

exposed subpopulations representing children, adult males, and adult females were evaluated. There are no residential exposures to consider at this time.

a. *Acute exposure and risk.* An aRfD of 0.20 mg/kg/day was used in an acute dietary risk analysis. The aRfD is based on oral NOAEL's of 20 mg/kg/day in the acute neurotoxicity and teratology studies in rats, divided by an uncertainty factor of 100 (interspecies safety factor = 10, intraspecies safety factor = 10). There was no evidence from the developmental or chronic studies that milbemectin induces any estrogenic or other endocrine effects. Therefore, the FQPA additional 10X uncertainty factor was not used.

The estimated screening level water concentrations of milbemectin in surface and ground water are 0.813 µg/L (peak EEC from GENEEC) and 0.005 µg/L (from SCIGROW), respectively. The acute DWLOCs for milbemectin for the most susceptible populations were calculated to be 6,990.83 µg/L, 5,985.45 µg/L and 1,987.55 µg/L for males, 13–19 years; females, 13+ years, nursing; and all infants, respectively.

Since the screening level water concentrations were orders of magnitude less than the acute drinking water levels of concerns (DWLOC's), the Agency should have no concern about exposures from drinking water.

b. *Chronic exposure and risk.* A RfD of 0.03 mg/kg/day was used in a chronic dietary risk analysis. The RfD is based on NOAEL of 3 mg/kg/day derived from the dog 90-day and 12-month feeding studies, the lowest of those derived from the chronic feeding studies. In view of the fact that no special sensitivity in offspring were observed in any test and that no reproductive or teratogenic effects were observed, an uncertainty factor of 100 (interspecies safety factor = 10, intraspecies safety factor = 10) was used for milbemectin. Based on the review of data from the reproduction and teratology studies, no additional FQPA safety factor was applied to infants, since no additional toxicity to or sensitivity of the fetal or nursing infant test animals was seen during exposure to the test material.

The estimated screening level water concentrations of milbemectin in surface and ground water are 0.434 µg/L (56 day average EEC from GENEEC) and 0.005 µg/L (from SCIGROW), respectively. The chronic DWLOCs for milbemectin for the most susceptible populations were calculated to be 1,049.30 µg/L, 899.13 µg/L and 299.08 µg/L for males, 13–19 years; females, 13+ years, nursing; and non-nursing infants, respectively.

Since the screening level water concentrations were orders of magnitude less than the chronic DWLOC's, the Agency should have no concern about exposures from drinking water.

2. *Non-dietary exposure.* There are no current non-food uses for milbemectin registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended. No non-dietary exposures are expected for the general public. Secondary exposure would not be expected since milbemectin is not expected to be taken up by plants from the soil. The low application rates and short soil half-life are not conducive to buildup in the environment.

D. Cumulative Effects

At this time, the Agency has not reviewed available information concerning the potentially cumulative effects of milbemectin and other substances that may have a common mechanism of toxicity. For purposes of this petition only, the Agency is considering only the potential risks of milbemectin in its aggregate exposure.

E. Safety Determination

1. *U.S. population.* As pointed out above in dietary exposure-food, the acute dietary exposure of all infants and non-nursing infants (<1 yr. old) would be only 0.58% at the 99.9th percentile of the proposed aRfD and the chronic dietary exposure of non-nursing infants would be only 0.4% of the proposed RfD. The percentages of aRfD and chronic RfD for the U.S. population and all other subgroups are below these amounts.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of milbemectin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. No developmental or reproductive effects have been observed in any study with milbemectin. The calculation of safety margins with respect to these segments of the population were taken into consideration in the tolerance method validation (TMRC) estimates with respect to the risk associated with the percentage of the reference dose being consumed. It is concluded that

there is a reasonable certainty of no harm to infants and children from aggregate exposure to milbemectin residues.

