

2014 - 2016 CFP

Demonstration of Knowledge Committee

Teleconference: 8

Wednesday September 30, 2015

2:00pm – 3:30p.m. EST

Call-In Number: 877-394-5901

Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes

FDA Advisors: Stephen Hughes

CDC Advisor: Vince Radke

Scribe: Susan Tyjewski

AGENDA ITEMS:

1. Welcome, Call to Order	Michelle	
2. Roll-Call,	Michelle	
3. Review of last meeting's minutes	All	
4. Discussion will begin with # 14 amended language	All	
5. Brief overview of entire PDF document	Michelle	
6. Review voting process and timeline	Michelle	

ATTENDANCE:

Robert	Brown	
Francie	Buck	✓
Deborah	Crabtree	✓
Hector	Dela Cruz	
Mark	Earnest	
Lisa	Ford	
Robert	Gilliland	✓
Michelle	Haynes	✓
Yao-Wen	Huang	
Julie	Hults	✓
Lucia	James-Davis	✓
Shanna	Lively	
Mark(Mick)	Miklos	✓
Eric	Moore	✓
Sheri	Morris	✓
Linda	Zaziski	✓
Dale	Yamnik	✓
Todd	Taylor	✓

Christine	Sylvis	✓
Stephen	Hughes	✓
John	Marcello	
Vince	Radke	
Petra	Balli	
Susan	Deslauriers	
Rob	Erwin	✓
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	
Susan	Tyjewski	✓
Sharon	Wood	✓
Brad	Peters	
David	Lawrence	

Meeting Minutes:

- Welcome
- Antitrust Statement Reminder

2014 - 2016 CFP

Demonstration of Knowledge Committee

- Are there any comments/changes to the minutes of June 19? No
- Discussion begins - There are three tables that summarize our committee work.
 - Mic refers to Method 12 which is a recommendation to replace demonstration with duties. He acknowledges Dale and Sherry for their input.
 - Stephen clarifies that section 2.102.11 requires someone to be on site with knowledge. Section 2.102.12 requires someone on staff to be a CFPM but does not require them to be on site.
 - The FDA would be reluctant to eliminate section B.
 - This may not be the charge of the committee which is to recommend alternate methods.
 - Sherry comments that the charge of the committee is to list alternative methods discussed whether they are viable or not.
 - Mic will take a look at the language in the 2nd bullet in view of Stephen's comments.
- Going to the beginning – discussion on improving how the Pros & Cons are written.
 - Dale volunteers to provide improved wording on
 - Page 1 – Pro 1
 - Page 2 – Con 1
 - Page 2 – Con 2
 - Minor changes to Con 3 & Con 4 are offered and accepted.
 - Michelle reads modified language for Page 2 Pro 1. It is accepted.
- Returning to the Alternative Methods.
 - Mic proposes that we strike Method 3 because that is not the committee's charge. Agreed.
 - Method 4 – wording modified during call.
 - Clarification on Method 11 – food safety principles be demonstrated instead of responding to questions.
 - Discussion on how some methods are thematically the same but the order should be changed. For voting the order will be
 - Method 2
 - Method 10
 - Method 9
 - Method 12
 - Discussion on whether Method 5 should be removed because it's covered in other methods. Dale offers to improve wording on this for voting.
 - Remove Method 7 – it refers to computer tablets.
- **Next Steps**
- All adjusted wording will be submitted to Michelle on Monday by noon.
- The link to the survey will be sent out on Tuesday and you'll have one week to review.
- We will have another meeting after the results of the survey are analyzed so the final report can be discussed.

2014 - 2016 CFP

Demonstration of Knowledge Committee

Teleconference: 9

Friday November 6, 2015

2:00pm – 3:30p.m. EST

Call-In Number: 877-394-5901

Access Code: 2995496#

Co-Chairs: Eric Moore, Michelle Haynes

FDA Advisors: Stephen Hughes

CDC Advisor: Vince Radke

Scribe: Susan Tyjewski

AGENDA ITEMS:

1. Roll call	Michelle	
2. Reminder on anti-trust statement	Michelle	
3. Review of last meeting's minutes	Michelle	
4. Review of remaining timeline for report submission	Michelle	
5. Discussion of survey results	All	
6. Proposal of issues that the committee would like to submit for 2016 CFP	All	

