Urea TRED

[Federal Register: April 15, 2002 (Volume 67, Number 72)]
[Notices]
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From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr15ap02-71]

ENVIRONMENTAL PROTECTION AGENCY
[OPP-34255; FRL-6860-6]

Urea; Notice of Pesticide Report on FQPA Tolerance Reassessment Progress

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

SUMMARY: This notice constitutes the Agency's report on the Food Quality Protection Act (FQPA) tolerance reassessment progress for urea, announces the Agency's tolerance reassessment decision, and releases the science assessment for tolerance reassessment decision and related documents supporting this decision to the public. The Agency's reassessment of dietary risk, including public exposure through food and drinking water as required by the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by FQPA, indicates that urea poses no risk concerns within the limits of the existing exemptions; therefore, no risk mitigation is needed. There will be no changes to the 78 urea exemptions from the requirement of a tolerance as a result of this reassessment decision. EPA views this action as noncontroversial and anticipates no adverse comments. By law, EPA is required by August 2002 to reassess 66% of the tolerances in existence on August 2, 1996, or about 6,400 tolerances. EPA is counting 78 exemptions from the requirement of a tolerance as reassessments made toward the August 2002 review deadline.

DATES: Comments, identified by docket control number OPP-34255, must be received on or before May 15, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-34255 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph Nevola, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8037; and e-mail address: nevola.joseph]@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or the Federal Food, Drug, and Cosmetic Act (FFDCA); environmental, human health, and agricultural advocates; pesticides users; and members of the public interested in the use of pesticides. Since other entities 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 person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ``Laws and Regulations,'' ``Regulations and Proposed Rules,'' and then look up the entry for this document under the ``Federal Register --Environmental Documents.'' You can also go directly to the Federal Register listings at http://www.epa.gov/fedrgstr/. In addition, copies of documents related to the Agency's report on FQPA tolerance reassessment progress for urea released to the public may also be accessed at http://www.epa.gov/pesticides/reregistration/status.htm.

2. In person. The Agency has established an official record for this action under docket control number OPP-34255. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity

Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. How Can I Respond to this Action?

A. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-34255 in the subject line on the first page of your response.

1. By mail. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. In person or by courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. Electronically. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/ 8.0/9.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-34255. Electronic comments may also be filed online at many Federal Depository Libraries.

B. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have

any questions about CBI or the procedures for claiming CBI, please consult the person identified under FOR FURTHER INFORMATION CONTACT.

III. Report on FQPA Tolerance Reassessment Progress

A new registration for urea was approved on August 23, 1995, with an approved label date of February 20, 1996, for use as an active ingredient (frost protectant) to reduce ice formation by ice-nucleating bacteria which are naturally present on leaf surfaces. Tolerance exemptions associated with that frost protectant use are codified in 40 CFR 180.1117. Exemptions associated with uses of urea as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, in pesticide formulations applied to growing crops only, and in pesticide formulations applied to animals are codified in 40 CFR 180.1001(c), (d), and (e), respectively. Therefore, exemptions associated with use of urea as an active and inert ingredient are subject to reassessment in accordance with FFDCA as amended by FQPA. FQPA requires EPA to re-evaluate existing tolerances/exemptions to ensure that children and other sensitive subpopulations are protected from pesticide risk.

The Agency has completed its assessment of the dietary risk of urea, and has determined that the level of dietary risk from exposure as a result of the currently registered uses of urea is not of concern. Therefore, no mitigation measures are needed and no further actions are warranted at this time. Urea does not pose unreasonable adverse effects to the environment when used according to its approved labeling. In addition, EPA finds that there is a reasonable certainty that no harm will result from aggregate exposure to the urea residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA considers a total of 78 exemptions from the requirement of a tolerance, 75 exemptions in 40 CFR 180.1117 and 3 exemptions in 180.1001, to be reassessed under FQPA. All of those 78 exemptions were found to meet the FQPA safety standard.

The risk assessment and other documents pertaining to the reassessment of the urea exemptions from a requirement of a tolerance are available on the Internet at http://www.epa.gov/pesticides/reregistration/status.htm and the public docket for viewing (see Unit I.B.2).

This notice of a tolerance reassessment for urea starts a 30-day public comment period during which the public is encouraged to submit comments on the Agency's risk assessment and tolerance exemption reassessment. The Agency is providing an opportunity, through this notice, for interested parties to comment in accordance with procedures described in Unit II. of this document. All comments will be carefully considered by the Agency. If any comment causes the Agency to revise its decision on reassessment of these exemptions from the requirement of a tolerance, EPA will publish notice of its amendment in the Federal Register.

