

REVIEW STATEMENT

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1. Scope of Expertise

My professional expertise ranges from issues of risk governance (Aven and Renn 2010, Renn 2008:2009; Sellke and Renn 2010) over risk perception and communication (OECD 2001; Renn 1998, 2009); risk management and regulation (Aven and Renn 2010; Bauman and Renn 1987; Gillett et al, 1991; Pinkau and Renn 1998; Radandt et al. 2008; Renn and Klinke 2001; Streffer et al. 2003), precaution and precautionary principle (Dreyer and Renn 2009; Renn 2007; 2008; 2009; Renn and Elliott 2009; Renn et al. 2009) and public participation in environmental decision making (Renn 1999; 2001; 2006; US-National Research Council 2008; Webler et al. 1995). I also have some familiarity with REACH regulation in Europe (Benighaus and Renn 2008; Renn and Elliott 2009).

I am trained as a social scientist and worked in the fields of risk governance, technology assessment and public participation in science-based conflicts. Given this expertise I cannot comment on the sections dealing with the section of chemicals, their properties, the scientific criteria for selecting chemicals or products in the list of concerns or priority lists and the methodologies for risk and hazard assessment. Therefore I will focus on five aspects only: the selection of what is included in the regulation; the similarities and differences to REACH; some suggestions for hazard analysis; the public consultation and notification process and comments on the conflict resolution methods that are suggested in the proposed regulation. At the end I will list some minor points and a general assessment of the total proposal.

2. Selection criteria

The proposed regulations specify the inclusion criteria for the chemicals to be regulated under the new provision. Several exceptions are listed, in particular, those that would conflict with existing legislation. Consumer products are defined as a “products or part of products that are used, bought or leased for use by a person for any purposes” (ATTACHMENT B, SEPTEMBER 14, 2010, R-2015-05; p. 10 lines 5 and 6). This definition is very broad. I welcome the intention to include everything that is appropriated by consumers to be included but there may be ambiguities or overarching risk-benefit considerations that may justify a different procedure. For example, the use of Cadmium-Tellurium (CdTe) in present photovoltaic cells will probably meet the

criteria for a hazardous chemical (as it is persistent and it might even be toxic for human health and the environment). It is certainly less toxic than Cadmium but its toxicity is still not understood by science (Fraunhofer CSP 2010, Zayed and Philippe 2010). Within the EU solar cells are not classified as consumer products. If they were classified as consumer products the present REACH regulation would probably not allow CdTe to be used in photovoltaic cells on the roofs of individual homes. This chemical is banned in all consumer products in the EU. The example of CdTe might be an indicator that some products such as solar cells may be desirable for other purposes and politically demanded for energy security and environmental reasons. Therefore, I would suggest that the legislation includes a provision that other products could be exempted from the list if other overarching criteria would suggest so. One could add that such a decision has to be approved by a legislative body.

Section 69301(b)(3) specifies that the regulations do not apply to any consumer product that is manufactured or stored in, or transported through, California solely for use outside of California. It also provides that the burden of proof in establishing that a consumer product meets the above criteria is on the manufacturer of that consumer product. One should include that consumer products that are likely to create emissions or waste during storage and transportation should be regulated (may be by another act) and that consumer products where the manufacturer is unknown should also be covered by the legislation. In this case the responsibility for the hazard assessment should be with the distributor or seller. This has probably been covered by Section 69301.4(a)(2) but the language was not totally clear to me. There should be a non-ambiguous provision that regulates the chain of responsibility if the manufacturer is not known, untraceable or out of reach.

