Available online at www.sciencedirect.com

ScienceDirect

Procedia Food Science 6 (2016) 23 – 30

Procedia Food Science

International Conference of Sabaragamuwa University of Sri Lanka 2015 (ICSUSL 2015)

Challenges in risk assessment: quantitative risk assessment

Liesbeth Jacxsens[a,*] , Mieke Uyttendaele[a], Bruno De Meulenaer[b]

[a]*Laboratory of Food Microbiology and Food Preservation, Department of Food Safety and Food Quality, Faculty of Bio-Science Engineering, Ghent University, Coupure Links 653, 9000, Ghent, Belgium*
[b]*NutriFOODchem, Department of Food Safety and Food Quality, Faculty of Bio-Science Engineering, Ghent University, Coupure Links 653, 9000, Ghent, Belgium*

Abstract

The process of risk analysis consists out of three components, risk assessment, risk management and risk communication. These components are internationally well spread by Codex Alimentarius Commission as being the basis for setting science based standards, criteria on food safety hazards, e.g. setting maximum limits of mycotoxins in foodstuffs. However, the technical component risk assessment is hard to elaborate and to understand. Key in a risk assessment is the translation of biological or chemical pathways into a mathematical framework. Within the International Training Program 'ITP food safety, quality assurance and risk analysis' of Ghent University, department of Food Safety and Food Quality, we developed for low and middle income countries and emerging countries a training module on risk assessment. In where (semi-) quantitative probabilistic risk assessment calculations or qualitative risk rankings are trained for both microbial and chemical food safety hazards along the agro-food chain. This presentation will explain these methodologies demonstrated with examples from former ITP trainees.

Peer-review under responsibility of International Conference of Sabaragamuwa University of Sri Lanka 2015 (ICSUSL 2015).

Keywords: Risk assessment; international; risk analysis; probabilistic

* Corresponding author. Tel.: +32 9 264 60 85
E-mail address: liesbeth.jacxsens@ugent.be

Peer-review under responsibility of International Conference of Sabaragamuwa University of Sri Lanka 2015 (ICSUSL 2015).
doi:10.1016/j.profoo.2016.02.004

1. Introduction

Risk-analysis is the process of 3 distinct but closely connected components: risk assessment, risk management and risk communication (Fig.1.). Risk assessment as such exists out of Hazard identification: During the hazard identification, biological, chemical, and physical agents that may cause adverse health effects and which may be present in a particular food or group of foods, are identified; Exposure assessment: Exposure assessment is defined as the qualitative and/or quantitative evaluation of the likely intake of the hazard via food or environment as well as exposure from other sources, if relevant; Hazard characterization: in the process of the hazard characterization, the nature of the adverse health effects or negative effects on the environment associated with the hazard is evaluated in a qualitative and/or quantitative way (dose-response relationship) and Risk characterization: During the risk characterization, all the evidence from the previous three steps is combined in order to obtain a risk estimate (i.e. an estimate of the likelihood and severity of the adverse health effects / negative effect on the environment that would occur in a given population with associated uncertainties) and respond to the questions posed by the risk managers.

The process of risk assessment can be performed qualitative (risk ranking) or quantitative (deterministic or probabilistic), depending on the nature of data available and also the questions to be answered. With quantitative risk assessment, the risk on infection caused by microbiological hazards or impact on human health of chemical hazards can be calculated for a certain population, or subpopulation (e.g. infants, elderly). Scenario analysis leads to the evaluation of several 'what if' interventions along the agro-food chain on the exposure e.g. what if a sorting is conducted of the nuts in the companies to remove the molded nuts and to decrease the mycotoxin concentration with 10%. Outcomes of scenario analysis will lead to define the most interesting intervention to reduce the exposure. Sensitivity analysis will give insights in which issues are playing a major role in the contamination and the final exposure (e.g. importance of initial contamination of raw materials, temperature abuse and multiplication of pathogens, consumer behavior, etc.). When no quantitative data are available a risk ranking can be performed, to compare risks from several hazards so no absolute exposure or risk on illness will in this case be the outcome. But by comparing e.g. pathogens on fruits and vegetables, a priority can be set on which pathogen/commodity the highest priority has to be set [1].

