Comments on Proposal by the

Office of Environmental Health Hazard Assessment on

Hazard Traits pursuant to SB 509 (Simitian)

Submitted by Amy D. Kyle, PhD MPH, on February 15, 2011 via email to Fran Kammerer, Office of Environmental Health Hazard Assessment, P. O. Box 4010, Sacramento, California 95812-4010 at fkammerer@oehha.ca.gov

I appreciate the opportunity to comment on the proposal developed by the Office of Environmental Health Hazard Assessment (OEHHA) to carry out elements of SB 509, passed in 2008 as part of the California Green Chemistry Initiative.

Background on the context for the proposal

Everybody agrees that the idea of green chemistry is inspirational. Who wouldn't prefer to have products and processes that are free of toxicity and "benign by design?"

The metaphor of "green chemistry," like sustainability and pollution prevention, reflects evolution toward a new phase in environmental protection focused on designing systems and materials to avoid negative attributes.

Environmental protection of the 1970s was about pollution control. At that time, we thought that we could identify safe levels of a few pollutants and control them with technologies. These strategies achieved significant gains. Both air and water in the US, overall, are substantially less polluted now than they were forty years ago.

While implementing pollution control strategies, we have learned that it is better to prevent pollution in the first place than to try to control or remediate it. It turns out that there are a lot of chemicals and materials that pose hazards, and controlling all of them has proved to be more than the regulatory system can handle. It also turns out that some individuals and groups are far

more sensitive than others to effects of chemicals, and that estimating and managing these hazards has proved to be too complex to be done in many or most cases.

We have also learned that there is a lot of gratuitous toxicity in ingredients of products that we use every day. We don't need to have lead in toy trains, but we do. We don't need to have carcinogens in lotions, but we do. We don't need to have respiratory toxicants in building materials, but we do.

What this all means is that more attention is needed for more agents in more products and uses. We need chemical manufacturers to look for ways to take the hazards out of the chemicals they make and product manufacturers to look for ways to take hazards out of ingredients they use. We need retailers to look for ways to take the hazards out of the product lines they feature on their shelves. We need parents and teachers and janitors to be vigilant about the products that they use around babies and children. And of course we need the government to take a stronger role in assessing and managing hazards.

For this to happen, everybody needs better information. We need reliable information that can be used by businesses, workers, parents, consumers, and janitors to pick products to get rid of the gratuitous hazards now present in daily life. The government needs reliable information as well.

We need to think about information differently. We need to be developing metrics that are comparative rather than absolute and that allow for selection of the best option among several. There is a lot of discussion about alternatives analysis, and it can be a useful tool to help parties look for ways to reduce hazard throughout a product line. However, alternatives analysis is only as good as the information available to support the assessment of alternatives.

Within the academic sector, green chemistry is a vitally important area of research and training. We see new papers in journals every day about progress toward greener attributes of chemical and metrics to assess them. We all look forward to the day when we no longer need to worry about hazards of any chemicals or materials in toys or food or makeup or computers or sofas because the transition to green chemistry has happened.

In the meantime, we are starting to take steps toward reducing hazards. As you are well aware, in the last few years, the Legislature in California, like several states, has acted to restrict uses of chemicals such as lead, mercury, phthalates, and certain flame retardants.

Partly as a result of the intensity of lobbying related to the scientific findings about the chemicals addressed in the ban bills, the Legislature began to discuss ways to delegate decisions about chemicals to scientists. At the same time, the administration was promoting a "green chemistry" initiative. In 2008, the Legislature passed SB 509 and AB 1879, known as the "green chemistry" legislation to reduce hazards in products sold in the State. Mr. Feuer authored AB 1879 and Senator Simitian authored SB 509. In many forums, the sponsors have spoken about their intent to create a scientifically based program to assess and reduce hazards. At many hearings, we have heard comments from other legislators as well about their interest in having scientific assessments performed by scientists. The legislation was portrayed as providing a way for that to happen.

The proposal

The proposal would implement portions of SB 509, Senator Simitian's bill to improve the availability of information about hazard traits of chemicals. SB 509 authorized the State to establish a clearinghouse of information about chemicals that would be accessible to the public and to businesses interested in reducing their toxic footprint, as well as government agencies such as the Department of Toxic Substances Control and others.

There is widespread agreement that information about chemical hazards is important. If you don't have access to information about hazards of chemicals in use and potential alternatives, it is difficult to choose safer chemicals and reduce hazards. It is probably fair to say that one lesson that emerged from the experience with the safer consumer products regulations put forward last fall was that it is important to identify high hazard chemicals, also known as "chemicals of concern" and it is also important to identify lower hazard chemicals that might be used instead.

Senator Simitian recognized the critical role that reliable information would play in enabling selection of safer alternatives by the state, businesses and consumers. SB 509 authorized the state to establish a clearinghouse. It directed the Office of Environmental Health Hazard Assessment (OEHHA) to ensure a scientific basis for the design of the clearinghouse and to determine, based on scientific knowledge, the hazard traits of chemicals that are important to know about. The clearinghouse was to then to be designed to be able to accommodate information about these traits.

One of the strengths of the clearinghouse concept is that information available through a clearinghouse can serve audiences with very different tolerances of hazard. For example, parents seeking products for their children may seek products with very little hazard compared to what might be regulated by the government.

The proposal represents the identification of hazard traits by the state's scientists at OEHHA after a scientifically based review. OEHHA looked at what we have learned about the hazards that can be associated with chemicals. This proposal shows the hazard traits that are valuable to know about when assessing chemical hazards, based on current scientific knowledge. They are divided into four categories that are similar to those adopted in the globally harmonized system (GHS) for warnings under development by the United Nations.