3. Comparison with REACH

The proposed legislation is rather similar to the REACH regulation in the EU. REACH requires companies that produce and import chemicals to assess the risks arising from their use and to take the necessary measures to manage any risk they identify. The objective is to reverse the burden of proof from public authorities to industry for ensuring the safety of chemicals on the market. REACH has also been designed to treat existing and new chemicals in the same way and to streamline bureaucratic procedures by simplifying the registration process. REACH can be summarized as follows (Renn and Elliott 2009):

- substances of high concern, including those that are carcinogenic, mutagenic or toxic to reproduction (CMRs), persistent, bio-accumulative and toxic (PBTs) or very persistent and very bio-accumulative (vPvBs);
- streamlining the licensing and authorization process by only requiring essential safety and use information for chemicals manufactured or imported in volumes of 1-10 tons per year;

- encouraging research and innovation by lengthening the trial period, raising the threshold for the registration of research substances (from currently 10 kg to one ton) and simplifying the regulation for downstream users;
- preventing increased bureaucracy for downstream enterprises by utilizing existing systems for the exchange of safety information in so-called Safety Data Sheets (SDS).

The main element of REACH is obliging all companies to register chemicals that were manufactured or imported in quantities of more than one ton per year and per manufacturer/importer in a central database. Some groups of substances would not have to be registered (such as certain intermediates, polymers and some chemicals managed under other EU legislation). The registration process includes:

- The intrinsic properties and hazards of each substance (such as physicochemical, toxicological and eco-toxicological properties). This information - if not already available - can be found through a variety of means such as computer modeling and epidemiological studies, or through testing.
- The use(s) of the substance identified by the importer or manufacturer or by their customers. A report of an assessment of risks for human health and the environment, and how those risks are adequately controlled, for the identified uses for substances produced or imported in volumes of 10 tons or more per year per manufacturer or importer (known as chemical safety reports). For lower volumes, safety information produced for the safety data sheets will be submitted as part of the technical dossiers.

The information required is proportional to production volumes and the risks that a substance poses. The safety information will be passed down the supply chain. To cope with the large number of 'existing' substances a phased approach is proposed. The deadlines for registration are set according to the volume of the substance on the market or the hazard. The shortest deadlines apply to very high volume substances (above 1000 tonnes), and carcinogenic, mutagenic or reproduction toxic substances above 1 ton. These will have to be registered within 3 years.

The proposed California legislation echoes many of REACH provisions but also expands the scope by adding sections that promote green chemistry functions. This is not covered by REACH. For example, **Section 69302.2(a)** requires DTSC to prepare two chemicals lists: **(1)** Chemicals under Consideration, and **(2)** Priority Chemicals. The Chemical under Consideration list serves two functions. First, it serves as notification to manufacturers that certain chemicals are being considered for listing as a Priority Chemical and allows the manufacturers to redesign a product voluntarily. REACH also requires manufacturers to list chemicals, but only those that meet either the hazard or risk criteria listed in the various annexes of REACH. It does not provide incentives for substitution. The second purpose of identifying assessment gaps is served by both REACH and the proposed DTSC regulation. The two lists are meant to identify potential chemical data gaps, whether hazard trait information or product information,

by providing a pool of chemicals from which to obtain or generate additional information.

REACH and the proposed California regulation have de minimis thresholds. The California regulation states: If a manufacturer determines that its Priority Product contains a Priority Chemical at or below the de minimis level listed by DTSC and the product is not restricted from being eligible for a de minimis exemption request, then a de minimis exemption request may be filed (**Section 69305.3**). In addition, the proposed California regulation has special exceptions for small business operations. This has been discussed in the REACH context for many years, but later rejected (BDI, VCH and VCI 2004). The transition times for producing the information were estimated as feasible for even small enterprises and the de minimis thresholds were regarded as wide enough to allow small companies that produce only small amounts of chemicals to be exempted from cumbersome reporting efforts. However, similar to the California regulation, REACH includes provision for assistance to small and medium sized companies.

The criteria for listing chemicals or products (concern or priority) show similar features when REACH is compared with the proposed California regulation although the language is different. As a matter of fact the set of criteria for judging eco-toxicity is much more comprehensive in the California regulation than in REACH (which is stronger related to human health). I was not able to detect any criterion in REACH that is not directly or indirectly covered by the new proposed regulation. In addition, both regulatory frameworks have provisions to include new criteria if new information is available or science and development creates new chemicals or products that need additional criteria for their assessments. Interesting to note that REACH and the new California regulation includes (still vague) provisions for nanomaterials.

4. Prioritization

Section 69301.1(d) states that chemical and consumer product prioritization processes should seek to identify and give priority to those chemicals, and the consumer products that contain them, that pose the greatest public health and environmental threats, are most prevalently distributed in commerce and used by consumers, and for which there is the greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in public health or environmental harm. These prioritization criteria advance the goals of the authorizing statutes and are reflective of the best scientific approaches to these issues.

This provision includes the highly ambiguous term “can result”. In the EU the term “can” is interpreted in a rather precautionary manner. Even if there is no conclusive evidence of harm the substance can be regulated provided that there is enough scientific data that suggests a negative impact on health or the environment (Fisher 2002; Resnik 2003). The word “precaution” or “precautionary principle” is avoided in the proposed

legislation but many provisions in the regulation (articles 3 and 4) support a precautionous approach to regulation. However, the regulation is not quite clear whether hazard traits are sufficient for regulatory actions (such as a ban) or whether there needs to be sound evidence for a harmful effects either on human health or the environment.

Furthermore, **section 25252** requires that the identification and prioritization process include, but should not be limited to, consideration of a chemical's: (1) volume in commerce in California; (2) potential for exposure to the chemical in a product; and (3) potential effects on sensitive subpopulations. Although these three general rules are later specified, they may be difficult to apply in particular when little is known about dose-effects and exposure. For purposes of identifying chemicals that exhibit a hazard trait, DTSC is using hazard traits developed by OEHHA. This reference to OEHHA may not be sufficient in setting priorities. In addition, the provision to limit the scope of chemicals subject to the prioritization process by only considering chemicals for which there is one or more exposure pathways that could pose a threat to public health and/or the environment is open for a range of possible interpretations (sections **25257.1(c)**; **69302.1(a)(2)**): Are, for example, young children *exposed* to phthalates in toys when they touch them but never swallow particles? I would suggest specifying exposure as any means that humans or ecosystems get in contact with the chemical regardless whether the type or means of exposure is known to be harmful.

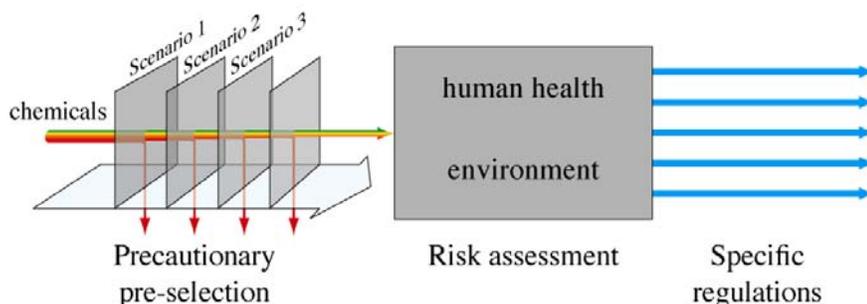
There is often not enough information available for judging the effects on human health and the environment. In this case the prioritization must rest on hazard rather than risk or exposure criteria. The hazardous characteristics are much better known to science than the risks (including dose-response relationships and exposure). DTSC is authorized under the new proposed regulation to use as prioritization factors, to the extent applicable, density, dissociation constant, explosiveness, flammability, flash point, granularity, melting or boiling point, oxidizing properties, partition coefficient, stability in organic solvents and relevant degradation byproducts, surface tension, vapor pressure, viscosity, water solubility, and other physical, chemical, or quantum properties specific to nanomaterials. The inclusion of new chemicals such a nanomaterials demonstrates that the legislation keeps up with the new chemical developments. Yet, I think that this list is not complete (what about bioaccumulation, which is then mentioned separately in **Section 69302.3(b)(2)**, and other sections as being a relevant criterion for priority chemicals). **Section 69302.3(b)(25)** allows, however, the consideration, as chemical prioritization factors, of those hazard traits not specifically identified in this subsection, such as those that may be identified by OEHHA and are not specifically identified above. This provision also addresses advancements in science and technology that detect or identify other hazard traits not currently detectable. In this sense the list is open and can be amended at any time. This is certainly necessary to cope with the advances in science and technology.