ATTENDANCE:

Robert	Brown	✓
Francie	Buck	✓
Deborah	Crabtree	
Hector	Dela Cruz	✓
Mark	Earnest	✓
Lisa	Ford	
Robert	Gilliland	
Michelle	Haynes	✓
Yao-Wen	Huang	
Julie	Hults	✓
Lucia	James-Davis	✓
Shanna	Lively	✓
Mark(Mick)	Miklos	
Eric	Moore	
Sheri	Morris	✓
Linda	Zaziski	✓
Dale	Yamnik	✓
Todd	Taylor	✓

Christine	Sylvis	
Stephen	Hughes	✓
John	Marcello	
Vince	Radke	✓
Petra	Balli	
Susan	Deslauriers	✓
Rob	Erwin	✓
Christina	Eckhardt	
Laura	Nelson	
Tara	Paster	✓
Susan	Tyjewski	✓
Sharon	Wood	v
Brad	Peters	
David	Lawrence	

Meeting Minutes:

- Welcome
- Antitrust Statement Reminder

2014 - 2016 CFP

Demonstration of Knowledge Committee

- Review of minutes of Sept. 30 meeting. Any comments or questions? - No
- Timeline for report submissions
 - Final report must be turned in to Susan Quam by Dec. 4.
 - The following volunteered to help with the final report.
 - Tara
 - Dale
 - Linda
 - Hector
 - The Issues must be submitted by Jan. 15.
- Discussion on the Survey Results
- Dale recommended that the questions be put in order by the % of agreement with the high on top and the low at the bottom. Also questions with the level of agreement split closely be removed.
 - A comment was made that only 12 out of the 21 voting members participated by voting. There will be a reminder sent out with a survey deadline.
- Discussion continued on questions where the % of agreement was close and if they should be deleted.
 - There was a motion to eliminate Q1 because Q2 is a restatement.
 - The motion was seconded and no one opposed.
 - Q1 will be removed.
 - There was a motion to eliminate Q20 in favor of Q21.
 - The motion was seconded and no one opposed.
 - Q20 will be removed.
 - There was a motion to eliminate Q3.
 - The motion was seconded and no one opposed.
 - Q3 will be removed.
 - Discussion on Q39 and Q40 determined that they were not exactly the same. Q39 recommends eliminating the code section and Q40 recommends modifying. They will both stay.
- Proposal for the issue submission
 - Recommend the acceptance of the final report
 - This committee did not complete the complete charge.
 - Item # 4 of the original charge.
 - Identify the pro's and con's of alternative methods to demonstrate knowledge if/when the CFPM is not onsite. Although not limited to the following areas, the committee should assess the pro's and con's of each alternative method in light of the following areas:
 - a. Differentiation between knowledge and application.
 - b. Emphasis on risk factors;
 - c. Ease of uniform assessment by regulators and industry;
 - d. Enabling the Person in Charge to demonstrate knowledge even when there is a language barrier.

2014 - 2016 CFP

Demonstration of Knowledge Committee

- e. What corrective action should be taken when there is not a demonstration of knowledge from the Certified Food Protection Manager or the Person in charge.
- Recommend the committee be re-formed to complete the charge and also list the alternative methods to be evaluated by the new committee.
 - Recommend the committee propose either to change the language in the food code or provide an alternative method.
- It was agreed that the committee will request a meeting time at the CFP on Friday afternoon and also present a report on Sunday morning.
- The final report will be prepared and submitted to Susan Quam by Dec. 4.
- Meeting adjourned.

2014 - 2016 CFP

Demonstration of Knowledge Committee

2-102.11 Demonstration.

