

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 Indoxacarb on Collards and FFDCA Tolerances

The State of Georgia requested an emergency exemption use for indoxacarb (Avaunt®) for control of the diamondback moth in collards, since this pest appears to have developed resistance to almost all available chemical alternatives. Although spinosad has provided satisfactory diamondback moth control until recently, field failures were detected in 2002, suggesting that resistance may be involved. According to the State, potential yield losses tend to be either 0% or 100%, since in affected fields the damage level may be considered either acceptable or a cause for rejection, in which case the crop would not be harvested. The State estimated an overall 10% decrease in yield in the absence of effective insecticides and a doubling of insecticide costs from \$24.50 to \$49.00 because of a lack of efficacy leading to repeated applications. The 10% estimate represents anticipated total losses in a few fields and minor losses in fields with manageable moth populations. EPA has authorized under FIFRA section 18 the use of indoxacarb on collards for control of diamond back moth in Georgia. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of indoxacarb in or on collards. In doing so, EPA considered the safety standard in section 408(b)(2) of the FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of the FFDCA would be consistent with the safety standard and with FIFRA section 18. 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 this tolerance without notice and opportunity for public comment as provided in section 408(l)(6) of the FFDCA. Although this tolerance will expire and is revoked on June 30, 2006, under section 408(l)(5) of the FFDCA, residues of the pesticide not in excess

of the amounts specified in the tolerance remaining in or on collards 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 this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether indoxacarb meets EPA's registration requirements for use on collards or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of indoxacarb by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Georgia to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing FIFRA section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for indoxacarb, 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 indoxacarb and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a time-limited tolerance for combined residues of indoxacarb [(S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy) phenyl] amino] carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate] and its R-enantiomer [(R)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl] amino] carbonyl]indeno[1,2-e][1,3,4]

oxadiazine-4a(3H)-carboxylate] in or on collards at 3.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by indoxacarb and the endpoints used in risk assessment are discussed in Unit III.A. and B. of the final rule on indoxacarb pesticide tolerances published in the **Federal Register** of July 18, 2002 (67 FR 47299) (FRL-7186-2). Please refer to that document should you desire detailed toxicological information on indoxacarb.

The Agency has identified an acute dietary endpoint for females 13 years and older and for the general population, including infants and children. The acute population adjusted dose (aPAD) for females is 0.02 milligrams/kilogram/day (mg/kg/day). The acute dietary endpoint for the general population including infants and children is 0.12 mg/kg/day. The chronic population adjusted dose (cPAD) for all populations is 0.02 mg/kg/day. Indoxacarb has been classified as "not likely" to be carcinogenic to humans.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.564) for the combined residues of indoxacarb, in or on a variety of raw agricultural commodities including alfalfa, head lettuce, peanuts, potatoes, and soybeans. Additionally, there are tolerances for milk, milk fat, meat, fat and meat by-products of cattle, goat, hog, horse, and sheep. Risk assessments were conducted by EPA to assess dietary exposures from indoxacarb in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. The Dietary Exposure Evaluation Model (DEEM® version 7.76) analysis evaluated the individual food consumption as reported by respondents in the U.S. Department of Agriculture (USDA) 1989-1992 nationwide Continuing