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March 8, 2013

Cynthia Oshita
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
PROPOSITION 65 IMPLEMENTATION, EXTERNAL AFFAIRS AND LEGISLATION
1001 I Street
Sacramento, California 95812-4010

***Re: Presentation to the Developmental and Reproductive Toxicant
Identification Committee***

Dear Ms. Oshita:

The companies and associations identified below request one hour to make an oral presentation to the Developmental and Reproductive Toxicant Identification Committee (“DART IC” or “Committee”) at the DART IC meeting on March 18, 2013. Please ensure that a copy of this letter is forwarded to the Committee Chair.

As background, Bayer CropScience LP, SC Johnson and & Son, Inc., Valent BioSciences LLC, the Consumer Specialty Products Association and the Western Plant Health Association all have submitted written comments relevant to this matter, either in response to OEHHHA’s January 12, 2012 Request for Relevant Information (“Request”) regarding deltamethrin, or in response to the publication of the Hazard Identification Document (“HID”) for deltamethrin. All believe that the weight of scientific evidence does not support the designation of deltamethrin as a reproductive toxicant for purposes of Proposition 65, and have demonstrated by their comments that significant harm will occur to them, their customers, their members and the general public if the chemical were to be listed in appropriately. These companies and associations will be able to assist the DART IC to evaluate the scientific evidence more effectively if the Committee will allow them to present their comments in a single presentation. In the end, this will allow these companies and associations to present their comments more efficiently, with less concern for duplication than if they were to proceed one-by-one, and to respond more directly to concerns or questions that the Committee may raise.

We understand from the notation on the Tentative Agenda for the March 18 meeting (copy attached) that the Committee has allocated only one hour for public comments. The agenda also calls for a briefing on this subject by the OEHHHA Staff. Typically, the staff presentation at Committee meetings requires an hour in itself and embraces all of the data

addressed in the HID. Without disputing the appropriateness of such a comprehensive presentation from the Staff, it may be unreasonable to restrict responsive comments from *all* interested parties to one hour, and to restrict the companies and associations above to just a *fraction* of an hour, depending on how many parties appear at the meeting and desire to comment.¹

We also note from the agenda that the Committee will not entertain public comment until after the Committee concludes its discussion of the data, as presented by the OEHHA staff. Given this order of presentation, it further would appear unreasonable to so limit the time for presentations from well-qualified experts who are familiar with the data that are the subject of the HID and are particularly well-qualified to speak. Indeed, we believe the Committee will find their comments informative and will want to hear them.

The companies and associations above intend to make their presentation with three speakers: Larry Sheets, Ph.D., DABT (Bayer); Jay Murray, Ph.D., DABT (Consulting Toxicologist); and the undersigned counsel. The three speakers will be prepared to address all of the data in the HID (as necessary), and will present their views as to why the data do not support listing. Dr. Sheets has studied this compound for over twenty years and is intimately familiar with all of the data addressed in the HID; he is particularly knowledgeable regarding the data submitted to US EPA, the California DPR and other regulatory bodies worldwide that have assessed these data. Dr. Murray, well known to the Committee, has reviewed all of the studies and is prepared to address in particular the studies from the public literature that are described in the HID as evidence of adverse effects, and many flaws in these studies which may not be apparent otherwise. In addressing the data, we will be responsive to the views expressed by the Committee in their discussion; will not address matters that appear not to require discussion; will address questions that may be raised by the Committee; and will take no more time than is necessary to do so. If our presentation and questions from the Committee do not require the full hour, we will not take the full hour.

The commitments above notwithstanding, there are several points we wish to convey to the Committee that deserve the allocation of time we are requesting. For example, the HID presents the data in a confusing fashion, particularly in its Executive Summary, which may be the most prominent of all the written materials before the Committee. The Executive Summary fails to identify the studies summarized therein or cross-reference the studies to the more lengthy summaries in the body of the document, leaving the reader with the incorrect impression that data from all of the studies summarized in the Executive Summary are of the same quality and reliability, and should be given equal credence. On a related point, many of the studies described in the Executive Summary as evidence of adverse effects are flawed in fundamental ways that render the data of very low quality. As the most egregious example, many of these low-quality studies were not actually conducted on deltamethrin as the test article, but rather on formulated end-products that consisted primarily of other chemicals, sometimes completely unidentified in

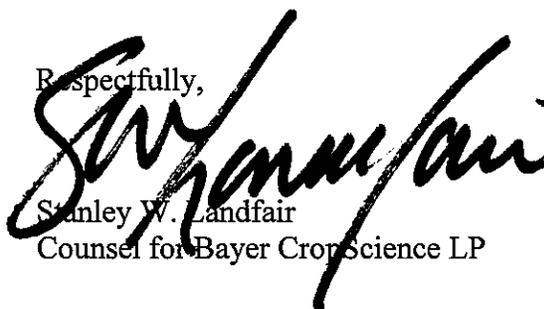
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the reports and oftentimes including aromatic hydrocarbons. By contrast, the Executive Summary inexplicably does not include summaries of the higher quality, GLP studies that demonstrate no adverse effects and, worse yet, fails to point out that omission. Discussing only the lower-quality data that purport to show adverse effects, the Executive Summary thus implies to the reader that deltamethrin should be listed, without regard to the weight of the scientific evidence.

