Assessment and Management of Nano Risk:

A Regulatory Perspective

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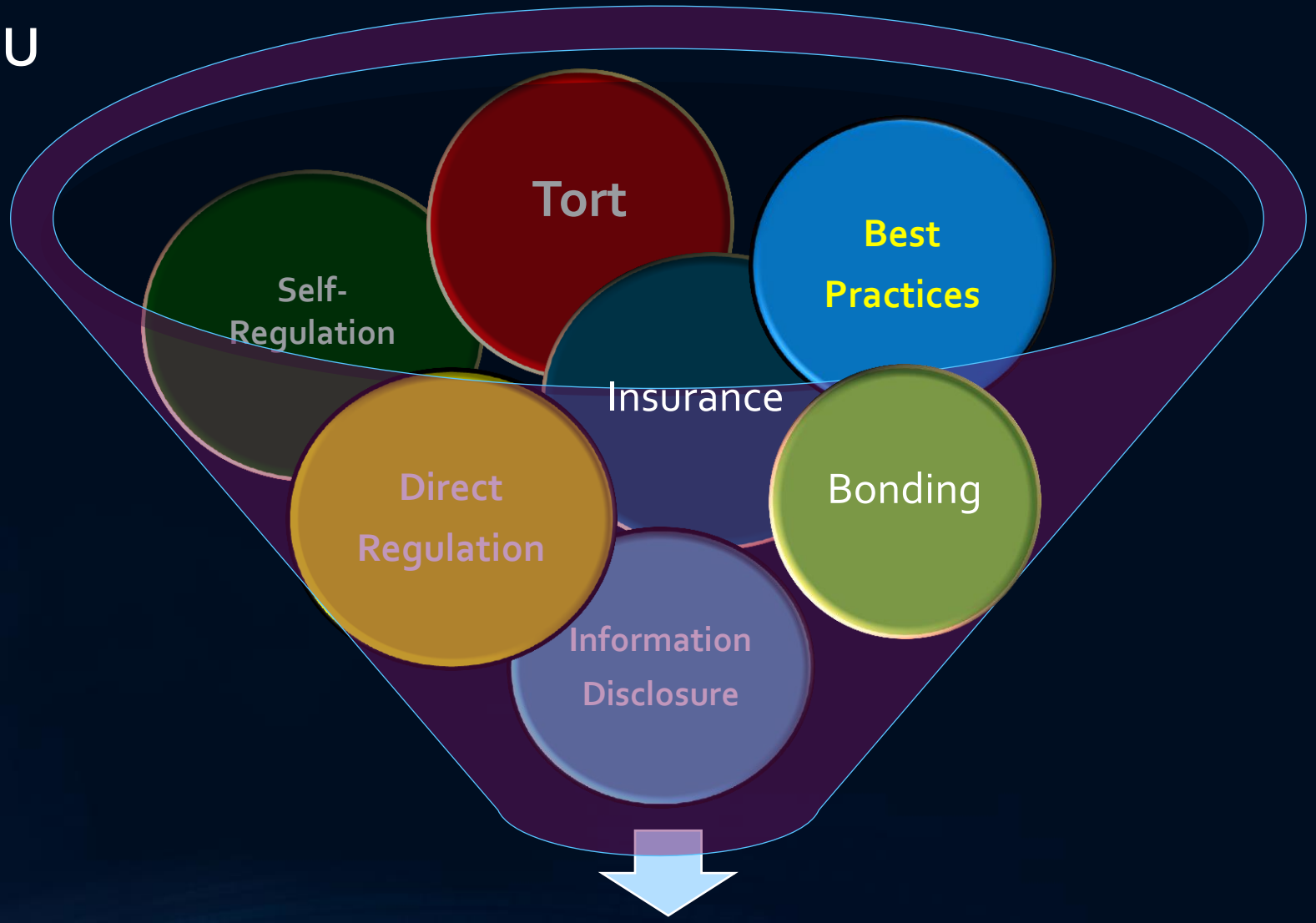
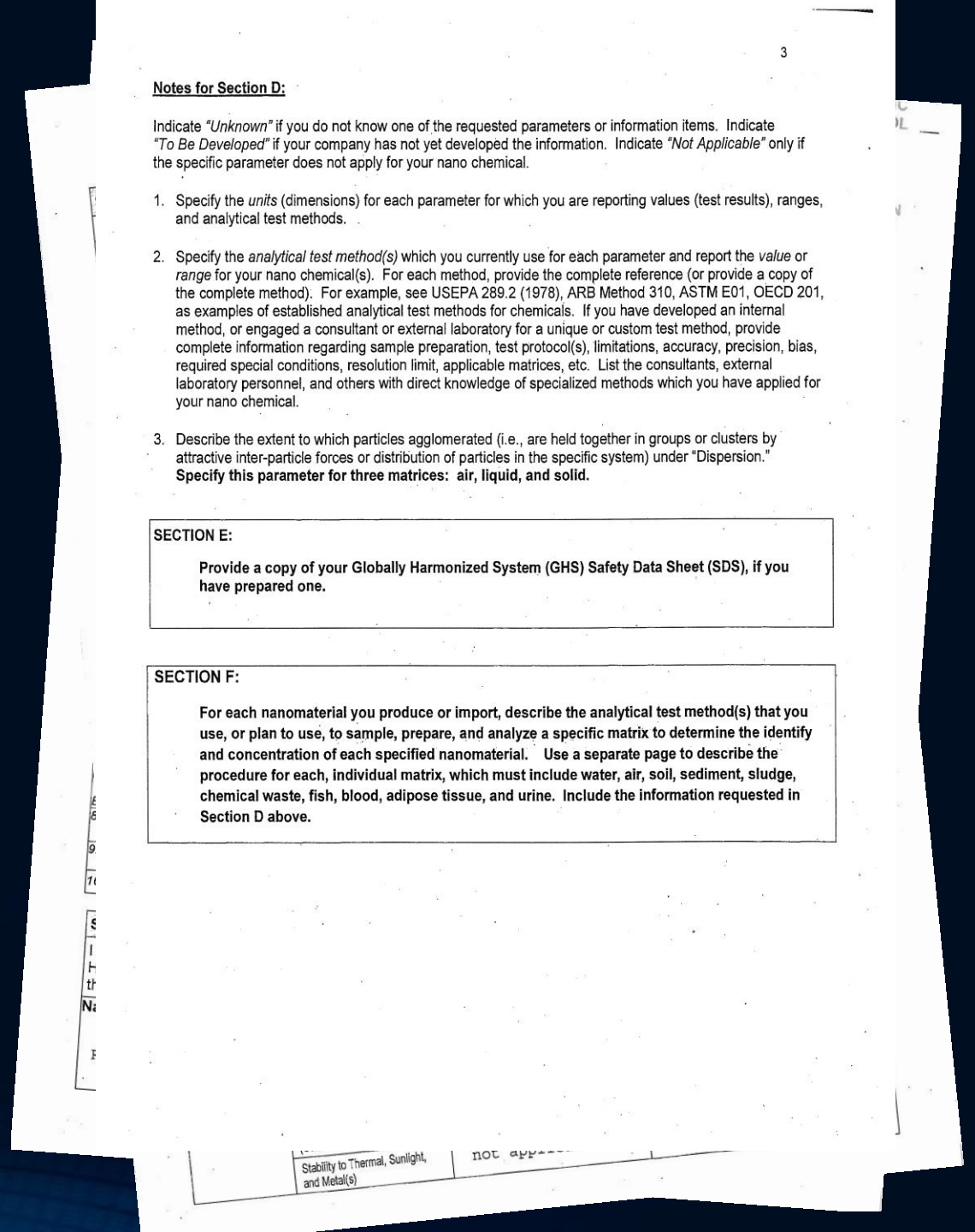
The Road That Stretches On Ahead

- Non-Federal Regulatory Action: California Dreaming
- Decision Needs in the Regulatory Context
- Tools and Methods
- Concluding Thoughts

The Policy Milieu



Information Disclosure: California Style



Notes for Section D:

Indicate *"Unknown"* if you do not know one of the requested parameters or information items. Indicate *"To Be Developed"* if your company has not yet developed the information. Indicate *"Not Applicable"* only if the specific parameter does not apply for your nano chemical.

