

ROP Committee Supporting Documents

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Appendix 5 – Email from FDA CFSAN clarifying when HACCP plans must be submitted.

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Table 1: Summary of code and Annex changes proposed by 2009-2012 ROP committee and the rationale for each change.

Table 1A. Section 1-201.10 changes

Food Code	Recommended Changes	Rationale
1-201.10 (1) Reduced oxygen packaging means:		
a) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and	No recommended changes	
b) A process as specified in Subparagraph (1) (a) of this definition that involves a FOOD for which the HAZARDS Clostridium botulinum or Listeria monocytogenes require control in the final PACKAGED form:	No recommended changes	
1-201.10 (2) Reduced oxygen packaging includes:	No recommended changes	
a) Vacuum PACKAGING, in which air is removed from a PACKAGE of FOOD and the PACKAGE is HERMETICALLY SEALED so that a vacuum remains inside the PACKAGE;	No recommended changes	
b) Modified atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the PACKAGING material or the respiration of the FOOD. Modified atmosphere PACKAGING includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;	No recommended changes	
c) Controlled atmosphere PACKAGING, in which the atmosphere of a PACKAGE of FOOD is modified so that until the PACKAGE is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, no respiring FOOD, and impermeable PACKAGING material;	No recommended changes	
d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotropic pathogens; or	No recommended changes	
e) Sous vide PACKAGING, in which raw or partially cooked FOOD is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychotropic pathogens.	Sous vide PACKAGING, in which raw or partially cooked FOOD is vacuum packaged in an impermeable bag, cooked in the bag, rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotropic pathogens.	Adding the vacuum packaging language brings this in line with the accepted understanding of sous vide and with the process outlined in Annex 6 2 (B) 4b

New	<p>1-201.10 (3) Reduced Oxygen Packaging does not include:</p> <ul style="list-style-type: none"> a) Placing product in a bag and sealing it immediately prior to or after cooking, cooling or reheating the product as long as the product is: <ul style="list-style-type: none"> i. Labeled with the time and date the product is placed in the bag; P ii. Removed from the bag within 48 hours of the time product is placed in the bag; P 	<p>Short term storage of food products held in cold storage at temperatures of 41o F or below in oxygen barrier bags for less than 48 hours does not allow sufficient time for the production of Clostridium botulinum nor the rapid and progressive growth of Listeria monocytogenes.</p> <p>The current code allows up to 48 hours to cool product from 41o F to 34o F for reduced oxygen packaging. As long as product is stored below 41o F no regulatory action would be taken on this product until the product reached the end of the 48 hour time period.</p> <p>The 48 hour time frame is validated by numerous studies reviewed by the CFP's ROP committee. The Skinner-Larkin model for pathogen growth (see Annex 2 for references) shows that the 48 hour time frame is a conservative estimate and C. botulinum and L. monocytogenes would take far longer to produce toxin or grow to dangerous levels.</p>
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Table 1B. Section 3-502.11 changes

3-502.11 Variance Requirement		
A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before:	No recommended changes	
A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement;	No recommended changes	
B) Curing FOOD;	No recommended changes	
C) Using FOOD ADDITIVES or adding components such as vinegar:	(C) Using FOOD ADDITIVES or adding components such as vinegar, except as specified in 3-502.12 (D)(2)(e)(iii) .	This change will allow ROP processes to add an acidifying agent to reduce pH to below 5.0 so that product may be held at below 41° F for up to 30 days. Research has shown that this yields an acceptable method with a built in safety margin to allow ROP processes without the need for going through the variance process.
1) As a method of FOOD preservation rather than as a method of flavor enhancement, or	No recommended changes	
2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD);	No recommended changes	
D) Packaging FOOD using a REDUCED OXYGEN PACKAGING method except where the growth of and toxin formation by Clostridium botulinum and the growth of Listeria monocytogenes are controlled as specified under § 3-502.12;	No recommended changes	
E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption;	No recommended changes	
F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT;	No recommended changes	
G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; or	No recommended changes	
H) Sprouting seeds or beans.	No recommended changes	

Table 1C. Section 3-502.12 changes

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria	No recommended changes	
<i>Clostridium botulinum</i> and <i>Listeria monocytogenes</i> Controls	No recommended changes	
A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of <i>Clostridium botulinum</i> and the growth of <i>Listeria monocytogenes</i> .	No recommended changes	
B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that:	No recommended changes	
1) Identifies the FOOD to be PACKAGED;	No recommended changes	
2) Except as specified under ¶¶ (C) - (E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria:	No recommended changes	
(a) Has an AW of 0.91 or less,	No recommended changes	
(b) Has a PH of 4.6 or less,	No recommended changes	
(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, or	No recommended changes	
(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables;	No recommended changes	
3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:	No recommended changes	
(a) Maintain the FOOD at 5oC (41oF) or below, and	No recommended changes	
(b) Discard the FOOD if within 14 calendar days of its PACKAGING it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;	No recommended changes	
4) Limits the refrigerated shelf life to no more than 14 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;	No recommended changes	
5) Includes operational procedures that:	No recommended changes	
(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶ 3-301.11(B),	No recommended changes	
(b) Identify a designated work area and the method by which:	No recommended changes	

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, and	No recommended changes	
(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, and	No recommended changes	
(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; and	No recommended changes	
NEW	<u>(d) If pH is used as a barrier to growth of <i>Clostridium botulinum</i> and <i>Listeria monocytogenes</i> such as in 3-502.12 (D)(2)(e)(iii), delineate equilibrium pH measurement, instrument calibration, and recordkeeping procedures.</u>	Monitoring of pH as a control for pathogens <i>C. botulinum</i> and <i>L. monocytogenes</i> is important to the safety of the product to ensure that the proper food product pH is consistently maintained.
6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the:	No recommended changes	
(a) Concepts required for a safe operation,	No recommended changes	
(b) EQUIPMENT and facilities, and	No recommended changes	
(c) Procedures specified under Subparagraph (B)(5) of this section and 8-201.14(D).	No recommended changes	
NEW	<u>(7) Is provided to the regulatory authority prior to implementation.</u>	The consequences of an ill conceived plan to conduct ROP operations in a food establishment can be serious; and since many food establishments are only inspected by their regulatory authority once or twice a year; requiring notification of the regulatory authority by the food establishment is a prudent requirement. This will allow the regulatory authority to be made immediately aware of the food establishment's intention to conduct ROP operations and will also give the regulatory authority the option to review the plan to ensure that the requirements of 3-502.12 are being followed. Prior approval is not recommended to facilitate a food establishment initiating operations without a lengthy review process. Furthermore, the Food Code is quite specific in its requirements to conduct this operation safely.
Fish		
C) Except for FISH that is frozen before, during, and after PACKAGING, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method.	No recommended changes	

Cook-Chill or Sous Vide		
D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES FOOD using a cook-chill or sous vide process shall:	(D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) FOOD using a cook-chill or sous vide process shall:	This change limits the following paragraphs of this section to only potentially hazardous foods (time / temperature controlled for safety foods). If a food is non-PHF (non-TCS) it will not support the growth of pathogens and therefore should not be subject to either variance or ROP provisions of the code.
1) Implement a HACCP PLAN that contains the information as specified under 8-201.14(D);	No recommended changes	
2) Ensure the FOOD is:	No recommended changes	
(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER,	No recommended changes	
(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under § 3-401.11,	(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under § 3-401.11 (A-B) . ^P	This change limits items which can be packaged using Sous Vide or Cook Chill technologies to only those foods which are fully cooked. Undercooked, partially cooked or raw foods cannot be safely prepared using sous vide or cook chill technologies therefore these paragraphs are eliminated and only the paragraphs that provide appropriate thermal lethality are included in this reference, i.e. 3-401.11 (A) & (B).
(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4,	No recommended changes	
(d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F),	No recommended changes	
(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and subsequently:	(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3- 501.14 and subsequently . ^P	Word not needed based on changes below
(i) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of PACKAGING;	No recommended changes	
(ii) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the FOOD must be consumed or discarded;	(ii) Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours 7 days , at which time the FOOD must be consumed or discarded; ^P	This change is driven by data which shows that there is no growth of Clostridium botulinum during the first seven days of storage at 41° F or less. Data supporting this change is based upon research by Skinner and Larkin and more information can be found in the Committee's report. Additionally, Listeria monocytogenes growth is prevented since this pathogen would have been eliminated through the cook step during the sous vide or cook chill

		process. All other pathogen growth is controlled by storage at temperatures at or below 41° F.
(iii) Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from PACKAGING, at which time the food must be consumed or discarded; or	(iii) Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from PACKAGING, at which time the food must be consumed or discarded; P or <u>(iii) Has an equilibrium pH of 5.0 or less, verified by a properly calibrated digital pH meter, and held at 5°C (41°F) or less until consumed or discarded within 30 days after the date of PACKAGING; P or</u>	Original text not needed in light of the changes to 3-502.12 (D) (2) (e) (ii) above. The new language is based upon research which shows that C. botulinum and L. monocytogenes cannot grow if a food has a pH below 5.0 and a temperature below 41° F. The growth of L. monocytogenes and other pathogens are also controlled by the same factors as listed for 3-502.12 (D) (2) (e) (ii).
(iv) Held frozen with no shelf life restriction while frozen until consumed or used.	No recommended changes	
(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily,	No recommended changes	
(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, and	No recommended changes	
(h) Labeled with the product name and the date PACKAGED;P _f and	No recommended changes	
3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP PLAN and:	No recommended changes	
(a) Make such records available to the REGULATORY AUTHORITY upon request, and	No recommended changes	
(b) Hold such records for at least 6 months; and	No recommended changes	
4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.	No recommended changes	
Cheese	No recommended changes	
E) A FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:	No recommended changes	
1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;	No recommended changes	
2) Have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and as specified under (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section;	No recommended changes	

