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Application of modelling in HACCP plan development

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Abstract

Incorporating Hazard Analysis Critical Control Points (HACCP) in the initial stages of food product development allows for an assessment of the risk and severity of hazards, which may be associated with the raw materials used, their processing, the system of distribution, and the intended use. Implementation of a HACCP plan provides a mechanism to ensure that product safety is continuously achieved. Models developed to predict microbial survival and growth may become an integral tool to evaluate, control, document, and even defend the safety designed into a food product. This paper will examine some current uses of modelling to design critical control parameters and aid in regulatory decisions.

Keywords: HACCP; Statistical process control; Predictive microbiology; Challenge test; Modelling; Risk assessment; Database

Companies are becoming increasingly aware that they must develop state-of-the-art, safety assurance plans to address the potential hazards that may be associated with their products, how they are marketed and used by the consumer. The risk associated with each known hazard must be acceptable.

Regulatory agencies must be able to verify that risk assessments and methods chosen by a company to achieve a described level of safety are appropriate. Application of HACCP provides a method to demonstrate that product safety objectives are continuously achieved. This approach to the manufacture of food products should replace or minimise the costly and potentially less effective inspection processes and end product testing currently practised.

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The use of databases is foreseen as one means to allow access to the vast knowledge available necessary to conduct an in-depth risk assessment. Including databases designed to have predictive abilities, they will provide support for making decisions, but more importantly they should offer aid in formulating more precise questions regarding hazard analysis and risk assessment. These topics include: the prevalence and levels of pathogens on raw materials; the products associated with food borne disease; factors limiting microbial growth and survival; processing failures which have resulted in food borne disease related to equipment, sanitation, recontamination, etc.; the ability of regional distribution and marketing systems to maintain refrigerated storage; the likelihood that regional consumer practices may lead to thermal abuse of refrigerated products; cooking before consumption; and information concerning the epidemiological aspects of risk analysis, e.g. minimal infective dose, high risk consumer groups, etc.

1. HACCP and food safety

HACCP is a system to identify and prevent the potential food safety problems with the manufacture, distribution and use of a food product. Microbial hazard analysis attempts to identify the pathogens in raw materials, routes for pathogens to enter the processing environment, the methods for their elimination, and potential problems with the finished product when not handled appropriately. Risk is an estimation of how likely a potential hazard could result in a problem. The severity of the resulting food safety problem is inversely related to the level of risk acceptable.

Identification of preventive measures which eliminate or limit the risk from a potential hazard is a primary goal of HACCP plan development. Preventive measures are implemented at critical control points (CCP) where a potential hazard associated with a food material, environmental location, manual procedure or mechanical process can be controlled. A critical control point able to eliminate a hazard is termed a CCP1, while a CCP2 designates a control designed to minimise the risk of a hazard. CCP parameters are characterised by a critical limit and a target value bounded by tolerance limits, within which the desired level of control is obtained. A critical limit separates acceptable from unacceptable. Implementation of a HACCP system requires that CCP's are monitored. Deviations from target values would initiate corrective actions described in the HACCP plan. The controls employed in a HACCP system should be regularly tested to verify their efficacy. Lastly, HACCP plans require that processing records are maintained, documenting that processing procedures were diligently implemented.

2. Statistical process control

Variation of CCP parameters. One objective of continuous processes is to insure that the finished product conforms to specifications. Variation is an inherent

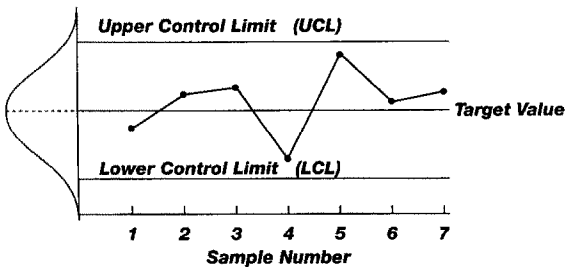

Fig. 1. Statistical process control chart.

characteristic of each production step. This variation is due either to chance or to traceable causes. The chance variation is known as the natural tolerance of a process. Non-random causes of variation may be related to malfunctioning or deteriorating equipment, lack of uniformity of raw or intermediary materials, different workers, etc. Statistical quality control is employed to help separate random from non-random variation, thereby assuring greater continuity and process control. A process is said to be in control if the source of variation is only from random events.

