than liqueurs prepared with other caseinates (3, 5 and 6). While no relationship was evident between the calcium content of the caseinate and the increase in apparent viscosity of cream liqueurs during storage at 45°C, electrostatic interactions appear to be important; the different effects of the reducing agent also suggests a role for sulphydryl groups in the apparent viscosity increases. Previous work has indicated that modification of caseins can occur during caseinate manufacture[8,18]; differences in the level or type of modification may contribute to differences in caseinate related increases in the apparent viscosity of cream liqueurs on storage.

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# Putting HACCP into practice

R EARLY
Harper Adams Agricultural College, Newport, Shropshire TF10 8NB, UK

*Food manufacturers have the responsibility to protect consumers from foodborne hazards. The Hazard Analysis Critical Control Point (HACCP) method of food safety control is accepted as the best way to assure consumer safety in the production of foods. It is a preventive approach to food safety management and, in practice, requires the completion of 14 stages which result in the development, implementation and maintenance of HACCP systems. Effective use of HACCP gives food manufacturers greater confidence regarding consumer safety, compliance with legislation and ability continuously to improve food safety control.*

Review.


## Introduction

Food manufacture is not without risk for the consumer. During the last decade or so, the trend in food poisoning incidents has been seen to rise nationally. It may be that more people are reporting food poisoning than in the past, but factors such as the increase in consumption of industrially processed foods, changes in the way we take our meals, with more meals eaten away from the home, and the intensification of agriculture may also contribute to the problem.

That food manufacturers carry a great responsibility for the safety of consumers is undeniable and, in this, the dairy industry is no exception. Milk may transmit a variety of pathogens[1] and although some traditional milk products continue to demonstrate the occasional presence of food poisoning microorganisms, eg, *Listeria monocytogenes* in soft and semi-soft cheeses,[2] on the whole, milk products have a good safety record. This is due mainly to pasteurization, which was introduced to combat milkborne disease.[3,4] Unfortunately, food poisoning outbreaks involving the dairy industry do occur and it is reported[5] that from 1985 to 1989 almost 2000 people in England and Wales were affected by foodborne disease associated with milk and milk products. Incidents concerning the contamination of milk powder by *Salmonella* spp[6] and hazelnut yogurt by *Clostridium botulinum*[7] were extremely serious and well reported by the news media, with the latter incident causing a 25% fall in yogurt sales over many months.[8]

In recent years the Food Safety Act 1990 has served to focus attention on the protection of consumers, and with the Act has come a particular understanding of the terms 'reasonable precautions' and 'due diligence'. Consequently, the contribution of formal quality assurance systems to food safety management has been recognized. As with quality management, prevention has become the byword for food safety management. In seeking to comply with the requirements of the Food Safety Act, and to ensure ability to mount a competent defence in the event of prosecution under the Act, many food manufacturers have implemented Hazard Analysis Critical Control Point (HACCP) systems. As a preventive approach to food safety management, HACCP is widely regarded as the best method of securing consumer safety.[9] It is also an approach to food safety management which is entirely compatible with systematic methods of quality assurance, such as that advocated by the ISO 9000: 1994 series of quality system standards.[10]

## THE HACCP SYSTEM

The HACCP method of food safety management has been in existence for some 30 years. It was developed for the American space programme by the Pillsbury Company working in conjunction with the National Aeronautics and Space Agency (NASA), the US Armed Forces Natick Laboratory and the US Air Force Space Laboratory Project Group.[11] The purpose of HACCP was to ensure the production of defect free foods for astronauts, who might otherwise experience certain difficulties if subjected to food poisoning in a zero gravity environment a long way from medical attention. Given that HACCP has been available to the food industry since the 1960s, it is surprising that few food companies have sought to use the approach until recent years. Although it has taken time to achieve general acceptance, HACCP is now advocated by the US National Advisory Committee on Microbiological Criteria for Foods,[12] the Codex Committee on Food Hygiene[13] and the European Communities Council.[14] In the UK the use of HACCP is implied by the Food Safety (General Food Hygiene) Regulations 1995, under the Food Safety Act 1990. No standard exists for the practice of HACCP, although the seven Principles of HACCP (Fig. 1) which define the application of HACCP are recognized internationally, and there is an argument for the harmonization of HACCP methodology through training.[15] As with use of the ISO 9000:1994 quality system standards, which should be interpreted to meet the needs of particular businesses,[16] the seven Principles of HACCP should be interpreted to meet food safety requirements according to the circumstances of specific products and processes.

