

- Food manufacturing (NAIC code 311)
- Pesticide manufacturing (NAIC code 32532)

#### *B. How Can I Get Copies of This Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-0272. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The 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/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

## **II. Background and Statutory Findings**

In the **Federal Register** of December 7, 2001 (66 FR 63534) (FRL-6737-9), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 0F6194) by Eco Lab Inc., 370 N. Wabasha Street, St. Paul, MN

55102. That notice included a summary of the petition prepared by Eco Lab Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance is established for residues of decanoic acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of decanoic acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of decanoic acid up to 170 parts per million (ppm) per application on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants. The sanitizer is applied by immersion, coarse spray, or circulation technique as appropriate to the equipment. The solution, once applied is allowed to drain and dry and there is no potable water rinse.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean 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." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA assesses the hazards of the pesticide through examination and review of available toxicology data. Second, EPA examines the potential route(s) and duration(s) of exposure to the pesticide through food, drinking water, and through other exposures that can occur as a result of pesticide use in residential settings.

## **III. Aggregate Risk Assessment and Determination of Safety**

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for an exemption from the requirement of a tolerance for residues of decanoic acid on all food up to 170 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

### *A. Toxicological Profile*

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available toxicology data from the open scientific literature as well as the data submitted in support of this action and has considered its validity, completeness and reliability and the relationship to human risk. EPA has also considered available information on potential differences in sensitivity to the toxicity of the pesticide in major identifiable subgroups of consumers, including infants and children. The natures of the toxic effects caused by decanoic acid (capric acid) are discussed in this unit.

### *B. Acute Toxicity*

The acute oral toxicity of decanoic acid is low lethal dose (LD)<sub>50</sub> >10 grams/kilograms (g/kg) as is the acute dermal toxicity (LD<sub>50</sub> > 5 g/kg). Decanoic Acid is a moderate to severe skin irritant when applied undiluted to intact or abraded rabbit skin for 24 hours. Decanoic acid is also a severe eye irritant when applied as a 5% solution.

### *C. Subchronic Toxicity*

As reported in Patty's Industrial Hygiene and Toxicology, 4th ed., rats fed capric acid at 10% in the diet for 150 days showed no adverse effects from treatment. In another study, rats administered approximately 4 g decanoic acid /kg/day for 6 weeks showed reduced body weight gain and increased plasma triglyceride levels. In a longer term study in which rats were fed 2.5 g/kg/day decanoic acid for 47 weeks, no adverse toxicological effects were noted. Dogs administered 4.4 g/kg/day decanoic acid for 102 days showed no adverse effects of treatment.

### *D. Developmental and Reproductive Effects*

In a study by Hendrich *et al.* (JAOCS, Vol. 70, no. 8, August 1993, pages 797-802), the potential reproductive effects of decanoic acid were examined in