1. Specify the *units* (dimensions) for each parameter for which you are reporting values (test results), ranges, and analytical test methods.

2. Specify the *analytical test method(s)* which you currently use for each parameter and report the *value* or *range* for your nano chemical(s). For each method, provide the complete reference (or provide a copy of the complete method). For example, see USEPA 289.2 (1978), ARB Method 310, ASTM E01, OECD 201, as examples of established analytical test methods for chemicals. If you have developed an internal method, or engaged a consultant or external laboratory for a unique or custom test method, provide complete information regarding sample preparation, test protocol(s), limitations, accuracy, precision, bias, required special conditions, resolution limit, applicable matrices, etc. List the consultants, external laboratory personnel, and others with direct knowledge of specialized methods which you have applied for your nano chemical.

3. Describe the extent to which particles agglomerated (i.e., are held together in groups or clusters by attractive inter-particle forces or distribution of particles in the specific system) under "Dispersion." **Specify this parameter for three matrices: air, liquid, and solid.**

SECTION E:

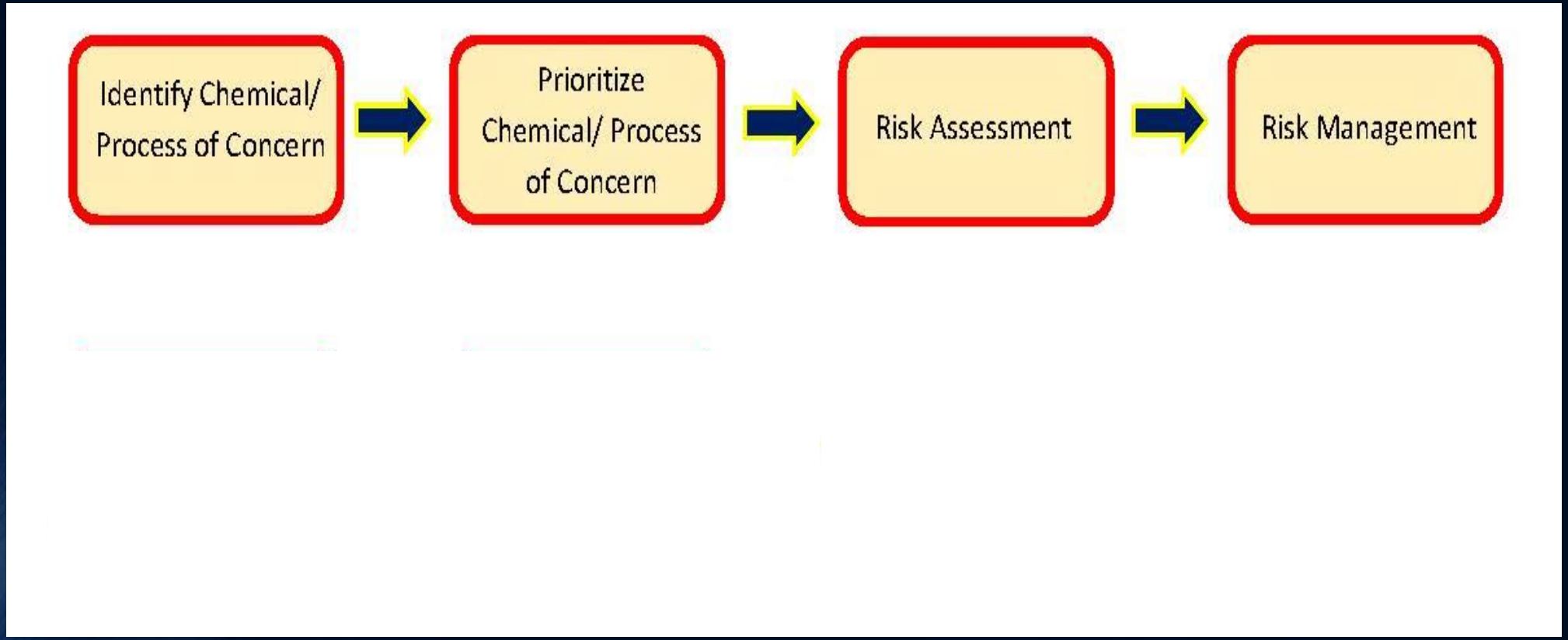
Provide a copy of your Globally Harmonized System (GHS) Safety Data Sheet (SDS), if you have prepared one.