As a final point, we believe that the allocation of one hour for a presentation by the three persons above on behalf of the companies and associations above would not prolong the public meeting unduly or preclude the Committee from accomplishing its agenda. At the present time, we are aware of no other parties that have identified themselves as having an interest in this decision, and allowing the presentation described above would accommodate fully all of the parties that have demonstrated an interest by submitting comments in writing. This is the only point in the process of considering this important chemical that provides for any interaction between the Committee and the manufacturer and user community in this important decision.

For all of these reasons, we believe the allocation of one hour to the parties above is appropriate and fair. We thus ask the Committee to exercise discretion to accommodate our request. At the very least, the Committee should apportion time equitably, after evaluating the time available and the number of parties that desire to present oral comments, to allow these companies and associations to be fully heard.

Respectfully,

A large, stylized handwritten signature in black ink, appearing to read "Stanley W. Landfair".

Stanley W. Landfair
Counsel for Bayer Crop Science LP

cc: George Alexeeff, Ph.D., DABT, Director
Carol Monahan-Cummings, Chief Counsel

ⁱ Our concerns on this point may be moot, and the Committee may find this decision easier, if the companies and associations above are the only parties that desire to present oral comments, when the public meeting takes place. If that is to occur, or if there are only a few persons that desire to present comments, we trust the Committee will exercise its discretion fairly to allow all parties to be fully heard.

OEHHA

Office of Environmental Health Hazard Assessment

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Proposition 65

TENTATIVE AGENDA FOR THE MARCH 18, 2013 MEETING OF THE DEVELOPMENTAL AND REPRODUCTIVE TOXICANT IDENTIFICATION COMMITTEE [03/08/13] UPDATED 03/06/13

The Developmental and Reproductive Toxicant Identification Committee of OEHHA's¹ Science Advisory Board identifies chemicals for addition to the list of chemicals known to the State to cause reproductive toxicity (Health and Safety Code section 25249.8). The Committee serves as the "State's Qualified Experts" for determining whether a chemical has been clearly shown, through scientifically valid testing according to generally accepted principles, to cause reproductive toxicity.

A public meeting of this committee will be held on **Monday, March 18, 2013** in the Byron Sher Auditorium of the California Environmental Protection Agency headquarters building located at 1001 I Street, Sacramento beginning at 10:00 am and continuing until all business is conducted or 5:00 pm. **The meeting will be webcast:** The URL for the webcast (not active until the day and time of the meeting) is: <http://calepa.ca.gov/Broadcast/>.

The tentative agenda for this meeting is given below. The order of items on the agenda is provided for general reference only. The order in which items are taken up by the Committee is subject to change at the discretion of the Chair.

For planning purposes of the meeting, if you plan to make public comments in the form of a presentation to the Committee, please provide an estimate of the time you will need, and the reason you are requesting additional time, to Cynthia Oshita at Cynthia.Oshita@oehha.ca.gov by 5:00 p.m. on March 12, 2013. If you have special accommodation or language needs, please contact Ms. Oshita at (916) 445-6900 or at her email address also by March 13, 2013. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

I. INTRODUCTION AND ADMINISTRATION OF THE OATH OF OFFICE TO NEWLY APPOINTED MEMBERS

II. CONSIDERATION OF A CHEMICAL AS KNOWN TO THE STATE TO CAUSE REPRODUCTIVE TOXICITY

A. Deltamethrin (Revised Hazard Identification document available)

- Staff presentation
- Committee discussion
- Public comments*
- Committee discussion and decision

III. OVERVIEW OF THE PROCESS FOR PROVIDING PEER REVIEW OF OEHHA RISK ASSESSMENTS (added 3/6/13)

- Staff presentation
- Public Comments
- Committee discussion and recommendations

IV. STAFF UPDATES

V. COMMITTEE COMMENTS

VI. PUBLIC COMMENTS

VII. SUMMARY OF COMMITTEE ACTIONS

* Generally public comments should be limited to 5 minutes, which may be changed if time allows and at the discretion of the chair. Commenters may ask the chair for additional time in advance by sending a request to Cynthia Oshita at Cynthia.Oshita@oehha.ca.gov at least three business days in advance of the meeting. The request should specify the name(s) of the commenter(s), the amount of time requested, and (briefly) the reasons for additional time. A total of one hour has been allocated for public comments concerning the listing decision, which can be extended at the discretion of the chair.

¹ The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for

the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code, section 25249.5 et seq. (commonly known as Proposition 65).

Flex Your Power Website



Energy efficiency and conservation information. Find incentives/rebates, technical assistance, retailers, product guides, case studies and more.

AMBER ALERT: Save a Child



AMBER ALERT empowers law enforcement, the media and the public to combat abduction by sending out immediate information.

OEHHA is one of five agencies under the umbrella of the California Environmental Protection Agency (Cal/EPA).

[Air Resources Board](#) | [Department of Pesticide Regulation](#) | [Department of Toxic Substances Control](#)
[Office of Environmental Health Hazard Assessment](#) | [State Water Resources Control Board](#)

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