

combined exposures were subtracted from the appropriate dose and drinking water levels of comparison (DWLOCs) were calculated and compared to EECs in groundwater and surface water. The EECs were generated using SCIGROW (groundwater) and PRZM-EXAMS (surface water). SCIGROW is a regression model designed to estimate a screening level of a pesticide concentration at an agricultural site which is highly vulnerable to leaching due to permeable soil overlaying shallow ground water. PRZM-EXAMS is used to estimate concentration that might occur in vulnerable surface water (assumes 87% of the basin is cropped and entire cropped area is treated). Both models assumed 3 applications at 1.5 lbs ai/acre (highest registered/proposed rate). The resulting EECs were less than the DWLOCs indicating aggregate exposures are less than EPA's level of concern.

12. *Comment.* Additional issues not apparently being addressed by EPA such as negative impacts on beneficial insects. Bystander or beneficial insects have been detrimentally effected by the herbicide. Kutlesa and Caveny found that the herbicide had a number of neurotoxic impacts on the skipper butterfly at levels of herbicide experienced in the field. Ahn et al found that glufosinate was toxic to some but not all predatory insects at levels of the herbicide experienced in the field. Studies showing that helpful predatory insects or bystander insects are poisoned by the herbicide seem to have been ignored by regulators of the herbicide.

Agency response. This comment raises an issue concerning the pesticide's registrability under FIFRA and is not directly relevant to the safety determination under FFDCA. For registrations of a pesticide under FIFRA, EPA requires non-target insect data if the proposed use will result in exposure to honey bees (40 CFR 158.590). Two studies on the toxicity of glufosinate ammonium to bees indicates that the herbicide (technical and a formulated product) is practically non-toxic to bees via contact and oral routes. The cited studies suggest that glufosinate ammonium may cause mortality to insects, other than bees, and mites may also be affected. The issues of the hazard to non-target insects will be addressed via registration under FIFRA.

13. *Comment.* Additional issues not apparently being addressed by EPA such as glufosinate residues in other crop varieties. Muller et al studied glufosinate metabolites in transgenic and unmodified sugar beet, carrot, purple foxtail and thorn apple, and

they found that unmodified (i.e., non-genetically engineered) crops contained glufosinate mainly while GM crops contained higher levels of glufosinate and acetyl glufosinate. Beriault et al studied phloem transport of glufosinate and acetylglufosinate in canola in GM canola and unmodified canola and found that both chemicals were highly mobile.

Agency response. Common toxicity studies conducted with glufosinate ammonium, *N*-acetyl-glufosinate, and 3-MP indicate that *N*-acetyl-glufosinate and 3-MP exhibit toxic effects at doses equal to or greater than glufosinate ammonium. Based on these toxicity studies, EPA concluded that *N*-acetyl-glufosinate, and 3-MP are not likely to be more toxic than glufosinate ammonium (risk assessment assumes they are of equal toxicity to parent). The field trial data were submitted for the transgenic crops monitored for residues of glufosinate ammonium, *N*-acetyl-glufosinate, and 3-MP in/on all food/feed commodities. Therefore, the higher residues in transgenic crops and/or greater mobility of the residues of concern has been taken into consideration.

14. *Comment.* Two hundred and twenty four comments were received that were opposed to establishing tolerances for glufosinate ammonium in genetically engineered (GE) rice and cotton. They included some or all of the following comments from the campaign to halt the introduction of GE Crops:

I am writing in reference to Bayer CropScience's August 15th petition to establish a tolerance for Glufosinate in or on Rice and cotton. I believe that by approving the residues requested by Bayer you will be exposing the public to unnecessary health risks, potentially increasing use of toxic herbicides on rice and cotton, and endangering the livelihoods of farmers by shutting off valuable export markets that are rejecting transgenic crops. I am concerned about the loss of overseas markets for farmers growing transgenic crops and for farmers whose own ability to market their crops is threatened by genetic pollution. Many countries throughout the world are refusing transgenic crops and USDA organic standards strictly prohibit the use of transgenic seeds. Glufosinate tolerance levels have not been established by the international food standards commission, Codex Alimentarius. Events such as StarLink and last year's ProdiGene incident highlight the inadequacies of our current system in keeping transgenic crops segregated. In Canada, farmers growing transgenic crops have detected triple herbicide resistance in weeds and volunteer canola plants as a result of gene transfer, rendering the herbicides useless. If Bayer's petition is approved, it will only be a matter of time before red rice, which is the same species as cultivated rice and also one of the most virulent weeds on

rice farms, becomes resistant to Glufosinate. Similar gene transfer in rice will lead to the need for new, more toxic herbicides. Peer-reviewed scientific studies have shown Glufosinate to be "highly toxic" to aquatic animals such as clams, oysters, water fleas, fish and birds at doses as low as 0.5 ppm. As rice is grown in an aquatic environment, the adoption of Glufosinate tolerant rice will have tragic impacts for the ecosystems of rice growing areas. The EPA classifies Glufosinate as "persistent" and it has been found in the edible parts of spinach, wheat and radishes more than 120 days after being sprayed with the chemical. The approval of Glufosinate tolerant rice and cotton will send us a step backward in our efforts toward a more sustainable agriculture. Please take action to ensure that our current system of agriculture moves toward one that is less reliant on chemicals, and ensures our farmers a prosperous livelihood. I strongly urge you to deny Bayer's request for approval of Glufosinate tolerance and to work with other government agencies to enact a more rigorous approval and testing process for transgenic crops.

Forty one comments were in favor of establishing the tolerances for glufosinate ammonium. They stated that growers need the new technology to control weed species.

Agency Response. EPA has concluded that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to glufosinate-ammonium and its metabolites from established and proposed tolerances. The issues of the hazard to non-target organisms and crop resistance will be addressed via registration under FIFRA. The growing of Herbicide Tolerant crops and potential effects on shipment of crops overseas is addressed by USDA and FDA in their pre-marketing review of Plant-Incorporated Protectant Seeds. EPA is responsible for the safety of the pesticide to be applied to the growing crop.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement