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Application of a HACCP–QMRA approach for managing the impact of climate change on food quality and safety

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ABSTRACT

The work presented focuses on predictive modelling for estimating the risk to consumers due to consumption of food contaminated with Specific Foodborne Pathogens (SFP) or estimating the remaining shelf life of the product. An approach based on integration of the existing Hazard Analysis and Critical Control Point (HACCP) approach with the Quantitative Microbial Risk Assessment (QMRA) is presented which is developed as part of the Chill-On EC FP6 research project. The paper describes the main principles of operation of the system and introduces elements of practical implementation and operation of the HACCP system combined with QMRA as well as a Shelf Life Predictor (SLP). The possibility for managing the impact of climate change by using HACCP–QMRA–SLP in supply chains is discussed.

1. Introduction

There seems to be a growing consensus on the inevitability of the climate change due to increase of the concentration of greenhouse gasses in the atmosphere. The climate change would manifest in various ways, most of the time with negative implications on the economy, environment, human health and other various aspects of which in the present case the focus is on food safety. The issue of impact of climate change on food quality and safety has not been discussed sufficiently in open literature and is now receiving more attention (Jaykus et al., 2008; Miraglia et al., 2009).

This work focuses only on the impact of climate change on increasing vulnerability of food due to microbial contamination. The mechanisms by which climate change may influence the food safety are various and have been discussed elsewhere (e.g., Jaykus et al., 2008; Miraglia et al., 2009). For example, increased water temperature may promote growth of microorganisms which would in turn increase the microbial load on the fish products or even cause contamination by species not normally present in those waters since climate change could allow warmer climate pathogens to survive the more northern zones. Effects of climate change may not necessarily influence the growth of certain pathogen, it may affect the natural microflora of the food product and this in turn may create better conditions for growth of certain pathogens. The ways by which climate change may influence the contamination of food products with SFP and growth of SFP are not well known and are not in the focus of this research.

In this work it is considered whether the predictive modelling would be able to reduce the impact of the climate change on the safety and quality of food products. A system which is developed as part of the Chill-On EC FP6 Programme based on a HACCP–QMRA–SLP approach should be able to indicate that the environmental conditions are changing in such a way that can affect the safety and/or quality of certain food product in the supply chain. The QMRA and SLP should be able to detect these changes before they are detected by HACCP or the supply chain operators, providing this way sufficient time for corrective actions in order to reduce the impact of the climate change on the food product's safety and quality in the supply chain. It is proposed that the system would make use of continuous monitoring of environmental parameters, e.g., temperature, pH, as well as results of testing for SFP and Specific Spoilage Organisms (SSO). The system would use the Supply Chain (SC) data stored in the system database over a period of time in order to recalculate periodically changes in model parameters used for prediction of risk levels or shelf life, e.g., probability for contamination of the product with certain pathogen, growth rate, initial count of spoilage microorganisms, etc. Application of appropriate statistical analysis would identify significant variations in the trends in terms of decreased safety or shelf life of the product which would require further attention and corrective actions. Such system can be applied for reducing the negative impact on the food products due to climate change and possibly due to seasonal variations.

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2. HACCP, current EU regulations, and QMRA

Hazard Analysis and Critical Control Point (HACCP) concept was first developed in the 1960s by NASA (Untermann, 1999). It was designed to prevent microbial, physical and chemical hazards in food for the space missions. Today HACCP is an internationally recognized system (set of guidelines) and is widely used for safe food production. Successful HACCP system manifests that it is applied along the complete food SC. When properly applied it ensures consistent food safety levels.

The new food law in EU, Regulation 178/2002 (Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January2002) that was applied from 1st January 2005 states that food companies have the primary responsibility for safe food production. As implemented from 1st January 2006, the new food hygiene law Regulation 852/2004 (Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004) requires all food companies in all member states (except farms) to operate food safety programmes based on the seven HACCP principles contained in the Codex Alimentarius.

The introduction of HACCP rises to the issue of national and international equivalence of implemented HACCP in food SCs. At the national level there is a need for competent authority who would validate the implemented HACCP. At the international level it is necessary to determine the equivalence of HACCP procedures implemented in different countries. It is not clear whether the current regulations can provide assurance of equivalence on international level, which in most cases means that compliance for export based solely on home regulations cannot be established.

Though QMRA is the necessary step needed to inform and properly conduct the hazard analysis step of HACCP and to identify adequate control mechanisms for the critical control points (e.g., Notermans & Mead, 1996; Tuominen, Hielm, Aarnisalo, Raaska, & Maijala, 2003), HACCP itself is a qualitative approach. There are suggestions that HACCP in the future should evolve in such a way to incorporate also the Quantitative Microbial Risk Assessment (QMRA) (McMeekin et al., 2006; Notermans & Mead, 1996). It has been pointed out that qualitative risk assessment cannot address the process's inherent variability in any meaningful manner (Buchanan & Whiting, 1998). Since QMRA is a quantitative approach, a synthesis of both approaches should produce a food safety system which will be able to offer higher reliability. One of the aspects where QMRA can clearly help HACCP is that it can provide quantitative estimates of the risk in the critical control points taking into account the variability of the parameters in the food SC. It is also possible that HACCP integrated with QMRA will be easier to compare for equivalence world-wide, due to the added quantitative dimension. If the QMRA is implemented in practice, the determination of equivalence between very different systems could become more straightforward.

