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Submitted by email on September 13, 2010 to: fkammerer@oehha.ca.gov

Dear Ms. Kammerer:

I am writing to provide comments on the August 8, 2010, pre-regulatory draft document entitled "Green Chemistry Hazard Traits, Endpoints, And Other Relevant Data" released by your office for the implementation of SB 509 and the Governor's Green Chemistry Initiative.

The draft represents an important contribution to providing a scientific underpinning to a more transparent approach to assessing chemicals and providing information to the public. I congratulate OEHHA on the scientific quality of this analysis. It reflects a breadth of understanding of health effects of chemicals that is rare in any governmental organization.

I appreciate the opportunity to offer comments and suggestions.

Background

By way of background, the provisions for identification of hazard traits as a matter of science in SB 509 reflects language originally incorporated in other bills by Senator Simitian and Mr. Feuer, the sponsors of the legislation passed in conjunction with the governor's "Green Chemistry" initiative. Though earlier versions of this language included a list of traits in the legislation, SB 509's mandate to look to the state's scientists to identify hazard traits is in keeping with the goals of the Legislature and the Governor.

The idea behind this language was to improve the scientific quality and transparency of the information about chemicals available to the government, to the public, and to businesses. The idea of "hazard traits" was to reflect current scientific knowledge about the inherent properties or

attributes of chemicals that could be of concern. Many or most other initiatives have focused on either very old assessments of the attributes of interest for chemicals or on very narrow ones. The identification of hazard traits allows the State of California to fully reflect the significant gains in knowledge that have been achieved over the last twenty years of research.

This is very much in keeping with the stated goal of the Legislature to make the "Green Chemistry" initiative a science-based program. The most consistent theme emerging from the oversight and informational hearings held over the last two years has been the interest of the Legislature to have scientists make the scientific assessments. The hazard traits are an essential component of this.

A second idea behind the identification of hazard traits was to promote scientific innovation. There is widespread agreement that testing methods are due for an upgrade to improve reliability, validity, and speed, as well as to reduce cost. The hazard traits specify what we want to know about in order to make decisions for our families, communities, and products. Specific testing and assessment methods can then be identified for these traits. We would not expect that the hazard traits will change over time (or not very much). On the other hand, we do hope and expect that better, faster, cheaper methods will become available and be validated for use. Defining the hazard traits and then the methods that provide information relevant for these traits allows for a systematic approach to this innovation, also a widely shared goal.

Scientific Components of the Proposal

I have three comments related to the scientific components of the program.

First, OEHHA has identified hazard traits into categories for toxicological, ecological, exposure, and physical aspects, which make sense as categories and are similar to those used in other contexts. They also make the document easier to understand and would provide a reasonable way to structure categories in the Clearinghouse.

Second, it is important to provide a framework that clearly distinguishes cases where there is information about a chemical and it appears to have low likelihood of posing a hazard and cases where there is simply no information and so the chemical has an unknown hazard. It is essential to make this aspect of assessment more transparent for the varied users of data, including government agencies, businesses, workers, and the public. This needs further development beyond the notion of "unclassifiable" provided in the current draft. In addition, it may be worth considering a way to incorporate findings that chemicals are "benign by design." Such green-chemistry methods do not as yet appear to be available, but perhaps they will be in the future, and it might be useful to allow for this at the design phase for the Clearinghouse.

Third, it is essential that the framework for the Clearinghouse retain a scientific basis. There are elements of the proposal that diverge from a scientific approach. One important example is the provision that carcinogens and reproductive toxicants can be identified only if they appear on certain lists. This strays from the premise that this program is to be scientifically based and so needs to be removed. A second example is the language that provides that OEHHA may conduct certain assessments only when "requested" by the Department of Toxic Substances Control. What is the purpose behind this? It would seem to detract from the scientific foundation and so

should be stricken. Finally, the draft seems to place far too much weight on "authoritative bodies." This is a very backward looking approach in that authoritative bodies move slowly and do not keep up with current science. Why should the people of California have to wait for slow-moving bureaucracies to take actions before being able to find out about current research results about chemicals that they may be using or considering using? This will vastly reduce the value and transparency of the Clearinghouse.

Specific Technical Comments

I have a few specific comments and suggestions.

Neurodevelopmental effects should be distinguished specifically in the specification of traits. While such effects conceptually fall into developmental effects, in practice the testing methods that are capable of detecting them are different from those commonly described as being for "developmental" effects. Also, the time frame of interest for development of the brain extends beyond the period of sexual maturation, defined as the relevant time frame for developmental effects. So, it is important to build into the information design the capacity to determine whether data are available specifically about neurodevelopmental effects. This is essential for assessments that can be protective of children, of course, so is of public policy concern.

The draft might address signaling more generally. Now it focuses on disruption of endocrine effects. There are other forms of signaling in the body at the cellular level and at the level of the organism. It seems that the current design may not capture data about these very well. Also, the emerging evidence of links between chemical exposure and diabetes should be better reflected, so that such information may be incorporated into the Clearinghouse in the future.

The draft does not address concerns for sensitive populations. Perhaps this could be considered as a "flag" on chemicals where there may be specific concerns for sensitive populations. It needs to be addressed in some way in the information design of the Clearinghouse.

I wonder if you might consider traits related to global distribution of pollutants and for those that have contaminated food chains. These would both seem to be informative to decisions about chemical use. It would seem that we might want to avoid using chemicals that become globally distributed or that contaminate food chains.

The language about a "class one" and a "class two" hazard trait seems awkward. What you are trying to distinguish here is a different strength of evidence but not a different hazard trait. The hazard trait is the same. Perhaps you might consider other ways to try to get this across. You might have a chemical with "class two" evidence of a hazard trait but very high potency that would be of greater concern than a chemical of "class one" evidence but lower potency. That will be hard to get across given this terminology.

In closing, it seems important to emphasize the need for the discussion of the regulation to include the question of resources for both DTSC and OEHHA to implement the "Green Chemistry" initiative. This could include a discussion of any additional legal authority that may be needed.

Finally, I want to note that, as an employee of the University of California, I submit these comments as an individual with relevant expertise. As I am sure you know, only the Regents speak for the University.

Very truly yours,

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