US Environmental Protection Agency
Office of Pesticide Programs

EPA Response to Letter from American Bird Conservancy Regarding BASF Product Pyraclostrobin (Headline)

October 9, 2009

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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dr. Michael Fry
Director, Conservation Advocacy
American Bird Conservancy
1731 Connecticut Ave., NW
Washington, DC 20009

Dear Dr. Fry:

Thank you for your letter of July 29, 2009. Your letter was a follow up to comments you made at the PPDC meeting in April 2009, during which you expressed concern over the Agency's (EPA's) recent approval of certain plant health claims for the strobilurin fungicide, pyraclostrobin (Headline). Subsequent to your comments at the PPDC meeting, the Agency posted on its website a letter dated February 13, 2009, from university scientists critical of the plant health label language as well as the Agency's response to that letter. You also commented in your letter of July 29 on the Agency's response to the letter from the university scientists.

First, to clarify, EPA regards the plant health claims on Headline's label to be plant regulator claims and therefore pesticidal. "Pesticide" is defined by the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) to include "plant regulators." FIFRA § 2(u)(2). "Plant regulator" is defined as "*any substance or mixture of substances intended, through physiological action*, for accelerating or retarding the rate of growth or rate of maturation, or *for otherwise altering the behavior of plants* or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments." FIFRA § 2(v) (emphasis added).

The Headline product is the first fungicide to have an expanded EPA approved plant health claim on the label. However, there have been previously approved label statements for fungicide products such as "improved benefits" or statements that identify an additional benefit to a specific indicator of plant health as far back as 1995. These earlier approved statements do not include the expanded terminology of plant health that appears on the Headline label. More recently a claim, "promoting enhanced plant health and yield", was approved on an insecticide product. With regard to whether a single active ingredient can be registered for two uses simultaneously, a single product can have multiple uses under FIFRA if each use separately passes the statutory tests (no unreasonable adverse effects or reasonable certainty of no harm) and the directions for use are clearly written.

No claims on pesticide labeling may be false or misleading – whether they relate to pesticidal activity or other characteristics of a product. If a pesticide's labeling is false or

misleading in any way, the product is misbranded and it is unlawful to sell or distribute the product. See FIFRA §§ 2(q)(1)(A); 12(a)(1)(E).

The Agency has historically maintained that for pesticide products intended to control plant pathogens, insect pests or weeds, effectiveness can be observed by users in the field who will then make their buying decisions accordingly. EPA thinks that policy is equally appropriate for plant regulators. The Agency believes the effectiveness of a product to improve plant health will also be observable by users in the field and therefore the Agency has not required that efficacy studies be submitted supporting plant regulator claims nor has the Agency expended its resources for review of such studies. Rather, the Agency has focused its resources for these products on assessing and mitigating risks to public health and the environment. The Agency does, however, review efficacy data for "public health" claims, (i.e., claims to control human pathogens or their vectors), as efficacy for these products cannot readily be observed by the general public.

Although the Agency does not request the submission of efficacy data for the registration of agricultural products, manufacturers are required to have the data within their files to substantiate the claims. While EPA does not regularly review efficacy data for non-public health claims, no claims made in pesticide labeling may be false or misleading. At this time, EPA has not reviewed any efficacy data and therefore has no evidence indicating that the plant regulator claims made on the Headline label are false or misleading. Should such evidence come to EPA's attention, EPA may choose to commence cancellation proceedings to remove the plant regulator use or enforcement against Headline as misbranded. If you have information that indicates the plant health claims for Headline are "false or misleading," please provide it to us for our review. In this regard, Dr. Paul Vincelli (University of Kentucky) just last week forwarded to the Agency data which our scientists will review.

As you have noted, the University scientists also expressed concern regarding the potential for resistance development as well as nontarget effects (e.g., on beneficial fungi). In our 6/4/09 response letter, the Agency encouraged the submission of any data or information documenting such outcomes. To date no such information has been provided with respect to resistance concerns. However, last week Dr. Vincelli also forwarded two journal documents "relating to the impact of strobilurin fungicides on entomopathogenic fungi." Our scientists will review this information. If you have any information relevant to these issues, please provide it for our review.

The Agency is particularly concerned that the long-term viability of the strobilurin class of fungicides is not compromised due to development of pathogen resistance. Your contention that a grower/user focused on the plant regulator (versus fungal pathogen) claim might not heed resistance management recommendations is certainly logical. Thus, I have asked OPP's Resistance Management Workgroup to explore this issue specifically and to develop some recommendations for consideration, including the possibility of implementation of mandatory/enforceable (as opposed to advisory) resistance management labeling on certain products.

Any information can be provided directly to Arnet (Skee) Jones (jones.arnet@epa.gov), Branch Chief for the Biological Analysis Branch in our Biological and Economic Analysis

Division, who has been leading this effort. Please also copy Cynthia Giles-Parker (giles-parker.cynthia@epa.gov), Branch Chief of the Fungicides Branch in our Registration Division, in your communications with Skee.

Regarding the PPDC meeting this October, we will provide a time for brief discussion of this topic. As there has been continuing interest in this issue, we will make your July 29, 2009, letter and this response available for public viewing on our web site at http://www.epa.gov/pesticides/regulating/index.htm. Further, we will make public any additional information/data you provide to document your concerns. In addition, the Agency will make available the written review of such information. If you are interested in presenting information to our scientists in person, we would also be happy to arrange a meeting. Please feel free to contact Skee at (703) 305-7416 or Cynthia (703) 305-7740 to do so.

Sincerely,

Debra Edwards

Debra Edwards, Ph.D., Director
Office of Pesticide Programs

cc: Lois Rossi, Director, Registration Division