Risk analysis; Theory and reality

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Introduction.

At the GATT Uruguay Round of 1994, where the World Trade Organisation (WTO) was established [14], a free trade of safe food was agreed. It was decided that safety should be based on sound science. Risk analysis is prescribed as the method to be used to ensure that the requirements of sound science are met. To avoid that all food producers for each of their products should carry out a risk analysis the WTO also agrees with the use of internationally accepted criteria as alternative. However, the criteria set should be based on the use of risk analysis as well [4, 7, 11]. It may be expected that the interest in the use of internationally accepted criteria will increase. They will be the basis for safe food production [1]. HACCP is pre-eminently the managerial tool to meet the criteria set. Also the European Commission has embodied risk analysis in the Hygiene Directive 93/43/EEC.

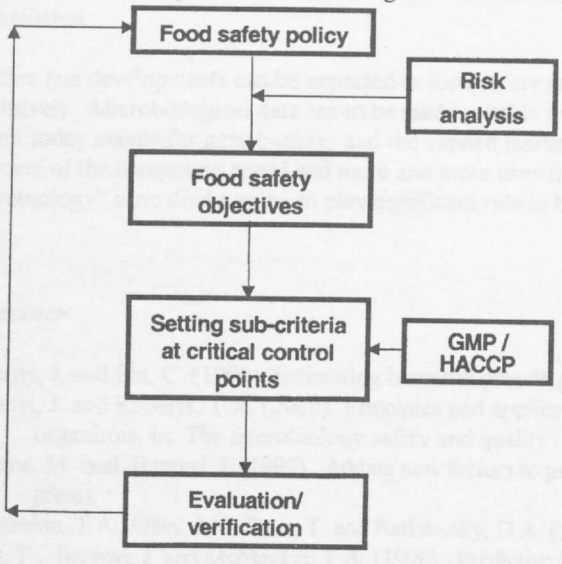

Figure 1 Food Safety Policy and Objectives and RA

Figure 1 presents how criteria (or food safety objectives) are established for contaminants and additives, for which increasing consensus exist. In addition it is demonstrated how Good Manufacturing Practice and HACCP are the instruments in the food production area to meet the criteria established.

If internationally established quantitative criteria are the basis for safe food production the traditional, largely qualitative HACCP system can easily be transformed into a fully quantitative one [12]. This is possible if critical control points (CCPs) will be defined as operations (practices, procedures, processes, etc.) at which control should be exercised to achieve the criteria established. There are various means for controlling potentially hazardous bacteria [10]. They include among others heating, irradiation, drying, acidification, storage conditions, etc. In some cases stabilization of numbers of micro-organisms, i.e. prevention of growth, may be sufficient, for example, for toxin producing organisms such as *Staphylococcus aureus*, which is not hazardous in low numbers. If such CCPs are not present in a food production operation they should be introduced. The absence of potentially hazardous agents (chemicals, additives, etc.) and organisms from raw materials would be an advantage. However, low numbers of pathogenic organisms are generally present in most raw food materials, especially those of animal origin.

Product formulation is a key factor in reducing bacterial hazards. Curing, drying. acidification, etc. not only stabilize bacterial populations, but can also effect some reduction in the numbers of any pathogens present.

To meet the established end product criteria by the above-indicated practices, procedures, process formulations, etc. at each of the CCPs criteria should be established. Meeting these criteria should guarantee that the final criteria are met. This means that at the CCPs indeed a quantitative control can be exercised.

Due to the increasing knowledge of microbial behavior in food, it becomes increasingly possible to determine quantitatively the effects of control measures. Thus, a more quantitative approach to HACCP is no longer merely hypothetical. In a quantitative HACCP approach, emphasis is placed on well-developed GMP and on CCPs that allow quantitative control of hazards. A quantitative HACCP minimizes the number of CCPs, which helps the system to stay 'user friendly' and avoids the serous pitfall of being to cumbersome to function effectively.

