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The HACCP concept: identification of potentially hazardous micro-organisms

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The hazard analysis critical control point (HACCP) concept is becoming an increasingly important aspect of Good Manufacturing Practices in safe food production. HACCP is a systematic means of controlling any microbiological hazard that may arise in a food processing or handling operation and aims to identify problems before they occur. The first step is to establish the hazardous organisms associated with a particular food product. An approach is presented here that permits identification of potentially hazardous bacteria. It is based on a list of all those bacteria that are known to cause foodborne disease in man. Following an evaluation of raw materials, the production process, possibilities for contamination etc., deletions from or additions to the list are made. For the organisms that are retained, it is necessary to determine whether or not they have caused foodborne disease involving identical or related food products. Where this is not the case, the organism can be deleted. In cases of doubt, an organism should not be deleted from the list of potentially hazardous agents. A more precise evalation of the hazards will be made during the identification of critical control points (CCPs) and the setting of control criteria at each CCP.

Introduction

Foodborne disease is one of the most widespread problems of the contemporary world. From recent sentinel and population studies carried out in The Netherlands (Hoogenboom-Verdegaal et al. 1992, Notermans and Hoogenboom-Verdegaal 1992, Notermans and van de Giessen 1993) it has become clear that some 300 cases of acute gastroenteritis per 1000 individuals occur each year. At least 40–50% of the disorders are caused by micro-organisms (*Campylobacter, Salmonella, Clostridium perfringens* etc) which are almost exclusively transmitted by food or water. Results of the WHO surveillance programme (Report 1991) indicate that, in European countries, the number of agents of foodborne disease continues to increase. For example, toxigenic *Escherichia coli* of serotype 0157:H7 and *Listeria monocytogenes* may be classified among the 'newer' pathogens (MacDonald et al. 1988, Gellin and Broome 1989) while *S. enteritidis* has been recognized as a foodborne pathogen for many years, but only

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recently has given rise to a dramatic increase in illness (St Louis et al. 1988, Madden 1990). Traditionally, quality control of food products is based on inspection and testing of the end product. However, this approach may fail to detect some contaminated batches. Since it is only possible to test a small number of units from a batch, unsafe units may be missed, leading to the false assumption that the whole batch is safe (ICMSF 1986). To improve the situation, training in Good Manufacturing Practices (GMP) has been introduced as an additional means of controlling food production. However, GMP is largely a matter of personal opinion instead of an objective approach to risk assesment. One aspect of GMP is development of the Hazard Analysis Critical Control Point (HACCP) concept. HACCP is a systematic approach to the control of potential hazards in a food operation. It aims to identify problems before they occur, and establish measures for their control at the stages in production that are critical to ensuring the safety of the food. Control is proactive since remedial

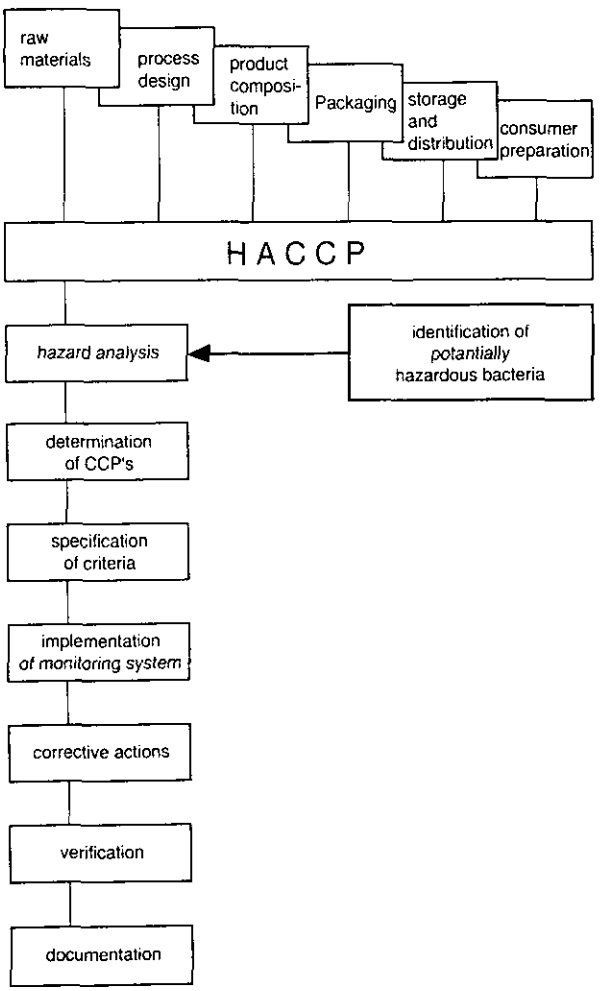

Fig. 1. The HACCP-approach and information needed to identify hazardous bacteria.