## THE PRACTICE OF HACCP

HACCP is a systems approach to food safety management and pragmatic interpretation of the seven Principles leads to the recognition of three phases in the process of HACCP:

- Hazard Analysis concerns information gathering and decision making about a product and its manufacturing process, the identification of hazards and the selection of points and methods for control;
- the output of Hazard Analysis is the HACCP plan, which is implemented as the HACCP system;
- on confirmation of satisfactory implementation, the HACCP system is operated, maintained and developed to assure food safety.

In practice, the phases are transformed into 14 stages which must be completed systematically if an effective strategy for food safety management is to be realized.

### Stage 1: Agreeing the scope of assessment

A HACCP assessment should concern only a specific food product and its associated manufacturing process. The first stage of Hazard Analysis is to define the scope of the assessment. Milk manufacturing processes are often long and involved, containing a number of unit operations and having many inputs and outputs. It is easy to attempt a large analysis without realizing the complications that will be met: especially when the concept of HACCP is new and unpractised. Consequently, it is better to break the manufacturing process into manageable pieces and to analyse successive stages in the overall process. Each stage can be considered to have a customer–supplier relationship in much the same way that the overall business process is a customer to external suppliers. This concept fits well with the concept of the total quality chain running through the business, and it may later be possible to bring the results of separate analyses together in a single HACCP plan. Take, for example, cheddar cheese production. The scope of assessment of cheddar cheese production could extend from the cow to the consumer. The agreement of such a scope would result in a mammoth task. If it were necessary to exercise food safety control from the cow to the consumer, then the process could be broken into five distinct stages:

- the production of raw milk and delivery to the creamery;
- raw milk reception and processing;
- the production and maturation of cheese;
- the grading, selection and prepacking of cheese;
- the distribution and supply of prepacked cheese.

In practice, however, consideration would be given to the degree of control the owners of the HACCP might be able to exercise over different stages of the process. If the creamery is the owner of the HACCP, then it is likely that no more control can be exercised over milk production than over any other purchased product, eg, rennet, annatto, salt. Equally, control of the distribution and supply activity may be delegated by contract to a distribution subcontractor. So, the effective scope of the assessment and resulting HACCP plan would be from raw milk reception to the despatch of prepacked cheese. Food safety issues which exist outside the scope would then be managed by the agreement of specifications with suppliers, the inspection and testing of incoming purchased materials and supplier assurance audits, etc. Clearly, as far as raw milk is concerned, recognition would be given to the possible existence of pathogens in the milk and control would be exercised through pasteurization by the creamery.

### Stage 2: Selecting the HACCP team

The Hazard Analysis should be carried out by a HACCP team, which will also prepare the HACCP plan and oversee implementation of the HACCP system. Clearly, the HACCP team should have relevant knowledge of the product and process under assessment. For team composition most authorities recommend a core team of a qualified food technologist, with appropriate knowledge of microbiology if a qualified microbiologist is not available, and also a production specialist and an engineer. People with specialist expertise may also join the team and not necessarily for the entire assessment, but for as long as their skills are needed. The presence of production operators

**Principle 1**
Identify the potential hazard(s) associated with food production at all stages, from growth, processing, manufacture and distribution, until the point of consumption. Assess the likelihood of occurrence of the hazard(s) and identify the preventive measures for their control.

**Principle 2**
Determine the points/procedures/operational steps that can be controlled to eliminate the hazard(s) or minimize its likelihood of occurrence - (Critical Control Point (CCP)). A "step" means any stage in food production or manufacture including agricultural practice, raw material receipt, formulation, processing, storage, transport, retail and consumer handling.

**Principle 3**
Establish targets and tolerances which must be met to ensure that each CCP is under control.

**Principle 4**
Establish a monitoring system to ensure control of the CCP by scheduled testing or observations.

**Principle 5**
Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

**Principle 6**
Establish procedures for verification which include supplementary tests and procedures to confirm that the HACCP system is working effectively.

**Principle 7**
Establish documentation concerning all procedures and records appropriate to these principles and their application.