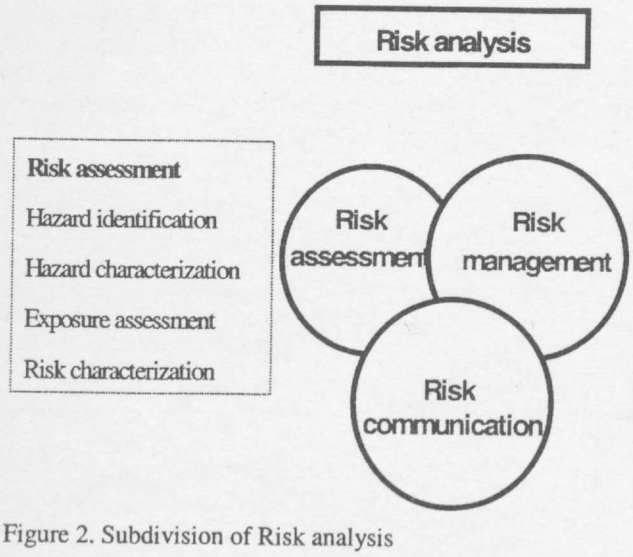

Figure 2. Subdivision of Risk analysis

Principles of quantitative risk analysis

Figure 2 illustrates the risk analysis process as recommended by FAO/WHO expert consultations [5] and subsequently adopted by the Codex Alimentarius Commission [2]. The figure shows the arrangement of the various risk assessment steps and their relation with risk management. In the FAO/WHO model the risk analysis process is subdivided into three components: (i) risk assessment, (ii) risk management and (iii) risk communication.

Risk assessment. Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to additives, contaminants, pathogenic micro

-organisms, etc.. The purpose of risk assessment is documentation and analysis of scientific evidence to measure risk and to identify factors that influence it for use by risk managers. The outcome is called risk estimate. The process of risk assessment consists of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment and (iv) risk characterisation.

The goal of hazard identification is to identify potential adverse health effects in humans associated with exposure to additives, contaminants, pathogenic micro-organisms, etc. It is a qualitative approach.

An identification procedure of microbiological hazards present in food may be based on producing a list (based among others on literature data) of pathogenic micro-organisms able to cause foodborne disease. After producing such a list, it is determined whether or not the organisms are likely to be present in the raw materials used and/or may enter the food processing area. Only those organisms that have never been found can be deleted. Of the remaining organisms, it must be established whether or not they are completely destroyed during processing. If so, they too can be removed from the list. Following, recontamination should be considered. A next step is to consider whether or not the listed organisms have ever caused a foodborne disease involving either an identical or related food product. Where this is not the case, the organism can be deleted.

Hazard characterisation is 'the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food'. Where practicable, dose-response relationships should be assessed for all adverse effects produced by the substances evaluated. This implies that dose-response relationships should be estimated for effects such as changes in organ function (in case of additives and contaminants) clinical symptoms, etc. For additives and contaminants, epidemiological data are of value when verifying the dose-response assessments obtained in experimental animals. For pathogenic micro-organisms such data may also be used to derive dose-response curves directly applicable to humans. There are numbers of uncertainties in the hazard characterisation, and introduction of an uncertainty factor has to be considered. In case of pathogenic micro-organisms hazard characterisation also involves the evaluation of the characteristics of the organism in relation to the product, processing conditions, storage conditions, etc. This information is necessary to estimate for example the outgrowth of the organism in the food product of interest.

Exposure assessment is the qualitative and/or quantitative estimation of the likely intake of biological, chemical and physical agents via food. The ultimate goal of exposure assessment is to estimate the level of hazardous agents in food at time of consumption. It requires specific expertise and concerns information on food consumption (e.g. from intake surveys) and the concentration and distribution of the hazardous agent in a food. For foodborne microbiological hazards the concentration of organisms may be based on product surveillance, storage testing experiments in addition with enquiring storage conditions of the product and use of mathematical models that predicts the growth and death of organisms [9, 8].

