From: Rodia, Carmen <Rodia.Carmen@epa.gov>
Sent: Tuesday, August 04, 2015 3:49 PM
To: Nancy Delaney; Charlotte Sanson; Dan Dyer
Cc: Lewis, Susan; Herndon, George; Rosenblatt, Daniel; Gebken, Richard
Subject: DRAFT List of Required Additional Studies for Flubendiamide

Good afternoon Nancy, Charlotte and Dan, as a follow-up to our most recent teleconference call on Thursday, July 30, 2015, I am submitting to Bayer a DRAFT list of the items that the Registration Division presented to Bayer in order to address the uncertainties related to flubendiamide.

New Data:

Guideline Number	Title of Study	Date Due
Non-Guideline	Bayer must conduct an expanded suite of stream/pond water monitoring representative of all current outdoor uses that are listed on the existing flubendiamide labels. The Agency and Bayer will collaborate on establishing monitoring sites using available modeling tools on a more refined geographic and use site basis to identify likely areas where accumulation of flubendiamide and its NNI-0001-des-iodo (des-iodo) and NNI-0001-3-OH-hydroxy-perfluoroalkyl degradates will be a factor under shorter durations of pesticide use.	**[DATE]**
NOTE: The focus of monitoring on areas predicted to be of accumulation concern over shorter durations of pesticide use will develop a data set in a more rapid and economical manner to test the findings of the available modeling supporting risk assessment for flubendiamide. Bayer must submit a draft protocol for the above referenced study for review by the Agency on or before **[DATE]**.		
Non-Guideline	To be consistent with current Agency policy concerning an effect data set for pollinators, honeybee adult oral acute (OECD 213) and chronic (non-guideline) as well as larval acute (OECD 237) and chronic (non-guideline) studies would constitute the baseline data set for pollinators. Because data with parasitoid hymenopterans and the effects in semi-field studies suggest that developmental and chronic endpoints are of potential concern for flubendiamide and its NNI-0001-des-iodo (des-iodo) and NNI-0001-3-OH-hydroxy-perfluoroalkyl degradates, the bee larval acute study and the larval chronic study must be performed. These studies may be performed in tiers.	**[DATE]**
NOTE: There presently are acute adult toxicity studies with honeybees and bumble bees as well as parasitoid wasps for flubendiamide. The honeybee testing included acute contact studies with adults as well as a semi-field study. The data showed minimal toxicity to adults and only transient effects on brood development and flight intensity under semi-field conditions, with recovery. Bumblebee studies were comprised of greenhouse exposure to treated tomatoes, and no effects were observed. The available parasitoid wasp studies showed effects on survival and reproduction. Given the above data summary, it is doubtful that the additional adult data will be materially important. Bayer must submit a draft protocol for the above referenced study for review by the Agency on or before **[DATE]**.		
850-1010	Acute water only toxicity testing with ephemeropteran (mayfly) species	**[DATE]**
850-1010	Acute water only toxicity testing with plecopteram (stonefly) species	**[DATE]**
850-1010	Acute water only toxicity testing with tricopteran (caddisfly) species	**[DATE]**
NOTE: The underlying claim of receptor specificity for terrestrial arthropods has only limited data to support its application to aquatic systems. To address this area of uncertainty, Bayer must conduct the above referenced water only acute invertebrate studies to provide additional confirmation that receptor specificity of the compound will not affect benthic/epibenthic macroinvertebrate species commonly used to determine biologically-based water quality. Bayer must submit a draft protocol for the above referenced studies for review by the Agency on or before **[DATE]**.		
Non-Guideline	Bayer must conduct sediment toxicity testing with the following additional species (*Hyalella azteca* and *Leptocheirus plumulosa*).	**[DATE]**

NOTE: The existing dataset for sediment organism toxicity addresses a single species (*Chironomus tentans*) to emergence (OPPTS GLN 28-d). Again, as in the case of water only testing, there is considerable uncertainty in the representation of this single species as an adequate surrogate for the variety of in-faunal species. To address this uncertainty, and be consistent with current EPA sediment testing policy, Bayer must conduct the above referenced sediment toxicity testing. To the extent possible by protocol, these studies should continue through developmental periods commensurate with the available chironomid testing and involve spiked sediment as opposed to overlying water. Bayer must submit a draft protocol for the above referenced study for review by the Agency on or before **[DATE]**.		
Non-Guideline	A two-year, multi-season sampling, biomonitoring effort that provides comparison of benthic macroinvertebrate community analysis with appropriate reference sites should be provided. This effort should address a variety of use sites and be targeted to areas of high proposed flubendiamide projected use and high field runoff potential. This monitoring should be for flubendiamide and its NNI-0001-des-iodo (des-iodo) and NNI-0001-3-OH-hydroxy-perfluoroalkyl degradates.	**[DATE]**
NOTE: Bayer must conduct a biomonitoring study to provide confirmation that any residues observed in the monitoring study, as compared to the aforementioned laboratory toxicity studies, is not associated with adverse benthic community effects *in situ*. Bayer must submit a draft protocol for the above referenced study for review by the Agency on or before **[DATE]**.		

I would also like to remind Bayer of a number of administrative items that will need to be completed as soon as possible in order to help us all move toward this potential path forward. Among the items presented to Bayer last week were the following:

- Bayer must withdraw the following list of submitted PRIA applications in writing well in advance of August 31, 2015:

Registration/Petition Numbers	Description of Applications	Affected Decision Numbers
71711-26 (FLUBENDIAMIDE TECHNICAL)	R170/R175; Establish Tolerances for Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493617, 495233, and 495235
264-1025 (BELT SC Insecticide)	R170.2/R170.3/R175; Establish Tolerances for Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493618, 495242, and 495244
PP #4F8283	R170/R175; Establish Tolerances for Grassland (Pasture and Rangeland Grasses, Forage, and Hay, and Animal Commodities)	493619

- Prior to August 31, 2015, the PRIA conclusion date for the submitted R350 application to increase the PHI on tobacco (EPA Reg. No. 264-1025 (BELT SC Insecticide; Decision No. 491208) must be renegotiated for completion by HED in 2016;
- Bayer will agree not to submit any additional Section 3 outdoor uses during the potential 3 year extension of the time-limited registrations for flubendiamide;
- Bayer will reduce all applications on all 5 flubendiamide product labels to 1 application per crop season as part of label amendments that will be submitted to the Agency;
- Bayer will remove aerial applications on all 5 flubendiamide product labels;
- Bayer will agree to submit progress reports on the additional data capture every six (6) months to the Agency during the potential 3 year extension of the time-limited registrations for flubendiamide;
- Prior to August 31, 2015, Bayer and the Agency will sign a new preliminary acceptance letter outlining all of these items as well as the additional data that are listed above; and
- All additional data must completed by the end of the 2nd year of the potential 3 year extension in order to provide EFED with adequate time to review the submitted additional data.

Please review the above information and use it as the basis of Bayer's upcoming proposal to continue the registration of flubendiamide beyond its current August 31, 2015 expiration date. These are our initial broad thoughts, and let's plan to talk later this week to finalize! We are still looking forward to hearing from Bayer for potential dates/times for the Jack Housenger meeting. If you have any questions, please contact me directly. Regards, Carmen Rodia.

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