

**PART 401—GENERAL CROP
INSURANCE REGULATIONS—
REGULATIONS FOR THE 1988 AND
SUBSEQUENT CONTRACT YEARS**

1. The authority citation for 7 CFR part 401 is revised to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

2. Section 401.114 is amended by revising 10. Contract Changes to read as follows:

§ 401.114 Canning and processing tomato endorsement.

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10. Contract Changes

The date by which contract changes will be available in your service office is November 30 (December 17 for the 1998 crop year only) preceding the cancellation date for counties with a February 15 cancellation date and December 31 preceding the cancellation date for all other counties.

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3. Section 401.120 is amended by revising 9. Contract Changes to read as follows:

§ 401.120 Rice endorsement.

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9. Contract Changes

The date by which contract changes will be available in your service office is December 31 preceding the cancellation date for counties with an April 15 cancellation date and November 30 (December 17 for the 1998 crop year only) preceding the cancellation date for all other counties.

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**PART 454—FRESH MARKET TOMATO
(GUARANTEED PRODUCTION PLAN)
CROP INSURANCE REGULATIONS**

4. The authority citation for 7 CFR part 454 is revised to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

5. In § 454.7(d), the insurance policy is amended by revising section 16. Contract Changes to read as follows:

**§ 454.7 Guaranteed Production Plan of
Fresh Market Tomato Crop Insurance
Policy.**

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16. Contract Changes

We may change any terms and provisions of the contract from year to year. If your price election at which indemnities are computed is no longer offered, the actuarial table will provide the price election which you are deemed to have elected. All contract changes will be available at your service office by November 30 (December 17 for the 1998 crop year only) preceding the cancellation date for counties with a February 15 cancellation date, and by December 31 preceding the cancellation date for counties with an April 15 cancellation date. Acceptance of changes

will be conclusively presumed in the absence of notice from you to cancel the contract.

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**PART 457—COMMON CROP
INSURANCE REGULATIONS;
REGULATIONS FOR THE 1994 AND
SUBSEQUENT CONTRACT YEARS**

6. The authority citation for 7 CFR part 457 is revised to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

7. Section 457.104 is amended by revising 4. Contract Changes to read as follows:

**§ 457.104 Cotton crop insurance
provisions.**

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4. Contract Changes

The contract change date is November 30 (December 17 for the 1998 crop year only) preceding the cancellation date (see the provisions of Section 4 (Contract Changes) of the Common Crop Insurance Policy).

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8. Section 457.105 is amended by revising 4. Contract Changes to read as follows:

**§ 457.105 Extra long staple cotton crop
insurance provisions.**

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4. Contract Changes

The contract change date is November 30 (December 17 for the 1998 crop year only) preceding the cancellation date (see the provisions of section 4 (Contract Changes) of the Common Crop Insurance Policy).

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9. Section 457.108 is amended by revising 4. Contract Changes to read as follows:

**§ 457.108 Sunflower seed crop insurance
provisions.**

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4. Contract Changes

The contract change date is November 30 (December 17 for the 1998 crop year only) preceding the cancellation date (see the provisions of Section 4 (Contract Changes) of the Basic Provisions).

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10. Section 457.109 is amended by revising 4. Contract Changes to read as follows:

**§ 457.109 Sugar beet crop insurance
provisions.**

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4. Contract Changes

In accordance with the provisions of section 4 (Contract Changes) of the Basic Provisions, the contract change date is April 30 preceding the cancellation date for counties with a July 15 or August 31 cancellation date and November 30 (December 17 for the 1998 crop year only)

preceding the cancellation date for all other counties.

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11. Section 457.113 is amended by revising 4. Contract Changes to read as follows:

**§ 457.113 Coarse grains crop insurance
provisions.**

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4. Contract Changes

The contract change date is November 30 (December 17 for the 1998 crop year only) preceding the cancellation date (see the provisions of Section 4 (Contract Changes) of the Common Crop Insurance Policy).

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12. Section 457.150 is amended by revising 4. Contract Changes to read as follows:

**§ 457.150 Dry bean crop insurance
provisions.**

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4. Contract Changes

In accordance with section 4 (Contract Changes) of the Basic Provisions, the contract change date is November 30 (December 17 for the 1998 crop year only) preceding the cancellation date.

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Signed in Washington, D.C., on November 26, 1997.

Kenneth D. Ackerman,
*Manager, Federal Crop Insurance
Corporation.*

[FR Doc. 97-31544 Filed 11-26-97; 3:08 pm]

BILLING CODE 3410-08-P

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

**Common Crop Insurance Regulations,
Fresh Market Tomato (Dollar Plan)
Crop Insurance Provisions; Correction**

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule, correction.

SUMMARY: The document contains a correction to the final rule that was published on Friday, March 28, 1997 (62 FR 14775-14780). The rule pertains to the insurance of fresh market tomatoes (dollar plan).

EFFECTIVE DATE: December 2, 1997.

FOR FURTHER INFORMATION CONTACT:
Linda Williams, Insurance Management Specialist, Research and Development Division, Federal Crop Insurance Corporation, United States Department of Agriculture, 9435 Holmes Road, Kansas City, MO 64131, telephone (816) 926-7730.

