legumes and grain	16	7	9
Yersinia	19	2	3	2	7	3	2	4	NA	9	Carrots	16	7	9
Salmonella	3	2	3	2	7	3	3	3	NA	9	Raspberries	16	7	9
Norovirus	11	2	4	1	7	3	2	4	NA	9	Tomatoes	16	7	9
Norovirus	19	2	4	1	7	3	2	4	NA	9	Carrots	16	7	9
Pathogenic *E. coli*	28	3	2	3	8	3	3	1	NA	7	Sprouted seeds	15	8	7
Salmonella	17	2	3	2	7	3	3	2	NA	8	Leafy greens mixed with other fresh FoNAO	15	7	8
Shigella	16	2	2	2	6	3	2	4	NA	9	Fresh herbs	15	6	9
Shigella	19	2	2	2	6	3	2	4	NA	9	Carrots	15	6	9
Hepatitis A	38	2	2	3	7	3	2	3	NA	8	Dehydrated vegetables and fruit	15	7	8
Norovirus	4	2	4	1	7	3	2	3	NA	8	Other berries	15	7	8
Bacillus	15	2	3	1	6	1	4	4	NA	9	Leafy greens eaten raw as salads	15	6	9
Norovirus	2	2	4	1	7	3	2	3	NA	8	Strawberries	15	7	8
C. perfringens	16	2	3	1	6	1	4	4	NA	9	Fresh herbs	15	6	9
C. perfringens	32	2	3	1	6	1	4	4	NA	9	Spices and dry powdered herbs	15	6	9
Shigella	17	2	2	2	6	3	2	2	NA	7	Leafy greens mixed with other fresh FoNAO	13	6	7
Cryptosporidium	17	2	3	1	6	3	2	2	NA	7	Leafy greens mixed with other fresh FoNAO	13	6	7
S. aureus	14	2	3	1	6	1	2	4	NA	7	Fresh pods, legumes and grain	13	6	7
Bacillus	17	2	3	1	6	1	4	2	NA	7	Leafy greens mixed with other fresh FoNAO	13	6	7
S. aureus	28	2	3	1	6	1	2	1	NA	4	Sprouted seeds	10	6	4

NA: Not applicable; criteria 1: strength of associations between food/pathogen combinations; criteria 2: incidence of illness; criteria 3: burden of disease; criteria 4: dose-response relationship; criteria 5: prevalence of contamination; criteria 6: consumption; criteria 7: combined pathogen growth potential and shelf-life.

Table 36: Model output for scenario 4 (without dose-response relationship criterion).

