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Incorporation of elements of quantitative risk analysis in the HACCP system

S. Notermans[a,*], G.C. Mead[b]

[a]*National Institute of Public Health and the Environment, P.O. Box 1, 3720 BA Bilthoven, The Netherlands*

[b]*The Royal Veterinary College, University of London, Boltons Park, Hawkshead Road, Potters Bar, Hertfordshire EN6 INB, UK*

Abstract

Foodborne bacterial diseases cause considerable morbidity and mortality throughout the world. Preventive measures such as good manufacturing practices (GMP), supplemented by the hazard analysis critical control point (HACCP) system, have been introduced as a means of ensuring the production of safe food. However, their use does not necessarily provide quantitative information on the risks associated with the consumption of a particular food product. To obtain such information, elements of quantitative risk analysis (QRA) need to be used. QRA is defined as a stepwise analysis of the health risks associated with a specific type of food product, resulting in an estimation of the probability of occurrence of adverse effects on health following consumption of the food in question. It also includes an analysis of the nature of the risks. Taking this definition, five successive steps can be recognized: hazard identification, exposure assessment, dose response assessment, risk characterization and risk management. Food production is a dynamic activity, involving changes in, e.g. the composition and microbial quality of raw materials due to seasonal variation. Also, there may be continuing changes in processing conditions and in product composition due to consumer demands. Therefore, it will be desirable to incorporate QRA in existing safety assurance systems, such as HACCP, when sufficient information is available to permit this approach.

Keywords: Safe food; Quantitative risk analysis; GMP; HACCP

* Corresponding author.

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1. Introduction

The occurrence of foodborne disease is one of the most widespread problems in the contemporary world. Sentinel and population studies carried out in The Netherlands have revealed that some 300 cases of acute gastro-enteritis per 1000 individuals occur each year (Notermans and Hoogenboom-Verdegaal, 1992; Notermans and Van de Giessen, 1993). At least 40–50% of cases are caused by organisms such as *Campylobacter*, *Salmonella* and *Clostridium perfringens* that are usually transmitted by food or water. Results of the WHO surveillance programme (WHO, 1992) indicate that the number of causative agents of foodborne disease continues to increase. For example, toxigenic *Escherichia coli* of serotype O157:H7 and *Listeria monocytogenes* may be classified among the 'newer' pathogens (MacDonalds et al., 1988; Gellin and Broome, 1989), while *S. enteritidis* has been recognized as a foodborne pathogen for many years, but has only recently given rise to a dramatic increase in illness (Madden, 1990).

In order to reduce foodborne disorders, various control measures have been established over the years. Traditional surveillance of end-products may be inadequate for detecting unsafe batches. To improve the situation, good manufacturing practices (GMP) have been introduced, although GMP merely reflect general guidelines instead of providing an objective approach to risk assessment. For this reason, the concept has been extended by introducing the hazard analysis critical control point (HACCP) system. With HACCP, control procedures are directed at specific operations that are crucial to food safety and the effects of which on product contamination can be quantified. Control is proactive since remedial action is taken in advance. The principles of HACCP have been described by the Codex Alimentarius Commission (Codex, 1991). A very important part of the system is the specification of control criteria, which are limits for characteristics of a physical, chemical or biological nature and must be used to ensure that an operation is under control at a particular critical control point (CCP). An operation is only under control when the hazard is eliminated or reduced to acceptable levels. However, the HACCP system is still being applied in a largely qualitative manner. For proper risk management, a more quantitative determination of the hazards associated with food consumption is necessary. In order to obtain such information, elements of quantitative risk analysis needs to be incorporated into HACCP.

In this paper quantitative risk analysis will be discussed and its introduction into HACCP considered.

2. Quantitative risk analysis

Quantitative risk analysis (QRA) can be defined as a stepwise analysis of hazards that may be associated with a particular type of food product, permitting an estimation of the probability of occurrence of adverse effects on health from consuming the product in question. It also includes a characterization of unacceptable risks. Starting from this definition, the first step to be taken is to identify the

potential hazards. Thus, hazard identification is the first component of QRA. The next step is to estimate quantitatively the negative consequences of the hazards. To gain information on this point, it will be necessary to know the consumer exposure rate to each hazard via the food product under examination. This component is referred to as exposure assessment. After the likely exposure to a potential hazard has been determined, it must be related to the negative consequences of consuming the product. Quantitative information on the adverse health effects of exposure can be obtained from the dose response assessment. It is always important to remember that QRA aims to provide quantitative information on the likely occurrence of a specific hazard at the level of the entire population (or a certain sector of the population). It does not aim to predict the risk to any single individual. The necessary information will follow from the dose response assessment. However, a particular risk may be unacceptable and, to decide whether this is so, the risk in question needs to be characterized in detail. A key aspect is to estimate the severity of the hazard (on the basis of morbidity and mortality data). Risk characterization is, therefore, an additional component of QRA, when applied to safe food production. The final step in QRA concerns risk management, which includes all activities that are undertaken to render a hazardous product acceptable.

