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### ► To cite this version:

Pietro Stella, Olivier Cerf, Marta Hugas, Kostas P. Koutsoumanis, Christophe Nguyen-The, et al.. Ranking the microbiological safety of foods: A new tool and its application to composite products. Trends in Food Science and Technology, 2013, 33 (2), pp.124-138. 10.1016/j.tifs.2013.07.005 . hal-01329380

**HAL Id: hal-01329380**

**<https://hal.science/hal-01329380v1>**

Submitted on 29 May 2020

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# Ranking the microbiological safety of foods: A new tool and its application to composite products

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A methodology based on the combination of two complementary approaches to rank microbiological risks in foods is presented. In the forward approach data on the pathogenicity of hazards and their behaviour in food during processing and following steps, up to consumption, are used in decision trees to qualitatively estimate the risk associated with foods. In the backward approach risks are evaluated based on the analysis of data available on the past occurrence of hazards and food-borne outbreaks. The categorisation of foods using the forward approach should prevail, and whenever it leads to a likely risk for a given food, the risk can be further qualified with the results from the backward approach. The methodology developed was applied to rank the public health risk posed by certain composite products, which contain both processed products of animal origin and products of plant origin (e.g., bread, cakes, chocolate). Despite limitations in the data available for these foods, valuable results were obtained. The method is therefore considered suitable for application with success to other types of food, and is proposed as a tool for risk managers to rank foods based on their potential food safety risks.

## Introduction

In the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures it is stated that sanitary measures should be based on an assessment of the risks to humans, taking into account risk assessment techniques. In the European Union (EU), the general principles governing food and feed safety are laid down in Regulation (EC) No 178/2002 (General

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Food Law), and indicate that food legislation has to be based on risk analysis. The risk analysis framework (CAC, 2007) consists of three components: risk assessment, risk management and risk communication. It is recognised that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential to protect public health of consumers.

The use of risk ranking within the food safety risk analysis framework is becoming more and more widespread, since it is often considered as an efficient starting point for setting priorities and allocating resources based on risk (Batz *et al.*, 2004; EFSA, 2012b; Haagsma, Havelaar, Janssen, & Bonsel, 2008; Newsome *et al.*, 2009; Ross & Sumner, 2002). Risk ranking can be applied in the framework of risk assessment activities, and could be defined as the analysis and ranking of the combined probability of food contamination, consumer exposure and public health impact of certain foodborne hazards (EFSA, 2012b). The results of the ranking should be considered in the light of the accuracy, and not be considered absolute. In other instances, additional factors are incorporated in the prioritisation (e.g., economic impact, socio-cultural impact, implications on international trade, etc.), and thus risk ranking may become an integral part of risk management. The Food and Agriculture Organization of the United Nations (FAO) developed a generic framework for risk management where risk ranking represents a possible step of the preliminary risk management activities. In this framework, the primary criterion for ranking is the relative level of risk each issue presents to consumers, so that risk management resources can be optimally applied to reduce overall foodborne public health risks (FAO/WHO, 2006).

Microbiological risks posed by foods depend on the hazards involved, their pathogenicity, their survival and growth in foods, and on the potential control measures applied during food production, distribution and preparation. For example, food products that have undergone a pasteurisation treatment without possible recontamination can be regarded as of low risk for non-sporeforming organisms. When no microbicidal treatment is applied to foods in their final package or just before aseptic packaging, certain microbiological hazards, like *Salmonella* spp. strains of high infectivity, can pose risks even if present at low numbers and without any subsequent growth in the product. Adequate cooking before consumption, if applied, reduces such organisms sufficiently to assure safety of the food. Other hazards, like *Listeria monocytogenes*, need first to grow and reach amounts sufficient to cause relevant levels of risk in foods eaten without prior cooking. These organisms are also readily inactivated with adequate cooking. Potential growth of the organisms depends on intrinsic and extrinsic factors associated with the food, and can be prevented by certain characteristics of the food and by storage conditions. Toxin-forming bacteria, like *Clostridium botulinum*, also need to grow before relevant amounts of toxin can be formed. In this case cooking can also be effective in inactivating the toxin if this is heat labile, as for

*C. botulinum*. By contrast, enterotoxin from *Staphylococcus aureus*, which also needs microbial growth to be produced, is heat resistant and cannot be inactivated by cooking.

In the EU, the European Food Safety Authority (EFSA) is, since 2002, the body responsible for risk assessment, providing independent scientific advice to the EU risk managers in relation to the EU legislation and policies in all fields having a direct or indirect impact on food and feed safety. In the framework of its support activities, EFSA was asked by the European Commission to assess the public health risks represented by certain composite products (EFSA, 2012a). In EU legislation composite products are defined as “a 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 primary product is an integral part of the production of the final product” (Decision 2007/275/EC). Currently, imports of composite products into the EU are subject to rules in relation to both public health and animal health aspects. However, according to the above Decision, some of the controls are currently derogated for certain composite products.

To develop harmonised risk-based public health rules for implementation during import of such derogated products, the European Commission asked EFSA to identify and profile the microbiological hazards for public health related to import of certain composite products (Table 1). In order to do so, two complementary approaches (Fig. 1) were developed to allow assessment and ranking of potential microbiological risks posed by foods. In the first approach the pathogenicity of hazards and their evolution in food during processing and following steps up to consumption were used in decision trees to qualitatively estimate the risk associated to foods (“forward approach”). In the second approach, risks were evaluated based on the analysis of data available on the past occurrence of hazards in foods and foodborne outbreaks (“backward approach”).

The objective of this paper is to present a methodology based on the combination of the two above approaches to

**Table 1. Composite products currently derogated from certain controls at import into the EU and dealt with in this paper.**

Biscuits
Bread
Cakes
Chocolate
Confectionery (including sweets)
Unfilled gelatine capsules
Food supplements packaged for the final consumer, containing small amounts of animal product, and those including glucosamine, chondroitin, or chitosan
Meat extracts and meat concentrates
Olives stuffed with fish
Pasta and noodles not mixed or filled with meat product
Soup stocks and flavourings packaged for the final consumer, containing meat extracts, meat concentrates, animal fats, or fish oils, powders or extracts

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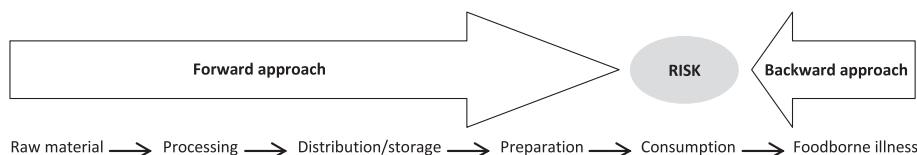


Fig. 1. Combination of a forward and a backward approach (adapted from EFSA, 2012b).

rank microbiological risks in foods. This allows basing the assessment on both the specific characteristics of a certain food and the hazards potentially associated with it, while integrating also past evidence on the occurrence of hazards and outbreaks to further qualify the risk. The methodology developed was applied to composite products, but is equally applicable to other types of food. It is considered particularly useful when there is a need to assess microbiological risks posed by foods, like for instance in the case of risk-based controls for food at imports or when already in the market.