Control charts track the performance at a processing step. These charts are adapted to the principles of HACCP where a central line indicates the target value for a CCP, bounded by upper and lower acceptance values or tolerance limits, as indicated on Fig. 1. A process step is considered to be in control when no cycles or trends are observed and the observations are normally distributed around the target value. Determination of upper and lower tolerance limits are normally based on the need to achieve a given specification. In this case, the population mean is given and the variance must be known. The purpose of the control chart is to identify whether the observed sample values differ from the specified target value by amounts greater than expected to be due to chance alone, i.e. tolerance. Statistical process control enables the following advantages: (1) the specifications of the final product are predictable and have a minimal amount of variation; (2) corrective actions can be quickly taken when there is evidence of deterioration, and while the output is still within the critical limits; (3) process control ensures better quality and safety at lower inspection costs; and (4) lower variation allows easier revisions of specifications. A process which is in control reduces waste, and documents long term quality/safety of a product for the producer and client.

Establishment of tolerance limits is dependent of the inherent variation of the process and the tolerance acceptable to achieve the desired levels of safety or quality. Thus, the tolerance limits for each CCP should be established based on the ability of a micro-organism to either survive a specified process at a CCP1, or to overcome the growth limiting effect of a CCP2. Only a mathematical analysis would allow evaluation of the acceptable variability among CCP2's in a a food preservation system where several growth limiting factors act together to minimise a potential hazard.

In process control, critical control points are typically associated with physical and chemical measurements such as: pressure, weight, temperature, thickness, flow rate, moisture and pH. Monitoring in real-time saves the delay of laboratory analysis, eliminates error associated with sample size and sampling, and the potential changes in sample prior to analysis. Sensors available for direct measurement of chemical parameters include: ion-selective electrodes, ion-selective field effect transistors, metal oxide gas sensors and bio-sensors. Indirect measurement of chemical and physical parameters can be obtained with fibre optic, near infrared spectroscopy, refractometry and microwave and radio frequency technologies. Applications are foreseen where real-time evaluation of sensor measurements would be analysed with a mathematical equation or model. These calculations would in-turn generate a control algorithm for direct adjustment of the manufacturing process in a feedback loop. Data from on-line sensors, statistical process control and control algorithms will increasingly be employed to assure and document that manufacturing quality and safety standards are continuously achieved.

3. Examples of how models could aid in decision making processes

Regulation promulgation. Public health authorities, including those of the EEC, USA and Australia, have stipulated that cutting rooms for chilled meat carcasses should be maintained at 10°C to prevent the growth of Salmonella and other pathogenic bacteria. This regulation could be viewed as a CCP2 in a HACCP plan. The CSIRO Division of Food Research (Smith, 1985), has used bacterial growth models to demonstrate that strict reliance on environmental temperature is not the most important facet of abattoir management and hygiene. Models were developed to relate the lag time and growth rate of coliform bacteria in fresh meat to temperature in the range between 10 and 40°C.

The lag times and growth rates predicted for coliforms were slightly more rapid than those observed for the coliform bacteria, and for *Salmonella typhimurium* and *Escherichia coli* (Table 1). The time and temperature relationships described by

Table 1
Predicted [a,b] and observed lag (and generation) times (h) for coliform bacteria on meat and the implications for codes of practice in abattoirs (after Smith, 1985)

Temp °C	Predicted coliforms	Observed		
		Coliforms	*E. coli*	*S. typhimurium*
25	1.8 (0.7)	1.9 (0.8)	2.0 (0.8)	1.8 (0.8)
20	2.9 (1.3)	3.0 (1.5)	3.2 (1.4)	3.4 (1.6)
15	5.9 (2.6)	5.9 (2.6)	6.1 (2.6)	7.0 (2.7)
10	17.3 (7.9)	23.3 (6.7)	27.0 (6.9)	45.0 (9.7)

[a] $T = 3.40 + 18.58\sqrt{R}$ ($r^2 = 0.98$), where R is generations per hour.
[b] $T = 3.00 + 29.09\sqrt{L}$ ($r^2 = 0.96$), where L is lag time (h).

the model were used to support the proposal that abattoir temperatures should be regulated based on the processing times during which the number of coliform bacteria do not increase. Thus, the formulas above could be used to relate the efficiency of a manufacturing process to an appropriate environmental temperature required to maintain product hygiene. These modifications were suggested to improve worker comfort, reduce occupational hazards and energy costs, without compromising product safety. Increasing cutting room temperatures to match processing time of chilled meat, must be accompanied by the good manufacturing practices of systematic movement of product across the cutting room, rapid chilling of cut meat and periodic cleaning. McClure and Roberts (1992) note that this model is currently being applied by the food industry.

