From: Dana Sargent
Sent: Wednesday, December 16, 2015 10:35 PM
To: jones.jim@epa.gov
Cc: Housenger.jack@Epa.gov; 'Lewis, Susan'
Subject: Flubendiamide

Dear Mr. Jones:

I would like to confirm that you are aware of a new development that warrants your attention. In communications today with OPP, as follow up to our meeting with you yesterday, and our subsequent proposed label mitigation, we were informed that EFED used a new ecotoxicity endpoint in the risk assessments it presented to you today. It is our understanding that EPA is using this new endpoint as the basis for determining the acceptability of our proposed label mitigation and to inform your pending decision about extending the registration of flubendiamide. Given the importance of this endpoint and resulting modeling scenarios to our ongoing conversations, we have asked that OPP promptly provide a copy of the EFED summary and modeling scenarios (including any changes to underlying assumptions).

The timing of the notification of this change, at such a critical point in the registration process, lacks appropriate transparency at a minimum. This benthic organism endpoint was the basis of our many meetings and discussions thus far. It was the foundation for all the risk analyses Bayer prepared and EPA reviewed and discussed with Bayer. EPA never told Bayer that it was changing the endpoint or even that EPA was reevaluating the endpoint. Even in yesterday's meeting with you and the CEO's of both Bayer CropScience and Nichino America, EPA failed to inform us of this critical change. This lack of clarity and disclosure undercuts the integrity of our prolonged scientific discussions and renders them useless.

In our conversations today, OPP proposed to meet with us as early as next week. It is important that we understand the relationship of that meeting and its relevance to our ongoing discussions, as well as its impact, if any, on your decision and its timing.

Freundliche Grüße / Best regards,

Dana Sargent
VP, NA Regulatory Affairs

Bayer CropScience

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