### Ranking foods through a forward approach

With this approach, the characteristics of hazards and their evolution in the foods during food processing and following steps up to consumption are analysed in decision trees to qualitatively estimate the risk associated to foods.

#### Data needs and sources

The data needed to apply this approach include:

- hazard-related data: information on certain characteristics of the hazards considered (e.g. pathogenicity, ability to sporulate, production of toxins, optimum and limit survival/growth parameters);
- food-related data: information on the physico-chemical parameters of the food that can have an impact on survival, growth and inactivation or inhibition of the hazards, such as pH and  $a_w$ ;
- processing-related data: information on the treatments applied during the production, distribution and preparation of food and their effects on the hazard.

Collection of the above information forms part of hazard identification, which is the first step in risk assessment and in Hazard Analysis and Critical Control Points (HACCP). This stage is very relevant for the subsequent steps, but often gets limited attention and/or does not follow a structured approach.

#### Hazard- and food-related data

Hazard- and food-related data are important in order to understand the behaviour of pathogens in terms of survival and growth in food all along the food chain. Survival and growth of microorganisms indeed depend on various factors, which have been described in the literature (Jay, 2000; Mossel, Cory, Struijk, & Baird, 1995; Ray, 2004). The characteristics of the hazards can also influence the risk of illness for exposed consumers.

Scientific publications can be used to obtain general information on those parameters and inform the assessment, but some assumptions need to be made, especially in relation to the similarity of the food under assessment with the one described in the publications. Scientific publications, quantitative microbiology models and databases may also be used in order to estimate survival, growth and inactivation of microorganisms in food.

Three hazard categories were defined on the basis of their need or not to grow and/or produce toxins to cause disease in humans (Table 2):

1. hazards for which growth in food may not be needed to cause illness;
2. hazards for which growth in food is usually needed to cause illness;
3. hazards for which growth in food is needed for the production of toxins or toxic metabolites that may cause illness.

Hazards were allocated to the first two categories on the basis of two reference values, defined as “Dose-1% value” and “P1 value”, calculated on the basis of infectivity, pathogenicity, and virulence data currently available in scientific publications (see detailed calculations in EFSA (2012a)). The two values represent, respectively, the estimated dose (total number of cells ingested) that causes a certain effect in 1% of the individuals exposed, and the estimated probability of a certain effect when the ingested dose is represented by one cell. They should be updated in the future when additional data on these or other hazards become available. Non-toxin forming organisms with a Dose-1% value smaller than 1000 cells were classified as hazards that may not need growth in food to cause illness, and others were classified as usually requiring growth in food to cause illness. It is noted that if a Dose-1% threshold of 100 or 10,000 cells was selected to categorise hazards, the same categorisation would be obtained.

Factors considered here as having a major impact on hazard survival and growth were pH,  $a_w$  (intrinsic factors) and temperature (extrinsic factor). Other factors should be considered whenever their impact on hazards is documented, and results from predictive microbiology could be also taken into account. Examples of minimum limits of the selected parameters for growth of pathogens can be found in several publications (FDA, 2011; ICMSE, 1996; IFT, 2003; NACMCF, 2010). NACMCF (2010) provided estimations of combinations of temperature, pH and  $a_w$  values that may allow growth of pathogenic bacteria.

**Table 2. Examples of hazards classified according to their need to growth in foods for a significant probability of illness, with examples of Dose-1%<sup>a</sup>, P1<sup>b</sup>, T growth<sup>c</sup>, pH growth<sup>d</sup> and a<sub>w</sub> growth<sup>e</sup> values, as extracted or calculated from several sources (Cassin, Lammerding, Todd, Ross, & McColl, 1998; Delignette-Muller & Cornu, 2008; Eden *et al.*, 1977; EFSA, 2005; FAO/WHO, 2002, 2004, 2009; FDA, 2005, 2011; Golden, Crouch, Latimer, Kadry, & Kause, 2009; Han, Paik, & Kim, 2003; ICMSF, 1996; IFT, 2003; Jaloustre, 2011; Keet, 1974; Lund, 1996; NACMCF, 2010; Ostroff *et al.*, 1994; Ramalho, Afonso, Cunha, Teixeira, & Gibbs, 2001; Teunis *et al.*, 2008; Thompson & Gravel, 1986).**

	Pathogen	Sporigen	Population exposure	Dose-1% value <sup>a</sup>	P1 value <sup>b</sup>	T growth <sup>c</sup>	pH growth <sup>d</sup>	a <sub>w</sub> growth <sup>e</sup>
Growth in food may not be needed to cause illness	Norovirus	–	no growth in food is possible, highly infectious (probability of infection for a single particle of 0.5)			not applicable (no grow in food)	not applicable (no grow in food)	not applicable (no grow in food)
	Parasites	–	no growth in food is possible, ingestion of a few parasites may cause infection			not applicable (no grow in food)	not applicable (no grow in food)	not applicable (no grow in food)
	<i>Salmonella</i> (salmonellosis)	–	any exposed people	4.1	2.5 · 10 <sup>-3</sup>	5.2	3.7	0.94
	<i>Shigella</i>	–	any exposed people	8.8	1.2 · 10 <sup>-3</sup>	6.1	4.8	0.96
	<i>Campylobacter jejuni</i> (diarrheal disease)	–	adults	2.9	3.5 · 10 <sup>-3</sup>	30.0	4.9	0.99
	EHEC (e.g. <i>E. coli</i> O157) (haemolytic uremic syndrome)	–	children < 6 years	8.4	1.2 · 10 <sup>-3</sup>	6.5	4.0	0.95
			children 6–10 years	41.9	2.4 · 10 <sup>-4</sup>			
	<i>Yersinia enterocolitica</i>	–	no dose–response model available, involved in water-borne infections and growth in water does not seem possible			–1.3	4.2	0.95
Growth in food is usually needed to cause illness	<i>Listeria monocytogenes</i> (severe listeriosis)	–	more susceptible sub-population	9.5 · 10 <sup>9</sup>	1.1 · 10 <sup>-12</sup>	–0.4	4.39	0.92
			less susceptible sub-population	4.2 · 10 <sup>11</sup>	2.4 · 10 <sup>-14</sup>			
	<i>Vibrio parahaemolyticus</i> (enterocolitis)	–	adults	2.2 · 10 <sup>4</sup>	4.6 · 10 <sup>-7</sup>	5.0	4.8	0.94
	<i>Clostridium perfringens</i>	+		1.5 · 10 <sup>6</sup>	6.9 · 10 <sup>-9</sup>	10.0	5.0	0.93
	<i>Bacillus cereus</i> (diarrhoeic)	+	no dose–response model available, at least 10 <sup>5</sup> –10 <sup>6</sup> cells per serving of foods causing illness			4.0	4.3	0.92
Growth in food is needed for production of toxins or toxic metabolites that may cause illness <sup>f</sup>	<i>Clostridium botulinum</i>	+	no data available			10.0 (proteolytic)	4.6 (proteolytic)	0.93 (proteolytic)
						3.0 (non-proteolytic)	5.0 (non-proteolytic)	0.97 (non-proteolytic)
	<i>Staphylococcus aureus</i>	–	no data available			7.0 (growth)	4.0 (growth)	0.83 (growth)
						10.0 (toxin production)	4.5 (toxin production)	0.88 (toxin production)
	<i>Bacillus cereus</i> (emetic)	+	no data available			4.0	4.3	0.92
	Bacteria producing biogenic amines	–	no data available			no data available	no data available	no data available