3) Labels the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; and	No recommended changes	
4) Discards the REDUCED OXYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING.	No recommended changes	
8-201.13 When a HACCP Plan is Required		
A) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:	No recommended changes	
1) Submission of a HACCP PLAN is required according to LAW;	No recommended changes	
2) A VARIANCE is required as specified under Subparagraph 3-401.11(D)(4), § 3-502.11, or 4-204.110(B);	No recommended changes	
3) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.	No recommended changes	
B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN as specified under § 3-502.12.	(B) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN which is provided to the regulatory authority prior to implementation as specified under § 3-502.12.	The consequences of an ill conceived plan to conduct ROP operations in a food establishment can be serious; and since many food establishments are only inspected by their regulatory authority once or twice a year; requiring notification of the regulatory authority by the food establishment is a prudent requirement. This will allow the regulatory authority to be made immediately aware of the food establishment's intention to conduct ROP operations and will also give the regulatory authority the option to review the plan to ensure that the requirements of 3-502.12 are being followed.
C) Before engaging in an activity that requires a HACCP PLAN, a PERMIT applicant or PERMIT HOLDER shall submit to the REGULATORY AUTHORITY for approval a properly prepared HACCP PLAN as specified under § 8-201.14 and the relevant provisions of this Code if:	No recommended changes	
4) Submission of a HACCP PLAN is required according to LAW;	No recommended changes	
5) A VARIANCE is required as specified under Subparagraph 3-401.11(D)(4), § 3-502.11, or 4-204.110(B);	No recommended changes	
6) The REGULATORY AUTHORITY determines that a FOOD preparation or processing method requires a VARIANCE based on a plan submittal specified under § 8-201.12, an inspectional finding, or a VARIANCE request.	No recommended changes	
D) A PERMIT applicant or PERMIT HOLDER shall have a properly prepared HACCP PLAN as specified under § 3-502.12.	No recommended changes	

Table 1D. Annex changes

<p>3-502.11 Variance Requirement (From Food Code Annex 3)</p>		
<p>Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.</p>	<p>No recommended changes</p>	
<p>The concept of variances may be new to some regulatory authorities. Some jurisdictions may not have a formal process to respond to industry requests for variances, although informal allowances may have been allowed in specific situations. Recognizing the opportunity to use the variance process may require additional rulemaking, or at least policy development, at the jurisdictional level. Rulemaking can be used to outline the procedures for a variance request, including the information required in section 8-103.11. In addition, the rulemaking process can address the regulatory authority's responsibility to consider an industry's variance application and an appeals process in case a variance is not given due consideration or is denied. The Conference for Food Protection Variance Committee recommended that regulatory agencies adopt a variance review process. General guidance regarding administrative procedures is given below.</p>	<p>No recommended changes</p>	
<p>Regulatory authorities considering implementing variances have encountered issues relating to their authority or technical, scientific ability to evaluate or validate a variance request. From any variance request there may emerge a set of complex issues and scientific competencies beyond the ability of the regulatory authority to validate. The Conference for Food Protection Variance Committee recommended that rulemaking should reflect a multi-level matrix of regulatory agencies ranging from local regulatory authorities through FDA and reflected that recommendation in the following flow chart. The regulatory authority is encouraged to seek input and guidance from authoritative sources such as processing authorities, professional associations, or academia. Within the Variance Committee's model, the process for seeking FDA advice begins with the Regional Food Specialists.</p>	<p>No recommended changes</p>	
<p>Except for the Interstate Travel Program, FDA generally does not directly regulate retail and food service establishments, including entertaining variances for that segment of the industry. FDA is still exploring processes for handling variances on a national basis such as those received from national chain businesses. In conjunction with the 2000 CFP Variance Committee, FDA will continue to explore ways to provide assistance and guidance to regulators regarding access to scientific and technical resources in order to make science-based decisions regarding variances.</p>	<p>No recommended changes</p>	
<p>FDA recommends that regulatory authorities develop a written administrative</p>	<p>No recommended changes</p>	

process that is consistent with, and addresses the information contained in, Food Code sections 8-103.10, 8-103.11, and 8-103.12, and follow a process consistent with the recommendations of the CFP Variance Committee as shown in its flow chart.		
Model Administrative Procedures for Regulators to Address Variances:		
A) Designate an agency team and assign a leader to address variance requests.	No recommended changes	
B) Establish an agency review process leading to approval or denial of variance applications. For food safety issues, include recommendations for consulting with food processing authorities, food scientists, academia, professional organizations, other government agencies including the FDA Regional Food Specialist, or other experts external to the agency.	No recommended changes	
C) Set reasonable timelines for decision making. Determine if the variance application addresses an intrastate or interstate issue.	No recommended changes	
a) For variances that have interstate or national implications, especially those that address food safety, regulators are urged to contact and work closely with their FDA Regional Food Specialist to determine if a national policy related to the issue exists. Regulators are encouraged to be consistent with national policies, guidelines, or opinions.	No recommended changes	
b) For variances that address intrastate issues, regulators are also encouraged to determine if other State or national guidance exists, and to stay consistent with it.	No recommended changes	
D) Make the agency's decision. Inform the applicant.	No recommended changes	
a) If the variance request is approved, determine the starting date and document all special provisions with which the applicant must comply.	No recommended changes	
b) If the variance request is denied, inform the applicant as to the reasons for the denial, the applicant's right to appeal, and the appeal process.	No recommended changes	
5) Inform other interested parties, including the FDA Regional Food Specialist.	No recommended changes	
a) For variances having interstate or national implications, especially those that address food safety, regulators are urged to inform their FDA Regional Food Specialist so that FDA is aware of, and can appropriately disseminate the information regarding food safety variances that may affect food establishments in other jurisdictions, such as national chains.	No recommended changes	
b) For variances that address intrastate issues, regulators are encouraged to share the information as if it were an interstate issue.	No recommended changes	
6) Document all agency actions and decisions in the facility's file. Consider including documentation of special variance provisions on the establishment's permit to operate.	No recommended changes	
7) If the variance is approved, inform the inspector assigned to that facility and train the inspector on the variance provisions, including the implementation of the industry's HACCP plan, if required.	No recommended changes	

<p>8) Establish procedures to periodically review the status of the variance, determine if it successfully accomplishes its public health objective, and ensure that a health hazard or nuisance does not result from its implementation.</p>	<p>No recommended changes</p>	
<p>9) Establish written procedures for withdrawing approval of the variance if it is not successful.</p>	<p>No recommended changes</p>	
<p>3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria. (From Food Code Annex 3)</p>		
<p>Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal environment of the package contains less than the normal ambient oxygen level (typically 21% at sea level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food establishments has the advantage of providing extended shelf life to many foods because it inhibits spoilage organisms that are typically aerobic.</p>	<p>No recommended changes</p>	
<p>This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allow the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cm²/m³/24 hours or greater. A reduced oxygen atmosphere will result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.</p>	<p>This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial activity also plays a role here. Packaging material that readily allows the transmission of oxygen is usually designated by an Oxygen Transfer Rate of 10,000 cc/m² cm²/m³/24 hours or greater. A reduced oxygen atmosphere will often result with an Oxygen Transmission rate of 10-100. The process of cooking drives off oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus, microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen transmission.</p>	<p>Corrects inaccurate description of OTR to that found in the US FDA Fisheries HACCP Guide.</p>
<p>NEW</p>	<p><u>If packaging material OTR is to be used as a barrier to C. botulinum growth and an exemption from ROP HACCP requirements in sections 3-502.11 and 3-502.12 the operator must provide scientific evidence to the regulatory authority that the packaging, under it's intended use, maintains an oxygen atmosphere for the duration of the refrigerated shelf life. At the time of this writing, only one packaging product possesses an OTR greater than 10,000 cc/m²/24h with scientific evidence acceptable to the FDA that it maintains an</u></p>	<p>Suggested text clarifies 10 K bag exclusion. Would require variance for all uses other than that approved by FDA Seafood HACCP Guidance for raw seafoods.</p>

	<p><u> aerobic atmosphere when shrink packaging raw seafood with no inclusions (marinades, oils, etc). The packaging allows oxygen to pass permitting resident bacteria to spoil the seafood before the toxin of C. botulinum could develop.</u></p>	
<p>Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic C. botulinum and L. monocytogenes are able to multiply well below 5°C (41°F). For this reason, C. botulinum and L. monocytogenes become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.</p>	<p>Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some pathogenic microorganisms but non-proteolytic C. botulinum and L. monocytogenes are able to multiply <u>slowly well</u> below 5°C (41°F). For this reason, C. botulinum and L. monocytogenes become the pathogens of concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as</p>	<p>Clarifies current text so that it does not suggest that <i>C. botulinum</i> or <i>L. monocytogenes</i> grow quickly at refrigeration temperatures.</p>
<p>When followed as written, the ROP methods in this section all provide controls for the growth and/or toxin production of C. botulinum and L. monocytogenes without a variance. Paragraph 3-502.12 (B) identifies an ROP method with secondary barriers that will control C. botulinum and L. monocytogenes when used in conjunction with a food storage temperature of 5°C (41°F) or less. They include aw of 0.91 or less; pH of 4.6 or less; cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high levels of competing microorganisms. C. botulinum will not produce toxin below an aw of 0.91. Nitrite, used in meat and poultry curing, inhibits the outgrowth of C. botulinum spores. Most foodborne pathogens do not compete well with other microorganisms, therefore foods that have a high level of spoilage organisms or lactic acid bacteria can safely be packaged using ROP. Other intrinsic or extrinsic factors can also control the growth and/or toxin production of C. botulinum and L. monocytogenes.</p>	<p>No recommended changes</p>	
<p>New</p>	<p><u>Non-potentially hazardous food (non-time/temperature control for safety food) as defined by interaction tables A and B (section 1-201.10) contain pH and Aw intrinsic factors that prevent the growth of both C. botulinum and L. monocytogenes. Therefore these foods are exempt from the reduced oxygen packaging HACCP requirements of 3-502.11 or 3-502.12 provided they are as received and not modified in the operation and labeled as non-potentially hazardous foods.</u></p>	<p>Adds text to clarify non-PHF exclusion from ROP HACCP 3-502.11 or 3-502.12 as proposed above.</p>

<p>Naturally fermented cheeses, as identified in ¶ 3-502.12(E), that meet the Standards of Identity for hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187, respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of factors could include some or all of the following: a lower pH, production of organic acids, and natural antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient air temperatures. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey, Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of L. monocytogenes under modified atmosphere conditions.</p>	<p>No recommended changes</p>	
<p>When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of C. botulinum and L. monocytogenes. Non-proteolytic <i>C. botulinum</i> spores are able to germinate and produce toxin at temperatures down to 3°C (38°F). Therefore, to control for toxin production by <i>C. botulinum</i>, an anaerobe, ROP foods must be held at 3°C (38°F) or less. <i>Listeria monocytogenes</i> is able to grow, although very slowly, at temperatures down to - 1°C (30°F). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential.</p>	<p>When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary barriers such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of C. botulinum and L. monocytogenes. Non-proteolytic <i>C. botulinum</i> spores are able to germinate and produce toxin at temperatures down to 3°C (38°F). Therefore, to control for toxin production by <i>C. botulinum</i>, an anaerobe, ROP foods must be held at 3°C (38°F) or less. Listeria monocytogenes is able to grow, although very slowly, at temperatures down to - 1°C (30°F). The lag phase and generation time of both pathogens becomes shorter as the storage temperature increases. In ¶ 3-502.12(D), cook-chill processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold storage temperatures to inhibit growth and/or toxin production of any</p>	<p>Added text to clarify need to obtain a variance for low temperature cooking processes, e.g. sous vide.</p>