The proposal provides authoritative references to support the traits included. It also provides definitions keyed to those used in authoritative sources. This places this review within the evolution of knowledge and practice in this area. It advances the state of the art in this area by considering and building upon definitions put forward over time by other authoritative entities.

The traits reflect gains in scientific knowledge in recent years. They include traits that have been demonstrated to be important to public health but that may not have been much understood back in the 1960s and 1970s, when many of the traditional methods were adopted. The proposal represents a more scientifically valid starting point than older references such as the "CMR" list that dates from the 1960s. Identifying hazard traits in a transparent way allows for public discussion and consideration of what we want to know about in organizing information to support the work of making decisions about chemicals. It is an essential first step toward a scientifically based program.

Information relevant to hazard traits

The proposal discusses the types of information that might be considered relevant for each hazard trait. This is very important in contributing toward a transition toward use of more modern methods for assessing chemicals. The National Academy of Sciences has recommended that a transition be made to incorporate newer methods and more current scientific understanding. Several entities have projects oriented towards advancing this. There is a need

for a discussion about how such a transition would occur. The proposal contributes toward this by discussing kinds of information that might be considered for the different traits.

We all hope that the day will come when green chemistry has advanced to the point where we have new metrics that allow us to determine that chemicals are benign by design and not of health concern. Perhaps others can comment on how far in the future that may be. But for now, chemicals safety programs are still using the methods of the 1970s and 1980s. We have new approaches such as REACH, the Globally Harmonized System (GHS), and Design for Environment (DfE), but they still use methods developed by a previous generation. There is a real need for focused discussion about how to move beyond this.

Builds on Existing Work

The OEHHA proposal also discusses the use of findings by authoritative bodies. It shows when the findings of existing authoritative bodies are relevant for specific hazard traits. This contributes to the Legislature's goal to rely on existing information and determinations as much as possible. It is detailed and specific and provides useful guidance to the Clearinghouse and other contexts.

Protecting Children from Hazards

One concern is the treatment of hazards that are of great concern for children. We are all familiar with lead and the enormous toll that lead exposure has taken on the cognitive abilities of those exposed as children in the US and around the world. Lead causes neurodevelopmental effects, meaning that it affects the development of the brain and reduces the cognitive abilities of those who are exposed, down to very low levels of exposure with no clear threshold. The widespread use of lead in gasoline led to widespread exposure to children of earlier generations to lead and has led to enormous costs in the US and around the world. The evidence of the connection between lead and ADHD is beginning to emerge. [1] We are still relying on

[1] See for example, Froehlich TE, Lanphear BP, Auinger P, Hornung R, Epstein JN, Braun J, Kahn RS.. Pediatrics. 2009 Dec; 124 (6):e1054-63. Association of tobacco and lead exposures with attention-deficit/hyperactivity disorder.

epidemiology to detect agents that cause neurodevelopmental effects. Results have been reported for other widely used compounds including pesticides. [2]

Whether chemicals might have a similar trait is very important to know. Testing for neurodevelopmental effects is not commonly done, leading to inadequate management of these effects and tremendous costs. [3]

The current draft proposal will exacerbate this problem because it treats data about reproductive and development effects as being identical to data about neurodevelopmental effects. This is simply not the case. In many or all of the national and international testing regimes, a distinction is made between testing protocols that are capable of detecting reproductive effects, developmental effects, and neurodevelopmental effects. The testing protocols that are deemed acceptable in regimes such as REACH for detecting developmental effects are not designed to and would not detect neurodevelopmental effects if they occurred. Consequently, a chemical can be tested and found to be "negative" for developmental effects without obtaining any information whatsoever about whether it might cause neurodevelopmental effects. They are not the same thing.

I would recommend that this be explicitly addressed in the design of the clearinghouse so that it is easy to determine whether information is available for a chemical about this issue and whether there is any cause for concern. This should be done by distinguishing between "developmental effects," and "neurodevelopmental effects," and not accepting testing regimes for the latter that test only for the former. Otherwise the information in the clearinghouse will be misleading.

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[2] See, for example:

Eskenazi B, Marks AR, Bradman A, Harley K, Barr DB, Johnson C, Morga N, Jewell NP. Environ Health Perspectives. 2007 May; 115 (5):792-8. Organophosphate pesticide exposure and neurodevelopment in young Mexican-American children.

Eskenazi B, Rosas LG, Marks AR, Bradman A, Harley K, Holland N, Johnson C, Fenster L, Barr DB. Basic Clinical Pharmacol Toxicol. 2008 Feb;102(2):228-36. Pesticide toxicity and the developing brain.

Grandjean P, Weihe P, White RF, Debes F, Araki S, Yokoyama K, Murata K, Sørensen N, Dahl R, Jørgensen PJ. Neurotoxicol Teratol. 1997 Nov-Dec;19(6):417-28. Cognitive deficit in 7-year-old children with prenatal exposure to methylmercury.

[3] Grandjean P and Landrigan PJ. Lancet. 2006 Dec 16;368(9553):2167-78. Developmental neurotoxicity of industrial chemicals

No Data is Not the Same as No Hazard

One area that needs additional attention would be to distinguish between cases where data were available to suggest that a chemical did not have a hazard trait and cases where data were not available at all. At present, the proposal appears to treat "no data" the same as "no hazard." It is a tricky problem in a number of contexts for chemicals policies to distinguish between chemicals that are thought to be of low hazard and chemicals that have simply not been assessed. There is a tendency to treat chemicals with no data the same as those with no problem. The approach needs to clearly distinguish between these cases.

In closing, I would like to commend OEHHA for an important advance in chemicals policy development.

About the author

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