<sup>a</sup> Dose-1% value: estimated dose (total number of cells) that causes a certain effect in 1% of the individuals exposed.

<sup>b</sup> P1 value: estimated probability of a certain effect when the ingested dose is represented by one cell.

<sup>c</sup> T growth value: growth limiting temperature when all other parameters (pH, a<sub>w</sub>, oxygen concentration) are at optimum values.

<sup>d</sup> pH growth value: growth limiting pH when all other parameters (temperature, a<sub>w</sub>, oxygen concentration) are at optimum values.

<sup>e</sup> a<sub>w</sub> growth value: growth limiting a<sub>w</sub> when all other parameters (temperature, pH, oxygen concentration) are at optimum values.

<sup>f</sup> Toxin produced by *C. botulinum* is heat sensitive, while toxins produced by *S. aureus* and *B. cereus* (emetic) and biogenic amines are heat stable.

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Considering each factor individually, with all others set at optimum, foods would not permit growth of (or toxin production from) any of the hazards listed in Table 2 if they are kept frozen (lowest  $T_{min}$  is  $-1.3$  °C), or have a pH below 3.7, or have an  $a_w$  below 0.83.

### Processing-related data

Processing-related data need to be collected on a case-by-case basis, since they depend on the specific food under consideration, and mainly consist of whether the food has been submitted to an adequate pasteurisation treatment and/or is properly cooked prior to consumption. If pasteurisation or cooking are not considered to provide an adequate inactivation of the hazard, a worst-case scenario should be considered.

### Ranking foods

For each hazard category a separate decision tree is used in order to rank foods (Fig. 2). The trees have been built on a common basis and include a number of questions specific to the hazard category. Compared to the first tree, the second and third ones include additional questions, which take into account the possibility of the food under assessment to support microbial growth and of the microorganism to produce toxins, as well as heat sensitivity of the toxins produced.

All the three trees should be applied to the food under assessment. Replies should be based on the hazard-, food-, and processing-related data discussed above. For any question, depending on the information available, the worst-case scenario should be considered. This may lead to an



Fig. 2. Decision trees for categorisation of risks in composite products.

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overestimation of the risk posed by certain foods, and it will be a task of the risk manager to decide, on a case-by-case basis, on the application of control measures proportionate to the risk. A more detailed analysis may also follow to better quantify the risk.

Replying to the question “*Microbicidal treatment without recontamination?*” (e.g., pasteurisation or sterilisation) requires unambiguous information on the processing conditions and their level of control by the processor. Otherwise it should be assumed that the food has not received a microbicidal treatment and/or could have been recontaminated. The target to be considered would be pasteurisation for hazard category 1, which do not include spore forming bacteria (Table 2), and sterilisation for hazard categories 2 and 3 which include spore forming bacteria, since pasteurisation would not be sufficient for their inactivation.

Replying to the question “*Supports growth?*” requires consideration of the most permissive component and/or interface between components in the food. For example:

- in the absence of knowledge on the physico-chemical composition of the food, and if the food is not shelf-stable (i.e. it permits growth of spoilage micro-organisms), growth of pathogenic bacteria must be assumed as possible;
- if the food composition and storage temperature are known and fall within the growth limits of the pathogen, the answer should be positive; however, knowledge of additional information may lead to a negative reply (e.g. a short shelf-life or the presence of additional antimicrobial hurdles);
- if the food consists of ingredients of contrasting physico-chemical characteristics, it may include conditions at interfaces between ingredients or components which change the characteristics when equilibrium is reached, and growth may be allowed, especially at the interface.

In the absence of sufficient information on the food composition, the answer to the question “*Toxin production possible?*” should be positive if growth of the pathogen was assessed as possible in the previous question.

The question “*Cooking before consumption?*” is referred to cooking as a process modifying the structure and/or sensory properties of foods, and able to inactivate foodborne viruses, parasites, vegetative bacteria and heat labile toxins such as botulinum toxins.

Replying to all questions posed in the decision trees leads to the categorisation of a food as of *low risk*, *moderate risk*, or *qualified presumption of risk (QPR)*, for the hazards considered by each tree. *Low risk* means that the composition and processing of the food should allow inactivation of the pathogen and/or their toxins or prevent the pathogen from reaching hazardous levels at consumption. *Moderate risk* concerns those foods cooked before consumption and for which the risk cannot be classified as low. The hazard may be still present at the moment of its preparation by the consumer, and the possibility of cross-contamination in consumer’s kitchen of other foods

consumed raw, or that the food is actually eaten without prior cooking, must be considered. The degree of reliability of cooking by the consumer and the method of cooking will influence the level of inactivation of a pathogen, and may allow further classification of the risk as low, moderate or high. The term *qualified presumption of risk* is designed to mean that the pathogens considered by this tree have the potential to cause disease via consumption of the product, if present in the food or its ingredients. In such a case additional information should be sought in order to further qualify the risk, as indicated in the decision trees of Fig. 2.

#### The example of composite products

The forward approach was applied in the framework of an EFSA scientific opinion related to the assessment of the public health risks posed by certain composite products (EFSA, 2012a).

Data from the abovementioned sources were used, together with expert opinion, as the basis for informing replies to the decision trees developed. Table 3 outlines the process leading to the results obtained from the application of the forward approach to the composite products under assessment, including the answers to the different questions of the decision trees. For example, in the case of a confectionery product pasteurised in its final package, tree 1 was used for hazards for which growth in food may not be needed to cause illness (e.g. *Salmonella* spp.), and since the reply to the first question is affirmative (pasteurisation without recontamination), the product was considered to be of low risk. In the case of dry biscuits, for hazards that usually require growth in food to cause illness (e.g. *L. monocytogenes*), tree 2 was used, and, if the conditions are such that no growth is possible ( $a_w$  below 0.88 or, specifically for *L. monocytogenes*, below 0.92), the risk is also classified as low.