There are many sources of uncertainty in exposure assessment relating to both under- and over-estimates. These uncertainties should be reflected in the risk characterisation. Whilst it is seldom possible to provide fully quantitative assessments of uncertainties, information on whether a negative or possible bias has been introduced should be provided.

Risk characterisation is the quantitative and/or qualitative estimation, including attendant uncertainties about the probabilities of occurrence and severity of known or potential adverse health effects in a given population. It is the last step in a risk assessment from which the risk management strategy can be formulated. Although the Codex Alimentarius document does not suggest that identification and quantification of the factors contributing to the risk is a part of risk characterisation, it is logical to include it. There are several possible means of gaining information about factors that contribute to risk and their impact. One possibility is to carry an out case-control study in which unacceptable products are compared with acceptable ones.

Risk management. Risk management is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. The purpose of risk management is to identify acceptable risk levels and to develop and implement control options within the framework of public health policy. For this they need to be informed about factors contributing to the risk and their quantitative effect. A cost-benefit analysis of options would also support risk management.

The outcome of the risk management is the food safety objectives. Food safety objectives may be for example banning or declining the use of additives, setting maximum levels for contaminants and pathogenic micro-organisms, the obligatory use of Good Manufacturing Practices (GMP) and control options at the national level (e.g. curtailment of a production area or facility). In setting food safety objectives such as maximum levels risk managers should include the difficulty of control, the feasibility of monitoring, including the availability of suitable methods of analysis and the economic importance of the food.

Risk communication. Risk communication is defined as the interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties. Communication starts with providing information about the food safety policy to all parties involved in the risk analytical process. This policy is the basis for the purpose and scope of both the risk assessment and risk management activities. Risk assessors and risk managers should include clear, interactive communication with each other and with consumers and other interested parties in al aspects of the process.

General principles for the uses of risk assessment

To carry out an adequate risk assessment a number of general principles are of interest. These principles comprises:

a) Risk assessment for (microbial hazards) must be soundly based on science. All available data relevant to the risk assessment should be considered. These data are likely to come from different sources. Where scientific data are limited, otherwise incomplete or conflicting, informed judgements might be made on the basis of the best information available.

b) There must be a functional separation between risk assessment and risk management. The aims of risk assessment and risk management are different and they should not be mixed up. However, certain interactive elements are essential for a systematic

risk analysis process. Where, risk management issues may affect the decision-making process used in risk assessment, the implications of this must be made clear in the final report.

c) A structured approach must be used when conducting a risk assessment of hazards. The structured approach must include the four risk assessment components: hazard identification. Hazard characterization, exposure assessment (especially for microbial contamination the key factors contributing to the exposure) and risk characterisation. The sequence of use may vary depending on the purpose of the risk assessment.

d) A risk assessment must clearly state both the purpose of the assessment and the format of the risk estimate that will be the output. In case of *S.enteritidis* and eggs the purpose may be to identify the factors contributing to the risk and their impact. It provides the risk manager with options to control the risk adequately.

e) Risk assessment must be transparent. This requires that the assessment is documented in full and that a complete record is made of the assessment. Any assumption or judgement made during the assessment, and which may have affected the outcome of the estimate, should also be described. The formal record should be made available on request.

f) The risk estimate must contain a detailed description of uncertainty and where this arose during the risk assessment process. Uncertainty informs about the limitations of the risk assessment. Such limitations should be recorded in the report.

g) Data must be of sufficient quality and precision such that the uncertainty in the risk estimate is minimised as far as possible. It is important that the best information and expertise is used.

h) Risk estimates, where possible, must be re-evaluated over time when new data become available.

The use of quantitative risk analysis to set food safety objectives

The first activity in producing safe food is establishing a food safety policy. A food safety policy should present a general outline what is acceptable or not acceptable. Using quantitative risk analysis the food safety policy is substantiated into food safety objectives. The objectives may include banning the use of an additive, maximum permitted levels, approving the use of GMP, etc. etc. Food producers have to adhere to the food safety objectives (see figure 1).