The legal authority for tolerance reassessment is provided by FFDCA, as amended in 1996. Section 408(q) of FFDCA directs that:

The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the FQPA of 1996, as expeditiously as practicable, assuring that--66% of such tolerances and exemptions are reviewed within 6 years (i.e., by August 3, 2002) of the date of enactment of such Act (i.e., on August 3, 1996), and--shall determine whether the tolerance or exemption meets the requirements of sections 408(b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under section 408(d)(4) or (e)(1) to modify or revoke the tolerance or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

Under section 408 of the FFDCA, a tolerance may only be maintained if EPA determines that the tolerance is safe based on a number of factors, including an assessment of the aggregate exposure to the pesticide and an assessment of the cumulative effects of such pesticide and other substances that have a common mechanism of toxicity. In section 408(b)(2), the term ``safe,'' with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

IV. Background

Urea is an active ingredient in only one active registration, where it is used

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as a frost protectant. The exemptions associated with urea use as a frost protectant are found at 40 CFR 180.1117. For counting purposes, there are 75 commodities exempt from the requirement of a tolerance (squash, winter and summer, counts as two; cotton counts as three because it also includes hay and seed; and casaba, crenshaw, and persian melon, count as one entry).

Urea is also present in certain pesticide formulations as an inert ingredient where it is used as a stabilizer, an inhibitor, and as an adjuvant/intensifier for herbicides. One exemption for urea from the requirement of a tolerance when used as a stabilizer or inhibitor is found in 40 CFR 180.1001(c) for inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. Another exemption for urea when used as an adjuvant/intensifier for herbicides is found in 40 CFR 180.1001(d) for inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only. In addition, an exemption for urea when used as a stabilizer or inhibitor is found in 40 CFR 180.1001(e) for inert (or occasionally active) ingredients in pesticide formulations applied to animals.

Urea is a naturally occurring compound in humans and is approved for several therapeutic uses in humans with relatively few toxicities. In addition, urea is considered Generally Recognized As Safe

(GRAS) by the U.S. Food and Drug Administration (FDA) for use in food. Urea is included in ``Direct Food Substances Affirmed as Generally Recognized as Safe'' (21 CFR 184.1923), where the affirmation of GRAS as a direct human food ingredient is based on current good manufacturing practice and conditions of use as a formulation and fermentation aid.

EPA has reaffirmed data waivers granted for all subchronic, chronic, developmental, reproduction, mutagenicity, and metabolism studies based on available data from literature studies concerning urea. A recent search of the published scientific literature concerning urea since 1980 showed no basis for toxicological concern.

V. Use Summary

Urea was registered by EPA in 1995 for use as a frost protectant pesticide under the trade name Enfrost. Enfrost is a 43% liquid formulation of urea that can be applied commercially to a wide variety of field crops, vegetables, fruit trees and ornamentals to reduce frost damage. There are currently no residential uses for urea as a pesticide product. Enfrost is the only currently registered pesticide product containing urea as an active ingredient. Enfrost provides frost protection by modifying the protein produced by ice-nucleating bacteria. Enfrost has not been actively produced or sold by the registrant, Entek Corporation, since 1995. However, the registrant wishes to maintain active registration of Enfrost for potential future production and use.

In addition to its use as a frost protectant, urea is used as an inert pesticide ingredient as a stabilizer, inhibitor, or intensifier. Also, several million tons of urea are produced annually for use in fertilizer and as an animal feed supplement. Moreover, urea is used in the manufacture of dyes, fire retardant paints, plasticizers, and stabilizers for explosives.

VI. Hazard Characterization

With the exception of six acute toxicity studies submitted by the registrant, the urea toxicity data base is comprised of the available literature data. These data are considered by the Agency to be sufficient to assess the potential hazard to humans, including special sensitivity of infants and children.

1. Acute toxicity. The six acute toxicological studies indicate that the frost protectorant is a slight eye irritant and has a low toxicity to animals when administered via the oral, dermal, or inhalation routes of exposure.

2. Subchronic toxicity. Urea produced no severe toxicity in dogs injected subcutaneously with 30-40 milliliters/kilograms/day (mL/kg/ day) of 10% urea solution for 45 days. With plasma levels ranging from 200-700 mg/100 mL (10 to 30-fold above normal), the only clinical symptoms observed were drowsiness and diuresis. Necropsy indicated no adverse organ pathology.

