

STATEMENT

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Topics:

1. The initial Candidate Chemicals are chemicals listed by one or more of the sources named in the regulations and have hazard traits that have public health and environmental concerns.

The broad list of chemicals is now called the “Candidate Chemicals” list. The regulations define “Candidate Chemical” as a chemical that is a candidate for designation as a “Chemical of Concern” (COC). A “Candidate Chemical” that is the basis for a product-chemical combination being listed as a Priority Product is designated as a “Chemical of Concern” with respect to that product. NOTE: For virtually all practical purposes, this change in terminology does not affect the duties of responsible entities subject to the regulations.

Revised regulations include the following two additional lists from authoritative organizations to the list of lists for the initial Candidate Chemicals list:

- 1. Chemicals classified as Category 1 respiratory sensitizers by the European Union in Annex VI to European Commission Regulation 1272/2008.*
- 2. Chemicals identified as priority pollutants in California under the federal Clean Water Act has been expanded to include section 303(d) chemicals in addition to the section 303(c) chemicals.*

These lists of chemicals meet the same criteria that were used to identify the sources of chemicals that were in the July proposal. The lists are supported by an authoritative organization, used to limit exposure, and are consistent with similar programs in other states. In all cases, the chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard trait in Chapter 54 and the chemical lists are reviewed and updated periodically

Statement:

According to my reading of the regulations for identifying and classifying chemicals, most of the reviewers’ comments have been incorporated. There is a clear differentiation between the characterization of the hazardous properties of a chemical and the corresponding risks, which includes exposure and dose-response effects. As mentioned in my earlier statements, I strongly recommend to use two main criteria for characterizing hazards, such as pervasiveness and

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ubiquity of exposure, to alert the regulators to chemicals that have a high loading of these two characteristics even if negative impacts have not yet been observed¹. There is sufficient evidence that high persistency and ubiquitous exposure are normally highly correlated with some delayed environmental damage. Such damage could also affect human health.

With respect to the procedure of identifying and characterizing chemicals, the proposed legislation considers the potential identification pathways specified for the EU REACH regulation as well as for the existing Federal and state legislations in the United States. This appears sufficient in my view.

As a social scientist, I cannot comment the completeness or adequacy of the list of chemicals that have been attached to the existing documents. It is, however, essential that the list of chemicals is constantly monitored and updated. This can go in both directions: sometimes preliminary suspicions turn out to be unjustified, so that candidates on the list may be removed due to better evidence about their potential harm. Sometimes allegedly innocuous substances turn out to be more severe than estimated. Then they should be added to the list even if there were tested before. In particular in connection with nanoparticles, it is also mandatory to review from time to time some of the hazard criteria such as production volume, concentration in product and contamination pathways. As far as I can tell, I can see that such flexibility in changing the criteria and adapting them to new developments and innovative products is incorporated into the language of the proposed regulation.

In essence, I do not see any reasons for further changes.

2. Evaluation criteria for prioritizing the product-chemical combinations in Article 3 are sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products. Revised regulations specify the key prioritization criteria as critical factors necessary to identify potential Priority Products. The product-chemical combination identified and nominated for Priority Product listing must meet the key prioritization criteria.

The language for the key prioritization criteria have been clarified to illustrate that they must be met for proposing any Priority Product. Also, the phrase “ability to”, as in “The Chemical(s) of Concern in the product have a significant ability to contribute to or cause adverse public health and environmental impacts” has been replaced with “potential”: “There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product.” The revised proposed

¹ Mueller-Herold, U., Morosini, M. and Olivier Schucht, O. (2005): Choosing Chemicals for Precautionary Regulation: A Filter Series Approach. In: *Environmental Science and Technology* 39 (1): 683–69.

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regulations define “potential” to mean that the phenomenon described is reasonably foreseeable based on reliable information.

The revised proposed regulations require the Department to evaluate product-chemical combinations to determine potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures which must contribute to or cause significant or widespread adverse impacts.