Additives and contaminants. There is increasing consensus that the food safety policy is an international activity. FAO and WHO are the international bodies, which have the task to set this policy. They have delegated this task to the FAO/WHO Codex Alimentarius Commission (CAC) which was established in 1962 as an intergovernmental organisation for developing standards, guidelines or other recommendations for food in order to protect the health of consumers and facilitate international trade. The risk assessment for additives and contaminants is carried out by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The outcome of the risk assessment, the risk characterisation, is the starting point for the Codex Alimentarius Committee on Food Additives and Contaminants (CCFAC). This Committee in which all Member Sates are represented carry out the risk management part of the risk analysis. They do the standard setting which have to be adopted by the CAC (figure 3).

Risk assessment is a well-established activity for additives and contaminants. Momentarily, for evaluating disease characteristics of additives and contaminants with the potential to cause an adverse health effect dose-response relationships are determined. From the dose-response relationship the so-called no observed effect levels are estimated. The experiments are carried out with animals and are based on a data package. The estimated no observed effect level is used as the basis of the acceptable daily intake for additives and/or provisional tolerable daily/weekly intake for contaminants through the application of uncertainty factors.

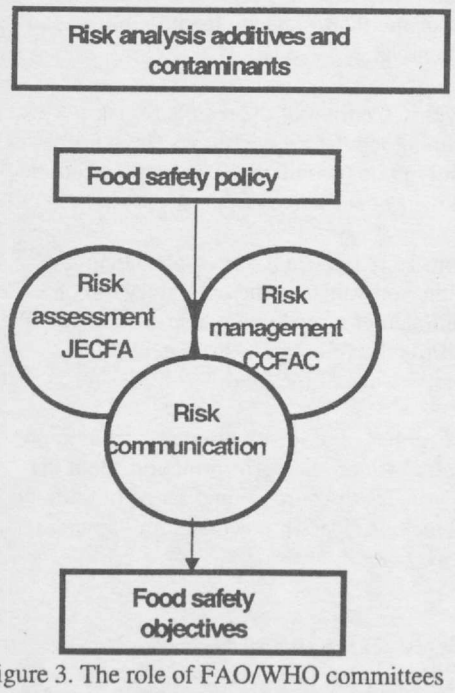

Figure 3. The role of FAO/WHO committees in translating FSP in FSO

Micro-organisms. Although risk analysis for additives and contaminants has been used for some decades in setting standards, risk analysis for foodborne pathogens is a newly emerging discipline. Criteria, guidelines, etc. are set by the Committee for Food Hygiene (CCFH). The establishing of criteria, guidelines, etc. for pathogenic organisms are almost based on analytical results obtained from examinations of foodborne disease outbreaks. At this moment the CCFH lacks the assistance of a JECFA like body to carry out risk assessment studies for foodborne pathogens.

The use of quantitative risk analysis in the food production area

As indicated in figure 1 principles of quantitative risk analysis can also be used at the food production area. Starting point in safe food production are the (international) established legal food safety objectives and additional safety objectives set by the food Production Company itself. To adhere to these objectives food producers made use of the general rules such as GMP. In addition the use of HACCP is mandatory in most countries. HACCP is a systematic approach to the identification, assessment and control of hazards in a particular food operation. It aims to identify problems before they occur, and establishes measures for their control at stages in production that are critical to ensure the safety of the food. Control is proactive since remedial action is taken in advance of problems developing. This managerial activity should guarantee that the objectives set are indeed fulfilled. For this in HACCP so-called critical control points are identified. These points are defined as steps, points,

At these points criteria are specified, so that if they are met, the final food produced is safe. To transform the traditional, largely qualitative HACCP system into a quantitative one, use can be made of elements of quantitative risk analysis as is demonstrated in figure 1. An important starting point is that in HACCP a hazard is defined accordingly to the definition used in risk analysis: An agent with the potential to cause an adverse health effect.

Examples from practice

Three examples, which have recently been worked out or are being worked at our Institute, are given.

