

Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 966

[Docket No. AMS-FV-06-0208; FV07-966-1 IFR]

Tomatoes Grown in Florida; Change in Handling Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule changes the handling requirements currently prescribed under the Florida Tomato marketing order (order). The order regulates the handling of tomatoes grown in Florida, and is administered locally by the Florida Tomato Committee (Committee). This rule limits the use of inverted lids on tomato containers to the handler whose information initially appeared on the lid. This rule helps ensure that lids do not contain the information for more than one active handler and aids in maintaining the positive identification and traceability of Florida tomatoes.

DATES: Effective February 7, 2007; comments received by April 9, 2007 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; Fax: (202) 720-8938; E-mail: moab.docketclerk@usda.gov; or Internet: <http://www.regulations.gov>. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public

inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

William Pimental, Marketing Specialist; or Christian Nissen, Regional Manager, Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; telephone: (863) 324-3375, Fax: (863) 325-8793, or E-mail: William.Pimental@usda.gov or Christian.Nissen@usda.gov.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail: Jay.Guerber@usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 125 and Order No. 966, both as amended (7 CFR part 966), regulating the handling of tomatoes grown in Florida, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing USDA would rule on the petition. The Act provides that the district court of the United States in any district in which

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the handler is an inhabitant, or has his or her principal place of petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule changes the handling requirements currently prescribed under the order. This rule limits the use of inverted lids on tomato containers to the handler whose information initially appeared on the lid. This rule helps ensure that lids do not contain the information for more than one active handler and aids in maintaining the positive identification and traceability of Florida tomatoes. This action was unanimously recommended by the Committee at a meeting on October 4, 2006.

Section 966.52 of the order provides the authority to establish pack and container requirements for tomatoes grown under the order. This includes fixing the size, weight, capacity, dimensions, markings, or pack of the container or containers which may be used in the handling of tomatoes.

Section 966.323 of the order's administrative rules prescribes the handling regulations for Florida tomatoes. Section 966.323(a)(3) delineates the requisite container requirements for weight, markings, and appearance. The section specifies, in part, that each container or lid must show the name and address of the registered handler.

The majority of Florida tomatoes are packed in containers that have a separate lid. Most lids are preprinted with the handler's name and address. In addition, most lids can be inverted by reversing the lid so the blank side is on the outside, and the preprinted information is flipped to the underside of the lid. This is done so new information can be printed on the lid. This rule amends § 966.323(a)(3) by limiting the use of inverted lids on tomato containers to the handler whose information first appeared on the lid.

Inverted lids have been used in minimal quantities in past seasons, usually when a tomato packing operation was purchased by another entity. Any containers included in the purchase could be used by the purchasing handler by inverting the lids so the purchaser's information could be affixed on the clean side. Usually there were not many containers remaining, so

the containers requiring inverted lids were fairly limited in quantity.

Recently, container sales companies have started offering their container overruns at discounted prices to tomato handlers. These containers usually have preprinted handler and product information on the lids. The Committee is concerned this could significantly increase the number of inverted lids being used by the industry and could pose problems with the positive identification and traceability of tomatoes.

In their discussion of this issue, the committee agreed the ability to positively identify product is a necessity in today's marketplace. The Committee expressed concern that the practice of inverting lids could result in misidentification and confusion in cases where tomatoes need to be traced back to their origin. The Committee recognized that in the past, most of the containers being used with an inverted lid were associated with a handler purchasing another operation. Consequently, the original owner of the lid was no longer in business, and the container was only printed with the information for one active handler.

This would not be the case with handlers using overrun containers. The overrun containers being made available are containers produced in excess of orders, with the majority preprinted with handler information. Therefore, once inverted, the lids on the overrun containers would be printed with the information for two active handlers. The Committee is concerned that having multiple handler information on a container, even with the lid inverted, could pose problems when trying to track tomatoes back to the original handler.

The Committee believes it is of critical importance that Florida tomatoes can be traced from the farm to the end-user. Proper handler identification on a container is an important part of this traceability. Allowing the use of containers with an active registered handler's information on the exterior of the lid and another on the interior could allow for misidentification and confusion in product identification. The Committee believes by limiting the use of inverted lids to the handler whose name originally appeared on the lid, positive identification and traceability will be better maintained.

In addition, in cases related to marketing order compliance, it is also important to be able to identify the original source of tomatoes. Allowing the use of inverted lids could result in the intentional misrepresentation of the

origin of the tomatoes. The box lids could be reinverted to display the handler information originally printed on the box without that handler's knowledge. Limiting the use of inverted lids on tomato containers by anyone other than the handler whose information first appeared on the lid will help alleviate any misidentification or uncertainty in product identification.

