

REVIEW STATEMENT

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1. Scope of Expertise

My professional expertise ranges from issues of risk governance (Klinke and Renn 2012; Renn et al. 2012; Renn et al. 2012; Aven and Renn 2010; Sellke and Renn 2010; Renn 2008) over risk perception and communication (OECD 2001; Renn 1998, 2009); risk management and regulation (Radandt et al. 2008; Renn and Klinke 2001; Streffer et al. 2003; Aven and Renn 2010); 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; 2008; US-National Research Council 2008). 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 natural science aspects of the questions posed to me.

2. Issue 1: List of Chemicals

The use of the chemicals lists developed by the sources named in the regulations identifies chemicals with hazard traits that have public health and environmental concerns to produce an initial Chemicals of Concern (CoC) list. (See Attachment 4 and 4-A)
SEE ATTACHMENT 4 – JULY 18, 2012
TEXT OF PROPOSED REGULATIONS
ARTICLE 2, SECTION 69502.2

The list of chemicals considered appears quite exhaustive and complete. There should be a sunshine clause that additional chemicals can be included in the list if new data or insights into toxic or eco-toxic consequences is available or the lists mentioned are augmented. Likewise, if any of these chemicals is removed it should also be removed from this list.

For public communication, it may be wise to classify the reasons for chemicals to be on the list. One might distinguish between acute toxic, genotoxic, detrimental for reproduction, eco-toxic, hazardous without clear visible damages (such as lack of exposure), other reasons and then allocate each of these chemicals into a risk

characterization scheme (such as seriousness and probability of harm, exposure, characterization of vulnerable endpoints). This characterization can be quantitative if reliable data is available or qualitative if causal connections are established but not yet quantified. Such a characterization may help regulators to take the appropriate (proportional) action but also assist consumers in judging the seriousness of the threat posed to them. A potential scheme to classify chemicals with special problematic hazard traits such as persistence and ubiquity was one of my recommendations in my comments from July 2010.

Last point: I think that the introductory sentence misses an additional verb. In my view, endpoints cannot be applied but this may sound strange only to me since I am a non-native speaker of English. I would augment the sentence as follows:

This article applies to all chemicals that exhibit a hazard trait or AFFECTS an environmental or toxicological endpoint, and that are present in products that are placed into the stream of 12 commerce in California. (Article 2, 10 and 11).

3. Issue 2: Prioritization

Use of the initial product prioritization criteria in the chemical and product prioritization process in Article 3 are sufficient to identify all types of consumer products with CoCs as potential Priority Products. Use of the key prioritization criteria considers those critical factors which identify the potential Priority Products during the initial phase as high priority.

SEE ATTACHMENT 4 – JULY 18, 2012

TEXT OF PROPOSED REGULATIONS

ARTICLE 3, SECTION 69503.2

Article 3, Section 69503.2 lists more than 40 criteria of high priority. First, this number seems to be too high for being used to prioritize a large list of chemicals, second, many criteria are redundant, and thirdly, different classification principles have been used to complete the list. It looks like a large laundry list with the intension not to miss anything. I would suggest a more systematic approach to the priority list, which could follow from the risk characterization above.

- a) Chemicals that threaten human health (toxic, genotoxic, reproductive)
- b) Chemicals that threaten the environment (endangered species, ecosystem integrity, purity of water, soil and air)
- c) Chemicals that show hazardous traits that could lead to damages over time (high persistence, ubiquitous distribution, chemicals that may lead to damages up- or downstream the value chain, chemicals that will likely disintegrate into more harmful substances)
- d) Chemicals that can lead to harm if combined with other chemicals or used in special contexts in which damage is likely to occur

For each of the four categories, prioritization should be performed according to the likelihood that the harm is experienced the seriousness of this harm, the sensitivity of the endpoints, and the symbolic value the endpoint has for society (for example highly appreciated landscapes).