Pathogen	FoNAO group	Consequences criteria 1	2	3	Total score	Exposure criteria 4	5	6	7	Total score		Final total score SUM	Consequences	Exposure
Salmonella	15	4	3	2	9	NA	3	4	3	10	Leafy greens eaten raw as salads	19	9	10
Salmonella	22	2	3	2	7	NA	3	4	3	10	Bulb and stem vegetables	17	7	10
Salmonella	11	2	3	2	7	NA	3	4	3	10	Tomatoes	17	7	10
Pathogenic *E. coli*	14	2	2	3	7	NA	3	4	3	10	Fresh pods, legumes and grain	17	7	10
Salmonella	9	2	3	2	7	NA	3	3	4	10	Melons	17	7	10
Bacillus	32	4	3	1	8	NA	4	4	1	9	Spices and dry powdered herbs	17	8	9
Salmonella	28	4	3	2	9	NA	3	1	3	7	Sprouted seeds	16	9	7
Norovirus	15	4	4	1	9	NA	2	4	1	7	Leafy greens eaten raw as salads	16	9	7
Shigella	14	3	2	2	7	NA	2	4	3	9	Fresh pods, legumes and grain	16	7	9
Norovirus	22	3	4	1	8	NA	2	4	1	7	Bulb and stem vegetables	15	8	7
Pathogenic *E. coli*	28	3	2	3	8	NA	3	1	3	7	Sprouted seeds	15	8	7
Salmonella	17	2	3	2	7	NA	3	2	3	8	Leafy greens mixed with other fresh FoNAO	15	7	8
Yersinia	19	2	3	2	7	NA	2	4	2	8	Carrots	15	7	8
Salmonella	32	2	3	2	7	NA	3	4	1	8	Spices and dry powdered herbs	15	7	8
Shigella	16	2	2	2	6	NA	2	4	3	9	Fresh herbs	15	6	9
Norovirus	3	4	4	1	9	NA	2	3	1	6	Raspberries	15	9	6
Salmonella	3	2	3	2	7	NA	3	3	2	8	Raspberries	15	7	8
Bacillus	15	2	3	1	6	NA	4	4	1	9	Leafy greens eaten raw as salads	15	6	9
C. perfringens	16	2	3	1	6	NA	4	4	1	9	Fresh herbs	15	6	9
C. perfringens	32	2	3	1	6	NA	4	4	1	9	Spices and dry powdered herbs	15	6	9
Norovirus	11	2	4	1	7	NA	2	4	1	7	Tomatoes	14	7	7
Norovirus	19	2	4	1	7	NA	2	4	1	7	Carrots	14	7	7
Salmonella	31	2	3	2	7	NA	3	3	1	7	Nuts and nut products	14	7	7
Shigella	19	2	2	2	6	NA	2	4	2	8	Carrots	14	6	8
Hepatitis A	38	2	2	3	7	NA	2	3	1	6	Dehydrated vegetables and fruit	13	7	6
Norovirus	4	2	4	1	7	NA	2	3	1	6	Other berries	13	7	6
Shigella	17	2	2	2	6	NA	2	2	3	7	Leafy greens mixed with other fresh FoNAO	13	6	7
Norovirus	2	2	4	1	7	NA	2	3	1	6	Strawberries	13	7	6
S. aureus	14	2	3	1	6	NA	2	4	1	7	Fresh pods, legumes and grain	13	6	7
Bacillus	17	2	3	1	6	NA	4	2	1	7	Leafy greens mixed with other fresh FoNAO	13	6	7
Cryptosporidium	17	2	3	1	6	NA	2	2	1	5	Leafy greens mixed with other fresh FoNAO	11	6	5
S. aureus	28	2	3	1	6	NA	2	1	2	5	Sprouted seeds	11	6	5

NA: Not applicable; criteria 1: strength of associations between food/pathogen combinations; criteria 2: incidence of illness; criteria 3: burden of disease; criteria 4: dose-response relationship; criteria 5: prevalence of contamination; criteria 6: consumption; criteria 7: combined pathogen growth potential and shelf-life.

Table 37: Model output for scenario 5 (without prevalence of contamination criterion).