In addition to human health impacts, the proposed California regulation includes a long list of ecological impacts that could justify the listing of a chemical in the priority list.

To my knowledge this list is very extensive and much more detailed than in other legal documents. Again similar to the effects on human health there is a sunshine clause (**Section 69302.3(d)(5)**) which allows for additional criteria and impact pathways if more information or insights are available.

The main problem, however, remains: Is it justified to place chemicals on the priority list if they rank high on several hazard criteria but exposure and effects are contested or not investigated? I would suggest here to consider a proposal by U. Mueller-Herold and others for using specific scenarios as filters to prioritize risk management. (Mueller-Herold et al. 2009; Mueller-Herold et al. 2005). The model of Mueller-Herold et al. was developed for the EU as a means to prioritize chemicals on the basis of hazard traits. The proposed process includes a screening stage (see Figure 1) in order to identify chemicals deserving special attention or even to eliminate substances of high concern at an early stage. For the screening stage, a filter series approach was developed and applied. Each filter is designed to screen for a particular scenario.

Figure 1: Extended assessment scheme for chemicals

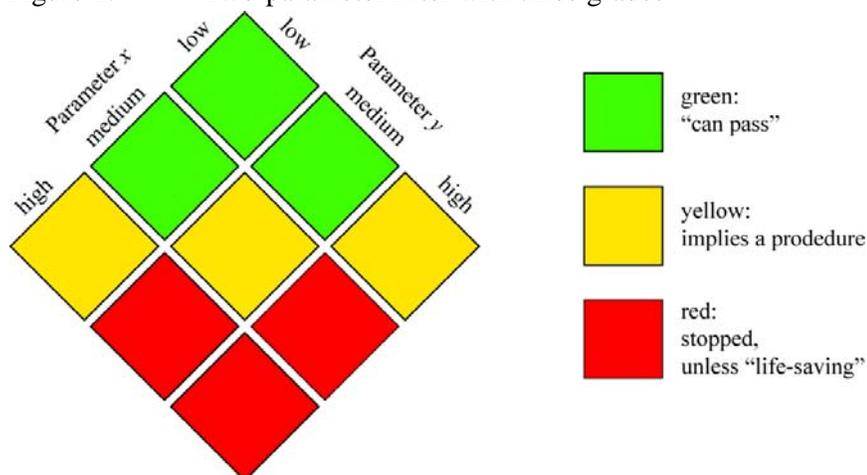


Source: Renn et al. (2003)

Precautionary filters can be conceptualized as classification schemes with three outcomes: green (“may pass”), yellow (“needs further consideration”), and red (“will be stopped”). For filters based on two assessment parameters – with each parameter having the grades *high / medium / low* - the outcomes are defined using these grades of the two parameters (Figure 2).

- green: medium/low, low/low, low/medium
- yellow: high/low, medium/medium, low/high
- red: high/medium, high/high, medium/high

Figure 2: Two-parameter filter with three grades



Source: Renn et al. (2003)

If a substance is classified as red by at least one filter, it should be listed on the priority list, if it is classified as yellow it should be on the list of concerns. All chemicals that are in the green area do not need to be listed unless other hazard criteria would suggest otherwise.

The document studies two scenarios that are used as screening filters: ubiquity and bioaccumulation (time and space). Scenario 1 (ubiquity) is essentially due to the interplay of mobility and longevity. The potential for mobility and longevity is expressed by two proxy measures: characteristic isotropic spatial (CIS) range (ρ) and characteristic isotropic global (CIG) half-life (τ). Characteristic isotropic spatial (CIS) range F is the typical distance a molecule would travel before degradations under earth-like but spatially isotropic conditions where concentrations quickly equilibrate between the atmosphere, the surface layer of the oceans, and the upper layer of the soil. Characteristic isotropic global (CIG) half-life τ is the typical overall lifetime of a molecule under conditions as for F .

