HACCP in the dairy industry

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Most dairy products have an excellent safety record, due to well-controlled processing conditions. The main potential hazards are microbiological. Pasteurisation, however, has proved to be successful as a CCP to control classical zoonoses as well as newer foodborne pathogens. Chemical hazards are less important and have in most cases been taken care of by the suppliers of raw materials. Physical hazards are related mainly to packaging. The dairy industry uses a variety of technologies (e.g. heating, drying, chilling, freezing, curing, fermenting), but the HACCP concept can be successfully applied in all types of production lines. The WHO text is used as background document for some comments specific to the dairy industry.

Keywords: HACCP; dairy industry; overview

INTRODUCTION

The dairy industry has many years’ experience with the basic principles of HACCP. The fact that brucellosis, tuberculosis and some other zoonoses can be milk-borne was already known in the last century, and the boiling of milk before consumption was recognized as an effective preventive measure. Pasteurization was introduced in the dairy industry partly to combat these diseases, and heating requirements took into account the heat resistance for these zoonotic agents. In HACCP terminology, *Mycobacterium bovis* was identified as a potential hazard, pasteurization as a critical control point (CCP) and critical limits were established to ensure reduction to acceptable levels. Later *Salmonella*, *Campylobacter* and *Listeria monocytogenes* were added to the list of potential hazards in raw milk, and mandatory pasteurization has been proven to be an essential preventive measure (Sharp, 1986).

The dairy industry has two distinguishing features. First, although it uses many different processes such as concentrating, drying, fermenting, freezing and canning to manufacture a wide variety of products, its main raw material is a single, primary agricultural product. Second, a killing step can be applied to control many potential microbiological hazards without significantly changing the product.

This article will discuss the principal aspects of HACCP in this industry. It emphasizes the application of the system, as described by Codex (1993), and not the details of its implementation.

LOGICAL SEQUENCE FOR THE APPLICATION OF HACCP

The WHO text (WHO, 1993) should be read as a complement to this text; it provides complete background information on HACCP. Some more general remarks and some particularities of the dairy industry are given below.

Assembly of HACCP team

Apart from the ‘normal’ participants in a HACCP study, a representative of the agricultural service or purchaser should participate. Close contacts with the farmers or their cooperatives have always been normal in dairy operations. Educational programmes to improve hygiene have been carried out in most countries, often by or with assistance from the dairy factory or industry. In most, if not all dairies, someone is familiar with, or has access to information concerning

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the agricultural practices applied in the milk collection area. This knowledge is essential in a HACCP study.

Description of the product

The dairy industry is perhaps unique in terms of the length of its experience with many of its products. Cheeses and yoghurts have been produced for thousands of years; condensed milk was already industrially produced more than 100 years ago. Most dairy products have an excellent safety record, indicating that the normal manufacturing practices are safe. However, other factors such as changing technology, less acidity, new consumer demands – for fewer preservatives and calories, longer shelf-lives and more ‘natural’ products – have to be taken into account. New tastes and flavours may introduce new hazards; for instance, problems with VTEC Escherichia coli and (O'Mahony et al., 1993). Also, the addition of non-dairy raw materials and ingredients may be a source of problems.

Identification of intended use

Dairy products are often intended for specific dietary use. Target consumers may be athletes who need extra proteins; members of such a group are not particularly susceptible to pathogens. However, babies, patients, the very old and in the case of Listeria, pregnant women may be more prone to acquiring a foodborne disease. The product use instructions for these consumer categories should receive particular attention.

Construction of flow diagram and facility layout

Many milk processing lines have simple flow diagrams: milk reception, cooling, standardization, pasteurization; followed by fermentation, or evaporation and drying, or holding and freezing, or sterilization. These processes are followed by packing; hygienic precautions vary at this step (aseptic conditions to completely ‘open’ filling).

Although the flow diagrams may seem simple, the flow of the product and possibilities for recontamination are not always obvious. Pumps, pipes, valves, bypasses, holding or balance tanks, conveyor belts, air handling and cleaning systems may complicate the safe manufacture of dairy products. Drains, of no interest in the past as long as they did not become clogged, are now recognized as sources of hazards. A well trained dairy operator knows how to use a water hose to clean the factory; he also has to know that sometimes water can do more harm than good.