Legal standard for pasteurized milk

One of the legal standards for pasteurized milk is that the numbers of *Bacillus cereus* is $< 10^4$ organisms per ml at time of consumption. The factors, which determine the *B.cereus* count in milk at time of consumption, are the spore load of *B.cereus* after pasteurization, the storage time and temperature. The effect of each factor can be calculated as well as what the costs are to control each factor. It is clear that for a final managerial decision the wishes of the consumer (especially storage conditions) should be taken into consideration [11].

Escherichia coli 0157:H7 in Dutch dry and fermented sausages

The background of this RA was the question what the risk was of infecting the consumer with *E. coli* 0157:H7 by the production of dry, fermented sausages in which beef was used as a raw material.
Firstly the possibilities of survival of *E. coli* 0157:H7 in three types of sausages was studied [6]; one with a relative low wateractivity (a_w) and an relative high pH, one with a relative high wateractivity and a relative low pH and one where both the wateractivity and the pH were relative high. The products were contaminated with approx. 10^5 CFU/gr of *E. coli* 0157:H7. During production (drying) the contamination was reduced with approx. 2 log units. During stockholding a further reduction tok place. After storage of 6 weeks *E. coli* 0157:H7 was still detectable (after enrichment) in all products. After storage of 11 weeks at 25 °C no pathogen could be found. However, after storage at 7 °C the pathogen was still detectable. Besides the presence of the pathogens, the possibility to produce verotoxines was studied. It was shown that if the bacteria were present they also were able to produce the verotoxines.
The following risk factors for *E. coli* 0157:H7 in the 3 types of sausages were identified [3]:
Introduction of *E. coli* 0157:H7 in beef

- frequency of occurrence and numbers of *E. coli* 0157:H7 in faeces
- faecal contamination during slaughter
- cross-contamination
- trimmings originating from the carcass surface

Reduction

- dilution, depending on (mass)percentage of beef in sausage
- reduction as a consequence of ripening and drying
- reduction during storage
- storage time and temperature

Exposure

For all the risk factors data were gathered. The distribution of probability is depending on the number of data available If no or little data were available assumptions were made, based on expert opinions considering the Dutch situation. If no or little data are available the uncertainty of the probability distribution is based on the expected minimum and maximum values set. All risk factors with their accompanying probability distribution were put into a model, which used Monte Carlo simulations and Latin Hypercube sampling.

Table 1 Risk of disease by consuming 50 grams of the different products

	Sausage with relative low a_w and relative high pH	Sausage with relative high a_w and relative low pH	Sausage with relative high a_w and relative high pH
Average possibility of being taken ill	1 in approx. 76,000	1 in approx. 3500	1 in approx. 25,000
Probability that the consumer will **not** be taken ill	99.94 %	99.16 %	99.93

Use of non potable water in slaughterhouses

In the EU a new Council Directive (98/83EU) has been published concerning the quality of water for human consumption. Article 2 states that in food production plants water must be used which is fit for human consumption. An exception is made if the national authority is convinced that the quality will not harm the safety of the end-product.

Based on this new opportunity a study was made of the (re-)use of water in pig slaughterhouses. Distinctions could be made in the use of water, for instance water which will not come in to contact with the end product (typically cleaning water), water which might get into contact (water for CIP purposes) and water which will come into contact (showers, scalding tank etc). Another distinction that could be made was based on where in the process water was used. Combining the purpose and moment of application in combination with the amount used it was concluded that the scalding tank was the crucial factor. The hypothesis being that water of a different quality could be used in the process up to and including scalding [13].

Three types of hazards are normally associated with risk analysis, i.e. physical, chemical and microbiological hazards. The physical hazards associated with the use of water were conceived to be non existent.
Chemical hazards were potentially present. By constraining the source of water to water from the water treatment installation of the slaughterhouse chemical hazards were considered to be absent. A possible exception might be formed by catastrophes and/or malicious actions. This was concluded from the fact that sediment of water treatment installations contain no toxic minerals in dangerous concentrations. The sediment, however, was relatively (in terms of environmental impact) high in copper, due to copper which originates from faeces. Another argument is that if toxic compounds are present the biological water treatment will not function properly. A last argument for not considering chemical hazards is that if chemicals from the water will get in to contact with the product, the concentration will be significantly lowered if calculated per kg of end product (meat).