SECTION F:

For each nanomaterial you produce or import, describe the analytical test method(s) that you use, or plan to use, to sample, prepare, and analyze a specific matrix to determine the identify and concentration of each specified nanomaterial. Use a separate page to describe the procedure for each, individual matrix, which must include water, air, soil, sediment, sludge, chemical waste, fish, blood, adipose tissue, and urine. Include the information requested in Section D above.

Stability to Thermal, Sunlight, and Metal(s)

Direct Regulation: Classic



Direct Regulation: AB 1879

Alternatives Analysis Decision Framework




DATA

- Human Health Impact
- Ecological Impact
- Environmental Impact
- Technical Performance
- Economic Impact

Evaluation


1


2


3


4

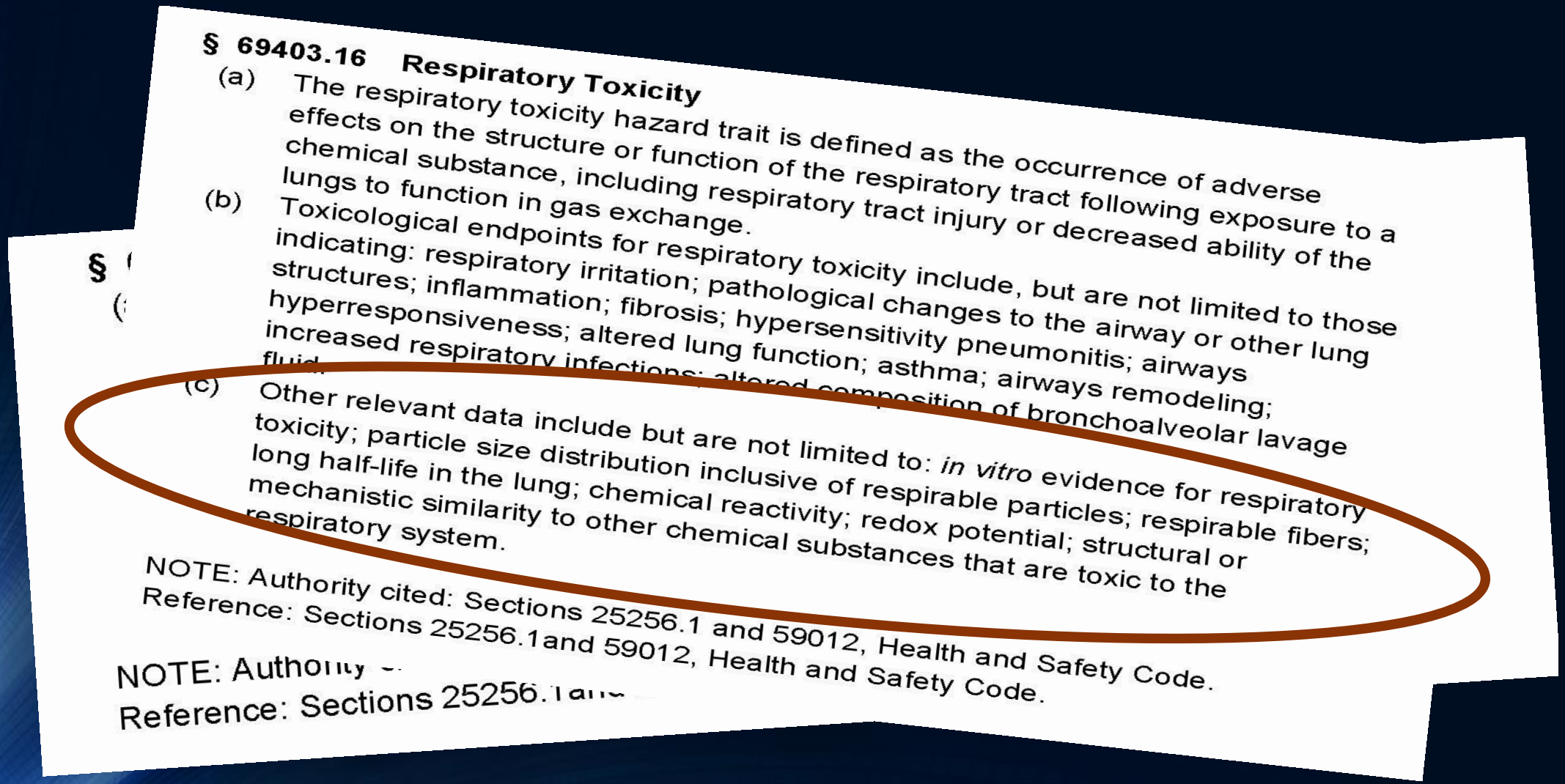
Article 6. Regulatory Responses

§ 69506. Regulatory Response Selection Principles.

(a) Need for Regulatory Response. The Department shall identify and require implementation of one or more regulatory responses for Priority Products and/or selected alternative products when the Department determines such regulatory responses are necessary to protect public health and/or the environment. In selecting regulatory responses, the Department shall seek to maximize the use of alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible.

(b) Inherent Protection Preference. In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection. For these purposes, "inherent protection" refers to avoidance or reduction of adverse impacts, exposures, and/or adverse waste and end-of-life effects that is achieved through the redesign of a product or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a Chemical of Concern or replacement Candidate Chemical in a product.

California Coverage of Engineered Nano Materials (ENM)