These things have to be examined at this stage of the HACCP study. Updated drawings of all the pipes and bypasses, clean in place (CIP) lines, filters and their maintenance schemes, descriptions of pest eradication programmes, diagrams of traffic flow within the factory etc. are necessary. Normal values, as well as extremes, for temperatures and residence times should be examined. Results of line and environment monitoring should be scrutinized for indicators of potential microbiological hazards.

A HACCP study also needs data on the microbiology of the factory and its environment (Kleiss et al., 1994). Which potential hazards have found access to the line environment? Which microorganisms can be found in drains, air handling units, insulation material around pipes or even spray dryers? Can pests enter the production or storage rooms; if so, which potential pathogens could they carry and shed? For many products these questions may seem far-fetched, but at this stage it is better to raise, and answer, any potential questions.

The dairy industry is an old one, but the product range is always in evolution. A good safety record may lead to complacency (Lecos, 1986; van Schothorst, 1986), thus a very thorough analysis, which notes any information that might be useful in the future, has to be done at this stage.

On-site confirmation of flow diagram and facility lay-out

This stage may be the most important one, because action at all the following stages is based on the assumption that all potential hazards have been identified. Facility and line layout drawings are usually two-dimensional; chemical and physical hazards may be part of the three-dimensional reality. Spread and multiplication of microorganisms can be a consequence of human behaviour, or of hidden residues which are not indicated on the engineering charts. Drains which were located logically when the factory was constructed may now be inaccessible for cleaning because of new line constructions. A protective lid acting as a barrier has been removed, without noting it on the drawings. Condensation water in a dry environment can become a source of a microbiological hazard when not properly taken care of.

The documentation of this part of the study should include results of line inspections. If certain observations, which could have lead to the identification of a hazard, were not taken up for further analysis, the reasons should be noted.

Listing of all hazards associated with each step and consideration of any control measures to eliminate or minimize hazards

The presence of chemical contaminants in milk can be traced to feeding practices (aflatoxins, nitrates), animal husbandry practices (pesticides), veterinary therapy (antibiotics), pollution (lead, radioactive elements) or accidents. These factors must be controlled at the farm level: by the farmers, their associations or cooperatives, agricultural services and inspection agencies. Microbiological hazards include the classical zoonotic agents in certain regions of the world, or the more
common contaminants such as Salmonella, Campylobacter, Listeria, E. coli, Staphylococcus aureus, Bacillus cereus etc. Moulds, viruses and parasites are of less or no concern. Almost all potential microbiological hazards can be eliminated with a heat treatment (pasteurization or sterilization). B. cereus is an exception; however, illness due to this organism is unlikely to be caused by the normal use of dairy products (Christiansson, 1993; Sutherland, 1993).

The use of fruits and other ingredients in products such as ice-cream, yoghurt and white cheeses is common nowadays. They should be carefully looked at, because dairy people may be unfamiliar with their microbiology and chemistry, and because they are often added after pasteurization. Fermentation is not very effective in reducing potential microbiological hazards. Proper selection of the suppliers (based on their application of the HACCP system) and careful choice of purchasing specifications is therefore very important.

The environment of the dairy lines is an important potential source of hazards. A line is rarely a closed operation, i.e. with a continuous barrier between product and line environment from pasteurization until packing. Consequently, the potential hazards in the line and in environment need to be listed. Salmonellosis, staphylococcosis, and listeriosis have been epidemiologically linked to dairy products. However, since the production technologies vary widely, the causative microorganisms are potential hazards only in some dairy lines. Listeria is not commonly found in dry, warm environments (Cox et al., 1989). Staphylococci can be found, but are rarely a potential hazard (Kleiss et al., 1994). Preventive measures are, in all these cases, included in Codes of Good Hygienic Practices (IDF, 1994). In critical environments, specific measures may be necessary to control potential hazards. It is worth mentioning here that a HACCP system is effective only in lines where good manufacturing practices (GMP) are followed.

Other hazards which are less important, but should not be overlooked, are physical hazards and the hazards related to packaging material. The possibility of the presence of physical hazards can, of course, never be excluded. Its occurrence is unlikely because of the hygiene way in which milk is handled. Packaging material should not be a source of hazards, although returnable glass, as environment-friendly material, may pose some problems.