2.1. Hazard identification

Hazard identification gives a qualitative indication of the potential microbial hazards arising from the consumption of a particular food product. Information on potentially hazardous bacteria can be obtained from, e.g. surveys of the microbial composition of raw materials and from epidemiological surveillance of foodborne infections and intoxications (Richmond, 1990/1992; WHO, 1992). Bacteria causing foodborne diseases of known aetiology are presented in Table 1a. These data are compiled from surveillance programmes in The Netherlands, Canada and WHO-Europe. However, bacteria listed in Table 1a represent only the predominant organisms that have been reported officially to the authorities. A survey of the literature, as carried out by Notermans et al., 1994a, reveals some 25 other organisms which have caused foodborne disorders in the past (Table 1b).

Recently, a simple procedure for the identification of potentially hazardous organisms has been elaborated (Notermans et al., 1994a). A flow sheet of the proposed approach is presented in Fig. 1. The first step in this approach is to make a list of all bacteria that are known to cause foodborne disease. After producing such a list, it is necessary to determine whether or not the organisms are likely to be present in the raw materials used for the product in question. 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. During processing, and even afterwards, re-contamination may occur. If such contamination could involve any pathogenic bacteria, then these organisms must be included in the list. The next point is 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 from the list. The organisms remaining on the list are now separated into two groups: those that are infectious and those capable of forming toxins which cause illness when ingested. All infectious bacteria present are regarded as potentially hazardous. For toxinogenic bacteria, growth must occur before any toxin is produced, so it must be established whether or not growth in the food is possible. If not, the organism is removed from the list. If, however, growth can occur, the organism must be regarded as potentially hazardous. This system can easily be converted into a computer-assisted expert system. However, it must be recognised that our knowledge of foodborne pathogens is still incomplete. In most foodborne illnesses the type of food involved is not identified and, in many cases of illness, no food poisoning organisms are isolated from the sufferer. As a consequence not all foodborne pathogens have been identified. Thus, in the course of time, 'new' organisms will be identified as causative agents. Recent examples are the recognition of *S. enteritidis* and *Arcobacter* spp. as foodborne infectious organisms (Madden, 1990; Stampi et al., 1992). Therefore, the proposed system must be continuously updated. All new findings resulting from the analysis of foodborne disease should be incorporated into the identification system.

Table 1
Bacteria as causative agents of foodborne diseases of known etiology and reported in The Netherlands (Notermans and Van de Giessen, 1993), Canada (Todd, 1991) and WHO Surveillance Programme in Europe (WHO, 1992)

(a) Bacteria of known etiology	
Bacillus cereus	*Klebsiella spp.*
Bacillus subtilis	*Proteus penneri*
Brucella spp.	*Salmonella spp.*
Campylobacter spp.	*Shigella spp.*
Clostridium botulinum	*Staphylococcus aureus*
Clostridium perfringens	*Streptococcus spp.*
Enterobacter cloacae	*Vibrio parahaemoliticus*
Escherichia coli	*Yersinia enterocolitica*
Francisella tularensis	

(b) Other bacteria reported as agents of foodborne diseases (Notermans et al., 1994a)	
Acetobacter melanogenus	*Listeria monocytogenes*
Aeromonas spp.	*Mycobacterium spp.*
Bacillus anthracis	*Pasteurella multocida*
Bacillus brevis	*Plesiomonas shigelloides*
Bacillus licheniformis	*Proteus spp.*
Citrobacter spp.	*Providencia spp*
Clostridium bifermentans	*Pseudomonas aeruginosa*
Corynebacterium spp.	*Pseudomonas cocovenans*
Coxiella burnetii	*Streptobacillus moniliformis*
Erysipelothrix spp.	*Streptococci* of group A
Flavobacterium farinofermentans	*Vibrio cholerae*
Hafnia alvei	*Vibrio spp.*
Leptospira spp.	