action is taken in advance. Figure 1 presents the principles of HACCP and its seven steps, as set out by the Codex Alimentarius Commission (Codex 1991). The first step in HACCP is to identify potential hazards associated with food production at all stages up to the point of consumption. In the case of bacteria, it is necessary to identify all types that may be hazardous when present in a particular food. In this paper an approach to identifying these organisms is presented. The exercise is limited to bacteria that cause foodborne disease.

Principles in identifying potentially hazardous micro-organisms

A flow sheet of the proposed approach is presented in Fig. 2. First a list is made

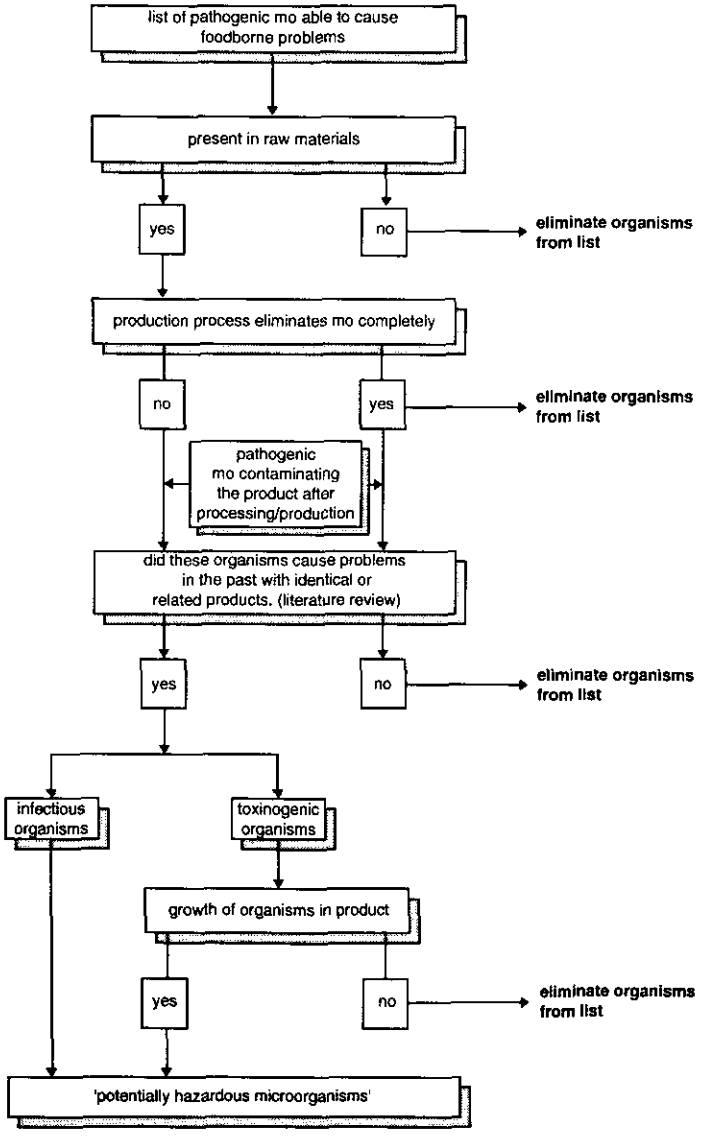

Fig. 2. Hazard analysis: identification of 'potentially hazardous micro-organisms (MO)'.

of all bacteria that are known to cause foodborne disease. After producing such a list, it is necessary to determine whether or not the organisms are likely to be present in the raw materials used. Only those organisms that have never been found can be deleted. Of the remaining organisms, it must be established whether or not they are completely destroyed during processing. If so, they, too, can be removed from the list. During processing and even after processing re-contamination may occur. If such contamination could involve any pathogenic bacteria, then these organisms must be included in the list. The next general point to consider is whether or not the listed organisms have ever caused a foodborne disease involving either an identical or related food product. Where this is not the case, the organism can be deleted. The organisms remaining on the list are now separated into two groups: those that are infectious and those capable of forming toxins which cause illness when the food is consumed. All infectious bacteria present are regarded as potentially hazardous. For toxinogenic bacteria, growth must occur before toxin is produced, so it must be established whether or not growth in the food is possible. If not, the organism is removed from the list. If, however, growth can occur, the organism must be regarded as potentially hazardous.