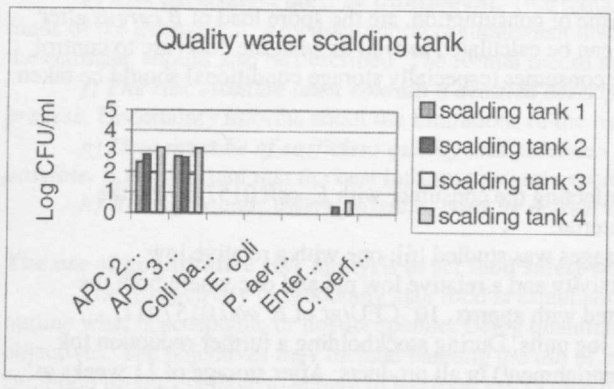

Figure 4 Microbiological quality of water in scalding tank

This leaves the microbiological hazards like parasites, viruses and bacteria. Parasitic infection of humans transferred from water used in the slaughtering process through meat to humans was believed to be absent. (Water treatment was expected to be of process water devoid of water of human activities (sanitary etc.)) Of the viruses it was known that they can be transferred by water. The only water transferable virus, which can be harmful for humans, is the Rota virus which can be present in cattle. As this was a study of a pig slaughterhouse Rota virus was expected not to be present. This leaves bacteria as remaining hazard.

The Council directive describes the bacteria, which should be monitored in case of water for human consumption. These are:

- CFU at 22 °C and 37 °C.
- Coli bacteria and *E. coli* .
- Enterococci .
- *Pseudomonas aeruginosa.*
- *Clostridium perfingrens.*

As the scalding tank has a temperature of approx. 60 °C reuse of water might lead to a shift to thermotolerant bacteria. However within this group of bacteria no pathogenic bacteria are present. Development of *Clostridium*-spp is not to be expected in this situation because they grow anaerobically and the environment is typical aerobic.

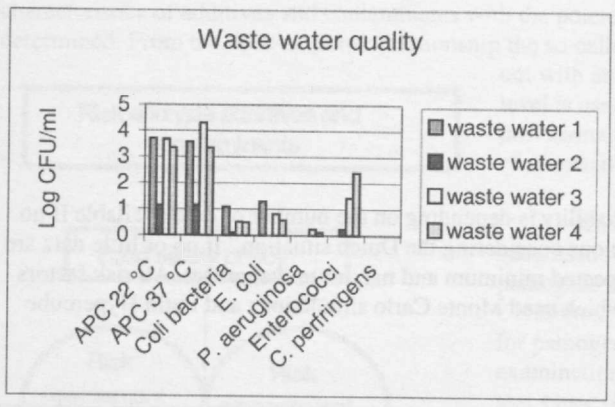

Figure 5 Microbiological quality of waste water

In order to assess the risk involved in using water from a waste treatment installation in the scalding tank, samples were taken from waste treatment units and from scalding tanks of 4 pig slaughterhouses. The results show (figure 4 and 5) that CFU of water from a wastewater treatment unit are slightly (0.5 to 1 log unit) higher, than the CFU of water from a scalding tank. The other microbiological parameters were occasionally detectable in water from the waste water treatment but hardly ever in water from the scalding tank. This latter can be attributed to the temperature in the tank.
Based on the figures on the quality of water from the waste water treatment one might say that this water could be used as processing water in the scalding tank.
To demonstrate this a calculation, with a great number of assumptions, was made of the difference in bacterial load using potable water vs. water from the waste water treatment.