The second scenario called bioaccumulation refers to a phenomenon that combines bio-concentration and bio-magnification. Bio-concentration relates to the partition of a chemical between an organism and a surrounding inorganic medium (e.g., leaves/ air, fish/water). Bio-magnification denotes the heterotrophic enhancement of concentration in subsequent elements of the food chain (grass/cow, cow/man). As fat tissue is the relevant storage medium in living organisms and as octanol is the chemical proxy usually representing organismic fat, bio-concentration is related either to a chemical's octanol-water partition coefficient (K_{ow}) or to its octanol-air partition coefficient (K_{oa}) K_{ow}/K' , with K' KH/RT being the chemical's dimensionless Henry's law constant. K_{ow} is a direct measure for bioaccumulation from water into aquatic species, whereas K_{oa} is a direct measure for bioaccumulation into plants from air.

Mueller-Herold et al. were able to demonstrate that by using these two filter scenarios they could retroactively validate the banning of POPs and other organic chemicals in the course of the last three decades. All banned chemicals under the Montreal, Kyoto and Stockholm treaties ranked red on the two filters, while 80% of those chemicals not yet regulated under these regimes were rated green, only 20% yellow or red (see Table 1).

TABLE 1. Result of the Chemical Classification Problem

reference chemicals classification	HPVCs	Montreal, Kyoto, Stockholm
<i>inconspicuous (green)</i>	80%	0%
<i>precarious (red)</i>	0%	100%

^a As green + yellow + red add up to 100%, green + red can add to less than 100%, i.e., to 80%.

This proposal was introduced as an addition to the REACH framework for finding a fast, non-bureaucratic, and inexpensive way to include precautionary measures in the REACH regime (Renn et al. 2003; 2009). The filters that were tested in the report were based on assessment parameters such as potential to long-range transport, persistence, and bioaccumulation. The parameters applied to three types of substances: persistent organic chemicals, high production volume chemicals, and a group of nonreferential test chemicals. So far, the EU Commission has not adopted this amendment to the REACH regime; however, more research is under way to test more specific guidelines for using hazard information for regulatory purposes.

5. Notification and public consultation

The sections on notifications are similar to those known from other chemical related regulations (for example REACH). It seems to me that these sections are well articulated and constitute a state-of-the-art approach compared to international regulatory frameworks. Section **69301.6(c)(1)** requires all companies to make data and information available to DTSC that have been provided under the REACH, TSCA, or CEPA programs. This saves money and efforts.

The regulation specifies the consequences of non-compliance (for example in **Section 69301.4(g)(2)**). The penalties for late or incomplete information appear as not being very harsh yet I have no specific experience in this area and trust that private liability claims (tort) would supplement the provisions about public fines. In section **69301.6(b)** there is a provision (2) that DTSC is required to pay to the extent resources are available for the information that is readily available, but for which there is a charge, in a usable format in the public domain. I find it strange that DTSC is asked to pay for information that is not used for proprietary purposes. I would suggest to require all information to be conveyed free of any charge to DTSC unless other legal provisions mandate DTSC to pay for such data.

Article 11 implicitly acknowledges that small businesses are differently situated from large businesses. The requirements of Chapter 53 may be more challenging for small businesses to fulfill than for larger businesses. In light of that, DTSC has established some ability to work with small businesses to aid in their compliance with the regulations and be somewhat flexible with the time lines for compliance for small businesses. As mentioned in part 1 of this document, it may be difficult to negotiate different times scales for different actors. I would rather suggest providing more (even free) assistance to small companies, but keeping the deadlines identical for all informants.

In line with the freedom of information act **Section 69301.7** mandates that all information (except propriety data) is available to public scrutiny through internet webpages. The section further specifies the types of information that DTSC will post on its website. In order to implement these regulations, making information available to the public, consumers, responsible entities and other persons in the supply chain is seen as critical. I agree with this statement. DTSC may, at its discretion, respond to public comments. Furthermore, **Section 69306.8(b)** obliges DTSC to consider public comments on the proposed regulatory response determination notice. DTSC may, at its discretion, respond to some or all public comments received. This provision holds DTSC accountable to take public input into account in its final determination on applying regulatory responses.