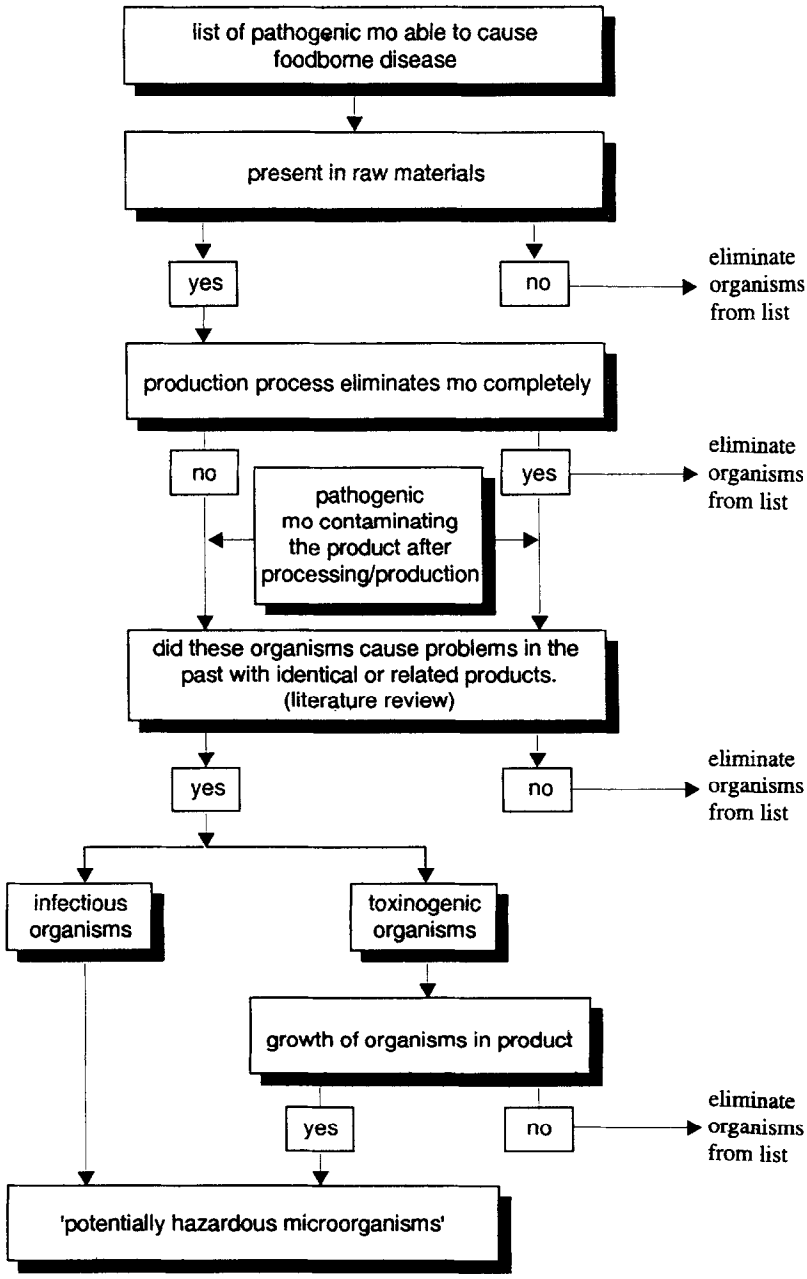

Fig. 1. Hazard identification: identification of 'potentially hazardous micro-organisms (MO)'. Adapted from Notermans et al. (1994a).

After the potential hazards have been identified, human exposure to the potentially hazardous organisms must be assessed. This is the next step in QRA.

2.2. Exposure assessment

Exposure assessment is the quantitative estimation of the dose of potentially hazardous organisms to which the consumer is exposed at the time of consumption. After identification of the organisms, information is needed on their numbers and distribution in (raw) food components that are intended for processing. Such information provides the basis for determining the effects of processing, product composition, etc. on the level of contamination of the end-product at the time of consumption. For this assessment, use can be made of several techniques, such as surveillance tests, storage tests and microbiological challenge testing, each with its own characteristics and field of application. Also, use can be made of mathematical models to predict growth or death of the organisms of interest. Mathematical computer models are convenient tools for determining effects of factors that control the safety of food products. These include intrinsic factors such as a_w, pH, Eh, preservatives and extrinsic factors such as storage temperature and time, destruction by heat or irradiation. For example, with Food Micro-model, which was developed in the U.K. for different pathogenic microorganisms, it is possible to predict the effects of some of the above-mentioned factors on microbial growth. As far as storage tests and microbiological challenge testing are concerned, these are specified in more detail in the papers of Notermans et al. (1994b).

All these tests and models can provide information on the likely numbers of organisms or quantity of toxin present in a food at the point of consumption. In Fig. 2, a theoretical example is presented of human exposure to *Bacillus cereus* as a consequence of drinking pasteurised milk. Data presented in this figure were obtained by enumerating *B. cereus* after storing the milk at 7°C until the expiry date (Beumer and te Giffel, pers. commun.).

When the frequence distributions of potentially hazardous organisms in the food are known, it is necessary to determine whether or not these levels are acceptable; in other words, whether they present a threat to the health of the consumer and, if so, to what extent. Such information can be obtained by assessing the dose response relationship.

2.3. Dose response assessment

This is the process of obtaining information on the adverse effects on human health of exposure to potentially hazardous organisms. So far, there is not much information on dose response relationships, although some is available from analysing foodborne disease outbreaks and from human volunteer studies. In Fig. 3 the infectivity and probability of disease from *Campylobacter jejuni*, as determined in human volunteer studies, is presented (Black et al., 1988). From these results, it can be concluded that even small numbers of *C. jejuni* may cause infection. In turn, infection may result in disease. However, no clear correlation is observed between

the occurrence of disease and dose ingested. Table 2 gives the probability of foodborne infection from several groups of organisms, largely determined in volunteer studies. The disadvantage of volunteer studies is that they do not reflect the normal exposure to pathogenic organisms among the general population. Therefore, information on naturally occurring foodborne infections should also be used. Foodborne disease caused by organisms such as non-host specific *Salmonella* spp., *S. typhi*, *Campylobacter* spp., *Vibrio* spp., *Clostridium botulinum* (causing infant botulism) and *Escherichia coli* O157, have been well documented. From the data available, dose-response curves can sometimes be constructed. For some organisms, the infective dose may be rather low and even a single organism has a finite probability of causing an infection (Rose and Gerba, 1991).

