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Issues in Time and Temperature Abuse of Refrigerated Foods

The cold chain plays a monumental role in modern global trade in all food commodities. Increasingly, market demand has heightened the importance of uncompromised food safety and quality as it travels through sectors that include farming, food processing transportation/distribution, retailing and ultimately as it ends up in the foodservice industry or on the consumer's table. Food companies spend millions of dollars to ensure the integrity and wholesomeness of their refrigerated products, yet many are faced with the necessity of recalling products that have been adulterated or contaminated along points of the cold chain.

Refrigerated storage is now one of the most widely practiced methods of controlling microbial growth in perishable foods. As a result of this practice, refrigerated storage of perishable foods has been shown to be a potential risk factor for the development of microbial hazards leading to foodborne illness. Control of the storage temperature is vital in maintaining the quality and safety of refrigerated foods throughout the food continuum (gate to plate). As a consequence, it is important that good chill/storage procedures are in place to ensure that such foods not only achieve their required shelf lives but are safe for consumption by the end user. While major manufacturers and retailers operate a constant and effective cold chain, surveys in the U.S. have revealed that 20% of domestic and commercial refrigerators operate at a temperature of >10°C (50°F).

Over the years, the traditional definition of "perishable foods" has been massaged and revised. The term "potentially hazardous foods" (PHF) has been found to better describe the factors that relate to pathogenic bacterial growth in foods. Even this definition continues to be challenged with the advent of scientific anecdotes.

In 2001, the Institute of Food Technologists (IFT) panel found that Australia and Canada use terms similar to the U.S. Food and Drug Administration (FDA) Food Code definition of PHF, and its associated requirements. Other regulatory entities have temperature control requirements but do not use the same term. While temperature requirements for these chilled (refrigerated) foods are identified, other regulations for temperature control generally do not present guidelines or any framework to determine which foods fall into the "chilled" category. There are sometimes lists of products that need to be temperature controlled included within these definitions. These products generally have a history of association with illness in the absence of temperature control.

During storage, microbial flora of food products is not static. It is affected by many factors, however the length of time and the temperature at which it is kept have the greatest impact on food safety and quality. The importance of monitoring temperatures under the Hazard Analysis and Critical Control Points (HACCP) food safety management program and HACCP-based food safety programs during processing, distribution, retail display and consumer storage of PHF is key to ensuring that temperature abuse does not occur. Even with proper handling (e.g., hygienic to prevent contamination), the grower/manufacturer/distributor continues to be responsible for ensuring that the environment for transportation and distribution is such that it controls not only biological, but also chemical and physical hazards.

Regulatory communities exhibit inconsistencies and provide conflicting recommendations with regard to length of time PHF may be kept within the "danger zone" (less than 60°C or 140°F or above 4°C or 40°F) prior to disposal.

For example, the FDA 2005 Food Code dictates that food shall be cooked and served, served if ready-to-eat (RTE), or discarded, within 4 hours from the point in time when the food is removed from temperature control if time only, rather than time in conjunction with temperature control is used as the public health control. The Code further indicates that under more strict conditions, including monitoring of the food temperature at the warmest point to ensure that it does not exceed 21°C (70°F), the food may be kept a maximum of up to 6 hours before corrective action is taken ['3-501.19]. However, a Canadian Food Inspection Agency (CFIA) fact sheet insists that 2 hours is the maximum time that these products may be kept in the "danger zone." The Canadian Food Inspection System Good Transportation Practices Code and the Food Retail and Food Services Code mimic these recommendations.

To further complicate matters, when industry is faced with a known temperature-abused product, it must decide on the proper course of action to dispose of the PHF. Destroying product is not always the best option. Can the product, for example, be served immediately, re-evaluated, or perhaps, further processed? Cost-recovery, as a priority, must not compromise food safety by allowing food to be sold which could result in illness. An enhanced decision process can be achieved by applying HACCP-based food safety principles and a sound scientific foundation can provide a guide for industry to determine corrective action(s).

At present, there is limited research that supports the data provided by regulatory bodies. The research findings using various factors such as introduced pathogens, food characteristics, temperatures and time all point to valid results but appear to be inconsistent. We will attempt to dissect these truisms in order to expose the reader to the complexity of the problem in the real world of the food supply chain.

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Understanding Time, Temp and Microbial Growth

The need for time/temperature control is primarily determined by the potential for contamination with and survival of pathogenic microorganisms of concern, and the potential for subsequent growth and/or toxin production. The following non-inclusive list of factors, and any combination thereof, may be considered when determining whether a food requires time/temperature control during storage, distribution and handling at retail in food service to assure consumer protection: initial microflora present, type and composition of food (e.g., water activity, pH, acidity, nutrient content) and processing methods (e.g., heating, cooling, preservatives, and antimicrobial agents).