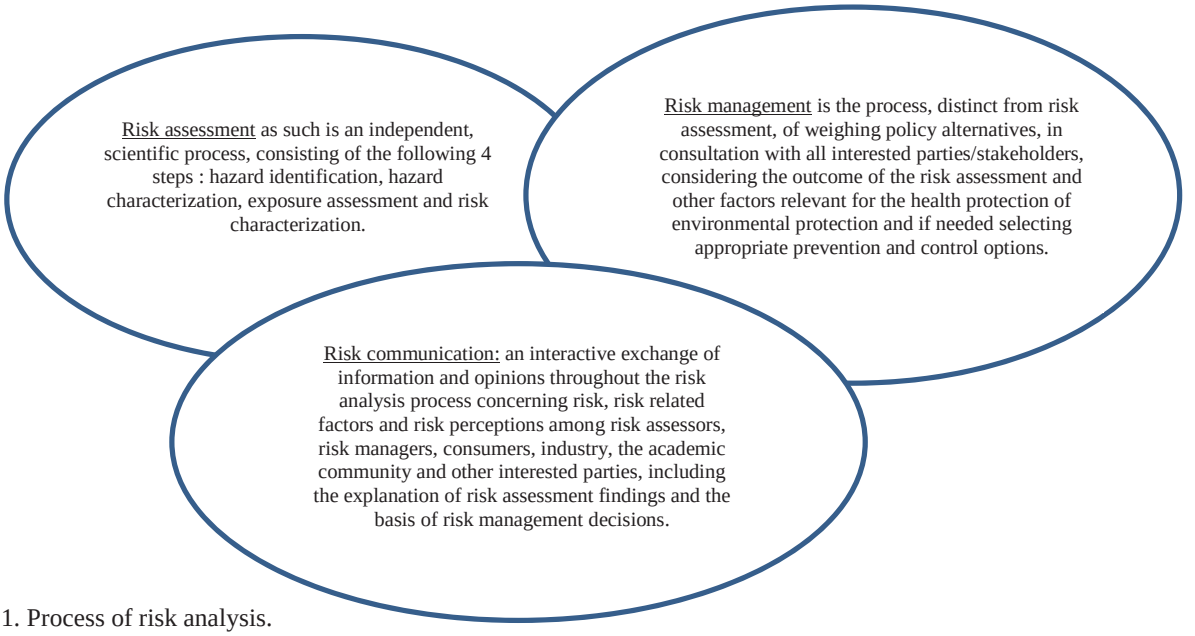


Fig. 1. Process of risk analysis.

1. Methodology

For hazard identification, primary data resulting from laboratory tests could be applied supplemented with scientific literature or grey literature (e.g. WHO, FAO, EFSA, EPA) as sources of information to gain insight in the problem. Typical contamination data (prevalence and concentration), food chain information (time/temperature conditions, different steps in the chain), behaviour of the hazard in the chain (e.g. growth information of pathogens, contamination routes, chemical reactions in case of contaminants, etc.) are collected. If contamination data (prevalence or fraction of samples being positive or above limit of detection (LOD) and concentration data expressed as CFU/g or ppm) are not available or not enough available, a risk ranking can be conducted in order to set priorities in multiple hazards (comparative risk ranking).

For an exposure assessment, two data sets are needed, being distribution of contamination of the hazard at moment of consumption and the distribution of the consumption information for the (sub) population. In order to have insight in the contamination levels of the hazard at moment of consumption, food products can be screened for the specific hazard (see hazard identification) but often due to a lack of resources alternatives have to be sought for. Therefore, the food chain has first to be fragmented to evaluate the impact of different steps on the prevalence and the concentration of the hazards (e.g. mycotoxin concentration upon harvest followed by mycotoxin concentration after sorting cereals). Therefore, a Modular Process Model can be applied (Table 1). In each step, the prevalence (or positive fraction) and concentrations (of the positive fraction) can be evaluated. This methodology can be conducted both for microbiological or chemical hazards. Based, on mathematical modelling predictions (predictive microbiology) or assumptions can be made to calculate the final concentration at the moment of consumption. For microbiological hazards, consumer behavior (e.g. transport distance to home, home preparation practices, etc.) can be of influence on the final concentration of the pathogens or toxins before consumption. Consumer behavior information is of importance and can differ widely depending on the cultural habits. Also consumption information (frequency of consumption and consumed portion) may differ within or between populations. Specific subgroups in a population as infants, children adults or elderly persons may have a different consumption pattern.