3. Chronic toxicity and carcinogenicity. Animal studies provide no evidence of adverse chronic or carcinogenic effects. One year feeding studies in male and female C57B1/6 mice and Fisher 344 rats reported no evidence of treatment-related cancer at doses up to 4.5% of the diet. Studies in the susceptible mouse strain (Strain A) also indicate no evidence of urea tumorigenicity.

4. Developmental and reproductive toxicity. In a developmental toxicity study, pregnant Wistar rats produced healthy offspring with no reported evidence of teratogenic effects. A study of pregnant cows receiving 0.44 grams/kilograms urea showed no effects on reproductive performance nor were the calves affected.

Urea has also been evaluated in monkeys for its ability to induce abortion. The mode of action is similar to the hyperosmolar effect of large doses of hypertonic saline and dextrose. However, such high intrauterine exposures would not be expected to occur from exposure to urea used as a frost protectant or inert pesticide ingredient. Urea is currently classified by FDA in category C for therapeutic use, ``Safety for use during pregnancy has not been established.''

5. Absorption, metabolism, and excretion. Urea is extremely soluble in water and oral doses are rapidly absorbed and distributed in humans. Urea is a normal human body constituent and is constantly being produced through amino acid and protein metabolism where urea is formed through a cyclic mechanism.

Urea has long been used as a dietary supplement for ruminants as a source of nitrogen for protein synthesis. Urea nitrogen can also contribute part of the amino acid requirements in humans. Utilization of urea nitrogen has been demonstrated both in malnourished children and adults.

6. Therapeutic uses. Urea is approved for several therapeutic uses in humans with relatively few toxicities. Urea is used primarily as an osmotic agent for inducing diuresis and reducing intraoccular and intracranial pressure. Urea has also been used as a topical anesthetic for the treatment of mouth and throat inflammation (10-15% urea gel, liquid or solution), to debride necrotic and infected tissues, i.e. fingernails and toenails. It is also used in the treatment of sickle- cell anemia and to ammoniate dentrifices as well as a basic ingredient in the synthesis of medically important compounds such as barbiturates and urethanes.

7. FQPA considerations. EPA evaluated the available hazard and exposure data for urea and concluded that the data provide no indication of increased sensitivity of infants and children from exposure to urea. Due to the expected low toxicity of urea, the Agency has not used a safety factor analysis to assess the risk. For the same reasons, the additional ten-fold (FQPA 10X) safety factor to account for enhanced sensitivity of infants and children is not necessary.

VII. Exposure Assessment

Based on the hazard assessment of urea, exposures to this compound resulting from reasonably anticipated patterns of usage present a reasonable certainty of no harm to human health. Given the low toxicity of urea, a more detailed assessment of risks resulting

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from exposure to urea, when used either as a frost protectant or pesticide inert ingredient, is not necessary.

VIII. Environmental Fate and Transport

Available data from literature reviews show that urea degrades rapidly in most soils, generally hydrolyzed to ammonium through soil urease activity. In various soils, the hydrolysis may near completion within 24 hours; however, the rate of hydrolysis can be much slower depending upon soil type, moisture content, and urea formulation. Soil adsorption studies show that urea adsorbs very weakly to soil; therefore, leaching is possible. Ultimate urea degradation produces ammonia and carbon dioxide as volatile products. Biodegradation is expected to be the major fate process in the aquatic ecosystem. The rate of biodegradation generally decreases with decreasing temperatures. Naturally-occurring phytoplankton increases the degradation rate because phytoplankton use urea as a nitrogen source. In phytoplankton-rich waters, degradation occurs much faster in sunlight than in the dark. Abiotic hydrolysis of urea occurs very slowly in relation to biotic hydrolysis.

IX. Summary of Risk Assessment Findings

From the available animal studies and other data, EPA has concluded that urea exhibits a low toxicity and exposures to urea used either as an active or inert pesticide ingredient present a reasonable certainty of no harm to human health. The Agency's analysis of extensive toxicological data in numerous species supports the 1995 decision to grant permanent exemptions from the requirement of a tolerance for residues of the frost protectant when used before harvest in the production of raw agricultural commodities.

X. Tolerance Reassessment Summary

Based on reevaluation of existing data, EPA believes there is sufficient basis to maintain exemption from the requirement of a tolerance for residues of the frost protectant urea when used before harvest in the production of the raw agricultural commodities listed in 40 CFR 180.1117 and inert uses of urea listed in 40 CFR 180.1001.

