

**Conference for Food Protection
2014 Issue Form**

**Internal Number: 005
Issue: 2014 I-014**

Council Recommendation:	Accepted as Submitted _____	Accepted as Amended _____	No Action _____
Delegate Action:	Accepted _____	Rejected _____	

All information above the line is for conference use only.

Title:

Update Section 8-201.14 to better agree with NACMCF HACCP definitions

Issue you would like the Conference to consider:

The 2013 Food Code Preface states in Part 4: *The model Food Code provisions are consistent with, and where appropriate incorporate, federal performance standards for the same products and processes.* However, the Food Code section 8-201.14 uses terminology and formatting related to Hazard Analysis and Critical Control Point (HACCP) that does not match that used by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). Therefore, this issue seeks to update Section 8-201.14 to better agree with HACCP definitions and processes published by NACMCF (HACCP Principles & Application Guidelines. August 1997. Available at: <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm>). This document is attached.

Public Health Significance:

Reducing confusion and inconsistency in HACCP requirements in the Food Code with that of NACMCF will enable operators and regulatory professionals to better address HACCP in retail and foodservice operations.

Justifications:

Overall - added three headings: Preliminaries, HACCP Plans; and Prerequisites/Supporting information. This is consistent with NACMCF HACCP.

Line1: A HACCP "plan" is just a small portion of HACCP. What is being referred to here is a HACCP "Program" or HACCP "System".

A1: Currently the Food Code does not specify that HACCP documents include any identifying information such as described in the NACMCF HACCP protocols.

A2: for clarity

A3: clarifies a flow chart is needed for each different process (e.g. cook chill, vacuum packaging, making jerky, etc.).

A4: Clarifies *what* information is desired

A5: Makes this requirement optional for the Regulatory Authority. Exact formulations/recipes may not be needed to justify food safety of a process.

B1: Adds a requirement for a Hazard Analysis and Controls document as defined in NACMCF HACCP.

B2: Uses NACMCF terminology to describe a "Critical Control Point (CCP) Summary".

C1: Moved from previous location

C2: Adds a requirement to include blank CCP recordkeeping forms

C3a: Clarifies that an Regulatory Authority may request support (e.g. Validation documentation) from a Process Authority

C3b: Clarifies that an operator can provide evidence that they meet guidelines or performance standards from other governmental HACCP programs. See Food Code Preface excerpted text below:

The model Food Code provisions are consistent with, and where appropriate incorporate, federal performance standards for the same products and processes. Federal performance standards in effect define public food safety expectations for the product, usually in terms of lethality to a pathogenic microorganism of particular concern. Use of performance standards as the measure of regulatory compliance means establishments are free to use innovative approaches in producing safe products, in lieu of adherence to traditional processing approaches, such as specified cooking times and temperatures, that achieve the same end. Federally inspected establishments demonstrate compliance with performance standards by showing that their process adheres to an appropriately designed, validated HACCP plan.

Retail processors may be given the same opportunity as federally-regulated establishments to use innovative techniques in the production of safe foods. Retail establishments may apply to the regulatory authority for a variance to use a specific federal food safety performance standard for a product or a process in lieu of compliance with otherwise applicable specifications in the Food Code. However, to show compliance with the federal performance standard, the retail processor must, like a federally inspected establishment, show that processing controls are in place to ensure that the standard is being met. Thus, a request for a variance based on a federal performance standard must be supported by a validated HACCP plan with record keeping and documented verification being made available to the regulatory authority.

It is intended that the Food Code will be amended to incorporate federal HACCP regulations and guidelines by inclusion in the text of the Food Code, by reference, or through the issuance of interpretations. This will provide alternatives to the preapproval of HACCP plans, such as simplified HACCP plans in line with the Fish and Fishery Products model, if the product is produced under a HACCP plan developed in conformance with such regulation or guideline. In so doing, the need for preapproved plans under the more intensive regimen of the Food Code will be significantly reduced. HACCP plans are key to the use of performance standards as measures of regulatory compliance. Performance standards issued by the Food Safety and Inspection Service are applicable to a broad range of meat, poultry, and egg products. Federal performance standards are acceptable, equivalent alternatives to the command-and-control provisions that now provide specific times and temperatures for processing various products. Federal performance standards may be used to determine the safety of a product or process under the Food Code if authorized under a variance granted in accord with the Code's variance provisions, and demonstrated by adherence to a validated HACCP plan, consistent with the Code's HACCP provisions.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting the 2013 Food Code be amended as follows (new language is underlined; language to be deleted is in strikethrough format):

8-201.14 Contents of a HACCP Plan.

For a food establishment that is required under § 8-201.13 to have a HACCP Program, the document and specifications shall indicate:

A. HACCP preliminary information as follows:

1. General information including operator name, address, contact person information, HACCP team members, and any other application or submission information as designated by the REGULATORY AUTHORITY;

A 2. A categorization of the types of potentially hazardous foods (time/temperature control for safety foods) that are to be controlled under [DS1] a HACCP process such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority; ^{Pf}

~~B 3. For each separate HACCP Plan, as defined in paragraph B below, A a flow diagram or chart by specific food or category type identifying individual steps in the process; critical-control points and providing information on the following:~~

~~(1) 4. Ingredients, materials, and equipment used in HACCP processes the preparation of that food,~~ ^{Pf} describing safe source, food grade status, and cleanability status respectively;

~~(2) 5. If requested by the Regulatory Authority, Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;~~

^{Pf}

~~C. Food employee and supervisory training plan that addresses the food safety issues of concern;~~ ^{Pf}

B. HACCP Plan information for each separate process as follows:

1. A chart delineating hazards and controls for each step defined in a flow chart and identifying steps that are critical control points

~~D. 2. A Critical control points summary statement of standard operating procedures for the plan under consideration including clearly identifying:~~

~~(1a) Each critical control point,~~ ^{Pf}

~~(2b) The critical limits for each critical control point,~~ ^{Pf}

~~(3c) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge,~~ ^{Pf}

~~(4d) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points,~~

^{Pf}

~~(5e) Action to be taken by the designated FOOD EMPLOYEE or person in charge if the critical limits for each critical control point are not met,~~ ^{Pf} and

~~(6f) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed;~~ ^{Pf} and

C. Prerequisite programs and supporting documents as follows:

~~(G1.). Food employee and supervisory training plan that addresses the food safety issues of concern;~~ ^{Pf}

(2.). Copies of blank records forms required in (B)(2)(f) of this section.

(E3.) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal that may consist of: ^{Pf}

(a). A letter of support from a process authority citing acceptable science-based evidence of safety; and/or.

(b). A document referencing existing federal performance standards such as USDA FSIS HACCP, US FDA Seafood HACCP or US FDA Juice HACCP, used to determine the safety of a product or process.

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Attachments:

α "NACMCF Published Guidelines (Journal of Food Protection)"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.