Time alone, at ambient temperatures, may be used to control the safety of products. The duration should not be greater than the lag phase of the pathogen(s) in the product. During this lag phase, the cells are assimilating nutrients and increasing in size. The lag time and generation time of a microorganism depends on temperature; therefore, for a specific food product, *the shelf life* or *use period* required for safety may vary depending on the temperature at which the product is stored. In other words, the longer a product is allowed to stay in the "danger zone," the greater the potential for the microorganisms to grow to the point where sufficient numbers will exist to cause infestation (live bacteria) or intoxication (from toxins). Generally, as storage temperature decreases, the lag phase before growth (time before an increase in numbers of cells is apparent) extends and the rate of growth decreases. In addition, as the minimum temperature for growth is approached, the maximum population size attainable often decreases. The range of the temperatures in which microorganisms can grow is extremely wide.

Fluctuation of temperature during storage greatly impacts growth, sublethal injury, and death of microorganisms. Fluctuations readily happen during storage, transport, retail display, and at the home. A fluctuation of temperature in food from 4.4°C to 10°C to 12°C (40°F to 50°F to 54°F) not only stimulates rapid growth of psychrotrophic pathogenic and spoilage bacteria, but many mesophilic spoilage and pathogenic bacteria are also able to grow and their spores germinate in this range.

The types of microorganisms that may be found in various refrigerated foods are diverse. To further complicate matters, each type of microorganism has its own preferred growth temperature range known as minimum, optimum and maximum temperature. These microorganisms are classed into categories: thermophiles (grow at high temperatures, range 45°C to 70°C [113°F to 158°F]); meshophiles (grow at ambient temperature, range 10°C to 45°C [50°F to 113°F]) and psychrophiles (grow at cold temperature, range -5°C to 20°C [23°F to 68°F]). Under ideal conditions some bacteria may grow and divide every 20 minutes. Consequently, one bacterial cell may increase to 16 million cells in 8 hours.

Foods pose a health hazard when microorganisms that may invade the body (e.g., *Salmonella* spp., *Listeria monocytogenes*, *Escherichia coli* O157:H7 and *Campylobacter* spp.) or toxins that are ingested with food (e.g., those produced by *Clostridium botulinum*, *Staphylococcus aureus* and *Bacillus cereus*) are present. The growth risk of foodborne pathogens is predominantly the combination of the minimum growth temperatures, the growth rate at chill temperatures and the time and temperature(s) of storage.

The suggested temperature specification for refrigeration of foods has been revisited from time to time as knowledge and technology have advanced. Initially 7°C (45°F) was considered the optimal temperature; however, technological improvements have made it economical to have domestic refrigeration units working at a temperature of 4-5°C (40-41°F). For perishable products ≤4.4°C (40°F) is considered a desirable refrigeration temperature. Optimum refrigeration in commercial facilities not only demands that appropriate temperatures are maintained but requires that the relative humidity and proper spacing of products is observed. Even these measures cannot control all pathogenic bacterial growth. For example *L. monocytogenes*, *Yersinia enterocolitica*, *Aeromonas hydrophila*, *B. cereus* and *C. botulinum* will multiply at recommended "good" refrigeration temperatures (5°C [41°F]). There are other bacteria (*Salmonella* spp., *E. coli* and *S. aureus*), that, although unable to grow at temperatures below 5°C (41°F), will take advantage of temperature abuse and grow. Some bacterial species will not grow at temperatures below 5°C (41°F), but will survive at these temperatures. In addition, some microorganisms are capable of initiating growth at temperatures greater than 10°C (50°F), including *C. botulinum*, *B. cereus*, *C. perfringens* and *Campylobacter* spp.

With refrigerated foods, temperature control is essential, not only to maintain the microbiological safety and quality of foods but to minimize changes in the biochemical and physical properties of the food. The temperatures of storage of refrigerated foods may vary greatly and fluctuate during manufacture, distribution, retail sale and in the home. Consequently, during the life of refrigerated food, considerable opportunities exist for temperature abuse. Thus, the greater the temperature abuse, the greater the potential for microbial growth.

Consideration must not only be given to the temperature and maximum storage times but the types of foods placed under similar conditions and time will affect the quality and safety of each food in question. As shown below, PHF that fall into a category of food product tend to encourage growth and proliferation of specific microorganisms. Some examples of PHF include:

> *"The greater the* **abuse** *of temperature, the greater the potential for microbial* **growth."**

Meat and poultry products. The principal pathogens of concern are *S. aureus*, entehemorrhagic *E. coli*, *Salmonella* spp., *L. monocytogenes*, *Campylobacter jejuni/coli*, *Y. enterocolitica*, and *C. perfringens* and *C. botulinum*.