Fig. 1. The 7 principles of HACCP. Adapted from: Joint FAO/WHO Codex Alimentarius Commission. 1993. Guidelines for the application of hazard analysis critical control point (HACCP) system. In *Training considerations for the application of the HACCP system to food processing and manufacturing*, pages 17 & 18. Geneva: World Health Organization, WHO/FNU/FOS/93.3.

should not be overlooked. One of the team members should act as Team Leader, responsible for coordinating the team, establishing timetables, setting objectives for the team and individuals, collating the results of separate activities, etc. A key role for the Team Leader is communicating with senior management. It is important that senior managers are kept informed of progress and are minded to provide resources as necessary.

For some companies, particularly smaller businesses, difficulties often arise in finding enough suitably qualified and/or experienced people to form a team. Consultants may be the solution and may be used to address specific issues. Alternatively, training should be considered as a means of bringing knowledge to the team. For example, a team member may complete an advanced food hygiene course in a relatively short space of time, gaining a sufficient understanding of issues of microbiology, hygiene and food safety to compensate for the lack of a specialist microbiologist.

**Stage 3: Understanding the product**

It would be interesting to know how many dairy companies, large and small, really understand the products they make! When carrying out a Hazard Analysis, a complete understanding must be gained of the product under assessment and of any issues which may bear on food safety. This means considering:

- the composition of the product and the specification to which it is made, ie, chemical, microbiological, physical standards;
- factors affecting microbial growth in the product, eg, storage temperature, pH, water activity ($a_w$), redox potential (E*h*), relative humidity (RH), modified atmosphere packaging (MAP), etc;
- the components of the product, ie, raw materials, ingredients and packaging, their sources, and the possibility of hazards being imported with purchased products;
- factors affecting microbial growth during the storage of purchased products, eg, storage temperature, pH, $a_w$, E*h*, RH, MAP, etc.

An assessment must be made of all factors which might affect the food safety of the product. For example, the introduction of a pathogen via an ingredient, which, although dormant in the ingredient, finds favourable growth conditions in the environment of the product. In the absence of first-hand experience, an understanding of the hazards associated with raw materials, ingredients and packaging, and with milk products themselves, can be gained by reviewing epidemiological data. Although food safety incidents may not have been reported for a specific product, they may have occurred with similar products or with products of an entirely different nature, but based on the same raw materials and ingredients. Lateral thinking is required. As well as reviewing the literature, suppliers of purchased products should be able to advise on food safety issues. Products themselves may be tested microbiologically to detect the presence of pathogens or indicator organisms and challenge testing can provide insight to the risks associated with products. Chemical and physical analysis can also be used to determine whether the conditions are suitable for microbial survival and growth, eg, pH, $a_w$ and E*h*.

The process of understanding the product will necessitate the review of product specifications and purchasing specifications. In the event that specifications have not been kept up to date or, indeed, do not exist, then HACCP should provide the impetus to bring necessary documentation to order.

**Stage 4: Understanding the product's use**

While dairy companies may make products that represent no risk to the consumer up to the point of purchase, it is possible that product abuse by the consumer may create a risk. An assessment must be made of the likelihood of a hazard developing during storage and use of the product by consumers. For example:

- What might be the chances of low levels of *Listeria monocytogenes* growing to dangerous levels in a soft cheese stored under warm or cool conditions rather than chilled conditions? Or, indeed, as *Listeria monocytogenes* is non-competitive, what might be the chances of the microorganism developing to dangerous levels in a soft cheese stored too long under chilled conditions?
- To what extent might phthalate migrate from a plastics packaging material into a fatty food stored for a period of time by the consumer, and to what degree might the consumer be at risk?
- What might be the chances of damage to ultra high temperature containers causing leaking seams, through which pathogens may enter and grow?

Recognition of the hazards which may occur due to consumer actions allows food manufacturers to formulate suitable advisory information for use in educating consumers on matters of food hygiene and food safety. Importantly, the responsibility of consumers for their own health and safety is made clear.

In addition to assessing the hazards which may occur during product use, the hazards of food components to sensitive groups should also be considered. Formulated foods may be made from a variety of ingredients, some of which may be allergens. Foods containing wheat protein are hazardous to people with coeliac disease and nuts are known, in some instances, to promote allergic reactions. Nuts can also choke young children and infants. Shell fish and some food colourings are known to cause allergic reactions. Food manufacturers are responsible for knowing whether their products represent a hazard to sensitive groups and for ensuring that consumers are warned appropriately, usually through labelling, if a risk exists.