Overall results obtained with this approach are summarised in Fig. 3. Some food categories (confectionery, cakes, pasta and noodles) may include products with very diverse compositions and that may be processed in very different ways. Therefore they were ranked to different risk levels, according to the assumptions made on their composition and processing.

Meat extracts and meat concentrates are submitted to a microbicidal treatment during production, and subsequent recontamination appears unlikely. If this happens, growth of pathogens or toxin production can be excluded, because of the low  $a_w$  (<0.80) and high salt content (Lund, Baird-Parker, & Gould, 2000). These products are normally subject to an additional heat treatment before consumption, which would be sufficient to inactivate hazards that do not need growth to cause illness. Similar considerations hold for the soup stocks and flavourings considered by this paper. Therefore, these four categories of products were considered to be of low risk, and were not run through the decision trees.

Table 3. Tables for categorisation of risk in composite products based on the decision trees developed.						
Hazards for which growth in food may not be needed to cause illness (based on Tree 1)						
Microbicidal treatment without recontamination?	Cooking before consumption?		Risk	Example of application to certain composite products		
–	–		low	soup stocks and flavourings, meat extracts, meat concentrates		
Y	–		low	confectionery (sterilised), confectionery (pasteurised)		
N	Y		moderate	pasta and noodles		
N	N		QPR	biscuits, bread, cakes (low $a_w$ , e.g. fruit loaf), cakes (high $a_w$ , e.g. with cream), chocolate, confectionery (not heat treated), confectionery (sweets), food supplements (dry powder), unfilled gelatine capsules, olives with fish		
Hazards for which growth in food is usually needed to cause illness (based on Tree 2)						
Microbicidal treatment without recontamination?	Supports growth?	Cooking before consumption?		Risk	Example of application to certain composite products	
–	–	–		low	soup stocks and flavourings, meat extracts, meat concentrates	
Y	–	–		low	confectionery (sterilised)	
N	N	–		low	biscuits, bread, cakes (low $a_w$ , e.g. fruit loaf), chocolate, confectionery (sweets), pasta and noodles (dry), food supplements (dry powder), unfilled gelatine capsules	
N	Y	Y	Y	moderate	pasta and noodles (fresh)	
N	Y	Y	N	QPR	cakes (high $a_w$ , e.g. with cream), confectionery (pasteurised), confectionery (not heat treated), olives with fish	
Hazards for which growth in food is needed for the production of toxins or toxic metabolites that may cause illness (based on Tree 3)						
Microbicidal treatment without recontamination?	Supports growth?	Toxin production possible?	Toxin heat resistant?	Cooking before consumption?	Risk	Example of application to certain composite products
–	–	–	–	–	low	soup stocks and flavourings, meat extracts, meat concentrates
Y	–	–	–	–	low	confectionery (sterilised)
N	N	–	–	–	low	biscuits, bread, cakes (low $a_w$ , e.g. fruit loaf), chocolate, confectionery (sweets), pasta and noodles (dry), food supplements (dry powder), unfilled gelatine capsules
N	Y	N	–	–	low	
N	Y	Y	N	Y	moderate	
N	Y	Y	N	N	QPR	olives with fish
N	Y	Y	Y	–	QPR	cakes (high $a_w$ , e.g. with cream), confectionery (pasteurised), confectionery (not heat treated), pasta and noodles (fresh)

Evaluation of the forward approach

The level of knowledge of all the food parameters identified as having an impact on survival and growth of pathogens clearly influences the level of confidence in replying to the questions included in the decision trees, and as a consequence the general outcome of the exercise. For example, in the case of composite products discussed above, it was difficult to reply to certain questions, since the definition of some of the products was somehow unclear (e.g., confectionery), or because some products may contain items with very different characteristics (e.g., cakes and biscuits may have a very wide  $a_w$  range). Lack of information would lead to a *qualified presumption of risk*, but information on the food and its processing conditions may allow to further qualify the risk as moderate or low. Despite this, it was possible to apply the approach to all the

composite products considered, which illustrates its flexibility. In addition to ranking risks, the approach could help risk managers to identify food products for which information is lacking, and the type of information needed to adequately assess the level of risk.

A difficulty is associated with composite heterogeneous products, made of ingredients with different physico-chemical properties, which may also change over time. In those foods, loss or gain or redistribution of moisture as well as migration of acids and other antimicrobial compounds from one region or food component to another may occur until equilibrium is reached (Guillard, Broyart, Bonazzi, Guilbert, & Gontard, 2003a, 2003b; Hong, Bakshi, & Labuza, 1986; Karathanos & Kostaropoulos, 1995; Roca, Adeline, Guillard, Guilbert, & Gontard,

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Hazards	Biscuits, bread and bakery products	Cakes (low $a_w$ , e.g. fruit loaf)	Cakes (high $a_w$ , e.g. with cream)	Chocolate	Confectionery and sweets*				Pasta and noodles	Food supplements (dry powder)	Soup stocks and flavourings	Unfilled gelatine capsules	Olives with fish	Meat extracts and meat concentrates
					st	ps	nh	sw	dry	fresh				
Growth in food may not be needed to cause illness	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Low risk	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)
Growth in food is usually needed to cause illness	Low risk	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Low risk	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)
Growth in food is needed for production of toxins or toxic metabolites that may cause illness	Low risk	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Low risk	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)	Qualified presumption of risk (QPR)

\*st: confectionery (sterilised); ps: confectionery (pasteurised); nh: confectionery (not heat treated); sw: sweets

Low risk
  Moderate risk
  Qualified presumption of risk (QPR)

Fig. 3. Results from the application of the forward approach.

2008). Specific attention should be given to the interfaces between ingredients or components in such composite products. Combinations of components may create more favourable conditions for growth compared to those in the individual components, or certain components may be more permissive to microbial survival, growth or resistance than others. For example, contact between two ingredients, one with a low  $a_w$  and a neutral pH, and one with high moisture and low pH (e.g., sandwiches with some types of cheese slices and tomato slices), may permit neutralisation of the low pH and increase of the  $a_w$  at the interface. While growth would not occur in the separated components, it could therefore be possible at the interface. Considering the above, when replying to the questions posed by the decision trees in relation to such composite products, the behaviour of the hazard must be considered not only for each of the individual food components and ingredients that are most permissive for its survival and growth, but also for their interfaces, where conditions might be more permissive. In such a case, application of predictive models at dynamic conditions may provide an estimation of the growth potential of representative hazards (Van Impe, Nicolai, Schellekens, Martens, & Debaerdemaeker, 1995).

It is evident that the application of the decision trees does not allow a full assessment of risks, but it proposes a categorisation of the composite products into *low risk*, *moderate risk* and *QPR* for the hazards considered by each tree. It also allows risk managers applying the trees to evaluate the specific situation in a short time-frame and to further qualify foods with the *moderate risk* and *QPR* status. The tables built on the basis of the decision tree, and shown in Table 3, are proposed as possible tools to facilitate the practical application of the trees for the categorisation of risks.