	<p>surviving pathogens is essential. <u>Cooking at low temperatures below that stated in 3-401.11 (A-C) may not destroy vegetative cells and may in fact become an incubation temperature for some pathogens. Any use of these low cooking temperatures combined with ROP packaging must be approved via the variance process.</u></p>	
<p>Four separate options are provided in (D)(2)(e). These time-temperature combinations will provide equivalent food safety protection without need for a variance. The first is cooling the bagged product to 1°C (34°F) and holding for up to 30 days after the product is sealed in the bag. The second is cooling bagged product to 1°C (34°F), removing product to a different refrigeration unit and holding at any temperature up to 5°C (41°F) for up to 72 hours with the total storage time not to exceed 30 days. This situation is often encountered when a central kitchen prepares and stores the bagged product at 1°C (34°F) then transports it to a satellite kitchen under their control where it can be held at 5°C (41°F) or less. The third option is cooling to 3°C (38°F) and holding for no more than 72 hours from packaging. The fourth option can be used without a restricted shelf life while the bagged product is held frozen until thawed to be consumed or used in another preparation.</p>	<p>Four separate options are provided in (D)(2)(e). These time-temperature combinations will provide equivalent food safety protection without need for a variance. The first is cooling the bagged product to 1°C (34°F) and holding for up to 30 days after the product is sealed in the bag. The second is cooling bagged product to <u>5°C (41°F), 1°C (34°F), removing product to a different refrigeration unit</u> and holding at any temperature up to 5°C (41°F) for up to <u>7 days 72 hours with the total storage time not to exceed 30 days. This situation is often encountered when a central kitchen prepares and stores the bagged product at 1°C (34°F) then transports it to a satellite kitchen under their control where it can be held at 5°C (41°F) or less.</u> The third option <u>relies on a secondary barrier, pH. When the pH is at or below 5.0 C. botulinum and L. monocytogenes cannot grow at 5°C (41°F). Therefore, 30 days storage is permitted. Note that when using pH as a barrier, a pH measurement, calibration and recordkeeping SOPs are required.</u> is cooling to 3°C (38°F) and holding for no more than 72 hours from packaging. The fourth option can be used without a restricted shelf life while the bagged product is held frozen until thawed to be consumed or used in another preparation.</p>	<p>Changes this section to accommodate the proposed changes made to 3-502.12 (D)(2)(e) and 3-502.12 (D)(2)(e)(iii). Reference to central and satellite kitchens deleted because It appeared extraneous.</p>
<p>Since there are no other controlling factors for C. botulinum and L. monocytogenes in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate. New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide products at 1°C (34°F) or 3°C (38°F) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if</p>	<p>Since there are no <u>may not be</u> other controlling factors for C. botulinum and L. monocytogenes in a cook-chill or sous vide packaging system, temperature control must be continuously monitored electronically and visually examined twice daily to verify that refrigeration temperatures are adequate. New technology makes it relatively easy to continuously and electronically monitor temperatures of refrigeration equipment used to hold cook chill and sous vide</p>	<p>Corrected text acknowledges that there may be other controlling factors. The 38°F option has been deleted in the recommended changes to 3-502.12 (D)(2)(e)(iii).</p>

<p>temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures which can be displayed using computer software.</p>	<p>products at 1°C (34°F) or 3°C (38°F) 5°C (41°F) or less. Thermocouple data loggers can connect directly with commonly available thermocouple probes. Recording charts are also commonly used. Temperature monitors and alarm systems will activate an alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record temperatures which can be displayed using computer software.</p>	
<p>Since surveys have shown that temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide processing methods cannot be distributed outside the control of the food establishment doing the packaging.</p>	<p>No recommended changes</p>	
<p>Time is also a factor that must be considered in ROP. The 14 day "use by" date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by" date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 34°F or less with an option of 3°C (38°F) for up to 72 hours after packaging with stringent temperature monitoring and recording requirements. These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast chillers to safely use cook chill and sous vide processes.</p>	<p>Time is also a factor that must be considered in ROP. <u>Processes that use ROP packaging for storage less than 48h do not pose a hazard for pathogen growth when refrigerated at 5°C (41°F) or less and are exempt from the HACCP requirement of sections 3-502.11 and 3-502.12. Examples are sous vide cooking provided a proper cooking temperature is used according to 3-401.11 (A-C) followed by immediate service and enhanced cooling of foods using ROP bags. The main factors in this exemption are that the food must be date marked and consumed or removed from packaging after 48h.</u> The 14 day "use by" date is required label information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by" date. This is considered a safe time period because two barriers to growth are required to be present. When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process <u>or inhibiting their growth</u>, preventing recontamination, and then refrigerating at 34°F or less with an option of 3°C (38°F) for up to 72 hours after packaging with stringent temperature monitoring and recording requirements. <u>The 7 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing recontamination, and then refrigerating at 5°C (41°F) or less.</u> These criteria allow both institutional-sized cook chill operations that may feed thousands daily, often including transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast</p>	<p>Clarifies that some uses of ROP "bags" do not pose a risk especially those uses within a 48h time frame. Secondly, clarifies time factors in the safety of ROP based on extensive studies by Dr's Skinner and Larkin of the US FDA.</p> <p>The Skinner-Larkin data indicates that it would take 9 days at 41°F to pose a potential risk for <i>C. botulinum</i> toxin production at the earliest.</p> <p>The 7 days shelf life was determined to match the current date-marking for <i>L. monocytogenes</i> and provide an extra 2 day margin of error in <i>C. botulinum</i> toxin production at 41°F.</p> <p>J Food Prot. 1998 Sep;61(9):1154-60. Conservative prediction of time to Clostridium botulinum toxin formation for use with time-temperature indicators to ensure the safety of foods. Skinner GE, Larkin JW.</p> <p>Dr. Skinner is still with the FDA and joined the committee on two calls. He validated that the science, cited above, was still accurate and up to date.</p>

	chillers to safely use cook chill and sous vide processes.	
The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors in these cheeses plus the normal refrigeration temperature of 41°F or less to maintain safety.	No recommended changes	
A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing procedures. C. botulinum and L. monocytogenes are potential hazards which must be controlled in most foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping, corrective actions, and verification procedures will vary based on the type of food and type of ROP technology used.	No recommended changes	
When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under section 3-502.11 providing evidence that the ROP methodology intended for use is safe.	When a food establishment intends to use ROP technology but does not use one of the secondary barriers defined in section 3-502.12 (a single barrier of 34°F combined with the criteria specified in paragraph 3-502.12(D), or hard or semisoft cheeses manufactured using Standards of Identity for those cheeses), the operator must submit an application for a variance under section 3-502.11 providing evidence that the ROP methodology intended for use is safe. <u>It is highly recommended that the operator and/or the regulatory authority consult a process authority to validate the scientific evidence the ROP methodology intended for use is safe.</u>	This change is recommended to help assure that adequate ROP methodologies are used.
Unfrozen raw fish and other seafood are specifically excluded from ROP because of these products' natural association with C. botulinum type E which grows at or above 30C (37-38oF). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.	Unfrozen raw fish and other seafood are specifically excluded from ROP <u>without a variance</u> because of these products' natural association with C. botulinum type E which grows at or above 3°C (37-38°F). Fish and seafood that are frozen before, during and after the ROP packaging process are allowed.	Corrects text that implies ROP of non-frozen fish with a variance is not permitted.

<p>Annex 6 2 (B) Definitions: The term ROP can be used to describe any packaging procedure that results in a reduced oxygen level in a sealed package. The term is often used because it is an inclusive term and can include packaging options such as:</p>	No recommended changes	
<p>1) Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a plastic or metal crimp.</p>	<p>Cook-chill is a process that uses <u>an plastic impermeable</u> bag filled with hot cooked food <u>and</u> from which air has been expelled and which is closed with a plastic or metal crimp <u>and are then sealed or crimped closed.</u></p>	Alignment with definitions in 1-201.10
<p>2) Controlled Atmosphere Packaging (CAP) is an active system which continuously maintains the desired atmosphere within a package throughout the shelf-life of a product by the use of agents to bind or scavenge oxygen or a sachet containing compounds to emit a gas. CAP is defined as packaging of a product in a modified atmosphere followed by maintaining subsequent control of that atmosphere.</p>	No recommended changes	
<p>3) Modified Atmosphere Packaging (MAP) is a process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. MAP is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen, 0.03% carbon dioxide.</p>	No recommended changes	
<p>4) Sous Vide is a specialized process of ROP for ingredients that require refrigeration or frozen storage (PHF/TCS food) until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization/cooking step that reduces bacterial load but is not sufficient to make the food shelf-stable. The process involves the following steps:</p>	No recommended changes	
<p>a) Preparation of the raw materials (this step may include grilling or broiling for color of some or all ingredients):</p>	No recommended changes	
<p>b) Packaging of the product immediately before cooking, application of vacuum, and sealing of the package;</p>	No recommended changes	
<p>c) Pasteurization/cooking of the product using required time/temperature parameters;</p>	No recommended changes	
<p>d) Rapid and monitored cooling of the product at or below 3°C (38°F) or 1°C (34°F) or frozen; and</p>	No recommended changes	
<p>e) Reheating of the packages 74°C (165°F) for hot holding or to any temperature for immediate service before opening and service.</p>	No recommended changes	
<p>5) Vacuum Packaging reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.</p>	<p>Vacuum Packaging reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is Vacuum Skin Packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.</p>	The phrase near-perfect is vague and non quantifiable.