List of pathogenic bacteria involved in foodborne disease

A list of pathogenic bacteria should be compiled from an analysis of actual outbreaks of foodborne disease. Several countries, as well as the WHO, produce yearly summaries of such incidents. Bacteria that are causative agents of foodborne diseases of known aetiology are presented in Table 1. In this table, results are given from surveillance programmes in The Netherlands, Canada and WHO-Europe. In all cases, the organisms are almost identical, except that the WHO list contains some uncommon agents. These include *Francisella tularensis* which caused an unidentified

Table 1. Bacteria as causative agents of foodborne diseases of known etiology, as reported in different countries.

The Netherlands 1983–1990[a]	Canada 1984–1986[b]	WHO surveillance programme in Europe[c]
Bacillus cereus	*Bacillus cereus*	*Bacillus cereus*
Bacillus subtilis	*Bacillus subtilis*	*Brucella*
Campylobacter spp.	*Campylobacter* spp.	*Campylobacter* spp.
Clostridium botulinum	*Clostridium botulinum*	*Clostridium botulinum*
Clostridium perfringens	*Clostridium perfringens*	*Clostridium perfringens*
Escherichia coli	*Enterobacter cloaca*	*Escherichia coli*
Salmonella spp.	*Escherichia coli* 0157:H7	*Francisella tularensis*
Shigella spp.	*Salmonella* spp.	*Klebsiella* spp.
Staphylococcus aureus	*Shigella* spp.	*Proteus penneri*
Yersinia enterocolitica	*Staphylococcus aureus*	*Salmonella* spp.
	Streptococcus spp.	*Shigella* spp.
	Yersinia enterocolitica	*Staphylococcus aureus*
		Vibrio parahemolyticus
		Yersinia enterocolitica

[a]Notermans and van de Giessen (1993).
[b]Todd (1991).
[c]Report (1991).

disease in Norway, a *Klebsiella* food-poisoning caused by dietetic food in a medical care facility in Israel, and *Proteus penneri* which was present in cheese imported into Denmark. However, sentinel and population studies, as carried out in The Netherlands (Hoogenboom-Verdegaal et al. 1992, Notermans and van de Giessen 1993), have revealed that only a small proportion of all foodborne illness is reported to the authorities. In The Netherlands this proportion is less than 1% and, despite the fact that all reported cases are taken seriously, with laboratory investigation wherever possible, the causative agent is established in only 17·2% of cases (Notermans and van der Giessen 1993). These results indicate that the bacteria listed in Table 1 represent only the predominant organisms. It is obvious therefore, that any list of potentially hazardous micro-organisms must include both common and uncommon organisms. We have tried to identify these organisms from publications dealing with foodborne disease that have appeared over the last 25 years. The agents of so-called sporadic foodborne disease are presented in Table 2. A number of the bacteria included in this table are regarded as opportunistic pathogens, e.g. *L. monocytogenes*. However, it is not always clear whether the organisms in question were really the causative agents, despite their being isolated from the food at the time of the investigation. At that point other organisms may have declined in number. Safe food production is still based on general principles of good hygiene. One such principle is ensuring the absence of faecal contamination which would indicate the possible presence of pathogens. Testing for specific indicator organisms, e.g. thermotolerant *Escherichia coli*, can be part of the verification stage of the HACCP system.

Presence of pathogenic bacteria in raw food materials

Whether or not a pathogenic bacterium presents a possible hazard depends mainly on its occurrence in raw materials. Tables 1 and 2 include organisms such as *C. botulinum, L. monocytogenes* and *Salmonella* which are frequently present. There are also bacteria that only originate from diseased animals (e.g. *F. tularensis, P. multocida. Leptospira* spp., *Erysipelothrix* spp.). The reservoir for *V. cholerae* and other *Vibrio* spp. is water, infected humans and possibly human sewage. Other pathogens such as *Mycobacterium* spp. originate predominantly from faeces of infected cattle. Only when a herd is infected is the organism likely to be detected in raw milk. Organisms such as *C. jejuni* and *Vibrio* spp. will not survive in dry products and are not thought to be present in such materials. Any pathogenic organisms in Tables 1 and 2, that are absent from raw materials and are unlikely to be introduced subsequently can be removed from the proposed list. In cases of doubt, however, they should be retained. Most ready-to-eat food products are made from several different raw ingredients and this may complicate the decision to remove or retain a particular organism.