Critical control point development. Rapid cooling of meat and offal after slaughter reduces the opportunity for the growth of pathogenic bacteria, thereby minimising a potential health hazard. Therefore, control of cooling time and temperature is critical. Gill and collaborators have presented a temperature function integration technique to assess the hygienic adequacy of meat cooling processes (Gill, 1986; Gill et al., 1991a,b; Reichel et al., 1991). Models for the growth rate of *E. coli* in media were developed for both aerobic and anaerobic conditions (Reichel et al., 1991). Comparison of observed to predicted growth, demonstrated that 76% of calculated proliferation values were within one generation of the value determined by bacterial enumeration. Sixty percent of these values predicted faster growth than observed. All predictions where growth differed by greater than one generation from the observed, erred toward over estimation. Fewer than 8% of predictions differed by 1.5 generations, and no predictions resulted in greater than 2 generations difference. The authors note that plate count methods are subject to error in the range of 1 generation.

This model (Reichel et al., 1991) of the effect of temperature on *E. coli* growth was used to characterize the potential for pathogen growth during meat cooling after slaughter. Proliferation values were calculated from time/temperature histories observed at commercial abattoirs known to demonstrate exemplary use of Good Manufacturing Practices. The cooling temperature histories measured were used to calculate the number of bacterial generations which would be expected in good facilities under proper management. These proliferation values were suggested as being an objective and practical criterion to set general standards for hygienic control. The results suggest, that an evaluation of hygienic conditions in a plant can be determined from the cooling temperature histories from a minimum of 20 random samples. Hygienic adequacy would be characterised by processes where the average number of calculated generations would be 7 or less, and where 80% of samples resulted in ≤ 10 generations. Greater than 14 generations in any single sample would be indicative of poor hygienic control. Processors could use the number of permissible generations as a criterion to identify CCP2's and validate their implementation of HACCP. Authorities would in turn be able to evaluate the hygienic standards of many types of slaughter processes based on biological rather than on environmental parameters.

Table 2
Prediction of a_W [a,b] for multicomponent food in the high moisture range (a_W 0.90–1.00) (after Nieto and Toledo, 1989)

Fish sausage recipe	a_W	
	observed	predicted
1	0.970	0.973
5	0.960	0.961
10	0.943	0.944
15	0.928	0.932
20	0.912	0.914
25	0.891	0.900

[a] Post processing a_W is predicted from weights of dry ingredient per 100 g water in the final formulation.
[b] $a_W = c_1 - c_2(\text{NaCl}) - c_3(\text{NFDM}) - c_4(\text{NaCl} \times \text{NFDM}) - c_5(\text{Lard})$; NFDM, non-fat dry milk.

Formulation optimisation and on-line control. Precise a_w adjustment is essential for the safety and quality of many high moisture, shelf stable and refrigerated products. These products typically have an a_w greater than 0.90 and a pH > 4.6. Mild heating treatments eliminate vegetative microorganisms, while a combination of hurdles, e.g. a_w, salt in water phase, pH, refrigeration, etc., control microbial out-growth of spores. A model for the preparation of a shelf stable fish sausage based on the a_w reducing capacity of soluble and insoluble ingredients and their interactions has been developed (Nieto and Toledo, 1989). A factorial design considered the effect of the primary components, fish (85 g, 77.0% moisture), NaCl (0–9 g), non-fat dry milk (NFDM) (0–20 g) and lard (0–20 g), on the resulting a_w of the formulation. Observed and predicted a_w values for a selected number of formulations are presented in Table 2. NaCl accounted for 94.6% of the variation in the measured a_w; however, a_w reductions due to NFDM, lard and the interaction of NaCl with NFDM were statistically significant and provided microbial inhibition in the a_w range 0.92–0.97. The equations developed could predict the contribution of each insoluble solid ingredient (in dry weight per 100 g water) to the final a_w after processing.
The application of this type of formula optimisation model in a HACCP plan could be envisioned. For example, if the moisture of a raw material was to vary, then the precise control of a_w of the final product could be affected. It is currently feasible to continuously monitor moisture during production. The percentage of water in a raw material could then be used to calculate the optimum formula, and control the additions of a_w depressing ingredients to ensure that the final product specifications are achieved.