Appendix 2 -Table 2: References summarizing growth limitation of psychrotrophic *Clostridium botulinum*. 1 page

CFP ROP Committee 2011 - Growth limitation of psychrotrophic *Clostridium botulinum*

Author	Year	Reference	Aw	pH	WPS	Comments
Peck	1997	Trends in Food Science and Technology 8:186-192	≤ 0.97	≤ 5.0	≥ 3.5%	Review article
Graham and Peck	1997	Letters in Applied Microbiology 24:95-100			≥ 4.5%	Detected growth at 4.5% salt in 2 weeks at 8°C and 4% salt in 11 weeks at 5°C.
FDA	2001	Fish and Fisheries Product Hazards and Controls Guidance Chap 13	≤ 0.97	≤ 5.0	≥ 5.0%	Simply cites growth limits.
ECFF	2006	Recommendations for the Production of Prepackaged Chilled Foods	≤ 0.97	≤ 5.0		European Chilled Foods Federation (ECFF)
Peck et al	2008	Trends in Food Science & Technology 19: 207-216	≤ 0.97	≤ 5.0	≥ 3.5%	Updated review article.
Peck	2006	Clostridium botulinum and the safety of minimally heated chilled foods: an emerging issue? Journal of Applied Microbiology, 101, 556-570.	≤ 0.97	≤ 5.0	≥ 5.0%	Peck also cites the ECFF data for WPS at 3.5%. No explanation is provided as to the difference.
Lund & Peck	2000	Lund, B.M. and Peck, M.W. (2000) Clostridium botulinum. In The Microbiological Safety and Quality of Food ed. Lund, B.M., Baird-Parker, T.C. and Gould, G.W. pp. 1057–1109. Gaithersburg: Aspen	≤ 0.94*			*The minimum water activity permitting growth is 0.97 and 0.94 with NaCl and glycerol, respectively, as humectants. Other salts and sugars studied were 0.97.
Lindstrom et al	2006	International Journal of Food Microbiology 108 (2006) 92 – 104.	≤ 0.97	≤ 5.0	≥ 5.0%	Hazard and control of group II (non-proteolytic) <i>Clostridium botulinum</i> in modern food processing
MW Peck	2011	Personal communication. The 3.5% WPS is considered a historical data number, since no outbreaks have ever occurred in these products. Very few products are salted above this level. Data for growth between 3.5% - 5% WPS all show growth only after 30 days or more at 4-5°C. However, data show growth in less than 30 days at >5°C.				

Based on the above references the recommendation for growth limits from the committee should be ≤ 0.97 Aw and pH ≤ 5.0, WPS ≥ 5.0%. It is recognized that few products will have WPS of ≥ 5%. Products with 3.5% or more WPS would require additional scientific and mathematical model evidence of safety at designated refrigeration temperatures for 30 days maximum storage.

Appendix 3 - Table 3: References summarizing growth limitation of *Listeria monocytogenes*. 2 pages

CFP ROP Committee 2011 - Growth limitation of *Listeria monocytogenes*

Author	Year	Reference	Aw	pH	WPS	Comments
FDA	2008	Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance	≤ 0.92	≤ 4.4	-	Complete growth inhibition at any temperature. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm#formulate
USDA	2002	http://haccpalliance.org/sub/food-safety/fsisdirective102403.pdf	< 0.92 @ 5°C	< 4.5 < 5.5 @ Aw < 0.95		These products are stable with respect to growth of <i>L. monocytogenes</i> by any of the following means. Also included is, "the presence of an antimicrobial agent (e.g., sodium or potassium lactate, sodium diacetate) that has been validated through scientific studies to inhibit growth of <i>L. monocytogenes</i> ".
FDA	2001	Fish and Fisheries Product Hazards and Controls Guidance Chap 13	≤ 0.92	≤ 4.4	≥ 10.0%	Complete growth inhibition at any temperature.
EC	2005	EC Regulation 2073/2005	≤ 0.92 ≤ 0.94 @ pH ≤ 5.0	≤ 4.4		Complete growth inhibition at any temperature. "At 4°C the pH and aw limits for growth predicted by all the models are considerably higher ..."
Tienungoon, Ratkowsky, McMeekin, Ross	2000	Growth Limits of <i>Listeria monocytogenes</i> as a Function of Temperature, pH, NaCl, and Lactic Acid		≤ 5.0 @ 5°C		http://www.ncbi.nlm.nih.gov/pmc/articles/PMC92408/
Koutsoumanis	2004	http://www.sciencedirect.com/science?_ob=MIimg&imagekey=B6WFP-4BWVTF1-3-14&cdi=6800&user=464852&pii=S0740002003001084&origin=gateway&coverDate=08%2F31%2F2004&sk=999789995&view=c&wchp=dGLbVIW-zSkzV&md5=180ae8d3066f86b18807c1de05cccece&ie=/sdarticle.pdf		≤ 4.96 @ 4°C		The value obtained was only at Aw 0.99. This paper led to a growth/no growth model.
Farber et al	1989	The effect of various acidulants on the growth of <i>Listeria monocytogenes</i>		≤ 5.0 @ 5°C		http://onlinelibrary.wiley.com/doi/10.1111/j.1472-765X.1989.tb00319.x/pdf
Reyser and Marth	2007	<i>Listeria</i> , listeriosis, and food safety		≤ 5.0 @ 5°C	-	

McClure et al	1991	The effects of temperature, pH, sodium chloride and sodium nitrite on the growth of <i>Listeria monocytogenes</i>		$\leq 5.0 @ 5^{\circ}\text{C}$		https://docs.google.com/viewer?a=v&pid=explorer&chrome=true&srcid=OBx-grmwZp8OaZDIyZTU1ZTYtMjhkZC00NDMyLTkxZTItNDg1MjdhMjFmNDU3&hl=en
Downes and Ito	2001	Compendium of methods for the microbiological examination of foods		$\leq 5.23 @ 4^{\circ}\text{C}$		(p 524) ref - George et al 1988 Letters Applied Microbiol 6:153 Journal of Food Protection. 67: 2698-2702. Provides various parameters of inhibition of LM in meats at 41oF. pH values 4.8 - 5.6 with WPS 2.5-14.4. See http://www.meathaccp.wisc.edu/validation/assets/CL%20for%20LM.pdf
Ingham, Buege, Dropp, and Losinski.	2004	Survival of <i>Listeria monocytogenes</i> during storage of ready-to-eat meat products processed by drying, fermentation, and/or smoking				
Health Canada	2004	Policy on <i>Listeria monocytogenes</i> in Ready-to-Eat Foods	≤ 0.92	$\leq 5.0 @ 5^{\circ}\text{C}$	-	http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_politique_toc-eng.php
Health Canada	2010	Policy on <i>Listeria monocytogenes</i> in Ready-to-Eat Foods	≤ 0.92	$\leq 5.0 @ 5^{\circ}\text{C}$		http://members.wto.org/crnattachments/2010/sps/CAN/10_43_22_00_e.pdf

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm>

Appendix 4- Committee summary of time to toxin formation of *C. botulinum* in foods with attached reference article (Skinner-Larkin paper reviews extensive research done by FDA scientists regarding time to toxin formation of *C. botulinum* in foods).

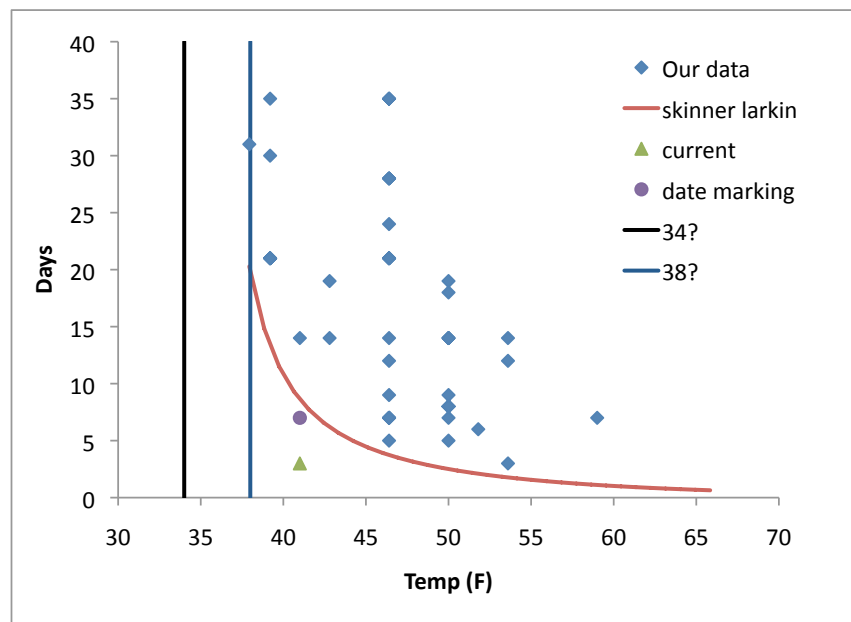
Status Report
Temperature Control Subcommittee
CFP ROP committee
January 19, 2011
Version 3

Three review articles were used to create a table summarizing the published literature on *Clostridium botulinum* time to growth or toxin production. Those three studies were: Lindstrom et al 2006, Graham et al, 1997 and Betts, 1995. A (mostly complete) excel spreadsheet containing the data from those studies is being shared with the committee.

A figure summarizing some of those data is show below, together with a line indicting the prediction from the most conservative Skinner-Larkin model (1998, JFP 61: 1154-1160). Note that the Skinner and Larkin paper is in the Google docs directory Brian set up, so you can download a copy if you are interested. You will note that the Figure from their manuscript contains many more points than our modest effort.

Also shown in the figure are key time temperature combinations, as well as key temperatures that Brian asked about in his January 18, 2011 email.

Jenny Scott has reached out to John Larkin and Guy Skinner. They have hundreds of articles included in their model and Guy continues to monitor the literature. So far he has not seen anything inconsistent with the model (although our committee needs to double-check the last 5 years). Guy can manipulate the database to give us data on food only, food other than seafood, media only. He can give us all the worst case data (e.g., for food at 3.3, it is the beef stew, with time to toxicity of 31 days). Guy will also join us on our call on Monday.



Conservative Prediction of Time to *Clostridium botulinum* Toxin Formation for Use with Time-Temperature Indicators To Ensure the Safety of Foods

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ABSTRACT

Integrating-type time-temperature indicators (TTIs) may be utilized to warn food processors and consumers about storage conditions that may have rendered a food potentially hazardous. As an example of how integrated TTIs could be manufactured to emulate an infinite set of time-temperature situations, a set of conditions which have supported *C. botulinum* growth and toxin production was compiled. The time-temperature curve representing conservative times required for toxin formation was constructed with data from literature relating to toxin formation as a function of temperature in any media or food product. This set of critical time-temperature data is fit by a conservative empirical relationship that can be used to predict combinations of incubation times and storage temperatures that represent a potential health risk from *C. botulinum* in foods. A TTI could be constructed to indicate deviation from such a given set of conditions to bring attention to foods that may have been exposed to potentially hazardous temperatures with respect to *C. botulinum* toxin formation.