Effect of processing raw food materials

Processing can have a considerable effect on the microbial condition of raw materials. If, for example, these materials are dried (milk powder etc), organisms such as *Campylobacter* and *Vibrio* spp. will be completely eliminated (Stern and Kazmi 1989, Twedt 1989). On the other hand, drying only partially inactivates organisms such as *Salmonella*. Heating, too, will destroy pathogens present in

Table 2. Literature review of unusual or additional agents of foodborne disease.

Bacteria	Source/reservoir	Foods involved	References
Actobacter melanogenus	Contaminant of yeast	Homemade lager	Bryan (1979)
Aeromonas spp.	Fish, water	Salt mackerel, fish, water	Bryan (1979), Von Gravenitz and Zinterhofer (1970), Wadström and Ljung (1991)
Alcaligenes faecalis	Soil, vegetation	Meat, poultry	Bryan (1979)
Bacillus anthracis	Infected animals	Raw and undercooked meat	Brachman (1977), Bryan (1979)
Bacillus brevis		Fermented corn flour	Meng et al. (1988)
Bacillus licheniformis	Soil, air	Ground meat	Gilbert et al. (1979)
Citrobacter spp.	Faeces of animals and man	Corn pudding, raw milk, meat	Bryan (1979), Edwards and Ewing (1972)
Clostridium bifermentans	Soil	Potato pie	Bryan (1979)
Corynebacterium	Obligate parasite of man	Raw milk, ice cream	Barret and Mason (1978), Bryan (1979)
Coxiella burnetii	Animals, dust, aerosols	Milk	Bryan (1979), Leedom (1974)
Erysipelothrix spp.	Infected animals and fish	Fish, meat	Bryan (1979)
Flavobacterium farinofermentans			Wenn (1984)
Havnia alvei	Faeces of man		Reina et al. (1993), Westblom and Milligan (1992)
Leptospira	Infected animals	Meat, ham, milk?	Bryan (1979)
Listeria monocytogenes	Faeces, vegetation, infected animals	Milk products, meat, vegetables	Bryan (1979), Gellin and Broome (1989)
Mycobacterium spp.	Man, diseased cattle	Raw milk	Francis (1985), Meyers and Steele (1969), Youmans (1979)
Pasteurella multocida	Infected animals	Poultry, vegetables	Reilly and Tourrier Wadström and Ljung (1991)
Plesiomonas shigelloides	Water, fish, oysters		Bryan (1979)
Proteus spp.	Faeces of animals and man	Head cheese, ham, soft cheese	Bryan (1979), Edwards and Ewing (1972), Zietze (1984)
Providencia spp.	Faeces of animals and man	Chicken	Bryan (1979), Edwards and Ewing (1972)
Pseudomonas aeruginosa	Skin lesions, human faeces, water, sewage, soil	Milk, rabbits, syrup	Bryan (1979), Doggett (1979), Youngh (1979)
Pseudomonas cocovenenans		Fermented corn flour poorly fermented bongkrek	Paul (1966), Zhao et al. (1990)
Streptobacillus moniliformis	Rats	Raw milk	Bryan (1979)
Streptococci of group A	Food handlers (wounds, respiratory secretors)	Miscellaneous, salads	Farley et al. (1993)
Vibrio cholerae	Sea water, human sewage, shellfish, man	Raw mussels, fish, shrimp, raw vegetables	Sakazaki (1979)
Vibrio spp.	Sea water, shellfish, crustacea	Raw oysters, shellfish	Ji (1989), Lowry et al. (1986), Pollak et al. (1983), Blake et al. (1980)

raw materials. If the heating involves sterilizing temperatures, then all vegetative organisms will be killed and they can be removed from the list of potentially hazardous agents. An example is vacuum-packed potatoes which are packed and then heat-treated at 100°C for 38 min, followed by 115°C for 4 min. This process will eliminate all vegetative bacteria. With this particular product, only *C. botulinum, C. perfringens, C. bifermentans, B. cereus, B. subtilis* and *B. licheniformis* remain as potentially pathogenic bacteria. All other organisms can be disregarded.