§ 69403.16 Respiratory Toxicity

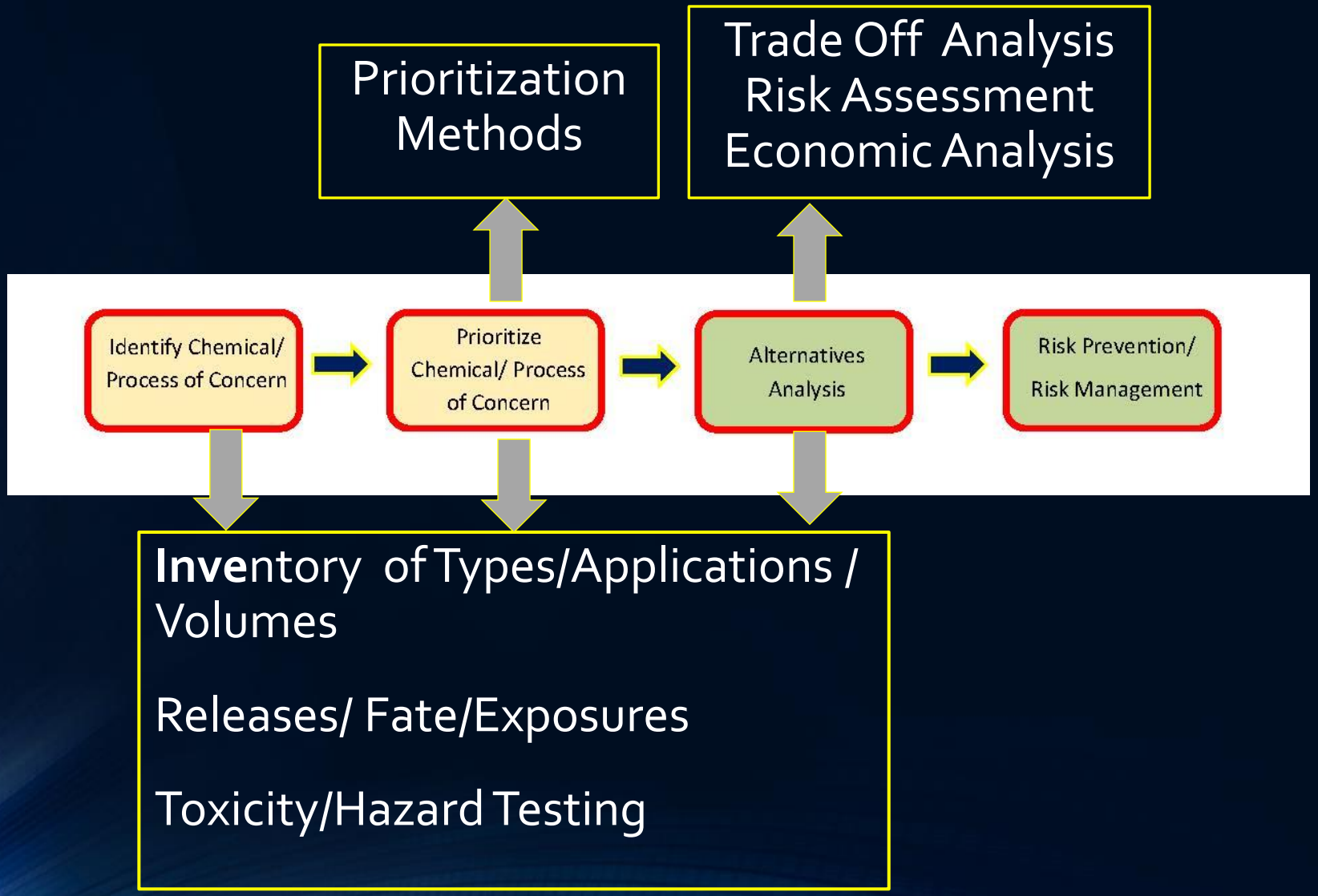
(a) The respiratory toxicity hazard trait is defined as the occurrence of adverse effects on the structure or function of the respiratory tract following exposure to a chemical substance, including respiratory tract injury or decreased ability of the lungs to function in gas exchange.

(b) Toxicological endpoints for respiratory toxicity include, but are not limited to those indicating: respiratory irritation; pathological changes to the airway or other lung structures; inflammation; fibrosis; hypersensitivity pneumonitis; airways hyperresponsiveness; altered lung function; asthma; airways remodeling; increased respiratory infections; altered composition of bronchoalveolar lavage fluid.

(c) Other relevant data include but are not limited to: *in vitro* evidence for respiratory toxicity; particle size distribution inclusive of respirable particles; respirable fibers; long half-life in the lung; chemical reactivity; redox potential; structural or mechanistic similarity to other chemical substances that are toxic to the respiratory system.

NOTE: Authority cited: Sections 25256.1 and 59012, Health and Safety Code. Reference: Sections 25256.1and 59012, Health and Safety Code.