Recent consumer attitudes have stimulated the development of new and innovative foods. Through renewed awareness, consumers are altering their eating habits and purchasing foods formulated to meet specific dietary needs or desires (i.e. light syrups and low-fat or low-salt processed meats). Changing lifestyles are resulting in consumer demand for refrigerated precooked foods and sous-vide processed products that require minimal preparation time in the home. By packaging these new foods under vacuum, modified, or controlled atmosphere, food processors have been able to significantly extend the shelf life of many foods. Concerns about the safety of some of these products exist, especially considering the potential for temperature abuse (37). The thermal treatment imposed on these products, often referred as pasteurization, may be insufficient to inactivate spores of *Clostridium botulinum*. Focus on these products exists because many of them rely on refrigeration temperatures as their only barrier against pathogenic microorganism growth and/or toxin production. In the United States, the food distribution chain is unable to ensure that foods will not be temperature abused at some time between processing and consumption. Use of time-temperature indicators (TTIs) can minimize potential public health risks associated with certain types of foods by monitoring product temperatures during distribution and on the retail shelf.

Temperature abuse. The importance of monitoring critical control point (CCP) temperatures during processing, distribution, retail display, and consumer storage of perishable foods is emphasized by the potential for temperature abuse reported by a number of researchers. Daniels (13) monitored refrigeration temperatures in retail operations and consumers' homes. Results showed that many refrigerated foods are exposed to temperatures above 10°C. The survey showed that in supermarkets tested, fresh meat cases were the area with the best temperature control; only 4% of the products were above 10°C. Delicatessen sections of supermarkets surveyed had the worst temperature control; 26% of foods were at temperatures above 10°C and 12.9170 were above 12.8°C. Davidson (14) showed that it was not uncommon for retail display temperatures to range from 7 to 10°C. Van Garde and Woodburn (44) discovered that up to 20% of the home refrigerators surveyed were set at temperatures in excess of 10°C. This indicated the potential for temperature abuse at the consumer level.

Psychrotrophic pathogens are receiving attention because of their ability to grow at or below 5°C (34). Such pathogens include *Yersinia enterocolitica*, enterotoxigenic *Escherichia coli*, *Listeria monocytogenes*, *Aeromonas hydrophila*, and nonproteolytic strains of *Clostridium botulinum*. Existence of documented temperature abuse throughout the food chain is important because nonproteolytic strains of *C. botulinum* have been found to produce toxin at temperatures as low as 3.3°C, and proteolytic strains have been shown to produce toxin at temperatures above 10°C (39, 40). Because of the potential for temperature abuse, it is necessary to devise a cost-effective means to monitor the temperature conditions of individually packaged foods during distribution and storage to ensure the safety of modified- or controlled-atmosphere-packaged (MAP) foods.

Risks from potential toxin production by *Clostridium botulinum*. Recent technologies such as controlled atmosphere packaging (CAP), modified-atmosphere packaging (MAP) and *sous-vide* processing have been shown to successfully extend the shelf life of many minimally processed new-generation refrigerated foods such as fish, meats, poultry, pasta, and salads. Some new-generation refrigerated foods rely on low temperatures as the primary or only barrier against potential growth and/or toxin production by pathogenic microorganisms (21). Some of these foods represent potential health hazards because they have been shown to support the growth of *C. botulinum*. Many have a pH and a water activity (aW) capable of supporting *C. botulinum* spore outgrowth and toxin production, and many have received a heat treatment intended to reduce or eliminate competitive vegetative cells but not sufficient to inactivate spores. Specific concerns regarding the safety of refrigerated foods of extended durability with specific reference to *C. botulinum* have been addressed (11, 12, 15, 19, 20, 23, 24, 27, 29, 33, 35) as have the safety issues of *sous-vide* processed products (3, 5, 31, 37).

Concerns regarding *C. botulinum* in refrigerated foods has led to the establishment of guidelines to help ensure their safe manufacture. In response to growing concerns about the relationship between storage temperatures and food safety, the *Fish and Fisheries Products Hazards & Controls Guide* (17) incorporated time-temperature guidance for maximum cumulative exposure time for seafoods, intended to prevent

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germination, growth and toxin production by the various types of *C. botulinum*. A discussion of guidelines and recommendations issued by other regulatory agencies and associations is presented by Lund and Notermans (27) and Peck (35).

Recent outbreaks of botulism were attributed to inadequate processing or temperature abuse of commercially available products. Foods implicated in such outbreaks include kapchunka (a commercially available ready-to-eat, air-dried, salt-cured, uneviscerated whole fish) (6) or similar products (7, 9, 10) and garlic in oil (7, 8). Accurate and reliable Ms represent potential devices for indicating temperature abuse of such products during their shelf life.

Essential performance criteria for a time-temperature indicator. Individual product TTIs have yet to become widely used for several reasons. Use of these TTIs could result in food processors losing money from the destruction of temperature-abused food. Processors would also lose economically if food considered a potential health hazard is destroyed because the TTIs incorrectly indicated temperature abuse. Presently, TTIs can be costly, have no reliability history, lack durability, and frequently lack the ability to measure the integrated effect of time and temperature (22, 45). However, because of their potential advantages, significant research is under way to make TTIs less expensive, more useful and reliable.

Time-temperature response must be reliable. Whether an indicator is a partial- or a full-history indicator, exposure of food products to a sudden increase in temperature should be registered within a reasonable amount of time. It is important that indicator response time at particular temperatures be verified (12). Malcata (28) noted that the TTIs in his study responded more quickly to temperature changes than did the foods and that the heat transfer limitations of a food can result in a 15% error in registered indicator temperature, an estimate most likely on the conservative side.

Most TTIs do not measure actual food product temperature, rather the temperature above the surface of a package (22). Taoukis et al. (41) discussed the importance of the position in which the time-temperature indicator is attached to a product and how this position may affect the indicator reading.

Safeguards must be engineered into TTIs to either prevent their removal after placement on a package or to indicate whether or not they have been removed from a package. Indicators should not be transferred from one package to another (22) and should be properly labeled so they are not affixed to the wrong product.

If TTIs utilize a color change to alert consumers to potential problems in safety or shelf life, it is imperative that any color change can be clearly interpreted by the untrained consumer with normal vision (41). Indiscrete or gradual changes in indicator color may increase the likelihood that consumers may misinterpret an indication of temperature abuse or expired shelf life. Certain colors may represent a problem for a percentage of the population that is color blind (41). Indicator response may be affected by light under certain circumstances (41). Lingle (26) and Blixt (-F) have also discussed these problems.

Certain pH-based colorimetric indicators may demonstrate accelerated time-temperature responses at low temperatures after extended exposure to elevated temperatures (41, 42). These authors also note that TTI accuracy must not change with indicator age, because the outward diffusion of the TTI reactant gases leaking through the containment film could influence the fundamental chemical reactions of some chemically based indicators and lead to erroneous readings (41).

Use of TTIs in an actual processing facility introduces additional nonfood materials into the processing operation. TTIs containing crystals polymers, enzymes and chemical compounds such as phthalates and dyes represent an additional potential public health hazard by their introduction into food-processing areas. As with broken mercury-in-glass thermometers, broken indicators could potentially lead to leakage of the chemicals into individual food products or into larger quantities of food. If TTIs are to be used directly in contact with foods, their composition and the chemical they contain must comply with pertinent government regulations. In addition, some small TTIs may represent a health hazard in the consumer's home because they could inadvertently be swallowed, particularly by children (22).

Types of time-temperature indicators. Numerous types of time-temperature indicators are presently available for monitoring food temperature. Wells and Singh (45) categorized TTIs into two classes, partial history or full history by their response. Partial-history TTIs can be referred to as temperature indicators (TIs), as they indicate that a specified temperature has been reached or exceeded (22, 45). Full-history indicators respond independently of threshold temperatures. Upon activation full-history TTIs monitor the continuous integrated time-temperature history to which the integrator is exposed. The integrated data can be used to obtain a product's relative time of exposure to particular storage temperatures. Fu et al. (18) established a term T_{eff} to describe data obtained from integrated TTIs. T_{eff} is used to quantify an exposure of an indicator or food to an unknown set of time-temperature conditions. Labuza and Fu (25) defined T_{eff} as the constant temperature resulting in the same quality change as the variable temperature distribution over the same time period. Fu et al. (18) further explained that if one assumes some rate constant versus temperature model, the calculated T_{eff} should represent some measurable amount of change, irrespective of the exact time-temperature conditions of exposure. In other words, two Ms could indicate the same T_{eff} after being exposed to two totally different combinations of time and temperature. The description of T_{eff} assumes that there is no "history effect" (18). The term "history effect" is used to explain differences in microbiological growth or lag-phase behavior in terms of previous conditions of storage temperatures to which the microorganisms were exposed. Prior storage temperatures may lead to either positive or negative history effects on the lag phase (18). Ng et al. (32) reported that transferring microbial cells grown at near optimum temperatures to lower incubation temperatures may result in a positive history effect, or a shorter lag phase or growth rates greater than expected for those temperatures. On the contrary, introduction of cells grown at temperatures well below their optimum to higher temperatures may result in a negative history effect, or a lag-phase extension or lower growth rate due to phenomena such as sublethal injury (38). Fu et al. (18) and Labuza and Fu (25) note that predictive models could result in false estimations if such history effects are not accounted for.

From a safety perspective, the most conservative, yet effective, means for ensuring that a food product is not temperature-abused may be to set a fixed temperature (e.g. 3.3°C) that the product is not allowed to exceed. TTIs exist which indicate that a specific temperature endpoint has been reached or exceeded. Endpoint indicators may be designed to indicate temperature abuse of refrigerated foods or thawing of frozen food. One obvious drawback of this endpoint monitoring method is the ability of a food processor to maintain adequately low food storage temperatures, even if the target fixed temperature is set at 5°C. Another problem is that in numerous cases a food product may be held above the fixed temperature for a short time, but not long enough to adversely influence food safety at that time. Depending on the specific food product composition and the specific hazard of concern, such a product may be erroneously deemed a potential health hazard and discarded if a fixed temperature requirement is utilized and exceeded.