### Ranking foods through a backward approach

With this approach, risks are ranked based on the analysis of data available on the presence of hazards in food and occurrence of foodborne outbreaks.

### Data needs and sources

Availability of sound data in relation to the past occurrence of hazards in the foods of interest and of associated documented foodborne outbreaks in humans is crucial for a successful application of this approach. In particular, useful data would include:

- data on the occurrence of microbiological hazards of concern in the foodstuff of interest;
- data on documented human outbreaks attributed to the specific foodstuff of interest, for which the responsible microbiological hazard was identified.

The above data may be collected from several sources of information, ranging from official reports of competent authorities of the countries/regions under study, to international reports, scientific literature, and any other database containing data useful for the purpose. For example, in a European context, data in relation to zoonoses, zoonotic agents, antimicrobial resistance and foodborne outbreaks are collected by EU Member States and published yearly by EFSA and the European Centre for Disease Prevention and Control (ECDC) in a summary report (<http://www.efsa.europa.eu/en/zoonosessc/docs/zoonosescsumrep.htm>), and some data on food alerts are available through the Rapid Alert System for Food and Feed (RASFF) ([http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)).

### Ranking foods

The method developed in order to rank foods is based on the collection and analysis of the data indicated above. The data available (e.g., reported outbreaks, reported occurrence in food, number of food alerts and references in published scientific papers) are summarised for each hazard/food combination. Subsequently, scientific experts are identified and expert opinion is used to establish the criteria allowing integration and scoring of all data, and ranking of the potential risk posed by the different hazard/food combinations.

In the next section, a description is provided of the method used in the example of composite products. Adaptations may be needed when applying this approach to other foods, depending on the type of data available. Criteria

used and information sources may also be subject to revision depending on the availability of new or updated data.

#### The example of composite products

The backward approach was applied in the framework of an EFSA scientific opinion related to the assessment of the public health risks posed by certain composite products (EFSA, 2012a).

A search among the data available from the EU summary reports for years 2004–2009 was performed in order to collect information on the prevalence of zoonotic agents and verified foodborne outbreaks reported in the composite products under evaluation (EFSA, 2006a, 2006b, 2007, 2009, 2010a, 2011). Prevalence data on many of those products was scarce, and no data at all were available in relation to some products (i.e., food supplements, meat extracts and meat concentrates) and hazards. The available prevalence data for zoonotic agents reported in the composite products of interest are summarised in Table 4.

EU foodborne outbreak data considered included only information on those outbreaks for which a link between human cases and implicated foodstuffs was established by laboratory analysis or epidemiological evidence (“verified outbreaks”). No data on verified outbreaks were reported for some of the composite products under study. A total of 279 outbreaks were reported, with 5929 associated cases of human illness. 91% of the outbreaks were linked to bakery products in general. 79% of the outbreaks were linked to cakes, and in more than half of these the source identified was cakes and desserts having as ingredient raw eggs that were not submitted to subsequent processing. The latter should not be considered composite products according to EU legislation, since they contain unprocessed products of animal origin. However, it can be difficult to distinguish these products from the ones containing processed eggs or processed after inclusion of raw eggs, and reported outbreak information allowing their distinction is often missing. Therefore all available data for cakes and desserts were used. Fig. 4 summarises the proportion of outbreaks related to the different zoonotic agents in the composite products for which data were available. Overall, *S. Enteritidis* was implicated in 78% of the verified outbreaks and in 70% of the cases of illness reported. Ten deaths were reported as linked to the reported outbreaks, nine of which in *Salmonella* spp.-related outbreaks (linked to cakes) and one in a staphylococcal enterotoxins-related one (linked to pasta).

In addition to the official data summarised above, and in order to further inform the application of the method, more information was collected through a screening of published scientific articles. Most of the information retrieved related to foodborne outbreaks in bakery products, cakes, chocolate, confectionery, pasta and noodles. Overall, in those products the most frequent hazard identified as responsible for outbreaks was represented by *Salmonella* spp., often originating from raw eggs used for the icing of the products or from food handlers, followed by staphylococcal enterotoxins (Gill *et al.*, 1983; Ibeh & Izuagbe, 1986). Viruses

were also described in bakery products and cakes (Papafragkou *et al.*, 2008). Other hazards seemed to be anecdotal. The number of scientific papers collected that describe the occurrence and origin of foodborne outbreaks is reported in Table 4.

Finally, information was also used from alerts notified through the RASFF during the period 2001–2011. RASFF is an EU network aimed at sharing information on direct and indirect risks to humans deriving from food and feed and respective mitigating measures taken by authorities across Europe. Hazards identified include bacterial agents already reported within prevalence and outbreak data (Table 4).

More details on the above data gathered for composite products are available in a scientific opinion of the EFSA Panel on Biological Hazards (EFSA, 2012a).

Five experts, among the authors of this paper, were asked to independently provide criteria for judging the relevance of the data obtained from the four different sources of information (prevalence data, outbreak data, scientific literature, and RASFF alerts) when defining the microbiological hazards of highest concern for the different composite products. In particular, a structured approach was followed, made up of the following steps:

- A form was developed in order to collect, from each expert, independent criteria and scores to establish the relevance of each hazard/food combination.
- Each expert filled in the form developed. Table 5 reports an example of the form as fulfilled by one of the experts (the text in bold represents the judgement of the expert).
- Based on the criteria defined, a score was calculated for each hazard/food/data source combination for each individual expert. For example, according to the data available, 25 *Salmonella* spp. outbreaks were described in the food category “biscuits, bread and bakery products”. According to the criteria established by the expert above (Table 5), the respective score attributed to this hazard/food combination with respect to outbreak data was 10 (4 points because the number of outbreaks was higher than 10 and 1 point because the outbreaks represented more than 50% of the total outbreaks reported for that specific food category, with the final score being multiplied by 2, correction factor giving more weight to outbreak data).
- Scores obtained were summed up to obtain a total score for each hazard/food combination for each individual expert. These scores were then normalised on a 1–100 scale, so to make the scores comparable between experts. Following up from the example above, by summing up the four scores obtained for the four data sources for the combination biscuits, bread and bakery products/*Salmonella* spp. (10 for outbreaks, 1 for prevalence, 1 for scientific publications, and 1 for RASFF alerts) a total score of 13 was obtained for this hazard/food combination. This was then normalised in a 1–100 scale, equalling to 96, since  $13.5$  was the highest score obtained for all hazard/food combinations according to the criteria defined by the expert (i.e.,  $(13 \cdot 100)/13.5 = 96$ ). It is noted that, as an alternative, the highest possible score obtainable from each expert could have been used for normalisation purposes (e.g. 16.5 instead of 13.5 in the example above). However, the procedure followed allowed to give equal weight to all experts even if there was a structural difference in the criteria and scoring system provided, and did not affect