Decision Needs under AB 1879



Regulatory Design Principles

- Transparent
- Flexible
- Pragmatic
- Consistent
- Rigorous

PROTECTIVE

Identify … Fate

- Experimen… from particular applicatio…
- Developme… models
- Developmen… rious applications
- Developmen… determine exposure con…

…et al, 2013

Critical Review

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Environmental Science & Technology

Modeling Approaches for Characterizing and Evaluating Environmental Exposure to Engineered Nanomaterials in Support of Risk-Based Decision Making

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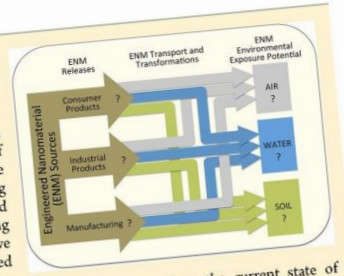
Supporting Information

ABSTRACT: As the use of engineered nanomaterials becomes more prevalent, the likelihood of unintended exposure to these materials also increases. Given the current scarcity of experimental data regarding fate, transport, and bioavailability, determining potential environmental exposure to these materials requires an in depth analysis of modeling techniques that can be used in both the near- and long-term. Here, we provide a critical review of traditional and emerging exposure modeling approaches to highlight the challenges that scientists and decision-makers face when developing environmental exposure and risk assessments for nanomaterials. We find that accounting for nanospecific properties, overcoming data gaps, realizing model limitations, and handling uncertainty are key to developing informative and reliable environmental exposure and risk assessments for engineered nanomaterials. We find methods suited to recognizing and addressing significant uncertainty to be most appropriate for near-term environmental exposure modeling, given the current state of information and the current insufficiency of established deterministic models to address environmental exposure to engineered nanomaterials.



1. INTRODUCTION

The introduction of engineered nanomaterials (ENMs) to the natural environment is inevitable with the increasing ubiquity of nanotechnology in applications ranging from industry to consumer products. As these novel materials are produced and utilized across an increasingly broad range of applications, there is potential across all stages of the value chain for their release to the environment and for possible unknown effects.[1−3] Maximizing potential benefits of nanotechnology, while minimizing unintended negative consequences, ultimately depends upon understanding and managing possible related impacts. In the past decade, a number of studies have started to investigate the potential health, environmental, and safety impacts of ENMs. A Spring 2012 review of the International Council on Nanotechnology (ICON) database of nanorelated publications, however, reveals that, of all related environmental health and safety publications, approximately 90% represent toxicity and effects research while only 10% involve environmental fate and transport studies.[4] Given that a main purpose of environmental health and safety research into ENMs is to inform risk assessments and that risk is a product of both hazard and exposure, the importance of understanding environmental exposure to these materials through their fate and transport behavior is paramount to characterizing, and ultimately managing, their potential risk.

The need and appreciation for environmental exposure research is increasing. Multiple organizations and researchers involved with advancing nano- environmental health and safety (nanoEHS) issues have specifically called for additional investigation of the potential for environmental exposure to ENMs.[5−9] Three recent workshops held by EPA's National Center for Environmental Assessment identified fate and

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PERSPECTIVE

A Multi-Stakeholder Perspective on the Use of Alternative Test Strategies for Nanomaterial Safety Assessment

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Prioritizi

- Verbal Argu
- Decision Ana
- Probabilistic

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RESEARCH PAPER

Risk-based classification system of nanomaterials

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Mark Chappell · Myriam Merad

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Abstract Various stakeholders are increasingly interested in the potential toxicity and other risks associated with nanomaterials throughout the different stages of a product's life cycle (e.g., development, production, use, disposal). Risk assessment methods and tools developed and applied to chemical and biological materials may not be readily adaptable for nanomaterials because of the current uncertainty in identifying the relevant physico-chemical and biological properties that adequately describe the materials. Such uncertainty is further driven by the substantial variations in the properties of the original material due to variable manufacturing processes employed in nanomaterial production. To guide scientists and engineers in nanomaterial research and application as well as to promote the safe handling and use of these materials, we propose a decision support system for classifying nanomaterials into different risk categories. The classification system is based on a set of performance metrics that measure both the toxicity and physico-chemical characteristics of the original materials, as well as the expected environmental impacts through the product life cycle. Stochastic multicriteria acceptability analysis (SMAA-TRI), a formal decision analysis method, was used as the foundation for this task. This method allowed us to cluster various nanomaterials in different ecological