SUPPLEMENTARY INFORMATION:**Background**

The final rule that is the subject of this correction was intended to provide policy changes to better meet the needs of the insured, include the current fresh market tomato (dollar plan) endorsement under the Common Crop Insurance Policy for ease of use and consistency of terms, and to restrict the effect of the current fresh market tomato (dollar plan) endorsement to the 1997 and prior crop years.

Need for Correction

As published, the final regulation contained a technical error which may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication on March 28, 1997, of the final regulation at 62 FR 14775-14780 is corrected as follows:

PART 457—[CORRECTED]**§ 457.139 [Corrected]**

On page 14780, in the first column, in § 457.139, the paragraph following section 14(b)(4)(ii)(B) is corrected to read:

“(5) Multiplying the result of section 14(b)(4) by your share.”

Signed in Washington D.C. on November 25, 1997.

Kenneth D. Ackerman,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 97-31545 Filed 12-1-97; 8:45 am]

BILLING CODE 3410-08-P

NUCLEAR REGULATORY COMMISSION**10 CFR Parts 30 and 32**

RIN 3150-AF70

Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to permit NRC licensees to distribute a radioactive drug containing one microcurie of carbon-14 urea to any person for “in vivo” diagnostic use. The NRC has determined that the radioactive component of such a drug in capsule form presents an insignificant radiation risk and, therefore, regulatory control of

the drug for radiation safety is not necessary. This amendment makes the drug more widely available and reduces costs to patients, insurers, and the health care industry. This action grants a petition for rulemaking (PRM-35-12) from Tri-Med Specialties, Inc. and completes action on the petition.

EFFECTIVE DATE: January 2, 1998.

ADDRESS: Copies of the public record, including the final regulatory analysis and any public comments received on the proposed rule, may be examined and copied for a fee in the Commission's Public Document Room at 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6233 or e-mail at ANT@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. The Petition for Rulemaking.
- II. Proposed Rule, Public Comments, and NRC Responses.
- III. Summary of the Final Amendments.
- IV. Description of the Final Amendments.
- V. Agreement State Compatibility.
- VI. Finding of No Significant Environmental Impact: Availability.
- VII. Paperwork Reduction Act Statement.
- VIII. Regulatory Analysis.
- IX. Regulatory Flexibility Certification.
- X. Small Business Regulatory Enforcement Fairness Act.
- XI. Backfit Analysis.

List of Subjects**I. The Petition for Rulemaking**

On October 6, 1994, the Commission docketed a petition for rulemaking (Docket No. PRM-35-12) from Tri-Med Specialties, Inc (Tri-Med). In a letter dated August 23, 1994, Tri-Med petitioned the NRC to amend its regulations “to allow for the general licensing and/or exemption for the commercial distribution by licensed pharmaceutical manufacturers of a capsule containing one micro-Curie (μ Ci) of C-14-urea for in vivo diagnostic testing.” The purpose of this diagnostic test is to detect the presence of the bacterium *Helicobacter pylori* (*H. pylori*), a cause of peptic ulcers in humans.

Following the receipt of the petition, the NRC published for public comment a notice of receipt of petition for rulemaking in the **Federal Register** on December 2, 1994 (59 FR 61831). The comment period closed on February 15, 1995. The NRC received 315 public comment letters, of which 313 supported the petition (they were

mostly form letters) and 2 letters opposed the petition.

II. Proposed Rule, Public Comments, and NRC Responses

A proposed rule was published on June 16, 1997 (62 FR 32552) that would permit NRC licensees to distribute capsules containing one microcurie C-14 urea to any person for “in vivo” diagnostic use. The public comment period closed on July 16, 1997.

In the preamble of the proposed rule, the NRC stated that, because the capsules present an insignificant radiological risk to the public and the environment, the NRC believes the capsules could be distributed for “in vivo” diagnostic use to persons exempt from licensing.

This change makes the drug more widely available and reduces costs to patients, insurers, and the health care industry.

The NRC received seven public comment letters on the proposed rule: three from industry, three from State agencies, and one from a physician associated with a university medical facility. Four commenters supported the rule, one opposed the rule, and two provided comments but did not explicitly state whether they supported or opposed the rule. Public comments and NRC's responses are presented below.

Comment 1: Under the proposed distribution, the NRC should not be forbidding research use of this drug by the same physicians who may use it clinically. Research use also should be permitted under this exemption because the radiological risk for using C-14 capsules is insignificant.

Response: The NRC did not change the final rule in response to this comment. A common rule entitled “Federal Policy for the Protection of Human Subjects; Notices and Rules” was promulgated by 16 Federal agencies on June 18, 1991 (56 FR 28002) and was intended to ensure the protection of human research subjects. This rule was adopted to implement a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research which was established on November 9, 1978, by Public Law 95-622. The Federal Policy requires that Federal agencies that conduct, fund, support, or regulate research involving human subjects ensure adequate protection of the rights of the human subjects. The Federal policy represents a societal determination that any research (including research involving radioactive material) must provide for