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

Regulation	Pro	Con
(A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection; PF		
(C) Responding correctly to the inspector's questions as they relate to... (1) Describing the relationship between the prevention of foodborne disease and the personal hygiene of a FOOD EMPLOYEE; PF		
(C) Responding correctly to the inspector's questions as they relate to... (2) Explaining the responsibility of the PERSON IN CHARGE for preventing the transmission of foodborne disease by a FOOD EMPLOYEE who has a disease or medical condition that may cause foodborne disease; PF		
(C) Responding correctly to the inspector's questions as they relate to... (3) Describing the symptoms associated with the diseases that are transmissible through FOOD; PF		

2014 - 2016 CFP Demonstration of Knowledge Committee

Regulation	Pro	Con
(C) Responding correctly to the inspector's questions as they relate to... (4) Explaining the significance of the relationship between maintaining the time and temperature of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD and the prevention of foodborne illness; PF		
(C) Responding correctly to the inspector's questions as they relate to... (5) Explaining the HAZARDS involved in the consumption of raw or undercooked MEAT, POULTRY, EGGS, and FISH; PF		
(C) Responding correctly to the inspector's questions as they relate to... (6) Stating the required FOOD temperatures and times for safe cooking of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD including MEAT, POULTRY, EGGS, and FISH;PF		
(C) Responding correctly to the inspector's questions as they relate to... (7) Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of TIME/TEMPERATURE CONTROL FOR SAFETY FOOD;PF		

2014 - 2016 CFP

Demonstration of Knowledge Committee

Regulation	Pro	Con
<p>(C) Responding correctly to the inspector's questions as they relate to... (8) Describing the relationship between the prevention of foodborne illness and the management and control of the following:</p> <ul style="list-style-type: none"> (a) Cross contamination, PF (b) Hand contact with READY-TO-EAT FOODS, PF (c) Handwashing, PF and (d) Maintaining the FOOD ESTABLISHMENT in a clean condition and in good repair; PF 		
<p>(C) Responding correctly to the inspector's questions as they relate to... (9) Describing FOODS identified as MAJOR FOOD ALLERGENS and the symptoms that a MAJOR FOOD ALLERGEN could cause in a sensitive individual who has an allergic reaction. PF</p>		
<p>(C) Responding correctly to the inspector's questions as they relate to... (10) Explaining the relationship between FOOD safety and providing EQUIPMENT that is:</p> <ul style="list-style-type: none"> (a) Sufficient in number and capacity, PF and (b) Properly designed, constructed, located, installed, operated, maintained, and cleaned; PF 		

2014 - 2016 CFP
Demonstration of Knowledge Committee

Regulation	Pro	Con
(C) Responding correctly to the inspector's questions as they relate to... (11) Explaining correct procedures for cleaning and SANITIZING UTENSILS and FOOD-CONTACT SURFACES of EQUIPMENT; PF		
(C) Responding correctly to the inspector's questions as they relate to... (12) Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections; PF		
(C) Responding correctly to the inspector's questions as they relate to... (13) Identifying POISONOUS OR TOXIC MATERIALS in the FOOD ESTABLISHMENT and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to LAW; PF		
(C) Responding correctly to the inspector's questions as they relate to... (14) Identifying CRITICAL CONTROL POINTS in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Code; PF		

2014 - 2016 CFP

Demonstration of Knowledge Committee

Regulation	Pro	Con
(C) Responding correctly to the inspector's questions as they relate to... (15) Explaining the details of how the PERSON IN CHARGE and FOOD EMPLOYEES comply with the HACCP PLAN if a plan is required by the LAW, this Code, or an agreement between the REGULATORY AUTHORITY and the FOOD ESTABLISHMENT; PF		
(C) Responding correctly to the inspector's questions as they relate to... (16) Explaining the responsibilities, rights, and authorities assigned by this Code to the: (a) FOOD EMPLOYEE, PF (b) CONDITIONAL EMPLOYEE, PF (c) PERSON IN CHARGE, PF (d) REGULATORY AUTHORITY; PF		
(C) Responding correctly to the inspector's questions as they relate to... (17) Explaining how the PERSON IN CHARGE, FOOD EMPLOYEES, and CONDITIONAL EMPLOYEES comply with reporting responsibilities and EXCLUSION or RESTRICTION of FOOD EMPLOYEES.		
Alternative Method to Demonstrate Knowledge if/when CPM is Not Onsite	Pro	Con
1.		

Pro/Con Listing for 2-102.11(A)

2-102.11 Demonstration

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

A) Complying with this Code by having no violations of PRIORITY ITEMS during the current inspection; Pf

Pro 1: This is a good way to show knowledge because it allows the PIC to demonstrate operational controls as they relate to Food Code requirements.

Pro 2: Having no PRIORITY ITEMS allows both regulators and industry to easily know when a food establishment is in compliance with the demonstration of knowledge requirements. It also allows both the inspector and industry to know which sections of the Food Code to focus training on.

