



JOHN ELIAS BALDACCI
GOVERNOR

STATE OF MAINE
MAINE DEPARTMENT OF AGRICULTURE, FOOD & RURAL RESOURCES
BOARD OF PESTICIDES CONTROL
28 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0028

SETH BRADSTREET
COMMISSIONER
HENRY JENNINGS
DIRECTOR

T0: Board Members
FROM: Lebelle Hicks, PhD DABT
RE: Medical Advisory Committee Review, “*Bacillus thuringiensis*-Corn Crystalline and Vegetative Insecticidal Proteins,” and Registrant Comments

DATE: December 7, 2009

Attached is the draft final review of the Medical Advisory Committee’s (MAC’s) report “*Bacillus thuringiensis*-Corn Crystalline and Vegetative Insecticidal Proteins.” Some of the comments made by Monsanto have been incorporated into the review and others are addressed below.

Monsanto commented that the EPA’s 1998 Reregistration Eligibility Decision (RED) document for *Bacillus thuringiensis* (*Bt*) should have been included in the review (see excerpt from Hull e-mail below). One of the reasons for performing the review is that the Board has historically recognized that the *Bt* proteins in the genetically modified crops are to be treated in a different manner than insecticides containing intact *Bt* subspecies.

Monsanto also suggested that the review should have included 73 additional references, predominantly livestock studies and review articles. The MAC concluded at their last meeting that combing the literature for more studies would not add to their knowledge base.

From Christine Hull’s 11/3/09 e-mail:

“In the executive summary of the report, it is written, “It was the consensus of the Medical Advisory Committee that the data required by EPA for registration of Bt corn products for application in sweet corn is inadequate to perform a human health risk assessment. It was also agreed that there is a relative absence of non-industry controlled safety data on Bt foods re: human health - the MAC would support the generation of such data prior to further registrations.”

In light of the MAC’s summary, we are providing additional reference information with regards to testing of the Cry proteins contained in these PIPs.

In the March 1998 Reregistration Eligibility Decision (RED) document for *Bacillus thuringiensis*, EPA stated that a battery of acute/pathogenicity tests was considered sufficient to perform a risk assessment for Bt microbial pesticides. For Cry proteins introduced into biotech crops, there is no need for pathogenicity or acute irritation studies since there is no exposure to Bt microbial formulations, but an acute high dose oral study is still required to provide confirmatory safety evidence for the Bt Cry protein. If there are no adverse effects observed after acute oral hazard dosing with a Cry protein, no further safety testing is needed. This is based on the known acute and specific mode of

action of Cry proteins in controlling target insect pests, and their absence of toxicity in non-target organisms.

Monsanto contacted EPA to confirm that this is still current EPA policy. John Kough, EPA Biopesticides and Pollution Prevention Division, confirmed the current testing policy and rationale for the Bt Cry proteins in crops and how that relates to what is done for microbials. He is available to the Maine BPC to answer any questions.

(Kough.John@epamail.epa.gov)”

The question for the Board is: Does the Board wish to accept the MAC report as presented or expand it with details from EPA’s RED for *Bt* microbial products or further review of the livestock diet studies?