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Alternatives Analysis Decision Framework




DATA

- Human Health Impact
- Ecological Impact
- Environmental Impact
- Technical Performance
- Economic Impact

Evaluation


1


2


3


4

- Verbal-Argumentative
  - Intuitive –"going with yo
  - Embedded values/weig
  - Narrative justification
- Decision Analytical A
  - Systematic—clear dec
  - Explicit values/weight
  - Narrative and formal

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Use Of Multi-Criteria Decision Analysis in Regulatory Alternatives Analysis: A Case Study of Lead Free Solder

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Case Study

ABSTRACT

Regulators are implementing new programs that require manufacturers of products containing certain chemicals of concern to identify, evaluate, and adopt viable, safer alternatives. Such programs raise the difficult question for policymakers and regulated businesses of which alternatives are "viable" and "safer." To address that question, these programs use "alternatives analysis," an emerging methodology that integrates issues of human health and environmental effects with technical feasibility and economic impact. Despite the central role that alternatives analysis plays in these programs, the methodology itself is neither well-developed nor tailored to application in regulatory settings. This study uses the case of Pb-based bar solder and its non-Pb-based alternatives to examine the application of 2 multi-criteria decision analysis (MCDA) methods to alternatives analysis: multi-attribute utility analysis and outranking. It develops and evaluates an alternatives analysis methodology and supporting decision-analysis software for use in a regulatory context, using weighting of the relevant decision criteria generated from a stakeholder elicitation process. The analysis produced complete rankings of the alternatives, including identification of the relative contribution to the ranking of each of the highest level decision criteria such as human health impacts, technical feasibility, and economic feasibility. It also examined the effect of variation in data conventions, weighting, and decision frameworks on the outcome. The results indicate that MCDA can play a critical role in emerging prevention-based regulatory programs. Multi-criteria decision analysis methods offer a means for transparent, objective, and rigorous analysis of products and processes, providing regulators and stakeholders with a common baseline understanding of the relative performance of alternatives and the trade-offs they present. *Integr Environ Assess Manag* 2013;9999:1–13. © 2013 SETAC

Keywords: Alternatives analysis Alternatives assessment Chemicals Multi-criteria decision analysis Regulation

INTRODUCTION

Chemical regulation in its various forms relies primarily on a risk management paradigm in which use of a chemical is permitted so long as exposures are kept below acceptable levels. Acceptable exposure levels are based on a variety of standards. Some rely largely on the performance of best available control technologies, others are based more heavily on health concerns and risk assessment. The risk management paradigm has been subject to criticism on a variety of grounds (Leadership Council 2011). A different paradigm has begun to emerge in Europe and some states in the United States. Rather than asking what level of exposure to the subject chemical is acceptable, this prevention-based paradigm asks whether there are viable alternative chemicals that are safer.

Today in California and Maine, regulators are beginning to implement new programs that require manufacturers of products containing certain chemicals of concern to identify, evaluate and adopt potential safer alternatives (Assemb. B. 1879 2008; Maine 2011). In the European Union, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) program imposes similar obligations on certain particularly dangerous listed chemicals (REACH 2006). Although such prevention-based programs ostensibly avoid the thorny issues associated with establishing acceptable exposure and risk levels, they raise a potentially more difficult question for policymakers and regulated businesses: which alternatives are "viable" and "safer"?

To address that question, prevention-based programs use "alternatives analysis," a newly emerging methodology that integrates issues of human health and environmental effects with technical feasibility and economic impact. Alternatives analysis is a scientific method for prioritizing different courses of action; in this case for determining the viability of safer substitutes for existing products or processes that use hazardous substances. Alternatives may include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, and changes to component/product design (Sinsheimer et al. 2007). The methodology compares the alternatives to the regulated product and to one another across a variety of attributes, typically including public health, environmental, technical, and economic. It is a value-based balancing of the

All Supplemental Data may be found in the online version of this article.
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