



November 18, 2013

Reduced Oxygen Packaging in the 2013 US FDA Food Code

Brian A. Nummer, Ph.D



Reduced Oxygen Packaging (ROP) is considered a specialized process under the US FDA model Food Code. It includes vacuum packaging, cook-chill and sous vide processes. Essentially anytime an operator places food in an impermeable ROP type bag it is ROP. The main implication for ROP is the Food Code requires operators to document and implement a HACCP-based food safety system.

In 2010 an issue was submitted by Dr. Nummer to the Conference for Food Protection (CFP) in hopes of simplifying the ROP portions of the model Food Code. The result was the formation of a CFP committee charged with exactly that task. The committee members are credited at the end of this article.

After working two years from 2010-2012, the committee presented six issues to the biannual CFP meeting. All were approved by Council III and subsequently approved by the delegates. CFP then forwarded the approved issues on to FDA CFSAN for their consideration on placement into the food code.

A summary of the changes regarding ROP made in the 2013 Food code are found in the following table.

ROP Changes in 2013 Food Code

1. ROP HACCP is **NOT** required for foods placed in *and subsequently removed* from bags within 48 hours.
2. Clarifies that non-potentially hazardous foods (non-TCS) foods do **NOT** require ROP HACCP documentation or implementation.
3. Clarifies that cook-chill and sous vide foods **must be fully cooked** to meet requirements in 3-502.12 no variance ROP HACCP.
4. Cook-chill and sous vide foods may be cooled to $\leq 41^{\circ}\text{F}$ and held for up to 7 days.
5. Cook-chill and sous vide foods held at $\leq 34^{\circ}\text{F}$ may be moved to $\leq 41^{\circ}\text{F}$ and held for up to 7 days (not to exceed original 30 day shelf life at $\leq 34^{\circ}\text{F}$).
6. No variance two hurdle/barrier vacuum packaging may be stored at $\leq 41^{\circ}\text{F}$ for up to 30 days (previously 14 days).
7. No variance ROP HACCP documentation **must be submitted** to the Regulatory Authority (approval not required) before implementation.

Let's look at each issue and the final code from the 2013 model US FDA Food Code. The Conference for Food Protection issues involved were 2012 III-09 through III-014. The issues, *as accepted*, can be found on the CFP website using this [link](#).

CFP Issue 2012-III-09

Essentially issue III-009 was the committee's submission of a report to Council III and CFP. The report can be found on the CFP website. No FDA action was requested on this issue.

CFP Issue 2012-III-010

This issue had two items. The first sought to correct the definition of sous vide packaging in 1-201.10(B) Reduced Oxygen Packaging.

Text in red is quoted from US FDA materials.

Revised "Reduced Oxygen Packaging" subparagraph (2)(e), to delete the phrase "placed in a hermetically sealed, impermeable bag" and replace it with "vacuum packaged in an impermeable bag" so it clearly defines the sous vide process as outlined in Annex 6(2)(B)(4)(b). It now reads: "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 psychrotrophic pathogens" (2013 FDA. [Summary of Changes in the FDA Food Code 2013](#)).

WHY: The ROP committee felt that the term hermetically sealed was more applicable to canning or bottling processes and vacuum packaging was more appropriate to sous vide. We left the term "impermeable" to imply a bag that has some oxygen transfer inhibition. For example a zip lock or thin food storage bag is not considered impermeable.

The second item in this issue was to change the definition of Reduced Oxygen Packaging to exclude processes that did not include extended storage. The

issue was approved; however we were told that it is not possible to place code language in a definition. So, this change was added as a new paragraph in 3-502.12:

(F) A HACCP Plan is not required when a FOOD ESTABLISHMENT uses a REDUCED OXYGEN PACKAGING method to PACKAGE TIME/TEMPERATURE CONTROL FOR SAFETY FOOD that is always:

- (1) Labeled with the production time and date,*
- (2) Held at 5°C (41°F) or less during refrigerated storage, and*
- (3) Removed from its PACKAGE in the FOOD ESTABLISHMENT within 48 hours after PACKAGING. (2013 US FDA model Food Code).*

WHY: This change was desired to acknowledge the many processes that might use ROP-type impermeable bags that are not considered a special hazard due to the short amount of storage time (≤ 48 hours). The science supports that ROP foods held at $\leq 41^{\circ}\text{F}$ (≤ 48 hours) would not be considered a potential hazard for *Clostridium botulinum* nor *Listeria monocytogenes*. This would permit the following potential processes:

- Sous vide for immediate service. Basically using sous vide to cook and not for prolonged storage.
- Bagging foods for the purpose of rapid cooling. Cook-chill type bagging is an excellent method to rapidly and efficiently chill hot foods in an ice bath.
- Vacuum bagging foods with spices or marinades to help infuse the spice or marinade quicker.
- Packaging foods for any purpose provided they are removed from the bags in 48 hours or less.

There are a couple of situations where this cannot be used to avoid ROP HACCP. The first is vacuum packaging as a retail consumer package for presentation or convenience. For example an operator might slice deli beef and vacuum package it for a consumer to take home. This would not be permitted under this paragraph since it was not opened in the food facility. The second situation was an oversight in coding the language of this issue. It was assumed that operators could not re-package foods using ROP after being packaged once and opened after 48 hours without a variance.

