



U.S. Department of Agriculture



Office of Inspector General
Office of Inspections and Research

Inspection Report

Food Safety and Inspection Service's Evaluation of the Carbon Monoxide-Based Modified Atmospheric Packaging Under the Generally Recognized as Safe Regulatory Process

Report No. 24901-01-IR
March 2008



UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL
Washington, DC 20250



March 4, 2008

REPLY TO
ATTN OF: 24901-01-IR

TO: Alfred V. Almanza
Administrator
Food Safety and Inspection Service

FROM: Rod DeSmet /s/
Assistant Inspector General
for Inspections and Research

SUBJECT: Food Safety and Inspection Service's Evaluation of the Carbon Monoxide-Based Modified Atmospheric Packaging Under the Generally Recognized as Safe Regulatory Process

This report presents the results of our inspection of the issues surrounding the use of carbon monoxide (CO) as a component of Modified Atmospheric Packaging (MAP) for case-ready fresh meat. The U.S. Food and Drug Administration (FDA) reviewed CO-based MAP systems jointly with the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) as specified in a memorandum of understanding (MOU) between FDA and FSIS. Under this collaborative process, FDA evaluated the safety, and FSIS evaluated the suitability, of CO-based MAP for use in meat in accordance with each agency's respective authorities. In this instance, FSIS and FDA evaluated CO-based MAP systems under a category of food ingredients known as Generally Recognized as Safe (GRAS).

Your response to our draft, dated February 1, 2008, is included in its entirety in Exhibit A, with excerpts incorporated into the Findings and Recommendations section of the report. Based on your response, we were able to reach management decision on the report's two recommendations. Please follow your internal agency procedures for reporting final action to the Chief Financial Officer.

Please note that Departmental Regulation 1720-1 requires final action to be completed within 12 months of management decision.

We appreciate the courtesies and cooperation extended to us during the inspection.

Executive Summary

Results in Brief

The Office of Inspector General (OIG) undertook this review as the use of Carbon Monoxide (CO)-based Modified Atmospheric Packaging (MAP) systems came under heightened scrutiny by the national press. Members of the public asked the U.S. Food and Drug Administration (FDA), via a Citizen’s Petition, to consider banning the practice out of concern for food safety and the potential for the packaging to deceive the consumer as to the freshness of the meat.

FDA reviewed CO-based MAP systems jointly with the Food Safety and Inspection Service (FSIS) as specified in a memorandum of understanding (MOU) between FDA and FSIS. Under this collaborative process, FDA evaluated the safety, and FSIS evaluated the suitability, of CO-based MAP for use in meat in accordance with each agency’s respective authorities. In this instance, FSIS and FDA evaluated CO-based MAP systems under a category of food ingredients known as Generally Recognized as Safe (GRAS).

Overall, we found that the suitability determinations made by FSIS regarding the CO-based MAP systems were consistent with the agency’s understanding of the MOU, the Federal Meat Inspection Act (FMIA), and FSIS’ regulations. However, our review identified two areas where FSIS needs to more clearly explain to its stakeholders how the agency applied the regulations and guidance used in its decision-making. The use by FSIS of the “permanent change” standard to determine whether meat may “appear better or of greater value” is not addressed in any agency-issued guidance or policy. Furthermore, FSIS has not established guidance or a policy which defines “processing aids.”

In reviewing FSIS’ process for making suitability determinations, we found that some of the information FSIS uses is gathered by FDA under a 1997 proposed rule, rather than under a final rule, as is required by law.

Recommendations In Brief

We recommend that FSIS take the following actions:

1. FSIS needs to provide written guidance on the definitions of the terms “better or of greater value” and “processing aids,” to eliminate ambiguity for stakeholders.
2. FSIS needs to consult with the Office of General Counsel (OGC) specifically regarding any potential issues for the

agency when completing GRAS reviews that are conducted under processes established by a proposed rule issued by FDA in 1997 that, as of the date of the report, has not been finalized.

Agency Response FSIS has agreed to implement the recommendations made in this report.

OIG Position We concur with the agency's response and have reached management decision for both of the recommendations within this report.