The alternative to adhering to a set fixed temperature is to establish a maximum integrated combination of time and temperature below which the food must be held. The integrated relationship results in an infinite number of combinations of potentially hazardous time-temperature growth conditions which must be understood in order to evaluate a product's safety. A standard curve of a pathogenic microorganism's generation

time or minimum time to toxin formation as a function of storage temperature (T_{eff}) would need to be established to resolve this issue. A TTI could be manufactured to comply with a scientifically selected set of conditions and indicate whether the integrated time-temperature boundary relationship has been violated.

Specific TTIs could be applied for a pathogen that may be present in a food, assuming the appropriate data is present for the TTI to model. For a microorganism such as *Staphylococcus aureus*, where proliferation to significant numbers is associated with production of enterotoxin, a TTI designed to model generation time as a function of temperature may be appropriate. For spore-forming pathogens such as *Bacillus cereus* and *C. botulinum*, a TTI modeling the relationship of time required for toxin production as a function of storage temperature would be used.

The objective of this project was to develop a conservative relationship between time to *C. botulinum* toxin formation and storage temperature that can be incorporated into a TTI. The impact of a positive growth history effect was tested against the conservative model using *C. botulinum* type E spores in vacuum-packaged fresh salmon fillets under conditions of fluctuating temperature.

MATERIALS AND METHODS

Clostridium botulinum type E spore preparations. *C. botulinum* type E strains (Birmingham, Minnesota, Beluga, G21-E, and 070) previously isolated from seafood products implicated in foodborne botulism were used in this study. Spore suspensions of individual strains were grown in trypticase-peptone-glucose-yeast extract (TPGY) medium at 28°C for 10 days (*Bacteriological Analytical Manual* [161]). Spores of each strain were harvested by centrifugation, washed three times with sterile distilled water and resuspended in sterile distilled water. Spore numbers per milliliter in each strain suspension were determined by the three-tube most probable number (MPN) method with TPGY broth as the culture medium. Equal numbers of the spores from each strain were mixed to form a spore mixture and diluted with sterile distilled water to contain 3.5×10^6 spores per ml. The spore mixture was stored at 4 - 1 °C until used.

Fish source, inoculation, packaging, and storage conditions. To illustrate validation of the *C. botulinum* time-to-toxin curve from potential positive history growth effects, an inoculation study was performed to obtain *C. botulinum* toxin production data at fluctuating temperatures. Fresh salmon fillets were obtained immediately after processing, skinned and cut into appropriate portions, and packaged within 24 h. Fresh salmon portions, each weighing 90 to 120 g were cut from fillets, then surface inoculated on both sides with the non-heat-shocked spore mixture to obtain an inoculum level of 1×10^8 spores per g of fish. An aliquot from a known inoculum ($i \times 10^8$ spores per ml) ranging from 0.90 to 1.2 ml was dispensed on both sides of the fillet on the basis of weight and spread with a sterile glass rod. Inoculated fillets were vacuum packaged in a high-barrier film bag (O, transmission rate of 3 to 6 cm³/m²/24 h at 4.4°C, 1 arm (ca. 101 kPa) pressure, and Oslo humidity) with a Multivac Model A316 Vacuum Packaging Machine (Multivac, Inc., Kansas City, Mo.) equipped with a built-in vacuum pump. Vacuum-packaged fillets were stored under two temperature schemes. Treatment 1 involved an initial 24-h incubation at $16 \pm 1^\circ\text{C}$, followed by incubation at $8 \pm 1^\circ\text{C}$ until toxin formation. Treatment 2 involved an initial 24-h incubation at $16 \pm 1^\circ\text{C}$, followed by a 24-h incubation at $8 - 1^\circ\text{C}$, and then incubation at $16 \pm 1^\circ\text{C}$ until toxin presence was confirmed. Samples were taken daily to determine the presence of toxin.

Analysis for presence of *C. botulinum* toxin. Two vacuum-packaged fillets were removed from incubation each day for analysis for the presence of toxin. The whole fillet from each package was blended with 200 ml of cold gel-phosphate buffer (pH 6.2) for 2 min in a Stomacher 400 (Tekmar Co., Cincinnati, Ohio). The homogenate was centrifuged at $12,000 \times g$ for 20 min at 4°C, and the supernatant was passed through a sterile 0.45 μ -pore-size analytical filter. The clear filtrate was tested for the presence of *C. botulinum* toxin by the standard mouse bioassay (16). The filtrate was divided into three portions: the first was treated with trypsin (1:50; Difco Laboratories, Detroit, Mich.) for 1 h at 35°C (1.8 ml of filtrate, 0.2 ml of 5% trypsin solution) to activate type E toxin; the second was boiled for 10 min to serve as the negative control during confirmations; the third was neither trypsin-treated nor boiled. Each filtrate portion (trypsinized and nontrypsinized) was injected intraperitoneally into two mice (0.5 ml per mouse) and the mice were observed for 48 h for symptoms typical of botulism. All sample filtrates causing mouse deaths were confirmed by mouse protection tests using type E-specific antitoxin. Deaths due to toxin were confirmed by injecting boiled extracts as described (16).

RESULTS

Predictive curve for toxin formation by *Clostridium botulinum*. Data from the Food and Drug Administration and the literature were used to generate a plot of time to *C. botulinum* toxin formation as a function of incubation temperature under optimum growth conditions. Figure 1 shows a plot of the accumulated data, representing more than 1,800 data points. Data for all types of *C. botulinum* which have been implicated in causing human botulism were collected (type A, proteolytic types B and F, type E, and nonproteolytic types B and F). No attempt was made to distinguish between *C. botulinum* types for the purpose of this curve. It is well documented that different types of *C. botulinum* show great diversity with respect to their growth characteristics. However, because of the desire to be conservative, all data obtained for time to *C. botulinum* toxin formation as a function of incubation temperature were plotted on one graph, not separately by *C. botulinum* type, product, or growth medium. Experimental data obtained from the literature were generated under a variety of temperatures in growth systems ranging from jellied ox tongue to laboratory media.

Experimental validation of the conservative nature of the data in Figure 1 is not easily accomplished. When it is taken into consideration the infinite number of different time-temperature history paths to which a food product can be subjected, a validation protocol that would exercise all the areas of the time-to-toxin domain was considered impossible. Instead, the authors decided that as much of the available literature containing data for time to *C. botulinum* toxin formation as possible needed to be accumulated and the data entered into Figure 1. This would help to ensure that all of the fastest time-to-toxin data existing in published research papers or reviews were included. It was decided that since the data in Figure 1 were not selectively added to the plot, the boundary curve exhibited in Figure 1 was in fact self-validating. After the initial recording of data into Figure 1, only one point during the 5 years of data collected was found to extend the conservative boundary. At 16°C the original curve established a minimum time to *C. botulinum* toxin formation of 1.5 days. A point published by Meng and Genigeorgis (30) showed that toxin was detected in a turkey roll after 1 day of incubation at 16°C. Because the literature is being continually reviewed and newly published data collected and used to challenge the existing curve, the authors believe that the boundary established in Figure 1 is self-validating. Once a validated boundary for minimum time to *C. botulinum* toxin formation is established, an equation describing the boundary conditions is needed. This mathematical expression is integral to the development of a reliable TTI.

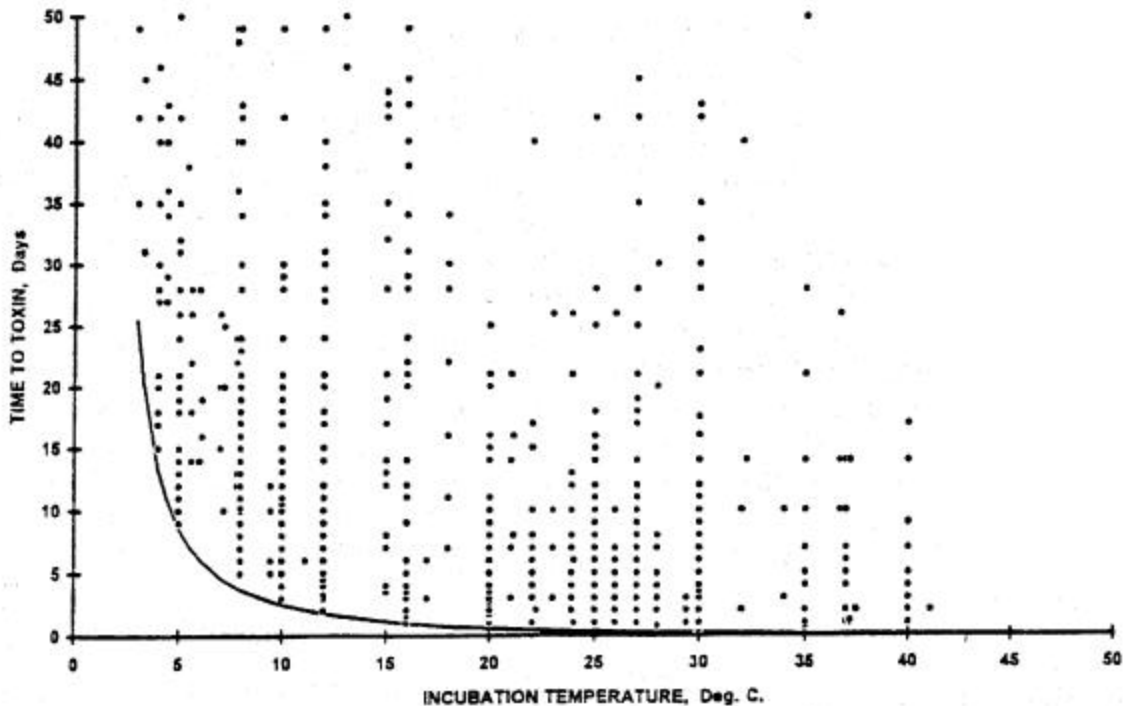
Baker and Genigeorgis (1) applied regression analysis to data accumulated for fish (rockfish, salmon, and sole) to generate an empirical, generalized conservative predictive polynomial equation for lag time (LT) of *C. botulinum* toxin formation as a function of incubation temperature, spore inoculum level, and initial aerobic plate count. Their generalized equation is shown as Equation 1.

$$\log LT = 0.974 - 0.042(T) + 2.74(1/T) - 0.091 (\log \text{ spore inoculum}) + 0.035(\log \text{ initial APC}) \quad [1]$$