4. Alternatives Analysis Thresholds

The principles outlined in the proposed regulations that will allow the department to develop Alternatives Analysis Threshold based on best available technologies is scientifically understood
SEE ATTACHMENT 4 – JULY 18, 2012
TEXT OF PROPOSED REGULATIONS
ARTICLE 3, Section 69503.5

Article 3, Section 69503.5 provides reasons for exemption. The provisions seem to assume that there is a single threshold that may be relevant in comparison for potential alternative chemicals. However, if different endpoints are considered, such as human health, environmental quality or persistence, the comparison may involve the use of trade-offs between these different endpoints. One alternative to an existing chemical may fare much better on protecting human health but worse with respect to water pollution. Another alternative may do the opposite. I am not sure if this conflicting value problem is adequately addressed (it might be in some other sections that were not sent to me).

There are two potential solutions to this problem. One is to use minimum standards (thresholds for each criterion) that all have to be considered when making the comparison between the chemical under consideration and potential substitutes. However, this solution can mean that a risk that is just above all thresholds is preferred over a risk that has excellent scores on all categories but one. The other alternative is to establish a rating system for designing trade-offs between the various dimensions. However, assigning these tradeoffs imply a valuation process that includes subjective judgments about relative degree of seriousness. Such an approach would require a full multi-criteria decision making process.

Another problem is the sections with the reason for exemption. If a chemical poses a serious threat to human health or the environment (line 31 to 40), it may not be sufficient to grant an exemption if the chemical has been used frequently or is part of a natural ingredient.

5. Adverse Impacts

**The definitions of the various “adverse” impacts and general usage of the term “adverse” impacts is used throughout the regulations. Within the context of the definitional and general use of the term “adverse” impacts in the regulations and when scientific information is available, a qualitative or quantitative determination of adverse impact can be made, and is adequately protective of public health and the environment.
SEE ATTACHMENT 4 – JULY 18, 2012 FOR CONTEXTUAL USE OF “ADVERSE”**

The definition of what is called adverse is still quite controversial in the regulatory literature (Hood et al. 2011). There are two problems associated with this term: a) manifest harm versus potential for harm and b) physical harm versus socially constructed harm (Renn 2008).

The first aspect covers the issue whether adverse effects require the empirical manifestation of experienced harm versus the presence of a hazard that could lead to harm but there is either no exposure or hardly any vulnerability. By stating that hazardous traits could also be sufficient to be in the list of chemicals of high concern the proposed legislation is clearly in the camp of potential harm. However, this is always a judgment call where to draw the line. Pure oxygen can be hazardous to humans under specific circumstances but hardly anyone would place oxygen on the list of hazardous chemicals. The second line is whether perceived risks or psychosomatic reactions should be included in the list of adverse effects. When people respond to magnetic fields from transmitter stations with severe headaches or other symptoms is this an adverse effect even though most toxicologists cannot see any causal connection between exposure to low magnetic fields and human health. The so-called multiple chemical syndrome is a testimony to this problem. Often it depends on societal definition processes (for example inclusion in the DC10 list of psychological diseases) whether a symptom is “officially” recognized as an adverse effect.

I would suggest providing clearer statements about these two aspects in the definition:

- a) to include potential for harm not only experienced harm and
- b) to limit the adverse effects to those that are officially recognized by the respective medical or ecological authorities.

Many definitions in the proposed legislation are simply tautological such as: “Adverse air quality impacts” means air emissions of any of the air contaminants listed below that have the ability to result in adverse public health, ecological, soil, or water impacts” (69051. 30-31).

Any human action has impacts: so the categorization of consequences of human intervention into beneficial, neutral or adverse impacts requires some value judgment. Often beneficial consequences for one type of endpoints can be detrimental for another

type of endpoints. Again one needs to make trade-offs between the two types of consequences.

6. Final comment

**Reviewers are not limited to addressing only the specific issues presented above, and are asked to contemplate the following questions:
In reading the supporting documentation in Attachment 4 and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed rule not described above? If so, please comment with respect to the statute language given above.**

In my view the supporting documentation is convincing and provides sufficient background to understand the issues mentioned. I would have preferred a more systematic approach but this might be the price to pay if everything is being framed in a typical legal language.

Taken as a whole, I have the feeling that the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices.

