

General Interest

Managing the Risk of Staphylococcal Food Poisoning from Cream-Filled Baked Goods To Meet a Food Safety Objective

CYNTHIA M. STEWART,¹* MARTIN B. COLE,¹ AND DONALD W. SCHAFFNER²

¹Food Science Australia, P.O. Box 52, North Ryde, New South Wales 1670, Australia; and ²Department of Food Science, Rutgers University, 65 Dudley Road, New Brunswick, New Jersey 08901-8520, USA

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ABSTRACT

The International Commission on Microbiological Specifications for Foods (ICMSF) has recently proposed a scheme for the management of microbial hazards for foods that involves the concept of food safety objectives (FSOs). FSOs are intended to specify the maximum levels of hazardous agents required to meet a given public health goal. This scheme offers flexibility for the food industry in terms of allowing the use of alternative but equivalent means for achieving a given FSO. This paper illustrates the application of the ICMSF model via the analysis of the microbiological hazard of *Staphylococcus aureus* in cream-filled baked goods. Cream-filled baked goods have a notorious history as vehicles for foodborne illness, particularly staphylococcal food poisoning. Although the numbers of cases reported in the United States and Europe have declined in recent years, staphylococcal food poisoning may be much more common than is recognized, particularly in other countries. The ICMSF principles for setting FSOs and the use of performance criteria, process criteria, and validation in relation to hazard analysis critical control point and good hygiene practice plans for managing *S. aureus* in cream-filled baked goods are described.

The focus of risk assessment has traditionally been on reducing chemical or microbial risks to reasonable levels. This approach leads to difficulties, particularly since trade is becoming increasingly global; not only do the technological capabilities of different countries, and even those of different companies within the same country, differ, but ideas of what is “reasonable” also differ from country to country, and acceptable risk may be culturally defined. The International Commission on Microbiological Specifications for Foods (ICMSF) has recently proposed a scheme for the management of microbial hazards in foods, and this scheme uses the concept of food safety objectives (FSOs) to address these issues (44, 79). An FSO is defined as a statement of the frequency or maximum concentration of a microbiological hazardous agent in a food considered acceptable for consumer protection (79), and this concept allows the establishment of different equivalent control measures to achieve this concentration. Control measures are the actions and activities used to prevent, eliminate, or reduce a food safety hazard to a tolerable level and generally fall into three categories: controlling initial levels of a hazardous agent, preventing an increase in the levels of a hazardous agent, and reducing the levels of a hazardous agent.

FSOs are intended to communicate the maximum levels of a microbiological hazard required to meet a given public health goal and to facilitate the acceptance of different but equivalent means of meeting these goals. FSOs

differ from microbiological criteria in that they are broader in scope and are intended to communicate the levels of control considered necessary for consumer protection, with their performance being expressed in terms of the frequency or concentration of a microbiological hazard. They specify goals that can be incorporated into the design of control measures used in food operations. FSOs provide a basis for measuring the effectiveness and adequacy of control systems adopted by industry, government, and/or regulatory agencies.

The ICMSF (44) describes in detail a sequence of activities for establishing a comprehensive food safety system. Briefly, the series of steps is as follows: (i) risk managers in government use epidemiological evidence to link human illness with a microbiological agent and, if possible, a food; (ii) risk managers in government, with input from other stakeholders, perform an evaluation to decide whether an FSO should be established; (iii) a risk evaluation is carried out by an expert panel or through a microbial risk assessment; (iv) risk managers in government develop an FSO for the hazard-food combination, i.e., the maximum frequency and/or concentration of a microbial hazard in food considered tolerable for consumer protection; (v) risk managers in industry and government, with input from other stakeholders, assess whether the FSO is achievable through the application of good hygiene practices (GHP), good manufacturing practices (GMP), and the hazard analysis critical control point (HACCP) system; and (vi) once it is determined that the FSO is achievable, the food man-

* Author for correspondence. Tel: +612 9490 8522; Fax: +612 9490 8581; E-mail: cindy.stewart@foodscience.afisc.csiro.au.

ufacturer (in collaboration with others involved the food chain, where appropriate) establishes performance and process-product criteria to meet the FSO and implements the process through GHP and HACCP plans. If the proposed FSO is not technically feasible, then modifications to the product, the process (if technically possible), and/or the FSO may be necessary. If no technically achievable solutions can be found and the risk is too great, then it may be necessary to ban the product and/or the process or, in the case of a new product or process, not to introduce the product onto the market. As new information regarding a particular hazard or product emerges, FSOs may be modified.

The following definitions of terms will be used throughout this paper (3, 79).

Food safety objective (FSO): A specified maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection (ALOP). (For example, the level of *Listeria monocytogenes* in ready-to-eat foods should not exceed 100 CFU/g at the time of consumption.)

Performance criterion: The required outcome of a step or a combination of steps that contribute to assuring that an FSO is met. (For example, a performance criterion could be a 6-log₁₀ reduction in the level of the target microorganism.)

Step: A point, procedure, operation, or stage in the food chain (including stages involving raw materials) from primary production to final consumption.

Performance standard: A performance criterion expressed as a regulatory standard.

Process criterion: The control parameters for a step or combination of steps that can be applied to achieve the performance criterion. (For example, a process criterion could consist of heating for 2 min at 70°C or high-pressure treatment at 500 MPa for 7.5 min.)

The FSO definition is based on the fact that the risk characterization curve of the risk assessment relates the risk (health impact) to the concentration or frequency of the hazard at the point of consumption. Since the FSO expresses the level of a hazardous agent at the moment of consumption (44), another term is needed to describe levels at other points in the food chain. Several terms have been proposed for this purpose. In this document, the term *performance criterion*, as defined above, will be used. More detailed discussions of this scheme can be found elsewhere (44, 69). This scheme offers flexibility for the food industry by allowing the use of alternative but equivalent means for achieving a given FSO.

This article is intended to illustrate the application of the ICMSF principles for setting FSOs and the use of performance criteria, process criteria, and validation in relation to HACCP and GHP plans according to the model used by the ICMSF (44). This manuscript illustrates the type of governmental microbial risk assessment that would provide a solid basis for the determination of an FSO. Once an FSO had been established, the food industry would be respon-

sible for choosing the appropriate product and process design to meet this FSO, as illustrated in this paper. The microbiological hazard considered in this paper is *Staphylococcus aureus* in cream-filled baked goods. Hypothetical values are used throughout the paper where assumptions are necessary to illustrate the concept of the procedure. No attempt has been made to validate their accuracy.

Foodborne staphylococcal poisoning is one of the most prevalent causes of gastroenteritis worldwide (45). This illness is caused by the ingestion of food that contains one or more preformed toxins produced by *S. aureus*. Humans are common carriers of enterotoxigenic *S. aureus* in the nose, throat, and skin. The microorganism may also be present in large numbers in skin infections and can easily be transferred to food during handling (58). Vehicles of transmission include cooked proteinaceous foods (frequently ham), baked goods (usually with cream or custard fillings), and salads mixed with cooked proteinaceous foods (37). In outbreaks associated with cream-filled baked goods such as custard-filled puffs, chocolate éclairs, and Boston cream pies, it is almost always the cream or custard filling that is the contaminated portion of the food, since these fillings are excellent microbial growth mediums. Foodborne outbreaks associated with cream-filled baked goods are attributed primarily to contamination by food handlers followed by inadequate refrigeration during manufacture and/or storage (12, 49).

Cream-filled baked goods can be categorized into three types on the basis of the basic procedures used for their manufacture (43). To produce foods in the first category (e.g., chocolate éclairs, Napoleons, and imitation cream pies), filling ingredients are combined, cooked, and dispensed into prebaked pastry tubes or shells, and then icing is added. To produce foods in the second category (e.g., custard pies), preformed baked or unbaked pastry shells are filled with combined, uncooked filling, and then the entire pastry is cooked, cooled, and packaged. To produce foods in the third category (e.g., Nesselrode pies), prebaked pastry shells are filled with ingredients, some of which have been combined and cooked, but other ingredients are added without first being cooked, and there is no final baking of the completed pastry (1).