Table 1. Example of Modular Process Model applied on soft cheese production for *Salmonella* spp. (based on the work of Selah Tamara for Nabulsi cheese in rural areas in Palestina, ITP food safety training 2014, Ghent University)

Step in the chain	Food product	Description of potential contamination route	Impact on prevalence	Impact on concentration
Rawmilk	Raw milk	Cross contamination due to milking procedure (hands, recipients, cow, etc.)	Y	Y
Heating at 30°C	Raw milk	Temperature abuse and multiplication	N	Y
Leaving for 2 hours at 20-25°C	Heated milk	Heat treatment and reduction of pathogens	Y	Y
Leaving for 18 hours at 11-13°C	Fermented milk	Multiplication during ripening	N	Y
Leaving for 120h in refrigerator – including cross contamination in consumers kitchen	Soft Cheese	Multiplication during ripening Cross contamination by consumers (e.g. storing raw poultry)	Y	Y
OUTPUT : distribution of contamination at moment of consumption (CFU/g)				

When each step in the process is described, a mathematical translation is needed of the identified biological or chemical pathways to come to a quantitative exposure assessment. Therefore, typically distributions are attributed to the microbiological or chemical pathways. Depending on the nature of the available data we can perform these calculations in a deterministic way (min, mean, max), or in a probabilistic manner (attribution of distributions on concentration and consumption data, Fig. 2.), resulting in a distribution of the exposure of the population. This method of working has to be performed for each step in the chain. For probabilistic calculations, software is necessary to perform the simulations. Widely applied software is @Risk (Pallisade, US), where Monte Carlo simulations are conducted, by multiplying random a point on the distribution of the contamination and a distribution on the consumption (Fig. 2.). The last method is providing the most information of the exposure compared to deterministic

and next to min, max, also the full spectrum of exposure and percentiles can be derived e.g. P50, P75 or P90 (Fig. 2.).

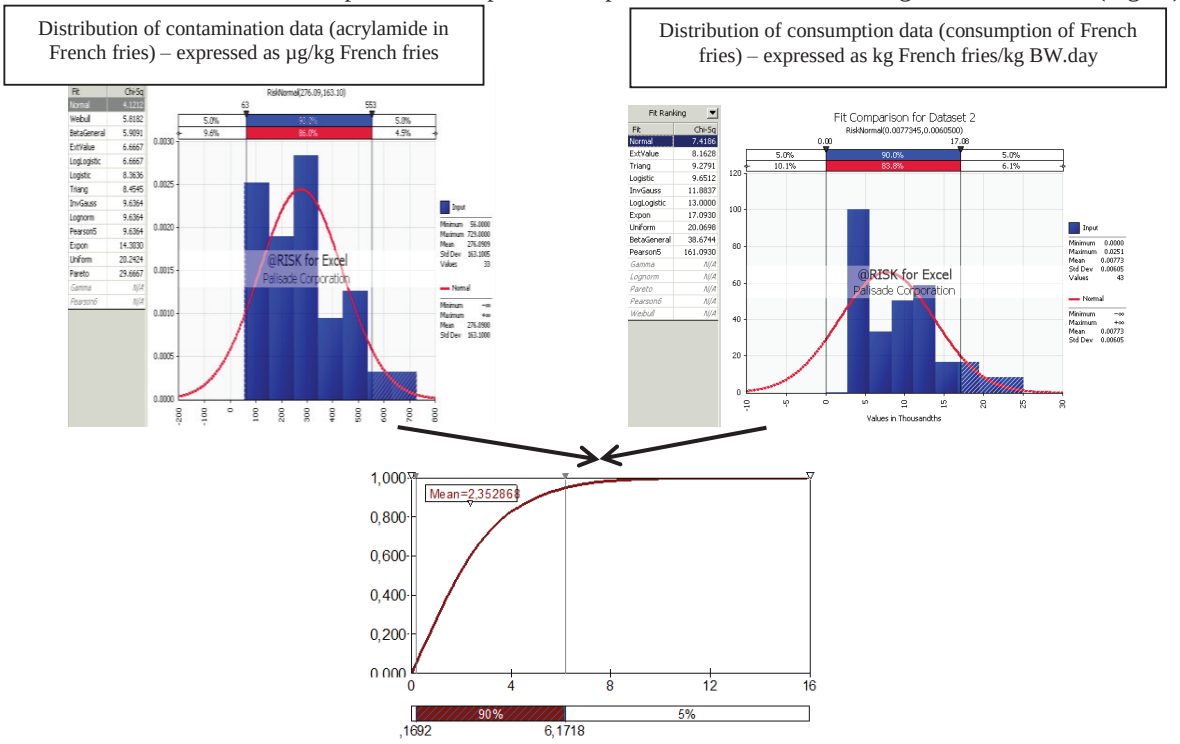


Fig. 2. Attribution of distribution (fitting – red line) to data on concentration (left : example of acrylamide in French fries, right : example of consumption data of Belgian consumers' eating French fries resulting in the exposure to acrylamide by consumption of French fries (expressed as µg/kg BW.day), illustrated as a cumulative distribution (exposure distribution obtained via Monte Carlo simulations).

