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Good Manufacturing Practices for Refrigerated Foods

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ABSTRACT

Good Manufacturing Practices are essential for the manufacture and distribution of refrigerated foods that are safe from microbiological hazards. A refrigerated foods manufacturer should use a comprehensive program that evaluates, identifies, and then controls potential hazards at every step in the development and manufacturing environment. A set of GMPs for refrigerated foods is presented that reviews food safety practices in ingredient receipt and handling, product development, processing, packaging, storage and distribution, and record keeping.

There is a growing interest today in the area of refrigerated foods, both from the perspective of the consumer as well as industry *(2,6)*. The major population segment of today's consumer is comprised of the "Baby Boom Generation," their parents and grandparents. This group, representing 64% of the U.S. population, reportedly has a high interest in personal health, diet, and fitness *(1,8)*. This healthier attitude and lifestyle is calling for healthier and less caloric food, less smoking, reduced consumption of alcoholic beverages, better diet, and more exercise. Food manufacturers are using these findings in their development of new products.

Other factors are also contributing to the growing interest in refrigerated foods. Today, women are estimated to be participating in the work force at a level of over 50% *(9)*. Almost 3/4 of women between the ages of 25-54 are working. Thus, there are more families with dual incomes than ever before. This provided for two things: 1) less available time at home for the preparation of meals, and 2) more income used for more convenient meals. Thus, the lack of time dictates the need for more convenient meals, either to be picked up and then made at home, or to be eaten away from home. Of the nation's adult population, nearly 64% report a purchase of food for take-out during a month, and 37% report increasing use of their microwave ovens at home. The trend of purchasing more ready-to-eat food from supermarket delis and salad bars is also increasing *(5)*.

Refrigerated foods, from a food manufacturer's perspective, appear to have all the attributes desired by consumers: convenience, freshness, and quality. Convenience can be incorporated into the foods by making them microwavable, thereby requiring less time for meal preparation. Freshness and quality need to be present to compete with the freshly-made restaurant and deli menus. However, to make refrigerated foods a practical as well as a profitable venture, a reasonable shelf-life to enable a national distribution of the brand is necessary. Shelf-life poses the greatest challenge from a microbiological perspective. The microbiological pathogens that represent potential hazards in these refrigerated products require special consideration during product development, in processing, and through their storage and distribution *(6)*. A refrigerated food, to attain the desired shelf-life, will need to have not only these pathogens controlled, but also the variety of spoilage microflora that are able to multiply under refrigerated storage *(4)*. The immediate microbiological need is to recognize the potential hazards and to take the appropriate steps to eliminate or control the hazardous situation. These appropriate steps involve the use of Good Manufacturing Practices (GMPs) for refrigerated foods. This paper deals with the GMPs to be considered in developing, processing, and marketing refrigerated foods. A more concise version of these GMPs has already been published by the Refrigerated Foods and Microbiological Criteria Committee (now called the Microbiology and Food Safety Committee) of the National Food Processors Association *(7)*. This presentation is based upon this published version. A more comprehensive version of the GMPs is in the process of being written by the Committee (V.N. Scott, personal communication).

Temperature abuse of refrigerated foods during processing, storage, distribution, retailing, or in the hands of the consumer may allow the rapid and progressive growth of infectious or toxigenic microorganisms, or the slower growth of *Clostridium botulinum*. Partially processed refrigerated foods present a significant danger. Elimination of the competitive microflora in these minimally processed foods may allow surviving, pathogenic sporeformers to grow unimpeded. Post-process contaminants also would find no competition to restrict their growth. However, refrigeration alone does not guarantee safety from pathogenic microorganisms. Several species (including nonproteolytic types of *C. botulinum*, *Yersinia enterocolitica*, *Listeria monocytogenes*, and *Aeromonas hydrophila*) may grow at refrigeration temperatures as low as 38°F *(6,7)*. Thus, while proper refrigeration may aid in obtaining the desired quality during its shelf-life, it is recognized that it no longer can guarantee the product's safety. Other safety factors, also called barriers or hurdles, are

recommended for refrigerated foods to inhibit or minimize the multiplication of the pathogenic microorganisms during refrigerated storage or as a result of temperature abuse of the product. These barriers are safety factors of a physical, biological, or chemical nature which retard or prevent the growth of microorganisms including those which may be infectious or toxigenic.

Examples of barriers could include, but not be restricted to, 1) acid pH, 2) controlled moisture or water activity, 3) competitive microflora, 4) preservatives, or 5) thermal processing. Modified or controlled atmospheres cannot independently serve as barriers. However, such conditions may partially help to control the pathogenic microorganisms when used in conjunction with another barrier. Use of modified or controlled atmospheres must be carefully evaluated. Indeed, whatever barrier is used should have sufficient scientific evidence available to support its effectiveness. A process authority, knowledgeable in the heating, cooling, and refrigeration procedures, should be consulted to establish the adequacy of the process, and verify the efficacy of the barriers.

There are several federal regulations that do provide guidelines applicable to refrigerated foods. These would include 21 Code of Federal Regulations Part 110, "Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food"; 9 CFR Part 318, Meat Inspection Regulations, and 9 CFR Part 381, Poultry Products Inspection Regulations. The USDA in their Policy Memo 110 lists additional requirements for refrigerated foods that fall under their jurisdiction.

The one notable difference between recently published GMPs *(7)* and the federal regulations, deals with the acceptable upper temperature limit for refrigerated foods. While the regulations use 45°F, other documents suggest 40°F to be the upper limit. Basically, the case can be argued that while 40°F may at the present time be unrealistic for practical implementation, it is the desired goal. Refrigerated products stored at <40°F may achieve significant shelf-life extensions due to the maintenance of quality and organoleptic characteristics as well as providing for greater microbiological safety. The microbial growth rate decreases with decreasing temperatures. Thus, pathogenic microorganisms would present less of a danger in product stored at 40°F than at 45°F. Although some pathogens may grow at temperatures below 40°F, their rate of growth in this range is quite slow. The risk they present is therefore also low, even with the anticipated shelf-life extension. Low temperature refrigeration used in conjunction with an additional, effective barrier would even further reduce the safety risk.

Much is being said today about the use of the Hazard Analysis Critical Control Point (HACCP) program for use with all processed foods. The HACCP program should also be used to assure the safety of refrigerated foods. In addition to HACCP, GMP plant sanitation guidelines should be provided and strictly adhered to for each manufacturing facility.

INGREDIENTS

The microbiological quality of food ingredients does not improve with storage and handling. Generally, the quality is at its highest upon receipt. A good manufacturing program will aim to preserve and extend this initial quality to the finished product. In this regard, food ingredients should be evaluated as part of the HACCP program to assess their microbiological risk. The possible hazards associated with particular ingredients at the time of receipt, and potentially aggravated in processing, storage, and distribution or in the hands of the consumer need to be identified. The International Commission on Microbiological Specifications for Food (ICMSF), and the National Academy of Sciences/National Research Council (NAS/NRC) have developed programs to evaluate foods based on hazard characteristics that they possess *(3,10)*. The number of hazards possessed by a particular food or ingredient determines its potential risk. As an example, with the NAS/NRC program, a food is assessed on its possession of three hazards: Hazard A - if the ingredient contains potentially harmful microorganisms; Hazard B - if the manufacturing process does not contain a controlled processing step that effectively destroys these harmful microorganisms; and Hazard C - if there is a substantial potential for microbiological abuse (i.e. loss of temperature control) in distribution or in consumer handling that could render the product harmful when consumed. Then, based on the number of hazard, a food is classified into a risk category. The greater the number of hazards, the greater the risk. Each risk category has a recommended sampling plan to test for the microbiological pathogens. Such a program should be used for all ingredients that are to be used in a refrigerated food. While the NAS/NRC program was developed for *Salmonella*, it has application for other foodborne pathogens associated with refrigerated foods.

The potential microbiological hazard of each ingredient used in a refrigerated food needs to be determined. Ingredients would be particularly hazardous if they were used in a nonsterile product designed and intended for consumption by infants, the elderly, the ill, or the immunocompromised. To minimize the potential risk from hazardous microorganisms, the use of microbiological specifications for ingredients may be necessary. The ingredients should have specifications that need to be met by their manufacturer. These ingredients should be accompanied by a certificate of compliance indicating appropriate testing confirmed the specifications. The food processor should routinely audit these ingredients to verify conformance to their required specifications.

For potentially hazardous, non-shelf stable or perishable ingredients, refrigerated, or frozen storage must be used to maintain microbiological integrity. The ingredient temperature upon receipt should be checked to verify proper temperature control during shipping. Ideally, a continuous recording of the temperature during transit should be provided to assure that temperature abuse had not occurred.