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Abbreviations Used in This Report

CO	Chemical formula for carbon monoxide
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
GRAS	Generally Recognized as Safe
MAP	Modified Atmospheric Packaging
MOU	Memorandum of Understanding
OIG	Office of Inspector General
OGC	Office of General Counsel

Background and Objective

Background

OIG performed a review of the issues surrounding the use of CO as a component of MAP for case-ready fresh meat. OIG undertook this review as the use of CO-based MAP systems came under heightened scrutiny by the national press after members of the public asked FDA, via a Citizen's Petition, to consider banning the practice out of concern for food safety and the potential for the packaging to deceive the consumer as to the freshness of the meat. FDA reviewed CO-based MAP systems jointly with the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) as specified in a memorandum of understanding (MOU) between FDA and FSIS. Under this collaborative process, FDA evaluated the safety, and FSIS evaluated the suitability, of CO-based MAP for use in meat in accordance with each agency's respective authorities (i.e. the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 (FFDCA) for FDA, and the Federal Meat Inspection Act, 21 U.S.C. §§ 601 et seq. (FMIA), for FSIS). In this instance, FSIS and FDA evaluated CO-based MAP systems under a category of food ingredients known as Generally Recognized as Safe (GRAS).

Objective

Our review assessed whether FSIS' suitability determinations for CO-based MAP systems were consistent with:

- The January 2000, MOU between FDA and FSIS entitled "Regarding the Listing or Approval of Food Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products," which specifies the collaboration between FDA and FSIS on reviews of food ingredients used in meat and poultry.
- FSIS regulations in 9 C.F.R. § 424.23, the FMIA, and applicable guidance.

Findings and Recommendations

Overall, we found that the suitability determinations made by FSIS regarding the CO-based MAP systems were consistent with the agency's understanding of the MOU, the FMIA, and FSIS' regulations. However, our review identified two areas where FSIS needs to more clearly explain to its stakeholders how the agency applied the regulations and guidance used in its decision-making. Clarification of the regulations and guidance by FSIS will promote a better understanding of the agency's decision-making processes. FSIS needs to explain its application of the regulatory policies in an open, consistent, legally sound, and predictable manner to ensure public confidence in the reliability of the agency's determinations. The two areas needing further clarification are detailed below.

1. FSIS' determination of whether CO-based MAP systems meet the definition of prohibited ingredients.

Existing laws and regulations prohibit the use of ingredients that make meat "appear better or of greater value than it is" (See 21 U.S.C. § 601(m)(8) and 9 C.F.R. § 424.23(a)). An FSIS official stated that the agency only considers substances that "permanently" change meat to have the potential to make the product "appear" (to be of) "better or of greater value." An example of a prohibited ingredient that has the potential to add value to meat is paprika. Paprika is a colorant that permanently changes the color of meat by making the fat appear red (and thus makes the meat product look leaner). In contrast, the CO component of the CO-based MAP systems is a gas with a temporary effect. Once the package is opened, the CO gas is no longer in contact with the meat and the meat reverts to its normal appearance.

On this basis, FSIS has determined that the CO component of the CO-based MAP systems is a permissible ingredient. The use by FSIS of the "permanent change" standard to determine whether meat may "appear better or of greater value" is not addressed in any agency-issued guidance or policy. FSIS should publicly clarify its application of this standard for its stakeholders.

2. FSIS' determination that CO-based MAP systems should be evaluated under "processing aids" because of the temporary effect that CO has on the meat.

FSIS has not established a policy which defines "processing aids." Rather, FSIS issued guidance¹ stating that it will make determinations on a case-by-case basis by applying FDA's definition as set forth in 21 C.F.R. § 101.100(a)(3). The definition of "processing aid" is summarized in FSIS' guidance as, "...there is no lasting functional effect, and there is an insignificant amount present in the finished product under the proposed conditions of use." This lack of a clearly stated policy hinders FSIS' efforts to communicate its decision-making process in a straightforward and supportable manner. FSIS should provide a clear policy for the evaluation methods it will employ to ensure consistency and transparency in applying this definition.

Recommendation 1 FSIS needs to provide written guidance on the definitions of the terms "better or of greater value" and "processing aids" to eliminate ambiguity for stakeholders.

FSIS Response FSIS accepts this recommendation and will issue written guidance on the definitions of the terms "better or of greater value" and "processing aids" in March 2008. In these documents, FSIS will provide general information about these two matters that will provide a context within which to understand how the agency made its determinations about the CO-based MAP system. FSIS has already begun preparing the recommended compliance guides.

OIG Position We concur with the agency response for this recommendation and have reached management decision.

FDA's 1997 Proposed Rule In reviewing FSIS' process for making suitability determinations, we found that some of the information FSIS uses is gathered by FDA under a proposed rule, rather than under a final rule, as is required by law.