**Stage 5: Mapping the process flow**

Having considered the product, attention should be turned to the process. A detailed examination of the process covered by the scope of assessment should be carried out to identify the points or places where hazards may either be introduced to, or arise within the product. For example, pathogens may enter the process with ingredients, they may survive certain heat treatments and they may be encouraged to grow if product is held for sufficient time at a suitable temperature. To assist in thinking and judgment in the identification of hazards, a map or flow diagram is required of the process under assessment. The process flow diagram should be drawn using all relevant information, eg, architectural plans, engineering drawings, first-hand knowledge of the process, etc. The flow diagram should detail all of the inputs to and outputs from the process as well as data concerning processing conditions, eg, temperature, time, pH, $a_w$, RH, gas tension, etc.

**Stage 6: Confirming the process**

While the process flow diagram can be prepared in an office, it cannot be confirmed as accurate except by 'walking the process'. This means following the process from start to finish, according to the agreed scope, and examining every aspect of every activity undertaken as part of the process. In some respects confirmation of the process is like quality assurance auditing, in that objective evidence is sought that what is supposed to be happening is in fact happening. In this instance, however, the documentation may be revised to comply with existing practice, rather than the other way round. The features of the process under consideration may vary in nature. Some may consist of plant and equipment, others may consist of practices carried out by staff. All should be examined and an accurate record should be made of inputs, outputs, process flows, processing conditions such as temperature, time, pH, etc.

Processes can be subject to change and the changes may not be reflected in documentation, so a true understanding may not be reached until this stage of the Hazard Analysis has been completed. When walking the process, every effort should be made to detect unauthorized changes as well as authorized changes which have not been documented. Judgment may be needed at times to determine whether unrecorded changes are detrimental to product safety and quality, as well as to production efficiency and costs. Sometimes a detailed technical analysis may be necessary to determine the full implications of changes.

**Stage 7: Identifying hazards and deciding preventive measures**

When all of the information and data concerning the product and the process, generated in stages 3, 4, 5 and 6, is assembled, then hazards associated with the product and process can be identified. The hazards may be biological, chemical or physical in nature. Microbial hazards of significance to milk include *Mycobacterium tuberculosis*, *Coxiella burnetii*, *Salmonella* spp, *Campylobacter* spp, *Listeria monocytogenes*, *Escherichia coli* O157:H7, *Staphylococcus aureus* and *Clostridia* spp. Clearly, in the production of formulated foods, other pathogens may be significant, as the result of contaminated non-dairy ingredients. Other biological hazards include pests, such as rodents, insects and birds, as they may carry pathogens and have the potential to contaminate products, processing equipment and the production environment. In this context, people should also be considered as a major source of potential hazard. The possibility of microbial hazards entering foods from the production environment is a major consideration for most dairy businesses, as during the handling of liquid milk, production environments are often wetted. Production environments should be well surveyed for sources of hazard, as should plant and equipment. Appropriate tests such as crack tests on spray dryers[17] should be used to highlight sources of hazard.

A wide variety of potential chemical hazards may be associated with the manufacture of dairy products. They include agro-chemicals, veterinary chemicals and cleaning chemicals used on the farm, mycotoxins and pesticide residues finding their way into milk from feedstuffs and cleaning chemicals and analytical chemicals used in processing dairies. A variety of sources of potential chemical hazard exist within the milk chain and all should be considered, though some may not be so obvious, eg, getter elements in fluorescent light tubes and monomers in plastics packaging. As with chemical contaminants, there is a diversity of physical hazards which have the potential to affect milk products and which should be considered. They include glass derived from the farm or the factory, metal fragments falling off plant and equipment or remaining after engineering activity, sample pots broken in the production environment, plastics from packaging materials, etc. By working methodically through the information and data concerning the product and the process, in conjunction with general knowledge of food safety issues concerning dairy products and other food materials of relevance, and by using sources of epidemiological data, real hazards and potential hazards may be distinguished.

**Stage 8: Deciding where the critical control points are**
When the hazards have been identified the Critical Control Points (CCPs) must be identified. CCPs may be points, operations and places in the process and their identification is a matter of logic as the following questions should be answered: (1) Do preventive measures exist? (2) Is the step specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level? (3) Could contamination with identified hazards occur in excess of acceptable levels or could these increase to unacceptable levels? (4) Will a subsequent step eliminate identified hazards or reduce likely occurrence to an acceptable level?