3. Application of QMRA and SLP in food SCs

Microbiological hazards in food can normally be present in the raw food material or contamination can occur as a result of poor hygiene during processing from equipment, staff handling the food and temperature abuses. When pathogen microorganisms are present in food, the number of cells may not be high enough to cause illness in people. The SFP become dangerous when their number increases to a point where they can cause illness or produce toxins that are harmful. To prevent illness in people due to consumption of contaminated food, conditions which can lead to increase in microbial counts need to be kept under control. This can be done by combining HACCP and QMRA into a new system. This is why application of the QMRA in food SCs for enhancing the safety of the food products is becoming more attractive (McMeekin et al., 2006) .

The main purpose of the QMRA is to provide an estimate of the risk to consumers due to contamination of food with pathogen bacteria. The QMRA consists of the following elements (see Fig. 1): (i) hazard identification, (ii) exposure assessment, (iii) hazard characterization and (iv) risk characterization.

3.1. Hazard identification

Hazard identification is the essential step in the QMRA where the Specific Foodborne Pathogens (SFP) relevant to the considered SC are identified. This step will be SC specific in terms of SFP that might be present or introduced at a certain point in the SC. The knowledge on the type of SFP of relevance to the food SC would be normally derived from past screenings for pathogen bacteria in the SC.

3.2. Exposure assessment

In this study the exposure assessment refers only to the ingested number of cells of SFP by the consumer, though exposure assessment can include also microbial toxins and toxic chemicals. A food SC can be very complex and can have many steps and processes. According to the Modular Process Risk Model (MPRM) (European Commission, 2003; Nauta, 2002), it is assumed that at various stages of the SC one of the six basic processes can be assigned, i.e., (i) growth, (ii) inactivation, (iii) partitioning, (iv) mixing, (v) removal and (vi) cross contamination. The input parameters in each of these modules are the number of the microorganisms and their prevalence. The number of the microorganisms and their prevalence for each successive process could be obtained in two different ways: (i) by using the mathematical model to estimate the number of the microorganisms and their prevalence at the end of the previous process, which automatically become the input variables for the next process in the chain, or (ii) by measurement in control points between processes.

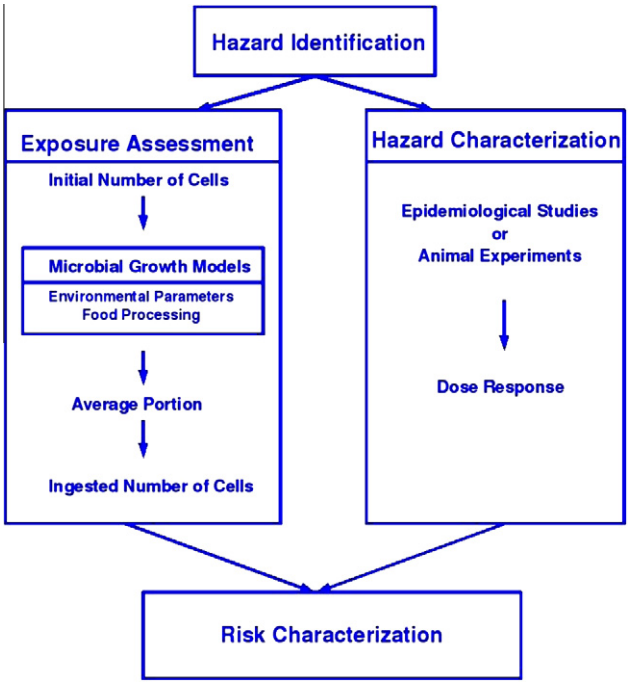

Fig. 1. Elements of the QMRA.

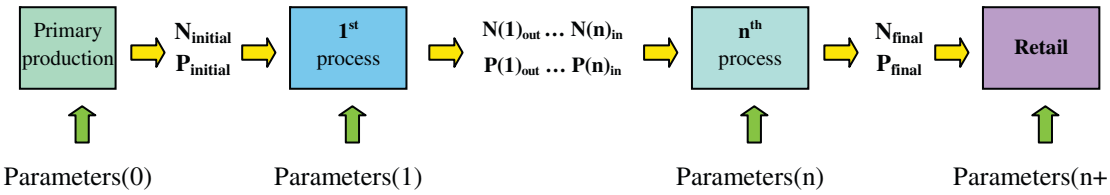

Fig. 2. SC steps represented as input–output basic processes (N – number of microorganisms; P – prevalence).

Each step in a SC presented in Fig. 2 could be classified in one of the six basic processes related to the various stages in the SC. Basic input and output variables in each step are the concentration of bacterial organisms (N) and prevalence (P). These quantities should be considered as uncertain variables in the model. The variability in the model is a consequence of the variability in the environmental conditions as well as variability in the SC. The variability in the SC includes uncertainty in different steps of the SC, such as exact time when the product arrives or departs certain point along the SC. The uncertainty in different environmental and SC parameters can be included into the mathematical model by using stochastic models, e.g., Monte Carlo simulation. The MPRM is not straightforward to implement and requires significant amount of data which is not usually available. Further in this paper only microbial growth and cross contamination are considered without reducing the generality of the conclusions in this work.

The concentration of the SFP in the product is a stochastic quantity. In order to establish the probability density function (PDF) for presence of the SFP in certain concentration in the product, historic data on the incidence, prevalence and count of pathogens in the product are required. This information has to be collected through testing of the product over certain period of time, e.g., 1 year, in order to produce reliable data. The testing would also provide data to determine the probability for cross contamination in the SC. The length of the required period depends on how often the testing is performed. The PDF for finding certain number of cells of certain pathogen bacteria in the SC can be further used in the exposure assessment, i.e., in the microbial growth models.