Statement:

I totally agree with the change of the language from “ability to” to “potential of”. Within a more precautionary understanding of risk management, regulation should not wait for a final proof of negative impact. If there is sufficient evidence that a chemical can cause negative impacts and if there is a reasonable cause to assume that these impacts are likely to affect the environment or human health within the context in which this chemical is being used, regulatory action may be justified. I think it would be beneficial to stress that the potential to do harm, i.e. the description of the hazardous properties of a chemical, is not sufficient for being placed on the chemical candidate list. In addition, it should be requested that there is a realistic option that this potential for harm is released into the environment within the context in which this chemical is used. This may include potential pathways of exposure, the potential volume that is being incorporated or released into the environment, and the knowledge about dose-effect relationships. A chemical that can never reach a human being or is not released into the environment at all should be treated differently than a chemical that will affect humans or the environment in course of its destined use.

This line of argumentation provides a middle ground between a fully precautionary and a fully evidence-based approach to risk management². It does not require that harm is being confirmed either by animal studies or by epidemiological investigations. However, it is also not sufficient to list chemicals according to their potential of harmful effects, with the exception of high persistence and ubiquitous dispersion (see above). A chemical may enter the list if it contains specific hazards *and* if there is reasonable evidence to suggest that such a hazard can be released into the environment or incorporated by human beings.

² Renn, O (2007): Precaution and Analysis: Two Sides of the Same Coin? In: *EMBO Reports*, 8: 303-305

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3. The principles outlined in the proposed regulations that establish the Alternatives Analysis Threshold for COCs that are contaminants in Priority Products is scientifically understood and practical

In the revised proposed regulations The Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There will not be an Alternatives Analysis Threshold provision for an intentionally added ingredient. A list of proposed Priority Products will be subject to California's Administrative Procedure Act (APA) for rulemaking. The APA requires proposals to be made public (public notice) with supporting documentation as to the necessity of the new requirements. Although the revised regulations are silent on this issue, the Department can use the APA rulemaking process in the future to allow for the establishment of an alternative analysis threshold for a product-chemical combination should the need arise.

Statement:

I fully agree with the changes that were made to the provisions on alternative analysis thresholds. In the first version this parallel route could have been interpreted as a loophole for reducing the amount of testing and for circumventing the more onerous procedure for being listed or removed from the list. I also go along with the narrow list of exemptions that is now being inserted into the language of the regulations.

I have two minor reservations: the first one refers to nanoparticles for which a volume-based threshold may be rather irrelevant³. Most of these nanoparticles impact on the environment or inflict harm on human health on the basis of surface exposure rather than on the overall dose. I'm not sure whether this specific hazard criterion has been included as an exemption to the list of exemption. Exemption rules that are purely based on volume may not be sufficient.

The second reservation concerns public scrutiny. It would be wise to allow for more public review if a chemical is pursuing the alternative analysis threshold route⁴. It may be beneficial to expand the time and intensity for public review if such a route is taken.

³ Pleus, R.C. (2013): The State of the Science: Human Health, Toxicology, and Nanotechnology Risks. In: J.A. Shatkin (ed.): *Nanotechnology. Health and Environmental Risks*, CRC Press, Taylor und Francis: Boca Raton, pp. 79-116

⁴ Klinke, A. and Renn; O. (2012): Adaptive and Integrative Governance on Risk and Uncertainty. In: *Journal of Risk Research*, 15: 3 (2012), 273-292.

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4. The definitions of the various “adverse” impacts and general usage of the terms “adverse” impacts and “adverse effects” is used throughout the proposed regulations. A qualitative or quantitative determination of adverse impact or effect can be made, and is adequately protective of public health and the environment when reliable information is available.

Minor clarifications were made to these terms, including, in some instances, changing “impact” to “effect”, where appropriate.

Statement

Since the term “adverse” has many meanings in the English language, it may be prudent to be more specific about its specific meaning within the context of this regulation. I feel now more comfortable with the explanations that have been inserted in the new version. However, there are still some weaknesses in the definitions and conceptualizations of the word “adverse”. I would recommend specifying the term to denominate negative impacts on ecosystem services, landscape appearance and biodiversity in relation to environmental impacts and on human health and well-being in relation to life quality. I believe that these categories cover everything what needs to be included in this term.

In my view, impacts and effects are very difficult to distinguish. Effects may be more specifically connected to causal chains, while impacts may also include intervening variables that are not yet known. Impacts characterize sequential and associative consequences related to a system of preceding events. There is also the word “consequence”, which means something similar. Yet I believe that the use of the two terms “impact” and “effect” are almost synonymous and therefore I do not recommend any changes in the latest version of the document.