For foods in the first category, there is considerable opportunity for recontamination of the bulk filling during cooling, transferring, and dispensing, while foods in the third category have the greatest likelihood of contamination, since some ingredients are not cooked at all. Although foods in the second category are essentially sterile after baking, postbaking contamination on the top or on the surfaces of cut edges can lead to the growth of *S. aureus* and can result in foodborne illness. This paper will focus on an analysis of microbiological hazards in cream-filled baked goods in the first two categories, which make up the majority of the cream-filled baked goods produced and consumed around the world.

RISK ASSESSMENT

Hazard identification. *S. aureus* was determined to be the etiological agent in 367 of 1,869 documented bacterial

foodborne outbreaks (19.6%) from 1973 to 1987 (8), and from 1993 to 1997 this pathogen was involved in 42 documented outbreaks of food poisoning in the United States, resulting in 1,413 cases of illness and 1 death (55). It is estimated by the Centers for Disease Control and Prevention that *S. aureus* causes 185,060 illnesses, 1,753 hospitalizations, and 2 deaths per year in the United States, all via the consumption of contaminated foods (50). Although death is uncommon with this type of food poisoning, it can occur and is usually associated with children or older individuals who often have other medical complications (11). Because it is so prevalent, *S. aureus* has been extensively studied to determine the physical and chemical parameters that affect its growth and toxin formation (10, 11, 43, 45).

S. aureus is a facultative anaerobe that can grow at 7 to 48°C, at a pH of 4 to 10, and at a relative humidity (RH; commonly referred to as water activity) of $\geq 85\%$, depending on the humectant used (42). Approximately 30 to 50% of the human population carries the microorganism, with its main habitat being the nose (10). *S. aureus* cells are readily killed by pasteurization or cooking; however, the microorganism's enterotoxins are heat stable and can survive even the high temperatures ($\sim 121^\circ\text{C}$) used to process low-acid canned foods (42). The F_{150} value (based on °F) for *S. aureus* in custard has been reported to be 5.2 min (2). Although it is widely known that growth and subsequent toxin production can be prevented by storing "potentially hazardous" foods at $<5^\circ\text{C}$ (22, 42, 64), poor personal hygiene-handling practices and inadequate refrigeration of foods are the main factors contributing to staphylococcal foodborne disease (7, 8, 47, 48, 55).

Hazard characterization. Almost all cases of staphylococcal food poisoning (SFP) are due to the ingestion of toxins produced by *S. aureus* rather than by any other staphylococcal species (45). The nine major staphylococcal enterotoxins (SE) that have been identified are SEA through SEE and SEG through SEJ, with SEC being further divided into three major antigenic subtypes, SEC₁ through SEC₃ (6, 23). More recently, Orwin et al. (57) reported on the biological and biochemical properties of SEK. Most foodborne outbreaks are associated with SEA and SED, since these toxins can be produced in foods with wider ranges of pH, RH, and E_h values than those in which SEB and SEC can be produced; however, the potential for any SE to cause human illness cannot be discounted. SEA alone or in combination with other staphylococcal enterotoxins was associated with 79% of outbreaks occurring in the United Kingdom from 1969 to 1990, with SED being implicated in 29% (82).

Characteristics of illness caused by SE include vomiting and diarrhea, severe abdominal cramps, a normal or subnormal temperature during the acute stage, a noticeably increased pulse rate, cold sweats, prostration, muscular cramping, dehydration, and a mild headache, and these symptoms occur 1 to 6 h after the ingestion of the toxin. Acute symptoms last for 1 to 8 h, with complete recovery occurring typically within 1 to 2 days. Intoxication is not usually lethal. Elderly people are typically more susceptible

to morbidity and mortality from foodborne gastroenteritis than are younger individuals (6).

The number of staphylococci required to cause illness cannot be predicted with certainty because many variables, including environmental factors (food composition, temperature, etc.) and bacterial factors (strain, type of toxin, etc.), affect the amount of SE produced in a contaminated food. It is likely that the combination of conditions allowing toxin production in a food is unique for each isolated case or SFP outbreak. According to the guideline given by the U.S. Food and Drug Administration (FDA) for assessing general risk, the effective dose of SE may be achieved when the population of *S. aureus* reaches a level of $>10^5$ CFU/g (19). Although the amount of toxin required to produce illness in humans depends on individual weight and sensitivity, the scientific community generally agrees that a dose of 0.1 to 1.0 $\mu\text{g}/\text{kg}$ of body weight will cause illness in humans (42). The basal level of 1 ng/g of contaminated food is sufficient to cause illness, and levels of 1 to 5 μg of ingested toxin have been associated with many outbreaks (45). The results of a study in which human volunteers ingested partially purified SEB showed that 20 to 25 μg of toxin (0.4 $\mu\text{g}/\text{kg}$ of body weight) was sufficient to cause vomiting (61). One of the most useful studies for the prediction of the minimum oral dose of SE required to cause SFP in humans was a well-documented investigation of an outbreak involving school children who consumed contaminated chocolate milk. The minimum dose of SEA required to cause illness in this outbreak was estimated to be 144 ± 50 ng per carton of milk (26).

Exposure assessment. Although cream-filled baked goods have a notorious history as vehicles for foodborne illness, particularly SFP, the percentage of reported outbreaks in which cream-filled baked goods have been implicated in the United States has decreased over time (12). During the 35-year period from 1938 to 1972, 439 outbreaks arising from the ingestion of cream-filled baked goods were reported in the United States. *S. aureus* was implicated in most (85.2%) of these outbreaks. From 1961 to 1971, cream-filled baked goods were vehicles in only 50 (9.5%) reported outbreaks of staphylococcal intoxication, whereas in previous decades they were usually the most commonly reported vehicles of this foodborne illness (12). Although reported outbreaks are declining in the United States, SFP may be much more common than is recognized, especially in other countries (58).

Table 1 provides summary data for a number of *S. aureus* outbreaks associated with bakery products. SFP outbreaks involving as many as 1,800 cases have been associated with a variety of cream-filled bakery products, including custard pies, éclairs, and various types of cream-filled cakes. When tested, the levels of *S. aureus* in the implicated baked goods were high, ranging from 10^6 to 10^9 CFU/g. SEA was the type of toxin most often detected. In a report from the United Kingdom, levels of *S. aureus* present in foods incriminated in outbreaks occurring in the United Kingdom from 1969 to 1990 ranged from 0 to 1.5×10^{10} CFU/g, with the median level being 3×10^7

TABLE 1. Foodborne outbreaks due to *Staphylococcus aureus* contamination of bakery products^a

Location (year)	No. of cases	<i>S. aureus</i> level (CFU/g)	Toxin detected	Associated food	Reference
United States (1962)	2	2.15×10^8	SEA	Cream (imitation)-filled doughnut	49
United Kingdom/Wales (1969-1972)	NA	1.5×10^8	SEA	Vanilla cake	33
United Kingdom/Wales (1969-1972)	NA	1×10^9	SEA	Torta cream cake	33
France (1969)	100	1×10^6 - 9.6×10^6	SEA	Custard pie	18
Flight originating in Brazil (1976)	28	1×10^9	SED	Chocolate éclairs	20
Sheffield, UK (1983)	36	1×10^9	SEA	Vanilla slices	28
Caribbean Cruise Ship (1983)	215	NA	NA	Cream filled pastry	80
Spain (NK)	1,800	$>5 \times 10^6$	SEA	Easter cake with cream filling	11
Brazil (1994)	12	1.2×10^8	SEA	Cream-filled cake	58
Thailand (1990)	485	1.8×10^8	SEA, SEC	Éclairs	74
Mexico (1984)	100	NA	NA	Mocha cake	25

^a NA, data not available; NK, not known.

CFU/g (82). In 77% of these incidents, the pathogen was present at $>10^6$ CFU/g.

