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PAPER

A risk assessment approach to evaluating food safety based on product surveillance

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This paper outlines a risk assessment approach to food safety evaluation, which is based on testing a particular type of food, or group of similar foods, for relevant microbial pathogens. The results obtained are related to possible adverse effects on the health of consumers. The paper also gives an example of the way the risk assessment approach may be used in practice. The proposed system seeks to provide information on the exposure of consumers to microbial pathogens when the food is consumed. It reflects the successful application of good manufacturing practices and HACCP principles on the part of the producer, as well as the effect of consumer handling of the product, on the exposure rate. The information obtained on factors affecting exposure to microbial hazards and their impact on consumers would allow risk management and communication to be carried out effectively. A practical example is presented concerning the risk assessment of Bacillus cereus *in pasteurized milk. © 1998 Elsevier Science Ltd. All rights reserved*

INTRODUCTION

Traditionally, food safety is assessed retrospectively through the testing of randomly selected food samples by the appropriate regulatory body. This approach may confirm that the food meets certain statutory criteria at the point of sampling, but gives no real information on the safety of the food in question at the time of consumption, or whether the control criteria are effective in protecting consumers.

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Increasingly the production of safe food is based on the use of good quality raw materials and the application of Good Manufacturing Practices (GMP) and the Hazard Analysis Critical Control Point (HACCP) system. In addition risk analysis is becoming the new cornerstone in producing acceptable, safe food. According to the agreements of the World Trade Organisation (WTO), especially the agreement on the application of sanitary and phytosanitary measures — the SPS agreement, the setting of control criteria should have a scientific basis. For this purpose, quantitative risk analysis is considered to be a logical approach that can provide the necessary insight into the process of setting such criteria. Elements of quantitative risk analysis can also be introduced into the HACCP system, for example, in setting criteria at CCPs (Notermans and Mead, 1996).

These developments require re-evaluation of traditional food testing, as carried out by producers,

retailers and regulatory bodies. Among the new requirements is a need to verify the safety of foods being produced on the basis of GMP and the HACCP system (EU Directive 93/43). It is also necessary to verify the effectiveness of safety criteria set by regulatory authorities. Therefore, the verification process should include information on any health hazards associated with the product in question. If an unacceptable hazard is likely to occur, the factors contributing to this situation and their relative impact should be considered.

In this paper, an outline is given of an evaluation system that includes the above-mentioned aspects. Firstly, the general principles of the risk analysis approach and the stages involved are described. A practical example is then presented concerning evaluation of the safety of pasteurized milk in relation to the presence of *Bacillus cereus*.

OUTLINE OF THE PROPOSED SURVEILLANCE SYSTEM

The general principles

The general principles applied are based on the framework *Principles and Guidelines for the Application of Microbiological Risk Assessment* agreed upon by the Codex Committee on Food Hygiene at a consultation on risk assessment (Codex Committee on Food Hygiene, 1996). For this, a particular group of closely related food products is selected. Reasons for the choice include information obtained from routine testing, reported complaints, new information relating to food safety, etc.

The products in question are sampled on a statistical basis and tested for relevant pathogenic organisms; the results obtained are evaluated in relation to possible consequences for the health of consumers. If necessary, factors that may contribute to a health hazard are identified and, where possible, quantified. These would form the basis for discussions with food producers and consumer organizations with a view to improving product safety.

Stages involved

Statement of purpose

This stage refers to the nature of the problem. It is necessary that the purpose of the risk assessment is clearly stated. The output form and possible output alternatives should be defined. During this stage, the cause of concern, the goals, breadth and focus of the risk assessment should be defined. The same applies to the output and may be an estimate of the annual occurrence of illness and factors contributing to a hazardous situation.

Hazard identification

Hazards are defined as chemical, physical and biological agents which are capable of causing adverse health effects and may be present in a particular food or group of foods. For microbial agents, the purpose of hazard identification is to identify the micro-organisms or microbial toxins of concern and to determine whether a micro-organism or microbial toxin is a potential hazard in the food. Thus, before testing the products, a hazard identification should be carried out. Hazards can be identified from relevant data sources such as the scientific literature, the database obtained from routine testing, expert consultation, etc. Relevant data also include among others results of epidemiological studies and laboratory animal and clinical studies.

Hazard characterization

Hazard characterization is the qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical and physical agents that may cause harm and that may be present in the food. A dose–response assessment should be performed if data are obtainable.