2. Results and discussion

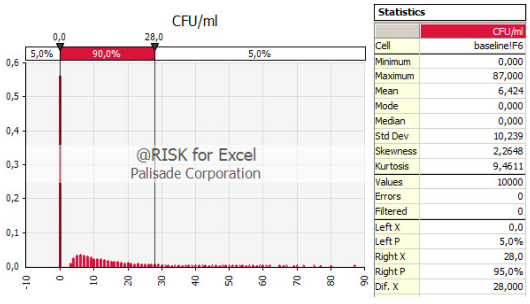
Key in microbiological and chemical exposure assessment is the translation of these biological or chemical pathways into a mathematical model. So, distribution fitting can be applied, as illustrated in Figure 2 for chemical hazards but also know distributions can be fitted to the data. An example of this is given in Table 2, for the contamination of raw milk with a known prevalence (based on sampling in Palestina for *Salmonella* in 25 mL raw milk). As no information is available on the concentration of *Salmonella* in the raw, an assumption is made and a Pert distribution is attributed (PERT(min, most likely, max)).

Table 2. Illustration of mathematical description of initial contamination of raw milk (investigated prevalence in 25 mL and assumed initial concentration), based on available data in Palestina (after [2]).

When these models are run in @Risk, an output is generated and is illustrated in Fig. 3. Results of the simulation for node 1 showed that *Salmonella* level in raw milk was maximum 87 CFU/ml with a mean of 6,42 CFU/mL and median of 0 CFU/mL (Fig. 2.).

Node	Unit operation (Pathogen event)	Description	variable	Unit			
1	Primary Production (Initial contamination)	Input (extent): level of Salmonella in raw milk	Ie 1	log cfu/ml	=RiskPert(0,5,1;2)	1.00 33	Theoretical assumption: Contamination at low (0,5), medium (1), and high (2) CFU/mL
		Input (incidence): prevalence of S. in milk	Ii 1	%	=RiskDiscrete({0\1};{44\56})	1	56% is the median from some studies which showed prevalence of Salmonella in raw milk at the primary production (Martinez, 2011)
		Output: initial contamination at primary product	Out 1	cfu/ml	=RiskOutput()+IF(Ii1=1;0;ROUNDDOWN(POWER(10;Ie1);0))	0/87	Oscar (2004)

Fig.3. Distribution of initial contamination of milk at primary production for *Salmonella* (as output of Table 2), generated via @Risk software



In a next step of this soft cheese production, the initial raw milk is heated till 30°C, which allows growth of *Salmonella* when present. The mathematical translation of this event is given in Table 3. Time/temperature conditions are collected based on observations during cheese production and growth is predicted based on predictive microbiology. As outcome, the concentration of *Salmonella* in the milk (CFU/mL) after this step is generated.

Table 3. Mathematical translation of potential growth of *Salmonella* during heating of raw milk to 30°C (after Selah, 2014).

Likewise, each step in the production of the cheese can be simulated (e.g. in case of this soft cheese from Palestina,

Node	Unit operation (Pathogen event)	Description	variable	Unit	Formula	Value/ output	Ref.
2	Warm milk at 30 º C Primary growth	Temperature during 2ed step	T1	º C	=RiskUniform (20;30)	25	Average T during milk warming min = 20º C max = 30º C
		Time during 2ed step	t1	h	=RiskUniform (0,16;0,25)	0.205	The time of milk worming between 10 – 15 min.
		Logarithmic growth /hour	Lg/h	Log conc /h		0.617	The logarithmic growth per hour is calculated using Predictive Microbiology (ComBase)
		Input (extent): potential G. event(log. G. during node 2)	Ie 2	Log	=Lg/h *t1	0.1264	Because the temperature range is within the temperature range for growth of Salmonella, i.e. 5.2-46.2oC (Yates, 2011) so that the potential growth will always occur therefore the logarithmic growth is log growth per hour multiplied by time for warming
		Input (incidence): predicted incidence potential G. during process 2	Ii 2	%	=RiskDiscrete({0\1};{0\100})	1	The prevalence is 100% (assumed)

		Output: number of cell at the end of warming.	Out 2	CFU /mL	=RiskOutput( )+IF(Ii2=1;ROUN DDOWN(PO WER(10;Ie21 4)*out1;0);out 1)	0/1 15	Oscar (2004)

Table 1) and final, the concentration at moment of consumption can be multiplied with the consumption information to calculate the exposure (CFU/serving). A typical serving is between 100 and 200 g in this case. This information can be inserted into a UNIFORM distribution (UNIFORM(min, max). And included in the modelling. In this presented case study, also two scenarios are included. Scenario 1 simulates a pasteurisation of the raw milk and thus a reduction in the initial contamination. While scenario 2 includes good practices along the production, so better initial raw milk quality, better time/temperature contaminations and no cross contamination in household kitchens. From Table 4 the impact of these 'what if' scenarios can be compared with the baseline situation over the different steps in the production of the food product.