Several investigators have reported on the prevalence of *S. aureus* in cream-filled baked goods. In Nebraska, Sumner et al. (71) reported isolating *S. aureus* from 30% of cream puffs (12 cream puffs) and 11.1% of long johns (6 long johns) obtained from local bakeries. In a survey of bakeries in New York City in the early 1950s, 10 (30.3%) of 33 éclairs, 3 (12%) of 25 Napoleons, and 6 (19%) of 31 Nesselrode pies were found to contain *S. aureus* (1). Nichols et al. (53) found *S. aureus* in 0.5% of desserts and cakes (5 desserts and cakes) examined in the United Kingdom, and Wieneke et al. (82) reported that the microorganism was found in 8% of milk samples and desserts containing milk or cream (including vanilla slices and trifles) (23 samples). Conditions necessary for these foods to become vehicles for foodborne disease (12) include (i) contamination of ingredient(s) or of the baked goods themselves with enterotoxigenic *S. aureus*; (ii) sufficient nutrients to support the growth of enterotoxigenic *S. aureus*; (iii) an RH high enough to permit the growth of enterotoxigenic *S. aureus* or a water content differential sufficient to cause water migration, which creates pockets of moisture that will permit growth; (iv) a pH that allows the growth of enterotoxigenic *S. aureus*; (v) an oxidation-reduction potential in a range

that will allow the growth of enterotoxigenic *S. aureus*; (vi) storage temperatures within the range in which enterotoxigenic *S. aureus* cells grow; (vii) the absence of competitive microflora in the product; and (viii) sufficient time to permit growth to levels that lead to the production of enterotoxin.

Results of epidemiological studies show that the behavior of the food handler is the factor that most often contributes to SFP outbreaks (32). Hand contact with ready-to-eat foods is an important route through which pathogens may enter the food supply (14, 36). Food workers may transmit pathogens to foods from contaminated surfaces, from another food, or from contaminated hands.

The incidence of nasal carriage of *S. aureus* among the healthy adult population outside the hospital is estimated to be 10 to 40% (32), with approximately 15 to 20% of humans carrying enterotoxin-producing staphylococci (78). Several reports on the isolation of *S. aureus* from food handlers have been published (Table 2). Percentages of food handlers testing positive for the carriage of *S. aureus* have ranged from 26 to 38.5%. From 8.0 to 44.4% of those testing positive for *S. aureus* were carrying enterotoxigenic strains.

Guzewich and Ross (36) reviewed scientific literature published from 1975 to 1998 for articles describing foodborne disease outbreaks believed to have been caused by the contamination of food by food handlers. A total of 72 articles reported 81 outbreaks involving 16 different pathogens. Hepatitis A (34.57% of the outbreaks), Norwalk-like viruses (25.93% of the outbreaks), and *S. aureus* (7.41% of the outbreaks) were the microorganisms most frequently identified as etiologic agents. Seventy-two (89%) of the outbreaks were attributed to the consumption of food at a food service establishment, and nine (11%) were attributed to the consumption of foods prepared at home. This review provides evidence that food workers can serve as a source of infection and that hand contact with foods represents a means by which contamination may occur (36).

Foodborne outbreaks associated with cream-filled baked goods are frequently attributed to inadequate refrigeration during manufacture or storage (12, 49). The average

TABLE 2. *Staphylococcus aureus* isolated from food handlers^a

Location	No. of food handlers examined	No. (%) of food handlers positive for <i>S. aureus</i>	No. (%) of food handlers positive for enterotoxigenic <i>S. aureus</i>	Reference
Japan	470	122 (26)	82 (17.4)	84
Germany	268	99 (36.9)	8 (8)	78
Japan	400	154 (38.5)	88 (22)	52
Spain	NA	81	36 (44.4)	31
Spain	300	80 (26.7)	NA	32

^a NA, data not available.

food handler may not understand that many foods should be refrigerated when they are not being prepared or served. Moreover, the consumer may not appreciate that unrefrigerated cream-filled baked goods can become vehicles for foodborne illness.

Notermans and van Otterdijk (54) reported that *S. aureus* can proliferate in artificially inoculated (10^3 CFU/g) vanilla custard during storage at 22°C. After 24 h, numbers increased by 4 to 5 log₁₀ units but no SEA was detected; after 48 h, numbers increased by 6 to 7 log₁₀ units and SEA was detected at levels of up to 6 µg/100 g of sample. Anunciacao et al. (5) reported on *S. aureus* inoculation studies involving cream-filled cakes. Their findings show that with an inoculum size of 10^3 CFU/g of cream filling and incubation of the cake at 27 to 29°C, SEA was detectable at 18 h at levels of 10^6 CFU/g. Refrigeration of identically inoculated cream-filled cakes prevented the growth of staphylococci; no growth occurred and no enterotoxin was detected even with an initial inoculum of 10^6 CFU/g.

Custard pie fillings are cooked as the pie bakes and are essentially free of vegetative cells after baking. Any post-baking contamination of the filling with *S. aureus* can lead to the growth of the microorganism and potential illness when the pie is consumed. Preonas et al. (60) reported that raw custard inoculated with 10^{10} *S. aureus* cells per pie contained no detectable *S. aureus* after baking for 37 min at an oven temperature of 193°C. The top and cut surfaces of baked slices were then inoculated with 10^3 to 10^4 CFU/cm² and incubated at 30°C. Growth was rapid on the cut surfaces, with numbers reaching $>10^8$ CFU/cm² within 24 h. There was a 24-h lag time before growth occurred on the top surface, and it took >72 h before numbers reached 10^8 CFU/cm². This difference was thought to be due to the oily, cakelike layer on the top surface of the pie. Pereira et al. (59) reported on inoculation studies involving unbaked cream pies. Unsterilized and sterilized fillings were inoculated with 10^4 CFU of five low-enterotoxin D-producing strains of *S. aureus* per g and incubated at 25, 30, and 37°C for 24 h. SED was produced by all strains in the sterilized cream filling at all three temperatures. SED was not detected in any of the unsterilized cream fillings held at 25°C; three strains produced detectable levels of SED at 30°C, and all strains produced detectable levels of SED in unsterilized cream fillings when incubated at 37°C. The level of *S. aureus* growth was about 1 log₁₀ lower for the unsterilized cream filling, most likely because of competition with mesophilic spoilage microorganisms.

Risk characterization. In 2000, the population of the United States was 281,421,906 (4). The estimated total number cases of SFP in the United States was 185,060 per year (50). Baked goods, usually with cream or custard fillings, were reported to cause 10% of the SFP outbreaks occurring from 1977 to 1981 (37), and bakery products were reported to cause 3% of the SFP outbreaks occurring from 1973 to 1987 (8). If we assume that cream-filled baked goods are responsible for 6.5% of SFP outbreaks, the number of cases of SFP caused by cream-filled baked goods per year can be estimated as $185,060 \times 6.5\% =$

$12,029$, with $281,421,906/12,029 = 1$ case per 23,395 people per year, or 43 cases per 1 million people per year. It is appropriate to base the risk characterization on the entire U.S. population, as is done here, since all consumers are susceptible to SFP, although it should be noted that some individuals (i.e., children and infants, immunodeficient individuals, and elderly individuals) are more susceptible to staphylococcal enterotoxins, and subsequent illness may be more severe for these individuals (9).

RISK MANAGEMENT

Appropriate level of consumer protection. In the context of food safety, an ALOP is a statement of the degree of public health protection to be achieved by the food safety systems implemented within a country and is often framed in a context of continual improvement in relation to disease reduction. An FSO, by definition, is linked to the determination of an ALOP. The level of protection, rather than being explicitly expressed, may be based on estimates from data on incidences of domestic illness. In many situations currently pertaining to food safety, risks associated with particular hazards may have been estimated, but a societal decision on an ALOP has not have been made. A public health goal could be to reduce the number of cases of illness attributable to the consumption of cream-filled baked goods by some value (e.g., a 50% reduction to ≤ 22 cases per million people). The underlying assumption is that there are practical means by which the public health goal can be achieved. Further details on ALOP are given by the ICMSF (44).

Establishing an FSO. Owing to the widespread presence of *S. aureus* on the skin of healthy people, the microorganism's eradication from the food supply is likely to be an impossible objective. There is general agreement among scientists that *S. aureus* must be present at levels higher than $\sim 10^5$ CFU/g of food before it is able to produce enough toxin to cause illness when ingested, although in some cases smaller numbers have apparently been implicated (37). In fact, a common source of confusion in identifying SFP is the assumption that large numbers of *S. aureus* should be found in the implicated food; however, when food is examined, there may not be a correlation between the numbers of staphylococci present and the levels of detectable enterotoxin for the following reasons: (i) during the delay between the consumption of food and its refrigeration or laboratory analysis, staphylococcal cells may begin to die, leading to lower detectable counts; (ii) the microorganisms may have been killed as a result of processing after the production of enterotoxin; (iii) enterotoxigenic strains of staphylococci may be outgrown by nonenterotoxigenic strains after enterotoxin production; and (iv) cells may be nonuniformly distributed in certain solid foods (35, 37).