3.2.1. Microbial growth models

The microbial growth models are used to predict the growth of microorganisms in the product under certain environmental conditions. During the development of the mathematical models for growth of particular microorganism the first step is to perform laboratory experiments in order to provide the necessary data. The product will not be free from other microflora which would be SC and product specific. It is reported that growth of one kind of species might influence the growth of another one (e.g., Buchanan & Bagi, 1999; Mejlholm & Dalgaard, 2007). Therefore, two different ways are possible for developing microbial growth models. The first one would be to develop a general model including multi species competition taking into account the environmental variables, e.g., pH, NaCl%, temperature. Such model from mathematical point of view is feasible and could be applied to various food SCs provided that the required data from laboratory is available. As the model becomes more general the requirements for data derived from laboratory experiments increases, due to the number of variables and species represented in the model. Therefore, obtaining data for such models may not be practical due to costs and complexity.

The second option to develop a microbial growth model is by preparing a SC specific model. In this case laboratory experiments are carried out where the product from the SC is contaminated with SFP of interest. The experiments for determining the parameters for growth of SSO are usually performed with the spoilage microorganisms already present in the product, leading this way to SC specific data. Such models are less complex and less costly. They are relevant to the specific SC since the product used in the experiments is the one from the SC itself and therefore the chemistry and the microflora on the product used in the experiment will be close or identical to the one found in the SC. This provides conditions for higher level of agreement between the model predictions and the actual microbial growth in the product. It is important to note that such models would be reliable as long as the conditions in the SC stay within the range of parameters used in the experiments.

If there are significant changes in the SC conditions, e.g., average temperature rise due to climatic change, the HACCP–QMRA–SLP system would detect such trend through the shift in the quantitative predictions helping this way determine when something needs to be changed or adapted in the SC.

The microbial growth models can be deterministic or probabilistic/stochastic. There were a number of deterministic models reported in the literature (e.g., Baranyi & Roberts, 1994; Hills & Wright, 1994; McKellar, 1997; Ratkowsky, Olley, McMeekin, & Ball, 1982; Zwietering, Wijtzes, De Wit, & Van't Riet, 1992).

The stochastic models have the advantage of being able to take into account the high level of biological variability among cell population and uncertainty in model parameters (e.g., Delignette-Muller & Rosso, 2000; Nauta, 2000; Poschet, Geeraerd, Scheerlinck, Nicolai, & Van Impe, 2003; Ross, 1993).

The QMRA works with the probability for presence of certain SFP in the supply chain products and therefore can be implemented only with the stochastic model for microbial growth. The SLP can be implemented with both, deterministic or stochastic models for microbial growth. While the stochastic models offer more utility when dealing with uncertainty and variability, they are also more demanding in terms of data requirements and CPU usage.

3.3. Hazard characterization

An essential part of the QMRA is a suitable dose response model for estimating the probability for illness due to ingestion of certain number of SFP cells. However, the accurate dose–response relation is difficult to describe for two reasons: (1) the variability in both host susceptibility and microorganism infectivity; and (2) the lack of experimental data (Farber, Rose, & Harwig, 1996; Holcomb et al., 1999; Marks, Coleman, Lin, & Roberts, 1998; Yang, 2003).

Several statistical models have been used to describe microbial dose response relation. The most often reported dose response models for SFP in the literature are the exponential, Beta-Poisson, Weibull-Gamma and Gompertz, which are given by Relations (1)–(4), respectively (Buchanan, Smith, & Long, 2000; Coleman & Marks, 1998; Kang, Kodell, & Chen, 2000; Medema, Teunis, Havelaar, & Haas, 1996; Regli, Rose, Haas, & Gerba, 1991; Todd & Harwig, 1996).

$$P(d) = 1 - \exp(-r \cdot d), \tag{1}$$

$$P(d) = 1 - \left(1 + \frac{d}{\beta}\right)^{-\alpha}, \tag{2}$$

$$P(d) = 1 - \left(1 + \frac{d^b}{\beta}\right)^{-\alpha}, \quad (3)$$

$$P(d) = 1 - \exp(-\exp(a + b \cdot f(d))), \quad (4)$$

where P is probability for the consumer to become ill, d is dose and r, α, β, a, b are model parameters.

3.4. Implementation of the SLP

The implementation of the SLP model is simpler than the implementation of the QMRA model. The SLP model uses a microbial growth model similarly to the QMRA. The selection of SSO to be used as spoilage indicators would be product and SC specific. The rejection point, in terms of microbial count, is determined by experiments involving sensory evaluation.

4. QMRA and SLP implementation in a food SC

The main benefit of the implementation of the QMRA and SLP modules in a SC is related to near-real-time data processing and provision of information to the SC operators on the risk levels to consumers and remaining shelf-life of the product taking into account variations in environmental parameters. Such implementation requires means for real-time data supply to the QMRA and SLP modules. How is this implemented is a separate issue and will not be discussed in the current work. Here it will be assumed that the technology which transfers automatically data from sensors in the SC to the QMRA and SLP modules exists. It will be considered that the QMRA and SLP modules are part of a Decision Support System (DSS). The frequency with which the data is transmitted to the DSS depends on the environmental parameters of interest. For example, temperature is expected to change much more rapidly than pH and therefore should be transmitted with higher frequency especially in parts of the SC where temperature abuse is more likely.