LITERATURE

Aven, T. and Renn, O.: *Risk Management and Governance*. Heidelberg and New York (Springer 2010)

Benighaus, C. and Renn, O.: *Communicating Chemical Risks*. Stuttgart Contributions to Risk and Sustainability Research. Vol. 10. Stuttgart (University of Stuttgart Press: April 2008)

Dreyer, M. and Renn, O. (Eds.): *Food Safety Governance. Integrating Science, Precaution and Public Involvement*. Heidelberg and New York (Springer 2009)

Hood C., Rothstein H., Baldwin R.: *The Government of Risk: Understanding Risk Regulation Regimes*. Oxford, NY (Oxford University Press 2001)

Klinke, A. and Renn, O. 2001: "A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based and Discourse-Based Management," *Risk Analysis*, **22**: 6 (2001), 1071-1194

Klinke, A. and Renn, O. 2012: Adaptive and Integrative Governance on Risk and Uncertainty. *Journal of Risk Research*, 15: 3 (2012), 273-292

OECD: *Guidance Document on Risk Communication for Chemical Risk Management*. Authors: O. Renn, H. Kastenholz and W. Leiss. Paris (OECD 2002)

- Radandt S.; Rantanen, J. and Renn, O.: "Governance of Occupational Safety and Health and Environmental Risks," in: *Risks in Modern Society*, edited by H.-J. Bischof. Berlin and Heidelberg (Springer 2008), pp. 127-258
- Renn, O.: "Implications of the Hormesis Hypothesis for Risk Perception and Communication," *Human & Environmental Toxicology*, **17**: 2 (1998), 431-438
- Renn, O.: "A Model for an Analytic Deliberative Process in Risk Management," *Environmental Science and Technology*, **33**: 18 (1999), 3049-3055
- Renn, O.: "The Role of Social Science in Environmental Policy Making: Experiences and Outlook," *Science and Public Policy*, **28**: 6 (2001), 427-437
- Renn, O.: "Participatory Processes for Designing Environmental Policies," *Land Use Policy*, **23** (2006), 123-248
- Renn, O.: "Precaution and Analysis: Two Sides of the Same Coin?" *EMBO Reports*, 8 (April 2007), 303-305
- Renn, O.: *Risk Governance. Coping with Uncertainty in a Complex World*. London (Earthscan 2008)
- Renn, O.: "Risk Communication: Insights and Requirements for Designing Successful Communication Programs on Health and Environmental Hazards," in: *Handbook of Risk and Crisis Communication*, edited by R.L. Heath and H. Dan O'Hair. London (Taylor and Francis 2009), pp. 80-98
- Renn, O. and Elliott, E. D.: "Precautionary Regulation of Chemicals in the US and Europe," in: *Precautionary Risk Appraisal and Management. An Orientation for Meeting the Precautionary Principle in the European Union*, edited by O. Renn, P.-J. Schweizer, U. Müller-Herold and A. Stirling. Bremen (Europäischer Hochschulverlag 2009), pp. 248-290
- Renn, O. and Klinke; A.: "Environmental Risk – Perception, Evaluation and Management: Epilogue," in: *Environmental Risks: Perception, Evaluation and Management*, edited by G. Böhm; J. Nerb; T. McDaniels and H. Spada. Amsterdam et al. (Elsevier Science 2001), pp. 275-299
- Renn, O.; Schweizer, J.-P.; Müller-Herold, U. and Stirling, A. (Eds.): *Precautionary Risk Appraisal and Management. An Orientation for Meeting the Precautionary Principle in the European Union*. Bremen (Europäischer Hochschulverlag 2009)
- Renn, O.; Klinke, A. and van Asselt, M.: "Coping with Complexity, Uncertainty and Ambiguity in Risk Governance: A Synthesis," *AMBIO*, **40**: 2 (2011), 231-246
- Sellke, P. and Renn, O.: "Risk, Society, and Environmental Policy: Risk Governance in a Complex World," In: *Environmental Sociology: European Perspectives and*

Interdisciplinary Challenges, edited by M. Gross and H. Heinrichs. Berlin (Springer 2010), pp. 295-322

Streffer, C.; Bücken, J.; Cansier, A.; Cansier, D.; Gethmann, C.F.; Guderian, R.; Hanekamp, G.; Henschler, D.; Pösch, G.; Rehbinder, E.; Renn, O.; Slesina, M. and Wuttke, K.: *Environmental Standards. Combined Exposures and Their Effects on Human Beings and Their Environment*. Berlin (Springer 2003)

US-National Research Council of the National Academies: *Public Participation in Environmental Assessment and Decision Making*. Washington, D.C. (The National Academies Press: September 2008)