

INDUSTRY TARGETS DATA QUALITY OF INTERNATIONAL RESEARCH BODIES

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An industry group is targeting the data quality standards of international scientific bodies in recent petitions aimed at ensuring that federal managers employ new federal data quality requirements before outside studies are used in regulations.

But activists are characterizing the move as another industry effort to weaken federal regulations by "bullying" scientific institutions such as universities and key global health bodies such as the World Health Organization (WHO). And international scientists say if unchallenged, the petition could restrict U.S. decision-makers' access to critical data and may represent an effort by industry to manipulate science in its favor.

The industry-funded Center for Regulatory Effectiveness (CRE) submitted a petition Sept. 8 to the Departments of Agriculture and Health & Human Services asserting that WHO studies aimed at developing 2005 Dietary Guidelines must comply with the Data Quality Act (DQA) in order to be used. The act allows outside parties to challenge the validity of studies federal agencies rely on or information they release. CRE sources say the petition is intended to set a precedent that would extend to EPA regulations based on research developed by international organizations such as the International Agency for Research on Cancer (IARC), which is a part of WHO.

In the petition, CRE says the agencies must carry out a pre-dissemination review before WHO studies can be used as a basis for the guidelines, including public notice and comment, that details how the report may fall short of complying with DQA and their plans for ensuring compliance. Last month, academic leaders reacted with outrage to a CRE warning to research universities that their work must comply with the DQA or they could lose federal funding. *Relevant documents are available on InsideEPA.com.*

And activists say from the beginning of industry's push to pass the DQA the effort was about suppressing critical information from policymakers by "bullying research organizations here and abroad."

"This is more proof that this measure, which was adopted in the dead of night with no congressional hearings, is aimed at keeping everyone in the dark," according to one environmentalist. "This most recent petition is geared towards preventing international organizations CRE disapproves of from generating information in the first place."

But a CRE source says the purpose of the request is to give industry and other stakeholders a say in the development of policy and ensure that agencies do not use international studies as a means to readdress an issue that has been opposed by industry when it was originally presented in a federal study based on U.S. sources.

In addition, CRE officials maintain that international studies must also undergo new federal peer reviews under standards proposed by the Bush administration through the Office of Management & Budget (OMB). OMB proposed Draft Review Standards for

Regulatory Science on August 29, which requires that agencies employ peer review to evaluate the findings of agency research. The proposed standards will take effect on January 1, 2004 (*see related story*).

This is "another way to challenge flawed data," another CRE source says, calling the effort an "additional arrow in [industry's] quiver" to challenge new regulations. For example, CRE plans to target the Lyon-based IARC body, which evaluates the carcinogenicity of chemical compounds, including dioxin. One CRE source says EPA has relied on IARC findings to develop human health and site-specific assessments at Superfund and other waste sites. With "more and more globalization of toxicology and environmental assessment going on," it is becoming more important for international studies to be open to stakeholder review and internal agency peer review, the source adds.

But a source with IARC says such petitions, if not challenged by agencies, "will make a lot of good science inaccessible to US decision making," by placing restrictions on its use. According to the source, CRE is trying to "manipulate scientific analysis" by giving companies input on research, which would "censor" the information that EPA and other agencies rely upon. The result is that Americans may be exposed to higher levels of carcinogens because of new barriers to sufficient research on the cancer-causing nature of various chemicals, the source says.