



**US Environmental Protection Agency
Office of Pesticide Programs**

**Letter from American Bird Conservancy
Regarding BASF Product Pyraclostrobin
(Headline)**

July 29, 2009



Shaping the future for birds

Debra Edwards, Director
U.S. Environmental Protection Agency
Office of Pesticide Programs
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July 29, 2009

Dear Debbie,

I wanted to follow up on the comments I made at the last PPDC with regard to the BASF product Headline™. I was very critical of the proposed new label and I wanted to make sure my comments were put in writing. Subsequent to my comments, EPA has posted a letter from many university plant pathologists critical of the registration decision, and has also posted a response to that letter from Registration Division (RD). My comments to the response letter can be found below.

I have served on the PPDC subcommittees dealing with factual label statements, and in all our conversations and communications, it has seemed very clear that EPA has been careful to regulate non-pesticide claims appearing on labels. In the case of Headline™, EPA has, in the letter dated January 23, 2009, conditionally granted a label for a non-fungicidal use of a fungicide. Whether this is a "plant regulator" registration or a non-pesticide registration was not clear in the RD letter to BASF. This label seems to be a great departure from regulating pesticides, and opens a broad range of issues which should be thoroughly vetted by the public before the Agency embarks on a new initiative of licensing registered toxic substances as growth promoters and stress reducers. From my reading of FIFRA (7 USC 136(v)) it appears that the "plant health" label might be granted under the "plant regulator" classification for a pesticide, although there appears to be considerable controversy as to whether Headline™ actually is efficacious in this regard.

According to excerpts from the BASF press release of January 29, 2009:

"BASF announced today that Headline® fungicide is the first fungicide to have EPA approved Plant Health claims on its label. " Is this true, or would there be a new label, not for use as a fungicide? If the registration is still for a fungicide, is the "plant health" claim a non-pesticide use, or can a single active ingredient be registered for two uses simultaneously?

BASF continues: "We believe this is a new precedent for the agricultural community," Headline improves Plant Health by acting on three unique areas of the plant's growth. These Plant Health benefits are improved growth efficiency, excellent disease control, and enhanced tolerance to



stress conditions such as drought, heat, cold temperatures and ozone damage. " Is there factual evidence for these non-pesticide claims, as would be required for claims under FIFRA 40 CRF 156.10(a)(5)? BASF is currently advertizing these "plant health" claims on their soybean website at: <http://www.soygrowers.com/sym/HEADLINE%20SOY.pdf> I believe EPA should request that BASF remove these claims from their website until independently proven, given the uncertainty of the claim as refuted by data provided by experts cited below.

In response to the BASF January press release, a group of 46 university plant pathologists presented data contradicting the BASF claims of enhanced plant health and productivity in disease free situations, and wrote to OPP requesting a secondary review of the label, and not go forward in initiating a whole new classification of labels based on "Plant Health" claims. The plant pathologists were additionally very critical of wide-spread use of a fungicide without evidence of disease, because of the greatly increased probability of developing resistance to pathogens susceptible to pyraclostrobin or other strobilurins. They furthermore cautioned against indiscriminant fungicide use, because of the probability of non-target impacts, particularly suppression of beneficial fungi that help keep insect pathogens in check. The response letter from RD clearly did not address the issues of concern to the university pathologists. It listed 3 areas of concern by the pathologists: (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.

In their response RD states: 1) that the Headline label contains language to reduce sequential applications and limit the maximum seasonal use, and to rotate with fungicide classes with different modes of action. The label to which RD is referring is the fungicide label, not a "plant health" label. However, BASF certainly would not recommend using other fungicides on its "plant health" label, because the label use is not directed at controlling fungi nor avoiding resistance. The "plant health" label, on the contrary, would encourage the use of this fungicide on many crops without regard to disease or disease resistance. The EPA response is completely off the mark.

With regard to the second concern, the EPA response is more to the point, as it requests data documenting non-target impacts, although it should be apparent that use of a fungicide without target pathogens present would inevitably lead to non-target impacts if susceptible beneficial fungi were present.

Thirdly, regarding claim substantiation, RD states that the Agency does not require any efficacy data for registration of products, except for those with "public health" claims. It appears that OPP is willing to register any pesticide product for any reason other than a "public health" claim





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without any efficacy data, regardless of the fact that the product in question may have no efficacy for its claims on the label. The unprecedented action by RD to allow registration of a fungicide for non-fungicidal claims deserves thorough discussion and allowance for a period of public comment since it would represent a change of policy.

I would like to request that the issue of registration, efficacy, and factual claims on labels be put on the October 2009 PPDC agenda, and that Headline™ registration be postponed until all sides of this issue be heard by the public. EPA has the specific charge to protect the environment from unregulated use of toxic substances. In the case of Headline™, EPA has chosen to disregard the toxicity of the product to non-target organisms and disregard obvious potential harm from early selection for resistance of target pathogens in favor of unsubstantiated novel claims of "plant health". The registration, while probably within the definition of plant regulator, appears to be very unwise, as this registration would undermine the legitimate fungicidal uses of the entire class of strobilurin fungicides.

I look forward to a response and continuing the discussion of label issues at the PPDC,
Thank you very much,

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