In the case of pasteurization only vegetative cells will be reduced by a certain factor. Thus, the conditions of pasteurization may be critical, and no relevant organism should be ignored. The same applies to any other processing treatment that only reduces the number of vegetative cells. In the HACCP system, determination of critical control points (CCPs) requires a more precise evaluation of certain processing stages and involves the setting of control criteria. The first step in an HACCP analysis merely aims to establish the potentially hazardous organisms. This implies that all pathogenic bacteria with the potential to cause foodborne disease must be taken into account. Only when such organisms are totally absent can they be disregarded.

Recontamination

Recontamination of (heat) processed products is a common feature in food production. In the past it has become clear that spoilage organisms such as *Pseudomonas* spp. can become indigenous to processing plants (Stanley 1983, Notermans et al. 1991). It has also been observed that pathogenic organisms such as *S. aureus* and *L. monocytogenes* can easily colonize processing equipment. *S. aureus* is one of the organisms associated with poultry processing equipment such as the defeathering machines and evisceration equipment (Notermans et al. 1982). *L. monocytogenes* has been found to be indigenous to cheese factories and several meat processing plants (Lovett 1989). As a consequence, contamination or recontamination of a processed product may easily occur. Other sources of contamination are food handlers. They may be carriers of several pathogens such as *S. aureus* and *Shigella* (Hacibektasoglu et al. 1993). Contaminants can also be spread by workers' hands, cleaning cloths, and from raw materials to cooked foods. Therefore, avoidance of contamination or recontamination is often a matter of applying GMP during processing. In principle HACCP is an extension of GMP and it will fail if GMP in a processing plant is insufficient. Only when GMP cannot prevent recontamination of the product should the organisms of concern be included in the list of potentially hazardous agents.

Previous experience of foodborne diseases

In the case of vacuum-packed cooked potatoes, only spore-forming organisms will be present, provided that packs reatain their integrity. However, not all of these organisms have caused foodborne disease involving similar or related products. A literature review reveals that only proteolytic *C. botulinum* (Seals et al. 1981, Miller 1984), *C. bifermentans* (Bryan 1979) and *B. cereus* (Palma 1985) have caused foodborne disease associated with such products. *C. perfringens* has never caused a potato-borne disorder in man. In consequence, it seems that this organism can be eliminated from the list of potential hazards. In general, the need for a

literature search is evident as a first step. However, not all foodborne diseases have been reported and not all foodborne pathogens are recognized. In the HACCP system, a verification step has been included (Fig. 1). Tests that are appropriate for verification purposes are carried out periodically to ensure that controls are achieving their overall objectives and that no hazards have been overlooked or new ones introduced. This stage may include consideration of any consumer complaints about the food in question.

With completely new types of product and novel processes, some caution is required. If the implications of new types of product and/or processing procedures are not well understood, pathogenic organisms cannot be eliminated from the proposed list with any certainty.

Infectious versus toxinogenic bacteria

In principle two types of bacteria can be recognized in relation to foodborne disease: those that infect the victim and those causing an intoxication by release of toxin either in the food or in the intestinal tract. Infectious organisms such as *Salmonella, Campylobacter* and *Shigella* can cause disorders if present in low numbers. Toxinogenic organisms such as *C. botulinum* and *S. aureus* generally cause illness only when multiplication occurs and toxin is formed. Detectable quantities of staphylococcal enterotoxin are observed only when the count of *S. aureus* has reached > 6·0 $\log^{10}$ cfu g^{-1} (Notermans and van Otterdijk 1985). From foodborne disease outbreaks it has become clear that large numbers of *C. perfringens* and *B. cereus* must also be ingested to produce intoxication (Labbe 1989, Kramer and Gilbert 1989). With the latter organism, however, toxin produced during growth in food may persist under conditions of thermal processing that would destroy the organism itself.

Infectious organisms should not be deleted from the list of potentially hazardous agents. On the other hand, toxinogenic organisms can be ignored if they are unable to grow in the food under consideration. Only when growth is possible should they be regarded as potentially hazardous. Growth of these organisms is determined by factors such as product composition, storage temperature and storage time. Other factors such as pH, a_w and Eh are also important. Some of the relevant factors are shown in Table 3. Strains of group I *C. botulinum* will not multiply if the storage temperature is < 10°C, the pH value < 4·6, the a_w < 0·94 or the redox potential > + 200 mV. However, a pH value < 4·6 is not always able to prevent growth of *C. botulinum*. Odlaug and Pflug (1978) listed 35 incidents of botulism associated

Table 3. Conditions which do not allow multiplication of some toxinogenic micro-organisms.

