

offer under section 17. In this regard, the regulation will require that commodities must be moved from one transportation conveyance to another at such a facility.

*Comment:* Two respondents (representing one port and one port association) stated that the proposed rule is somewhat ambiguous and, regardless of intent, may be construed as a set-aside for the Great Lakes and therefore in violation of Article 1, section 9, clause 6 of the Constitution of the United States prohibiting any regulation of commerce or revenue giving a preference to the ports of one State over those of another.

*Response:* Any comments regarding the constitutionality of section 17 of the MSA are beyond the scope of this rulemaking.

*Comment:* One commodity supplier suggested that the 25 percent limit in section 17 of the MSA be administered on a monthly basis.

*Response:* CCC does not have the option of administering the 25 percent limitation on a monthly basis. Section 17 specifically states that a 25 percent cap applies to the total annual tonnage of processed, bagged and fortified commodities furnished under Title II, Public Law 480. CCC will monitor tonnage allocated to Great Lakes ports over the year to ensure that it does not exceed the cap.

*Comment:* One commenter stated that the proposed rule was deficient because it did not set out any "reasonable requirements for financial and operational integrity" to be applicable to vessel operators interested in carrying Title II, Pub. L. 480 cargo. Section 901b(c)(3)(C)(I) of the Merchant Marine Act, 1936, as amended by section 17 of the MSA, provides that "[I]n awarding any contract for the transportation by vessel from the Great Lakes port range \* \* \* each agency \* \* \* shall consider expressions of freight interest for any vessel from a vessel operator who meets reasonable requirements for financial and operational integrity \* \* \*."

*Response:* Section 17 of the MSA does not have direct application to CCC because CCC does not award ocean transportation contracts. In any event, CCC does impose requirements with regard to financial, operational, and performance integrity of carriers submitting rate and service quotations. CCC now requires that carriers possess (1) a satisfactory performance record, (2) a satisfactory record of integrity and business ethics, (3) adequate financial resources, and (4) the ability to comply with the required delivery schedule, taking into consideration all existing commercial and governmental business

commitments. We have evaluated the written comments received in response to CCC's proposed rule, along with comments recorded in the public forum held on March 13, 1997. For purposes of meeting requirements of section 17 of MSA, CCC has decided to adopt, as a final rule, a procedure to permit Great Lakes intermodal bridge-port offers at facilities capable of loading ocean going vessels as a Great Lakes port range allocation.

To properly assess the impact that section 17 of the MSA has upon the Title II program and the manner in which CCC has implemented it, a cost benefit evaluation will be made within 3 years of the effective date of this rule. Collection of data after implementation of this rule is of particular importance to the evaluation, since no ocean going service and limited intermodal service has been available in the Great Lakes for Public Law 480 shipments.

No comments were received concerning CCC's clarification of § 1496.5(b)(1) and the amendment proposed is being adopted as final without any substantive change.

#### List of Subjects in 7 CFR Part 1496

Agricultural commodities; Exports.

Accordingly, 7 CFR part 1496 is amended as follows:

#### PART 1496—PROCUREMENT OF PROCESSED AGRICULTURAL COMMODITIES FOR DONATION UNDER TITLE II, PUBLIC LAW 480

1. The authority citation for part 1496 is revised to read as follows:

**Authority:** 7 U.S.C. 1721-1726a; 1731-1736g-2; 46 U.S.C. App. 1241(b), and 1241(f).

2. In § 1496.5, paragraphs (b)(1) and (f) are revised to read as follows:

##### § 1496.5 Consideration of bids.

\* \* \* \* \*

(b)(1) *Availability of ocean service.* Prior to receipt of offers from commodity suppliers, CCC will review ocean freight information from available sources including, but not limited to, trade journal newspapers, port publications, and steamship publications to determine the availability of appropriate ocean service.

\* \* \* \* \*

(f) *Great Lakes ports.* (1) Commodities offered for delivery "free alongside ship" (f.a.s.) Great Lakes port range or intermodal bridge-port Great Lakes port range that represent the overall (foreign and U.S. flag) lowest landed cost will be awarded on that basis. Such offers will not be reevaluated on a lowest landed cost U.S.-flag basis unless CCC determines that 25 percent of the total

annual tonnage of bagged, processed or fortified commodities furnished under Title II of Public Law 480 has been, or will be, transported from the Great Lakes port range during that fiscal year.

(2) CCC will consider commodity offers as offers for delivery "intermodal bridge-port Great Lakes port range" only if:

(i) The offer specifies delivery at a marine cargo-handling facility that is capable of loading ocean going vessels at a Great Lakes port, as well as loading ocean going conveyances such as barges and container vans, and

(ii) The commodities will be moved from one transportation conveyance to another at such a facility.

\* \* \* \* \*

Signed at Washington, DC, on February 26, 1998.