This may be too lenient in my view. In terms of improving risk communication, DTSC might consider to have professional communicators screen the professional webpages and translate them into a language that laypeople in particular consumers can understand. If funds are available, a chat room or a forum would also be helpful in order to assure that all affected parties can raise questions and get assistance in their quest for meaningful information. Since consumer products are the target of the regulation it is essential that the average consumer is able to understand the information and is able to act prudently on the basis of this information. In general, risk communication needs are not well addressed in the proposed legislation.

6. Conflict Resolution

Section 69302.2(b) specifies the public review and comment process that DTSC must follow before finalizing the Chemicals under Consideration and Priority Chemicals lists. The section ensures that the public and other interested parties have input into the chemical listing process. Some of the significant features of the public information requirements are:

- (1) an open and transparent process that includes a public comment period prior to finalizing the lists of chemicals and products that must undergo an alternatives analysis to examine ways to develop a safer consumer product;
- (2) small business considerations;

- (3) specifically requiring DTSC to post on its website implementation progress by making information available, that is not considered confidential information (trade secret), as it is received or developed;
- (4) requiring an accredited assessor to review manufacturer's alternatives assessments; and
- (5) a petition process to request inclusion of a chemical or product in the prioritization process.

Provisions (4) and (5) relate to the problem of conflict between manufacturer's assessment and DTSC judgments. **Section 69304(a)** allows any person, referred to as the petitioner, to petition DTSC to evaluate a chemical or a consumer product using the chemical or product prioritization processes specified in articles 2 and 3. **Section 69304(b)** requires DTSC to respond within 60 days of receiving a petition.

I highly welcome the possibility that petitions can be issued and also that if an alternative assessment process is chosen (article 5) an accredited assessor has to be involved. This provision helps to reduce the probability of judicial review and avoid often expensive and time-consuming litigation.

The process of conflict dispute resolution is mainly specified in **Article 7 (Section 69307)** describing the main procedures necessary to deal with a manufacturer's request to dispute a decision of DTSC under Chapter 53 that applies to the responsible entity's or manufacturer's product. **Section 69307.2(a)** specifies the information the responsible entity or manufacturer must supply to DTSC if it pursues a dispute with the Director of DTSC. **Section 69307.2(c)** specifies that either the Director or the Director's designee has to respond to such a request on behalf of DTSC. The decision has to be made within sixty (60) days of receipt of the Director-level dispute. The internal appeal is thus related directly to the director of DTCS which in my eye underlines the importance of an informal and quick dispute resolution process. The attribution of conflict resolution to the level of directorship amplifies the importance of informal dispute resolution. I would also advise to have the director deal with these issues personally (within reasonable time constraints) as to demonstrate to the manufacturers that their arguments are treated seriously and that their concerns will gain the attention of the highest level of the administration.

In addition to the informal appeal process, **Section 69307.3** specifies which decisions or actions of DTSC are subject to the formal dispute resolution procedures set out in Sections 69307.4 through 69307.7. **Section 69307.6 (e)** provides that a manufacturer may not seek judicial review of a decision by DTSC unless and until DTSC issues a final order on the petition. This petition is necessary to establish when a manufacturer has exhausted all administrative remedies and is able to pursue judicial relief. **Section 69307.7(c)** establishes a "firewall" between the DTSC staff involved in the decision making and review of petitions for review and those who made the initial decisions under review.

In my eyes, the possibilities of formal appeals are not fully employed in the document. Since there is a long list of disadvantages of litigation in terms of resources, time and “surprises” (de Sadeleer 2003), there should be more intermediate possibilities to resolve conflicts. I would suggest adding to the list of provisions the following points:

- (1) If the informal process does not lead to an agreement between the appealing manufacturer and DTSC, a formal mediation process can be initiated if both parties agree.
- (2) In case that such mediation process is launched both parties agree on a certified mediator who is responsible for developing together with the parties a potential solution to the conflict. The mediator is free to consult independent experts and to issue reviews of the argumentation of both sides.
- (3) Within a time period of 90 days the mediator should provide a suggestion for the resolution of the conflict. If both parties agree this suggestion is then implemented.
- (4) If either of the two parties disagree with the proposed solution the case may be forwarded to judicial review. All documents that were produced or used in the mediation process can also be used in court.

