

US EPA ARCHIVE DOCUMENT



**U.S. Environmental Protection Agency
Office of Pesticide Programs**

Carbofuran Registration Review Status

December 2009

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Case 0101

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Date: 12-9-2009

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Introduction

The Food Quality Protection Act of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program pursuant to Section 3(g), and will review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data it believes are needed to make a registration review decision. In the case of carbofuran, the Agency's decision, finalized in the August 2006 Reregistration Eligibility Decision (RED) Document for carbofuran was that pesticide products containing the active ingredient carbofuran were not eligible for Reregistration. The regulatory process to implement that decision by tolerance revocation and registration cancellation is ongoing. The Agency will therefore not be opening a registration review docket for carbofuran. The Agency expects growers to successfully transition to the available alternative pesticides or cultural practices that pose fewer risks.

Status Update for Carbofuran

Final Decision and Tolerance Revocation:

This is the Environmental Protection Agency's status update for the registration review of carbofuran. Carbofuran is an N-methyl carbamate pesticide that poses health risks to humans and the environment.

In August 2006, after several public comment periods on the risk assessments, EPA announced that no uses of carbofuran were eligible for Reregistration. The following timeline lists actions relating to carbofuran registrations after the RED was completed on 2006.

- April-October 2007. Registrant submitted new data and information on carbofuran.
- January 2008. EPA published a draft Notice of Intent to Cancel (NOIC) and revised risk assessments and benefits analyses based on information received during 2007; and requested review by the FIFRA Scientific Advisory Panel (SAP) and the U.S. Department of Agriculture (USDA), as required by statute.
- February 2008. FIFRA SAP meeting on draft NOIC. As part of the process to cancel carbofuran registrations, the Agency presented the rationale for its decision, as well as reviews of new data submitted throughout 2007.
- March 2008. The SAP agreed with EPA's rationale. (*Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held February 5-8, 2008 on the Agency's Proposed Action under FIFRA 6(b) Notice of Intent to Cancel Carbofuran*).
- March 2008. USDA commented on the benefits analyses that EPA should consider pest resistance management, benefits on a local level, effects on consumers and trade, risks of alternative chemicals, emergency exemption issues, crops other than corn and potatoes, and should conduct a crop-by-crop benefits analysis.
- July 22, 2008. EPA responded to each of USDA's concerns.
- July 31, 2008. EPA proposed to revoke all tolerances for carbofuran (73 FR 44864).
- August 2008. EPA notified the World Trade Organization (WTO) that the Agency had proposed to revoke all carbofuran tolerances.
- March 18, 2009. EPA's product cancellation order confirmed and finalized the registrant's voluntary cancellation of some uses of carbofuran (74 FR 11551). Uses which have not been voluntary cancelled are: corn, sunflower, potato, pumpkin, spinach grown for seed and pine seedlings.
- May 15, 2009. The Agency issued its final rule revoking all tolerances for carbofuran (74 FR 23046) and addressing all public comments received on the proposed rule.
- May 2009. EPA notified the WTO that the Agency had revoked all carbofuran tolerances.
- October 30, 2009. FMC Corporation, the National Corn Growers Association, the National Sunflower Association, and the National Potato Council, jointly filed objections to EPA's tolerance revocations and a request for a hearing.
- November 18, 2009. EPA denied all objections and hearing requests and provided the rationale for each denial (74 FR 59608).
- November 19, 2009. The registrant filed a motion with the DC Circuit Court of Appeals requesting a stay of the Agency's decision and expedited review of the merits of the case.
- November 30, 2009. EPA filed a brief responding to FMC's motion.
- December 7, 2009. FMC responded to EPA's brief.

The DC Circuit Court of Appeals is in the process of considering FMC's motion.

As a result of EPA tolerance revocation actions, after December 31, 2009, food crops with residues of carbofuran will be considered adulterated, unless those food crops were treated with carbofuran prior to December 31, 2009. Use of carbofuran on voluntarily cancelled non-food crops according to label directions is allowed until stocks are depleted. Use on the non-food uses of pine seedlings and spinach grown for seed will be subject to any existing stocks provisions in the future cancellation order.

The final carbofuran Decision Document and supporting materials including all correspondence, reports, and risk assessments are available electronically at www.regulations.gov in docket number EPA-HQ-OPP-2005-0162. The draft NOIC and associated risk assessments, SAP charge questions, presentations by the Agency and the public, SAP report and the Agency's response can be found in the SAP docket number EPA-HQ-OPP-2007-1088.

Anticipated Actions

As many uses of carbofuran have already been voluntarily cancelled, and all tolerances have been revoked, the Agency will be proceeding to finalize the draft Notice of Intent to Cancel of January 2008 and cancel all remaining carbofuran products and uses due to risks to applicators and wildlife.