The FDA advises that a staphylococcal toxin dose of <1.0 µg in contaminated food will produce symptoms of staphylococcal intoxication and that this toxin level is reached when *S. aureus* populations exceed 10^5 CFU/g (19). A study on staphylococcal growth and enterotoxin in cream-filled cake at room temperature (27 to 29°C) deter-

mined that enterotoxin was not produced at detectable levels until counts reached at least 9.3×10^5 CFU/g (5). An FSO would recognize that it is not possible to eliminate the contamination of foods with *S. aureus*. To minimize contamination, GHP or GMP and HACCP systems that are specific to the control of *S. aureus* at all stages of manufacture, storage, transport, and retail can be applied. Research should also continue to develop additional or improved barriers with which to control the growth of *S. aureus* in cream-filled baked goods. Such research might include the development of food additives and/or studies leading to an improved understanding of growth boundaries with regard to RH, solute-specific effects, and pH (67, 68).

On the basis of the epidemiologic and prevalence data presented above, the following illustrative example of an FSO is proposed: the concentration of *S. aureus* shall not have exceeded 10^4 CFU/g at any time in the filling prior to the consumption of cream-filled baked goods. This proposal is consistent with an earlier recommendation from the ICMSF (40) as well as other standards used around the world (17, 83).

Control measures. It is anticipated that manufacturers of cream-filled baked goods can easily meet the proposed FSO for their products at the time of manufacture if the filling is adequately cooked at some point in the process and recontamination is prevented. However, if cream-filled baked goods are recontaminated while the filling is cooling or during handling, there is potential for concentrations of *S. aureus* to exceed 10^4 CFU/g in these goods by the time they are consumed, especially if these products are inadequately refrigerated and there are no additional barriers to growth. To reduce the incidence of SFP associated with cream-filled baked goods, other risk management options may need to be considered.

When GHP or GMP procedures and HACCP systems are used to achieve the expected level of control of microbiological hazards (the FSO), it is important to consider available control measures in the context of steps used in manufacture. In this example, the control of *S. aureus* so that the concentration of the microorganism will not exceed 10^4 CFU/g when cream-filled baked goods are consumed will involve the following control measures.

1. *Controlling initial levels in raw materials* by using only pasteurized dairy and egg products for fillings and by handling raw materials during storage and preparation in a way that will minimize an increase in *S. aureus* levels due to contamination or growth.
2. *Reducing levels during the cooking of cream or custard fillings in the manufacturing process* by using heat to reduce the concentration of *S. aureus* in the fillings and by establishing a performance criterion for cooking that results in process criteria (e.g., critical limits) that can be incorporated into the HACCP plan.
3. *Minimizing recontamination between the cooking of cream or custard and the filling of pastry shells or cakes* by adopting GHP-GMP measures, i.e., the separation of raw ingredients and cooked products, an environmental

management and monitoring program, and sanitary practices for equipment and personnel.

4. *Preventing an increase in *S. aureus* levels between manufacturing and preparation for serving* by controlling during storage and distribution any increase in the *S. aureus* level that may occur after recontamination. Measures that may be taken to achieve this goal include maintaining adequate refrigeration of fillings and baked goods that are capable of supporting *S. aureus* growth, using labeling instructions for consumers, altering the formulation by reducing pH or RH, and using safe, acceptable additives.

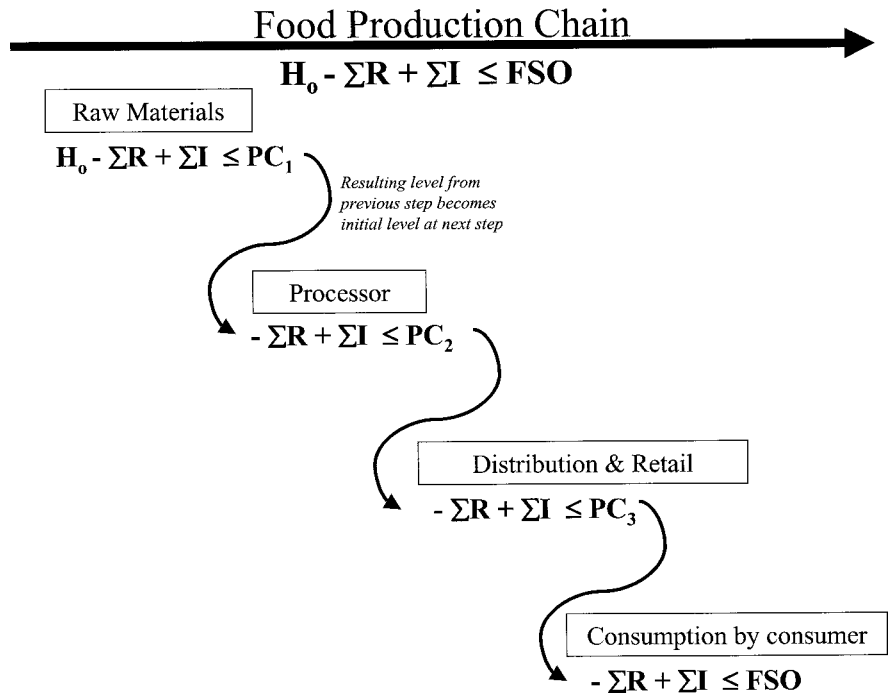
Performance criteria. A performance criterion is the outcome required at one or more steps in the food chain in order to achieve an FSO (44). Performance criteria are usually applied for steps at which hazards either can be reduced or may increase. The performance criterion for one step can become the initial level (H_0) for the next step in the food chain, and the outcomes of all of the control measures should ensure that the hazard level remains below the FSO (Fig. 1).

The equation $H_0 - \Sigma R + \Sigma I \leq \text{FSO} = 4.0$ (where FSO is the food safety objective [$4 \log_{10}$ or 10^4 CFU/g], H_0 is the initial level of the hazardous agent, ΣR is the total (cumulative) reduction in the level of the hazardous agent, ΣI is the total (cumulative) increase in the level of the hazardous agent, and FSO, H_0 , R , and I are expressed in \log_{10} units) can be used to arrive at a single performance criterion or a series of performance criteria for the control measures needed to achieve an FSO for cream-filled baked goods (44). An overview of considerations for H_0 , I , and R for each step in the food chain for *S. aureus* in cream-filled baked goods is given in Table 3. Specific steps are demonstrated in the following examples with both text and illustrations.

Controlling initial levels in raw materials. Pasteurized dairy products should be used in the production of cream-filled baked goods to avoid *S. aureus* that may be present in raw milk and cream. Staphylococci are eradicated by high-temperature-short-time pasteurization and ultra-high-temperature treatments commonly used in the pasteurization of milk (35, 56). When liquid dairy products are received at the bakery, they should immediately be placed in refrigerated storage (41), since no *S. aureus* growth will occur at $<5^\circ\text{C}$ (42). If pasteurized milk and eggs are used, it can be assumed that no *S. aureus* cells will be present.

Garcia et al. (32) reported that *S. aureus* can be present at high concentrations ($>10^3$ CFU per swab) in the anterior nares of food handler carriers. Several studies have shown that *S. aureus* can grow to high levels and/or produce enterotoxin in various custard and cream fillings in <24 h at $\sim 24^\circ\text{C}$ at inoculum levels of 10^2 to 10^3 CFU/g (5, 54, 59). If pasteurized liquid dairy ingredients are used (and therefore no *S. aureus* cells are present), it can be assumed that the presence of *S. aureus* in the cream filling or custard prior to cooking would be due to contamination via food handlers, equipment, or aerosols. Therefore, for the purposes of this example, the initial number in the filling mix is assumed to be ≤ 100 CFU/g

FIGURE 1. Schema demonstrating the use of a performance criterion at each step in the food chain to achieve the FSO at the point of consumption. H_0 is the initial level of the hazardous agent, ΣR is the total (cumulative) reduction in the level of the hazardous agent, ΣI is the total (cumulative) increase in the level of the microbiological hazard, and PC is the performance criterion.



(i.e., $H_0 = 2$) owing to the contamination of ingredients by food workers or contaminated equipment.