Urea Inert Ingredient Exemptions

Inert Ingredient	Current	Reassessment	Uses

	Tolerance	Decision	
Exemption listed in 40 CFR 180.1001(c) Urea	Exempt	Same	Stabilizer, inhibitor
Exemption listed in 40 CFR 180.1001(d) Urea (CAS 57-13-6)	Exempt	Same	Adjuvant/ intensifier for herbicides
Exemption listed in 40 CFR 180.1001(e) Urea	Exempt	Same	Stabilizer, inhibitor

Urea Active Ingredient Exemptions (40 CFR 180.1117)

Commodity	Current Tolerance	Reassessment Decision	Corrected Commodity Definition
Alfalfa	Exempt	Same	
Almonds	Exempt	Same	Almond
Apples	Exempt	Same	Apple
Apricots	Exempt	Same	Apricot
Artichokes	Exempt	Same	Artichoke, globe
Asparagus	Exempt	Same	
Avocados	Exempt	Same	Avocado
Beans	Exempt	Same	Bean
Bell peppers	Exempt	Same	Pepper, bell
Blackberries	Exempt	Same	Blackberry
Blueberries	Exempt	Same	Blueberry
Boysenberries	Exempt	Same	Boysenberry
Broccoli	Exempt	Same	
Brussels sprouts	Exempt	Same	
Caneberries	Exempt	Same	Caneberry
Canola	Exempt	Same	
Cantaloupes	Exempt	Same	Cantaloupe
Carrots	Exempt	Same	Carrot
Cauliflower	Exempt	Same	
Casaba	Exempt	Same	Muskmelon
Celery	Exempt	Same	

Cherries	Exempt	Same	Cherry, sweet and cherry, tart
Chili peppers	Exempt	Same	Pepper, nonbell
Chinese cabbage (bok choy, napa)	Exempt	Same	Cabbage, Chinese, bok choy Cabbage, Chinese, napa
Cooking peppers	Exempt	Same	Pepper, nonbell sweet
Corn	Exempt	Same	
Cotton	Exempt	Same	
Crenshaw	Exempt	Same	Muskmelon
Cucumbers	Exempt	Same	Cucumber
Figs	Exempt	Same	Fig
Grapefruit	Exempt	Same	
Grapes	Exempt	Same	Grape
Honeydew melon	Exempt	Same	
Hops	Exempt	Same	Hop, dried cones
Kiwifruit	Exempt	Same	
Kohlrabi	Exempt	Same	
Lemons	Exempt	Same	Lemon
Lentils	Exempt	Same	Lentil
Lettuce	Exempt	Same	
Limes	Exempt	Same	Lime
Macadamia nuts	Exempt	Same	Nut, macadamia
Musk melon	Exempt	Same	Muskmelon
Nectarines	Exempt	Same	Nectarine
Olives	Exempt	Same	Olive
Onions	Exempt	Same	Onion, dry bulb Onion, green
Oranges	Exempt	Same	Orange, sweet
Peaches	Exempt	Same	Peach
Pears	Exempt	Same	Pear
Peanuts	Exempt	Same	Peanut
Peas	Exempt	Same	Pea
Persian melon	Exempt	Same	Muskmelon
Pistachios	Exempt	Same	Pistachio
Plums	Exempt	Same	Plum
Potatoes	Exempt	Same	Potato
Pumpkin	Exempt	Same	
Prunes	Exempt	Same	Plum, prune

Radish	Exempt	Same	
Raspberries	Exempt	Same	Raspberry
Rice	Exempt	Same	
Safflower	Exempt	Same	
Sorghum	Exempt	Same	Sorghum, grain
Spinach	Exempt	Same	
Spinach (New Zealand)	Exempt	Same	Spinach, New Zealand
Squash (winter and summer)	Exempt	Same	Squash, summer Squash, winter
Strawberries	Exempt	Same	Strawberry
Sugar beets	Exempt	Same	Beet, sugar
Sunflower	Exempt	Same	
Sweet pepper	Exempt	Same	Pepper, nonbell, sweet
Table beets	Exempt	Same	Beet, garden
Tangerines	Exempt	Same	Tangerine
Tomatoes	Exempt	Same	Tomato
Walnuts	Exempt	Same	Walnut
Watermelon	Exempt	Same	
Zucchini	Exempt	Same	Squash, summer

List of Subjects

Environmental protection.

Dated: March 28, 2002.
Lois A. Rossi,
Director, Special Review and Reregistration Division, Office of
Pesticide Programs.

[FR Doc. 02-9071 Filed 4-12-02; 8:45 a.m.]
BILLING CODE 6560-50-S