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March 5, 2013

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***Re: Transmission of Regulatory Studies to DART IC Members***

Dear Dr. Alexeeff and Ms. Monahan-Cummings:

We are writing on behalf of our client Bayer CropScience LP to request OEHHA's assistance in providing copies of Bayer CropScience guideline studies to the Developmental and Reproductive Toxicant Identification Committee ("DART IC" or "Committee") to assist the Committee in its consideration of deltamethrin, which is on the agenda for the DART IC meeting on March 18, 2013.

As you are aware, several of the studies referred to in the Department's Hazard Identification Document on deltamethrin were generated to satisfy requirements for registration of that chemical as a pesticide within the meaning of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and certain provisions of the State's Food & Agricultural Code. For purposes of this letter, we refer to those studies as the "Regulatory Studies," which include the following six studies pertinent to the issue of reproductive and developmental toxicity, as they are cited in the Hazard Identification Document: (1) Gilmore, RG, LP Sheets and HE Hoss (2006); (2) Hoberman, AM (1992); (3) Richard, J (2001); (4) Schardein, JL (1990a); (5) Schardein, JL (1990b); and (6) Wrenn, J (1980).

Copies of these studies are in the possession of the United States Environmental Protection Agency and Department of Pesticide Regulation, OEHHA's sister agency. Under Section 10(g) of FIFRA and Section 6254.2 of the California Public Records Act (which incorporates FIFRA § 10(g)), they are available for inspection by any federal or State agency, and by any member of the public, except for any person or agent of a person engaged in the business of manufacturing or distributing pesticide products as a "multinational producer."

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Given the nature of the Regulatory Studies and the toxicological endpoints they address, it is appropriate for the Committee to review them (and perhaps inappropriate not to review them) in determining whether deltamethrin should be listed as a chemical “known to the State to cause reproductive toxicity” for purposes of Proposition 65. In order to do so, however, the Committee members would be required to travel to Sacramento on their own time to gain access to them in the DPR data library. This clearly is not practical, and likely will cause the Committee not to review the studies at all. At the least, it would work a severe hardship on any Committee members inclined to make that effort.

Alternatively, the DART IC members could obtain their own copies of the Regulatory Studies, either from US EPA or DPR, by filing requests under the federal Freedom of Information Act or the California Public Records Act. In this case, either agency would send copies of the studies directly to the Committee members, but the requesting members would be required to make such requests and submit in support of their requests an Affirmation of Status to confirm that they are not affiliated with a multinational pesticide producer. We believe it would be inappropriate to place this burden on the Committee members. Moreover, it is unlikely that this could be accomplished by all of the members and the studies be delivered to them timely, given that the meeting is scheduled for March 18.

For all of these reasons, we propose that Bayer be permitted to make copies of the Regulatory Studies available to the Committee members immediately by sending them on electronic disks to OEHHA, with the understanding that OEHHA would forward them promptly to the Committee members for review in their private offices or homes for the purpose of conducting the Committee’s work.

We understand, however, that OEHHA policy would require that these studies be posted on the OEHHA website if they are submitted to the Committee (as with other material submitted to the Committee for its review). This would be contrary to the purposes of the above-described provisions of FIFRA and the California Public Records Act, however, which expressly allow the studies to be reviewed by governmental bodies such as OEHHA and the DART IC without requiring Bayer to sacrifice its proprietary interests in the studies. Posting the studies would enable competitors to obtain the studies in full without the registrant’s knowledge, studies which could then be applied to facilitate registrations by competitors, particularly in less developed countries outside the United States where data ownership is not confirmed as rigorously as in the United States.

Under these circumstances, we believe it would serve the interests of all parties, including the general public, if the Committee members were to return their copies to OEHHA promptly after the conclusion of the March 18 DART IC meeting, and OEHHA were to refrain from publishing the studies on its website, or elsewhere. Instead of publishing the data, OEHHA

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would indicate in its record of the proceedings that any person with an interest in reviewing the studies may do so at the DPR data library, or may file a request to DPR under the Public Records Act.

Please advise me of your availability to discuss this proposal. As stated above, we believe it would satisfy the interests of all parties, without compromising the rights of any.

Respectfully,  
  
Stanley W. Landfair  
Counsel for Bayer CropScience LP

SWL/cgk

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