Reducing *S. aureus* levels during cooking of cream or custard fillings in the manufacturing process. If the initial numbers of *S. aureus* in the filling mix could be as high as 100 CFU/g (i.e., $H_0 = 2$), then theoretically, no reduction via thermal processing (i.e., the cooking of filling) would be needed to meet the FSO of 4.0, since $2 \leq 4$. However, if any viable cells remain in the filling, by the time the baked goods are consumed there is potential for concentrations to exceed 10^4 CFU/g, especially if there are no additional barriers to growth and/or if refrigerated stor-

age is not used during all stages of distribution and storage. To ensure that the FSO is met at the point of consumption, it is necessary to apply a stringent cooking process for the filling. For this example, it will be assumed that a 5-log_{10} reduction ($\Sigma R = 5$) during cooking will achieve the desired result given an initial concentration of ≤ 100 CFU/g ($H_0 = 2$). Therefore, a 5-log_{10} reduction would result in a final concentration of $\leq 10^{-3}$ CFU/g (< 1 CFU/kg) after cooking. This could be expressed as the following performance criterion: the concentration of *S. aureus* after cooking shall be $\leq 10^{-3}$ CFU/g. This criterion is illustrated in Figure 2 and demonstrated in the following equations: $H_0 - \Sigma R + \Sigma I$

TABLE 3. Considerations for H_0 , ΣI , and ΣR for each step in the food chain for *Staphylococcus aureus* in cream-filled baked goods

Steps in food production chain	Include in equation	Reason
Processing stage		
Prevention of growth		
Growth (ΣI)	+	Product not formulated to prevent growth
Growth ($\Sigma I = 0$)	-	Product formulated to prevent growth
Cooking of cream filling		
Pathogen present (H_0)	+	Present in small numbers
Pathogen reduced by process (ΣR)	+	Eliminated
Prevention of recontamination		
Recontamination (ΣI)	+	Minimized with aseptic/hygienic filling and packaging
In-pack pasteurization		
Pathogen reduced by process (ΣR)	+	Eliminated
Distribution and retail stage		
Recontamination (ΣI)	±	Unlikely if appropriately packaged
Growth (ΣI)	±	Unlikely if chilled during distribution or formulated to prevent growth
Consumer stage		
Recontamination (ΣI)	±	Possible through product handling
Growth (ΣI)	±	Possible depending on time-temperature storage

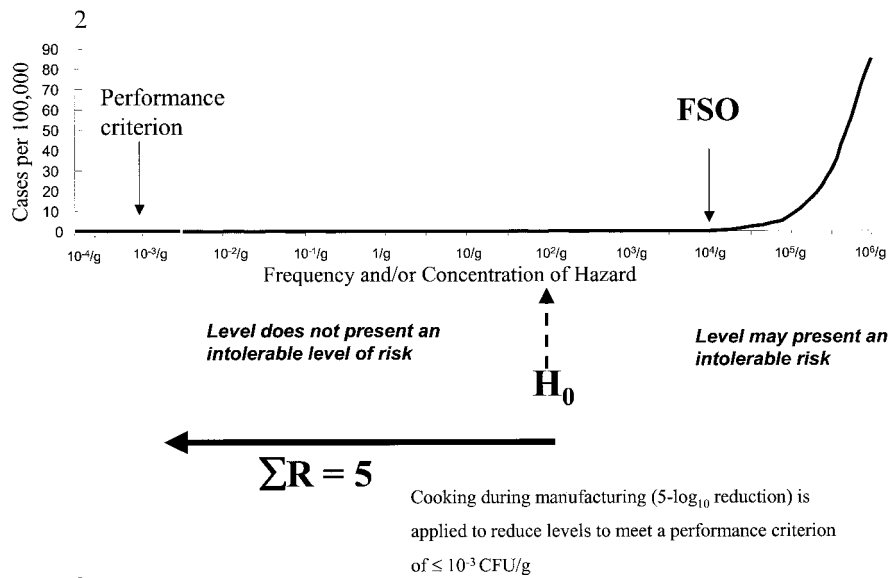


FIGURE 2. Control measure: reducing the levels of *S. aureus* during the cooking of cream or custard fillings. H_0 is the initial level of the hazardous agent, and ΣR is the total (cumulative) reduction in the level of the microbiological hazard.

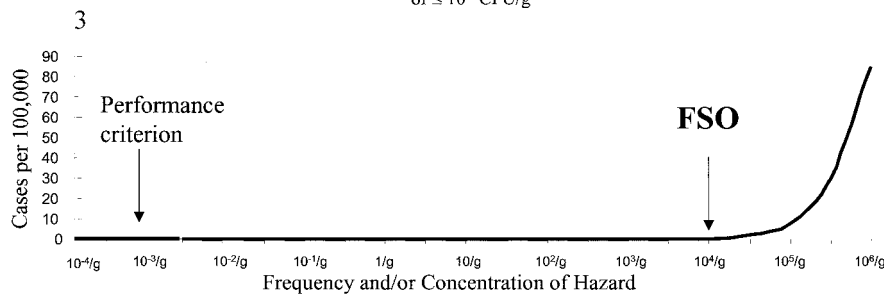


FIGURE 3. Control measure: preventing recontamination with *S. aureus* between the cooking of cream or custard filling and the filling of pastry shells. H_0 is the initial level of the hazardous agent, ΣR is the total (cumulative) reduction in the level of the hazardous agent, and ΣI is the total (cumulative) increase in the level of the microbiological hazard.

Preventing recontamination between cooking and packaging through effective GHP and HACCP

$$H_0 - \Sigma R + \Sigma I \leq \text{Performance criterion } (< 10^{-3} \text{ CFU/g})$$

$$2 - 5 + \Sigma I \leq -3$$

$$\Sigma I \leq 0$$

\leq performance criterion for this step in manufacturing, and $H_0 - \Sigma R + \Sigma I \leq -3$ (10^{-3} CFU/g or 1 CFU/kg). If the initial number could be shown to be < 100 CFU/g through stringent raw material selection and if no increase during handling and storage occurred ($\Sigma I = 0$), a 5-log_{10} reduction would be adequate to meet the performance criterion for this step ($\leq 10^{-3}$ CFU/g [or 1 CFU/kg]). Hence, $2 - \Sigma R + 0 \leq -3$, and $\Sigma R = 5$.

Preventing recontamination between cooking of cream or custard and filling of pastry shells. Preventing recontamination of the cream filling after cooking is difficult. Since *S. aureus* is commonly found on the skin and mucous membranes of humans, most contamination of cream-filled baked goods occurs either while the filling is cooling or during handling (43). *S. aureus* can be recovered at different frequencies depending on the sanitary conditions during production; in fact, the level of *S. aureus* in cooked, cooled fillings can be used as a measure of human contact (41). The FDA concluded in 1966 that bakeries operating under the best sanitary conditions can produce cream-filled baked goods with no detectable levels of *S. aureus*, whereas those operating under poor conditions cannot (72).

Although levels of *S. aureus* in the cooked cream fill-

ing or custard (meeting our performance criterion) are $< 10^{-3}$ CFU/g (< 1 CFU/kg), recontamination and subsequent growth due to improper holding prior to the filling of the baked goods may lead to levels exceeding this performance criterion. Certain control measures (i.e., GHP-GMP procedures) can be important in insuring that our performance criterion for *S. aureus* in cream-filled baked goods is met. Such measures include the laying out of the bakery or plant to keep raw ingredients separated from cooked products as well as to control dust and aerosols; the maintenance, cleaning, and sanitization of equipment; low-temperature storage; and the use of hygienic practices by food handlers (43). As discussed above, experience with foodborne outbreaks associated with cream-filled baked goods indicates that contamination via food handlers followed by storage at temperatures above refrigeration temperatures is a major factor in the causation of illness. The food handler acts as a reservoir from which the pathogen is dispersed and contaminates the product. Therefore, the health and hygiene of personnel are critical and in fact may be considered critical control points (41).

The sanitization of equipment that comes in contact with cooked fillings should be monitored, since such equip-

FIGURE 4. Control measure: preventing an increase in *S. aureus* levels between manufacturing and serving. H_0 is the initial level of the hazardous agent, ΣR is the total (cumulative) reduction in the level of the hazardous agent, and ΣI is the total (cumulative) increase in the level of the microbiological hazard.

