



June 15, 2015

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Sent via email: whiteld@niehs.nih.gov

Re: ACC comments on NTP Research Project: Updating Level Of Concern Categories

Dear Dr. White:

The American Chemistry Council (ACC)¹ appreciates the opportunity to provide comments to the National Toxicology Program (NTP) Board of Scientific Counselors (BSC).² We have closely followed the development of the NTP Office of Health Assessment and Translation (OHAT) systematic review methods and while we do not necessarily agree with all the specifics of the OHAT approach,³ we greatly appreciate the leadership NTP is providing in this area.

ACC is supportive of the NTP effort to update the Level of Concern (LoC) categories and we are encouraged that the NTP is working with Drs. Wallsten and Budescu as technical advisors. We have reviewed the NTP Research Project proposal and below provide some comments and suggestions to help improve the quality of the project.

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$812 billion enterprise and a key element of the nation's economy. It is the largest exporting sector in the U.S., accounting for 12 percent of U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

² These comments relate to the NTP RESEARCH PROJECT: UPDATING LEVEL OF CONCERN CATEGORIES, available at: http://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2015/june/bsc_loc_508.pdf.

³ See ACC comments provided on June 11, 2013 and June 25, 2013 available at: http://ntp.niehs.nih.gov/ntp/ohat/evaluationprocess/publiccomm/beck20130611_508be.pdf and http://ntp.niehs.nih.gov/ntp/about_ntp/bsc/2013/june/beck20130625_508.pdf.



Understanding the Audience:

We applaud the effort to enhance the understanding of what the LoC categories mean and to identify strategies for improving the framework as a risk communication tool. However, to do this well, NTP must first clearly define the intended audience. What constitutes an appropriate communication tool for one audience may not be appropriate for another audience.

The OHAT website states “NTP and the National Institute of Environmental Health Sciences established the NTP Office of Health Assessment and Translation (OHAT) to serve as an environmental health resource to the public and to regulatory and health agencies.”⁴ As the public is distinctly different from regulatory agencies, we believe that before this project begins, the NTP should clearly identify the audience of concern. Even if the primary audience is public health agencies, the tool must still be easily understood by the general public.

Decreasing the Number of Categories Should Not Be Taken Lightly:

In reviewing this project proposal, we reviewed how frequently the six LoC categories had been used in completed evaluations.⁵ Our analysis showed the following:

Category	Frequency of use
Serious Concern for Adverse Effects	2
Concern for Adverse Effects	4
Some Concern for Adverse Effects	7
Minimal Concern for Adverse Effects	13
Negligible Concern for Adverse Effects	10
Insufficient Hazard and/or Exposure Data	10

Considering how frequently the minimal and negligible categories were used, history tells us that differentiating between these lower concern levels is indeed practical and is likely a reflection of available scientific information. Seeking to limit what the science tells us by narrowing the categories may limit the utility of robust scientific databases, and may possibly provide a disincentive to conduct further research.

Current OHAT Language is Confusing

ACC has concerns that the current language in the OHAT systematic review methods (including “suspected” and “presumed”) is confusing and misleading. For instance, in the OHAT method, “suspected” equates with low or moderate evidence, which means that it is less likely than not; yet the word “suspected,” to the general public, implies a consideration that something is true, which is closer in definition to the common use of “presumed”. This terminology is confusing and must be corrected. In addition, while the old terms discussed levels of concerns, the new terms define levels of evidence. These two approaches are distinctly different and it is unclear why NTP is making this change. Further elaboration of the planned approach would be useful.

⁴ See: <http://ntp.niehs.nih.gov/pubhealth/hat/index.html>.

⁵ This review did not include: cancer chemotherapy use and diabetes and obesity.

NTP states on page 2 of the Research Project proposal, that

Second, it appears that the public and some of NTP's scientific advisors have experienced confusion regarding the meaning of LoC categories, in particular the meaning of "some concern" and "minimal concern" (NTP 2008). This confusion indicates a need to establish more appropriate labels for LoC categories and clarify what the various LoC categories mean.

There should be reconsideration of the names of the categories followed by focus group testing not solely by experts *but also by* the public to test true public understanding. NTP must ensure that this important stakeholder group understands how well the words match with true levels of concern. Without including the public in this important step, NTP risks creating a situation similar to the one cited in 2008 where there appeared to be public confusion on the meaning of the categories. NTP should also consider incorporating an approach which considers the confidence in the judgments that are being made. This determination of confidence, or uncertainty, will be tied to the quality of evidence and NTP has not yet addressed this important topic.

Stakeholder Testing is Important

In reviewing the aims of the project, it appears that the project will do outreach and testing only among experts. As the public is likely a key audience for this tool, if not the main audience, the protocol should include steps that engage the general public to ensure appropriate understanding of the categories and what they mean.

Further Descriptions of Exposure are Necessary

NTP has not provided any details regarding plans to measure and characterize exposure. As this is a new area for OHAT, further descriptions of the sources of information that will be used and the context in which it will be presented and used would be useful information. We note that some exposure context is provided in the NTP Report on Carcinogens, but this information is provided at a broad population level which has little meaning to inform individual exposure potential. Efforts should be made to better characterize exposures in this current effort.

NTP Should Take Public Comment on the Proposed Categories Before Testing

In addition to conducting testing with the public, it may be useful to include a step that includes public input before the testing of new categories begins, rather than arbitrarily testing a set of categories that has not been sufficiently vetted with multiple stakeholder groups. Public participation is an essential aspect of all government regulatory decisions and is equally important when it comes to communicating and understanding risks. NTP activities should always consider the range of views being expressed. This understanding will likely improve the content of the Agency's decisions. While this project is being shared with the Board of Scientific Counselors, we suggest that NTP also explicitly seek input from the public on any proposed categories and descriptors before testing them. ACC commented on the OHAT LoC evidence categories when the systematic review methods were being developed. No responses to these comments were received, but we are most disappointed by the fact that OHAT never had any substantive discussion with the public on this topic. We encourage a different approach for this

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project and hope that NTP will consider meaningful public engagement that includes a two-way dialogue.

Thank you for the opportunity to provide these comments. We hope you will find them constructive and useful as you work towards updating the LoC categories. We would be happy to meet with NTP staff to discuss any of our comments and recommendations. Please feel free to contact me either by phone (202-249-6417) or by email (nancy_beck@americanchemistry.com) with any questions.

Sincerely,

[Redacted]

Nancy B. Beck, PhD, DABT
Senior Director
Regulatory and Technical Affairs