4. Risk assessment

Predictive microbiology as a screening technique. Consumer perception, legislative response, special interest groups, and company marketing departments all demand

less use of preservatives including salt. In the meantime, the market for high-quality, 'fresh', convenience foods is increasing. The introduction of novel food processes and packaging systems, also introduces new risks. Food processors must be able to address and defend the safety of their products, especially as their responsibilities are being extended unto its use by the consumer. Challenge tests are used to assess risk in a food product, by simulating storage conditions with inoculated samples. These tests are perceived as a source of experimental documentation of a product's safety.

Databases are being developed to predict the survival and growth of selected bacteria in culture media as affected by basic factors such as pH, a_w, salt and temperature. Combinations of these and other growth limiting factors are increasingly being sought to inhibit the growth of microorganisms in food products. Validation of the ability of databases to predict the survival and growth of microorganisms in selected foods is very important. Demonstrating the utility for predictive microbiology will encourage further factorial designed research with different types of base medium (i.e. meat, starch, etc.), inhibitory ingredients and physical processes. Eventually, models could be compiled for general use as a developmental aid for the assessment of the safety of new food formulations. Accurate predictions should eventually reduce challenge tests designs, providing cost and time savings. Good correlation between predicted and observed values will help to validate challenge test results, thus, minimising the need for extensive replication.

Use of a database in risk assessment. Vacuum and modified atmosphere (MA) packaging effectively help preserve the quality of fresh fish. They allow for extended shelf life, adding to the convenience of the product. However, the concern that psychrotrophic strains of *Clostridium botulinum* could grow and produce toxin in the absence of organoleptic spoilage limits the use of this technology. The need for general guidelines to regulate this technology is clear as there are many types of fish originating from different sources, processed, and packaged using various technologies, and exposed to a wide range of time/temperature conditions during distribution and sale.

Many inoculated pack studies have been conducted with MA package fish (Reddy et al., 1992). A database could be created from these data and challenge study results from independent laboratories. In turn, this database could be used to define 'fail-safe' guidelines for marketing of high quality fresh fishery products based on the type of MA packaging used and on storage temperatures. The feasibility of developing such guidelines has been demonstrated by the modelling data from a series of inoculated pack experiments (Baker and Genigeorgis, 1990). The experimental designs and data analysis were presented as being representative of a 'worst-case-scenario'. The resulting model defined a 'fail-safe' region, which effectively separated safe storage conditions from the times to toxicogenesis in MA packaged fish published by other research groups.

It will become increasingly difficult to evaluate individual challenge tests without such a database. For example, a study was presented at the Second Annual

Research Conference of the National (USA) Center for Food Safety and Technology (NCFST) to evaluate the safety of tilapia fillets inoculated with *C. botulinum* type E packaged under vacuum and an atmosphere composition of 75% CO_2 and 25% N. The results compared time to spoilage with time to toxicogenesis for samples stored at 4, 8, and 16°C. The time before toxicogenesis predicted at 8 and 16°C by the model described above (Baker and Genigeorgis, 1990), matched the time to toxicogenesis observed in the tilapia. The NCFST concluded that the results presented for the tilapia challenge study would need to be confirmed before a recommendation could be made. The question arises: How many times will this type of challenge test need to be repeated before each individual processor is able to gain approvals? A 'fail-safe' guideline could be used to regulate this type of product. The use of challenge testing would then be reserved for demonstrating when novel processes are significantly safer than the general standard, i.e. processes which use secondary barriers to limit pathogen growth.

Fail-safe marketing strategies. Shelf lives of 35 to 45 d at 8°C are normal for certain commercial meat emulsion products, e.g. liver sausage. The safety of these products with respect to *C. botulinum* relies on a combination of factors in addition to refrigeration. Challenge tests were conducted to evaluate how formulation and processing developments would affect product safety. Available databases or models contained the factorial information necessary to help with these evaluations. The challenge tests were designed to compare the incubation times and temperatures required for packages inoculated with *C. botulinum* spores to become toxic, compared to the abusive storage conditions considered possible during distribution and mishandling by retailers and consumers.

Thermal abuse may be additive as a product passes through distribution, to the retailer and is finally stored by the consumer. Continuous storage at 12°C for 45 d (1.3 × shelf life) was an important criteria to simulate long-term, low-temperature abuse. High-temperature thermal abuses included: the careless storage of product at 16°C for 20 d at the retail level and/or by the consumer; and accidental short-time and high-temperature thermal abuses such as 20°C for 1 d, or 25°C for 0.5 d, as might occur by taking the product on a picnic, leaving it on the kitchen counter on a summer day, or in a hot car.