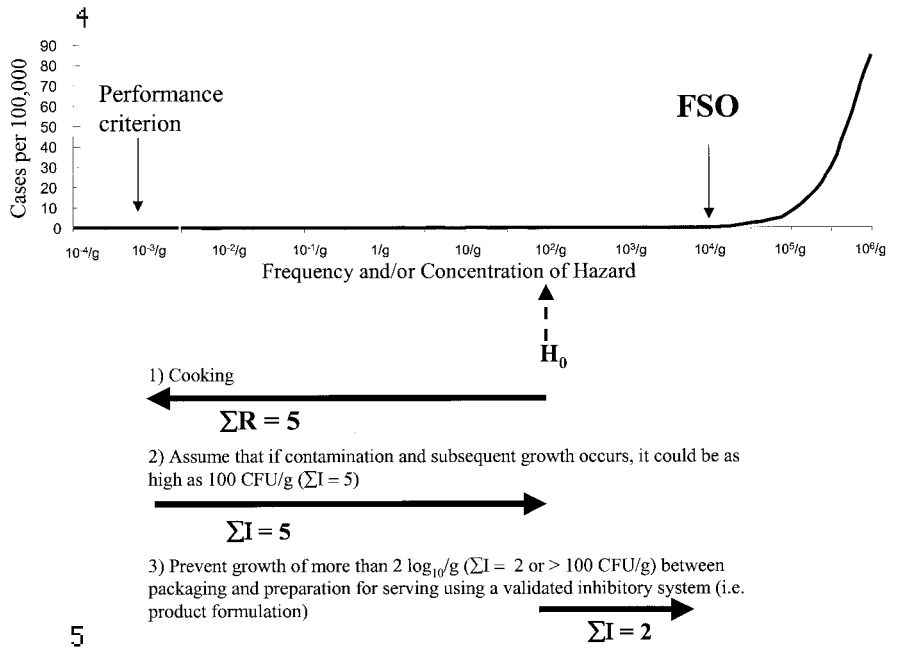
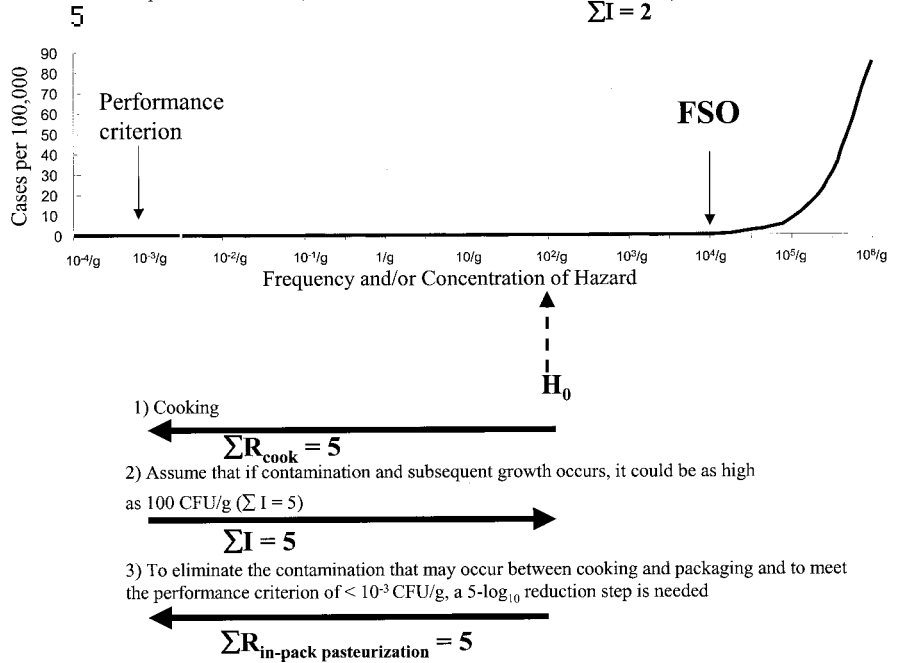


FIGURE 5. Control measure: reducing levels of *S. aureus* in the product after packaging with the use of in-package pasteurization. H_0 is the initial level of the hazardous agent, ΣR is the total (cumulative) reduction in the level of the hazardous agent, and ΣI is the total (cumulative) increase in the level of the microbiological hazard.



ment provides considerable opportunities for the recontamination of bulk filling during cooling, conveyance, and dispensation. Such contamination can occur via equipment used for unpasteurized products and then for cooked products and by the touching of cooked cream fillings or finished baked goods after handling unpasteurized products (12, 43). Additionally, during the mixing of batters or fillings or during the whipping of cream, fine droplets are produced, and these aerosols can be carried by air currents to other areas and contaminate other products. Dust can be generated from powdered ingredients that may settle across a room and, if contaminated, spread pathogens. Ventilation should therefore be designed so that filtered air flows from the finished product area to the production area (12).

It is difficult to assign a performance criterion with respect to recontamination, since any recontamination has the potential to reach high levels through growth followed by sub-

sequent toxin production during distribution and storage. To ensure that the performance criterion of $\leq 10^{-3}$ CFU/g (≤ 1 CFU/kg) is not exceeded because of recontamination of the filling after cooking and subsequent growth due to improper holding prior to the filling of the baked goods, there must be no recontamination, and I must be zero in the equations $H_0 - \Sigma R + \Sigma I \leq$ performance criterion for this step in manufacturing, $H_0 - \Sigma R + \Sigma I \leq 10^{-3}$ CFU/g, $-3 - 0 + \Sigma I \leq -3$, and $\Sigma I = 0$ (see Fig. 3).

Preventing an increase in *S. aureus* levels between manufacturing and serving. If the increase in the *S. aureus* concentration due to recontamination of cooked cream filling and subsequent growth due to improper holding prior to the filling of the baked goods is assumed to be as high as 100 CFU/g (i.e., a 5- \log_{10} increase from 10^{-3} CFU/g [$\Sigma I = 5$]) and the FSO of $\leq 10^4$ CFU/g at the time of con-

sumption still needs to be met, there can be no more than a 100-fold increase during the storage and distribution of the finished cream-filled baked goods before these goods are consumed (see Fig. 4). Hence, $H_0 - \Sigma R + \Sigma I \leq \text{FSO}$, $2 - 0 + 2 \leq 4$, and $\Sigma I \leq 2$ during distribution and storage of the finished product. If recontamination and subsequent growth (to levels of up to 100 CFU/g) occur, a ≥ 100 -fold increase must be controlled with the appropriate formulation (i.e., the appropriate RH and pH levels), with the addition of inhibitory ingredients, or with the refrigeration of the final product during distribution and/or the establishment of a use-by date that is within the time required for a 100-fold increase.

Reducing *S. aureus* levels in the product after packaging (in-package pasteurization). Experience indicates that recontamination of the cream filling after cooking is the most common reason for the presence of *S. aureus* in cream-filled baked goods. If the increase in the *S. aureus* concentration due to recontamination after cooking of the filling and subsequent growth due to improper storage is assumed to be as high as 100 CFU/g, then an in-package pasteurization treatment could be applied to achieve a 5- \log_{10} reduction and still meet the performance criterion of $<10^{-3}$ CFU/g (<1 CFU/kg). As demonstrated in the equations below, if cooking provides an initial 5- \log_{10} reduction and recontamination results in a level of 100 CFU/g, then an in-package pasteurization treatment could be used to provide an additional 5- \log_{10} reduction and to meet the performance criterion of $<10^{-3}$ CFU/g. The combined cooking (R_{cook}) and subsequent in-package pasteurization (R_{ipp}) steps needed to produce a 10- \log_{10} reduction ($\Sigma R = 10$) are illustrated in Figure 5 and demonstrated in the following equations: $H_0 - \Sigma R + \Sigma I \leq$ performance criterion for this step in manufacturing, $H_0 - \Sigma R + \Sigma I \leq -3$, $2 - \Sigma R$ ($R_{\text{cook}} + R_{\text{ipp}}$) $+ 5 \leq -3$, and $\Sigma R = 10$ (cooking $R = 5$, in-package pasteurization $R = 5$).

