Two Thumbs Up For CLARITY

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Before going to a restaurant or a new movie, there's a good chance you'll check some reviews from sources that you trust. Why? Because restaurant and movie critics make their living finding the best food and entertainment so you don't have to take a chance on a bad experience.

Something similar happens in science with the peer review process. In this process scientific experts critically evaluate the work of other scientists to help ensure the quality and credibility of scientific results. If a study hasn't been peer reviewed, how do you know if you can trust the results?

A good example of how this works just happened with a scientific peer review of the CLARITY Core Study, which was conducted by senior scientists with FDA's National Center for Toxicological Research to resolve any remaining uncertainties about the safety of BPA. The size and scope of the study, which involved lifetime exposure of laboratory animals to BPA, are unprecedented.

The results of the study were released in February in the form of a Draft Report from the U.S. National Toxicology Program (NTP), which provided funding for the study as part of the CLARITY-BPA program (Consortium Linking Academic and Regulatory Insights on BPA Toxicity). Overall, the results indicate that BPA has very little potential to cause health effects even when people are exposed to it throughout their lives.

As stated in the conclusion of the Draft Report, "*BPA produced minimal effects that were distinguishable from background*." To test the quality of the study and the credibility of that conclusion, NTP organized a peer review of the study by a panel of six independent

scientific experts. The scientists were selected by NTP because they had expertise that is relevant to the CLARITY Core Study, but did not have any conflicts related to previous research on BPA.

The experts received the full Draft Report along with all comments submitted by the public since the Draft Report was released in February. After a two-month period of deliberation, the peer review panel met in a public forum on April 26 to discuss the findings of their review and to hear from any outside participants who wished to speak.

At that meeting the peer review panel first received presentations from the FDA scientists who conducted the study, and then the panelists had the opportunity to ask clarifying questions. In general the peer review panel was supportive of the design and conduct of the study and the statistical methodology used to analyze the results.

The peer review panel then critically evaluated the key conclusions included in the Draft Report and offered thoughtful recommendations to improve and strengthen the conclusions. Those recommendations will be carefully considered by FDA and NTP senior scientists and incorporated, as appropriate, into a Final Report that is expected to be released by August. In parallel, the study will be published in the scientific literature later this year.

It is expected that the results of the CLARITY study will be used by government bodies worldwide in their future evaluations of the safety of BPA. That process has already been initiated by FDA. In a statement released in conjunction with the report, Dr. Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at the U.S. Food and Drug Administration (FDA) noted: "*our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers.*"