KOCH INDUSTRIES INC

February 15, 2011

Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Via Electronic Mail: fkammerer@oehha.ca.gov

RE: Proposed Regulations to Amend Division 4.5, Title 22, California Code of Regulations Chapter 54. Green Chemistry Hazard Traits.

Dear Ms. Kammerer:

Koch Industries, Inc. (KII) and its affiliate companies appreciate this opportunity to comment on the Proposed Regulations to Amend Division 4.5, Title 22, California Code of Regulations Chapter 54, Green Chemistry Hazard Traits ("Proposed Regulations") presented by the Office of Environmental Health Hazard Assessment (OEHHA) . KII owns a diverse group of companies involved in refining and chemicals; process and pollution control equipment and technologies; minerals; fertilizers; polymers and fibers; commodity trading and services; and forest and consumer products. KII companies have a presence in nearly 60 countries with approximately 70,000 employees – over 1,400 of whom are in California.

KII recognizes the significant changes reflected in the Proposed Regulations in response to the September 2010 stakeholder comment submittal. However, KII continues to be concerned with the lack of coordination between the Proposed Regulations and the Department of Toxic Substances Control (DTSC) proposed safer alternatives regulations. Scrutiny needs to be employed in the development of the applicable hazard traits in the Proposed Regulations given the direct and significant influence this will have on the evolving DTSC process. KII recognizes that the DTSC proposed safer alternatives regulations are currently on hold and suggests that the OEHHA adopt a similar hold and align the development schedule to foster the greatest level of coordination and cooperation between the two efforts.

316.828.8363 Tel
316.828.5074 Fax
316-200-5701 Cell

4111 E. 37th Street North
Wichita, Kansas 67220
anne.monine@kochind.com

Summary of Concerns

1. Existing Systems and Databases: A new California-only system for evaluation of, and creating a database for, hazard traits as proposed under the draft regulation is inefficient, duplicative, and will make it unnecessarily difficult to leverage existing information on chemicals. A non-standard approach will slow the development of the Toxics Information Clearinghouse (TIC) database and require substantial effort from DTSC and OEHHA to convert the information to the unique California system, both initially and on an ongoing basis. California should align with existing systems, such as Health and Environmental Research Online (HERO) or Organisation for Economic Co-operation and Development (OECD), rather than creating a California stand-alone system (an independent state-based classification system that will not enhance the existing data available and result in a waste of resources). KII also supports the suggestion by the Green Chemistry Alliance (GCA) to look to the information available through the Globally Harmonized System (GHS) for Classification and Labeling. OEHHA has not provided sufficient justification as to why existing systems might be inadequate.

2. Balanced Approach: The Proposed Regulations only consider positive data, not the negative or contrary data that may be available. The weight of evidence (WOE) relied upon for any decision making clearly depends on consideration of all evidence – positive and negative – that may be available regarding a hazard trait or chemical. The format considered by OEHHA is therefore distorted and biased. OEHHA needs to implement a WOE approach considering all credible evidence – positive and negative – that may be available about substances included in the TIC. A WOE approach would examine information available from credible, peer-reviewed studies that are based on scientifically accepted methodologies. This approach will allow the evaluators to make a reasonable scientific determination of a chemical's hazard based on the best available science.

3. Cost to State: OEHHA's Notice of Proposed Regulation suggests that the Proposed Regulations will "not impose new duties on OEHHA or any other state agency other than the need to periodically review and update the regulation to keep up with changing scientific knowledge and methodologies." Reference, pg 5. KII disagrees with this assessment and suggests that further review is needed. The budget considerations for creating an extensive and duplicative TIC should be carefully reviewed prior to proceeding. Extensive resources will be needed to evaluate the information entering the TIC, to investigate the validity of sources of information and in the maintenance of informationstored on the TIC. OEHHA should not underestimate the costs associated with these Proposed Regulations. Given that there are existing systems available, it is unclear why OEHHA would not leverage those systems and eliminate duplicative resource demands necessary to develop and maintain an accurate, credible and reliable California specific system.

4. Data Quality and Data Flags: If OEHHA moves forward with establishing a California specific system, it will be critically important to ensure the quality of data entered into the system. Data quality is the reliability and utility of data which is particularly important in a clearinghouse situation. KII recommends that OEHHA incorporate a data quality system to verify the reliability and utility of the data selected for the TIC, and develop a proposal for periodically updating the information. OEHHA's process should include review of the data and other information available, updating where needed, removal of old or discredited information, elimination of duplication, and where possible confirming the accuracy and credibility of information. While it is KII understanding that OEHHA and DTSC plan to standardize the

data on the site, the Proposed Regulations do not clearly identify the process for which and the responsible parties by whom this standardization will be undertaken. In addition, OEHHA should consider the use of data flags to differentiate values included on the TIC (including valid values, estimated values, interpolated values, minimum detectable limits (MDL) values, and missing values). Finally, OEHHA should consider annotating the data on the TIC to indicate the limits on its use or provide context on the appropriate use of the information so that a lay person can have a better understanding and data is not misused.

