

**Appendix D**  
**Industry Protocol for Establishing the Shelf Stability of Pumpkin Pie**  
**American Bakers Association**



# **Industry Protocol for Establishing the Shelf Stability of Pumpkin Pie**

## **Introduction:**

This protocol provides a process that a manufacturer may use to demonstrate the shelf stability of a pumpkin pie product as per the Food Code sections 1-210.10B(61)(a) and (61)(c)(v).

- ”(61)(a) 'Potentially hazardous food' means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:
- (i). the rapid and progressive growth of infectious or toxigenic microorganisms;
  - (ii). the growth and toxin production of *Clostridium botulinum*...”

The Food Code goes on to state that a 'potentially hazardous food' does not include:

- (61)(c)(v). A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms can not occur, ... and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms;

Note: The above definition is excerpted from The Model Food Code section 1-201.10B(61). The complete definition as it appears in the Food Code is in Appendix 3 of this document.

It is the responsibility of the manufacturer to produce and distribute a safe food product. Product and process validation are complex issues with no single method that will work in all cases. Therefore, this protocol is a guide and does not replace good science or good judgment applied by the manufacturer to their product and process. Furthermore, this protocol does not limit the ability of the manufacturer to develop additional data beyond those described in this protocol to demonstrate the safety of their food product. Pumpkin pie products that fail to meet the criteria of this protocol must be refrigerated during distribution and retail display to maintain food safety unless shelf stability has been established through an equivalent science-based method of process validation.

## **Scope:**

This protocol applies only to pumpkin pies intended for distribution and display at retail at ambient temperatures without refrigeration. Any manufacturer of shelf stable pumpkin pie products can use the criteria of this protocol. A 'manufacturer' is defined as any establishment that bakes a pumpkin pie that is distributed or displayed at retail without refrigeration.

## **Objective:**

The objective of this protocol is to define the product and process criteria that a manufacturer may use to establish that their pumpkin pie product meets the requirements of the Model Food Code sections 1-210.10B(61)(a) and (61)(c)(v) and is therefore safe for distribution and retail display without refrigeration. See Appendix 2 for the basis of how this protocol builds on the Model Food Code.

## **Criteria 1: Compliance with Good Manufacturing Practices (GMPs)**

### **Requirement:**

The manufacturer must maintain and demonstrate compliance with all applicable GMP requirements in the manufacture of the pumpkin pie product as identified in 21 CFR:

#### **Part 110.10 Personnel**

- a) Disease control
- b) Cleanliness
- c) Education and training
- d) Supervision

#### **Part 110.20 Plant and grounds**

- a) Grounds
- b) Plant construction and design

#### **Part 110.35 Sanitary operations**

- a) General maintenance
- b) Substances used in cleaning and sanitizing; storage of toxic materials.
- c) Pest control
- d) Sanitation of food-contact surfaces
- e) Storage and handling of cleaned portable equipment and utensils

#### **Part 110.37 Sanitary facilities and controls**

- a) Water supply
- b) Plumbing
- c) Sewage disposal
- d) Toilet facilities
- e) Hand-washing facilities
- f) Rubbish and offal disposal

#### **Part 110.40 Equipment and utensils**

#### **Part 110.80 Processes and controls**

Part 110.110 Natural and unavoidable defects in food for human use that present no health hazard.

### **Validation:**

The manufacturer is responsible for maintaining and demonstrating via inspection their compliance with GMP requirements.

### **Rationale:**

Complying with GMPs is a required step in developing a safe and sanitary production process that is capable of manufacturing a wholesome food product. Compliance to GMPs is the foundation upon which the other criteria of this protocol are built and without which this protocol cannot be successful.

## **Criteria 2: Internal Bake Temperature**

### **Requirement:**

The pumpkin pie product must be baked to achieve an internal temperature of at least 180° F (82° C) at the coolest point in the product.

### **Validation:**

Perform a process validation study to identify variation in internal product temperature after baking due to location in the oven and to identify the coolest point in the product. Repeat this process validation study when significant changes are made to the product or baking process. Use this process study to establish a routine temperature validation test and perform that test periodically on product immediately after bake to validate that the internal temperature reaches at least 180° F (82° C) at the coolest point. Demonstrate compliance through periodic temperature measurements taken and documented during processing or through effective alternative means defined by the manufacturer.

### **Rationale:**

Exposing a food to a temperature of 165° F (74° C) for 15 seconds results in an effective destruction of vegetative microorganisms (See 1999 Model Food Code Section 3-401.11(A)(3)). The requirement of 180° F (82° C) provides a 15 degree safety buffer to assure that an adequate kill of vegetative microorganisms is achieved. Pumpkin pies are relatively dense and uniform in structure resulting in a slow but uniform heat penetration. The performance of a process validation study assures that the manufacturer understands the baking characteristics of the oven and the product and has established a routine test that assures that adequate heat penetration has been achieved in all parts of the pie.

