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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2015-0794; FRL-9940-41]

Registration Review; Draft Human Health and Ecological Risk Assessments; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's draft human health and ecological risk assessments for the registration review of a group of pesticides identified individually in this document in the table in Unit III, and opens a public comment period. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed a comprehensive draft human health and ecological risk assessment for the identified pesticides. After reviewing comments received during the public comment period on each assessment, EPA may issue revised risk assessments and explain any changes to the draft risk assessments, and respond to substantive comments on the risk assessments. EPA may also request public input on risk mitigation before completing a proposed registration review decision for the identified pesticides. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0794, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact*: The Chemical Review Manager (CRM) identified in the table in Unit III.

For general questions on the registration review program contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8015; email address: *dumas.richard@epa.gov*.

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, farm worker, and agricultural advocates;

the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others may also 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 Chemical Review Manager listed in the table in Unit III.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/commenting-epa-dockets#tips*.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document compared to the general population.

II. Authority

EPA is conducting its registration review of these pesticides pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations for the pesticides listed in the table to ensure that they continue to satisfy the FIFRA standard for registration—that is, that these pesticides can still be used without unreasonable adverse effects on human health or the environment.

Table–Draft Risk Assessments Being Made Available for Public Comment

Registration Review Case Name and Number	Docket ID Number	Chemical Review Manager and Contact Information
Azoxystrobin 7020	EPA-HQ-OPP-2009-0835	Veronica Dutch *dutch.veronica@epa.gov* (703) 308-8585
Bensulfuron-methyl 7216	EPA-HQ-OPP-2011-0663	Moana Appleyard *appleyard.moana@epa.gov* (703) 308-8175
Bifenazate 7609	EPA-HQ-OPP-2012-0633	Garland Waleko *waleko.garland@epa.gov* (703) 308-8049
Boric Acid and Sodium Borate Salts 0024	EPA-HQ-OPP-2009-0306	Moana Appleyard *appleyard.moana@epa.gov* (703) 308-8175
Ethephon	EPA-HQ-OPP-2010-0098	Marquea D. King

0382		*king.marquea@epa.gov* (703) 305-7432
Hymexazol 7016	EPA-HQ-OPP-2010-0127	Caitlin Newcamp *newcamp.caitlin@epa.gov* (703) 347-0325
Lithium hypochlorite 3084	EPA-HQ-OPP-2013-0606	Donna Kamarei *kamarei.donna@epa.gov* (703) 347-0443
Pronamide 0082	EPA-HQ-OPP-2009-0326	Wilhelmena Livingston *livingston.wilhelmena@epa.gov* (703) 308-8025

Azoxystrobin. Draft Human Health and Ecological Risk Assessments (EPA-HQ-OPP-2009-0835). Azoxystrobin is a systemic fungicide and antimicrobial registered for use on a variety of terrestrial food and feed crops, including vegetables, fruits and nuts; terrestrial non-food crops, including turf and ornamentals; and non-crop sites including additives for the manufacture of paint, rubber, paper products, textiles, and adhesives. The Agency has conducted draft human health and ecological risk assessments for the conventional and antimicrobial uses of azoxystrobin. A full endangered species assessment has not been completed for azoxystrobin at this time. For foliar applications, the ecological risk assessment identifies risks of concern for aquatic plants, freshwater fish, aquatic invertebrates, and mammals. For seed treatments, risks of concern are identified for birds and mammals. The conventional uses of azoxystrobin are associated with inhalation risks of concern for residential handlers and some occupational post-application scenarios even with maximum personal protective equipment (PPE). The antimicrobial uses of azoxystrobin are not associated with ecological risks of concern, but the human health risk assessment identifies potential risks of concern for residential and occupational handlers. Azoxystrobin has not been assessed under the endocrine disruptor screening program (EDSP) or for risks to pollinators.

Bensulfuron-methyl. Draft Human Health Risk Assessment (EPA-HQ-OPP-2011-0663). Bensulfuron-methyl is a sulfonylurea herbicide that acts by inhibiting acetolactate synthase.

Bensulfuron-methyl is registered for use to control broadleaf weeds and sedges in aquatic rice production. Tolerances have been established for crayfish, rice, and rice straw. There are no registered residential uses of bensulfuron-methyl. Bensulfuron- methyl was first registered in 1989, and a Final Work Plan was published in February 2012. The ecological risks of bensulfuron-methyl were assessed together with all other sulfonylureas in the Preliminary Ecological Risk Assessment for Registration Review of 22 Sulfonylurea Herbicides, published in September 2015. EPA conducted a human health risk assessment and did not identify any risks of concern for dietary, residential, occupational, or aggregate exposure. Bensulfuron-methyl was not on either initial list of chemicals to be screened under the EDSP, nor has an endangered species or pollinator assessment been conducted at this time.

Bifenazate. Draft Human Health and Ecological Risk Assessments (EPA-HQ-OPP-2012-0633). Bifenazate is a selective carbazate miticide/insecticide that is registered for use to control the motile stage of mites in agricultural and non-agricultural sites including on bearing and non-bearing fruit and vegetable crops, cotton, conifer plantations, ornamentals, and in greenhouses, as well as indoor and outdoor residential, commercial, institutional, and recreational areas. The human health non-occupational drift assessment was updated in registration review for bifenazate and found no risks of concern. In the recent June 2014, new use assessment, all dietary, residential, occupational, and aggregate risks were not of concern. In the ecological assessment, chronic risks of concern were identified for mammals and birds. There are acute risks identified for listed birds, freshwater fish, freshwater invertebrates, and estuarine and marine invertebrates. There is also potential acute and chronic risk to terrestrial invertebrates. Bifenazate was not on either initial list of chemicals to be screened under the EDSP, nor has an endangered species or pollinator assessment been conducted at this time.

