

FIFRA/FQPA

New Bt corn registered, exempted from food tolerance

EPA last week exempted a *Bacillus thuringiensis* (*Bt*) protein and related genetic material from the requirement of a tolerance when it is produced in corn as a plant-incorporated protectant.

The modified Cry3A protein (mCry3A), developed by Syngenta Seeds Inc. from the tenebrionis strain of *Bt*, along with the genetic material needed for its production, was registered by the agency last month.

The protective protein is considered non-toxic and non-allergenic. The genetic material necessary for its production was exempted under a blanket exemption for all nucleic acids.

The protein is produced within the corn plant due to the incorporation of bacterial genetic material created in event MIR604, so the lines carrying it are called MIR604 CRW (corn rootworm) resistant corn, with the brand name Agrisure RW. The insect protection has been stacked with other traits, including Liberty Link and RoundUp Ready herbicide tolerances and corn borer protection. Syngenta expects the seed to be available for planting in 2007.

The insecticidal activity of the protein occurs in the insect's gut. At a specific gut pH, which varies among insect groups, the protein breaks down the gut lining, followed by breakdown of other body parts and collapse.

Even at very high doses, mCry3A had no effects on mice. Since toxic proteins act via acute mechanisms and at very low dose levels, EPA uses a tiered system with more intensive toxicity tests required only if significant effects are observed.

The mCry3A protein originates from a non-allergenic source. It is rapidly degraded in synthetic gastric fluid, it lacks sequence identity with known toxins or allergens, and it is not glycosylated when expressed in corn. These characteristics indicate minimal risk of allergenicity.

EPA expects mCryA3, as the third *Bt*-based rootworm protectant, to lower seed prices and increase adoption of plant-incorporated protection against rootworm, reducing use of chemical insecticides. In the United States, corn rootworm protection is the single largest use of conventional insecticides, many of which are highly toxic to humans

and the environment, while mCry3A-expressing corn poses no foreseeable risks to human health or the environment.

EPA found that, unlike chemical insecticides, mCry3A did not harm beneficial insects, whether predators, parasitoids, or pollinators. Greater survival of beneficial organisms, which are commonly killed by chemical insecticides, can reduce the impact of secondary pests, such as aphids and leafhoppers, on corn. No adverse effects on endangered or threatened species are expected.

EPA has found no significant risk of mCry3A-producing genetic material to wild plants or soil microbes.

Some restrictions have been included in the registration of mCry3A-protected corn, which will expire Sept. 30, 2010. Non-mCry3A-protected corn must be grown on a refuge with 20% of planted acreage to ensure unexposed insects are available to breed with any insects that survive exposure to delay any resistance development. Syngenta must monitor compliance with this requirement as well as develop and educate others about a remedial action plan for resistance development. The company must also study the fate of mCry3A in soil and its effects on non-target invertebrates.

The final rule on tolerance was published in the Nov. 1 *Federal Register* and became effective the same day. Objections and requests for hearings, citing Docket Number EPA-HQ-OPP-2006-0784, must be received by Jan. 2, 2007.

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