Additionally, once in the control of the food manufacturer, one or more temperature monitoring systems should be used to verify appropriate temperature control during storage. Time/temperature limits of refrigerated storage should be placed on all potentially hazardous and perishable ingredients. Any reuse of these ingredients or rework of product should be carefully monitored. This would require careful records documenting the use of these lots with each produc-

tion lot of product. Appropriate criteria should be established to help minimize the microbiological safety problems associated with refrigerated foods.

PRODUCT DEVELOPMENT

Good Manufacturing Practices are as critical in the product development phase as elsewhere in the manufacturing process. Incorporation of GMPs in the product development process sets the stage for their later use in processing. In addition to ingredient evaluation using HACCP principles, evaluation to assure adequate control of critical points in processing should occur as early as possible in product development. Whenever a processing system or its prototype is identified for a particular product, evaluations to assess its microbiological safety become critical. Critical Control Point evaluation should include, but not be limited to, raw material and ingredient handling, time/temperature adequacy, sanitation requirements, prevention of cross contamination, and food handling and employee hygiene. The evaluation should identify the item, the potential hazard, the proper controls, procedures, and monitoring systems to be used at each critical point, and the person that has the accountability for the item.

The barriers or safety factors should be built into the food product during the product development stage. As noted earlier, refrigeration alone is insufficient to guarantee the microbiological safety of refrigerated food products. This is particularly true when one considers that proper refrigeration probably will not be maintained at some point during distribution, storage, display, or consumer handling. The growth inhibition of the psychotropic pathogenic microorganisms will require the incorporation of one or more barriers into the product. An interaction of these factors may create the desired inhibitory conditions.

Use of barriers in refrigerated products carries with it the requirement of verifying their efficacy. Pathogen inoculation studies, or challenge tests with appropriate microorganisms, should be conducted to evaluate the functioning of the barriers and their ability to preserve product safety. Such inoculated samples should be incubated at appropriate abuse temperatures to simulate temperature abuse. The recommended temperature is within a range of 50°F to 85°F. Consideration of the worst case scenario for the specific product should be used in choosing the abuse temperature and storage time. This testing is essential to demonstrate the effectiveness of the barriers in preventing pathogen multiplication, thereby maintaining the safety of the product. The data and records demonstrating the safety of the barriers should be reviewed by a knowledgeable process authority. These records should then be kept. Use of a process authority in the development of usable barriers for specific products is recommended.

PROCESSING

A HACCP analysis of the plant processing system is necessary. Such an analysis should use a flow diagram, whereon critical control points in the process would be identified. These critical points in the process would be those where the failure to control such a point would allow a microbiological hazard to exist or develop. Each of the Critical Control Points should also have the potential hazard identified as well as its control. Analysis should include, but not be limited to, ingredient storage and handling, time/temperature adequacy of the process, fabrication, packaging integrity, and finished product storage and distribution.

Thermal processing equipment must be adequate to enable both the proper heating and the proper cooling of the food, when these processes are necessary. If perishable foods or ingredients, capable of supporting pathogenic or spoilage microflora, must be heated and held during processing, they must be maintained at or above 140°F during the holding period. This particular requirement on the appropriate temperature for holding such food is currently undergoing review by the federal agencies. A minimum holding temperature of 130°F for such foods may be declared sufficient in the near future.

Basic food hygiene principles need to be practiced when preparing and handling refrigerated foods. Cross contamination of processed product from in-process or raw product must be avoided. This can be achieved through proper sanitation of all product contact surfaces, including portable equipment - pans, trays, utensils - as well as proper handling by individuals. Raw ingredients must be handled separately from in-process and finished products at all times. If possible, personnel handling raw product should be different and kept separate from those handling finished product. Traffic control within the plant should restrict cross traffic between raw, processing and finished product areas.

Refrigeration systems should maintain in-process refrigerated foods at 40°F or below as appropriate for the food. Cooling systems should reduce the internal temperature of hot foods, including hot-filled items, from 140°F to less than 45°F within 4 h. Refrigerated foods should be chilled to 45°F or less prior to casing. These foods should then be brought to 40°F or less within 24 h after casing. Portable equipment, which would include trays, troughs and pans, used in the processing of refrigerated foods must allow the specific heating, cooling, and refrigeration requirements to be met. Thus, shallow containers to allow for uniform and rapid heating and cooling of foods should be used as appropriate. The recommended cooling guidelines specified above are also being reevaluated by the federal agencies. The proposed guidelines would require reducing the internal temperature of hot foods from 130°F to 40°F within 4 h.