## **Criteria 3: Cooling and Packaging Baked Product**

### **Requirement:**

The baked product must be cooled to ambient temperature with adherence to GMPs and maintenance of hygienic personnel practices in order to minimize post-bake contamination. Pies must be adequately cooled before packaging to minimize moisture condensation on the inside of the package.

Finished product must be packaged within 4 hours of leaving the oven in a clean, protective package. The package must fully enclose and protect the finished product from environmental contamination and inadvertent human contact during distribution and display. The package must contain air and must not be vacuum-packed or flushed with non-oxygen containing gases.

### **Validation:**

Perform the following:

- Confirm that the package completely encloses the product to protect it against contamination during distribution and display.
- Confirm that the package is sealed to prevent unintentional opening during distribution and display.
- Confirm that the product is packaged and sealed within 4 hours of leaving the oven.

Rationale:

When the product exits the oven it is essentially free of vegetative microorganisms. Assure the safety of the product by controlling and minimizing the introduction of spoilage bacteria onto the product during cooling and packaging. The package protects the product from contamination during distribution and display. The result is a wholesome, safe product delivered to the consumer.

**Criteria 4: Microbial Analysis for Process Validation**

Requirement:

Microbial testing is performed using standardized methods at the beginning and end of the intended product use life to validate that the manufacturing process is capable of producing a wholesome pumpkin pie product that is microbiologically stable for distribution and display without refrigeration.

Perform the following microbiological analyses on representative samples of intact, finished, packaged product within 24 hours of being packaged.

**Table 1**

<b>Microbiological Tests of Product within 24 hours of packaging</b>	<b>Test Method Reference*</b>
Aerobic Plate Count	AOAC / BAM
Coagulase positive Staphylococcus aureus	AOAC / BAM
Coliforms	AOAC / BAM
Salmonella	AOAC / BAM
Oxidation Reduction Potential	Test filling as is

\* - or equivalent standardized method

Store additional samples of intact, finished, packaged product at 90° F (32° C) for the duration of the product's intended use life. See Appendix 1 for the definition of product use life.

Set up the following microbiological analyses on representative samples of intact, finished, packaged product after storage at 90° F (32° C) for the duration of the product's intended use life.

**Table 2**

<b>Microbiological Tests of Product at the end of Product Use Life (stored at 90°F (32° C))</b>	<b>Test Method Reference*</b>
Aerobic Plate Count	AOAC / BAM
Coagulase positive Staphylococcus aureus	AOAC / BAM
Coliforms	AOAC / BAM
Salmonella	AOAC / BAM

\* - or equivalent standardized method

The acceptance limits for the microbiological testing of the finished product at the beginning and end of product use life are as follows in Table 3.

**Table 3 – Finished Product Microbiological Test Limits**

<b>Microbiological Test</b>	<b>Microbial Limits For intact product &lt;24 hours after packaging</b>	<b>Microbial Limits for intact product at the end of product use life (stored at 90°F (32° C))</b>
Aerobic Plate Count (APC)	1000 cfu per gram	100,000 cfu per gram
Coagulase positive S. aureus	<10 per gram	<10 per gram
Coliforms	<10 per gram	<10 per gram
Salmonella	Negative per 125 grams	Negative per 125 gram
Oxidation Reduction Potential	>100 mv	NA

The pumpkin pie product must be shown to not support the growth or toxin production of Clostridium botulinum. This is done by measuring the Oxidation Reduction Potential of the pie filling after baking and achieving an acceptably high positive value.

Validation:

Microbiological testing of the finished pumpkin pie product must be performed initially to validate the process and repeated if any significant changes are made in the ingredients, process, packaging, distribution or display of the product. Results of these tests must be documented.

The packaged pumpkin pie product must be stored after baking under ambient atmospheric conditions with no modified atmosphere or vacuum packing. The normal ambient oxygen concentration and the resulting oxidation-reduction potential in the pie are inhibitory to the growth and toxin production of the anaerobic bacterium Clostridium botulinum.

Rationale:

The microbial testing performed as part of this protocol will enumerate the total level of microorganisms, and selective pathogenic species, if present in a finished pumpkin pie product at the beginning and the end of the product use life.

The thermal treatment during the baking process effectively kills vegetative bacterial cells and would destroy the toxin from Clostridium botulinum if it were present. Since the finished pumpkin pie is cooled, packaged and stored at normal ambient atmospheric conditions, the oxygen concentration [O<sub>2</sub>], which is measured by the Oxidation Reduction Potential test, creates an environment that is inhibitory to the growth and toxin production of Clostridium botulinum.

These analyses, when combined with the other criteria of this protocol, demonstrates the adequacy of the manufacturing process to produce a wholesome finished product that will be microbiologically stable during the product's intended use life.