Fig. 3 shows a possible implementation of the QMRA module. The necessary Real-Time Data (RTD) and input parameters for risk assessment analysis of microbial contamination along the SC is provided through communication with the DSS and from the data base. The operation of the module depends on the SC specific data which enables preparation of primary and secondary models for SFP of interest. A dose response model for each SFP is also necessary together with the process analysis module. The QMRA itself is imagined as a generic software module and can operate for various food SCs, providing that the database with the necessary information, e.g., for calibration of the microbial growth models and dose response model, can be produced. As can be seen in Fig. 3, a possibility for updating the databases exists. Such updates are necessary in order to take into account changes in the SC, or in order to fine tune the models to the specific SC. The experiments for establishing the parameters of the microbial growth models are usually conducted in a laboratory environment. In the experiments if a product from the SC is used higher probability for agreement between the model predictions and actual microbial growth rates in the SC is expected. This however does not guarantee a perfect agreement between the model's predictions and the observations in the SC. Fine tuning of the models can be further carried out in the specific SC in order to achieve higher accuracy of the predictions. There is also another aspect to this process which is related to slow changes in the SC, e.g., climate change, which may affect the chemical composition and microflora of the product. By using data from microbiological testing in the SC, the QMRA model can be fine tuned or re-calibrated periodically. In this way the relevance of the model to the product in the SC is guaranteed to a higher level despite the changes in the SC parameters due to variations

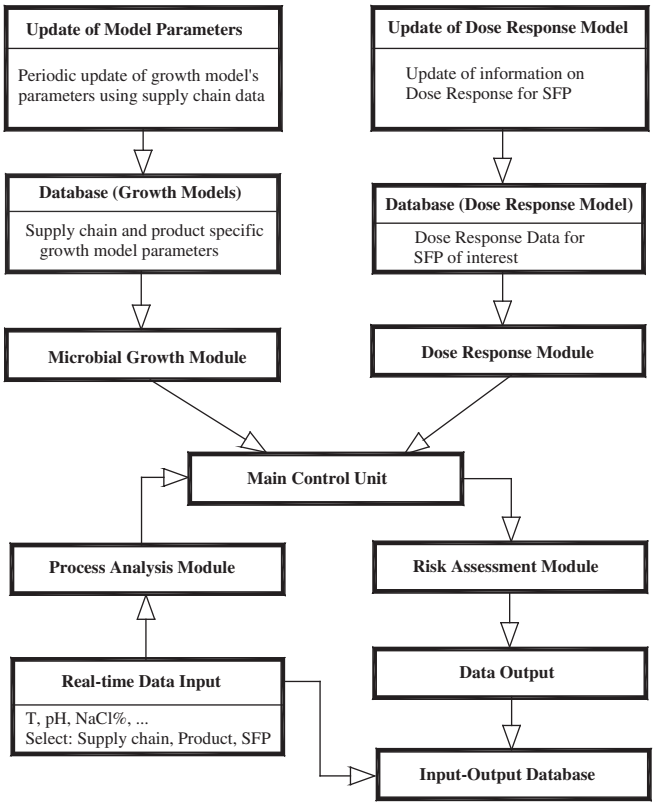

Fig. 3. Block diagram of the QMRA module.

in temperature as a result of climate change. This consideration may also be applicable to seasonal variation in temperature though the temperature change in this case happens in much shorter period of time which may not allow for proper statistical analysis in order to establish the significance of the changes. The above discussion is also valid for the SLP model.

4.1. Operation of the QMRA and SLP modules in real time

An efficient supply of real-time data along the SC is essential for successful operation of the DSS. It may occur that in some parts of the food SC such real-time data supply is not possible. For these parts sensors with data loggers should be used and the data should be retrieved and sent to the DSS once the link is established again.

The environmental temperature as one of the most important parameters for predictive microbiology should be monitored in real time using thermometers with data loggers and where possible the data should be transmitted/sent to the DSS in real time. The simplified data transmission between the DSS and QMRA/SLP is presented in Fig. 4. Since the role of the QMRA and SLP are to predict future state of the product, this assumes use of SC environmental parameters which are yet to be recorded. Fig. 5 shows the SC temperature profile, where separate processes are indicated. In this example we consider that the product is at the point "t_1" in the SC. The temperature profile is provided to the modules as two vectors where the first one contains the time of the measurement and the second one contains the recorded temperature. The vectors up to t_1 are known since they have been recorded through real time monitoring (RTM), however, the vectors do not exist for the remaining part of the SC. For the remaining part of the SC the historic data should be used. This can be implemented by finding the average temperature from the historic data in each point of relevance in the SC. Using the PDF for the temperature in relevant points in the SC is also possible, however, this approach would in-