Pro 3: Easy for the inspector to evaluate.

Pro 4: If you accept the assumption that performance is a direct reflection of the PIC's level of knowledge, then the absence of Priority Item violations is indicative of the individual's knowledge. Additionally, full compliance may be indicative that the principles and the elements of a food safety management system are in place to control risk.

Con 1: Inspections capture conditions at a facility at a given point in time, and as such, may miss some systemic failures that are present and ongoing but not detectable at the moment. Although the desired end is the elimination of risk factors and full compliance with this Code works to that end, it might be argued that this subsection is Demonstration of Compliance rather than Demonstration of Knowledge.

Con 2: Could be subjective in the day to day reality of conducting inspections. Relies on regulator's judgment resulting in lack of consistency.

Con 3: The undue focus on Priority Items to the exclusion of Priority Foundation and Core violations could overlook potential threats to Food Safety.

Con 4: Studies have shown that knowledge and behavior do not always go hand-in-hand.

Con 5: Language barriers may cause a loss of effective communication between inspectors and operators.

Pro/Con Listing for 2-102.11(C)

2-102.11 Demonstration

Based on the RISKS inherent to the FOOD operation, during inspections and upon request the PERSON IN CHARGE shall demonstrate to the REGULATORY AUTHORITY knowledge of foodborne disease prevention, application of the HAZARD Analysis and CRITICAL CONTROL POINT principles, and the requirements of this Code. The PERSON IN CHARGE shall demonstrate this knowledge by:

C) Responding correctly to the inspector's questions as they relate to the specific FOOD operation. The areas of knowledge include.....

Pro 1: This gives the inspector the opportunity to ask customized questions directly related to operation being observed; not just utilizing standard questions.

Pro 2: This gives the PIC the opportunity to explain the processes performed in their food establishment which can often be validated with operations manuals and other training tools.

Pro 3: Gives a clear understanding for regulators and industry of the requirements and rationale to demonstrate Food Code knowledge as it pertains to their operations.

Pro 4: PIC is able to demonstrate food safety knowledge by successfully answering questions pertaining to their operation.

Pro 5: It addresses the importance of the PIC having knowledge of the risks and how they relate to foodborne illness.

Pro 6: If completely and correctly answered, the PIC can establish him/herself as properly trained, knowledgeable and engaged in the management of food safety in the establishment. It reflects that systems for managing food safety are in place even if momentary execution might be lacking.

Pro 7: Through Q&A the inspector is able to determine training needs.

Pro 8: This essentially amounts to an abbreviated CFPM oral exam. If the PIC is able to successfully answer all questions posed, they clearly have a solid understanding of basic food safety principals pertaining to their operation.

Con 1: Inspector's questions could be easily misunderstood by a PIC, especially if the inspector is not properly trained on asking appropriate questions relevant to the establishment's operation. This could also result in a degree of inconsistency based on the types and numbers of questions asked of the PIC by the inspector. For instance, there is no standard for how many questions a PIC must answer correctly to demonstrate knowledge.

Con 2: Inspector may focus on the questions and may not make observations of behaviors a higher priority.

Con 3: Regulators need to ensure only questions relevant to the operation are asked and that answers given for a food establishment's procedures that exceed the minimum requirement (such as temperatures) are not debited if in compliance with food establishment's standards.

Con 4: If a PIC is not accompanying an inspector at the time the inspector has a question, the inspector may need to take extra time at the end of the inspection to return to an area with the PIC to question the food establishment's procedure, thereby adding additional time for completion of the inspection. In some cases, if the PIC is not with the inspector, the inspector may have entirely forgotten the question he had regarding that process by the time the PIC rejoins the inspection.

Con 5: The number of questions asked and the percent that must be answered correctly in order to "pass" these criteria for demonstration of knowledge is not standardized resulting in inconsistent application from one inspector to another.

Con 6: The quality of an interview is as much a function of the interviewer's ability as it is the interviewee's competence. If the inspector does not ask questions properly/clearly, then the PIC's ability to successfully answer them will be limited. This "oral exam" also assumes that the inspector is a subject matter expert, has no competency issues, and knows the correct answers to the questions posed. On a more practical level, in many establishments English is not the primary language of the PIC or kitchen staff. Clearly, communication barriers are difficult to overcome in these situations. CFPM classes/exams overcome this by way of bilingual instructors and translated study materials/exams; however, it is far more challenging to overcome this in an on-site interview with an inspector.