The purpose of hazard characterization is to provide an estimate of the nature, severity and duration of the adverse effects associated with harmful agents in food. Factors to consider relate to the micro-organisms, the dynamics of infection and the affected individual.

As indicated above a central feature of hazard characterization is the establishment of a dose–response relationship. In the absence of a known relationship, existing regulations or generally accepted good food manufacturing practices may be taken into account. In addition, expert advice could be sought.

Exposure assessment

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 a food at the time of consumption. This may include an assessment of actual or anticipated human exposure. For foodborne microbiological hazards, exposure assessment might be based on the possible extent of food contamination by a particular agent, and on dietary information.

To obtain proper exposure data, a statistical sampling plan should be developed and it would be preferable to take samples at the time the contaminated food is consumed. However, relevant information can be obtained from consumers and used in conjunction with either product storage tests or challenge testing. Also, use can be made of predictive models to estimate human exposure to the target pathogens. Consumer enquiries should provide, among others, information on patterns of product consumption, conditions of domestic storage and indications of groups that consume the food in question.

Risk characterization

Risk characterization is the quantitative and/or qualitative estimation, including attendant uncertainties about the probability of occurrence and severity of known or potential adverse health effects in a given population. Risk characterization is the last step in a risk assessment from which the risk management strategy can be formulated. Risk managers should first determine whether or not the calculated responses to the hazard are acceptable according to severity, economic and social consequences, etc. If not, they need to be informed about the main factors contributing to the unacceptable risk. Although the Codex document does not suggest that this aspect is a part of risk characterization, it is logical to include identification and quantification of the factors involved. There are several possible means of gaining information about factors that contribute to risk and their impact. One possibility is to carry out a case-control study in which unacceptable products are compared with acceptable ones.

Production of a formal report

The risk assessment should be fully and systematically documented. For clarity a formal report should be prepared, indicating any constraints and assumptions relative to the risk assessment and this should be made available to independent parties on request.

It is important that all aspects are dealt with in a logical and open manner. All steps, results, decisions, etc. should be noted and a comprehensive report produced. If the estimated risk is deemed to be unacceptable, the report should also indicate the aspects which are important from the risk assessment point of view. These are of interest to both the producers (or their representatives) and consumer organizations to improve the situation.

A PRACTICAL EXAMPLE: A RISK ASSESSMENT APPROACH EVALUATING THE SAFETY OF PASTEURIZED MILK WITH RESPECT TO *BACILLUS CEREUS*

Selection of pasteurized milk and *B. cereus*

In The Netherlands pasteurized milk is the main milk drink, the annual amount consumed being approximately 10^9–10^{10} units of 100 ml. It is a relatively homogenous product, always produced under almost identical conditions and, in consequence, is easy to deal with.

An important reason for selecting *B. cereus* as a hazardous organism is the recognition that spores of psychrotrophic *B. cereus* are known to be present in the product after processing (Helmy *et al.*, 1984; Christiansson *et al.*, 1989; Crielly *et al.*, 1994). Notermans *et al.* (1997) demonstrated the presence of *B. cereus* spores in pasteurized milk in numbers varying from 1–100 per 100 ml, the highest numbers being found during the grazing period for cows. Studies (Christiansson *et al.*, 1989; Notermans *et al.*, 1997) reveal that the organisms can multiply rapidly in milk, especially under the storage conditions used in private households. Although *B. cereus* is a well-established pathogen, there are also indications that the organism is the predominant cause of spoilage in pasteurized milk (Notermans *et al.*, 1997). Visible spoilage due to *B. cereus* is often observed in milk produced in the summer (Van Netten *et al.*, 1990). Taken together, the above information justifies reconsideration of the safety of pasteurized milk. Since several aspects are involved in this exercise, a risk analysis approach is obviously required and should focus on the criteria applied in production and recommending storage conditions for the product.

Hazard identification

Although several other hazards are associated with milk consumption only *B. cereus* is considered in the present study. The reason is that these organisms are representative of other aerobic spore-formers that are known to be present and, among them, *B. cereus* predominates and is the most important pathogen. Furthermore, unlike vegetative organisms, spores are not destroyed by pasteurization.