**Keith Kelly,**

*Executive Vice President, Commodity Credit Corporation.*

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## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

#### 9 CFR Part 417

[Docket No. 98-003N]

#### Establishment Review of Product Production Records

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice on complying with the HACCP system regulations.

**SUMMARY:** The Food Safety and Inspection Service is publishing this document to provide information to owners and operators of federally inspected establishments about what actions they must take to comply with the requirement, in the hazard analysis and critical control point system regulations, to review the records associated with production of a product prior to its shipment for distribution. The regulations do not prescribe how establishments meet this requirement and, thus, are sufficiently flexible to accommodate various records' review schemes. However, establishments must determine that all critical limits were met and, when appropriate, that corrective actions were taken. Establishments must also ensure the completeness of their records before shipping the product for distribution.

**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 part 417 of the regulations, Hazard Analysis and Critical Control Point (HACCP) Systems.\*

Part 417 requires federally inspected establishments to determine the food safety hazards reasonably likely to occur in the production process and to develop and implement a HACCP plan, or plans, to control these hazards (§ 417.2(a), (b), and (c)). Under part 417, establishments control food safety hazards through monitoring procedures that apply critical limits at critical control points and, when deviations occur, by taking corrective actions that restore establishment control and keep adulterated food out of commerce, as documented in records that are subject to establishment verification (§§ 417.2(c), 417.3, and 417.5).

To ensure that HACCP plans are implemented effectively and function as intended to control food safety hazards and prevent the distribution of adulterated livestock products and poultry products, part 417 also requires that establishments conduct validation and verification activities (§ 417.4(a)). Verification includes review of the records that the establishment must keep to document a HACCP plan in operation (§ 417.5(a)(3)). For a particular product, verification does not end until, in accordance with § 417.5(c), the establishment has reviewed the records associated with its production.

Paragraph (c) of § 417.5 provides that:

Prior to shipping product, the establishment shall review the records associated with the

production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

As federally inspected establishments prepare to implement HACCP plans under part 417, the Agency has received inquiries about what actions establishments must take to comply with this paragraph of the regulations. In particular, people have asked whether an establishment can satisfy the requirement for a final, records-based verification by using any procedure other than one in which a single reviewer looks at all the records for the product as it is assembled on the shipping dock and loaded for transportation from the establishment.

FSIS is publishing this notice to provide information to owners and operators of federally inspected establishments on the types of procedures that the Agency anticipates will satisfy this requirement. The essence of § 417.5(c) is to require that establishments take responsibility not only for developing and implementing HACCP plans, but also for maintaining control of products until they ensure that establishment personnel have applied those plans appropriately and effectively. FSIS has not prescribed how establishments comply, and it views the regulations as sufficiently flexible to accommodate records' review schemes in addition to the procedure described in the previous paragraph.

Establishment personnel can review production records at any point after processing and before shipment of the product, including, for example, at the end of the day of production before a product goes into on-site storage, while a product is in on-site storage, or during preparation of shipping documents before assembling product for transportation from the establishment. Consistent with the regulations, an establishment also can initiate checks for records' completeness earlier and accomplish the review in stages. For example, an establishment that slaughters and bones cattle carcasses one day and prepares ground beef the next could make one reviewer responsible for performing slaughter

and boning records' review on the first day and carry the review forward to the second day, when another reviewer assumes responsibility for the remaining tasks necessary to ensure that there has been an establishment determination that all critical limits were met and, if appropriate, corrective actions were taken and that production records are otherwise complete and then signs and dates the review. In addition, establishments that maintain records on computers in accordance with § 417.5(d) may be able to accomplish much of the record checking electronically.

The crucial concern is that there be verification that establishment controls have ensured proper product disposition, so that adulterated product is not distributed. FSIS has not, at this point, ruled out the possibility that a company might operate in compliance with this regulation despite the fact that the records-based verification is being conducted when the company transfers a product from the preparation establishment to another, storage location and holds the product there, maintaining control of the product, until the company completes the review and releases the product for shipment to retail outlets. Industry members interested in instituting a records' review scheme that includes this type of feature may wish to consult with the Agency about the types of safeguards needed to ensure that product is not shipped for distribution until the required verification is performed. (In §§ 318.309(d)(1)(viii) and 381.309(d)(1)(viii), the canning and canned products' regulations address a similar situation as an exception, for which an establishment must obtain area supervisor approval, to the prohibition against shipping product from the establishments before the end of the required incubation period.) FSIS also notes that establishment compliance with part 417 requirements does not affect the applicability of section 10 of the FMIA or section 9(a) of the PPIA (21 U.S.C. 610 and 458(a)); in particular, transporting, or offering for transportation, adulterated livestock products or poultry products is prohibited.

Done at Washington, DC, on: February 27, 1998.

**Thomas J. Billy,**  
Administrator.

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\* 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.