Table 4. Contamination (mean) and exposure to *Salmonella* along the production of soft cheese in Palestina for the current situation (baseline scenario) and two what if scenarios (after[2])

Node	Raw milk (baseline scenario)	Pasteurized milk without Good practices (scenario 1)	Pasteurized milk with Good practices (scenario 2)
Rawmilk	87 CFU /ml	1 CFU /ml	1 CFU /ml
Heating at 30°C	115 CFU /ml	1 CFU /ml	1 CFU /ml
Leaving for 2 hours at 20-25°C	2863 CFU /g	32 CFU /g	24 CFU /g
Leaving for 18 hours at 11-13°C	8410CFU /g	96 CFU /g	19 CFU /g
Leaving for 120h in refrigerator – including cross contamination in consumers kitchen	9067 CFU /g	736 CFU /g	0 CFU/g
Serving	$1{,}3x10^6$ CFU/portion	$1{,}1x10^5$ CFU/portion	0 CFU/portion

It is clear from the above table that the contamination of *Salmonella* in Nabulsi cheese reduced from 9067 CFU/g in case of its made from raw milk to reach 736 CFU/g due to pasteurize milk only and then to reach 0 CFU/g due to pasteurize the milk and implementation of good practices (e.g. avoiding cross-contamination, better temperature conditions), and the serving reduced from $1{,}3x10^6$ CFU/ portion in baseline scenario to reach $1{,}1x10^5$ CFU/g in the first scenario then minimized to reach 0 CFU/g in the 2nd scenario.

In a next step, hazard characterisation and risk characterisation can be conducted to shift from exposure to calculation on risk of illness or burden of disease. Several dose/response relationships has been reported for *Salmonella* (. The minimum infective dose for *Salmonella* is between 10 – 10^6 (ref thesis Olivier).

If the minimum infective dose was kept at 10 or 10^3 or 10^5*Salmonella* for this study, then the entire population who consumed the Nabulsi cheese were at risk, if it was kept at 10^6 then 15% of population were not at risk. It could be inferred from the detailed statistics that 50%, 90%, 95% and 99% of the population had the exposure level of equal to or less than $1{,}3x10^6$; $1{,}7x10^6$; $1{,}7x10^6$and $1{,}8x10^6$ CFU respectively.

The result of assessment has shown that the Nabulsi cheese sold to the Palestinian population could have a high level of *Salmonella*, which represents a risk associated with insufficient boiling and poor hygiene of consumers at home. This result confirms that the raw milk has a bad microbiological quality and no implementation for good practices during cheese manufacturing. Milk should be pasteurized and food safety management control should be implemented along the Palestinian cheese chain production.

4. Conclusions

It is not evident to perform a risk assessment to come to science based decisions making. Raw data on contaminations, food chain information need to be compiled with mathematical knowledge and simulations. The gap between biological and chemical pathways and mathematical modelling is key. However, with limited data available and good knowledge of food chain, modelling basic risk assessment calculations can be conducted. This was presented by the various cases in our ITP food safety were low, middle and emerging countries are participating. These risk assessment studies not always will give the full picture of burden of diseases, but are important to gain insights in most contributing steps in the chain (sensitivity analysis) or to evaluate what if possibilities (scenario analysis).

Acknowledgements

This review was conducted as a result of the experience gathered from the VLIR UOS sponsored intensive training program on Food Safety, Quality Assurance and Risk Assessment at Ghent University, Belgium. (www.itpfoodsafety.UGent.be). We would like to thank all our collaborators in the Department of Food Safety and Food Quality for their support in this training, in particular Prof. Bruno De Meulenaer for his co-promotor-ship of this training program, Anne-Marie De Winter and Marian Mareen for their administrative support in hosting the trainees. And the 108 trainees so far, for their contribution in the lectures, exercises, E-learning modules and improving the lectures on risk assessment.

References

1. EFSA, 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) EFSA Journal 2013;11(1):3025

Oscar, T. P. A quantitative risk assessment model for *Salmonella* and whole chickens. *International Journal of Food Microbiology*, (2004). *93*, 231-247.

2. Selah, T. Quantitative risk assessment, food safety management system, monitoring and sampling of *Salmonella* in raw Nabulsi cheese in rural area in Palestine. Case study 2 dissertation in the frame of ITP food safety, Ghent University, December 2014.