US Environmental Protection Agency
Office of Pesticide Programs

EPA Response to Letter from Universities Regarding the Strobilurin, Pyraclostrobin (Headline), Supplemental Label

June 4, 2009

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Diane Brown-Rytlewski
Extension Outreach Specialist, Field Crops
Department of Plant Pathology
164A Plant Pathology Building
Michigan State University
East Lansing, MI 48824

Dear Dr. Brown-Rytlewski,

I am responding to your letter, dated February 13, 2009, to Mr. John Bazuin in the Registration Division of EPA's Office of Pesticide Programs. In your letter, you outlined three major concerns with recent label claims approved by this Office for Headline (pyraclostrobin) products: (1) increased use of the product that "almost guarantees earlier selection for resistance in certain pathogen populations to a valuable class of fungicides," (2) increased use of the product such that non-target impacts are seen, including "suppression of beneficial fungi" that help keep certain insect pathogens in check, and (3) lack of claim substantiation.

With respect to your first concern, prevention of resistance development, particularly to reduced risk chemistries, is an important issue to the Agency (EPA). In fact, the Office of Pesticide Programs has recently formed an internal resistance management workgroup to review our engagement on this issue and to develop a strategic work plan to address emerging areas of concern. Our scientists have started conversing with a wide range of key stakeholders in this effort, including growers, university research scientists and extension specialists, USDA, American Phytopathological Society, Weed Science Society of America, Entomology Society of America, and Canada's Pest Management Regulatory Authority (PMRA). Later this year, we expect to make public our strategic work plan through our web site and will welcome comments from you and your colleagues. Arnet (Skee) Jones, a Branch Chief in our Biological and Economic Analysis Division, has been leading this effort.

I would like to note that the manufacturer of Headline has complied with Agency recommendations to include resistance management language on product labeling. Thus, the Headline label contains language intended to reduce sequential applications of the product and to limit the maximum seasonal-use rate. Also, there is a recommendation to rotate to fungicide classes with different modes of action. Other manufacturers have also complied with the Agency's recommendation to incorporate resistance management language on their labels, based on the Agency's Pesticide Registration Notice 2001-5 (http://www.epa.gov/PR_Notices/pr2001-5.pdf). Further, all products in the strobilurin class of fungicides carry resistance management labeling, including language that promotes rotation of this class of chemicals with chemicals that

have a different mode of action. Nevertheless, we would appreciate receiving any data or other documentation of which you are aware that indicates the current resistance management approach through labeling has not been effective for strobilurin fungicides, including pyraclostrobin. This information can be provided directly to Arnet (Skee) Jones at Jones.Arnet@epa.gov

We would be interested in learning more about your second concern, i.e., avoidance of adverse effects on beneficial fungi and subsequent insect pest flares or outbreaks. Such outcomes would be counter to IPM goals and could increase risks due to the need for increased use of insecticides. Again, we would welcome any data or information documenting such outcomes, particularly as they relate to any increases in use of strobilurin fungicides. As above, this information should be provided directly to Skee Jones.

With respect to your third concern, claim substantiation, the Agency does not routinely require an applicant to submit efficacy data on pesticide products intended to control plant pathogens, insect pests or weeds. For some time, the Agency has allocated resources for product efficacy data review to "public health" products, i.e., those with claims to control human pathogens or their insect vectors. Our reasoning in this approach is that for most agricultural pesticides, effectiveness can be observed by users in the field who will then make their buying decisions accordingly and, thus, our resources are better focused on assessment of human health and environmental risk assessment and effective risk management.

As there has been continuing interest in this issue, we have made your February 13 letter available for public viewing and will similarly post this response on our web site. Further, we will make public any additional information/data you provide to document your concerns as well as our written review of that data/information. If you are interested in presenting information to our scientists in person, we would also be happy to arrange a meeting. I can be contacted at Rossi.Lois@epa.gov or 703 305 5447.

Sincerely,

/s/ Jeffrey Kempkes, Associate Director for Lois Rossi
6/4/09

Lois Rossi, Director
Registration Division

Cc: Debra Edwards, Director, OPP/EPA
Jack Housenger, Acting Director, BEAD/OPP/EPA
Larry Elworth, Chief Agriculture Counselor, EPA
Teung Chin, OPMP, USDA
Paul Vincelli, University of Kentucky
Tom Allen, Mississippi State University
Gary C. Bergstrom, Cornell University
Carl Bradley, University of Illinois
John Damicone, Oklahoma State University
Erick De Wolf, Kansas State University
Anne Dorrance, The Ohio State University/OARDC

C. Richard Edwards, Purdue University
Roger Elmore, Iowa State University
Paul Esker, University of Wisconsin
Ron French, Texas A&M University
Arvydas Grybauskas, University of Maryland
Marvin Harris, Texas A&M University
Don Hershman, University of Kentucky
Charla Hollingsworth, University of Minnesota
Bob Hunger, Oklahoma State University
Thomas Isakeit, Texas A&M University
Doug Jardine, Kansas State University
Bryan Jensen, University of Wisconsin
Paul Jepson, Oregon State University
Doug Johnson, University of Kentucky
Steven B. Johnson, University of Maine Cooperative Extension
Chad Lee, University of Kentucky
Jonathan Lundgren, USDA-ARS
Ian MacRae, Northwest Research & Outreach Center
Marcia McMullen, North Dakota State University
Daren Mueller, Iowa State University
Lawrence E. Osborne, South Dakota State University
Pierce A. Paul, The Ohio State University/OARDC
Guy B. Padgett, Louisiana State University
Palle Pedersen, Iowa State University
Steve Rideout, Virginia Tech – Eastern Shore
Alison Robertson, Iowa State University
Tom Royer, Oklahoma State University
Gregory Shaner, Purdue University
Erik L. Stromberg, Virginia Polytechnic Institute and State University
Greg Walker, University of California Riverside
Stephen Wegulo, University of Nebraska
Kiersten Wise, Purdue University
Sandra Sardanelli, University of Maryland
Natalie P. Goldberg, New Mexico State University
Dr. Norman C. Leppla, University of Florida
Erick Larson, Ph.D., Mississippi State University
Thomas Chase, South Dakota State University
Christina DiFonzo, Michigan State University