Since mediation has been proven to provide faster and more reasonable results compared to litigation (US-National Research Council 2008) I would highly recommend to have this alternative way of resolving disputes be integrated into the proposed California legislation.

7. Other minor points

- (1) A potential problem can occur with **Article 3**. The provision that a product purchased outside of California and brought into California for personal use, including a product that is purchased as a gift, is not considered in the legislation may lead to the emergence of out-of-state sales points close to the border that sell cheaper products that would not meet the regulations in California. It is not clear to me how realistic this scenario may be, but in Europe we had faced and still face the situation that at the borders between the Eastern EU countries and bordering non-EU countries open markets have been established right behind the borders that provide inexpensive consumer products that tend to be partially toxic or environmentally harmful.
- (2) **Section 69305.5(a)(2)(C)1. and 2.** specify that an alternative must be eliminated from further consideration if the person conducting the AA determines that: **1.** based on the Chemical Hazard Assessment, potential exposures to the chemical in the alternative would pose a greater threat of harm to public health or the environment than is posed by the Priority Chemical in the Priority Product; and **2.** based on the Exposure Potential Assessment, that there is the same or a greater potential for the public or the environment to be exposed to the chemical in the alternative, than to be exposed to the Priority Chemical in the Priority Product. This provision is very

important and missing from many other legal frameworks. There is a richness of evidence that substitutes often pose more risks than the substance that they replace or that they are associated with more uncertainties than the original substance (Graham and Wiener 1995). However, one should assist manufactures to develop substitutes that are clearly lower in risk than the substances that they replace (in line with the goal of green chemistry).

- (3) **Section 69301.1(b)** states that adverse impacts on public health and the environment that may result from the production, use or end-of-life management of consumer products and consumer product ingredients should be significantly reduced or eliminated, to the extent technologically and economically feasible. This echoes the need for a transition to green technology. However, the term economically feasible is open to a wide range of interpretations. This section might be more precise on what economically feasible means. One could also specify a procedure by which economic feasibility is tested and approved.
- (4) Following the same line of argumentation, **Section 69305.5(d)(4)** specifies that the Multimedia Life Cycle Evaluation must include an assessment of economic impacts associated with the Priority Product and any alternative being considered. This includes any increase or decrease in jobs or businesses, of doing business, and the costs of goods to consumers. Evaluation and comparison of economic impacts must take into account both internalized and externalized costs during the life cycle of the Priority Product or product component and all alternatives being considered, and shall include an evaluation of the range of projected costs. I also welcome the inclusion of economic assessments in the process of balancing pros and cons for chemicals and products. However, there should be a clear priority for human and environmental health. One possibility to address this priority is to allow manufactures to use the most cost-efficient method to determine alternatives that are all below the threshold of being listed as a chemical/product of concern or priority. Only if none of the options can pass this test even after investing reasonable resources to reduce the risk economic costs may be used as an important criterion to select the substance or product within the range of the next level of concern (slightly above threshold). This suggestion seems to be compatible with **Section 69306.5** which stipulates that once a safer alternative exists, that is functionally equivalent and technologically and economically feasible, that alternative should be made available for California consumers.
- (5) **Section 69306.3(a)** requires that the responsible entity make available the information specified in sections 69306.3(a)(1) through 69306.3(a)(6) to consumers when the selected alternative contains a Priority Chemical at levels that exceed the de minimis exemption level specified in section 69301.2(a)(24), or the manufacturer does not select an alternative for a Priority Product or component after the AA Report has been completed. This section is necessary to provide retailers and consumers with the necessary information to make informed purchasing decisions and project use and management for products that contain a Priority Chemical. Products that contain a Priority Chemical and have longer life spans, than the manufacturer or responsible entity, should be well accounted for and a product