LT represents lag time for *C. botulinum* toxin formation, T represents temperature in degrees Celsius, spore inoculum represents the number of spores that are initially present in the sample (number of spores per gram) and initial APC (aerobic plate count) is the assumed initial number of bacteria that are present in the sample (CFU per gram). Equation 1 was derived for lag time data for *C. botulinum* toxin production in vacuum-packaged fish at refrigeration temperatures and is similar in shape to the one being sought to represent the lower boundaries of the data presented in Figure 1. Equation 1 is a simple polynomial equation having no real kinetic basis and it was felt that it could be modified to conservatively represent the boundary conditions for *C. botulinum* toxin production presented in Figure 1. A simplified, conservative version of Equation 1 is expressed by Equation 2. The lower and upper temperature limits of the curve are 3.3 and 40°C, respectively, because these are the minimum and maximum temperatures where toxin data were obtained.

$$\log LT - 0.65 - 0.0525(T) + 2.74(1/T) \quad [2]$$

The curve generated by Equation 2 is plotted in Figure 1. It is understood that Equation 2 is strictly empirical: it has no actual kinetic basis. Equation 2 represents an example of a mathematical relationship for estimating the boundary conditions conservatively predicting *C. botulinum* toxin production at various temperatures under the most ideal conditions for which data could be obtained. As previously mentioned, the curve depicts boundary conditions for all *C. botulinum* types and therefore is extremely conservative. It could be argued that the curve is for nonproteolytic types exclusively, because it extends down to 3.3°C. Proteolytic types of *C. botulinum* do not grow and produce toxin between 3.3 and 10°C (35,-40). At temperatures just above the 10°C lower limit for proteolytic *C. botulinum* types, toxin production is very slow. If enough data could be generated or obtained for proteolytic types of *C. botulinum* at temperatures approaching the lower boundaries of growth, a separate model could be generated. In addition, numerous subsets of data could be made on the basis of particular food types such as fish, and these individual data sets could be modeled. The predictive value of these models would depend on the quantity and quality of data upon which they are based, and may provide some information useful in planning challenge studies by providing estimates for time-to-toxin formation at a specific incubation temperature. The curve generated in the present work for *C. botulinum* is conservative, and therefore may not necessarily represent the most appropriate model for every food system or pathogen application. As conservative as the integrated time-temperature equation displayed in Figure 1 may appear, it is in fair agreement with the guidelines provided in the Fish and Fisheries Products Hazards & Controls Guide (17) for germination, growth and toxin production by the various types of *C. botulinum* in seafood. In addition, the boundary conditions exhibited by Equation 2 are very similar to the predicted plot generated by the USDA/ARS Pathogen Modeling Program (PMP) version 5.0 (43) for nonproteolytic types of *C. botulinum* (types E, F, and B) in fish and media under ideal growth conditions. The PMP version 5.0 prediction for nonproteolytic *C. botulinum* toxin production in fish is based on data obtained by Baker and Genigeorgis (1) from vacuum packed fish meat (43). This same data was used by Baker and Genigeorgis (1) to derive Equation 1. Even though the boundary conditions established by Equation 2 are conservative, they still represent an advantage over a maximum-registering TI. For example, a hazard analysis critical control point (HACCP) plan for a refrigerated food may include distribution temperature as a critical control point (CCP) because of the potential for *C. botulinum* toxin



formation at abuse temperatures. Using TIs to monitor a CCP requires setting a fixed temperature such as 4°C as a critical limit, whereas, use of an integrated TTI allows a combination of time-temperature boundary conditions as described previously in Figure 1. A food product exposed to 5°C for a short time period would be in violation of the critical limit if TIs were used; however, a TTI manufactured to respond to the curve in Figure 1 would not indicate the product to be a potential hazard for approximately 9 days at the same temperature. The actual specific minimum time required for *C. botulinum* toxin production depends on the variables such as specific food product, number of competitive microflora, present spore load, inhibitors present, etc. Therefore, each food could have its own conservative curve of boundary conditions.

Validation by using fluctuating temperature data. Although the 1,800 data points on which Equation 2 is based should make the equation self-validating, an experiment was performed to determine if the model held for data obtained under conditions of fluctuating temperatures and would withstand any possible temperature effects. The realization that survival of *Escherichia coli* 0157:147 strains are apparently significantly affected by conditions of growth makes the subject of history effects very important and a phenomenon which must be considered in microbiological modeling. Vacuum-packaged salmon fillets from treatment 1 (24-h incubation at 16°C, then 8°C until toxin formation) and treatment 2 (24-hour incubation at 16°C, 24 h at 8°C, 16°C until toxin formation) of the validation storage study developed toxin after 6 and 5 days of incubation, respectively. Toxin results of Reddy et al. (j6) indicated that vacuum-packaged samples prepared identically to those in this research developed toxin in 13 and 3 days at 8 and 16°C, respectively. These experimentally obtained times to toxin formation are greater than the values of 3.74 days at 8 and 0.96 days at 16 °C calculated by Equation 2, again demonstrating the conservative ability of the equation to predict potentially hazardous conditions of storage.

Modified-atmosphere-packaged fish were selected as a test matrix because they represent an actual food product which has been shown to rapidly support toxin formation by *C. botulinum* under certain conditions. Time-to-toxin data obtained by Reddy et al. (36) was used to convert the data obtained in the fluctuating-temperature experiments into equivalent days to toxin formation at a constant temperature. Equivalent days were calculated by using the ratio of time to *C. botulinum* toxin formation at 16 and at 8°C obtained by Reddy et al. (36) under the same experimental conditions, assuming a logarithmic relationship between time to toxin development and incubation temperature. Expressing the data as equivalent times allows comparison of lag-phase data obtained under fluctuating temperatures with results obtained under static temperature conditions (Figure 1).

Treatment 1 resulted in toxin formation in 6 days, which is equivalent to 8.4 and 2.5 days at 8 and 16°C, respectively. The equivalent time of 8.4 days at 8°C, obtained by moving the spores from a higher (16°C) to a lower (8°C) incubation temperature, is shorter than the 13 days required for toxin formation at a constant incubation temperature of 8°C. This represents a positive history effect by reducing the lag phase for toxin formation to a time less than that obtained at a constant temperature. Fu et al. (18) reported a significant positive history effect on lag phase of *Pseudomonas fragi* by using a single stepwise temperature distribution shift. Zwietering et al. (46) and Baranyi et al. (2) noted that once a cell population is growing exponentially, the growth rate instantaneously adapts to temperature changes. These researchers state, however, that temperature changes around the cell's lower growth limit may result in a lag resulting in predictive model deviations. This could explain the negative history effects observed by Fu et al. (18). Further research should be performed to study the history effects of microbiological growth.

Labuza and Fu (25) reported that negative history effects would lead to underprediction of growth rate or overestimation of lag phase conditions which would not result in the potential health consequences which may be caused by a positive history effect. Treatment 2 resulted in toxin formation in 5 days, which would be equivalent to 14.4 and -1.3 days at 8 and 16°C, respectively.

Because of the possible existence of positive history effects that may affect the prediction of microbiological growth or lag phase, a model should be conservative enough to account for this phenomenon. For this reason, the equivalent times obtained for the fluctuating-temperature conditions were compared to the predicted time-to-toxin values given by Equation 2. All equivalent times presented in this manuscript calculated from data obtained under

fluctuating-temperature treatments are longer than the predicted time to *C. botulinum* toxin formation calculated by using Equation 2 (3.74 days at 8°C and 0.96 days at 16°C).

The one experiment presented in this manuscript is not enough to thoroughly challenge the present model for all possible history effects which may be generated. It is used as an illustrative example of how history effects should be considered in validating a predictive microbiological model. In the history effect validation study presented here, neither treatment supported toxin formation in less time than was predicted.

DISCUSSION

The use of time-temperature indicators designed to operate reliably and accurately appears to have potential for helping to increase the safety of certain food products. TTIs may be used to indicate temperature-abused foods or as part of a HACCP plan to monitor the various critical control points (CCPs) involved with the processing, distribution, and sale of a refrigerated food. The curve for *C. botulinum* toxin formation as a function of incubation temperature presented in this publication is based on a compilation of data and could be used to define the most conservative integrated boundary conditions that TTIs must predict to indicate potentially hazardous storage conditions. This curve represents *C. botulinum* toxin production in all growth matrices and is not specific to any one matrix. Data sets for particular applications such as individual food groups or specific pathogens can be compiled for numerous applications. Such relationships could be modeled using appropriate types of integrated TTIs. If found to be adequately conservative, an integrated relationship between time required for toxin formation and incubation temperature such as that shown in Equation 2 would: represent an improvement over a maximum registering type of TI which monitors a maximum allowable storage temperature (e.g., 3.33 or 10°C). Use of this integrated relationship of time and temperature would allow for a more accurate evaluation of the potential safety concerns regarding foods that are exposed to temperature abuse.

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Appendix 5 – Email from FDA CFSAN clarifying when HACCP plans must be submitted.

Brian Nummer

From: Scott, Jenny <Jenny.Scott@fda.hhs.gov>
Sent: Thursday, March 10, 2011 10:59 AM
To: Brian Nummer; Charles McGuffey; Christopher Gordon; Dale Yamnik; Dale Grinstead; Don Schaffner; Goldberg, Dan; henry Blade; Ivory Cooper; Jessica Fletcher; Joe Graham; Joel Ortiz; Karen Reid; kevin Dreesman; Larry Payton; Linton, Richard H.; Moore, Veronica; osnyder@hi-tm.com; Richard Parker; 'Robert Jue'; stephen kenny; Thomas Schwartz
Cc: Smith, Kevin
Subject: RE: ROP HACCP Plan pre-approval or not??

Brian et al. -

Apologies from FDA for not weighing in earlier, but our retail experts on this have not been available.

I would interpret Food Code section 8-201.13 to say that a HACCP plan must be submitted for approval under A, which includes foods for which a variance is required. Packaging under ROP requires a variance, except when it doesn't - and this includes foods in which C bot and Lm are controlled as described in 3-502.12, which has criteria for ROP packaging without a variance. This section says you have to have a HACCP plan, but since no variance is involved, the HACCP plan does not need to be submitted for approval per 8-201.13 (A). (B) is silent on submission for approval, it just says you have to have a HACCP plan. (This interpretation appears to be what others have concluded as well.) Kevin Smith has indicated this is consistent with his interpretation and with what we have communicated in the past.