**Table 4. Data on prevalence, papers collected and RASFF alerts for zoonotic hazards in certain composite products. Prevalence is based on data reported in the EU (2004–2009). Papers include peer-reviewed scientific publications describing the occurrence and origin of foodborne outbreaks. RASFF alerts refer to alerts launched from 01/01/2001 to 16/08/2011. Information is reported in the table only when available. More detailed information is reported in EFSA (2012a).**

Hazards	Type of evidence <sup>a</sup>	Biscuits, bread and bakery products (no cakes)	Cakes (no raw eggs)	Cakes (raw eggs)	Chocolate	Confectionery/sweets	Pasta and noodles	Food supplements	Soups (and flavourings)	Gelatine	Stuffed olives
<i>Bacillus cereus</i>	<i>o</i>	5.9% (2)	2.1% (2)	—	12.5% (1) <sup>b</sup>	—	35.3% (6)	—	—	—	—
	<i>s</i>	3	1 <sup>c</sup>	—	2	1	4	1	—	1	—
	<i>r</i>	2 <sup>d,e</sup>	—	—	—	—	2	2	—	—	—
<i>Campylobacter</i>	<i>p</i>	0% (11)	0% (12) <sup>c</sup>	—	—	0% (43)	0% (21)	—	—	—	—
<i>Clostridium</i> spp.	<i>o</i>	—	—	—	12.5% (1) <sup>b</sup>	—	—	—	—	—	—
	<i>r</i>	1 <sup>d,e</sup>	—	—	—	—	—	—	—	—	—
<i>Cronobacter</i>	<i>p</i>	—	0% (15) <sup>c</sup>	—	—	—	0% (15)	—	—	—	—
<i>Escherichia coli</i> (pathogenic)	<i>p</i>	0% (2)	0% (19) <sup>c</sup>	—	—	0% (4)	2.5% (120)	—	—	—	—
	<i>s</i>	—	1 <sup>c</sup>	—	—	1	—	—	—	—	—
	<i>r</i>	1 <sup>e</sup>	—	—	—	—	1	1	—	—	—
Histamine	<i>p</i>	—	—	—	100% (10)	—	—	—	—	—	—
<i>Listeria monocytogenes</i>	<i>p</i>	1.6% (1089)	0.4% (4155) <sup>c</sup>	—	0% (167)	1.0% (3959)	2.1% (941)	—	0% (32)	—	—
	<i>s</i>	—	—	—	1	1	—	1	—	—	—
	<i>r</i>	1 <sup>e</sup>	—	—	1	—	—	—	—	—	—
<i>Salmonella</i> spp.	<i>o</i>	73.5% (25)	69.1% (65)	100% (126)	75% (6) <sup>b</sup>	—	35.3% (6)	—	—	—	—
	<i>p</i>	0.3% (17,680)	0.4% (9473) <sup>c</sup>	—	0.1% (1120)	0.6% (9838)	0.7% (3557)	—	0% (136)	0% (4)	—
	<i>s</i>	6	18 <sup>c</sup>	—	5	8	3	—	—	—	—
	<i>r</i>	4 <sup>e</sup>	—	—	6	9	4	3	—	—	—
<i>Staphylococcus aureus</i>	<i>o</i>	8.8% (3)	6.4% (6)	—	—	—	29.4% (5)	—	—	—	—
	<i>p</i>	0% (2)	—	—	14.3% (28)	13.5% (37)	0% (25)	—	—	—	—
	<i>s</i>	—	5 <sup>c</sup>	—	1	3	3	—	—	—	—
	<i>r</i>	3 <sup>e</sup>	—	—	1	1	1	—	—	—	—
Streptococci	<i>s</i>	—	—	—	—	—	1	—	—	—	—
<i>Yersinia enterocolitica</i>	<i>p</i>	0% (2)	—	—	—	1.7% (180)	—	—	—	—	0% (6)
	<i>s</i>	—	—	—	1	—	1	—	—	—	—
Viruses	<i>o</i>	—	20.2% (19)	—	—	—	—	—	—	—	—
	<i>s</i>	1	4 <sup>c</sup>	—	—	—	—	—	—	—	—

<sup>a</sup> *o* = outbreaks: percentage of outbreaks due to the hazard out of the total number of outbreaks in that composite product (number of outbreaks in brackets); *p* = prevalence: prevalence of the hazard in the composite product (total number of samples tested in brackets); *s* = number of scientific papers collected; *r* = number of RASFF alerts reported.

<sup>b</sup> Outbreaks are reported together for chocolate and confectionery.

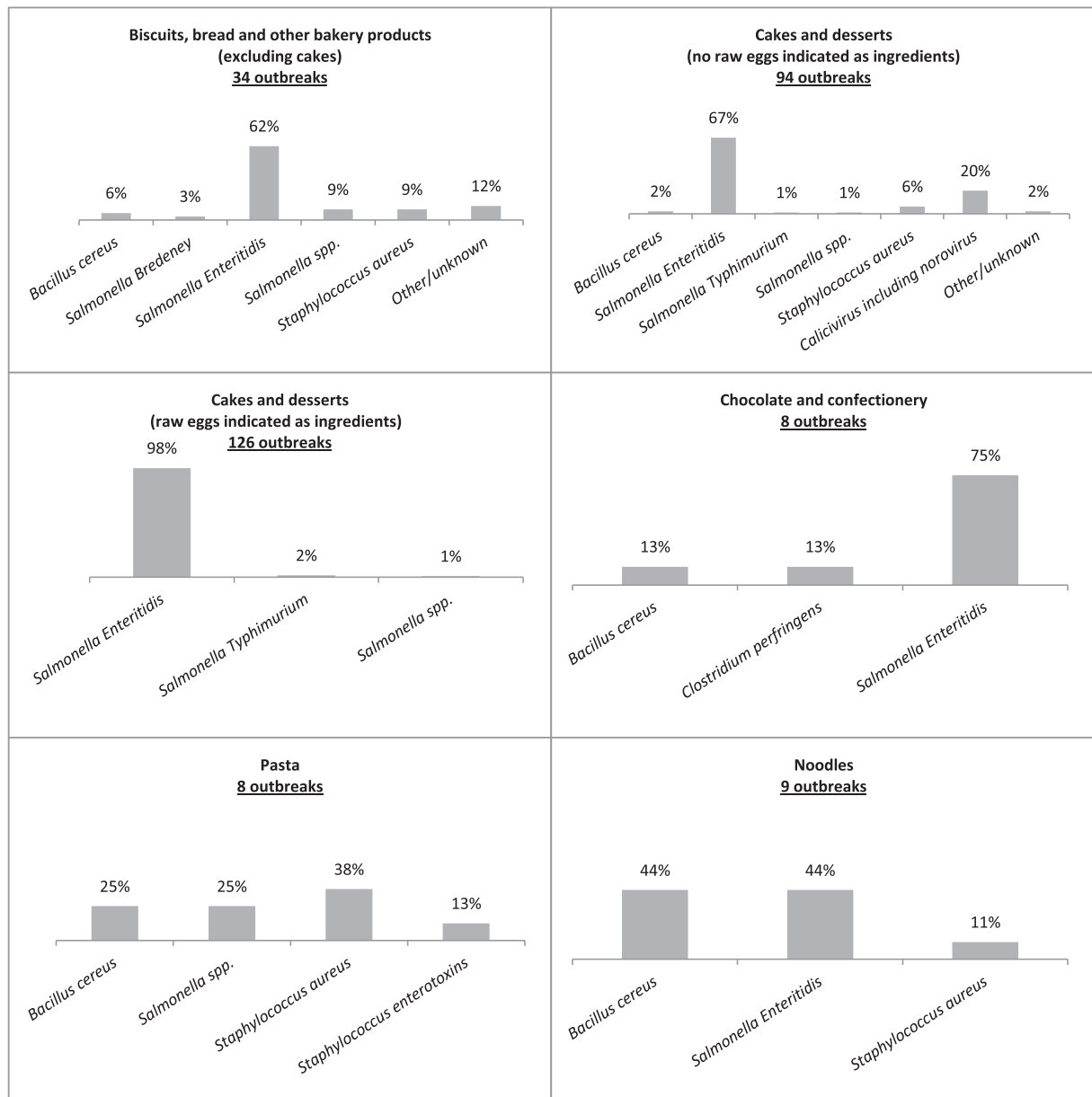
<sup>c</sup> Scientific papers and prevalence are reported together for cakes.