KII suggests that OEHHA review the "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" issued by the Office of Management and Budget (OMB) to help with ensuring data reliability. See, 67 Fed. Reg. 8452 (February 22, 2002). In the Guidelines, OMB discusses approaches that help to ensure the quality, objectivity, utility, and integrity of information and to establish administrative mechanisms to allow affected persons to seek and obtain correction of information when needed. KII encourages OEHHA to review and incorporate the OMB definitions of "quality", "utility", "objectivity", and "integrity" as the Proposed Regulations are further developed.

5. Unclear Scope: The Purpose and Applicability section of the Proposed Regulation (Section 69401) fails to outline the scope of chemicals and chemical information that will be available on the TIC. The applicability section should identify the universe of chemicals that will be included, how the chemical information will be identified and who will decide what is appropriate for inclusion. If OEHHA intends a phased-in approach, the Proposed Regulations should state so clearly. KII also recommends referencing how the chemicals under consideration contemplated in Health and Safety Code Section 25252 will be incorporated or prioritized, if at all. Finally, KII suggests that OEHHA focus the hazard traits on those traits with scientific consensus and include the appropriate study protocol(s) for each of the endpoints. OEHHA should avoid developing or unilaterally establishing alternative definitions and/or new hazard traits.

6. Prioritization: Information available on the TIC should be prioritized and "scrubbed" to avoid causing consumer confusion. The purpose of the TIC is to "make the clearinghouse accessible to the public." H&S Code Section 25256. But accessibility is only valuable if the information is accurate, readily understandable, and presented in the proper context. OEHHA must balance the goal of accessibility with OMB's requirements for information quality, utility, objectivity, and integrity. Overloading the TIC with useless information or so much information that the public does not know how to interpret and use the information fails to meet the accessibility requirement.

Conclusion

KII encourages OEHHA to (1) suspend further work on the Proposed Regulation and work with DTSC to better coordinate with the Safer Alternatives Regulation and the Brown Administration; and (2) take additional time to continue work on the list of hazard traits for the TIC.

Given the concerns raised above, in Attachment 1, and in the Green Chemistry Alliance (GCA) comment letter dated February 15, 2011, clearly more work is needed. KII also supports the comments submitted by the American Cleaning Institute (ACI), and KII specifically points OEHHA to ACI's comments related to environmental hazard traits. California does not need to create a state-only system given the

existing databases and hazard traits that are being investigated by United States Environmental Protection Agency, and in other jurisdictions. KII strongly encourages OEHHA to work closely with DTSC to evaluate where existing systems may have gaps and focus on those areas, rather than duplicating efforts. Finally and importantly, the OEHHA Proposed Regulations must clearly identify how the information will be used and incorporate a weight of evidence approach to prioritization.

KII respectfully submits the attached comments regarding OEHHA's Proposed Regulations (December, 2010). For further information or questions regarding our comments, please contact Heather Bowman (316-828-7065).

Sincerely,

Anne Monine
Director, Environmental Excellence
Koch Industries, Inc.

Enclosure: Attachment 1

cc: Secretary, CalEPA
Undersecretary, CalEPA
Deputy Secretary for Policy, CalEPA
Director, OEHHA
The Honorable Leonard Robinson, Acting Director, DTSC
Office of the Governor

Attachment 1

Koch Industries, Inc. Detailed Comments on:
Proposed Regulations to Amend Division 4.5, Title 22, California Code of Regulations
Chapter 54. Green Chemistry Hazard Traits.

1. Existing Systems and Databases

As mentioned in our cover letter, KII is concerned that the Proposed Regulations outline a new California-only system for evaluation of, and creating a database for, hazard traits that, as proposed, is inefficient, duplicative and will make it unnecessarily difficult to use existing information on chemicals. KII encourages OEHHA to harmonize as much as possible with existing international and national systems that already identify the information elements necessary to study and characterize chemicals. Some examples include:

A. *EPA HERO Database*: OEHHA's Proposed Regulation is a duplication of the Health and Environmental Research Online (HERO) database. HERO includes references and data from the "Integrated Risk Information System (IRIS), a database that supports critical agency policymaking for chemical regulation." See, http://cfpub.epa.gov/ncea/hero/index.cfm. This is an evergreen database which is constantly updated with new information and studies. The website has been developed to provide the public with easy access to the studies used in EPA's science assessments and policymaking.

B. *OECD Chemical Databases* – OECD has developed several chemical databases to improve the health and safety information available to the public. These databases include: (i) eChemPortal, (ii) EXICHEM (existing chemicals) Pointer Database, (iii) New Industrial Chemicals Information Directory, (iv) Integrated High Production Volume Chemicals Database, (v) International Directory for Emergency Response Centers, (vi) Pollutant Release and Transfer Registers (PRTR) databases, and (vii) Database on Chemical Risk Assessment Models. See, http://www.oecd.org/linklist/0,3435,en_2649_34365_2734144_1_1_1_1,00.html#41477030 The global nature of the chemicals marketplace requires that California look to these existing databases as a source for the information requested in SB 509.

