Message

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]
Sent: 1/6/2018 10:48:01 PM
To: Mantus, Ellen [EMantus@nas.edu]; Fryberger, Teresa [TFryberger@nas.edu]
Subject: IRIS requirements in the FY 17 Appropriations Bill

Hi, this is the FY17 language we were alluding to on Friday.
Tina
==========

The explanatory statement says: *Integrated Risk Information System (IRIS).- The Committees are aware of efforts to implement the 2011 National Academy of Science' s (NAS) Chapter 7 and 2014 NAS report recommendations for the IRIS program, including six specified recommendations. These recommendations include objective evaluation of the strengths and weaknesses of critical studies, the need for weight of evidence evaluation and integration, and clearer rationale for selecting studies to calculate toxicity values. Additionally, the NAS identified specified recommendations and considerations when evaluating the hazards of formaldehyde. The Committees believe that EPA should contract with the NAS to conduct the peer review of the revised draft IRIS assessment of formaldehyde, should it be released in fiscal year 2017, to verify the recommendations from the previous NAS report of2011 have been fully resolved scientifically.*

The House report says: *Integrated Risk Information System (IRIS) and other assessments.—At least six critical recommendations from the National Academy of Sciences (NAS) have yet to be implemented including objective evaluation of the strengths and weaknesses of critical studies, the need for weight of evidence evaluation and integration, and clearer rationale for selecting studies to calculate toxicity values. Additionally, the NAS identified specific concerns that need to be addressed when evaluating the hazards of formaldehyde. The Committee believes it is essential for the NAS to peer review the revised draft assessment of formaldehyde to verify whether EPA has addressed all previous recommendations. In addition, for all draft or final EPA risk assessments issued in fiscal year 2017, the Committee directs the Agency to provide clear criteria for judging the quality of all key studies and to provide a description of how all evidence will be integrated, based on its strengths and weaknesses, in advance of releasing any future draft assessments. When evaluating the potential carcinogenic effects of substances, the Agency shall also present non-linear modeling approaches. Consistent with EPA's Risk Characterization Handbook (EPA, 2002), draft and final hazard and exposure assessments, produced by EPA offices, should also include the distribution of estimated hazards, exposures, or risks, including central tendency values.*

The Senate report says: *Integrated Risk Information System.—The Committee is aware of efforts by the Agency to implement the 2011 National Academy of Science's [NAS] Chapter 7 and 2014 NAS report recommendations for the Integrated Risk Information System [IRIS] but remains concerned that the recommendations have not been fully implemented. In published appendices that accompany final IRIS assessments, EPA has detailed some of the Agency's deficiencies in meeting the NAS high-priority reforms. The Committee directs the Agency to convene an interagency working group to be Co-Chaired with the Office of Information and Regulatory Affairs and to include relevant executive branch stakeholders to review compliance with the NAS recommendations in IRIS assessments issued since the 2014 NAS report. The working group shall focus specifically on transition from the use of single point estimates of hazard and exposure*

to presenting more complete information on the distribution of estimated hazards, exposures, and/or risks, including central tendency values; on processes for evaluating study quality, relevance, and risk of bias; the use of a transparent and reproducible weight-of evidence process for applying scientific findings; the selection of an adverse outcome; and the use of default linear low-dose extrapolation and other default modeling approaches to hazard determinations. The Committee directs the Agency to issue a report to the Committees of Appropriations of the House and Senate on the findings of the working group and the implementation plans of its findings within 180 days of enactment of this act. The working group report shall also include a timetable for EPA's full implementation of the NAS recommendations for all IRIS assessments issued since the 2014 NAS report.