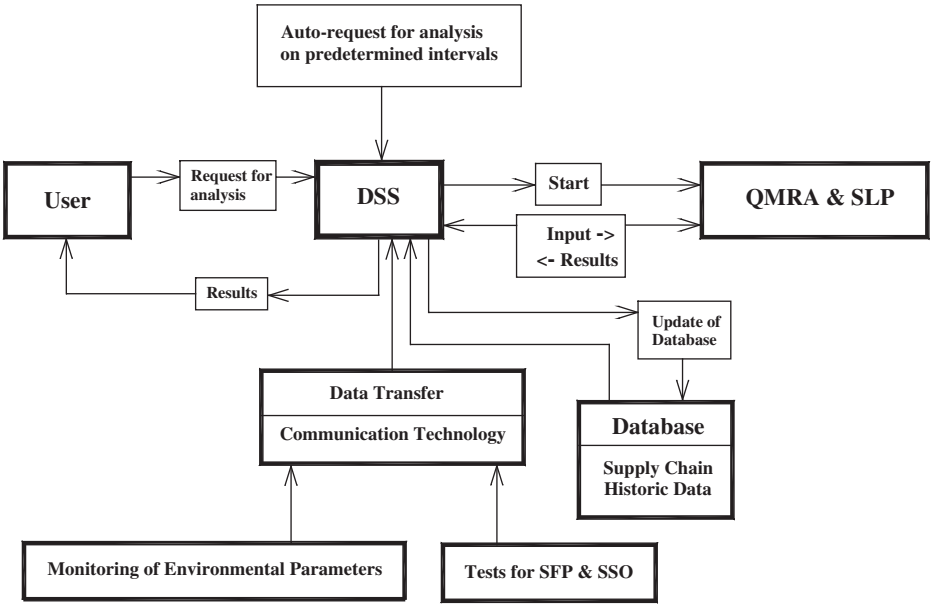

Fig. 4. Block diagram of interaction of DSS and QMRA and data transfer.

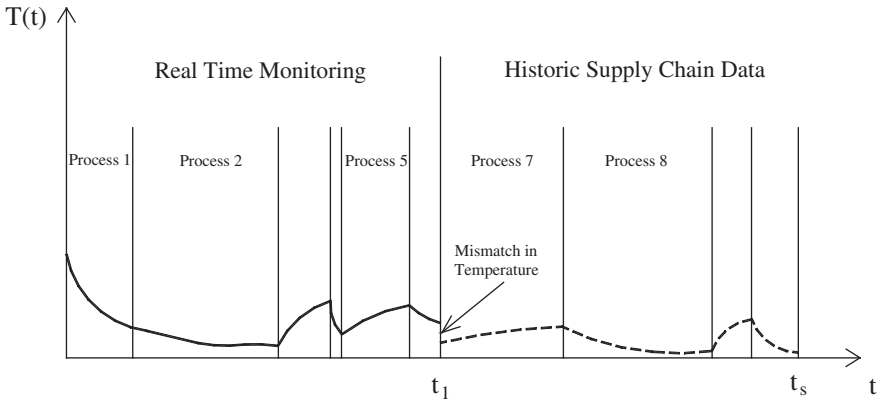

Fig. 5. Construction of temperature vector using real time monitoring and historic SC data.

crease the computational time. Since the QMRA estimate is based on the RTM up to a certain point in the SC and on the historic data in the remaining part of the SC, as the location in the SC changes, the QMRA estimate may change as well. In case that the RTM data is close to the historic data, the QMRA estimate would be approximately constant throughout the SC.

It is worth noting that the QMRA model assumes that the pathogens are always present in the product. The probability for finding a SFP in the product can be determined by using data from past testing for the SFP at a certain step in the SC. The probability that a SFP is not present in the product is zero unless the SFP has never been detected through past testing, in which case this particular SFP would not be relevant for this particular product in the SC and would not be included in the QMRA. Considering the previous research work on influence of climate change and seasonal variations on pathogen outbreaks (e.g., Bentham & Langford, 1995; Fleury, Charron, Holt, Allen, & Maarouf, 2006; Koelle, Pascual, & Yunus, 2005; McMichael et al., 2003; Rose et al., 2001), it is likely that the PDF defining the probability for presence of pathogens in certain step in the SC would vary due to seasonal variations and climate change. For the operation of the QMRA model it is not important to understand the mechanism behind the change of the probability for finding a certain concentration of the SFP in the product. The QMRA operates by employing the PDF defining the probability for presence of pathogens in certain step in the SC, which is obtained from previous testing, and calculating the probability for presence of a certain SFP in certain concentration in the product at the end of the supply chain. The probability for finding certain concentration of the SFP in the product is used together with the dose response models to obtain the probability for the consumer to become ill.

One aspect that is currently not defined is the acceptable risk for the consumers to become ill. This is not defined by the law and requires further research taking into account the industry as well as the socio-economic point of view.

The law (e.g., Commission Regulation (EC) No. 2073/2005 of 15 November 2005) defines in the EU for some food products the maximum allowable concentration, in some cases absence, of given SFP, e.g., *Listeria monocytogenes*, *Salmonella*, *Escherichia coli*, in certain quantity of the product, e.g., 10 g, 25 g, see Table 1. In this case the dose response model is not required in the QMRA since the probability for the consumer to become ill is not calculated. Starting from the PDF for finding the SFP in certain concentration, the probability for the concentration of the SFP exceeding the limit can be calculated depending on the temperature profile in the SC. One has to take into account, where absence of SFP in

Table 1
Food safety criteria (Commission Regulation (EC) No. 2073/2005 of 15 November 2005).

Food category	Micro-organisms/their toxins, metabolites	Sampling-plan[a]		Limits	Analytical reference method[b]	Stage where the criterion applies
		n	*c*			
Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes[c]	*Listeria monocytogenes*	10	0	Absence in 25 g	EN/ISO 11290-1	Products placed on the market during their shelf-life
Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g[d]	EN/ISO 11290-2[e]	Products placed on the market during their shelf-life
		5	0	Absence in 25 g[f]	EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it
Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes[e,g]	*Listeria monocytogenes*	5	0	100 cfu/g	EN/ISO 11290-2[e]	Products placed on the market during their shelf-life
...	...	...	...	...	...	...