Fish and seafood products. Indigenous pathogens including *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, and *C. botulinum* Type E, and enteric microorganisms such as *Salmonella* spp. and *Shigella* spp. Other non-indigenous pathogens such as *L. monocytogenes* and *S. aureus* can be present in cooked products as a result of processing, handling or post-processing environment. The concern with most smoked seafood products is *C. botulinum* growth and toxin production.

Fruits and vegetables. Pathogenic bacteria such as *Salmonella* and *E. coli* O157:H7 are not usually associated with fruit, but pathogens can be present. Human pathogens have been isolated from many kinds of vegetables and include *Salmonella* spp., *Shigella* spp., *Y. enterocolitica*, *E. coli* O157:H7, *L. monocytogenes*, *C. botulinum*, and *B. cereus*.

Egg and egg products. The principal human pathogens of concern in eggs and egg products are of the genus *Salmonella* (e.g., *Salmonella* Enteritidis). *L. monocytogenes* is also a concern in processed eggs. Eggs and egg products will easily support the growth of spoilage and pathogenic microorganisms.

Milk and milk products. The principal pathogens of concern are *Salmonella* spp., *L. monocytogenes*, *S. aureus*, enterohemorrhagic *E. coli*, *C. jejuni*, *C. botulinum*, and *B. cereus*. The microbiological quality of the milk will also contribute to the microbial ecology of the final product, especially in cheeses where milk is not pasteurized. *Salmonella* spp., *L. monocytogenes* (mainly in soft, high moisture, high pH cheeses), enterohemmorrhagic *E. coli* O157:H7 (due to post-process contamination), *S. aureus* (due to faulty cheesemaking process), *Shigella* spp. and *C. botulinum* (due to faulty process) have been implicated in outbreaks associated with the consumption of various cheeses. For processed cheese, there is a concern with the growth and toxin production of *C. botulinum.*

Managing Food Safety

There is a wide range of foods that fall into the PHF category, thus requiring special handling practices. Raw and varietal meats, poultry, fish, dairy, eggs, prepared salads, fresh fruits and vegetables, to name a few, are all good examples of foods that provide an excellent media in or on which microorganisms can flourish. Many factors, in addition to time and temperature controls, contribute to the ultimate safety of consuming a food product. These include proper handling conditions, post-process and cross-contamination, hygienic methods of storage, transportation and distribution and personnel factors, among others. In order to better manage the history and acceptability of foods, they are labeled with safe handling instructions, which may include time and temperature control information.

While these controls are intended to maintain the integrity and safety of a food at this last step in the consumer chain, Good Agricultural Practices, Prerequisite Programs, HACCP-based and HACCP food safety programs have been and are being developed and implemented by on-farm and post-farm sectors of the food supply chain in order to manage the risks from farm gate to consumer plate. For example, the Canadian government is working closely with industry representing all sectors involved in the food chain. Producers, processors, transporters, distributors, retailers, restaurateurs, and even manufacturers of packaging materials are enthusiastic participants in this new government food safety initiative headed up by Agriculture and Agri-Food Canada under the Agricultural Policy Framework (Canadian Food Safety and Quality Program). This is a Canada-wide partnership between the provinces, territories, national Federation of Agriculture, a multitude of food industry trade organizations and the CFIA.

Predictive Micro Modeling

In addition to these fundamental food safety programs, predictive modeling is a tool that can be used to aid decision making for more effective cold chain food safety management. The main objective of predictive modeling is to describe, mathematically, the likelihood of growth and/or survival of specific microorganisms in food (total spoilage flora or a pathogenic population) under prescribed growth conditions. Models can be used to predict the probability of growth, the time until growth occurs or the growth rate of microorganisms. The results will then enable the cold chain players involved to handle a food in a prescribed manner by creating acceptable environmental conditions (time/temperature) based on science. In the event of deviation, this data may be used to decide upon viable corrective actions, as consequences become more apparent.

Over the past decade, there has been considerable work done on predictive modeling of a wide range of pathogenic bacteria. The types of models used vary greatly and in order to make them accessible to the food sector, several have been packaged in user-friendly, applications-oriented software. Two systems currently available for predicting the growth of food pathogens are the United Kingdom's Ministry of Agriculture, Fisheries and Food "Food MicroModel" system and the USDA's Pathogen Modeling Program. For a simple quantitative assessment of the microbial quality of the cold chain, another modeling approach based on predictive microbiology and probabilistic simulations has made use of the so-called time-temperature equivalent (TTE) approach. Again, these predictive models are designed to foster the food company's ability to make more consistent and reliable decisions pertaining to the release, further processing, sale and even the destruction of product.