F. International Tolerances

No Codex maximum residue levels have been established for residues of milbemectin. Milbemectin is not yet registered for use on any crop in Canada or Mexico. National maximum residue levels (MRL's) for milbemectin in Japan are as follows: Apple, Pear, Peach, Citrus, Melon, Watermelon, Cucumber, Eggplant, Adzuki-bean - 0.2 ppm, Strawberry, Cherry, Grape - 0.5 ppm, and Tea - 2 ppm. National MRL's for milbemectin in Taiwan are as follows: Small berry (Grape, Strawberry, Star fruit, etc.), Tree fruit (Pear, Apple, Cherry, Peach, Plum, etc.), Vegetables (Eggplant, Cucumber, Tomato, etc.), Melon (Watermelon, Muskmelon, etc.) - 0.2 ppm; Tea - 2 ppm. In general, where national MRL's differ from those proposed to EPA, they are associated with agricultural and regulatory practices that differ from those common in the U.S.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7216-3]

Public Water System Supervision Program Revision for the State of South Carolina

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given that the State of South Carolina is revising its approved Public Water System Supervision Program. South Carolina has adopted drinking water regulations revising the interim enhanced surface water treatment rule and disinfection by-product rule. EPA has determined that the interim enhanced surface water treatment rule and disinfection by-product rule revisions meet all minimum federal requirements, and are no less stringent than the corresponding federal regulations. Therefore, EPA has tentatively decided to approve these State program revisions.

All interested parties may request a public hearing. A request for a public hearing must be submitted by June 24, 2002 to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial

request for a public hearing is made by June 24, 2002, a public hearing will be held. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective on June 24, 2002. Any request for a public hearing shall include the following information: (1) The name, address, and telephone number of the individual, organization, or other entity requesting a hearing. (2) A brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intends to submit at such hearing. (3) The signature of the individual making the request; or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, at the following offices:

South Carolina Department of Health and Environmental Control, Bureau of Water, 2600 Bull Street, Columbia, South Carolina 29201.

Environmental Protection Agency, Region 4, Drinking Water Section, 61 Forsyth Street, SW, Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Janine Morris, EPA Region 4, Drinking Water Section at the Atlanta address given above (telephone 404-562-9480).

Authority: (Section 1401 and section 1413 of the Safe Drinking Water Act, as amended (1996), and 40 CFR part 142).

Dated: May 7, 2002.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7216-5]

Public Water Supervision Program Revision for the State of Tennessee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of tentative approval.

SUMMARY: Notice is hereby given that the State of Tennessee is revising its approved Public Water System Supervision Program. Tennessee has adopted drinking water regulations which incorporate the requirements of

the Interim Enhanced Surface Water Treatment Rule and the Stage 1 Disinfection/Disinfectants Byproducts Rule. EPA has determined that these revisions are no less stringent than the corresponding federal regulations. Therefore, EPA intends to approve this State program revision.

All interested parties may request a public hearing. A request for a public hearing must be submitted by June 24, 2002 to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by June 24, 2002, a public hearing will be held. If no timely and appropriate request for a hearing is received, and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective on June 24, 2002. Any request for a public hearing shall include the following information: (1) The name, address, and telephone number of the individual organization, or other entity requesting a hearing; (2) A brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; (3) The signature of the individual making the request, or, if the request is made on the behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, at the following offices: Tennessee Department of Environment and Conservation, Division of Water Supply, 401 Church Street, L&C Tower, Sixth Floor, Nashville, Tennessee, 37243-1549, or at the Environmental Protection Agency, Region 4, Drinking Water Section, 61 Forsyth Street Southwest, Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Fred Hunter, EPA Region 4, Drinking Water Section at the Atlanta address given above, or by telephone at (404) 562-9477.

Authority: Sections 1401 and 1413 of the Safe Drinking Water Act, as amended (1996), and 40 CFR parts 141 and 142.

Dated: May 7, 2002.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7216-4]

Public Water Supervision Program Revision for the State of Tennessee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of tentative approval.

SUMMARY: Notice is hereby given that the State of Tennessee is revising its approved Public Water System Supervision Program. Tennessee has adopted drinking water regulations which provide minor revisions to the Lead and Copper Rule. EPA has determined that these revisions are no less stringent than the corresponding federal regulations. Therefore, EPA intends to approve this State program revision.

All interested parties may request a public hearing. A request for a public hearing must be submitted by June 24, 2002 to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by June 24, 2002, a public hearing will be held. If no timely and appropriate request for a hearing is received, and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective on June 24, 2002. Any request for a public hearing shall include the following information: (1) The name, address, and telephone number of the individual organization, or other entity requesting a hearing; (2) A brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; (3) The signature of the individual making the request, or, if the request is made on the behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, at the following offices: Tennessee Department of Environment and Conservation, Division of Water Supply, 401 Church Street, L&C Tower, Sixth Floor, Nashville, Tennessee 37243-1549, or at the Environmental Protection Agency, Region 4, Drinking Water Section, 61 Forsyth Street Southwest, Atlanta, Georgia 30303.