As indicated previously, *B. cereus* is a well-established pathogen and is frequently the diagnosed cause of gastrointestinal disorders (Kramer and Gilbert, 1989). From the analysis of consumer illnesses, it is evident that dairy products account for a substantial proportion of cases of foodborne disease. Several outbreaks have been reported in which milk or milk products containing *B. cereus* were implicated (Bannerjee and Black, 1986; Bryan, 1983; Bulyba *et al.*, 1973; WHO Surveillance Programme for Control of Foodborne Infections and Intoxications in Europe, 1995). Investigations carried out by for example Granum *et al.* (1993), Te Giffel *et al.* (in press) and Ogihara *et al.* (1992) reveal that almost all strains of *B. cereus* isolated from milk could produce enterotoxin. Also, it has been claimed that the toxin is produced in milk (Christiansson *et al.*, 1989).

In view of the evidence discussed above, the organism should be considered as a potential hazard in pasteurized milk.

Hazard characterization

There are two type of *B. cereus* food poisoning. The first, caused by an emetic toxin, results in vomiting, while the second, caused by enterotoxin, is associated with diarrhoea. Since dairy products have never been involved in the production of emetic toxin by *B. cereus*, this aspect is not considered here. The incubation time for diarrhoea caused by *B. cereus* varies from 6 to 16 h and symptoms last for about a day. Only occasionally does the disease last for several days, when hospitalization may be necessary (Granum *et al.*, 1995). No dose–response relationship exists for

B. cereus and no such relationship can be deduced reliably from reported outbreaks. Nevertheless, a summary of the results from a large number of foodborne outbreaks, made by Kramer and Gilbert (1989), revealed that the levels of *B. cereus* in foods causing the diarrhoeal syndrome varied from 1.2×10^3–10^8 organisms g^{-1}. The median value was around 10^7 organisms g^{-1}. Infection experiments carried out with human volunteers by Hauge (1955) supported the notion that *B. cereus* could induce diarrhoea in man. However, Dack *et al.* (1954) failed to produce food-poisoning symptoms with *B. cereus*. Recently, Langeveld *et al.* (1996) carried out a quantitative volunteer study. Over a period of 3 weeks, the subjects were exposed to *B. cereus* that was naturally present in pasteurized milk, following storage for 3–14 days at 7.5°C. The total number of *B. cereus* ingested varied from 10^5 to $> 10^8$ organisms in the amount of milk consumed. No indications were obtained that these organisms caused harm to the volunteers.

The discrepancy between reported outbreaks and certain human volunteer studies may be explained by assuming that not all strains of *B. cereus* have the potential to cause food poisoning. It was observed by one of us (S. Notermans, unpublished results) that strains isolated from patients suffering from a *B. cereus* infection produced at least 10-fold more toxin than isolates tested at random. Another reason for the observed discrepancy may be that resistance develops in humans due to regular exposure.

Because there is no realistic dose–response relationship, existing regulations or generally accepted good food manufacturing practices should be taken into account. In the regulations of many European countries, levels of 10^4–10^5 *B. cereus* ml^{-1} or g^{-1} of a food product are set as critical limits for acceptance of the food (unpublished inquiry results). In the diagnosis of foodborne disorders presumed to be caused by *B. cereus*, levels of $> 10^5$ organisms g^{-1} are considered as highly indicative that *B. cereus* is responsible. From a hygiene point of view, the presence of *B. cereus* in excess of 10^5–10^6 organisms g^{-1} suggests that generally accepted principles of good food handling practice are not being observed.

Exposure assessment

In this study, use has been made of the recently estimated human exposure to *B. cereus* as a consequence of milk consumption (Te Giffel *et al.*, in press; Notermans *et al.*, 1997). One approach was based on surveillance testing of pasteurized milk at the time of consumption (Te Giffel *et al.*, in press), the other on storage testing and enquiries made in households to determine practical storage conditions (Notermans *et al.*, 1997).

There are clear differences in the results of these two approaches to estimating consumer exposure. The differences could be related partly to the different conditions of the two studies. Te Giffel *et al.* (in press) tested 334 samples over a period of 5 months from a limited area of The Netherlands and therefore the results may not be fully representative. The temperature of the stored milk was found to vary from −1°C to 17.9°C, with a mean of 7.4°C; 43% of the samples were held below 7°C. The storage time for the pasteurized milk varied from 2 to 12 days. In the estimation of exposure based on storage testing and determination of domestic storage conditions, Notermans *et al.* (1997) examined 125 refrigerators and found that the temperature where the milk was stored varied from <5°C to 13°C, with the median between 5 and 7°C. Most (71%) of the refrigerators had a temperature below 7°C. Storage times for the milk were identical to those reported by Te Giffel *et al.* (in press).