C. *European Commission, International Uniform Chemical Information Database* (IUCLID) – This is a software application to capture, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. This is the tool used by many to fulfill obligations under EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) directive. See, http://iuclid.eu/index.php?fuseaction=home.iuclidHome

The extent of testing that has already been or will be completed and incorporated into these databases should be relied upon by California. These databases can be used to help efficiently and effectively populate (if necessary) a California-centric database. Many of these databases already employ a framework for addressing the issues of categories, tiered testing, acute versus chronic toxicity, judging study quality/reliability, and weight of evidence approaches that are not addressed in OEHHA's Proposed Regulations. Instead of creating a California specific approach, KII encourages the evaluation and use of these existing sources of data as required by the Health and Safety Code §25257.1.

2. Balanced Approach

KII is concerned that the Proposed Regulation only considers positive data, not the negative or contrary data that may be available. Introducing a weight of evidence (WOE) methodology for ranking chemicals consistent with the methods proposed by Calabrese and colleagues may be a useful first step to addressing this problem[1]. Such a system would enable OEHHA and DTSC to evaluate the data inputs to the TIC and present information to the public that is scientifically valid and balanced.

3. Cost to State

OEHHA's Notice of Proposed Regulation suggests that the Proposed Regulations will "not impose new duties on OEHHA or any other state agency other than the need to periodically review and update the regulation to keep up with changing scientific knowledge and methodologies." Reference, pg 5. KII suggests that OEHHA and DTSC should survey the creators of other chemical databases, such as EPA, the EC for IUCLID, and OECD to determine a more realistic cost implication for the evaluation of hazard traits and creation of a database. The cost involved for ensuring data quality and creating the new unique California specific classification system and database will be expensive. OEHHA should not underestimate the costs associated with this Proposed Regulation.

4. Data Quality and Data Flags

Data quality is the reliability and effectiveness of data which is particularly important in a clearinghouse situation. KII recommends that OEHHA incorporate a data quality system to verify the reliability and utility of the data selected for the TIC, and a proposal for periodically updating the information. OEHHA's process should include review of the data and other information available, updating where needed, removing old or discredited information, removing duplication, and where possible confirming the information.

An approach that OEHHA may want to consider that is consistent with WOE method using "all" evidence available, is an approach where some evidence is weighted as more

[1] Calabrese, E.J., Baldwin, L. A.,Kostecki, P.T.,& Potter,T.L. (1997). A toxicologically based weight-of-evidence methodology for the relative ranking of chemicals of endocrine disruption potential. Regulatory Toxicology and Pharmacology, 26, 36–40.

reliable than others. In the WOE literature, Klimisch *et al.* (1997)[2] describe an approach that addresses the quality of toxicological studies, an approach that could be used more generally to assign any scientific study into one of four reliability categories:

a. Reliable without restriction (i.e., conforming to good laboratory practices (GLP) or some other set of quality criteria)
b. Reliable with restriction (i.e., well documented and scientifically acceptable, but falling short of GLP)
c. Not reliable (not well documented or used unacceptable methods)
d. Not assignable (e.g., abstracts)

Evidence that is considered reliable (with or without restriction) is subsequently used in the risk assessment; evidence judged to be "not reliable" or "not assignable" is not automatically included, but may be used on a case-by-case basis depending upon expert judgment.

5. Unclear Scope

The Purpose and Applicability section of the Proposed Regulation (Section 69401) fails to outline the scope of chemicals and chemical information that will be available on the TIC. The applicability section should identify the universe of chemicals that will be included, how the chemical information will be identified and who will decide what is appropriate for inclusion. If OEHHA intends a phased in approach, that should be made clear. KII also recommends referencing how the chemicals under consideration contemplated in Health and Safety Code Section 25252 will be incorporated or prioritized, if at all.

KII incorporates the concerns outlined in the GCA comment letter (February 15, 2011) and attachment. KII directs OEHHA to carefully review GCA's comments explaining the complexity of the draft, concerns with the list of "icities" and emerging traits.

6. Prioritization

The regulations fail to provide the basis for the TIC envisioned by SB 509. All that the regulations attempt to do is outline a variety of different types of endpoints and hazard traits as well as precursors to hazard traits and endpoints. The Proposed Regulations fail to provide standards for data quality and specific test methods eligible to be available through the TIC. Health and Safety Code §25256.2(a). Due to this overly broad approach, every chemical and hazard trait including precursors to hazard traits would end up being listed in the database. The process for prioritization must incorporate WOE and data quality factors. Failing to prioritize the information on the database merely creates a duplicative and redundant database as mentioned in above in Section 1. Furthermore, the inclusion of precursors to hazard traits also exceeds the statutory authority provided by

[2] Klimisch, H.J., Andreae, M., & Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology, 25(1), 1–5.

SB 509. Health and Safety Code §25256.1. Without prioritization and scoping of data and chemicals, OEHHA and DTSC will fail to achieve the purpose of SB 509 – to create a consumer friendly clearinghouse of information on chemicals. Instead, OEHHA's Proposed Regulations would create a website with so much information that it will be impossible to use for any purpose. More work is needed to understand how the universe of chemicals and hazard traits will be selected and prioritized.