There were two additional definition amendments made, but these were trivial and can be found in the 2012 CFP Council III Issue documents.

CFP Issue 2012 III-011

This issue also had three important parts. The first was a simple language correction to emphasize that ROP HACCP is required **ONLY** for potentially hazardous foods (as defined in Chapter one Tables A and B). Note that the 2013 food code has changed this terminology to Time/temperature control for safety foods (TCS Foods) and they dropped reference to PHF foods.

What implication does this have on operators and regulators? It is important to analyze your food products for pH and Aw to address their classification as TCS foods. Table A. in Chapter 1 would be used to assess cook-chill and sous vide process (cooked and packaged), while Table B. is used for vacuum packaging processes.

PHF for cook-chill and sous vide (Table A)			
a _w Values	pH Values		
	4.6 or less	> 4.6 – 5.6	> 5.6
0.92 or less	Non-PHF/non-TCS**	Non-PHF/non-TCS	Non-PHF/non-TCS
> 0.92 – 0.95	Non-PHF/non-TCS	Non-PHF/non-TCS	PA***
> 0.95	Non-PHF/non-TCS	PA	PA

* PHF means "Potentially Hazardous Food"
 ** TCS means "Time/Temperature Control for Safety Food"
 *** PA means "Product Assessment Required"

The second item amended 3-502.12 (D)(2)(b) to read:

Cooked to heat all parts of the FOOD to a temperature and for a time as specified under §§ 3-401.11 (A), (B), and (C). (2013 US FDA model Food Code).

WHY: This was added by the ROP committee to acknowledge that the cooking exceptions in paragraph D allowing raw service of TCS foods with disclaimers cannot be used in ROP processes. So, basically, an operator would not be able to undercook foods using

an ROP without a variance and scientific support for the safety of the food.

The last item in this issue is a major change in the cook-chill sections of 3-502.12 (D)(2)(e). This section specifies that cook-chill or sous vide foods must be chilled to 41°F and:

(ii) Held at 5°C (41°F) or less for no more than 7 days, at which time the FOOD must be consumed or discarded; (2013 US FDA model Food Code).

PHF for vacuum packaging (Table B)				
a _w Values	pH Values			
	< 4.2	4.2 – 4.6	> 4.6 – 5.0	> 5.0
< 0.88	Non-PHF/non-TCS**	Non-PHF/non-TCS	Non-PHF/non-TCS	Non-PHF/non-TCS
0.88 – 0.90	Non-PHF/non-TCS	Non-PHF/non-TCS	Non-PHF/non-TCS	PA***
> 0.90 – 0.92	Non-PHF/non-TCS	Non-PHF/non-TCS	PA	PA
> 0.92	Non-PHF/non-TCS	PA	PA	PA

* PHF means "Potentially Hazardous Food"
 ** TCS means "Time/Temperature Control for Safety Food"
 *** PA means "Product Assessment Required"

WHY: This section was based on extensive scientific research done by Dr. Skinner of the US FDA. Essentially the published data indicated that foods were safe from botulism toxin formation at 41°F for 9 days. The committee chose 7 days to be a little more conservative and to match the *Listeria monocytogenes* date marking parameter of 7 days.

What are the implications of this change for operators and regulators? The main change is that operators could now chill foods to ≤ 41°F using the parameters specified in 3-501.14 (Cooling 135 to ≤ 70 in 2 h and 135 to ≤ 41 in 6h) and stop. There is no longer a need to further cool foods to ≤ 38 or ≤ 34°F before they can be stored at ≤ 41°F. This change permits 7 days storage at ≤ 41°F where previously only 3 days were permitted.

This section also implies that operators who store ROP foods at ≤ 34°F for up to 30 days can remove those foods to ≤ 41°F and get 7 days storage shelf life provided it does not exceed the original 30 day shelf life.

CFP Issue 2012-III-012

This issue has two main items. The first is the ROP committee wanted to recognize the science that supports that ROP foods with an equilibrated pH ≤ 5.0 can safely be stored at $\leq 41^\circ\text{F}$ for ≤ 30 days after the date of packaging with a variance. This recognizes the science that indicates that neither *Listeria monocytogenes* nor *Clostridium botulinum* can grow (at all) when the two hurdles of pH ≤ 5 **AND** temperature of storage $\leq 41^\circ\text{F}$ are both used.

The second item in this issue changed the vacuum packaging shelf life from 14 days to 30 days provided the food meets one of the four hurdle/barrier options specified.

(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:

(a) Maintain the FOOD at 5oC (41oF) or below, Pf and

(b) Discard the FOOD if within 30 calendar days of its PACKAGING if it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption;

(4) Limits the refrigerated shelf life to no more than 30 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. ([2013 US FDA model Food Code](#)).

WHY: The committee recognized the science that supports when one of the hurdles/barriers listed in this section together with refrigeration at $\leq 41^\circ\text{F}$ are used no growth of either *L. monocytogenes* nor *C. botulinum* would occur in the 30 days permitted shelf life.