The results of both approaches (*Figure 1*) can be compared with model predictions using the method of Zwietering *et al.* (1996) and the data on storage conditions from Notermans *et al.* (1997). This is also presented in *Figure 1*. The mathematical basis for predicting the *B. cereus* counts is given in Appendix 1. Note that the model follows a worst case scenario and therefore will show the highest exposure. Also, as in the study of Notermans *et al.* (1997), storage times and temperatures were considered to be independent, which, obviously, may not be true. Thus, visually spoiled milk was excluded from the calculations of Notermans *et al.* (1997). The study of Te Giffel *et al.* (in press) shows the lowest exposure. This is quite remarkable, since the higher mean storage temperature in their study would predict the opposite.

It must be remembered that the level of consumer exposure to pathogenic organisms in food cannot be determined precisely. Growth of bacteria in food is a dynamic process and is determined by several factors. The data in *Figure 1* are the best currently available and can be used as the starting point for risk assessment.

Risk characterization

From the hazard characterization, it appears that exposure to *B. cereus* does not necessarily have any bearing on the risk of becoming ill. Also, it should be noted that consumers in The Netherlands seldom report complaints from the consumption of pasteurized milk. However, foodborne illness caused by *B. cereus* is generally mild and often may not be recognized as food related. Therefore, in the absence of realistic information, other parameters need to be considered, including the indications from existing regulations and good food handling practices. From these sources, levels of *B. cereus* of 10^4–10^5 organisms g^{-1} food product should be considered as the extreme limit.

The exposure results based on storage testing, inquiries in private households and surveillance

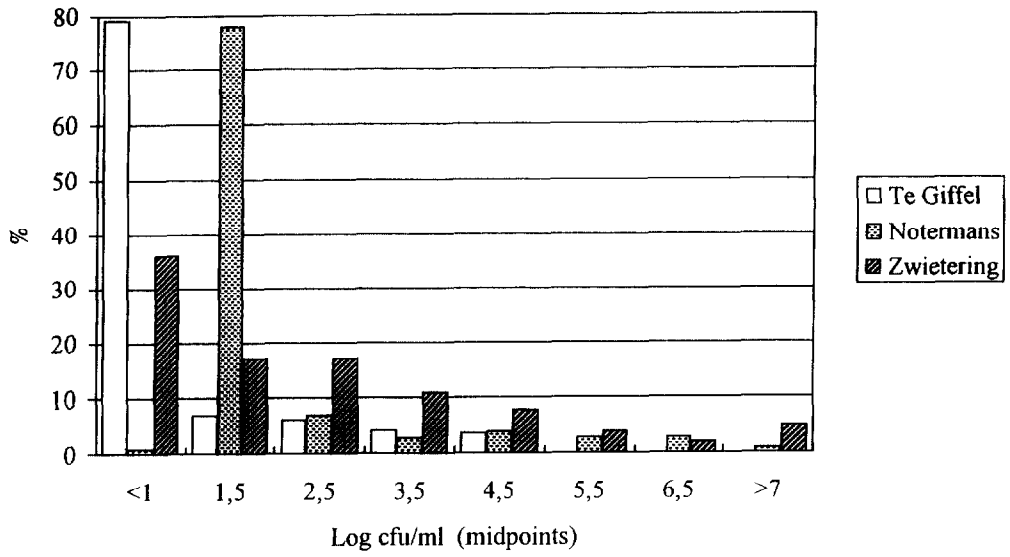

Figure 1 Exposure to *Bacillus cereus* from consumption of milk. The figure shows the proportion of milk units containing different levels of *B.cereus* at the time of consumption. Exposures are based on surveillance testing (Te Giffel *et al.*, in press), storage testing and enquiries in households (Notermans *et al.*, 1997) and predictions made by Zwietering *et al.* (1996).

testing demonstrate that a substantial amount of pasteurized milk consumed in The Netherlands contains *B. cereus* at levels in excess of those quoted above (see *Figure 1*).