If the results of the exposure assessment are combined with dose response curves (as demonstrated in Fig. 4) the probability of disease can be estimated in a quantitative manner. It must be recognized, however, that several factors may influence not only the probability of infection but also the fatality rate. Factors such as the host individual, type of food and the organism itself will exert a considerable influence on susceptibility to infection and or disease. More research is needed to obtain reliable information on dose-response relationships and the factors influencing this relationship. For the time being, a conservative approach is necessary. This is based on the application of the dose response relationship in relation to infection rather than disease.

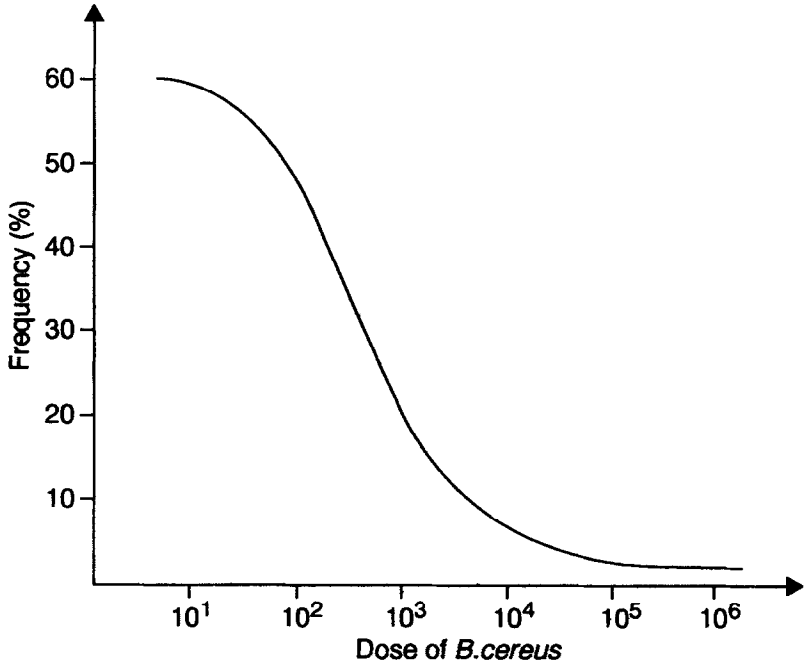

Fig. 2. Frequency of human exposure to *B. cereus* after drinking pasteurised milk (exposure curve), based on results of Beumer and te Giffel (pers. commun.).

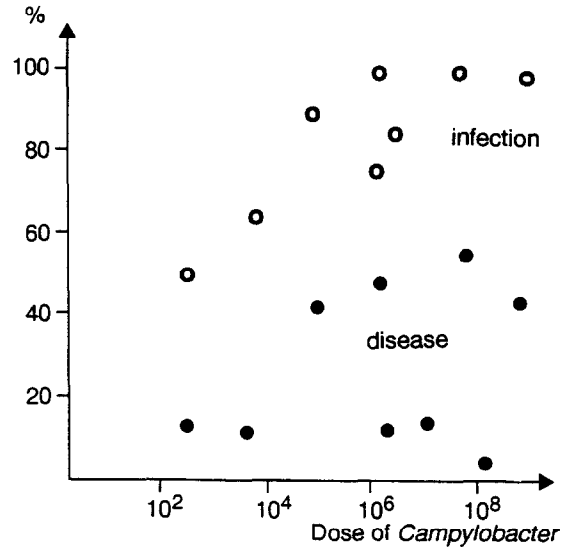

Fig. 3. Exposure of human volunteers to *Campylobacter*. Exposure may result in infection; infection may result in disease. Results are based on work of Black et al. (1988).

If the probability of illness caused by a food is unacceptable, then risk characterization should be carried out.

2.4. Risk characterization

Risk characterization is defined as the ranking of disorders according to severity, perception and economic and social consequences, enabling a decision to be made on the acceptance of a particular risk. Risk characterization, however, should also include determination of causative factors contributing to the risk from a particular food product. This knowledge facilitates the action needed to reduce the risk effectively. Such factors can also be recognized in advance and an example, given by Baird-Parker (1994), is presented in Table 3. It concerns the risk of the presence of psychrotrophic strains of *C. botulinum* in a chilled complete meal. The analysis shows that contamination of product ingredients will probably determine the contamination level of the end-product. If an unacceptable level of contamination is found, attention should be focused primarily on the ingredients used.

The next step in QRA is risk management.

2.5. Risk management

Risk management is the complex of analyses and judgements which aim to reduce the probability of occurrence of unacceptable risks. This definition implies that attempts to control such risks are carried out in a cost-effective manner. For this, it is important that any activity leading to an unacceptable product is

identified (risk characterization) and, if possible, the effect quantified. In general, various methods are available to convert an unsafe product into a safe one. Examples are the use of better quality raw materials, increasing the heating temperature, further lowering of the a_w, shortening the distribution time. Choosing the best method depends on cost-effectiveness. Cost-profit analysis should also be a part of this exercise to make an economically sensible decision.

It should be borne in mind that when a certain risk is accepted, there may still be an unnecessarily high degree of product safety. Adjustment might allow a more cost-effective production process or an improvement in the quality of the product.