Section 8e of the Act provides that when certain domestically produced commodities, including tomatoes, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. As this rule changes the container requirements under the domestic handling regulations, no corresponding change to the import regulations are required.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 100 producers of tomatoes in the production area and approximately 70 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$6,500,000 (13 CFR 121.201).

Based on industry and Committee data, the average annual price for fresh Florida tomatoes during the 2005-06 season was approximately \$10.27 per 25-pound container, and fresh shipments totaled 47,880,303 25-pound cartons of tomatoes. Committee data indicates approximately 27 percent of the handlers handle 95 percent of the total volume shipped outside the regulated area. Based on the average price, about 75 percent of handlers could be considered small businesses under SBA's definition. In addition,

based on production, grower prices as reported by the National Agricultural Statistics Service, and the total number of Florida tomato growers, the average annual grower revenue is below \$750,000. Thus, the majority of handlers and producers of Florida tomatoes may be classified as small entities.

This rule changes the handling requirements currently prescribed under the order. This rule limits the use of inverted lids on tomato containers to the handler whose information initially appeared on the lid. This rule helps ensure that lids do not contain the information for more than one active handler and aids in maintaining the positive identification and traceability of Florida tomatoes. This rule revises § 966.323(a)(3), which specifies the requisite container requirements. Authority for this action is provided in § 966.52 of the order. The Committee unanimously recommended this change at a meeting held on October 4, 2006.

At the meeting, the Committee discussed the impact of this change on handlers in terms of cost. This rule could result in a slight increase in cost for handlers that were considering purchasing the container overruns. However, Committee members stated that plain containers are readily available on the market at reasonable prices. Consequently, the difference in cost between a discounted overrun container and a plain blank container should be minimal.

In addition, last season the industry packed more than 47 million cartons of tomatoes. The available quantities of overrun containers are limited, confining the cost benefit to those containers available. When compared to the total containers needed, the overall cost savings associated with using overrun cartons would be negligible. Also, in previous seasons, overrun containers were not available for purchase. Therefore, container cost for all handlers should be similar to those in previous seasons.

Further, this rule provides the benefit of helping to maintain the traceability and proper identification of Florida tomatoes, which outweighs the minor cost savings associated with using overrun containers. The costs and benefits of this rule are not expected to be disproportionately different for small or large entities.

One alternative to this action was to allow the use of inverted lids. However, Committee members agreed that having the information for more than one active handler appear on a carton was confusing and could make traceability and proper identification difficult. Therefore, this alternative was rejected.

This action will not impose any additional reporting or recordkeeping requirements on either small or large tomato handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Committee's meeting was widely publicized throughout the Florida tomato industry and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the October 4, 2006, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

This rule invites comments on a change to the container requirements currently prescribed under the Florida tomato marketing order. Any comments received will be considered prior to finalization of this rule.

After consideration of all relevant material presented, including the Committee's recommendation, and other information, it is found that this interim final rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2006–07 season has begun, and handlers are currently packing tomatoes; (2) the Committee unanimously recommended this change

at a public meeting and interested parties had an opportunity to provide input; (3) handlers are aware of this change; and (4) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

■ For the reasons set forth in the preamble, 7 CFR part 966 is amended as follows:

PART 966—TOMATOES GROWN IN FLORIDA

■ 1. The authority citation for 7 CFR part 966 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 966.323 paragraph (a)(3)(ii) is revised to read as follows:

§ 966.323 Handling regulation.

* * * * *

(a) * * *
(3) * * *

(ii) Each container or lid shall be marked to indicate the designated net weight and must show the name and address of the registered handler (as defined in 966.7) in letters at least one-fourth (1/4) inch high, and such containers must be packed at the registered handler's facilities. The use of inverted, previously printed container lids is limited to the registered handler identified by the labels or marks that originally appeared on the lid.

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Dated: February 1, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. 07–502 Filed 2–5–07; 8:45 am]

BILLING CODE 3410–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

New Animal Drugs; Hydrogen Peroxide

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Eka Chemicals, Inc. The NADA provides for

immersion use of hydrogen peroxide solution for control of mortality in certain freshwater-reared finfish species in several life stages due to various fungal and bacterial diseases.

DATES: This rule is effective February 6, 2007.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Eka Chemicals, Inc., 1775 West Oak Commons Ct., Marietta, GA 30062–2254, filed NADA 141–255 for 35% PEROX–AID (hydrogen peroxide) for control of mortality in freshwater-reared finfish eggs due to saprolegniasis, for control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and for control of mortality in freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*). The NADA is approved as of January 11, 2007, and the regulations are amended in part 529 (21 CFR part 529) by adding § 529.1150 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Eka Chemicals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for this firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc–2), this approval qualifies for 7 years of exclusive marketing rights beginning January 11, 2007, because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not