PROCESS AND PRODUCT CRITERIA

Each manufacturer must determine the parameters for the cooking of the cream or custard filling that will provide the desired product quality and cost and, in this example, ensure that the performance criterion (i.e., $<10^{-3}$ CFU/g or <1 CFU/kg) is met. The parameters adopted by one bakery may be different from those adopted by others owing to differences in equipment, desired product quality, types of raw materials, procedures for filling baked goods with the cream or custard, intrinsic properties of the filling, and other factors.

To meet the performance criterion, knowledge of the heat sensitivity of *S. aureus*, particularly in cream or custard fillings, is required. For example, the temperatures involved in normal baking are sufficiently high to destroy all non-spore-forming bacteria as well as the vegetative cells of sporeformers; both salmonellae and staphylococci are destroyed by baking. The cooking of fillings to temperatures of 76 to 82°C is likewise historically known to be destructive (65). There is no evidence that fillings processed with a decontamination step have ever been implicated as

a source of foodborne illness because of the survival of staphylococci. The effectiveness of such a decontamination step is likely due to the low initial concentration of staphylococci and their sensitivity to heat. Table 4 summarizes reported thermal destruction values for *S. aureus* in cream or custard fillings and milk. Although decimal reduction times (D -values) for the heat inactivation of *S. aureus* in milk are readily available, no D -values for the heat inactivation of *S. aureus* in custard or cream fillings could be found in the literature. The one reported D -value for *S. aureus* in custard is a D_{60} -value of 7.68 to 7.82 min (3). It is important that any thermal processes be validated, and such validation may be accomplished by a number of different means (44).

In the absence of an FSO, it may be appropriate to establish default criteria for certain control measures (44). These fail-safe criteria are typically less flexible and provide a safe harbor for food operators lacking either the resources or the desire to develop the information necessary for alternative criteria specific to their products and operations. Given the information on the thermal inactivation of *S. aureus* in the preceding paragraph, an example of a default criterion may be the cooking of custard or cream filling until the internal temperature is 82°C.

Product criteria that are intended to prevent growth during storage and distribution should be validated through challenge studies involving inoculated cream or custard filling to assess the likely increase (ΣI) in the *S. aureus* level before the recommended use-by date. Many factors should be considered when such studies are conducted (39, 44). Predictive modeling can also provide an estimate of a pathogen's behavior. For example, both the U.S. Department of Agriculture (USDA) Pathogen Modeling Program (available at the USDA website [<http://www.arserrc.gov/mfs/pathogen.html>]) and the Food MicroModel (available at <http://www.foodmicromodel.com>), developed in the United Kingdom through the Ministry of Agriculture, Fisheries and Food, include *S. aureus* growth kinetic models (16, 73, 81). For all of the above-mentioned models, NaCl was the humectant chosen to control the relative humidity in the system, and therefore care should be taken when these data are used for predicting the behavior of *S. aureus* in systems in which different humectants are used (63, 67, 68, 77).

Growth boundary models can also provide an estimate of the likelihood of a pathogen's ability to survive and grow under given conditions. For *S. aureus*, Stewart et al. (68) have developed growth boundary models based on RH (adjusted with various humectants) and pH, both with and without potassium sorbate. Table 5 presents some shelf life determinations based on various pH and RH combinations, and Table 6 presents some shelf life determinations based on various combinations of pH, RH, and 1,000 ppm of potassium sorbate. Validation of the model predictions in the commercial product should be conducted via challenge studies, especially since it is often difficult to predict whether specific fillings will support staphylococcal growth because of the migration of water from the pastry or cake to the interface of the filling or cake, which can create localized areas of high RH (12, 65).

TABLE 4. Reported thermal destruction values for *Staphylococcus aureus* in cream and custard fillings and in milk^a

Product	Temp (°C)	D-value (min)	F-value	Reference
Custard	54.4	NA	530, 540 ^b	2
	57.2	NA	165, 180 ^b	2
	60.0	7.68, 7.82 ^b	53, 59 ^b	2
	62.8	NA	16.5, 19.5 ^b	2
	65.6	NA	5.2, 6.6 ^b	2
Cream filling	65	NA	8	38
	75	NA	<4	38
	85	NA	3	38
Reheated custard puffs	190.6 ^{c,d}	NA	30	70
	204.4 ^{c,d}	NA	25	70
	218.3 ^{c,d}	NA	25	70
	232.2 ^{c,d}	NA	20	70
Reheated éclair	216–220 ^e	NA	15	34
Skim milk	60.0	3.28, 3.44 ^b	NA	75
	65.6	0.39, 0.28 ^b	NA	75
Milk	50	10	NA	42
	55	3	NA	42
	60	0.9	NA	42
	65	0.2	NA	42
	70	0.1	NA	42
	75	0.02	NA	42

^a NA, data not available.

^b Values for two strains tested.

^c Temperature of oven in which whole product was placed.

^d Maximum temperatures for filling within pastry were 75°C for 5 min and 76.7°C for 6 to 8 min for uncovered and covered pans, respectively.

TABLE 5. Generic shelf life estimates and conservative shelf life determinations (68) for glycerol and sucrose-fructose models with no potassium sorbate^a

RVP	pH 6.6	pH 6.0	pH 5.5	pH 5.0	pH 4.6
Generic shelf life estimates					
0.94					
0.92	Hours	Hours	Hours	Hours	Days
0.90	Hours	Hours	Hours	Days	Days
0.88	Days	Days	Days	Days	Weeks
0.86	Weeks	Weeks	Weeks	Months	Months
	Months	Months	Months	Months	Months
Days to growth as determined by Stewart et al. (68) for the glycerol model with no potassium sorbate					
0.94	0.5	0.4	0.5	1.2	3.6
0.92	0.7	0.6	0.8	2.3	7.6
0.90	2.2	1.9	3.3	10.2	37.5
0.88	15.0	15.5	30.1	103	421
0.86	238	284	620	2,408	10,783
Days to growth as determined by Stewart et al. (68) for the sucrose-fructose model with no potassium sorbate					
0.94	0.3	0.2	0.4	1.1	3.8
0.92	1.0	1.0	1.8	5.7	21.8
0.90	8.3	9.1	18.6	67.4	285
0.88	154	196	449	1,836	8,566
0.86	6,542	9,609	24,920	114,860	590,056

^a Generic shelf life estimates are based on the data and assumptions of Stewart et al. (68) for the glucose and sucrose-fructose models with no potassium sorbate. RVP, relative vapor pressure; hours, <2 days; days, 2 to 13 days; weeks, 13 to 60 days; months, >60 days.

TABLE 6. Generic shelf life estimates and conservative shelf life determinations (68) for glycerol and sucrose-fructose models with 1,000 ppm of potassium sorbate^a

RVP	pH 6.6	pH 6.0	pH 5.5	pH 5.0	pH 4.6
Generic shelf life estimates					
0.94	Hours	Hours	Days	Weeks	Months
0.92	Hours	Days	Days	Weeks	Months
0.90	Days	Days	Weeks	Months	Months
0.88	Weeks	Weeks	Months	Months	Months
0.86	Months	Months	Months	Months	Months
Days to growth as determined by Stewart et al. (68) for glycerol model with 1,000 ppm of potassium sorbate					
0.94	0.6	1.3	4.6	29.7	199
0.92	0.8	2.0	8.0	57.9	428
0.90	2.3	6.8	31.5	258	2,098
0.88	16.2	54.7	284	2,626	23,529
0.86	256	1,001	5,869	61,151	1,132,410
Days to growth as determined by Stewart et al. (68) for the sucrose-fructose model with 1,000 ppm of potassium sorbate					
0.94	0.7	2.0	8.4	64.4	496
0.92	2.6	8.0	38.7	334	2,827
0.90	20.7	74.5	407	3,962	36,982
0.88	384	1,595	9,846	107,999	1,110,135
0.86	16,324	78,419	545,955	6,755,342	76,465,355

^a Generic shelf life estimates are based on the data and assumptions of Stewart et al. (68) for the glucose and sucrose-fructose models with 1,000 ppm of potassium sorbate. RVP, relative vapor pressure; hours, <2 days; days, 2 to 13 days; weeks, 13 to 60 days; months, >60 days.