Risk management should also include a system that guarantees that QRA is carried out adequately in a food processing environment. This means that it should be incorporated into an accepted food safety control system such as HACCP.

3. Application of quantitative risk analysis in safe food production

Food production is a dynamic activity. The composition and microbial quality of raw materials may change due to seasonal effects. Product composition may vary according to consumer demand. Also, processing conditions will change continuously. In addition, processing procedures will vary from plant to plant. Therefore, it will be necessary to incorporate QRA in existing quality assurance schemes, such as the HACCP system. To introduce QRA into HACCP, the following steps should be followed. Firstly, potential hazards must be identified. Initially, all are regarded as potential until it has been demonstrated (e.g. by quantitative estimation) that the risk of occurrence is acceptable. Acceptability depends on the frequency and

Table 2
Probability of foodborne infection/illness caused by several groups of micro-organisms (adapted from Notermans et al., 1994a)

A. Infectious organism	Average probability of infection from exposure to 1 organism
Campylobacter	7.0×10^{-3}
Salmonella	2.3×10^{-3}
Shigella	1.0×10^{-3}
Vibrio cholerae classical	7.0×10^{-6}
Vibrio cholerae El Tor	1.5×10^{-5}
B. Organisms causing toxico-infection	Threshhold (numbers required to cause disease)
Clostridium perfringens	10^5
Bacillus cereus (diarrheal type)	10^5
C. Organisms causing intoxication	Quantity of toxin causing symptoms
Clostridium botulinum	0.5–5 ng
Staphylococcus aureus	0.5–5 ug
Bacillus cereus (vomiting type)	?

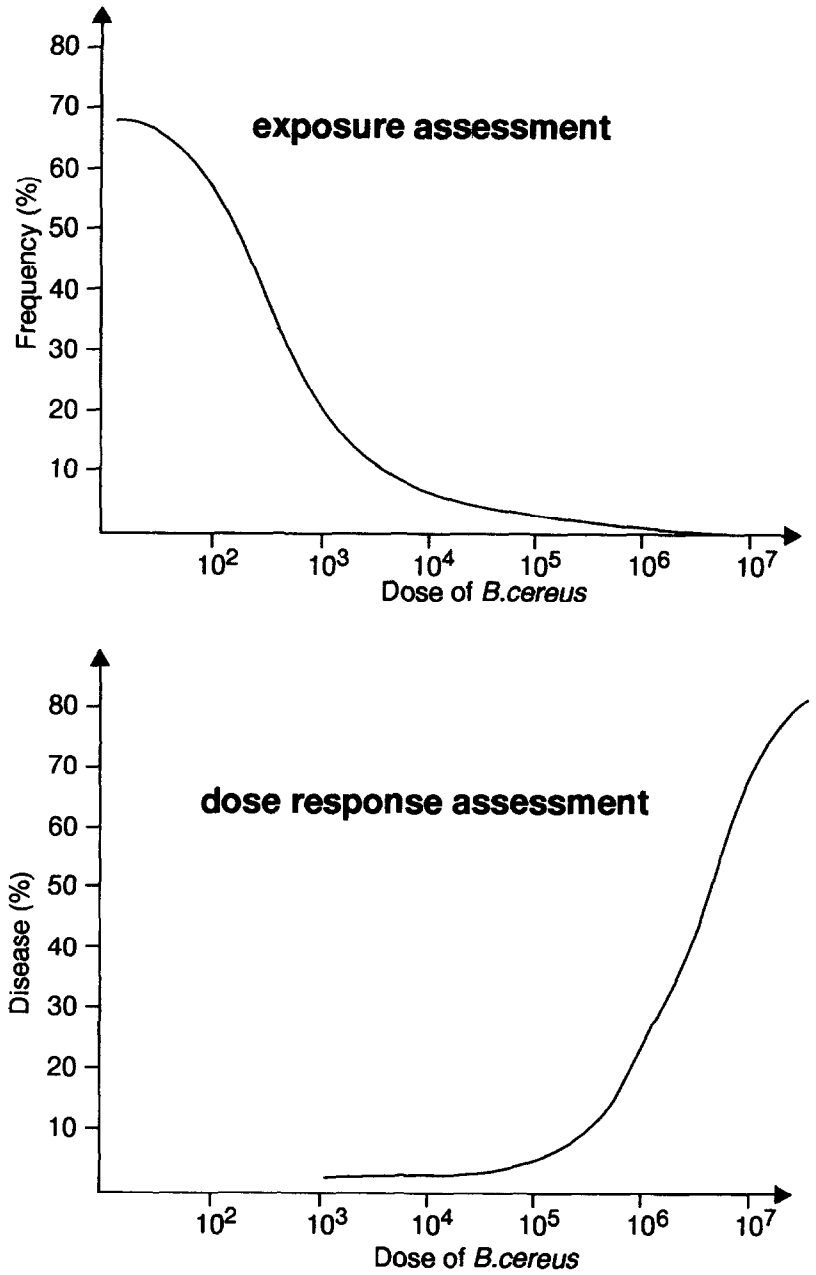

Fig. 4. Combining the exposure curve with the dose response relationship will give the number of individuals becoming ill (the dose response relationship presented is artificial).

severity of a hazard, and also on the costs involved in reducing the risk. Estimation of frequency can be based on exposure analysis (at the time of consumption) and on dose response assessment.