Factors to Consider

As described, so many factors involving the growth of pathogens make it difficult to have a general policy whereby potential microbial contamination is controlled to an acceptable level across a wide spectrum of foods. It is important to distinguish between foods that are refrigerated with the intent of being further processed like raw ground beef, and those which are to be consumed without further processing like potato salad or luncheon meats. Refrigerated foods that need further cooking or preparation will tend to require shared responsibility for food safety between the supplier and the final preparer of the product. In essence, this will constitute a kill step (e.g., cooking), which cannot be afforded to ready-to-consume products.

The USDA's Food Safety and Inspection Service (FSIS) Meat and Poultry Hotline recommends that foods subjected to temperature abuse can remain at room temperature for up to 2 hours. It recommends that food, once taken from the refrigerator or freezer, or from being thoroughly cooked or reheated, may be kept at room temperature for 2 hours when the temperatures are below 32°C (90°F). When temperatures are 32°C (90°F) and above, 1 hour at room temperature is recommended.

The recommendation for keeping food at room temperature for no longer than 2 hours is very conservative. This is due to the fact that lag phases may vary depending on the bacteria, the food substrate and the actual ability of the microorganism to grow after the lag phase to levels (or produce toxin) that can cause illness. The U.S. Centers for Disease Control and Prevention, Department of Health and Human Services' Emergency Preparedness & Response bulletin concurs with the FSIS Hotline, reiterating: "Throw away perishable foods (including meat, poultry, fish, eggs and leftovers) that have been above 40 degrees Fahrenheit (F) for 2 hours or more." The recently published FDA 2005 Food Code dictates that food shall be cooked and served, served if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control if time only, rather than time in conjunction with temperature control is used as the public health control. This Code further indicates that under stricter conditions, including the monitoring of the food temperature at the warmest point to ensure that it does not exceed 21°C (70°F), the food may be kept up to 6 hours maximum before corrective action is taken.

Even with these two recommendations, it is possible to keep microbial growth in check and offer safe food beyond the 2-, 4-, or 6-hour recommended holding periods if conditions are not conducive to pathogen growth. All things being equal, a relationship exists between the temperature and the length of time at which a food is stored. For example, to control the growth of *Salmonella* species, foods must not be exposed to temperatures between 5.2°C and 10°C (42-50°F) for more than 14 days, between 11°C and 21°C (52-70°F) for more than 6 hours or above 21°C (70°F) for more than 3 hours. Snyder suggests that *C. perfringens* multiplies very rapidly at 20°C (68°F). Considering both germination time (2 hours) and time for 10 multiplications of *C. perfringens*, if food is held for 4 hours at about 44.4°C (112°F), it should be safe.

To date, only time-temperature indicators (TTIs) attached to the package surface can be used to help reveal a rise in the cold chain temperature or an abusive storage condition of a food product. Foodpath conducted a test that included the use of these external indicators, as well as stainless steel data loggers, placed inside boxes together with the product. This cross-referencing revealed that boxed chicken on the test pallet increased from an average temperature of 3.0°C to 20.5 C when exposed to an average ambient temperature of 35°C over a period of 14.5 hours. Frequent swab samples over the test period revealed that the average aerobic colony count showed no significant increase in the first 10 hours, but a significant increase in the number of bacteria during the next 4 hours.

The results of holding one skid of 540 kg of raw chicken product under conditions of continuous temperature abuse were recorded using 50 time/temperature monitoring devices strategically placed at various locations in 18 kg lined boxes on the pallet. The temperature log showed that even under these extreme conditions, it takes considerably more than 2 hours of temperature abuse before the product temperature moves significantly higher.

Next Steps

Regulatory bodies need to deliver non-conflicting clear and concise guidance with regard to the length of time refrigerated PHF may reside within the danger zone. This guidance must be based on sound science and of practical use for all food handlers. It must be understood that these recommendations will be used to develop monitoring procedures that will assist in decision-making regarding when product is safe for release and what to do when a deviation occurs. Specific recommendations, such as the importance of checking ttemperature recording devices at regular intervals and testing them for accuracy, should also be articulated by regulatory agencies and standard-setting bodies to food chain companies. Not only should information about time-temperature control be communicated to the cold chain players but also to everyone in the household, from parents who buy and prepare foods to the child who takes a lunchbox to school. Each has their specific role to play in ensuring that foods are safe to eat. ■

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