- **At the beginning of product life:** Low microbial counts at the beginning of product life confirm preparation under hygienic conditions. An Oxidation Reduction Potential of at least 100 mv indicates that the product will not support the growth of anaerobic bacteria.
- **At the end of product life:** Moderate APC counts (< 2 log increase) at the end of product life indicate that there are not unsafe levels of microbial growth. High microbial counts at the end of product life indicate that the product is not stable. The limits shown in Table 3 are conservative from food safety and epidemiological perspectives and are based on industry experience.
- **90° F (32° C) Storage temperature:** Storing the product for its intended use life at 90° F (32° C) provides an additional safety factor to assure that the product will be safe and wholesome. 90° F (32° C) is a conservatively high temperature that takes into account potential distribution, shelf display and home storage temperatures.



## **Criteria 5: Finished Product Shelf Life Labeling**

### **Requirement:**

Manufacturers and/or retailers must label their pumpkin pies intended for distribution or display at retail without refrigeration with either “sell by...” or “use by...” dating to inform consumers of the intended use life of the product. Manufacturers and/or retailers are encouraged to label a “use by...” date.

The purpose of “sell by...” or “use by...” dating is to inform consumers of the intended use life of the product and to ensure proper rotation and disposal of past age product.

The manufacturer determines the intended product use life based on product stability studies that take into account the microbial stability of the product (Criteria 4 of this protocol) as well as other factors such as flavor and texture. The manufacture may establish an intended product use life that is shorter than indicated by microbial testing due to sensory factors such as taste and texture.

Manufacturers must label their pumpkin pie products that meet the criteria of this protocol with the instructional phrase “**Refrigerate after opening**” to advise consumers to refrigerate the pie after opening to protect against unintentional contamination of the product. The statement must be printed on a prominent display panel.

Manufacturers must also provide a mark on the package to inform regulators and retail store personnel that the product meets the criteria of this protocol and is safe for distribution and retail display at room temperature without refrigeration. The required mark is “**RT**”, which stands for ‘Room Temperature’. This symbol must be printed on the package label immediately after the ‘sell by’ or ‘use by’ date, in the same size type.

### **Validation:**

Confirm the presence of “use by...” or “sell by...” dating and the instructional phrase on the package.

### **Rationale:**

“Use by...” or “sell by...” dating is marked on the package to communicate to the consumer the fact that shelf stable pumpkin pies have a limited and short intended use life based on product stability testing.

The instruction to the consumer to “refrigerate after opening” provides protection from unintentional contamination of the product during handling in the home. “Refrigerate after opening” is a technically sound and due diligence approach to assist the consumer in maintaining and consuming a safe and wholesome product within the intended product use life.

The symbol “RT” on the package immediately following the “sell by” or “use by” date, informs the regulator and store personnel that the product meets the criteria of this protocol and is safe for room temperature display without refrigeration.

## **Appendix 1 – Intended Product Use Life**

Define product use life as:

- if “**use by...**” dating is provided on the retail package, the intended product use life is the length of time from when the product is placed into the final retail package until midnight on the date printed on the retail package. For an extended production run, use the length of time from the earliest start time until midnight of the date printed on the retail package.
- if “**sell by...**” dating is provided on the retail package, the product use life must be at least as long as the following calculation: multiply by 1.3 the length of time from when the product is placed into the final retail package until midnight on the date printed on the package. For an extended production run, use the length of time from the earliest start time.

The factor of 1.3 represents a reasonable length of time beyond the “sell by...” date for consumption of the product. The National Institute of Standards and Technology (NIST) Handbook 130, considers “a reasonable period for consumption to be one third of the appropriate total shelf life of the perishable food”.

## **Appendix 2 – Basis for Establishing the Shelf Stability of Pumpkin Pie Products Under the Model Food Code**

The Industry Protocol for Establishing the Shelf Stability of Pumpkin Pie provides a methodology for establishing that specific pumpkin pie products can be safely held by food establishments at room temperature and require no refrigeration prior to purchase by consumers under the Model Food Code (MFC).

### **1. General Scope of Application of the Model Food Code**

Pursuant to section 311(a) of the Public Health Service Act, which provides for Federal assistance to states with respect to the "prevention and suppression of communicable diseases," FDA maintains the MFC to assist states in establishing effective programs to prevent foodborne illness. 42 U.S.C. 243;21 C.F.R. 5.10(a). Specifically, the MFC is intended "to assist food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail segment of the food industry." Model Food Code 1999 at ii. Accordingly, the MFC does not itself constitute a federal law or regulation, but rather FDA recommendations to the States concerning the safe handling of food by food establishments at the retail level. The Model Food Code and related interpretive guidance documents serve to inform the development of regulatory requirements in the States.

