

CRE URGES FDA TO INFORM BPA REVIEWERS OF DATA QUALITY ACT STANDARDS

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The Center for Regulatory Effectiveness is pressing FDA to tell Science Board advisers who are analyzing the agency's bisphenol A risk assessment that studies they review must meet Data Quality Act standards. Some lawmakers and consumer advocates charge that FDA unfairly excluded certain studies in its risk assessment, and CRE says FDA might improve its defense were its advisers to keep DQA requirements in mind.

FDA doesn't have to include in risk assessments studies that don't meet DQA standards.

DQA stipulates that agencies instruct outside experts who sit on advisory panels not inject policy into reviews, and advisers must be informed about DQA standards such as objectivity and utility. DQA also mandates that agencies use the best possible scientific data to make regulatory decisions.

But there is no paper trail indicating FDA has informed Science Board members about DQA's peer review guidelines, CRE's Jim Tozzi says.

Tozzi does not know whether studies left out of the BPA risk assessment meet DQA standards.

CRE outlines its concerns in a letter to FDA food center director Stephen Sundlof on Wednesday (Oct. 15).

FDA caught some flak from consumer advocates at its BPA public meeting in late September. They said the assessment ignored studies funded by the National Institutes of Health. FDA said it relied primarily on two multi-generation rodent studies because they offered the best available data. It said it reviewed hundreds of other studies but they lacked quality and utility.

Lawmakers, including House Energy and Commerce Committee Democrats and Senate Finance Committee ranking Republican Charles Grassley (R-IA), have also criticized FDA for its study selection.

The parties have called on FDA to assign equal weight to all BPA studies when reviewing possible risks, but it is not FDA's responsibility to do so, Tozzi says. DQA stipulates that agencies use the best available studies, not all of them irrespective of quality.

The agency issued a draft report in August asserting that studies show BPA is safe as currently used in plastic bottles and food containers.