Examples of preservatives that have been found to be effective in inhibiting *S. aureus* growth include potassium sorbate, sodium benzoate, sodium nitrate, sodium propionate, butylated hydroxyanisole, and sodium acid pyrophosphate in combination with potassium sorbate (24, 66, 76). The effectiveness of weak acids or their salts is usually increased by a decrease in pH to 3 to 5, at which a large proportion of the acid is undissociated. The pH of most commercial custards used in bakeries is typically 5.8 to 6.6 (12), so lowering the pH to <5 may not be practical and/or may cause the final quality or flavor of the product to be unacceptable to the consumer.

As discussed by the ICMSF (44), a uniform procedure for validating code-dating practices to ensure the safety of perishable foods with extended shelf lives has not been developed. When the effectiveness of code dating is validated, a number of factors should be considered, including the physiological state of the microorganisms involved, the inoculation methods, the inoculum level, the source and number of strains used, the storage temperature(s), the natural competitive flora, and the product formulation (44). Additionally, new strategies are needed to ensure that consumers receive sufficient product safety information about the storage and shelf lives of refrigerated products so that consumers can store these products properly and use or discard them when the shelf life expires (30). A recent report from an expert panel charged with reviewing the scientific basis for requiring temperature control for foods concluded in part that while some foods would always require temperature control to prevent pathogen growth, other foods could be held at ambient temperatures for different lengths of

time (sometimes days or weeks) before a significant increase in risk occurred (39).

GHP AND HACCP

As discussed in the introduction, a set FSO must be technically achievable by GHP and HACCP systems. The scientific literature and common practice both support the idea that the cornerstones of the control of pathogens in cream-filled baked goods are proper sanitary technique and refrigeration (1, 12). Improper holding temperatures is the factor most frequently reported to contribute to foodborne outbreaks and has specifically been reported to play a role in up to 98% of SFP outbreaks (Table 7). Poor personal hygiene is the next most reported contributing factor, with contaminated equipment and inadequate cooking also being implicated (Table 7).

The growth of *S. aureus* and subsequent toxin production in cream fillings can be prevented by refrigeration at temperatures of <5°C (22, 64). It has been suggested that bulk cream filling or cream-filled baked goods should not be held at 5.5 to 52.2°C for more than three cumulative hours, including chilling time (12). More recently, guidelines for chilled foods have stated that foods should be cooled rapidly so that they do not remain in the temperature range of 21 to 49°C for longer than 2 to 3 h and that the foods should be continually cooled so that their temperatures fall to 7°C in another 4 to 6 h (13). Cream-filled baked goods should be transported and stored at retail under refrigeration at ≤5°C (43).

Practices involving the health and hygiene of personnel and the manipulation of foods after cooking may be con-

TABLE 7. Numbers of reported foodborne outbreaks for which factors thought to contribute were reported^a

Etiologic agent or vehicle	No. of outbreaks for which factors were reported	No. of outbreaks thought to involve contributing factor				Reference
		Improper holding temperatures	Poor personal hygiene	Inadequate cooking	Contaminated equipment	
Cream-filled pastries	367	262	110	12	21	12
<i>Staphylococcus aureus</i>	131	84	43	NA	22	37
<i>S. aureus</i>	272	267	193	60	117	8
Bakery products	51	37	34	6	29	8
<i>S. aureus</i>	42	37	18	15	3	7
Foodborne outbreaks	134	60	41	4	2	48
<i>S. aureus</i>	NA	25	12	3	6	55

^a For many outbreaks, more than one factor was responsible. NA, data not available.

sidered critical control points and as such must be monitored (15, 41). A number of approaches for detecting infected food handlers and preventing them from handling foods have been tried, but all of these approaches have been found to have significant limitations. A working group of the World Health Organization Regional Office for Europe concluded that the routine examination of all food handlers should have a low priority because limitations associated with the monitoring of the health status of food handlers prevent such a procedure from being useful as a control measure. A more effective approach would be the education of food handlers. The strict supervision and control of food hygiene can be part of the HACCP system. Further details are given by the ICMSF (41).

Hands as well as contaminated gloves can serve as vectors for the transmission of microorganisms to foods. The hands of food handlers play a central role in the transfer of bacteria and viruses from person to person, from person to surfaces or vice versa, and from person to food (36). Thorough hand washing can effectively remove transient microfloras from the hands but is not effective in removing resident microfloras such as *S. aureus*, which can be buried deep within the pores, where they are protected by sebaceous gland secretions (12, 36, 46). Therefore, the washed hand can remain a potential source of cross-contamination. Chen et al. (21) showed that although the washing of hands according to U.S. food code regulations (29) reduced bacterial levels, it did not eliminate bacteria from hands initially inoculated with $\sim 10^7$ CFU of *Enterobacter aerogenes*. Additionally, these investigators reported that bacterial transfer among hands, foods, and kitchen surfaces are variable and that faucet spigots may be a significant source of cross-contamination. A study by Scott and Bloomfield (62) showed that contact between fingers and surfaces with low levels of *S. aureus* contamination can allow the transfer of the microorganism in numbers that can pose a potential infection hazard.

Although an intact vinyl or latex glove will provide protection from the transmission of microorganisms from hands to foods, the use of gloves alone does not provide a sufficient barrier to the transmission of pathogenic microorganisms from food employees to consumers (27). A study

by Montville et al. (51) showed lower rates of transfer of *E. aerogenes* from food to hands and from hands to food when subjects wore gloves than when they did not, but the results of Montville et al.'s study also indicated that glove use does not completely eliminate the risk of cross-contamination. Gloves worn for long periods or used while handling contaminated foods can become contaminated with transient microorganisms. Gloved hands often perspire, allowing bacteria such as *S. aureus* to multiply rapidly, so that if the glove is subsequently punctured or ripped, large numbers of bacteria can leak from the glove (12). Gloved hands are seldom washed as frequently as bare hands, and it is not unusual for food employees to put gloved hands to their mouths or noses without changing their gloves. Montville et al. (51) indicated that a combination of hand rinsing and glove use is more effective than glove use alone, and these investigators stress the importance of properly washed hands in conjunction with gloves that are frequently changed. Even with the best intentions with regard to personal hygiene and hygienic handling of fillings and pastries, contamination can still occur (12). A review by Guzewich and Ross (36) provides a comprehensive summary of current information from scientific literature provided to the FDA about the effectiveness of interventions, such as various hand-washing methods, in preventing or minimizing contamination of ready-to-eat foods by food workers.

ACCEPTANCE CRITERIA FOR FINAL PRODUCT

Organoleptic criteria. No organoleptic criteria are applicable to the assessment of the likelihood of the presence of *S. aureus* in cream-filled bakery products.

Chemical and physical criteria. No chemical or physical criteria are applicable to the assessment of the likelihood of the presence of *S. aureus* in cream-filled cakes.

Microbiological criteria. For plants that are using a validated kill step and at which it is known that the risk of recontamination is being controlled through effective GHP and HACCP programs, there is little value in testing the end product, since a comprehensive management system can keep contamination frequencies at <0.5% (44). Under

these circumstances, the frequency of defective units is too low for detection with any practical sampling plan (44).

In a situation in which a product is crossing international borders and nothing is known about the product or the manufacturing process, end product testing may be appropriate. The ICMSF has provided guidance with regard to sampling plans for *S. aureus* in a variety of foods and under a variety of conditions (40). For frozen ready-to-eat bakery products with low-acid or high-water activity ingredients, case 8 ($n = 5, c = 1$) would apply. The lot would be rejected if more than one sample was found to contain pathogen levels of $>10^2$ but $<10^4$ CFU/g or if any sample was found to contain a pathogen level of $>10^4$ CFU/g. When case 8 is applied, there is a 95% probability that a positive lot would be detected when the mean concentration is 209 CFU/g.

SUMMARY

The ICMSF has responded to the need for a science-based management system for determining equivalency of control measures for safe food production (44, 79). The recently proposed scheme for the management of microbial hazards for foods includes the concept of FSOs, which provide a basis for measuring the effectiveness or adequacy of control systems adopted by industry, government, and/or regulatory agencies. FSOs should be technically achievable by the general industry through the application of appropriate food safety management systems, e.g., GHP or GMP and HACCP systems. Performance and process-product criteria are established, and the process is then implemented through GHP and HACCP plans. This article has illustrated the application of the ICMSF principles for setting FSOs and the use of performance criteria, process criteria, and validation in relation to HACCP and GHP plans by considering the microbiological hazard of *S. aureus* in cream-filled baked goods.

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