Parameters involved in the risk of being exposed to 'unacceptable' levels of *B. cereus* at the time milk is consumed comprise: (i) the initial number of spores present (N_0), (ii) the storage time (t), and (iii) the storage temperature (T) (Notermans *et al.*, 1997). Based on the predictive model developed by Zwietering *et al.* (1996) and following a worst-case scenario, the effect of these parameters can be quantified, as shown in Appendix 1. The resulting equation

$$\log(N/N_0) = 0.013T^2t \qquad (1)$$

shows the relationship between the final number of *B. cereus* cells in pasteurized milk (N) and the parameters mentioned above. *Figure 2* shows how the concentration of cells (N), reflecting storage time and temperature, can be predicted by equation (1) for an initial count $N_0 = 0.1$ CFU ml^{-1}. More generally, *Figure 3* shows the isolines representing the relationship between log (N/N_0) and the storage temperature

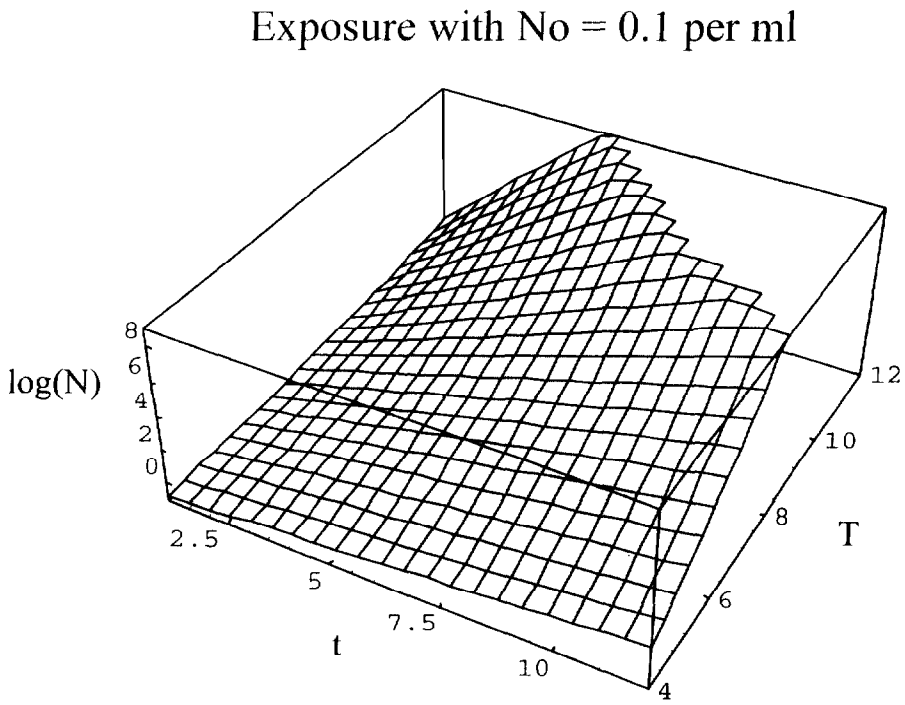

Figure 2 The predicted concentration of cells (N) after storage for t days at temperature T, with an initial count $N_0 = 0.1$ cells ml^{-1}, following the worst-case scenario model of Zwietering *et al.* (1996). With long storage at high temperature, the number exceeds 10^8 cells ml^{-1}.

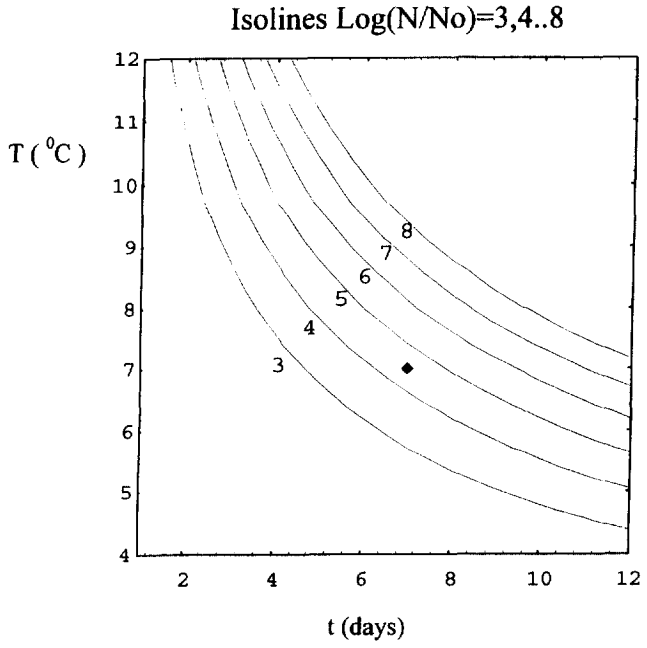

Figure 3 Isolines representing log (N/N_0) in relation to storage temperature and time (days), as given by equation (1). The dot (♦) in the figure represents the Dutch specification for storage temperature (7°C) and time (7 days). At this point log (N/N_0) = 4.5. Calculations are based on the model of Zwietering *et al.* (1996) and represent the worst-case situation.