	Clostridium botulinum		*Staphylococcus aureus*	*Bacillus cereus*	*Clostridium perfringens*
	Group I	Group II			
Temperature	< 10°C	< 3·5°C	< 10°C	< 4°C	< 15°C
pH	< 4·6°C	< 5·0	< 4·5	< 4·4	< 5·0
a_w	< 0·94	< 0·97	< 0·86	< 0·91	< 0·95
Eh	> + 200 mV	> + 200 mV			> + 350 mV

with acid or acidified foods in the USA. Several of these foods contained acid-tolerant micro-organisms such as yeasts and moulds. Moulds of the genera *Aspergillus, Penicillium* and *Mycoderma* have the ability to raise the pH during growth, at least in their immediate vicinity, to a level that would allow *C. botulinum* to develop, while the overall pH remains well below 4·6. Combined effects of a_w, pH etc. will inhibit growth at much higher levels. However, growth inhibition produced by a combination of factors must be studied in more detail and in relation to specifications for control criteria: the third step in HACCP.

The same considerations apply to *S. aureus*. Under certain growth conditions no enterotoxin will be produced. Although growth of *S. aureus* can be observed at a_w 0·90 production of enterotoxin B or C will hardly ever occur (Notermans and Heuvelman 1983). A more precise determination of conditions for growth and toxin production is needed in relation to specifications for control criteria.

In summary, if infectious agents are present, or may be present, in the product they should not be eliminated from the list of potentially hazardous organisms. The same applies in the case of toxinogenic organisms unless multiplication is impossible.

Discussion

HACCP is a systematic approach to the control of potential hazards in a food operation and aims to identify problems before they occur. The first step in HACCP is to identify the hazards associated with a particular food product. An attempt has been made here to identify potentially hazardous bacteria. The general principles of the proposed approach are based on a list of all bacteria that are known to cause foodborne disease. Following an evaluation of raw food materials, the production process, contamination or recontamination after processing etc., bacteria are either deleted from or added to the list. Producing a list of bacteria that are known to cause foodborne disease has some drawbacks. It is not always known whether such a list contains all potentially hazardous organisms. This is particularly true for the so-called opportunistic pathogens such as *Aeromonas* spp. and certain *Bacillus* spp. Furthermore, not all foodborne diseases have a known aetiology and the causative organism is not always identified (Notermans and van der Giessen 1993). Therefore it seems that the proposed list is only a rough guide to the potentially hazardous bacteria. The same applies to subsequent stages of the HACCP approach. However, organisms can be deleted from the list if they are either absent from the raw materials or eliminated completely during the production process. In cases of doubt the organisms should be retained. Contamination or recontamination during or after the production process may be a weak point. Once again, however, in cases of doubt, the organisms in question must be retained.

The list of potentially hazardous organisms may still contain a relatively large number of organisms. Therefore it is proposed to delete organisms that have never caused foodborne disorders in the past with identical or related products. Although this approach may seem inappropriate, especially for new types of product and in relation to the possible presence of unsuspected pathogens, the problem is covered by the HACCP concept and concerns the sixth step: verification. Thus, verification should not be restricted to the control criteria at specific CCPs. It should also include an analysis of any consumer

complaints that occur after consumption of the product. If serious disorders are recognized, the HACCP analysis must be repeated.

In general, a considerable number of potentially hazardous bacteria will need to remain on the final list. To facilitate the application of HACCP, it is worthwhile to group the listed organisms. The groups should be based on common properties such as sensitivity to heat and minimum growth temperature. The conditions of processing and composition of the products will largely determine the relevant clusters.

Establishing the relevant, hazardous organisms in a particular food is but one step in implementing the HACCP system. The stages that follow must include an assessment of the hazards associated with each organism and the probability of their occurrence. While there are some foods for which the list of potential pathogens is extensive, it is clear that measures adopted to control one type of organism are also likely to be adequate for others that could be present, i.e. those within a group, as defined above. Furthermore, steps to eliminate or control *Clostridium botulinum*, a spore-forming organism, may also control most other bacteria. One of the key objectives of HACCP is to keep control measures as simple as possible. Otherwise, the chances of adoption and implementation of the system are slight. This does not mean that a proper hazard analysis is necessarily a simple matter. In practice, the analysis usually involves a multidisciplinary team that provides an appropriate spread of expertise and experience. Only then are all possible hazards likely to be identified, evaluated and suitably controlled.

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