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Ms. Corey Yep
Associate Deputy Director
Office of Legislation and Regulatory Policy
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814

September 29, 2011

Re: UCLA Sustainable Technology and Policy Program (STPP) Recommendations regarding Alternatives Analysis Methods under AB 1879

Dear Ms. Yep:

I am writing on behalf of STPP's regulatory alternatives analysis project team, which includes me, Peter Sinsheimer, Ann Blake and Igor Linkov. Funded by a grant from the Public Health Trust, in early August 2011 we completed a research project "Developing Regulatory Alternatives Analysis Methodologies for the California Green Chemistry Initiative". Among other things, this project examined the feasibility of using formal decision analysis aids (specifically two forms of multi-criteria decision analysis or "MCDA") in the context of AB 1879.¹ On August 15, 2011, we presented the results of that study to staff and managers involved in the development of the green chemistry regulations at the Department of Toxic Substances Control (DTSC). At that meeting, we were asked whether and how our alternatives analysis model (including the MCDA elements) could be practically integrated into the green chemistry regulations. This letter briefly outlines one recommended approach for integrating an MCDA-based alternatives analysis process into the regulations.

In developing the recommendations, we assumed that the agency would choose a "permitting" or "approval" type approach to regulation; that is, individual manufacturers (or groups of manufacturers) would submit individual alternatives analyses to which the agency would respond. This is in contrast to a more centralized approach in which the agency engages in a sector- or product-based rulemaking procedure culminating in a generally applicable rule. We also assumed that (i) either the agency or an agency-approved/certified third party would review and approve/reject/modify submissions by the regulated entities, and (ii) the agency alone would be responsible for issuing any regulatory response regarding the product of concern. Taking those assumptions into account, our recommendations include four elements:

● Regulations

- The regulations should articulate a set of narrative decision principles guiding the evaluation of the regulated product (the "baseline product") and its alternatives. See Peter J. Sinsheimer and Timothy F. Malloy, Integrating

¹ See UCLA Sustainable Technology & Policy Program, DEVELOPING REGULATORY ALTERNATIVES ANALYSIS METHODOLOGIES FOR THE CALIFORNIA GREEN CHEMISTRY INITIATIVE: FINAL REPORT (August 1, 2011).

Safer Alternatives into Chemical Policy: Developing a Regulatory Framework for AB 1879 (Sustainable Technology & Policy Program 2009). The narrative principles should describe the decision framework to be used by the agency in evaluating the safety and viability of potential alternatives (such as a full compensatory approach; a tiered, screening approach; elimination by aspects; etc.)

- The regulations should establish a default set of evaluation criteria derived from the “A-M” list and other relevant factors, and clearly articulate the relative weight to be accorded the criteria expressed either qualitatively or quantitatively.
- The regulations should set out standard data submission requirements with respect to each of the default criteria consistent with the OEHHA regulations under SB 509, and with the best available science. The data submission requirements should include metrics for the criteria, testing methods or other means of evaluating chemicals/products, and data quality and assurance standards.
- The regulations should provide for the performance of an AA by the regulated entity, in accordance with a work plan reviewed and approved by DTSC. The entity’s final AA will be considered, along with other information and input, during the agency’s deliberations regarding regulatory response.

⊙ Work Plan Requirements

- The work plan will identify the relevant criteria drawn from the default criteria set out in the regulations, and include specific justification for excluding default criteria or adding to them.
- The work plan will identify the alternatives to be included in the AA, and will provide justification for that selection.
- The work plan will set out the metrics as well as available data and the data collection plan for any missing data, including test methods and QA/QC.
- The proposed work plan will be subject to public review and comment.
- Based upon its review, and after considering public comment, DTSC will identify necessary additions/modifications to the work plan.

⊙ Manufacturer AA Report

- The regulated entity will perform the AA in accordance with the work plan as approved by DTSC.
- The data regarding performance of the baseline product and the alternatives will be presented in a format set out in the work plan.
- The evaluative aspect of the AA (assessing the performance under the decision framework, taking into account the weighting accorded the various criteria in the regulations) could be performed in any reasonable manner so

long as it is consistent with the narrative decision principles and is rigorous and transparent.

- The draft AA report will be subject to public review and comment.
- Based upon its review, and after considering public comment, DTSC will identify necessary additions/modifications to the AA Report.

⊙ DTSC Review Process

- Interested third parties may submit their own AA reports regarding the baseline product and alternatives identified by the regulated entity as well as other potential alternatives.
- DTSC will generate an MCDA report focused upon the evaluative aspect of the AA (assessing the performance under the decision framework, taking into account the weighting accorded the various criteria in the regulations). It will use an MCDA model developed for these purposes and associated publicly-accessible software. The MCDA model would be consistent with the regulations, including specifically the narrative decision principles. The MCDA report will use the data generated by the regulated entity (and any other relevant data obtained by DTSC), evaluated using the MCDA model.²
 - ⊙ The MCDA Report would be available as part of the record for any subsequent proposed regulatory response, at which time interested parties could address it in their comments on the proposed regulatory response.
 - ⊙ Manufacturers required to perform an AA are not required to use this MCDA model, but may choose to do so if they desire.
- DTSC management will use the DTSC MCDA report, the Manufacturer AA Report, any other submitted AA's, public comment, and the narrative decision principles to identify regulatory action, if any, required under the statute.
- Because the DTSC's use of MCDA will simply assist the agency in reviewing and evaluating data and inform its decisions, but will not itself impose any obligations upon manufacturers or other parties, it will not constitute an underground regulation. *See Californians for Pesticide Reform v. Department of Pesticide Regulation*, 184 Cal. App. 4th 887 (2010) (holding an internal prioritization process for pesticides that imposed no obligations on regulated entities was not subject to the APA under the internal management exception).

In developing these recommendations, we attempted to address several legal and practical constraints faced by the agency. First, the regulations must be promulgated expeditiously, meaning there would be little time to fully develop an MCDA-based approach if it were to be embedded in the regulations. Second, the restrictions on underground regulation severely

² Use of data generated under the approved work plan should minimize burdens on DTSC. With properly designed MCDA software, generation of the DTSC MCDA report should place relatively limited resource burdens on the agency.

limit the agency's ability to mandate the use of MCDA generally or any particular MCDA method by regulated entities absent rulemaking. Third, the agency's resources are severely limited due to the state of California's budget. With those constraints in mind, the recommendations integrate MCDA as a decision aid for the agency's evaluation of the AA's submitted by the regulated entity and other interested parties and its development of a regulatory response. This approach averts treatment of MCDA as an underground regulation, and provides manufacturers and others with the flexibility to develop their own evaluative methods while ensuring consistency across cases in DTSC review. It also facilitates smooth modification of the MCDA method as DTSC gains experience in its use in this regulatory context.

We hope that you find these recommendations useful. Please do not hesitate to contact us if you have any questions or comments, or would like to discuss these recommendations or the project further. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Timothy F. Malloy', written in a cursive style.

Timothy F. Malloy
Professor of Law