Boric Acid and Sodium Borate Salts. Draft Human Health and Ecological Risk Assessments (EPA-HQ-OPP-2009-0306). Boric acid and its sodium salts are inorganic compounds with registrations for use as active ingredients in insecticides, acaricides, herbicides, algaecides, fungicides, and wood and material preservatives. In small quantities, boron is an essential nutrient for aquatic vertebrates and invertebrates and plants. There is also evidence that boron is essential or, if not essential, beneficial in birds and mammals, in small quantities. Boric acid and its sodium salts are also present as inert ingredients in pesticide products and as ingredients in non-pesticide consumer products. The Agency issued a Final Work Plan for boric acid in October 2009. The ecological risk assessment identifies potential risks to terrestrial invertebrates, birds, mammals, reptiles, terrestrial-phase amphibians, aquatic organisms, and terrestrial plants. For birds and mammals, risk is primarily associated with the granular formulations and bait uses. For aquatic organisms, risk is primarily associated with discharge of swimming pool, hot tub, and spa effluent directly to surface waters, to storm drains, roadways, and potentially from storage of treated wood. For terrestrial plants, risk is primarily associated with discharge of effluent from swimming pools, hot tubs, and spas. The human health risk assessment did not identify risks of concern. Boric acid was not on either initial list of chemicals to be screened under the EDSP, nor has an endangered species or pollinator assessment been conducted at this time.

Ethephon. Draft Human Health and Ecological Risk Assessments (EPA-HQ-OPP-2010-0098). Ethephon, 2-chloroethylphosphonic acid, is an organophosphonate plant growth regulator intended to promote fruit ripening, abscission, flower induction, breaking of apical dominance (inhibition of the growth of lateral buds by the terminal bud of a shoot), and other plant responses through the release of ethylene gas, a natural plant hormone. EPA conducted a human health risk assessment and identified aggregate risks of concern for children ages 1-2

years old. EPA also conducted an ecological risk assessment and identified potential risks to birds, mammals, and non-target plants. A full endangered species assessment has not been completed for ethephon at this time. At this time, ethephon has not been evaluated for its potential to affect endocrine systems in mammals and wildlife, nor has an assessment of risks to pollinators been conducted.

Hymexazol. Draft Human Health and Ecological Risk Assessments (EPA-HQ-OPP-2010-0127). Hymexazol is a systemic fungicide for control of foliar and soil-borne plant diseases. There is only one existing registration as a commercial seed treatment for sugar beets. Hymexazol may be applied only using commercial seed treatment equipment. A Final Work Plan for hymexazol was published by the Agency in September 2010, and data were then required in a generic data call-in, dated October 2011. The reviews of the required data have been incorporated into the draft risk assessments. The Draft Human Health Risk Assessment identified no dietary risks of concern but identified potential risk to occupational workers (individuals treating/mixing seed and individuals doing multiple activities). The Draft Ecological Risk Assessment identified potential risks to mammals and birds. Hymexazol was not on either initial list of chemicals to be screened under the EDSP, and a complete endangered species assessment has not been conducted at this time.

Lithium hypochlorite. Draft Ecological Risk Assessment (EPA-HQ-OPP-2013-0606). Lithium hypochlorite is an algicide, disinfectant, and fungicide. Its primary pesticidal use is to control algae, bacteria, and mildew in swimming pool water systems, hot tubs, and spas. EPA conducted a qualitative ecological risk assessment on the swimming pool uses of lithium hypochlorite as part of registration review. EPA previously conducted human health and ecological risk assessments at the time of the Reregistration Eligibility Decision (RED) for lithium hypochlorite in 1993. Lithium hypochlorite was not on either initial list of chemicals to be

screened under the EDSP, and an endangered species assessment has not been conducted at this time.

Pronamide. Draft Human Health and Ecological Risk Assessments (EPA-HQ-OPP-2009-0326). Pronamide, also called propyzamide, 3,5-dichloro-N-(1,1-dimethyl-2-propynyl)benzamide, is a selective, systemic, pre-and post-emergence herbicide registered for the control of grasses and broadleaf weeds in several food and feed crops as well as woody ornamentals, Christmas trees, grasses grown for seed or turf (sod), golf course turf, recreational area turf, and fallow land. EPA conducted a human health risk assessment and did not identify any risks of concern for dietary, residential, occupational, or aggregate exposure. EPA also conducted an ecological risk assessment and identified potential risks to birds, mammals, and plants. An endangered species and pollinator assessment has not been completed for pronamide at this time. Pronamide was evaluated for its potential to affect endocrine systems in mammals and wildlife and the results of the Agency's review are found in the weight of evidence review in this registration review docket.

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's draft human health and ecological risk assessments for the pesticides identified in this document. Such comments and input could address, among other things, the Agency's risk assessment methodologies and assumptions, as applied to this draft risk assessment. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to the draft human health and ecological risk assessments. EPA may then issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments. In the **Federal Register** notice announcing the availability of the revised risk assessment, if the revised risk assessment indicates risks of concern, the Agency may provide a

comment period for the public to submit suggestions for mitigating the risk identified in the revised risk assessment before developing a proposed registration review decision on the pesticides identified in this document.

1. *Other related information*. Additional information on pesticides identified in this document is available on the Pesticide Registration Review Status webpage. Information on the Agency's registration review program and its implementing regulation is available at *http://www.epa.gov/pesticide-reevaluation/registration-review-process*.

2. *Information submission requirements*. Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

• To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.

• The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

• Submitters must clearly identify the source of any submitted data or information.

• Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

Authority: 7 U.S.C. 136 *et seq*.

Dated: December 24, 2015.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

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