FDA published a proposed rule on April 17, 1997 (62 Fed. Reg.18,938), in order to establish a process whereby producers would provide a notification to FDA of a self-determination that a proposed ingredient is GRAS. As part of the GRAS process, FDA

¹ Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings at: <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N/IngridGuid.htm>.

would determine whether it questioned the GRAS determination, or whether it found that the producer's notification did not provide a sufficient basis for a GRAS determination. FDA has not published a final rule in the Federal Register to implement the proposed rule. Nonetheless, FDA has been operating for many years as though the proposed rule was final. Federal law requires publication of substantive rules as actually adopted by an agency (See 5 U.S.C. §§ 552(a), 553).² To the extent that FSIS currently relies on the producer's self-determination notification to FDA that a product is GRAS when making suitability determinations, such reliance may subject FSIS' determinations to challenge under the Administrative Procedures Act.³

Recommendation 2 FSIS needs to consult with OGC regarding the appropriateness of relying upon a producer's self-determined GRAS notice submitted pursuant to FDA's proposed rule, as part of FSIS' suitability determination procedures.

FSIS Response On December 23, 1999, FSIS published a final rule (64 FR 72168) adopting FDA's regulation on the use of food ingredients (21 CFR 424.21). In this document, FSIS made clear its intention to function under FDA's proposal on the GRAS notification process. OGC reviewed this planned course of action as part of its review of the final rule and found no problem with this approach. In March 2008, FSIS will consult with OGC to reaffirm that its determinations of ingredient safety and suitability are not affected by the status of the FDA proposed rule. FSIS already has done so on a preliminary basis.

OIG Position We concur with the agency response for this recommendation and have reached management decision. FSIS needs to consult with OGC specifically regarding any potential issues for the agency when completing GRAS reviews that are conducted under processes established by a proposed rule issued by FDA in 1997 that, as of the date of this report, has not been finalized.

² See also United States v. Gavrilovic, 551 F.2d 1099, 1101 n.3 (8th Cir. 1977) ("Section 553 of the Act [5 U.S.C. § 553] requires publication in the Federal Register of proposed rule making; opportunity to be heard; a statement in the rule of its basis and purpose; and publication in the Federal Register of the rule as adopted."); Rowell v. Andrus, 631 F.2d 699, 703 (10th Cir. 1980) (finding that the Administrative Procedures Act, 5 U.S.C. § 553(d), regarding publication of substantive rules prior to their effective date, requires publication of rules "as actually adopted by an agency" rather than the publication of a "general notice of proposed rule making").

³ OIG is not questioning FSIS' authority to make such determinations in general. FSIS has the authority to regulate the ingredients in meat and meat products under the FMIA. See 21 U.S.C. § 601(m); 7 C.F.R. §§ 2.18(a)(1)(ii)(B), 2.53(a)(2)(ii).



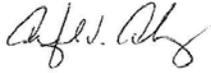
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To: Rod DeSmet
Assistant Inspector General for Inspections and Research
Office of Inspector General

From: Alfred V. Almanza 
Administrator

Subject: Office of Inspector General (OIG) Official Draft Report –Inspection of the
CO-based Modified Atmospheric Packaging Regulatory Review Process
(Audit No. 24901-01-IR)

We appreciate the opportunity to review and comment on this official draft report. The Food Safety and Inspection Service (FSIS) has carefully reviewed the official draft report and accepts both of its recommendations. FSIS suggests a single revision to the report, explained below.

OIG states on page 2 of the official draft of this report: “we found that some of the information FSIS uses is gathered by FDA under a proposed rule, rather than under a final rule, as is required by law.” FSIS recommends that you delete the phrase “as is required by law” from this sentence. The phrase implies that FSIS is required by law to use suitability information only if it has been collected under an FDA final regulation. This is not the case. Further, the next paragraph in the report adequately explains the situation regarding FDA’s proposed rule.

Responses to Recommendations

Recommendation 1: Provide written guidance on the definitions of the terms “better or of greater value” and “processing aids.”

FSIS Response: FSIS accepts this recommendation and will issue written guidance on the definitions of the terms “better or of greater value” and “processing aids.” In these documents, FSIS will provide general information about these two matters that will provide a context within which to understand how the Agency made its determinations about the CO-based MAP system. FSIS has already begun preparing the recommended compliance guides.

Estimated Completion Date: March 2008

Recommendation 2: Consult with USDA’s Office of General Counsel (OGC) regarding the appropriateness of relying upon a producer’s self-determined GRAS notice submitted pursuant to FDA’s proposed rule, as part of FSIS suitability determination procedures.

FSIS Response: On December 23, 1999, FSIS published a final rule (64 FR 72168) adopting FDA’s regulation on the use of food ingredients (21 CFR 424.21). In this document, FSIS made clear its intention to function under FDA’s proposal on the GRAS notification process. OGC reviewed this planned course of action as part of its review of the final rule and found no problem with this approach. FSIS will consult with OGC to reaffirm that its determinations of ingredient safety and suitability are not affected by the status of the FDA proposed rule. FSIS already has done so on a preliminary basis.

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