

Done at Washington, DC, on: January 26, 1998.

Thomas J. Billy,
Administrator.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 97-074N]

Contents of HACCP Plans

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Compliance with the HACCP system regulations.

SUMMARY: The Food Safety and Inspection Service is publishing this document to ensure that the owners and operators of federally inspected establishments are aware that its hazard analysis and critical control point (HACCP) system regulations require that an HACCP plan be a self-contained document. In particular, the Agency does not view references to good manufacturing practices, or establishment actions in accordance with good manufacturing practices, as satisfying the requirements for the contents of an HACCP plan. Among other things, an HACCP plan must list the critical control points for each food safety hazard reasonably likely to occur in the production process, the critical limits that must be met at each of the critical control points, and the procedures, and frequency with which they will be performed, that will be used to monitor each critical control point to ensure compliance with critical limits and to verify that the plan is being effectively implemented. An HACCP plan also must identify the corrective actions to be followed in response to deviations from critical limits at critical control points.

FOR FURTHER INFORMATION CONTACT: Patricia F. Stolfa, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 205-0699.

SUPPLEMENTARY INFORMATION: The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) to protect the health

and welfare of consumers by preventing the distribution of livestock products and poultry products that are unwholesome, adulterated, or misbranded. To further the goal of reducing the risk of foodborne illness from meat and poultry products to the maximum extent possible, FSIS issued the Pathogen Reduction-Hazard Analysis and Critical Control Point (HACCP) Systems final rule (61 FR 38806, July 25, 1996). As amended by that rule, FSIS's regulations require federally inspected establishments to take preventive and corrective measures at each stage of the food production process where food safety hazards occur.

The regulations on HACCP systems, part 417,* require a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures an establishment can apply to control them (§ 417.2(a)(1)) and, whenever this analysis reveals one or more such hazards, development and implementation of a written HACCP plan (§ 417.2(b)(1)). In § 417.2(c), the regulations specify minimum requirements for the contents of each HACCP plan, including requirements to list the food safety hazards for each process; list the critical control points for each of the identified hazards; list the critical limits that must be met at each of the critical control points; list the procedures, and frequency with which they will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits; and list the verification procedures, and the frequency with which they will be performed, that the establishment will use in accordance with § 417.4 (*i.e.*, to verify that the plan is being effectively implemented) (paragraphs (c)(1), (c)(2), (c)(3), (c)(4), and (c)(7) of § 417.2). In addition, a HACCP plan must include all corrective actions that have been developed in accordance with § 417.3(a), which requires the identification of the corrective action to be followed in response to a deviation from a critical limit (§ 417.2(c)(5)).

Given the explicit requirements to list critical control points, critical limits,

* Part 417 requirements will apply as of January 26, 1998, in establishments with 500 or more employees; January 25, 1999, in establishments with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than \$2.5 million); and January 25, 2000, in establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

and monitoring and verification procedures and to develop and identify corrective actions, and the Agency's statement, in issuing part 417, that it was clarifying requirements for the identification of critical control points within a HACCP plan (61 FR 38825), FSIS is concerned that some industry members and consultants to industry think that they can comply with § 417.2(c) by referring to good manufacturing practices, or establishment actions in accordance with good manufacturing practices. While FSIS has considered good manufacturing practices in developing some requirements that protect the public against livestock products and poultry products that are misbranded or economically adulterated (21 U.S.C. 453 and 601), the Agency has not adopted specific good manufacturing practices as part of its regulations.

The Agency is publishing this notice to ensure that the owners and operators of federally inspected establishments are aware that references to good manufacturing practices, or establishment actions in accordance with good manufacturing practices, rather than stating the critical control points, critical limits, monitoring and verification procedures, and corrective actions themselves is insufficient to satisfy the requirements of § 417.5(c). Part 417 requires that a HACCP plan be a self-contained document.

Moreover, the function of critical control points and critical limits is to prevent, eliminate, or reduce to an acceptable level one or more food safety hazards. By definition, critical limits are maximum and minimum values (§ 417.1), and by regulation, critical limits must be designed, at a minimum, to ensure that applicable targets or performance standards established by FSIS, and any other requirement in FSIS's regulations (9 CFR chapter III) pertaining to the specific process or product, are met (§ 417.2(c)(3)). To determine whether critical limits are met and, if not, prevent the distribution of adulterated food and future deviations, the regulations require plan-specific monitoring, verification, and corrective action procedures.

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