



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 23, 1993

PR NOTICE 93-12

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, AND REGISTRANTS
OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticides and Petitions for Tolerance

SUBJECT: Status of Dried Hops under the Federal Food, Drug and Cosmetic Act

This notice announces a change in EPA guidelines with respect to the classification of dried hops under the Federal Food, Drug and Cosmetic Act (FFDCA). Under this revision, hops will be considered for regulatory purposes as a raw agricultural commodity in both the fresh (green) and dried forms. Previously, green hops have been considered a raw agricultural commodity (RAC), while dried hops have been classified as a processed food. EPA intends to apply this revised classification in all future regulatory actions involving hops, including those under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

I. BACKGROUND

Under the FFDCA, EPA sets tolerances for pesticide residues in RACs under section 408 and in processed foods and feeds under section 409. If pesticide residues concentrate in a processed food above the RAC tolerance level, the "flow-through" exception of section 402 does not apply, and a section 409 tolerance is needed. Under section 408, EPA may establish a section 408 RAC tolerance based upon risk/benefit principles. However, under the Delaney clause of section 409, EPA may not establish a section 409 tolerance for a pesticide that induces cancer in man or animal in a processed food, regardless of the level of risk presented by the pesticide residues.

Under longstanding EPA (and prior FDA) policy, hops have been treated as a RAC in their fresh form, and as a processed food in their dried form. Thus, when residues concentrate in the drying process, the dried hops require a section 409 tolerance. If the pesticide in question induces cancer in man or animals, the Delaney Clause prohibits the establishment of the section 409 tolerance for residues in dried hops. Moreover, under current EPA policy, if a section 409 tolerance is needed on the (processed) dried hops, but cannot be granted, EPA will neither establish a tolerance on the green hops nor register the



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pesticide under FIFRA for use on growing hops. The practical result is that, without needed tolerances on dried hops, a pesticide may not be registered for use on growing hops.

II. HOPS

EPA has been considering for some time whether dried hops are properly classified as a processed food. The FFDCA defines a RAC as "food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing." Elsewhere the FFDCA lists canning, cooking, freezing, dehydration, and milling as examples of processing activities for RACs.

Hops are a unique commodity, used almost exclusively as a flavoring agent for beer. Harvested in a fresh form (green hops), they are immediately dried in kilns. This on-farm drying is necessary to prevent spoilage and always occurs prior to the shipment of the dried hops to beer manufacturers. While the drying of hops is, in the most general sense, a form of dehydration, both EPA and FDA have traditionally treated many forms of dried or partially dried food as RACs, e.g., peanuts, grains. Hops growers, both domestic and international, have asserted that dried hops should be considered a RAC because the drying process takes place immediately upon harvest, before the hops leave the farm or enter commerce, i.e., "prior to marketing."

III. CONGRESSIONAL DIRECTIVE

On October 28, 1993, President Clinton signed Public Law 103-124, the appropriations act including EPA funding for FY94, which contains language directly addressing the status of hops:

None of the funds provided for in this Act may be used within the Environmental Protection Agency during any period of fiscal year 1994 to classify or conduct any activities resulting from the classification of hops as a processed commodity for the purposes of administering regulation pursuant to the Federal Food, Drug, and Cosmetic Act . . . and the Federal Insecticide, Fungicide, and Rodenticide Act . . .

In the Congressional report accompanying the bill, the Senate Appropriations Committee clearly indicated its belief that EPA has erroneously construed existing law in classifying dried hops as a processed food:

Dried hops have been misclassified by EPA for years as a processed commodity in the administration of regulations dealing with pesticide use, rather than what the Committee believes to be their proper classification as a raw agricultural commodity. . . . The provision in the bill is designed to correct the misclassification of dried hops by EPA and rightly classify dried hops as a raw agricultural commodity . . .

IV. EPA ACTIONS TO IMPLEMENT THE CONGRESSIONAL DIRECTIVE

Because EPA agrees with Congress' view of the proper interpretation of the term RAC, EPA is by this notice changing its classification of dried hops. This section explains the regulatory and procedural implementation of this classification.

- A. **Revision of Pesticide Assessment Guidelines.** By this notice, EPA is revising its Pesticide Assessment Guidelines (Subdivision O) to specify that dried hops are a raw agricultural commodity.
- B. **New petitions for tolerance.** EPA will review petitions for tolerances for dried hops under the provisions of FFDCA sec. 408. This means that:
 1. New petitions for hops tolerances should be submitted in accordance with procedures in 40 CFR 180.7, including appropriate fees under § 180.33.
 2. Residue data are no longer required for green hops; residue data are required for dried hops only. EPA intends to establish tolerances only on the RAC dried hops in the future, and no longer needs residue data on both to determine whether residues concentrate or not upon drying of the green hops.
- C. **Pending petitions for tolerance.** EPA will evaluate currently pending petitions for section 409 tolerances for dried hops under FFDCA sec. 408 (40 CFR Part 180). petitioners are not required to take any action to modify such petitions, such as submitting revised proposed tolerances. No fees are required. If a current petition proposes tolerances separately for green and dried hops, EPA will establish only the dried hops tolerance under section 408. At least two pesticide petitions for hops—for fosetyl-Al and bifenthrin—are currently pending, and have been for some time awaiting resolution of the classification of hops. EPA intends to propose these tolerances under section 408 in the very near future.
- D. **Existing tolerances for green and dried hops.** EPA intends to replace section 409 tolerances for dried hops with section 408 tolerances as time and resources permit. Until that time, section 409 tolerances will remain in effect for enforcement purposes. Dried hops bearing residues at or below the established section 409 tolerance level in Part 185 will not be considered adulterated under the FFDCA. Any person seeking to replace a section 409 tolerance in Part 185 with a section 408 RAC tolerance in Part 180 may submit a petition to establish such a tolerance, and may concurrently request the revocation of the section 409 tolerance.
- E. **FIFRA section 18 exemptions.** EPA's reclassification of hops will be applied in all regulatory actions, including those under FIFRA. In a policy issued on May 7, 1993, EPA announced that it would deny certain pending section 18 exemptions and revoke existing section 18 exemptions. EPA adopted this policy because, as explained in Section I above,

the Delaney Clause prohibition on establishment of section 409 tolerances for pesticides that induce cancer in man or animal precludes a demonstration of "progress toward registration" for such pesticides, as required by EPA regulations implementing FIFRA sec. 18 (40 CFR 166.25). Today's notice does not change that policy.

However, because of the reclassification of dried hops as a RAC, the reason for the denial of emergency exemptions for hops under the May 7, 1993, policy no longer exists. States who seek section 18 exemptions for use on hops are no longer precluded from demonstrating progress toward registration. Accordingly, EPA's policy of May 7 no longer applies to requests for exemptions for hops uses. EPA may deny such section 18 exemptions for other reasons, but will not deny them because of Delaney prohibitions.

V. IMPLEMENTATION

EPA will consider this revised classification of hops in all future regulatory decisions involving hops. Before amending any existing regulations or establishing new tolerances for hops, EPA will seek public comment.

VI. FOR FURTHER INFORMATION

- General questions on this policy may be directed to Jean Frane, Policy and Special Projects Staff, Office of Pesticide Programs, at 703-305-5944.
- Questions concerning individual pesticide petitions should be directed to Product Managers in the Registration Division.
- Questions on section 18 exemptions may be directed to Rebecca Cool of the Emergency Response and Minor Use Section, Registration Division, at 703-308-8417.


Douglas D. Campt, Director
Office of Pesticide Programs