

Carbofuran Cancellation Process¹

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This EDIS publication provides a brief history of carbofuran's use in the United States, describes risks associated with carbofuran use, and outlines the U.S. Environmental Protection Agency's (EPA) stated rationale for revoking its regulations that have allowed carbofuran residues in food. This publication also describes the EPA's plans announced in 2008 to cancel the pesticide's registration due to risks carbofuran poses to pesticide applicators and to birds in treated fields.

Carbofuran Background

Carbofuran is a carbamate insecticide/nematicide, first registered in the United States in 1969. Carbofuran is classified as a restricted-use pesticide due to acute oral and inhalation toxicity. Carbofuran inhibits cholinesterase enzymes, affecting nerve-impulse transmission. Several formulations of the trade product, Furadan[®], are currently available (Figure 1). Although carbofuran has various registered uses, some of the commodities carbofuran is applied to in Florida include potato, corn, sugarcane, and cotton.

In the late 1990s, to reduce risks posed to drinking water and the natural environment due to carbofuran use, the manufacturer, Food Machinery

and Chemical Corporation (FMC), made a number of changes to labels for flowable carbofuran. These changes included reducing the label-allowed application rates and numbers of applications.



Figure 1. Furadan 4F is an example of a carbofuran trade product currently on the market. Credits: Crop Data Management System (CDMS)

To date, three human studies have been conducted for carbofuran – one oral and two dermal. In May 2006, these studies were reviewed by the EPA's Human Studies Review Board (HSRB). The Board concluded that, while the studies were informative, the results are not appropriate for use by the EPA in either the individual carbofuran or carbamate cumulative risk assessment. The EPA did not use the results of the human studies in the risk assessment for carbofuran. Carbofuran is classified by the EPA as “Not Likely” to be a human carcinogen.

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Ecological Effects

Carbofuran is:

- Very highly toxic to birds on an acute basis and highly toxic on a sub-acute basis. A chronic-effect level could not be established because all concentrations tested caused mortality in the test subjects.
- Highly toxic to mammals on an acute basis. Chronic toxicity testing on laboratory rats showed reduced offspring survival and body-weight reductions.
- Very highly toxic to freshwater and estuarine/marine fish on an acute basis. The available chronic test showed larval survival as the most sensitive endpoint for freshwater fish. Embryo hatching was indicated as the most sensitive endpoint for estuarine/marine fish.
- Very highly toxic to freshwater and estuarine/marine invertebrates on an acute basis. Chronic tests showed reproductive effects.

Pesticide Reregistration

All pesticides sold or distributed in the United States must by law be registered by the EPA, based on scientific studies showing that the pesticide can be used without posing unreasonable risks to people or to the environment. Additionally, the Food Quality Protection Act (FQPA) of 1996 protects the public from health risks presented with exposure to excessive pesticide residues in/on foods and everyday surroundings, such as in the home and at places of employment. This FQPA amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) with respect to the EPA's process of establishing tolerances for pesticide residues in food and in the atmosphere. As a result, pesticides first registered by the EPA before November 1, 1984, must be reregistered to ensure that the pesticides meet today's more-stringent standards, which are due to advances in scientific knowledge.

In evaluating pesticides for reregistration, EPA obtains and reviews comprehensive studies from pesticide producers describing each pesticide's effects

to human health and the environment. To implement provisions of the Food Quality Protection Act (FQPA) of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity.

EPA develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet current standards for human health and safety. According to the EPA, these are the pesticides that can be used without posing unreasonable risks to human health and the environment.

When a pesticide is eligible for reregistration, EPA explains in a Reregistration Eligibility Decision (RED) reasons for the decision on whether to reregister the pesticide or cancel registration for the pesticide.

Tolerance Revocation

Due to considerable risks associated with carbofuran in food and drinking water, EPA is revoking its regulations that have allowed carbofuran residues in food. Because dietary exposures to infants and children are of particular concern, the EPA is moving to revoke carbofuran tolerances first, before cancelling carbofuran registrations. This approach provides the most direct and timely means to realize protection of children from dietary risks. It also allows multiple stakeholders an additional opportunity to comment.