Establishment of Critical Control Points

Decision trees, such as the one used by Codex or those described by ILSI Europe (1993) are, in our experience, useful for keeping the HACCP study systematic and disciplined. One of the practical problems is the distinction between CCPs and control points (CPs), which are less critical in ensuring safety. Loss of control at many CPs may affect safety, and such points are usually described in codes of good hygienic practices. Decision trees are particularly helpful to decide which CPs are CCPs. The terminology of the WHO is clearer in this respect than that of the Codex. Many hygienic practices are preventive (Codex) in nature, fewer are control (WHO) measures.

The first step in the dairy industry is milk reception. The Codex decision tree begins with the question: do preventive (control) measures exist (for the hazard under consideration)? The checks carried out at this step are related more to general quality inspection than to safety assurance. Tests for antibiotic residues may be carried out to prevent problems with fermentation, although prevention of allergic reactions to penicillin is another objective. In the first case, the milk reception is a CP; in the second case, for the penicillin hazard, it is a CCP. (Assuming that by testing and sorting the hazard is reduced to an acceptable level). Usually, adherence to good agricultural practices by the farmers is considered to be a more effective control. This step is never a CCP for microbiological hazards.

The next step, cooling, is normally a CP, not a CCP. Under GMP, it is practically impossible for potential pathogens to multiply to the point that they are likely to cause safety problems. Pasteurization is the next major step. For many products, pasteurization is a CCP, but it is a only a CP in the production of evaporated milk sterilization in cans. The purpose of this step is to render the raw material(s) safe by eliminating the hazards posed by the likely presence of heat sensitive pathogenic microorganisms. The parameters to accomplish this are heating time and temperature.

Next, the pasteurized milk is cooled. Although GMP will include the necessary maintenance of the equipment, leaks in the barrier between the milk and the cooling fluid can occur and cannot always be predicted. A slight over-pressure on the pasteurized milk side controls the recontamination hazard.

The line environment before and during this step is normally not an important source of potential hazards. It is, in principle, a closed system, which is mostly cleaned in place. (The CIP system should, of course, be included in the HACCP study). Moreover, even if microbiological hazards are introduced (for instance with the addition of ingredients), pasteurization is an effective control measure.

The environment can become an important aspect of the line after the killing step. In many cases, there is no tight barrier between the product and its environment. Hygienic practices are the measures to control the hazard of recontamination, but some situations are not easily dealt with. Cleaning of conveyor belts in ice-cream production, air and dust handling in spray drying, sanitation of ripening rooms in cheese production are only a few of many examples. Trying to eliminate potential contaminants at the source is the most efficient way to control the hazards, but if the buildings or machinery are old, this is difficult. This was demonstrated with the emergence of the challenge of L. monocytogenes.
Establishment of critical limits for each CCP

Since testing of incoming raw material is not normally the means to control potential hazards, critical limits need not be established at the reception of raw materials.

Time and heating temperature are the CCP parameters in pasteurization. A minimum of 72°C for 15s is effective in reducing potential hazards in milk to acceptable levels (IDF, 1994). In many instances target levels of 73°C and higher are used instead of these critical limits. This allows for a normal variation of the temperature, without endangering product safety. An over-pressure on the pasteurized side of 0.5bar is sufficient to prevent recontamination.

Acidity or pH may be parameters necessary to prevent unacceptable growth of potential pathogens during fermentation in yoghurt or cheese production. A certain level should be reached in a specified amount of time, taking into account the specific conditions (starter culture, temperature, buffering capacity of the product etc.). Again, such limits are critical only when contamination of the product is likely (or probable, depending on the risk assessment criteria).

The establishment of critical limits to assure the control of recontamination is more difficult than those governing growth or survival of microorganisms. Recontamination is related to the build-up of 'nests' of microbes in cracks, crevices, void spaces, dead ends etc. Conditions in such 'niches', and thus numbers of potential contaminants during a certain amount of time, can be predicted. The critical limit is the time between two cleaning sessions. Such fixed intervals are used in the dairy industry, apparently with good results, even if they are not based on sophisticated calculations. Predictive models should be used to determine cleaning frequencies for new lines or products.

Establishment of critical limits for physical hazards is possible only rarely; sometimes it can be done, e.g. in setting the sensitivity of metal detectors. GMP is, in principle, the control measure for these hazards and monitoring is done by visual observation rather than by sophisticated testing equipment.