The use of an HACCP Decision Tree to assist the identification of CCPs is recommended by Mayes,[18] the Campden Food and Drink Research Association[19] and Food Linked Agro Industrial Research.[20] Some authorities also recommend the classification of CCPs. The International Commission on Microbiological Specifications for Foods[21] advocates CCP1 where hazards can be eliminated and CCP2 where they can only be reduced to acceptable levels. The International Association of Milk, Food and Environmental Sanitarians[22] promotes the use of CCPe where hazards are eliminated, CCPp where hazards are prevented but not necessarily eliminated and CCPr where hazards are not eliminated or prevented, but are reduced, minimized or delayed. To avoid confusion, the classification of hazards should be undertaken with care: especially when experience with HACCP is limited.

**Stage 9: Setting critical limits**
Targets and tolerances, which define compliance with product and processing standards should be set for the CCPs. Legal requirements must, of course, be observed. Targets and tolerances may concern one or more parameter for a CCP and must relate to any preventive measure or process step which demonstrates that the CCP is under control. Examples of parameters which are commonly measured in the dairy industry are temperature, time, flow rate, weight, moisture level, pH, $a_w$, available chlorine, as well as various microbiological parameters.

**Stage 10: Monitoring**
Monitoring requirements for each CCP should be established. Monitoring may be defined as a planned sequence of measurements or observations which demonstrate that a CCP is either under control, or that control has been lost and must be restored immediately. Monitoring may be in-line, on-line or off-line. It should be remembered, however, that the longer it takes to obtain the results of monitoring activities the more problematical may be control of the hazard. Monitoring activities such as off-line microbial testing can take some days, during which time the product must be regarded as potentially non-conforming. Such product cannot easily be released to customers until confirmed as satisfactory, unless positive recall procedures are in place.

**Stage 11: Preventive and corrective action**
Preventive and corrective action plans should be established for each CCP. The plans should define:

- how to prevent loss of control when evidence suggests such a possibility, and
- how to return control when loss is confirmed.

Preventive and corrective action plans should be supported by procedures for the identification, segregation, inspection and testing, and use of product arising during periods when CCPs are out of control.

**Stage 12: HACCP plan implementation**
Throughout the HACCP assessment, product information and data, process information and data, details of hazards and the requirements for hazard control should be documented, as appropriate, in purpose designed forms. The process flow diagram will, of course, also be documented. This then forms the basis of the HACCP plan, which defines the requirements for food safety management. The plan itself may be a document which lists the CCPs, identifies the hazards and defines targets and tolerances, control requirements, monitoring requirements and preventive and corrective action requirements. Personnel responsible for control, monitoring and preventive and corrective action activities should also be identified. When the HACCP plan is complete it needs to be implemented. Depending on complexity, however, implementation may be entire or section by section, according to judgment.

**Stage 13: Verification**
Verification requirements should be established, and verification should be carried out to confirm that the HACCP system is working according to plan. Verification should concern specifically the control of CCPs, compliance with targets and tolerances, the effectiveness and suitability of monitoring activities and the effectiveness and suitability of preventive and corrective action. During verification, evidence should be gathered to confirm that the plan is suitable for the product and process concerned. Modification of the plan and the system may be made according to the results of verification. Verification activities should normally be scheduled although, in the event of unexpected problems arising, unscheduled verification may be undertaken.

**Stage 14: Maintenance audit**
A full audit of the HACCP plan, the HACCP system and all associated documentation should be carried out at least once a year. The

purpose of audit is to confirm that the strategy for food safety encompassed by HACCP continues to be suitable for its purpose. As the result of audit, however, the HACCP system may be developed to meet the requirements of new and changing circumstances. This may mean partial or full reassessment and appropriate revision of the plan.

## CONCLUSIONS

That HACCP is here to stay is unquestionable and certainly, with the increased concern that the BSE (bovine spongiform encephalopathy) crisis has generated regarding food safety throughout the food chain, HACCP is likely to become an ever present feature of the path from the field to the table. The dairy industry represents a major section of that path and has a well earned reputation for providing quality products which are safe to eat. The industry is dynamic though, and in recent years many dairy companies have sought opportunities outside the core business of milk processing. In addition to milk, they now handle a variety of non-milk food materials which bring new and often significant problems. Given the evolution the industry in recent years, the scope of the industry today and now increased consumer concerns about food, the logic of HACCP cannot fail to appeal as a means of assuring the industry's continued good reputation. Consequently, we should expect to see all dairy businesses, great and small, using HACCP as a key part of their overall quality assurance strategy: for their own benefit and for the benefit of consumers.

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