According to a statement released by the EPA on July 24, 2008, even though carbofuran is used on a small percentage of the U.S. food supply and therefore the likelihood of human exposure through food is low, EPA has identified risks that do not meet their rigorous food safety standards. EPA is taking the necessary steps to address these risks to ensure that the U.S. has the safest food supply possible. Children and others should continue to eat a variety of foods, as recommended by the federal government and nutritional experts.

In a Federal Register notice signed in July 2008, EPA is proposing to revoke all U.S. carbofuran tolerances. EPA specifically will request comment on whether any individual carbofuran tolerances, or group of tolerances, meet the Federal Food, Drug, and Cosmetic Act (FFDCA) safety standard. It is possible that one or more individual carbofuran tolerances could be maintained, if information is provided to demonstrate that the tolerance(s) would be safe.

Revoking carbofuran tolerances is part of a broader series of EPA actions to cancel all uses of carbofuran in the U.S. due to human dietary, occupational, and ecological risks of concern. After moving to revoke carbofuran tolerances, EPA subsequently plans to publish a Notice of Intent to Cancel all carbofuran registrations.

EPA establishes tolerances for pesticides that may be found on foods and can also revoke tolerances to better safeguard public health and the environment. The EPA must modify or revoke any tolerance that it determines is unsafe, that is, that does not meet the safety standard of the FFDCA. The EPA is proposing to revoke all tolerances for carbofuran because exposure through food and drinking water does not meet the FFDCA safety standard.

Voluntary Cancellation of Certain Uses

Following a public comment period, EPA granted a request from the registrant, FMC Corporation, for voluntary cancellation of certain uses of and products containing flowable and granular carbofuran effective March 18, 2009. All federally registered uses of carbofuran have been canceled except four food crop uses (field corn, potatoes, pumpkins and sunflowers) and two non-food crop uses (pine seedlings and spinach grown for seed). Certain state Special Local Need registrations are also being canceled, as requested. Existing stocks of the canceled products could be used until depleted, until December 31, 2009, the effective date for revocation of the associated food tolerances. Carbofuran products labeled for non-food uses (pine seedlings, spinach grown for seed) and voluntarily cancelled non-food use (ornamentals)

may continue to be used in accordance with label directions, including geographical restrictions.

Notice of Intent to Cancel (NOIC)

EPA also is proceeding on the path toward cancellation of carbofuran registrations, which will address risks to pesticide applicators and risk to birds in treated fields. In 2006, in addition to dietary risks, EPA identified significant occupational and ecological risks from the use of carbofuran. Although carbofuran uses have benefits, EPA concluded that carbofuran products pose an unreasonable risk to human beings and the natural environment, and these risks outweigh the benefits of continued use. Therefore, all uses of carbofuran must be cancelled.

In January 2008, EPA submitted for FIFRA Scientific Advisory Panel (SAP) and the U.S. Department of Agriculture (USDA) review a draft NOIC. After considering the SAP's responses and USDA's comments, EPA determined that cancellation remained warranted. EPA plans to issue a final carbofuran NOIC after taking steps to revoke the tolerances.

By law, EPA was required to reassess by August 2006 all tolerances that were in existence as of August 2, 1996. In August 2006, EPA published its conclusion that no carbofuran uses met the statutory standards and that, therefore, no carbofuran uses were eligible for reregistration. The EPA announced its intention to cancel all uses of carbofuran due to ecological and occupational risks of concern, as well as dietary risks from carbofuran residues on food crops and in contaminated drinking water.

After EPA issued the interim RED, the manufacturer, FMC, submitted for EPA review a number of studies addressing ecological and human dietary risk, as well as other informational documents. EPA reviewed all submitted data and documents, as well as additional data developed by the EPA's Office of Research and Development. While these submissions resulted in certain refinements to the assessment, EPA continues to assert that all uses of carbofuran should be canceled.

EPA may cancel a pesticide registration on their own initiative when the risks associated with use of the pesticide are unacceptable, and the registrants have not made necessary changes to the terms and conditions of registration to address the unacceptable risks. Because FMC has not requested voluntary cancellation to address the risks of carbofuran, EPA initiated the cancellation process under FIFRA guidelines.

Regulatory Conclusion

Based on the assessment of ecological and human health risks associated with carbofuran uses, the EPA has determined that all uses of carbofuran are ineligible for reregistration. EPA is proposing to retain tolerances for sugarcane, rice, bananas, and coffee for imported commodities.

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Additional Information

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