Pathogen	FoNAO group	Consequences criteria 1	2	3	Total score	Exposure criteria 4	5	6	7	Total score		Final total score SUM	Consequences	Exposure
Salmonella	15	4	3	2	9	3	NA	4	3	10	Leafy greens eaten raw as salads	19	9	10
Salmonella	22	2	3	2	7	3	NA	4	3	10	Bulb and stem vegetables	17	7	10
Salmonella	11	2	3	2	7	3	NA	4	3	10	Tomatoes	17	7	10
Pathogenic *E. coli*	14	2	2	3	7	3	NA	4	3	10	Fresh pods, legumes and grain	17	7	10
Salmonella	9	2	3	2	7	3	NA	3	4	10	Melons	17	7	10
Norovirus	15	4	4	1	9	3	NA	4	1	8	Leafy greens eaten raw as salads	17	9	8
Shigella	14	3	2	2	7	3	NA	4	3	10	Fresh pods, legumes and grain	17	7	10
Salmonella	28	4	3	2	9	3	NA	1	3	7	Sprouted seeds	16	9	7
Norovirus	22	3	4	1	8	3	NA	4	1	8	Bulb and stem vegetables	16	8	8
Yersinia	19	2	3	2	7	3	NA	4	2	9	Carrots	16	7	9
Shigella	16	2	2	2	6	3	NA	4	3	10	Fresh herbs	16	6	10
Norovirus	3	4	4	1	9	3	NA	3	1	7	Raspberries	16	9	7
Pathogenic *E. coli*	28	3	2	3	8	3	NA	1	3	7	Sprouted seeds	15	8	7
Salmonella	17	2	3	2	7	3	NA	2	3	8	Leafy greens mixed with other fresh FoNAO	15	7	8
Salmonella	32	2	3	2	7	3	NA	4	1	8	Spices and dry powdered herbs	15	7	8
Salmonella	3	2	3	2	7	3	NA	3	2	8	Raspberries	15	7	8
Norovirus	11	2	4	1	7	3	NA	4	1	8	Tomatoes	15	7	8
Norovirus	19	2	4	1	7	3	NA	4	1	8	Carrots	15	7	8
Shigella	19	2	2	2	6	3	NA	4	2	9	Carrots	15	6	9
Bacillus	32	4	3	1	8	1	NA	4	1	6	Spices and dry powdered herbs	14	8	6
Hepatitis A	38	2	2	3	7	3	NA	3	1	7	Dehydrated vegetables and fruit	14	7	7
Norovirus	4	2	4	1	7	3	NA	3	1	7	Other berries	14	7	7
Salmonella	31	2	3	2	7	3	NA	3	1	7	Nuts and nut products	14	7	7
Shigella	17	2	2	2	6	3	NA	2	3	8	Leafy greens mixed with other fresh FoNAO	14	6	8
Norovirus	2	2	4	1	7	3	NA	3	1	7	Strawberries	14	7	7
Bacillus	15	2	3	1	6	1	NA	4	1	6	Leafy greens eaten raw as salads	12	6	6
C. perfringens	16	2	3	1	6	1	NA	4	1	6	Fresh herbs	12	6	6
C. perfringens	32	2	3	1	6	1	NA	4	1	6	Spices and dry powdered herbs	12	6	6
Cryptosporidium	17	2	3	1	6	3	NA	2	1	6	Leafy greens mixed with other fresh FoNAO	12	6	6
S. aureus	14	2	3	1	6	1	NA	4	1	6	Fresh pods, legumes and grain	12	6	6
Bacillus	17	2	3	1	6	1	NA	2	1	4	Leafy greens mixed with other fresh FoNAO	10	6	4
S. aureus	28	2	3	1	6	1	NA	1	2	4	Sprouted seeds	10	6	4

NA: Not applicable; criteria 1: strength of associations between food/pathogen combinations; criteria 2: incidence of illness; criteria 3: burden of disease; criteria 4: dose-response relationship; criteria 5: prevalence of contamination; criteria 6: consumption; criteria 7: combined pathogen growth potential and shelf-life.

ABBREVIATIONS

BIOHAZ	EFSA Panel on Biological Hazards
BS EN ISO	British Standard European Norm International Organization for Standardization
CDC	US Centre for Disease Control and Prevention
DALY	Disability Adjusted Life Years
EFSA	European Food Safety Authority
EN/ISO	European Norm International Organization for Standardization
EU	European Union
FoNAO	Food(s) of non-animal origin
FoAO	Food(s) of animal origin
HACCP	Hazard Analysis and Critical Control Points
HAV	Hepatitis A virus
ISO/TS	ISO Technical Specifications
MAP	Modified atmosphere packaging
NMKL	Nordic Committee on Food Analysis
NoV	Norovirus
PCR	Polymerase Chain Reaction
RASFF	Rapid Alert System on Food and Feed
RRT	Risk ranking tool
STEC	Shiga-toxin producing *Escherichia coli*
ToR	Terms of reference
USDA	US Department of Agriculture
US FDA	US Food and Drug Administration
VTEC	Verocytotoxin-producing *Escherichia coli*