and time. Here, it can be seen that if, for example, the initial count of *B. cereus* present in pasteurized milk is 0.1 organisms ml^{-1} (N_0) and the maximum acceptable number at the time the milk is consumed is 10^4 ml^{-1} (N), isoline log (N/N_0) = 5 represents the critical values for combinations of T and t. Above this line, the maximum acceptable number of cells will be exceeded. If, however, the initial count is 1 organism ml^{-1}, the isoline 4 becomes relevant.

In The Netherlands, the prescribed storage conditions for pasteurized milk are equivalent to 7°C for a maximum of 7 days. If the initial number of *B. cereus* were 0.1 organisms ml^{-1}, the expected number after storage would be about 3.5 log units ml^{-1}, which is below the limit of 4. However, should the initial count be 1 organism ml^{-1}, as may be the case during the grazing period in summer time (Notermans *et al.*, 1997) the limit of 10^4 ml^{-1} would be exceeded.

CONCLUSIONS

From the above, it is evident that the public health consequences of the predicted exposure to *B. cereus*, following consumption of pasteurized milk, are not clear. Nevertheless, the estimated number of *B. cereus* present in pasteurized milk at the time of consumption may be considered unacceptably high, and will depend upon the initial number of *B. cereus* spores and the storage time and temperature. To improve the situation, the producer (initial count) and retailers and consumers (storage time and temperature) have their separate responsibilities. Obviously, discussion is needed between producers of pasteurized milk, consumer organizations and the responsible authority. Important aspects to consider include:

- If the recommended storage conditions, as shown on the pack, are taken to the limit, consumer exposure to *B. cereus* by the expiry date could reach 10^4 *B. cereus* ml^{-1}. This is only valid if the initial number of *B. cereus* present is <1 ml^{-1}
- It seems that many consumers do not adhere to the recommended storage conditions, and will consume the milk up to the point that visible spoilage occurs. In The Netherlands, *B. cereus* is the predominant organism causing spoilage of pasteurized milk.
- Exposure to high numbers of *B. cereus* may lead to human food poisoning and could result in a negative product image.
- The producer, retailer, consumer and the regulatory authority all have some responsibility for the safety of food products at the time of consumption.
- The image of pasteurized milk could be enhanced by recommending a shorter storage time.
- Retailers are generally interested in a rapid turnover of products in their shops. A more limited expiry date for fresh pasteurized milk could help this process.

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APPENDIX 1

According to Zwietering *et al.* (1996) the concentration of organisms N can be predicted by

$$\ln(N) = \ln(N_0) + b^2(T - T_{min})t$$

where N_0 is the initial number of cells, T is the storage temperature, t is the storage time, T_{min} is the minimum temperature for growth and b is a parameter dependent on for example pH and a_w. As given by Zwietering *et al.* (1996) for *B. cereus* in pasteurized milk, $T_{min} = 0°$ C and $b = 0.0354$. This represents the worst-case situation, where the lag time is neglected and the optimum growth rate in pasteurized milk is assumed. The following equation results [equation (1) in the main text]:

$$\ln(N) = \ln(N_0) + 0.013T^2t$$

For freshly pasteurized milk from six milk processing plants, sampled over a 1-year period, Notermans *et al.* (1997) found a mean initial number for N_0 of 0.091 CFU ml^{-1} milk, leading to a formula for the predicted N, depending on T (in °C) and t (in days):

$$\ln(N_{T,t}) = 0.013T^2t - 1.04$$

Using this formula and assuming independence of storage time and temperature, it is possible to calculate the probability of exposure to more than 10^x cells by summing the products of the relative frequencies of temperature T and time t, as found by Notermans *et al.* (1997), for those combinations of T and t where $\log(N_{T,t}) > x$:

$$P(\text{Exposure} > 10x) = \Sigma_{\log N > xP}(T) \times P(t)$$

This leads to a predicted exposure as shown in *Figure 1.*