Establishment of a monitoring system for each CCP

Monitoring results should indicate trends towards loss of control, so that corrective actions can be taken immediately. In order to accomplish this, rapid tests are needed or, even better, automatic devices. A good example is the flow diversion valve commonly used in pasteurization. When a temperature deviation is measured which exceeds the normal variation, a valve immediately directs the milk leaving the pasteurizer back to the balance tank containing the milk to be pasteurized (Lelieveld, 1994). The output of the pump used to feed the pasteurizer, as well as the pressure differential between the pasteurized side and the cooling side in a plate heat exchanger, should be monitored. Most such devices have recorders attached to them.

Visual observation is the most frequently used monitoring procedure, but it is not sufficient if the results are not noted systematically. Moreover, a minimum observation frequency must be established. The operator should be alert and aware of the symptoms which might indicate the need for increased vigilance. Unfortunately, unforeseen breaks can occur; the operator should know how to react. Increased monitoring after the break might be necessary.

Microbiological tests are not suitable for many monitoring purposes. Since unacceptable survival and growth are governed by time, temperature, pH, aw, preservatives etc., i.e. physicochemical parameters, there is no need for microbiological tests to monitor these hazards. Microbiological tests may still be necessary to check the effectiveness of hygienic measures to control spread and (re)contamination (van Schothorst and Oosterom, 1984).

Establishment of corrective actions

Two kinds of corrective actions have to be established: how to restore control, and how to prevent a product manufactured when the process was out of control from harming the consumer. Restoration of control is sometimes easily achieved (readjustment of temperature), sometimes it needs major investments (elimination of Salmonella from a spray dryer environment).

The dairy industry, like other industries, faces the problem of what to do with products or semi-finished products which cannot be safely consumed. Often, the product can be reprocessed; however, this may require a rapid HACCP study because, when no previous experience exists, the product to be 'reworked' should be regarded as a new raw material.

Establishment of verification procedures

Certain analyses used in the dairy industry should be classified as verification instead of monitoring tests; e.g. determination of coliforms to check pasteurization effectiveness; of salmonellae in milk powder to check prevention of recontamination of milk powder, of Listeria and staphylococci in ice-cream to check hygiene. These tests should not be used for release purposes. The HACCP system should ensure product safety by allowing release only when monitoring results indicate that the line is under control.

Many dairy products are subjected to legislation which specifies tests and limits. Application of HACCP leads to automatic compliance with these specifications if their purpose is to verify the safety of the product. Sometimes such specifications are not meaningful for the dairy industry, and other verification tests are used.

Establishment of record keeping and documentation

Many factories keep records dealing with monitoring,
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verification and consumer complaints. Factories that have received ISO 9000 accreditation have more extensive records available. The application of HACCP requires even more detailed record keeping; software packages for coping with these requirements are available.

Implementation of the HACCP plan

The basic principles behind the HACCP concept have been in use for many years in the dairy industry under the rubric of common sense. Because the dairy industry has a very good overall safety record, there has been no need to adopt the HACCP system with all its ramifications. This will change now in the European Union, and several publications give HACCP plans for the dairy industry (ICMSF, 1988; Varnam and Sutherland, 1993). These generic or model plans are useful to give guidance, and furnish ideas or reference values, but they cannot substitute for a HACCP study which requires even more detailed record keeping; software packages for coping with these requirements are available.

Review of the HACCP plan

It is logical to assume that many older HACCP plans were established by putting 'old wisdom' into a new format. When _Listeria_ emerged as a new hazard in the dairy industry, some of this old wisdom was no longer applicable, and HACCP plans had to be reviewed. _E. coli_ O157 H7 and other VTEC _E. coli_ have emerged as contaminants of raw milk. Some results indicate that certain _E. coli_ strains are more acid-tolerant than other pathogens (M.P. Doyle, personal communication 1993), and the infective dose may be low. Although the measures to prevent other microbiological hazards will be equally effective in keeping this new hazard under control, certain dairies might wish, in the light of these new data, to review their plans.

Accessibility and cleanability of dairy equipment is improving, some errors made in the past are now clearly described (Lelieveld, 1994). Such data may trigger a thorough inspection of the old lines and a review of HACCP plans.

The important message of this stage is: remain vigilant, and fight complacency. Evidence of regular inspections with this document, we conclude that it gives good general guidance and can serve very well as a reference text, also because it contains a very useful list of definitions. Certainly improvements can be made, but if this text is used by trainers who have experience with HACCP in practice, these imperfections will not pose important problems. The importance of the document is that it provides trainers all over the world with the same basic principles, and training is the best route to understanding HACCP.

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