It seems to me that we would be better off titling 8-201.13 "Submission of HACCP plans." Then A can stay as is and B can say something like "A permit holder shall have a properly prepared HACCP plan as specified under 3-502.12 available for review during inspections but need not submit the plan to the regulatory authority for approval before engaging in the activity described in 3-502.12."

Kevin doesn't think this concept is as unclear as other parts of the Code, but he thinks something along the lines of my suggested edits to 8-201.13 may help with clarity. He thinks (B) could be placed in italics to indicate that it does not establish any additional requirement but is instead just reminding readers that ROPing in accordance with 3-502.12 does not require a variance and does not require submission of a HACCP plan to the RA. It may also be an option to build the exception language right into the introductory phrase of 8-201.13(A).

The one thing we need to consider is the provision in 8-201.13(A)(1) - that is, if the submission of a HACCP plan for a given process was required by LAW then it would need to be submitted even if it was for a process that is covered under 3-502.12 and that the Food Code indicated can be done without a variance.

Jenny

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Appendix 6 – Committee issue voting summary with individual members suggested edits.

Last Name	First Name			Issue 1	Issue 2 Revised definitions for Reduced Oxygen packaging	ROP Issue 3, sous vide issue, time and temp as controls	ROP Issue 4, sous vide, pH and temp as controls	ROP Issue 5, Requirement to submit HACCP plan to Regulatory Authority	ROP Issue 6, Changes to Public Health Annex and inclusion of additional references
Grinstead	Dale				As written	As written	As written	As written	As written
Nummer, Ph.D.	Brian A.				As written	As written	As written	As written	As written
McGuffey	Charles E.	Industry - Retail Food Stores	7-Eleven, Inc.		As written	As written	As written	As written	As written
Schwarz	Thomas L.	Industry - Food Service	International Flight Services Association Rhode Island Department of Health		As written	As written	Does not approve	Approve with edits	As written
Blade	William Henry	Regulatory - State	Department of Health		As written	As written	Approve with edits	As written	As written
Schaffner	Donald	Academia	Rutgers University		As written	As written	As written	As written	As written
Ortiz	Joel	Industry - Retail Food Stores	Whole Foods Market		As written	As written	As written	As written	As written
Payton	Larry	Industry - Food Service	Tokyo Gardens Sushi		As written	As written	As written	As written	As written
Gordon	Christopher	Regulatory - State	Virginia Department of Health		As written	As written	As written	Does not approve	As written
Fletcher	Jessica	Industry - Food Service	Mohegan Tribe		As written	As written	As written	As written	As written
Dreesman	Kevin	Regulatory - State	Illinois Department of Health		As written	As written	As written	As written	As written
Kenney	Stephen	Industry - Food Service	Darden Restaurants		As written	As written	As written	As written	As written
Parker	Richard	Industry - Retail Food Stores	HEB		As written	As written	As written	As written	As written
Snyder	Oscar Peter	Other - Consultant	Hospitality Institute of Tech and Mgmt Washington State Department of Health		Approve with edits	Approve with edits	Approve with edits	As written	Approve with edits
Graham	Joe	Regulatory - State	Department of Health		As written	As written	As written	As written	As written
Yamnic	Dale	Industry	Yum Brands		As written	As written	As written	As written	As written
Goldberg	Dan	Industry - Food Service	Walt Disney Parks and Resorts US		no vote due to position change	no vote due to position change	no vote due to position change	no vote due to position change	no vote due to position change

ROP Committee Issue comments or reasons for opposition

These comments were provided with final issue voting by committee members. They are listed here to potentially assist the FDA in crafting language. All issues were approved by committee members. There were two individual opposition votes to the six issues, but neither specified a reason.

ROP Committee Issue 6

I approve Issue 6 with the following recommendations for changing the Annex 3. Below are my comments for consideration.

Regarding the FDA Food Code 2009: Annex 3 – Public Health Reasons / Administrative Guidelines – Chapter 3, Food, at the 4th paragraph, beginning, "Most foodborne pathogens are anaerobes or facultative anaerobes..." it says in the sentence, "For this reason, *C. botulinum* and *L. monocytogenes* become the pathogens of concern for ROP." This is partially true, but *Salmonella* and pathogenic *E. coli* are also organisms of concern, just like *Listeria*, if the ROP product is mishandled or somehow cross-contaminated. This should be included in the discussion.

On page 3, in the paragraph, "Time is also a factor that must be considered in ROP," we have this 48-hour time limit. There is no scientific basis for 48 hours or 72 hours. The scientific basis is 7 days. We should change this limitation to the 7-day rule.

At the end of this same paragraph, it says, "The 30 day shelf life for cook chill and sous vide is based on killing all vegetative cells in the cooking process..." This is not technically correct. It is reducing all pathogenic vegetative cells to an Appropriate Level of Protection; in other words, a 5-log reduction of pathogenic vegetative cells.

If you have any questions, please contact me.

--

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ROP Committee Issue 4

Sorry folks, I just am not comfortable with "pH" and "equilibrium pH" being used here without some further clarification. Extending the ROP shelf life based on pH level is dependent on initially achieving an equilibrium pH in the ROP product that will then continue to hold up during cold storage. If this limited application of food acidification is not clear or too complex for operators or regulators, there could be a problem. I worry that a few drops of vinegar in a bag of raw meat may show "pH" below 5, but after ROP cooking and storage and equilibrium, it won't suffice for extending ROP shelf life like we want it to. Or regulators may not understand that the pH needs to be measured at equilibrium for the shelf life to be

safely extended. If we concretely state, or make reference to, what is meant by equilibrium pH and how it may be determined, I think it will help operators to properly acidify ROP foods they intend to store, and will help Inspectors/Officials to determine whether variances can be issued safely.

Maybe this could be handled in the Definitions section or an Annex of some sort, but here's some brief additions for Issue 4 that would address this concern, and I could go along with the following:

Line number:

Line 15 ... with an equilibrium pH lower than 5.0 and held at 41o F or below....

Line 20 & 21 ... how they will monitor measure equilibrium pH using calibrated instruments and maintain records of pH findings.

Further explanation and methods for determination of equilibrium pH are available at FDA's Draft Guidance for Industry: Acidified Foods, September 2010" (accessible at

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/AcidifiedandLow-AcidCannedFoods/ucm222618.htm#ftn9>). ...

Line 42 ... to add an acidifying agent to reduce equilibrium pH to below 5.0 so...

Does this make sense to everybody?

Henry

[Henry Blade]

ROP Committee Issue 5

Issue - line 2 - "their HACCP plan" to "its HACCP plan"

line 4 - add "approval" after "authority"; change "them" to "the appropriate authority"; change "they" to "it"

Significance - Delete both sentences and replace with "The ROP Committee does not recommend prior approval of the establishment's HACCP plan because the Food Code already includes quite specific requirements on how to conduct this operation safely."

[Tom Schwarz]

I approve Issue 4 with the following recommendations. Below are my comments for consideration.

On page 2, beginning line 81, 3-502.12(B)(5), if we are going to have *L. monocytogenes*, we need to include the possibility of cross-contamination of *Salmonella* or *E. coli*. In this case, the critical pH is not 4.4 for *L. monocytogenes*, but rather, 4.2 for *Salmonella* and *E. coli*. We need to modify the text in order to account for the possible contamination by *Salmonella* and *E. coli*.

--

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I approve Issue 3 with the following recommendations. Below are my comments for consideration.

On lines 18-19, it says, "Since paragraphs (C) and (D) in 3-401.11 refer to raw or undercooked products, these would not be acceptable cook temperatures." Raw and undercooked products are common with fish sous vide. In addition, the target pathogen for fish is *Vibrio parahaemolyticus* or *Vibro vulnificus*, and these are controlled with much lower pasteurization temperatures. This has not been covered here. When we specifically say sous vide, we need to allow for fish pasteurization temperatures. Also, I know of no undercooked product that is then cooked sous vide. I suggest we remove "undercooked product" from consideration.

On page 2, lines 80-81, (D)(2)(d), it says, "sealed immediately after cooking and before reaching a temperature below 57C (135F)". A better word than "reaching" would be "cooling to" a temperature before 57C.

Under (D)(2)(e), "Cooled to 5C (41F) in the sealed PACKAGE," at (i) (line 86), there is no reason for cooling to 34F (i). This is conservative regulatory writing. The critical temperature is 36F (3C). If it is a fish / seafood related item, it needs to be cooled to 36F (3C) in an appropriate period of time and held at that temperature. If it is meat, poultry, or mixed products, it is cooled to 41F and held for 7 days. We are not fudging the temperatures for type *E. C. botulinum*; so, why should we fudge the temperatures for cooling of the product and cold holding at 34F, if we want 30 days? 36F is adequate.

--

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I approve Issue 2 with the following recommendations. Below are my comments for consideration.

In the submission, Revised definitions for Reduced Oxygen packaging, on line 50, it says, "vacuum packaged in an impermeable bag." It is not impermeable. It has a low oxygen transfer rate. "Impermeable" should be changed to "low oxygen transmission rate."

On line 51, we should add the word, "spore," between "psychrotrophic" and "pathogens," because the vegetative pathogenic cells have been reduced to an Appropriate Level of Protection, and all we need to worry about it is the non-proteolytic type *E. C. botulinum* spore.

With both sous vide and cook-chill, since they are sealed, there is no chance of recontamination after the product is cooked. We need to write documents referring to cook-chill and sous vide excluding *Listeria monocytogenes*, since it will not be in the finished product.

The USDA makes no restrictions on storage times and temperatures for sous vide / cook-chill meat and poultry products. The USDA does not consider type E *C. botulinum* to be a significant risk in meat and poultry items. We are adding more control to the retail code that the USDA does not believe is necessary. This is not a level playing field. I believe we should write this for fish to have type E non-proteolytic *C. botulinum* control, but not meat and poultry, vegetables, etc.

On page 2, line 7, it says, "from which air has been expelled." Actually, the bag is twisted and clipped or sealed, but there is no special provision for expelling the air. On the same line, it also says, "closed with a plastic or metal crimp." There are a number of machines that bar-seal packages and are commonly used in retail commissaries. The sentence should be modified to include bar-sealed packages.

Also, a number of cook-chill facilities are producing cups of soup, pumping from the kettles into the cups, which are sealed and sold as cups of soup. A provision for other containers needs to be allowed for.

--

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