### **2. Refrigeration of Foods Held for Sale by Food Establishments**

The MFC provides for refrigeration of foods held for sale in food establishments when foods are deemed to be "potentially hazardous." Cognizant of the complexities of food matrices and food handling and their relationships to food safety, the MFC does not attempt to define the category by describing foods that are "potentially hazardous." Rather, the MFC takes a factually based approach which focuses specifically on whether the particular "form" of any food held for sale in a food establishment, in fact, requires temperature control for that food to be safely delivered to into the consumer's hands.

Specifically, section 1-210.10B(61) of the MFC provides that "potentially hazardous food" is a "food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting...the rapid and progressive growth of infectious or toxigenic microorganisms; [or]...the growth and toxin production of *Clostridium botulinum*..." Model Food Code 1999 at 1-210.10B(61)(a). For heat-treated foods of plant or animal origin, the definition specifically excludes those forms that "are modified in a way that results in mixtures that do not support [such] growth" of unsafe microorganisms. Id. At 1-210.10B(61)(b). The definition further provides a selected list of criteria that may be used to establish that particular forms of food are not "potentially hazardous" and require no refrigeration in food establishments to be delivered safely into the hands of consumers. Section 1-210.10B(61)(c)(v) specifically provides that "laboratory evidence" may be used to demonstrate that unsafe microbial growth "can not occur" in the particular food because of barriers including the use of preservatives, or "combination[s] of barriers that inhibit the growth of microorganisms." Other listed criteria specifically recognize that such "barriers" to unsafe microbial growth may not only be chemical (e.g., preservatives), but may include physical barriers to environmental contamination. See Model Food Code 1999 at 1-210.10B(61)(c)(i) and (iv)(excluding certain packaged food, and shell eggs based on the natural barrier provided by the intact shell). This provision excludes from the "potentially hazardous food" category, and thus the need for refrigeration by food establishments, specific forms of food presented for consumer sale for which effective chemical and physical barriers to unsafe microbial growth have been erected, as demonstrated by laboratory evidence.

In contrast, a wholly separate basis for exclusion from the "potentially hazardous food" definition applies when chemical and physical barriers cannot be demonstrated to block unsafe microbial growth during the product shelf life. Section 1-210.10(B)(61)(c)(vi) provides that a food that contains unsafe microorganisms may nonetheless be excluded from the "potentially hazardous food" category when evidence shows that food "does not support the growth of microorganisms...at a level sufficient to cause illness." Such a showing might be made through evidence showing that unsafe microorganisms do not grow to unsafe levels during the product shelf life. Section 1-210.10B(61)(c)(vi) may provide a separate potential basis for establishing the shelf stability of pumpkin pie products that do not conform with the Industry Protocol.

This Protocol specifies manufacturing, heat-treatment, and post-bake handling practices that have been established scientifically to render pumpkin pie safe to be held by food establishments for sale to consumers without refrigeration during the shelf life of the product. The Industry Protocol also specifies laboratory methods and procedures that should be used by manufacturers under section 1-210.10B(61)(c)(v) to develop laboratory evidence demonstrating that "the rapid and progressive growth of infectious or toxigenic microorganisms...or *C. botulinum* can not occur" in pumpkin pie products manufactured, distributed, and sold to consumers in conformance with this Protocol. Model Food Code 1999 at 1-210.10B(61)(c)(v). The Industry Protocol constitutes a basis for establishing that particular pumpkin pie products are excluded from the definition of "potentially hazardous food," and can be held by food establishments without refrigeration during the shelf life of the product under the MFC.

### **Appendix 3 – The Model Food Code definition of “Potentially Hazardous Food”**

#### **(61) Potentially Hazardous Food.**

(a) **"Potentially hazardous food"** means a FOOD that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

- (i) The rapid and progressive growth of infectious or toxigenic microorganisms;
- (ii) The growth and toxin production of ***Clostridium botulinum***; or
- (iii) In raw shell eggs, the growth of ***Salmonella Enteritidis***.

(b) **"Potentially hazardous food"** includes an animal FOOD (a FOOD of animal origin) that is raw or heat-treated; a FOOD of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.

(c) **"Potentially hazardous food"** does not include:

- (i) *An air-cooled hard-boiled egg with shell intact;*
- (ii) *A FOOD with an  $a_w$  value of 0.85 or less;*
- (iii) *A FOOD with a pH level of 4.6 or below when measured at 24° C (75° F);*
- (iv) *A FOOD, in an unopened HERMETICALLY SEALED CONTAINER, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;*
- (v) *A FOOD for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of **S. Enteritidis** in eggs or **C. botulinum** can not occur, such as a FOOD that has an  $a_w$  and a pH that are above the levels specified under Subparagraphs (c)(ii) and (iii) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or*
- (vi) *A FOOD that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though the FOOD may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.*