2,4-D, 2,4-DP, and 2,4-DB; Decision Not to Initiate Special Review

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[Notices]
[Page 44510-44511]
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ENVIRONMENTAL PROTECTION AGENCY
[EPA-HQ-OPP-2007-0434; FRL-8133-9]

2,4-D, 2,4-DP, and 2,4-DB; Decision Not to Initiate Special Review

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: This notice announces EPA's Decision Not to Initiate a Special Review for 2,4-D, 2,4-DB and 2,4-DP. Based on extensive scientific review of many epidemiology and animal studies, the Agency finds that the weight of the evidence does not support a conclusion that 2,4-D, 2,4-DB and 2,4-DP are likely human carcinogens. The Agency has determined that the existing data do not support a conclusion that links human cancer to 2,4-D exposure. This conclusion applies to 2,4-DB and 2,4-DP because they were considered for Special Review based solely on their similarity to 2,4-D. In addition, because they are used significantly less than 2,4-D, their contribution to exposure is minimal relative to 2,4-D. Because the Agency has determined that the existing data do not support a conclusion that links human cancer to 2,4-D exposure, the Agency is not initiating a Special Review of 2,4-D, 2,4-DB and 2,4-DP. This decision was first proposed on March 23, 1988 (53 FR 9590).

FOR FURTHER INFORMATION CONTACT: Richard P. Dumas, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8015; fax

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0434. Publicly available docket materials are available either in the electronic docket at http://www.regulations.gov, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Drive Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Facility Docket telephone number is (703) 305-5805.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the ``Federal Register'' listings at http://www.epa.gov/fedrgstr/.

II. Background

A. What Action is the Agency Taking?

On September 22, 1986, the Agency issued a preliminary notification of Special Review of 2,4-D. Because of their similarity to 2,4-D, on December 3, 1986, EPA issued preliminary notifications of Special Review of 2,4-DB and 2,4-DP. These notices were issued because of concerns for epidemiological links of 2,4-D, 2,4-DB and 2,4-DP to non-Hodgkin's lymphoma from both occupational and residential exposure. A proposed decision Not to Initiate Special Review was published on March 23, 1988 ((53 FR 9590; FRL-3353-3)) based on findings that such a link is not supported by the existing data. Two sets of comments were received in response to the proposal, both on behalf of the 2,4-D Task Force. Both sets supported the proposed decision, but questioned the need for a new cancer study. The latter point is moot because the registrant ultimately conducted and submitted an acceptable cancer study. The final decision was deferred until a more comprehensive review of 2,4-D was completed. This review was completed with the signature of the Reregistration Eligibility Decision for 2,4-D in June of 2005.

To address the potential link of non-Hodgkin's lymphoma to 2,4-D exposure, a joint Science Advisory Board/Scientific Advisory Panel Special Joint Committee was convened to review available epidemiological and other data on 2,4-D. In 1992, the Committee concluded that ``the data are not sufficient to conclude that there is

a cause and effect relationship between exposure to 2,4-D and non-Hodgkin's lymphoma.'' 2,4-D was classified as a Group D, ``not classifiable as to human carcinogenicity.'' To help better inform the Agency, EPA requested further histopathological examinations of mouse and rat tissue from previously conducted studies. These exams were submitted and reviewed, and on March 16, 1999, the Agency notified the 2,4-D Task Force that the EPA would continue to classify 2,4-D as a Group D carcinogen.

The Agency has twice recently reviewed epidemiological studies linking cancer to 2,4-D exposure. In the first review, completed January 14, 2004, EPA concluded there is no additional evidence that would implicate 2,4-D as a cause of cancer (EPA, 2004). The second review of available epidemiological studies occurred in response to comments received during Phase 3 of the Public Participation Process for the 2,4-D RED. EPA's report, dated December 8, 2004, found that none of the more recent epidemiological and animal studies support a conclusion that 2,4-D, 2,4-DB and 2,4-DP are likely human carcinogens. Because the Agency has determined that the existing data do not support a conclusion that links human cancer to 2,4-D exposure, it has decided not to initiate a Special Review of 2,4-D, 2,4-DB and 2,4-DP.

B. What is the Agency's Authority for Taking this Action?

A pesticide product may be sold or distributed in the United States only if it is registered or exempt from registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended (7 U.S.C. 136 et seq.). Before a product can be registered it must be shown that it can be used without causing ``unreasonable adverse effects on the environment,'' FIFRA section 3(c)(5). The term ``unreasonable adverse effects on the environment'' is defined in FIFRA section 2(bb) as ``any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.'' The burden of proving that a pesticide meets this standard for registration is, at all times, on the proponent of initial or continued registration. If at any time the Agency determines that a pesticide no longer meets this standard, the Administrator may cancel this registration under section 6 of FIFRA.

The Special Review process provides a mechanism to permit public participation in EPA's deliberations prior to issuance of any Notice of Final

[[Page 44511]]

Determination describing the regulatory action which the Administrator has selected. The Special Review process, which was previously called the Rebuttable Presumption Against Registration (RPAR) process, is described in 40 CFR part 154, published in the Federal Register of November 27, 1985 (50 FR 49003, 49015; FRL-2914-6). The purpose of this process is to determine whether some or all registrations of a particular active ingredient or ingredients meet the FIFRA standard for registration, or whether amendment of the terms and conditions of registration or cancellation of portions or all of the registrations is appropriate.

Prior to formal initiation of a Special Review, a preliminary

notification is sent to registrants and applicants for registration pursuant to 40 CFR 154.21 announcing that the Agency is considering commencing a Special Review. Registrants and applicants for registration are allowed 30 days from receipt of the notification to comment on the Agency's proposal to commence a Special Review.

If the Agency determines, after issuance of a notification pursuant to 40 CFR 154.21, that it will not conduct a Special Review, it is required under 40 CFR 154.23 to issue a proposed decision to be published in the Federal Register. That regulation requires that a period of not less than 30 days be provided for public comment on the Proposed Decision Not to Initiate a Special Review. Subsequent to receipt and evaluation of comments on the Proposed Decision Not to Initiate a Special Review, pursuant to 40 CFR 154.25 the Administrator must publish in the Federal Register his final decision regarding whether or not to initiate a Special Review. As discussed above, the Agency previously published a notice pursuant to 40 CFR 154.23 for these compounds, considered public comments and has decided not to initiate the Special Review under 40 CFR 154.25(b).

List of Subjects

Environmental protection, Pesticides and pest.

Dated: July 30, 2007.

James B. Gulliford,

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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Notices For 2008 2007 2006 2005 2004 2003 2002 2001 2000 1999 1998 1997 1996 1995 1994