<sup>d</sup> One alert positive for sulphite reducing anaerobes and attributed here to both *Bacillus cereus* and *Clostridium* spp.

<sup>e</sup> RASFF alerts are reported together for biscuits, bread, bakery products and cakes.

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**Fig. 4.** Number and proportion of reported verified outbreaks due to different zoonotic agents in certain composite products in the EU in 2004–2009.

the results obtained. The alternative procedure might be appropriate when assessing one single food product.

- A global average score was then calculated for each hazard/food combination, on the basis of the final scores obtained applying the criteria defined by each of the five experts.
- Finally, the same experts agreed on thresholds of the global average scores to define the importance of the combination hazard/composite product within a four-steps scale, ranging from a situation in which there was no evidence of hazard/food association (score: 0–20) to one in which a medium (score: 21–50), high (score: 51–80) or very high (score: 81–100) importance of association was identified based on the data available.

The results obtained from the application of the backward approach, integrating all the information available for the composite products under assessment, are displayed

in Fig. 5. Hazards are grouped in the same three hazard categories defined in the forward approach, allowing an easier comparison of the results obtained with the two approaches.

Very high importance of association resulted for *Salmonella* spp. and cakes, for which 191 confirmed outbreaks (3878 human cases) were reported in the EU from 2004 to 2009, and for *Salmonella* spp. and biscuits, bread and bakery products, for which 25 confirmed outbreaks (527 human cases) were reported in the same period. High importance was identified for the association of *S. aureus* with cakes (6 confirmed outbreaks, 46 human cases) and for the association of *Salmonella* spp. with chocolate/confectionery and with pasta/noodles (6 confirmed outbreaks linked to each of the two categories, 150 and 112 human cases respectively).

**Table 5. Example of the form filled in by one of the experts with criteria and scores used for judging the relevance of the data available when defining the microbiological hazards of highest concern for certain composite products. Parts completed by the expert are in bold. Each expert independently completed a form. Global average scores were calculated as explained in the text (Section 3.3).**

	Criterion	Score
Scoring outbreaks		
Number of outbreaks reported ( <i>n</i> )	$n < 3$	1
	$3 \leq n < 6$	2
	$6 \leq n < 10$	3
	$n > 10$	4
Score corrections	<b>outbreaks for combination hazards/food <math>\geq 50\%</math> of all outbreaks reported for that food</b>	+1
	<b>weighting factor</b>	$\times 2$
Scoring prevalence		
Prevalence reported ( <i>p</i> )	$p < 0.5\%$	1
	$0.5\% \leq p < 2\%$	2
	$2\% \leq p < 5\%$	3
	$p \geq 5\%$	4
Score corrections	<b><math>p = 0\%</math> and number of samples tested <math>&gt; 100</math></b>	-1
	<b><math>p \geq 0\%</math> and number of samples tested <math>\leq 100</math></b>	-1
	<b>weighting factor</b>	$\times 1$
Scoring scientific papers		
Number of scientific papers identified ( <i>n</i> )	$n < 5$	1
	$5 \leq n < 11$	2
	$n \geq 11$	3
Score corrections	<b>weighting factor</b>	$\times 0.5$
Scoring RASFF alerts		
Number of alerts reported ( <i>n</i> )	$n \geq 1$	1
Score corrections	<b>weighting factor</b>	$\times 1$

Additional data that may become available in the future on the hazards and composite products considered, or on other relevant hazards, should be taken into account to update the assessment.

### Evaluation of the backward approach

The potential to successfully use the backward approach is clearly dependent on the quantity and quality of the data available for the combination hazard/food under assessment. In the example given above (composite products), data used to inform the backward approach were extracted from some EU multi-country prevalence and outbreak databases. Data available in those databases are largely dependent on the efficiency of the diagnostic, outbreak investigation and reporting efforts and systems in place in the different countries. When using data from different sources and countries, and often from different regions of the same country, it should be considered that monitoring and surveillance schemes may not be fully harmonised, and that the distribution and prevalence of microbial

pathogens in foods, as well as sources and frequency of foodborne outbreaks, may differ depending on the geographical location. Furthermore, hazards resulting more frequently in sporadic cases will be underrepresented. In addition, in the EU databases used, a detailed description of the type of products for which data are reported, and of the type and relative amount of their ingredients, is normally not provided. Instead, a general classification of the products is given. This complicates the extraction and analysis of prevalence and outbreak data for the specific products of interest. For example, when searching for information related to some specific types of cakes (e.g., high moisture cakes), it is difficult to know whether the data available relate to this particular category of cakes or to other types of cakes. All these types of reporting bias may interfere with the application of the approach and its results.

In addition, prevalence and outbreak data are evolving with time, and therefore the assessments performed should be regularly updated.

In the example presented in this paper, EU RASFF data were also used, but those data suffer from a number of reporting limitations (EFSA, 2010b) and cannot be considered as fully representative of the real situation.

Despite the various limitations and potential bias in the data discussed, all sources of information related to the food under assessment may be useful when applying the backward approach. The relative importance of the different sources of information can be weighted by the experts during the elicitation process, and this allows combining quantitative data and expert opinion.