stewardship organization that collects and administers the program should be established when the products are manufactured and distributed for use in California. Product-specific stewardship plans are a necessary component to provide retailers, consumers, collection facilities and local government with the necessary information to ensure a successful end-of life collection plan. I think the instrument of product-specific stewardship is an innovative and effective way to add a dynamic aspect of continuous improvement to the process. I would also strengthen the role of this plan and make it more mandatory in the process. The problem with many chemical regulations is that once the information on a specific chemical or product is collected, processed and interpreted it will not be considered again until a general review is due. The product-specific stewardship plan is an excellent instrument to initiate a continuous review process and provide a continuous incentive for risk reduction or product replacement even in the interim times between reviews. However, such a plan must have “teeth” to be effective.

8. Overall Assessment

The emphasis on green chemistry as described in all the documents is a step in the right direction. It emphasizes “benign by design” and proposes substances that do not need special precaution in the phases of manufacturing, transportation, consumption or use and discharge. The document encourages the development of green chemistry. Although not part of this regulation, it might be wise to support research and development in this area by State funds.

I also welcome the focus on Multimedia Life Cycle Evaluation. Article 5 provides incentives to start substituting early and ensures a swift but responsive way to replace priority chemicals or products. **Section 69305.1** allows a manufacturer and/or responsible to voluntarily embark on early product reformulation or redesign, without first performing a Tier II AA. If a Tier I AA Report is submitted it must be based on the “The Green Screen for Safer Chemicals” guidance document prepared by Clean Production Action, a non-profit organization that collaborates with industry, government and other non-governmental organizations to design and deliver strategic solutions for chemicals, sustainable materials and environmentally preferable products. The Green Screen specifies four benchmarks that must be evaluated in the quest for safer alternatives to Priority Chemicals. Each benchmark defines a progressively safer chemical:

- Benchmark 1: Avoid — chemical of high concern
- Benchmark 2: Use but search for safer substitutes
- Benchmark 3: Use but still opportunity for improvement
- Benchmark 4: Prefer — safer chemical

I would suggest adding to the benchmark 4 an amendment that further testing is required to reduce uncertainty along the road of application and consumption.

This brings me to two general points of criticism: The first one relates to uncertainty. There is little treatment of uncertainty in the document. Many chemicals are not well characterized and others may have many hazardous traits but there is little information on exposure or dose-response. With some new material being marketed, for example nanomaterials, new protocols for risk assessment need to be developed that include for example surface-to-mass ratios rather than dose in itself. The regulation provides little assistance what to do when effects are highly contested or uncertain. If this happens one can rely more on hazard criteria as pointed out in section 4 of this document or alternatively rely on criteria that promise to decrease potential vulnerabilities. Among them are: strict monitoring of effects, strict liability, limitation of marketing to essential services, extra barriers for exposure, and many others (Klinke and Renn 2002). It is outside of my scope of legal expertise to judge whether dealing with uncertainty in a regulatory framework can or should be covered in this proposed California regulation but I would suggest that this topic is given more attention.

The second point refers to the exclusion of public risk perception and concerns from the document. There are ample examples that perception of chemical risks influences consumer behavior and can even amplify or attenuate the physical risk to which consumers are exposed (Benighaus and Renn 2009). In addition, concerns have a major impact on public acceptance of technologies and may trigger behavioral (such as boycotts) or political responses (such as demonstrations). The recently developed framework of risk governance issued by the Risk Governance Council in Geneva suggests to add to the normal risk assessment a concern assessment at least when the use of the product or chemical seems to be contested in society (IRGC 2005; Renn 2008). This inclusion of a scientific analysis of perceptions and concerns is often valuable when judging exposure, handling of hazardous material or public responses. It may be difficult to ask manufacturers to provide data on risk perception and concerns but, at least, for the DTSC it would be valuable to have a concern assessment done before regulatory actions are designed and announced. This is also essential for having an effective risk communication program.

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