To calculate the theoretical bacterial load of water in the scalding tank the following assumptions were made:
CFU count on the pig skin before the scalding tank 6 log/cm^2, after the scalding tank 4 log/cm^2. Pig surface is 1 m^2.
Theoretically this means that 10 log CFU per pig are transferred to scalding tank. 500 pigs per hour in a scalding tank of 80 m^3 leads in time to a bacterial load as depicted in figure 6 (dotted curved line). However results from literature (straight dotted line) and own observations (cubicles and dots) it appears that the bacterial load will be ultimately approx. 3 log units. This difference can be explained by the killing effect of the temperature of approx. 60 °C of the water in the tank.

Enterobacteriaceae have a decimal reduction time at 60 °C of approx. 1-2 minutes. Psychotrophic micro-organisms (a.o. *Pseudomonas* spp.) have a D_{60} of approx. 0.5 minutes. This means that with a scalding time of 7-12 minutes hardly any of these micro-organisms will survive. This is supported by the results of the microbiological analysis of the scalding water in the 4 different slaughterhouses.

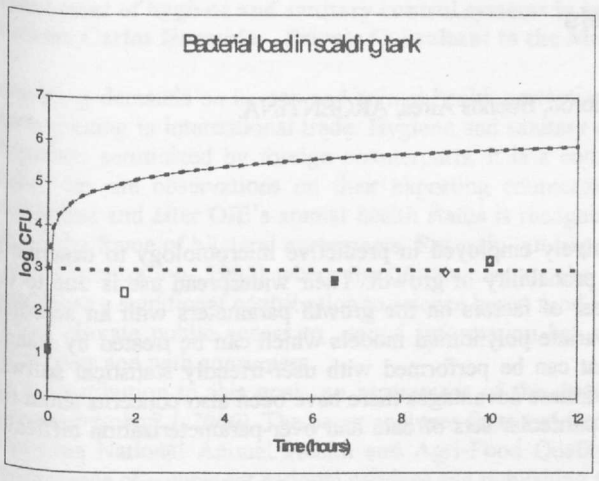

Figure 6 Scalding water quality, theoretical data and data from practice

If at the beginning of the day water from the waste water treatment is used to fill the scalding tank, one might conclude that this will not add to the microbiological load on the end product. One could argue that this is not the case for the first couple of pigs. (theoretically under the assumptions taken above this will be true for the first 50 pigs). However one has to take into consideration that the temperature of water in the scalding tank has to be 60 °C before slaughtering procedures are started. This means that the temperature will be elevated in scalding water some time before the first pig enters the tank.

In this type of pig slaughterhouse (no drum skinning) all pigs will get into contact with scalding water. It can be argued that water in the process before the scalding tank might also be of a different quality than drinking water. This is for instance true for the use of water in the lairage and for cleaning purposes of transport trucks. In order to reduce the microbiological load of process water additional treatments like chlorination or UV treatment might be considered. The scenario of use of process water in the process up and including the scalding tank might however be re-evaluated when slaughtering of salmonella free animals is considered.

Conclusions

In theory Quantitative Risk Analysis (QRA) based on sound scientific data is the preferred solution. However, as shown in the examples, QRA in practice is cumbersome, time consuming and still deals with a lot of uncertainties. In general the narrower the subject of QRA is defined, the bigger the possibility of getting the relevant data with the accompanying variability.

The first example dealt with 3 variables, which could relatively easy be determined. In the second one, we had to deal with only one pathogen but with approx. 10 variables influencing this pathogen in the products. Several assumptions had to be made. The last example had to deal with the 3 classical hazards. In this example a reduction to only one category, pathogens, was used. In this reduction a lot of assumptions were involved. Also the theoretical calculations were based on assumptions, which in themselves were not far beside the truth, but certainly are open for debate.

It is obvious that HACCP is a powerful instrument in containing the risks involved in meat production. It is also obvious that small and middle large enterprises lack the resources to do QRA on the complex risks that they are facing at this moment and will be facing in the future. Qualitative Risk Analysis, sometimes referred to as "gut feeling" , will for the foreseeable future be the main method of risk analysis in practice. Implementation of a HACCP system, even though based on "gut feeling" , will at least trigger awareness of food safety with producers of meat and meat products.

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