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II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for combined residues of the insecticide lambda-cyhalothrin and its epimer, in or on wild rice at 1.0 parts per million (ppm), grass forage at 5.0 ppm and grass hay at 6.0 ppm. These tolerances will expire and are revoked on December 31, 2005. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 of the FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . ."

Section 18 of the FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Lambda-Cyhalothrin on Wild Rice and Pasture Grass and FFDCA Tolerances

The State of Minnesota requested the use of lambda-cyhalothrin on wild rice to control unusually high populations of riceworms because the registered alternatives were ineffective. The State of New York requested the use of lambda-cyhalothrin to control alfalfa weevil (*Hypera postica*), Armyworms (*Spodoptera spp.*) and Potato leafhopper (*Empoasca fabae*) on alfalfa/clover/grass mixed stands. The use of insecticides is the only practical means of controlling the three major pests that infest alfalfa/clover/grass mixed stands and there are no pesticides registered to control insect pests in these stands of mixed of alfalfa/clover/grass. Experts estimate a 35% yield loss if these mixed stands are not protected. EPA has authorized under section 18 of FIFRA the use of lambda-cyhalothrin on wild rice for control of rice borers in Minnesota and pasture grass for control of alfalfa weevil, armyworms and potato leafhoppers on alfalfa/clover/grass mixed stands in New York. After having reviewed the submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of lambda-cyhalothrin in or on wild rice and grass forage and grass hay. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerances under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with section 18 of FIFRA. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that

the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although these tolerances will expire and are revoked on December 31, 2005, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on wild rice, grass forage and grass hay after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether lambda-cyhalothrin meets EPA's registration requirements for use on wild rice and pasture grass or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of lambda-cyhalothrin by a State for special local needs under section 24(c) of FIFRA. Nor do these tolerances serve as the basis for any States other than Minnesota and New York to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 of FIFRA as identified in 40 CFR part 166. For additional information regarding the emergency exemption for lambda-cyhalothrin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

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 lambda-cyhalothrin and to make a determination on aggregate exposure, consistent with section