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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop Production (NAICS 111, e.g.)
- Animal Production (NAICS 112, e.g.)
- Food Manufacturing (NAICS 311, e.g.)
- Pesticide Manufacturing (NAICS 32532, e.g.)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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 an official public docket for this action under docket identification (ID) number OPP-2003-0220. 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, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

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 March 20, 2002 (67 FR 12990) (FRL-6824-4), 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 7F4845) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. That notice included a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant. There were no comments received in response to the notice of filing.

The original petition requested that 40 CFR 180.505 be amended by establishing a tolerance for combined residues of the insecticide emamectin benzoate, 4'-epi-methylamino-4'-deoxyavermectin B₁ benzoate (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B_{1a} and a maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B_{1b} benzoate), and its metabolites 8,9 isomer of the B_{1a} and B_{1b} component of the parent insecticide in or on the raw agricultural commodities fruiting vegetables (except Cucurbits) group at 0.02 parts per million (ppm), *Brassica* leafy vegetables group at 0.025 ppm, leafy vegetables (except *Brassica*) group at 0.1 ppm, cottonseed at 0.025 ppm, cotton gin byproducts at 0.5 ppm.

Based on the EPA analysis of the residue chemistry and toxicological databases, the petition was subsequently revised to express the tolerance as the combined residues of emamectin, (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B_{1a}

and maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4'-deoxy-4'-epi-amino-avermectin B_{1a} and 4'-deoxy-4'-epi-amino-avermectin B_{1b}; 4'-deoxy-4'-epi-amino-avermectin B_{1a} (AB_{1a}); 4'-deoxy-4'-epi-(N-formyl-N-methyl)amino-avermectin (MFB_{1a}); and 4'-deoxy-4'-epi-(N-formyl)amino-avermectin B_{1a} (FAB_{1a}), in or on *Brassica* leafy vegetables (crop group 5) at 0.05 ppm; turnip greens at 0.05 ppm; cotton, undelinted seed at 0.025 ppm; cotton gin byproduct at 0.05 ppm; leafy vegetables (except *Brassica*) (crop group 4) at 0.10 ppm; fruiting vegetables (crop group 8) at 0.02 ppm; and tomato paste at 0.15 ppm. In addition, tolerances are established for indirect or inadvertent combined residues of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB_{1a} + 8,9-ZB_{1b}) in or on milk and fat of cattle, goats, hogs, horses, and sheep at 0.003 ppm; meat byproducts, except liver, of cattle, goats, hogs, horses, and sheep at 0.005 ppm; liver of cattle, goats, hogs, horses, and sheep at 0.020 ppm; and meat of cattle, goat, hogs, horses, and sheep at 0.002 ppm. Note that the tolerance expression in 40 CFR 180.505 is being changed from emamectin benzoate to emamectin since the enforcement method, Method 244-92-3, Revision 1, analyzes residues of emamectin MAB₁ isomers (not emamectin benzoate), 8,9-ZMA, AB_{1a}, MFB_{1a}, and FAB_{1a} in/on crops.

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. For further discussion of the regulatory