In the following, the integration of QRA and HACCP is considered. For this, each of the seven steps of HACCP (Codex, 1991) will be evaluated from the QRA point of view.

3.1. Hazard analysis

The first step in the HACCP system is the hazard analysis, in which all potential health risks that a particular food may present to the consumer are identified and assessed. In most HACCP publications it is stated that expertise in food safety is needed to discriminate between those risks that are significant and those that are too slight to be included in the HACCP plan. As stated above, the starting point in QRA requires that a judgement about the significance of a hazard should be based on the probability of occurrence (risk) and should be determined quantitatively. Therefore, introduction of QRA into HACCP implies that, as a first step, hazard identification is carried out according to the principles of QRA. This means that the frequency and severity of the hazard are not assessed in the traditional manner in the first step of HACCP. It is more obvious that estimation of the frequency as required for QRA, should be part of the third step of HACCP, as discussed below.

3.2. Identification of critical control points (CCPs)

For HACCP purposes, CCPs are defined as points, steps or procedures at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels (Bryan, 1992). For products such as raw ground beef, pathogens cannot be eliminated unless the product is irradiated. In such cases, the goal for HACCP is to minimize the possibility of contamination with pathogens and the potential for growth of these organisms. In such cases, it is clear that no quantitative data on the final presence of pathogenic organisms will be obtained, although this is necessary for QRA. Another example is the evisceration stage in poultry processing. Of course, contamination of carcasses by intestinal contents is a real hazard at this stage and may lead to e.g. an increase in the *Salmonella* load

Table 3
Example of risk characterization for a long-life, ready-to-eat, chill-stored food in relation to the presence of psychrotrophic strains of *Clostridium botulinum* (following Baird-Parker, 1994)

$P_s = P_e + P_a + P_{pa} + P_n$
$10^{-6} = <10^{-8} + <10^{-7} + <10^{-9} + 0.8 \times 10^{-6}$
P_s = probability of contamination with psychrotrophic spores
P_e = probability of contamination from environment
P_a = probability of contamination during assembly
P_{pa} = probability of contamination from packaging
P_n = probability of contamination from product ingredients

on the carcasses. This hazard can be reduced to some extent by operating the equipment properly. Even so, the effect is difficult to quantify, and will never reduce the *Salmonella* hazard to acceptably safe levels. In relation to QRA, CCPs are operations (e.g. steps, processes) where risks can be reduced through control of procedures, practices, etc. They are only meaningful if they can be managed in such a way that the risk is reduced and the reduction can be quantified. In terms of QRA, CCPs should be **operations (practices, procedures, processes, etc.) at which a measurable degree of control can be exercised to achieve a quantifiable reduction in a hazard or its stabilization, that leads to an acceptable, safe food product on a quantitative basis.** CCPs are only meaningful if they can reduce the potential risk to a desired degree. Processes, practices etc. which fulfil this criterion are heating, drying, storage time and distribution time. In addition the choice of raw materials may be crucial to ensure a safe food. The *Salmonella* hazard in poultry meat production could be entirely avoided if it were possible to process only birds originating from *Salmonella*-free farms. Another possibility for reducing the hazard to acceptable and quantifiable levels is to pasteurize the product after processing.

In a food processing environment there are various activities that are relevant to the production of safe food and which do not meet the above mentioned definition of a CCP. Examples are correct operation of equipment, cleaning and disinfection of the plant, exclusion of infected workers and personal hygiene. These general hazards are best controlled by GMP.

3.3. Specification of criteria

Specification of criteria (step 3) is a very important aspect of the HACCP system and must ensure that the activities at a particular CCP are under control. A criterion is defined as a prescribed limit or tolerance that must be met to ensure that a CCP effectively controls a health hazard. However, in most cases criteria are not based on sound assessments.

In terms of QRA the activities at a particular CCP must result in an acceptable safe food product at the time of consumption. Acceptability depends on, e.g. the calculated probability of causing disorders. An attractive approach that permits such a specification is based on the identification of potentially hazardous organisms (step 1 of HACCP) and information on numbers present in (raw) food materials. Storage tests, microbiological challenge testing and mathematical models are tools to predict growth or death of these organisms during processing and handling after distribution. They can also provide information on the expected bacterial load at the time of consumption. Ultimately, quantitative risk assessment can be used to judge acceptance or non-acceptance of the product. If microbial levels are acceptable, criteria at specific CCPs can be established. This implies a complete description of activities at each CCP and takes account of parameters such as temperature, time, a_w, etc.