[a] *n* = Number of units comprising the sample; *c* = number of sample units giving values over the limit.
[b] The most recent edition of the standard shall be used.
[c] Regular testing against the criterion is not useful in normal circumstances for the following ready-to-eat foods: – Those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g., products heat treated in their final package). – Fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds. – Bread, biscuits and similar products. – Bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products. – Sugar, honey and confectionery, including cocoa and chocolate products. – Live bivalve molluscs.
[d] This criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.
[e] One milliliter of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.
[f] This criterion applies to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.
[g] Products with pH $\leqslant$ 4.4 or a_w; $\leqslant$0.92, products with pH $\leqslant$ 5.0 and a_w; $\leqslant$ 0.94, products with a shelf-life of less than 5 days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

the product is required, that the testing procedures for certain SFP have detection limits which can be expressed in cfu/g. In this case the probability that the concentration of SFP would be above the detection limit at some point in the supply chain can be calculated. This calculation does not provide the probability that the SFP would be absent, the calculation would show the probability that the SFP is not detected when the analytical reference method is used.

It is postulated here that the steps where the product is exposed to uncontrolled ambient temperature, e.g., loading and unloading of the product, would be the most vulnerable to the changes in the average ambient temperature.

There are certain issues that arise when implementing such a system. One of them is that at certain time *t* the product would not always be in the same location in the SC. This makes the use of the historic data a bit more complicated since the historic data cannot be simply replaced from certain time *t* onward. Apparently the actual location of the product in the SC must be known in order to be able to use the historic data. The other issue is that the temperature at certain location obtained from real time monitoring and from historic data may not match. The above issues can be resolved with careful considerations.

The SLP can be implemented as deterministic or stochastic model while the QMRA should be implemented only as a stochastic model since it will provide a probability for illness upon consumption of the product. The deterministic model uses less number of operations and therefore is faster, however the utility of the stochastic model is higher.

5. Integrating HACCP with QMRA

There are several differences between the HACCP and the QMRA approach. The main differences are given below:

(i) HACCP is qualitative analysis while QMRA is quantitative analysis.
(ii) HACCP deals with a variety of hazards while QMRA considers SFPs only.
(iii) HACCP is operated by people while QMRA module can operate independently of SC (SC) actors by receiving real-time data from sensors and by performing analysis at predefined intervals. QMRA can also launch a warning to predefined set of SC operators, depending on the location of the product in the SC.
(iv) HACCP defines critical control points (CCP) and limits that have to be preserved in order to keep risks of food poisoning within acceptable limits. QMRA can provide almost continuous information, while the product is at any point within the SC, on the risk of illness at the moment of consumption.
(v) The DSS can incorporate the SLP module as well. Though the SLP is not related to the risks to consumers, HACCP procedures may be implemented in order to utilize both, the QMRA as well as the SLP module, with a notion that the SLP results are not utilized by the HACCP.

With the integration of the QMRA and SLP as parts of the DSS with the HACCP it is expected that the following improvements can be achieved:

(i) The risk assessment provided by QMRA upgrades the HACCP decision with quantitative information.
(ii) More accurate and nearly-continuous SC predictions on the risk levels for the consumers and remaining shelf life depending on the monitoring data in the SC.
(iii) Warnings sent to SC operators independent of the HACCP and location of control points in the SC.
(iv) The verification procedures of the HACCP for a pathogen is helped by the QMRA.

(v) Procedures (testing) implemented in HACCP to verify accuracy of the QMRA and SLP.
(vi) The corrective actions for the HACCP can be added to the DSS, therefore reducing possibility for errors.
(vii) Full compatibility of the HACCP–QMRA system with the HACCP procedures required in different countries can be achieved.
(viii) Early detection of change in the SC which require corrective actions by periodical analysis of historic data using the QMRA and SLP models.

The interaction of QMRA and HACCP is seen through several steps which are described below.

5.1. Design of HACCP with the help of QMRA

It is important to analyze the whole SC as made of successive stages (see Fig. 6). What happens in the previous stage affects the quality and safety of the product in the next stage. Traceability is very important for analyzing the propagation of the risk levels through the SC. In order to define the HACCP it is important to define the control points in the SC. This can be done with the help of the QMRA. The historic data will provide the average, minimum and maximum temperatures for various stages and will help define probability distribution for certain temperature in certain stage. Sensitivity analysis can be performed for various steps of the SC and those steps that can have higher impact on the safety and quality of the product can be identified through analysis of the impact of variations of the environmental parameters, e.g., temperature, on the safety and quality of the SC product. Past data is required in order to be able to employ the QMRA and SLP in the SC.

When a SC is designed, the historic data will not be available; however, this should not affect the design of the separate stages in the SC. The required data for stochastic analysis would become available after certain period of time once the system is operational within the SC and the implemented HACCP can then be reviewed with the help of the QMRA.

5.2. Enhancing HACCP decisions in control points by using QMRA

In each control point the results of the QMRA analysis can be used in order to confirm that the safety of the product has not been compromised. The QMRA will provide an estimate of the probability that the consumer becomes ill due to consumption of the product. This estimate will be based on the information from tests for selected SFP, which will be performed in required points in the SC, and the data supplied on environmental parameters (T, pH, NaCl%). If data from tests is not available then historic data can be used, but only after the system has been operational in the SC sufficiently long period of time to generate reliable historic data. The historic data will not give the actual state, but it will give the probability for certain state based on past data, e.g., PDFs for prevalence and bacterial count. The HACCP should be designed in such way that the procedures are specified for the case when the QMRA information is available in certain part of the chain or when it is not available due to problems in communication with the DSS. If the information from the DSS was not available at certain point the decision of the HACCP has to be checked for that point as soon as the QMRA information becomes available.