The challenge tests demonstrated that the mishandling conditions cited above would not directly lead to a health hazard (Fig. 2). Greater than 2 d of abusive storage at 25°C were required before toxin was detected. This abuse was at least 75% longer than the 12 h considered likely. Products remained safe for 7–10 d of 20°C storage. Toxin was not detected in any of the products even after storage for 30 d at 16°C. Although such storage conditions would be contrary to distribution, retail sale and label instructions for such a product, the abuse scenario represented conservative limits for which product safety is not impaired. Using this abuse scenario as a 'fail-safe' boundary for the evaluation of these challenge tests was a conservative approach. Surveys of food temperatures in retail and household refrigerators rarely found storage temperatures as high as 16°C (Harris, 1989; Evans et al., 1991; Van Garde and Woodburn, 1987). Thus, these challenge test

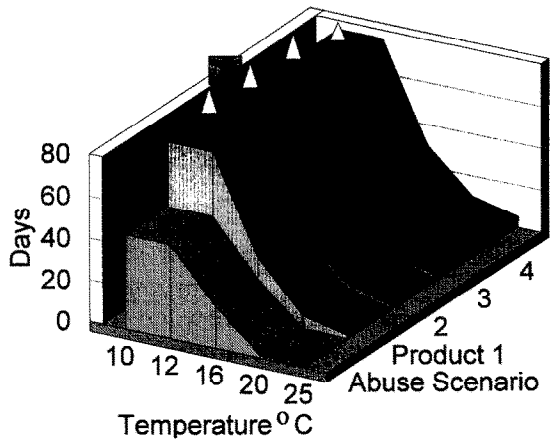

Fig. 2. Comparison of 'fail-safe' thermal abuse scenario with a challenge test of products inoculated with *Clostridium botulinum* spores. (a) Products inoculated with 10^4 proteolytic *C. botulinum* spores from a pool of types A, B and F. (b) No toxicity was observed at the end of storage.

results support the safety of a product heavily contaminated with *C. botulinum* spores, well beyond what may be considered reasonable commercial or consumer storage abuses.

Times and temperatures used in challenge tests must be selected to reflect the regional capabilities to maintain refrigeration during distribution and retail, and conditions of consumer use. There must be a balance between the storage temperatures expected and an appropriate level of secondary barriers used to prevent bacterial growth. A future database could tabulate surveys of refrigeration practices and consumer habits in local markets. This information would help producers and regulators determine the degree of thermal abuse expected in a given market, and the "fail-safe" boundaries appropriate to limit the risk from a potential hazard. In a documented risk analysis, safety should be demonstrated giving consideration to the products "particular characteristics, with a view to being properly informed of risks which these products might present" and the "use to which the product could be put" (Van Schothorst and Jongeneel, 1992). Such a practical risk assessment should fulfil the intent of the EEC directives concerning liability for defective products (85/374/EEC).

5. Conclusion

More than any other single person in a company, the food microbiologist needs to be aware of the variables influencing the safety of a product, i.e. raw materials, processing, production conditions, packaging, distribution, storage and use by the consumer. Increasingly, these individuals are being called upon to develop plans to assure that a product can be safely marketed. Databases, models and expert

systems will help these specialists to better utilise the vast knowledge available to rapidly conduct an in depth hazard analyse. The effort invested in HACCP plan development is a cost effective consumer protection method and an insurance policy against potential legal action, financial loss, and negative publicity which might result from safety deviations. The HACCP plan documents the overall safety designed into the production of a food and specifies why the monitoring of CCP's ensure that safety objectives are achieved.

The potential for predictive microbiology to offer decision support and aid in process optimisation is the subject of extensive research worldwide. A limited number of publications have begun to demonstrate practical applications for databases, modelling, and expert systems; more will certainly follow. The design of experimental methodology to predict bacterial growth in foods is believed to be a quality improving technology. Expanding the knowledge base of microbial responses to environmental stresses is being pursued with the goals to optimise product and process designs, and accelerate technology transfer from research to manufacture at a lower development cost. Designing quality/safety into products and processes should reduce the need for expensive inspections, while providing the greatest assurance that a safe product, adapted to consumer use, will be marketed.

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