In short: for the specification of risk-based criteria, exposure assessment followed by risk assessement (dose response assessment) should be carried out. In Fig. 5 a flow sheet of the approach is presented. This is limited to bacterial hazards

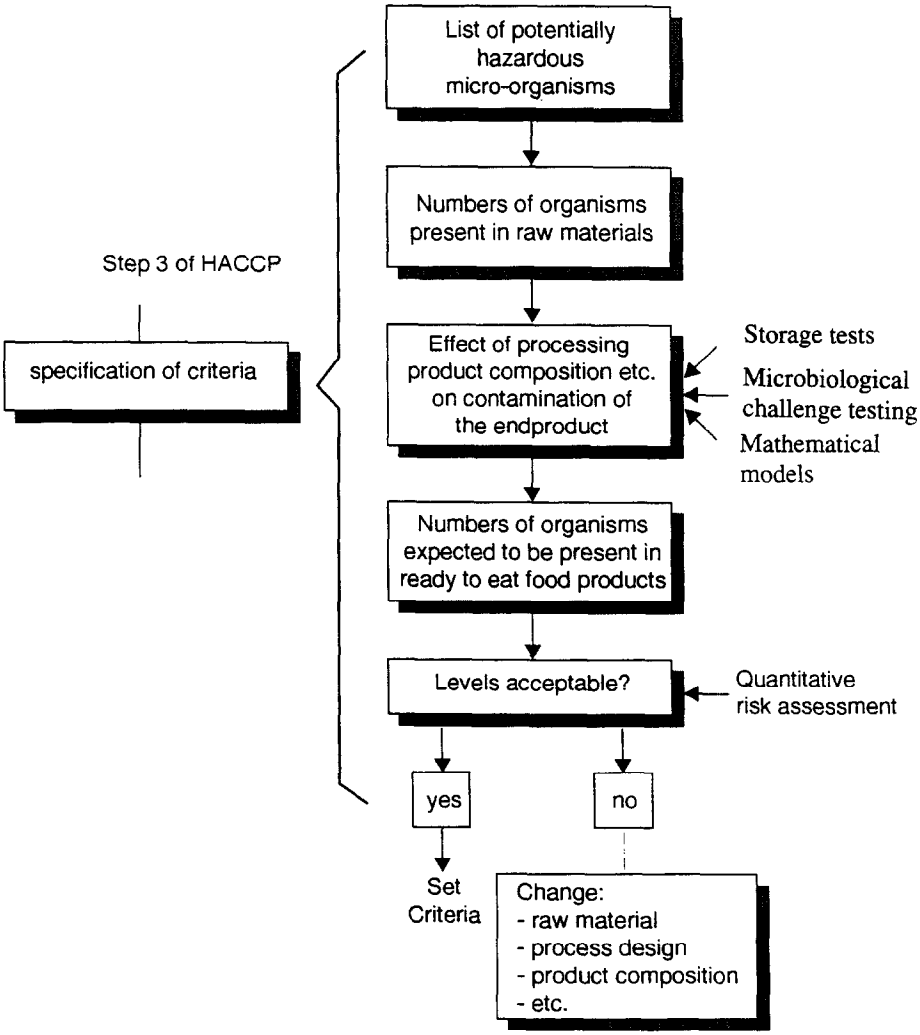

Fig. 5. Possibilities for setting criteria based on the principles of quantitative risk analysis.

associated with foodborne disease, and shows the steps involved in setting criteria at CCPs.

3.4. Implementation of a monitoring system

Once criteria at the CCPs have been established, appropriate monitoring procedures (step 4) must be chosen. In general, the current monitoring approaches for HACCP, as described by, e.g. IAMFES (1991) can be applied. Wherever possible, however, monitoring should be based on quantitative determinations instead of the usual subjective observations.

3.5. Corrective actions

Appropriate and immediate action is needed if the results of monitoring indicate that the criteria are not met at a certain CCP (step 5). In such a case the process is out of control and the probability that the product will cause disorders will increase. Plans should be prepared on how to handle the situation, if monitoring indicates that safety criteria at a particular control point are not being met. For quantitative purposes, the expected effect of these plans on the safety of the end product should be estimated in advance.

Revision should also be undertaken if the production process is changed. This should also involve updating the HACCP system, and is particularly important when 'new' pathogens are identified or new information, e.g. relating to sensitive groups of the population becomes available.

3.6. Verification

Verification of the system (step 6) implies that a careful check is carried out, in order to demonstrate that everything is proceeding as planned, according to the evidence obtained. Verification should be carried out by quality control staff. The task of regulatory agency personnel remains auditing, which is not a part of the verification process.

As well as general verification activities, such as applying test procedures, calibration of testing equipment, etc., other more specific measures are needed. These are necessary when fresh information becomes available on foodborne disorders and on 'new' pathogens. It must be remembered that not all foodborne pathogens are currently recognised. Also, the characteristics of known pathogens are not always described completely. Furthermore, an analysis should be made of reported disorders, changes in the process and any new information that becomes available. If there are any consequences for the safety of the product, the HACCP system should be updated. Updating implies verification of the list of potentially hazardous organisms, carrying out new storage tests, risk assessment procedures, etc.

3.7. Documentation

Documentation is the final item of HACCP (step 7) and involves a description of all activities that are undertaken in the framework of HACCP. In general, the system in current use is appropriate.

4. Concluding remarks

For the production of safe food, the basic rules of GMP should be applied, although failure to do so does not necessarily result in an unsafe product. However, if critical control points are not under control, the safety of the end-product is at risk.