The continued use and the effectiveness of the barriers designed to ensure microbiological safety need to be verified. Systems should be in place to monitor the barriers use and functionality, as well as other critical control points. Monitoring devices that are properly calibrated (i.e. thermometers, temperature recorders) and/or monitoring systems (i.e. microbiological) to verify the continued adequacy of the process should be used. All records of critical control points or of process adequacy must be immediately audited and retained. Corrective action must be taken whenever necessary.

An incubation program should be established using prescribed temperatures to monitor the microbiological shelf-life

of the product. The microbiological integrity of the processing line may affect the desired shelf-life of the product. Thus, Good Manufacturing Practices in the area of plant sanitation are critical. Plant and equipment sanitation guidelines should be provided and strictly adhered to for each manufacturing facility.

PACKAGING

HACCP analysis should also include identifying the critical control points associated with packaging. Structural, chemical and microbiological specifications of packaging materials, and the final package itself, should be defined and monitored. Verification of the safety of microwavable packages, especially those containing microwave susceptors, needs to be tested and documented. Records of all testing should be maintained. As appropriate, packaging material should include a certificate of compliance from the manufacturer verifying conformance to requirements. The food manufacturer should routinely audit to verify conformance.

Package integrity should be adequate to exclude contamination by microorganisms during storage, distribution, and sale. Tamper evident packaging should be used where possible. Refrigerated foods that may pose a potential spoilage or health hazard if temperature abused, should be prominently labeled "Keep Refrigerated." Those foods which are refrigerated only for quality, and not for spoilage or safety, should be labeled "Refrigerate for Quality." Date coding to specify the shelf-life of the product should be used on each package.

STORAGE & DISTRIBUTION

Storage temperature of the refrigerated product should be maintained at 40°F or lower to maximize shelf-life and quality, and minimize any potential microbiological hazard. Distribution practices from the processor to the retailer should also enable the maintenance of product temperatures at 40°F or lower as appropriate for the food. Time/Temperature recorders should be used to monitor the temperature history of the food during storage and distribution. Time/Temperature integrators are more geared to measuring the product quality as opposed to the product safety.

RECORD KEEPING

An integral part of a good manufacturing program for refrigerated foods would be the record keeping requirement. While record keeping is recommended for some areas and required for others, its importance in assuring the production of safe food products cannot be overstated. However, keeping records alone is insufficient. All records must be reviewed in a timely manner, and corrective action taken wherever and whenever necessary. To summarize the proposed record keeping requirements for the various areas:

Ingredients

Supplier certificates documenting compliance with the food processor's requirements/specifications.
Processor audit records verifying supplier compliance.
Receipt and storage temperature records of limited shelf-life ingredients.

Product Development

Sufficient data and records to establish the efficacy of barriers in maintaining product safety from microbiological hazards.

Sufficient data and records establishing the shelf-life of the product.

Documentation of the adequacy of the processing procedures from a knowledgeable process authority.

Processing

Records from all monitored Critical Control Points.

System records verifying the continued effectiveness of the barrier.

Records verifying the continued adequacy of the process.

Packaging

Records indicating compliance with specification of the packaging materials.

Records of the processor verifying audit and compliance to specifications.

Records from microwavable packages/susceptors verifying no hazard to food safety.

Storage & Distribution

Temperature records indicating proper storage.

A Good Manufacturing Practices Program, to be effective, needs to take into consideration the complete refrigeration foods system...from ingredients receipt, storage and handling, through product development, processing, packaging, storage, and distribution. The incorporation of barriers into the product to prevent the growth of pathogenic microorganisms or their production of toxin is a key factor in such a system. With the potential for temperature abuse at any point in the system, the food manufacturer needs to build in safety, through the use of appropriate barriers, to assure food safety to the consumer. However, a good refrigerated foods program will also need to be more comprehensive, incorporating temperature control, food hygiene principles, and good sanitation practices. Then, not only will the products be safe, but they will provide the convenience, freshness and quality that is being sought by the consumer.

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