Finally, it is noted that the identification of an association of a food product with a hazard through the backward approach is based on the evidence that some specific products in that food category were implicated in outbreaks or showed a high prevalence of certain hazards. This does not necessarily imply that the risk should be considered high for all types of products in that food category. The broader is the category under assessment, like cakes in the composite products considered, the more this may happen. Conversely, absence of confirmed outbreaks, or low prevalence, do not preclude potential risks. The backward approach is based on data from the past, and cannot anticipate changes in food production practices, or changes in the origin of the foods or their ingredients.

### Integration of the forward and backward approaches

Overall, and following to the considerations expressed above, the categorisation of foods from the forward approach should prevail over the results obtained with the backward approach, because the former takes into account the specific characteristics of the food and hazard under assessment. Whenever the forward approach leads to a low risk, this is due to the intrinsic composition or processing of the food, independently of the information available from the backward approach. In contrast, whenever the

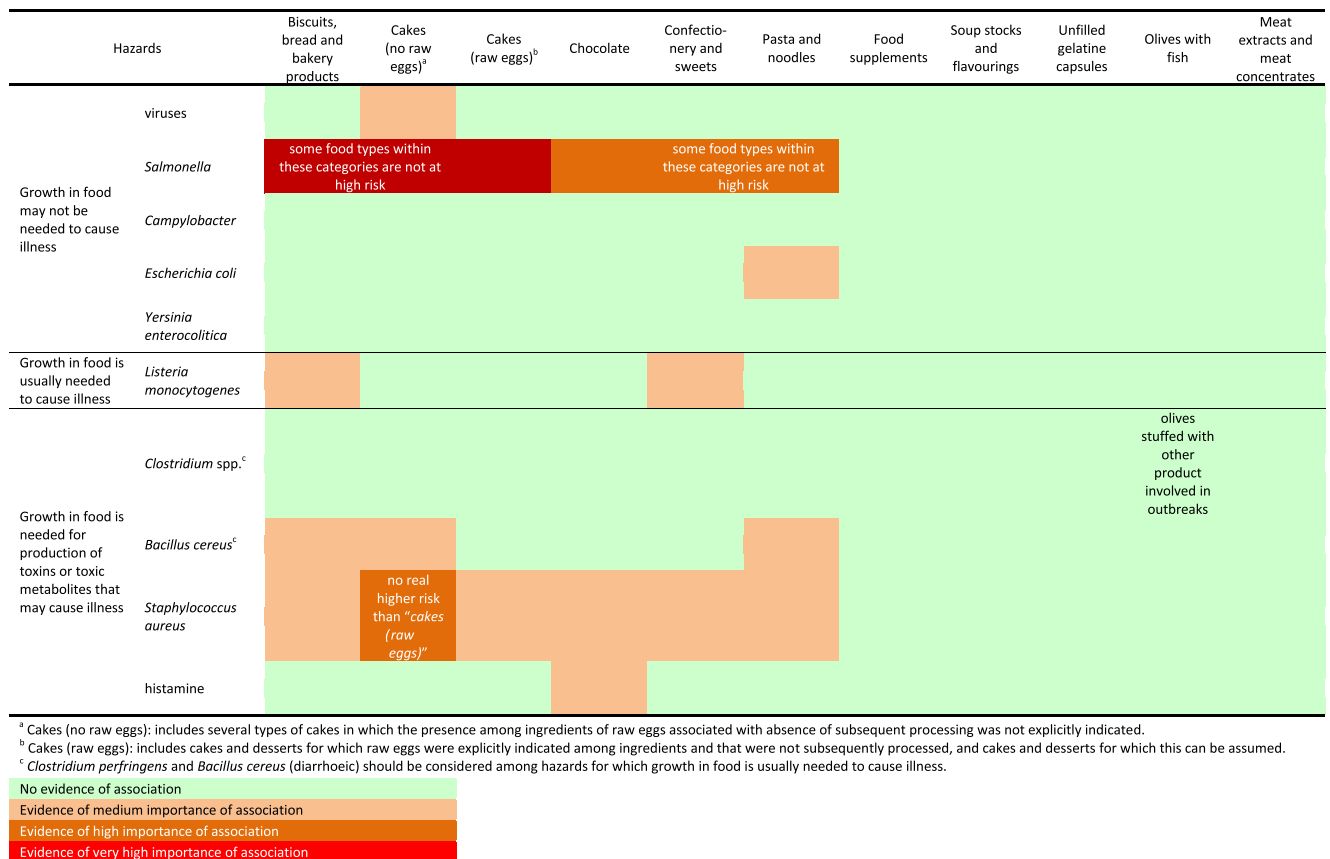


Fig. 5. Results from the application of the backward approach.

application of the forward approach leads to a likely risk for a given food, the risk can be further qualified with the results from the backward approach.

When integrating in this way the results obtained with the two approaches for composite products, it can be concluded that among the foods resulting in *moderate risk* or *qualified presumption of risk* according to the forward approach, combinations of hazards and categories of composite products of highest concern would be the ones for which a high to very high importance of association was identified by the backward approach, i.e. *Salmonella* spp. in biscuits, bread, cakes, chocolate, some types of confectionery and sweets, pasta and noodles, and *S. aureus* in some types of cakes.

## Conclusion

The methodology described in the present paper was applied in order to identify the microbiological hazards of importance in certain composite products and to rank the products with respect to the food safety risk they may pose. Data available for such foods are scarce compared to other foods. This is mainly due to the heterogeneity of products included in the same category of composite products assessed, and to the many interactions that may take place between the different ingredients and components in the same product. Similar difficulties are likely to occur

in other situations where risk managers and legislation make use of food categories, which are frequently very heterogeneous with respect to features important in influencing microbiological risks. This also leads to some complications in the collection of data on the occurrence of hazards in and outbreaks originated from these products. A considerable degree of uncertainty derives from the resulting lack of data available for consideration.

Despite this and other limitations discussed above, it was possible to apply the methodology developed to composite products, obtaining valuable results. The method is therefore considered suitable for application with success to other types of food, and is proposed as a tool for risk managers to rank foods based on their potential food safety risks and to identify food products for which information is lacking.

## Disclaimer and acknowledgements

This manuscript is published under the sole responsibility of the authors, and shall not be considered as an EFSA output. The authors wish to thank the members of the EFSA Panel on Biological Hazards (BIOHAZ) that adopted the EFSA Opinion on "*Public health risks represented by certain composite products containing food of animal origin*" (EFSA, 2012a). This paper is largely based on the mentioned Opinion.

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Stella, P. (Auteur de correspondance), Cerf, O., Hugas, M., Koutsoumanis, K. P., Nguyen The, C., Sofos J. N., Valero, A., Zwietering, M. H. (2013). Ranking the microbiological safety of foods: A new tool and its application to composite products. *Trends in Food Science and Technology*, 33 (2), 124-138 . DOI : 10.1016/i.tifs.2013.07.005

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