The principles of quantitative risk analysis are simple and comprise five, succesive, closely related components permitting a quantitative estimation of the risks associated with the consumption of a particular food product. Analysis is possible even before a product has been actually produced. In consequence, QRA would allow foods to be designed for safety. QRA is cost-effective since risk management activities are based on the scientific approach of calculating the probabilities of disorders. As demonstrated, QRA could easily be integrated in quality assurance systems, such as HACCP. Fig. 6 summarizes the integration of QRA into the HACCP system. At present, however, QRA is in its infancy for this purpose and a number of uncertainties exist. This applies particularly to hazard identification and in determining dose response relationships, and includes the problem that some causative agents of foodborne disease have yet to be recognised. It is necessary, therefore, to look out for new and emerging pathogens and to update the system continuously. Dose response relationships are weak points in QRA because reliable data are scarce. This is especially true for certain sensitive groups among the human population. If, however, the probability of illness is based on a dose-response relationship calculated from an analysis of known foodborne disorders, the sensitive groups would be included. It is clear that more research is needed, especially as far as dose response is concerned. This would include the effect of infective dose in relation to the type of food and distribution of pathogens in a food product, bearing in mind that there will rarely be an homogenous distribution.

Research is also needed to provide a better understanding of the critical assumptions involved in following the distribution and numbers of particular pathogens throughout the food production and processing chain. It must be remembered that the actual absence criteria for infectious organisms in ready to eat food products are not realistic, because an absolute absence is not achievable and cannot be demonstrated by normal sampling and testing procedures. The principles of QRA clearly demonstrate that absolute safe food does not exist. Increasingly, the safety of food will be based on controlling all steps in the food production process. However, such control must be carried out in the most effective manner which can only be achieved in the long term by applying QRA.

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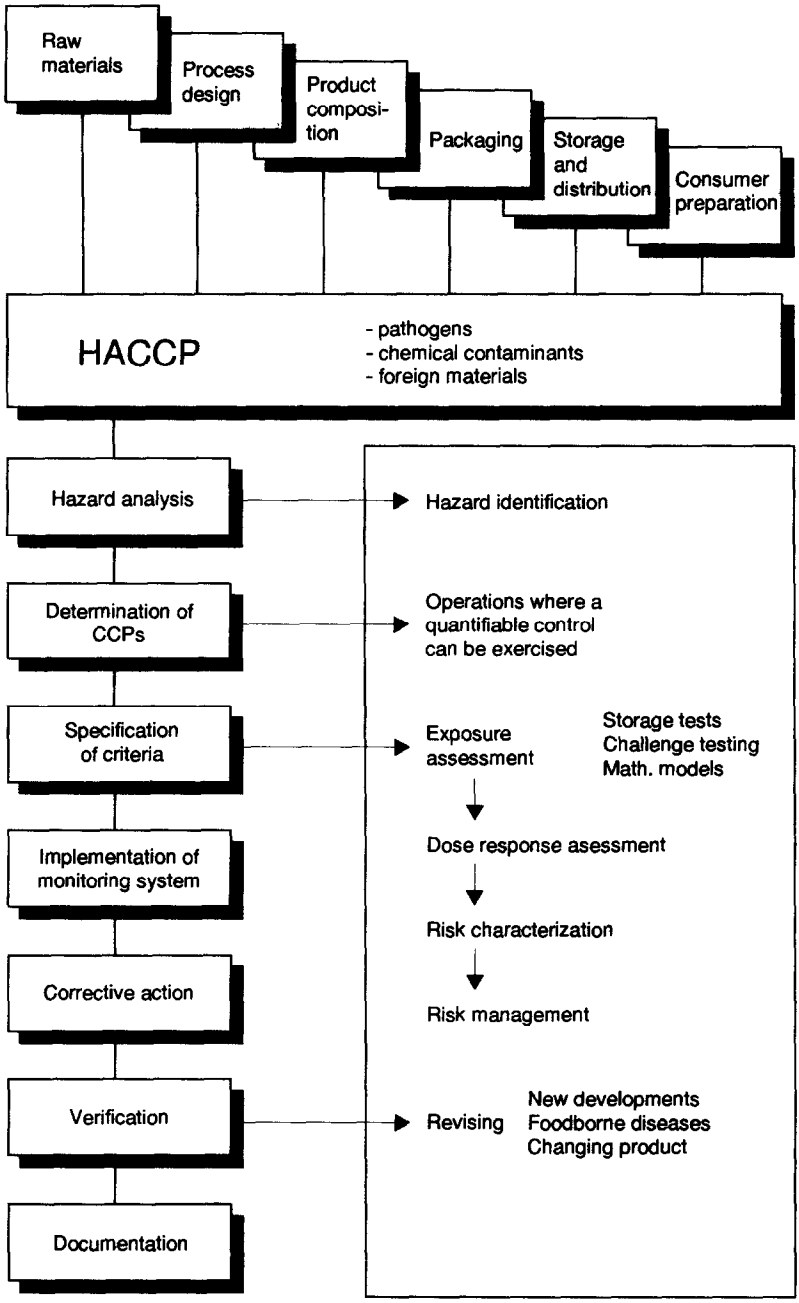

Fig. 6. Proposal to introduce quantitative risk analysis into the HACCP concept.

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