5.3. Warnings sent to SC operators if the risk level is unacceptable

The DSS will receive constant supply of data from the SC during some stages, though ideally the DSS would receive SC data constantly in all stages of the SCs. The QMRA will periodically estimate the current risk levels to the consumers at the point of consumption of the product. If the risk levels are higher than acceptable a warning is sent to the pre-specified SC actors requesting immediate action. The SC operators can at that point order testing for SFP in order to establish the actual state of the product. Therefore, the QMRA (DSS) will send a warning when the product is not in a control point and an increased risk has been estimated due to information received from sensors.

5.4. Verification of the HACCP helped by the QMRA

The verification procedures of the HACCP for pathogen bacteria will be helped by the QMRA. The QMRA will analyze the safety in the SC and will define whether something needs to be changed. Having the QMRA implemented in the SC provides possibility to monitor the variations in the risk levels to the consumers. The HACCP itself is a qualitative approach and operates by setting limits in control points in the SC. As long as the limits are not exceeded, the HACCP considers that the food in the SC is safe for the consumer. The QMRA on the other hand can detect changes in the risk level even when the limits in the control points are not exceeded and can provide early warning if the conditions in the SC are changing in such way that affects the safety and the shelf life of the product.

5.5. Verification of the QMRA helped by HACCP

Apart from implementing procedures which will make use of the QMRA predictions, the HACCP should also have procedures

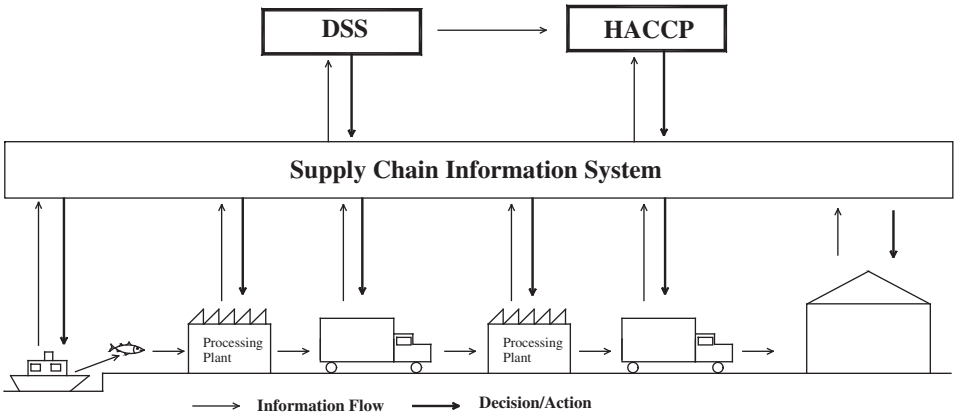

Fig. 6. SC analysis using DSS (QMRA and SLP) – HACCP approach.

which will test the safety of the product, through testing for SFP which should be done in such a way to provide also data for verification of the accuracy of the QMRA predictions. The QMRA can only be tested towards historic data and not towards testing in a single shipment. Testing in a single shipment can suggest either lower or higher probability for infection with SFP than what the real probability would be if each single unit of product is tested.

5.6. Implementation of SLP and HACCP

The SLP can be implemented and used independently of the HACCP in the SC. Since HACCP is concerned with the safety of the product and the SLP with the estimation of remaining shelf life, they are not directly related and one can argue that they should be implemented separately. However, having HACCP integrated with SC, it may be easier to use the implemented HACCP to ensure that the expected shelf life of the product is met by the SC. The limits in the HACCP are defined according to the risk assessment carried out for the SC. If the SLP would require more stringent limits in order to secure the required shelf life, it would not affect the safety of the product if these limits are introduced in the HACCP which would satisfy both, the shelf life as well as the safety requirements. Therefore it makes sense to consider the implementation of the SLP together with the HACCP since the same parameters will affect the safety and the shelf life of the product.

The HACCP–QMRA–SLP system is currently being implemented within the Chill-On FP6 EC funded project. Field trials for testing of the system will be carried out in the second half of 2009 and beginning of 2010 and the results from the trials will follow.

5.7. Aspects of the practical operation of the system

The concept is shown in Fig. 6. The figure shows a simplified fish SC. It can be seen that the data is passed from the SC, preferably in continuous fashion, at selected intervals through the SC information system to the DSS. The frequency with which environmental parameters are passed to the DSS depends on how rapidly these parameters can change. For example, at the beginning of the SC, information on pH and NaCl% would be required. Later in the SC measurements of NaCl% are not required unless food processing takes place, which could change NaCl content. pH would slightly change with time, therefore, if the QMRA model includes pH it would have to be recorded. The temperature is the parameter which can change more rapidly than the other parameters and is also more important than the other parameters so it would be recorded with higher frequency.