Con 7: Nervousness, intimidation, and anxiety are all factors that may affect the employee's ability to relay accurate answers to the regulator's questions.

Alternative Methods for Demonstrating Knowledge

Method 1: The person in charge can demonstrate Food Code knowledge through practical means such as showing how they take temperatures, calibrate a thermometer, mix or test sanitizer, showing a posted employee health policy or list of major food allergens, etc.

Method 2: Establishment is in compliance with 2-103.11.

Method 3 : Recommend *modifying* Section 2-102.11 of the Food Code as follows:

Section 2-102.11 (B) would remain as currently written in the Food Code and would be followed by this:

- If the Certified Food Protection Manager is not present, and because the distinction between knowledge and application is vague and difficult to articulate which often leads to frustration between operators and regulators, the PIC shall be a food handler certificated through an ANSI-ASTM accredited program or its equivalent. The PIC shall substantiate knowledge through direct application of (A) through (O) of the Duties Section of the Food Code (2-103.11.) The successful completion of these tasks should adequately demonstrate the PIC's knowledge.
 - Eliminate Section 2-102.11 (A). The number of times that an establishment has no priority violations is statistically insignificant. There is also the suspicion among regulators that a lack of priority violations could be accidental and not a true reflection of demonstration of knowledge.
 - Eliminate Section 2-102.11 (C). The Food Code already articulates the duties of a PIC in Section 2-103.11. In addition, the entirety of the risk based inspection identifies whether an establishment is controlling risk and, by extension, whether knowledge is being demonstrated through application. The current list of 17 questions found in 2-102.11 (C) could be moved to Annex 5 as guidelines for inspectors who wish to have dialogue with PICs.

Method 4: Employees are completing tasks correctly.

Method 5: Having one or more food handlers who are certificated through an ANSI-ASTM accredited program or equivalent and who comply with section 2-103.11 of this Code, thus applying practical means knowledge to the successful completion of tasks.

Method 6: The PIC can show evidence of demonstration of knowledge through the use of job aides or other means.

Method 7: Change the Demonstration of Knowledge criteria. Instead of meeting one of the three options to be in compliance, change it to having to meet two of the three options to be in compliance.

Method 8: The establishment has a food handler certificated program through an ANSI-ASTM program or equivalent and one or more employees is certificated through the program.

Method 9: Change the code language in 2-102.11 (C) to: "Demonstrating food safety principles based on the specific food operation. The areas of knowledge include:..."

Method 10: Recommend *eliminating* Section 2-102.11 within the Food Code as follows:

This method seeks to replace the Demonstration Section, in its entirety with reliance instead on the Duties Section as it might be performed by ANSI-ASTM accredited food handlers:

Allow the Duties Section of the Food Code (2-103.11) to substantiate demonstration of knowledge in lieu of the Demonstration Section (2-102.11). The distinction between knowledge and application is vague and difficult to articulate and this can lead to frustration between operators and regulators. Having one or more food handlers certificated through an ANSI-ASTM accredited program or equivalent and who comply with (A) through (O) of Section 2-103.11 by applying practical knowledge to the successful completion of tasks should adequately demonstrate knowledge of the PIC.

- Eliminate Section 2-102.11 (A). The number of times that an establishment has no priority violations is statistically insignificant. There is also the suspicion among regulators that a lack of priority violations could be accidental and not a true reflection of demonstration of knowledge.
- Eliminate Section 2-102.11 (B). The Food Code already requires the presence of a CFPM in Section 2-102.12 (A). The FDA Risk Factor Study correlates the presence of a CFPM with better control of risk factors and provides justification for the requirement in the Food Code to have at least one CFPM per establishment.
- Eliminate Section 2-102.11 (C). The Food Code already articulates the duties of a PIC in Section 2-103.11. In addition, the entirety of the risk based inspection identifies whether an establishment is controlling risk and, by extension, whether knowledge is being demonstrated through application. The current list of 17 questions found in 2-102.11 (C) could be moved to Annex 5 as guidelines for inspectors who wish to have dialogue with PICs.