What are the implications of this change for operators and regulators? Operators may now expand their shelf life for vacuum packaged foods from 14 to 30 days provided the food meets one of the specified hurdles/barriers as follows:

(a) Aw ≤ 0.91 or less, (b) pH ≤ 4.6 , (c) Is a meat or poultry product cured at a USDA regulated processing plant and is received in an intact package, or (d) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables.

CFP Issue 2012-III-013

This issue had one main item. The request was that for ALL ROP HACCP processes that operators notify their regulators they will be doing ROP using HACCP under 3-502.12 (no variance). Section 3-502.12 (B) now has a new paragraph:

(7) Is provided to the REGULATORY AUTHORITY prior to implementation as specified under ¶ 8-201.13(B).

A new paragraph 8-201.13 (B) has been added:

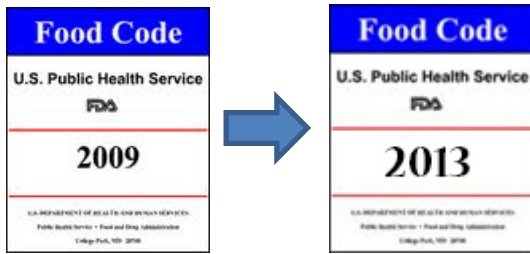
(B) Before engaging in REDUCED OXYGEN PACKAGING without a VARIANCE as specified under § 3-502.12, a PERMIT applicant or PERMIT HOLDER shall submit a properly prepared HACCP PLAN to the REGULATORY AUTHORITY. ([2013 US FDA model Food Code](#)).

WHY: The ROP committee felt that some operators were potentially processing foods using ROP with a deficient or incorrect HACCP system. Therefore, operators are now required to submit the documents to the Regulatory Authority before starting ROP. Note that only submission is required and not approval as in the variance process. The submission will serve as notice to the Regulatory Authority and they may follow up as their respective jurisdictions deem necessary.

CFP Issue 2012-III-014

This last CFP issue simply detailed all of the changes made to the code so that the Annex to the food code can be updated.

Using the new food code for ROP: Operators



So how does an operator go about using the new code regarding ROP when their jurisdiction has not formally adopted the 2013 code? This is a tricky answer. First and foremost, contact your Regulatory Authority to check on the status of their handling of ROP under the 2013 Food Code. They may have adopted some or all of these changes in some manner or are in the process of doing so.

If the Regulatory Authority has not adopted the new code, then start a dialogue. You are encouraged to do this via one of your trade groups or restaurant association so that 100 different operators are not all spending time doing the same thing. Be sure that your Regulatory Authority is working with their state and Federal FDA counterparts. No need replicating work that is being or has already been done at another regulatory level.

In the absence of any formal policy or when your Regulatory Authority is in an endless “process of adoption”, it is acceptable to write a waiver request to your Regulatory Authority. Note I am using the term “waiver”. If the request involves an issue that defines an ROP process as one that doesn’t need ROP HACCP (e.g. 48 h exclusion), then submit that information in your request, but don’t include any HACCP documentation. If the process you wish to use requires HACCP (e.g. Cook chill for 7 day storage at $\leq 41^{\circ}\text{F}$), then submit that as a variance request supported with complete HACCP documentation. Variance requests supported by a newer edition of the food code normally do not require a Process Authority or scientific references to justify the process.

Keep in mind that all regulations regarding foodservice are local or state. The FDA model Food Code is just that – *a model*. It is not official. It is a guideline that states and other jurisdictions use to write their own food codes. There is no guarantee that your local or state Regulatory Authority will accept these provisions related to reduced oxygen packaging in the 2013 US FDA model Food Code.

Using the new food code for ROP: Regulators

It is strongly encouraged that Regulatory jurisdictions consider these changes to the ROP portions of the Food Code as soon as possible. It is understood that acceptance of the 2013 Food Code can take years. Hopefully, Regulators can use their administrative or rulemaking processes to adopt some of the new ROP code quickly.

Please feel free to disseminate this document and attach any local, state or other jurisdictional guidance for your operators. Please forward a copy to the author at brian.nummer@usu.edu for reference.

*ROP Committee members and
author bio*

The 2010-2012 CFP Reduced Oxygen Packaging Committee included: Brian Nummer (Chair), Dale Grinstead (Co-Chair), Dan Goldman, Thomas Schwarz, Veronica Moore, Charles McGuffey, Christopher Gordon, Don Schaffner, Henry Blade, Jessica Fletcher, Joe Graham, Joel Ortiz, Kevin Dreesman, Larry Payton, Pete Snyder, Richard Parker, and Stephen Kenny.

About the Author: Dr. Nummer is a food microbiologist and retail-foodservice food safety subject matter expert. He chaired the CFP ROP committee and continues to work in this area providing best practices for both operators and regulators. Dr. Nummer is currently the Senior Food Safety Advisor to Walt Disney Parks and Resorts helping maintain continuous improvement on their world class food safety system. Dr. Nummer is also the Director of the Retail-foodservice food safety consortium and Extension Specialist in Food Safety at Utah State University.