Though HACCP should be implemented in the whole SC, normally different SC operators implement the HACCP at CCPs which are located in their part of the SC. SC operators implementing HACCP will be able to receive the data from the SC directly at the point where they are and from the DSS for the whole SC. They will receive the results of analysis performed by the QMRA and will follow the procedures to protect the consumers' health. Among the actions that might be taken we mention here: removal of the product from the supply chain, keeping the product in the supply chain while acknowledging shorter shelf life, or, for uncooked meat products, redirection to a processing plant, e.g., for production of pet food. The classical HACCP works with critical limits, but in this case there are also results of analysis which show in more accurate way the probability for certain risk level to the consumer at time of purchase/consumption of the product. The critical limits may not be sufficiently clear indicators of the safety of the product in certain point in the SC if the previous temperature in the SC up to that point is not analyzed. Therefore it may happen that the DSS shows that the risk is increased, based on the available data up to that point in the SC though the HACCP shows that everything is normal since the limit/s has/ve not been exceeded at the CP, and vice versa. The DSS may conclude that despite slight temperature abuse in certain part of the SC the product is still safe for consumption, though the HACCP will consider the product unsafe since the critical limits have been exceeded. Such conflicts would require further attention in order to be resolved. This would most likely involve more extensive testing than the routinely performed one in order to determine whether the product is safe. The data obtained may be used to adapt the HACCP which will resolve such conflicts in the future. Though it seems as if such system would introduce conflicting situations, such system would be more reliable than a system which is based on a single approach, HACCP or QMRA. Since HACCP and QMRA are based on different principles, qualitative and quantitative, respectively, the probability that both systems fail (give wrong estimate) at same instance is minimal.

6. Adaptation of food SCs to climate change

As the average temperature in the food SC changes this affects the temperature of the product in the SC. This is especially true for the periods when the product is exposed to uncontrolled environment where higher temperature abuse can occur.

The QMRA and the SLP are estimating the Risk Level (RL) and the remaining Shelf Life (SL) for the product and this enables one to analyse the trends in RL and SL in order to establish whether there are significant changes in these two SC parameters. Such changes in RL and SL due to change in average temperature in the SC could be periodical/seasonal or they could be long term changes related to global warming/climatic change. The advantage of applying such an approach to estimating RL and SL in SCs stems from the fact that HACCP and the SC operators cannot quantify the impact of the slight changes in temperature in the product on the RL to consumers and SL of the product. Since the HACCP requires continuous/periodic verification, QMRA can provide a very efficient tool for this task. Instead of looking just at environmental parameters, e.g., temperature, in the SC the QMRA can provide estimates of changes in RL due to change in the temperature profile of the SC. How this would be implemented is not discussed here, however, statistical methods should be employed in analysis of RL and SL over a period of time in order to establish whether a significant change in the SC has occurred which requires attention.

Similarly to HACCP, the QMRA and SLP implementations require that both are continuously validated in terms of accuracy of their predictions. This can be carried out by testing the product in the SC for SFP and SSO and comparing the predictions of the QMRA and the SLP models, respectively, with the actual state. The QMRA can be validated in respect to the probability for presence of SFP in the product and PDF for concentrations of SFP at the end of the supply chain. The SLP can be validated in respect to the predicted remaining shelf life. The validation should be carried out over a period of time sufficiently long to apply statistical methods in order to establish whether good agreement exists between model predictions and the actual state in the SC.

It is possible to design the QMRA and SLP in such a way that the models utilize the data from testing in the SC and automatically correct the QMRA and SLP predictions. Such corrections cannot be done on the basis of one disagreement with microbial tests; the corrections would have to be performed using data collected over a long period of time where the system would utilize all the data in that period and adjust the model's parameters in order to achieve higher agreement. The initial implementation of the QMRA and SLP would be based on laboratory microbial growth experiments, however, after certain period of time when there is enough amount of SC data, calibration of the models could be carried out which would bring the predictions closer to the actual SC state.

Such implementation of the QMRA and SLP would be able to adapt its accuracy despite the changes in average temperatures in the SC due to global warming. It is very probable that the secondary models of the QMRA and SLP would be prepared for temperature range which would include the average temperature shift due to climatic change. Yet the models may not provide satisfactory accuracy due to variations induced by climatic change influencing the chemistry and microflora which further may affect the microbial growth, making the prepared models less adequate. The climatic change may also change the initial microbial load of the product which may affect both, the RL and SL of the product.

In order for such a system to be operational the HACCP in the SC must be adapted in addition to the QMRA and SLP tools. The HACCP should include such procedures that would help the verification and adaptation of the QMRA and SLP to any changes in the SC. On the other hand the QMRA and SLP would help adapt the implemented HACCP to the SC variations. In other words, the HACCP and QMRA, and the SLP where implemented, would be considered as a single system which would secure the required quality and safety of the product.

The HACCP can be periodically verified using the QMRA. The QMRA can provide estimate when the risk to consumer due to consumption of the product has reached unacceptable levels and can trigger review of the HACCP procedures in order to bring the risk to an acceptable level. The QMRA can include statistical analysis which would report a trend of increase in levels of risk, though the critical limits in the control points have not been exceeded. This would allow time for corrective actions before the HACCP and the SC safety are compromised. During the redesign of the HACCP the QMRA can be used to define the necessary changes in order to achieve the risk reduction. Processes and procedures in the SC can be reviewed and adapted in this way in order to reduce the risk to consumers and increase the SL.

The HACCP would have to be adapted in a way to include tests which would collect sufficient data for calibration of the models. It should also include checks for predictions given by the QMRA and can also be used as a platform that would include steps for use of the SLP. Though the SLP is not part of the HACCP it makes sense to use the HACCP in order to implement the SLP in an efficient way without adding a separate system to the SC.

7. Conclusions

A new system is discussed which would utilize a HACCP–QMRA–SLP approach to secure safety and quality of food products. Various aspects of the implementation are discussed together with the benefits of such system for increasing the safety and quality of food products in SCs. A possibility to use the system for reduction of impact of climate change and seasonal temperature variations on product quality and safety are discussed. It is expected that the system will be able to provide early warning for changes in risk levels to consumers as well as shelf life of the product in the SC due to climatic change and possibly due to seasonal temperature variations.

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